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January 31, 2005

RECEIVED
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OFFICE OF
FOOD ADDITIVE SAFETY

Laura Tarantino, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Lyc-O-Mato® Powder GRAS Notification

Dear Dr. Tarantino:

In accordance with proposed 21 CFR § 170.36 (a notice of a claim for exemption based on a GRAS determination) published in the Federal Register (62 FR 18937-18964), I am submitting in triplicate, as the representative of the notifier, LycoRed Natural Products Industries, Ltd, P.O. Box 320, Hebron Road, Industrial Zone, Beer-Shiva 84102, Israel, a GRAS notification of Lyc-O-Mato® Powder for use as a dietary addition of lycopene, at levels up to 2,222 mg/kg Lyc-O-Mato® Powder (containing 0.9% lycopene). Lyc-O-Mato® Powder will be used in baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups and sauces. A GRAS expert panel report, setting forth the basis for the GRAS determination, as well as CVs of the members of the GRAS panel, are enclosed.

Best regards,

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition

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1. GRAS Exemption Claim

A. Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36 (c) (1)

Lyc-O-Mato® Powder has been determined to be generally recognized as safe (GRAS) and, therefore, exempt from the requirement of premarket approval, under the conditions of its intended use as described below. The basis for this finding is described in the following sections.

Signed,

Date 21 Jan 05

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
Burdock Group
888 Seventeenth Street, NW, Suite 810
Washington, DC 20006

(i) Name and Address of the Notifier

Morris Zelkha, Ph.D., President
Lycored Natural Products Ind., Ltd.
Hebron Road – Industrial Zone
P.O. Box 320
Beer Sheva – 84102 Israel

Agent to Notifier:

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
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(ii) Common Name of the Notified Substance

The common name of Lyc-O-Mato® Powder has been defined as:

Tomato powder containing lycopene

(iii) Conditions of Use

Lyc-O-Mato® Powder is intended to be used as ingredients to provide consumers with a supplementary source of lycopene in their diets. Lyc-O-Mato® Powder will be used up to 2,222 mg/kg (containing 0.9% lycopene), as a nutrient supplement, to give a maximum of 20 mg/kg lycopene to the following food products: baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups and sauces.

(iv) Basis of GRAS Determination

Pursuant to 21 CFR § 170.3, Lyc-O-Mato® Powder has been determined GRAS by scientific procedures for their intended conditions of use. The safety of Lyc-O-Mato® Powder is supported by use of their constituents in tomato-based foodstuffs for millennia, as well as animal and clinical studies. This determination is based on the views of experts who are qualified by scientific training and experience to evaluate the safety of substances used as ingredients in food.

(v) Availability of Information

The data and information that serve as a basis for this GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at a reasonable time at the office of:

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
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Alternatively, copies of data and information can be provided to FDA upon request, by contacting Dr. Burdock.

2. Detailed Information About the Identity of the Notified Substance

A. Identity

Lyc-O-Mato® Powder is prepared from the pulp from naturally-selected, non-genetically modified, hybrid, high lycopene content (150-250 ppm) varieties of tomato (*Lycopersicon esculentum* (L.) Karst Ex. Farwell; trade names include: Lycogold™ or LRT 90™ and Lycorich™ or LRT 89™), by a water extraction process. The product contains the water-soluble solids from the fruit.

Common or Usual Name:

The common name of Lyc-O-Mato® Powder has been defined as:

Tomato powder containing lycopene

Table 1. General description and analytical information of Lyc-O-Mato® Powder

Botanical Source	*Lycopersicon esculentum* (L.) Karst Ex. Farwell.
Physical description	Dark red, free flowing powder.
Packaging	Packaged under nitrogen in laminate bags.
Storage	Store at 25°C.
Labeling	Tomato powder containing lycopene.
Functional Use in Food	Source of supplemental lycopene.

B. Composition

Chemical composition of the tomato powder containing lycopene is summarized in Table 2. Lyc-O-Mato® Powder is a water-soluble powder produced from tomatoes that contains a high lycopene content, with lower levels of other carotenoids, phytosterols and tocopherols.

Table 2. Chemical analysis of Lyc-O-Mato® Powder*.

Chemical Analysis	Value
Soluble fibers	13.4%
Total lycopene	0.92%
alpha-Tocopherols	0.3%
Other Carotenoids†	0.146%
Total dietary fiber	56.8%
Lipids	8.2%

*Additional information is given in Table 3; †Carotenoids analyzed include phytoene, phytofluene, and ß-carotene.

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Method of Manufacture of Lyc-O-Mato® Powder

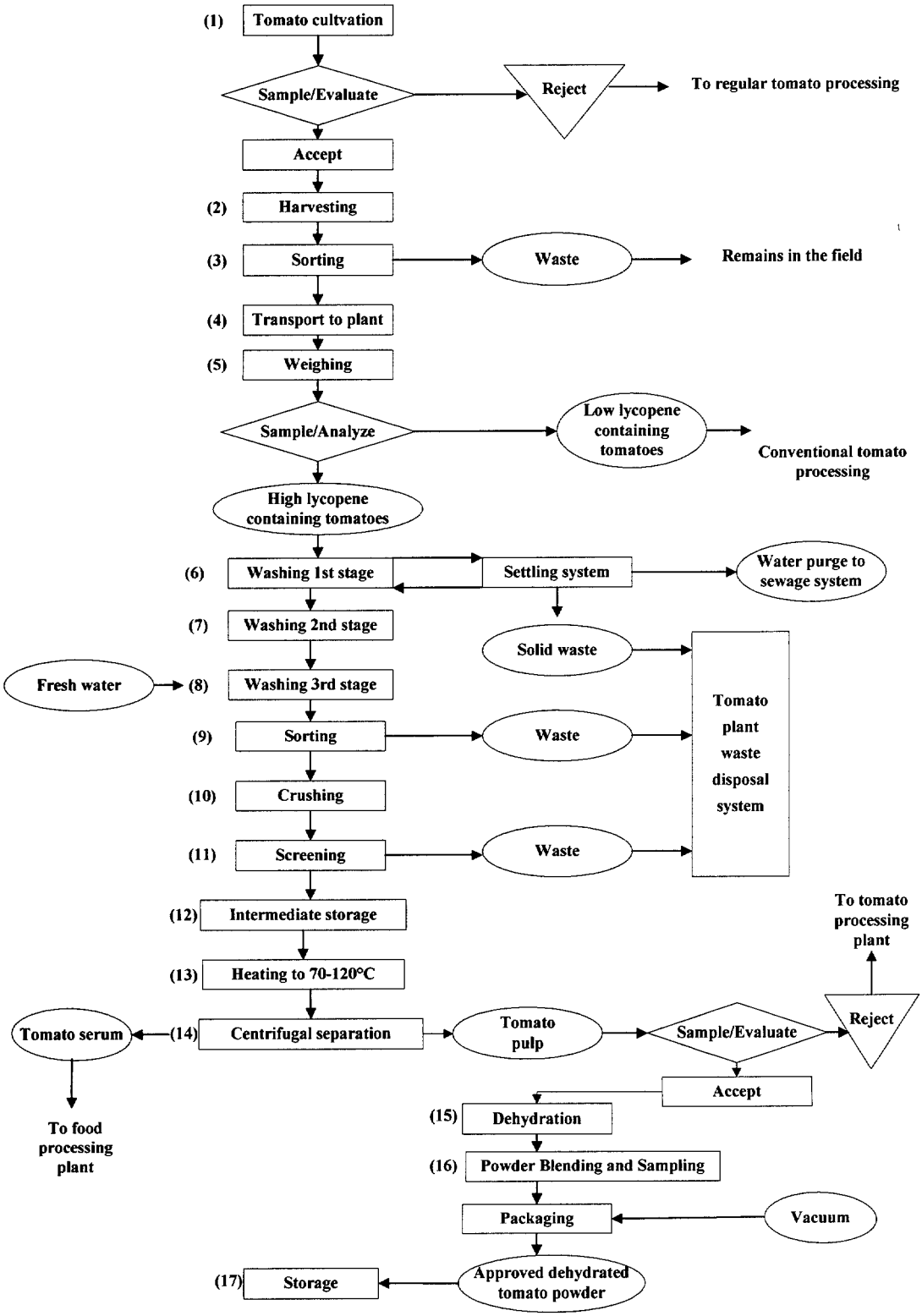

Figure 1. Lyc-O-Mato® Powder production scheme.

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C. Specifications for Food Grade Material

Table 3. Specifications of Lyc-O-Mato® Powder.

Analysis	Method	Specification	Batch Analysis Results (N=3-12) Range	Average
Appearance	LAB/223/01	Free flowing red powder	Passes	Passes
Lycopene identity	LAB/109/01[a]	HPLC retention time	24 - 25.2 min	24.8 ± 0.6 min
Total lycopene[b]	LAB/223/01[a]	0.8 - 2.0%	0.8 - 1.35%	0.92% (N=5)
% *trans*-Lycopene	LAB/109/01[a]	90 - 95%	90-91%	90.4 ± 0.11% (N=4)
Total carotenoids[c]	LAB/223/01[a]	0.95-2.15%	0.95-1.50%	1.07% (N=5)
Other carotenoids	LAB/118/01[a]	Phytoene: min 0.05% Phytofluene: min 0.05% ß-carotene: min 0.01%	0.069 - 0.077% 0.060 - 0.066% 0.01 - 0.011%	0.073% (N=5) 0.063% (N=5) 0.010% (N=5)
Alpha- tocopherols	LAB/118/01	Min 0.2%	0.28 - 0.31 %	0.3% (N=5)
Unsaponifiable matter	Std. Institute SOP	Max 3.0%	1.5 - 2.3%	1.9 ± 0.2% (N=4)
Protein (by analysis of amino acids)	Analyst SOP	Max 17%	14.7 - 15.8%	15.2% (N=5)
Protein (by Kjeldahl analysis of nitrogen)	Miloda SOP	Max 20%	19.2 - 19.7%	19.5% (N=5)
Fructose	Analyst SOP	Max 9%	6.1 - 8.7%	7.1% (N=5)
Glucose	Analyst SOP	Max 7.5%	4.7 - 7.1%	5.9% (N=5)
Soluble fibers	AOAC 991.43	Min 12%	13.0 - 13.7%	13.4% (N=5)
Insoluble fibers	AOAC 991.43	Min 40%	43.1 - 43.7%	43.3% (N=5)
Total dietary fibers	AOAC 991.43	Min 52%	56.3 - 57.4%	56.8% (N=5)
Lipids	Miloda SOP	Min 7%	8.1 - 8.2%	8.2% (N=5)
Particle size	LAB/224/01	95% less than 1 mm	Passes	Passes
Water	Karl Fisher	10% max	2.5 to 10.5%	8.1% (N=10)
Sulphated ash	AOAC 34.104	Max 7%	4.7 to 5.4%	5.2% (N=7)
Pesticides	DFG-S19[e]	Meets USP 24 NF 19/561	Meets USP	Total ≤ 3 ppm
Heavy metals	I.C.P.[e]	Pb < 2ppm Ag, Mo, Cd, Ni, Hg all <1ppm	Meets limits	Each < 1ppm
Arsenic	I.C.P.[e]	As < 2ppm	Meets limits	≤ 0.5 ppm
Microbiology	USP 24 NF 19/<61>	Total count: < 1000/g Mold, Yeast: < 100/g each *Escherichia coli*: 0/10g *Salmonella* sp.: 0/10g *Coagulase positive staphylococcus:* 0/10g *Staphylococcus aureus:* 0/10g	Meets limits	All less than limits

[a]LycoRed Method, SOP available on request; [b]Combined *cis*- and *trans*-lycopenes; [c]Calculated as lycopene; [d]Analyst method SOP available on request; [e]Analysis method SOP available on request.

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III. Self Limiting Levels of Use

At high levels (exceeding the concentrations proposed), certain food items may acquire an undesirable red color.

IV. Basis of GRAS Determination

The determination that Lyc-O-Mato® Powder is GRAS is on the basis of scientific procedures. See attached- DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

BURDOCK GROUP
Consultants

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

January, 2005

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DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

January 20, 2005

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DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

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DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

1. SUMMARY

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel)[1], qualified by their scientific training and relevant national and international experience to evaluate the safety of food ingredients, was requested by LycoRed Natural Product Industries Ltd. (hereafter referred to as LycoRed) to determine the Generally Recognized As Safe (GRAS) status, based on scientific procedures, of Lyc-O-Mato® Powder. Lyc-O-Mato® Powder is to be used as an ingredient to provide consumers with a supplementary source of lycopene in their diets, so that total daily consumption of lycopene from all sources does not exceed 120 mg *per* day of lycopene. In particular, the Expert Panel has evaluated the proposed use of Lyc-O-Mato® Powder at specified levels in the foods described in this document. A comprehensive search of the scientific literature was conducted for safety and toxicity information on lycopene and related compounds and, along with supporting documentation, was made available to the Expert Panel. In addition, the Expert Panel independently evaluated materials submitted by LycoRed and other materials deemed appropriate and necessary. Following an independent, critical evaluation, the Expert Panel conferred and unanimously agreed to the decision described herein.

2. INTRODUCTION

Lyc-O-Mato® Powder is a dehydrated powder of the pulp of tomatoes that contain a significant lycopene content. Lycopene (ψ,ψ-carotene), the predominant colorant in tomatoes, is an acyclic carotenoid with 11 linear conjugated double bonds (Figure 1). Lycopene is increasingly the subject of intense study because of its potential ability to help maintain the healthy structure and function of the body. Humans do not synthesize lycopene and depend entirely on dietary sources of lycopene such as red and pink colored vegetables and fruits. Lyc-O-Mato® Powder is a good source of lycopene that can be used as an ingredient to provide consumers with a supplementary source of lycopene in their diets. This dossier is a summary of the scientific evidence that supports the general recognition that Lyc-O-Mato® Powder is safe for human consumption as a food ingredient.

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[1] Modeled after that described in Section 201(s) of the Federal Food, Drug, and Cosmetic Act, as amended. See also attachments (*curriculum vitae*) documenting the expertise of the Panel members.

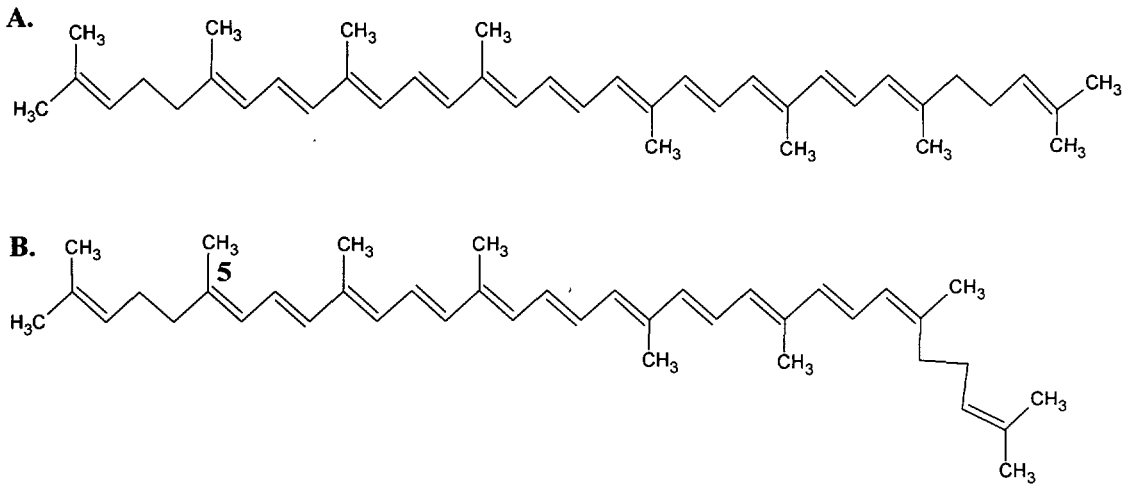

Figure 1 Structures of all-*trans*-Lycopene (A) and 5-*cis*-Lycopene (B)

2.1. Mechanism of Action: Antioxidant

Similar to other carotenoids, lycopene acts as an antioxidant, giving rise to the hypothesis that it protects cells against the damaging effects of free radicals. The anti-oxidant properties of lycopene rely on the conjugated double bond system (Figure 1). This system allows the establishment of a resonance condition and stabilizes carbon-centered radicals {Burton, 1984 #211}(Burton and Ingold, 1984). Lycopene is an anti-oxidant carotenoid with the highest singlet oxygen quenching ability of over thirty various naturally occurring antioxidants (Di Mascio *et al.*, 1989). *In vitro*, carotenoids quench singlet oxygen-induced lipid peroxidation and intercept the propagation step of lipid peroxidation {Rice-Evans, 1997 #212;Burton, 1984 #211}(Burton and Ingold, 1984; Rice-Evans *et al.*, 1997). Some *in vitro* studies have reported that the antioxidant activity of β-carotene and possibly other carotenoids may have shifted into pro-oxidant activity; however, the conditions used to demonstrate this pro-oxidant activity appear non-physiological and required artificially high oxygen concentrations (Burton and Ingold, 1984; Palozza *et al.*, 1997). Thus, it is unlikely that carotenoids are pro-oxidants *in vivo* under normal physiological conditions. An important distinction between lycopene and other carotenoids, such as β-carotene, is that lycopene is not a vitamin A precursor. This and other differences between lycopene and β-carotene are discussed in greater detail below (see β-carotene human intervention trials).

2.2. Regulatory Status

The European Union's Scientific Committee on Food has ruled that the use of lycopene (Natural Yellow 27) prepared from natural foods (such as tomatoes) by physical processes (*i.e.*, solvent extraction) and containing not less than 5% lycopene, is acceptable for use as a colorant in foods including tomato products, confectionery products, and beverages (EU, 1995; EUSCF, 1975). The Committee did not establish an Acceptable Daily Intake (ADI) for lycopene in

humans. Lycopene extracted from tomato is also an allowed food colorant in Japan, where it is used in processed vegetable products, soft drinks and confectionery products at levels from 50 to 200 parts *per* million (ppm). The FDA has recently reveiewed a GRAS self-affirmation determination for synthetic lycopene as a food ingredient and has released an "FDA has no questions" statement, concurrent with the acknowledgement that some uses of the synthetic lycopene my require a color additive listing (BASF, 2002).

Lyc-O-Mato® Oleoresin 6% is currently under final review by the FDA's Division of Petition Review, Office of Food Additive Safety as a food color additive (Color Additive Petition #1C0273) submitted 4 September 2001 (Orstan, A., 2002). The proposed use of tomato lycopene at concentrations up to 50 ppm in foods has received preliminary approval and a regulation concerning its use is currently in preparation and was proposed to be released for public comment in the near future.

In addition, the Office of Food Additive Safety has reviewed the information concerning the use of Lyc-O-Mato® Powder as a color additive (Orstan, A., 2003). The vegetable juice regulation, 21 CFR 73.260, provides for the preparation of a color additive either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of dried vegetables. However, the regulation also specifies "where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard." The standard of identity for tomato juice (21 CFR 156.145, 2003) applies to a liquid product, whereas LycoRed's product is a powder. However, 21 CFR 73.260 (2003) states that vegetable juice color additive may be concentrated or dried. Therefore, the Office of Food Additive Safety concluded that "...a product prepared by drying of tomato juice (*i.e.,* Lyc-O-Mato Powder) initially conforming to 21 CFR 156.145 will fall under 21 CFR 73.260 and that it may be used as a color additive in foods sold in the U.S."(Orstan, A., 2003).

3. DESCRIPTION, MANUFACTURING PROCESS AND SPECIFICATIONS

3.1. Description

The large family of carotenoids is based upon the same C_{40} isoprenoid skeleton. The vast arrays of different structures are brought about through cyclization, addition, elimination, rearrangement and substitution of the isoprenoid skeleton (Rice-Evans *et al.*, 1997). The carotenoids are classified into two major categories: the oxygen-containing xanthophylls (*e.g.* lutein, zeaxanthin, β-cryptoxanthin) and the non-oxygen containing carotenoid hydrocarbons (*e.g.* β-carotene, lycopene). The subject substance of this GRAS monograph is Lyc-O-Mato® Powder, which consists of lycopene, the predominant colorant and antioxidant in the tomato powder, and natural tomato fibers. Lycopene is a hydrocarbon carotenoid composed solely of carbon and hydrogen. Lycopene has 11 conjugated double bonds, which account for its spectral absorbance maximum of approximately 472 nm and its intensely red-orange to red color in concentrated forms (Figure 1). The physical and chemical properties of lycopene and specifications for Lyc-O-Mato® Powder are provided in Table 1 and Table 3, respectively. Similar to other carotenoids, lycopene acts as an anti-oxidant, giving rise to the hypothesis that it protects cells against the damaging effects of free radicals.

Table 1. Physical and chemical properties of all-trans-lycopene (Budavari *et al.*, 1996).

Characteristic	Value
CAS No.	all-*trans*: 502-65-8 all-*cis* : 4418-71-7 15-*cis* : 59092-07-8 13-*cis* : 13018-46-7 9-*cis* : 64727-64-6
Mol. Wt.	536.85
Chemical formula	$C_{40}H_{56}$
Percent Composition	C = 89.5%, H = 10.5%
Melting Point	172-173°C; mp approximately 105°C then solidifies again
Appearance	Long, deep red needles from carbon disulfide + ethanol, from methylene chloride + methanol.
Physical form	Solid
Assay	Absorption max, *trans*-form (petroleum ether): 446, 472, 505 nm ($E_{1cm}^{1\%}$ 2250, 3450, 3150). 15,15'-*cis*-form: mp approximately 105°C then solidifies again; absorption max (petroleum ether): 361, 444, 470, 502 nm ($E_{1cm}^{1\%}$ 1110, 1280, 1660, 1280).
Solubility	One gram dissolves in 50 ml carbon disulfide, in 3 L boiling ether, in 12 L boiling petroleum ether, in 14 L hexane at 0°C. Soluble in chloroform, benzene. Almost insoluble in methanol and ethanol.

3.2. Manufacturing Process and Specifications

Lyc-O-Mato® Powder is manufactured by a patented process (United States Patent, #5,837,311) involving a centrifugation method of the separation of a naturally-selected, non-genetically modified, hybrid, high lycopene content (150-250 ppm) variety of tomato (*Lycopersicon esculentum* (L.) Karst. Ex. Farwell; tradenames Lycogold™, or LRT 90™, and Lycorich™ or LRT 89™ may also be used). The powder contains 0.8% lycopene on average, with the balance made up of tomato protein, sugars, dietary fibers and other carotenoids (Table 3).

Production of the tomato lycopene powder is accomplished as follows. High lycopene content tomatoes are used to prepare tomato pulp (Figure 2). After sorting and washing, the tomatoes are crushed and screened to remove stems and seeds. The resulting tomato juice is passed through a heat exchanger at 80 to 90°C and centrifuged to produce tomato pulp. Pulp with a satisfactory lycopene content (>1200 ppm lycopene) is cooled and dehydrated. The resulting powder is then blended and sampled. The Lyc-O-Mato® Powder product is evaluated for acceptability, as defined by it's specifications (Table 3), as well as microbial counts, pesticide residue, lycopene concentration, moisture and black particles (an indication of overheating- not more than five particles *per* gram is acceptable). Lots not meeting specifications are reprocessed. Lots may be mixed to achieve the final lycopene level (0.8%). Only those lots meeting specifications are packaged. Acceptable powder is packaged under vacuum in multi-layer laminate bags to protect the lycopene from oxidation. The final product, Lyc-O-Mato® Powder, is packaged in 1, 10 and 25 kg aliquots packed under nitrogen or vacuum in 1, 2, 3, 5 and 10 kg laminate bags. An oxygen absorber is added to remove traces of oxygen. The production process for Lyc-O-Mato® Powder introduces no exogenous substances or solvents to the tomato pulp.

Lyc-O-Mato® Oleoresin 6% is a separate product obtained from tomato pulp, *via* an ethyl acetate extract of the tomato pulp, which increases the lycopene content to 6%, on average. The major phytonutrient in Lyc-O-Mato® Oleoresin 6% is lycopene, with phytonutrient ratios similar to that found in whole tomatoes (Table 2). Lyc-O-Mato® Powder and Lyc-O-Mato® Oleoresin 6% both utilize the same initial tomato pulp raw ingredient. However, Lyc-O-Mato® Powder is a dehydrated powder of the pulp of tomatoes that contain a significant lycopene content, while the 6% Oleoresin extract contains a significant source of lycopene from the extracted serum of the tomato pulp. Lyc-O-Mato® Powder is produced from ripe tomatoes, with the phytonutrient ratios found in whole tomatoes maintained in the Lyc-O-Mato® Powder product (Table 2).

Table 2. Phytonutrient content in ripe tomatoes, Lyc-O-Mato® Powder and Lyc-O-Mato® Oleoresin 6%

Nutrient	Ripe Tomato		Lyc-O-Mato® Powder			Lyc-O-Mato® Oleoresin 6%	
	Content	Ratio to Lycopene	Content	Content in the lipid phase*	Ratio to Lycopene	Content	Ratio to Lycopene
Lycopene	160 ppm	100%	0.83%	10.2%	100%	6%	100%
Phytoene	16 ppm	10%	0.075%	0.92%	9%	0.6%	10%
Phytofluene	14.5 ppm	9.1%	0.066%	0.81%	7.9%	0.54%	9.0%
Tocopherols	55 ppm	34.5%	0.30%	3.69%	36%	2.0%	33.3%

*Calculated values. Based on 8.14% lipids in Lyc-O-Mato Powder

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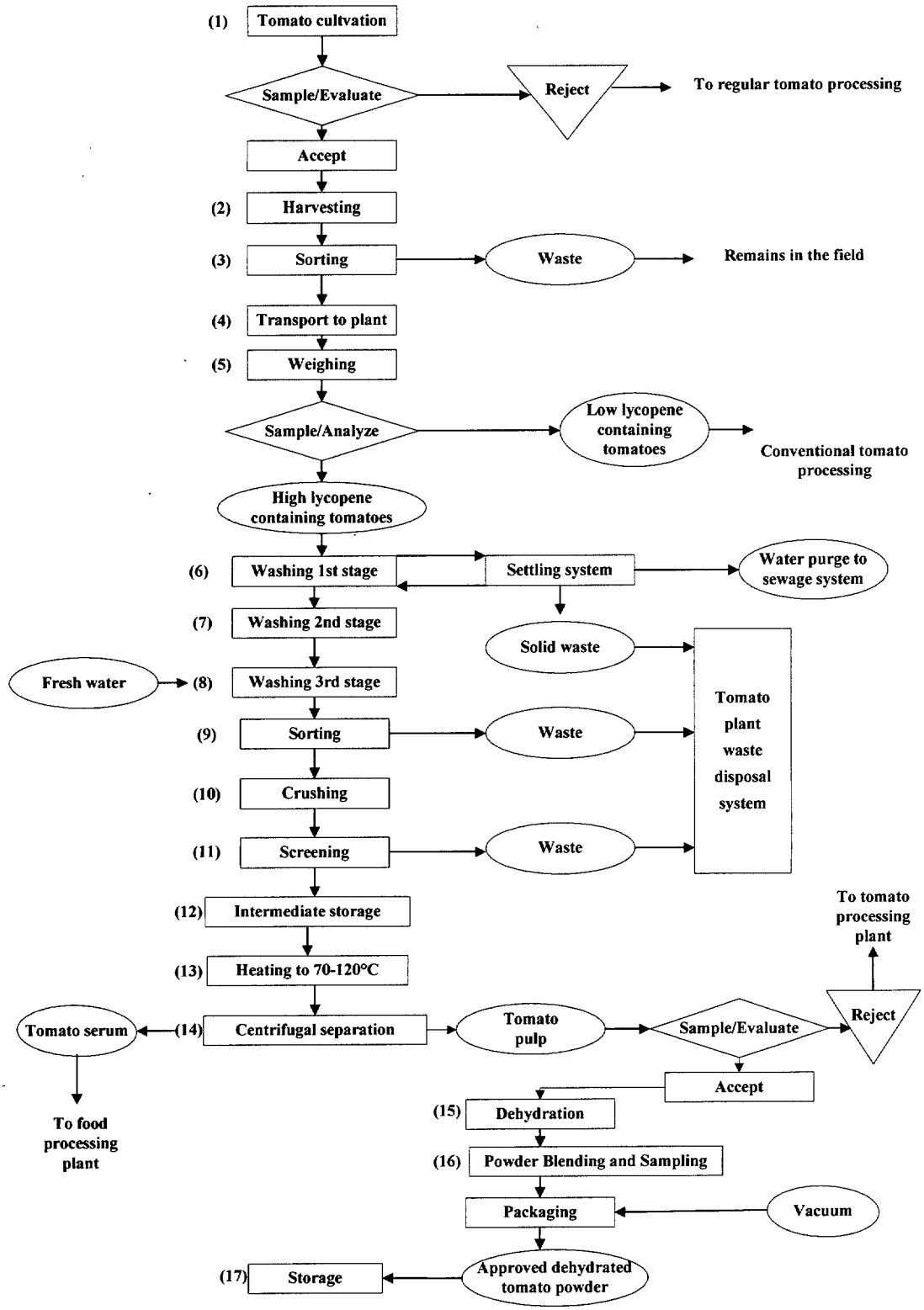

FIGURE 4: Powder Production Scheme

Figure 2. Lyc-O-Mato® Powder Production Scheme

Table 3. Specifications of Lyc-O-Mato® Powder

Analysis	Method	Specification	Batch Analysis Results (N=3-12) Range	Average
Appearance	LAB/223/01	Free flowing red powder	Passes	Passes
Lycopene identity	LAB/109/01[a]	HPLC retention time	24 - 25.2 min	24.8 ± 0.6 min
Total lycopene[b]	LAB/223/01[a]	0.8 to 2.0%	0.8 - 1.35%	0.92% (N=5)
% *trans*-Lycopene	LAB/109/01[a]	90 to 95%	90-91%	90.4 ± 0.11% (N=4)
Total carotenoids[c]	LAB/223/01[a]	0.95-2.15%	0.95-1.50%	% (N=5) ← 1.066
Other carotenoids	LAB/118/01[a]	Phytoene: min 0.05%	0.069 to 0.077%	0.073% (N=5)
		Phytofluene: min 0.05%	0.060 to 0.066%	0.063% (N=5)
		ß-carotene: min 0.01%	0.01 to 0.011%	0.010% (N=5)
Alpha- tocopherols	LAB/118/01	Min 0.2%	0.28 to 0.31 %	0.3% (N=5)
Unsaponifiable matter	Std. Institute SOP	Max 3.0%	1.5 to 2.3%	1.9 ± 0.2% (N=4)
Protein (by analysis of amino acids)	Analyst SOP	Max 17%	14.7 to 15.8%	15.2% (N=5)
Protein (by Kjeldahl analysis of nitrogen)	Miloda SOP	Max 20%	19.2 to 19.7%	19.5% (N=5)
Fructose	Analyst SOP	Max 9%	6.1 to 8.7%	7.1% (N=5)
Glucose	Analyst SOP	Max 7.5%	4.7 to 7.1%	5.9% (N=5)
Soluble fibers	AOAC 991.43	Min 12%	13.0 to 13.7%	13.4% (N=5)
Insoluble fibers	AOAC 991.43	Min 40%	43.1 to 43.7%	43.3% (N=5)
Total dietary fibers	AOAC 991.43	Min 52%	56.3 to 57.4%	56.8% (N=5)
Lipids	Miloda SOP	Min 7%	8.1 to 8.2%	8.2% (N=5)
Particle size	LAB/224/01	95% less than 1 mm	Passes	Passes
Water	Karl Fisher	10% max	2.5 to 10.5%	8.1% (N=10)
Sulphated ash	AOAC 34.104	Max 7%	4.7 to 5.4%	5.2% (N=7)
Pesticides	DFG-S19[e]	Meets USP 24 NF 19/561	Meets USP	Total ≤ 3 ppm
Heavy metals	I.C.P.[e]	Pb < 2ppm Ag, Mo, Cd, Ni, Hg all <1ppm	Meets limits	Each < 1ppm
Arsenic	I.C.P.[e]	As < 2ppm	Meets limits	≤ 0.5 ppm
Microbiology	USP 24 NF 19/<61>	Total count: < 1000/g Mold, Yeast: < 100/g each *Escherichia coli*: 0/10g *Salmonella* sp.: 0/10g *Coagulase positive staphylococcus:* 0/10g *Staphylococcus aureus:* 0/10g	Meets limits	All less than limits

[a]LycoRed Method, SOP available on request; [b]Combined *cis*- and *trans*-lycopenes; [c]Calculated as lycopene; [d]Analyst method SOP available on request; [e]Analysis method SOP available on request.

3.3. Stability

Lyc-O-Mato® Powder is very stable for at least two years at 4°C, with some minimal degradation occurring after 2 years of storage at room temperature (LycoRed, 2003a; b).

Lyc-O-Mato® Powder was evaluated for its use in foods by assessing the stability of lycopene at concentrations in food ranging from 30 to 240 ppm (Table 4). Equivalent commercial products or foods formulated with β-carotene were used as controls if appropriate.

Table 4. Levels of Lyc-O-Mato® Powder tested for stability in the indicated foods

Food	Lyc-O-Mato® Powder (ppm)[a]	Storage Period	Storage Temperature	*Percent* decrease in Lycopene
Biscuits	50	6 months	21°C	4.6%
Beef cutlets	30	3 months	-18°C	0.4%
Turkey cutlets	30	3 months	-18°C	2.7%
Mayonnaise	40	1 month	4°C	13%
LycoSoy Crispsticks	240	6 months	21°C	22.1%
Yogurt	40	1 month	4°C	12%

[a]ppm=parts *per* million

After formulation and processing, the foods were analyzed for color using Hunter Colorimetry and samples taken for HPLC analysis of lycopene content. The foods were then stored for 5 days at normal storage temperatures (room temperature, 4°C, or frozen, as appropriate) under fluorescent light to assess lycopene stability. After storage, the foods were again analyzed by Hunter Colorimetry and HPLC.

No obvious color changes were seen in the foods by visual inspection and Hunter Colorimetry showed no significant changes in total color. HPLC analysis and recovery studies showed little loss of lycopene from the foods in storage (LycoRed, 2003c). Ninety five *percent* of the added lycopene was recovered at the time of formulation and ninety *percent* was recovered five days after formulation, which are very high levels of recovery. Thus, the chemical stability of lycopene under these food processing conditions demonstrates that Lyc-O-Mato® Powder is a stable food ingredient in a variety of foods.

4. ESTIMATED DAILY INTAKE

The intake profile (amount and frequency) by individuals in USDA's Continuing Survey of Food Intakes by Individuals 1994-96 (CSFII 1994-96, 2000) was used to calculate the estimated daily intake (EDI) of Lyc-O-Mato® Powder and lycopene for individuals consuming the food groups selected for the addition of Lyc-O-Mato® Powder *per* this GRAS evaluation. The reference to lycopene in this GRAS review is due to its biological significance. Lyc-O-Mato® Powder will be added to the target foods presented in APPENDIX A.

The mean and 90th percentile EDIs were calculated (as indicated in Table 5) for: (1) current lycopene intake from natural sources[2] (Table 5, line 'A'); (2) lycopene intake following addition of Lyc-O-Mato® Powder to the selected foods (Table 5, line 'B'); (3) lycopene intake following addition of Lyc-O-Mato® Powder as a color additive (Table 5, line 'C') and; (4) total estimated EDI from foods in which lycopene occurs naturally, plus processed foods to which it is added (Table 5, line 'D').

Foods in which lycopene is a naturally present constituent were identified using the USDA-NCC[3] carotenoid database as reported by Holden *et al.* (1999). The USDA-NCC database also provided the concentration of lycopene in these foods. Foods and food products were selected that included fruits, vegetable products, meat products, as well as tomato and tomato products. Food and lycopene consumption was estimated by (1) weighting the data for estimation of consumption by individuals in the entire United States population and (2) multiplying the estimated food consumption (grams food/day) with the lycopene concentration (mg lycopene/g food). The consumption analysis of all individuals that consume lycopene-containing foods contained within the table of foods presented in APPENDIX A, on the same days that they consumed any of the foods given in APPENDIX A, indicates that the mean daily intake for lycopene from natural sources for these individuals is estimated to be 6.1 mg/day, with a 90th percentile intake of 13.7 mg/day (Table 5, line A). If Lyc-O-Mato® Powder is added to the selected foods at the levels specified in Appendix A, the mean and 90th percentile lycopene maximal consumption will be 20.0 mg/day and 35.9 mg/day, respectively (Table 5, line B).

It should be noted that the Color Additive Petition for Lyc-O-Mato® Powder is equivalent to current Good Manufacturing Practice for the addition of tomato juice as a color additive[4] (Orstan, 2003; FDA, 2003a,b). The addition of Lyc-O-Mato® Powder (as a color additive) would be similar (but not concurrent with) Lyc-O-Mato® Oleoresin 6% as a color additive (Orstan, 2002), since lycopene is the determining constituent that gives color in both the Powder and the Oleoresin. The addition of Lyc-O-Mato® Oleoresin 6% to foods (as a color additive) is set at a maximum addition of 50 ppm of liquid, solid or semisolid food; therefore, we can assume that Lyc-O-Mato® Powder may also be added to foods at a maximum of 50 ppm lycopene. In addition, assuming Lyc-O-Mato® Powder was added to all foods eaten (3000 grams/person/day, liquid and solids) at 50 ppm, the total amount of lycopene that could be consumed as a color additive would be 150 mg/day. In reality, the addition of lycopene as a color additive at this maximal level of 150 mg/day would be very difficult to achieve.[5]

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[2] Lycopene occurs naturally in select fruits and vegetables, and therefore, in select processed foods. The foods that naturally contain lycopene and were present in the selected target foods were used to determine who may consume lycopene in an additive manner, when also consuming foods that contain added lycopene.

[3] United States Department of Agriculture-Nutrition Coordinating Center.

[4] 21 CFR 73.260 (b) Uses and restrictions. Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

[5] This is an extremely conservative assumption as (1) the 3000 gms/day includes foods which would not be colored (*e.g.*, water; fresh vegetables, meat, poultry and dairy products and; other products whose standard of

Combining the current intake of lycopene found naturally in foods and the added intake levels (additional lycopene consumption from Lyc-O-Mato® Powder as both a food ingredient and as a color additive) equals the total lycopene consumption level from foods. The estimated total mean consumption of lycopene, if Lyc-O-Mato® Powder were added to the selected foods at the levels specified in APPENDIX A (as a food ingredient summed with that added as a color additive) would be 31.4 mg/day, while the 90th percentile consumption of lycopene would be 58.8 mg/day, (Table 5, line D).

A possible source of lycopene in the diet is from consumption of dietary supplements. The 1987 National Health Interview Survey identified that 51.1% of the adults aged 19-99 years in the US consumed a vitamin/mineral supplement in the past year, but that only 23.1% did so daily (Subar and Block, 1990). Multivitamins were the most commonly consumed supplement at that time. Lyc-O-Mato® Oleoresin is available as a dietary supplement (Lyc-O-Mato® Lycopene Softgels™, Healthy Origins, Pittsburgh, PA), with one 250 mg Lyc-O-Mato® Oleoresin capsule providing 15 mg lycopene. Because there isn't any available statistical data on consumption of dietary supplements that are a source of lycopene, we have used the levels reported in labeling as a basis for estimating consumption ranges (Healthy Origins, 2003). Thus, the potential theoretical lycopene consumption from dietary supplements may equal 30 mg[6] (Table 5, line E) from 500 mg Lyc-O-Mato® Oleoresin 6%. These estimates need to be added to those in Table 5 to arrive at the total potential theoretical background consumption of lycopene from both conventional food and dietary supplements (Table 5, line F).

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identity would preclude addition of a color additive); (2) there are certain technical limitations of Lyc-O-Mato® Powder as a food color (*e.g.*, the development of a strong tomato flavor at higher use levels) and; (3) all foods consumed (solid and liquid) would be colored red; in reality, few foods are colored red (exposure to citrus red color was 0.00008474 mg/kg; carmine color was 0.03686 mg/kg; grape skin extract was 0.06398 mg/kg, canthaxanthin was 0.001483 mg/kg, cochineal was 0.002683 mg/kg); as compared to foods colored brown, *e.g.*, caramel color, which is consumed at a level of 132 mg/kg (~8000 mg/day) (Clydesdale, 1997a; 1997b; 1997c; 1997d; 1997e; 1997f). However, because addition of lycopene as a color additive to all foods is technically impossible, if it is assumed that half of the liquid consumed (1500/2 = 750 grams) and half of the solid/semi-solid food consumed (1500/2 = 750 grams) is either fresh or standardized, precluding the addition of color and, of the remaining 1500 grams, one half is technically incompatible with the addition of lycopene, the remaining 750 grams is colored with lycopene (to the exclusion of all ~125 color additives/adjuncts), at 50 ppm, approximately 38 mg could be consumed.

[6] The website recommends two 15 mg capsules *per* day.

Table 5. Natural lycopene intake, predicted lycopene intake following supplementation of select foods at the indicated levels (Appendix A) and potential total lycopene intake (predicted + current) for individuals consuming selected supplemented foods and dietary supplements.

Lycopene intake from:	*Per* Person (mg/day) Mean	90th Percentile
A. Consumption from food containing lycopene naturally	6.1[a]	13.7
B. Possible maximum consumption with Lyc-O-Mato® Powder as an added ingredient to food [b]	20.0	35.9
C. Lycopene consumed as a color additive [c]	5.3	9.2
D. Total from conventional food (current + added)	31.4	58.8
E. Potential dietary supplement use	30	60
F. Potential total lycopene from all sources (food + dietary supplements)	61.4	118.8

[a] Levels calculated using consumption values from CSFII 1994-1996 (CSFII 1994-96, 2000) and food lycopene concentrations from Holden *et al.*, 1999, for foods with naturally-occurring lycopene that were consumed by individuals that also ate the target foods.
[b] Lycopene levels calculated using consumption values from CSFII 1994-1996 (CSFII 1994-96, 2000) and lycopene levels from the addition of Lyc-O-Mato Powder to the proposed foods given in Appendix A (See text for details).
[C] Derived from the use of Lyc-O-Mato 6% Oleoresin used according to it's Color Additive Petition (Orstan, 2002), as the lycopene is the constituent that gives color, so theoretically the same amount of lycopene from either the Oleoresin or the Powder would be needed to achieve the same color. The Oleoresin and the Powder would not be used in the same product.

5. ABSORPTION, DISTRIBUTION, METABOLISM AND ELIMINATION (ADME)

Lyc-O-Mato® Powder is a food ingredient source of lycopene, which is the most abundant carotenoid in Lyc-O-Mato® Powder. Lycopene is the major biologically active substance contained in Lyc-O-Mato® Powder and is therefore reviewed for its biological effects. There were numerous studies identified in the public literature that reported on the ADME of lycopene from various sources.

Carotenoids, which are fat-soluble compounds, are absorbed in parallel with fat digestion and absorption. Chylomicrons are the main intestinal lipoprotein particles responsible for the transport of carotenoids, retinyl esters and other fat-soluble vitamins in the lymphatic system. Thus, the carotenoid pattern in chylomicrons is an early indicator for the composition of carotenoids after absorption from the gut, before any liver-dependent modifications will occur. Lipoproteins are structured such that the more polar constituents (*e.g.*, water-soluble) are situated toward the outside of the lipoprotein, whereas the more non-polar compounds (*e.g.*, fat-soluble), such as lycopene, are located toward the inner core (Bierer *et al.*, 1995). In the systemic circulation, chylomicrons are processed to chylomicron remnants, which are taken up primarily by the liver (Wingerath *et al.*, 1995). Once in the liver, the internalized hydrocarbon carotenoids (*e.g.*, lycopene) are then assembled into very low-density lipoproteins (VLDL) and released into

the blood circulation, or in the case of β-carotene, are also utilized to produce retinoids (Wingerath *et al.*, 1995).

Interactions between carotenoids exist that can affect the bioavailability of other carotenoids (reviewed in van den Berg, 1999). The best evidence of this occurring is between the hydrocarbon carotenoid β-carotene and the oxycarotenoids lutein and canthaxanthin. However, evidence demonstrating interactions between lycopene and other carotenoids is equivocal with many discrepancies between studies.

The predominant form of lycopene in foods, including Lyc-O-Mato® Powder (90-95%), is all-*trans*-lycopene, but the predominant forms of lycopene identified in human serum and tissues are the *cis*-isoforms. Some investigators have suggested that the *cis*-lycopene isomers that are in food are preferentially absorbed (Boileau *et al.*, 2002), while others have suggested and provided evidence indicating that the *trans*-isomer is isomerized to the *cis*-isomers by the gastric milieu prior to absorption (Holloway *et al.*, 2000; Re *et al.*, 2001). The proportions of the *cis/trans* isomers in serum appear to be constant regardless of the isomer distribution in the supplement/diet; thus, serum isomer distribution appears to be independent of that in the supplement/diet. The majority (>50%) of tissue and serum lycopene consists as the 9-*cis*-, 13-*cis*- and 15-*cis*-isomers, while the 5-*cis*- and 9-*cis* are the main *cis*-isomers in plasma.

Lycopene is found predominantly in the adrenals and testes, with significant amounts also found in the liver, adipose tissue, prostate, kidney and ovary. Elimination of lycopene is by first-order kinetics providing a plasma half-life of 12 to 33 days (Brown *et al.*, 1989; Burri *et al.*, 2001; Rock *et al.*, 1992; Stahl and Sies, 1992). Human studies on the absorption and bioavailability, distribution, metabolism and elimination of lycopene are summarized below.

5.1. Absorption and Bioavailability

In men and women on self-selected diets, 43% and 35% of the total carotenoids measured in plasma were lycopene, respectively (Micozzi *et al.*, 1992; Yong *et al.*, 1994).

Olmedilla *et al.* (2002) reported the results from a multicenter, placebo-controlled intervention study designed to study the serum response of carotenoids and tocopherols. Healthy male and female volunteers (N=400) were recruited from five European regions. Subjects given ~222 mg/day Lyc-O-Mato® extract (containing 13.3 mg/day lycopene) for 20 weeks had a two-fold increase in serum lycopene. In addition, the isomer distribution of lycopene in the serum remained constant, regardless of the lycopene isomer composition contained within the various natural extracts in the capsules from the different treatment groups. In Spanish volunteers, additional data showed that the serum response to lycopene supplementation reached a plateau after 4 weeks.

In a crossover study, fifteen female and nine male volunteers were given lycopene (5 mg/day) for four weeks, in the form of capsules containing processed tomato oleoresin, processed tomato oleoresin formulations or synthetic lycopene, after a 2-week lycopene depletion period (Böhm, 2002). Plasma lycopene levels were elevated in all groups at the end of the study period, relative to week 1 of supplementation. The greatest absorption of lycopene was

observed in subjects consuming capsules containing tomato lipids combined with lycopene crystal sizes < 10 μm in diameter.

A double-blind, randomized, crossover study was conducted in healthy men (N=10) who received either all-*trans* β-carotene (0.11 mmol; 60 mg) or all-*trans* lycopene (0.11 mmol; 60 mg) or by a combined oral dose of 0.11 mmol each (Johnson *et al.*, 1997). The carotenoids were of a purified crystalline form dispersed in corn oil. Serum lycopene concentrations significantly increased at 5 hours, compared to baseline, after the lycopene dose, then slowly returned to baseline. The 24-hour area under the curve (AUC) for lycopene was significantly greater when lycopene was ingested with β-carotene than when ingested alone. Thus, in this study ingestion of a combined dose of β-carotene and lycopene improved the absorption of lycopene in men.

Tyssandier *et al.* (2002) studied the short-term (24 hour) and long-term (3-week) interactive effects of carotenoids, including lycopene, on carotenoid absorption in women (N=20). The lycopene groups received: (a) 96 g tomato puree/day (14.98 mg lycopene + 1.50 mg β-carotene); (b) 1 Lyc-O-Mato® Oleoresin 6% pill/day (15 mg lycopene) + 92 g chopped spinach/day (11.93 mg lutein + 7.96 mg β-carotene), or; (c) 96 g tomato puree/day (14.98 mg lycopene + 1.50 mg β-carotene) + 2 lutein pills (12 mg lutein). Plasma carotenoid levels in chylomicrons were measured on the day before the supplementation period, the first day of each supplementation period and the day after the supplementation period ended. Contrary to the research by Johnson *et al.* (1997), in the short-term (24 hours), consumption of β-carotene and/or lutein with lycopene decreased serum lycopene levels (AUC) relative to consumption of lycopene (tomato puree) alone. However, there were no interactive effects on lycopene levels (nmol/L) observed following 3-weeks combined consumption of the carotenoids.

A study done by Walfisch *et al.* (2003) determined the concentrations of tomato carotenoids in human tissue after supplementation with a tomato oleoresin (subjects were given 30 mg lycopene, which also contained 3 mg phytoene, 2.8 mg phytofluene, 0.8 mg β-carotene and 10 mg tocopherols, *per* day). The average length of treatment was 24±3 and 25±2 days for the lycopene and placebo (soya oil) groups, respectively, with a range of 6 to 52 days. Serum lycopene concentrations after lycopene treatment was significantly higher (2.2-fold), as well as tissue lycopene concentrations (1.6- and 1.4-fold for the skin and adipose parts of the tissue), than the placebo controls.

Lycopene bioavailability from a single dose of fresh tomatoes or tomato paste (23 mg lycopene) was studied in healthy subjects (N=5) (Gartner *et al.*, 1997). The pattern of lycopene isomers was the same in both fresh tomatoes and tomato paste. Compared to fresh tomatoes, ingestion of tomato paste was found to yield 2.5-fold higher total lycopene and all-*trans*-lycopene peak concentrations and 3.8-fold higher area under the curve (AUC) responses. The AUC response for the *cis*-isomers, but not the peak *cis*-lycopene concentration, was significantly higher after ingestion of tomato paste compared to fresh tomatoes.

Stahl and Sies (1992) studied the absorption of lycopene from processed (boiled with 1% corn oil for 1 hour) and unprocessed tomato juice in humans. Serum lycopene concentrations increased only when processed tomato juice was consumed. Peak serum lycopene concentrations

were reached between 24 and 48 hours. Absorption was dose-dependent, but not linear, as there was greater absorption at lower doses. Absorption of 9-*cis* and 13-*cis* isomers was somewhat better than the all-*trans* form.

Men (N=30) on a controlled diet were fed defined daily doses of carotenoids, including lycopene, from foods (broccoli, carrots, or tomato juice) for 6 weeks (Micozzi *et al.*, 1992). Compared with baseline, lycopene declined in all groups except the tomato-juice group.

In a randomized, crossover study design, the bioavailability of lycopene from tomato juice and two dietary supplements, each containing 70-75 mg lycopene, was studied in healthy volunteers (N=15) (Paetau *et al.*, 1998). Subjects ingested lycopene-rich tomato juice, Lyc-O-Mato® Oleoresin 5% (the same formulation as Lyc-O-Mato® Oleoresin 6%, but with average lycopene concentration of 5%), lycopene beadlets, and a placebo for 4 weeks each while consuming self-selected diets. Compared to the placebo group, plasma lycopene concentrations were significantly higher in subjects consuming all forms of lycopene sources with no differences in mean lycopene levels (~0.24 μmol/L) between the treatment groups. Thus, lycopene appears to be equally bioavailable from tomato juice and the supplements used in this study. Subjects in the three treatment groups also had increased plasma concentrations of phytofluene and phytoene, which were present in small amounts in tomato juice, Lyc-O-Mato® Oleoresin 5% and lycopene beadlets. *Beta*-carotene, *zeta*-carotene, and 2,6-cyclolycopene-1,5-diol (a metabolite of lycopene), also present in tomato juice and both supplements, were significantly increased with consumption of the tomato juice and lycopene beadlets, but not with Lyc-O-Mato® Oleoresin 5% consumption.

Following seven days of a lycopene-free diet, plasma lycopene concentrations were measured in healthy female subjects (N=11) that consumed 25 g tomato puree daily (containing 7.0 mg lycopene) for 14 consecutive days (Pellegrini *et al.*, 2000). The mean plasma lycopene levels increased approximately 3-fold by day 14 (0.57 μmol/L) when compared with baseline plasma levels (0.13 μmol/L). In a slightly longer study, plasma lycopene concentrations increased by 3-fold in adult women (N=9) that consumed 25 g tomato puree (containing 7 mg lycopene) for 14 consecutive days, after a 7-day washout period (Porrini and Riso, 2000). The mean plasma lycopene concentrations were 0.13 μmol/L and 0.55 μmol/L at day 0 and day 14, respectively.

Porrini *et al.* (1998) studied the relationship between duration of lycopene intake and food matrix on plasma lycopene concentrations in healthy female subjects. Following a one-week lycopene-free washout period, subjects were given 16.5 mg/day total lycopene in tomato purée or fresh raw tomato for a single day (N=9) or seven consecutive days (N=10). In subjects consuming tomato products for a single day, the plasma area under the curve (AUC) (calculated from time 0 to 104 hours after consumption) for total lycopene and all-*trans*-lycopene, but not *cis*-lycopene, was significantly increased in the tomato purée group compared with the raw tomato group. In subjects consuming tomato products for seven consecutive days, the AUC (calculated from day 0 to day 11 after first consumption) for total-, *trans*- and *cis*-lycopene was significantly higher in the tomato purée group compared with the raw tomato group. Thus, evidence suggests that there is a significant effect of food matrix on lycopene bioavailability.

Thirty-six (18 male and 18 female) healthy subjects consumed a daily, single serving of tomato sauce (21 mg lycopene *per* ½ cup), tomato soup (12 mg lycopene *per* 1 cup) or juice (17 mg lycopene *per* 8 oz.) for four weeks, after a two-week washout period (Allen *et al.*, 2003). Changes in plasma and buccal mucosal cell (BMC) lycopene concentrations were evaluated and it was found that plasma total lycopene concentrations decreased from 1.05±0.07 to 0.54±0.04 μmol/l after two weeks on a lycopene-free diet. Total plasma lycopene concentrations increased for those consuming sauce, soup and juice for two weeks, compared with the values at the end of the washout period, 2.08 (192%), 0.91 (122%) and 0.99 (92%) μmol/l, respectively. Interestingly, concentrations of lycopene in BMCs did not change following a two-week lycopene-free diet, but the lycopene concentrations in BMC did significantly increase for those subjects consuming sauce, from 1.26±1.01 nmol/μg protein at the end of the washout period, to 3.34 nmol/μg protein. This study suggests that tissue lycopene concentrations may change much more slowly than blood concentrations.

After a 3-week lycopene-restricted washout period, healthy subjects ingested 25 mg lycopene/day for 8 weeks from Lyc-O-Mato® Oleoresin 6% in whey protein (lactolycopene; N=4M/6F), tomato paste (positive control; N=5M/7F) or a placebo of whey proteins (N=4M/7F) while consuming their self-selected diets (Richelle *et al.*, 2002). Plasma lycopene concentrations reached a maximum after 2 weeks of supplementation in both lycopene-treated groups and then a plateau was maintained until the end of the treatment. Mean plasma lycopene concentrations at week 8 were significantly increased in the treatment groups compared with placebo controls, but they were not different from each other (lactolycopene group=0.58 μmol/L; tomato paste group=0.47 μmol/L). Although lycopene was present mainly as all-*trans* isomers (>90%) in both lactolycopene and tomato paste products, plasma lycopene enrichment consisted of 40% as all-*trans* and 60% as *cis*-isomers. These results indicate that the lactolycopene formulation and tomato paste exhibited similar lycopene bioavailability in plasma.

In a crossover study, renal transplant patients (N=15) were randomized to daily consumption (400 ml/day) of either tomato juice or synthetic orange drink (lacking lycopene) for 4 weeks (Sutherland *et al.*, 1999). At week 4, plasma lycopene levels were significantly higher in patients that consumed tomato juice (1.57 μmol/L) compared with baseline levels (0.86 μmol/L) and in patients that consumed orange drink (0.91 μmol/L).

In a crossover study designed to measure the interactions of carotenoids during absorption, a study group of males (N=20) on a carotenoid-restricted diet received a single oral dose of 15 mg lycopene (Lyc-O-Mato® Oleoresin 5%) plus 15 mg β-carotene (in the form of palm oil carotenoids). The areas under the curve (AUCs) for the lycopene plus β-carotene group was similar to the AUC for the β-carotene only group (van den Berg and van Vliet, 1998). Therefore, ingestion of a combined dose of β-carotene and lycopene (from Lyc-O-Mato® Oleoresin 5%) did not interfere with the absorption of either carotenoid.

In a split plot design, men and women (N=33/group) consumed whole tomatoes, mildly homogenized tomatoes or severely homogenized tomatoes that were either minimally or extensively heated (van het Hof *et al.*, 2000). The tomato products were consumed daily (22 mg/day lycopene) for 4 days. Plasma lycopene levels were measured at day 0 and day 4. The

greatest lycopene absorption was observed in extensively heated, severely homogenized tomatoes. Thus, the intactness of the cellular matrix of tomatoes determines the bioavailability of carotenoids and matrix disruption by mechanical homogenization and/or heat treatment enhances the bioavailability.

Following two weeks on a low-carotenoid diet, female adults (N=22) were randomized into three groups that received 5 mg/day lycopene for six weeks provided through a daily portion of tomatoes (N=6), tomato juice or Lyc-O-Mato® Oleoresin 6% in soft gel capsules (Böhm and Bitsch, 1999). Plasma lycopene levels increased to a similar level in subjects consuming Lyc-O-Mato® Oleoresin 6% and tomato juice, but no increase in plasma lycopene was observed in those consuming raw tomatoes. Thus, lycopene from Lyc-O-Mato® Oleoresin 6% capsules and tomato juice (processed tomatoes) was better absorbed from the intestine than lycopene from raw tomatoes.

In a crossover study, Lee *et al.* (2000) compared the effect of consumption of tomato products containing extra-virgin olive oil *vs.* tomato products containing sunflower oil, on plasma lycopene levels. Subjects (N=3M/5F) consumed tomato products (canned tomatoes (230 g) and tomato soup (200 g); ~ 46 mg lycopene) prepared with the same oil daily for 7 days. Results showed that the oil composition does not affect the absorption of lycopene from tomato products because similar mean levels of plasma lycopene were obtained on feeding tomatoes with either olive oil (1.2 μmol/L) or sunflower oil (1.14 μmol/L).

Following a two week carotenoid-depletion period, healthy male volunteers (N=23) consumed successively for two weeks each, 330 mL tomato juice (40 mg lycopene), 330 mL carrot juice (15.7 mg α-carotene and 22.3 mg β-carotene) and 10 g spinach powder preparation (11.3 mg lutein and 3.1 mg β-carotene) served with main meals (Müller *et al.*, 1999). During the tomato juice intervention, plasma concentrations of *trans*- and *cis*-lycopene increased three-fold, compared to the depletion period, with no differences between the levels of each isomer. Lycopene oxidation products could also be demonstrated in plasma and were significantly elevated compared to control. After two weeks of consuming carrot juice, α- and β-carotene levels increased 8.6- and 3.2-fold, respectively. Following the spinach consumption, the lutein concentration increased two-fold, while the β-carotene concentrations maintained a two-fold elevation above baseline. This work indicates a high level of bioavailability of carotenoids from these processed vegetable products.

After an overnight fast, subjects (N=3M/3F) received a single dose of lycopene (38 mg) with β-carotene (40 mg) in a standard meal containing 43 g of fat (O'Neill and Thurnham, 1998). The lycopene was isolated from tomatoes. Plasma carotenoid levels were tracked for 8 hours after dosing. Approximately 1.0 mg of the 38 mg lycopene dose (~2.6%) was absorbed. A two- to three-fold inter-individual variation in lycopene was observed, but was not sex-dependent.

In a controlled intervention study, male and female subjects consumed 330 ml/day tomato juice (47.1 mg/day lycopene; N=29) or mineral water (N=21) for 8 weeks (Watzl *et al.*, 2000). Tomato juice consumption resulted in significantly increased plasma lycopene concentrations over time with no significant differences in the levels of the *trans*- and *cis*-isomers at week 8.

In a four-week study, female students (N=16-17/group) were given 1, 2 or 3 cans of tomato juice *per* day and a control group received apple juice (Sakamoto *et al.*, 1994). Compared with their baseline levels, serum lycopene levels were significantly elevated in the groups receiving 2 or 3 cans *per* day. All three tomato juice groups had significantly elevated serum lycopene levels compared with the apple juice group. A large amount of the serum lycopene was identified as the *cis*-isomer.

5.2. Distribution

The pharmacokinetics and tissue distribution of lycopene after an acute oral administration of lycopene (5% lycopene, as a fine granular powder) to male Beagle dogs at concentrations of 10, 30 and 50 mg/kg bodyweight was determined. Lycopene did not cause any observable adverse effects as measured by food consumption, body weight changes, clinical signs and clinical observations (Korytko *et al.*, 2003). Red material was observed in the feces after dosing, but this was interpreted to be unabsorbed lycopene. Plasma lycopene concentrations after single doses of 10, 30 and 50 mg/kg bodyweight lycopene peaked approximately 15 hours after dosing (785-997 nmol/L lycopene). The apparent plasma half-life of lycopene in dogs following a single dose was approximately 36 hours.

Male Beagle dogs dosed with 30 mg/kg bodyweight/day lycopene for 28 days obtained a steady-state plasma concentration of between 785 and 997 nmol/L lycopene, after four days of dosing. The highest concentration of lycopene was in the liver, one and five days after the 28-day dosing period ended (65.6 and 91.0 nmol/g, respectively). Lycopene concentrations in the adrenals, spleen and lymph node were 18.5-26.4, 7-10.6 and 5.16-5.38 nmol/g, respectively. Lycopene concentrations in the prostate were 0.143 and 0.181 nmol/g, one and five days after cessation of treatment, respectively. All other tissues had concentrations generally at levels less than 0.7 nmol/g. This data indicates that lycopene dosing in dogs results in lycopene concentrations in dog prostate that are of the same order of magnitude as those in human prostate (Korytko *et al.*, 2003).

Healthy Japanese female subjects were randomized to one of three treatment groups that consumed a control drink (control group; 0 mg lycopene; N=10), 160 g of tomato juice (low dose group; 15 mg lycopene; N=11) or 480 g of tomato juice (high dose group; 45 mg lycopene; N=10) for one menstrual cycle (Maruyama *et al.*, 2001). Plasma lycopene increased in the low and high dose groups relative to the control group. Sixty-nine *percent* of lycopene in plasma was distributed in the low-density-lipoprotein (LDL) fraction and 24% in the high-density-lipoprotein (HDL) fraction. In the low dose group, the lycopene concentration increased 160% in each of the very-low-density-lipoprotein (VLDL) + intermediate-density-lipoprotein (IDL), LDL and HDL fractions. In the high dose group, the lycopene concentration increased 270% in both the VLDL+IDL and LDL fractions, and 330% in the HDL fraction.

Concentrations of carotenoids, including lycopene, were determined in liver, kidney and lung tissue from autopsies of subjects (N=20; 4 months to 86 years). Within the same patient, total mean carotenoid concentrations in liver (21.0 nmol/g tissue) were always greater than in kidney (3.1 nmol/g tissue) or lung (1.9 nmol/g tissue. Lycopene concentrations ranged from 0.2

to 20.7 nmol/g tissue in the liver, 0.1 to 2.4 nmol/g tissue in the kidney and less than 0.1 to 4.2 nmol/g tissue in the lung (Schmitz *et al.*, 1991).

Kaplan *et al.* (1990) determined the carotenoid content, including lycopene, in 10 different human organs obtained at autopsy (N=16). The median levels of lycopene varied disproportionately between organs with the highest levels in the adrenal and testes (11.56 and11.43 μg/g wet tissue weight, respectively), with the liver containing 1.31 μg/g lycopene. Much lower lycopene levels (1% of adrenal levels) were identified in subcutaneous fat, pancreas, kidneys, heart, thyroid, ovary and spleen.

The isomeric composition of lycopene was measured in serum and seven human tissues (Stahl *et al.*, 1992). 9-*cis*-, 13-*cis*- and 15-*cis*-Lycopene combined accounted for more than 50% of total lycopene identified, with all *trans*-lycopene and other isomers accounting for the rest of the lycopene measured. The highest levels of lycopene were observed in the adrenals and testes (1.9 and 4.34 nmol/g wet tissue weight), with levels 1.5 and 3.4 times higher than found in the liver (1.28 nmol/g), respectively. Lycopene was also present in the ovary, fat and kidney tissues and the serum.

Concentrations of lycopene were quantitated in serum and prostate tissue from men (N=25; ages 53 to 74 years) undergoing prostatectomy for localized prostate cancer (Clinton *et al.*, 1996). Lycopene concentrations ranged from 0 to 2.58 nmol/g prostate tissue with a mean of 0.80 nmol/g tissue. all-*trans* Lycopene accounted for 12 to 21% and *cis* isomers for 79 to 88% of total lycopene in prostate tissues. Lycopene concentrations in the serum ranged between 0.60 and 1.9 nmol/ml, with 27 to 42% all-*trans* lycopene and 58 to 73% *cis*-isomers.

Van Breemen *et al.* (2002) found that serum levels of lycopene are an imperfect indicator of prostate levels. Total and all-*trans*-lycopene was measured in both the serum and prostate tissue in men with clinical prostate adenocarcinoma before and after consumption of tomato sauce based pasta dishes (each providing 30 mg of lycopene *per* day) for three weeks, before radical prostectomy. Total lycopene in the serum increased two-fold from 35.6 to 69.9 μg/dL, after dietary supplementation with tomato sauce, while the total lycopene in the prostate tissue increased three-fold from 0.196 to 0.582 ng/mg of tissue. The mean proportion of all-*trans*-lycopene in prostate tissue increased from 12.4% of total lycopene to 22.7% after dietary intervention. However, all-*trans*-lycopene increased only 2.8% in the serum.

Plasma concentrations of lycopene were measured in men (N=121) and women (N=186) participating in two prospective investigations of dietary etiologies (Ascherio *et al.*, 1992). This study was undertaken to gain knowledge of dietary and other factors that influence blood concentrations of specific carotenoids and tocopherols. The bioavailability of lycopene from these varied diets was evidenced by the detectable serum lycopene levels. Lycopene was the predominant plasma carotenoid in the study population, with mean lycopene concentrations at 0.82 μmol/L in men and 0.76 μmol/L in women. However, among the non-smokers, dietary assessment of carotenoid intake (as obtained through two, one-week questionnaires) did not correlate with plasma levels of lycopene.

Paetau *et al.* (1999) reported significantly increased lycopene concentrations in buccal mucosa cells (BMCs) in subjects (N=15) consuming Lyc-O-Mato® Oleoresin 5% (the same as Lyc-O-Mato® Oleoresin 6%, but with average lycopene concentration of 5%) or lycopene beadlets, but not lycopene-rich tomato juice. There was only a weak correlation between BMC lycopene levels and plasma lycopene levels. Alternatively, Richelle *et al.* (2002) reported a good correlation between increased plasma lycopene concentrations and increased lycopene concentrations in BMCs in subjects that consumed 25 mg lycopene/day for 8 weeks from Lyc-O-Mato® Oleoresin 6% in whey protein (lactolycopene) or tomato paste.

Lymphocyte lycopene concentrations increased by 80% in adult women (N=9) that consumed 25 g tomato puree (containing 7 mg lycopene) for 14 consecutive days, after a 7-day washout period (Porrini and Riso, 2000).

Zaripheh *et al.* (2003) examined the time course of tissue uptake of lycopene and its metabolism by measuring the appearance of polar ^{14}C-labeled compounds in tissues of F344 rats dosed with ^{14}C-lycopene and found the recovery of the ^{14}C dose (including tissues, gastrointestinal contents, feces and urine) was 74±4.8%, up to 168 h after administration. A comparison of the ventral plus anterior prostate tissues found that the dosolateral prostate lobe had the highest lycopene concentration at 3.4±0.9 nmol lycopene/g tissue, followed by the ventral (1.7±0.09 nmol/g) and seminal vesicles (0.7±0.06 nmol/g).

5.3. Metabolism

In human serum, a metabolite of lycopene was identified (5,6-dihydroxy-5,6-dihydrolycopene), which apparently resulted from oxidation of lycopene to a lycopene epoxide intermediate, which then underwent metabolic reduction (Khachik *et al.*, 1995). Oxidative and enzyme-catalyzed cleavage products of lycopene were determined after lycopene was incubated with a post-mitochondrial fraction of rat intestine and cofactors with or without soy lipoxygenase, at 37°C for up to 90 min (Ferreira *et al.*, 2004). The oxidative products included: 1) 1,16,17-trinor-2-ene-5,8-lycopenal-furanoxide ($C_{37}H_{50}O$); 2) lycopene-5,6,5',6'-diepoxide ($C_{40}H_{56}O_2$); 3) lycopene-5,8-furanoxide isomer (I) ($C_{40}H_{56}O$); 4) lycopene-5,8-epoxide isomer (II) ($C_{40}H_{56}O$); and 5) 3-keto-lycopene-5',8'-furanoxide ($C_{40}H_{56}O_2$). The enzymatic cleavage products found were 3-keto-apo-13-lycopenone ($C_{18}H_{24}O_2$); and 3,4-dehydro-5,6-dihydro-15,15'-apo-lycopenal ($C_{20}H_{28}O$). Lycopene epoxide was identified in the plasma of men that consumed lycopene (Müller *et al.*, 1999). In breast milk and serum of lactating mothers (N=3), an oxidative metabolite of lycopene was identified (epimeric 2,6-cyclolycopene-1,5-diol) that contained a novel five-membered-ring end group (Bertram *et al.*, 2000; Khachik *et al.*, 1997).

Metabolism of ^{14}C-lycopene in F344 male rats (administered *via* gavage) resulted in all-*trans* and major *cis* isomers of lycopene being the primary isomeric forms found in the hepatic tissue, compared with the other minor *cis* isomers or polar products (Zaripheh *et al.*, 2003). In the seminal vesicle, 40% of the ^{14}C was in the form of all-*trans*, 5-*cis* and major *cis* isomers of lycopene. However, a large percentage (38%) was also present as polar products of lycopene. In the prostate, 67% of ^{14}C was in the form of polar products, even at three hours post-dosing.

Tomato juice prepared from homogenization and centrifugation of whole tomatoes inhibits the enzymatic function of adenosine deaminase in human prostate tissue. Adenosine

deaminase is a key enzyme in nucleotide metabolism and DNA turnover (Durak *et al.*, 2003). Dietary supplementation of lycopene to rats (300 μg/rat/day for seven days) in parallel with 2,4,6-trinitrobenzenesulfonic acid (TNBS)-induced cholitis significantly decreased the level of myeloperoxidase activity from the control (1.26±0.9 *vs.* 3.59±1.29 Units/g wet weight, respectively; $p<0.05$) (Reifen *et al.*, 2001). Administration of lycopene or lycopene in conjunction with vitamin E (200 ppm lycopene alone or with 540 ppm vitamin E) in male Copenhagen rats four weeks prior to and eighteen days following the injection of MatLyLu Dunning prostate cancer cells into the ventral prostate suppressed the genes involved in steroid metabolism and signaling. Lycopene reduced steroid 5-α-reductase 1 expression in both the lycopene and the co-treated group. Additionally, lycopene treatment significantly reduced local expression of IL-6, an autocrine growth factor in prostate cancer, as well as insulin and IGF-I transcription (Siler *et al.*, 2004).

In addition, lycopene administration (2.5 mg/kg bodyweight/day, four days/week for fourteen weeks) to male Syrian hamsters receiving a 0.5% solution of DMBA in liquid paraffin (painted on the their right buccal pouches three times *per* week for 14 weeks) decreased DMBA-induced lipid peroxidation. A subsequent increase in the activities of glutathione-dependent enzymes (glutathione peroxidase, glutathione-S-transferase and glutathione reductase) was also noted, as compared to control DMBA-treated hamsters (Bhuvaneswari *et al.*, 2002). The incidence of tumors in the DMBA-treated hamsters was 100%, while the DMBA-treated hamsters receiving lycopene had no tumors, although preneoplastic lesions such as dysplasia, were observed in three of the six animals. No malignant or preneoplastic lesions were seen in hamsters treated with lycopene alone.

5.4. Elimination

In a study conducted to determine the effects of processing food on lycopene absorption in humans, the estimated serum half-life of lycopene was 2-3 days (Stahl and Sies, 1992).

In a controlled, crossover study, men (N=30) on a low carotenoid diet were fed a single dose of carotenoids, including lycopene, from broccoli (600 g), carrots (270 g), or tomato juice (180 g) (Brown *et al.*, 1989). The estimated plasma half-life for lycopene was determined to be approximately 14 days.

To investigate the effect of a low carotenoid diet on plasma carotenoid levels, including lycopene, healthy male subjects (N=12) housed in a live-in metabolic unit were fed a low carotenoid diet for 13 weeks (Rock *et al.*, 1992). Blood samples were drawn on days 2-3, 14-15, 35-36 and 63-64. The estimated mean plasma half-life of lycopene was between 12 and 33 days.

As part of two carotenoid isotopic studies, Burri *et al.* (2001) measured serum concentrations of carotenoids, including lycopene, in healthy young adult women (N=19) that were fed controlled low carotenoid diets for approximately 10 weeks. Serum lycopene concentrations decreased during depletion and followed first-order kinetics with a half-life of 26 days. Half-life was unrelated to physical or demographic characteristics such as body mass, body fat, racial background or age in the relatively homogeneous groups.

In a study designed to measure the lycopene absorbance of various tomato oleoresin preparations, plasma lycopene levels significantly decreased 21 to 52 %, compared to basal values, after volunteers (N=24) consumed a diet low in lycopene for 14 days (Böhm, 2002).

Zaripheh *et al.* (2003) found that the major route of ^{14}C elimination, after ^{14}C-lycopene administration to F344 male rats, was through the feces, followed by a small amount eliminated in the urine (within the first 24 hours, 36±0.6% of the ^{14}C dose was excreted *via* the feces, whereas 1±0.02% was excreted through urine).

6. SAFETY EVALUATION

Lyc-O-Mato® Powder is made directly from processed tomatoes containing high amounts of lycopene. As such, the main biologically active constituent of Lyc-O-Mato® Powder, other than dietary fiber, which is not readily absorbed into the body, is lycopene. Lyc-O-Mato® Powder is processed from the same tomatoes as Lyc-O-Mato® Oleoresin 6%. The Oleoresin is obtained from the serum of the tomato, while the Powder is obtained from the pulp of the tomato. The lycopene contained within both of these products are processed from the same tomatoes. Therefore, safety studies determining the safety of tomato-derived products that contain substantial amounts of the biologically active ingredient, lycopene, including Lyc-O-Mato® Oleoresin 6%, will also be reviewed for this safety assessment of Lyc-O-Mato® Powder.

6.1. Acute Studies

Acute lethality studies were conducted on two batches of Lyc-O-Mato® Oleoresin 6% (Matulka *et al.*, 2004). Sprague-Dawley rats (N=5/sex; 124 to 162 g) received a single 5000 mg/kg dose of undiluted Lyc-O-Mato® Oleoresin 6% by gavage and were observed for 14 days. No signs of systemic toxicity were noted for 14 days after administration of the oleoresin. The animals were sacrificed and necropsy showed no macroscopic abnormalities in the abdominal and thoracic cavities. One female died 4 hours after dosing; this rat demonstrated signs of distress 2 hours after dosing and at necropsy showed hemorrhagic lungs, dark liver and dark kidney. It was concluded that the death of this single animal was inconsistent with the lack of any symptoms in the other animals and may have been due to maldosing. These studies demonstrated that the LD_{50} for Lyc-O-Mato® Oleoresin 6% was greater than 5000 mg/kg bodyweight.

Lyc-O-Mato® Oleoresin 6% was applied with semi-occlusion for 24 hours at 2000 mg/kg to a shaved area of intact skin on Sprague-Dawley rats (N=5/sex) (Matulka *et al.*, 2004). After 24 hours, the bandage was removed and the animals were observed for 14 days for evidence of toxicity. No deaths or signs of systemic toxicity were observed during this period. After the 14 days, macroscopic examination of the abdominal and thoracic cavities showed no abnormalities. It was concluded that the acute dermal LD_{50} of Lyc-O-Mato® Oleoresin 6% is greater than 2000 mg/kg in rats.

In male Wistar rats (N=8/group) fed 300 mg/kg lycopene in their diet for 16 days, no adverse effects were observed on growth, liver weight, lung weight, kidney weight or small intestine cytochrome P450 expression and activity (Jewell and O'Brien, 1999).

Mice (N=30/group) fed a diet containing 700 ppm lycopene (approximately 90 mg/kg body weight *per* day) for 2 weeks had no reported adverse effects or changes in liver weight (Black, 1998).

Milani *et al.* (1970) reported lycopene to be non-toxic to: (1) rats at 50 mg/kg orally and subcutaneously at 50 mg/kg and 100 mg/kg; (2) guinea pigs at 20 mg/kg subcutaneously and; (3) mice at 3 g/kg administered orally, subcutaneously or intraperitoneally.

6.2. Subchronic Studies

CD rats (N=20/sex/group; 96-132 g) were given 0, 45, 450 or 4500 mg/kg/day Lyc-O-Mato® Oleoresin 6% by gavage for 13 weeks (Matulka *et al.*, 2004). No deaths occurred during the treatment period. There were no differences in bodyweight gain, food intake, or food conversion efficiency between test and control animals. Test animals had no ocular lesions, changes in hematology, urinalysis changes, changes in organ weights, or macroscopic or microscopic differences from control animals. Test animals did exhibit low alkaline phosphatase blood levels in comparison to controls, but the toxicological significance of this finding is unclear. Plasma levels of lycopene did not increase for the 450 mg/kg/day dosage over those found with the 45 mg/kg/day indicating lycopene absorption was saturated at higher doses. Thus, oral administration of Lyc-O-Mato® Oleoresin 6% was well tolerated with no evidence of toxicity at doses of 45, 450 or 4500 mg/kg/day. The No Observed Adverse Effect Level (NOAEL) of Lyc-O-Mato® Oleoresin 6% was 4500 mg/kg/day.

In an extensive carotenoid feeding study, carotenoids, including lycopene, were fed to rats and dogs (Zbinden and Studer, 1957). The lycopene studies had four groups:

(1) Rat (N=10F/10M), 1000 mg/kg body weight/day, direct feeding, 100 days---authors claim that the animals ate about 10 g lycopene total (each)

(2) Rat (N=15F/15M), 1000 mg/kg diet/day, feed additive, 200 days---authors claim that the animals ate about 2.5 g lycopene total (each)

(3) Rat (N=18F/13M, second generation), 1000 mg/kg diet/day, feed additive, 60 days---authors claim that the animals ate approx. 0.8 g lycopene total (each)

(4) Dog (N=1F), 100 mg/kg body weight/day, direct feeding, 192 days---authors claim that the animal ate approximately 272 g lycopene total

During the first weeks of the study, two spontaneous deaths occurred in Group #1 that were not reported to be treatment related. Otherwise, all rats grew at same pace as controls. No significant changes were observed in hematology; or in histopathology on liver, kidneys, adrenal glands, spleen, pancreas, testis, ovaries, skin, bone and bone marrow.

For Groups #2 and #3, the authors observed no significant differences between test and control animals with respect to food intake or body weight. There were neither spontaneous deaths nor the need to sacrifice any animals due to disease in either group. Hematology was normal in both test and control groups. No significant differences were observed in reproduction

(gestation period, litter size, average pup weight, *etc.*). Histopathology showed that females (but not males) stored lycopene in the liver as coarse-granulated pigment; otherwise, the liver was normal. Also, no significant changes were observed in the kidneys, adrenal glands, spleen, pancreas, testes, epididymis, ovaries, lungs, heart, bones and bone marrow. No pigment storage (outside of the liver) was observed. The authors noted that based on consumption of lycopene, the rats ate about 50 mg/kg *per* day, the equivalent of a daily dose of 3 g/day of lycopene in a 60 kg human or about the amount found in 20 kg of concentrated tomato paste.

For the single dog in Group #4, lycopene was administered in gelatin capsules, orally. No intolerance symptoms were observed. Body weight increased normally during the experiment. No significant change in blood chemistry was observed. All organs appeared normal at termination. The authors noted that liver contained 22.6 mg/g tissue and kidneys 0.6 mg/g tissue of lycopene at termination of the experiment. They also noted that in the 192 day test, the dog ate a lycopene amount equivalent to that found in 10,000 to 15,000 kg of tomatoes.

Breinholt *et al.* (2003) determined that administration of lycopene (*via* diet) to male Fischer 344 rats at 0.05g/kg diet (3.2 mg/kg bodyweight/day lycopene) or lycopene (0.05 g/kg diet) combined with quercetin (0.1g/kg diet, determined dose at 8 mg/kg bodyweight/day) for ten weeks, actually increased the number of preneoplastic ACF[7] in the colon, as compared to controls ($7.0 \times 10^{-5} \pm 1.8 \times 10^{-4}$, $8.7 \times 10^{-4} \pm 2.2 \times 10^{-3}$, *vs.* not detected in controls, respectively). Interestingly, all antioxidants and antioxidant combinations tested (*i.e.*, lycopene, quercetin, resveratrol or a mixture of lycopene and quercetin) in this system significantly increased the level of lymphocytic DNA damage. This information indicates that moderate to high doses of antioxidants consumed together may form a pro-oxidant mechanism and modulate carcinogenesis.

Dietary lycopene intake has been reported to inhibit oxidative actions on various tissues. The effects of the dietary ingestion of tomato powder (lyophilized tomato juice containing 0.16% lycopene) were studied in male ICR mice that had become hypercholesterolemic by the feeding of an atherogenic[8] diet (Suganuma and Inakuma, 1999). Mice fed the atherogenic diet for four months had significantly increased plasma lipid peroxide concentrations. In addition, the amount of relaxation of the aorta through stimulation with acetylcholine was significantly reduced in the mice fed the atherogenic diet. Mice fed the atherogenic diet with the addition of 20% tomato powder did not have a significant increase in plasma lipid peroxide concentrations, while the acetylcholine-induced vaso-relaxation effect on the aorta did not differ from the control diet. Notably, the addition of tomato powder to the atherogenic diet did not affect the growth of the mice.

The ingestion of tomato powder (20% w/w of the diet) by male C57BL/6NCrj mice for four weeks prior to MPTP[9]-induced selective destruction of the dopaminergic nigrostrie prevented a decrease in the striatal dopamine levels (Suganuma *et al.*, 2002). MPTP induces a

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[7] Aberrant crypt foci.
[8] Atherogenic = Ability to form degenerative changes in arterial walls.
[9] 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine.

Parkinson's-like neurological syndrome. Two injections of MPTP (15 mg/kg body weight) 20 hours apart induced a significant decrease in dopamine levels in the striatum. Ingestion of the same concentration of tomato powder (20% w/w) without the addition of MPTP did not affect the striatal levels of dopamine. MPTP is believed to act through a metabolite (MPP^{+}[10]) by disrupting oxidative phosphorylation, leading to decreased ATP levels in the brain, while also coupling with neuromelanin and accelerating the production of active oxygen, which may facilitate destruction of neural membranes. The lycopene contained in the tomato powder is an antioxidant and may prevent dopaminergic neurons from oxidative stress.

6.3. Eye Studies

Two separate eye irritation studies using different batches of Lyc-O-Mato® Oleoresin 6% (0.1 mL, approximately 5-6% lycopene by weight) were conducted (Matulka *et al.*, 2004). Lyc-O-Mato® Oleoresin 6% (0.1 mL, approximately 6% lycopene by weight) was applied into the conjunctival sac of the right eye of New Zealand white rabbits (N=6) pretreated with a local anesthetic (Ophthaine) to minimize pain. Ocular damage/irritation was assessed at 1, 24, 28 and 72 hours; and 7 days following treatment using Draize evaluation criteria. In both studies, Lyc-O-Mato® Oleoresin 6% was scored as a Moderate Eye Irritant (class 5 on a 1 to 8 scale).

6.4. Skin Studies

Two separate skin irritation studies using different batches (Nos. 620106, 620207) of Lyc-O-Mato® Oleoresin 6%, were conducted (Dreher, 1994a,b). In each test, Lyc-O-Mato® Oleoresin 6% was applied directly to the shaved skin (dorsal/flank area; 0.5 mL oleoresin under a 2.5 x 2.5 cm gauze patch) of New Zealand white rabbits (N=6). The patch was removed four hours after oleoresin application and any residual material was removed by swabbing with diethyl ether. Test sites were examined and scored for irritation at 1, 24, 48 and 72 hours after patch removal using the Draize system for erythema and edema formation. Both batches of Lyc-O-Mato® Oleoresin 6% produced very slight to well-defined erythema and slight to moderate edema in all animals. An averaging of the scores for the six animals in each test resulted in a primary irritation index of 4.3 (on a scale of 0 to 8). The two tested batches of Lyc-O-Mato® Oleoresin 6% were classified as a "Moderate Irritants" according to the Draize classification scheme.

A skin irritation study was repeated using the same protocol as the earlier studies, but with a different batch (No. 511008) of tomato oleoresin, Lyc-O-Mato® Oleoresin 6%, that was produced at a later date than the earlier batches (Matulka, *et al.*, 2004). However, unlike the earlier studies, application of 0.5 ml of the tested batch of Lyc-O-Mato® Oleoresin 6% did not produce any effects and was classified as a "Non-Irritant" to skin.

In an acute dermal toxicity study, Lyc-O-Mato® Oleoresin 6% (batch No. 620207) was applied with semi-occlusion for 24 hours at 2000 mg/kg to a shaved area of intact skin on Sprague-Dawley rats (N=5/sex) (Matulka, *et al.*, 2004). After 24 hours, the bandage was removed and the animals were observed for 14 days for evidence of primary irritation according to the standard Draize scale. Incidents of hemorrhage of the dermal capillaries were noted in one

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[10] 1-methyl-4-phenylpyridinium ion.

male and one female animal, two to four days after treatment, however no erythema or edema formation was observed in any animal. It was concluded that the Lyc-O-Mato® Oleoresin 6% tested was not a skin irritant.

The results from these skin irritation studies are inconsistent and suggest that irritation in rabbits from an application of the earlier batches of Lyc-O-Mato® Oleoresin might have been due to the presence of lactic acid, which was not present in the latter material[11] that was tested in rats. Alternatively, irritation may be species specific with irritation in the rabbit, but not in the rat.

The skin contact sensitization potential of Lyc-O-Mato® Oleoresin 6% (Batch No. 620207) was evaluated in the albino guinea pig (N=20/test group; N=10 controls) (Matulka *et al.*, 2004). Shaved shoulder regions areas of the animals received three intradermal injections (0.1 mL each) of Freund's Complete Adjuvant, a 5% (wt/vol) dilution of oleoresin in arachis oil, and a 5% (wt/vol) dilution of the oleoresin in a 1:1 mixture of Freund's Complete Adjuvant plus arachis oil. On day 7, the same area on each animal was treated with a topical application of 25% (wt/wt) Lyc-O-Mato® Oleoresin 6% in petroleum jelly and a dressing was applied for 48 hours. Observations for erythema and edema were made at 1 and 24 hours following removal of the dressing. Control animals were injected with carriers only and challenged with 5% (wt/wt) Lyc-O-Mato® Oleoresin 6% in petroleum jelly. Animals were scored according to reactions of test *vs.* control animals. The Lyc-O-Mato® Oleoresin 6% produced a 35% (7 out of 20 test animals) sensitization rate and was classified as a "Moderate Sensitizer" to guinea pig skin in these studies. This effect might have been due to the lactic acid present in the batch of oleoresin used in the study.

6.5. Genotoxicity

Salmonella typhimurium strains TA1535, TA1537, TA1538, TA98 and TA100 and *Escherichia coli* strain WP2uvrA$^-$ were treated with five dilutions of Lyc-O-Mato® Oleoresin 6% (up to 250 μg lycopene *per* plate) (Batch No. 620207) with and without metabolic activation according to the Ames plate incorporation method (Matulka *et al.*, 2004). Lyc-O-Mato® Oleoresin 6% was found to be non-mutagenic under the conditions of the test. Addition of lycopene (as a tomato oleoresin) to the diet of benzo[a]pyrene-treated (BaP) male Muta™ Mouse mice had organ specific mutagenic effects. Mutagenesis was dose-dependently decreased in the prostates of BaP-treated mice, but the addition of the tomato oleoresin increased BaP-induced mutagenesis in the colon and lung (Guttenplan *et al.*, 2001).

6.6. Carcinogenesis

Animal studies have reported anti-carcinogenic effects from lycopene. For example, feeding tomato juice containing up to 17 mg/kg lycopene to rats for up to 35 weeks significantly protected the animals from nitrosamine-induced bladder cancer and N-methylnitrosourea-induced (NMU) colon cancer (Narisawa *et al.*, 1998; Okajima *et al.*, 1998). In another study, addition of 50 mg/kg lycopene in the drinking water of mice for 21 weeks resulted in a

[11] LycoRed Natural Product Industries Ltd., personal communication.

significant reduction in nitrosourea-induced lung adenomas and carcinomas in male mice (Kim *et al.*, 1997).

A significant increase in survival time was noted when male Wistar rats treated with NMU were fed a diet of tomato powder (13 mg lycopene/kg), as compared to the control diet of lipid beadlets (P=0.009) (Boileau *et al.*, 2003). In contrast, prostate cancer-specific mortality of the control and lycopene-fed (161 mg lycopene/kg diet) rats was similar (P = 0.63). The tomato powder and lycopene beadlet diets had similar patterns of lycopene isomers and percentages of total lycopene in the *cis* conformation and, similar concentrations of lycopene isomers in the plasma. Kim *et al.*, (2004) also examined the effects of the feeding of a tomato extract (10% tomato powder) or lycopene beadlets (0.25% lycopene) on acute liver injury caused by the oxidant carbon tetrachloride (CCl_4). The 10% tomato powder, but not the lycopene beadlets, partially inhibited CCl_4-induced hepatic injury, based on the serum activities of aspartate aminotransferase and sorbitol dehydrogenase. No effect was seen on serum *beta*-glucoronidase activity, a marker for lysosomal injury. These data support the hypothesis that tomatoes must contain phytochemicals in addition to lycopene that may modulate tissue injury and prostate carcinogenesis.

Lycopene (2.5 mg/kg) administered intragastrically three times *per* week for 21 weeks to male Wistar rats during N-methyl-N'-nitro-N-nitrosoguanidine (MNNG)-induced gastric carcinogenesis in the presence of saturated sodium chloride (as the promoting agent) significantly lowered the concentrations of lipid peroxides (as determined by plasma thiobarbituric acid reactive substances) and enhanced antioxidant levels (GSH, vitamin C and vitamin E) in the plasma (Velmurugan *et al.*, 2002).

6.7. *In vitro* studies

Lavelli *et al.* (2001) reported that the antioxidant activities of "whole tomato" (*e.g.*, includes lipophilic constituents) and hydrophilic tomato powder fractions of a whole tomato varied, as measured by the α-linolenic acid/Rose Bengal system, xanthine oxidase/xanthine system, myeloperoxidase/NaCl/H_2O_2 system and the linoleic acid/$CuSO_4$ system. Although the hydrophilic extract of the partially fractionated tomato powder (*e.g.*, lacking serum) still contained phenolic and ascorbic acid contents, they were 2.6- and 16-fold lower, respectively, as compared to those of the corresponding whole fruit extract. In the α-linolenic acid/rose Bengal/$CuSO_4$ model system, low concentrations of the extracts of both products had a pro-oxidant activity. Increasing extract concentrations sharply increased the antioxidant activity, which reached maximum levels of inhibition at about 4800 and 13,000 μg, respectively. The higher concentration of the hydrophilic powder could be due to its lower content of phenolics, some of which are known to act as copper chelators. In the myeloperoxidase system, the concentration of the whole tomato powder and the hydrophilic fraction to inhibit peroxidation by fifty percent (I_{50} value) was 3750±50 and 6070±50 μg, respectively. It was determined that the hydrophilic antioxidant fraction of tomato powders had both scavenging/quenching activities and copper chelating activity, while the lipophilic antioxidant fraction of tomato had only scavenging/quenching activities.

In vitro studies have shown that lycopene can inhibit cell proliferation in human mammary and lung cancer cells (Fuhrman *et al.*, 1997) and the production of transformed loci in

methylchloranthrene-treated C3H/10T1/2 mouse embryo fibroblasts (Araujo *et al.*, 1995; Bertram *et al.*, 1991; Levy *et al.*, 1995). Lycopene caused a concentration-dependent reduction in HL-60 promyelocytic leukemia cell growth accompanied by inhibition of cell cycle progression in the GO/G1 growth phase (Amir *et al.*, 1999). The lycopene effect was enhanced, synergistically, by 1,25-dihydroxyvitamin D3, a known anticancer agent (Bernardi *et al.*, 2002). In a related study, the lycopene inhibition of MCF7 mammary cancer cells appears due to lycopene interference with insulin-like growth factor I (IGF-I) receptor signaling and cell growth cycle progression (Karas *et al.*, 2000).

Lycopene dose-dependently inhibited proliferation of KB-1 human oral tumor cells at 3, 5 and 7 μmol/L (close to the 1 μmol/L physiologic level of lycopene in basal human serum). Lycopene at these doses also significantly up regulated both the transcription and expression of connexin 43, a key protein in the formation of gap-junctional communication (Livny *et al.*, 2002). Gap-junction communication is an inhibitory mechanism of cancer cell proliferation.

Lycopene inhibits the proliferation of LNCaP cells dose-dependently, from 10^{-9} to 10^{-5} M lycopene (after a 48-hour incubation period), compared to vehicle-treated cells (Kim *et al.*, 2002). In contrast, the same group found that lycopene at 10^{-6} and 10^{-5} M had significant stimulatory effects on the proliferation of human osteoblast-like osteosarcoma SaOS-2 cells, at all time points from 24 to 144 hours (Kim *et al.*, 2003).

Induction of cytochrome P450E1 expression during arachidonic acid (AA) administration leads to oxidative stress. AA administration to Hep2E1 cells expressing cytochrome P450E1 increased the production of hydrogen peroxide and lipid peroxidation in these cells, while the administration of lycopene (10 μM) concurrently with AA significantly ($P<0.001$) decreased the generation of hydrogen peroxide and lipid peroxidation products (Xu *et al.*, 2003).

In contrast to the above study, Yeh and Hu (2001) determined that oxidized lycopene (10 mM lycopene in tetrahyrofuran, incubated at 60°C in open air for one hour, with degradation determined as the loss of absorbance at 470 nm) decreased Hs68 cell viability and induced apoptotic cell death, as shown by the increased histone-associated DNA fragmentation. Oxidative DNA damage, expressed as the molar ratio of 8-OH-dG to 10^5 molecules of deoxyguanosine (dG), was significantly and dose-dependently increased at 20 and 40 μM oxidized lycopene concentrations. This study indicates that the storage and handling of lycopene-containing products may affect the quality and function of the lycopene contained within those products.

6.8. Observations in Humans

Fruits and vegetables that contain lycopene have been a normal part of the human diet since antiquity. Moreover, numerous clinical studies using tomato products have demonstrated that consumption of these tomato products and lycopene is safe and well tolerated. A reported side effect from excessive lycopene consumption is lycopenemia, a condition when an excess of lycopene in the blood leads to deposition in the liver forming fatty cysts. The skin takes on the red color found in tomatoes. Lycopenemia is considered harmless and is readily reversible when lycopene ingestion is discontinued. The following is a summary of two clinical studies that

carefully documented the safety of Lyc-O-Mato® Oleoresin 6% and two case reports of lycopenemia.

No lycopene-induced toxicity was observed in Spanish volunteers that were enrolled in a multicenter, placebo-controlled intervention study in healthy males and females (N=400) recruited from five European regions (France, Republic of Ireland, Northern Ireland, The Netherlands and Spain) designed to study the serum response of carotenoids and tocopherols (Olmedilla *et al.*, 2002). Subjects were given ~222 mg/day Lyc-O-Mato® extract (containing 13.3 mg/day lycopene) for 20 weeks. Plasma lycopene levels increased 2-fold (~1.2 μmol/L) compared with placebo controls. No significant changes in biochemical (plasma glucose, cholesterol, triacylglycerol, uric acid, albumin, aspartate aminotransferase (AST), total bilirubin, calcium, creatinine, alkaline phosphatase, low density lipoprotein (LDL), total protein, urea, iron or hematological indices (hemoglobin concentration, red cell (RBC) Count, HGB, HCT, MCV, MCH, MCHC)[12], white cell indices (number and *percentage* of neutrophils, lymphocytes, monocytes, eosinophils, basophils), platelet count and mean platelet volume were observed throughout the study[13]. Carotenodermia[14] developed in 25% of the subjects, but this was considered harmless and was readily reversible when carotene ingestion is discontinued.

Reich *et al.*(1960) reported a case of lycopenemia in a woman who consumed 2 liters of tomato juice daily for 'several years,' being equivalent to a daily dosage of up to 160 mg of lycopene. She had a previous history of the same condition. The woman was admitted to the hospital with chest pains and apparent jaundice, but an examination showed no indication of jaundice, so the physicians looked to carotenoid intake to explain the coloration of the skin.

After three weeks on a diet free of tomato juice, total blood carotenoid levels were 3.7 μg/mL (α- and β-carotene=1.5 μg/mL; lycopene=1.1 μg/mL; lutein=1.1 μg/mL). The expected total carotenoid levels were ~1 μg/mL. It was estimated that the total carotenoid levels had dropped about 19% during the 3 weeks of tomato juice deprivation. Thus, the approximate level of the four carotenoids in the serum at the time of admission was approx. 4.4 μg/mL, or approximately 4X the expected level in normal serum.

The woman was also diagnosed with cholelithiasas[15] and a cholecystectomy was performed. During this process, there was an opportunity to examine the patient's bile for carotenoid content. By colorimetry analysis, the bile contained approximately 7.6 mg carotenoids/mL. The patient's liver was enlarged and had a "strange" orange-yellow color. A biopsy found indications of carotenoid (lycopene) accumulation, indicated as masses of butter-yellow, non-doubly refractile material within the liver cells.

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[12] RBC=red blood cell; HGB=hemoglobin; HCT=hematocrit; MCV= mean corpuscular volume; MCH= mean corpuscular HGB; MCHC=mean corpuscular HGB concentration.

[13] These specific endpoints were not published with the article, but were provided in response to an inquiry in an e-mail from Begoña Olmedilla (bolmedilla.hpth@salud.madrid.org).

[14] The authors of this study used the term carotenodermia, however this was in all likelihood lycopenemia.

[15] Cholelithiasis = the presence of gallstones in the gallbladder.

The authors of this study distinguish this first reported case of lycopenemia from carotenemia by the much deeper orange skin hue observed in the patient; and due to the fact that, unlike cases of carotenemia reported to date, the patient did not have diabetes, hypothyroidism, nephrosis or lipemia---conditions which have been associated with carotenemia in other cases. In addition, the liver from the lycopenemic patient was orange yellow and gave histologic evidence of storage of carotenoid pigments (the livers of patients with carotenemia have been reported as normal in color).

Reich *et al.* (1960) concluded that, in spite of the observations made, lycopene was neither toxic nor beneficial to the patient, and they characterized lycopene as simply an "adventitious visitor" to her body.

Lycopenemia was reported in a 19-year old Italian woman that sought medical attention after developing a cutaneous discoloration lasting 3 months (La Placa *et al.*, 2000). Her diet for three years consisted of four to five big red tomatoes and pasta with tomato sauce daily. A "yellow-orange" pigmentation was observed on the forehead, nasolabial folds, palms and soles. She reported recurrent abdominal pain. Hepatic echographia revealed a digitate area relatively hypoechogenic, measuring 2 cm in diameter, in the upper portion of the parenchyma, which the authors suggested consisted of deposits of lycopene. Blood cell count and laboratory tests, including liver enzymes, were normal. Restricting the diet of tomatoes resulted in a complete regression of pigmentation within 6 weeks and disappearance of the abdominal pain.

7. β-CAROTENE HUMAN INTERVENTION TRIALS

The Expert Panel considered whether reported results of studies of β-carotene have any relevance to the safety of lycopene. Randomized clinical trials of β-carotene supplementation as a chemopreventive agent have reported contradictory results. In two of four intervention trials (Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study (ATBC) 1994; U.S. Beta Carotene and Retinol Efficacy Trial (CARET) Omenn *et al.*, 1996a; Omenn *et al.*, 1996b), increased lung cancer risk was measured among heavy smokers who received pharmacologic doses of β-carotene either alone (20 mg/day; ATBC) or β-carotene (30 mg/day) plus retinyl palmitate (25,000 IU/day; CARET). No increased risk for other types of cancers was observed. In contrast, no increases in lung cancer or any other cancer incidences were observed in any subjects, including smokers, consuming high doses of β-carotene (50 mg on alternate days; ~25 mg/day) from the U.S. Physician's Health Study (Hennekens *et al.*, 1996). Moreover, a large study conducted in a high-risk population in Linxian, China found that supplementation with 15 mg β-carotene, 50 μg selenium and 30 mg vitamin E daily for 5 years reduced the number of deaths from gastric cancer (Blot *et al.*, 1993). The results from these human intervention studies are difficult to interpret given their different designs and study populations, but one possible explanation is that physiological doses (<20 mg/day) of β-carotene have no adverse effects, whereas pharmacological doses (>20 mg/day) may cause a slight increase in lung cancer risk in heavy smokers. At this time, however, the data are inconclusive and the risk, if any, from β-carotene consumption will require further study.

The specific molecular and cellular mechanism(s) underlying the reported effects of β-carotene in these studies has not been identified. While several hypotheses have been put forward, the most credible of these relates to β-carotene's pro-vitamin A activity and altered retinoid signaling. Because lycopene is not a pro-vitamin A carotenoid, lycopene will not affect these retinoid pathways.

7.1. Hypothesis for β-Carotene Effects: Altered Retinoid Signaling

Wang *et al.* (1999) studied ferrets that were given a β-carotene supplement (at a dose equivalent to those used in the clinical trials) or exposed to cigarette smoke, or both for 6 months. They chose ferrets as a model because ferrets metabolize β-carotene in much the same way as humans (Wang and Krinsky, 1997). The results showed a proliferative response in lung tissue in all β-carotene-supplemented animals and this response was enhanced by exposure to tobacco smoke. Histological analysis revealed localized keratinized squamous metaplasia (a precancerous lesion) in all of the ferrets in the high-dose groups of β-carotene, with or without exposure to smoke. The β-carotene treated groups had significantly lower concentrations of retinoic acid in lung tissue and they exhibited 18% to 73% reductions in retinoic acid receptor beta (RARβ) gene expression. The authors proposed that the increased production of β-apocarotenals (from eccentric cleavage of β-carotene) in the ferret lung might promote lung tumorigenesis through interference with retinoid signaling *via* depression of retinoic acid levels (required for normal cell growth and regulation) and down regulation of RARβ (a tumor suppressor gene).

A subsequent study using the same ferret model reported that the β-carotene effects were dose-dependent (Liu *et al.*, 2000). Physiological doses of β-carotene (equivalent to 6 mg/day in humans) were not harmful, and instead protected against lung damage induced by cigarette smoke. No protection from smoke-induced lung tissue damage was observed in the ferrets given high doses of β-carotene (equivalent to 30 mg/day in humans). At the end of the study, β-carotene levels in lung tissue increased 25-fold in the low-dose group, and 202-fold in the high-dose group. Thus, it appears that the most plausible explanation for the results of these studies is that β-carotene may interfere with retinoid signaling at high doses.

7.2. β-Carotene *vs.* Lycopene

It is apparent from the studies summarized above that there are significant differences between β-carotene and lycopene. Whereas β-carotene alters retinoid signaling, this activity has not been reported for lycopene, a non-provitamin A carotenoid. Therefore, it is the Expert Panel's view that the data described above with respect to β-carotene are not relevant to a safety assessment of lycopene.

8. EVALUATION

Lyc-O-Mato® Powder is a tomato concentrate that contains an average of approximately 1% lycopene. Tomatoes are a normal component of the American diet with an estimated average annual consumption of processed tomato products equal to nine million metric tons. Tomato lycopene extracts are approved food colorants in the EU and Japan. In the US, all of the major constituents in Lyc-O-Mato® Powder are either approved food ingredients (food additives, GRAS) or are normal constituents found in commonly consumed foods at similar concentrations.

Lyc-O-Mato® Powder is stable at ambient temperatures for up to two (2) years and is stable as an added ingredient to a variety of foods. As the major biologically active constituent, lycopene, is equivalent to that found in Lyc-O-Mato® Oleoresin 6%, the toxicological assays used to determine the safety of Lyc-O-Mato® Oleoresin 6% were used to evaluate the safety of lycopene contained in Lyc-O-Mato® Powder.

Topical application of Lyc-O-Mato® Oleoresin 6% produced equivocal results. Initial tests indicated that Lyc-O-Mato® Oleoresin 6% was moderately irritating to rabbit skin and eyes and was a moderate sensitizer to guinea pig skin. A later study on a new batch of Lyc-O-Mato® Oleoresin 6% indicated that it was not a skin irritant to rabbits. The earlier results were most likely due to the presence of lactic acid in that batch of Lyc-O-Mato® Oleoresin 6%. The current method of manufacturing described in this document produces Lyc-O-Mato® Powder without lactic acid.

Lyc-O-Mato® Oleoresin 6% was found to be non-toxic in acute and subchronic animal studies. In separate tests, a single oral administration of 5000 mg/kg Lyc-O-Mato® Oleoresin 6% (containing 300 mg/kg lycopene) or single dermal application of 2000 mg/kg Lyc-O-Mato® Oleoresin 6% (containing 120 mg/kg lycopene) to rats resulted in no lethality or toxicity by two weeks. A ninety-day subchronic study in rats identified the NOAEL from oral exposure to Lyc-O-Mato® Oleoresin 5% to be the highest dose tested, 4500 mg/kg/day (containing 225 mg/kg/day lycopene). Lyc-O-Mato® Oleoresin 6% was not mutagenic in an Ames assay and reports indicate that lycopene–rich tomato extracts are anti-carcinogenic in animal studies.

Lycopene is fat-soluble and absorbed in parallel with overall fat digestion and absorption. Both Lyc-O-Mato® Powder and Lyc-O-Mato® Oleoresin 6% contain predominantly all-*trans* lycopene (90-95% of the lycopene present). However, the proportions of the *cis*/*trans* isomers in serum appear constant regardless of the isomer distribution in the supplement/diet, thus serum isomer distribution appears to be independent of that in the supplement/diet. Serum steady-state levels following lycopene supplementation are reached at about four weeks. Lycopene is found predominantly in the testes and adrenals with significant amounts found in the liver, adipose tissue, prostate, kidney and ovary. The majority (>50%) of tissue and serum lycopene consist of the 9-*cis*-, 13-*cis*- and 15-*cis*-isomers, while the 5-*cis*- and 9-*cis* are the main *cis*-isomers in plasma. Lycopene is eliminated by first-order kinetics with a plasma half-life of 2 to 33 days.

Human clinical intervention studies indicate that long-term consumption of Lyc-O-Mato® Oleoresin 6% is well tolerated. No clinically significant toxicity was observed in an ongoing

clinical intervention study in which subjects consumed up to 2000 mg/day Lyc-O-Mato® Oleoresin 6% (containing 120 mg/day lycopene) supplements for 4 to 10 months, although one subject developed treatment-related diarrhea that subsided after the Lyc-O-Mato® Oleoresin 6% supplementation was stopped. In a multicenter, placebo-controlled intervention study, no clinically significant toxicity was reported following 20 weeks consumption of ~222 mg/day Lyc-O-Mato® Oleoresin 6% (containing 13.3 mg/day lycopene).

Reported side effects from excessive consumption of lycopene from any source are carotenodermia[16] and lycopenemia[17], which are not considered health hazards and are reversible conditions. Carotenodermia[18] was observed in 25% of the subjects in one arm of the multicenter study. However, there were no reports of carotenodermia developing in subjects from the other arms of this study nor was carotenodermia reported in the ongoing study in which subjects consumed 2000 mg/day Lyc-O-Mato® Oleoresin 6% (containing 120 mg/day lycopene) supplements for up to ten months. Case reports of lycopenemia indicate that the condition was not considered adverse and was reversed upon reduction of excessive lycopene from the diet.

Lycopene is a non-provitamin A carotenoid, which does not alter retinoid signaling like the provitamin A carotenoid, β-carotene. Therefore, it is the Expert Panel's view that the data reported with respect to β-carotene are not relevant to a safety assessment of lycopene.

The NOAEL for Lyc-O-Mato® Oleoresin 6% in rats is 4500 mg/kg/day (equivalent to 270,000 mg/day in a 60 kg human) and the highest tolerable intake of Lyc-O-Mato® Oleoresin 6% in humans identified is at least 2000 mg/day. Thus, based on the generally available data establishing the Lyc-O-Mato® Oleoresin 6% NOAEL at 4500 mg/kg/day (containing 225 mg/kg/day lycopene), the Panel has used a safety factor of 135 and established a conservative acceptable daily intake (ADI) of Lyc-O-Mato® Oleoresin 6% of 33 mg/kg/day or 2000 mg/day for a 60 kg individual, which provides for a safe intake of 120 mg/day lycopene.

Combining the 90th percentile lycopene consumption levels from foods supplemented with Lyc-O-Mato® Powder (mg/day) with the 90th percentile current consumption level of lycopene from conventional foods (13.7 mg/day), the estimated daily intake of lycopene from conventional foods is 35.9 mg/day. The 90th percentile consumption of lycopene as a color additive (in the foods reported here) is proposed to be 9.20 mg/day. In addition, lycopene is sold as a dietary supplement with potential dietary supplement use at the 90th percentile at 60 mg/day. Thus, the potential theoretical maximum lycopene consumption at the 90th percentile may reach 118.8 mg/day. This theoretical intake level represents a conservative estimate because it is unlikely that an individual would consume lycopene from conventional foods at the 90th percentile level. Even this conservative estimate, however, is within the proposed ADI of 120 mg/day lycopene.

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[16] Carotenodermia is characterized by a yellowish discoloration of the skin. It is considered harmless and is readily reversible when carotene ingestion is discontinued.

[17] A similar condition as carotenodermia – an excess of lycopene in the blood leads to deposition in the liver forming "fatty cysts". The skin takes on the red color found in tomatoes. It is considered harmless and is readily reversible when lycopene ingestion is discontinued.

[18] The authors of this study used the term carotenodermia, however this was in all likelihood lycopenemia.

A letter concerning the use of Lyc-O-Mato® Powder as a color additive has been reviewed by the FDA, and found to fall within the federal guidelines for dried juice and vegetable extracts as color additives. This use may have an additive effect on Lyc-O-Mato® Powder consumption as an ingredient. In realistic terms however, saturation of the diet with lycopene could not be achieved for a number of technical and esthetic reasons (see section on consumption) and, as a result, the use of Lyc-O-Mato® Powder, is largely self-limiting. This self-limiting nature of Lyc-O-Mato® Powder provides some realistic boundaries for a still conservative estimate for lycopene ingestion (as a color) at as much as 38 mg. The addition of 38 mg/day as a color additive to the 90th percentile of 109.6 mg/day for all other purposes, would yield a total exposure of approximately 150 mg/day – an amount 16% greater than the ADI and well within the NOAEL, still allowing a safety factor >100. Lastly, and importantly, the only adverse events that have been reported from high intakes of lycopene (*i.e.*, one case study reported a calculated dose of 160 mg/day lycopene for several years) were skin discoloration and deposits of lycopene in the liver, both of which are reversible upon cessation of lycopene-containing foods. Therefore, even at high doses of lycopene consumption, toxicity would not be expected.

9. CONCLUSION

After critically evaluating the information available, the Expert Panel has determined that, based on common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food, there is reasonable certainty that Lyc-O-Mato® Powder, produced in accordance with current Good Manufacturing Practice (cGMP), will not be harmful under the intended conditions of use, and is therefore Generally Recognized As Safe (GRAS), by scientific procedures, when used as an ingredient to provide consumers with a supplementary source of lycopene in their diets, so that total daily consumption of lycopene from all sources does not exceed 120 mg lycopene. In particular, the Expert Panel has evaluated the proposed use of Lyc-O-Mato® Powder at specified levels in the foods noted in this GRAS document and has concluded that such use results in an estimated intake that is below 120 mg/day lycopene and is therefore Generally Recognized As Safe (GRAS).

10. CERTIFICATION

The undersigned authors of this document—a dossier in support of GRAS status determination for food ingredient use of Lyc-O-Mato® Powder—hereby certify that, to the best of their knowledge and belief, this document is a complete and balanced representation of available information, favorable as well as unfavorable, known by the authors to be relevant to evaluation of the substance described herein.

20 JAN 05

Ray A. Matulka, Ph.D.
Toxicologist
Burdock Group

Date

1/20/05

James C. Griffiths, Ph.D., DABT
Director of Toxicology
Burdock Group

Date

11. SIGNATURES

George A. Burdock, Ph.D., D.A.B.T. Burdock Group	20 Jan 05 Date
	1/24/05 Date
Norman I. Krinsky, Ph.D. Tufts University School of Medicine	21 Jan 05 Date

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13. APPENDIX A

Table 6. Foods selected for consumption analysis of Lyc-O-Mato Powder supplementation (ordered by food code).

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
	TOTAL NUMBER OF CONSUMERS (WTD)	2.57E+08	
	TOTAL AMOUNT OF FOOD CONSUMED (WTD)	5.13E+09	85550284
	MEAN AMOUNT OF FOOD CONSUMED PER PERSON (WTD)	19.98	0.333
	50TH PERCENTILE CONSUMERS	16.34	0.272
	90TH PERCENTILE CONSUMERS	35.94	0.599
	95TH PERCENTILE CONSUMERS	45.57	0.759
11220000	MILK CONDENSED SWEETENED NS AS TO DILUTION	0.08	0.001
11220100	MILK CONDENSED SWEETENED UNDILUTED	0.41	0.007
11220200	MILK CONDENSED SWEETENED DILUTED	0.64	0.01
11310000	MILK IMITATION FLUID SOY BASED	0.53	0.01
11320000	MILK SOY READY-TO-DRINK NOT BABY	3.11	0.05
11330000	MILK SOY DRY RECONSTITUTED NOT BABY	3.47	0.06
11340000	MILK IMITATION FLUID NONSOY SWEETENED NOT CHOCOLATE	2.62	0.04
11410000	YOGURT NS AS TO TYPE OF MILK/FLAVOR	1.41	0.02
11411010	YOGURT PLAIN NS AS TO TYPE OF MILK	1.5	0.02
11411100	YOGURT PLAIN WHOLE MILK	3.28	0.05
11411200	YOGURT PLAIN LOWFAT MILK	2.95	0.05
11411300	YOGURT PLAIN NONFAT MILK	2.46	0.04
11420000	YOGURT VANILLA LEMON COFFEE NS AS TO MILK TYPE	2.81	0.05
11421000	YOGURT VANILLA LEMON COFFEE WHOLE MILK	3.38	0.06
11422000	YOGURT VANILLA LEMON COFFEE LOWFAT MILK	2.33	0.04
11423000	YOGURT VANILLA LEMON COFFEE NONFAT MILK	2.87	0.05
11424000	YOGURT VANILLA LEMON COFFEE NONFAT MILK LOW CAL SWEET	2.19	0.04
11425000	YOGURT CHOCOLATE NS AS TO TYPE OF MILK	1.63	0.03
11427000	YOGURT CHOCOLATE NONFAT MILK	2.32	0.04
11430000	YOGURT FRUIT VARIETY NS AS TO MILK TYPE	2.55	0.04
11431000	YOGURT FRUIT VARIETY WHOLE MILK	3.45	0.06
11432000	YOGURT FRUIT VARIETY LOWFAT MILK	2.47	0.04
11433000	YOGURT FRUIT VARIETY NONFAT MILK	3.55	0.06
11433500	YOGURT FRUITED NONFAT MILK LOW CAL SWEETENER	2.89	0.05
11459990	YOGURT FROZEN NS AS TO FLAVOR NS TO TYPE OF MILK	8.87	0.15
11460000	YOGURT FROZEN NOT CHOCOLATE TYPE OF MILK NS	2.78	0.05
11460100	YOGURT FROZEN CHOCOLATE TYPE OF MILK NS	3.7	0.06
11460160	YOGURT FROZEN CHOCOLATE LOWFAT MILK	2.07	0.03
11460170	YOGURT FROZEN NOT CHOCOLATE LOWFAT MILK	2.62	0.04
11460190	YOGURT FROZEN NS AS TO FLAVOR NONFAT MILK	4.24	0.07
11460200	YOGURT FROZEN CHOCOLATE NONFAT MILK	2.82	0.05
11460250	YOGURT FROZEN NOT CHOCOLATE W/ SORBET/SORBET-COATED	1	0.02

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
11460300	YOGURT FROZEN NOT CHOCOLATE NONFAT MILK	2.07	0.03
11460400	YOGURT FRZ CHOCOLATE NONFAT MILK W/ LOW-CAL SWEET	2.18	0.04
11460410	YOGURT FRZ NOT CHOC NONFAT MILK W/ LOW-CAL SWEET	2.76	0.05
11460430	YOGURT FROZEN CHOCOLATE WHOLE MILK	3.09	0.05
11460440	YOGURT FROZEN NOT CHOCOLATE WHOLE MILK	1.16	0.02
11461200	YOGURT FROZEN SANDWICH	2.27	0.04
11461270	YOGURT FROZEN CONE NOT CHOCOLATE LOWFAT MILK	1.42	0.02
11511000	MILK CHOCOLATE NFS	3.71	0.06
11511100	MILK CHOCOLATE WHOLE MILK BASED	3.77	0.06
11511200	MILK CHOCOLATE REDUCED FAT MILK BASED	4.54	0.08
11511300	MILK CHOCOLATE SKIM MILK BASED	3.12	0.05
11512000	COCOA HOT CHOCOLATE NOT FROM DRY MIX W/WHOLE MILK	3.12	0.05
11512500	HOT CHOCOLATE DRINK W/ EVAP MILK PUERTO RICAN	3.75	0.06
11513000	COCOA & SUGAR MIXTURE MILK ADDED NS TYPE MILK	3.55	0.06
11513100	COCOA & SUGAR MIXTURE WHOLE MILK ADDED	3.94	0.07
11513200	COCOA & SUGAR MIXTURE LOWFAT MILK ADDED	5.05	0.08
11513300	COCOA & SUGAR MIXTURE SKIM MILK ADDED	3.13	0.05
11514100	COCOA SUGAR & DRY MILK MIXTURE WATER ADDED	3.62	0.06
11514300	COCOA W/ NF DRY MILK LO CAL SWEETENER WATER ADDED	3.12	0.05
11516000	COCOA WHEY LO CAL SWEETNER MIX LOWFAT MILK ADDED	4.17	0.07
11519000	MILK BEVERAGE NOT CHOCOLATE W/ WHOLE MILK	4.32	0.07
11520000	MILK MALTED UNFORTIFIED FLAVOR NS	2.94	0.05
11525000	MILK MALTED FORTIFIED NATURAL FLAVOR (INCL OVALTINE	3.68	0.06
11526000	MILK MALTED FORTIFIED CHOCOLATE (INCL OVALTINE)	3.64	0.06
11527000	MILK MALTED FORTIFIED (INCL OVALTINE)	4.74	0.08
11531000	EGGNOG MADE W/ WHOLE MILK (INCLUDE EGG NOG NFS)	3.43	0.06
11541000	MILK SHAKE NS AS TO FLAVOR OR TYPE	3.16	0.05
11541110	MILK SHAKE HOMEMADE OR FOUNTAIN-TYPE CHOCOLATE	4.71	0.08
11541120	MILK SHAKE HOMEMADE/FOUNTAIN-TYPE NOT CHOCOLATE	4.49	0.07
11541400	MILK SHAKE WITH MALT (INCL MALTED MILK W/ICE CREAM)	4.51	0.08
11541500	MILK SHAKE MADE W/ SKIM MILK CHOCOLATE	2.9	0.05
11541510	MILK SHAKE MADE W/ SKIM MILK NOT CHOCOLATE	3.31	0.06
11542100	CARRY-OUT MILK SHAKE CHOCOLATE	4.23	0.07
11542200	CARRY-OUT MILK SHAKE NOT CHOCOLATE	3.35	0.06
11551050	MILK FRUIT DRINK (INCL LICUADO)	2.61	0.04
11552200	MILK-BASED FRUIT DRINK (INCL ORANGE JULIUS)	6.55	0.11
11560000	CHOC-FLAVORED DRINK WHEY-&MILK-BASED(INCL YOO-HOO)	3.05	0.05
11612000	INSTANT BREAKFAST POWDER MILK ADDED	3.09	0.05
11613000	INSTANT BFAST PWDR SWT W/ LO CAL SWT MILK ADDED	3.31	0.06
11623000	MEAL SUPPLEMENT / REPLACEMENT PREPARED RTD	4.6	0.08
11641000	MEAL REPLACEMENT MILK BASED HIGH PROTEIN LIQUID	3.2	0.05

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
11810000	MILK DRY NOT RECONSTITUTED NS AS TO FAT	1.35	0.02
11811000	MILK DRY WHOLE NOT RECONSTITUTED	0.53	0.01
11812000	MILK DRY LOWFAT NOT RECONSTITUTED	0.25	0
11813000	MILK DRY NONFAT NOT RECONSTITUTED	3.73	0.06
11830100	COCOA W/DRY MILK & SUGAR DRY MIX NOT RECONST	0.24	0
11830110	COCOA POWDER W/ NFD MILK LOW CAL SWEETENER DRY	3.2	0.05
11830150	COCOA POWDER NOT RECONSTITUTED (NO DRY MILK)	0.32	0.01
11830160	COCOA-FLAVORED BEVERAGE POWDER W/ SUGAR DRY MIX	1.41	0.02
11830210	MILK MALTED DRY FORTIFD NOT RECONST NOT CHOC	0.9	0.02
11830260	MILK MALTED DRY FORTIFIED NOT RECONST CHOC	0.61	0.01
11830400	MILK BEV POWDER DRY NOT RECONST NOT CHOC	1.5	0.02
11830800	INSTANT BREAKFAST POWDER NOT RECONSTITUTED	5.92	0.1
11830810	INSTANT BFAST PWDR SWT W/ LO CAL SWT NOT RECONSTUT	3.7	0.06
11830970	MEAL REPLACEMENT PROTEIN TYPE MILK-BASE POWDER	5.8	0.1
11831500	NUTRIENT SUPPLEMENT MILK-BASE HIGH PROT NOT RECONST	5.4	0.09
11835100	MEAL REPLACEMENT POSITRIM DRINK MIX DRY POWDER	0.54	0.01
12100100	CREAM FLUID NS AS TO LIGHT HEAVY OR HALF & HALF	5.55	0.09
12110100	CREAM LIGHT FLUID (INCL COFFEE CRM TABLE CREAM)	5.93	0.1
12120100	CREAM HALF & HALF	5.13	0.09
12130100	CREAM HEAVY FLUID	4.95	0.08
12140000	CREAM HEAVY WHIPPED SWEETENED	2.29	0.04
12140100	CREAM WHIPPED PRESSURIZED CONTAINER	2.87	0.05
12310100	SOUR CREAM (INCL W/ CHIVES)	2.94	0.05
12310300	SOUR CREAM REDUCED FAT	4.66	0.08
12310350	SOUR CREAM LIGHT	4.75	0.08
12310370	SOUR CREAM FAT FREE	2.96	0.05
12320200	SOUR CREAM FILLED SOUR DRESSING NONBUTTERFAT	0.74	0.01
12350000	DIP SOUR CREAM BASE (INCLUDE BUTTERMILK-TYPE DIP)	4.82	0.08
12350020	DIP SOUR CREAM BASE REDUCED CALORIE	3.96	0.07
12350100	SPINACH DIP SOUR CREAM BASE	2.22	0.04
13110000	ICE CREAM NFS	6.52	0.11
13110100	ICE CREAM REGULAR NOT CHOCOLATE	5.07	0.08
13110110	ICE CREAM REGULAR CHOCOLATE	4.98	0.08
13110120	ICE CREAM RICH FLAVORS OTHER THAN CHOCOLATE	2.88	0.05
13110130	ICE CREAM RICH CHOCOLATE	5.25	0.09
13110200	ICE CREAM SOFT SERVE NOT CHOCOLATE	4.17	0.07
13110210	ICE CREAM SOFT SERVE CHOCOLATE	1.82	0.03
13110400	MILK DESSERT FRZN FLAVORS NOT CHOC (NO BUTTERFAT)	2.1	0.04
13120050	ICE CREAM BAR OR STICK NOT CHOC- OR CAKE-COVERED	2.52	0.04
13120100	ICE CREAM BAR/STICK CHOCOLATE COVERED	2.11	0.04
13120110	ICE CREAM BAR CHOCOLATE/CARAMEL COVERED W/ NUTS	2.1	0.04
13120121	ICE CREAM BAR RICH ICE CREAM THICK CHOC COVER	1.85	0.03
13120140	ICE CREAM BAR/STICK CHOC ICE CREAM CHOC COVER	1.79	0.03
13120300	ICE CREAM BAR CAKE-COVERED	2.33	0.04

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FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
13120500	ICE CREAM SANDWICH	1.83	0.03
13120550	ICE CREAM COOKIE SANDWICH (INCLUDE CHIPWICH)	1.23	0.02
13120710	ICE CREAM CONE CHOC-COVERED W/ NUTS NOT CHOC	1.86	0.03
13120720	ICE CREAM CONE CHOC-COVERED OR DIPPED NOT CHOC	2.29	0.04
13120730	ICE CREAM CONE NO TOPPING NOT CHOCOLATE	3.62	0.06
13120770	ICE CREAM CONE NO TOPPING CHOCOLATE ICE CREAM	2.73	0.05
13120790	ICE CREAM SUNDAE CONE (INCL DRUMSTICK ALL FLAVORS)	3.38	0.06
13120800	ICE CREAM SODA NOT CHOCOLATE	8.51	0.14
13121100	ICE CREAM SUNDAE FRUIT TOPPING W/ WHIPPED CREAM	5.21	0.09
13121200	ICE CREAM SUNDAE PREPACKAGED NOT CHOCOLATE	5.82	0.1
13121300	ICE CREAM SUNDAE CHOCOLATE TOPPING W/ WHIPPED CREAM	5.21	0.09
13122500	ICE CREAM PIE COOKIE CRUST FUDGE TOPPING WHIP CREAM	7.27	0.12
13124100	SORBET & ICE CREAM	2.23	0.04
13125100	ICE CREAM W/ SHERBET	8.12	0.14
13130300	LIGHT ICE CREAM NOT CHOCOLATE (FORMERLY ICE MILK)	3.06	0.05
13130310	LIGHT ICE CREAM CHOCOLATE (FORMERLY ICE MILK)	3.72	0.06
13130350	LIGHT ICE CREAM PREMIUM NOT CHOC (FORMERLY ICE MILK)	3.16	0.05
13130360	LIGHT ICE CREAM PREMIUM CHOCOLATE (FORMERLY ICE MILK)	2.84	0.05
13130590	LIGHT ICE CREAM SOFT SERVE NS FLAVOR (FORMERLY ICE MILK)	2.76	0.05
13130600	LIGHT ICE CREAM SOFT SERVE NOT CHOC (FORMERLY ICE MILK)	7.26	0.12
13130610	LIGHT ICE CREAM SOFT SERVE CHOC (TASTEE FRZ DAIRY QUEEN)	6.91	0.12
13130620	LIGHT ICE CREAM SOFT SERVE CONE NOT CHOC (DAIRY QUEEN)	7.79	0.13
13130630	LIGHT ICE CREAM SOFT SERVE CONE CHOC (FORMERLY ICE MILK)	9.82	0.16
13135000	LIGHT ICE CREAM SANDWICH (DAIRY QUEEN) (FORMERLY ICE MILK)	1.89	0.03
13140100	LIGHT ICE CREAM BAR/STICK CHOC-COATED (FORMERLY ICE MILK)	1.61	0.03
13140550	LIGHT ICE CREAM CONE CHOCOLATE (FORMERLY ICE MILK)	3.02	0.05
13140660	LIGHT ICE CREAM SUNDAE CHOC / FUDGE TOP (W/O WHIP CREAM)	5.21	0.09
13140670	LIGHT ICE CREAM SUNDAE FRUIT TOP (W/O WHIP CREAM)(ICE MILK)	5.21	0.09
13140680	LIGHT ICE CREAM SUNDAE NO FRUIT/CHOC TOP (W/O WHIP CREAM)	5.21	0.09
13140700	LIGHT ICE CREAM CREAMSICLE OR DREAMSICLE (FORMERLY ICE MILK)	2.04	0.03
13140900	LIGHT ICE CREAM FUDGESICLE (FORMERLY ICE MILK)	2.68	0.04
13142000	MILK DESSERT BAR/STICK FROZEN W/ COCONUT	4.07	0.07
13150000	SHERBET ALL FLAVORS	4.55	0.08
13160100	MILK DESSERT FZN LOWFAT W/LOW CAL SWEET NOT CHOC	3.77	0.06

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
13160150	MILK DESSERT FROZ NONFAT W/ LOW CAL SWEETENER CHOCOLATE	3.41	0.06
13160160	MILK DESSERT FROZ NONFAT W/ LOW CAL SWEETENER NOT CHOC	6.05	0.1
13160200	MILK DESSERT FROZEN LOWFAT NOT CHOCOLATE	5.08	0.08
13160210	MILK DESSERT FROZEN LOWFAT CHOCOLATE	5.19	0.09
13160400	MILK DESSERT FROZ MILK-FAT FREE NOT CHOC	4.82	0.08
13160410	MILK DESSERT FROZ MILK-FAT FREE CHOC	4.39	0.07
13160600	MILK DESSERT FROZ W/ LOW CAL SWEETENER NOT CHOC	3.63	0.06
13160650	MILK DESSERT FROZ W/ LOW CAL SWEETENER CHOCOLATE	1.81	0.03
13161600	MILK DES BAR FROZEN LOFAT MILK&LO CAL SWEETENER	2.27	0.04
13161630	LIGHT ICE CREAM BAR/STICK W/ LOW-CAL SWEETENER CHOC COAT	1.91	0.03
13200110	PUDDING NFS	3.82	0.06
13210110	PUDDING BREAD (INCLUDE W/ RAISINS)	5.15	0.09
13210220	PUDDING CHOCOLATE RTE NS FROM DRY MIX OR CANNED	4.65	0.08
13210280	PUDDING NOT CHOC RTE NS FROM DRY MIX OR CANNED	6.12	0.1
13210290	PUDDING NOT CHOC RTE LO CAL W/ ART SWTNER	2.05	0.03
13210300	CUSTARD	4.39	0.07
13210350	CUSTARD PUERTO RICAN STYLE (FLAN)	4.68	0.08
13210410	PUDDING RICE	5.41	0.09
13210450	PUDDING RICE FLOUR W/ NUTS (INDIAN DESSERT)	3.95	0.07
13210500	PUDDING TAPIOCA MADE FROM HOME RECIPE MADE W/ MILK	5.73	0.1
13210520	PUDDING TAPIOCA MADE FROM DRY MIX MADE W/ MILK	4.8	0.08
13210710	PUDDING INDIAN (MILK MOLASSES CORNMEAL-BASED)	3.74	0.06
13210750	PUDDING PUMPKIN	7.21	0.12
13220110	PUDDING NOT CHOCOLATE PREPARED FROM DRY MIX MILK ADDED	8.14	0.14
13220120	PUDDING CHOCOLATE PREPARED FROM DRY MIX MILK ADDED	6.4	0.11
13220210	PUDDING NOT CHOC FROM DRY LOW CAL ARTIFICIAL SWEET W/MILK	12.04	0.2
13220220	PUDDING CHOC FROM DRY LOW CAL ARTIFICIAL SWEET MILK ADDED	4.9	0.08
13220235	PUDDING CAN CHOC FAT FREE	4.21	0.07
13220245	PUDDING CANNED NOT CHOC FAT FREE	3.66	0.06
13230110	PUDDING CANNED NOT CHOCOLATE	4.09	0.07
13230130	PUDDING CANNED CHOCOLATE	4.02	0.07
13230200	PUDDING CANNED CHOC & NON-CHOC FLAVORS COMBINED	3.34	0.06
13230500	PUDDING CANNED TAPIOCA	3.06	0.05
13230510	PUDDING CANNED TAPIOCA FAT FREE	4.72	0.08
13241000	PUDDING W/ FRUIT & VANILLA WAFERS	9.38	0.16
13250000	MOUSSE CHOCOLATE	2.9	0.05
13250100	MOUSSE NOT CHOCOLATE	0.51	0.01
13252500	BARFI/BURFI INDIAN DESSERT FROM MILK/CREAM/RICOTTA	2.78	0.05
13411000	WHITE SAUCE MILK SAUCE	15.88	0.26

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
13412000	MILK GRAVY QUICK GRAVY	7.7	0.13
14200100	CHEESE COTTAGE NFS	2.14	0.04
14201010	CHEESE COTTAGE CREAMED	3.51	0.06
14201200	COTTAGE CHEESE FARMER'S	2.08	0.03
14202010	CHEESE COTTAGE W/ FRUIT	12.33	0.21
14203010	CHEESE COTTAGE DRY CURD	2.18	0.04
14203020	CHEESE COTTAGE SALTED DRY CURD	3.43	0.06
14203510	P.R. WHITE CHEESE (QUESO DEL PAIS BLANCO)	2.55	0.04
14204010	CHEESE COTTAGE LOWFAT	4	0.07
14204030	CHEESE COTTAGE LOWFAT W/ VEGETABLES	6.16	0.1
14205010	CHEESE COTTAGE LOW SODIUM	8.6	0.14
14206010	CHEESE COTTAGE LOWFAT LOW SODIUM	3.08	0.05
14210000	CHEESE YOGURT NFS	1.56	0.03
14301010	CHEESE CREAM	2.57	0.04
14303010	CHEESE CREAM LOWFAT	1.92	0.03
14410200	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE	1.88	0.03
14410210	CHEESE PROCESSED AMERICAN/CHEDDAR LOW SODIUM	1.45	0.02
14410300	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE LOWFAT	1.8	0.03
14410330	CHEESE PROC CHEESE PRODUCT AMER/CHED RED FAT	1.62	0.03
14410340	CHEESE PROC CHEESE PROD AMER/CHED RED FAT & SODIU	1.55	0.03
14410350	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE NONFAT	1.43	0.02
14410380	CHEESE PROCESSED CREAM CHEESE PRODUCT NONFAT	1.09	0.02
14410500	CHEESE PROCESSED CHEESE FOOD	1.07	0.02
14410600	CHEESE PROCESSED W/VEGETABLES(INCL PEPPER CHEESE)	1.39	0.02
14410710	CHEESE PROCESSED MOZZARELLA LOW SODIUM	1.34	0.02
14420000	CHEESE SPREAD NFS	3.52	0.06
14420100	CHEESE SPREAD AMERICAN OR CHEDDAR CHEESE BASE	4.77	0.08
14420140	CHEESE SPREAD AMER/CHED BASE LOW FAT LOW SODIUM	3.44	0.06
14420200	CHEESE SPREAD CREAM CHEESE OR NEUFCHATEL BASE	3.61	0.06
14420300	CHEESE SPREAD PRESSURIZED CAN	12.88	0.21
14501010	IMITATION CREAM CHEESE	1.5	0.03
14502010	IMITATION CHEESE AMERICAN OR CHEDDAR TYPE	3.26	0.05
14502040	IMITATION CHEESE AMER/CHEDDAR TYPE LOW CHOLESTERO	2.12	0.04
14610210	COTTAGE CHEESE W/ GELATIN DESSERT & FRUIT	7.41	0.12
14620100	DIP CREAM CHEESE BASE	7.86	0.13
14620120	SHRIMP DIP CREAM CHEESE BASE (INCL CLAM DIP)	4.52	0.08
14620150	DIP CHEESE W/ CHILI PEPPER (CHILI CON QUESO)	9.13	0.15
14620200	DIP CHEESE BASE OTHER THAN CREAM CHEESE	9.34	0.16
14630200	CHEESE SOUFFLE	4.75	0.08
14640000	CHEESE SANDWICH	8.3	0.14
14640100	CHEESE SANDWICH GRILLED	7.95	0.13
14640200	CHEESE SANDWICH HOAGIE	14.19	0.24
14650100	CHEESE SAUCE	9.29	0.15
14650150	CHEESE SAUCE MADE W/ LOWFAT CHEESE	18.58	0.31

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
14650160	ALFREDO SAUCE	17.79	0.3
14660200	CHEESE NUGGETS FRIED (INCL BANQUET BRAND)	8.78	0.15
14710100	CHEDDAR CHEESE SOUP	3.4	0.06
20000200	GROUND MEAT NFS	3.4	0.06
21304200	BEEF SHORTRIBS BBQ W/ SAUCE NS AS TO FAT	1.7	0.03
21304210	BEEF SHORTRIBS BBQ W/ SAUCE LEAN & FAT	2.64	0.04
21304220	BEEF SHORTRIBS BBQ W/ SAUCE LEAN ONLY	3.89	0.06
21500000	GROUND BEEF RAW	4	0.07
21500100	GROUND BEEF OR PATTY	3.23	0.05
21500110	GROUND BEEF MEATBALLS MEAT ONLY NS AS TO REG/LEAN	3.4	0.06
21500200	GROUND BEEF OR PATTY BREADED COOKED	1.45	0.02
21501000	GROUND BEEF REGULAR COOKED	3.72	0.06
21501200	GROUND BEEF LEAN COOKED	3.66	0.06
21501300	GROUND BEEF EXTRA LEAN COOKED	3.6	0.06
21540100	GROUND BEEF W/ TEXTURED VEGETABLE PROTEIN COOKED	2.37	0.04
22002000	PORK GROUND OR PATTY COOKED	2.33	0.04
22002100	PORK GROUND GROUND OR PATTY BREADED COOKED	3.53	0.06
22321110	HAM SMOKED OR CURED GROUND PATTY	0.46	0.01
22701030	PORK SPARERIBS BBQ W/ SAUCE NS FAT EATEN	2.72	0.05
22701040	PORK SPARERIBS BBQ W/ SAUCE LEAN & FAT EATEN	3.09	0.05
22701050	PORK SPARERIBS BBQ W/ SAUCE LEAN ONLY EATEN	2.17	0.04
23322100	DEER BOLOGNA	2.86	0.05
24198720	CHICKEN GROUND	1.94	0.03
24207000	TURKEY GROUND	3.44	0.06
25210110	FRANKFURTER WIENER OR HOT DOG NFS	3.81	0.06
25210150	FRANKFURTER OR HOT DOG CHEESE-FILLED	1.29	0.02
25210210	FRANKFURTER OR HOT DOG BEEF	4.38	0.07
25210220	FRANKFURTER OR HOT DOG BEEF & PORK	4.73	0.08
25210230	FRANKFURTER OR HOT DOG BEEF AND PORK LOWFAT	3.92	0.07
25210250	FRANKFURTER OR HOT DOG MEAT & POULTRY FAT FREE	3.22	0.05
25210280	FRANKFURTER OR HOT DOG MEAT & POULTRY	4.85	0.08
25210310	FRANKFURTER OR HOT DOG CHICKEN	4.3	0.07
25210410	FRANKFURTER OR HOT DOG TURKEY	4.5	0.08
25210610	FRANKFURTER OR HOT DOG BEEF LOWFAT	3.03	0.05
25210700	FRANKFURTER OR HOT DOG MEAT & POULTRY LOWFAT	2.33	0.04
25220100	BEEF SAUSAGE NFS	4.86	0.08
25220110	BEEF SAUSAGE BROWN & SERVE LINKS COOKED	1.42	0.02
25220120	BEEF SAUSAGE SMOKED STICK (INCLUDE BEEF JERKY)	8.67	0.14
25220130	BEEF SAUSAGE SMOKED	4.88	0.08
25220140	BEEF SAUSAGE FRESH BULK PATTY OR LINK COOKED	1.9	0.03
25220350	BRATWURST COOKED	4.84	0.08
25220360	BRATWURST W/ CHEESE	3.86	0.06
25220390	BOLOGNA BEEF LOW FAT	1.57	0.03
25220400	BOLOGNA PORK AND BEEF	2.62	0.04
25220410	BOLOGNA NFS	2.44	0.04

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
25220420	BOLOGNA LEBANON	2.8	0.05
25220430	BOLOGNA BEEF	2.77	0.05
25220440	BOLOGNA TURKEY	2.62	0.04
25220460	BOLOGNA PORK	1.76	0.03
25220470	BOLOGNA BEEF LOWER SODIUM	2.63	0.04
25220480	BOLOGNA CHICKEN BEEF & PORK	2.53	0.04
25220500	BOLOGNA BEEF & PORK LOWFAT	2.26	0.04
25220510	CAPICOLA	2.34	0.04
25220650	CHICKEN & BEEF SAUSAGE SMOKED	1.39	0.02
25220710	CHORIZOS	2.86	0.05
25220910	HEAD CHEESE	1.37	0.02
25221110	KNOCKWURST	0.46	0.01
25221250	PEPPERONI	2.6	0.04
25221310	POLISH SAUSAGE	6.35	0.11
25221350	ITALIAN SAUSAGE	4.33	0.07
25221400	SAUSAGE (NOT COLD CUT) NFS	1.83	0.03
25221410	PORK SAUSAGE FRESH BULK PATTY OR LINK COOKED	2.72	0.05
25221420	PORK SAUSAGE BROWN & SERVE COOKED	1.96	0.03
25221430	PORK SAUSAGE COUNTRY STYLE FRESH COOKED	2.78	0.05
25221460	PORK & BEEF SAUSAGE	4.81	0.08
25221470	PORK & BEEF SAUSAGE BROWN & SERVE COOKED	3.07	0.05
25221480	METTWURST	4.01	0.07
25221500	SALAMI NFS	2.87	0.05
25221510	SALAMI SOFT COOKED	7.53	0.13
25221520	SALAMI DRY OR HARD	2.14	0.04
25221530	SALAMI BEEF	3.13	0.05
25221610	SCRAPPLE COOKED	1.87	0.03
25221650	SMOKED LINK SAUSAGE PORK	3.14	0.05
25221660	SMOKED LINK SAUSAGE PORK & BEEF	8.3	0.14
25221680	SMOKED SAUSAGE PORK	5.91	0.1
25221810	THURINGER (INCLUDE SUMMER SAUSAGE)	2.85	0.05
25221840	TURKEY BREAKFAST SAUSAGE BULK	4.08	0.07
25221850	TURKEY SAUSAGE SMOKED	3.08	0.05
25221870	TURKEY&PORK SAUSAGE FRESH BULK PATTY OR LINK COOKED	5.34	0.09
25221880	TURKEY PORK & BEEF SAUSAGE REDUCED FAT SMOKED	4.6	0.08
25221890	TURKEY PORK & BEEF SAUSAGE LOWFAT SMOKED	7.01	0.12
25221910	VIENNA SAUSAGE CANNED	6.2	0.1
25221920	VIENNA SAUSAGE CHICKEN CANNED	1.21	0.02
25230110	LUNCHEON MEAT NFS	4.08	0.07
25230210	HAM SLICED PREPACKAGED OR DELI LUNCHEON MEAT	3.13	0.05
25230220	HAM SLICED LOW SALT PREPACKAGED/DELI LUNCH MEAT	2.69	0.04
25230230	HAM SLICED EXTRA LEAN PREPACKAGED/DELI	3.19	0.05
25230310	CHICKEN/TURKEY LOAF PREPACK/DELI LUNCHEON MEAT	3.04	0.05
25230430	HAM & CHEESE LOAF	6.11	0.1

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
25230510	HAM LUNCH MEAT CHOP MINCED PRESSD MINCED NOT CANNED	2.81	0.05
25230520	HAM LUNCHEON MEAT CHOPPED SPICED LOWFAT NOT CAN	2.85	0.05
25230530	HAM/PORK LUNCHEON MEAT CHOPPED CAN (INCL SPAM)	4.2	0.07
25230560	LIVERWURST	2.67	0.04
25230610	LUNCHEON LOAF (OLIVE PICKLE OR PIMIENTO)	3.47	0.06
25230710	SANDWICH LOAF LUNCHEON MEAT	2.37	0.04
25230790	TURKEY HAM SLICED XTRA LEAN PKG'D DELI	3.59	0.06
25230800	TURKEY HAM	2.68	0.04
25230810	VEAL LOAF	1.98	0.03
25230820	TURKEY PASTRAMI	4.48	0.07
25230840	TURKEY SALAMI	2.33	0.04
25230900	TURKEY OR CHICKEN BREAST PKG'D/DELI LUNCHEON MEAT	3.61	0.06
25231110	BEEF SLICED PREPACKAGED/DELI LUNCHEON MEAT	3.35	0.06
25231150	CORNED BEEF PRESSED	4.12	0.07
25240000	MEAT SPREAD OR POTTED MEAT NFS	4.73	0.08
25240110	CHICKEN SALAD SPREAD	0.04	0
25240210	HAM DEVILED OR POTTED	1.79	0.03
27111000	BEEF W/ TOMATO-BASED SAUCE (MIXTURE)	3.56	0.06
27111050	SPAGHETTI SAUCE W/ BEEF/MEAT HOMEMADE-STYLE	5.46	0.09
27111300	MEXICAN BEEF STEW NO POTATOES TOMATO SAUCE	8.87	0.15
27113300	SWEDISH MEATBALLS W/ CREAM OR WHITE SAUCE (MIXTURE)	4.83	0.08
27114000	BEEF W/ (MUSHROOM) SOUP (MIXTURE)	1.88	0.03
27115000	BEEF W/ SOY-BASED SAUCE (MIXTURE)	5.33	0.09
27115100	STEAK TERIYAKI W/ SAUCE (MIXTURE)	8.44	0.14
27116200	BEEF W/ BARBECUE SAUCE (MIXTURE)	3.97	0.07
27116300	BEEF W/ SWEET & SOUR SAUCE (MIXTURE)	10.8	0.18
27116350	STEWED SEASONED GROUND BEEF MEXICAN	11.95	0.2
27116400	STEAK TARTARE (RAW GROUND BEEF & EGG)	0.49	0.01
27120030	HAM/PORK W/ BARBECUE SAUCE	2.98	0.05
27120090	HAM/PORK W/ (MUSHROOM) SOUP-BASE SAUCE (MIXTURE)	4.21	0.07
27120100	HAM/PORK W/ TOMATO-BASED SAUCE (MIXTURE)	5.34	0.09
27120110	SAUSAGE W/ TOMATO-BASED SAUCE (MIXTURE)	3.99	0.07
27120150	PORK OR HAM W/ SOY-BASED SAUCE (MIXTURE)	4.82	0.08
27141000	CHICKEN CACCIATORE (INCLUDE CHICKEN W/TOMATO SAUCE)	3.77	0.06
27141030	SPAGHETTI SAUCE W/ POULTRY HOMEMADE	4.22	0.07
27141050	STEWED CHICKEN W/ TOMATO SAUCE MEXICAN STYLE	5.48	0.09
27143000	CHICKEN OR TURKEY W/ CREAM SAUCE (MIXTURE)	2.99	0.05
27144000	CHICKEN W/ (MUSHROOM) SOUP-BASED SAUCE (MIXTURE)	10.41	0.17
27146000	CHICKEN W/ BARBECUE SAUCE (MIXTURE)	3.14	0.05
27146200	CHICKEN W/ CHEESE SAUCE (MIXTURE)	5.89	0.1
27150110	SHRIMP COCKTAIL (SHRIMP W/ COCKTAIL SAUCE)	3.94	0.07
27150140	CLAM SAUCE WHITE	24.85	0.41

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27150160	SHRIMP W/ LOBSTER SAUCE (MIXTURE)	1.98	0.03
27150190	LOBSTER SAUCE (BROTH-BASED)	35.1	0.59
27150210	FISH SAUCE (BAGOONG)	2.07	0.03
27150310	FISH W/ TOMATO-BASED SAUCE (MIXTURE)	4.01	0.07
27150350	SARDINES W/ TOMATO-BASED SAUCE (MIXTURE)	2.66	0.04
27151050	SHRIMP IN GARLIC SAUCE P.R. (CAMARONES AL AJILLO)	1.54	0.03
27160010	MEAT W/ BARBECUE SAUCE NS AS TO TYPE OF MEAT	1.55	0.03
27160100	MEATBALLS NS AS TO TYPE OF MEAT W/ SAUCE	2.76	0.05
27162050	SPAGHETTI SAUCE W/ COMBINATION OF MEATS HOMEMADE	6.02	0.1
27211000	BEEF & POTATOES NO SAUCE (MIXTURE)	7.37	0.12
27211100	BEEF STEW W/ POTATOES TOMATO-BASED SAUCE	10.05	0.17
27211190	BEEF & POTATOES W/ CREAM OR WHITE SAUCE (MIXTURE)	12.1	0.2
27211550	STEWED SEASONED GROUND BEEF W/ POTATOES MEXICAN	7.32	0.12
27212050	BEEF & MACARONI WITH CHEESE SAUCE (MIXTURE)	12.4	0.21
27212100	BEEF & NOODLES W/ TOMATO-BASED SAUCE (MIXTURE)	8.06	0.13
27212300	BEEF & NOODLES W/ CREAM OR WHITE SAUCE (MIXTURE)	7.67	0.13
27212400	BEEF & NOODLES W/ (MUSHROOM) SOUP (MIXTURE)	3.05	0.05
27213000	BEEF & RICE NO SAUCE (MIXTURE)	2.05	0.03
27213100	BEEF & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	11.29	0.19
27213120	PORCUPINE BALLS W/ TOMATO-BASED SAUCE (MIXTURE)	4.34	0.07
27213300	BEEF & RICE W/ CREAM SAUCE (MIXTURE)	5.95	0.1
27213400	BEEF & RICE W/ (MUSHROOM) SOUP (MIXTURE)	3.83	0.06
27213500	BEEF & RICE W/ SOY-BASED SAUCE (MIXTURE)	1.83	0.03
27214110	MEAT LOAF W/ BEEF W/ TOMATO SAUCE	5.01	0.08
27220110	PORK & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	36.6	0.61
27220150	SAUSAGE & RICE W/ (MUSHROOM) SOUP (MIXTURE)	2.24	0.04
27220210	HAM & NOODLES NO SAUCE (MIXTURE)	13.46	0.22
27220310	HAM & RICE NO SAUCE (MIXTURE)	10.5	0.17
27220520	PORK & POTATOES W/ CHEESE SAUCE	5.34	0.09
27236000	VENISON/DEER & NOODLE MIXTURE W/ CREAM/WHITE SAUCE	20.37	0.34
27242000	CHICKEN OR TURKEY & NOODLES NO SAUCE (MIXTURE)	5.07	0.08
27242300	CHICKEN OR TURKEY & NOODLES W/ CREAM OR WHITE SAUCE	7.93	0.13
27242310	CHICKEN & NOODLES W/ CHEESE SAUCE	2.4	0.04
27242400	CHICKEN & NOODLES TOMATO-BASED SAUCE (MIXTURE)	11.58	0.19
27243000	CHICKEN & RICE NO SAUCE (MIXTURE)	6.38	0.11
27243300	CHICKEN & RICE W/ CREAM SAUCE (MIXTURE)	7.33	0.12
27243400	CHICKEN & RICE W/ (MUSHROOM) SOUP-BASED SAUCE	15.25	0.25
27243500	CHICKEN & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	5.46	0.09
27243600	CHICKEN & RICE W/ SOY-BASED SAUCE (MIXTURE)	10.46	0.17
27250130	SHRIMP & NOODLES W/ CHEESE SAUCE	10.17	0.17
27250610	TUNA NOODLE CASSEROLE W/ CREAM OR WHITE SAUCE	9.62	0.16
27250630	TUNA NOODLE CASSEROLE W/ (MUSHROOM) SOUP	4.7	0.08
27250710	TUNA & RICE W/ (MUSHROOM) SOUP (MIXTURE)	9.11	0.15

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27250810	FISH & RICE W/ TOMATO-BASED SAUCE	7.97	0.13
27260100	MEAT LOAF W/ BEEF & PORK W/ TOMATO SAUCE	3.6	0.06
27311110	BEEF POTATOES & VEG (W/ CAR/DK GREEN) NO SAUCE	6.93	0.12
27311120	BEEF POTATOES & VEG (NO CAR/DK GREEN) NO SAUCE	2.94	0.05
27311210	CORNED BEEF POT & VEG(W/ CAR/DK GREEN) NO SAUCE	7.1	0.12
27311310	BEEF STEW W/ POT & VEG(W/ CAR/DK GRN) TOMATO SAUCE	7.06	0.12
27311320	BEEF STEW W/ POT & VEG (NO CAR/DK GREEN) TOM SAUCE	9.47	0.16
27311610	BEEF POT & VEG (INCL CAR/DK GRN) (MUSHROOM) SOUP	4.24	0.07
27313020	BEEF NOODLES & VEG (NO CARROTS/DK GREEN) NO SAUCE	3.47	0.06
27313150	BEEF NOODLES & VEG (W/ CAR/DK GREEN) SOY SAUCE	9.3	0.15
27313310	BEEF NOODLES VEG(INCL CARROTS/DK GREEN) SOUP	6.1	0.1
27313320	BEEF NOODLES VEG (NO CARROTS/DK GREEN) SOUP	4.07	0.07
27315210	BEEF RICE & VEG (W/ CAR/DK GREEN) TOMATO SAUCE	11.54	0.19
27315220	BEEF RICE & VEG (NO CAR/DK GREEN) TOMATO SAUCE	5.34	0.09
27315510	BEEF RICE & VEG (INCL CAR/DK GRN) SOY-BASED SAUCE	6.68	0.11
27315520	BEEF RICE & VEG (NO CAR/DK GRN) SOY-BASED SAUCE	11.58	0.19
27320320	PORK RICE & VEG (INCL CAR/DK GRN) SOY-BASED SAUCE	12.43	0.21
27320330	PORK RICE & VEG (NO CAR/DK GRN) SOY-BASED SAUCE	6.97	0.12
27330210	LAMB STEW W/ POT & VEG (INCL CAR/DK GRN) TOM SAUCE	8.1	0.13
27343010	CHICKEN NOODLES & VEG (INCL CAR/DK GRN) NO SAUCE	5.65	0.09
27343470	CHICKEN NOODLES VEG (INCL CAR DK GRN) CREAM SAUCE	8.45	0.14
27343480	CHICKEN NOODLES VEG (NO CAR/DK GRN) CREAM SAUCE	4.3	0.07
27343520	CHICKEN NOODLES VEG (NO CAR/DK GRN) TOMATO SAUCE	4.8	0.08
27343960	CHICKEN NOODLES & VEG(NO CAR/DK GRN) CHEESE SAUCE	7.84	0.13
27343970	CHICKEN NOODLES VEG (W/ CAR/DK GRN) CREAM SAUCE	7.64	0.13
27345310	CHICKEN RICE & VEG (INCL CAR/DK GRN) SOY SAUCE	6.45	0.11
27345320	CHICKEN RICE & VEG (NO CAR/DK GRN) SOY SAUCE	1.16	0.02
27345410	CHICKEN RICE & VEG(INCL CAR/DK GRN) SOUP-BASED SCE	5.27	0.09
27345510	CHICKEN RICE & VEG (INCL CAR/DK GRN) TOMATO SAUCE	8	0.13
27345520	CHICKEN RICE & VEG (NO CAR/DK GRN) TOMATO SAUCE	4	0.07
27347210	CHICKEN STUFFING VEG (NO CAR/DK GRN) NO SAUCE	6.1	0.1
27350080	TUNA NOODLE CASSEROLE W/ VEG CREAM OR WHITE SAUCE	8.21	0.14
27350100	FISH NOODLES VEG (NO CAR/DK GRN) CHEESE SAUCE	7.84	0.13
27350410	TUNA NOODLE CASSEROLE W/ VEG & (MUSHROOM) SOUP	2.59	0.04
27410210	BEEF & VEG (W/ CAR/DK GREEN NO POTATO) NO SAUCE	4.03	0.07
27410220	BEEF & VEG (NO CAR/DK GREEN NO POTATO) NO SAUCE	4.95	0.08
27414200	BEEF W/ VEG (NO CAR/DK GRN NO POT) SOUP	3.65	0.06
27415100	BEEF & VEG (W/ CAR/DK GREEN NO POTATO) SOY SAUCE	4.81	0.08
27415200	BEEF & VEG (NO CAR/DK GREEN NO POTATO) SOY SAUCE	6.85	0.11
27416200	BEEF GROUND W/ EGG & ONION (MIXTURE)	4.9	0.08
27416300	BEEF TACO FILLING: BEEF CHEESE TOMATO TACO SAUCE	1.56	0.03
27418310	CORNED BEEF W/ TOMATO SAUCE & ONION P.R. STYLE	6.6	0.11
27420060	PORK & VEG (W/ CAR/DK GREEN NO POTATO) NO SAUCE	3.47	0.06
27420170	PORK AND ONIONS W/ SOY-BASED SAUCE	4.05	0.07
27420350	PORK & VEG (NO CAR/DK GREEN NO POTATO) NO SAUCE	2.61	0.04

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27420470	SAUSAGE & PEPPERS NO SAUCE	3.3	0.05
27420500	PORK & VEG (INCL CAR/DK GRN) SOY-BASED SAUCE	4.43	0.07
27420510	PORK & VEG (NO CAR/DK GRN) SOY-BASED SAUCE	9.3	0.15
27440110	CHICK/TURK & VEG (W/ CAR/DK GRN NO POT) NO SAUCE	5.79	0.1
27440120	CHICK/TURK & VEG (NO CAR/DK GRN NO POT) NO SAUCE	3.47	0.06
27445110	CHICKEN & VEG (INCL CAR/DK GRN NO POT) SOY SAUCE	4.17	0.07
27445120	CHICKEN & VEG (NO CAR/DK GRN NO POT) SOY SAUCE	5.33	0.09
27446410	CHICKEN & VEG (NO CAR/DK GRN)(NO POT) CHEESE SAUCE	3.79	0.06
27450410	SHRIMP & VEG (W/ CAR/DK GREEN NO POT) SOY SAUCE	5.55	0.09
27450420	SHRIMP & VEG (NO CARROT/DK GREEN NO POT) SOY SAUCE	4.57	0.08
27450510	TUNA CASSEROLE W/ VEG & SOUP NO NOODLES	3.83	0.06
27450700	FISH & VEG (INCL CAR/DK GRN NO POT) TOMATO SAUCE	4.8	0.08
27450710	FISH & VEG (NO CAR/DK GRN NO POT) TOMATO SAUCE	9.6	0.16
27450740	FISH & VEGETABLES (W/ CAR/DK GRN) SOY-BASED SAUCE	0.75	0.01
27450750	FISH & VEGETABLES (NO CAR/DK GRN) SOY-BASED SAUCE	3.47	0.06
27510700	MEATBALL & SPAGHETTI SAUCE SUBMARINE SANDWICH	3.95	0.07
27513060	ROAST BEEF SANDWICH W/ BACON & CHEESE SAUCE	4.05	0.07
27520500	PORK BBQ SAUCE ONIONS & DILL PICKLES ON WHITE ROLL	4.05	0.07
28110340	SALISBURY STK GRAVY POT VEG SOUP DESSERT(FRZ MEAL)	5.38	0.09
28110620	SHORTRIBS W/ BBQ SAUCE POTATOES & VEG (FROZ MEAL)	6.39	0.11
28110640	MEATBALLS SWEDISH IN SAUCE W/ NOODLES (FROZ MEAL)	6.76	0.11
28143080	CHICKEN W/NOODLES & CHEESE SAUCE (DIET FROZEN MEAL)	5.22	0.09
28143170	CHICKEN IN CREAM SAUCE W/ NOODLES & VEG (FROZ MEAL)	4.37	0.07
28143210	CHICKEN IN ORANGE SAUCE W/ RICE (DIET FROZEN MEAL)	4.86	0.08
28150510	FISH IN LEMON SAUCE W/ STARCH ITEM VEG (FROZ MEAL)	5.29	0.09
28310150	OXTAIL SOUP	4.48	0.07
28310210	CHILI BEEF SOUP	7.85	0.13
28310220	CHILI BEEF SOUP CHUNKY	1.44	0.02
28310230	MEATBALL SOUP MEXICAN STYLE (SOPA DE ALBONDIGAS)	5.8	0.1
28310320	BEEF NOODLE SOUP P.R. (SOPA DE CARNE Y FIDEOS)	2.33	0.04
28310330	BEEF & NOODLE SOUP ORIENTAL (VIETNAMESE PHO BO)	4.96	0.08
28311010	PEPPERPOT (TRIPE) SOUP (INCL MENUDO/MONDONGO SOUP)	6	0.1
28315100	BEEF VEG SOUP W/POTATO STEW TYPE (INCL CHUNKY STY)	4.84	0.08
28315120	BEEF VEG SOUP W/ NOODLES STEW TYPE CHUNKY STYLE	1.76	0.03
28315130	BEEF VEG SOUP W/ RICE STEW TYPE CHUNKY STYLE	11.76	0.2
28315140	BEEF VEGETABLE SOUP MEXICAN STYLE (SOPA / CALDO DE RES)	7.11	0.12
28315150	MEAT & CORN HOMINY SOUP MEXICAN STYLE (POZOLE)	4.8	0.08
28316020	BEEF & MUSHROOM SOUP CANNED LOW SODIUM (INCL BEEF	2.31	0.04
28317010	BEEF STROGANOFF SOUP CHUNKY STYLE	2.43	0.04
28320130	HAM RICE & POTATO SOUP P.R.	2.94	0.05
28320150	PORK VEGETABLE SOUP W/ POTATOES STEW TYPE	4.73	0.08
28320300	PORK W/VEG (NO CAR BROC &/OR DK GREEN)SOUP ORIENTAL	2.79	0.05

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28340150	MEXICAN STYLE CHICKEN BROTH SOUP STOCK	2.96	0.05
28340210	CHICKEN RICE SOUP P.R. (SOPA DE POLLO CON ARROZ)	4.75	0.08
28340220	CHICKEN SOUP W/ NOODLES & POTATOES P.R.	10.05	0.17
28340310	CHICKEN GUMBO SOUP	3.8	0.06
28340510	CHICKEN NOODLE SOUP CHUNKY	2.53	0.04
28340530	CHICKEN SOUP	6.24	0.1
28340580	CHICKEN SOUP W/VEGS(BROC CRT CELERY POTS)ORIENTAL	4.95	0.08
28340590	CHICKEN CORN SOUP HOME RECIPE	2.63	0.04
28340610	CHICKEN VEGETABLE SOUP STEW TYPE (INCL CHUNKY)	5.14	0.09
28340630	CHICKEN VEG SOUP W/ RICE STEW TYPE CHUNKY STYLE	6.6	0.11
28340640	CHICKEN VEG SOUP W/ NOODLES STEW TYPE CHUNKY STYL	2.94	0.05
28340660	CHICKEN OR TURKEY VEGETABLE SOUP HOME RECIPE	3.12	0.05
28340670	CHICKEN VEGETABLE SOUP W/RICE MEXICAN(SOPA / CALDO DE POLLO)	6.62	0.11
28340690	CHICKEN VEG SOUP W/ POTATO & CHEESE CHUNKY	6.6	0.11
28340750	HOT & SOUR SOUP (INCLUDE HOT & SPICY CHINESE SOUP)	3.23	0.05
28345020	CHICKEN SOUP CREAM OF MADE W/ MILK REDUCED SODIUM	3.69	0.06
28345030	CHICKEN SOUP CREAM OF MADE W/ WATER REDUCED SODIUM	5.56	0.09
28345110	CHICKEN SOUP CREAM OF NS AS TO MILK OR WATER	2.99	0.05
28345120	CHICKEN/TURKEY SOUP CREAM OF W/ MILK	3.31	0.06
28345130	CHICKEN SOUP CREAM OF PREPARED W/ WATER	5.98	0.1
28345140	CHICKEN SOUP CREAM OF CANNED UNDILUTED	1.87	0.03
28345160	CHICKEN & MUSHROOM SOUP CREAM OF W/ MILK	3.04	0.05
28350050	FISH CHOWDER (INCL FISHERMAN'S SOUP SEAFOOD CHOWD)	3.78	0.06
28350120	CRAB SOUP TOMATO BASE	1.49	0.02
28351110	FISH & VEGETABLE SOUP NO POTATOES (SOPA DE PESCADO)	2.74	0.05
28355350	SALMON SOUP CREAM STYLE	3.24	0.05
28355420	SHRIMP SOUP CREAM OF W/ MILK	0.57	0.01
28355450	SEAFOOD SOUP W/ POTATOES & VEGETABLES (INCL DK GREEN LEAF)	3.41	0.06
28355470	SEAFOOD SOUP W/ VEGETABLES (INCL DK GREEN LEAFY)	2.77	0.05
28355480	SEAFOOD SOUP W/ VEGETABLES (EXCL DK GREEN LEAFY)	2.99	0.05
28520000	GRAVY/SAUCE CHINESE(SOY SCE STOCK/BOUILL CRNSTRCH)	0.51	0.01
28520100	OYSTER-FLAVORED SAUCE	5.42	0.09
28522000	MOLE POBLANA (SAUCE)	21.13	0.35
32300100	EGG DROP SOUP	3.16	0.05
41201020	BAKED BEANS W/ TOMATO SAUCE	10.41	0.17
41201040	BAKED BEAN W/ PORK & SWEET SAUCE	9.15	0.15
41207030	BEANS DRY COOKED W/ GROUND BEEF	18.34	0.31
41420250	HOISIN SAUCE	21	0.35
41420300	SOY SAUCE	9.05	0.15
41420350	SOY SAUCE REDUCED SODIUM	2.78	0.05
41420400	TERIYAKI SAUCE (INCLUDE ORIENTAL BARBECUE SAUCE)	4.93	0.08
41420450	WORCESTERSHIRE SAUCE	6.62	0.11

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
41601010	BEAN SOUP NFS	5.4	0.09
41601020	BEAN W/ BACON OR PORK SOUP	3.88	0.06
41601030	BLACK BEAN SOUP	3.23	0.05
41601040	LIMA BEAN SOUP	3.1	0.05
41601050	SOYBEAN SOUP MADE W/ MILK	1.93	0.03
41601060	BEANSOUPW/MACARONI&MEAT(INCL PASTA E FAGIOLE W/MEAT	8.42	0.14
41601070	SOYBEAN SOUP MISO BROTH	3.17	0.05
41601080	PINTO BEAN SOUP	4.94	0.08
41601090	BEAN SOUP W/ MACARONI (INCL PASTA E FAGIOLI)	4.08	0.07
41601110	BEAN & HAM SOUP CHUNKY STYLE (INCL CAMPBELL'S OLD	5.41	0.09
41601130	BEAN SOUP MIXED BEANS (INCL 15-BEAN SOUP)	4.12	0.07
41601140	BEAN SOUP HOME RECIPE	3.99	0.07
41601150	BEAN SOUP W/ VEG & RICE CAN RED SODIUM W/ WATER/RTS	3.69	0.06
41601180	BEAN & HAM SOUP HOME RECIPE	4.39	0.07
41602020	GARBANZO OR CHICKPEA SOUP	1.55	0.03
41602030	SPLIT PEA & HAM SOUP	4.61	0.08
41602050	SPLIT PEA SOUP	5.14	0.09
41602070	SPLIT PEA SOUP CAN REDUCED SODIUM W/ WATER/RTS	4.59	0.08
41603010	LENTIL SOUP	4.88	0.08
41812450	VEGETARIAN CHILI (MADE W/ MEAT SUBSTITUTE)	14.37	0.24
42204050	PEANUT SAUCE	34.05	0.57
51000100	BREAD NS AS TO MAJOR FLOUR	3.59	0.06
51000110	TOAST NS AS TO MAJOR FLOUR	2.45	0.04
51000180	BREAD HOMEMADE/PURCH AT A BAKERY NS AS TO FLOUR	5.28	0.09
51000190	BREAD HOMEMADE/PURCH AT A BAKERY TOASTD NS FLOUR	6.32	0.11
51000200	ROLL NS AS TO MAJOR FLOUR	2.32	0.04
51000230	ROLL NS AS TO MAJOR FLOUR TOASTED	1.98	0.03
51101000	BREAD WHITE	3.53	0.06
51101010	BREAD WHITE TOASTED	2.53	0.04
51101050	BREAD WHITE HOMEMADE OR PURCHASED AT A BAKERY	4.49	0.07
51101060	BREAD WHITE HOMEMADE OR PURCH AT A BAKERY TOASTED	3.41	0.06
51102010	BREAD WHITE W/ WHOLE WHEAT SWIRL	6.24	0.1
51105010	BREAD CUBAN (INCLUDE SPANISH PORTUGUESE)	2.06	0.03
51105040	BREAD CUBAN TOASTED (INCLUDE SPANISH PORTUGUESE)	9.72	0.16
51107010	BREAD FRENCH OR VIENNA	3.57	0.06
51107040	BREAD FRENCH OR VIENNA TOASTED	2.96	0.05
51109010	BREAD ITALIAN GRECIAN ARMENIAN	3.22	0.05
51109040	BREAD ITALIAN GRECIAN ARMENIAN TOASTED	1.98	0.03
51109100	BREAD PITA	3.46	0.06
51109110	BREAD PITA TOASTED	3.76	0.06
51111010	BREAD CHEESE (INCLUDE ONION CHEESE)	6.98	0.12
51111040	BREAD CHEESE TOASTED (INCLUDE ONION CHEESE)	1.44	0.02
51113010	BREAD CINNAMON	4.21	0.07

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
51113100	BREAD CINNAMON TOASTED	2.8	0.05
51115020	BREAD CORNMEAL AND MOLASSES TOASTED	3.48	0.06
51119010	BREAD EGG CHALLAH	10.2	0.17
51119040	BREAD EGG CHALLAH TOASTED	4.45	0.07
51119100	BREAD LOWFAT 98% FAT FREE	6.48	0.11
51119110	BREAD LOWFAT 98% FAT FREE TOASTED	2.64	0.04
51121010	BREAD GARLIC	3.18	0.05
51121040	BREAD GARLIC TOASTED (INCLUDE TEXAS TOAST)	3.64	0.06
51122000	BREAD REDUCED CALORIE/HIGH FIBER	3.41	0.06
51122010	BREAD REDUCED CALORIE/HIGH FIBER TOASTED	2.93	0.05
51122050	BREAD REDUCED CALORIE/HIGH FIBER ITALIAN	6.93	0.12
51122060	BREAD REDUCED CALORIE/HIGH FIBER ITALIAN TOASTED	1.66	0.03
51122100	BREAD REDUCED CALORIE/ HIGH FIBER W/ FRUIT/NUTS	3.48	0.06
51122110	BREAD REDUCED CALORIE/HI FIBER W/FRUIT/NUTS TOAST	1.56	0.03
51122300	BREAD WHITE SPECIAL FORMULA ADDED FIBER	3.36	0.06
51123010	BREAD HIGH PROTEIN	4.5	0.08
51127010	BREAD POTATO	2.72	0.05
51127020	BREAD POTATO TOASTED	1.91	0.03
51129010	BREAD RAISIN	3.43	0.06
51129020	BREAD RAISIN TOASTED	2.89	0.05
51133010	BREAD SOUR DOUGH	2.85	0.05
51133020	BREAD SOUR DOUGH TOASTED	2.45	0.04
51135000	BREAD VEGETABLE	7.76	0.13
51135010	BREAD VEGETABLE TOASTED	7.2	0.12
51140100	BREAD DOUGH FRIED	7.15	0.12
51150000	ROLL WHITE SOFT	3.28	0.05
51150100	ROLL WHITE SOFT TOASTED	2.95	0.05
51151060	ROLL WHITE SOFT HOMEMADE/PURCH AT A BAKERY	2.69	0.04
51152000	ROLL WHITE SOFT REDUCED CALORIE/ HIGH FIBER	2.53	0.04
51153000	ROLL WHITE HARD	3.19	0.05
51153010	ROLL WHITE HARD TOASTED	1.71	0.03
51154550	ROLL EGG BREAD	1.68	0.03
51154600	ROLL CHEESE	3.7	0.06
51155000	ROLL FRENCH OR VIENNA	3.29	0.05
51155010	ROLL FRENCH OR VIENNA TOASTED	3.06	0.05
51156500	ROLL GARLIC	1.82	0.03
51157000	ROLL HOAGIE SUBMARINE	5.26	0.09
51157010	ROLL HOAGIE SUBMARINE TOASTED	4.45	0.07
51158100	ROLL MEXICAN BOLILLO	8.42	0.14
51159000	ROLL SOUR DOUGH	3.2	0.05
51180010	BAGEL	3.37	0.06
51180020	BAGEL TOASTED	2.95	0.05
51180030	BAGEL W/ RAISINS	4.07	0.07
51180040	BAGEL W/ RAISINS TOASTED	3	0.05
51180080	BAGEL W/ FRUIT OTHER THAN RAISINS	3.2	0.05

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
51180090	BAGEL W/ FRUIT OTHER THAN RAISINS TOASTED	3.23	0.05
51182010	BREAD STUFFING (INCLUDE HOMEMADE STUFFING NFS)	3.41	0.06
51182020	BREAD STUFFING W/ EGG	4.7	0.08
51184000	BREAD STICK HARD	5.47	0.09
51184010	BREAD STICK SOFT	23.22	0.39
51184020	BREAD STICK NS AS TO HARD OR SOFT	8.66	0.14
51184030	BREAD STICK SOFT PREP W/ GARLIC & PARMESAN CHEESE	21.18	0.35
51184100	BREAD STICK HARD LOW SODIUM	6.22	0.1
51185000	CROUTONS	2.83	0.05
51186010	MUFFIN ENGLISH (INCLUDE SOUR DOUGH)	4.36	0.07
51186020	MUFFIN ENGLISH TOASTED	2.76	0.05
51186120	MUFFIN ENGLISH W/ RAISINS TOASTED	2.34	0.04
51186160	MUFFIN ENGLISH W/ FRUIT OTHER THAN RAISINS	6.33	0.11
51186180	MUFFIN ENGLISH W/ FRUIT OTHER THAN RAISINS TSTD	2.86	0.05
51187000	MELBA TOAST	0.84	0.01
51188100	PANNETONE (ITALIAN-STYLE SWEET BREAD)	4.96	0.08
51201010	BREAD 100% WHOLE WHEAT	3.62	0.06
51201020	BREAD 100% WHOLE WHEAT TOASTED	2.44	0.04
51201060	BREAD 100% WHOLE WHEAT HOME-MADE	5.5	0.09
51201070	BREAD 100% WHOLE WHEAT HOME-MADE TOASTED	5.34	0.09
51201120	BREAD 100% WHOLE WHEAT W/ RAISINS TOASTED	4.32	0.07
51201150	BREAD PITA 100% WHOLE WHEAT	3.13	0.05
51201160	BREAD PITA 100% WHOLE WHEAT TOASTED	4.47	0.07
51202020	MUFFIN ENGLISH 100% WHOLE WHEAT TOASTED	2.36	0.04
51202060	MUFFIN ENGLISH WHOLE WHEAT W/ RAISINS TOASTED	2.73	0.05
51208000	BAGEL 100% WHOLE WHEAT	2.65	0.04
51208010	BAGEL 100% WHOLE WHEAT TOASTED	2.64	0.04
51208100	BAGEL 100% WHOLE WHEAT W/ RAISINS	3.36	0.06
51208110	BAGEL 100% WHOLE WHEAT W/ RAISINS TOASTED	2.77	0.05
51220000	ROLL 100% WHOLE WHEAT	3.49	0.06
51220030	ROLL 100% WHOLE WHEAT HOME RECIPE/BAKERY	4.22	0.07
51300110	BREAD WHOLE WHEAT OTHER THAN 100%/NS AS TO 100%	3.18	0.05
51300120	BREAD WHOLE WHEAT OTHER THAN 100%/NS 100% TOAST	2.28	0.04
51300140	BREAD WHOLE"" WHEAT HOME RECIPE/BAKERY	3.92	0.07
51300150	BREAD WHOLE"" WHEAT HOME RECIPE/BAKERY TOASTED	3.58	0.06
51300220	BREAD WHOLE WHEAT NS AS TO 100% W/ RAISINS TOASTED	3.24	0.05
51301010	BREAD WHEAT OR CRACKED WHEAT	3.05	0.05
51301020	BREAD WHEAT OR CRACKED WHEAT TOASTED	2.52	0.04
51301040	BREAD CRACKED WHEAT HOME RECIPE/BAKERY	16.92	0.28
51301050	BREAD CRACKED WHEAT HOME RECIPE/BAKERY TOASTED	4.05	0.07
51301120	BREAD WHEAT OR CRACKED WHEAT W/ RAISINS	3.07	0.05
51301130	BREAD WHEAT OR CRACKED WHEAT W/ RAISINS TOASTED	1.82	0.03
51301510	BREAD CRACKED WHEAT REDUCED CALORIE/ HIGH FIBER	2.93	0.05
51301520	BREAD CRACKED WHEAT RED CALORIE/ HI FIBER TOAST	2.61	0.04
51301540	BREAD FRENCH WHOLE"" WHEAT HOMEMADE	2.1	0.04

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
51301600	BREAD PITA WHOLE"" WHEAT	2.32	0.04
51301620	BREAD PITA CRACKED WHEAT	1.82	0.03
51301630	BREAD PITA CRACKED WHEAT TOASTED	2.46	0.04
51301700	BAGEL WHEAT	2.75	0.05
51301710	BAGEL WHEAT TOASTED	3.53	0.06
51301750	BAGEL WHOLE"" WHEAT	3.51	0.06
51301760	BAGEL WHOLE"" WHEAT TOASTED	3.71	0.06
51301800	BAGEL WHEAT W/ RAISINS	4.05	0.07
51301810	BAGEL WHEAT W/ RAISINS TOASTED	2.89	0.05
51302020	BREAD WHEAT BRAN TOASTED	3.96	0.07
51303010	MUFFIN ENGLISH WHEAT OR CRACKED WHEAT	2.37	0.04
51303040	MUFFIN ENGLISH WHOLE"" WHEAT TOASTED	2.73	0.05
51303060	MUFFIN ENGLISH WHEAT W/ RAISINS TOASTED	2.73	0.05
51320010	ROLL WHEAT OR CRACKED WHEAT	3.42	0.06
51320500	ROLL WHOLE WHEAT NS AS TO 100%	3.59	0.06
51320530	ROLL WHOLE"" WHEAT HOME RECIPE/BAKERY	3.59	0.06
51401010	BREAD RYE	3.06	0.05
51401020	BREAD RYE TOASTED	2.8	0.05
51401030	BREAD MARBLE RYE & PUMPERNICKEL	3.12	0.05
51401060	BREAD RYE REDUCED CALORIE/ HIGH FIBER (INCL LESS)	2.32	0.04
51401070	BREAD RYE REDUCED CALORIE/ HIGH FIBER TOASTED	2.74	0.05
51404010	BREAD PUMPERNICKEL	8.43	0.14
51404020	BREAD PUMPERNICKEL TOASTED	0.95	0.02
51404500	BAGEL PUMPERNICKEL	3.43	0.06
51404510	BAGEL PUMPERNICKEL TOASTED	2.79	0.05
51420000	ROLL RYE	2.58	0.04
51421000	ROLL PUMPERNICKEL	2.16	0.04
51421100	ROLL PUMPERNICKEL TOASTED	3.96	0.07
51501010	BREAD OATMEAL	2.54	0.04
51501020	BREAD OATMEAL TOASTED	3.12	0.05
51501040	BREAD OAT BRAN	3.32	0.06
51501050	BREAD OAT BRAN TOASTED	1.93	0.03
51501060	BREAD OAT BRAN REDUCED CALORIE/ HIGH FIBER	2.76	0.05
51501070	BREAD OAT BRAN REDUCED CALORIE/HI FIBER TOASTED	2.15	0.04
51502010	ROLL OATMEAL	4.32	0.07
51503010	MUFFIN ENGLISH OAT BRAN TOASTED	2.73	0.05
51601010	BREAD MULTIGRAIN TOASTED	2.58	0.04
51601020	BREAD MULTIGRAIN	3.18	0.05
51601210	BREAD MULTIGRAIN W/ RAISINS	1.56	0.03
51601220	BREAD MULTIGRAIN W/ RAISINS TOASTED	1.44	0.02
51602010	BREAD MULTIGRAIN REDUCED CALORIE/ HIGH FIBER	3	0.05
51602020	BREAD MULTIGRAIN REDUCED CALORIE/ HI FIBER TOAST	2.57	0.04
51620000	ROLL MULTIGRAIN	2.05	0.03
51630000	BAGEL MULTIGRAIN	3.11	0.05
51630010	BAGEL MULTIGRAIN TOASTED	3.2	0.05

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
51630100	BAGEL MULTIGRAIN W/ RAISINS	1.46	0.02
51630110	BAGEL MULTIGRAIN W/ RAISINS TOASTED	1.31	0.02
51630200	MUFFIN ENGLISH MULTIGRAIN	3.16	0.05
51630210	MUFFIN ENGLISH MULTIGRAIN TOASTED	1.36	0.02
51805010	BREAD SUNFLOWER MEAL	8.42	0.14
52101000	BISCUIT BAKING POWDER OR BUTTERMILK TYPE NFS	2.39	0.04
52101100	BISCUIT BAKING POWDER OR BUTTERMILK FROM MIX	3.41	0.06
52102040	BISCUIT BAK POWDER OR BUTTERMILK FROM REFRG DOUGH	2.41	0.04
52103000	BISCUIT BAKING POWDER/BUTTERMILK TYPE COMMERCIALLY BAKED	4.13	0.07
52104010	BISCUIT BAKING POWDER OR BUTTERMILK HOMEMADE	3.7	0.06
52104100	BISCUIT CHEESE	3.3	0.05
52104200	BISCUIT CINNAMON-RAISIN	4.86	0.08
52105100	SCONES	2.01	0.03
52105200	SCONE WITH FRUIT	2.48	0.04
52201000	CORNBREAD PREPARED FROM MIX	5.95	0.1
52202060	CORNBREAD HOMEMADE	4.43	0.07
52204000	CORNBREAD STUFFING	3.56	0.06
52206010	CORNBREAD MUFFIN STICK ROUND	3.5	0.06
52206020	CORNBREAD MUFFIN STICK ROUND TOASTED	2.7	0.05
52206060	CORNBREAD MUFFIN STICK ROUND HOMEMADE	5.42	0.09
52207010	CORN FLOUR PATTIES OR TARTS FRIED	1.09	0.02
52209010	HUSH PUPPY	3.35	0.06
52215000	TORTILLA NFS	3.16	0.05
52215100	TORTILLA CORN	8.08	0.13
52215200	TORTILLA FLOUR (WHEAT)	8.23	0.14
52215260	TORTILLA WHOLE WHEAT	10.61	0.18
52215300	TACO SHELL CORN	4.13	0.07
52215350	TACO SHELL FLOUR	10.21	0.17
52301000	MUFFIN NFS	3.65	0.06
52302010	MUFFIN FRUIT & OR NUTS	3.74	0.06
52302100	MUFFIN FRUIT FAT FREE CHOL FREE	4.46	0.07
52302500	MUFFIN CHOCOLATE CHIP	2.56	0.04
52302600	MUFFIN CHOCOLATE	2.31	0.04
52303010	MUFFIN WHOLE WHEAT	2.59	0.04
52304010	MUFFIN WHEAT BRAN (INCLUDE W/ RAISINS & NUTS)	3.64	0.06
52304040	MUFFIN BRAN W/ FRUIT LOWFAT	3.61	0.06
52304060	MUFFIN BRAN W/ FRUIT NO FAT NO CHOLESTEROL	3.92	0.07
52304100	MUFFIN OATMEAL	4.55	0.08
52304150	MUFFIN OAT BRAN	2.68	0.04
52304200	MUFFIN OAT BRAN WITH FRUIT AND/OR NUTS	3.11	0.05
52306010	MUFFIN PLAIN	5.18	0.09
52306500	MUFFIN PUMPKIN W/ RAISINS	1.94	0.03
52306550	MUFFIN ZUCCHINI	3.11	0.05

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
52306700	MUFFIN CARROT (INCL W/ RAISINS/NUTS)	2.81	0.05
52308010	MATZO FRITTERS	34.8	0.58
52403000	BREAD NUT	3.76	0.06
52404060	BREAD PUMPKIN (INCLUDE W/ RAISINS)	5.92	0.1
52405010	BREAD FRUIT W/O NUTS	5.46	0.09
52405100	BREAD FRUIT & NUT	4.07	0.07
52407000	BREAD ZUCCHINI (INCL SQUASH BREAD W/ NUTS)	2.57	0.04
52408000	BREAD IRISH SODA	7.29	0.12
53102000	CAKE APPLESAUCE NS AS TO ICING	2.92	0.05
53102100	CAKE APPLESAUCE W/O ICING	1.88	0.03
53102200	CAKE APPLESAUCE W/ ICING	1.71	0.03
55101000	PANCAKES PLAIN (INCLUDE PANCAKES NFS)	2.45	0.04
55101010	PANCAKES REDUCED CALORIE HIGH FIBER	2.19	0.04
55103000	PANCAKES W/ FRUIT (INCLUDE BLUEBERRY PANCAKES)	3.34	0.06
55105000	PANCAKES BUCKWHEAT	3.47	0.06
55105100	PANCAKES CORNMEAL	2.87	0.05
55105200	PANCAKES WHOLE WHEAT	1.9	0.03
55105300	PANCAKES SOURDOUGH	1.63	0.03
55201000	WAFFLE PLAIN	2.95	0.05
55202000	WAFFLE WHEAT BRAN OR MULTIGRAIN	2.2	0.04
55203000	WAFFLE FRUIT	2.07	0.03
55205000	WAFFLE 100% WHOLE WHEAT OR 100% WHOLE GRAIN	0.89	0.01
55206000	WAFFLE OAT BRAN	1.69	0.03
55207000	WAFFLE MULTI-BRAN (INCLUDE EGGO NUTRIGRAIN)	2.82	0.05
55211000	WAFFLE PLAIN FAT FREE	2.12	0.04
55211050	WAFFLE PLAIN LOWFAT	4.29	0.07
55301000	FRENCH TOAST PLAIN (INCLUDE ROMAN MEAL)	8.4	0.14
55301050	FRENCH TOAST STICKS PLAIN	5.31	0.09
55401000	CREPE PLAIN (INCLUDE FRENCH PANCAKE)	2.73	0.05
55501000	FLOUR & WATER PATTY (INCLUDE CHINESE PANCAKE)	2.27	0.04
55701000	CAKE MADE W/ GLUTINOUS RICE	2.63	0.04
55801000	FUNNEL CAKE	3.38	0.06
58100600	ENCHILADA W/ CHICKEN TOMATO-BASE SAUCE	5.84	0.1
58100900	ENCHILADA W/ SEAFOOD TOMATO SAUCE	3.44	0.06
58101800	GROUND BEEF W/ TOMATO SAUCE ON A CORNBREAD CRUST	11.68	0.19
58103250	TAMALE PLAIN MEATLESS NO SAUCE MEXICAN	1.54	0.03
58107000	GROUND BEEF W/ TOMATO SAUCE ON A PIZZA CRUST	10.69	0.18
58120110	CREPES FILLED W/ MEAT FISH OR POULTRY W/ SAUCE	8.4	0.14
58126150	TURNOVER MEAT & CHEESE TOMATO SAUCE	3.76	0.06
58127220	CROISSANT FILLED W/CHICKEN BROCCOLI & CHEESE SAUCE	3.49	0.06
58131110	RAVIOLI FILLING NS TOMATO SAUCE	3.75	0.06
58131320	RAVIOLI MEAT-FILLED W/ TOMATO OR MEAT SAUCE	6.85	0.11
58131323	RAVIOLI MEAT-FILLED W/ TOMATO OR MEAT SAUCE CANNED	6.02	0.1
58131510	RAVIOLI CHEESE-FILLED NO SAUCE	2.1	0.03

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
58131520	RAVIOLI CHEESE-FILLED W/ TOMATO SAUCE	3.58	0.06
58131523	RAVIOLI CHEESE-FILLED W/ TOMATO SAUCE CANNED	3.18	0.05
58131530	RAVIOLI CHEESE-FILLED W/ MEAT SAUCE	24.11	0.4
58131600	RAVIOLI CHEESE&SPINACH-FILLED W/ CREAM SAUCE	3.88	0.06
58132110	SPAGHETTI W/ TOMATO SAUCE MEATLESS	8.26	0.14
58132113	PASTA W/ TOMATO SAUCE & CHEESE CANNED	6.84	0.11
58132310	SPAGHETTI W/TOMAT SAUCE & MEAT SAUCE	8.5	0.14
58132313	PASTA W/ TOMATO SAUCE & MEAT/MEATBALLS CANNED	6.89	0.11
58132710	SPAGHETTI W/ TOMATO SAUCE & FRANKFURTERS/HOT DOG	5.31	0.09
58132713	PASTA W/ TOMATO SAUCE & FRANKFURTERS/HOT DOGS CANNED	5.42	0.09
58132800	SPAGHETTI W/ CLAM SAUCE NS AS TO RED OR WHITE	21.26	0.35
58132810	SPAGHETTI W/ RED CLAM SAUCE	14.58	0.24
58132820	SPAGHETTI W/ WHITE CLAM SAUCE	20.13	0.34
58132910	SPAGHETTI W/ TOMATO SAUCE & CHICKEN OR TURKEY	21.26	0.35
58133110	MANICOTTI CHEESE-FILLED NO SAUCE	4.16	0.07
58133120	MANICOTTI CHEESE-FILLED W/ TOMATO SAUCE MEATLESS	7.1	0.12
58133130	MANICOTTI CHEESE-FILLED W/ MEAT SAUCE	16.47	0.27
58134110	STUFFED SHELLS CHEESE-FILLED NO SAUCE	3.86	0.06
58134610	TORTELLINI MEAT-FILLED W/ TOMATO SAUCE	7.14	0.12
58134620	TORTELLINI CHEESE-FILLED MEATLESS W/TOMATO SAUCE	6.37	0.11
58134650	TORTELLINI MEAT-FILLED NO SAUCE	3.68	0.06
58134660	TORTELLINI CHEESE-FILLED W/ CREAM SAUCE	10.67	0.18
58134710	TORTELLINI SPINACH-FILLED W/ TOMATO SAUCE	1.07	0.02
58134720	TORTELLINI SPINACH-FILLED NO SAUCE	0.32	0.01
58145115	MACARONI/NOODLES W/CHEESE FROM MIX W/PREPARED CHEESE SAUCE	7.25	0.12
58146100	PASTA W/ TOMATO SAUCE MEATLESS	8.98	0.15
58146110	PASTA W/ MEAT SAUCE (INCLUDE AMER CHOP SUEY)	9.33	0.16
58146120	PASTA W/ CHEESE & MEAT SAUCE	7.78	0.13
58146130	PASTA W/ CARBONARA SAUCE	5.48	0.09
58146150	PASTA W/ CHEESE & TOMATO SAUCE MEATLESS	11.03	0.18
58147100	PASTA W/ PESTO SAUCE	11.68	0.19
58147110	MACARONI OR NOODLES W/ BEANS & TOMATO SAUCE	6.18	0.1
58155410	SOUPY RICE W/ CHICKEN P.R. (ASOPAO DE POLLO)	9.66	0.16
58161300	WHITE RICE W/ TOMATO SAUCE	5.26	0.09
58161310	RICE BROWN W/ TOMATO SAUCE	7.04	0.12
58163450	SPANISH RICE W/ GROUND BEEF	8.12	0.14
58301050	LASAGNA W/ CHEESE & MEAT SAUCE (DIET FROZEN MEAL)	5.91	0.1
58302060	SPAG W/ BEEF TOM-BASED SAUCE LOWFAT RED SODIUM FRZ DIET	5.88	0.1
58302080	NOODLES W/ VEG TOM-BASED SAUCE FRZ DIET	6.07	0.1
58304050	SPAGHETTI W/ MEAT & MUSHROOM SAUCE (DIET FROZ MEAL)	6.72	0.11
58304060	SPAGHETTI W/ MEAT SAUCE (DIET FROZEN MEAL)	5.76	0.1
58304250	MANICOTTI W/ CHEESE TOMATO SAUCE (DIET FROZ MEAL)	6.41	0.11

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
58305250	PASTA W/ VEGETABLES & CHEESE SAUCE (DIET FROZ MEAL)	5.71	0.1
58400000	SOUP NFS	2.95	0.05
58400100	NOODLE SOUP NFS	4.43	0.07
58400200	RICE SOUP NFS	3.16	0.05
58401010	BARLEY SOUP (INCLUDE BEEF/CHICKEN/MUSHROOM BARLEY)	3.39	0.06
58402010	BEEF NOODLE SOUP	2.99	0.05
58402030	BEEF RICE SOUP	1.48	0.02
58402100	BEEF NOODLE SOUP HOME RECIPE	2.99	0.05
58403010	CHICKEN NOODLE SOUP (INCLUDE CHICKEN & STARS SOUP)	5.06	0.08
58403020	CHICKEN NOODLE SOUP CANNED UNDILUTED	0.38	0.01
58403030	CHICKEN NOODLE SOUP CANNED LOW SODIUM	5.03	0.08
58403040	CHICKEN NOODLE SOUP HOME RECIPE	6.14	0.1
58403050	CHICKEN NOODLE SOUP CREAM OF	2.25	0.04
58403060	CHICKEN NOODLE SOUP CAN RED SODIUM READY-TO-SERVE	4.35	0.07
58403100	NOODLE & POTATO SOUP P.R.	6	0.1
58404010	CHICKEN RICE SOUP (INCL TURKEY RICE SOUP)	6.19	0.1
58404030	CHICKEN OR TURKEY RICE SOUP HOME RECIPE	4.54	0.08
58404040	CHICKEN RICE SOUP CAN RED SODIUM PREP W/ WATER/RTS	2.78	0.05
58404050	CHICKEN RICE SOUP CAN REDUCED SODIUM W/ MILK	1.5	0.03
58404100	RICE AND POTATO SOUP P.R.	3.04	0.05
58404510	CHICKEN SOUP W/ DUMPLINGS POTATOES	4.63	0.08
58404520	CHICKEN SOUP W/ DUMPLINGS	5.85	0.1
58406010	TURKEY NOODLE SOUP	5.3	0.09
58406020	TURKEY NOODLE SOUP HOME RECIPE	5.91	0.1
58407010	INSTANT SOUP NOODLE (INCLUDE MEAT & VEG FLAVORS)	5.04	0.08
58407030	SOUP MOSTLY NOODLES(INCL SPAGHETTI SOUP TOP RAMEN)	5.55	0.09
58407040	INSTANT SOUP RICE (INCLUDE MEAT/CHICKEN FLAVOR)	2.94	0.05
58407050	INSTANT SOUP NOODLE W/ EGG SHRIMP OR CHICKEN	1.47	0.02
58408010	WON TON (WONTON) SOUP	4.2	0.07
58408500	NOODLE SOUP W/ VEGETABLES ORIENTAL STYLE	11.17	0.19
58421020	SOPA DE FIDEO AGUADA MEXICAN STYLE NOODLE SOUP	5.73	0.1
58421080	SOPA DE TORTILLA MEXICAN STYLE TORTILLA SOUP	2.94	0.05
63101110	APPLESAUCE STEWED APPLES NS AS TO ADDED SWEETENER	5.04	0.08
63101120	APPLESAUCE STEWED APPLES UNSWEETENED (INCL FRESH)	6.17	0.1
63101130	APPLESAUCE STEWED APPLES W/ SUGAR	6.07	0.1
63101140	APPLESAUCE STEWED APPLES W/ LOW CALORIE SWEETENER	9.68	0.16
63101150	APPLESAUCE / OTHER FRUITS(INCLUDE MOTT'S FRUIT PAK)	6.76	0.11
71301000	WHITE POTATO COOKED W/ SAUCE NS AS TO SAUCE	9.25	0.15
71508120	WHITE POT STUFF W/HAM BROC &CHEESE SAUCE BKD W/PEEL	8.51	0.14
71801000	POTATO SOUP NS AS TO MADE W/MILK OR WATER	2.88	0.05
71801010	POTATO SOUP CREAM OF W/ MILK	3.44	0.06
71801020	POTATO SOUP PREPARED W/ WATER	4.84	0.08
71801100	POTATO & CHEESE SOUP	3.12	0.05

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
71802010	MACARONI & POTATO SOUP	4.48	0.07
71851010	PLANTAIN SOUP P.R. (SOPA DE PLATANO)	1.46	0.02
72125252	SPINACH COOKED FROM FROZEN W/ CHEESE SAUCE	3.27	0.05
72201230	BROCCOLI COOKED NS AS TO FORM W/ CHEESE SAUCE	3.04	0.05
72201231	BROCCOLI COOKED FROM FRESH W/ CHEESE SAUCE	5.65	0.09
72201232	BROCCOLI COOKED FROM FROZEN W/ CHEESE SAUCE	4	0.07
72201251	BROCCOLI COOKED FROM FRESH W/ CREAM SAUCE	3.83	0.06
72201252	BROCCOLI COOKED FROM FROZEN W/ CREAM SAUCE	3.5	0.06
72202010	BROCCOLI CASSEROLE (BROC NOODLES CREAM SAUCE)	5.32	0.09
72302000	BROCCOLI SOUP (INCLUDE CREAM OF BROCCOLI SOUP)	3.27	0.05
72302100	BROCCOLI CHEESE SOUP PREP W/ MILK	3.88	0.06
72305000	ESCAROLE SOUP	10.88	0.18
72307000	SPINACH SOUP	1.72	0.03
72308500	DARK-GREEN LEAFY VEGETABLE SOUP MEATLESS ORIENTAL	5.53	0.09
73501000	CARROT SOUP CREAM OF W/ MILK	3.19	0.05
74402010	TOMATO CHILI SAUCE (CATSUP TYPE)	8.61	0.14
74402250	ENCHILADA SAUCE RED	18.9	0.31
74402260	ENCHILADA SAUCE GREEN	6.25	0.1
74402310	GREEN TOMATO-CHILE SAUCE RAW	10.07	0.17
74402350	GREEN TOMATO-CHILE SAUCE COOKED	11.63	0.19
74403010	TOMATO SAUCE	13.39	0.22
74404010	SPAGHETTI SAUCE	3.42	0.06
74404030	SPAGHETTI SAUCE W/ MEAT CANNED NO EXTRA MEAT	4.75	0.08
74404050	SPAGHETTI SAUCE LOW SODIUM	4.01	0.07
74404060	SPAGHETTI SAUCE FAT FREE	6.83	0.11
74406010	BARBECUE SAUCE (INCLUDE ARBY'S SAUCE)	3.08	0.05
74406050	BARBECUE SAUCE LOW SODIUM	4.23	0.07
74406100	STEAK SAUCE TOMATO-BASE (INCLUDE A-1)	4.7	0.08
74406500	COCKTAIL SAUCE	3.72	0.06
74601000	TOMATO SOUP NFS	2.12	0.04
74601010	TOMATO SOUP CREAM OF PREP W/ MILK	4.89	0.08
74602010	TOMATO SOUP PREPARED W/ WATER	4.19	0.07
74602030	TOMATO SOUP CANNED UNDILUTED	2.02	0.03
74602050	TOMATO SOUP INSTANT TYPE PREPARED W/ WATER	1.27	0.02
74602100	TOMATO SOUP CANNED LOW SODIUM READY-TO-SERVE	4.34	0.07
74603010	TOMATO BEEF SOUP PREPARED W/ WATER	1.49	0.02
74604010	TOMATO BEEF NOODLE SOUP PREPARED W/ WATER	2.08	0.03
74604500	TOMATO NOODLE SOUP PREPARED W/ WATER	3.03	0.05
74605010	TOMATO RICE SOUP PREPARED W/ WATER	2.69	0.04
74606010	TOMATO VEGETABLE SOUP PREP W/ WATER	3.47	0.06
74606020	TOMATO VEGETABLE SOUP W/NOODLES PREPARED W/ WATER	2.29	0.04
75232050	SEAWEED PREPARED W/ SOY SAUCE	28.8	0.48
75401011	ASPARAGUS FROM FRESH CREAMED OR W/ CHEESE SAUCE	5.08	0.08

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
75405010	BEETS WITH HARVARD SAUCE	6.71	0.11
75409011	CAULIFLOWER FROM FRESH CREAMED(INCL W/ CHEESE SAUCE)	7.51	0.13
75411031	CORN COOKED FROM FRESH W/ CREAM SAUCE MADE W/ MILK	4.34	0.07
75412070	EGGPLANT W/ CHEESE & TOMATO SAUCE	8.1	0.14
75417021	PEAS COOKED FROM FRESH W/ MUSHROOM SAUCE	3.33	0.06
75418040	SQUASH SUMMER CASSEROLE W/ CHEESE SAUCE	8.88	0.15
75440510	VEG COMBINATION (NO CAR/ DK GRN) W/ CHEESE SAUCE	6.19	0.1
75450500	VEG COMBINATION (INCL CAR DK GRN) W/ CREAM SAUCE	3.11	0.05
75460800	VEGETABLE COMB(INCL CAR/DK GRN) CKD W/ BUTTER SAUCE	6.87	0.11
75506100	MUSTARD SAUCE	9.4	0.16
75511010	PEPPERS HOT SAUCE (INCLUDE TABASCO SAUCE)	8.37	0.14
75601000	ASPARAGUS SOUP CREAM OF NS AS TO W/ MILK OR WATER	3.04	0.05
75601010	ASPARAGUS SOUP CREAM OF W/ MILK	6.07	0.1
75601200	CABBAGE SOUP	3.09	0.05
75601210	CABBAGE W/ MEAT SOUP	3.14	0.05
75602010	CAULIFLOWER SOUP CREAM OF W/ MILK	3.28	0.05
75604010	CORN SOUP CREAM OF W/ MILK	8.35	0.14
75604020	CORN SOUP CREAM OF PREPARED W/ WATER	2.99	0.05
75604510	CUCUMBER SOUP CREAM OF W/ MILK	1.52	0.03
75607000	MUSHROOM SOUP NFS	2.2	0.04
75607010	MUSHROOM SOUP CREAM OF PREP W/ MILK	3.07	0.05
75607020	MUSHROOM SOUP CREAM OF PREPARED W/ WATER	3.41	0.06
75607030	MUSHROOM SOUP CANNED UNDILUTED (INCL CREAM OF)	0.47	0.01
75607090	MUSHROOM SOUP CREAM OF CAN NS MILK/WATER RED SODIUM	3.01	0.05
75607100	MUSHROOM SOUP CREAM OF CAN PREP W/ MILK REDUCED SODIUM	5.2	0.09
75607140	MUSHROOM SOUP CREAM OF CAN PREP W/ WATER REDUCED SODIUM	7.26	0.12
75608100	ONION SOUP FRENCH	4.5	0.08
75609000	PEA SOUP NFS	9.18	0.15
75647000	SEAWEED SOUP	2.82	0.05
75649010	VEGETABLE SOUP PREP W/ WATER OR READY-TO-SERVE	4.21	0.07
75649020	VEGETABLE SOUP CANNED UNDILUTED	3.65	0.06
75649030	VEGETABLE SOUP CANNED LOW SODIUM	4.71	0.08
75649050	VEGETABLE SOUP MADE FROM DRY MIX	4.17	0.07
75649060	VEGETABLE SOUP DRY MIX NOT RECONSTITUTED	0.01	0
75649110	VEGETABLE SOUP HOME RECIPE	5.53	0.09
75649150	VEGETABLE NOODLE SOUP HOME RECIPE	4.89	0.08
75650990	MINESTRONE SOUP CANNED REDUCED SODIUM RTS	3.14	0.05
75651000	MINESTRONE SOUP HOME RECIPE	3.69	0.06
75651010	VEGETABLE BEAN SOUP PREPARED W/ WATER	4.51	0.08
75651020	VEGETABLE BEEF SOUP PREPARED W/ WATER	4.6	0.08

FOODCODE	Lycopene consumption from the addition of Lyc-O-Mato Powder	All Consumers mg/day	mg/kg/day
75651040	VEGETABLE NOODLE SOUP PREPARED W/ WATER	2.21	0.04
75651050	VEGETABLE CHICKEN SOUP W/ WATER OR READY-TO-SERVE	4.85	0.08
75651070	VEGETABLE RICE SOUP PREPARED W/ WATER	7.71	0.13
75651110	VEG CHICKEN RICE SOUP PREPARED W/ WATER / READY TO	6.12	0.1
75651140	VEG SOUP W/ CHICKEN BROTH MEXICAN STYLE (SOPA RANCHERA)	5.68	0.09
75651150	VEGETABLE NOODLE SOUP CAN RED SODIUM PREP W/ WATER/RTS	3.28	0.05
75652010	VEGETABLE BEEF SOUP HOME RECIPE	5.26	0.09
75652040	VEG BEEF SOUP W/ NOODLES HOME RECIPE	6.83	0.11
75652050	VEG BEEF SOUP W/ RICE HOME RECIPE	4.73	0.08
75656020	VEGETABLE SOUP CHUNKY STYLE	3.3	0.06
75656040	VEGETABLE SOUP W/ PASTA CHUNKY STYLE	4.67	0.08
81301020	LEMON-BUTTER SAUCE	8.71	0.15
81302010	HOLLANDAISE SAUCE	3.69	0.06
81302020	BEARNAISE SAUCE	6.4	0.11
81302050	TARTAR SAUCE	4.59	0.08
81302060	HORSERADISH SAUCE	11.27	0.19
81302070	PESTO SAUCE	2.21	0.04
81312000	TARTAR SAUCE LOW CALORIE	8.46	0.14
91361010	SWEET & SOUR SAUCE (INCLUDE VIETNAMESE SAUCE)	26.02	0.43
91361020	FRUIT SAUCE (INCLUDE ALL FRUITS)	1.29	0.02
91361050	DUCK SAUCE (INCLUDE CHAISNI SAUCE)	17.48	0.29
91361070	PLUM SAUCE ORIENTAL STYLE	0.14	0

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GEORGE A. BURDOCK, Ph.D.
Diplomate, American Board of Toxicology

CURRICULUM VITAE

PROFESSIONAL EXPERIENCE

Burdock Group **1988 - Present**
Vero Beach, Florida

Founder and President

Dr. Burdock is an internationally recognized authority on the safety of food ingredients, personal care products, and dietary supplements. He has more than twenty years experience dealing with regulatory issues related to product safety and risk assessment. As the President of the Burdock Group, Dr. Burdock provides safety and toxicity information on foods, food and feed additives, and drug excipients and contaminants to a varied client list, including Fortune 100 corporations, start-up companies, law firms, and trade associations. This information may be in the form of confidential reviews, regulatory petitions, Generally Recognized As Safe (GRAS) self-determinations, GRAS notifications, product contaminations, and litigation support. As a leading scientist in the food industry, Dr. Burdock is sought by scientific publishers to author and edit reference books on food additives, flavor ingredients, and regulatory matters and by clients to comment on proposed regulations or respond to communications from regulatory agencies including FDA and USDA.

Flavor and Extract Manufacturers' Association (FEMA) **1986 - 1992**
Washington, D.C.

Director of Scientific Affairs

Dr. Burdock managed the FEMA scientific programs, coordinated the research activities of the testing laboratories, and communicated with external consultants and allied industry committees working with FEMA.. As the primary scientific liaison, Dr. Burdock guided member companies for preparation of submissions to the FEMA Expert Panel for GRAS review, alerted Expert Panel and Association members to scientific developments in the food and flavor industry, and identified changes in the regulatory policies as a result of these developments. He authored and edited comprehensive literature reviews on flavor additives and other topics relevant to the Association's interests.

Shulton Research Division, American Cyanamid Corporation **1984 - 1986**
Clifton, New Jersey

Manager of Biological Services

Dr. Burdock directed the Product Safety section, Microbiological Research Services, the Clinical Evaluation Laboratory and the Product Evaluation Center. As the senior toxicologist, he was responsible for the toxicological and microbiologic safety of products applied to the test groups in the clinical evaluation laboratories and for those products released for public use. Dr. Burdock served as a corporate member of the Pharmacology/Toxicology Committee and the Cosmetic Ingredient Review Subcommittee of the Cosmetic, Toiletries and Fragrance Association. He represented the Consumer Products Division on toxicology issues within the corporation, and externally, with vendors, government agencies and trade associations

Hazleton Laboratories America, Inc. **1979 - 1984**
Vienna, Virginia

Senior Staff Scientist

As a Study Director, Dr. Burdock designed and managed toxicological studies and reproduction and teratology studies in a variety of species. Dr. Burdock had organizational oversight for compliance with regulatory requirements, quality assurance, budgetary monitoring, and for evaluating the performance of subcontractors. He negotiated program design and individual toxicity study requirements for the registration of substances with the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and other regulatory agencies. Dr. Burdock also supervised two laboratory sections, Teratology/Reproduction and Sub-Chronic Rodent Toxicology.

EDUCATION

Doctorate of Philosophy (Ph.D.), Toxicology, School of Pharmacy, University of Mississippi, 1980
Master of Combined Sciences, Physiology and Biochemistry, University of Mississippi, 1973
Bachelor of Science, Biology, University of Mississippi, 1969

CERTIFICATION

Diplomate, American Board of Toxicology, 1983; Recertified, 2003, 1998, 1993, 1988.
Fellow, American College of Nutrition, 2003.

PROFESSIONAL MEMBERSHIPS

American Chemical Society
American College of Nutrition, (Fellow)
American College of Toxicology
American Oil Chemists Society
Food and Drug Law Institute
Institute of Food Technologists
International Society for Regulatory Toxicology and Pharmacology (Vice President, President-elect & Councilor)
National Capital Area Chapter of the Society of Toxicology
Regulatory Affairs Professional Society
Society of Toxicology (Associate Member)

PUBLICATIONS

I.G. Carabin and **G.A. Burdock** (in press: January, 2005). Overweight and obesity in the United States - an overview. *Food Drug Law Institute Update.*

R.A. Isbrucker and **G.A. Burdock.** Risk and safety assessment on the consumption of licorice root (*Glycyrrhiza*), its extract and powder as a food ingredient, with emphasis on the pharmacology and toxicology of glycyrrhizin. (Submitted for publication: *Food and Chemical Toxicology*).

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G.A. Burdock, I.G. Carabin and M.G. Soni (2001). Safety assessment of *beta*-nitropropionic acid: A monograph in support of an acceptable daily intake in humans. *Food Chemistry* 75(1):1-27.

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M.G. Soni, S.A. White, W.G. Flamm and **G.A. Burdock** (2001). Safety evaluation of dietary aluminum. *Regulatory Toxicology and Pharmacology* 33:66-79.

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dimethylthiazole. *Acute Toxicology Data* 1(2): 95-96.

G.A. Burdock and R.A. Ford (1990). Acute oral toxicity (LD50) study in the rat with 3-methyl-4-phenyl-3-buten-2-one. *Acute Toxicology Data* 1(2): 96-97.
G.A. Burdock and R.A. Ford (1990). Acute oral toxicity (LD50) study in the rat with 3-(2-furylacrolein). *Acute Toxicology Data* 1(2): 97-98.

G.A. Burdock, B.M. Wagner, R.L. Smith, I.C. Munro and P.M. Newberne (1990). Recent progress in the consideration of flavoring ingredients under the food additives amendment. 15. GRAS substances. *Food Technology* 44(2):78, 80, 82, 84 & 86.

G.A. Burdock and R.L. Hall (1989). Pro-active flavor safety evaluation and management. In: *Trends in Food Product Development,* Seventh World Congress of Food Science and Technology, Singapore, October, 1987. A.H. Ghee, T.C. Yam and C. Tan. (Eds.). Singapore Institute of Food Science and Technology, Singapore. p. 359-366.

G.A. Burdock, R.A. Ford, A.M. Bottomley, and D.M. John (1987). An evaluation of the teratogenic potential of orally administered Phenylethyl Alcohol (PEA). *The Toxicologist* 7(1):176.

G.A. Burdock, R.H. Cox, S.L. Morseth, and L.W. Smith (1986). Teratogenicity study of 4-Nitro-N-Methylphthalimide (4-NPI). *The Toxicologist* 6(1):94.

G.A. Burdock, B.A. Kulwich, R.D. Alsakar and P.M. Marshall (1984). 90-Day dog study: Caprolactam. In *Proceedings of a Symposium on an Industry Approach to Chemical Risk Assessmen: Caprolactam and related compounds as a case study*, May 15-17, 1984. Industrial Health Foundation, Pittsburgh, PA.

J.A. Trutter, F.E. Reno, **G.A. Burdock** and D.W. Korte, Jr. (1984). Fertility study with a candidate antimalarial drug in the rat. *Journal of the American College of Toxicology* 3:172.

G.A. Burdock (1983). Diethanolamine-induced changes in liver and kidney of the neonatal rat. *The Toxicologist* 4(1):491.

G.A. Burdock, R. B. Hackett and L.W. Masten (1980). A comparison of hepatic microsomal enzyme induction by methadone, phenobarbital and 3-methylcholanthrene in the mouse. *Biochemical Pharmacology* 28:3476-3482.

J.C. Kapeghian, **G.A. Burdock** and L.W. Masten (1980). The effect of the route of administration of microsomal enzyme induction following repeated methadone administration in the mouse. *Biochemical Pharmacology* 28:3021-3025.

G.A. Burdock (1980). Some Toxic Effects of Diethanolamine in the Neonatal Rat. Doctoral Dissertation. Doctorate of Philosophy (Ph.D.), Toxicology, School of Pharmacy, University of Mississippi.

G.A. Burdock and L.W. Masten (1979). Diethanolamine-induced changes in the neonatal rat. *Toxicology and Applied Pharmacology* 48:A30.

J.C. Kapeghian, **G.A. Burdock** and L.W. Masten (1977). Effect of the route of administration on microsomal enzyme induction following repeated administration of methadone in the mouse. *Toxicology and Applied Pharmacology* 41:159.

G.A. Burdock, R. B. Hackett and L.W. Masten (1976). Dose-response relationship of oral methadone administration and liver microsomal enzyme activity. *Federation Proceedings* 35:469.

J.D. Catravas, I.W. Waters, **G.A. Burdock** and W.M. Davis (1975). Haloperidol and propanolol in the treatment of acute amphetamine intoxication in the dog. *Toxicology and Applied Pharmacology* 33:185.

REPORTS

G.A. Burdock (1993). High Dose Irradiation of Food. Report submitted to the Food Safety Unit, World Health Organization.

W.G. Flamm, P. Lombardo, A. Forbes, W. Nichols, J.B. Little, **G.A. Burdock** and J.A. Flamm (1992). Review of the wholesomeness of irradiated food. Report submitted to the Food Safety Unit, World Health Organization

Dr. Burdock was the author of numerous technical reports while serving as a consultant and a scientist for the Flavor and Extract Manufacturers' Association, Hazleton Laboratories and American Cyanamid. The content of these reports is proprietary and confidential to the sponsoring organizations.

CURRICULUM VITAE
Clare M. Hasler
January 2004

ADDRESS: Robert Mondavi Institute for Wine and Food Science

EDUCATION:

M.B.A.	2003	University of Illinois at Urbana-Champaign
Ph.D. (dual)	1990	Human Nutrition/Environmental Toxicology, Michigan State University
M.S.	1984	Nutrition Science, The Pennsylvania State University
B.S.	1981	Human Nutrition, Michigan State University

PROFESSIONAL APPOINTMENTS:

1990-1992	Post-Doctoral Fellow, Laboratory of Cellular Carcinogenesis and Tumor Promotion (Molecular Mechanisms Section), National Cancer Institute, National Institutes of Health
1992-2000	Director, Functional Foods for Health Program, University of Illinois
1992-1997	Visiting Assistant Professor, Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign
1992-1996	Visiting Assistant Professor, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago
1992-1997	Visiting Assistant Professor, Department of Human Nutrition and Dietetics, University of Illinois at Chicago
1998-1999	Co-Leader, Strategic Research Initiative on Food Safety and Functional Foods, Council for Food and Agricultural Research (C-FAR)
1998-2003	Assistant Professor, Division of Nutritional Sciences, University of Illinois at Urbana-Champaign
1999-2003	Adjunct Assistant Professor of Pharmacognosy, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago
2000-2003	Associate Director of Outreach and Industry Relations, Functional Foods for Health Program, University of Illinois
2004-Present	Executive Director, Robert Mondavi Institute for Wine and Food Science, University of California at Davis

PROFESSIONAL ASSOCIATIONS:

American Association for Cancer Research
American Association of Cereal Chemists
American Association for the Advancement of Science
American Nutraceutical Association
American Society for Nutritional Sciences
Gamma Sigma Delta
Institute of Food Technologists
Penn State Alumni Association
Sigma Xi, The Scientific Research Society

OFFICES HELD IN PROFESSIONAL SOCIETIES:

2003-2004	Chair, American Society for Nutritional Sciences, Nutrition Education Research Interest Section
2003-Present	American Association for the Advancement of Science, Electorate Nominating Committee, Section on Agriculture, Food and Renewable Resources

PROFESSIONAL AWARDS AND RECOGNITION:

1996	Emerging Leaders Award, Michigan State University, College of Human Ecology, Centennial Alumni Celebration
1997	Friend of Agriculture Award, Illinois Soybean Association
1998-Present	Scientific Expert on Functional Foods, International Food Information Council Media Guide on Food Safety & Nutrition
1998	Author, Institute of Food Technologists' Scientific Status Summary on Functional Foods
1998	"Top 25 Food Influential"(Mover and Shaker Award), Self Magazine
1999	Experiment Station Committee on Organization and Policy/Academic Committee on Organization and Policy (ESCOP/ACOP) Leadership Development Program
1999	Meritorious Service Award, United Soybean Board
2000	Recognition of Service Award, American Dietetic Association

EDITORIAL ACTIVITIES:

1993-2003	Editor, Functional Foods for Health Program ALERT, University of Illinois
1996-Present	Editorial Board, Journal of Nutraceuticals, Functional and Medical Foods
1997-Present	Editorial Board, Journal of Medicinal Food
1998-Present	Editorial Board, Journal of the American Nutraceutical Association
1998-Present	Editorial Board, Taste for Life
2000-Present	Editorial Board, Ingredients, Health & Nutrition
1999-2001	Editorial Board, Journal of Food Science, Food Chemistry & Toxicology Section
2001-2003	Editorial Board, Leatherhead Food Research Association Food Industry Journal
2002-Present	Editorial Board, Current Topics in Nutraceutical Research
2002-Present	Editorial Board, Applied Biotechnology, Food Science and Policy

ADVISORY BOARDS ACTIVITIES:

1998-2002	Centrum Center for Nutrition Science, Scientific Advisory Board
1998-2001	AgeWave/LifeSpring, Scientific Advisory Board
1999-2001	Campbell Soup Company, Scientific Advisory Board
2000-2001	NutritionGrocer.com, Scientific Advisory Board
2000-Present	American Council on Science and Health, Board of Scientific & Policy Advisors
2001-2002	Nutripharma, Scientific Advisory Board
2001-Present	Naturemade Vitamins, Women's Wellness Advisor
2002-Present	Dietary Supplement Health and Information Bureau, Scientific Advisory Board
2002-Present	Mushroom Council, Scientific Advisory Board
2003-Present	Publicis Dialog Nutrition Research Center, Scientific Advisory Board
2003-Present	Cranberry Institute, Scientific Advisory Board

RESEARCH AND PROGRAM SUPPORT:

Dr. Hasler has attracted over $3 million in funding research since 1996

Council for Food and Agricultural Research: *"Stimulating Functional Foods Research at the University of Illinois."* $80,000, CM Hasler (PI), 1996-1998.

United Soybean Board: "*Soy Protein Health Claim.*" $200,000, CM Hasler (contract manager), 1997-1999.

Council for Food and Agricultural Research: *"Amount of Soy Protein Needed to Lower Cholesterol.*" $93,760, SM Potter, CM Hasler (Co-PI), R Weigel, 1997-1998.

College of Agricultural, Environmental and Consumer Sciences, Value-Added Program: "*Stimulating Functional Foods Research at the University of Illinois.*" $25,000, CM Hasler (PI), 1997-1998.

Council for Food and Agricultural Research: *"Amount of Soy Protein Needed to Lower Cholesterol.*" $45,980, CM Hasler (PI), S Potter, R, 1998-1999.

California Prune Board: *"Assessing the Cholesterol Lowering Effects of Prune Puree in Human Subjects."* $86,848, CM Hasler (PI), P Bowen, E Emeson, 1998-1999.

Council for Food and Agricultural Research: *"Strategic Research Initiative on Food Safety and Functional Foods."* $148,800, CM Hasler (PI), 1998-1999.

Illinois Soybean Program Operating Board (ISPOB): *"Evaluation of the Use of the StratSoy "Ask an Expert" Website by Consumers."* $23,350, CM Hasler (PI), 1998-1999.

University of Illinois, Office of the Provost: *"Acquisition of an HPLC-MS to Facilitate Functional Foods Research."* $150,000, CM Hasler, (PI), 1999.

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United Soybean Board: *"Soy Health Claim Communication."* $7,500, CM Hasler (PI), 1999-2000.

Illinois Soybean Program Operating Board: *"Enhancing StratSoy as a Source of Information on Soybean Utilization and Health Benefits."* $30,000, S Thompson, P Khanna, CM Hasler (Co-PI), 2000-2001.

United States Department of Agriculture: *"Component Interactions for Efficacy of Functional Foods."* $2,400,000, E. Jeffery, C Hasler (Director of Outreach/Education), MA Smith, J Erdman, R MacDonald, 2000-2004.

Illinois Soybean Program Operating Board: *"Effects of Soy Protein Consumption in African-American Women with Mild Hypercholesterolemia."* $113,300, CM Hasler (PI), 2000-2003.

Illinois Soybean Program Operating Board: *"Enhancing StratSoy as a Source of Information on Soybean Utilization and Health Benefits."* $15,000, S Thompson, CM Hasler (Co-PI), Karl Weingartner, 2001-2002.

Campus Research Board: *"Effect of Soy on Markers of Cardiovascular Disease Risk in African-American Women."* $14,000, CM Hasler (PI), 2002-2003.

Almond Board of California: *"Effect of Almonds on Cardiovascular Health in African-American Women."* $89,750, CM Hasler (PI), pending.

RESEARCH PUBLICATIONS:

1. Hasler, CM, H Rothenbacher, DJ Mela, PM Kris-Etherton: The effect of exercise and hyperlipemic diet on aortic histopathology in the rat. *Atherosclerosis* 52:279-286, 1984.

2. Hasler, CM, H Rothenbacher, DJ Mela, PM Kris-Etherton: Exercise attenuates diet-induced arteriosclerosis in the adult rat. *Journal of Nutrition* 117:986-993, 1987.

3. Hasler, CM, MA Frick, MR Bennink, JE Trosko: TPA-induced inhibition of gap junctional intercellular communication does not involve free radical production. *Toxicology and Applied Pharmacology* 103:389-398, 1990.

4. Hasler, CM, MR Bennink, JE Trosko: Inhibition of gap junction-mediated intercellular communication by ∀-linolenate. *American Journal of Physiology* 216 (Cell Physiol. 30): C161-C168, 1991.

5. Madhukar, BV, CC Chang, CM Hasler, D de Feyter, SY Oh, B Lockwood, JE Trosko: Characterization of an *in vitro* human kidney epithelial system to study gap junctional intercellular communication. *In Vitro Toxicology* 4:630-640, 1991.

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6. Hasler, CM, JE Trosko, MR Bennink: Incorporation of n-3 fatty acids into cell phospholipids inhibits gap junctional intercellular communication. *Lipids* 26:788-792, 1991.

7. Hasler, CM, G Acs, PM Blumberg: Specific binding to protein kinase C by ingenol and its induction of biological responses. *Cancer Research* 52:202-208, 1992.

8. Hayashi, T, CM Hasler, SY Oh, BV Madhukar, CC Chang, JE Trosko: A human kidney epithelial cell culture as an in vitro model to study chemical modulation of intercellular communication. *In Vitro Toxicology* 9:3-17, 1996.

9. Getlinger, MJ, BH Arjmandi, NV Goyal, L Alekel, CM Hasler, BL Drum, SC Kukreja: The role of soy protein with normal or reduced isoflavone content in reversing ovarian hormone deficiency induced bone loss in rats. *American Journal of Clinical Nutrition* 68: 1358S-1363S, 1998.

10. Arjmandi, BH, R Birnbaum, NV Goyal, MJ Getlinger, S Juma, L Alekel, CM Hasler, BW Hollis, JL Drum, SC Kukreja: The bone modulating effect of soy protein in ovarian hormone deficiency is related to its isoflavone content. *American Journal of Clinical Nutrition* 68:1364S-1368S, 1998.

11. Wool, DL, AG Kanfer, J Michaels, S Thompson, CM Hasler: Evaluating the relevance of a web based "ask an expert" feature: Stratsoy and soy and human health queries: *Journal of Applied Communications* 84:7-22, 2000.

12. Teixeira, SM, SM Potter, R Weigel, S Hannum, JW Erdman, Jr., CM Hasler: Effects of feeding 4 levels of soy protein for 3 and 6 weeks on blood lipids and apolipoproteins in mildly hypercholesterolemic men: *American Journal of Clinical Nutrition* 71:1077-1084, 2000.

13. Pelletier S, S Kundrat, CM Hasler: Functional food consumption trends in Illinois: Positive effects of an educational program. *Journal of the American Dietetic Association*, 102:1297-1299, 2002.

14. Pelletier, S, S Kundrat, CM Hasler: Effects of a functional food nutrition education program with cardiac rehabilitation patients. *Journal of Cardiopulmonary Rehabilitation* (In press).

15. De Mejia, EG, T Bradford, C Hasler: The anticarcingenic potential of soybean lectin and lunasin. *Nutrition Reviews* (In press).

16. Rah, JH, CM Hasler, JE Painter, KM Chapman-Novakofski: Women's perspectives and consumption behaviors of soy products. *Journal of Nutrition Education and Behavior* (Accepted for publication).

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INVITED REVIEWS, POSITION PAPERS:

1. Hasler, CM: Functional foods: the western perspective. *Nutrition Reviews* 54: S6-S10, 1996.

2. Hasler, CM: Scientific status summary. Functional foods: their role in disease prevention and health promotion. *Food Technology*. 52: 63-70, 1998.

3. Unnevehr, L, MR Ward, CM Hasler: Regulating health claims on food products: The balance between consumer choice and consumer protection. *Choices*: First Quarter (March):26-30, 1998.

4. Hasler, CM: A new look at an ancient concept. *Chemistry & Industry*, Feb 2nd, (No.3): 84-89, 1998.

5. Hasler, CM: Probiotics and prebiotics: where are we today? (Foreward). *British Journal of Nutrition* 80:S195, 1998.

6. Thomson, C, A Bloch, CM Hasler: Position of the American Dietetic Association: functional foods. *Journal of the American Dietetic Association* 99: 1278-1285, 1999.

7. Hasler, CM, JB Blumberg: Introduction. Symposium on phytochemicals: biochemistry and physiology. *Journal of Nutrition* 129: 756S-757S, 1999.

8. Unnevehr, LJ, CM Hasler: Health claims and labeling regulation: How will consumers learn about functional foods? *AgBioforum* 3(1):262-265, 2000.

9. Hasler, CM: The changing face of functional foods: *Journal of the American College of Nutrition*, 19 (5): 499S-506S, 2000.

10. Hasler, CM, S Kundrat, D Wool: Functional foods and cardiovascular disease: *Current Atherosclerosis Reports* 2:467-475, 2000.

11. Hasler, CM, A Moag-Stahlberg, D Webb: Guidance for dietitians on how best to evaluate the safety efficacy and quality of nutraceuticals, functional foods and their ingredients. *Journal of the American Dietetic Association* 101:733-736, 2001.

12. Hasler, CM: The cardiovascular effects of soy products. *Journal of Cardiovascular Nursing* 16 (4): 50-63, 2002.

13. Hasler, CM: Functional foods: Benefits, concerns, and challenges—A position paper from the American Council on Science and Health. *Journal of Nutrition* 132:3772-3781, 2002.

14. Thomson, C, A Bloch, CM Hasler: Position of the American Dietetic Association: functional foods. *Journal of the American Dietetic Association* (In press).

LAY PUBLICTIONS, LETTERS TO EDITORS, BOOK FOREWARDS, EDITORIALS, INDUSTRY-RELATED PUBLICATIONS:

1. Hasler, CM: Narrowing the gap between food and drugs. *Cereal Foods World* 42: 462-463, 1997.

2. Hasler, CM, SC Finn: Soy: Just a hill of beans? *Journal of Women's Health* 7: 519-521, 1998.

3. Hasler, CM: Strain-independent variation of phytoestrogen content in soybeans mitigates significance of variation in genetically modified varieties (letter to the editor). *Journal of Medicinal Food* (letter to the editor) 2:279-280, 1999.

4. Teixeira, SR, S Hannum, JW Erdman, Jr., SM Potter, CM Hasler: There is still more to learn about soy (letter to the editor). *American Journal of Clinical Nutrition* 72:1588-1589, 2000.

5. Hasler, CM: Beyond the FDA health claim. *Taste for Life* 4 (No. 3): 26-27, 2001.

6. Hasler, CM: Soy and breast cancer. *Taste for Life* 4 (No. 4): 34-35, 2001.

7. Hasler, CM: Soy for menopause. *Taste for Life* 4 (No. 5): 40-41, 2001.

8. Hasler, CM: Come over to the dark side. *Taste for Life* 4 (No. 8): 12-13, 2001.

9. Hasler, CM: The latest on soy: Benefits go beyond the heart-health claim. *Taste For Life* 6 (No. 4): 25-27, 2003.

BOOKS EDITED:

1. Hasler, CM: *Regulation of Functional Foods and Nutraceuticals: A Global Perspective*, Iowa State Press/Institute of Food Technologists Press, 2003 (In press).

BOOK CHAPTERS:

1. Trosko, JE, BV Madhukar, CM Hasler, CC Chang: Modulated intercellular communication: consequence of extracellular molecules triggering intracellular communication. In: *Eicosanoids and Other Bioactive Lipids in Cancer and Radiation Injury*. Honn, KV, LJ Marnett, S Nigam, TL Walden, Jr., (Eds.), Kluwer Academic Publishers, Boston, pp. 285-295, 1991.

2. Hasler, CM, RL Huston, EM Caudill: The impact of the Nutrition Labeling and Education Act on functional foods. In: *Nutrition Labeling Handbook*. Shapiro R (Ed.), Marcel Dekker, Inc., pp. 471-493, 1995.

3. Hasler, CM, M Cullum: Functional foods in chiropractic. In: *Advances in Chiropractic*. Vol. 4. Mosby-Year Book, Inc.: pp. 601-637, 1996.

4. Hasler, CM: Phytochemicals: biochemical markers of ingestion, absorption and metabolism using flaxseed as a model. In: *Nutraceuticals--Designer Foods III: Garlic, Soy and Licorice*. Lachance PA (Ed.), Food & Nutrition Press, Inc., pp. 39-43, 1997.

5. Hasler, CM: Foreward. In: *Functional Foods: Biochemical & Processing Aspects*. Mazza G (Ed.), Technomic Publishing Inc., pp. xi-xiv, 1998.

6. Hasler, CM: Plants as medicine: The role of phytochemicals in optimal health. In: *Phytochemicals and Phytopharmaceuticals.* Shahidi F, S-T. Ho (Eds.). AOCS Press, Champaign, IL, Chapter 1, pp. 1-12, 2000.

7. Hasler, CM: Eggs as a functional food: technology update. In: *Egg Nutrition and Biotechnology*. Sim JS, S Nakai, W Guenter (Eds.), CAB International, Wallingford, U.K, Chapter 19, pp. 243-251, 2000.

8. Hasler, CM: Functional foods. In: *Present Knowledge in Nutrition*, 8th Edition. Bowman, B, R Russell (Eds.), ILSI Press, Washington, D.C., Chapter 64, pp. 740-749, 2001.

9. Hasler, CM, S Kundrat: Soy isoflavones as functional ingredients in women's health. In: *Phytoestrogens and Health.* Sarwar G, G Gilani, J Anderson (Eds.), AOCS Press, Champaign, IL, Chapter 2, pp. 32-50, 2002.

BOOK REVIEWS:

1. Hasler, CM: Functional Foods--Designer Foods, Pharmafoods, Nutraceuticals (Goldberg I, Ed.). *American Journal of Clinical Nutrition* 64:255, 1996.

2. Hasler, CM: Essentials of Functional Foods (Schmidl MK and Labusa TP, Eds.). *Food Technology* 55 (7): 87, 2001.

3. Hasler, CM: Nutraceuticals (Rapport L, Lockwood B, Eds.). *American Journal of Clinical Nutrition 77 (4) :996-997, 2003.*

BULLETINS, REPORTS, CONFERENCE PROCEEDINGS

1. Hasler, CM: New weapon in the war against chronic disease. *Illinois Research* 35, Spring/Summer: 21-23, 1993.

2. Hasler, CM: Scientists debate method for identifying human carcinogens. *Illinois Research* 35, Fall: 10, 1993.

3.

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4. Hasler, CM: Phytochemicals in Disease Prevention. *Nutri-News*, Mosby-Year Book, Inc.: 1-4, 1995.

5. Hasler, CM, RS Witwer: The application of bioactive ingredients in cold, non-carbonated, non-dairy beverages. *Teltech Technology Dossier Service, Teltech Resource Network Corporation*, May, 1996.

6. Hasler, CM: Oat beta-glucan, coronary eart disease risk, and health claims. *Scan's PULSE*, American Dietetic Association Publication for Sports, Cardiovascular, and Wellness Nutritionists. Vol. 15 (No.4):1-4, Fall 1996.

6. Hasler, CM: Soybeans and Human Health. *Proceedings of the Twenty-Fifth Soybean Seed Research Conference*, pp. 61-67, 1995.

7. Hasler, CM: Phytoestrogens and breast cancer. *Y-ME Hotline* 56: 1-2, March/April, 1996.

8. Hasler, CM: Soybeans and Human Health. *International Soybean Program (INSTOY) Soybean Processing and Utilization Course*, 1996.

9. Hasler, CM, D Nice, R Witwer: Bioactive ingredients for grain-based products. *Teltech Technology Dossier Service. Teltech Resource Network Corporation*, September, 1996.

10. Hasler, CM: Functional foods for health. *The Quest* (University of Illinois Cooperative Extension Service Bulletin, Knox County Unit), p. 2, March, 1997.

11. Hasler, CM: Public health implications of the soy protein health claim. *Soy Connection* 8 (No. 1), Winter 1999-2000: 1-3.

12. Hasler, CM (Editor): Functional foods: Trends in global market, scientific and regulatory development. *University of Illinois Functional Foods for Health Program*, 2001.

13. Hasler CM: Where do functional foods fit in the diet? National Agricultural Biotechnology Council (NABC) Report 14 on *Foods for Health,* 2002.

14. Childs N, CM Hasler, L Pike, F Shahidi, B Watkins, ME Camire: Nutraceuticals for Health Promotion and Disease Prevention. *Council for Agricultural Science and Technology Issue Paper* (In press).

INVITED LECTURES AND PRESENTATIONS:

The following are selected presentations since 1997 and do not include numerous regional presentations. Dr. Hasler has given more than 200 regional, national and international presentations (in 19 countries) since joining the University of Illinois in 1992.

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International [Selected]

Guelph Food Technology Center: *"Functional Foods Research at the University of Illinois,"* Toronto, Canada, May 5, 1997.

The University of Alberta: "*Where are We Now in Functional Foods for Health?"* Edmonton, Canada, September 5, 1997.

Fifth North American Chemical Congress: *"Plants as Medicine: The Role of Phytochemicals in Optimal Health,"* Cancun, Mexico, November 17, 1997.

Royal Society of Medicine: "*The Public Health Implications of Lycopene*," London, England, May 28, 1998.

Global Development and Opportunities in Functional Foods and Nutraceuticals Conference: *"Research Initiatives on Functional Foods in the U.S."* Copenhagen, Denmark, October 30, 1998, Chair, Pacific Rim Session.

Pan American College of Agriculture: *"Functional Foods: Research, Market & Regulatory Update,"* Zamorano, Honduras, May 24, 1999.

10th World Congress on Food Science & Technology: *"Cholesterol Lowering Margarine as a Functional Food,"* Sydney, Australia, October 4, 1999 (Plenary Speaker).

South East Asia Soyfood Symposium 2000: *"Soybeans–From Traditional to Functional Food, a Global Trend,"* Bangkok, Thailand, September 4, 2000.

New Zealand Nutrition Foundation: *"Soy as a Functional Food for Heart Health,"* Auckland, New Zealand, October 10, 2000.

Soy and Health Symposium 2000: *"Soybeans--A Global Trend: From Traditional to Functional Food,"* Manila, Philippines, November 17, 2000.

American Overseas Dietetic Association Annual Conference: *"Functional Foods Now: Current Science,"* Alicante, Spain, March 23, 2001.

Swedish Center of Excellence and Innovation in Functional Foods, Functional Foods–Where Academy and Market Meet: *"Functional Foods: Then, Now and the Future,"* Göteborg, Sweden, May 3, 2001 (Keynote Speaker).

University of the West Indies, Department of Chemistry: *"Functional Foods: Trends in Global Scientific and Regulatory Development,"* Kingston, Jamaica, December 12, 2001.

Nutraceuticals and Functional Foods Institute, Laval University: *"Functional Foods: Then, Now and the Future,"* Quebec, Canada, January 28, 2002.

000102

Agricultural Biotechnology International Conference: *"Active Molecules From Plants: Naturally Existing Phytochemicals,"* Saskatoon, Saskatchewan, Canada, September 16, 2002.

ILSI SE Asia Symposium on Functional Foods: *"Functional Food Science—Global Overview."* Beijing, China, November 25, 2002.

Richardson Centre for Nutraceutical and Functional Foods: *"Global Trends in Functional Foods and Nutraceuticals Research."* Winnipeg, Manitoba, Canada, May 28, 2003 (Keynote Speaker).

National [Selected]

Ohio State University Extension, 64th Annual Food and Dairy Industries Conference: *"Functional Foods and Disease Prevention: Fantasy or Reality?"* Columbus, OH, April 2, 1997, Meeting Co-Chair.

Food Update: *"Narrowing the Gap Between Food and Drugs,"* Tampa, FL, April 7, 1997.

Oklahoma City Dietetic Association Spring Convention: *"Phytochemicals,"* Oklahoma City, OK, April 16, 1997.

Institute of Food Technologists (IFT) Annual Meeting: *"Introduction--Prebiotics and Probiotics: Where are We Today?"* Orlando, FL, June 18, 1997, Symposium Co-Chair.

American Dietetic Association (ADA) 80th Annual Meeting and Exhibition: *"Functional Foods: Therapies of the Future?"* Boston, MA, October 27, 1997.

IFT (Maryland Section): . *"Functional Foods: The Future of Food Technology,"* Baltimore, MD, January 15, 1998.

Oregon Dietetics Association: *"Functional Foods,"* Portland, OR, March 23, 1998.
Oklahoma State University, Department of Nutritional Sciences: *"Functional Foods: Therapies for the 21st Century,"* Stillwater, OK, April 13, 1998.

University of Oklahoma, Department of Nutritional Sciences: *"Soy as a Functional Food,"* Oklahoma City, OK, April 14, 1998.

Oklahoma Dietetic Association: *"Functional Foods: Soy,"* Oklahoma City, OK, April 14, 1998.

Nebraska Dietetic Association: *"Phytochemicals & Functional Foods,"* Omaha, NE, April 23, 1998.

ADA 81st Annual Meeting, Flaxseed in Human Nutrition Symposium: *"Introductory Remarks,"* Kansas City, MO, October 20, 1998, Presiding Officer.

000103

American Association of Cereal Chemists/IFT Short Course on Functional Foods: *"Botanicals as Functional Foods,"* Orlando, FL, March 4, 1999.

The Pittsburgh Conference (PITTCON): *"Functional Foods for Cardiovascular Health,"* Orlando, FL, March 8, 1999.

The Pennsylvania Food Industry--Strengthening Partnerships for Growth: *"Nutraceuticals: A Regulatory Challenge,"* Harrisburg, PA, March 31, 1999.

Memorial Sloan-Kettering Cancer Center: *"Functional Foods and Cancer Prevention,"* New York, NY, April 30, 1999.

ADA 82nd Annual Meeting: *"Functional Foods 1999: What Does the Latest Science Say and Why Should We Care?"* Atlanta, GA, October 28, 1999.

Simmons School for the Health Sciences: *"Functional Foods,"* Boston, MA, April 4, 2000.

University of North Carolina Public Health Nutrition Update Conference: *"Functional Foods,"* Chapel Hill, NC, April 28, 2000.

Rachel Schemmel Endowed Lecture in Clinical Nutrition, Michigan Dietetic Association: *"Functional Foods,"* Grand Rapids, MI, May 11, 2000.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality,"* Harrisburg, PA, June 1, 2000.

IFT (St. Louis Section): *"Functional foods: Consumer, Regulatory, Market and Research Update,"* St. Louis, MO, February 6, 2001.

Society of Toxicology: *"From Dietary Supplements to Drugs: Indole-3-Carbinol & Phenethyl Isothiocyanate,"* San Francisco, CA, March 26, 2001, Session Co-Chair.

National Research Council Public Workshop, Opportunities in Agriculture: A Vision for USDA's Food and Agricultural Research in the 21st Century: *"Functional Foods: Impact on Health and Society,"* Washington, D.C., May 22, 2001.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality?"* Hershey, PA, May 31, 2001.

ADA 84th Annual Meeting, Nutrition in Complementary Care Practice Group: *"Soy for Your Heart, Your Bones & Weight Management,"* St. Louis, MO, October 21, 2001.

Foods for Health 14th Annual National Conference, National Agricultural Biotechnology Council (NACB): *"Where Do Functional Foods Fit in the Diet?"* University of Minnesota, Minneapolis, MN, May 20, 2002.

000104

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality?"* State College, PA, June 19, 2002.

Soyfoods 2003: *"Public Health Implications of Dietary Supplement Health Claims—Soy Protein."* Chicago, IL, July 11, 2003.

ADA 85th Annual Meeting: *"Bioavailability and Biotransformation of Isoflavones: An Alternative to HRT?"* Philadelphia, PA, October 22, 2002.

4th Annual Alternative & Complementary Medical Therapies: *"Phytochemicals in Chronic Disease Prevention—Stopping Cancer with Food."* Chicago, IL, December 15, 2002.

Soyfoods 2003: *"Marketing Soy to Health Professionals."* Miami, FL, February 26, 2003.

Texas Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Houston, TX, April 4, 2003.

Food and Drug Administration Grand Rounds Workshop on Functional Foods: *"Academic Research Trends in Functional Foods."* Washington, DC, April 8, 2003.

Louisiana Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Baton Rouge, LA April 24, 2003.

New Jersey Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Whippany, NJ, May 13, 2003.

THESES/GRADUATE STUDENTS DIRECTED:

Deborah Wool. *"Evaluation of the Use of the StratSoy "Ask an Expert" Website by Consumers."* M.S. Thesis, 1999.

Lulu Kurman. *"Effect of Prune Fiber on Blood Lipids in Human Subjects."* M.S. Thesis, 2000.

Amie Bell. *Effect of Prune Concentrate on Mammary and Colon Carcinogenesis."* M.S. Thesis, 2002.

Suzanne Pelletier. *"Evaluation of the Educational Program "Keeping Your Heart Healthy With Functional Foods" With Cardiac Rehabilitation Patients."* M.S. Thesis, 2002.

Veronita Ruseli. *"Effect of soy on Blood Pressure in African-American Women."* M.S. (non-thesis), 2003.

Mandy Wieczkoriewiz. *"The Effects of Soy Protein Consumption on Blood Lipids in Hypercholesterolemic African-American Women".* M.S. Thesis, 2003.

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GRADUATE STUDENT EXAMINING COMMITTEES:

Dr. Hasler has participated on approximately 30 MS and PhD examining committees since 1997.

TEACHING ACTIVITIES:

Dr. Hasler has developed three courses on the topic of functional foods:

- Food Science and Human Nutrition (FSHN) 495: *Physiologically Active Functional Foods: Science, Regulation and Business Issues* (Fall 1996, 1998, 2000). A 1-unit graduate course designed for extramural MS students in the Chicago area who are employed full-time in the food industry.
- Nutritional Science (NS) 410: *Functional Foods and Cardiovascular Health* (Fall 2001). A 0.25 unit graduate course taught every other year and which covers the scientific and regulatory issues related to a variety of functional foods for heart health.
- NS 410: *Phytomedicinals and Human Health* (Fall 1998). A 0.25 unit graduate course related to the scientific and regulatory principals of the major botanicals in the marketplace.

Dr. Hasler has also team taught (Spring 2000, 2001, 2002) or taught (Spring 2003) FSHN 496: *Graduate Seminar in Functional Foods*. This course is designed to enhance student presentation skills and involves the critical review of a research paper and a comprehensive review of a functional foods topic.

REVIEW PANELS:

2001-2003	National Institutes of Health, Office of Dietary Supplements, Annual Bibliography o Scientific Advances in Dietary Supplement Research
2002-2003	USDA National Research Initiative Competitive Grants Program, Improving Human Nutrition for Optimal Health

MEDIA RELATIONS ACTIVITIES:

Dr. Hasler has participated in numerous radio, print and television interviews, including being featured on CNN, Lifetime and Dateline NBC's feature story, *Foods of the Future* on December 31, 1999.

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CURRICULUM VITAE

NORMAN I. KRINSKY, Ph.D.

Professor Emeritus, Department of Biochemistry

Scientist,
Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University

Born:
Married:
Children:

EDUCATION

1948 B.S.	University of Southern California, Los Angeles, CA
1950 M.S.	University of Southern California, Los Angeles, CA (Biochemistry and Nutrition)
1953 Ph.D.	University of Southern California, Los Angeles, CA (Biochemistry, with Harry J. Deuel, Jr.)

PROFESSIONAL EXPERIENCE

1953-55	U.S. Public Health Service Post-doctoral Fellow; Harvard University (with George Wald)
1955-56	National Council to Combat Blindness Post-doc. Fellow; Harvard University (with George Wald)
1956-60	Instructor, Lecturer, Department of Biology, Harvard University
1960-64	Assistant Professor, Department of Pharmacology, Tufts University School of Medicine (TUSM)
1964-67	Associate Professor, Department of Pharmacology, TUSM
1967-69	Associate Professor, Department of Biochemistry, TUSM
1969-70	Professor, Department of Biochemistry, TUSM
1970-87	Professor, Department of Biochemistry and Pharmacology, TUSM
1973	Visiting Professor, Department of Physiology/Anatomy, University of California, Berkeley, CA
1981-82	Research Associate, Boston Veterans Administration Medical Center
1987-2000	Professor, Department of Biochemistry, Tufts University School of Medicine
1993-present	**Scientist, USDA Human Nutrition Research Center on Aging, Tufts University**
2000-present	**Professor Emeritus, Department of Biochemistry, Tufts Univ. School of Medicine**

RESEARCH INTERESTS

Function and metabolism of carotenoids, including antioxidant and anticarcinogenic actions and metabolism to retinoic acid and apocarotenoids. Role of carotenoids in primate macula. Analysis of tissue carotenoids. Biological oxidant damage, and mechanisms of lipophilic and hydrophilic protection.

EDITORIAL BOARDS

1984-1986	Journal of Free Radicals in Biology and Medicine

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1984-1986	Advances in Free Radical Biology and Medicine
1987-1994	Free Radical Biology and Medicine
1993-2003	Archives of Biochemistry and Biophysics
1994-2002	Free Radical Research
1997-present	Environmental & Nutritional Interactions
2002-present	Nutrition Reviews

PUBLICATIONS (see attached listing)

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PROFESSIONAL SOCIETIES

1948	American Association for the Advancement of Science (Fellow, 1966)
1949	Society of the Sigma Xi
1951	American Chemical Society
1951	New York Academy of Sciences
1959	American Society for Biochemistry and Molecular Biology
1972	American Society for Photobiology
1982	Society for Free Radical Research
1988	The Oxygen Society (2003: Society for Free Radical Biology and Medicine)
1988	International Society for Nutrition and Cancer
1993	European Retinoid Research Group
1994	International Carotenoid Society
1998	American College of Nutrition (Fellow, 1998)
1999	International Society for Coenzyme Q Research

PROFESSIONAL ACTIVITIES/HONORS

1950	Phi Sigma Award in the Biological Sciences, University of Southern California
1952	Phi Lambda Upsilon
1966	Fellow, American Association for the Advancement of Science
1967-1968	President, Tufts University Chapter, Society of the Sigma Xi
1975-1981	Secretary-Treasurer, American Society for Photobiology
1978	Organizing Committee, Fifth International Symp. on Carotenoids and Vitamin A, Madison, WI
1980	Co-Chairman, Workshop on Biological Chemiluminescence, American Society for Photobiology, Colorado Springs, CO
1981	Chairman, 1st Gordon Research Conference on "Oxygen Radicals in Biology and Medicine" Ventura, CA
1981-1984	Teaching Award, Tufts University School of Medicine
1982-1983	President, American Society for Photobiology
1984	Treasurer, Ninth International Congress on Photobiology, Philadelphia, PA
1987	Organizing Committee, Fourth International Congress on Oxygen Radicals, La Jolla, CA
1987	Chairman, Eighth International Symposium on Carotenoids, Boston, MA
1988-1991	Council, The Oxygen Society
1989-2000	Executive Committee, International Society for Nutrition and Cancer
1990	Lottie Arnrich Lecturer, Dept of Food & Nutrition, Iowa State University, Ames, IA May 1. 1990
1992	Chairman, 1st Gordon Research Conf. on "Chemistry and Biology of Carotenoids", Oxnard, CA
1993	Co-Chair, New York Academy of Sciences Conference on "Carotenoids in Human Health ", San Diego, CA
1993	Honorary Member, The Vitamin Society of Japan
1993	Distinguished Faculty Award, Tufts University School of Medicine
1994	Fellow, The Oxygen Society
1994	Co-Chair, Second International Conference on "Antioxidant Vitamins and ß-Carotene in Disease Prevention", October 10-12, Berlin, Germany
1994-1999	President, New England Free Radical/Oxygen Society
1995	Co-Chair, FASEB Summer Research Conference on "Antioxidant Nutrients in the Cellular Biology of Health and Disease", Saxtons River, VT
1995-1996	Secretary-General, The Oxygen Society
1996-1998	Advisory Committee, International Antioxidant Research Centre, King's College, London
1997	Mordechai Avron Memorial Lecturer, Nikken Sohonsha Corp., Gifu and Tokyo, Japan, 2/21/97

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1997	Award Lecturer, American College of Nutrition, New York, NY September 27, 1997
1997-1999	Chair, Panel on Antioxidants and Related Nutrients, Food & Nutrition Board, Inst. of Med./NAS
1998	Fellow, American College of Nutrition
1998	Dozor Visiting Professor, Ben-Gurion University of the Negev, Beer-Sheva, Israel
1999	Visiting Scholar, Linus Pauling Institute, Oregon State University, Corvallis, OR
1999	Honorary Member, Oxygen Club of California
1999	Lars Ernster Lecture, Oxygen Club of California 1999 World Congress, Santa Barbara, CA
2000	Robert S. Harris Lecture, Massachusetts Institute of Technology, Cambridge, MA
2001	National Associate, National Academy of Science/National Research Council
2002	Chair, Committee on the Examination of the Evolving Science for Dietary Supplements, Food & Nutrition Board, IOM/NAS
2003-2007	Member, Food Advisory Committee, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety, FDA
2003-2007	Chair, Nutrition Subcommittee, Food Advisory Committee, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety, FDA

RESEARCH TRAINEES: PRE-DOCTORAL

		PRESENT POSITION
1964-1967	Bernard P. Schimmer, Ph.D. "Chemical and Biochemical Reduction of Carotenoid Epoxides"	Professor, Banting & Best Dept. of Medical Research University of Toronto, Toronto, Canada
1967-1974	Frances Stern, Ph.D., M.D. "The Concentration, Turnover, Exchange & Enrichment of Cholesterol in Mitochondria and Mitochondrial Fractions"	Private Practice of Medicine New York, New York
1968-1974	Susan M. (Anderson) Deneke, Ph.D. "Mechanism of Photodynamic Oxidation and Lysis of a Model Membrane System (Liposomes)"	Associate Professor Department of Medicine Univ. of Texas, San Antonio, TX
1973-1980	Patricia C. Andrews, Ph.D. "Kinetic and Structure-Function Studies Concerning Human Myeloperoxidase	Senior Scientist Seradyne.1200 S. Madison Avenue Indianapolis, IN
1987-1991	Garry J. Handelman, B.S. "Characterization of Tissue Carotenoids, Their Breakdown Products, and Relationship to Biological Metabolites"	Assistant Professor University of Massachusetts Lowell, MA

RESEARCH TRAINEES: POST-DOCTORAL

		PRESENT POSITION
1963-1965	Mahtab S. Bamji, Ph.D.	Associate Director (Retired), National Institute of Nutrition Hyderabad, India
1964-1968	Micheline M. Mathews-Roth, M.D.	Assoc. Professor (Med), Channing Laboratory Harvard Medical School, Boston, MA

1966-1967	Judith Leff, Ph.D.	Consultant, New York, NY
1971	Joseph J. Cooney, Ph.D.	Chairman, Environmental Sciences Program University of Massachusetts, Boston, MA
1972	Andreja Kornhauser, Ph .D.	Director, Dermal & Ocular Branch Division of Toxicology, Food & Drug Administration, Washington, DC
1977	A.F.P.M. DeGoij, Ph.D.	Research Associate, Sylvius Laboratoria, Univ. of Leiden, Leiden, The Netherlands
1979-1989	S. Welankiwar, Ph.D.	Scientist, Duracell Technology Center, Needham, MA
1988	Florian J. Schweigert, D.V.M.	Professor, Nutrition Physiology Institute für Physiologie, Veterinary Faculty University of Leipzig. D-7010, Leipzig, FRG
1990-1992	Paulo Palozza, M.D.	Institute of General Pathology Catholic University, Rome. Italy
1996-1999	Pankaj Prakash, Ph. D.	USDA HNRCA, Boston, MA
1999-2003	Giancarlo Aldini, Ph. D.	University of Milan, Milan, Italy

RESEARCH TRAINEES - UNDERGRADUATES/MEDICAL STUDENTS

1964-1966	George E. Davis, TUSM, 1968
1966-1967	John J. Byrnes, TUSM, 1968
1973-1974	Philip H. Wade, Tufts University, 1973
1974	Nancy Watt, Tufts University, 1974
1974	Donna Moseley, Tufts University, 1974
1974	Jeffrey Millikan, Tufts University, 1974
1974	Cindy Christy, Tufts University, 1974
1974	Stephan J. Francis, TUSM, 1977
1974	Joann Simon, Hampshire College, 1975
1974-1975	Janet Arno, Tufts University, 1975
1975-1976	Daniel W. Stanford, Tufts University, 1979
1977-1978	Nancy Green, Tufts University, 1979
1979-1980	Cindy Parnes, Tufts University, 1981
1980	Christine McGrail, Tufts University, 1980
1980	James Grossweiner, Oberlin College, 1981
1980	Randy Patkin, Tufts University, 1981
1983-1984	Paul Rubin, Tufts University, 1984
1983-1984	Po-Wen Hsu, TUSM, 1987
1984-1985	Jane Lawrence, Tufts University, 1985

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1988-1989	John Solomonides, Tufts University 1990
1991	Soundos Moualla, Wellesley College 1992

FACULTY ACTIVITIES

TUFTS UNIVERSITY SCHOOL OF MEDICINE

1963-1966	Pre-Clinical Curriculum Study (Director)
1963-1967	Curriculum Committee
1967-1969	Faculty Medical Education Group
1968-1971	Committee on Extended Educational Opportunity (Chairman)
1968-1969	Health Information Sciences Committee
1969-1970	Advisory Committee on Medical Education
1970-1972	Committee on Faculty Affairs
1973-1978	Committee on Educational Affairs
1974-1975	Fringe Benefits Subcommittee, Faculty Affairs Committee
1974-1975	Admissions Committee
1977	Medical Bylaws Committee
1978-1979	Faculty Affairs Committee (Chairman)
1979-1981	Budgetary Advisory Subcommittee, Faculty Affairs Committee
1979-1981	Boston Tuition Scholarship Benefits Committee
1980-1983	Curriculum Coordinator, Year I
1980-1983	Student Promotions Committee
1981-1982	Ad Hoc Committee on Student Performance Evaluation
1981	Special Program Development Committee
1981-1983	Library and Educational Spaces Planning Subcommittee
1981-1986	Curriculum Committee
1982-1983	Committee on the Teaching of Nutrition at TUSM (Co-Chairman)
1982-1985	Ad Hoc Grievance Committee
1982-1983	Basic Science Appointment, Promotion and Tenure Committee
1983-1985	Task Force on Curriculum Planning
1983-1985	Faculty Advisor
1984-1987	Course Director, Biochemistry
1984-1987	Faculty Affairs Committee
1985-1987	Curriculum Committee Sub-Committee on Curriculum Planning and Implementation
1985-1990	Problem-Based Learning Committee
1988-1989	Curriculum Committee
1989-1992	Faculty Affairs Committee (Chairman, 1990-1992)
1991-1992	Self-Study Sub-Committee on Governance and Administration, LCME, (Chairman)
1992-1993	Steering Committee, RWJ Foundation Generalist Physician Initiative Program
1993-1994	Member, Faculty Senate
1994-1995	Member, Core Curriculum Collaborators Group
1994-1996	Member, Faculty Prizes/Awards Committee
1996-1998	Self-Study Sub-Committee on Governance and Administration, LCME

TUFTS-NEW ENGLAND MEDICAL CENTER

1963	Committee on the Role of the Basic Scientist in the Medical Center, (Chairman)
1968-1969	Audio-visual Task Force
1970-1971	Advisory Committee on Minority Opportunity and Planning
1982-1984	Board of Directors, Women's Resource Center

TUFTS UNIVERSITY

1966-1968	Policy and Program Committee, Graduate School of Arts and Sciences

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1967-1973	Molecular Basis of Biological Phenomena Program (Chairman)
1968-1971	Committee on Equal Educational Opportunity, Faculty of Arts and Sciences
1968-1970	Faculty Representative, Trustees Committee on Honorary Degrees
1970-1971	University-wide Committee on Equal Employment Advancement
1970-1971	Committee on Educational Planning
1978-1979	Advisory Committee on University Investments
1986-1987	Faculty Representative, Trustees Academic Affairs Committee
1993-1999	University-wide Benefits Advisory Committee

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SACKLER SCHOOL OF GRADUATE BIOMEDICAL SCIENCES

1983-1984 Faculty Secretary
1983-1987 Nominating Committee (Chairman)

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

1964-1965 Curriculum Committee

JEAN MAYER HUMAN NUTRITION RESEARCH CENTER ON AGING AT TUFTS UNIVERSITY

1995-2000 Promotions Committee

TEACHING EXPERIENCE

HARVARD UNIVERSITY

1956-1960 Biology 191 (Experimental Biochemistry)
1956-1960 Undergraduate Advisor, Department of Biology
1958 Biology 190 (General Biochemistry, with George Wald)

TUFTS UNIVERSITY SCHOOL OF MEDICINE

1960-1967 Pharmacology
1967-1999 Biochemistry (Course Director, 1984-1987, 1994)
1968-1986 Neuropharmacology
1974-1979 Biochemistry of Disease
1980-1985 Principles of Pharmacology
1985-1991 Problem-Based Learning Facilitator
1990 Nutrition and Medicine Facilitator

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

1960-1966 Pharmacology
1966-1968 Basic Health Sciences
1968-1988 Pharmacology
1984-1993 Biochemistry

TUFTS UNIVERSITY SCHOOL OF VETERINARY MEDICINE

1979-1985 Biochemistry
1980-1985 Neuropharmacology
1980-1985 Pharmacology

TUFTS UNIVERSITY GRADUATE SCHOOL OF ARTS AND SCIENCES

1960-1967 Graduate Pharmacology
1970 Mitochondrial Membranes and Bacterial Envelopes (BCM 294)
1972 Energy Flow in Biological Systems (BCM 214)
1974, 1978 Metabolic Pathways (BCM 213)
1978, 1982 Membranes (BCM 211)
1981- 1982 Advanced Biochemistry (BCM 223)

TUFTS UNIVERSITY SACKLER SCHOOL OF GRADUATE BIOMEDICAL SCIENCES

1984 Membranes (BCM 221)

1984-1999	Graduate Biochemistry (BCM 223)
1985	Recent Advances in Neurochem. and Neuropharm. (BCM 220)
1995	Free Radicals in Biology & Medicine (BCM 293)

TUFTS UNIVERSITY SCHOOL OF NUTRITION

1991, '93, '99 Dietary Antioxidants and Degenerative Diseases (Nutrition 291-DA)

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SCIENTIFIC CONFERENCES AND MEETINGS: INVITED PARTICIPATION

1. Invited Speaker: The Lipoprotein Nature of Rhodopsin Symposium on "Visual Mechanisms" (Sponsored by National Institutes of Health) Bethesda, Maryland, September 11-12, 1957.

2. Invited Speaker: The Role of Carotenoid Pigments as Protective Agents against Photosensitized Oxidations in Chloroplasts. Symposium on "Biochemistry of Chloroplasts" NATO Advanced Study Institute, Aberystwyth, Wales, U.K., August 5-9, 1965.

3. Invited Speaker: A Biochemical Basis for Carotenoid Function in Green Plants and Algae. Joint Japan-U.S. Seminar on "Carotenoid Biosynthesis and Related Topics" National Science Foundation/Japan Society for the Promotion of Science, Kyoto, Japan, November 29 - December 1, 1965.

4. Invited Speaker: Carotenoid De-epoxidation Reactions. Conference on "Photosynthetic Pigments" in honor of Harold H. Strain, Argonne National Laboratory, Argonne, Illinois, November 7-8,1968.

5. Invited Speaker: Minority Programs at Tufts University School of Medicine. Conference on "Minority Groups in Professional Schools" American Personnel and Guidance Association, Las Vegas, Nevada, March 30 - April 2, 1969.

6. Invited Participant: Minority Enrollment at Tufts University School of Medicine. Conference on "The Impact of Cultural and Economic Background on Programs to Recruit Negroes for Medicine" Macy Foundation, Princeton, NJ, April 13-16, 1969.

7. Invited Speaker: Evolution of Photosensitive Pigments in Microbes. Colloquium on "Photosynthetic Organisms: Origin and Evolution on Early Earth" 123rd meeting of the American Association for the Advancement of Science, Boston, MA, December 26, 1969.

8. Invited Speaker: The Protective Function of Carotenoid Pigments against Aerobic Photosensitivity. Colloquium on "Molecular Mechanisms of Photodynamic Action with and without Molecular Oxygen" VIth International Congress on Photobiology, Bochum, W. Germany, Aug. 21-25, 1972.

9. Sigma Xi Lecturer: Function of Carotenoids. University of Rhode Island, Kingston, RI, October 10, 1973.

10. Invited Speaker: Photosensitization and Protection of Biomembranes and Model Systems. Colloquium on "Photochemistry of Biomembranes" at the 2nd Meeting of the American Society for Photobiology, Vancouver, British Columbia, Canada, July 24, 1974.

11. Theme Speaker: Light and Life: Biochemical Responses to Light. New England Association of Chemistry Teachers 36th Summer Conference, St. Anselem's College, Manchester, New Hampshire, Aug. 20-24, 1974.

12. Invited Speaker: Singlet Oxygen Production in Biological Systems, Workshop on "The Role of Oxygen in the Production of Excited States in Biological Systems" Photobiology Group, Biophysical Society, Philadelphia, PA, February 18, 1975.

13. Invited Speaker: Damage and Protection against Singlet Oxygen. Workshop on "Free Radical Damage and Protection" Bioenergetics Group, Biophysical Society Seattle, WA, February 24, 1976.

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14. Invited Speaker: Cellular Damage Initiated by Visible Light. Symposium on "The Survival of Vegetative Microbes" Society for General Microbiology, Cambridge, England, April 5-8, 1976.

15. Invited Speaker: Non-Photosynthetic Functions of Carotenoids. Discussion. Meeting on "The Biochemical Functions of Terpenoids in Plants" The Royal Society, London, England, January 26-27, 1978.

16. Invited Speaker: Carotenoid Protection against Oxidation. Fifth International Symposium on "Carotenc and Vitamin A" Madison, WI, July 24-28, 1978.

17. Invited Participant: Joint Seminar on "Chemi- and Bio-energized Processes" Universidade de Sáo Paulo, Sáo Paulo, Brazil, August 5-7, 1978.

18. Invited Speaker: Cholesterol Oxidation by Either Polymorphonuclear Leukocyte or by Isolated Myeloperoxidase. International Conference on "Chemi- and Bio-energized Processes" Guaruja, Estado de Sáo Paulo, Brazil, August 8-10, 1978.

19. Invited Speaker: Carotenoid Pigments: Multiple Mechanisms for Coping with the Stress of Photosensitized Oxidations. Conference on "Strategies of Microbial Life in Extreme Environments" Dahlem Konferenzen, Berlin, Fed. Rep. Germany, November 20-24, 1978.

20. Invited Speaker: Is Singlet Oxygen Involved in Biological Chemiluminescence? Symposium on "Biological Basis of Chemiluminescence" American Society for Photobiology, Colorado Springs, CO, February 21, 1980.

21. Invited Speaker: Photosensitized Damage. Round Table on "Sensitized Photooxidation of Biomolecules" International Conference in Oxygen and Oxy-Radicals in Chemistry and Biology, Austin, TX, May 25-29, 1980.

22. Invited Speaker: Molecular Bases for Cellular Damage Initiated by Photosensitized Oxidations. Round Table on "Endogenous and Exogenous Inhibitors and Sensitizers. Fundamental Aspects" 8th International Congress on Photobiology, Strasbourg, France, July 20-25, 1980.

23. Invited Speaker: Interaction of Oxygen and Oxyradicals with Carotenoids Symposium on "Photochemical Toxicity" Food and Drug Administration, Bethesda, MD, March 16-17, 1981.

24. Invited Speaker: Possible Participation of Singlet Oxygen in Biological Systems. Symposium on "Radicals and Excited States in Biological Systems" Seventh International Biophysics Congress and Third Pan-American Biochemistry Congress, Mexico City, Mexico, August 24-28, 1981.

25. Invited Speaker: In vivo Analysis of UV-B Formation of 5.6-a-Epoxy- cholesterol. 2nd NCI/EPA/NIOSH Collaborative Workshop on "Progress on Joint Environmental and Occupational Cancer Studies" Rockville, MD, September 9-11, 1981.

26. Invited Speaker: The Biological Implications of Singlet Oxygen Production. Table Ronde Roussel Uclaf on "New Concepts of Free Radicals in Chemistry and Biology" Paris, France, October 22-23, 198[illegible]

27. Invited Speaker: Photosensitization. Singlet Oxygen Damage and Cancer. "International Workshop on Photobiology" Cheju, Korea, May 25-June 1, 1982.

28. Invited Speaker: Introduction to Photobiology and Photosensitization. Symposium on "Photobiology" Chosun University, Gwang Ju, Korea, June 2, 1982.

29. Invited Speaker: Free Radicals as Possible Mutagens and Carcinogens. Symposium on "Free Radicals and Cancer" Council for Tobacco Research, New York, NY, June 21, 1982.

30. Invited Speaker: Mutagenic and Carcinogenic Effects of Oxygen Radicals Symposium on "Possible Roles of Free Radicals in Aging" Gerontological Society of America, Boston, MA, Nov. 21, 1982.

31. Invited Speaker: Biology and Photobiology of Singlet Oxygen 3rd International Conference on Oxygen Radicals, Munich, FRG, July 10-15, 1983.

32. Invited Speaker: Comparison of the Oxidant Mechanisms of Myeloperoxidase and UV-B Irradiation EMBO Workshop on "Oxidative Enzymes-Damage and Consequences" Grottoferrata, Italy, October 2-7, 1983.

33. Public Lecture: New Findings on the Role of Provitamin A in Health and Disease. Institute for Research on Aging, University of California, San Diego, CA, September 13, 1984.

34. Invited Speaker: The Action of Carotenoids In vitro as Compared to their Function In vivo. Symposium on "Nutrition and Disease: Cancer" Helicon Foundation, San Diego, CA, September 15, 1984.

35. Invited Speaker: Detection and Biological Function of Active Oxygen Species School Lecture, American Society for Photobiology, New Orleans, and LA, June 27, 1985.

36. Invited Speaker: The Unique Singlet Oxygen Quenching Properties of Carotenoids. FASEB Summer Research Conference on "Micronutrients Retinoids" Saxtons River, VT, June 22-27, 1986.

37. Invited Speaker: Mechanisms of Inactivation of Oxygen Species by Carotenoids. 2nd International Conference on Anticarcinogenesis and Radiation Protection, National Bureau of Standards, Gaithersburg, MD, March 9-12, 1987.

38 Invited Speaker: Beta-carotene and Cancer: Overview and Rationale. VNIS Health Communications Conference: Beta-Carotene, Boca Raton, FL, April 11-12, 1987.

39. Invited Speaker: Overview of Carotenoids in Medicine. Eighth International Symposium on Carotenoids, Boston, MA, July 26-31, 1987.

40. Invited Speaker: Enzymic and Pigment Protection from Photodynamic Damage. FEMS/Society for Applied Bacteriology Symposium on "Homeostatic Mechanisms in Micro-organisms." Warwick University, Coventry, UK, September 14-18, 1987.

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41. Invited Speaker: The Evidence for the Role of Carotenes in Preventive Health Symposium on "Carotenes in Food and Health" Department of Food Science and Office of Continuing Professional Education, Rutgers, The State University of New Jersey, Iselin, NJ, December 3, 1987.

42. Invited Speaker: Carotenoids as Chemopreventive Agents. Third International Conference on "The Prevention of Human Cancer: Chemoprevention" Arizona Cancer Center, Tucson, AZ, January 12-15,

1988.

43. Invited Speaker: Theoretic and Experimental Basis for Anti-carcinogenic Effects of Retinoids. Workshop on "Emerging Role of Retinoids in the Treatment of Aging and Skin Cancer" Miami, FL, March 11-13, 1988.

44. Invited Speaker: Experimental Studies on Carotenoids and Cancer in Animal Models. Symposium on "The Biological Actions of Carotenoids" American Institute of Nutrition, Las Vegas, NV, May 1-6, 1988.

45. Invited Speaker: Biological Functions of Carotenoids and Retinoids. Symposium on "Biology of Human Skin Aging" American Academy of Dermatology, Philadelphia, PA, May 18-20, 1988.

46. Invited Speaker: Membrane Antioxidants. Conference on Biological Membranes in Cancer Cells, New York Academy of Sciences, Torgiano, Italy, June 13-18, 1988.

47. Invited Speaker: Pigment and Enzymic Protection Against Photodynamic Damage. Tenth International Congress of Photobiology. Jerusalem, Israel, October 31 1988.

48. Invited Speaker: Cancer Prevention: Animal and In vitro Studies. International Conference on "Anti-Oxidant Vitamins and Beta-Carotene in Disease Prevention" British Nutrition Foundation, London, U.K. October 2-4, 1989.

49. Invited Speaker: Carotenoid Metabolism. Workshop on "Carotenoids" FASEB Annual Meeting, Washington, DC, April 1, 1990.

50. Invited Speaker: Carotenoids and Cancer. Symposium on "Nutrition Related Cancer Research: A Interdisciplinary Update" Nutrition Council at Tufts, Boston, MA, April 25, 1990.

51. Invited Speaker: Carotenoid Function. Workshop on "Carotenoids" FASEB Annual Meeting, Atlanta, GA, April 20, 1991.

52. Invited Speaker: Role of Carotenoids. Seminar on "Recipe for Cancer Prevention: Food Issues for the 1990s" American Cancer Society and Nestlé Beverage Company, New York, NY, June 12, 1991.

53. Invited Speaker: Mechanisms of Action of Antioxidants. Conference on Molecular and Comparative Nutrition, US-Japan Malnutrition Panel, Bethesda, MD, July 22-24, 1991.

54. Invited Participant: National Heart, Lung and Blood Institute Workshop on "Antioxidants in the Prevention of Human Atherosclerosis" Bethesda, MD, September 5-6, 1991.

55. Invited Speaker: Carotenoids in Cellular and Animal Systems: Effects on Mutagenesis, Carcinogenesis and Age-related Diseases. Symposium on "Free Radicals and Aging" Society for Free Radical Research (Europe), Paris, France, September 26-28, 1991.

56. Invited Speaker: Conversion of Carotenoids to Retinoids. Symposium on "Retinoids: New Trends in Research and Clinical Applications" Palermo, Italy, October 21-24, 1991.

57. Invited Speaker: Beta-Carotene - Animal Data. Symposium on "Vitamins and Cancer Prevention" Pennington Biomedical Research Center, Baton Rouge, LA, October 30 November 1, 1991.

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58. Invited Speaker: Carotenoids as Biological Antioxidants. Symposium on "Active Oxygens, Lipid Peroxides and Antioxidants" 5th International Congress on Oxygen Radicals, Kyoto, Japan, November 17-21, 1991.

59. Invited Speaker: Excentric Cleavage Mechanism(s) for Carotenoid Metabolism. Gordon Research Conference on "Chemistry and Biology of Carotenoids" Oxnard, CA, March 9-13, 1992

60. Invited Speaker: Nutritional Factors an Their Influence on Mutagenicity and Malignant Transformation. Tobacco and Health Research Institute, University of Kentucky Symposium on "Tobacco Smoking and Nutrition: Influence of Nutrition on Tobacco Associated Health Risks" Lexington, KY, September 14-16, 1992

61. Invited Speaker: Excentric Cleavage of Carotenoids. New York Academy of Sciences Conference on "Carotenoids in Human Health" San Diego, CA, February 6-9, 1993.

62. Invited Speaker: Antioxidant Effects of Carotenoids. International Conference on "Critical Aspects of Free Radicals in Chemistry, Biochemistry and Medicine" Vienna, Austria, February 14-17, 1993.

63. Invited Speaker: Antioxidant Properties of Carotenoids. The Kurashiki Symposium for Medical Science, Kurashiki, Japan, May 21-22, 1993.

64. Invited Speaker: ß-Carotene: Disease Prevention and Its Health Impact. Japan Vitamin Society, Gifu City, Japan, May 25-27, 1993.

65. Invited Speaker: Function, Actions, and Associations of Carotenoids. Tenth International Symposium on Carotenoids, Trondheim, Norway, June 20-25, 1993.

66. Invited Speaker: Antioxidants: Classification and Mode of Action. Symposium on "Antioxidants and Disease Prevention: Biochemical, Nutritional, and Pharmacological Aspects" Stockholm. Sweden, June 30-July 3, 1993.

67. Invited Speaker: Carotenoid Metabolism. Symposium on "Retinoids: New Trends in Research and Clinical Applications" Genoa, Italy, October 4-7, 1993.

68. Invited Speaker: The Effects of Carotenoids on Cells. Workshop on "Cell Proliferation and Differentiation: Modulation by Free" Rome, Italy, October 8, 1993.

69. Invited Discussant: Antioxidant Nutrients. Symposium on "Nutritional Assessment of Elderly Populations Measure and Function" Boston, MA, October 11-13, 1993.

70. Invited Speaker: Clinical and Experimental Studies of ß-Carotene and Cancer. FDA Public Conference on Antioxidant Nutrients and Cancer and Cardiovascular Disease. Washington, DC, November 1-3, 1993.

71. Invited Speaker: Recent Research Findings on Beta-Carotene. Henkel Symposium on Vitamin E Palm Beach, FL, June 7-8, 1994.

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72. Invited Speaker: Comments on Antioxidant Vitamins and ß-Carotene. "Second International Conference on Antioxidant Vitamins and Beta Carotene in Disease Prevention" Berlin, Germany, October 10-12, 1994.

73. Invited Speaker: Plant Carotenoids and Related Molecules - Important Dietary Antioxidants. Symposium on "Free Radicals and Oxidative Stress - Environment, Drugs and Food Additives" Biochemical Society, Brighton, U.K., December 14-16, 1994

74. Invited Speaker: Antioxidants and Their Role in Human Health. 22nd Annual Texas Human Nutrition Conference, "Health Claims for Foods and Nutrients" Texas A & M Univ., Tyler, TX, February 3, 1995.

75. Plenary Lecture: An Overview of the Functions and Actions of Carotenoids: A Personal Perspective. 2nd Gordon Research Conference on Carotenoids, Ventura, CA February 5-9, 1995.

76. Invited Speaker: Carotenoids as Biological Antioxidants. 2nd Symposium on Vitamins and Biofactors, San Diego, CA February 15-19, 1995.

77. Invited Speaker: Overview of Carotenoids. USAID Workshop on the Bioavailability and Bioconversion of Carotenoids. Washington, DC April 4-5, 1995

78. Invited Speaker: Functions of Carotenoids. FASEB Summer Conference on Antioxidant Nutrients in the Cellular Biology of Health and Disease, Saxtons River, VT August 17-21, 1995

79. Invited Speaker: Biological Effects of Radicals on Carotenoids, 6th European Society for Photobiology, Cambridge, UK September 2-9, 1995.

80. Invited Speaker: Low Molecular Weight Antioxidants; You are What You Eat, Oxygen '95 Free Radical School, Annual Meeting of the Oxygen Society, Pasadena, CA November 17, 1995

81. Invited Speaker Carotenoids: Structure and Function, Workshop on "Potential Effects of Reducing Carotenoid Levels on Human Health" Department of Nutrition, Harvard School of Public Health, Boston, MA January 17th, 1996

82. Invited Speaker Metabolism and Mechanism of Action of Antioxidants, The Toxicology Forum, Givens Institute, Aspen, CO, July 9, 1996.

83. Invited Speaker Are the Oxidative Breakdown Products of Carotenoids Evidence of Antioxidant Action or the Generation of Biologically Active Molecules? VIII Biennial Meeting, International Society for Free Radical Research, Barcelona, Spain October 4, 1996

84. Invited Speaker ß-Carotene and Disease: A Causal Relationship? Oxygen '96, Annual Meeting of the Oxygen Society, Miami Beach. FL November 22, 1996

85. Invited Lecturer: Natural and Synthetic Carotenoids: Their Actions in Biology. 5th Mordechai Avron Memorial Lecture, Gifu and Tokyo, Japan, Nikken Sohonsha Corp., February 21 and 23, 1997

86. Invited Speaker: Overview of Lycopene, Carotenoids and Disease Prevention, International Symposium on the Role of Lycopene and Tomato Products in Disease Prevention, American Health Foundation/Tomato Research Council, New York, NY, March 3, 1997

87. Invited Speaker: Hypothetical Health Benefits Of ß-Carotene And Other Carotenoids, Society of Toxicology, Cincinnati, OH, March 11, 1997

88. Invited Lecturer: The Properties of Carotenoids that Define Their Actions (June 1) and The Actions of Carotenoids in Biology and Medicine (June 3), NATO Advanced Study Institute on Free Radicals, Oxidative Stress and Antioxidants. Pathological and Physiological Significance, Antalya, Turkey, May 24-June 4, 1997

89. Invited Speaker: Carotenoids and Chronic Degenerative Diseases, International Conference on Nutrition and Cancer, Irvine, CA July 16-July 19, 1997

90. Invited Speaker: The Antioxidant and Biological Properties of the Carotenoids, 7th Congress of the International Association of Biomedical Gerontology, Adelaide, Australia, August 15-August 18, 1997

91. Invited Speaker: Biochemistry of Carotenoids: Actions and Functions. American College of Nutrition Award Lecture, American College of Nutrition Annual Meeting, New York, NY, September 26-28, 1997

92. Invited Speaker: Measurement of Carotenoids, WORKSHOP on Quantitative Methods for Determination of Hydroxyl Radicals, Oxidation of Biological Molecules and Antioxidants, The Oxygen Society, San Francisco, CA, November 20-24, 1997.

93. Invited Speaker: Actions of Carotenoids, Oxygen Club of California, Santa Barbara, CA, February 7, 1998

94. Plenary Lecture: Carotenoids in Health and Disease, Gordon Research Conference on Oxygen Radicals in Biology, Ventura, CA, February 12, 1998

95. Invited Speaker: Role of Carotenoids in Health and Disease, The First Regional Meeting on Medical Sciences: "The Roles of Free Radicals in Health and Disease" Jerusalem and Amman, March 22-27, 1998

96. Invited Speaker: Activity of ß-Carotene Oxidation Products, European Conference on Biomedical Research and Peace, Paralimni, Cyprus, October 17-21, 1999

97. Invited Speaker: What is the Scientific Evidence for Establishing Carotenoids as Recommended Nutrients? Symposium on Dietary Antioxidants: the New Dietary Reference Indices; The Oxygen Society, New Orleans, LA, November 21, 1999

99. Invited Speaker: The Relationship Between Antioxidant and Chronic Disease Symposium on Dietary Reference Intakes, Experimental Biology '00, San Diego, CA April 17, 2000

100. Invited Speaker Carotenoids, Smoking and Cancer, 3rd International Conference on Antioxidants and Free Radicals in Health and Disease, Vancouver, BC, Canada July 23, 2000

101. Invited Speaker: Antioxidants and Chronic Diseases: How Much Science is Enough? Symposium on Dietary Reference Intakes, American Dietetic Association, Denver, CO October 18, 2000

102. Invited Speaker: Antioxidants and Chronic Diseases, Symposium on Dietary Reference Intakes, American Public Health Association, Boston, MA Nov. 13, 2000

103. Invited Speaker: Carotenoids in Health and Disease, Robert S. Harris Lecture, Massachusetts Institute of Technology, Cambridge, MA March 15, 2001

104. Invited Speaker Possible Biologic Mechanism for the Protective Role of Xanthophylls, Symposium on Lutein and Macular Degeneration, FASEB Meeting, Orlando, FL, April 1, 2001

105. Invited Speaker: Carotenoid Research in the Past and Present Millennia, CARIG Lecturer, EB'01 Conference, Orlando, FL, April 2, 2001

106. Invited Speaker: Possible Biologic Mechanism for the Protective Role of Xanthophylls in Age-Related Macular Degeneration, American Society of Nutritional Sciences (EB'01), Orlando, FL, April 1, 2001

107. Invited Speaker: Dietary Carotenoids: What do They Do? PAX Mechanisms Conference, Cambridge, MA, September 30, 2001

108. Invited Plenary Lecturer Historical Critical Evaluaiton of free Radical and Antioxidant Research Oxygen Club of California, Santa Barbara, CA, March 8, 2002

109. Invited Speaker: Health Benefits of Carotenoids, Helmut Sies Festschrift, L'Abbaye de Royamount, Royamount, France, July 15, 2002

110. Invited Speaker: Dietary Carotenoids Modify Human Plasma Lipid Oxidizability, International Society for Free Radical Research Meeting, Paris France, July 16-20, 2002

111. Invited Plenary Lecturer Human Requirements for Fat-Soluble Vitamins, XIIth European Meeting on Fat-Soluble Vitamins, Rieti, Italy March 13-15, 2003

112. Invited Speaker: Overview of Lutein and Zeaxanthin, Advisory Committee, National Eye Institute, May-17, 2004

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NORMAN I. KRINSKY, Ph. D. PUBLICATIONS

A. Peer Reviewed Journal Articles (99)

1. Ganguly, J, Krinsky, NI, Mehl, JW and Deuel, HJ Jr, Studies of the Distribution of Vitamin A as Ester and Alcohol and of Carotenoids in Plasma Proteins of Several Species. Arch. Biochem. Biophys. 38:275-282 (1952).

2. Krinsky, NI and Ganguly, J, Intracellular Distribution of Vitamin A Ester and Vitamin A Alcohol in Rat Liver. J. Biol. Chem. 202:227-232 (1953).

3. Ganguly, J and Krinsky, NI, Absence of Relationship between Vitamin A Alcohol Levels in Plasma and Liver of Rats. Biochem. J. 54:177-181 (1953).

4. Ganguly, J, Krinsky, NI, Pinckard, JH and Deuel, HJ, Jr., Untersuchungen über den Carotinoid-Stoffwechsel, XIV. Biologische Wirksamkeit von Echinenon. Z. Physiol. Chem. 295:61-66 (1953).

5. Ganguly, J, Krinsky, NI and Pinckard, JH, Isolation and Nature of Echinenone, a Provitamin A. Arch. Biochem. Biophys. 60:345-351 (1956).

6. Stefanini, M, Krinsky, NI and Magalini, SI, Studies on Platelets, XIX. Carotenoid Pigments in Human Platelets. J. Lab. Clin. Med. 50:225-228 (1957).

7. Krinsky, NI, Cornwell, DG and Oncley, JL, The Transport of Vitamin A and Carotenoids in Human Plasma. Arch. Biochem. Biophys. 73:233-246 (1958).

8. Krinsky, NI, Enzymatic Esterification of Vitamin A. J. Biol. Chem. 232:881-894 (1958).

9. Krinsky, NI, The Lipoprotein Nature of Rhodopsin. Arch. Ophthal. 60:688-694 (1958).

10. Goldsmith, TH and Krinsky, NI, The Epoxide Nature of the Carotenoid Neoxanthin. Nature (London) 188:491-493 (1960).

11. Krinsky, NI and Goldsmith, TH, The Carotenoids of the Flagellated Alga, Euglena gracilis. Arch. Biochem. Biophys. 91:271-279 (1960).

12. Krinsky, NI, A Relationship between Partition Coefficients of Carotenoids and their Functional Groups. Anal. Biochem. 6:293-302 (1963).

13. Krinsky, NI, Gordon, A and Stern, AI, The Appearance of Neoxanthin During the Re-greening of Dark-grown Euglena. Plant Physiol. 39:441-445 (1964).

14. Krinsky, NI and Levine, RP, Carotenoids of Wild Type and Mutant Strains of the Green Alga, Chlamydomonas reinhardi. Plant Physiol. 39:680-687 (1964).

15. Krinsky, NI, Carotenoid De-epoxidations in Algae. I. Photochemical Transformation of Antheraxanthin to Zeaxanthin. Biochim. Biophys. Acta 88:487-491 (1964).

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16. Bamji, MS and Krinsky, NI, Carotenoid De-epoxidations in Algae. II. Enzymatic Conversion of Antheraxanthin to Zeaxanthin. J. Biol. Chem. 240:467-470 (1965).

17. Mathews, MM and Krinsky, NI, The Relationship between Carotenoid Pigments and Resistance to Radiation in Non-photosynthetic Bacteria. Photochem. Photobiol. 4:813-817 (1965).

18. Krinsky, NI, The Carotenoids of the Brine Shrimp, Artemia salina. Comp. Biochem. Physiol. 16:181-187 (1965).

19. Krinsky, NI and Lenhoff, HM, Some Carotenoids in Hydra. Comp. Biochem. Physiol. 16:189-198 (1965).

20. Bamji, MS and Krinsky, NI, The Carotenoid Pigments of a Radiation-resistant Micrococcus sp. Biochim. Biophys. Acta 115:276-284 (1966).

21. Schimmer, BP and Krinsky, NI, The Structure of Neoxanthin and the Trollein-like Carotenoid from Euglena gracilis. Biochemistry 5:1814-1820 (1966).

22. Schimmer, BP and Krinsky, NI, Reduction of Carotenoid Epoxides with Lithium Aluminum Hydride. Biochemistry 5:3649-3657 (1966).

25. Mathews-Roth, MM and Krinsky, NI, Carotenoid Pigments and the Stability of the Cell Membrane of Sarcina lutea. Biochim. Biophys. Acta 203:357-359 (1970).

26. Mathews-Roth, MM and Krinsky, NI, Studies on the Protective Function of the Carotenoid Pigments of *Sarcina lutea*. Photochem. Photobiol. 11:419-428 (1970).

27. Mathews-Roth, MM and Krinsky, NI, Failure of Conjugated Octaene Carotenoids to Protect a Mutant of Sarcina lutea Against Lethal Photosensitization. Photochem. Photobiol. 11:555-557 (1970).

28. Cooney, JJ and Krinsky, NI, Photodynamic Killing of Acholeplasma laidlawii. Photochem. Photobiol. 16:523-526 (1972).

29. Kornhauser, A, Krinsky, NI, Huang, P-KC and Clagett, DC, A Comparative Study of Photodynamic Oxidation and Radiofrequency Discharge Generated $^1O_2$ Oxidation of Guanosine. Photochem. Photobiol. 18:63-69 (1973).

30. Anderson, SM and Krinsky, NI, Protective Action of Carotenoid Pigments against Photodynamic Damage to Liposomes. Photochem. Photobiol. 18:403-408 (1973).

31. Krinsky, NI, Bymun, EN and Packer, L, Retention of K^+ Gradients in Imidoester Cross-Linked Erythrocyte Membranes. Arch. Biochem. Biophys. 160:350-352 (1974).

32. Mathews-Roth, MM, Wilson, T, Fujimori, E and Krinsky, NI, Carotenoid Chromophore Length and Protection against Photosensitization. Photochem. Photobiol. 19:217-222 (1974).

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33. Anderson, SM, Krinsky, NI, Stone, MJ and Clagett, DC, Effect of Singlet Oxygen Quenchers on Oxidative Damage to Liposomes Initiated by Photosensitization or by Radiofrequency Discharge. Photochem. Photobiol. 20:65-69 (1974).

34. Krinsky, NI, Singlet Excited Oxygen as a Mediator of the Antibacterial Action of Leukocytes. Science 186:363-365 (1974).

35. Levine, PH, Weinger, RS, Simon, J, Scoon, KL and Krinsky, NI, Leukocyte-Platelet Interaction. Release of Hydrogen Peroxide by Granulocytes as a Modulator of Platelet Reactions. J. Clin. Investigation 57:955-963 (1976).

36. Deneke, CF and Krinsky, NI, Enhanced Dimol Emission of Singlet Oxygen by Cyclic Tertiary Amines. J. Am. Chem. Soc. 98:3041-3042 (1976).

37. Deneke, CF and Krinsky, NI, Inhibition and Enhancement of Singlet Oxygen ($^1\Delta_g$) Dimol Chemiluminescence. Photochem. Photobiol. 25:299-304 (1977).

38. Deneke, CF and Krinsky, NI, A Cheap and Durable Cuvet Washer. J. Chem. Educ. 54:257 (1977).

39. Krinsky, NI, Scoon, KL, Hardin, JC and Levine, PH, The Source of Hydrogen Peroxide and of Chemiluminescence Observed in Activated Human Platelet Preparations. Blood 50:597-602 (1977).

40. Lederman, DM, Cumming, RD, Petschek, HE, Levine, PH and Krinsky, NI, The Effect of Temperature on the Interaction of Platelets and Leukocytes with Materials Exposed to Flowing Blood. Trans. Am. Soc. Artif. Intern. Organs. 24:557-560 (1978).

41. Levine, PH, Hardin, JC, Scoon, KL and Krinsky, NI, Effect of Corticosteroids on the Production of Superoxide and Hydrogen Peroxide and the Appearance of Chemiluminescence by Phagocytosing Polymorphonuclear Leukocytes. Inflammation 5:19-27 (1981).

42. Andrews, PC and Krinsky, NI, The Reductive Cleavage of Myeloperoxidase in Half, Producing Enzymically Active Hemi-Myeloperoxidase. J. Biol. Chem. 256:4211-4218 (1981).

43. Krinsky, NI, Sladdin, DG, Levine, PH, Taub, IA and Simic, MG, Modification of Platelet Function by Radical Species Produced During Irradiation of Oxygenated Water. Thromb. Haemostasis 45:116-120 (1981).

44. Levine, PH, Sladdin, DG and Krinsky, NI, Superoxide, Xanthine Oxidase and Platelet Reactions. Further Studies on Mechanisms by which Oxidants Influence Platelets. Thromb. Haemostasis 45:290-293 (1981).

45. Krinsky, NI and Deneke, SM, The Interaction of Oxygen and Oxy-Radicals with Carotenoids. JNCI 69:205-210 (1982).

46. Andrews, PC and Krinsky, NI, A Kinetic Analysis of the Interaction of Human Myeloperoxidase with Hydrogen Peroxide, Chloride Ions and Protons. J. Biol. Chem. 257:13240-13245 (1982).

47. Andrews, PC and Krinsky, NI, Quantitative Determination of Myeloperoxidase Using Tetramethylbenzidine as Substrate. Anal. Biochem. 127:346-350 (1982).

48. Andrews, PC, Parnes, C and Krinsky, NI, Comparison of Myeloperoxidase and Hemi-Myeloperoxidase with Respect to Catalysis, Regulation and Bactericidal Activity. Arch. Biochem. Biophys. 228:439-442 (1984).

49. Peak, MJ, Foote, CS, Krinsky, NI and Peak, JG, Oxygen-Independent Direct DNA Backbone Breakage Caused by Rose Bengal and Visible Light. J. Photochem. 25:309-315 (1984).

50. Mathews-Roth, MM and Krinsky, NI, Effect of Dietary Fat Level on UV-B Induced Skin Tumors, and Anti-Tumor Action of Beta-Carotene. Photochem. Photobiol. 40:671-673 (1984).

51. Mathews-Roth, MM and Krinsky, NI, Carotenoid Dose Level and Protection Against UV-B Induced Skin Tumors. Photochem. Photobiol. 42:35-38 (1985).

52. Cunningham, ML, Krinsky, NI, Gioranazzi, SM and Peak, MJ, Superoxide Anion is Generated from Cellular Metabolites by Solar Radiation and its Components. J. Free Radic. Biol. Med. 1:381-385 (1985).

53. Ito, A, Krinsky, NI, Cunningham, ML and Peak, MJ, Comparison of the Inactivation of *Bacillus subtilis* Transforming DNA by the Potassium Superoxide and Xanthine-Xanthine Oxidase Systems for Generating Superoxide. Free Radical Biol. Med. 3:111-118 (1987).

54. Mathews-Roth, MM and Krinsky, NI, Carotenoids Affect Development of UV-B Induced Skin Cancer. Photochem. Photobiol. 46:507-509 (1987).

55. Krinsky, NI, Mathews-Roth, MM, Welankiwar, S, Sehgal, PK, Lausen, NCG and Russett, M, The Metabolism of [14C]-ß-Carotene and the Presence of Other Carotenoids in Rats and Monkeys. J. Nutr. 120:81-87 (1990).

56. Mathews-Roth, MM, Welankiwar, S, Sehgal, PK, Lausen, NCG, Russett, M and Krinsky, NI, Distribution of [^{14}C]Canthaxanthin and [^{14}C]Lycopene in Rats and Monkeys. J. Nutr. 120:1205-1213 (1990).

57. Krinsky, NI, Russett, MD, Handelman, GJ and Snodderly, DM, Structural and Geometrical Isomers of Carotenoids in Human Plasma. J. Nutr. 120:1654-1661 (1990).

58. Snodderly, DM, Russett, MD, Land, RI and Krinsky, NI, Plasma Carotenoids of Monkeys (*Macaca Fascicularis and Saimiri Sciureus*) Fed a Nonpurified Diet. J. Nutr. 120:1663-1671 (1990).

59. Handelman, GJ, Snodderly, DM, Krinsky, NI, Russett, MD and Adler, AJ, Biological Control of Primate Macular Pigment. Biochemical and Densitometric Studies. Invest. Ophthalmol. Vis. Sci 32:257-267 (1991).

60. Wang, X-D, Tang, G-W, Fox, JG, Krinsky, NI and Russell, RM, Enzymatic Conversion of ß-Carotene into ß-Apo-Carotenals and Retinoids by Human, Monkey, Ferret, and Rat Tissues. Arch. Biochem. Biophys. 285:8-16 (1991).

61. Mathews-Roth, MM, Lausen, N, Drouin, G, Richter, A and Krinsky, NI, Effects of Carotenoid Administration on Bladder Cancer Prevention. Oncology 48:177-179 (1991).

62. Handelman, GJ, van Kuijk, FJGM, Chatterjee, A and Krinsky, NI, Characterization of Products Formed During the Autoxidation of ß-Carotene. Free Radical Biol. Med. 10:427-437 (1991).

63. Palozza, P and Krinsky, NI, The Inhibition of Radical-Initiated Peroxidation of Microsomal Lipids by both α-Tocopherol and ß-Carotene. Free Radical Biol. Med. 11:407-414 (1991).

64. Tang, G, Wang, X-D, Russell, RM and Krinsky, NI, Characterization of ß-Apo-13-Carotenone and ß-apo-14'-Carotenal as Enzymatic Products of the Excentric Cleavage of ß-Carotene. Biochemistry 30:9829-9834 (1991).

65. Wang, X-D, Krinsky, NI, Tang, G and Russell, RM, Retinoic Acid can be Produced from Excentric Cleavage of ß-Carotene in Human Intestinal Mucosa. Arch. Biochem. Biophys. 293:293-304 (1992).

66. Palozza, P and Krinsky, NI, ß-Carotene and α-Tocopherol are Synergistic Antioxidants. Arch. Biochem. Biophys. 297:184-187 (1992).

67. Palozza, P, Moualla, S and Krinsky, NI, Effects of ß-Carotene and α-Tocopherol on Radical-Initiated Peroxidation of Microsomes. Free Radical Biol. Med. 13:127-136 (1992).

68. Palozza, P and Krinsky, NI, Astaxanthin and Canthaxanthin are Potent Antioxidants in a Membrane Model. Arch. Biochem. Biophys. 297:291-295 (1992).

69. Wang, XD, Krinsky, NI, Marini, R, Tang, G, Yu, J, Fox, JG and Russell, RM, Intestinal Uptake and Lymphatic Absorption of ß-Carotene in Ferrets: A Model for Human ß-Carotene Metabolism. Am. J. Physiol. 263:G480-G486 (1992).

70. Wang, X-D, Russell, RM, Marini, R, Tang, G, Dolnikowski, G, Fox, JG and Krinsky, NI, Intestinal Perfusion of ß-Carotene in the Ferret Raises Retinoic Acid Levels in Portal Blood. Biochim. Biophys. Acta 1167:159-164 (1993).

71. Wang, X-D, Krinsky, NI and Russell, RM, Retinoic Acid Regulates Retinol Metabolism via Feedback Inhibition of Retinol Oxidation and Stimulation of Retinol Esterification in Ferret Liver. J. Nutr. 123:1277-1286 (1993).

72. Palozza, P and Krinsky, NI, Antioxidant Effects of Carotenoids on Biological Membranes. Acta Medica Romano 31:131-140 (1993).

73. Wang, X-D, Krinsky, NI, Benotti, PN and Russell, RM, Biosynthesis of 9-*cis*-retinoic acid from 9-*cis*-ß-carotene in human intestinal mucosa in vitro. Arch. Biochem. Biophys. 313:150-155 (1994).

74. Kennedy, AR and Krinsky, NI, Effects of retinoids, ß-carotene and canthaxanthin on UV and X-ray-induced transformation of C3H10T1/2 cells *in vitro*. Nutr. Cancer 22:219-232 (1994).

75. Gaziano, JM, Hatta, A, Flynn, M, Johnson, EJ, Krinsky, NI, Ridker, PR, Hennekens, CH and Frei, B, Supplementation with ß-carotene in vivo and in vitro does not inhibit low density lipoprotein (LDL) oxidation. Atherosclerosis 112:187-195 (1995).

76. Wang, X-D, Marini, RP, Hebuterne, X, Fox, JG, Krinsky, NI and Russell, RM, Vitamin E enhances the lymphatic transport of ß-carotene and is conversion into vitamin A in the ferret. Gastroent. 108:719-726 (1995).

77. Gaziano, JM, Johnson, EJ, Russell, RM, Frei, B, Manson, JE, Stampfer, M, Ridker, PR, Hennekens, CH and Krinsky, NI, Discrimination in absorption or transport of ß-carotene isomers following oral supplementation with either all-*trans*- or 9-*cis*-ß-carotene. Am. J. Clin. Nutr. 61:1248-1252 (1995).

78. Hébuterne, X, Wang, X-D, Johnson, EJ, Krinsky, NI and Russell, RM, Intestinal absorption and metabolism of 9-*cis*-ß-carotene *in vivo*: biosynthesis of 9-*cis*-retinoic acid. J. Lip. Res. 36: 1264-1273 (1995).

79. Yeum, K-J, Lee-Kim, YC, Yoon, S, Lee, KY, Park, IS, Lee, KS, Kim, BS, Tang, G, Russell, RM and Krinsky, NI, Similar metabolites formed from ß-carotene by either human gastric mucosal homogenates, lipoxygenase or linoleic acid hydroperoxide. Arch. Biochem. Biophys. 321: 167-174 (1995).

80. Hammond, BR, Jr., Curran-Celentano, J, Judd, S, Fuld, K, Krinsky, NI, Wooten, BR and Snodderly, DM, Sex Differences in Macular Pigment Density: Relation to Plasma Carotenoid Concentrations and Dietary Patterns. Vision Research 36: 2001-2012 (1995).

81. Yeum, K-J, Booth, S, Sadowski, J, Lin, C, Tang, G, Krinsky, NI and Russell, RM Human Plasma Carotenoid Response to the Ingestion of Controlled Diets High in Fruits and Vegetables Am. J. Clin. Nutr., 64: 594-602 (1996)

82. Wang, X-D, Russell, RM, Stickel, F, Smith, D and Krinsky, NI ß-Oxidation in Rabbit Liver *in vitro* and in the Perfused Ferret Liver Contributes to Retinoic Acid Biosynthesis from ß-Apo-Carotenoic Acids. J. Biol. Chem., 271: 26490-26498 (1996)

83. Snodderly, DM, Shen, B, Land, RI, and Krinsky, NI, Dietary Manipulation of Plasma Carotenoid Concentrations of Squirrel Monkeys (*Saimiri sciureus)* J. Nutr. 127: 122-129 (1997)

84. Johnson, EJ, Krinsky, NI and Russell, RM, Bioavailability of all-*trans* and 9-*cis* isomers of ß-carotene in humans. J. Am. Coll. Nutr. 15: 620-624 (1997).

85. Hammond, BR, Jr., Johnson, EJ, Russell, RM, Krinsky, NI, Yeum, K-J, Edwards, R B and Snodderly, DM, Dietary Modification of Human Macular Pigment Density Invest. Ophthalmol. Vis. Sci. 38: 1795-1801 (1997)

86. Johnson, EJ, Qin, J, Krinsky, NI and Russell, RM, Ingestion by Men of a Combined Dose of ß-Carotene and Lycopene does not effect the Absorption of ß-Carotene but improves that of Lycopene. J. Nutr. 127: 1833-1837 (1997).

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87. Johnson, EJ, Qin, J, Krinsky, NI and Russell, RM, ß-Carotene Isomers in Human Serum, Breast Milk and Buccal after Continuous Oral Doses of all-*trans* and 9-*cis* ß-Carotene J. Nutr. 127: 1993-1999 (1997).

88. Yeum, K-J, Ahn, S-H, de Paiva, SAR, Lee-Kim, YC, Krinsky, NI and Russell, RM, Correlations between Carotenoid Concentrations in Serum and Breast Adipose Tissue of Women with Benign Breast Tumor or Breast Cancer. J. Nutrition, 128: 1920-1926 (1998)

89. Wang, X-D, Liu, C, Bronson, RT, Smith, DE, Krinsky, NI and Russell, RM Altered Retinoid Signaling and AP-1 Expression by ß-Carotene and Smoking Leads to Lung Metaplasia. J. Natl. Cancer Inst., 91: 60-66 (1999)

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91. Yeum, K.-Y., Ferreira, A.L.A., Smith, D., Krinsky, N.I. and Russell, R.M. The Effect of α-Tocopherol on The Mechanisms of ß-Carotene Cleavage. Free Radic. Biol. Med. 29:105-114 (2000)

92. Liu, C., Wang, X.-D., Bronson, R.T., Smith, D.E., Krinsky, N.I. and Russell, R.M. Effects of Physiological versus Pharmacological ß-Carotene Supplementation on Cell Proliferation and Histopathological Changes in the Lungs of Cigarette Smoke-exposed Ferrets. Carcinogenesis 21:101-110 (2000)

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Submission End

AM

Garcia, Edmundo

From: Ray Matulka [rmatulka@burdockgroup.com]
Sent: Friday, April 29, 2005 11:44 AM
To: Garcia, Edmundo
Cc: George Burdock
Subject: GRAS Notice 000163: Clarification
Sensitivity: Confidential

Dear Dr. Garcia,

Attached you should find a pdf file containing the Clarification Letter to address the issues brought to our attention *via* the e-mail dated 22MAR05 on the GRAS Notification No. 000163 (please see below).
A hardcopy color version has been sent *via* FedEx, which should be received Monday morning.
Please let me know if you have any questions.

Sincerely,

Ray A. Matulka

Toxicologist
Burdock Group
2001 9th Avenue, Suite 301
Vero Beach, FL 32960

Ph: 772-562-3900
FAX: 772-562-3908

-----Original Message-----
From: Garcia, Edmundo [mailto:Edmundo.Garcia@cfsan.fda.gov]
Sent: Tuesday, April 26, 2005 1:47 PM
To: 'gburdock@burdockgroup.com'; 'rmatulka@burdockgroup.com'
Subject: RE: GRAS Notice 000163

Good afternoon,

A few weeks ago I sent the message below and was wondering if you have had an opportunity to look into this issue.
Your prompt response would be greatly appreciated.

Regards,

Edmundo Garcia Jr.
Consumer Safety Officer
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food & Drug Administration

-----Original Message-----
From: Garcia, Edmundo
Sent: Tuesday, March 22, 2005 4:31 PM
To: 'gburdock@burdockgroup.com'

000147

Subject: GRAS Notice 000163

Dr. Burdock:

In our review of your GRAS notice submission we noticed that there were a couple of differences in the values you had previously submitted. For example in Table 5 Natural Lycopene intake from current consumption of food, you have listed 6.1 & 13.7 for the mean and 90th percentile and in your previous submissions your values were 8.2 & 15.7 respectively. Also, we need clarification regarding the identity of the ingredient (5% vs. 6% lycopene) used in the acute, subchronic and eye studies, particularly for your determination of the NOEL. In the previous GRAS notice (GRN 000156), the ingredient used in several studies was Lyc-O-Mato Oleoresin 5%. In the current GRAS notice (GRN 000163), the ingredient is described as Lyc-O-Mato Oleoresin 6% for those same studies. Further the NOEL (expressed on a lycopene basis) is different, based on use of the 5% vs. 6% number (see p 34, 4th paragraph of GRN 000163 and p. 30, 5th paragraph of the amendment to GRN 000156).
Also, you do not identify the "oxygen absorber" (p. 7 of GRN 163) and whether this substance is a food contact substance or a direct food ingredient.

Your prompt clarification of these issues would be greatly appreciated.

Sincerely,

Edmundo Garcia Jr.
Consumer Safety Officer
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food & Drug Administration

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April 28, 2005

Dr. Edmundo Garcia Jr.
Consumer Safety Officer
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: GRN Notice #000163 – Clarification Letter

Dear Dr. Garcia,

This letter is to clarify and amend the GRAS dossier[1] entitled "DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT." This dossier requests the addition of "Lyc-O-Mato® Powder" to the specified food categories, to be used as an ingredient to provide consumers with a supplementary source of lycopene in their diets. Several points have been raised concerning this GRAS dossier, and based on an email dated March 22, 2005; we submit the following clarifications and amendment to the GRAS Notification (GRN Notice #000163).

1. The FDA has reviewed this GRAS dossier, and asked for clarification based on noted variations in the values on the consumption of lycopene from food in this "Lyc-O-Mato® Powder" GRAS Notification (GRN No. 000163), when compared to the value of lycopene

[1] GRAS Notification Letter dated March 4, 2005.

consumption from food that was stated in the previous GRAS Notification for "Lyc-O-Mato® Oleoresin 6%" (GRN No. 000156).

2. The FDA has indicated that clarification is needed to determine if the "oxygen absorber" that is noted in this "Lyc-O-Mato® Powder" GRAS Notification (GRN No. 000163) is a food contact substance or a direct food ingredient.

3. The FDA has also requested clarification regarding the identity of the ingredient used in the acute, ocular and subchronic studies, particularly for the determination of the NOAEL in this "Lyc-O-Mato® Powder" GRAS Notification (GRN No. 000163).

1. Clarification – Natural lycopene intake from the consumption of food.

The previous "Lyc-O-Mato® Oleoresin 6%" GRAS dossier (GRN No. 000156) identified the mean and 90th percentile levels of natural (*i.e.*, background) consumption of lycopene from food, as being 8.2 and 15.7 mg/day, respectively. The current "Lyc-O-Mato® Powder" GRAS dossier (GRN No. 000163) identified the mean and 90th percentile levels of background consumption of lycopene from food, as being 6.1 and 13.7 mg/day, respectively.

The two different consumption analyses determined the background consumption of lycopene from those foods naturally containing lycopene, that were eaten by the two different eaters only populations that also ate the foods that were specifically targeted for the addition of the different Lyc-O-Mato® lycopene-containing products. The background lycopene consumption analyses were for each of the two different Lyc-O-Mato® products, because the target foods to which one Lyc-O-Mato® product will be added will be <u>different</u> from the targeted foods for the addition of a different Lyc-O-Mato® product. Therefore, the population base for each Lyc-O-Mato® product is different, and so the background consumption of lycopene by each population will be different.

2. Clarification – Identification of the "oxygen absorber" utilized in the packaging of "Lyc-O-Mato® Powder."

Details concerning the oxygen absorber, Ageless® oxygen absorber, which conforms to the FDA's food packaging regulations (21 CFR 178), are provided (Appendix A). In addition, Ageless® oxygen absorber does not come in contact with the food product. The "Lyc-O-Mato® Powder" is packed in a laminate bag, which is then inserted into a similar second bag. The

internal bag is folded, while the second bag is sealed under vacuum. The packet of Ageless® oxygen absorber is placed between the two bags, at the bottom of the package. As the internal bag is folded to prevent leakage of the powder, the residual oxygen slowly diffuses from the "Lyc-O-Mato® Powder" (in the first bag), and is captured by the Ageless® oxygen absorber in the second bag. The "Lyc-O-Mato® Powder" does not come into contact with the Ageless® oxygen absorber.

3. Amendment – Identity of Lyc-O-Mato® oleoresin used in acute, ocular and subchronic studies.

Specifications for "Lyc-O-Mato® Oleoresin 6%" in GRAS dossier (GRN No 000156) state that the lycopene content of this product may range between 5-8%, with 6% as the most commonly cited value. In review of the actual study data, the acute oral toxicity stated that the Lyc-O-Mato® Oleoresin batch utilized for the study actually contained 5% lycopene, but was still within the required specifications for the manufacture of this product (*i.e.,* 5-8%). The ocular studies and the subchronic study also utilized similar concentration products, *i.e.,* containing lycopene at 5%.

A letter from LycoRed Natural Products Industries, Ltd. (Appendix B) indicates that the spectrophotometric method utilized at the time of the subchronic rat toxicity study (1994) was only accurate to ±1 *percent*. The Client also indicated that other factors contribute to variations in the quantitative analysis of lycopene in food samples (*i.e.*, loss of carotenoids in diluent, physical losses during processing, adherence of carotenoids to the walls of the container or the spectrophotometric cuvette, and the isomerization and oxidation of carotenoids during analysis or storage before analysis). LycoRed Natural Products Industries, Ltd. concluded that the concentration of lycopene contained within "Lyc-O-Mato® Oleoresin 6%" is most commonly 6%, and calculations should be based on this number.

Therefore, in determining the NOAEL of "Lyc-O-Mato® Oleoresin 6%" from the subchronic study, the percentage of 6% should be utilized. As the highest dose utilized in the study was 4500 mg/kg/day, the NOAEL. This resulted in a lycopene consumption of 270 mg/kg/day, and not 225 mg/kg/day as was previously stated. To be precise, the lycopene concentration consumed by the rats could be changed to 270 mg/kg/day; therefore, the "safety factor" of 135 would be more precise when comparing this more precise NOAEL of 270

mg/kg/day to the proposed 120 mg/day (ADI). These differences do not materially change the conclusion that the intake of lycopene is safe.

Summary

In summary, the intake of background lycopene from foods consumed by individuals who would also consume lycopene by the addition of "Lyc-O-Mato® Powder," will be different from the background lycopene from foods for individuals consuming "Lyc-O-Mato® Oleoresin 6%"-containing products. In addition, the oxygen absorber utilized, as packaged, is safe for use in food products, and does not come into contact with the "Lyc-O-Mato® Powder." Finally, a review of the actual acute, ocular and subchronic study data, as well as a clarification letter from the LycoRed Natural Product Industries, Ltd., indicate that 6% lycopene-containing Lyc-O-Mato® oleoresin was used. Therefore, the NOAEL, based on the subchronic study, is 4500 mg/kg/day and the amount of lycopene was ingested was 270 mg/kg/day. The application of appropriate safety factors for the extrapolation to human consumption from this NOAEL confirms that 120 mg/day is a safe intake of lycopene. We regard any differences resulting from using 5% as opposed to 6%, the most commonly found value, as *de minimus* and to have no effect on the safety-in-use of this substance.

If you have any further questions regarding these or any other topics concerning the GRAS dossier (GRN Notice #000163) of the Generally Recognized as Safe (GRAS) status of "Lyc-O-Mato® Powder," please contact me.

Sincerely,

(b)(6) 29 Apr 05

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition

Appendix I

The following pages contain information regarding the packaging and use of the Ageless® oxygen absorber product. This information concerns proprietary information on the packaging of Lyc-O-Mato® Powder, and the Client wishes the following documents to be kept "Business Confidential."

MGC

Oxygen Absorber for preserving product freshness, purity, and integrity

AGELESS®

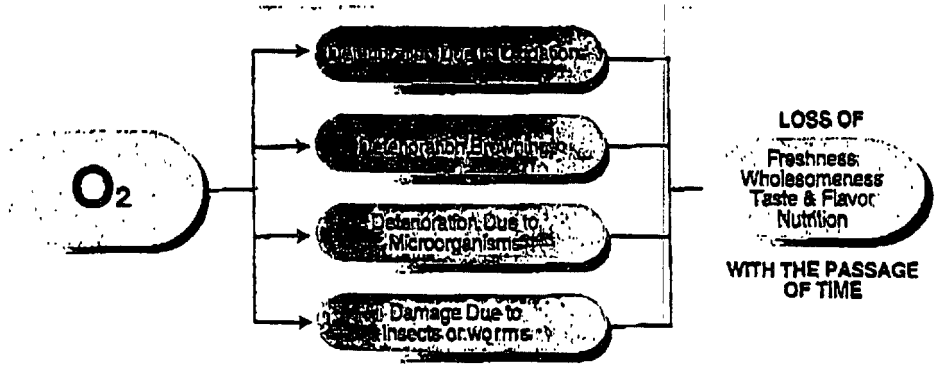
MITSUBISHI GAS CHEMICAL COMPANY, INC.

BEST ORIGINAL COPY

000154

Oxygen (O_2) is the Main Cause of the Deterioration of Foods

Food products lose their freshness,taste,flavor,wholesome goodness and important nutritional value when exposed to oxygen.



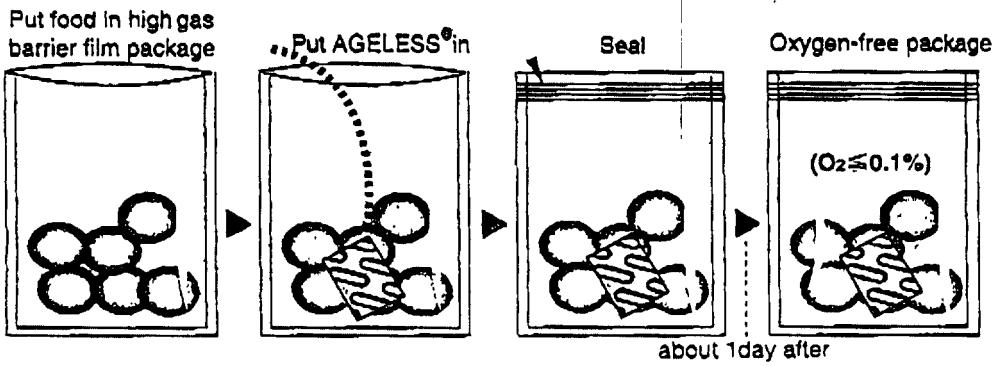
AGELESS® can reduce the oxygen in an airtight container down to 0.1% or less to prolong your product's shelf life.

To prevent mold,bacteria and insect infestation and the like,which thrive in an oxygen-rich packaging environment,simply insert the AGELESS® oxygen absorber packet into your food package and seal it.The result is longer-lasting freshness and improved quality products–with no unappetizing discoloration,deterioration or decomposition.

AGELESS® is simple to Use

■AGELESS® preserves the freshness of your products and prolongs their shelf life.

- It will contribute greatly to marketing and distribution of your products.
- It is easy to use.
- It is economical since it requires no expensive equipment.
- It is safe since it will never be directly mixed with your products.



Conventional preservatives,antioxidants,gas purging and vacuum packing often are not effective because they do not completely eliminate oxygen. Unique AGELESS® oxygen absorber works to chemically absorb oxygen without altering product composition or purity and without adding any chemicals or additives.

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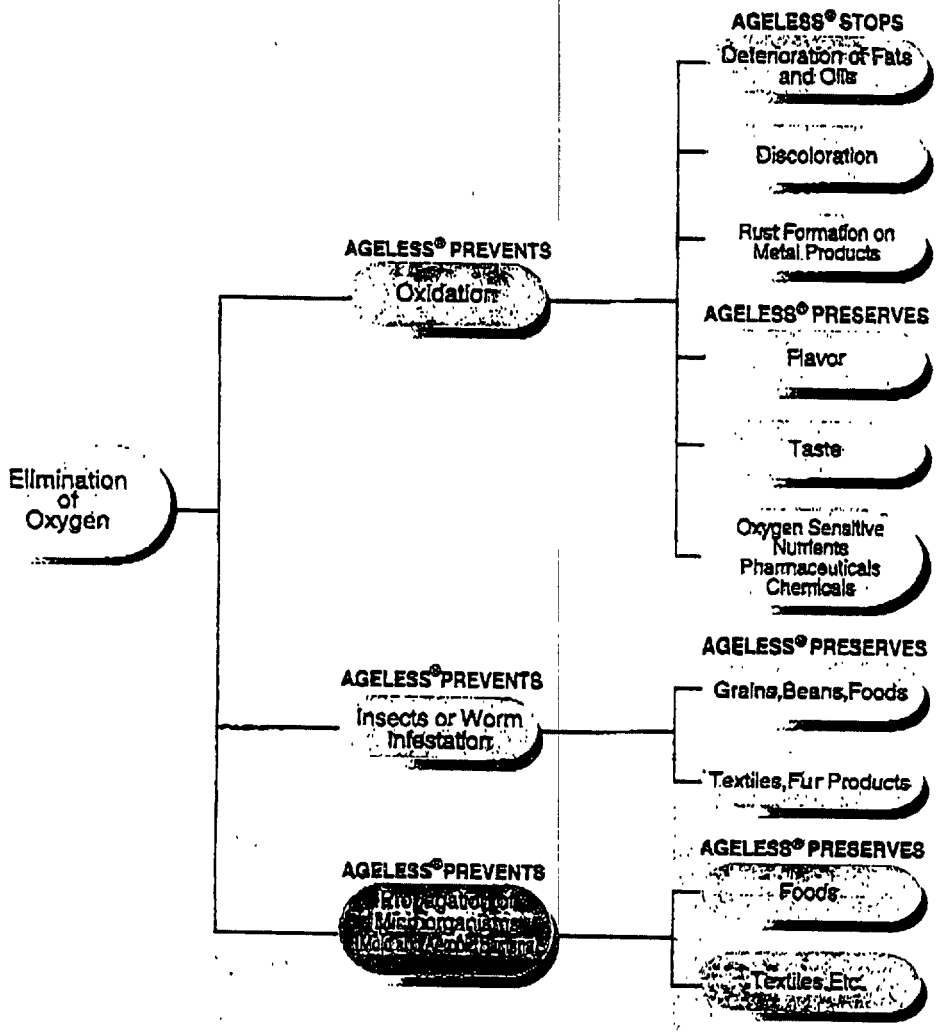
Direct Effects of AGELESS® (Elimination of Oxygen)



- AGELESS® can add important new marketing dimensions and cost-saving factors to your distribution cycle by extending product shelf life.
- AGELESS® helps to keep your product labels "clean" without chemical additives.
- AGELESS® prevents the growth of aerobic microorganisms.
- AGELESS® is easily inserted, without reducing packaging line productivity.
- AGELESS® does not mix directly with the product to change its formulation.
- The main chemical reactions that occur inside the AGELESS® sachet are:

$$Fe \rightarrow Fe^{2+} + 2e^-$$
$$\tfrac{1}{2}O_2 + H_2O + 2e^- \rightarrow 2OH^-$$
$$Fe^{2+} + 2(OH)^- \rightarrow Fe(OH)_2$$
$$Fe(OH)_2 + \tfrac{1}{4}O_2 + \tfrac{1}{2}H_2O \rightarrow Fe(OH)_3$$

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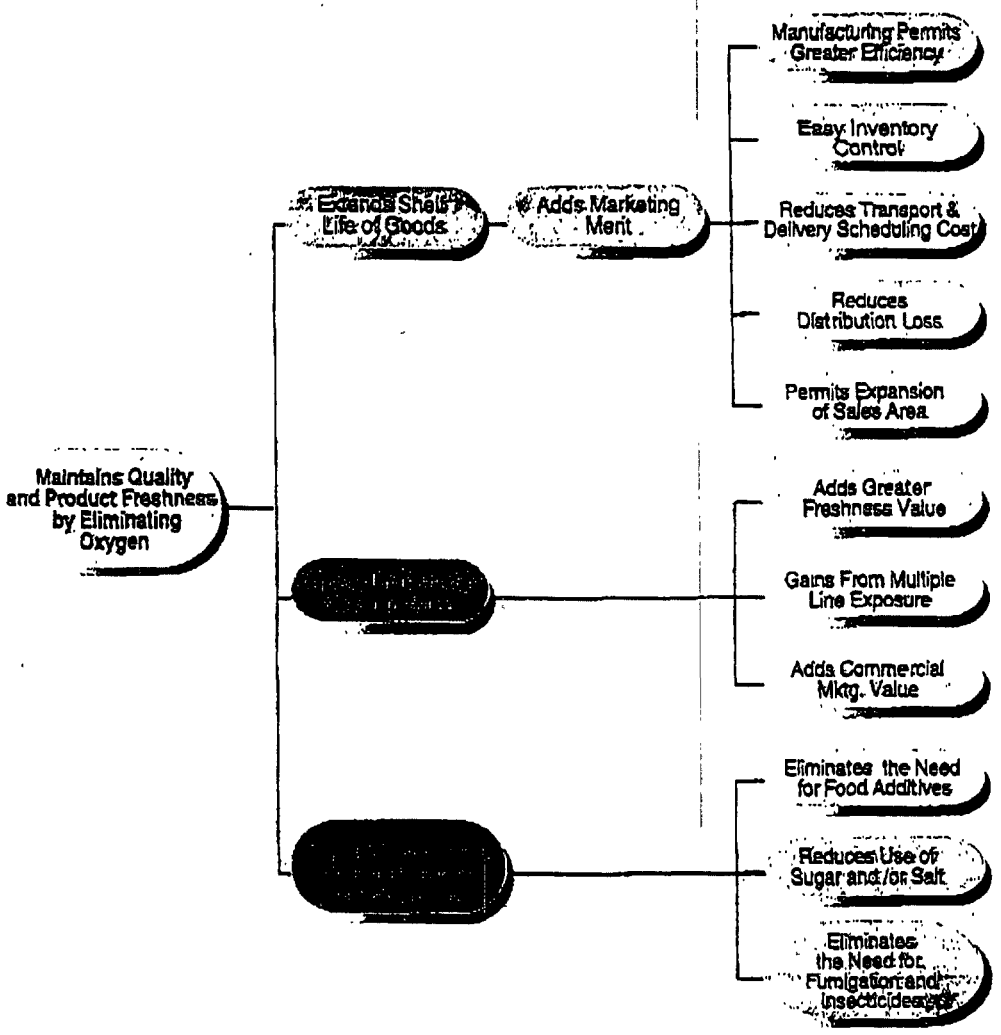
Benefits of Using AGELESS® (Marketing Merit)



By eliminating oxygen, AGELESS®
helps to maintain product freshness, which permits you to:

Extend product shelf life, which then permits:
- More convenient production scheduling
- Greater flexibility in inventory management
- More affordable transportation options
- Reduction of expired product lost through delayed distribution
- Geographic expansion of sales territory

Open markets for new products, which then adds:
- Greater freshness value
- Broader product line extensions
- Opportunities for even further development commercial value based on a unique marketing point of differentiation.

Respons to an increasing customer preference for natural foods, which enables the food processor to:
- Eliminate food additives and preservatives
- Maintaining unabridged flavor by reducing sugar and/or salt content
- Eliminate the need for fumigation and insecticides

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Protective Effect of Oxygen Absorber AGELESS® on Foods

FUNCTION : AGELESS® removes oxygen from a closed container.
APPLICATION : AGELESS® protects various food products from, for example,

Aerobic Microorganisms **Insects** **Discoloration** **Oxidation**

and preserves four important elements of food.

Taste **Flavor** **Freshness** **Nutrition**

Inhibition of the Growth of Mold

In an oxygen-free atmosphere(oxygen concentration of 0.1% or less), AGELESS® shows a marked ability to suppress the growth of mold. The experimental results tabulated below show the growth progress of blue molds even when food items are stored under rigorous inert gas replacement packaging technology. Food items sealed with AGELESS® did not show this mold development.

Pizza Crust Stored at 30°C for 10 days

AGELESS® packed Control

Oxygen Concentration and Mold Growth

Mold Growth on Bread vs. Oxygen Concentration 25°C room temperature

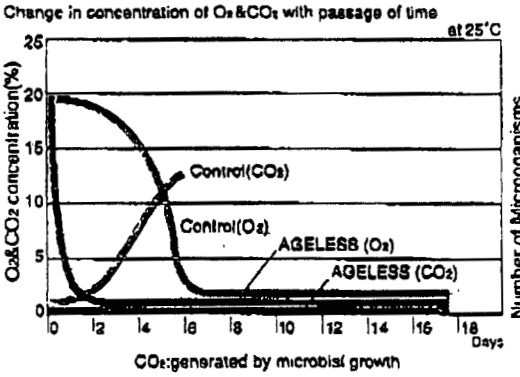
Filled gas composition		Daily change of mold growth									
AGELESS® PACKED											
0.2	99.8										
0.4	99.6									+++	+++
0.6	99.4					+++		+++		+++	+++
20.9*	79.1				+++	+++		+++		+++	+++

*atmospheric oxygen concentration
- no mold colony growth observed. +slight growth of colonies. +++many colonies of mold observed.

Inhibits Growth of Aerobic Microorganisms

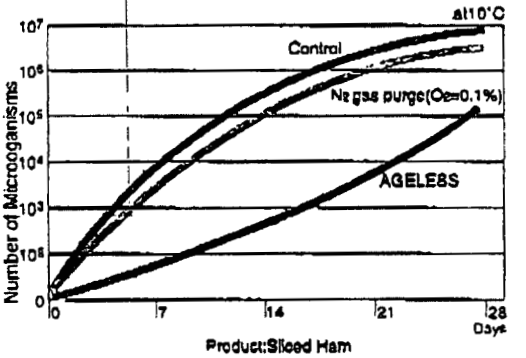
Pizza Crust Deterioration

Change in concentration of O_2 & CO_2 with passage of time



CO_2:generated by microbial growth

Change in Microbial Plate Count of Sliced Ham



Product:Sliced Ham

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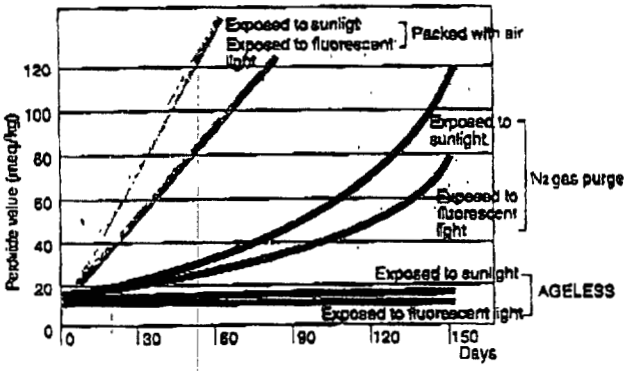
Prevention of Oxidation of Oils and Fats

Oil and fats in the food react with oxygen and deteriorate. This reaction is promoted especially under lighted conditions and/or at room temperature. Using AGELESS® can prevent this oxidization.

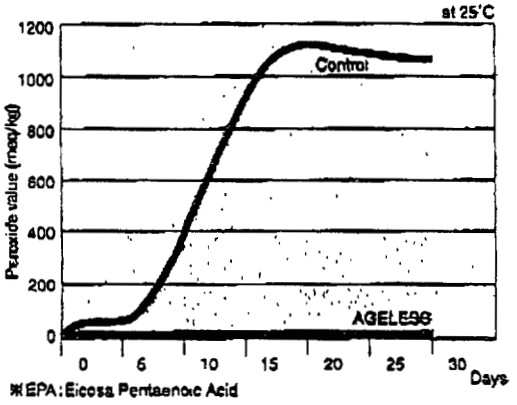
Salami Stored at 20°C for 1 week

AGLESS® packed Control

The effectiveness of AGELESS® in preventing deterioration due to exposure to light

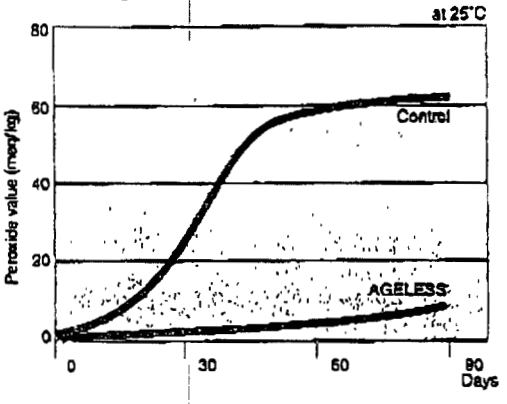


Effect of AGELESS® on fish oil (EPA)*



*EPA: Eicosa Pentaenoic Acid

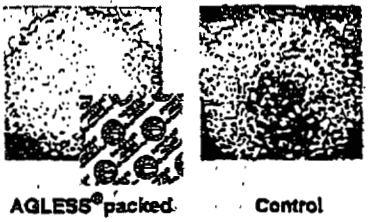
Preventing oxidation of roasted peanuts



Prevention of Damage by Insects, Worms and Their Eggs

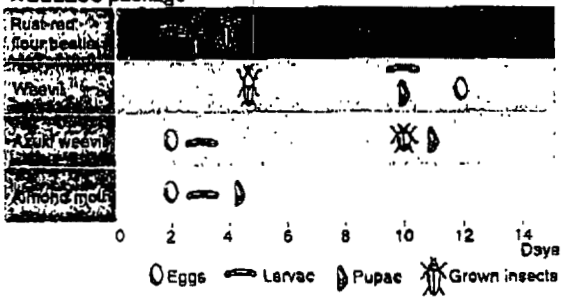
Oxygen -free packaging using AGELESS® allows you to prevent both adult insects and their eggs, a feat not effectively achieved by fumigation. The oxygen -absorbing agent is safe: no more worries about the insects listed below, often found growing in cereals. AGELESS® is also effective against mites hiding in bedding.

Polished rice Stored at 25°C for 1 month



AGLESS® packed Control

Number of days needed for 100% killing of insects by AGELESS package at 25°C



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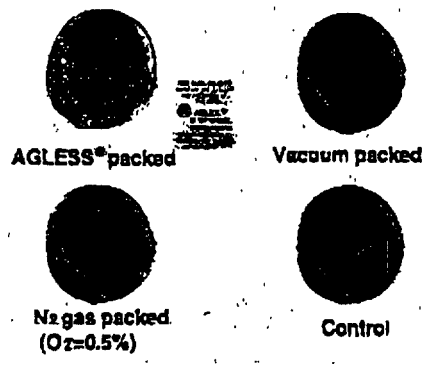
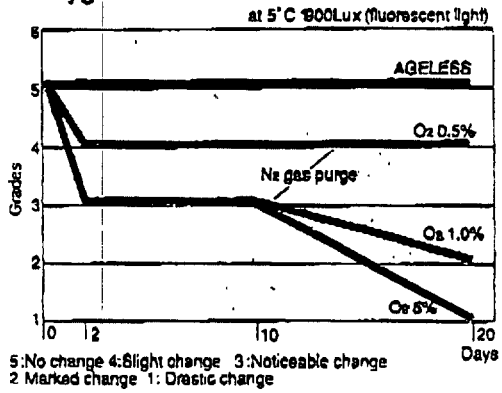
Prevention of Discoloration

Most foods are discolored by oxidation.The value of discolored food is lost not only in appearance but also the taste and safety.
This value can be protected by using AGELESS®

Ham Stored at 5°C for 1 month



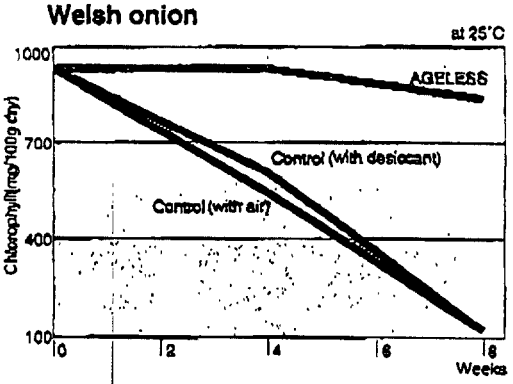
Change of color of sausage due to oxygen concentration



5:No change 4:Slight change 3:Noticeable change
2 Marked change 1: Drastic change

Noodle Stored at 25°C for 1 month

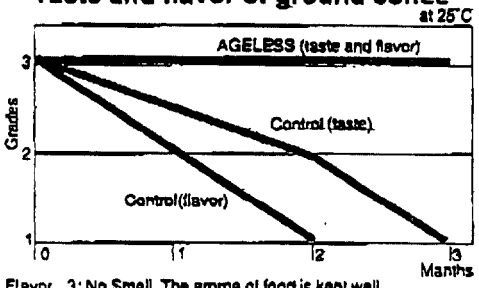
Change of chlorophyll of dehydrated Welsh onion



Maintenance of Taste, Flavor and Nutritive Elements

Whether or not a food is considered a delicacy is ultimately decided by the taste and flavor.Taste and flavor deteriorate gradually by oxidization and the nutrients (vitamin etc,) contained in food are also lost. AGELESS® can maintain the taste, flavor and nutrition in

Taste and flavor of ground coffee



Flavor 3: No Smell. The aroma of food is kept well
2: A little smell of oxidation. The food aroma is fading.
1: Smell of oxidation. The aroma has gone
Taste 3: The taste is like just after roasting.
2: Increased taste of oxidation.
1: The taste has gotten worse.

AGELESS® fights decomposition and deterioration in areas other than food manufacture and supply
AGELESS® can be even used for the medical and pharmaceutical industries, or cosmetics,and textiles : anywhere product quality can quickly deteriorate due to contact with oxygen.

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AGELESS® Product Suitability Chart

Series and Sizes of AGELESS®(Sachet styles)

■Series of AGELESS®

Z	Especially suitable for dry foods.	Z-PT: 0.95 or less (Z-PU: 0.9 or less / Z-PK: 0.85 or less)	1~4 days (differs by size)	4 hrs (1hr:Aw<0.85) Absorption of oxygen begins when sachet are removed from outer master bag. Use as quickly as possible.
S	Fast-working type Not suitable for use with desiccant.	0.65 ~0.95	0.5~2 days	1 hr from time when sachets are removed from outer master bag and spread out. Use as quickly as possible.
FX	Use for moist foods. Stable in air before use. Excellent in water resistance.	0.85 or more	0.5~1 days	8 hrs:RH<70% 4 hrs:RH70~90% If there is no moisture, effectiveness of AGELESS FX removed from master bag is not impaired. If possible, the package containing the remainder should be re sealed
E	Absorbs both O_2 and CO_2	0.3 or less For roasted coffee only.	Differs by size	4 hrs Absorption of O_2 begins when the master bag is opened.

※Each series is further divided into types more applicable to specific product situations. For more information, please ask sales office about detailed types of AGELESS.

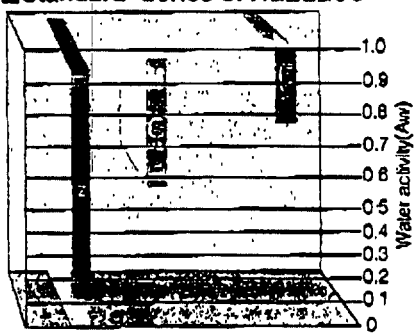
■Sizes of AGELESS®

Series	Size	O_2 absorption capacity(ml)	Equivalent air volume (ml)
FX, Z, S	20	20	100
	30	30	150
	50	50	250
	100	100	500
	200	200	1000
	300	300	1500
	500	500	2500
	1000	1000	5000
	2000	2000	10000

Series	Size	CO_2 absorption capacity(ml)	O_2 absorption capacity(ml)
E	250	250	25
	500	500	50
	1000	1000	100
	2000	2000	200

Choosing the AGELESS® to Meet the Water Activity(Aw) of Your Product

■Standard Series of AGELESS®



■APPLICATION

- ●Mold Prevention
  cakes, confectionary, cheese, pizza crust ---------- S-Series
- ●Insect Prevention
  rice, soybeans, cereal grains ---------- S, Z-Series
- ●Prevention of Discoloration
  dried vegetables, beef jerky, dried salami ---------- Z-Series
- ●Prevention of Oxidation
  all types of nuts, fried cakes, biscuits, cookies ---------- Z-Series

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New! Oxygen Absorber AGELESS®in New Styles

With the development of our new "oxygen absorbing plastic sheet," we are able to introduce oxygen absorbers in totally new styles.
These new products no longer use powder ingredients in a sachet.

In this new "oxygen absorbing plastic sheet," the active ingredient (activated iron powder) is contained within the plastic material.

You can create much more consumer friendly packages, because these new models can be designed to fit into your packages naturally and can serve multiple functions.

Types and Sizes of AGELESS®(New styles)

■Types of AGELESS®

Types of AGELESS®	Product Characteristics			
	Form	Water activity (Aw) of the product	Oxygen absorption velocity	Minimum moisture content (Aw = 0.75)
FL	Label type	1.00~0.80	0.5~1day	
FC	Card type	0.80~0.75	1~2days	8 hrs:RH<70% 4 hrs:RH70~90%
FS	New sachet type	1.00~0.85 0.85~0.75	0.5~1day 1~2day	

※We are now in the process of obtaining approval (direct contact of AGELESS in new styles with food) in each country worldwide.

What is Water Activity(Aw)

Aw is the ratio of water vapor pressure (p) generated by the product itself, to the maximum vapor pressure (Po) at a given temperature. It is also shown by the balanced relative humidity (RH%) generated by moisture transpired from the product when it is packed in a closed container.

$$Aw = \frac{P}{Po} = \frac{RH(\%)}{100}$$

AGELESS® FX, FL, FC and FS do not contain moisture needed for oxygen absorbing reactions,however, Z,S,and E begin absorption as they are exposed to air. AGELESS® FX, FL, FC and FS do not absorb oxygen under dry atmospheric conditions.

■Sizes of AGELESS®

Types	Size	O_2 absorption capacity(ml)	Equivalent air volume (ml)
	5	5	25
	10	10	50
	15	15	75
FC	20	20	100
FS	30	30	150
	50	50	250

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Easy to attach to packaging materials.

With adhesive on the back, these new AGELESS® products may be easily fixed inside the packaging. They can be attached automatically using a labelling machine.
(Some modification of packaging may be required depending on flexibility of your packaging materials.)
By attaching AGELESS® inside your packges,you don't need to worry that the consumer will mistake the sachet for something to eat.
As you can attach the new AGELESS® almost anywhere, it can be naturally integrated in your package.

This FL type can be used:
- to attach to the top web of thermally formed packages.
- to attach inside horizontally or vertically formed pouches.
- to attach to a specific position such as behind your label.

You can design your own inserts.

FC type is flexible in size and shape.
You can use the FC type as a coupon, message card and so on.
Even if a consumer tears it off, there is no possibility of releasing the active components.
We offer rectangular and round varieties as standard,but we can make AGELESS® in almost any shape you prefer.

This FC type can be used:
- as a "pasteboard" on which your product can be carried and introduced into a horizontal form fill seal machine.
- as a promotional card.
- as a coupon

A sachet style which no longer uses powder ingredients.

This new, slim FS type looks like current sachet styles, however it contains oxygen absorbing plastic sheet instead of powder ingredients. This FS type can be used in the same manner as current sachet types without the risk of spilling powder ingredients in case of accidental tearing or breaking open of the pouch.
Available in two forms individually packed or continuous rolls. The rolled products can be inserted with ordinary automatic inserting machines by adjusting the machine's sensor.

Possible uses: ●Aseptic cooked rice ●Processed meats ●Microwavable deli products.

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Selection of the Best AGELESS® to Meet Your Needs

Determine product requirements.

↓

Select oxygen barrier packaging material.

↓

Process [illegible] to meet your requirements.

↓

Perform a small-scale test evaluation.

↓

Conduct a confirmation test using actual production materials and equipment.

↓

Begin production.

Measurement of the Oxygen Volume in Your Container

In order to determine the correct AGELESS® size, you'll need to know the volume of oxygen in your container.
The amount of oxygen that can be absorbed is indicated (in milliliters) by the AGELESS® size number. (Example: FX-50 will absorb 50mℓ of oxygen.
Since oxygen makes up about 1/5 of the air, FX-50 will deoxygenate 250mℓ of air.)

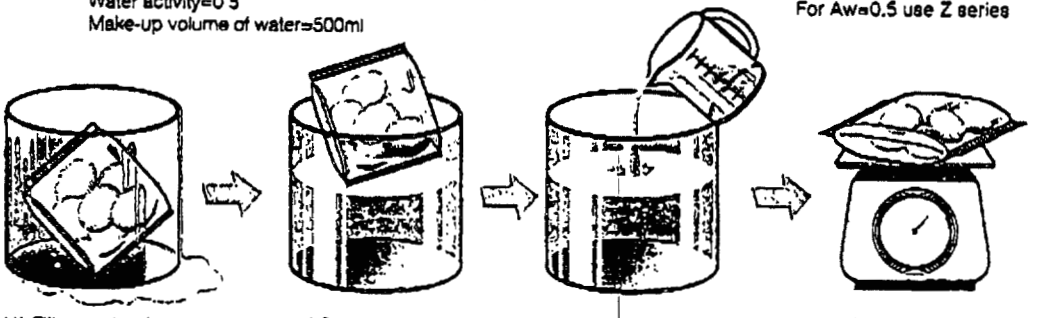
How to measure the oxygen in your container (specific gravity of the product can be assumed to be 1).

■ Where the container is an irregular shape, put the bag in water and measure the volume.

$$\text{Oxygen in container (ml)} = \left(\text{make-up water volume (ml)} - \frac{\text{Weight of product (g)}}{\text{Specific gravity (=1)}}\right) \times 0.21$$

Example: Specific gravity=1
Weight of product=350g
Water activity=0.5
Make-up volume of water=500ml

$$\left(500 - \frac{350}{1}\right) \times 0.21 \fallingdotseq 30\text{ml}$$ → AGELESS Z-30 should be used.
For Aw=0.5 use Z series



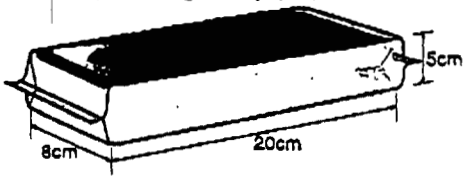
(1) Fill vessel with water. Place product container into vessel and let water overflow.
(2) Remove container from vessel.
(3) Measure the make-up volume of water.
(4) Measure the weight of food and container.

■ When using a box: Subtract the weight of product from volume of box

$$\text{Oxygen in container (ml)} = \left(\text{Length} \times \text{Width} \times \text{Height (cm)} - \frac{\text{Weight of product (g)}}{\text{Specific gravity (=1)}}\right) \times 0.21$$

Example: Specific gravity=1
Weight of product=400g
Water activity=0.85

Selection of either AGELESS S-100 or FX-100 suitable for Aw=0.85 depends upon food characteristics and the placement of the packet within the package.



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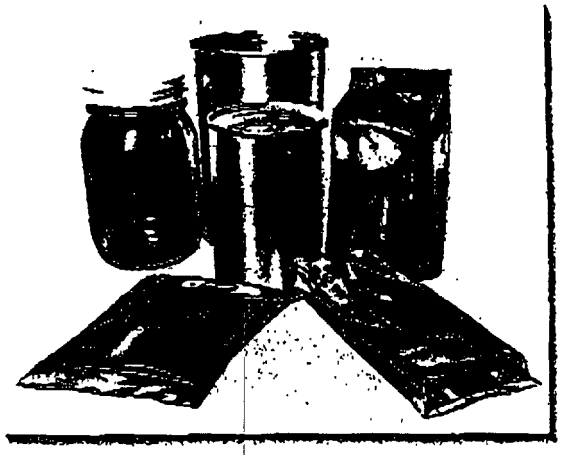
Selection of a Packaging Container for AGELESS® Packaging

AGELESS® works best when inserted into cans, bottles and film which offer a variety of airtight characteristics.



- **When using cans, make sure there is no leakage along seams.**
- **Glass bottles should have a tight seal between the bottle and closure.**
- **Film with oxygen permeability of 20 ml/m² atm·day or less is recommended.**
- **AGELESS® is not meant to be eaten. Be sure to place it in an appropriate place so that the consumer will not eat it by mistake.**

Aptitude	Type	Composition	Thickness (micron)	Vapor permeability (g/m² 24hrs)	Oxygen permeability cc/m²·atm·24hrs 20-25C	Remarks
Long-term preservation	Aluminum foil	PET/Al/PE	12/7/40	0	0	
	Aluminum deposition	PET/Al coating/PE	12/600Å/40	1~1.5	0.5~1.5	
	Si oxide coat	Si oxide coating/PET/PE	12/60	1~1.5	0.5~1.5	
	Ethylene vinyl alcohol	NYLON/EVOH/PE	20/17/40 15/50	7 4	0.3~4 0.5~3	
	Barrier nylon	MXD6/PE	15/40	9	5	
	PVDC coat	PVDC coating OPP/PE	20/40	4	5~15	
		PVDC coating PET/PE	12/50	4	6~10	
		PVDC coating ON/PE	15/50	7	6~10	
Short-term preservation	Polyamide	2-layer extruded film	100	7~9	17~60	For short preservation. Conduct sufficient tests before use.
		ON/PE	15/40	16	30~120	
	Polyester	PET/PE	12/40	15	50~120	
	Cellophane	PT/PE	20/40	20	10~200	
Inappropriate	Polypropylene	OPP/PE	20/40	6	1500~2000	Generally, these are not appropriate for use with AGELESS
		PP part coat	40		3000~	
	Polyethylene	PE	40~		2000~	

(Notes)* Figures in vapor permeability and oxygen permeability columns are reference values only.
The above abbreviations indicate the following:

PET -polyester
Al -aluminum
PE -polyethylene
OPP -oriented polypropylene
PVDC -polyvinylidene chloride
ON -oriented nylon
PT -cellophane

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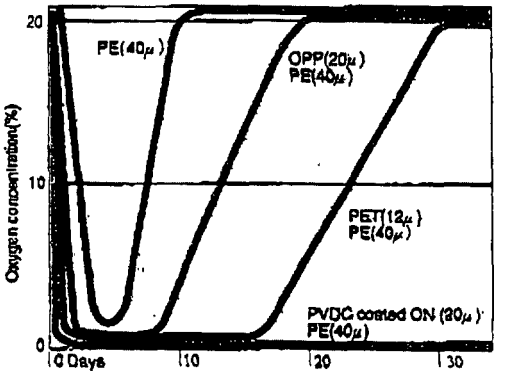
How AGELESS® Reduces Oxygen Concentration in Film Packages

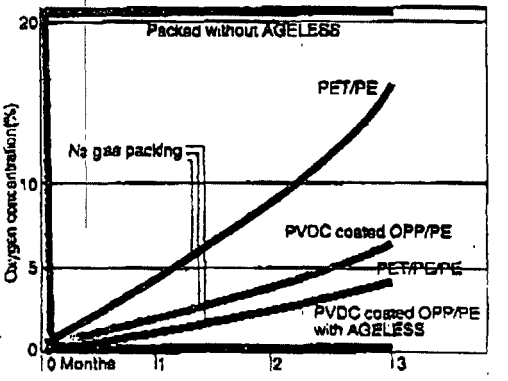
Oxygen concentration in a plastic film container reaches almost zero within a week in each of the illustrated packaging materials.
However, after 10 days or more (depending upon the packaging material selected), a return to ambient air oxygen levels (21% oxygen) is observed. An oxygen barrier layer, such as EVOH or PVDC is necessary to maintain the effectiveness of AGELESS®

■Atmospheric Oxygen Concentration



(When AGELESS is used under nominal capacity)

■ Oxygen Concentration in the Package at Room Temperature

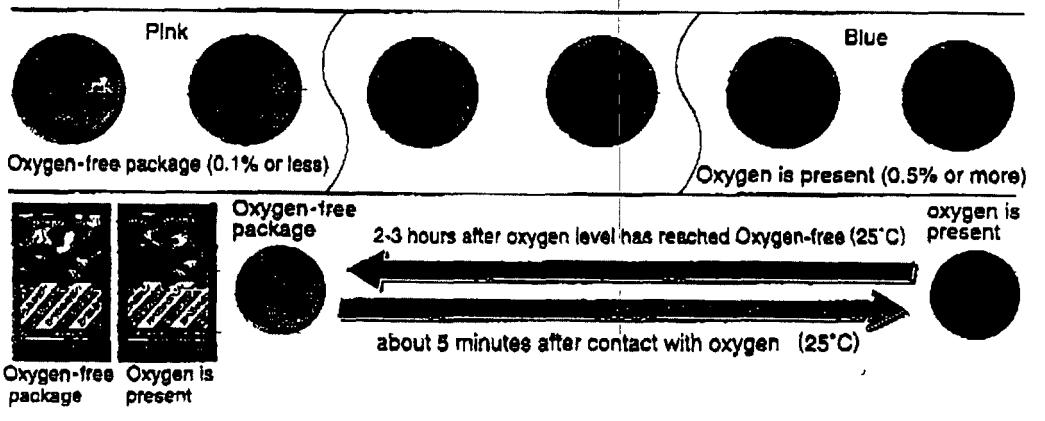


■ Easy Method to Check the Oxygen-Free Condition

AGELESS-EYE® Oxygen Indicator

The AGELESS-EYE® is an in-package monitor which indicates the presence of oxygen at a glance. Please use it for testing purposes only.

■Magnified



How to use the AGELESS-EYE®

When exposed to oxygen, the AGELESS-EYE® turns blue or purple, then returns to its original pink color as the oxygen in the container is reduced.

- ■Insert an AGELESS-EYE® indicator into the container with the AGELESS® oxygen absorber.
- ■The lower the temperature, the slower the color change.
- ■Total elimination of oxygen is seen at a glance.
- ■Store AGELESS-EYE® in a cool, (below 15°C) dark place with no oxygen until ready for use. Use AGELESS® Z or S to create an oxygen-free atmosphere. Because this uses a very delicate chemical reaction, please handle with care to maintain efficacy.
- ■Although AGELESS-EYE® is not hazardous, it is not meant to be eaten.

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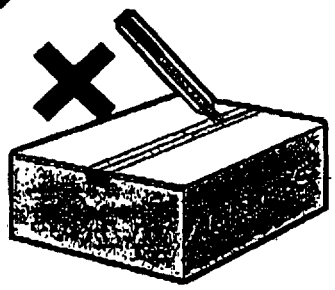
How to use AGELESS®

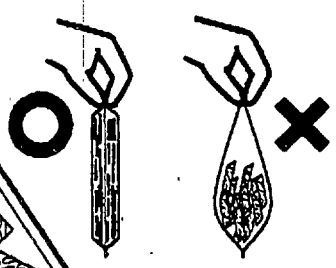
1 Opening the carton box.



⚠ When opening box, avoid using too sharp an edge. (There is a possibility of damaging master bag).

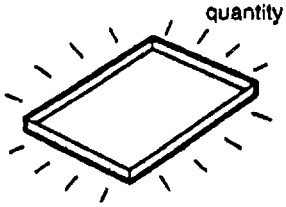
2 Check tightness of the master bag.

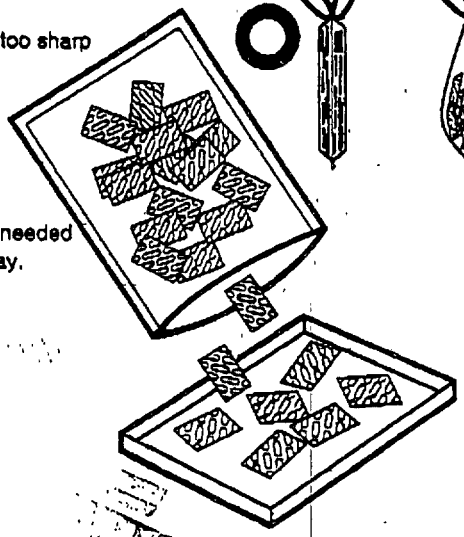
- AGELESS® is vacuum packed. if you hang master bag from one end, the packets should not slip.
- In case the packets should slip before opening DO NOT USE that master bag of AGELESS®



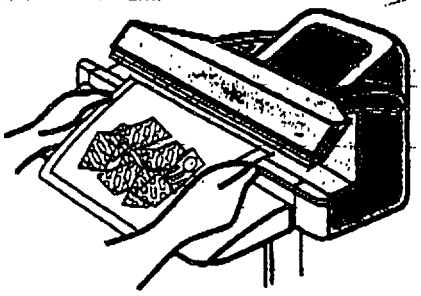
3 After opening master bag.

Spread out the needed quantity on a tray.





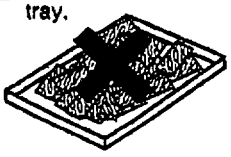
The sachets which are not used should be resealed in a master bag or discarded if their exposure to air exceeds the maximum.

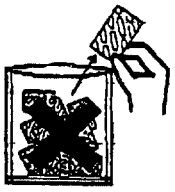


4 Remaining AGELESS®

⚠ The remaining sachets should be resealed in the pouch after pressing out the air.

⚠ Do not pile up AGELESS® in the tray.





⚠ Do not use AGELESS® one by one, leaving the pouch open to air.

Maxmum exposure time to open air.
※loose sachets form

Series	Time (25°C)
Z	4hrs(1hr:Aw<0.55)
S	※1hr
FX	8hrs:RH<70% 4hrs:RH70~90%
E	※4hrs
FL.FC FS	8hrs:RH<70% 4hrs:RH70~90%

- Proper handling and storage is important. Store in cool (below30°C) and dark place to maintain the efficacy of AGELESS® products.
- AGELESS® will become unable to demonstrate the effect expected by absorbing the oxygen in air before packing, if usage is mistaken.
  In order to fully exhibit an effect of AGELESS®, please keep the right handling method.

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AGELESS® Offers a Choice of Manual Insertion or Automatic Dispensing

AGELESS® is packaged to provide the customer maximum convenience.

Manual insertion

Simply place the AGELESS® sachet into the package, taking care that the AGELESS® sachet is not placed behind an insert separator or positioned snug against film or the container wall. Placement of AGELESS® into a free-flowing air stream ensures maximum performance.

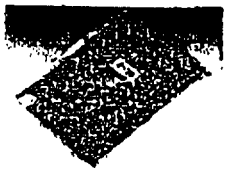
Automatic insertion

The compact, labor-saving AGELESS® sachet dispensing and inserting machine easily attaches onto existing on-line packaging equipment for automatic sanitary placement of AGELESS® application strip sachet into form/fill/seal packages, bottles, jars, pre-made containers and cans. The high-speed machine features accurate, reliable motion to ensure proper cuts.

For sachet styles

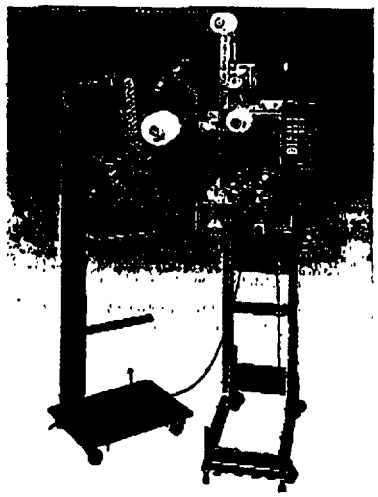
Loose sachets form

Roll form
(for automatic feeding)



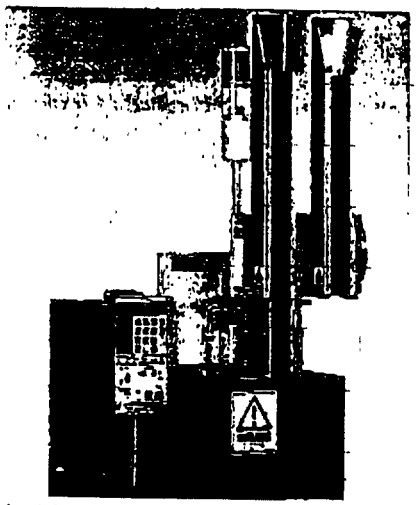
Belt (folded) form
(for automatic feeding)

Cartridge form
(FX-20 type only)



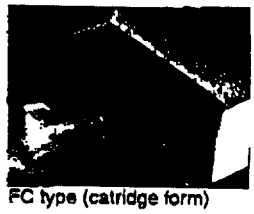
Automatic dispenser for sachet styles

For new styles

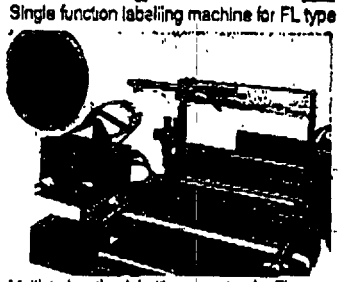


Card dispenser for FC type

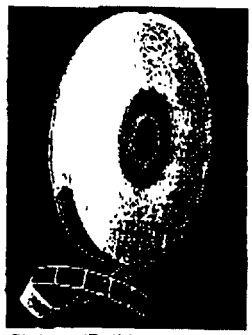
Single function labelling machine for FL type



FC type (catridge form)



Multiple function labelling machine for FL type



FL type (Roll form)

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Q1. Can AGELESS® be used for liquid products?

A. Liquid in an oxygen-permeable container can be stored with AGELESS® in an oxygen-barrier outer package. Even dissolved Oxygen can be absorbed by AGELESS® through the container material after a while.
Note: AGELESS is not designed to be in direct contact with liquid.

Q2. Can AGELESS® be used at low temperature?

A. Lower temperatures slow oxygen absorption rates. However, since product deterioration usually slows down at low temperature while activity of microorganisms also slows down, slower oxygen absorption does not create a problem. We also offer our special type of AGELESS®, which is SS type for frozen foods.

Q3. Can AGELESS® be used with vacuum packages?

A. Since the amount of air is already decreased in a vacuum package, a smaller size AGELESS® can be selected. However, in the case of a strong vacuum ratio, place the AGELESS® into a free air-flow stream, with some distance between the product and the packaging film.

Q4. Can AGELESS® be used with gas purge packaging?

A. AGELESS® can be used with the nitrogen gas replacement system. However, this combination will result in a slow rate of oxygen absorption due to the low initial oxygen concentration; therefore, select a larger size of AGELESS® to compensate for the delay in oxygen absorption. In addition, gas replacement will tend to result in a fluctuating replacement rate; therefore, when using AGELESS® with gas purge, please use a size of AGELESS® larger than the calculated size. Carbon dioxide gas replacement and mixed carbon dioxide-nitrogen gas replacement are not recommended for use with AGELESS®, as carbon dioxide will inhibit the oxygen absorption of AGELESS®.

Q5. Can AGELESS® be used with high-temperature sterilization methods?

A. If AGELESS® is used with high-moisture products in boiling or retort sterilization, the AGELESS® sachet may rupture, depending on the food characteristics, packaging form, and heating conditions, please make a test with the actual packaging material to judge the applicability of use.

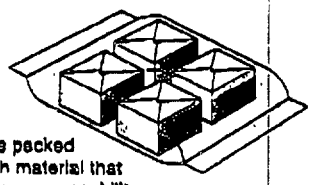
Q6. Will the deoxygenation rate be affected by the location in which AGELESS® is placed in the container?

A. Yes. Generally, AGELESS® will eliminate oxygen more quickly when placed directly on the product. Even with self-reacting AGELESS® types, deoxygenation will take longer when placed under the food tray than if placed on the product; therefore, application tests should be conducted with AGELESS® placed at the chosen locationu under actual conditions.

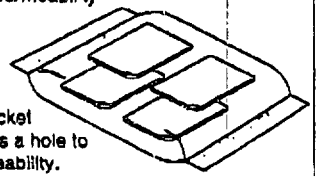
Good types of packing:

The tray has a lot of air space so that air can flow easily.

The tray has split compartments so that air can flow easily.

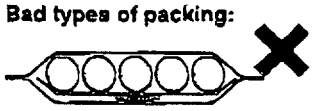


Each item in the cortainer is packed individualy with material that permits good gas permeability

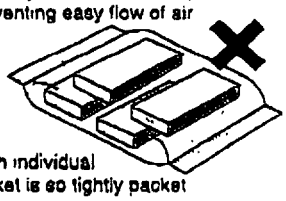


Each individual packet in the container has a hole to improve gas permeability.

Bad types of packing:



The tray has a flat bottom, preventing easy flow of air



Each individual packet is so tightly packet oxygen cannot escape.

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Q7. Sometimes AGELESS® heats up during production packaging; is this normal?

A. If the master bag containing a self-reacting type of AGELESS® is left open, or if the individual packets are taken one by one from the master bag, heat generated from the reactions of AGELESS® may accumulate in the bag, causing the bag to feel hot. Always spread ou the packets on a tray to avoid decreased performance. The roll and belt types may become hot during use, but this will not affect performance as long as they are used within the specified working time.

Q8. I use only a small quantity of AGELESS® at a time. Will opening and closing the master bag affect the performance of AGELESS®?

A. Repeated opening and closing of the master bag is not desirable, as it will cause the AGELESS® to repeatedly come into contact with air. We recommend that you divide the AGELESS® into small quantities and place these in bags constructed from a high gas barrier material so as to reduce the frequency of contact between AGELESS® and the atmosphere.

Q9. We had no problems in winter, but food spoilage occurred sooner when it became warmer.

A. In winter, the air temperature is low and the air is dry; consequently, the ability of microorganisms to propagate is reduced. The amount of microorganisms in the production environment and the initial number of viable bacteria are reduced, and microorganism growth during storage is suppressed; thus, food can be stored efficiently. However, when the weather is warm, microorganisms such as yeast and facultative anaerobes, which can grow in anaerobic conditions, will grow rapidly and may cause earlier food spoilage.

Generally, when AGELESS® is used with food susceptible to the growth of mold and food spoilage, storage testing in winter alone is not sufficient. Please conduct storage testing of the actual packaging material again during seasons with higher air temperatures, reevaluate the type and size of AGELESS® used, and set the expiration date accordingly. Please note that AGELESS® and other oxygen absorbers conduct are not effective in preventing spoilage due to anaerobic microorganisms. You should always carefully test your product to determine whether you have aproblem with these organisms or not.

AGELESS® is Safe to Use

Contents of AGELESS® and the AGELESS-EYE® have been tested and found to be practically non-toxic by Springborn Institute for Bioresearch Inc., United States Testing Company and Japan Food Research Laboratories. (LD_{50} Value of the contents for all types of AGELESS® is greater than16g/kg, which is considered essentially non-toxic.)

- According to an FDA opinion, "There would be no objection to inclusion in packages of food of the oxygen-absorbing sachets.... "They believe "it would be advisable to inform the consumer of the presence of the oxygen-absorbing sachets by labeling on the outside of the food package...."
- In case of misingestion by consumers, advice is available through doctors, hospitals or Poison Control Centers.

The major component of AGELESS® is powdered iron oxide.
AGELESS® is an odorless material that is not meant to be eaten.
Unlike most food preservatives, AGELESS® is not mixed into food.
After use, discard AGELESS® through ordinary disposal methods, with no special treatment required.

- Packaging materials meet CFR-21 regulations.

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Microorganism growth inhibition by AGELESS®

The oxygen absorber AGELESS® inhibits the growth of molds and other aerobic microorganisms, but does not inhibit the growth of obligate anaerobes, microaerophiles, facultative anaerobes, or yeasts. The use of AGELESS® with food products that are preferable to these microorganisms is carried out at your own risk; it is recommended that you conduct tests under actual packaging and distribution conditions, and design a method appropriate to your application, such as combined use with other food preserving methods (e.g., refrigeration). (Note that the growth of some kinds of mold cannot be fully prevented by AGELESS® under certain packaging conditions: (see the following data)

Microorganisms are closely associated with the decomposition and denaturalization of food. Therefore, when using AGELESS® as a food preservation method, it is necessary to be aware of the various kinds of microorganisms, their growth conditions and other characteristics, and the methods for suppressing their growth. Measures must also be in place to prevent fermentation and spoilage.

Kinds of Microorganisms and the effect of AGELESS®

Kinds of microorganisms				Characteristics	Comfortable Suitable Aw range for growth	Effect of AGELESS
Aerobic micro-organisms	Mold	Aspergillus Penicillium	Aflatoxin-producing molds	Unable to grow in anaerobic conditions	0.8 or more	AGELESS markedly inhibits growth
	Aerobic bacteria	Many Bacillus Pseudomonas				
Common Yeasts		Bread yeast Alcohol yeast		Grows well in aerobic conditions, but able to grow in low oxygen concentrations as well	0.8 or more	AGELESS cannot sufficiently inhibit growth
Facultative anaerobes		E. coli	Staphylococcus aureus Vibrio parahaemolyticus Pathogenic E. coli (e.g., O157)	Grows well in aerobic conditions, but able to grow in anaerobic conditions as well		AGELESS cannot inhibit growt
Microaerophiles		Most of lactic acid bacteria	Campylobacter	Grows best in low oxygen concentrations	0.9 or more	
Obligate anaerobes		Bifidobacterium	Clostridium botulinum Clostridium perfringens	Grows in anaerobic conditions		

"Food poisoning microorganisms" are such microorganisms that directly cause adverse effects on the human body. However, other microorganisms, such as some molds, cause adverse effects on the human body through the production of toxins. "Common microorganisms" do not directly cause adverse effects on the human body, but promote food decompostion.Inhibition of microorganisms, including the growth of common microorganisms, is important to maintain the freshness of food.

Precautions to be observed when using AGELESS®

The following precautions are necessary to prevent microorganism growth when AGELESS® is used for food with a water activity of 0.8 or higher.

(1) The expiration date of the food should be decided by tests using the actual packaging, in order to verify the effectiveness of AGELESS® please set an expiration date with an appropriate margin, considering an expiration date obtained without the use of AGELESS® as a reference.
(2) In production of high-moisture foods, with a water activity of 0.9 or higher, it is important to prevent microorganisms from starting of the growth process. Maintain a clean production environment.
(3) For food that is stored and distributed at low temperatures, continue to use the same storage and distribution conditions when used with AGELESS®
(4) If food ingredients are changed, and particularly if water activity has increased, a new set of confirmation tests using AGELESS® must be performed. Storage and distribution methods must be reevaluated as well.
(5) If mold (particularly colored spots of mold) has appeared despite the use of AGELESS® and the absence of pinholes, reevaluate the gas barrier properties of the packaging material.

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Sanitary control of food-production processing

The following sanitary controls must be practiced during the food-production process, regardless of the use of AGELESS®

(1) When resuming the use of production facilities and equipment idled for an extended period, perform a thorough cleaning and disinfection.

(2) Do not open the windows of food production and packaging rooms, even if the room temperature is high.

(3) Vigilance is required in spite of heat-processing, as some microorganisms are highly resistant to high-temperature conditions. Ensure that heat-treatment has been properly carried out.

(4) If food becomes spoiled or fermented despite having undergone heat-processing, examine the heat resistance of the causative microorganisms. If the causative microorganisms show resistance, determine whether the ingredients are contaminated with those microorganisms and take any necessary steps. For microorganisms that do not show resistance, improve the sanitation of the cooling and packaging processes performed following heating processes.

(5) High-moisture ingredients should be used within one day and not saved for the following day. If the ingredients must be saved, store them in a refrigerated or frozen state.

Prevention of botulism

Food poisoning caused by C.botulinum bacteria is highly lethal and must be prevented at all costs. Generally, botulism can be prevented by fulfilling one of the conditions given below. Maintain strict control of sanitation to guard against unforeseen circumstances.

- No contamination of C.botulinum to ingredients during production and distribution
- Storage and distribution temperatures of 3°C or lower, at which temperatures the bacteria cannot propagate
- Heat-disinfection with temperatures of 100°C at the food core for at least 6 hours or at 120°C for at least 4 minutes
- Food characteristics that do not permit growth of C.botulinum: set uniform conditions of water activity of 0.92 or lower (salt concentration ≦12%, sugar concentration≦ 55%) and pH of 4.5 or lower or 9.1 or higher
- Detoxification of toxins produced by C.botulinum by heating the core of food to 80°C for at least 20 minutes or to 100°C for at least 2 to 3 minutes
- To develop a procedure for avoiding C. botulinum, please contact your own commercial or industrial association, or local health service for specific procedures and applicability to any particular product.

Precautions for AGELESS® Use

Do not use in microwave ovens

AGELESS® must be removed from products before they are heated in a microwave oven. If a product containing AGELESS® is microwaved, the AGELESS® may spark, scorch the packaging, and in some cases ignite packaging material. Precautionary labeling should be used for products containing AGELESS® that are likely to be microwaved. Microwave-compatible types of AGELESS® are available; contact your sales representative for further information.

AGELESS® and Heat generation

Heat may be noticeable upon opening of a food package containing AGELESS.® This is due to the oxidation reactions of AGELESS.® However, the amount of heat generated is not sufficient to cause ignition.

AGELESS® and food discoloration

Products such as raw meat, red fish, processed squid, and Chinese noodles may show a brown discoloration when used with AGELESS.® Please make tests before using AGELESS® under actual packaging conditions.

Before using AGELESS®

Read this product manual prior to use. Always conduct application tests using actual packaging conditions to verify the effectiveness of AGELESS® prior to use.

If you have any questions about the effects of AGELESS®, do not hesitate to contact your AGELESS® distributor or sales office.

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AGELESS®

DNV

Accredited by the RvA

ISO 14001 REGISTERED FIRM

DNV Certification B.V., THE NETHERLANDS

ISO 9001 and 14001 CERTIFICATED

MITSUBISHI GAS CHEMICAL COMPANY, INC.

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e-mail:mgcsin@singnet.com.sg

- The infomation contained herein is general and should not take the place of the users' own application tests. Recommendations are made without guarantee, and we must necessarily disclaim all liability with respect to the use of AGELESS® supplied by MITSUBISHI GAS CHEMICAL COMPANY, INC. since the conditions of use are beyond our control.
- It is recommended that users of AGELESS® should carry out application tests with actual materials and equipment.
- It is advisable, according to the FDA, to inform the consumer of the presence of the oxygen-absorbing sachets by labeling on the outside of the food package so that a consumer does not mistake AGELESS® as a food or as an ingredient.

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MITSUBISHI GAS CHEMICAL COMPANY, INC.

Mitsubishi Building, 5-2, Marunouchi 2-chome, Chiyoda-ku, Tokyo, 100-8324, Japan
Telephone: Tokyo 5283- FAX:

QUALITY CERTIFICATE

Item : Oxygen Absorber, AGELESS ZPT-100EC
Shipping to : YAIL NOA LTD.

Date of Issue : 03rd Mar., 2005
Date of Shipment : 05th Mar., 2005

Test item	Spec. / Lot No.	4350FB	—
Package integrity	No leakage of powder	Passed	
Seal strength	More than 4.9 N/15mm [0.5 kgf/15mm]	Within spec.	
Oxygen absorption ability *	Less than 0.1 [vol.%]	Less than 0.1	
Judgment		Passed	

* Each pouch absorbs oxygen down to less than 0.1vol.% within 72 hours from 500ml of air at 25℃.

We hereby certify that AGELESS herein described has been manufactured in accordance with the standard.

MITSUBISHI GAS CHEMICAL COMPANY, INC.

(b)(6)

Masahito WATANABE
Manager, Quality Assurance Section,
AGELESS Department, Tokyo Factory.

11.03.05

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SU

September 25, 2006 REC'D SEP 27 2006

Laura Tarantino, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
Phone: (202)-418-3090

Dear Dr. Tarantino,

Please find enclosed a signed original and copy of the "Lyco-O-Mato® Powder GRAS Notification Amendment". Please feel free to contact me with any questions or comments.

Sincerely,

(b)(6)

J. David Luedeke, M.S.
Research Associate/Project Manager
Burdock Group
2001 9th Avenue
Suite 301
Vero Beach, FL 32960
Phone: 772-562-3900
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000211

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September 15, 2006

REC'D SEP 27 2006

Laura Tarantino, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Lyco-O-Mato® Powder GRAS Notification Amendment

Dear Dr. Tarantino:

As representative of the notifier, LycoRed Ltd. [LycoRed Natural Products Industries, Ltd.], Hebron Road – Industrial Zone, P.O. Box 320, Beer Sheva – 84102 Israel; Burdock Group, by this letter, is providing the Food and Drug Administration (FDA) a notice of intention to delete several food categories specifically and previously cited for the addition of tomato pulp powder (Lyc-O-Mato® Powder), the subject of a prior GRAS notification (GRN 000163[1]). In place of those deleted food use categories, another category will be substituted. This substitution of categories does not increase the Estimated Daily Intake described and is supported by the safety studies cited in the previous GRAS notification (GRN 000163).

The FDA has previously reviewed the GRAS status of tomato pulp powder for use in baked goods, ground meat products, meat analogues (vegetable protein-based), dairy products, soups, and sauces (GRN 000163). The GRN 000163 letter, dated August 8, 2005, acknowledged that the Agency had no further questions concerning the determination that the substance was GRAS for these uses. The Agency also stated in that letter that the common and usual name for the notified substance was tomato pulp powder. The substance trade name, Lyc-O-Mato® Powder, is composed of tomato pulp, containing lycopene, proteins, sugars, dietary fibers, lipids, and other carotenoids. The specifications for tomato pulp powder have not changed from the original notification.

Tomato pulp powder (as indicated in GRN 000163) is intended to be used to increase the consumption of lycopene in the diet when incorporated into the following food applications: baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups, and sauces. These foods are identified in GRN 000163, according to food codes given in the U.S. Department of Agriculture (USDA) 1994-1996, 98 Continuing Survey of

[1] See attached copy of the Notification Letter.

Food Intakes by Individuals (CSFII, 94-96, 98), and these codes have been used to calculate the Estimated Daily Intake (EDI) values for lycopene consumption. Other GRAS Notices concerning lycopene have been filed with the FDA, but due to the self-limiting nature of lycopene (*i.e.*, may cause an undesirable red color or tomato-like taste), lycopene from more than one source would not likely be added to a food product.

The previous GRAS notification (GRN 000163) for tomato pulp powder indicated that the powder consists of tomato pulp, containing lycopene, proteins, sugars, dietary fibers, lipids, and other carotenoids. GRN 000163 identified the mean and 90th percentile consumption of lycopene from the proposed food codes as 20.0 and 35.9 mg/day/person, respectively (GRN 000163). The previous GRAS notification (GRN 000163) estimated that the consumption of lycopene that occurs naturally in currently consumed foods is at a mean and 90th percentile of 6.1 and 13.7 mg/person/day, respectively. Lycopene consumed as a color additive, at the mean and 90th percentile, is estimated at 5.3 and 9.2 mg/day, respectively, with the average and high potential dietary supplement ingestion at 30 and 60 mg/person/day, respectively. The existing GRAS (GRN 000163) calculated the total high lycopene intake from these sources at 118.8 mg/person/day.

LycoRed Ltd. has recently determined the utility of the addition of tomato pulp powder to some of the foods presented in GRN 000163 APPENDIX A, to be impractical and nonviable in the marketplace and therefore do not contribute to lycopene exposure. In place of those abandoned food codes, LycoRed Ltd. will advise it's users that the GRAS determination now supports the remaining categories, and those food categories (beverages) presented in APPENDIX B. The addition of the new products does not change the estimated level of lycopene consumption stated in GRN 000163.

The concentration of tomato pulp powder added to the revised and expanded food categories (*i.e.*, remaining food codes from GRN 000163 and the expanded food categories presented in APPENDIX B) is presented in APPENDIX C. The mean daily intake of lycopene from the addition of tomato pulp powder to the revised foods (APPENDIX C) *via* the addition of the tomato pulp powder is 15.33 mg/day, with the 90th percentile consumption calculated at 28.92 mg/day. The amount of lycopene consumed from each food code, as estimated from the CSFII consumption database,[2] is presented in APPENDIX D. Consumption of lycopene at the mean and 90th percentile of 15.33 and 28.92 mg/day, respectively, from the addition of tomato pulp powder to the revised foods alters the average and high lycopene consumption to 56.73 and 111.82 mg/kg/day, respectively. This consumption level still allows for the overall daily consumption of lycopene to remain within the Acceptable Daily Intake (ADI) of 120 mg/day, as specified in the original GRAS dossier (GRN 000163).

Tomato pulp powder is composed of the same substance previously notified, and reference is made to the original submission (GRN 000163). Summaries of the safety data are also referenced in the original GRAS submission (GRN 000163), as a general recognition of safety. Additional preclinical and clinical studies have been published since the first GRAS notification that evaluates the effects of lycopene or tomato extract consumption, and are summarized in

[2] CSFII 1994-96 (2000) *Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96, 98.* Agricultural Research Service, US Department of Agriculture, Washington, DC. CD-ROM.

APPENDIX E. No adverse effects were noted in any of the preclinical or clinical studies published since the original GRAS submission. The Expert Panel that initially evaluated the available information on tomato pulp powder and concluded that tomato pulp powder, meeting food grade specifications and produced in accordance with current Good Manufacturing Practice (cGMP), was GRAS by scientific procedures for supplementing the diet with lycopene, was requested to reassess the GRAS status of tomato pulp powder in light of the proposed new uses in addition to permitted uses, and the removal of several categories (please see below).

In conclusion, the initial GRAS determination (GRN 000163) for tomato pulp powder employed an acceptable daily intake (ADI) of 120 mg/day lycopene, with the consumption of lycopene from the addition of tomato pulp powder at a mean and 90th percentile of 20.0 and 35.9 mg/person/day, respectively. This report shows that the requested removal of specified foods, and the addition of other foods and beverages, results in an estimated daily intake of lycopene from added tomato pulp powder at a mean and 90th percentile of 15.33 and 28.92 mg/person/day, still below the expected intake of lycopene from the addition of tomato pulp powder outlined in GRN 000163. Consequently, it is concluded that the use of tomato pulp powder, in the proposed substituted food categories, remains consistent with the safety data cited in the first GRAS determination (GRN 000163).

This GRAS notification is based on published, generally available and accepted scientific data, information, methods and principles, as well as experience based on common use in foods. LycoRed Ltd. has determined that the use of tomato pulp powder as an ingredient to supplement the diet with lycopene, is GRAS, and therefore, it is exempt from the premarket approval requirements of the Food, Drug and Cosmetic Act.

Sincerely,

(b)(6)

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An Evaluation of the Revised Uses of Tomato Pulp Powder (Lyc-O-Mato® Powder) By an Independent Expert GRAS Panel

This independent expert GRAS panel initially critically evaluated the available information on tomato pulp powder (trade name: Lyc-O-Mato® Powder) and concluded that tomato pulp powder, meeting food grade specifications and produced in accordance with current Good Manufacturing Practice (cGMP), was GRAS by scientific procedures for supplementing the diet with lycopene. The Expert Panel was requested to reassess the GRAS status of tomato pulp powder in light of the proposed new uses in addition to permitted uses, and the removal of several categories. Previous GRAS uses of tomato pulp powder include baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups and sauces, as allowed under the standards of identity. The foods to be abandoned are presented in APPENDIX A, with the expanded food uses presented in APPENDIX B (beverages). The Expert Panel members independently evaluated the new exposure data and additional published safety information (APPENDIX E) prior to unanimously concluding that the available information supports the GRAS status of tomato pulp powder for the proposed new uses (APPENDIX C). The additional information raised no safety concerns and was considered complementary to previous information.

The Expert Panel independently and collectively critically evaluated information generated since the first GRAS review. This information is consistent with that provided in the first GRAS determination and fully supports the GRAS status of tomato pulp powder. The Expert Panel has also evaluated the estimated consumption data for the proposed expanded uses of the tomato pulp powder. It is estimated that the consumption of lycopene that occurs naturally in currently consumed foods is at a mean and 90th percentile of 6.1 and 13.7 mg/person/day, respectively. The estimated consumption from existing GRAS uses, at the mean and 90th percentile of eaters only for the total population, is 20.0 and 35.9 mg/person/day, respectively. Lycopene consumed as a color additive, at the mean and 90th percentile, is estimated at 5.3 and 9.2 mg/day, respectively, with the average and high potential dietary supplement ingestion at 30 and 60 mg/person/day, respectively. The existing GRAS (GRN 000163) calculated the total high lycopene intake from these sources at 118.8 mg/person/day. The changes in the foods that the tomato pulp powder will be added (APPENDIX C) alters the consumption of lycopene, as a food ingredient, to a mean and 90th percentile intake of 15.33 and 28.92 mg/person/day, respectively. This alters the average and high lycopene consumption to 56.73 and 111.82 mg/kg/day, respectively. The Expert Panel has considered these values, and has determined that the safety evaluation from the initial GRAS (GRN 000163) may be applied to the revised food categories, since the consumption for the proposed new uses are within the ADI value of the initial GRAS determination.

The consumption estimates for these categories collectively are within the consumption estimates for the original GRAS determination. Consequently, the added categories do not raise the estimated exposure values beyond the original GRAS determination. Based on the aggregate information and data presented in this document, we, the Expert Panel, conclude that tomato pulp powder, meeting appropriate food grade specifications and produced in accordance with current Good Manufacturing Practice, is Generally Recognized As Safe (GRAS) by scientific

procedures, when used in the specified baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups and sauces, and beverages.

(b)(6)

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Burdock Group

15 Sept 06
Date

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Clare M. Hasler, Ph.D.

9/18/06
Date

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Tufts University School of Medicine

9/20/06
Date

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APPENDIX A

Foods removed from the original tomato pulp powder GRAS dossier (GRN 000163)

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
11220000	MILK CONDENSED SWEETENED NS AS TO DILUTION	0.0125
11220100	MILK CONDENSED SWEETENED UNDILUTED	0.0125
11220200	MILK CONDENSED SWEETENED DILUTED	0.0125
11410000	YOGURT NS AS TO TYPE OF MILK/FLAVOR	0.0133
11411010	YOGURT PLAIN NS AS TO TYPE OF MILK	0.0133
11411100	YOGURT PLAIN WHOLE MILK	0.0133
11411200	YOGURT PLAIN LOWFAT MILK	0.0133
11411300	YOGURT PLAIN NONFAT MILK	0.0133
11420000	YOGURT VANILLA LEMON COFFEE NS AS TO MILK TYPE	0.0133
11421000	YOGURT VANILLA LEMON COFFEE WHOLE MILK	0.0133
11422000	YOGURT VANILLA LEMON COFFEE LOWFAT MILK	0.0133
11423000	YOGURT VANILLA LEMON COFFEE NONFAT MILK	0.0133
11424000	YOGURT VANILLA LEMON COFFEE NONFAT MILK LOW CAL SWEET	0.0133
11425000	YOGURT CHOCOLATE NS AS TO TYPE OF MILK	0.0133
11427000	YOGURT CHOCOLATE NONFAT MILK	0.0133
11460100	YOGURT FROZEN CHOCOLATE TYPE OF MILK NS	0.0133
11460160	YOGURT FROZEN CHOCOLATE LOWFAT MILK	0.0133
11460190	YOGURT FROZEN NS AS TO FLAVOR NONFAT MILK	0.0133
11460200	YOGURT FROZEN CHOCOLATE NONFAT MILK	0.0133
11460400	YOGURT FRZ CHOCOLATE NONFAT MILK W/ LOW-CAL SWEET	0.0133
11460430	YOGURT FROZEN CHOCOLATE WHOLE MILK	0.0133
11461270	YOGURT FROZEN CONE NOT CHOCOLATE LOWFAT MILK	0.0133
11511000	MILK CHOCOLATE NFS	0.0125
11511100	MILK CHOCOLATE WHOLE MILK BASED	0.0125
11511200	MILK CHOCOLATE REDUCED FAT MILK BASED	0.0125
11511300	MILK CHOCOLATE SKIM MILK BASED	0.0125
11512000	COCOA HOT CHOCOLATE NOT FROM DRY MIX W/WHOLE MILK	0.0125
11512500	HOT CHOCOLATE DRINK W/ EVAP MILK PUERTO RICAN	0.0125
11513000	COCOA & SUGAR MIXTURE MILK ADDED NS TYPE MILK	0.0125
11513100	COCOA & SUGAR MIXTURE WHOLE MILK ADDED	0.0125
11513200	COCOA & SUGAR MIXTURE LOWFAT MILK ADDED	0.0125
11513300	COCOA & SUGAR MIXTURE SKIM MILK ADDED	0.0125
11514100	COCOA SUGAR & DRY MILK MIXTURE WATER ADDED	0.0125
11514300	COCOA W/ NF DRY MILK LO CAL SWEETENER WATER ADDED	0.0125
11516000	COCOA WHEY LO CAL SWEETNER MIX LOWFAT MILK ADDED	0.0125

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
11520000	MILK MALTED UNFORTIFIED FLAVOR NS	0.0125
11525000	MILK MALTED FORTIFIED NATURAL FLAVOR (INCL OVALTINE	0.0125
11526000	MILK MALTED FORTIFIED CHOCOLATE (INCL OVALTINE)	0.0125
11527000	MILK MALTED FORTIFIED (INCL OVALTINE)	0.0125
11531000	EGGNOG MADE W/ WHOLE MILK (INCLUDE EGG NOG NFS)	0.0125
11541000	MILK SHAKE NS AS TO FLAVOR OR TYPE	0.0125
11541110	MILK SHAKE HOMEMADE OR FOUNTAIN-TYPE CHOCOLATE	0.0125
11541120	MILK SHAKE HOMEMADE/FOUNTAIN-TYPE NOT CHOCOLATE	0.0125
11541400	MILK SHAKE WITH MALT (INCL MALTED MILK W/ICE CREAM)	0.0125
11541500	MILK SHAKE MADE W/ SKIM MILK CHOCOLATE	0.0125
11541510	MILK SHAKE MADE W/ SKIM MILK NOT CHOCOLATE	0.0125
11542100	CARRY-OUT MILK SHAKE CHOCOLATE	0.0125
11542200	CARRY-OUT MILK SHAKE NOT CHOCOLATE	0.0125
11560000	CHOC-FLAVORED DRINK WHEY-&MILK-BASED(INCL YOO-HOO)	0.0125
11612000	INSTANT BREAKFAST POWDER MILK ADDED	0.0125
11613000	INSTANT BFAST PWDR SWT W/ LO CAL SWT MILK ADDED	0.0125
11623000	MEAL SUPPLEMENT / REPLACEMENT PREPARED RTD	0.0125
11810000	MILK DRY NOT RECONSTITUTED NS AS TO FAT	0.0125
11811000	MILK DRY WHOLE NOT RECONSTITUTED	0.0125
11812000	MILK DRY LOWFAT NOT RECONSTITUTED	0.0125
11813000	MILK DRY NONFAT NOT RECONSTITUTED	0.0125
11830100	COCOA W/DRY MILK & SUGAR DRY MIX NOT RECONST	0.0125
11830110	COCOA POWDER W/ NFD MILK LOW CAL SWEETENER DRY	0.0125
11830150	COCOA POWDER NOT RECONSTITUTED (NO DRY MILK)	0.0125
11830160	COCOA-FLAVORED BEVERAGE POWDER W/ SUGAR DRY MIX	0.0125
11830210	MILK MALTED DRY FORTIFD NOT RECONST NOT CHOC	0.0125
11830260	MILK MALTED DRY FORTIFIED NOT RECONST CHOC	0.0125
12100100	CREAM FLUID NS AS TO LIGHT HEAVY OR HALF & HALF	0.2
12110100	CREAM LIGHT FLUID (INCL COFFEE CRM TABLE CREAM)	0.2
12120100	CREAM HALF & HALF	0.1
12130100	CREAM HEAVY FLUID	0.1
12140000	CREAM HEAVY WHIPPED SWEETENED	0.1
12140100	CREAM WHIPPED PRESSURIZED CONTAINER	0.2
12310100	SOUR CREAM (INCL W/ CHIVES)	0.1
12310300	SOUR CREAM REDUCED FAT	0.1
12310350	SOUR CREAM LIGHT	0.1
12310370	SOUR CREAM FAT FREE	0.1

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
12320200	SOUR CREAM FILLED SOUR DRESSING NONBUTTERFAT	0.1
12350000	DIP SOUR CREAM BASE (INCLUDE BUTTERMILK-TYPE DIP)	0.1
12350020	DIP SOUR CREAM BASE REDUCED CALORIE	0.1
12350100	SPINACH DIP SOUR CREAM BASE	0.1
13110000	ICE CREAM NFS	0.3158
13110110	ICE CREAM REGULAR CHOCOLATE	0.3158
13110130	ICE CREAM RICH CHOCOLATE	0.3158
13110210	ICE CREAM SOFT SERVE CHOCOLATE	0.3158
13120100	ICE CREAM BAR/STICK CHOCOLATE COVERED	0.3158
13120121	ICE CREAM BAR RICH ICE CREAM THICK CHOC COVER	0.3158
13120140	ICE CREAM BAR/STICK CHOC ICE CREAM CHOC COVER	0.3158
13120300	ICE CREAM BAR CAKE-COVERED	0.3158
13120500	ICE CREAM SANDWICH	0.3158
13120550	ICE CREAM COOKIE SANDWICH (INCLUDE CHIPWICH)	0.3158
13120710	ICE CREAM CONE CHOC-COVERED W/ NUTS NOT CHOC	0.3158
13120720	ICE CREAM CONE CHOC-COVERED OR DIPPED NOT CHOC	0.3158
13120730	ICE CREAM CONE NO TOPPING NOT CHOCOLATE	0.3158
13120770	ICE CREAM CONE NO TOPPING CHOCOLATE ICE CREAM	0.3158
13120790	ICE CREAM SUNDAE CONE (INCL DRUMSTICK ALL FLAVORS)	0.3158
13120800	ICE CREAM SODA NOT CHOCOLATE	0.3158
13121300	ICE CREAM SUNDAE CHOCOLATE TOPPING W/ WHIPPED CREAM	0.3158
13122500	ICE CREAM PIE COOKIE CRUST FUDGE TOPPING WHIP CREAM	0.3158
13130310	LIGHT ICE CREAM CHOCOLATE (FORMERLY ICE MILK)	0.3158
13130360	LIGHT ICE CREAM PREMIUM CHOCOLATE (FORMERLY ICE MILK)	0.3158
13130590	LIGHT ICE CREAM SOFT SERVE NS FLAVOR (FORMERLY ICE MILK)	0.3158
13130610	LIGHT ICE CREAM SOFT SERVE CHOC (TASTEE FRZ DAIRY QUEEN)	0.3158
13130630	LIGHT ICE CREAM SOFT SERVE CONE CHOC (FORMERLY ICE MILK)	0.3158
13140100	LIGHT ICE CREAM BAR/STICK CHOC-COATED (FORMERLY ICE MILK)	0.3158
13140550	LIGHT ICE CREAM CONE CHOCOLATE (FORMERLY ICE MILK)	0.3158
13140660	LIGHT ICE CREAM SUNDAE CHOC / FUDGE TOP (W/O WHIP CREAM)	0.3158
13140680	LIGHT ICE CREAM SUNDAE NO FRUIT/CHOC TOP (W/O WHIP CREAM)	0.3158
13140900	LIGHT ICE CREAM FUDGESICLE (FORMERLY ICE MILK)	0.3158
13160150	MILK DESSERT FROZ NONFAT W/ LOW CAL SWEETENER CHOCOLATE	0.3158

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
13160210	MILK DESSERT FROZEN LOWFAT CHOCOLATE	0.3158
13160410	MILK DESSERT FROZ MILK-FAT FREE CHOC	0.3158
13160650	MILK DESSERT FROZ W/ LOW CAL SWEETENER CHOCOLATE	0.3158
13161630	LIGHT ICE CREAM BAR/STICK W/ LOW-CAL SWEETENER CHOC COAT	0.3158
13200110	PUDDING NFS	0.3158
13210110	PUDDING BREAD (INCLUDE W/ RAISINS)	0.3158
13210220	PUDDING CHOCOLATE RTE NS FROM DRY MIX OR CANNED	0.3158
13210280	PUDDING NOT CHOC RTE NS FROM DRY MIX OR CANNED	0.3158
13210290	PUDDING NOT CHOC RTE LO CAL W/ ART SWTNER	0.3158
13210350	CUSTARD PUERTO RICAN STYLE (FLAN)	0.3158
13210410	PUDDING RICE	0.3158
13210450	PUDDING RICE FLOUR W/ NUTS (INDIAN DESSERT)	0.3158
13210500	PUDDING TAPIOCA MADE FROM HOME RECIPE MADE W/ MILK	0.3158
13210520	PUDDING TAPIOCA MADE FROM DRY MIX MADE W/ MILK	0.3158
13210710	PUDDING INDIAN (MILK MOLASSES CORNMEAL-BASED)	0.3158
13220110	PUDDING NOT CHOCOLATE PREPARED FROM DRY MIX MILK ADDED	0.3158
13220120	PUDDING CHOCOLATE PREPARED FROM DRY MIX MILK ADDED	0.3158
13220210	PUDDING NOT CHOC FROM DRY LOW CAL ARTIFICIAL SWEET W/MILK	0.3158
13220220	PUDDING CHOC FROM DRY LOW CAL ARTIFICIAL SWEET MILK ADDED	0.3158
13220235	PUDDING CAN CHOC FAT FREE	0.3158
13220245	PUDDING CANNED NOT CHOC FAT FREE	0.3158
13230110	PUDDING CANNED NOT CHOCOLATE	0.3158
13230130	PUDDING CANNED CHOCOLATE	0.3158
13230200	PUDDING CANNED CHOC & NON-CHOC FLAVORS COMBINED	0.3158
13230500	PUDDING CANNED TAPIOCA	0.3158
13230510	PUDDING CANNED TAPIOCA FAT FREE	0.3158
13241000	PUDDING W/ FRUIT & VANILLA WAFERS	0.3158
13250000	MOUSSE CHOCOLATE	0.3158
13250100	MOUSSE NOT CHOCOLATE	0.3158
13252500	BARFI/BURFI INDIAN DESSERT FROM MILK/CREAM/RICOTTA	0.3158
13411000	WHITE SAUCE MILK SAUCE	0.0638
13412000	MILK GRAVY QUICK GRAVY	0.0638
14200100	CHEESE COTTAGE NFS	0.0273
14201010	CHEESE COTTAGE CREAMED	0.0273
14201200	COTTAGE CHEESE FARMER'S	0.0273

000222

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
14202010	CHEESE COTTAGE W/ FRUIT	0.0273
14203010	CHEESE COTTAGE DRY CURD	0.0273
14203020	CHEESE COTTAGE SALTED DRY CURD	0.0273
14203510	P.R. WHITE CHEESE (QUESO DEL PAIS BLANCO)	0.0545
14204010	CHEESE COTTAGE LOWFAT	0.0273
14204030	CHEESE COTTAGE LOWFAT W/ VEGETABLES	0.0273
14205010	CHEESE COTTAGE LOW SODIUM	0.0273
14206010	CHEESE COTTAGE LOWFAT LOW SODIUM	0.0273
14210000	CHEESE YOGURT NFS	0.0316
14301010	CHEESE CREAM	0.1
14303010	CHEESE CREAM LOWFAT	0.1
14501010	IMITATION CREAM CHEESE	0.1
14502010	IMITATION CHEESE AMERICAN OR CHEDDAR TYPE	0.1
14502040	IMITATION CHEESE AMER/CHEDDAR TYPE LOW CHOLESTERO	0.1
14610210	COTTAGE CHEESE W/ GELATIN DESSERT & FRUIT	0.0273
14620100	DIP CREAM CHEESE BASE	0.1
14620120	SHRIMP DIP CREAM CHEESE BASE (INCL CLAM DIP)	0.1
14650160	ALFREDO SAUCE	0.0638
14660200	CHEESE NUGGETS FRIED (INCL BANQUET BRAND)	0.1
14710100	CHEDDAR CHEESE SOUP	0.0122
20000200	GROUND MEAT NFS	0.0353
21304200	BEEF SHORTRIBS BBQ W/ SAUCE NS AS TO FAT	0.0214
21304210	BEEF SHORTRIBS BBQ W/ SAUCE LEAN & FAT	0.0214
21304220	BEEF SHORTRIBS BBQ W/ SAUCE LEAN ONLY	0.0214
21500000	GROUND BEEF RAW	0.0353
21500100	GROUND BEEF OR PATTY	0.0353
21500110	GROUND BEEF MEATBALLS MEAT ONLY NS AS TO REG/LEAN	0.0353
21500200	GROUND BEEF OR PATTY BREADED COOKED	0.0353
21501000	GROUND BEEF REGULAR COOKED	0.0353
21501200	GROUND BEEF LEAN COOKED	0.0353
21501300	GROUND BEEF EXTRA LEAN COOKED	0.0353
21540100	GROUND BEEF W/ TEXTURED VEGETABLE PROTEIN COOKED	0.0353
22002000	PORK GROUND OR PATTY COOKED	0.0353
22002100	PORK GROUND GROUND OR PATTY BREADED COOKED	0.0353
22321110	HAM SMOKED OR CURED GROUND PATTY	0.0353
22701030	PORK SPARERIBS BBQ W/ SAUCE NS FAT EATEN	0.0214
22701040	PORK SPARERIBS BBQ W/ SAUCE LEAN & FAT EATEN	0.0214
22701050	PORK SPARERIBS BBQ W/ SAUCE LEAN ONLY EATEN	0.0214

000223

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
23322100	DEER BOLOGNA	0.0545
24198720	CHICKEN GROUND	0.0353
24207000	TURKEY GROUND	0.0353
25220100	BEEF SAUSAGE NFS	0.0545
25220110	BEEF SAUSAGE BROWN & SERVE LINKS COOKED	0.0545
25220120	BEEF SAUSAGE SMOKED STICK (INCLUDE BEEF JERKY)	0.0545
25220130	BEEF SAUSAGE SMOKED	0.0545
25220140	BEEF SAUSAGE FRESH BULK PATTY OR LINK COOKED	0.0545
25220350	BRATWURST COOKED	0.0545
25220360	BRATWURST W/ CHEESE	0.0545
25220390	BOLOGNA BEEF LOW FAT	0.0545
25220400	BOLOGNA PORK AND BEEF	0.0545
25220410	BOLOGNA NFS	0.0545
25220420	BOLOGNA LEBANON	0.0545
25220430	BOLOGNA BEEF	0.0545
25220440	BOLOGNA TURKEY	0.0545
25220460	BOLOGNA PORK	0.0545
25220470	BOLOGNA BEEF LOWER SODIUM	0.0545
25220480	BOLOGNA CHICKEN BEEF & PORK	0.0545
25220500	BOLOGNA BEEF & PORK LOWFAT	0.0545
25220510	CAPICOLA	0.0353
25220650	CHICKEN & BEEF SAUSAGE SMOKED	0.0545
25220710	CHORIZOS	0.0353
25220910	HEAD CHEESE	0.0353
25221110	KNOCKWURST	0.0545
25221250	PEPPERONI	0.0545
25221310	POLISH SAUSAGE	0.0545
25221350	ITALIAN SAUSAGE	0.0545
25221400	SAUSAGE (NOT COLD CUT) NFS	0.0545
25221410	PORK SAUSAGE FRESH BULK PATTY OR LINK COOKED	0.0545
25221420	PORK SAUSAGE BROWN & SERVE COOKED	0.0545
25221430	PORK SAUSAGE COUNTRY STYLE FRESH COOKED	0.0545
25221460	PORK & BEEF SAUSAGE	0.0545
25221470	PORK & BEEF SAUSAGE BROWN & SERVE COOKED	0.0545
25221480	METTWURST	0.0353
25221500	SALAMI NFS	0.0545
25221510	SALAMI SOFT COOKED	0.0545
25221520	SALAMI DRY OR HARD	0.0545

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
25221530	SALAMI BEEF	0.0545
25221610	SCRAPPLE COOKED	0.0353
25221650	SMOKED LINK SAUSAGE PORK	0.0545
25221660	SMOKED LINK SAUSAGE PORK & BEEF	0.0545
25221680	SMOKED SAUSAGE PORK	0.0545
25221810	THURINGER (INCLUDE SUMMER SAUSAGE)	0.0545
25221840	TURKEY BREAKFAST SAUSAGE BULK	0.0545
25221850	TURKEY SAUSAGE SMOKED	0.0545
25221870	TURKEY&PORK SAUSAGE FRESH BULK PATTY OR LINK COOKED	0.0545
25221880	TURKEY PORK & BEEF SAUSAGE REDUCED FAT SMOKED	0.0545
25221890	TURKEY PORK & BEEF SAUSAGE LOWFAT SMOKED	0.0545
25221910	VIENNA SAUSAGE CANNED	0.0545
25221920	VIENNA SAUSAGE CHICKEN CANNED	0.0545
25230110	LUNCHEON MEAT NFS	0.0545
25230210	HAM SLICED PREPACKAGED OR DELI LUNCHEON MEAT	0.0545
25230220	HAM SLICED LOW SALT PREPACKAGED/DELI LUNCH MEAT	0.0545
25230230	HAM SLICED EXTRA LEAN PREPACKAGED/DELI	0.0545
25230310	CHICKEN/TURKEY LOAF PREPACK/DELI LUNCHEON MEAT	0.0545
25230510	HAM LUNCH MEAT CHOP MINCED PRESSD MINCED NOT CANNED	0.0545
25230520	HAM LUNCHEON MEAT CHOPPED SPICED LOWFAT NOT CAN	0.0545
25230530	HAM/PORK LUNCHEON MEAT CHOPPED CAN (INCL SPAM)	0.0545
25230560	LIVERWURST	0.0545
25230610	LUNCHEON LOAF (OLIVE PICKLE OR PIMIENTO)	0.0545
25230710	SANDWICH LOAF LUNCHEON MEAT	0.0545
25230790	TURKEY HAM SLICED XTRA LEAN PKG'D DELI	0.0545
25230800	TURKEY HAM	0.0545
25230810	VEAL LOAF	0.0545
25230820	TURKEY PASTRAMI	0.0545
25230840	TURKEY SALAMI	0.0545
25230900	TURKEY OR CHICKEN BREAST PKG'D/DELI LUNCHEON MEAT	0.0545
25231110	BEEF SLICED PREPACKAGED/DELI LUNCHEON MEAT	0.0545
25231150	CORNED BEEF PRESSED	0.0545
25240000	MEAT SPREAD OR POTTED MEAT NFS	0.0545
25240110	CHICKEN SALAD SPREAD	0.0353
25240210	HAM DEVILED OR POTTED	0.0353
27113300	SWEDISH MEATBALLS W/ CREAM OR WHITE SAUCE (MIXTURE)	0.0214
27114000	BEEF W/ (MUSHROOM) SOUP (MIXTURE)	0.0122

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
27115000	BEEF W/ SOY-BASED SAUCE (MIXTURE)	0.0214
27115100	STEAK TERIYAKI W/ SAUCE (MIXTURE)	0.0214
27116200	BEEF W/ BARBECUE SAUCE (MIXTURE)	0.0214
27116300	BEEF W/ SWEET & SOUR SAUCE (MIXTURE)	0.0214
27116350	STEWED SEASONED GROUND BEEF MEXICAN	0.0353
27116400	STEAK TARTARE (RAW GROUND BEEF & EGG)	0.0353
27120030	HAM/PORK W/ BARBECUE SAUCE	0.0214
27120090	HAM/PORK W/ (MUSHROOM) SOUP-BASE SAUCE (MIXTURE)	0.0214
27120150	PORK OR HAM W/ SOY-BASED SAUCE (MIXTURE)	0.0214
27141000	CHICKEN CACCIATORE (INCLUDE CHICKEN W/TOMATO SAUCE)	0.0214
27143000	CHICKEN OR TURKEY W/ CREAM SAUCE (MIXTURE)	0.0214
27144000	CHICKEN W/ (MUSHROOM) SOUP-BASED SAUCE (MIXTURE)	0.0214
27146000	CHICKEN W/ BARBECUE SAUCE (MIXTURE)	0.0214
27146200	CHICKEN W/ CHEESE SAUCE (MIXTURE)	0.0214
27150110	SHRIMP COCKTAIL (SHRIMP W/ COCKTAIL SAUCE)	0.0214
27150140	CLAM SAUCE WHITE	0.1
27150160	SHRIMP W/ LOBSTER SAUCE (MIXTURE)	0.0214
27150190	LOBSTER SAUCE (BROTH-BASED)	0.6
27150210	FISH SAUCE (BAGOONG)	0.1
27151050	SHRIMP IN GARLIC SAUCE P.R. (CAMARONES AL AJILLO)	0.0214
27160010	MEAT W/ BARBECUE SAUCE NS AS TO TYPE OF MEAT	0.0214
27160100	MEATBALLS NS AS TO TYPE OF MEAT W/ SAUCE	0.0214
27211000	BEEF & POTATOES NO SAUCE (MIXTURE)	0.024
27211190	BEEF & POTATOES W/ CREAM OR WHITE SAUCE (MIXTURE)	0.024
27211550	STEWED SEASONED GROUND BEEF W/ POTATOES MEXICAN	0.0353
27212050	BEEF & MACARONI WITH CHEESE SAUCE (MIXTURE)	0.024
27212400	BEEF & NOODLES W/ (MUSHROOM) SOUP (MIXTURE)	0.0122
27213000	BEEF & RICE NO SAUCE (MIXTURE)	0.024
27213100	BEEF & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	0.024
27213300	BEEF & RICE W/ CREAM SAUCE (MIXTURE)	0.024
27213400	BEEF & RICE W/ (MUSHROOM) SOUP (MIXTURE)	0.0122
27213500	BEEF & RICE W/ SOY-BASED SAUCE (MIXTURE)	0.024
27220150	SAUSAGE & RICE W/ (MUSHROOM) SOUP (MIXTURE)	0.0122
27220210	HAM & NOODLES NO SAUCE (MIXTURE)	0.0214
27220310	HAM & RICE NO SAUCE (MIXTURE)	0.0214
27220520	PORK & POTATOES W/ CHEESE SAUCE	0.0214
27236000	VENISON/DEER & NOODLE MIXTURE W/ CREAM/WHITE SAUCE	0.0273
27242000	CHICKEN OR TURKEY & NOODLES NO SAUCE (MIXTURE)	0.0214

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
27242300	CHICKEN OR TURKEY & NOODLES W/ CREAM OR WHITE SAUCE	0.0214
27242310	CHICKEN & NOODLES W/ CHEESE SAUCE	0.0214
27243000	CHICKEN & RICE NO SAUCE (MIXTURE)	0.0214
27243300	CHICKEN & RICE W/ CREAM SAUCE (MIXTURE)	0.0214
27243400	CHICKEN & RICE W/ (MUSHROOM) SOUP-BASED SAUCE	0.0214
27243600	CHICKEN & RICE W/ SOY-BASED SAUCE (MIXTURE)	0.0214
27250130	SHRIMP & NOODLES W/ CHEESE SAUCE	0.0214
27250610	TUNA NOODLE CASSEROLE W/ CREAM OR WHITE SAUCE	0.0214
27250630	TUNA NOODLE CASSEROLE W/ (MUSHROOM) SOUP	0.0122
27250710	TUNA & RICE W/ (MUSHROOM) SOUP (MIXTURE)	0.0122
27311110	BEEF POTATOES & VEG (W/ CAR/DK GREEN) NO SAUCE	0.0214
27311120	BEEF POTATOES & VEG (NO CAR/DK GREEN) NO SAUCE	0.0214
27311210	CORNED BEEF POT & VEG(W/ CAR/DK GREEN) NO SAUCE	0.0273
27311610	BEEF POT & VEG (INCL CAR/DK GRN) (MUSHROOM) SOUP	0.0122
27313020	BEEF NOODLES & VEG (NO CARROTS/DK GREEN) NO SAUCE	0.0214
27313150	BEEF NOODLES & VEG (W/ CAR/DK GREEN) SOY SAUCE	0.0214
27313310	BEEF NOODLES VEG(INCL CARROTS/DK GREEN) SOUP	0.0122
27313320	BEEF NOODLES VEG (NO CARROTS/DK GREEN) SOUP	0.0122
27315510	BEEF RICE & VEG (INCL CAR/DK GRN) SOY-BASED SAUCE	0.0214
27315520	BEEF RICE & VEG (NO CAR/DK GRN) SOY-BASED SAUCE	0.0214
27320320	PORK RICE & VEG (INCL CAR/DK GRN) SOY-BASED SAUCE	0.0214
27320330	PORK RICE & VEG (NO CAR/DK GRN) SOY-BASED SAUCE	0.0214
27343010	CHICKEN NOODLES & VEG (INCL CAR/DK GRN) NO SAUCE	0.0214
27343470	CHICKEN NOODLES VEG (INCL CAR DK GRN) CREAM SAUCE	0.0214
27343480	CHICKEN NOODLES VEG (NO CAR/DK GRN) CREAM SAUCE	0.0214
27343960	CHICKEN NOODLES & VEG(NO CAR/DK GRN) CHEESE SAUCE	0.0214
27343970	CHICKEN NOODLES VEG (W/ CAR/DK GRN) CREAM SAUCE	0.0214
27345310	CHICKEN RICE & VEG (INCL CAR/DK GRN) SOY SAUCE	0.0214
27345320	CHICKEN RICE & VEG (NO CAR/DK GRN) SOY SAUCE	0.0214
27345410	CHICKEN RICE & VEG(INCL CAR/DK GRN) SOUP-BASED SCE	0.0122
27347210	CHICKEN STUFFING VEG (NO CAR/DK GRN) NO SAUCE	0.0214
27350080	TUNA NOODLE CASSEROLE W/ VEG CREAM OR WHITE SAUCE	0.0214
27350100	FISH NOODLES VEG (NO CAR/DK GRN) CHEESE SAUCE	0.0214
27350410	TUNA NOODLE CASSEROLE W/ VEG & (MUSHROOM) SOUP	0.0122
27410210	BEEF & VEG (W/ CAR/DK GREEN NO POTATO) NO SAUCE	0.0214
27410220	BEEF & VEG (NO CAR/DK GREEN NO POTATO) NO SAUCE	0.0214
27414200	BEEF W/ VEG (NO CAR/DK GRN NO POT) SOUP	0.0122
27415100	BEEF & VEG (W/ CAR/DK GREEN NO POTATO) SOY SAUCE	0.0214

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FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
27415200	BEEF & VEG (NO CAR/DK GREEN NO POTATO) SOY SAUCE	0.0214
27416200	BEEF GROUND W/ EGG & ONION (MIXTURE)	0.0353
27420060	PORK & VEG (W/ CAR/DK GREEN NO POTATO) NO SAUCE	0.0214
27420170	PORK AND ONIONS W/ SOY-BASED SAUCE	0.0214
27420350	PORK & VEG (NO CAR/DK GREEN NO POTATO) NO SAUCE	0.0214
27420470	SAUSAGE & PEPPERS NO SAUCE	0.0214
27420500	PORK & VEG (INCL CAR/DK GRN) SOY-BASED SAUCE	0.0214
27420510	PORK & VEG (NO CAR/DK GRN) SOY-BASED SAUCE	0.0214
27440110	CHICK/TURK & VEG (W/ CAR/DK GRN NO POT) NO SAUCE	0.0214
27440120	CHICK/TURK & VEG (NO CAR/DK GRN NO POT) NO SAUCE	0.0214
27445110	CHICKEN & VEG (INCL CAR/DK GRN NO POT) SOY SAUCE	0.0214
27445120	CHICKEN & VEG (NO CAR/DK GRN NO POT) SOY SAUCE	0.0214
27446410	CHICKEN & VEG (NO CAR/DK GRN)(NO POT) CHEESE SAUCE	0.0214
27450410	SHRIMP & VEG (W/ CAR/DK GREEN NO POT) SOY SAUCE	0.0214
27450420	SHRIMP & VEG (NO CARROT/DK GREEN NO POT) SOY SAUCE	0.0214
27450510	TUNA CASSEROLE W/ VEG & SOUP NO NOODLES	0.0122
27450740	FISH & VEGETABLES (W/ CAR/DK GRN) SOY-BASED SAUCE	0.0214
27450750	FISH & VEGETABLES (NO CAR/DK GRN) SOY-BASED SAUCE	0.0214
27520500	PORK BBQ SAUCE ONIONS & DILL PICKLES ON WHITE ROLL	0.0214
28110340	SALISBURY STK GRAVY POT VEG SOUP DESSERT(FRZ MEAL)	0.0122
28110620	SHORTRIBS W/ BBQ SAUCE POTATOES & VEG (FROZ MEAL)	0.0214
28110640	MEATBALLS SWEDISH IN SAUCE W/ NOODLES (FROZ MEAL)	0.0214
28143080	CHICKEN W/NOODLES & CHEESE SAUCE (DIET FROZEN MEAL)	0.0214
28143170	CHICKEN IN CREAM SAUCE W/ NOODLES & VEG (FROZ MEAL)	0.0214
28143210	CHICKEN IN ORANGE SAUCE W/ RICE (DIET FROZEN MEAL)	0.0214
28150510	FISH IN LEMON SAUCE W/ STARCH ITEM VEG (FROZ MEAL)	0.0214
28310150	OXTAIL SOUP	0.0122
28310210	CHILI BEEF SOUP	0.0122
28310220	CHILI BEEF SOUP CHUNKY	0.0122
28310230	MEATBALL SOUP MEXICAN STYLE (SOPA DE ALBONDIGAS)	0.0122
28310320	BEEF NOODLE SOUP P.R. (SOPA DE CARNE Y FIDEOS)	0.0122
28310330	BEEF & NOODLE SOUP ORIENTAL (VIETNAMESE PHO BO)	0.0122
28311010	PEPPERPOT (TRIPE) SOUP (INCL MENUDO/MONDONGO SOUP)	0.0122
28315100	BEEF VEG SOUP W/POTATO STEW TYPE (INCL CHUNKY STY)	0.0122
28315120	BEEF VEG SOUP W/ NOODLES STEW TYPE CHUNKY STYLE	0.0122
28315130	BEEF VEG SOUP W/ RICE STEW TYPE CHUNKY STYLE	0.0122
28315140	BEEF VEGETABLE SOUP MEXICAN STYLE (SOPA / CALDO DE RES)	0.0122

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FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
28315150	MEAT & CORN HOMINY SOUP MEXICAN STYLE (POZOLE)	0.0122
28316020	BEEF & MUSHROOM SOUP CANNED LOW SODIUM (INCL BEEF	0.0122
28317010	BEEF STROGANOFF SOUP CHUNKY STYLE	0.0122
28320130	HAM RICE & POTATO SOUP P.R.	0.0122
28320150	PORK VEGETABLE SOUP W/ POTATOES STEW TYPE	0.0122
28320300	PORK W/VEG (NO CAR BROC &/OR DK GREEN)SOUP ORIENTAL	0.0122
28340150	MEXICAN STYLE CHICKEN BROTH SOUP STOCK	0.0122
28340210	CHICKEN RICE SOUP P.R. (SOPA DE POLLO CON ARROZ)	0.0122
28340220	CHICKEN SOUP W/ NOODLES & POTATOES P.R.	0.0122
28340310	CHICKEN GUMBO SOUP	0.0122
28340510	CHICKEN NOODLE SOUP CHUNKY	0.0122
28340530	CHICKEN SOUP	0.0122
28340580	CHICKEN SOUP W/VEGS(BROC CRT CELERY POTS)ORIENTAL	0.0122
28340590	CHICKEN CORN SOUP HOME RECIPE	0.0122
28340750	HOT & SOUR SOUP (INCLUDE HOT & SPICY CHINESE SOUP)	0.0122
28345020	CHICKEN SOUP CREAM OF MADE W/ MILK REDUCED SODIUM	0.0122
28345030	CHICKEN SOUP CREAM OF MADE W/ WATER REDUCED SODIUM	0.0122
28345110	CHICKEN SOUP CREAM OF NS AS TO MILK OR WATER	0.0122
28345120	CHICKEN/TURKEY SOUP CREAM OF W/ MILK	0.0122
28345130	CHICKEN SOUP CREAM OF PREPARED W/ WATER	0.0122
28345140	CHICKEN SOUP CREAM OF CANNED UNDILUTED	0.0122
28345160	CHICKEN & MUSHROOM SOUP CREAM OF W/ MILK	0.0122
28350050	FISH CHOWDER (INCL FISHERMAN'S SOUP SEAFOOD CHOWD)	0.0122
28351110	FISH & VEGETABLE SOUP NO POTATOES (SOPA DE PESCADO)	0.0122
28355350	SALMON SOUP CREAM STYLE	0.0122
28355420	SHRIMP SOUP CREAM OF W/ MILK	0.0122
28355450	SEAFOOD SOUP W/ POTATOES & VEGETABLES (INCL DK GREEN LEAF)	0.0122
28355470	SEAFOOD SOUP W/ VEGETABLES (INCL DK GREEN LEAFY)	0.0122
28355480	SEAFOOD SOUP W/ VEGETABLES (EXCL DK GREEN LEAFY)	0.0122
28520000	GRAVY/SAUCE CHINESE (SOY SCE STOCK/BOUILL CRNSTRCH)	0.0214
28520100	OYSTER-FLAVORED SAUCE	0.2
28522000	MOLE POBLANA (SAUCE)	0.2
32300100	EGG DROP SOUP	0.0122
41201040	BAKED BEAN W/ PORK & SWEET SAUCE	0.0638
41207030	BEANS DRY COOKED W/ GROUND BEEF	0.0353
41420250	HOISIN SAUCE	0.6
41420300	SOY SAUCE	0.6

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FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
41420350	SOY SAUCE REDUCED SODIUM	0.6
41420400	TERIYAKI SAUCE (INCLUDE ORIENTAL BARBECUE SAUCE)	0.2
41420450	WORCESTERSHIRE SAUCE	0.6
41601010	BEAN SOUP NFS	0.0122
41601020	BEAN W/ BACON OR PORK SOUP	0.0122
41601030	BLACK BEAN SOUP	0.0122
41601040	LIMA BEAN SOUP	0.0122
41601050	SOYBEAN SOUP MADE W/ MILK	0.0122
41601060	BEANSOUPW/MACARONI&MEAT(INCL PASTA E FAGIOLE W/MEAT	0.0122
41601070	SOYBEAN SOUP MISO BROTH	0.0122
41601080	PINTO BEAN SOUP	0.0122
41601090	BEAN SOUP W/ MACARONI (INCL PASTA E FAGIOLI)	0.0122
41601110	BEAN & HAM SOUP CHUNKY STYLE (INCL CAMPBELL'S OLD	0.0122
41601130	BEAN SOUP MIXED BEANS (INCL 15-BEAN SOUP)	0.0122
41601140	BEAN SOUP HOME RECIPE	0.0122
41601150	BEAN SOUP W/ VEG & RICE CAN RED SODIUM W/ WATER/RTS	0.0122
41601180	BEAN & HAM SOUP HOME RECIPE	0.0122
41602020	GARBANZO OR CHICKPEA SOUP	0.0122
41602030	SPLIT PEA & HAM SOUP	0.0122
41602050	SPLIT PEA SOUP	0.0122
41602070	SPLIT PEA SOUP CAN REDUCED SODIUM W/ WATER/RTS	0.0122
41603010	LENTIL SOUP	0.0122
41812450	VEGETARIAN CHILI (MADE W/ MEAT SUBSTITUTE)	0.0353
42204050	PEANUT SAUCE	0.6
51000100	BREAD NS AS TO MAJOR FLOUR	0.06
51000110	TOAST NS AS TO MAJOR FLOUR	0.06
51000180	BREAD HOMEMADE/PURCH AT A BAKERY NS AS TO FLOUR	0.06
51000190	BREAD HOMEMADE/PURCH AT A BAKERY TOASTD NS FLOUR	0.06
51000200	ROLL NS AS TO MAJOR FLOUR	0.06
51000230	ROLL NS AS TO MAJOR FLOUR TOASTED	0.06
51101000	BREAD WHITE	0.06
51101010	BREAD WHITE TOASTED	0.06
51101050	BREAD WHITE HOMEMADE OR PURCHASED AT A BAKERY	0.06
51101060	BREAD WHITE HOMEMADE OR PURCH AT A BAKERY TOASTED	0.06
51102010	BREAD WHITE W/ WHOLE WHEAT SWIRL	0.06
51105010	BREAD CUBAN (INCLUDE SPANISH PORTUGUESE)	0.06
51105040	BREAD CUBAN TOASTED (INCLUDE SPANISH PORTUGUESE)	0.06

000230

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
51107010	BREAD FRENCH OR VIENNA	0.06
51107040	BREAD FRENCH OR VIENNA TOASTED	0.06
51109010	BREAD ITALIAN GRECIAN ARMENIAN	0.06
51109040	BREAD ITALIAN GRECIAN ARMENIAN TOASTED	0.06
51109100	BREAD PITA	0.06
51109110	BREAD PITA TOASTED	0.06
51111010	BREAD CHEESE (INCLUDE ONION CHEESE)	0.06
51111040	BREAD CHEESE TOASTED (INCLUDE ONION CHEESE)	0.06
51113010	BREAD CINNAMON	0.06
51113100	BREAD CINNAMON TOASTED	0.06
51115020	BREAD CORNMEAL AND MOLASSES TOASTED	0.06
51119010	BREAD EGG CHALLAH	0.06
51119040	BREAD EGG CHALLAH TOASTED	0.06
51119100	BREAD LOWFAT 98% FAT FREE	0.06
51119110	BREAD LOWFAT 98% FAT FREE TOASTED	0.06
51121010	BREAD GARLIC	0.06
51121040	BREAD GARLIC TOASTED (INCLUDE TEXAS TOAST)	0.06
51127010	BREAD POTATO	0.06
51127020	BREAD POTATO TOASTED	0.06
51129010	BREAD RAISIN	0.06
51129020	BREAD RAISIN TOASTED	0.06
51133010	BREAD SOUR DOUGH	0.06
51133020	BREAD SOUR DOUGH TOASTED	0.06
51135000	BREAD VEGETABLE	0.06
51135010	BREAD VEGETABLE TOASTED	0.06
51140100	BREAD DOUGH FRIED	0.06
51150000	ROLL WHITE SOFT	0.06
51150100	ROLL WHITE SOFT TOASTED	0.06
51151060	ROLL WHITE SOFT HOMEMADE/PURCH AT A BAKERY	0.06
51152000	ROLL WHITE SOFT REDUCED CALORIE/ HIGH FIBER	0.06
51153000	ROLL WHITE HARD	0.06
51153010	ROLL WHITE HARD TOASTED	0.06
51154550	ROLL EGG BREAD	0.06
51154600	ROLL CHEESE	0.06
51155000	ROLL FRENCH OR VIENNA	0.06
51155010	ROLL FRENCH OR VIENNA TOASTED	0.06
51156500	ROLL GARLIC	0.06
51157000	ROLL HOAGIE SUBMARINE	0.06

000231

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
51157010	ROLL HOAGIE SUBMARINE TOASTED	0.06
51158100	ROLL MEXICAN BOLILLO	0.06
51159000	ROLL SOUR DOUGH	0.06
51184010	BREAD STICK SOFT	0.2
51184020	BREAD STICK NS AS TO HARD OR SOFT	0.2
51184030	BREAD STICK SOFT PREP W/ GARLIC & PARMESAN CHEESE	0.2
51186010	MUFFIN ENGLISH (INCLUDE SOUR DOUGH)	0.0545
51186020	MUFFIN ENGLISH TOASTED	0.0545
51186120	MUFFIN ENGLISH W/ RAISINS TOASTED	0.0545
51186160	MUFFIN ENGLISH W/ FRUIT OTHER THAN RAISINS	0.0545
51186180	MUFFIN ENGLISH W/ FRUIT OTHER THAN RAISINS TSTD	0.0545
51187000	MELBA TOAST	0.06
51188100	PANNETONE (ITALIAN-STYLE SWEET BREAD)	0.06
51201010	BREAD 100% WHOLE WHEAT	0.06
51201020	BREAD 100% WHOLE WHEAT TOASTED	0.06
51201060	BREAD 100% WHOLE WHEAT HOME-MADE	0.06
51201070	BREAD 100% WHOLE WHEAT HOME-MADE TOASTED	0.06
51201120	BREAD 100% WHOLE WHEAT W/ RAISINS TOASTED	0.06
51201150	BREAD PITA 100% WHOLE WHEAT	0.06
51201160	BREAD PITA 100% WHOLE WHEAT TOASTED	0.06
51202020	MUFFIN ENGLISH 100% WHOLE WHEAT TOASTED	0.0545
51202060	MUFFIN ENGLISH WHOLE WHEAT W/ RAISINS TOASTED	0.0545
51220000	ROLL 100% WHOLE WHEAT	0.06
51220030	ROLL 100% WHOLE WHEAT HOME RECIPE/BAKERY	0.06
51300110	BREAD WHOLE WHEAT OTHER THAN 100%/NS AS TO 100%	0.06
51300120	BREAD WHOLE WHEAT OTHER THAN 100%/NS 100% TOAST	0.06
51300140	BREAD WHOLE"" WHEAT HOME RECIPE/BAKERY	0.06
51300150	BREAD WHOLE"" WHEAT HOME RECIPE/BAKERY TOASTED	0.06
51300220	BREAD WHOLE WHEAT NS AS TO 100% W/ RAISINS TOASTED	0.06
51301010	BREAD WHEAT OR CRACKED WHEAT	0.06
51301020	BREAD WHEAT OR CRACKED WHEAT TOASTED	0.06
51301040	BREAD CRACKED WHEAT HOME RECIPE/BAKERY	0.06
51301050	BREAD CRACKED WHEAT HOME RECIPE/BAKERY TOASTED	0.06
51301120	BREAD WHEAT OR CRACKED WHEAT W/ RAISINS	0.06
51301130	BREAD WHEAT OR CRACKED WHEAT W/ RAISINS TOASTED	0.06
51301510	BREAD CRACKED WHEAT REDUCED CALORIE/ HIGH FIBER	0.06
51301520	BREAD CRACKED WHEAT RED CALORIE/ HI FIBER TOAST	0.06
51301540	BREAD FRENCH WHOLE"" WHEAT HOMEMADE	0.06

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
51302020	BREAD WHEAT BRAN TOASTED	0.06
51303010	MUFFIN ENGLISH WHEAT OR CRACKED WHEAT	0.0545
51303040	MUFFIN ENGLISH WHOLE"" WHEAT TOASTED	0.0545
51303060	MUFFIN ENGLISH WHEAT W/ RAISINS TOASTED	0.0545
51320010	ROLL WHEAT OR CRACKED WHEAT	0.06
51320500	ROLL WHOLE WHEAT NS AS TO 100%	0.06
51320530	ROLL WHOLE"" WHEAT HOME RECIPE/BAKERY	0.06
51401010	BREAD RYE	0.06
51401020	BREAD RYE TOASTED	0.06
51401030	BREAD MARBLE RYE & PUMPERNICKEL	0.06
51401060	BREAD RYE REDUCED CALORIE/ HIGH FIBER (INCL LESS)	0.06
51401070	BREAD RYE REDUCED CALORIE/ HIGH FIBER TOASTED	0.06
51404010	BREAD PUMPERNICKEL	0.06
51404020	BREAD PUMPERNICKEL TOASTED	0.06
51420000	ROLL RYE	0.06
51421000	ROLL PUMPERNICKEL	0.06
51421100	ROLL PUMPERNICKEL TOASTED	0.06
51501010	BREAD OATMEAL	0.06
51501020	BREAD OATMEAL TOASTED	0.06
51501040	BREAD OAT BRAN	0.06
51501050	BREAD OAT BRAN TOASTED	0.06
51501060	BREAD OAT BRAN REDUCED CALORIE/ HIGH FIBER	0.06
51501070	BREAD OAT BRAN REDUCED CALORIE/HI FIBER TOASTED	0.06
51502010	ROLL OATMEAL	0.06
51503010	MUFFIN ENGLISH OAT BRAN TOASTED	0.0545
51620000	ROLL MULTIGRAIN	0.06
51630200	MUFFIN ENGLISH MULTIGRAIN	0.0545
51630210	MUFFIN ENGLISH MULTIGRAIN TOASTED	0.0545
51805010	BREAD SUNFLOWER MEAL	0.06
52105100	SCONES	0.0545
52105200	SCONE WITH FRUIT	0.0545
52201000	CORNBREAD PREPARED FROM MIX	0.0545
52202060	CORNBREAD HOMEMADE	0.0545
52204000	CORNBREAD STUFFING	0.03
52206010	CORNBREAD MUFFIN STICK ROUND	0.0545
52206020	CORNBREAD MUFFIN STICK ROUND TOASTED	0.0545
52206060	CORNBREAD MUFFIN STICK ROUND HOMEMADE	0.0545
52207010	CORN FLOUR PATTIES OR TARTS FRIED	0.0545

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
52209010	HUSH PUPPY	0.0545
52301000	MUFFIN NFS	0.0545
52302010	MUFFIN FRUIT & OR NUTS	0.0545
52302100	MUFFIN FRUIT FAT FREE CHOL FREE	0.0545
52302500	MUFFIN CHOCOLATE CHIP	0.0545
52302600	MUFFIN CHOCOLATE	0.0545
52303010	MUFFIN WHOLE WHEAT	0.0545
52304100	MUFFIN OATMEAL	0.0545
52304150	MUFFIN OAT BRAN	0.0545
52304200	MUFFIN OAT BRAN WITH FRUIT AND/OR NUTS	0.0545
52306010	MUFFIN PLAIN	0.0545
52306500	MUFFIN PUMPKIN W/ RAISINS	0.0545
52306550	MUFFIN ZUCCHINI	0.0545
52306700	MUFFIN CARROT (INCL W/ RAISINS/NUTS)	0.0545
52308010	MATZO FRITTERS	0.2
52403000	BREAD NUT	0.06
52404060	BREAD PUMPKIN (INCLUDE W/ RAISINS)	0.06
52405010	BREAD FRUIT W/O NUTS	0.06
52405100	BREAD FRUIT & NUT	0.06
52407000	BREAD ZUCCHINI (INCL SQUASH BREAD W/ NUTS)	0.06
52408000	BREAD IRISH SODA	0.06
53102000	CAKE APPLESAUCE NS AS TO ICING	0.024
53102100	CAKE APPLESAUCE W/O ICING	0.024
53102200	CAKE APPLESAUCE W/ ICING	0.024
55401000	CREPE PLAIN (INCLUDE FRENCH PANCAKE)	0.0273
55501000	FLOUR & WATER PATTY (INCLUDE CHINESE PANCAKE)	0.0273
55701000	CAKE MADE W/ GLUTINOUS RICE	0.0375
55801000	FUNNEL CAKE	0.0375
58103250	TAMALE PLAIN MEATLESS NO SAUCE MEXICAN	0.0214
58120110	CREPES FILLED W/ MEAT FISH OR POULTRY W/ SAUCE	0.0273
58127220	CROISSANT FILLED W/CHICKEN BROCCOLI & CHEESE SAUCE	0.0273
58131510	RAVIOLI CHEESE-FILLED NO SAUCE	0.0214
58131530	RAVIOLI CHEESE-FILLED W/ MEAT SAUCE	0.0214
58131600	RAVIOLI CHEESE&SPINACH-FILLED W/ CREAM SAUCE	0.0214
58132800	SPAGHETTI W/ CLAM SAUCE NS AS TO RED OR WHITE	0.0214
58132810	SPAGHETTI W/ RED CLAM SAUCE	0.0214
58132820	SPAGHETTI W/ WHITE CLAM SAUCE	0.0214
58133110	MANICOTTI CHEESE-FILLED NO SAUCE	0.0214

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
58133130	MANICOTTI CHEESE-FILLED W/ MEAT SAUCE	0.0214
58134110	STUFFED SHELLS CHEESE-FILLED NO SAUCE	0.0214
58134650	TORTELLINI MEAT-FILLED NO SAUCE	0.0214
58134660	TORTELLINI CHEESE-FILLED W/ CREAM SAUCE	0.0214
58134720	TORTELLINI SPINACH-FILLED NO SAUCE	0.0214
58145115	MACARONI/NOODLES W/CHEESE FROM MIX W/PREPARED CHEESE SAUCE	0.0214
58146110	PASTA W/ MEAT SAUCE (INCLUDE AMER CHOP SUEY)	0.0273
58146120	PASTA W/ CHEESE & MEAT SAUCE	0.0273
58146130	PASTA W/ CARBONARA SAUCE	0.0273
58147100	PASTA W/ PESTO SAUCE	0.0638
58155410	SOUPY RICE W/ CHICKEN P.R. (ASOPAO DE POLLO)	0.0122
58163450	SPANISH RICE W/ GROUND BEEF	0.0353
58301050	LASAGNA W/ CHEESE & MEAT SAUCE (DIET FROZEN MEAL)	0.0214
58304050	SPAGHETTI W/ MEAT & MUSHROOM SAUCE (DIET FROZ MEAL)	0.0214
58304060	SPAGHETTI W/ MEAT SAUCE (DIET FROZEN MEAL)	0.0214
58305250	PASTA W/ VEGETABLES & CHEESE SAUCE (DIET FROZ MEAL)	0.0214
58400000	SOUP NFS	0.0122
58400100	NOODLE SOUP NFS	0.0122
58400200	RICE SOUP NFS	0.0122
58401010	BARLEY SOUP (INCLUDE BEEF/CHICKEN/MUSHROOM BARLEY)	0.0122
58402010	BEEF NOODLE SOUP	0.0122
58402030	BEEF RICE SOUP	0.0122
58402100	BEEF NOODLE SOUP HOME RECIPE	0.0122
58403010	CHICKEN NOODLE SOUP (INCLUDE CHICKEN & STARS SOUP)	0.0122
58403020	CHICKEN NOODLE SOUP CANNED UNDILUTED	0.0122
58403030	CHICKEN NOODLE SOUP CANNED LOW SODIUM	0.0122
58403040	CHICKEN NOODLE SOUP HOME RECIPE	0.0122
58403050	CHICKEN NOODLE SOUP CREAM OF	0.0122
58403060	CHICKEN NOODLE SOUP CAN RED SODIUM READY-TO-SERVE	0.0122
58403100	NOODLE & POTATO SOUP P.R.	0.0122
58404010	CHICKEN RICE SOUP (INCL TURKEY RICE SOUP)	0.0122
58404030	CHICKEN OR TURKEY RICE SOUP HOME RECIPE	0.0122
58404040	CHICKEN RICE SOUP CAN RED SODIUM PREP W/ WATER/RTS	0.0122
58404050	CHICKEN RICE SOUP CAN REDUCED SODIUM W/ MILK	0.0122
58404100	RICE AND POTATO SOUP P.R.	0.0122
58404510	CHICKEN SOUP W/ DUMPLINGS POTATOES	0.0122
58404520	CHICKEN SOUP W/ DUMPLINGS	0.0122

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
58406010	TURKEY NOODLE SOUP	0.0122
58406020	TURKEY NOODLE SOUP HOME RECIPE	0.0122
58407010	INSTANT SOUP NOODLE (INCLUDE MEAT & VEG FLAVORS)	0.0122
58407030	SOUP MOSTLY NOODLES(INCL SPAGHETTI SOUP TOP RAMEN)	0.0122
58407040	INSTANT SOUP RICE (INCLUDE MEAT/CHICKEN FLAVOR)	0.0122
58407050	INSTANT SOUP NOODLE W/ EGG SHRIMP OR CHICKEN	0.0122
58408010	WON TON (WONTON) SOUP	0.0122
58408500	NOODLE SOUP W/ VEGETABLES ORIENTAL STYLE	0.0122
58421020	SOPA DE FIDEO AGUADA MEXICAN STYLE NOODLE SOUP	0.0122
58421080	SOPA DE TORTILLA MEXICAN STYLE TORTILLA SOUP	0.0122
63101110	APPLESAUCE STEWED APPLES NS AS TO ADDED SWEETENER	0.0428
63101120	APPLESAUCE STEWED APPLES UNSWEETENED (INCL FRESH)	0.0428
63101130	APPLESAUCE STEWED APPLES W/ SUGAR	0.0428
63101140	APPLESAUCE STEWED APPLES W/ LOW CALORIE SWEETENER	0.0428
63101150	APPLESAUCE / OTHER FRUITS(INCLUDE MOTT'S FRUIT PAK)	0.0428
71301000	WHITE POTATO COOKED W/ SAUCE NS AS TO SAUCE	0.0273
71508120	WHITE POT STUFF W/HAM BROC &CHEESE SAUCE BKD W/PEEL	0.0273
71801000	POTATO SOUP NS AS TO MADE W/MILK OR WATER	0.0122
71801010	POTATO SOUP CREAM OF W/ MILK	0.0122
71801020	POTATO SOUP PREPARED W/ WATER	0.0122
71801100	POTATO & CHEESE SOUP	0.0122
71802010	MACARONI & POTATO SOUP	0.0122
71851010	PLANTAIN SOUP P.R. (SOPA DE PLATANO)	0.0122
72125252	SPINACH COOKED FROM FROZEN W/ CHEESE SAUCE	0.0273
72201230	BROCCOLI COOKED NS AS TO FORM W/ CHEESE SAUCE	0.0273
72201231	BROCCOLI COOKED FROM FRESH W/ CHEESE SAUCE	0.0273
72201232	BROCCOLI COOKED FROM FROZEN W/ CHEESE SAUCE	0.0273
72201251	BROCCOLI COOKED FROM FRESH W/ CREAM SAUCE	0.0273
72201252	BROCCOLI COOKED FROM FROZEN W/ CREAM SAUCE	0.0273
72202010	BROCCOLI CASSEROLE (BROC NOODLES CREAM SAUCE)	0.0273
72302000	BROCCOLI SOUP (INCLUDE CREAM OF BROCCOLI SOUP)	0.0122
72302100	BROCCOLI CHEESE SOUP PREP W/ MILK	0.0122
72305000	ESCAROLE SOUP	0.0122
72307000	SPINACH SOUP	0.0122
72308500	DARK-GREEN LEAFY VEGETABLE SOUP MEATLESS ORIENTAL	0.0122
73501000	CARROT SOUP CREAM OF W/ MILK	0.0122
74402250	ENCHILADA SAUCE RED	0.2
74402260	ENCHILADA SAUCE GREEN	0.2

000236

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
74406010	BARBECUE SAUCE (INCLUDE ARBY'S SAUCE)	0.1
74406050	BARBECUE SAUCE LOW SODIUM	0.1
74406500	COCKTAIL SAUCE	0.1
75232050	SEAWEED PREPARED W/ SOY SAUCE	0.6
75401011	ASPARAGUS FROM FRESH CREAMED OR W/ CHEESE SAUCE	0.0638
75405010	BEETS WITH HARVARD SAUCE	0.0273
75409011	CAULIFLOWER FROM FRESH CREAMED(INCL W/ CHEESE SAUCE)	0.0273
75411031	CORN COOKED FROM FRESH W/ CREAM SAUCE MADE W/ MILK	0.0273
75417021	PEAS COOKED FROM FRESH W/ MUSHROOM SAUCE	0.0273
75418040	SQUASH SUMMER CASSEROLE W/ CHEESE SAUCE	0.0273
75440510	VEG COMBINATION (NO CAR/ DK GRN) W/ CHEESE SAUCE	0.0273
75450500	VEG COMBINATION (INCL CAR DK GRN) W/ CREAM SAUCE	0.0273
75460800	VEGETABLE COMB(INCL CAR/DK GRN) CKD W/ BUTTER SAUCE	0.0273
75506100	MUSTARD SAUCE	0.6
75511010	PEPPERS HOT SAUCE (INCLUDE TABASCO SAUCE)	0.6
75601000	ASPARAGUS SOUP CREAM OF NS AS TO W/ MILK OR WATER	0.0122
75601010	ASPARAGUS SOUP CREAM OF W/ MILK	0.0122
75601200	CABBAGE SOUP	0.0122
75601210	CABBAGE W/ MEAT SOUP	0.0122
75602010	CAULIFLOWER SOUP CREAM OF W/ MILK	0.0122
75604010	CORN SOUP CREAM OF W/ MILK	0.0122
75604020	CORN SOUP CREAM OF PREPARED W/ WATER	0.0122
75604510	CUCUMBER SOUP CREAM OF W/ MILK	0.0122
75607000	MUSHROOM SOUP NFS	0.0122
75607010	MUSHROOM SOUP CREAM OF PREP W/ MILK	0.0122
75607020	MUSHROOM SOUP CREAM OF PREPARED W/ WATER	0.0122
75607030	MUSHROOM SOUP CANNED UNDILUTED (INCL CREAM OF)	0.0122
75607090	MUSHROOM SOUP CREAM OF CAN NS MILK/WATER RED SODIUM	0.0122
75607100	MUSHROOM SOUP CREAM OF CAN PREP W/ MILK REDUCED SODIUM	0.0122
75607140	MUSHROOM SOUP CREAM OF CAN PREP W/ WATER REDUCED SODIUM	0.0122
75608100	ONION SOUP FRENCH	0.0122
75609000	PEA SOUP NFS	0.0122
75647000	SEAWEED SOUP	0.0122
81301020	LEMON-BUTTER SAUCE	0.2
81302010	HOLLANDAISE SAUCE	0.2
81302020	BEARNAISE SAUCE	0.2

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
81302050	TARTAR SAUCE	0.2
81302060	HORSERADISH SAUCE	0.6
81302070	PESTO SAUCE	0.0638
81312000	TARTAR SAUCE LOW CALORIE	0.2
91361010	SWEET & SOUR SAUCE (INCLUDE VIETNAMESE SAUCE)	0.6
91361020	FRUIT SAUCE (INCLUDE ALL FRUITS)	0.0428
91361050	DUCK SAUCE (INCLUDE CHAISNI SAUCE)	0.6
91361070	PLUM SAUCE ORIENTAL STYLE	0.0353

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APPENDIX B

Foods requested for addition to GRN 000163

FOODCODE	DESCRIPTION	Concentration (mg/g)
92201010	POSTUM (COFFEE SUBSTITUTE)	0.0125
92203000	CEREAL BEVERAGE (INCLUDE PERO BREAK AWAY)	0.0125
92306000	TEA HERBAL (INCLUDE SASSAFRAS LICORICE)	0.0125
92400000	SOFT DRINK NFS	0.0125
92410310	SOFT DRINK COLA-TYPE	0.0125
92410320	SOFT DRINK COLA-TYPE SUGAR-FREE	0.0125
92410330	SOFT DRINK COLA-TYPE W/ HIGHER CAFFEINE (INCL JOLT)	0.0125
92410340	SOFT DRINK COLA-TYPE DECAFFEINATED	0.0125
92410350	SOFT DRINK COLA-TYPE DECAFFEINATED SUGAR-FREE	0.0125
92410360	SOFT DRINK PEPPER-TYPE (INCL DR. PEPPER MR. PIBB)	0.0125
92410370	SOFT DRINK PEPPER-TYPE SUGAR-FREE	0.0125
92410390	SOFT DRINK PEPPER-TYPE DECAFFEINATED	0.0125
92410400	SOFT DRINK PEPPER-TYPE DECAFFEINATED SUGAR-FREE	0.0125
92410510	SOFT DRINK FRUIT-FLAVORED CAFFEINE FREE	0.0125
92410520	SOFT DRINK FRUIT-FLAV SUGAR-FREE CAFFEINE FREE	0.0125
92410550	SOFT DRINK FRUIT-FLAVORED W/ CAFFEINE	0.0125
92410560	SOFT DRINK FRUIT-FLAVORED W/ CAFFEINE SUGAR-FREE	0.0125
92510120	APPLE-CHERRY DRINK	0.0125
92510150	APPLE JUICE DRINK	0.0125
92510170	APPLE-CRANBERRY-GRAPE JUICE DRINK	0.0125
92510200	APPLE-ORANGE-PINEAPPLE JUICE DRINK	0.0125
92510310	BANANA-ORANGE DRINK	0.0125
92510610	FRUIT DRINK (INCLUDE FRUIT PUNCH & FRUIT ADE)	0.0125
92510630	FRUIT JUICE DRINK NFS	0.0125
92510650	TAMARIND DRINK P.R. (REFRESCO DE TAMARINDO)	0.0125
92510810	GRAPEADE & GRAPE DRINK	0.0125
92510820	GRAPE JUICE DRINK	0.0125
92510910	GRAPEFRUIT JUICE DRINK	0.0125
92511010	LEMONADE	0.0125
92511020	LEMON-LIMEADE	0.0125
92511110	LIMEADE	0.0125
92511190	ORANGE JUICE DRINK	0.0125
92511200	ORANGE-MANGO JUICE DRINK	0.0125

FOODCODE	DESCRIPTION	Concentration (mg/g)
92511220	ORANGE DRINK (INCLUDE ORANGE ADE YABA DABA DEW)	0.0125
92511250	CITRUS FRUIT JUICE DRINK (INCL 5-ALIVE)	0.0125
92511260	ORANGE-CRANBERRY JUICE DRINK	0.0125
92511270	ORANGE-PEACH JUICE DRINK	0.0125
92511280	ORANGE-GRAPE-BANANA JUICE DRINK	0.0125
92511310	PINEAPPLE-GRAPEFRUIT JUICE DRINK	0.0125
92511340	PINEAPPLE-ORANGE JUICE DRINK	0.0125
92511350	ORANGE-RASPBERRY JUICE DRINK	0.0125
92511400	RASPBERRY-FLAVORED DRINK	0.0125
92511510	STRAWBERRY-FLAVORED DRINK	0.0125
92512090	PINA COLADA NONALCOHOLIC	0.0125
92520410	FRUIT DRINK LOW CALORIE	0.0125
92520810	GRAPE DRINK LOW CALORIE	0.0125
92520910	LEMONADE LOW CALORIE	0.0125
92530110	APPLE DRINK W/ VITAMIN C ADDED	0.0125
92530310	CHERRY DRINK W/ VITAMIN C ADDED	0.0125
92530410	CITRUS DRINK W/ VITAMIN C ADDED	0.0125
92530510	CRANBERRY JUICE DRINK W/VIT C ADDED (INCL COCKTAIL)	0.0125
92530520	CRANBERRY-APPLE JUICE DRINK W/ VITAMIN C ADDED	0.0125
92530610	FRUIT PUNCH/DRINK/ADE W/ VIT C ADDED (INCL HI-C)	0.0125
92530710	GRAPE DRINK W/ VITAMIN C ADDED	0.0125
92530810	GRAPEFRUIT JUICE DRINK W/ VITAMIN C ADDED	0.0125
92530840	GUAVA JUICE DRINK W/ VIT C ADDED	0.0125
92530910	LEMONADE W/ VITAMIN C ADDED	0.0125
92531010	ORANGE DRINK & ORANGEADE W/ VITAMIN C ADDED	0.0125
92531020	ORANGE BREAKFAST DRINK FROM FROZEN CONCENTRATE	0.0125
92531030	ORANGE BREAKFAST DRINK	0.0125
92531120	PINEAPPLE-ORANGE JUICE DRINK W/ VITAMIN C ADDED	0.0125
92531150	PINEAPPLE-ORANGE-GRAPEFRUIT JUICE DRINK W/VITAMIN C	0.0125
92541010	FRUIT-FLAVORED DRINK FROM SWEETENED PWDR FORTIFIED W/ VIT C	0.0125
92541020	LEMONADE-FLAV DRINK FROM POWDER W/ SUGAR & VIT C	0.0125
92541040	LEMONADE-FLAV DRINK FROM POWDER LO CAL W/ VIT C	0.0125
92541100	APPLE CIDER DRINK FROM MIX SUGAR & VIT C ADDED	0.0125
92541120	APPLE CIDER DRINK FROM MIX LOW CAL VIT C ADDED	0.0125
92542000	FRUIT-FLAVORED DRINK FROM POWDER W/HI VIT C(TANG)	0.0125

FOODCODE	DESCRIPTION	Concentration (mg/g)
92544000	FRUIT-FLAVOR DRINK FROM UNSWEET PWDR W/ VIT C W/ SUGAR	0.0125
92550050	APPLE-WHITE GRAPE JUICE DRINK LOW CAL W/VIT C ADDED	0.0125
92550110	CRANBERRY JUICE COCKTAIL LO CAL W/ VIT C ADDED	0.0125
92550610	FRUIT-FLAVORED DRINK LOW CAL W/ VITAMIN C ADDED	0.0125
92551700	JUICE DRINK LOW CALORIE	0.0125
92552050	ORANGE BREAKFAST DRINK LOW CALORIE	0.0125
92552100	ORANGE-CRANBERRY JUICE DRINK LOW CAL W/ VIT C ADDED	0.0125
92553000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE LOW CAL	0.0125
92560000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE	0.0125
92582110	ORANGE BREAKFAST DRINK CALCIUM FORTIFIED	0.0125
92611100	OATMEAL BEVERAGE W/ MILK	0.0125
92613510	CORN BEV W/ CHOC & MILK (CHAMPURRADO ATOLE DE CHOC)	0.0125
92731000	FRUIT-FLAVORED DRINK NON-CARB FROM POWDER W/ SUGAR	0.0125
92741000	FRUIT-FLAVORED DRINK NON-CARB FROM LO CAL POWDER	0.0125
92900110	FRUIT-FLAVORED CONCENTRATE DRY W/ SUGAR & VIT C	0.0125
92900300	FRUIT-FLAV THIRST QUENCH BEV DRY CONC (GATORADE)	0.0125

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APPENDIX C

Foods selected for the consumption analysis of lycopene from the addition of tomato pulp powder, revised from the original GRAS dossier (GRN 000163; organized in ascending order by food code)

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
11310000	MILK IMITATION FLUID SOY BASED	0.0125
11320000	MILK SOY READY-TO-DRINK NOT BABY	0.0125
11330000	MILK SOY DRY RECONSTITUTED NOT BABY	0.0125
11340000	MILK IMITATION FLUID NONSOY SWEETENED NOT CHOCOLATE	0.0125
11430000	YOGURT FRUIT VARIETY NS AS TO MILK TYPE	0.0133
11431000	YOGURT FRUIT VARIETY WHOLE MILK	0.0133
11432000	YOGURT FRUIT VARIETY LOWFAT MILK	0.0133
11433000	YOGURT FRUIT VARIETY NONFAT MILK	0.0133
11433500	YOGURT FRUITED NONFAT MILK LOW CAL SWEETENER	0.0133
11459990	YOGURT FROZEN NS AS TO FLAVOR NS TO TYPE OF MILK	0.0133
11460000	YOGURT FROZEN NOT CHOCOLATE TYPE OF MILK NS	0.0133
11460170	YOGURT FROZEN NOT CHOCOLATE LOWFAT MILK	0.0133
11460250	YOGURT FROZEN NOT CHOCOLATE W/ SORBET/SORBET-COATED	0.0133
11460300	YOGURT FROZEN NOT CHOCOLATE NONFAT MILK	0.0133
11460410	YOGURT FRZ NOT CHOC NONFAT MILK W/ LOW-CAL SWEET	0.0133
11460440	YOGURT FROZEN NOT CHOCOLATE WHOLE MILK	0.0133
11461200	YOGURT FROZEN SANDWICH	0.0133
11519000	MILK BEVERAGE NOT CHOCOLATE W/ WHOLE MILK	0.0125
11551050	MILK FRUIT DRINK (INCL LICUADO)	0.0125
11552200	MILK-BASED FRUIT DRINK (INCL ORANGE JULIUS)	0.0125
11623000	MEAL SUPPLEMENT / REPLACEMENT PREPARED RTD	0.0125
11641000	MEAL REPLACEMENT MILK BASED HIGH PROTEIN LIQUID	0.0125
11830400	MILK BEV POWDER DRY NOT RECONST NOT CHOC	0.0125
11830800	INSTANT BREAKFAST POWDER NOT RECONSTITUTED	0.0125
11830810	INSTANT BFAST PWDR SWT W/ LO CAL SWT NOT RECONSTUT	0.0125
11830970	MEAL REPLACEMENT PROTEIN TYPE MILK-BASE POWDER	0.0125
11831500	NUTRIENT SUPPLEMENT MILK-BASE HIGH PROT NOT RECONST	0.0125
11835100	MEAL REPLACEMENT POSITRIM DRINK MIX DRY POWDER	0.0125
13110100	ICE CREAM REGULAR NOT CHOCOLATE	0.0316
13110120	ICE CREAM RICH FLAVORS OTHER THAN CHOCOLATE	0.0316
13110200	ICE CREAM SOFT SERVE NOT CHOCOLATE	0.0316
13110400	MILK DESSERT FRZN FLAVORS NOT CHOC (NO BUTTERFAT)	0.0316
13120050	ICE CREAM BAR OR STICK NOT CHOC- OR CAKE-COVERED	0.0316
13121100	ICE CREAM SUNDAE FRUIT TOPPING W/ WHIPPED CREAM	0.0316
13121200	ICE CREAM SUNDAE PREPACKAGED NOT CHOCOLATE	0.0316

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
13124100	SORBET & ICE CREAM	0.0316
13125100	ICE CREAM W/ SHERBET	0.0316
13130300	LIGHT ICE CREAM NOT CHOCOLATE (FORMERLY ICE MILK)	0.0316
13130350	LIGHT ICE CREAM PREMIUM NOT CHOC (FORMERLY ICE MILK)	0.0316
13130600	LIGHT ICE CREAM SOFT SERVE NOT CHOC (FORMERLY ICE MILK)	0.0316
13130620	LIGHT ICE CREAM SOFT SERVE CONE NOT CHOC (DAIRY QUEEN)	0.0316
13135000	LIGHT ICE CREAM SANDWICH (DAIRY QUEEN) (FORMERLY ICE MILK)	0.0316
13140670	LIGHT ICE CREAM SUNDAE FRUIT TOP (W/O WHIP CREAM)(ICE MILK)	0.0316
13140700	LIGHT ICE CREAM CREAMSICLE OR DREAMSICLE (FORMERLY ICE MILK)	0.0316
13142000	MILK DESSERT BAR/STICK FROZEN W/ COCONUT	0.0316
13150000	SHERBET ALL FLAVORS	0.0316
13160100	MILK DESSERT FZN LOWFAT W/LOW CAL SWEET NOT CHOC	0.0316
13160160	MILK DESSERT FROZ NONFAT W/ LOW CAL SWEETENER NOT CHOC	0.0316
13160200	MILK DESSERT FROZEN LOWFAT NOT CHOCOLATE	0.0316
13160400	MILK DESSERT FROZ MILK-FAT FREE NOT CHOC	0.0316
13160600	MILK DESSERT FROZ W/ LOW CAL SWEETENER NOT CHOC	0.0316
13161600	MILK DES BAR FROZEN LOFAT MILK&LO CAL SWEETENER	0.0316
13210300	CUSTARD	0.0316
13210750	PUDDING PUMPKIN	0.0316
14410200	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE	0.0545
14410210	CHEESE PROCESSED AMERICAN/CHEDDAR LOW SODIUM	0.0545
14410300	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE LOWFAT	0.0545
14410330	CHEESE PROC CHEESE PRODUCT AMER/CHED RED FAT	0.0545
14410340	CHEESE PROC CHEESE PROD AMER/CHED RED FAT & SODIU	0.0545
14410350	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE NONFAT	0.0545
14410380	CHEESE PROCESSED CREAM CHEESE PRODUCT NONFAT	0.0545
14410500	CHEESE PROCESSED CHEESE FOOD	0.0545
14410600	CHEESE PROCESSED W/VEGETABLES(INCL PEPPER CHEESE)	0.0545
14410710	CHEESE PROCESSED MOZZARELLA LOW SODIUM	0.0545
14420000	CHEESE SPREAD NFS	0.1000
14420100	CHEESE SPREAD AMERICAN OR CHEDDAR CHEESE BASE	0.1000
14420140	CHEESE SPREAD AMER/CHED BASE LOW FAT LOW SODIUM	0.1000
14420200	CHEESE SPREAD CREAM CHEESE OR NEUFCHATEL BASE	0.1000
14420300	CHEESE SPREAD PRESSURIZED CAN	0.1000
14620150	DIP CHEESE W/ CHILI PEPPER (CHILI CON QUESO)	0.1000
14620200	DIP CHEESE BASE OTHER THAN CREAM CHEESE	0.1000

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
14630200	CHEESE SOUFFLE	0.1000
14640000	CHEESE SANDWICH	0.1000
14640100	CHEESE SANDWICH GRILLED	0.1000
14640200	CHEESE SANDWICH HOAGIE	0.1000
14650100	CHEESE SAUCE	0.0638
14650150	CHEESE SAUCE MADE W/ LOWFAT CHEESE	0.0638
25210110	FRANKFURTER WIENER OR HOT DOG NFS	0.0545
25210150	FRANKFURTER OR HOT DOG CHEESE-FILLED	0.0545
25210210	FRANKFURTER OR HOT DOG BEEF	0.0545
25210220	FRANKFURTER OR HOT DOG BEEF & PORK	0.0545
25210230	FRANKFURTER OR HOT DOG BEEF AND PORK LOWFAT	0.0545
25210250	FRANKFURTER OR HOT DOG MEAT & POULTRY FAT FREE	0.0545
25210280	FRANKFURTER OR HOT DOG MEAT & POULTRY	0.0545
25210310	FRANKFURTER OR HOT DOG CHICKEN	0.0545
25210410	FRANKFURTER OR HOT DOG TURKEY	0.0545
25210610	FRANKFURTER OR HOT DOG BEEF LOWFAT	0.0545
25210700	FRANKFURTER OR HOT DOG MEAT & POULTRY LOWFAT	0.0545
25230430	HAM & CHEESE LOAF	0.0545
27111000	BEEF W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27111050	SPAGHETTI SAUCE W/ BEEF/MEAT HOMEMADE-STYLE	0.0214
27111300	MEXICAN BEEF STEW NO POTATOES TOMATO SAUCE	0.0214
27120100	HAM/PORK W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27120110	SAUSAGE W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27141030	SPAGHETTI SAUCE W/ POULTRY HOMEMADE	0.0214
27141050	STEWED CHICKEN W/ TOMATO SAUCE MEXICAN STYLE	0.0214
27150310	FISH W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27150350	SARDINES W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27162050	SPAGHETTI SAUCE W/ COMBINATION OF MEATS HOMEMADE	0.0214
27211100	BEEF STEW W/ POTATOES TOMATO-BASED SAUCE	0.0214
27212100	BEEF & NOODLES W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27213100	BEEF & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27213120	PORCUPINE BALLS W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27214110	MEAT LOAF W/ BEEF W/ TOMATO SAUCE	0.0214
27220110	PORK & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27242400	CHICKEN & NOODLES TOMATO-BASED SAUCE (MIXTURE)	0.0214
27243500	CHICKEN & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	0.0214
27250810	FISH & RICE W/ TOMATO-BASED SAUCE	0.0214
27260100	MEAT LOAF W/ BEEF & PORK W/ TOMATO SAUCE	0.0214

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
27311310	BEEF STEW W/ POT & VEG(W/ CAR/DK GRN) TOMATO SAUCE	0.0214
27311320	BEEF STEW W/ POT & VEG (NO CAR/DK GREEN) TOM SAUCE	0.0214
27315210	BEEF RICE & VEG (W/ CAR/DK GREEN) TOMATO SAUCE	0.0214
27315220	BEEF RICE & VEG (NO CAR/DK GREEN) TOMATO SAUCE	0.0214
27330210	LAMB STEW W/ POT & VEG (INCL CAR/DK GRN) TOM SAUCE	0.0214
27343520	CHICKEN NOODLES VEG (NO CAR/DK GRN) TOMATO SAUCE	0.0214
27345510	CHICKEN RICE & VEG (INCL CAR/DK GRN) TOMATO SAUCE	0.0214
27345520	CHICKEN RICE & VEG (NO CAR/DK GRN) TOMATO SAUCE	0.0214
27416300	BEEF TACO FILLING: BEEF CHEESE TOMATO TACO SAUCE	0.0214
27418310	CORNED BEEF W/ TOMATO SAUCE & ONION P.R. STYLE	0.0214
27450700	FISH & VEG (INCL CAR/DK GRN NO POT) TOMATO SAUCE	0.0214
27450710	FISH & VEG (NO CAR/DK GRN NO POT) TOMATO SAUCE	0.0214
27510700	MEATBALL & SPAGHETTI SAUCE SUBMARINE SANDWICH	0.0214
27513060	ROAST BEEF SANDWICH W/ BACON & CHEESE SAUCE	0.0214
28340610	CHICKEN VEGETABLE SOUP STEW TYPE (INCL CHUNKY)	0.0122
28340630	CHICKEN VEG SOUP W/ RICE STEW TYPE CHUNKY STYLE	0.0122
28340640	CHICKEN VEG SOUP W/ NOODLES STEW TYPE CHUNKY STYL	0.0122
28340660	CHICKEN OR TURKEY VEGETABLE SOUP HOME RECIPE	0.0122
28340670	CHICKEN VEGETABLE SOUP W/RICE MEXICAN(SOPA / CALDO DE POLLO)	0.0122
28340690	CHICKEN VEG SOUP W/ POTATO & CHEESE CHUNKY	0.0122
28350120	CRAB SOUP TOMATO BASE	0.0122
41201020	BAKED BEANS W/ TOMATO SAUCE	0.0638
51122000	BREAD REDUCED CALORIE/HIGH FIBER	0.0600
51122010	BREAD REDUCED CALORIE/HIGH FIBER TOASTED	0.0600
51122050	BREAD REDUCED CALORIE/HIGH FIBER ITALIAN	0.0600
51122060	BREAD REDUCED CALORIE/HIGH FIBER ITALIAN TOASTED	0.0600
51122100	BREAD REDUCED CALORIE/ HIGH FIBER W/ FRUIT/NUTS	0.0600
51122110	BREAD REDUCED CALORIE/HI FIBER W/FRUIT/NUTS TOAST	0.0600
51122300	BREAD WHITE SPECIAL FORMULA ADDED FIBER	0.0600
51123010	BREAD HIGH PROTEIN	0.0600
51180010	BAGEL	0.0545
51180020	BAGEL TOASTED	0.0545
51180030	BAGEL W/ RAISINS	0.0545
51180040	BAGEL W/ RAISINS TOASTED	0.0545
51180080	BAGEL W/ FRUIT OTHER THAN RAISINS	0.0545
51180090	BAGEL W/ FRUIT OTHER THAN RAISINS TOASTED	0.0545
51182010	BREAD STUFFING (INCLUDE HOMEMADE STUFFING NFS)	0.0300

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
51182020	BREAD STUFFING W/ EGG	0.0300
51184000	BREAD STICK HARD	0.2000
51184100	BREAD STICK HARD LOW SODIUM	0.2000
51185000	CROUTONS	0.4286
51208000	BAGEL 100% WHOLE WHEAT	0.0545
51208010	BAGEL 100% WHOLE WHEAT TOASTED	0.0545
51208100	BAGEL 100% WHOLE WHEAT W/ RAISINS	0.0545
51208110	BAGEL 100% WHOLE WHEAT W/ RAISINS TOASTED	0.0545
51301600	BREAD PITA WHOLE"" WHEAT	0.0600
51301620	BREAD PITA CRACKED WHEAT	0.0600
51301630	BREAD PITA CRACKED WHEAT TOASTED	0.0600
51301700	BAGEL WHEAT	0.0545
51301710	BAGEL WHEAT TOASTED	0.0545
51301750	BAGEL WHOLE"" WHEAT	0.0545
51301760	BAGEL WHOLE"" WHEAT TOASTED	0.0545
51301800	BAGEL WHEAT W/ RAISINS	0.0545
51301810	BAGEL WHEAT W/ RAISINS TOASTED	0.0545
51404500	BAGEL PUMPERNICKEL	0.0545
51404510	BAGEL PUMPERNICKEL TOASTED	0.0545
51601010	BREAD MULTIGRAIN TOASTED	0.0600
51601020	BREAD MULTIGRAIN	0.0600
51601210	BREAD MULTIGRAIN W/ RAISINS	0.0600
51601220	BREAD MULTIGRAIN W/ RAISINS TOASTED	0.0600
51602010	BREAD MULTIGRAIN REDUCED CALORIE/ HIGH FIBER	0.0600
51602020	BREAD MULTIGRAIN REDUCED CALORIE/ HI FIBER TOAST	0.0600
51630000	BAGEL MULTIGRAIN	0.0545
51630010	BAGEL MULTIGRAIN TOASTED	0.0545
51630100	BAGEL MULTIGRAIN W/ RAISINS	0.0545
51630110	BAGEL MULTIGRAIN W/ RAISINS TOASTED	0.0545
52101000	BISCUIT BAKING POWDER OR BUTTERMILK TYPE NFS	0.0545
52101100	BISCUIT BAKING POWDER OR BUTTERMILK FROM MIX	0.0545
52102040	BISCUIT BAK POWDER OR BUTTERMILK FROM REFRG DOUGH	0.0545
52103000	BISCUIT BAKING POWDER/BUTTERMILK TYPE COMMERCIALLY BAKED	0.0545
52104010	BISCUIT BAKING POWDER OR BUTTERMILK HOMEMADE	0.0545
52104100	BISCUIT CHEESE	0.0545
52104200	BISCUIT CINNAMON-RAISIN	0.0545
52215000	TORTILLA NFS	0.1000

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
52215100	TORTILLA CORN	0.1000
52215200	TORTILLA FLOUR (WHEAT)	0.1000
52215260	TORTILLA WHOLE WHEAT	0.1000
52215300	TACO SHELL CORN	0.1000
52215350	TACO SHELL FLOUR	0.1000
52304010	MUFFIN WHEAT BRAN (INCLUDE W/ RAISINS & NUTS)	0.0545
52304040	MUFFIN BRAN W/ FRUIT LOWFAT	0.0545
52304060	MUFFIN BRAN W/ FRUIT NO FAT NO CHOLESTEROL	0.0545
55101000	PANCAKES PLAIN (INCLUDE PANCAKES NFS)	0.0273
55101010	PANCAKES REDUCED CALORIE HIGH FIBER	0.0273
55103000	PANCAKES W/ FRUIT (INCLUDE BLUEBERRY PANCAKES)	0.0273
55105000	PANCAKES BUCKWHEAT	0.0273
55105100	PANCAKES CORNMEAL	0.0273
55105200	PANCAKES WHOLE WHEAT	0.0273
55105300	PANCAKES SOURDOUGH	0.0273
55201000	WAFFLE PLAIN	0.0353
55202000	WAFFLE WHEAT BRAN OR MULTIGRAIN	0.0353
55203000	WAFFLE FRUIT	0.0353
55205000	WAFFLE 100% WHOLE WHEAT OR 100% WHOLE GRAIN	0.0353
55206000	WAFFLE OAT BRAN	0.0353
55207000	WAFFLE MULTI-BRAN (INCLUDE EGGO NUTRIGRAIN)	0.0353
55211000	WAFFLE PLAIN FAT FREE	0.0353
55211050	WAFFLE PLAIN LOWFAT	0.0353
55301000	FRENCH TOAST PLAIN (INCLUDE ROMAN MEAL)	0.0545
55301050	FRENCH TOAST STICKS PLAIN	0.0545
58100600	ENCHILADA W/ CHICKEN TOMATO-BASE SAUCE	0.0273
58100900	ENCHILADA W/ SEAFOOD TOMATO SAUCE	0.0273
58101800	GROUND BEEF W/ TOMATO SAUCE ON A CORNBREAD CRUST	0.0214
58107000	GROUND BEEF W/ TOMATO SAUCE ON A PIZZA CRUST	0.0214
58126150	TURNOVER MEAT & CHEESE TOMATO SAUCE	0.0214
58131110	RAVIOLI FILLING NS TOMATO SAUCE	0.0214
58131320	RAVIOLI MEAT-FILLED W/ TOMATO OR MEAT SAUCE	0.0214
58131323	RAVIOLI MEAT-FILLED W/ TOMATO OR MEAT SAUCE CANNED	0.0214
58131520	RAVIOLI CHEESE-FILLED W/ TOMATO SAUCE	0.0214
58131523	RAVIOLI CHEESE-FILLED W/ TOMATO SAUCE CANNED	0.0214
58132110	SPAGHETTI W/ TOMATO SAUCE MEATLESS	0.0214
58132113	PASTA W/ TOMATO SAUCE & CHEESE CANNED	0.0214
58132310	SPAGHETTI W/TOMAT SAUCE & MEAT SAUCE	0.0214

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
58132313	PASTA W/ TOMATO SAUCE & MEAT/MEATBALLS CANNED	0.0214
58132710	SPAGHETTI W/ TOMATO SAUCE & FRANKFURTERS/HOT DOG	0.0214
58132713	PASTA W/ TOMATO SAUCE & FRANKFURTERS/HOT DOGS CANNED	0.0214
58132910	SPAGHETTI W/ TOMATO SAUCE & CHICKEN OR TURKEY	0.0214
58133120	MANICOTTI CHEESE-FILLED W/ TOMATO SAUCE MEATLESS	0.0214
58134610	TORTELLINI MEAT-FILLED W/ TOMATO SAUCE	0.0214
58134620	TORTELLINI CHEESE-FILLED MEATLESS W/TOMATO SAUCE	0.0214
58134710	TORTELLINI SPINACH-FILLED W/ TOMATO SAUCE	0.0214
58146100	PASTA W/ TOMATO SAUCE MEATLESS	0.0214
58146150	PASTA W/ CHEESE & TOMATO SAUCE MEATLESS	0.0214
58147110	MACARONI OR NOODLES W/ BEANS & TOMATO SAUCE	0.0214
58161300	WHITE RICE W/ TOMATO SAUCE	0.0214
58161310	RICE BROWN W/ TOMATO SAUCE	0.0214
58302060	SPAG W/ BEEF TOM-BASED SAUCE LOWFAT RED SODIUM FRZ DIET	0.0214
58302080	NOODLES W/ VEG TOM-BASED SAUCE FRZ DIET	0.0214
58304250	MANICOTTI W/ CHEESE TOMATO SAUCE (DIET FROZ MEAL)	0.0214
74402010	TOMATO CHILI SAUCE (CATSUP TYPE)	0.2000
74402310	GREEN TOMATO-CHILE SAUCE RAW	0.2000
74402350	GREEN TOMATO-CHILE SAUCE COOKED	0.2000
74403010	TOMATO SAUCE	0.2000
74404010	SPAGHETTI SAUCE	0.0240
74404030	SPAGHETTI SAUCE W/ MEAT CANNED NO EXTRA MEAT	0.0240
74404050	SPAGHETTI SAUCE LOW SODIUM	0.0240
74404060	SPAGHETTI SAUCE FAT FREE	0.0240
74406100	STEAK SAUCE TOMATO-BASE (INCLUDE A-1)	0.2000
74601000	TOMATO SOUP NFS	0.0122
74601010	TOMATO SOUP CREAM OF PREP W/ MILK	0.0122
74602010	TOMATO SOUP PREPARED W/ WATER	0.0122
74602030	TOMATO SOUP CANNED UNDILUTED	0.0122
74602050	TOMATO SOUP INSTANT TYPE PREPARED W/ WATER	0.0122
74602100	TOMATO SOUP CANNED LOW SODIUM READY-TO-SERVE	0.0122
74603010	TOMATO BEEF SOUP PREPARED W/ WATER	0.0122
74604010	TOMATO BEEF NOODLE SOUP PREPARED W/ WATER	0.0122
74604500	TOMATO NOODLE SOUP PREPARED W/ WATER	0.0122
74605010	TOMATO RICE SOUP PREPARED W/ WATER	0.0122
74606010	TOMATO VEGETABLE SOUP PREP W/ WATER	0.0122
74606020	TOMATO VEGETABLE SOUP W/NOODLES PREPARED W/ WATER	0.0122
75412070	EGGPLANT W/ CHEESE & TOMATO SAUCE	0.0214

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
75649010	VEGETABLE SOUP PREP W/ WATER OR READY-TO-SERVE	0.0122
75649020	VEGETABLE SOUP CANNED UNDILUTED	0.0122
75649030	VEGETABLE SOUP CANNED LOW SODIUM	0.0122
75649050	VEGETABLE SOUP MADE FROM DRY MIX	0.0122
75649060	VEGETABLE SOUP DRY MIX NOT RECONSTITUTED	0.0122
75649110	VEGETABLE SOUP HOME RECIPE	0.0122
75649150	VEGETABLE NOODLE SOUP HOME RECIPE	0.0122
75650990	MINESTRONE SOUP CANNED REDUCED SODIUM RTS	0.0122
75651000	MINESTRONE SOUP HOME RECIPE	0.0122
75651010	VEGETABLE BEAN SOUP PREPARED W/ WATER	0.0122
75651020	VEGETABLE BEEF SOUP PREPARED W/ WATER	0.0122
75651040	VEGETABLE NOODLE SOUP PREPARED W/ WATER	0.0122
75651050	VEGETABLE CHICKEN SOUP W/ WATER OR READY-TO-SERVE	0.0122
75651070	VEGETABLE RICE SOUP PREPARED W/ WATER	0.0122
75651110	VEG CHICKEN RICE SOUP PREPARED W/ WATER / READY TO	0.0122
75651140	VEG SOUP W/ CHICKEN BROTH MEXICAN STYLE (SOPA RANCHERA)	0.0122
75651150	VEGETABLE NOODLE SOUP CAN RED SODIUM PREP W/ WATER/RTS	0.0122
75652010	VEGETABLE BEEF SOUP HOME RECIPE	0.0122
75652040	VEG BEEF SOUP W/ NOODLES HOME RECIPE	0.0122
75652050	VEG BEEF SOUP W/ RICE HOME RECIPE	0.0122
75656020	VEGETABLE SOUP CHUNKY STYLE	0.0122
75656040	VEGETABLE SOUP W/ PASTA CHUNKY STYLE	0.0122
92203000	CEREAL BEVERAGE (INCLUDE PERO BREAK AWAY)	0.0125
92201010	POSTUM (COFFEE SUBSTITUTE)	0.0125
92541120	APPLE CIDER DRINK FROM MIX LOW CAL VIT C ADDED	0.0125
92541100	APPLE CIDER DRINK FROM MIX SUGAR & VIT C ADDED	0.0125
92510110	APPLE DRINK	0.0125
92530110	APPLE DRINK W/ VITAMIN C ADDED	0.0125
92510150	APPLE JUICE DRINK	0.0125
92510120	APPLE-CHERRY DRINK	0.0125
92510170	APPLE-CRANBERRY-GRAPE JUICE DRINK	0.0125
92510200	APPLE-ORANGE-PINEAPPLE JUICE DRINK	0.0125
92550050	APPLE-WHITE GRAPE JUICE DRINK LOW CAL W/VIT C ADDED	0.0125
92510220	APRICOT-PINEAPPLE JUICE DRINK	0.0125
92510310	BANANA-ORANGE DRINK	0.0125
92510410	BLACK CHERRY DRINK	0.0125
92530210	BLACK CHERRY DRINK W/ VITAMIN C ADDED	0.0125
92530310	CHERRY DRINK W/ VITAMIN C ADDED	0.0125

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
92530410	CITRUS DRINK W/ VITAMIN C ADDED	0.0125
92511250	CITRUS FRUIT JUICE DRINK (INCL 5-ALIVE)	0.0125
92582100	CITRUS JUICE DRINK CALCUIM FORTIFIED	0.0125
92551600	CITRUS JUICE DRINK LOW CALORIE	0.0125
92550110	CRANBERRY JUICE COCKTAIL LO CAL W/ VIT C ADDED	0.0125
92530510	CRANBERRY JUICE DRINK W/VIT C ADDED(INCL COCKTAIL)	0.0125
92550210	CRANBERRY-APPLE JUICE DRINK LO CAL VIT C ADDED	0.0125
92530520	CRANBERRY-APPLE JUICE DRINK W/ VITAMIN C ADDED	0.0125
92510610	FRUIT DRINK (INCLUDE FRUIT PUNCH & FRUIT ADE)	0.0125
92520410	FRUIT DRINK LOW CALORIE	0.0125
92510630	FRUIT JUICE DRINK NFS	0.0125
92530610	FRUIT PUNCH/DRINK/ADE W/ VIT C ADDED (INCL HI-C)	0.0125
92552000	FRUIT-FLAV DRINK FROM MIX HI VIT C ADDED LOW CAL	0.0125
92544000	FRUIT-FLAVOR DRINK FROM UNSWEET PWDR W/ VIT C W/ SUGAR	0.0125
92542000	FRUIT-FLAVORED DRINK FROM POWDER W/HI VIT C(TANG)	0.0125
92541010	FRUIT-FLAVORED DRINK FROM SWEETENED PWDR FORTIFIED W/ VIT C	0.0125
92550610	FRUIT-FLAVORED DRINK LOW CAL W/ VITAMIN C ADDED	0.0125
92582000	FRUIT-FLAVORED DRINK LOW CALORIE CALCIUM-FORTIFD	0.0125
92582050	FRUIT-FLAVORED DRINK VITAMIN & MINERAL FORTIFIED	0.0125
92560000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE	0.0125
92553000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE LOW CAL	0.0125
92520810	GRAPE DRINK LOW CALORIE	0.0125
92530710	GRAPE DRINK W/ VITAMIN C ADDED	0.0125
92510820	GRAPE JUICE DRINK	0.0125
92510810	GRAPEADE & GRAPE DRINK	0.0125
92510910	GRAPEFRUIT JUICE DRINK	0.0125
92550300	GRAPEFRUIT JUICE DRINK LOW CALORIE W/ VITAMIN C	0.0125
92530810	GRAPEFRUIT JUICE DRINK W/ VITAMIN C ADDED	0.0125
92510950	GUAVA JUICE DRINK	0.0125
92530840	GUAVA JUICE DRINK W/ VIT C ADDED	0.0125
92551700	JUICE DRINK LOW CALORIE	0.0125
92511010	LEMONADE	0.0125
92511000	LEMONADE FROZEN CONCENTRATE NOT RECONSTITUTED	0.0125
92520910	LEMONADE LOW CALORIE	0.0125
92530910	LEMONADE W/ VITAMIN C ADDED	0.0125
92541040	LEMONADE-FLAV DRINK FROM POWDER LO CAL W/ VIT C	0.0125
92541020	LEMONADE-FLAV DRINK FROM POWDER W/ SUGAR & VIT C	0.0125

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
92511020	LEMON-LIMEADE	0.0125
92511110	LIMEADE	0.0125
92531030	ORANGE BREAKFAST DRINK	0.0125
92582110	ORANGE BREAKFAST DRINK CALCIUM FORTIFIED	0.0125
92531020	ORANGE BREAKFAST DRINK FROM FROZEN CONCENTRATE	0.0125
92552050	ORANGE BREAKFAST DRINK LOW CALORIE	0.0125
92531010	ORANGE DRINK & ORANGEADE W/ VITAMIN C ADDED	0.0125
92511220	ORANGE DRINK (INCLUDE ORANGE ADE YABA DABA DEW)	0.0125
92511190	ORANGE JUICE DRINK	0.0125
92511230	ORANGE-APRICOT JUICE DRINK	0.0125
92511260	ORANGE-CRANBERRY JUICE DRINK	0.0125
92552100	ORANGE-CRANBERRY JUICE DRINK LOW CAL W/ VIT C ADDED	0.0125
92511280	ORANGE-GRAPE-BANANA JUICE DRINK	0.0125
92511240	ORANGE-LEMON DRINK	0.0125
92511200	ORANGE-MANGO JUICE DRINK	0.0125
92511270	ORANGE-PEACH JUICE DRINK	0.0125
92511350	ORANGE-RASPBERRY JUICE DRINK	0.0125
92511290	PAPAYA JUICE DRINK	0.0125
92512090	PINA COLADA NONALCOHOLIC	0.0125
92511310	PINEAPPLE-GRAPEFRUIT JUICE DRINK	0.0125
92531110	PINEAPPLE-GRAPEFRUIT JUICE DRINK W/ VIT C ADDED	0.0125
92511340	PINEAPPLE-ORANGE JUICE DRINK	0.0125
92531120	PINEAPPLE-ORANGE JUICE DRINK W/ VITAMIN C ADDED	0.0125
92531150	PINEAPPLE-ORANGE-GRAPEFRUIT JUICE DRINK W/VITAMIN C	0.0125
92511400	RASPBERRY-FLAVORED DRINK	0.0125
92531210	SRAWBERRY-FLAVORED DRINK W/ VITAMIN C ADDED	0.0125
92511510	STRAWBERRY-FLAVORED DRINK	0.0125
92510650	TAMARIND DRINK P.R. (REFRESCO DE TAMARINDO)	0.0125
92530950	VEGETABLE & FRUIT JUICE DRINK W/ VIT C	0.0125
92741000	FRUIT-FLAVORED DRINK NON-CARB FROM LO CAL POWDER	0.0125
92731000	FRUIT-FLAVORED DRINK NON-CARB FROM POWDER W/ SUGAR	0.0125
92613010	ATOLE (CORNMEAL BEVERAGE)	0.0125
92613510	CORN BEV W/ CHOC & MILK(CHAMPURRADO ATOLE DE CHOC)	0.0125
92611010	OATMEAL BEVERAGE P.R.	0.0125
92611100	OATMEAL BEVERAGE W/ MILK	0.0125
92900200	FRUIT-FLAV BEV DRY CONC LO CAL(INCL CRYSTAL LIGHT)	0.0125
92900300	FRUIT-FLAV THIRST QUENCH BEV DRY CONC (GATORADE)	0.0125
92900110	FRUIT-FLAVORED CONCENTRATE DRY W/ SUGAR & VIT C	0.0125

FOODCODE	DESCRIPTION	CONCENTRATION (mg/g)
92291300	POSTUM DRY POWDER	0.0125
92410300	SOFT DRINK COLA W/ HIGHER CAFFEINE SUGAR-FREE (INCL JOLT)	0.0125
92410310	SOFT DRINK COLA-TYPE	0.0125
92410340	SOFT DRINK COLA-TYPE DECAFFEINATED	0.0125
92410350	SOFT DRINK COLA-TYPE DECAFFEINATED SUGAR-FREE	0.0125
92410320	SOFT DRINK COLA-TYPE SUGAR-FREE	0.0125
92410330	SOFT DRINK COLA-TYPE W/ HIGHER CAFFEINE (INCL JOLT)	0.0125
92410520	SOFT DRINK FRUIT-FLAV SUGAR-FREE CAFFEINE FREE	0.0125
92410510	SOFT DRINK FRUIT-FLAVORED CAFFEINE FREE	0.0125
92410550	SOFT DRINK FRUIT-FLAVORED W/ CAFFEINE	0.0125
92410560	SOFT DRINK FRUIT-FLAVORED W/ CAFFEINE SUGAR-FREE	0.0125
92400000	SOFT DRINK NFS	0.0125
92400100	SOFT DRINK NFS SUGAR-FREE	0.0125
92410360	SOFT DRINK PEPPER-TYPE (INCL DR. PEPPER MR. PIBB)	0.0125
92410390	SOFT DRINK PEPPER-TYPE DECAFFEINATED	0.0125
92410400	SOFT DRINK PEPPER-TYPE DECAFFEINATED SUGAR-FREE	0.0125
92410370	SOFT DRINK PEPPER-TYPE SUGAR-FREE	0.0125
92306000	TEA HERBAL (INCLUDE SASSAFRAS LICORICE)	0.0125

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APPENDIX D

Consumption of lycopene as part of tomato pulp powder added to target foods, revised from the original tomato pulp powder GRAS dossier (GRN 000163)

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
11310000	MILK IMITATION FLUID SOY BASED	0.53	0.01
11320000	MILK SOY READY-TO-DRINK NOT BABY	3.11	0.05
11330000	MILK SOY DRY RECONSTITUTED NOT BABY	3.47	0.06
11340000	MILK IMITATION FLUID NONSOY SWEETENED NOT CHOCOLATE	2.62	0.04
11430000	YOGURT FRUIT VARIETY NS AS TO MILK TYPE	2.55	0.04
11431000	YOGURT FRUIT VARIETY WHOLE MILK	3.45	0.06
11432000	YOGURT FRUIT VARIETY LOWFAT MILK	2.47	0.04
11433000	YOGURT FRUIT VARIETY NONFAT MILK	3.55	0.06
11433500	YOGURT FRUITED NONFAT MILK LOW CAL SWEETENER	2.89	0.05
11459990	YOGURT FROZEN NS AS TO FLAVOR NS TO TYPE OF MILK	8.87	0.15
11460000	YOGURT FROZEN NOT CHOCOLATE TYPE OF MILK NS	2.78	0.05
11460170	YOGURT FROZEN NOT CHOCOLATE LOWFAT MILK	2.62	0.04
11460250	YOGURT FROZEN NOT CHOCOLATE W/ SORBET/SORBET-COATED	1.00	0.02
11460300	YOGURT FROZEN NOT CHOCOLATE NONFAT MILK	2.07	0.03
11460410	YOGURT FRZ NOT CHOC NONFAT MILK W/ LOW-CAL SWEET	2.76	0.05
11460440	YOGURT FROZEN NOT CHOCOLATE WHOLE MILK	1.16	0.02
11461200	YOGURT FROZEN SANDWICH	2.27	0.04
11519000	MILK BEVERAGE NOT CHOCOLATE W/ WHOLE MILK	4.32	0.07
11551050	MILK FRUIT DRINK (INCL LICUADO)	2.61	0.04
11552200	MILK-BASED FRUIT DRINK (INCL ORANGE JULIUS)	6.55	0.11
11623000	MEAL SUPPLEMENT / REPLACEMENT PREPARED RTD	4.60	0.08
11641000	MEAL REPLACEMENT MILK BASED HIGH PROTEIN LIQUID	3.20	0.05
11830400	MILK BEV POWDER DRY NOT RECONST NOT CHOC	0.19	0.00
11830800	INSTANT BREAKFAST POWDER NOT RECONSTITUTED	0.74	0.01
11830810	INSTANT BFAST PWDR SWT W/ LO CAL SWT NOT RECONSTUT	0.46	0.01
11830970	MEAL REPLACEMENT PROTEIN TYPE MILK-BASE POWDER	0.72	0.01
11831500	NUTRIENT SUPPLEMENT MILK-BASE HIGH PROT NOT RECONST	0.68	0.01
11835100	MEAL REPLACEMENT POSITRIM DRINK MIX DRY POWDER	0.54	0.01
13110100	ICE CREAM REGULAR NOT CHOCOLATE	5.07	0.08
13110120	ICE CREAM RICH FLAVORS OTHER THAN CHOCOLATE	2.88	0.05
13110200	ICE CREAM SOFT SERVE NOT CHOCOLATE	4.17	0.07

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
13110400	MILK DESSERT FRZN FLAVORS NOT CHOC (NO BUTTERFAT)	2.10	0.04
13120050	ICE CREAM BAR OR STICK NOT CHOC- OR CAKE-COVERED	2.52	0.04
13121100	ICE CREAM SUNDAE FRUIT TOPPING W/ WHIPPED CREAM	5.21	0.09
13121200	ICE CREAM SUNDAE PREPACKAGED NOT CHOCOLATE	5.82	0.10
13124100	SORBET & ICE CREAM	2.23	0.04
13125100	ICE CREAM W/ SHERBET	8.12	0.14
13130300	LIGHT ICE CREAM NOT CHOCOLATE (FORMERLY ICE MILK)	3.06	0.05
13130350	LIGHT ICE CREAM PREMIUM NOT CHOC (FORMERLY ICE MILK)	3.16	0.05
13130600	LIGHT ICE CREAM SOFT SERVE NOT CHOC (FORMERLY ICE MILK)	7.26	0.12
13130620	LIGHT ICE CREAM SOFT SERVE CONE NOT CHOC (DAIRY QUEEN)	7.79	0.13
13135000	LIGHT ICE CREAM SANDWICH (DAIRY QUEEN) (FORMERLY ICE MILK)	1.89	0.03
13140670	LIGHT ICE CREAM SUNDAE FRUIT TOP (W/O WHIP CREAM)(ICE MILK)	5.21	0.09
13140700	LIGHT ICE CREAM CREAMSICLE OR DREAMSICLE (FORMERLY ICE MILK)	2.04	0.03
13142000	MILK DESSERT BAR/STICK FROZEN W/ COCONUT	4.07	0.07
13150000	SHERBET ALL FLAVORS	4.55	0.08
13160100	MILK DESSERT FZN LOWFAT W/LOW CAL SWEET NOT CHOC	3.77	0.06
13160160	MILK DESSERT FROZ NONFAT W/ LOW CAL SWEETENER NOT CHOC	6.05	0.10
13160200	MILK DESSERT FROZEN LOWFAT NOT CHOCOLATE	5.08	0.08
13160400	MILK DESSERT FROZ MILK-FAT FREE NOT CHOC	4.82	0.08
13160600	MILK DESSERT FROZ W/ LOW CAL SWEETENER NOT CHOC	3.63	0.06
13161600	MILK DES BAR FROZEN LOFAT MILK&LO CAL SWEETENER	2.27	0.04
13210300	CUSTARD	4.39	0.07
13210750	PUDDING PUMPKIN	7.21	0.12
14410200	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE	1.88	0.03
14410210	CHEESE PROCESSED AMERICAN/CHEDDAR LOW SODIUM	1.45	0.02
14410300	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE LOWFAT	1.80	0.03
14410330	CHEESE PROC CHEESE PRODUCT AMER/CHED RED FAT	1.62	0.03
14410340	CHEESE PROC CHEESE PROD AMER/CHED RED FAT & SODIU	1.55	0.03
14410350	CHEESE PROCESSED AMERICAN/CHEDDAR TYPE NONFAT	1.43	0.02
14410380	CHEESE PROCESSED CREAM CHEESE PRODUCT NONFAT	1.09	0.02
14410500	CHEESE PROCESSED CHEESE FOOD	1.07	0.02

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
14410600	CHEESE PROCESSED W/VEGETABLES(INCL PEPPER CHEESE)	1.39	0.02
14410710	CHEESE PROCESSED MOZZARELLA LOW SODIUM	1.34	0.02
14420000	CHEESE SPREAD NFS	3.52	0.06
14420100	CHEESE SPREAD AMERICAN OR CHEDDAR CHEESE BASE	4.77	0.08
14420140	CHEESE SPREAD AMER/CHED BASE LOW FAT LOW SODIUM	3.44	0.06
14420200	CHEESE SPREAD CREAM CHEESE OR NEUFCHATEL BASE	3.61	0.06
14420300	CHEESE SPREAD PRESSURIZED CAN	12.88	0.21
14620150	DIP CHEESE W/ CHILI PEPPER (CHILI CON QUESO)	9.13	0.15
14620200	DIP CHEESE BASE OTHER THAN CREAM CHEESE	9.34	0.16
14630200	CHEESE SOUFFLE	4.75	0.08
14640000	CHEESE SANDWICH	8.30	0.14
14640100	CHEESE SANDWICH GRILLED	7.95	0.13
14640200	CHEESE SANDWICH HOAGIE	14.19	0.24
14650100	CHEESE SAUCE	3.62	0.06
14650150	CHEESE SAUCE MADE W/ LOWFAT CHEESE	7.24	0.12
25210110	FRANKFURTER WIENER OR HOT DOG NFS	3.81	0.06
25210150	FRANKFURTER OR HOT DOG CHEESE-FILLED	1.29	0.02
25210210	FRANKFURTER OR HOT DOG BEEF	4.38	0.07
25210220	FRANKFURTER OR HOT DOG BEEF & PORK	4.73	0.08
25210230	FRANKFURTER OR HOT DOG BEEF AND PORK LOWFAT	3.92	0.07
25210250	FRANKFURTER OR HOT DOG MEAT & POULTRY FAT FREE	3.22	0.05
25210280	FRANKFURTER OR HOT DOG MEAT & POULTRY	4.85	0.08
25210310	FRANKFURTER OR HOT DOG CHICKEN	4.30	0.07
25210410	FRANKFURTER OR HOT DOG TURKEY	4.50	0.08
25210610	FRANKFURTER OR HOT DOG BEEF LOWFAT	3.03	0.05
25210700	FRANKFURTER OR HOT DOG MEAT & POULTRY LOWFAT	2.33	0.04
25230430	HAM & CHEESE LOAF	6.11	0.10
27111000	BEEF W/ TOMATO-BASED SAUCE (MIXTURE)	3.56	0.06
27111050	SPAGHETTI SAUCE W/ BEEF/MEAT HOMEMADE-STYLE	5.46	0.09
27111300	MEXICAN BEEF STEW NO POTATOES TOMATO SAUCE	8.87	0.15
27120100	HAM/PORK W/ TOMATO-BASED SAUCE (MIXTURE)	5.34	0.09
27120110	SAUSAGE W/ TOMATO-BASED SAUCE (MIXTURE)	3.99	0.07
27141030	SPAGHETTI SAUCE W/ POULTRY HOMEMADE	4.22	0.07
27141050	STEWED CHICKEN W/ TOMATO SAUCE MEXICAN STYLE	5.48	0.09
27150310	FISH W/ TOMATO-BASED SAUCE (MIXTURE)	4.01	0.07

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
27150350	SARDINES W/ TOMATO-BASED SAUCE (MIXTURE)	2.66	0.04
27162050	SPAGHETTI SAUCE W/ COMBINATION OF MEATS HOMEMADE	6.02	0.10
27211100	BEEF STEW W/ POTATOES TOMATO-BASED SAUCE	10.05	0.17
27212100	BEEF & NOODLES W/ TOMATO-BASED SAUCE (MIXTURE)	7.19	0.12
27213100	BEEF & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	10.08	0.17
27213120	PORCUPINE BALLS W/ TOMATO-BASED SAUCE (MIXTURE)	4.34	0.07
27214110	MEAT LOAF W/ BEEF W/ TOMATO SAUCE	5.01	0.08
27220110	PORK & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	36.60	0.61
27242400	CHICKEN & NOODLES TOMATO-BASED SAUCE (MIXTURE)	11.58	0.19
27243500	CHICKEN & RICE W/ TOMATO-BASED SAUCE (MIXTURE)	5.46	0.09
27250810	FISH & RICE W/ TOMATO-BASED SAUCE	7.97	0.13
27260100	MEAT LOAF W/ BEEF & PORK W/ TOMATO SAUCE	3.60	0.06
27311310	BEEF STEW W/ POT & VEG(W/ CAR/DK GRN) TOMATO SAUCE	7.06	0.12
27311320	BEEF STEW W/ POT & VEG (NO CAR/DK GREEN) TOM SAUCE	9.47	0.16
27315210	BEEF RICE & VEG (W/ CAR/DK GREEN) TOMATO SAUCE	11.54	0.19
27315220	BEEF RICE & VEG (NO CAR/DK GREEN) TOMATO SAUCE	5.34	0.09
27330210	LAMB STEW W/ POT & VEG (INCL CAR/DK GRN) TOM SAUCE	8.10	0.14
27343520	CHICKEN NOODLES VEG (NO CAR/DK GRN) TOMATO SAUCE	4.80	0.08
27345510	CHICKEN RICE & VEG (INCL CAR/DK GRN) TOMATO SAUCE	8.00	0.13
27345520	CHICKEN RICE & VEG (NO CAR/DK GRN) TOMATO SAUCE	4.00	0.07
27416300	BEEF TACO FILLING: BEEF CHEESE TOMATO TACO SAUCE	1.56	0.03
27418310	CORNED BEEF W/ TOMATO SAUCE & ONION P.R. STYLE	5.18	0.09
27450700	FISH & VEG (INCL CAR/DK GRN NO POT) TOMATO SAUCE	4.80	0.08
27450710	FISH & VEG (NO CAR/DK GRN NO POT) TOMATO SAUCE	9.60	0.16
27510700	MEATBALL & SPAGHETTI SAUCE SUBMARINE SANDWICH	3.95	0.07
27513060	ROAST BEEF SANDWICH W/ BACON & CHEESE SAUCE	4.05	0.07
28340610	CHICKEN VEGETABLE SOUP STEW TYPE (INCL CHUNKY)	5.14	0.09
28340630	CHICKEN VEG SOUP W/ RICE STEW TYPE CHUNKY STYLE	6.60	0.11
28340640	CHICKEN VEG SOUP W/ NOODLES STEW TYPE CHUNKY STYL	2.94	0.05
28340660	CHICKEN OR TURKEY VEGETABLE SOUP HOME RECIPE	3.12	0.05
28340670	CHICKEN VEGETABLE SOUP W/RICE MEXICAN(SOPA / CALDO DE POLLO)	6.62	0.11
28340690	CHICKEN VEG SOUP W/ POTATO & CHEESE CHUNKY	6.60	0.11
28350120	CRAB SOUP TOMATO BASE	1.49	0.02
41201020	BAKED BEANS W/ TOMATO SAUCE	10.41	0.17
51122000	BREAD REDUCED CALORIE/HIGH FIBER	3.41	0.06

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
51122010	BREAD REDUCED CALORIE/HIGH FIBER TOASTED	2.93	0.05
51122050	BREAD REDUCED CALORIE/HIGH FIBER ITALIAN	6.93	0.12
51122060	BREAD REDUCED CALORIE/HIGH FIBER ITALIAN TOASTED	1.66	0.03
51122100	BREAD REDUCED CALORIE/ HIGH FIBER W/ FRUIT/NUTS	3.48	0.06
51122110	BREAD REDUCED CALORIE/HI FIBER W/FRUIT/NUTS TOAST	1.56	0.03
51122300	BREAD WHITE SPECIAL FORMULA ADDED FIBER	3.36	0.06
51123010	BREAD HIGH PROTEIN	4.50	0.08
51180010	BAGEL	3.37	0.06
51180020	BAGEL TOASTED	2.95	0.05
51180030	BAGEL W/ RAISINS	4.07	0.07
51180040	BAGEL W/ RAISINS TOASTED	3.00	0.05
51180080	BAGEL W/ FRUIT OTHER THAN RAISINS	3.20	0.05
51180090	BAGEL W/ FRUIT OTHER THAN RAISINS TOASTED	3.23	0.05
51182010	BREAD STUFFING (INCLUDE HOMEMADE STUFFING NFS)	3.41	0.06
51182020	BREAD STUFFING W/ EGG	4.70	0.08
51184000	BREAD STICK HARD	5.47	0.09
51184100	BREAD STICK HARD LOW SODIUM	6.22	0.10
51185000	CROUTONS	2.83	0.05
51208000	BAGEL 100% WHOLE WHEAT	2.65	0.04
51208010	BAGEL 100% WHOLE WHEAT TOASTED	2.64	0.04
51208100	BAGEL 100% WHOLE WHEAT W/ RAISINS	3.36	0.06
51208110	BAGEL 100% WHOLE WHEAT W/ RAISINS TOASTED	2.77	0.05
51301600	BREAD PITA WHOLE"" WHEAT	2.32	0.04
51301620	BREAD PITA CRACKED WHEAT	1.82	0.03
51301630	BREAD PITA CRACKED WHEAT TOASTED	2.46	0.04
51301700	BAGEL WHEAT	2.75	0.05
51301710	BAGEL WHEAT TOASTED	3.53	0.06
51301750	BAGEL WHOLE"" WHEAT	3.51	0.06
51301760	BAGEL WHOLE"" WHEAT TOASTED	3.71	0.06
51301800	BAGEL WHEAT W/ RAISINS	4.05	0.07
51301810	BAGEL WHEAT W/ RAISINS TOASTED	2.89	0.05
51404500	BAGEL PUMPERNICKEL	3.43	0.06
51404510	BAGEL PUMPERNICKEL TOASTED	2.79	0.05
51601010	BREAD MULTIGRAIN TOASTED	2.58	0.04
51601020	BREAD MULTIGRAIN	3.18	0.05

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
51601210	BREAD MULTIGRAIN W/ RAISINS	1.56	0.03
51601220	BREAD MULTIGRAIN W/ RAISINS TOASTED	1.44	0.02
51602010	BREAD MULTIGRAIN REDUCED CALORIE/ HIGH FIBER	3.00	0.05
51602020	BREAD MULTIGRAIN REDUCED CALORIE/ HI FIBER TOAST	2.57	0.04
51630000	BAGEL MULTIGRAIN	3.11	0.05
51630010	BAGEL MULTIGRAIN TOASTED	3.20	0.05
51630100	BAGEL MULTIGRAIN W/ RAISINS	1.46	0.02
51630110	BAGEL MULTIGRAIN W/ RAISINS TOASTED	1.31	0.02
52101000	BISCUIT BAKING POWDER OR BUTTERMILK TYPE NFS	2.39	0.04
52101100	BISCUIT BAKING POWDER OR BUTTERMILK FROM MIX	3.41	0.06
52102040	BISCUIT BAK POWDER OR BUTTERMILK FROM REFRG DOUGH	2.41	0.04
52103000	BISCUIT BAKING POWDER/BUTTERMILK TYPE COMMERCIALLY BAKED	4.13	0.07
52104010	BISCUIT BAKING POWDER OR BUTTERMILK HOMEMADE	3.70	0.06
52104100	BISCUIT CHEESE	3.30	0.05
52104200	BISCUIT CINNAMON-RAISIN	4.86	0.08
52215000	TORTILLA NFS	3.16	0.05
52215100	TORTILLA CORN	8.08	0.13
52215200	TORTILLA FLOUR (WHEAT)	8.23	0.14
52215260	TORTILLA WHOLE WHEAT	10.61	0.18
52215300	TACO SHELL CORN	4.13	0.07
52215350	TACO SHELL FLOUR	10.21	0.17
52304010	MUFFIN WHEAT BRAN (INCLUDE W/ RAISINS & NUTS)	3.64	0.06
52304040	MUFFIN BRAN W/ FRUIT LOWFAT	3.61	0.06
52304060	MUFFIN BRAN W/ FRUIT NO FAT NO CHOLESTEROL	3.92	0.07
55101000	PANCAKES PLAIN (INCLUDE PANCAKES NFS)	2.45	0.04
55101010	PANCAKES REDUCED CALORIE HIGH FIBER	2.19	0.04
55103000	PANCAKES W/ FRUIT (INCLUDE BLUEBERRY PANCAKES)	3.34	0.06
55105000	PANCAKES BUCKWHEAT	3.47	0.06
55105100	PANCAKES CORNMEAL	2.87	0.05
55105200	PANCAKES WHOLE WHEAT	1.90	0.03
55105300	PANCAKES SOURDOUGH	1.63	0.03
55201000	WAFFLE PLAIN	2.95	0.05
55202000	WAFFLE WHEAT BRAN OR MULTIGRAIN	2.20	0.04
55203000	WAFFLE FRUIT	2.07	0.03
55205000	WAFFLE 100% WHOLE WHEAT OR 100% WHOLE GRAIN	0.89	0.01

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
55206000	WAFFLE OAT BRAN	1.69	0.03
55207000	WAFFLE MULTI-BRAN (INCLUDE EGGO NUTRIGRAIN)	2.82	0.05
55211000	WAFFLE PLAIN FAT FREE	2.12	0.04
55211050	WAFFLE PLAIN LOWFAT	4.29	0.07
55301000	FRENCH TOAST PLAIN (INCLUDE ROMAN MEAL)	8.40	0.14
55301050	FRENCH TOAST STICKS PLAIN	5.31	0.09
58100600	ENCHILADA W/ CHICKEN TOMATO-BASE SAUCE	5.84	0.10
58100900	ENCHILADA W/ SEAFOOD TOMATO SAUCE	3.44	0.06
58101800	GROUND BEEF W/ TOMATO SAUCE ON A CORNBREAD CRUST	4.41	0.07
58107000	GROUND BEEF W/ TOMATO SAUCE ON A PIZZA CRUST	4.04	0.07
58126150	TURNOVER MEAT & CHEESE TOMATO SAUCE	3.76	0.06
58131110	RAVIOLI FILLING NS TOMATO SAUCE	3.75	0.06
58131320	RAVIOLI MEAT-FILLED W/ TOMATO OR MEAT SAUCE	6.85	0.11
58131323	RAVIOLI MEAT-FILLED W/ TOMATO OR MEAT SAUCE CANNED	6.02	0.10
58131520	RAVIOLI CHEESE-FILLED W/ TOMATO SAUCE	3.58	0.06
58131523	RAVIOLI CHEESE-FILLED W/ TOMATO SAUCE CANNED	3.18	0.05
58132110	SPAGHETTI W/ TOMATO SAUCE MEATLESS	8.26	0.14
58132113	PASTA W/ TOMATO SAUCE & CHEESE CANNED	6.84	0.11
58132310	SPAGHETTI W/TOMAT SAUCE & MEAT SAUCE	8.50	0.14
58132313	PASTA W/ TOMATO SAUCE & MEAT/MEATBALLS CANNED	6.89	0.11
58132710	SPAGHETTI W/ TOMATO SAUCE & FRANKFURTERS/HOT DOG	5.31	0.09
58132713	PASTA W/ TOMATO SAUCE & FRANKFURTERS/HOT DOGS CANNED	5.42	0.09
58132910	SPAGHETTI W/ TOMATO SAUCE & CHICKEN OR TURKEY	21.26	0.35
58133120	MANICOTTI CHEESE-FILLED W/ TOMATO SAUCE MEATLESS	7.10	0.12
58134610	TORTELLINI MEAT-FILLED W/ TOMATO SAUCE	7.14	0.12
58134620	TORTELLINI CHEESE-FILLED MEATLESS W/TOMATO SAUCE	6.37	0.11
58134710	TORTELLINI SPINACH-FILLED W/ TOMATO SAUCE	1.07	0.02
58146100	PASTA W/ TOMATO SAUCE MEATLESS	8.98	0.15
58146150	PASTA W/ CHEESE & TOMATO SAUCE MEATLESS	8.67	0.14
58147110	MACARONI OR NOODLES W/ BEANS & TOMATO SAUCE	6.18	0.10
58161300	WHITE RICE W/ TOMATO SAUCE	4.14	0.07
58161310	RICE BROWN W/ TOMATO SAUCE	7.04	0.12
58302060	SPAG W/ BEEF TOM-BASED SAUCE LOWFAT RED SODIUM FRZ DIET	5.88	0.10
58302080	NOODLES W/ VEG TOM-BASED SAUCE FRZ DIET	6.07	0.10

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
58304250	MANICOTTI W/ CHEESE TOMATO SAUCE (DIET FROZ MEAL)	6.41	0.11
74402010	TOMATO CHILI SAUCE (CATSUP TYPE)	8.61	0.14
74402310	GREEN TOMATO-CHILE SAUCE RAW	10.07	0.17
74402350	GREEN TOMATO-CHILE SAUCE COOKED	11.63	0.19
74403010	TOMATO SAUCE	13.39	0.22
74404010	SPAGHETTI SAUCE	3.42	0.06
74404030	SPAGHETTI SAUCE W/ MEAT CANNED NO EXTRA MEAT	4.75	0.08
74404050	SPAGHETTI SAUCE LOW SODIUM	4.01	0.07
74404060	SPAGHETTI SAUCE FAT FREE	6.83	0.11
74406100	STEAK SAUCE TOMATO-BASE (INCLUDE A-1)	4.70	0.08
74601000	TOMATO SOUP NFS	2.12	0.04
74601010	TOMATO SOUP CREAM OF PREP W/ MILK	4.89	0.08
74602010	TOMATO SOUP PREPARED W/ WATER	4.19	0.07
74602030	TOMATO SOUP CANNED UNDILUTED	2.02	0.03
74602050	TOMATO SOUP INSTANT TYPE PREPARED W/ WATER	1.27	0.02
74602100	TOMATO SOUP CANNED LOW SODIUM READY-TO-SERVE	4.34	0.07
74603010	TOMATO BEEF SOUP PREPARED W/ WATER	1.49	0.02
74604010	TOMATO BEEF NOODLE SOUP PREPARED W/ WATER	2.08	0.03
74604500	TOMATO NOODLE SOUP PREPARED W/ WATER	3.03	0.05
74605010	TOMATO RICE SOUP PREPARED W/ WATER	2.69	0.04
74606010	TOMATO VEGETABLE SOUP PREP W/ WATER	3.47	0.06
74606020	TOMATO VEGETABLE SOUP W/NOODLES PREPARED W/ WATER	2.29	0.04
75412070	EGGPLANT W/ CHEESE & TOMATO SAUCE	6.36	0.11
75649010	VEGETABLE SOUP PREP W/ WATER OR READY-TO-SERVE	4.21	0.07
75649020	VEGETABLE SOUP CANNED UNDILUTED	3.65	0.06
75649030	VEGETABLE SOUP CANNED LOW SODIUM	4.71	0.08
75649050	VEGETABLE SOUP MADE FROM DRY MIX	4.17	0.07
75649060	VEGETABLE SOUP DRY MIX NOT RECONSTITUTED	0.01	0.00
75649110	VEGETABLE SOUP HOME RECIPE	5.53	0.09
75649150	VEGETABLE NOODLE SOUP HOME RECIPE	4.89	0.08
75650990	MINESTRONE SOUP CANNED REDUCED SODIUM RTS	3.14	0.05
75651000	MINESTRONE SOUP HOME RECIPE	3.69	0.06
75651010	VEGETABLE BEAN SOUP PREPARED W/ WATER	4.51	0.08
75651020	VEGETABLE BEEF SOUP PREPARED W/ WATER	4.60	0.08
75651040	VEGETABLE NOODLE SOUP PREPARED W/ WATER	2.21	0.04

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
75651050	VEGETABLE CHICKEN SOUP W/ WATER OR READY-TO-SERVE	4.85	0.08
75651070	VEGETABLE RICE SOUP PREPARED W/ WATER	7.71	0.13
75651110	VEG CHICKEN RICE SOUP PREPARED W/ WATER / READY TO	6.12	0.10
75651140	VEG SOUP W/ CHICKEN BROTH MEXICAN STYLE (SOPA RANCHERA)	5.68	0.09
75651150	VEGETABLE NOODLE SOUP CAN RED SODIUM PREP W/ WATER/RTS	3.28	0.05
75652010	VEGETABLE BEEF SOUP HOME RECIPE	5.26	0.09
75652040	VEG BEEF SOUP W/ NOODLES HOME RECIPE	6.83	0.11
75652050	VEG BEEF SOUP W/ RICE HOME RECIPE	4.73	0.08
75656020	VEGETABLE SOUP CHUNKY STYLE	3.30	0.06
75656040	VEGETABLE SOUP W/ PASTA CHUNKY STYLE	4.67	0.08
92201010	POSTUM (COFFEE SUBSTITUTE)	2.25	0.04
92203000	CEREAL BEVERAGE (INCLUDE PERO BREAK AWAY)	0.74	0.01
92306000	TEA HERBAL (INCLUDE SASSAFRAS LICORICE)	4.75	0.08
92400000	SOFT DRINK NFS	6.33	0.11
92410310	SOFT DRINK COLA-TYPE	8.02	0.13
92410320	SOFT DRINK COLA-TYPE SUGAR-FREE	7.61	0.13
92410330	SOFT DRINK COLA-TYPE W/ HIGHER CAFFEINE (INCL JOLT)	4.58	0.08
92410340	SOFT DRINK COLA-TYPE DECAFFEINATED	5.68	0.09
92410350	SOFT DRINK COLA-TYPE DECAFFEINATED SUGAR-FREE	6.46	0.11
92410360	SOFT DRINK PEPPER-TYPE (INCL DR. PEPPER MR. PIBB)	7.71	0.13
92410370	SOFT DRINK PEPPER-TYPE SUGAR-FREE	5.87	0.10
92410390	SOFT DRINK PEPPER-TYPE DECAFFEINATED	4.85	0.08
92410400	SOFT DRINK PEPPER-TYPE DECAFFEINATED SUGAR-FREE	5.60	0.09
92410510	SOFT DRINK FRUIT-FLAVORED CAFFEINE FREE	6.04	0.10
92410520	SOFT DRINK FRUIT-FLAV SUGAR-FREE CAFFEINE FREE	4.82	0.08
92410550	SOFT DRINK FRUIT-FLAVORED W/ CAFFEINE	7.20	0.12
92410560	SOFT DRINK FRUIT-FLAVORED W/ CAFFEINE SUGAR-FREE	5.61	0.09
92510120	APPLE-CHERRY DRINK	3.13	0.05
92510150	APPLE JUICE DRINK	4.05	0.07
92510170	APPLE-CRANBERRY-GRAPE JUICE DRINK	3.02	0.05
92510200	APPLE-ORANGE-PINEAPPLE JUICE DRINK	4.71	0.08
92510310	BANANA-ORANGE DRINK	15.63	0.26
92510610	FRUIT DRINK (INCLUDE FRUIT PUNCH & FRUIT ADE)	4.79	0.08
92510630	FRUIT JUICE DRINK NFS	5.20	0.09

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
92510650	TAMARIND DRINK P.R. (REFRESCO DE TAMARINDO)	6.02	0.10
92510810	GRAPEADE & GRAPE DRINK	4.78	0.08
92510820	GRAPE JUICE DRINK	6.62	0.11
92510910	GRAPEFRUIT JUICE DRINK	9.67	0.16
92511010	LEMONADE	5.93	0.10
92511020	LEMON-LIMEADE	9.30	0.16
92511110	LIMEADE	7.44	0.12
92511190	ORANGE JUICE DRINK	4.87	0.08
92511200	ORANGE-MANGO JUICE DRINK	4.73	0.08
92511220	ORANGE DRINK (INCLUDE ORANGE ADE YABA DABA DEW)	3.57	0.06
92511250	CITRUS FRUIT JUICE DRINK (INCL 5-ALIVE)	5.01	0.08
92511260	ORANGE-CRANBERRY JUICE DRINK	6.71	0.11
92511270	ORANGE-PEACH JUICE DRINK	4.50	0.08
92511280	ORANGE-GRAPE-BANANA JUICE DRINK	5.14	0.09
92511310	PINEAPPLE-GRAPEFRUIT JUICE DRINK	18.75	0.31
92511340	PINEAPPLE-ORANGE JUICE DRINK	2.32	0.04
92511350	ORANGE-RASPBERRY JUICE DRINK	3.66	0.06
92511400	RASPBERRY-FLAVORED DRINK	2.79	0.05
92511510	STRAWBERRY-FLAVORED DRINK	3.13	0.05
92512090	PINA COLADA NONALCOHOLIC	3.00	0.05
92520410	FRUIT DRINK LOW CALORIE	6.01	0.10
92520810	GRAPE DRINK LOW CALORIE	3.00	0.05
92520910	LEMONADE LOW CALORIE	6.47	0.11
92530110	APPLE DRINK W/ VITAMIN C ADDED	3.01	0.05
92530310	CHERRY DRINK W/ VITAMIN C ADDED	2.63	0.04
92530410	CITRUS DRINK W/ VITAMIN C ADDED	4.86	0.08
92530510	CRANBERRY JUICE DRINK W/VIT C ADDED (INCL COCKTAIL)	4.35	0.07
92530520	CRANBERRY-APPLE JUICE DRINK W/ VITAMIN C ADDED	4.51	0.08
92530610	FRUIT PUNCH/DRINK/ADE W/ VIT C ADDED (INCL HI-C)	4.89	0.08
92530710	GRAPE DRINK W/ VITAMIN C ADDED	3.38	0.06
92530810	GRAPEFRUIT JUICE DRINK W/ VITAMIN C ADDED	3.29	0.05
92530840	GUAVA JUICE DRINK W/ VIT C ADDED	4.22	0.07
92530910	LEMONADE W/ VITAMIN C ADDED	4.91	0.08
92531010	ORANGE DRINK & ORANGEADE W/ VITAMIN C ADDED	4.41	0.07
92531020	ORANGE BREAKFAST DRINK FROM FROZEN CONCENTRATE	2.97	0.05

FOODCODE	DESCRIPTION	LYCOPENE (mg/day)*	LYCOPENE (mg/kg/day)
92531030	ORANGE BREAKFAST DRINK	4.18	0.07
92531120	PINEAPPLE-ORANGE JUICE DRINK W/ VITAMIN C ADDED	3.13	0.05
92531150	PINEAPPLE-ORANGE-GRAPEFRUIT JUICE DRINK W/VITAMIN C	3.14	0.05
92541010	FRUIT-FLAVORED DRINK FROM SWEETENED PWDR FORTIFIED W/ VIT C	5.58	0.09
92541020	LEMONADE-FLAV DRINK FROM POWDER W/ SUGAR & VIT C	7.61	0.13
92541040	LEMONADE-FLAV DRINK FROM POWDER LO CAL W/ VIT C	5.56	0.09
92541100	APPLE CIDER DRINK FROM MIX SUGAR & VIT C ADDED	3.91	0.07
92541120	APPLE CIDER DRINK FROM MIX LOW CAL VIT C ADDED	2.77	0.05
92542000	FRUIT-FLAVORED DRINK FROM POWDER W/HI VIT C(TANG)	3.80	0.06
92544000	FRUIT-FLAVOR DRINK FROM UNSWEET PWDR W/ VIT C W/ SUGAR	6.55	0.11
92550050	APPLE-WHITE GRAPE JUICE DRINK LOW CAL W/VIT C ADDED	5.18	0.09
92550110	CRANBERRY JUICE COCKTAIL LO CAL W/ VIT C ADDED	3.54	0.06
92550610	FRUIT-FLAVORED DRINK LOW CAL W/ VITAMIN C ADDED	5.67	0.09
92551700	JUICE DRINK LOW CALORIE	7.29	0.12
92552050	ORANGE BREAKFAST DRINK LOW CALORIE	10.04	0.17
92552100	ORANGE-CRANBERRY JUICE DRINK LOW CAL W/ VIT C ADDED	1.75	0.03
92553000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE LOW CAL	3.41	0.06
92560000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE	7.64	0.13
92582110	ORANGE BREAKFAST DRINK CALCIUM FORTIFIED	3.16	0.05
92611100	OATMEAL BEVERAGE W/ MILK	2.24	0.04
92613510	CORN BEV W/ CHOC & MILK (CHAMPURRADO ATOLE DE CHOC)	3.82	0.06
92731000	FRUIT-FLAVORED DRINK NON-CARB FROM POWDER W/ SUGAR	5.25	0.09
92741000	FRUIT-FLAVORED DRINK NON-CARB FROM LO CAL POWDER	6.04	0.10
92900110	FRUIT-FLAVORED CONCENTRATE DRY W/ SUGAR & VIT C	0.21	0.00
92900300	FRUIT-FLAV THIRST QUENCH BEV DRY CONC (GATORADE)	0.16	0.00

*Not all food codes present in APPENDIX C may be located in APPENDIX D, as not all foods queried may have been consumed by the study sample

APPENDIX E

Summaries of additional preclinical and clinical studies that have been published since the first GRAS notification that evaluates the effects of lycopene or tomato extract consumption

Lycopene treatment (4 mg/kg/day *via* gavage) ten days before adriamycin (ADR) injection (10 mg/kg *i.p.*)[3] or two days before and three days after ADR administration reduced ADR-induced cardiotoxicity and nephrotoxicity in rats. Lycopene normalized significant increases in plasma levels of creatinine and urea, and cardiac and kidney catalase levels, induced by ADR treatment, and also inhibited the formation of cardiac and real histopathological changes noted in ADR-treated rats. Lycopene pretreatment inhibited ADR-induced reductions in testes and epididymis weights, and sperm motility, restored malondialdehyde and reduced glutathione concentrations to control levels, and reverted ADR-induced histopathological alterations to control parameters (Atessahin *et al.*, 2006; Yilmaz *et al.*, 2006). A 31-day oral pretreatment with lycopene (1 mg/kg/day) significantly prevented myocardial damage and lipid peroxidation induced by ischemia and reperfusion (I-R) injury, and preserved antioxidant status and hemodynamic parameters (Bansal *et al.*, 2006). In addition, lycopene or tomato juice administration (*via* gavage) for three weeks in rats prior to I-R injury reportedly reduced I-R-induced lipid peroxidation, but only tomato juice ingestion improved post-ischemic ventricular function, and reduced myocardial infarct size and cariomyocyte apoptosis (Das *et al.*, 2005).

Lycopene at an acute dose of 6 mg/kg, or four daily doses at 1.5 mg/kg/day in rats, was neither cytotoxic or clastogenic, when compared to negative controls, but prevented cisplatin-induced chromosomal damage in rat bone marrow cells ($P<0.01$) (Sendao *et al.*, 2006). Lycopene has also been reported to inhibit the formation of oxidative stress due to muscle exhaustion, as well as gentamycin-induced nephritic toxicity, as indicated by the inhibition of chemical-induced changes in catalase and glutathione peroxidase activities (Kim *et al.*, 2004; Karahan *et al.*, 2005; Liu *et al.*, 2005). Carbon tetrachloride-induced hepatic toxicity in rats was partially inhibited by tomato powder (when administered at 10% of the diet), based on serum sorbitol dehydrogenase and serum aspartate aminotransferase activities (Kim *et al.*, 2004).

Porrini *et al.* (2005) evaluated the consumption of a beverage prototype (250 ml) containing Lyc-O-Mato® 6% (approximately 6 mg lycopene) by healthy volunteers for 26 days on the ability to improve protection against DNA damage in lymphocytes. Lyc-O-Mato® beverage consumption for 26 days significantly increased plasma lycopene levels, and significantly reduced DNA damage ($P<0.0001$) in lymphocytes subjected to oxidative stress, as determined by the COMET assay. Consumption of lycopene in a beverage, containing 5.7 mg lycopene, was also evaluated by Riso *et al.* (2006), who reported that production of the inflammatory mediator tumor necrosis factor (TNF)-*alpha* in whole blood was 34.4% lower at the end of the 26-day treatment. No other effects were noted. In addition, a Lyc-O-Mato® drink (250 ml *per* serving, twice *per* day; which resulted in the ingestion of 10 mg lycopene *per* day)

[3] *i p* = intraperitoneal

consumption for twelve weeks prevented erythema formation and was well tolerated (Aust *et al.*, 2005; Stahl *et al.*, 2006).

Mohanty *et al.* (2005) reported that lycopene (8 mg/day) for one year delayed or prevented high grade prostate intraepithelial neoplasia (HGPIN) from developing into occult prostate cancer, with an inverse relationship found between lycopene and PSA levels. Good patient tolerance and no toxicity was reported from lycopene ingestion. Lyc-O-Mato® tomato extract (250 mg extract/day, approximately 15 mg lycopene/day) administered for eight weeks to grade-1 hypertensive patients (n=31) was well tolerated, and significantly decreased systolic (P<0.01) and diastolic (P<0.05) blood pressure (Engelhard *et al.*, 2006).

Clark *et al.* (2006) administered lycopene at up to 120 mg/day (dose-escalating Phase I/II trial of 15, 30, 45, 60, 90, and 120 mg/day) to patients for one year, which did not result in any discernible response in serum prostate-specific antigen (PSA) levels in biochemically relapsed prostate cancer patients (n=36). Patients were assessed monthly for toxicity and compliance using pill counts. Toxicity was mild, with one patient discontinuing therapy because of diarrhea thought to be related to lycopene supplementation. No other lycopene-related toxicities were found. Plasma lycopene levels significantly increased during the first three months, and then plateaued for all six dose levels. These data confirm that the consumption of lycopene at levels up to 120 mg/day lack clinically documented adverse effects.

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January 31, 2005

Laura Tarantino, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Lyc-O-Mato® Powder GRAS Notification

Dear Dr. Tarantino:

In accordance with proposed 21 CFR § 170.36 (a notice of a claim for exemption based on a GRAS determination) published in the Federal Register (62 FR 18937-18964), I am submitting in triplicate, as the representative of the notifier, LycoRed Natural Products Industries, Ltd, P.O. Box 320, Hebron Road, Industrial Zone, Beer-Shiva 84102, Israel, a GRAS notification of Lyc-O-Mato® Powder for use as a dietary addition of lycopene, at levels up to 2,222 mg/kg Lyc-O-Mato® Powder (containing 0.9% lycopene). Lyc-O-Mato® Powder will be used in baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups and sauces. A GRAS expert panel report, setting forth the basis for the GRAS determination, as well as CVs of the members of the GRAS panel, are enclosed.

Best regards,

(b)(6)

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition

1. GRAS Exemption Claim

A. Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36 (c) (1)

Lyc-O-Mato® Powder has been determined to be generally recognized as safe (GRAS) and, therefore, exempt from the requirement of premarket approval, under the conditions of its intended use as described below. The basis for this finding is described in the following sections.

Signed,

(b)(6) Date 21 Jones

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
Burdock Group
888 Seventeenth Street, NW, Suite 810
Washington, DC 20006

000267

(i) Name and Address of the Notifier

Morris Zelkha, Ph.D., President
Lycored Natural Products Ind., Ltd.
Hebron Road – Industrial Zone
P.O. Box 320
Beer Sheva – 84102 Israel

Agent to Notifier:

George A. Burdock, Ph.D.
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Facsimile: 202-785-8666
Email: gburdock@burdockgroup.com

(ii) Common Name of the Notified Substance

The common name of Lyc-O-Mato® Powder has been defined as:

Tomato powder containing lycopene

(iii) Conditions of Use

Lyc-O-Mato® Powder is intended to be used as ingredients to provide consumers with a supplementary source of lycopene in their diets. Lyc-O-Mato® Powder will be used up to 2,222 mg/kg (containing 0.9% lycopene), as a nutrient supplement, to give a maximum of 20 mg/kg lycopene to the following food products: baked goods, ground meat products, meat analogues (substitutes based on vegetable protein), dairy products, soups and sauces.

(iv) Basis of GRAS Determination

Pursuant to 21 CFR § 170.3, Lyc-O-Mato® Powder has been determined GRAS by scientific procedures for their intended conditions of use. The safety of Lyc-O-Mato® Powder is supported by use of their constituents in tomato-based foodstuffs for millennia, as well as animal and clinical studies. This determination is based on the views of experts who are qualified by scientific training and experience to evaluate the safety of substances used as ingredients in food.

(v) Availability of Information

The data and information that serve as a basis for this GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at a reasonable time at the office of:

George A. Burdock, Ph.D.
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Fellow, American College of Nutrition
Burdock Group
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Alternatively, copies of data and information can be provided to FDA upon request, by contacting Dr. Burdock.

2. Detailed Information About the Identity of the Notified Substance

A. Identity

Lyc-O-Mato® Powder is prepared from the pulp from naturally-selected, non-genetically modified, hybrid, high lycopene content (150-250 ppm) varieties of tomato (*Lycopersicon esculentum* (L.) Karst Ex. Farwell; trade names include: Lycogold™ or LRT 90™ and Lycorich™ or LRT 89™), by a water extraction process. The product contains the water-soluble solids from the fruit.

Common or Usual Name:

The common name of Lyc-O-Mato® Powder has been defined as:

Tomato powder containing lycopene

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Table 1. General description and analytical information of Lyc-O-Mato® Powder

Botanical Source	*Lycopersicon esculentum* (L.) Karst Ex. Farwell.
Physical description	Dark red, free flowing powder.
Packaging	Packaged under nitrogen in laminate bags.
Storage	Store at 25°C.
Labeling	Tomato powder containing lycopene.
Functional Use in Food	Source of supplemental lycopene.

B. Composition

Chemical composition of the tomato powder containing lycopene is summarized in Table 2. Lyc-O-Mato® Powder is a water-soluble powder produced from tomatoes that contains a high lycopene content, with lower levels of other carotenoids, phytosterols and tocopherols.

Table 2. Chemical analysis of Lyc-O-Mato® Powder*.

Chemical Analysis	Value
Soluble fibers	13.4%
Total lycopene	0.92%
alpha-Tocopherols	0.3%
Other Carotenoids†	0.146%
Total dietary fiber	56.8%
Lipids	8.2%

*Additional information is given in Table 3; †Carotenoids analyzed include phytoene, phytofluene, and ß-carotene.

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Method of Manufacture of Lyc-O-Mato® Powder

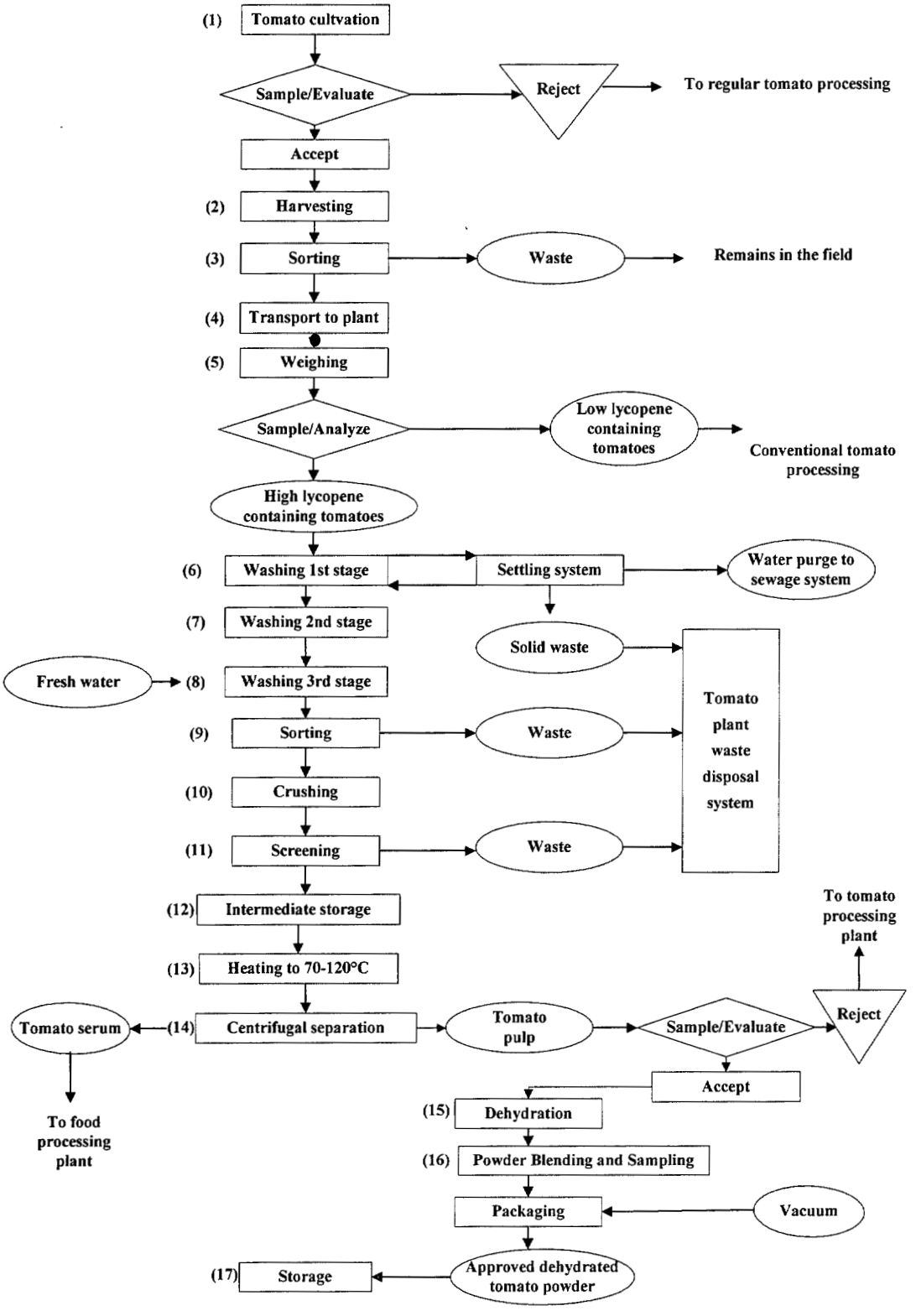

Figure 1. Lyc-O-Mato® Powder production scheme.

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C. Specifications for Food Grade Material

Table 3. Specifications of Lyc-O-Mato® Powder.

Analysis	Method	Specification	Batch Analysis Results (N=3-12) Range	Average
Appearance	LAB/223/01	Free flowing red powder	Passes	Passes
Lycopene identity	LAB/109/01[a]	HPLC retention time	24 - 25.2 min	24.8 ± 0.6 min
Total lycopene[b]	LAB/223/01[a]	0.8 - 2.0%	0.8 - 1.35%	0.92% (N=5)
% *trans*-Lycopene	LAB/109/01[a]	90 - 95%	90-91%	90.4 ± 0.11% (N=4)
Total carotenoids[c]	LAB/223/01[a]	0.95-2.15%	0.95-1.50%	1.07% (N=5)
Other carotenoids	LAB/118/01[a]	Phytoene: min 0.05% Phytofluene: min 0.05% ß-carotene: min 0.01%	0.069 - 0.077% 0.060 - 0.066% 0.01 - 0.011%	0.073% (N=5) 0.063% (N=5) 0.010% (N=5)
Alpha- tocopherols	LAB/118/01	Min 0.2%	0.28 - 0.31 %	0.3% (N=5)
Unsaponifiable matter	Std. Institute SOP	Max 3.0%	1.5 - 2.3%	1.9 ± 0.2% (N=4)
Protein (by analysis of amino acids)	Analyst SOP	Max 17%	14.7 - 15.8%	15.2% (N=5)
Protein (by Kjeldahl analysis of nitrogen)	Miloda SOP	Max 20%	19.2 - 19.7%	19.5% (N=5)
Fructose	Analyst SOP	Max 9%	6.1 - 8.7%	7.1% (N=5)
Glucose	Analyst SOP	Max 7.5%	4.7 - 7.1%	5.9% (N=5)
Soluble fibers	AOAC 991.43	Min 12%	13.0 - 13.7%	13.4% (N=5)
Insoluble fibers	AOAC 991.43	Min 40%	43.1 - 43.7%	43.3% (N=5)
Total dietary fibers	AOAC 991.43	Min 52%	56.3 - 57.4%	56.8% (N=5)
Lipids	Miloda SOP	Min 7%	8.1 - 8.2%	8.2% (N=5)
Particle size	LAB/224/01	95% less than 1 mm	Passes	Passes
Water	Karl Fisher	10% max	2.5 to 10.5%	8.1% (N=10)
Sulphated ash	AOAC 34.104	Max 7%	4.7 to 5.4%	5.2% (N=7)
Pesticides	DFG-S19[e]	Meets USP 24 NF 19/561	Meets USP	Total ≤ 3 ppm
Heavy metals	I.C.P.[e]	Pb < 2ppm Ag, Mo, Cd, Ni, Hg all <1ppm	Meets limits	Each < 1ppm
Arsenic	I.C.P.[e]	As < 2ppm	Meets limits	≤ 0.5 ppm
Microbiology	USP 24 NF 19/<61>	Total count: < 1000/g Mold, Yeast: < 100/g each *Escherichia coli*: 0/10g *Salmonella* sp.: 0/10g *Coagulase positive staphylococcus:* 0/10g *Staphylococcus aureus:* 0/10g	Meets limits	All less than limits

[a]LycoRed Method, SOP available on request; [b]Combined *cis*- and *trans*-lycopenes; [c]Calculated as lycopene; [d]Analyst method SOP available on request; [e]Analysis method SOP available on request.

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III. Self Limiting Levels of Use

At high levels (exceeding the concentrations proposed), certain food items may acquire an undesirable red color.

IV. Basis of GRAS Determination

The determination that Lyc-O-Mato® Powder is GRAS is on the basis of scientific procedures. See attached- DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

George A. Burdock, Ph.D.
Burdock Group
780 U.S. HWY 1
Suite 300
Vero Beach, FL 32962

Re: GRAS Notice No. GRN 000163

Dear Dr. Burdock:

The Food and Drug Administration (FDA) is responding to the notice, dated January 31, 2005, that you submitted on behalf of LycoRed Natural Products Industries, Ltd. (LycoRed), in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on February 5, 2005, filed it on February 14, 2005, and designated it as GRAS Notice No. GRN 000163.

The subject of the notice is tomato pulp powder. The notice informs FDA of the view of LycoRed that the use of tomato pulp powder as a direct food ingredient is GRAS, through scientific procedures, resulting in a maximum of 20 milligram (mg) lycopene/kilogram (kg) of food in the following food categories: baked goods, ground meat products, meat analogues (vegetable protein-based), dairy products, soups and sauces.

Our use of the term "tomato pulp powder" in this letter should not be considered an endorsement or recommendation of this term as an appropriate common or usual name for the purpose of declaring this substance in the ingredient statement of foods that contain these ingredients. As stated in 21 CFR 101.4, all ingredients must be declared by their common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for non-standardized foods. Issues associated with labeling and the appropriate common or usual name of a food are the responsibility of the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS).

As part of its notice, LycoRed includes a summary of conclusions of a panel of individuals (LycoRed's GRAS panel) who evaluated the data and information that are the basis for LycoRed's GRAS determination. LycoRed considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. LycoRed's GRAS panel evaluated the following: estimated dietary exposure; method of production of tomato pulp powder; nature and quantity of impurities; product specifications; and data, and information available from human clinical studies and pre-clinical toxicity studies with tomato products (e.g., tomato juice, tomato powder) and tomato lycopene extracts.[1] LycoRed's GRAS panel concluded that tomato pulp powder is GRAS for its intended use.

[1] "Tomato lycopene extract" refers to the ingredients described in GRN 000156 that contain several fat-soluble compounds present naturally in tomato, including a stated percentage (typically 6 percent) of lycopene.

LycoRed describes the method of manufacture of tomato pulp powder, prepared from a hybrid, high lycopene variety of tomato (*Lycopersicon esculentum* (L.) Karst Ex. Farwell). Tomatoes are selected for high lycopene content, washed, crushed, and screened to remove stems and seeds. The resulting tomato juice is passed through a heat exchanger and centrifuged to separate the tomato pulp from tomato serum. LycoRed also notes that the ratios of tocopherols, phytoene, and phytofluene to lycopene are similar for ripe tomato, tomato pulp powder, and tomato lycopene extract (containing 6 percent lycopene).

Tomato pulp powder contains approximately one percent lycopene, with the balance consisting of proteins, sugars, dietary fibers, lipids, and other carotenoids. It is a dark free-flowing powder and contains *trans* lycopene (Chemical Abstract Service Registry Number 502-65-8) as the predominant carotenoid.

LycoRed provides microbiological specifications as well as specifications for moisture and contaminants, including pesticides, heavy metals, residual solvent. LycoRed provides stability experiments conducted with tomato pulp powder and concludes that lycopene from tomato pulp powder is chemically stable under various processing conditions and is stable as an ingredient in a variety of foods.

LycoRed discusses the intended uses of tomato pulp powder, noting that its use is largely self-limiting. At high levels, certain food items may acquire a strong tomato flavor. Further, tomato pulp powder would not be compatible with all food systems, due in part to technical limitations (e.g., solubility, aesthetics), cost, and limited or restricted use in fresh and standardized foods.

LycoRed notes that all of the major constituents in tomato pulp powder are normal constituents of commonly consumed foods. In GRN 000163, LycoRed cites several published clinical trials using dietary intervention with tomatoes and tomato products. In GRN 000156, LycoRed discussed studies conducted with lycopene and tomato lycopene extracts (5 percent and 6 percent).

Potential Labeling Issues

Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FFDCA lays out the statutory framework for health claims. LycoRed describes the intended use of tomato pulp powder as having beneficial effects. Any claims concerning beneficial effects are under the purview of the ONPLDS. The Office of Food Additive Safety neither consulted with ONPLDS on potential beneficial effects nor evaluated the information in LycoRed's notice to determine whether it would support any claims made about lycopene on the label or in labeling.

Standards of Identity

In its notice, LycoRed states its intention to use tomato pulp powder in several food categories, including dairy products and baked goods for which a standard of identity exists. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Use in Meat Products

During its evaluation of GRN 000163, FDA consulted with the Labeling and Consumer Protection Staff of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS is responsible for determining the efficacy and suitability of food ingredients in meat and poultry

products as well as prescribing safe conditions of use. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads consumers.

FSIS requested that FDA advise LycoRed to seek regulatory guidance from FSIS, Labeling and Consumer Protection Staff, about the use of tomato pulp powder in meat products. LycoRed should direct such an inquiry to Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service, 1400 Independence Ave., S.W., Suite 602, Annex, Washington, DC 20250-3700. The telephone number for that office is (202) 205-0279 and the telefax number is (202) 205-3625.

Conclusions

Based on the information provided by LycoRed, as well as other information available to FDA, the agency has no questions at this time regarding LycoRed's conclusion that tomato pulp powder is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of tomato pulp powder. As always, it is the continuing responsibility of LycoRed to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

AUG 02 2005

Sincerely,

(b)(6)

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: Dr. Robert Post, Director
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GEORGE A. BURDOCK, Ph.D.
Diplomate, American Board of Toxicology

CURRICULUM VITAE

Burdock Group **1988-Present**
Vero Beach, FL and Washington DC

Founder and President

Dr. Burdock is an internationally recognized authority on the safety of food ingredients, personal care products, and dietary supplements. He has more than twenty years experience dealing with regulatory issues related to product safety and risk assessment. As the President of Burdock Group, Dr. Burdock provides safety and toxicity information on food, food and feed additives, drug excipients, and contaminants to a varied client list, including Fortune 100 corporations, start-up companies, law firms, and trade associations. This information may be in the form of confidential reviews, regulatory petitions, Generally Recognized As Safe (GRAS) self determinations, GRAS notifications, product contamination, and litigation support. As a leading scientist in the food industry, Dr. Burdock is sought by scientific publishers to author journal articles and edit reference books on food additives, flavor ingredients, and regulatory matters and by clients to comment on proposed regulations or respond to communications from regulatory agencies including the FDA and the USDA.

Flavor and Extract Manufactures' Association (FEMA) **1986-1992**
Washington, D.C.

Director of Scientific Affairs

Dr. Burdock managed the FEMA scientific programs, coordinated the research activities of the testing laboratories, and communicated with external consultants and allied industry committees working with FEMA. As the primary scientific liaison, Dr. Burdock guided member companies with the preparation of submissions to the FEMA Expert Panel for GRAS review, alerted Expert Panel and Association members to scientific developments in the food and flavor industry, and identified changes in the regulatory policies as a result of these developments. He authored and edited comprehensive literature reviews on flavor additives and other topics relevant to the Association's interests.

Shulton Research Division, American Cyanamid Corporation **1984-1986**
Clifton, New Jersey

Manger of Biological Services

Dr. Burdock directed the Product Safety section, Microbiological Research Services, the Clinical Evaluation Laboratory and the Product Evaluation Center. As the senior toxicologist, he was responsible for the toxicological laboratories and microbiologic safety of products applied to the test groups in clinical evaluation laboratories and for those products released for public use. Dr. Burdock served as a corporate member of the Pharmacology/Toxicology Committee and the Cosmetic Ingredient Review Subcommittee of the Cosmetic, Toiletries and Fragrance Association. He represented the Consumer Products Division on toxicology issues within the corporation, and externally, with vendors, government agencies, and trade associations.

Hazleton Laboratories America, Inc. **1979-1984**
Vienna, Virginia

Senior Staff Scientist

As a Study Director, Dr. Burdock designed and managed toxicological oversight for compliance with regulatory requirements, quality assurance, budgetary monitoring, testing of pharmaceuticals, food additives, pesticides, and evaluated the performance of subcontractors. He negotiated program design and individual toxicity study requirements for the registration of substances with FDA, EPA, and other regulatory agencies. Dr. Burdock supervised two laboratory sections -Teratology/Reproduction and Sub-Chronic Rodent Toxicology.

EDUCATION

Ph.D. in Toxicology, School of Pharmacy, University of Mississippi, 1980
Master of Combined Sciences, Physiology and Biochemistry, University of Mississippi, 1973
Bachelor of Science, Biology, University of Mississippi, 1969

CERTIFICATIONS

Diplomate, American Board of Toxicology, 1983; Recertified, 1988, 1993, 1998, 2003
Fellow, American College of Nutrition, 2003

PROFESSIONAL ORGANIZATIONS MEMBERSHIPS

American Botanical Council
American Chemical Society
American College of Nutrition
American College of Toxicology
American Society for Nutrition
American Society for Clinical Nutrition
Food and Drug Law Institute
Institute of Food Technologists

International Society of Regulatory Toxicology and Pharmacology
Society of Toxicology

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G.A. Burdock and L.W. Masten. (1979). Diethanolamine-induced changes in the neonatal rat. *Toxicology and Applied Pharmacology* 48:A30.

J.C. Kapeghian, **G.A. Burdock,** and L.W. Masten. (1977). Effect of the route of administration on microsomal enzyme induction following repeated administration of methadone in the mouse. *Toxicology and Applied Pharmacology* 41:159.

G.A. Burdock, R. B. Hackett, and L.W. Masten. (1976). Dose-response relationship of oral methadone administration and liver microsomal enzyme activity. *Federation Proceedings* 35:469.

J.D. Catravas, I.W. Waters, **G.A. Burdock,** and W.M. Davis. (1975). Haloperidol and propanolol in the treatment of acute amphetamine intoxication in the dog. *Toxicology and Applied Pharmacology* 33:185.

REPORTS

G.A. Burdock. (1993). High Dose Irradiation of Food. Report submitted to the Food Safety Unit, World Health Organization.

W.G. Flamm, P. Lombardo, A. Forbes, W. Nichols, J.B. Little, **G.A. Burdock,** and J.A. Flamm. (1992). Review of the wholesomeness of irradiated food. Report submitted to the Food Safety Unit, World Health Organization.

Dr. Burdock was the author of numerous technical reports while serving as a consultant and a scientist for the Flavor and Extract Manufacturers' Association, Hazleton Laboratories and American Cyanamid. The content of these reports is proprietary and confidential to the sponsoring organizations.

EDITORIAL REVIEW

Regulatory Toxicology and Pharmacology. (1997 to present) Elsevier Science. Manuscript reviews.

Journal of Agricultural and Food Chemistry. (1998 to present) American Chemical Society. Manuscript reviews.

Bee World. (1999 to present) International Bee Research Association. Manuscript reviews.

Italian Journal of Food Science. (1999 to present) Istituto di Industrie Agrarie, University of Perugia Manuscript reviews.

Journal of Agricultural Research. (1999 to present) Agricultural Research Service. Manuscript reviews.

Food and Chemical Toxicology. (1999 to present) Elsevier. Manuscript reviews.

International Journal of Toxicology. (2000 to present) Taylor & Francis. Manuscript reviews,

Update (2005) Food and Drug Law Institute. Editorial Board Member.

INVITED PRESENTATIONS AND ABSTRACTS

G.A. Burdock. Qualified Health Claims: A Critical Juncture. 2005 Institute of Food Technologists Annual Meeting and Food Expo. New Orleans, LA, 2005.

G.A. Burdock. Why Efficacy Trials for Dietary Supplements? Association of Clinical Research Professionals 2005 Conference and Exhibition – North America. Orlando, FL. 2005.

G.A. Burdock. Dietary Supplements and a Method for Determining Safety and Efficacy. Botanical Dietary Supplements: Scientific Perspectives and Public Health Pitfalls Congressional Science Briefings. Washington, DC. 2005.

G.A. Burdock Approving Preservatives: Not a 'Natural' Process. International Symposium on Natural Preservatives in Food Systems. Princeton, NJ. 2005.

G.A. Burdock. Regulatory Issues and the Effect on Your Bottom Line. South Florida Regional Chapter, Institute of Food Technologists. Fort Lauderdale, FL. 2004.

G.A. Burdock. The Dichotomy of Structure Function Claims. Food and Drug Law Institute, Qualified Health Claims Conference. 2004.

G.A. Burdock. Qualified Health Claims and the Role of Independent Experts (and a few other items). 2004 Institute of Food Technologists Annual Meeting and Food Expo. Las Vegas, NV. 2004.

G.A. Burdock. Premarket Notification for New Dietary Ingredient Notifications, Public Meeting. Food and Drug Administration/Center for Food Safety and Nutrition. College Park, MD. 2004.

G.A. Burdock. Efficacy Assessment of Functional Ingredients by Independent Experts. Institute of Food Technologists. Chicago, IL. 2003.

G.A. Burdock. When Accidents Happen – Risk Assessment for the Processing Plant. American Meat Institute. Chicago, IL. 2003.

G.A. Burdock. The GRAS status of Pycnogenol®. Vitafoods International. Geneva, Switzerland. 2003.

G.A. Burdock. Risk Assessment at the Processing Plant. Food Safety Inspection Service, U.S. Department of Agriculture. Washington, DC. 2003.

G.A. Burdock. Hot Topics (Dietary Supplements). Food and Drug Law Institute, Washington, DC 2003.

G.A. Burdock. Overview: Nutraceuticals, Dietary Supplements and Functional Food Ingredients. American College of Toxicology 23rd Annual Meeting. Hershey, PA. 2002.

G.A. Burdock. Pycnogenol®. SupplySide East International Trade Show and Conference. Seacacus, NJ. 2003.

G.A. Burdock. Safety Assessment of Foods Derived From Biotech Crops. 42nd Annual Meeting of the Society of Toxicology. Nashville, TN. 2002.

G.A. Burdock. Dietary Supplements at a Crossroads. Food and Drug Law Institute Food Week. Washington, DC. 2002.

G.A. Burdock. Determining the Safety of a Dietary Supplement (Ingredient). Food and Drug Law Institute. Washington, DC. 2002.

G.A. Burdock. Safety Assessment of Botanicals. Worldnutra 2002 3rd Annual International Conference and Exhibition on Nutraceuticals and Functional Foods. San Diego, CA. 2002.

G.A. Burdock. Safety Assessment of Botanicals. ILSI Workshop on Principles for the Safety Assessment of Botanicals and Botanical Preparations in Food and Food Supplements. Marseille, France. 2002.

G.A. Burdock. Ephedra, Is It As Toxic As Reported? 43rd Annual Meeting of the American College of Toxicology. San Antonio, TX. 2002.

G.A. Burdock. The Line Between Generally Recognized As Safe (GRAS) and Dietary Supplements. Toxicology Forum, Aspen, CO. 1999.

G.A. Burdock. DSHEA, GRAS and Functional Foods: Regulatory and Safety Criteria. American Chemical Society. 224th ACS National Meeting. Boston, MA. 2002.

CONTINUING EDUCATION

Clinical Pathology-The Granddaddy of Biomarkers. Society of Toxicology 44th Annual Meeting and Toxexpo. New Orleans, LA. March, 2005

Herbals and Dietary Supplements in Athletic Performance Enhancement: Fact vs. Fiction. Society of Toxicology 43rd Annual Meeting and Toxexpo. Baltimore, MD. March, 2004.

The Safety Assessment of Proteins: Applications to Agricultural Biotechnology. Society of Toxicology 43rd Annual Meeting and Toxexpo. Baltimore, MD. March, 2004.

Choice and Application of Classical, Population or Physiologically-Based PK for Chemical Assessment and Pharmaceutical Development. Society of Toxicology 42nd Annual Meeting and Toxexpo. Salt Lake City, UT, March,2003.

Medicinal Herbals and Dietary Supplements. Society of Toxicology 42nd Annual Meeting and Toxexpo. Salt Lake City, UT, March, 2003.

Dietary Supplement Use in the Elderly. American College of Nutrition Continuing Education Program. NIH Campus, Bethesda, MD. January, 2003.

International Regulatory Approval of Ingredients and Dietary Supplements. Institute of Food Technologists Annual Meeting. Chicago, IL. July, 2003.

Labeling of FDA Regulated Foods. Institute of Food Technologits. Orlando, FL. February, 2001.

Dietary Ingredients or Drugs? Food and Drug Law Institute. Washington, DC. July, 2000.

Reproductive Toxicology. American College of Toxicology – 20th Annual Meeting, Washington, DC. November, 1999

PROFESSIONAL ACHIEVEMENT AND RECOGNITION

Institute of Food Technologists, *Toxicology and Safety Evaluation Division*, (2006 Member at Large); Professional Member (2004 to present).

Society of Toxicology, *Food Safety Specialty Section*, (2005 – 2006 Vice President, 2004 – 2005 Vice President-Elect).

International Society of Regulatory Toxicology and Pharmacology (2005 - 2006 President; 2004 – 2005 Past Vice-President; Councilor)

FDA Advisory Committee Member, *Additives and Ingredients Subcommittee*. 2004 to present.

CURRICULUM VITAE
Clare M. Hasler
January 2004

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University of California at Davis
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Davis, CA 95616
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EDUCATION:

M.B.A.	2003	University of Illinois at Urbana-Champaign
Ph.D. (dual)	1990	Human Nutrition/Environmental Toxicology, Michigan State University
M.S.	1984	Nutrition Science, The Pennsylvania State University
B.S.	1981	Human Nutrition, Michigan State University

PROFESSIONAL APPOINTMENTS:

1990-1992	Post-Doctoral Fellow, Laboratory of Cellular Carcinogenesis and Tumor Promotion (Molecular Mechanisms Section), National Cancer Institute, National Institutes of Health
1992-2000	Director, Functional Foods for Health Program, University of Illinois
1992-1997	Visiting Assistant Professor, Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign
1992-1996	Visiting Assistant Professor, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago
1992-1997	Visiting Assistant Professor, Department of Human Nutrition and Dietetics, University of Illinois at Chicago
1998-1999	Co-Leader, Strategic Research Initiative on Food Safety and Functional Foods, Council for Food and Agricultural Research (C-FAR)
1998-2003	Assistant Professor, Division of Nutritional Sciences, University of Illinois at Urbana-Champaign
1999-2003	Adjunct Assistant Professor of Pharmacognosy, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago
2000-2003	Associate Director of Outreach and Industry Relations, Functional Foods for Health Program, University of Illinois
2004-Present	Executive Director, Robert Mondavi Institute for Wine and Food Science, University of California at Davis

PROFESSIONAL ASSOCIATIONS:

American Association for Cancer Research
American Association of Cereal Chemists
American Association for the Advancement of Science
American Nutraceutical Association
American Society for Nutritional Sciences
Gamma Sigma Delta
Institute of Food Technologists
Penn State Alumni Association
Sigma Xi, The Scientific Research Society

OFFICES HELD IN PROFESSIONAL SOCIETIES:

2003-2004	Chair, American Society for Nutritional Sciences, Nutrition Education Research Interest Section
2003-Present	American Association for the Advancement of Science, Electorate Nominating Committee, Section on Agriculture, Food and Renewable Resources

PROFESSIONAL AWARDS AND RECOGNITION:

1996	Emerging Leaders Award, Michigan State University, College of Human Ecology, Centennial Alumni Celebration
1997	Friend of Agriculture Award, Illinois Soybean Association
1998-Present	Scientific Expert on Functional Foods, International Food Information Council Media Guide on Food Safety & Nutrition
1998	Author, Institute of Food Technologists' Scientific Status Summary on Functional Foods
1998	"Top 25 Food Influential"(Mover and Shaker Award), Self Magazine
1999	Experiment Station Committee on Organization and Policy/Academic Committee on Organization and Policy (ESCOP/ACOP) Leadership Development Program
1999	Meritorious Service Award, United Soybean Board
2000	Recognition of Service Award, American Dietetic Association

EDITORIAL ACTIVITIES:

1993-2003	Editor, Functional Foods for Health Program ALERT, University of Illinois
1996-Present	Editorial Board, Journal of Nutraceuticals, Functional and Medical Foods
1997-Present	Editorial Board, Journal of Medicinal Food
1998-Present	Editorial Board, Journal of the American Nutraceutical Association
1998-Present	Editorial Board, Taste for Life
2000-Present	Editorial Board, Ingredients, Health & Nutrition
1999-2001	Editorial Board, Journal of Food Science, Food Chemistry & Toxicology Section
2001-2003	Editorial Board, Leatherhead Food Research Association Food Industry Journal
2002-Present	Editorial Board, Current Topics in Nutraceutical Research
2002-Present	Editorial Board, Applied Biotechnology, Food Science and Policy

ADVISORY BOARDS ACTIVITIES:

1998-2002	Centrum Center for Nutrition Science, Scientific Advisory Board
1998-2001	AgeWave/LifeSpring, Scientific Advisory Board
1999-2001	Campbell Soup Company, Scientific Advisory Board
2000-2001	NutritionGrocer.com, Scientific Advisory Board
2000-Present	American Council on Science and Health, Board of Scientific & Policy Advisors
2001-2002	Nutripharma, Scientific Advisory Board
2001-Present	Naturemade Vitamins, Women's Wellness Advisor
2002-Present	Dietary Supplement Health and Information Bureau, Scientific Advisory Board
2002-Present	Mushroom Council, Scientific Advisory Board
2003-Present	Publicis Dialog Nutrition Research Center, Scientific Advisory Board
2003-Present	Cranberry Institute, Scientific Advisory Board

RESEARCH AND PROGRAM SUPPORT:

Dr. Hasler has attracted over $3 million in funding research since 1996

Council for Food and Agricultural Research: *"Stimulating Functional Foods Research at the University of Illinois."* $80,000, CM Hasler (PI), 1996-1998.

United Soybean Board: *"Soy Protein Health Claim."* $200,000, CM Hasler (contract manager), 1997-1999.

Council for Food and Agricultural Research: *"Amount of Soy Protein Needed to Lower Cholesterol."* $93,760, SM Potter, CM Hasler (Co-PI), R Weigel, 1997-1998.

College of Agricultural, Environmental and Consumer Sciences, Value-Added Program: *"Stimulating Functional Foods Research at the University of Illinois."* $25,000, CM Hasler (PI), 1997-1998.

Council for Food and Agricultural Research: *"Amount of Soy Protein Needed to Lower Cholesterol."* $45,980, CM Hasler (PI), S Potter, R, 1998-1999.

California Prune Board: *"Assessing the Cholesterol Lowering Effects of Prune Puree in Human Subjects."* $86,848, CM Hasler (PI), P Bowen, E Emeson, 1998-1999.

Council for Food and Agricultural Research: *"Strategic Research Initiative on Food Safety and Functional Foods."* $148,800, CM Hasler (PI), 1998-1999.

Illinois Soybean Program Operating Board (ISPOB): *"Evaluation of the Use of the StratSoy "Ask an Expert" Website by Consumers."* $23,350, CM Hasler (PI), 1998-1999.

University of Illinois, Office of the Provost: *"Acquisition of an HPLC-MS to Facilitate Functional Foods Research."* $150,000, CM Hasler, (PI), 1999.

United Soybean Board: "*Soy Health Claim Communication.*" $7,500, CM Hasler (PI), 1999-2000.

Illinois Soybean Program Operating Board: *"Enhancing StratSoy as a Source of Information on Soybean Utilization and Health Benefits."* $30,000, S Thompson, P Khanna, CM Hasler (Co-PI), 2000-2001.

United States Department of Agriculture: *"Component Interactions for Efficacy of Functional Foods."* $2,400,000, E. Jeffery, C Hasler (Director of Outreach/Education), MA Smith, J Erdman, R MacDonald, 2000-2004.

Illinois Soybean Program Operating Board: *"Effects of Soy Protein Consumption in African-American Women with Mild Hypercholesterolemia."* $113,300, CM Hasler (PI), 2000-2003.

Illinois Soybean Program Operating Board: *"Enhancing StratSoy as a Source of Information on Soybean Utilization and Health Benefits."* $15,000, S Thompson, CM Hasler (Co-PI), Karl Weingartner, 2001-2002.

Campus Research Board: *"Effect of Soy on Markers of Cardiovascular Disease Risk in African-American Women."* $14,000, CM Hasler (PI), 2002-2003.

Almond Board of California: *"Effect of Almonds on Cardiovascular Health in African-American Women."* $89,750, CM Hasler (PI), pending.

RESEARCH PUBLICATIONS:

1. Hasler, CM, H Rothenbacher, DJ Mela, PM Kris-Etherton: The effect of exercise and hyperlipemic diet on aortic histopathology in the rat. *Atherosclerosis* 52:279-286, 1984.

2. Hasler, CM, H Rothenbacher, DJ Mela, PM Kris-Etherton: Exercise attenuates diet-induced arteriosclerosis in the adult rat. *Journal of Nutrition* 117:986-993, 1987.

3. Hasler, CM, MA Frick, MR Bennink, JE Trosko: TPA-induced inhibition of gap junctional intercellular communication does not involve free radical production. *Toxicology and Applied Pharmacology* 103:389-398, 1990.

4. Hasler, CM, MR Bennink, JE Trosko: Inhibition of gap junction-mediated intercellular communication by ∀-linolenate. *American Journal of Physiology* 216 (Cell Physiol. 30): C161-C168, 1991.

5. Madhukar, BV, CC Chang, CM Hasler, D de Feyter, SY Oh, B Lockwood, JE Trosko: Characterization of an *in vitro* human kidney epithelial system to study gap junctional intercellular communication. *In Vitro Toxicology* 4:630-640, 1991.

6. Hasler, CM, JE Trosko, MR Bennink: Incorporation of n-3 fatty acids into cell phospholipids inhibits gap junctional intercellular communication. *Lipids* 26:788-792, 1991.

7. Hasler, CM, G Acs, PM Blumberg: Specific binding to protein kinase C by ingenol and its induction of biological responses. *Cancer Research* 52:202-208, 1992.

8. Hayashi, T, CM Hasler, SY Oh, BV Madhukar, CC Chang, JE Trosko: A human kidney epithelial cell culture as an in vitro model to study chemical modulation of intercellular communication. *In Vitro Toxicology* 9:3-17, 1996.

9. Getlinger, MJ, BH Arjmandi, NV Goyal, L Alekel, CM Hasler, BL Drum, SC Kukreja: The role of soy protein with normal or reduced isoflavone content in reversing ovarian hormone deficiency induced bone loss in rats. *American Journal of Clinical Nutrition* 68: 1358S-1363S, 1998.

10. Arjmandi, BH, R Birnbaum, NV Goyal, MJ Getlinger, S Juma, L Alekel, CM Hasler, BW Hollis, JL Drum, SC Kukreja: The bone modulating effect of soy protein in ovarian hormone deficiency is related to its isoflavone content. *American Journal of Clinical Nutrition* 68:1364S-1368S, 1998.

11. Wool, DL, AG Kanfer, J Michaels, S Thompson, CM Hasler: Evaluating the relevance of a web based "ask an expert" feature: Stratsoy and soy and human health queries: *Journal of Applied Communications* 84:7-22, 2000.

12. Teixeira, SM, SM Potter, R Weigel, S Hannum, JW Erdman, Jr., CM Hasler: Effects of feeding 4 levels of soy protein for 3 and 6 weeks on blood lipids and apolipoproteins in mildly hypercholesterolemic men: *American Journal of Clinical Nutrition* 71:1077-1084, 2000.

13. Pelletier S, S Kundrat, CM Hasler: Functional food consumption trends in Illinois: Positive effects of an educational program. *Journal of the American Dietetic Association*, 102:1297-1299, 2002.

14. Pelletier, S, S Kundrat, CM Hasler: Effects of a functional food nutrition education program with cardiac rehabilitation patients. *Journal of Cardiopulmonary Rehabilitation* (In press).

15. De Mejia, EG, T Bradford, C Hasler: The anticarcingenic potential of soybean lectin and lunasin. *Nutrition Reviews* (In press).

16. Rah, JH, CM Hasler, JE Painter, KM Chapman-Novakofski: Women's perspectives and consumption behaviors of soy products. *Journal of Nutrition Education and Behavior* (Accepted for publication).

INVITED REVIEWS, POSITION PAPERS:

1. Hasler, CM: Functional foods: the western perspective. *Nutrition Reviews* 54: S6-S10, 1996.

2. Hasler, CM: Scientific status summary. Functional foods: their role in disease prevention and health promotion. *Food Technology*. 52: 63-70, 1998.

3. Unnevehr, L, MR Ward, CM Hasler: Regulating health claims on food products: The balance between consumer choice and consumer protection. *Choices*: First Quarter (March):26-30, 1998.

4. Hasler, CM: A new look at an ancient concept. *Chemistry & Industry*, Feb 2nd, (No.3): 84-89, 1998.

5. Hasler, CM: Probiotics and prebiotics: where are we today? (Foreward). *British Journal of Nutrition* 80:S195, 1998.

6. Thomson, C, A Bloch, CM Hasler: Position of the American Dietetic Association: functional foods. *Journal of the American Dietetic Association* 99: 1278-1285, 1999.

7. Hasler, CM, JB Blumberg: Introduction. Symposium on phytochemicals: biochemistry and physiology. *Journal of Nutrition* 129: 756S-757S, 1999.

8. Unnevehr, LJ, CM Hasler: Health claims and labeling regulation: How will consumers learn about functional foods? *AgBioforum* 3(1):262-265, 2000.

9. Hasler, CM: The changing face of functional foods: *Journal of the American College of Nutrition*, 19 (5): 499S-506S, 2000.

10. Hasler, CM, S Kundrat, D Wool: Functional foods and cardiovascular disease: *Current Atherosclerosis Reports* 2:467-475, 2000.

11. Hasler, CM, A Moag-Stahlberg, D Webb: Guidance for dietitians on how best to evaluate the safety efficacy and quality of nutraceuticals, functional foods and their ingredients. *Journal of the American Dietetic Association* 101:733-736, 2001.

12. Hasler, CM: The cardiovascular effects of soy products. *Journal of Cardiovascular Nursing* 16 (4): 50-63, 2002.

13. Hasler, CM: Functional foods: Benefits, concerns, and challenges—A position paper from the American Council on Science and Health. *Journal of Nutrition* 132:3772-3781, 2002.

14. Thomson, C, A Bloch, CM Hasler: Position of the American Dietetic Association: functional foods. *Journal of the American Dietetic Association* (In press).

LAY PUBLICTIONS, LETTERS TO EDITORS, BOOK FOREWARDS, EDITORIALS, INDUSTRY-RELATED PUBLICATIONS:

1. Hasler, CM: Narrowing the gap between food and drugs. *Cereal Foods World* 42: 462-463, 1997.

2. Hasler, CM, SC Finn: Soy: Just a hill of beans? *Journal of Women's Health* 7: 519-521, 1998.

3. Hasler, CM: Strain-independent variation of phytoestrogen content in soybeans mitigates significance of variation in genetically modified varieties (letter to the editor). *Journal of Medicinal Food* (letter to the editor) 2:279-280, 1999.

4. Teixeira, SR, S Hannum, JW Erdman, Jr., SM Potter, CM Hasler: There is still more to learn about soy (letter to the editor). *American Journal of Clinical Nutrition* 72:1588-1589, 2000.

5. Hasler, CM: Beyond the FDA health claim. *Taste for Life* 4 (No. 3): 26-27, 2001.

6. Hasler, CM: Soy and breast cancer. *Taste for Life* 4 (No. 4): 34-35, 2001.

7. Hasler, CM: Soy for menopause. *Taste for Life* 4 (No. 5): 40-41, 2001.

8. Hasler, CM: Come over to the dark side. *Taste for Life* 4 (No. 8): 12-13, 2001.

9. Hasler, CM: The latest on soy: Benefits go beyond the heart-health claim. *Taste For Life* 6 (No. 4): 25-27, 2003.

BOOKS EDITED:

1. Hasler, CM: *Regulation of Functional Foods and Nutraceuticals: A Global Perspective*, Iowa State Press/Institute of Food Technologists Press, 2003 (In press).

BOOK CHAPTERS:

1. Trosko, JE, BV Madhukar, CM Hasler, CC Chang: Modulated intercellular communication: consequence of extracellular molecules triggering intracellular communication. In: *Eicosanoids and Other Bioactive Lipids in Cancer and Radiation Injury*. Honn, KV, LJ Marnett, S Nigam, TL Walden, Jr., (Eds.), Kluwer Academic Publishers, Boston, pp. 285-295, 1991.

2. Hasler, CM, RL Huston, EM Caudill: The impact of the Nutrition Labeling and Education Act on functional foods. In: *Nutrition Labeling Handbook*. Shapiro R (Ed.), Marcel Dekker, Inc., pp. 471-493, 1995.

3. Hasler, CM, M Cullum: Functional foods in chiropractic. In: *Advances in Chiropractic*. Vol. 4. Mosby-Year Book, Inc.: pp. 601-637, 1996.

4. Hasler, CM: Phytochemicals: biochemical markers of ingestion, absorption and metabolism using flaxseed as a model. In: *Nutraceuticals--Designer Foods III: Garlic, Soy and Licorice*. Lachance PA (Ed.), Food & Nutrition Press, Inc., pp. 39-43, 1997.

5. Hasler, CM: Foreward. In: *Functional Foods: Biochemical & Processing Aspects*. Mazza G (Ed.), Technomic Publishing Inc., pp. xi-xiv, 1998.

6. Hasler, CM: Plants as medicine: The role of phytochemicals in optimal health. In: *Phytochemicals and Phytopharmaceuticals*. Shahidi F, S-T. Ho (Eds.). AOCS Press, Champaign, IL, Chapter 1, pp. 1-12, 2000.

7. Hasler, CM: Eggs as a functional food: technology update. In: *Egg Nutrition and Biotechnology*. Sim JS, S Nakai, W Guenter (Eds.), CAB International, Wallingford, U.K, Chapter 19, pp. 243-251, 2000.

8. Hasler, CM: Functional foods. In: *Present Knowledge in Nutrition*, 8th Edition. Bowman, B, R Russell (Eds.), ILSI Press, Washington, D.C., Chapter 64, pp. 740-749, 2001.

9. Hasler, CM, S Kundrat: Soy isoflavones as functional ingredients in women's health. In: *Phytoestrogens and Health*. Sarwar G, G Gilani, J Anderson (Eds.), AOCS Press, Champaign, IL, Chapter 2, pp. 32-50, 2002.

BOOK REVIEWS:

1. Hasler, CM: Functional Foods--Designer Foods, Pharmafoods, Nutraceuticals (Goldberg I, Ed.). *American Journal of Clinical Nutrition* 64:255, 1996.

2. Hasler, CM: Essentials of Functional Foods (Schmidl MK and Labusa TP, Eds.). *Food Technology* 55 (7): 87, 2001.

3. Hasler, CM: Nutraceuticals (Rapport L, Lockwood B, Eds.). *American Journal of Clinical Nutrition 77 (4) :996-997, 2003.*

BULLETINS, REPORTS, CONFERENCE PROCEEDINGS

1. Hasler, CM: New weapon in the war against chronic disease. *Illinois Research* 35, Spring/Summer: 21-23, 1993.

2. Hasler, CM: Scientists debate method for identifying human carcinogens. *Illinois Research* 35, Fall: 10, 1993.

3.

000294

4. Hasler, CM: Phytochemicals in Disease Prevention. *Nutri-News*, Mosby-Year Book, Inc.: 1-4, 1995.

5. Hasler, CM, RS Witwer: The application of bioactive ingredients in cold, non-carbonated, non-dairy beverages. *Teltech Technology Dossier Service, Teltech Resource Network Corporation*, May, 1996.

6. Hasler, CM: Oat beta-glucan, coronary eart disease risk, and health claims. *Scan's PULSE*, American Dietetic Association Publication for Sports, Cardiovascular, and Wellness Nutritionists. Vol. 15 (No.4):1-4, Fall 1996.

6. Hasler, CM: Soybeans and Human Health. *Proceedings of the Twenty-Fifth Soybean Seed Research Conference*, pp. 61-67, 1995.

7. Hasler, CM: Phytoestrogens and breast cancer. *Y-ME Hotline* 56: 1-2, March/April, 1996.

8. Hasler, CM: Soybeans and Human Health. *International Soybean Program (INSTOY) Soybean Processing and Utilization Course*, 1996.

9. Hasler, CM, D Nice, R Witwer: Bioactive ingredients for grain-based products. *Teltech Technology Dossier Service. Teltech Resource Network Corporation*, September, 1996.

10. Hasler, CM: Functional foods for health. *The Quest* (University of Illinois Cooperative Extension Service Bulletin, Knox County Unit), p. 2, March, 1997.

11. Hasler, CM: Public health implications of the soy protein health claim. *Soy Connection* 8 (No. 1), Winter 1999-2000: 1-3.

12. Hasler, CM (Editor): Functional foods: Trends in global market, scientific and regulatory development. *University of Illinois Functional Foods for Health Program*, 2001.

13. Hasler CM: Where do functional foods fit in the diet? National Agricultural Biotechnology Council (NABC) Report 14 on *Foods for Health,* 2002.

14. Childs N, CM Hasler, L Pike, F Shahidi, B Watkins, ME Camire: Nutraceuticals for Health Promotion and Disease Prevention. *Council for Agricultural Science and Technology Issue Paper* (In press).

INVITED LECTURES AND PRESENTATIONS:

The following are selected presentations since 1997 and do not include numerous regional presentations. Dr. Hasler has given more than 200 regional, national and international presentations (in 19 countries) since joining the University of Illinois in 1992.

International [Selected]

Guelph Food Technology Center: *"Functional Foods Research at the University of Illinois,"* Toronto, Canada, May 5, 1997.

The University of Alberta: "*Where are We Now in Functional Foods for Health?"* Edmonton, Canada, September 5, 1997.

Fifth North American Chemical Congress: *"Plants as Medicine: The Role of Phytochemicals in Optimal Health,"* Cancun, Mexico, November 17, 1997.

Royal Society of Medicine: "*The Public Health Implications of Lycopene,*" London, England, May 28, 1998.

Global Development and Opportunities in Functional Foods and Nutraceuticals Conference: *"Research Initiatives on Functional Foods in the U.S."* Copenhagen, Denmark, October 30, 1998, Chair, Pacific Rim Session.

Pan American College of Agriculture: *"Functional Foods: Research, Market & Regulatory Update,"* Zamorano, Honduras, May 24, 1999.

10th World Congress on Food Science & Technology: *"Cholesterol Lowering Margarine as a Functional Food,"* Sydney, Australia, October 4, 1999 (Plenary Speaker).

South East Asia Soyfood Symposium 2000: *"Soybeans–From Traditional to Functional Food, a Global Trend,"* Bangkok, Thailand, September 4, 2000.

New Zealand Nutrition Foundation: *"Soy as a Functional Food for Heart Health,"* Auckland, New Zealand, October 10, 2000.

Soy and Health Symposium 2000: *"Soybeans--A Global Trend: From Traditional to Functional Food,"* Manila, Philippines, November 17, 2000.

American Overseas Dietetic Association Annual Conference: *"Functional Foods Now: Current Science,"* Alicante, Spain, March 23, 2001.

Swedish Center of Excellence and Innovation in Functional Foods, Functional Foods–Where Academy and Market Meet: *"Functional Foods: Then, Now and the Future,"* Göteborg, Sweden, May 3, 2001 (Keynote Speaker).

University of the West Indies, Department of Chemistry: *"Functional Foods: Trends in Global Scientific and Regulatory Development,"* Kingston, Jamaica, December 12, 2001.

Nutraceuticals and Functional Foods Institute, Laval University: *"Functional Foods: Then, Now and the Future,"* Quebec, Canada, January 28, 2002.

Agricultural Biotechnology International Conference: *"Active Molecules From Plants: Naturally Existing Phytochemicals,"* Saskatoon, Saskatchewan, Canada, September 16, 2002.

ILSI SE Asia Symposium on Functional Foods: *"Functional Food Science—Global Overview."* Beijing, China, November 25, 2002.

Richardson Centre for Nutraceutical and Functional Foods: *"Global Trends in Functional Foods and Nutraceuticals Research."* Winnipeg, Manitoba, Canada, May 28, 2003 (Keynote Speaker).

National [Selected]

Ohio State University Extension, 64th Annual Food and Dairy Industries Conference: *"Functional Foods and Disease Prevention: Fantasy or Reality?"* Columbus, OH, April 2, 1997, Meeting Co-Chair.

Food Update: *"Narrowing the Gap Between Food and Drugs,"* Tampa, FL, April 7, 1997.

Oklahoma City Dietetic Association Spring Convention: *"Phytochemicals,"* Oklahoma City, OK, April 16, 1997.

Institute of Food Technologists (IFT) Annual Meeting: *"Introduction--Prebiotics and Probiotics: Where are We Today?"* Orlando, FL, June 18, 1997, Symposium Co-Chair.

American Dietetic Association (ADA) 80th Annual Meeting and Exhibition: *"Functional Foods: Therapies of the Future?"* Boston, MA, October 27, 1997.

IFT (Maryland Section): *"Functional Foods: The Future of Food Technology,"* Baltimore, MD, January 15, 1998.

Oregon Dietetics Association: *"Functional Foods,"* Portland, OR, March 23, 1998.
Oklahoma State University, Department of Nutritional Sciences: *"Functional Foods: Therapies for the 21st Century,"* Stillwater, OK, April 13, 1998.

University of Oklahoma, Department of Nutritional Sciences: *"Soy as a Functional Food,"* Oklahoma City, OK, April 14, 1998.

Oklahoma Dietetic Association: *"Functional Foods: Soy,"* Oklahoma City, OK, April 14, 1998.

Nebraska Dietetic Association: *"Phytochemicals & Functional Foods,"* Omaha, NE, April 23, 1998.

ADA 81st Annual Meeting, Flaxseed in Human Nutrition Symposium: *"Introductory Remarks,"* Kansas City, MO, October 20, 1998, Presiding Officer.

American Association of Cereal Chemists/IFT Short Course on Functional Foods: *"Botanicals as Functional Foods,"* Orlando, FL, March 4, 1999.

The Pittsburgh Conference (PITTCON): *"Functional Foods for Cardiovascular Health,"* Orlando, FL, March 8, 1999.

The Pennsylvania Food Industry--Strengthening Partnerships for Growth: *"Nutraceuticals: A Regulatory Challenge,"* Harrisburg, PA, March 31, 1999.

Memorial Sloan-Kettering Cancer Center: *"Functional Foods and Cancer Prevention,"* New York, NY, April 30, 1999.

ADA 82nd Annual Meeting: *"Functional Foods 1999: What Does the Latest Science Say and Why Should We Care?"* Atlanta, GA, October 28, 1999.

Simmons School for the Health Sciences: *"Functional Foods,"* Boston, MA, April 4, 2000.

University of North Carolina Public Health Nutrition Update Conference: *"Functional Foods,"* Chapel Hill, NC, April 28, 2000.

Rachel Schemmel Endowed Lecture in Clinical Nutrition, Michigan Dietetic Association: *"Functional Foods,"* Grand Rapids, MI, May 11, 2000.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality,"* Harrisburg, PA, June 1, 2000.

IFT (St. Louis Section): *"Functional foods: Consumer, Regulatory, Market and Research Update,"* St. Louis, MO, February 6, 2001.

Society of Toxicology: *"From Dietary Supplements to Drugs: Indole-3-Carbinol & Phenethyl Isothiocyanate,"* San Francisco, CA, March 26, 2001, Session Co-Chair.

National Research Council Public Workshop, Opportunities in Agriculture: A Vision for USDA's Food and Agricultural Research in the 21st Century: *"Functional Foods: Impact on Health and Society,"* Washington, D.C., May 22, 2001.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality?"* Hershey, PA, May 31, 2001.

ADA 84th Annual Meeting, Nutrition in Complementary Care Practice Group: *"Soy for Your Heart, Your Bones & Weight Management,"* St. Louis, MO, October 21, 2001.

Foods for Health 14th Annual National Conference, National Agricultural Biotechnology Council (NACB): *"Where Do Functional Foods Fit in the Diet?"* University of Minnesota, Minneapolis, MN, May 20, 2002.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality?"* State College, PA, June 19, 2002.

Soyfoods 2003: *"Public Health Implications of Dietary Supplement Health Claims—Soy Protein."* Chicago, IL, July 11, 2003.

ADA 85th Annual Meeting: *"Bioavailability and Biotransformation of Isoflavones: An Alternative to HRT?"* Philadelphia, PA, October 22, 2002.

4th Annual Alternative & Complementary Medical Therapies: *"Phytochemicals in Chronic Disease Prevention—Stopping Cancer with Food."* Chicago, IL, December 15, 2002.

Soyfoods 2003: *"Marketing Soy to Health Professionals."* Miami, FL, February 26, 2003.

Texas Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Houston, TX, April 4, 2003.

Food and Drug Administration Grand Rounds Workshop on Functional Foods: "*Academic Research Trends in Functional Foods.*" Washington, DC, April 8, 2003.

Louisiana Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Baton Rouge, LA April 24, 2003.

New Jersey Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Whippany, NJ, May 13, 2003.

THESES/GRADUATE STUDENTS DIRECTED:

(b)(6) *"Evaluation of the Use of the StratSoy "Ask an Expert" Website by Consumers."* M.S. Thesis, 1999.

(b)(6) *"Effect of Prune Fiber on Blood Lipids in Human Subjects."* M.S. Thesis, 2000.

(b)(6) *Effect of Prune Concentrate on Mammary and Colon Carcinogenesis."* M.S. Thesis, 2002.

(b)(6) *"Evaluation of the Educational Program "Keeping Your Heart Healthy With Functional Foods" With Cardiac Rehabilitation Patients."* M.S. Thesis, 2002.

(b)(6) *"Effect of soy on Blood Pressure in African-American Women."* M.S. (non-thesis), 2003.

(b)(6) *"The Effects of Soy Protein Consumption on Blood Lipids in Hypercholesterolemic African-American Women".* M.S. Thesis, 2003.

GRADUATE STUDENT EXAMINING COMMITTEES:

Dr. Hasler has participated on approximately 30 MS and PhD examining committees since 1997.

TEACHING ACTIVITIES:

Dr. Hasler has developed three courses on the topic of functional foods:

- Food Science and Human Nutrition (FSHN) 495: *Physiologically Active Functional Foods: Science, Regulation and Business Issues* (Fall 1996, 1998, 2000). A 1-unit graduate course designed for extramural MS students in the Chicago area who are employed full-time in the food industry.
- Nutritional Science (NS) 410: *Functional Foods and Cardiovascular Health* (Fall 2001). A 0.25 unit graduate course taught every other year and which covers the scientific and regulatory issues related to a variety of functional foods for heart health.
- NS 410: *Phytomedicinals and Human Health* (Fall 1998). A 0.25 unit graduate course related to the scientific and regulatory principals of the major botanicals in the marketplace.

Dr. Hasler has also team taught (Spring 2000, 2001, 2002) or taught (Spring 2003) FSHN 496: *Graduate Seminar in Functional Foods*. This course is designed to enhance student presentation skills and involves the critical review of a research paper and a comprehensive review of a functional foods topic.

REVIEW PANELS:

2001-2003	National Institutes of Health, Office of Dietary Supplements, Annual Bibliography o Scientific Advances in Dietary Supplement Research
2002-2003	USDA National Research Initiative Competitive Grants Program, Improving Human Nutrition for Optimal Health

MEDIA RELATIONS ACTIVITIES:

Dr. Hasler has participated in numerous radio, print and television interviews, including being featured on CNN, Lifetime and Dateline NBC's feature story, *Foods of the Future* on December 31, 1999.

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CURRICULUM VITAE

NORMAN I. KRINSKY, Ph.D.

Professor Emeritus, Department of Biochemistry
Tufts University School of Medicine
136 Harrison Avenue
Boston, MA 02111-1837 USA

Scientist,
Jean Mayer USDA Human Nutrition Research
Center on Aging at Tufts University

phone (617) 636-6861 FAX (617) 636-2409
E-mail: norman.krinsky@tufts.edu

Born: June 29, 1928 Iron River, MI, USA
Married: (b)(6)
Children: (b)(6)

EDUCATION

1948 B.S.	University of Southern California, Los Angeles, CA
1950 M.S.	University of Southern California, Los Angeles, CA (Biochemistry and Nutrition)
1953 Ph.D.	University of Southern California, Los Angeles, CA (Biochemistry, with Harry J. Deuel, Jr.)

PROFESSIONAL EXPERIENCE

1953-55	U.S. Public Health Service Post-doctoral Fellow; Harvard University (with George Wald)
1955-56	National Council to Combat Blindness Post-doc. Fellow; Harvard University (with George Wald)
1956-60	Instructor, Lecturer, Department of Biology, Harvard University
1960-64	Assistant Professor, Department of Pharmacology, Tufts University School of Medicine (TUSM)
1964-67	Associate Professor, Department of Pharmacology, TUSM
1967-69	Associate Professor, Department of Biochemistry, TUSM
1969-70	Professor, Department of Biochemistry, TUSM
1970-87	Professor, Department of Biochemistry and Pharmacology, TUSM
1973	Visiting Professor, Department of Physiology/Anatomy, University of California, Berkeley, CA
1981-82	Research Associate, Boston Veterans Administration Medical Center
1987-2000	Professor, Department of Biochemistry, Tufts University School of Medicine
1993-present	**Scientist, USDA Human Nutrition Research Center on Aging, Tufts University**
2000-present	**Professor Emeritus, Department of Biochemistry, Tufts Univ. School of Medicine**

RESEARCH INTERESTS

Function and metabolism of carotenoids, including antioxidant and anticarcinogenic actions and metabolism to retinoic acid and apocarotenoids. Role of carotenoids in primate macula. Analysis of tissue carotenoids. Biological oxidant damage, and mechanisms of lipophilic and hydrophilic protection.

EDITORIAL BOARDS

1984-1986	Journal of Free Radicals in Biology and Medicine
1984-1986	Advances in Free Radical Biology and Medicine
1987-1994	Free Radical Biology and Medicine
1993-2003	Archives of Biochemistry and Biophysics
1994-2002	Free Radical Research

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1997-present	Environmental & Nutritional Interactions
2002-present	Nutrition Reviews

PUBLICATIONS (see attached listing)

PROFESSIONAL SOCIETIES

1948	American Association for the Advancement of Science (Fellow, 1966)
1949	Society of the Sigma Xi
1951	American Chemical Society
1951	New York Academy of Sciences
1959	American Society for Biochemistry and Molecular Biology
1972	American Society for Photobiology
1982	Society for Free Radical Research
1988	The Oxygen Society (2003: Society for Free Radical Biology and Medicine)
1988	International Society for Nutrition and Cancer
1993	European Retinoid Research Group
1994	International Carotenoid Society
1998	American College of Nutrition (Fellow, 1998)
1999	International Society for Coenzyme Q Research

PROFESSIONAL ACTIVITIES/HONORS

1950	Phi Sigma Award in the Biological Sciences, University of Southern California
1952	Phi Lambda Upsilon
1966	Fellow, American Association for the Advancement of Science
1967-1968	President, Tufts University Chapter, Society of the Sigma Xi
1975-1981	Secretary-Treasurer, American Society for Photobiology
1978	Organizing Committee, Fifth International Symp. on Carotenoids and Vitamin A, Madison, WI
1980	Co-Chairman, Workshop on Biological Chemiluminescence, American Society for Photobiology, Colorado Springs, CO
1981	Chairman, 1st Gordon Research Conference on "Oxygen Radicals in Biology and Medicine" Ventura, CA
1981-1984	Teaching Award, Tufts University School of Medicine
1982-1983	President, American Society for Photobiology
1984	Treasurer, Ninth International Congress on Photobiology, Philadelphia, PA
1987	Organizing Committee, Fourth International Congress on Oxygen Radicals, La Jolla, CA
1987	Chairman, Eighth International Symposium on Carotenoids, Boston, MA
1988-1991	Council, The Oxygen Society
1989-2000	Executive Committee, International Society for Nutrition and Cancer
1990	Lottie Arnrich Lecturer, Dept of Food & Nutrition, Iowa State University, Ames, IA May 1. 1990
1992	Chairman, 1st Gordon Research Conf. on "Chemistry and Biology of Carotenoids", Oxnard, CA
1993	Co-Chair, New York Academy of Sciences Conference on "Carotenoids in Human Health ", San Diego, CA
1993	Honorary Member, The Vitamin Society of Japan
1993	Distinguished Faculty Award, Tufts University School of Medicine
1994	Fellow, The Oxygen Society
1994	Co-Chair, Second International Conference on "Antioxidant Vitamins and ß-Carotene in Disease Prevention", October 10-12, Berlin, Germany
1994-1999	President, New England Free Radical/Oxygen Society
1995	Co-Chair, FASEB Summer Research Conference on "Antioxidant Nutrients in the Cellular Biology of Health and Disease", Saxtons River, VT
1995-1996	Secretary-General, The Oxygen Society
1996-1998	Advisory Committee, International Antioxidant Research Centre, King's College, London
1997	Mordechai Avron Memorial Lecturer, Nikken Sohonsha Corp., Gifu and Tokyo, Japan, 2/21/97
1997	Award Lecturer, American College of Nutrition, New York, NY September 27, 1997
1997-1999	Chair, Panel on Antioxidants and Related Nutrients, Food & Nutrition Board, Inst. of Med./NAS

1998	Fellow, American College of Nutrition
1998	Dozor Visiting Professor, Ben-Gurion University of the Negev, Beer-Sheva, Israel
1999	Visiting Scholar, Linus Pauling Institute, Oregon State University, Corvallis, OR
1999	Honorary Member, Oxygen Club of California
1999	Lars Ernster Lecture, Oxygen Club of California 1999 World Congress, Santa Barbara, CA
2000	Robert S. Harris Lecture, Massachusetts Institute of Technology, Cambridge, MA
2001	National Associate, National Academy of Science/National Research Council
2002	Chair, Committee on the Examination of the Evolving Science for Dietary Supplements, Food & Nutrition Board, IOM/NAS
2003-2007	Member, Food Advisory Committee, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety, FDA
2003-2007	Chair, Nutrition Subcommittee, Food Advisory Committee, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety, FDA

RESEARCH TRAINEES: PRE-DOCTORAL		PRESENT POSITION
1964-1967	(b)(6) "Chemical and Biochemical Reduction of Carotenoid Epoxides"	Professor, Banting & Best Dept. of Medical Research University of Toronto, Toronto, Canada
1967-1974	(b)(6) "The Concentration, Turnover, Exchange & Enrichment of Cholesterol in Mitochondria and Mitochondrial Fractions"	Private Practice of Medicine New York, New York
1968-1974	(b)(6) "Mechanism of Photodynamic Oxidation and Lysis of a Model Membrane System (Liposomes)"	Associate Professor Department of Medicine Univ. of Texas, San Antonio, TX
1973-1980	(b)(6) "Kinetic and Structure-Function Studies Concerning Human Myeloperoxidase	Senior Scientist Seradyne.1200 S. Madison Avenue Indianapolis, IN
1987-1991	(b)(6) "Characterization of Tissue Carotenoids, Their Breakdown Products, and Relationship to Biological Metabolites"	Assistant Professor University of Massachusetts Lowell, MA

RESEARCH TRAINEES: POST-DOCTORAL		PRESENT POSITION
1963-1965	(b)(6)	Associate Director (Retired), National Institute of Nutrition Hyderabad, India
1964-1968	(b)(6)	Assoc. Professor (Med), Channing Laboratory Harvard Medical School, Boston, MA
1966-1967	(b)(6)	Consultant, New York, NY
1971	(b)(6)	Chairman, Environmental Sciences Program

		University of Massachusetts, Boston, MA
1972	(b)(6)	Director, Dermal & Ocular Branch Division of Toxicology, Food & Drug Administration, Washington, DC
1977	(b)(6)	Research Associate, Sylvius Laboratoria, Univ. of Leiden, Leiden, The Netherlands
1979-1989	(b)(6)	Scientist, Duracell Technology Center, Needham, MA
1988	(b)(6)	Professor, Nutrition Physiology Institute für Physiologie, Veterinary Faculty University of Leipzig. D-7010, Leipzig, FRG
1990-1992	(b)(6)	Institute of General Pathology Catholic University, Rome. Italy
1996-1999	(b)(6)	USDA HNRCA, Boston, MA
1999-2003	(b)(6)	University of Milan, Milan, Italy

RESEARCH TRAINEES - UNDERGRADUATES/MEDICAL STUDENTS

1964-1966	(b)(6)	TUSM, 1968
1966-1967		TUSM, 1968
1973-1974		, Tufts University, 1973
1974	(b)(6)	Tufts University, 1974
1974		Tufts University, 1974
1974	(b)(6)	Tufts University, 1974
1974		Tufts University, 1974
1974	(b)(6)	, TUSM, 1977
1974		, Hampshire College, 1975
1974-1975	(b)(6)	Tufts University, 1975
1975-1976		Tufts University, 1979
1977-1978	(b)(6)	, Tufts University, 1979
1979-1980		, Tufts University, 1981
1980	(b)(6)	Tufts University, 1980
1980		, Oberlin College, 1981
1980	(b)(6)	, Tufts University, 1981
1983-1984	(b)(6)	Tufts University, 1984
1983-1984		, TUSM, 1987
1984-1985		, Tufts University, 1985
1988-1989	(b)(6)	, Tufts University 1990
1991		, Wellesley College 1992
	(b)(6)	

FACULTY ACTIVITIES

TUFTS UNIVERSITY SCHOOL OF MEDICINE

1963-1966	Pre-Clinical Curriculum Study (Director)
1963-1967	Curriculum Committee
1967-1969	Faculty Medical Education Group
1968-1971	Committee on Extended Educational Opportunity (Chairman)
1968-1969	Health Information Sciences Committee
1969-1970	Advisory Committee on Medical Education
1970-1972	Committee on Faculty Affairs
1973-1978	Committee on Educational Affairs
1974-1975	Fringe Benefits Subcommittee, Faculty Affairs Committee
1974-1975	Admissions Committee
1977	Medical Bylaws Committee
1978-1979	Faculty Affairs Committee (Chairman)
1979-1981	Budgetary Advisory Subcommittee, Faculty Affairs Committee
1979-1981	Boston Tuition Scholarship Benefits Committee
1980-1983	Curriculum Coordinator, Year I
1980-1983	Student Promotions Committee
1981-1982	Ad Hoc Committee on Student Performance Evaluation
1981	Special Program Development Committee
1981-1983	Library and Educational Spaces Planning Subcommittee
1981-1986	Curriculum Committee
1982-1983	Committee on the Teaching of Nutrition at TUSM (Co-Chairman)
1982-1985	Ad Hoc Grievance Committee
1982-1983	Basic Science Appointment, Promotion and Tenure Committee
1983-1985	Task Force on Curriculum Planning
1983-1985	Faculty Advisor
1984-1987	Course Director, Biochemistry
1984-1987	Faculty Affairs Committee
1985-1987	Curriculum Committee Sub-Committee on Curriculum Planning and Implementation
1985-1990	Problem-Based Learning Committee
1988-1989	Curriculum Committee
1989-1992	Faculty Affairs Committee (Chairman, 1990-1992)
1991-1992	Self-Study Sub-Committee on Governance and Administration, LCME, (Chairman)
1992-1993	Steering Committee, RWJ Foundation Generalist Physician Initiative Program
1993-1994	Member, Faculty Senate
1994-1995	Member, Core Curriculum Collaborators Group
1994-1996	Member, Faculty Prizes/Awards Committee
1996-1998	Self-Study Sub-Committee on Governance and Administration, LCME

TUFTS-NEW ENGLAND MEDICAL CENTER

1963	Committee on the Role of the Basic Scientist in the Medical Center, (Chairman)
1968-1969	Audio-visual Task Force
1970-1971	Advisory Committee on Minority Opportunity and Planning
1982-1984	Board of Directors, Women's Resource Center

TUFTS UNIVERSITY

1966-1968	Policy and Program Committee, Graduate School of Arts and Sciences
1967-1973	Molecular Basis of Biological Phenomena Program (Chairman)
1968-1971	Committee on Equal Educational Opportunity, Faculty of Arts and Sciences
1968-1970	Faculty Representative, Trustees Committee on Honorary Degrees

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1970-1971	University-wide Committee on Equal Employment Advancement
1970-1971	Committee on Educational Planning
1978-1979	Advisory Committee on University Investments
1986-1987	Faculty Representative, Trustees Academic Affairs Committee
1993-1999	University-wide Benefits Advisory Committee

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SACKLER SCHOOL OF GRADUATE BIOMEDICAL SCIENCES

1983-1984 Faculty Secretary
1983-1987 Nominating Committee (Chairman)

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

1964-1965 Curriculum Committee

JEAN MAYER HUMAN NUTRITION RESEARCH CENTER ON AGING AT TUFTS UNIVERSITY

1995-2000 Promotions Committee

TEACHING EXPERIENCE

HARVARD UNIVERSITY

1956-1960 Biology 191 (Experimental Biochemistry)
1956-1960 Undergraduate Advisor, Department of Biology
1958 Biology 190 (General Biochemistry, with George Wald)

TUFTS UNIVERSITY SCHOOL OF MEDICINE

1960-1967 Pharmacology
1967-1999 Biochemistry (Course Director, 1984-1987, 1994)
1968-1986 Neuropharmacology
1974-1979 Biochemistry of Disease
1980-1985 Principles of Pharmacology
1985-1991 Problem-Based Learning Facilitator
1990 Nutrition and Medicine Facilitator

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

1960-1966 Pharmacology
1966-1968 Basic Health Sciences
1968-1988 Pharmacology
1984-1993 Biochemistry

TUFTS UNIVERSITY SCHOOL OF VETERINARY MEDICINE

1979-1985 Biochemistry
1980-1985 Neuropharmacology
1980-1985 Pharmacology

TUFTS UNIVERSITY GRADUATE SCHOOL OF ARTS AND SCIENCES

1960-1967 Graduate Pharmacology
1970 Mitochondrial Membranes and Bacterial Envelopes (BCM 294)
1972 Energy Flow in Biological Systems (BCM 214)
1974, 1978 Metabolic Pathways (BCM 213)
1978, 1982 Membranes (BCM 211)
1981- 1982 Advanced Biochemistry (BCM 223)

TUFTS UNIVERSITY SACKLER SCHOOL OF GRADUATE BIOMEDICAL SCIENCES

1984 Membranes (BCM 221)
1984-1999 Graduate Biochemistry (BCM 223)
1985 Recent Advances in Neurochem. and Neuropharm. (BCM 220)

1995 Free Radicals in Biology & Medicine (BCM 293)

TUFTS UNIVERSITY SCHOOL OF NUTRITION

1991, '93, '99 Dietary Antioxidants and Degenerative Diseases (Nutrition 291-DA)

SCIENTIFIC CONFERENCES AND MEETINGS: INVITED PARTICIPATION

1. Invited Speaker: The Lipoprotein Nature of Rhodopsin Symposium on "Visual Mechanisms" (Sponsored by National Institutes of Health) Bethesda, Maryland, September 11-12, 1957.

2. Invited Speaker: The Role of Carotenoid Pigments as Protective Agents against Photosensitized Oxidations in Chloroplasts. Symposium on "Biochemistry of Chloroplasts" NATO Advanced Study Institute, Aberystwyth, Wales, U.K., August 5-9, 1965.

3. Invited Speaker: A Biochemical Basis for Carotenoid Function in Green Plants and Algae. Joint Japan-U.S. Seminar on "Carotenoid Biosynthesis and Related Topics" National Science Foundation/Japan Society for the Promotion of Science, Kyoto, Japan, November 29 - December 1, 1965.

4. Invited Speaker: Carotenoid De-epoxidation Reactions. Conference on "Photosynthetic Pigments" in honor of Harold H. Strain, Argonne National Laboratory, Argonne, Illinois, November 7-8,1968.

5. Invited Speaker: Minority Programs at Tufts University School of Medicine. Conference on "Minority Groups in Professional Schools" American Personnel and Guidance Association, Las Vegas, Nevada, March 30 - April 2, 1969.

6. Invited Participant: Minority Enrollment at Tufts University School of Medicine. Conference on "The Impact of Cultural and Economic Background on Programs to Recruit Negroes for Medicine" Macy Foundation, Princeton, NJ, April 13-16, 1969.

7. Invited Speaker: Evolution of Photosensitive Pigments in Microbes. Colloquium on "Photosynthetic Organisms: Origin and Evolution on Early Earth" 123rd meeting of the American Association for the Advancement of Science, Boston, MA, December 26, 1969.

8. Invited Speaker: The Protective Function of Carotenoid Pigments against Aerobic Photosensitivity. Colloquium on "Molecular Mechanisms of Photodynamic Action with and without Molecular Oxygen" VIth International Congress on Photobiology, Bochum, W. Germany, Aug. 21-25, 1972.

9. Sigma Xi Lecturer: Function of Carotenoids. University of Rhode Island, Kingston, RI, October 10, 1973.

10. Invited Speaker: Photosensitization and Protection of Biomembranes and Model Systems. Colloquium on "Photochemistry of Biomembranes" at the 2nd Meeting of the American Society for Photobiology, Vancouver, British Columbia, Canada, July 24, 1974.

11. Theme Speaker: Light and Life: Biochemical Responses to Light. New England Association of Chemistry Teachers 36th Summer Conference, St. Anselem's College, Manchester, New Hampshire, Aug. 20-24, 1974.

12. Invited Speaker: Singlet Oxygen Production in Biological Systems, Workshop on "The Role of Oxygen in the Production of Excited States in Biological Systems" Photobiology Group, Biophysical Society, Philadelphia, PA, February 18, 1975.

13. Invited Speaker: Damage and Protection against Singlet Oxygen. Workshop on "Free Radical Damage and Protection" Bioenergetics Group, Biophysical Society Seattle, WA, February 24, 1976.

14. Invited Speaker: Cellular Damage Initiated by Visible Light. Symposium on "The Survival of

Vegetative Microbes" Society for General Microbiology, Cambridge, England, April 5-8, 1976.

15. Invited Speaker: Non-Photosynthetic Functions of Carotenoids. Discussion. Meeting on "The Biochemical Functions of Terpenoids in Plants" The Royal Society, London, England, January 26-27, 1978.

16. Invited Speaker: Carotenoid Protection against Oxidation. Fifth International Symposium on "Caroteno and Vitamin A" Madison, WI, July 24-28, 1978.

17. Invited Participant: Joint Seminar on "Chemi- and Bio-energized Processes" Universidade de Sáo Paulo, Sáo Paulo, Brazil, August 5-7, 1978.

18. Invited Speaker: Cholesterol Oxidation by Either Polymorphonuclear Leukocyte or by Isolated Myeloperoxidase. International Conference on "Chemi- and Bio-energized Processes" Guaruja, Estado de Sáo Paulo, Brazil, August 8-10, 1978.

19. Invited Speaker: Carotenoid Pigments: Multiple Mechanisms for Coping with the Stress of Photosensitized Oxidations. Conference on "Strategies of Microbial Life in Extreme Environments" Dahlem Konferenzen, Berlin, Fed. Rep. Germany, November 20-24, 1978.

20. Invited Speaker: Is Singlet Oxygen Involved in Biological Chemiluminescence? Symposium on "Biological Basis of Chemiluminescence" American Society for Photobiology, Colorado Springs, CO, February 21, 1980.

21. Invited Speaker: Photosensitized Damage. Round Table on "Sensitized Photooxidation of Biomolecules" International Conference in Oxygen and Oxy-Radicals in Chemistry and Biology, Austin, TX, May 25-29, 1980.

22. Invited Speaker: Molecular Bases for Cellular Damage Initiated by Photosensitized Oxidations. Round Table on "Endogenous and Exogenous Inhibitors and Sensitizers. Fundamental Aspects" 8th International Congress on Photobiology, Strasbourg, France, July 20-25, 1980.

23. Invited Speaker: Interaction of Oxygen and Oxyradicals with Carotenoids Symposium on "Photochemical Toxicity" Food and Drug Administration, Bethesda, MD, March 16-17, 1981.

24. Invited Speaker: Possible Participation of Singlet Oxygen in Biological Systems. Symposium on "Radicals and Excited States in Biological Systems" Seventh International Biophysics Congress and Third Pan-American Biochemistry Congress, Mexico City, Mexico, August 24-28, 1981.

25. Invited Speaker: In vivo Analysis of UV-B Formation of 5.6-a-Epoxy- cholesterol. 2nd NCI/EPA/NIOSH Collaborative Workshop on "Progress on Joint Environmental and Occupational Cancer Studies" Rockville, MD, September 9-11, 1981.

26. Invited Speaker: The Biological Implications of Singlet Oxygen Production. Table Ronde Roussel Uclaf on "New Concepts of Free Radicals in Chemistry and Biology" Paris, France, October 22-23, 1981.

27. Invited Speaker: Photosensitization. Singlet Oxygen Damage and Cancer. "International Workshop on Photobiology" Cheju, Korea, May 25-June 1, 1982.

28. Invited Speaker: Introduction to Photobiology and Photosensitization. Symposium on "Photobiology" Chosun University, Gwang Ju, Korea, June 2, 1982.

29. Invited Speaker: Free Radicals as Possible Mutagens and Carcinogens. Symposium on "Free

Radicals and Cancer" Council for Tobacco Research, New York, NY, June 21, 1982.

30. Invited Speaker: Mutagenic and Carcinogenic Effects of Oxygen Radicals Symposium on "Possible Roles of Free Radicals in Aging" Gerontological Society of America, Boston, MA, Nov. 21, 1982.

31. Invited Speaker: Biology and Photobiology of Singlet Oxygen 3rd International Conference on Oxygen Radicals, Munich, FRG, July 10-15, 1983.

32. Invited Speaker: Comparison of the Oxidant Mechanisms of Myeloperoxidase and UV-B Irradiation EMBO Workshop on "Oxidative Enzymes-Damage and Consequences" Grottoferrata, Italy, October 2-7, 1983.

33. Public Lecture: New Findings on the Role of Provitamin A in Health and Disease. Institute for Research on Aging, University of California, San Diego, CA, September 13, 1984.

34. Invited Speaker: The Action of Carotenoids In vitro as Compared to their Function In vivo. Symposium on "Nutrition and Disease: Cancer" Helicon Foundation, San Diego, CA, September 15, 1984.

35. Invited Speaker: Detection and Biological Function of Active Oxygen Species School Lecture, American Society for Photobiology, New Orleans, and LA, June 27, 1985.

36. Invited Speaker: The Unique Singlet Oxygen Quenching Properties of Carotenoids. FASEB Summer Research Conference on "Micronutrients Retinoids" Saxtons River, VT, June 22-27, 1986.

37. Invited Speaker: Mechanisms of Inactivation of Oxygen Species by Carotenoids. 2nd International Conference on Anticarcinogenesis and Radiation Protection, National Bureau of Standards, Gaithersburg, MD, March 9-12, 1987.

38 Invited Speaker: Beta-carotene and Cancer: Overview and Rationale. VNIS Health Communications Conference: Beta-Carotene, Boca Raton, FL, April 11-12, 1987.

39. Invited Speaker: Overview of Carotenoids in Medicine. Eighth International Symposium on Carotenoids, Boston, MA, July 26-31, 1987.

40. Invited Speaker: Enzymic and Pigment Protection from Photodynamic Damage. FEMS/Society for Applied Bacteriology Symposium on "Homeostatic Mechanisms in Micro-organisms." Warwick University, Coventry, UK, September 14-18, 1987.

41. Invited Speaker: The Evidence for the Role of Carotenes in Preventive Health Symposium on "Carotenes in Food and Health" Department of Food Science and Office of Continuing Professional Education, Rutgers, The State University of New Jersey, Iselin, NJ, December 3, 1987.

42. Invited Speaker: Carotenoids as Chemopreventive Agents. Third International Conference on "The Prevention of Human Cancer: Chemoprevention" Arizona Cancer Center, Tucson, AZ, January 12-15, 1988.

43. Invited Speaker: Theoretic and Experimental Basis for Anti-carcinogenic Effects of Retinoids. Workshop on "Emerging Role of Retinoids in the Treatment of Aging and Skin Cancer" Miami, FL, March 11-13, 1988.

44. Invited Speaker: Experimental Studies on Carotenoids and Cancer in Animal Models. Symposium on "The Biological Actions of Carotenoids" American Institute of Nutrition, Las Vegas, NV, May 1-6,

1988.

45. Invited Speaker: Biological Functions of Carotenoids and Retinoids. Symposium on "Biology of Human Skin Aging" American Academy of Dermatology, Philadelphia, PA, May 18-20, 1988.

46. Invited Speaker: Membrane Antioxidants. Conference on Biological Membranes in Cancer Cells, New York Academy of Sciences, Torgiano, Italy, June 13-18, 1988.

47. Invited Speaker: Pigment and Enzymic Protection Against Photodynamic Damage. Tenth International Congress of Photobiology. Jerusalem, Israel, October 31 1988.

48. Invited Speaker: Cancer Prevention: Animal and In vitro Studies. International Conference on "Anti-Oxidant Vitamins and Beta-Carotene in Disease Prevention" British Nutrition Foundation, London, U.K. October 2-4, 1989.

49. Invited Speaker: Carotenoid Metabolism. Workshop on "Carotenoids" FASEB Annual Meeting, Washington, DC, April 1, 1990.

50. Invited Speaker: Carotenoids and Cancer. Symposium on "Nutrition Related Cancer Research: An Interdisciplinary Update" Nutrition Council at Tufts, Boston, MA, April 25, 1990.

51. Invited Speaker: Carotenoid Function. Workshop on "Carotenoids" FASEB Annual Meeting, Atlanta, April 20, 1991.

52. Invited Speaker: Role of Carotenoids. Seminar on "Recipe for Cancer Prevention: Food Issues for the 1990s" American Cancer Society and Nestlé Beverage Company, New York, NY, June 12, 1991.

53. Invited Speaker: Mechanisms of Action of Antioxidants. Conference on Molecular and Comparative Nutrition, US-Japan Malnutrition Panel, Bethesda, MD, July 22-24, 1991.

54. Invited Participant: National Heart, Lung and Blood Institute Workshop on "Antioxidants in the Prevention of Human Atherosclerosis" Bethesda, MD, September 5-6, 1991.

55. Invited Speaker: Carotenoids in Cellular and Animal Systems: Effects on Mutagenesis, Carcinogenesis and Age-related Diseases. Symposium on "Free Radicals and Aging" Society for Free Radical Research (Europe), Paris, France, September 26-28, 1991.

56. Invited Speaker: Conversion of Carotenoids to Retinoids. Symposium on "Retinoids: New Trends in Research and Clinical Applications" Palermo, Italy, October 21-24, 1991.

57. Invited Speaker: Beta-Carotene - Animal Data. Symposium on "Vitamins and Cancer Prevention" Pennington Biomedical Research Center, Baton Rouge, LA, October 30 November 1, 1991.

58. Invited Speaker: Carotenoids as Biological Antioxidants. Symposium on "Active Oxygens, Lipid Peroxides and Antioxidants" 5th International Congress on Oxygen Radicals, Kyoto, Japan, November 17-21, 1991.

59. Invited Speaker: Excentric Cleavage Mechanism(s) for Carotenoid Metabolism. Gordon Research Conference on "Chemistry and Biology of Carotenoids" Oxnard, CA, March 9-13, 1992

60. Invited Speaker: Nutritional Factors an Their Influence on Mutagenicity and Malignant Transformation. Tobacco and Health Research Institute, University of Kentucky Symposium on "Tobacco Smoking and Nutrition: Influence of Nutrition on Tobacco Associated Health Risks" Lexington, KY,

September 14-16, 1992

61. Invited Speaker: Excentric Cleavage of Carotenoids. New York Academy of Sciences Conference on "Carotenoids in Human Health" San Diego, CA, February 6-9, 1993.

62. Invited Speaker: Antioxidant Effects of Carotenoids. International Conference on "Critical Aspects of Free Radicals in Chemistry, Biochemistry and Medicine" Vienna, Austria, February 14-17, 1993.

63. Invited Speaker: Antioxidant Properties of Carotenoids. The Kurashiki Symposium for Medical Science, Kurashiki, Japan, May 21-22, 1993.

64. Invited Speaker: ß-Carotene: Disease Prevention and Its Health Impact. Japan Vitamin Society, Gifu City, Japan, May 25-27, 1993.

65. Invited Speaker: Function, Actions, and Associations of Carotenoids. Tenth International Symposium on Carotenoids, Trondheim, Norway, June 20-25, 1993.

66. Invited Speaker: Antioxidants: Classification and Mode of Action. Symposium on "Antioxidants and Disease Prevention: Biochemical, Nutritional, and Pharmacological Aspects" Stockholm. Sweden, June 30-July 3, 1993.

67. Invited Speaker: Carotenoid Metabolism. Symposium on "Retinoids: New Trends in Research and Cli Applications" Genoa, Italy, October 4-7, 1993.

68. Invited Speaker: The Effects of Carotenoids on Cells. Workshop on "Cell Proliferation and Differentiation: Modulation by Free" Rome, Italy, October 8, 1993.

69. Invited Discussant: Antioxidant Nutrients. Symposium on "Nutritional Assessment of Elderly Populations Measure and Function" Boston, MA, October 11-13, 1993.

70. Invited Speaker: Clinical and Experimental Studies of ß-Carotene and Cancer. FDA Public Conference on Antioxidant Nutrients and Cancer and Cardiovascular Disease. Washington, DC, November 1-3, 1993.

71. Invited Speaker: Recent Research Findings on Beta-Carotene. Henkel Symposium on Vitamin E Palm Beach, FL, June 7-8, 1994.

72. Invited Speaker: Comments on Antioxidant Vitamins and ß-Carotene. "Second International Conference on Antioxidant Vitamins and Beta Carotene in Disease Prevention" Berlin, Germany, October 10-12, 1994.

73. Invited Speaker: Plant Carotenoids and Related Molecules - Important Dietary Antioxidants. Symposium on "Free Radicals and Oxidative Stress - Environment, Drugs and Food Additives" Biochemical Society, Brighton, U.K., December 14-16, 1994

74. Invited Speaker: Antioxidants and Their Role in Human Health. 22nd Annual Texas Human Nutrition Conference, "Health Claims for Foods and Nutrients" Texas A & M Univ., Tyler, TX, February 3, 1995.

75. Plenary Lecture: An Overview of the Functions and Actions of Carotenoids: A Personal Perspective. 2nd Gordon Research Conference on Carotenoids, Ventura, CA February 5-9, 1995.

76. Invited Speaker: Carotenoids as Biological Antioxidants. 2nd Symposium on Vitamins and

Biofactors, San Diego, CA February 15-19, 1995.

77. Invited Speaker: Overview of Carotenoids. USAID Workshop on the Bioavailability and Bioconversion of Carotenoids. Washington, DC April 4-5, 1995

78. Invited Speaker: Functions of Carotenoids. FASEB Summer Conference on Antioxidant Nutrients in the Cellular Biology of Health and Disease, Saxtons River, VT August 17-21, 1995

79. Invited Speaker: Biological Effects of Radicals on Carotenoids, 6th European Society for Photobiology, Cambridge, UK September 2-9, 1995.

80. Invited Speaker: Low Molecular Weight Antioxidants; You are What You Eat, Oxygen '95 Free Radical School, Annual Meeting of the Oxygen Society, Pasadena, CA November 17, 1995

81. Invited Speaker Carotenoids: Structure and Function, Workshop on "Potential Effects of Reducing Carotenoid Levels on Human Health" Department of Nutrition, Harvard School of Public Health, Boston, MA January 17th, 1996

82. Invited Speaker Metabolism and Mechanism of Action of Antioxidants, The Toxicology Forum, Givens Institute, Aspen, CO, July 9, 1996.

83. Invited Speaker Are the Oxidative Breakdown Products of Carotenoids Evidence of Antioxidant Action or the Generation of Biologically Active Molecules? VIII Biennial Meeting, International Society for Free Radical Research, Barcelona, Spain October 4, 1996

84. Invited Speaker ß-Carotene and Disease: A Causal Relationship? Oxygen '96, Annual Meeting of the Oxygen Society, Miami □Beach. FL November 22, 1996

85. Invited Lecturer: Natural and Synthetic Carotenoids: Their Actions in Biology. 5th Mordechai Avron Memorial Lecture, Gifu and Tokyo, Japan, Nikken Sohonsha Corp., February 21 and 23, 1997

86. Invited Speaker: Overview of Lycopene, Carotenoids and Disease Prevention, International Symposium on the Role of Lycopene and Tomato Products in Disease Prevention, American Health Foundation/Tomato Research Council, New York, NY, March 3, 1997

87. Invited Speaker: Hypothetical Health Benefits Of ß-Carotene And Other Carotenoids, Society of Toxicology, Cincinnati, OH, March 11, 1997

88. Invited Lecturer: The Properties of Carotenoids that Define Their Actions (June 1) and The Actions of Carotenoids in Biology and Medicine (June 3), NATO Advanced Study Institute on Free Radicals, Oxidative Stress and Antioxidants. Pathological and Physiological Significance, Antalya, Turkey, May 24-June 4, 1997

89. Invited Speaker: Carotenoids and Chronic Degenerative Diseases, International Conference on Nutrition and Cancer, Irvine, CA July 16-July 19, 1997

90. Invited Speaker: The Antioxidant and Biological Properties of the Carotenoids, 7th Congress of the International Association of Biomedical Gerontology, Adelaide, Australia, August 15-August 18, 1997

91. Invited Speaker: Biochemistry of Carotenoids: Actions and Functions. American College of Nutrition Award Lecture, American College of Nutrition Annual Meeting, New York, NY, September 26-28, 1997

92. Invited Speaker: Measurement of Carotenoids, WORKSHOP on Quantitative Methods for Determination of Hydroxyl Radicals, Oxidation of Biological Molecules and Antioxidants, The Oxygen Society, San Francisco, CA, November 20-24, 1997.

93. Invited Speaker: Actions of Carotenoids, Oxygen Club of California, Santa Barbara, CA, February 7, 1998

94. Plenary Lecture: Carotenoids in Health and Disease, Gordon Research Conference on Oxygen Radicals in Biology, Ventura, CA, February 12, 1998

95. Invited Speaker: Role of Carotenoids in Health and Disease, The First Regional Meeting on Medical Sciences: "The Roles of Free Radicals in Health and Disease" Jerusalem and Amman, March 22-27, 1998

96. Invited Speaker: Activity of ß-Carotene Oxidation Products, European Conference on Biomedical Research and Peace, Paralimni, Cyprus, October 17-21, 1999

97. Invited Speaker: What is the Scientific Evidence for Establishing Carotenoids as Recommended Nutrients? Symposium on Dietary Antioxidants: the New Dietary Reference Indices; The Oxygen Society, New Orleans, LA, November 21, 1999

99. Invited Speaker: The Relationship Between Antioxidant and Chronic Disease Symposium on Dietary Reference Intakes, Experimental Biology '00, San Diego, CA April 17, 2000

100. Invited Speaker Carotenoids, Smoking and Cancer, 3rd International Conference on Antioxidants and Free Radicals in Health and Disease, Vancouver, BC, Canada July 23, 2000

101. Invited Speaker: Antioxidants and Chronic Diseases: How Much Science is Enough? Symposium on Dietary Reference Intakes, American Dietetic Association, Denver, CO October 18, 2000

102. Invited Speaker: Antioxidants and Chronic Diseases, Symposium on Dietary Reference Intakes, American Public Health Association, Boston, MA Nov. 13, 2000

103. Invited Speaker: Carotenoids in Health and Disease, Robert S. Harris Lecture, Massachusetts Institute of Technology, Cambridge, MA March 15, 2001

104. Invited Speaker Possible Biologic Mechanism for the Protective Role of Xanthophylls, Symposium on Lutein and Macular Degeneration, FASEB Meeting, Orlando, FL, April 1, 2001

105. Invited Speaker: Carotenoid Research in the Past and Present Millennia, CARIG Lecturer, EB'01 Conference, Orlando, FL, April 2, 2001

106. Invited Speaker: Possible Biologic Mechanism for the Protective Role of Xanthophylls in Age-Related Macular Degeneration, American Society of Nutritional Sciences (EB'01), Orlando, FL, April 1, 2001

107. Invited Speaker: Dietary Carotenoids: What do They Do? PAX Mechanisms Conference, Cambridge, MA, September 30, 2001

108. Invited Plenary Lecturer Historical Critical Evaluaiton of free Radical and Antioxidant Research Oxygen Club of California, Santa Barbara, CA, March 8, 2002

109. Invited Speaker: Health Benefits of Carotenoids, Helmut Sies Festschrift, L'Abbaye de Royamount,

Royamount, France, July 15, 2002

110. Invited Speaker: Dietary Carotenoids Modify Human Plasma Lipid Oxidizability, International Society for Free Radical Research Meeting, Paris France, July 16-20, 2002

111. Invited Plenary Lecturer Human Requirements for Fat-Soluble Vitamins, XIIth European Meeting on Fat-Soluble Vitamins, Rieti, Italy March 13-15, 2003

112. Invited Speaker: Overview of Lutein and Zeaxanthin, Advisory Committee, National Eye Institute, May 17, 2004

A. Peer Reviewed Journal Articles (99)

1. Ganguly, J, Krinsky, NI, Mehl, JW and Deuel, HJ Jr, Studies of the Distribution of Vitamin A as Ester and Alcohol and of Carotenoids in Plasma Proteins of Several Species. Arch. Biochem. Biophys. 38:275-282 (1952).

2. Krinsky, NI and Ganguly, J, Intracellular Distribution of Vitamin A Ester and Vitamin A Alcohol in Rat Liver. J. Biol. Chem. 202:227-232 (1953).

3. Ganguly, J and Krinsky, NI, Absence of Relationship between Vitamin A Alcohol Levels in Plasma and Liver of Rats. Biochem. J. 54:177-181 (1953).

4. Ganguly, J, Krinsky, NI, Pinckard, JH and Deuel, HJ, Jr., Untersuchungen über den Carotinoid-Stoffwechsel, XIV. Biologische Wirksamkeit von Echinenon. Z. Physiol. Chem. 295:61-66 (1953).

5. Ganguly, J, Krinsky, NI and Pinckard, JH, Isolation and Nature of Echinenone, a Provitamin A. Arch. Biochem. Biophys. 60:345-351 (1956).

6. Stefanini, M, Krinsky, NI and Magalini, SI, Studies on Platelets, XIX. Carotenoid Pigments in Human Platelets. J. Lab. Clin. Med. 50:225-228 (1957).

7. Krinsky, NI, Cornwell, DG and Oncley, JL, The Transport of Vitamin A and Carotenoids in Human Plasma. Arch. Biochem. Biophys. 73:233-246 (1958).

8. Krinsky, NI, Enzymatic Esterification of Vitamin A. J. Biol. Chem. 232:881-894 (1958).

9. Krinsky, NI, The Lipoprotein Nature of Rhodopsin. Arch. Ophthal. 60:688-694 (1958).

10. Goldsmith, TH and Krinsky, NI, The Epoxide Nature of the Carotenoid Neoxanthin. Nature (London) 188:491-493 (1960).

11. Krinsky, NI and Goldsmith, TH, The Carotenoids of the Flagellated Alga, Euglena gracilis. Arch. Biochem. Biophys. 91:271-279 (1960).

12. Krinsky, NI, A Relationship between Partition Coefficients of Carotenoids and their Functional Groups. Anal. Biochem. 6:293-302 (1963).

13. Krinsky, NI, Gordon, A and Stern, AI, The Appearance of Neoxanthin During the Re-greening of Dark-grown Euglena. Plant Physiol. 39:441-445 (1964).

14. Krinsky, NI and Levine, RP, Carotenoids of Wild Type and Mutant Strains of the Green Alga, Chlamydomonas reinhardi. Plant Physiol. 39:680-687 (1964).

15. Krinsky, NI, Carotenoid De-epoxidations in Algae. I. Photochemical Transformation of Antheraxanthin to Zeaxanthin. Biochim. Biophys. Acta 88:487-491 (1964).

16. Bamji, MS and Krinsky, NI, Carotenoid De-epoxidations in Algae. II. Enzymatic Conversion of Antheraxanthin to Zeaxanthin. J. Biol. Chem. 240:467-470 (1965).

17. Mathews, MM and Krinsky, NI, The Relationship between Carotenoid Pigments and Resistance to Radiation in Non-photosynthetic Bacteria. Photochem. Photobiol. 4:813-817 (1965).

18. Krinsky, NI, The Carotenoids of the Brine Shrimp, Artemia salina. Comp. Biochem. Physiol. 16:181-187 (1965).

19. Krinsky, NI and Lenhoff, HM, Some Carotenoids in Hydra. Comp. Biochem. Physiol. 16:189-198 (1965).

20. Bamji, MS and Krinsky, NI, The Carotenoid Pigments of a Radiation-resistant Micrococcus sp. Biochim. Biophys. Acta 115:276-284 (1966).

21. Schimmer, BP and Krinsky, NI, The Structure of Neoxanthin and the Trollein-like Carotenoid from Euglena gracilis. Biochemistry 5:1814-1820 (1966).

22. Schimmer, BP and Krinsky, NI, Reduction of Carotenoid Epoxides with Lithium Aluminum Hydride. Biochemistry 5:3649-3657 (1966).

25. Mathews-Roth, MM and Krinsky, NI, Carotenoid Pigments and the Stability of the Cell Membrane of Sarcina lutea. Biochim. Biophys. Acta 203:357-359 (1970).

26. Mathews-Roth, MM and Krinsky, NI, Studies on the Protective Function of the Carotenoid Pigments of *Sarcina lutea*. Photochem. Photobiol. 11:419-428 (1970).

27. Mathews-Roth, MM and Krinsky, NI, Failure of Conjugated Octaene Carotenoids to Protect a Mutant of Sarcina lutea Against Lethal Photosensitization. Photochem. Photobiol. 11:555-557 (1970).

28. Cooney, JJ and Krinsky, NI, Photodynamic Killing of Acholeplasma laidlawii. Photochem. Photobiol. 16:523-526 (1972).

29. Kornhauser, A, Krinsky, NI, Huang, P-KC and Clagett, DC, A Comparative Study of Photodynamic Oxidation and Radiofrequency Discharge Generated $^1O_2$ Oxidation of Guanosine. Photochem. Photobiol. 18:63-69 (1973).

30. Anderson, SM and Krinsky, NI, Protective Action of Carotenoid Pigments against Photodynamic Damage to Liposomes. Photochem. Photobiol. 18:403-408 (1973).

31. Krinsky, NI, Bymun, EN and Packer, L, Retention of K^+ Gradients in Imidoester Cross-Linked Erythrocyte Membranes. Arch. Biochem. Biophys. 160:350-352 (1974).

32. Mathews-Roth, MM, Wilson, T, Fujimori, E and Krinsky, NI, Carotenoid Chromophore Length and Protection against Photosensitization. Photochem. Photobiol. 19:217-222 (1974).

33. Anderson, SM, Krinsky, NI, Stone, MJ and Clagett, DC, Effect of Singlet Oxygen Quenchers on Oxidative Damage to Liposomes Initiated by Photosensitization or by Radiofrequency Discharge. Photochem. Photobiol. 20:65-69 (1974).

34. Krinsky, NI, Singlet Excited Oxygen as a Mediator of the Antibacterial Action of Leukocytes. Science 186:363-365 (1974).

35. Levine, PH, Weinger, RS, Simon, J, Scoon, KL and Krinsky, NI, Leukocyte-Platelet Interaction. Release of Hydrogen Peroxide by Granulocytes as a Modulator of Platelet Reactions. J. Clin. Investigation 57:955-963 (1976).

36. Deneke, CF and Krinsky, NI, Enhanced Dimol Emission of Singlet Oxygen by Cyclic Tertiary Amines. J. Am. Chem. Soc. 98:3041-3042 (1976).

37. Deneke, CF and Krinsky, NI, Inhibition and Enhancement of Singlet Oxygen ($^1\Delta_g$) Dimol Chemiluminescence. Photochem. Photobiol. 25:299-304 (1977).

38. Deneke, CF and Krinsky, NI, A Cheap and Durable Cuvet Washer. J. Chem. Educ. 54:257 (1977).

39. Krinsky, NI, Scoon, KL, Hardin, JC and Levine, PH, The Source of Hydrogen Peroxide and of Chemiluminescence Observed in Activated Human Platelet Preparations. Blood 50:597-602 (1977).

40. Lederman, DM, Cumming, RD, Petschek, HE, Levine, PH and Krinsky, NI, The Effect of Temperature on the Interaction of Platelets and Leukocytes with Materials Exposed to Flowing Blood. Trans. Am. Soc. Artif. Intern. Organs. 24:557-560 (1978).

41. Levine, PH, Hardin, JC, Scoon, KL and Krinsky, NI, Effect of Corticosteroids on the Production of Superoxide and Hydrogen Peroxide and the Appearance of Chemiluminescence by Phagocytosing Polymorphonuclear Leukocytes. Inflammation 5:19-27 (1981).

42. Andrews, PC and Krinsky, NI, The Reductive Cleavage of Myeloperoxidase in Half, Producing Enzymically Active Hemi-Myeloperoxidase. J. Biol. Chem. 256:4211-4218 (1981).

43. Krinsky, NI, Sladdin, DG, Levine, PH, Taub, IA and Simic, MG, Modification of Platelet Function by Radical Species Produced During Irradiation of Oxygenated Water. Thromb. Haemostasis 45:116-120 (1981).

44. Levine, PH, Sladdin, DG and Krinsky, NI, Superoxide, Xanthine Oxidase and Platelet Reactions. Further Studies on Mechanisms by which Oxidants Influence Platelets. Thromb. Haemostasis 45:290-293 (1981).

45. Krinsky, NI and Deneke, SM, The Interaction of Oxygen and Oxy-Radicals with Carotenoids. JNCI 69:205-210 (1982).

46. Andrews, PC and Krinsky, NI, A Kinetic Analysis of the Interaction of Human Myeloperoxidase with Hydrogen Peroxide, Chloride Ions and Protons. J. Biol. Chem. 257:13240-13245 (1982).

47. Andrews, PC and Krinsky, NI, Quantitative Determination of Myeloperoxidase Using Tetramethylbenzidine as Substrate. Anal. Biochem. 127:346-350 (1982).

48. Andrews, PC, Parnes, C and Krinsky, NI, Comparison of Myeloperoxidase and Hemi-Myeloperoxidase with Respect to Catalysis, Regulation and Bactericidal Activity. Arch. Biochem. Biophys. 228:439-442 (1984).

49. Peak, MJ, Foote, CS, Krinsky, NI and Peak, JG, Oxygen-Independent Direct DNA Backbone Breakage Caused by Rose Bengal and Visible Light. J. Photochem. 25:309-315 (1984).

50. Mathews-Roth, MM and Krinsky, NI, Effect of Dietary Fat Level on UV-B Induced Skin Tumors, and Anti-Tumor Action of Beta-Carotene. Photochem. Photobiol. 40:671-673 (1984).

51. Mathews-Roth, MM and Krinsky, NI, Carotenoid Dose Level and Protection Against UV-B Induced Skin Tumors. Photochem. Photobiol. 42:35-38 (1985).

52. Cunningham, ML, Krinsky, NI, Gioranazzi, SM and Peak, MJ, Superoxide Anion is Generated from Cellular Metabolites by Solar Radiation and its Components. J. Free Radic. Biol. Med. 1:381-385 (1985).

53. Ito, A, Krinsky, NI, Cunningham, ML and Peak, MJ, Comparison of the Inactivation of *Bacillus subtilis* Transforming DNA by the Potassium Superoxide and Xanthine-Xanthine Oxidase Systems for Generating Superoxide. Free Radical Biol. Med. 3:111-118 (1987).

54. Mathews-Roth, MM and Krinsky, NI, Carotenoids Affect Development of UV-B Induced Skin Cancer. Photochem. Photobiol. 46:507-509 (1987).

55. Krinsky, NI, Mathews-Roth, MM, Welankiwar, S, Sehgal, PK, Lausen, NCG and Russett, M, The Metabolism of [14C]-ß-Carotene and the Presence of Other Carotenoids in Rats and Monkeys. J. Nutr. 120:81-87 (1990).

56. Mathews-Roth, MM, Welankiwar, S, Sehgal, PK, Lausen, NCG, Russett, M and Krinsky, NI, Distribution of [^{14}C]Canthaxanthin and [^{14}C]Lycopene in Rats and Monkeys. J. Nutr. 120:1205-1213 (1990).

57. Krinsky, NI, Russett, MD, Handelman, GJ and Snodderly, DM, Structural and Geometrical Isomers of Carotenoids in Human Plasma. J. Nutr. 120:1654-1661 (1990).

58. Snodderly, DM, Russett, MD, Land, RI and Krinsky, NI, Plasma Carotenoids of Monkeys (*Macaca Fascicularis and Saimiri Sciureus*) Fed a Nonpurified Diet. J. Nutr. 120:1663-1671 (1990).

59. Handelman, GJ, Snodderly, DM, Krinsky, NI, Russett, MD and Adler, AJ, Biological Control of Primate Macular Pigment. Biochemical and Densitometric Studies. Invest. Ophthalmol. Vis. Sci 32:257-267 (1991).

60. Wang, X-D, Tang, G-W, Fox, JG, Krinsky, NI and Russell, RM, Enzymatic Conversion of ß-Carotene into ß-Apo-Carotenals and Retinoids by Human, Monkey, Ferret, and Rat Tissues. Arch. Biochem. Biophys. 285:8-16 (1991).

61. Mathews-Roth, MM, Lausen, N, Drouin, G, Richter, A and Krinsky, NI, Effects of Carotenoid Administration on Bladder Cancer Prevention. Oncology 48:177-179 (1991).

62. Handelman, GJ, van Kuijk, FJGM, Chatterjee, A and Krinsky, NI, Characterization of Products Formed During the Autoxidation of ß-Carotene. Free Radical Biol. Med. 10:427-437 (1991).

63. Palozza, P and Krinsky, NI, The Inhibition of Radical-Initiated Peroxidation of Microsomal Lipids by both α-Tocopherol and ß-Carotene. Free Radical Biol. Med. 11:407-414 (1991).

64. Tang, G, Wang, X-D, Russell, RM and Krinsky, NI, Characterization of ß-Apo-13-Carotenone and ß-apo-14'-Carotenal as Enzymatic Products of the Excentric Cleavage of ß-Carotene. Biochemistry 30:9829-9834 (1991).

65. Wang, X-D, Krinsky, NI, Tang, G and Russell, RM, Retinoic Acid can be Produced from Excentric Cleavage of ß-Carotene in Human Intestinal Mucosa. Arch. Biochem. Biophys. 293:293-304 (1992).

66. Palozza, P and Krinsky, NI, ß-Carotene and α-Tocopherol are Synergistic Antioxidants. Arch. Biochem. Biophys. 297:184-187 (1992).

67. Palozza, P, Moualla, S and Krinsky, NI, Effects of ß-Carotene and α-Tocopherol on Radical-Initiated Peroxidation of Microsomes. Free Radical Biol. Med. 13:127-136 (1992).

68. Palozza, P and Krinsky, NI, Astaxanthin and Canthaxanthin are Potent Antioxidants in a Membrane Model. Arch. Biochem. Biophys. 297:291-295 (1992).

69. Wang, XD, Krinsky, NI, Marini, R, Tang, G, Yu, J, Fox, JG and Russell, RM, Intestinal Uptake and Lymphatic Absorption of ß-Carotene in Ferrets: A Model for Human ß-Carotene Metabolism. Am. J. Physiol. 263:G480-G486 (1992).

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72. Palozza, P and Krinsky, NI, Antioxidant Effects of Carotenoids on Biological Membranes. Acta Medica Romano 31:131-140 (1993).

73. Wang, X-D, Krinsky, NI, Benotti, PN and Russell, RM, Biosynthesis of 9-*cis*-retinoic acid from 9-*cis*-ß-carotene in human intestinal mucosa in vitro. Arch. Biochem. Biophys. 313:150-155 (1994).

74. Kennedy, AR and Krinsky, NI, Effects of retinoids, ß-carotene and canthaxanthin on UV and X-ray-induced transformation of C3H10T1/2 cells *in vitro*. Nutr. Cancer 22:219-232 (1994).

75. Gaziano, JM, Hatta, A, Flynn, M, Johnson, EJ, Krinsky, NI, Ridker, PR, Hennekens, CH and Frei, B, Supplementation with ß-carotene in vivo and in vitro does not inhibit low density lipoprotein (LDL) oxidation. Atherosclerosis 112:187-195 (1995).

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77. Gaziano, JM, Johnson, EJ, Russell, RM, Frei, B, Manson, JE, Stampfer, M, Ridker, PR, Hennekens, CH and Krinsky, NI, Discrimination in absorption or transport of ß-carotene isomers following oral supplementation with either all-*trans*- or 9-*cis*-ß-carotene. Am. J. Clin. Nutr. 61:1248-1252 (1995).

78. Hébuterne, X, Wang, X-D, Johnson, EJ, Krinsky, NI and Russell, RM, Intestinal absorption and metabolism of 9-*cis*-ß-carotene *in vivo*: biosynthesis of 9-*cis*-retinoic acid. J. Lip. Res. 36: 1264-1273 (1995).

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Human Plasma Carotenoid Response to the Ingestion of Controlled Diets High in Fruits and Vegetables
Am. J. Clin. Nutr., 64: 594-602 (1996)

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AMENDMENT TO THE DOSSIERS IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

September 12, 2007

09-24-07P04:35 RCVD

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AMENDMENT OT THE GRAS DOSSIERS IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

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AMENDMENT TO THE DOSSIERS IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF LYC-O-MATO® POWDER AS A FOOD INGREDIENT

1. EXECUTIVE SUMMARY

On a prior occasion, this independent expert GRAS panel critically evaluated the available information on Lyc-O-Mato® Powder[1] (*e.g.*, tomato pulp powder) meeting food grade specifications and produced in accordance with current Good Manufacturing Practice (cGMP), was GRAS by scientific procedures for supplementing the diet with lycopene. This GRAS determination was requested by LycoRed Ltd. [LycoRed Natural Products Industries, Ltd.], Hebron Road – Industrial Zone, P.O. Box 320, Beer Sheva – 84102 Israel, and notified to the FDA (GRN 000163).[2] In this GRAS determination, the literature was through April of 2003 was evaluated for information relevant to the GRAS determinations. On this occasion, the Expert Panel was requested to assess the current literature relevant to the GRAS determination of Lyc-O-Mato® Powder in response to the proposed use as ingredients in products previously determined to be medical foods, in addition to current uses. The Expert Panel members independently evaluated the additional published safety information and confirmed that the available information supports the GRAS status of Lyc-O-Mato® Powder as currently used. The Expert Panel also determined the proposed use as an ingredient in products previously defined as medical foods is also GRAS, on the basis of scientific procedures.

2. INTRODUCTION

Lycopene is a natural constituent of the typical U.S. diet, with mean lycopene consumption at approximately 8 mg/day. The available information indicates that current commercial enteral formulas do not provide lycopene to patients comparable to that which would be derived from a typical diet (Olmedilla *et al.*, 1996). LycoRed, Ltd. intends to market Lyc-O-Mato® Powder as an ingredient for addition to products previously determined to be medical foods at a level not to exceed 3 mg/100 kcal or 36 mg of lycopene/day.[3,4]

000345

[1]Dossier in support of the Generally Recognized As Safe (GRAS) status of Lyc-O-Mato® Powder as a food ingredient

[2]GRN 000163, http://www.cfsan.fda.gov/~rdb/opa-gras.html; site visited September 6, 2007

[3]The energy content of a supplemental product is typically in the range of 200 – 400 kcal *per* serving, with a suggested intake of 1 to 3 servings *per* day, depending on the product. The maximum daily intake of lycopene from products previously determined as medical foods taken as a supplement to the typical diet would be 36 mg/day.

[4] Because there is no specific deficiency, disease, syndrome or symptom arising from an absence of lycopene, the addition of lycopene, in and by itself, cannot render a food a "medical food" simply as the result of its addition to the food. In this GRAS Notification, tomato extract of lycopene is to be added to foods already determined to be medical foods.

The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods are in some cases, the sole source of calories and nutrients for a patient, but as often as not, certain medical foods are consumed as a caloric and nutritive supplement (*i.e.*, may be taken to supplement the typical diet), as a result of the patient not eating or being able to eat normally due to the patient's specific disease or condition.[5]

3. ESTIMATED DAILY INTAKE

Lyc-O-Mato® Powder (as indicated in GRN 000163), is intended to be used to increase the consumption of lycopene in the diet of the general population, when incorporated into specific food products as a food ingredient. These foods are identified in the original GRAS dossier, and as later modified through the GRAS Amendment dated September 15, 2006, according to food codes given in the U.S. Department of Agriculture (USDA) 1994-1996, 98 Continuing Survey of Food Intakes by Individuals (CSFII, 94-96, 98), and these codes have been used to calculate the Estimated Daily Intake (EDI) values for lycopene consumption (Table 1). Other GRAS Notices concerning lycopene have also been filed with the FDA, but due to the self-limiting nature of lycopene addition to food (*i.e.*, an undesirable red color or tomato-like taste), lycopene from more than one source would not likely be added to a food product. The GRAS dossier for Lyc-O-Mato® Powder identified the Acceptable Daily Intake (ADI) of lycopene at 120 mg/day.

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[5] 21 CFR 101.9(j)(8) Nutrition labeling of food. Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if: (i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube; (ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; (iv) It is intended to be used under medical supervision; and (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

Table 1. Current lycopene intake, predicted lycopene intake following supplementation of selected foods at the levels indicated in GRN 000163 and modified through the GRAS Amendment letter dated September 15, 2006, and total lycopene intake (predicted + current) for individuals consuming selected supplemented foods

	Per User (mg/day)	
Lycopene intake from:	**Mean**	**90th Percentile**
A. Current consumption from food[a]	6.1	13.7
B. Possible maximum consumption with Tomato powder as an added ingredient to food[a]	15.3	28.9
C. Consumption as a color additive[b]	5.3	9.2
D. Total consumption from conventional food (current + added)	26.7	51.8
E. Potential consumption from dietary supplement use	30.0	60.0
F. Total consumption from all sources (food + dietary supplements)	56.7	111.8

[a]Levels calculated using consumption values from CSFII 1994-1996, 1998 (2000) and food lycopene concentrations from Holden *et al.* (1999).
[b]GRN 000163

The addition of Lyc-O-Mato® Powder to products previously determined as medical foods is intended to supplement the patient's diet at a level not to exceed 3 mg/100 kcal or 36 mg of lycopene/day. While there is no question that patients receiving such a medical food as a sole source of nutrition would not exceed the ADI of lycopene because of the absence of other lycopene sources, the Expert Panel determined supplemental uses to the typical diet to also be consistent with the safe use of lycopene the following reasons:

- The lycopene consumption calculation (see table above), indicates a potential total consumption of lycopene from all sources at 56.7 mg/day (mean) and 111.8 mg/day (90th percentile). This total stipulated that consumption from food [*i.e.,* as a natural constituent of food, as an added ingredient (with limitations to specific foods) and as a color additive] was 26.7 mg/day (mean) and 51.8 at the 90th percentile. The Expert Panel reasoned that if a patient is receiving medical food to supplement his/her caloric intake, it is unlikely that the patient will be consuming enough conventional food to achieve the mean or 90th percentile intakes of lycopene.
- This total (above, 56.7 and 111.8 mg/day) also assumed an exaggerated consumption of lycopene as a dietary supplement at 30 mg/day (mean) and 60 mg/day (90th percentile). Because medical foods are administered under supervision of a physician, the Expert Panel reasoned that patients who receive medical food to supplement their caloric and nutritive intake would be unlikely to consume dietary supplements, at least to the extent of the exaggerated estimates identified above.

- Lastly, the only documented effect of over-consumption of lycopene is a skin color change and to this extent, consumption of lycopene is self-limiting. In addition, because a patient consumes medical foods under the supervision of a physician, the physician, as a trained observer, would notice the skin color change, investigate this phenomenon and subsequently caution the patient about over consumption of lycopene.

4. PRECLINICAL AND CLINICAL STUDIES

The following is a summary of additional preclinical and clinical studies published since the initial GRAS determinations conducted in 2003 that evaluate the effects of lycopene or tomato extract consumption.

Zaripheh and Erdman (2005) investigated the biodistribution of lycopene in groups of twelve male F344 rats through the use of radiolabeling techniques. For 30 days, the rats consumed lycopene-enriched (LP) (250 mg lycopene/kg/day) or control (CP) diets. The control diet provided an estimated daily dietary lycopene intake of 8 mg/day.[6] The rats were then gavaged with 0.152 mg lycopene; 50% of which was ^{14}C-labeled. Five or 24 hours following radiolabel administration, the rats were euthanized and examined for lycopene biodistribution. No adverse effects of diet or dose administration were apparent. A red color was observed in the liver and feces of the lycopene-fed rats. Serum total lycopene increased over time in both dietary groups, with the concentration greater in LP rats, than in CP rats ($P<0.05$). The *percentage* of the ^{14}C dose absorbed at 24 hours was lower (5.5±0.5%) in the rats fed lycopene, when compared to control-fed rats (6.9±0.4%, $P<0.05$). The total recovery of the ^{14}C dose from all tissues, intestinal contents, urine, and feces was higher in LP rats (75±6%) than in CP rats (57±6.5%) ($P<0.05$). Of the tissues analyzed, an increase in the *percentage* of ^{14}C-polar products occurred between 5 and 24 hours only in the prostate and seminal vesicles regardless of diet. Feeding lycopene also decreased the absorption of the single oral ^{14}C-lycopene dose. Overall, Zaripheh and Erdman (2005) found that lycopene absorption, tissue uptake, and catabolism were altered by previous lycopene consumption, and that lycopene is taken up by extrahepatic tissues from the postprandial triglyceride-rich fraction.

Commercially available lycopene is processed from several different sources, including a fungal biomass (*Blakeslea trispora*). A 90-day feeding study of *B. trispora*-derived lycopene at dietary levels of 0, 0.25, 0.5, and 1.0% in male and female Wistar rats (n=20 *per* group) found no evidence of lycopene toxicity at the highest dietary concentration as determined by clinical chemistry and neurobehavioral observations, assessment of motor activity, body weight and food

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[6] At the start of the study, the rats weighted 113 g so their initial daily intake was approximately 70 mg/kg/day (*i.e.*, 8 mg/0.113 kg). However, final body weights were not reported so an estimated range of daily intake cannot be calculated.

consumption, ophthalmoscopic examinations, hematology, urinalysis, organ weights, histopathology and gross pathology. Mean lycopene intake was estimated to be 0, 145, 291, and 586 mg/kg/day for males and 0, 156, 312, and 616 mg/kg/day for females. The authors reported that the No-Observed-Effect-Level (NOEL) was 1.0% dietary lycopene, the highest dose tested (Jonker *et al.*, 2003).

The effects of lycopene on adriamycin (ADR)-induced Sprague-Dawley rat cardiotoxicity and nephrotoxicity were evaluated by Atessahin *et al.* (2006b) and Yilmaz *et al.* (2006). Gavage treatment with lycopene at 4 mg/kg/day either ten days before intraperitoneal (*i.p.*) injection of 10 mg/kg ADR; or two days before and three days after *i.p.* ADR administration reduced ADR-induced cardiotoxicity and nephrotoxicity (Yilmaz *et al.*, 2006; Atessahin *et al.*, 2006b). Compared to controls not administered lycopene, treatment with lycopene normalized ADR-induced increases in plasma creatinine and urea as well as levels of cardiac and kidney catalase, and also inhibited the formation of cardiac and histopathological changes. In addition, lycopene pretreatment inhibited ADR-induced reductions in testes and epididymis weights, and sperm motility, and restored ADR-induced increases in malondialdehyde levels and reductions in glutathione concentrations back to control level status. Lycopene treatment also reverted ADR-induced histopathological alterations back to control parameters (Yilmaz *et al.*, 2006; Atessahin *et al.*, 2006b).

A 31-day oral pretreatment with lycopene (1 mg/kg/day) significantly prevented myocardial damage and lipid peroxidation induced by ischemia and reperfusion (I-R) injury in a Wistar albino rat animal model, and preserved antioxidant status and hemodynamic parameters (Bansal *et al.*, 2006). In addition, gavage administration of lycopene or tomato juice for three weeks to Sprague Dawley rats prior to I-R injury reportedly reduced I-R-induced lipid peroxidation, but only tomato juice ingestion improved post-ischemic ventricular function, reduced myocardial infarct size and reduced cardiomyocyte apoptosis (Das *et al.*, 2005).

Lycopene consumption has been linked with decreased oxidative damage. Sendao *et al.* (2006) investigated the cytogenetic effects of a single dose or four daily gavage administrations of lycopene on chromosomal damage induced by the anti-tumor drug cisplatin in Wistar rat bone marrow cells. In the single dose study, 24 hours prior to *i.p.* cisplatin (or saline control) treatment, lycopene (LycoRed) was administered at 0, 4, and 6 mg/kg. One day later, the rats were euthanized, and bone marrow slides prepared for chromosomal aberration analysis. For the repeated dose analysis, rats were treated with lycopene (0.5, 1.0, and 1.5 mg/kg) 72, 48, 24, and one hour before a single *i.p.* cisplatin or saline treatment. Rats exposed to cisplatin alone showed 22% and 22.6% abnormal metaphases, respectively, for the acute and subacute dosing regimens, whereas comparative saline treated controls showed only 2.6% and 2% abnormal metaphases. Single or repeated dose lycopene treatment alone did not increase chromosomal aberrations ($P>0.01$); however, those treatments significantly decreased incidences of cisplatin-induced chromosomal damage at all dose levels ($P<0.01$). The results of this study indicate that lycopene was not clastogenic, and that low doses of lycopene reduce cisplatin-induced chromosome damage in the bone marrow (Sendao *et al.*, 2006).

Lycopene (approximately 4 mg/kg/day) has also been reported to inhibit oxidative stress in rats (as seen by a reduction in xanthine oxidase and myeloperoxidase activities[7] in skeletal muscle tissue) due to muscle exhaustion and gentamycin-induced nephrotoxicity, as determined by renal failure in rats, as well as reduced malondialdehyde and glutathione levels, and reduced glutathione peroxidase and catalase activities in rat kidney tissue, when compared with gentamycin treatment alone (Kim *et al.*, 2004; Karahan *et al.*, 2005; Liu *et al.*, 2005).

Gavage administration of Lyc-O-Mato® 6% oleoresin to male Swiss mice at 1.25 mg/kg/day for five days prior to gastric *N*-methyl-*N'*-nitro-*N*-nitrosoguanidine (MNNG) administration protected against MNNG-induced genotoxicity and oxidative stress at 27 hours post-MNNG administration (Velmurugan *et al.*, 2005). Carbon tetrachloride-induced hepatic toxicity in male Sprague Dawley rats was partially inhibited by a diet containing 10% tomato powder (approximately equivalent to 10,000 mg/kg bodyweight/day), based on serum sorbitol dehydrogenase and serum aspartate aminotransferase activities (Kim *et al.*, 2004). Dietary lycopene at 40 mg/kg/day for 43 weeks significantly ($P<0.05$) inhibited the number and size of azoxymethane-induced colon tumors in Fisher 344 male weanling rats (Martinez-Ferrer *et al.*, 2006).

Turk *et al.* (2007) reported that daily gavage administration of lycopene along with daily subcutaneous (*s.c.*) injection of cyclosporine A (CsA) resulted in a marked amelioration of CsA-induced testicular toxicity.[8] Over a period of 21 days, male Sprague-Dawley rats were administered (*via* gavage) lycopene (10 mg/kg/day) and CsA (15 mg/kg/day) with subsequent evaluation of testicular toxicity and comparison of results to controls treated with CsA only (Turk *et al.*, 2007). The effects of daily lycopene gavage administration on cisplatin-induced testicular and spermatozoal toxicity were studied in male Sprague-Dawley rats. After being administered an acute *i.p.* dose of 7 mg/kg cisplatin, rats were administered lycopene at 4 mg/kg/day for five days, followed by evaluation of sperm concentration, sperm motility, total sperm abnormalities and, malondialdehyde and glutathione levels. When compared to the cisplatin-treated control group, the values of all examined parameters were normalized in the lycopene-treated rats (Atessahin *et al.*, 2006a).

Lycopene consumption has also been evaluated for an ability to decrease cigarette smoke-induced changes in a preclinical gastric cancer ferret model (Liu *et al.*, 2006). Ferrets that either were exposed or not exposed to cigarette smoke were administered daily gavage doses of lycopene at 0, 1.1, or 4.3 mg/kg for nine weeks. After exposure, the ferrets were euthanized, and gastric mucosal cells were isolated and analyzed for p53, Bax-1, cleaved caspase 3, and p21Cip1/Waf1 levels. Lycopene treatment attenuated a smoke-induced elevation in total p53 and phosphorylated p53 levels in the gastric mucosa. Smoke-induced changes in p53 target genes

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[7] Xanthine oxidase and myeloperoxidase have been indicated as responsible for exhaustive exercise-induced oxidative stress in several tissues, including muscle, liver, and heart (Liu *et al.*, 2005).

[8] Significant decreases in seminal vesicle weight, epidiymal sperm concentration, motility, testicular tissue glutathione (GSH), glutathione peroxidase and catalase activity, diameter of seminiferous tubules and germinal cell thickness, while it increased malondialdehyde levels and abnormal sperm rates (as determined by the visual evaluation of forward progressive sperm motility) along with degeneration, necrosis, and appearance of desquamative germ cells.

p21Waft/Cip1, Bax-1, as well as the cell proliferation and apoptosis markers of cleaved caspase 3, cylin D1, and proliferating cellular nuclear antigen (PCNA), were reduced in a dose-dependent fashion after lycopene consumption (Liu *et al.*, 2006).

Rao (2004) evaluated the effects of a four-week consumption of a tomato-rich diet on lycopene bioavailability and antioxidant properties. Healthy human subjects (n=17) first followed a diet low in lycopene content (*i.e.*, washout period), after which the subjects consumed a tomato-rich diet[9] that provided 30 mg lycopene/day. Compared to the washout period, daily consumption of 30 mg lycopene resulted in significant increases in serum lycopene (181.79±31.25 *vs.* 684.7±113.91 nmol/L, respectively) and the total antioxidant potential[10] (2.26±0.015 *vs.* 2.38±0.17 mmol/L Trolox equivalents, respectively), while serum lipid and protein oxidation was significantly reduced (all levels of significance at $P<0.05$). As reported in an English abstract of a Spanish paper by Madrid *et al.* (2006), a seven-day supplementation with pure tomato juice (119.9 μM; approximately 0.64 μg/L) to healthy volunteers (n=17) resulted in significant increases in plasma lycopene and HDL cholesterol levels, when compared to basal levels ($P<0.05$). Total antioxidant capacity,[11] and enzymatic antioxidants catalase and superoxide dismutase were not altered with lycopene consumption.

Porrini *et al.* (2005) evaluated the consumption of a beverage prototype (250 ml) containing Lyc-O-Mato® 6 *percent* (containing approximately 6 mg lycopene) by healthy volunteers for 26 days on the ability to improve protection against DNA damage in lymphocytes. Lyc-O-Mato®-containing beverage consumption for 26 days significantly increased plasma lycopene levels, and significantly reduced DNA damage in lymphocytes subjected to oxidative stress, as determined by the single-cell gel electrophoresis (COMET) assay ($P<0.0001$). This data is supported by *in vitro* data in the Hep3B human hepatoma cell line, which indicated that lycopene treatment inhibited tumor cell growth in a dose-dependent manner (0.2 – 50 μM lycopene after a 24-hour incubation period), and that lycopene-treated cells showed less DNA damage (*via* the COMET assay) than did placebo-treated cells (Yun *et al.*, 2005). Consumption of lycopene in a beverage containing 5.7 mg lycopene was also evaluated by Riso *et al.* (2006), who reported that production of the inflammatory mediator tumor necrosis factor (TNF)-*alpha* in whole blood was 34.4% lower after 26 days of treatment. No other effects were noted. In addition, a study evaluating the effects of tomato-based carotenoids on ultraviolet light-induced erythema reported that consumption of a Lyc-O-Mato®-containing drink that provided 10 mg lycopene *per* day for twelve weeks prevented erythema formation and was well tolerated (Aust *et al.*, 2005; Stahl *et al.*, 2006).

Mohanty *et al.* (2005) reported that daily consumption of 8 mg lycopene for one year delayed or prevented high grade prostate intraepithelial neoplasia from developing into occult prostate cancer, with an inverse relationship found between lycopene and prostate-specific antigen (PSA) levels. Good patient tolerance and no toxicity were reported from lycopene

[9] Tomato juice, tomato sauce, tomato paste, ketchup, spaghetti sauce, and ready-to-serve tomato soup.
[10] The overall antioxidant potential of serum was estimated using the ABTS decoloration assay (Re *et al.*, 1999).
[11] Total antioxidant capacity was measured by a luminol-enhanced chemiluminescence measurement (Lissi *et al.*, 1995).

ingestion. In evaluating the efficacy of lycopene in the treatment of oral leukoplakia,[12] Singh *et al.* (2004) administered placebo, 4, or 8 mg lycopene/day (Lyc-O-Mato® tomato extract) for three months to 58 patients both histologically and clinically diagnosed with oral leukoplakia. Histological analysis of the oral lesions after lycopene treatment found that both 4 and 8 mg lycopene/day treatment had significant positive responses (*i.e.*, $P<0.05$ and $P<0.001$, respectively) as measured by reversed hyperkeratosis and decreased lesion size on the oral lesions, compared with control treatment ($P<0.001$). The authors indicated that no side effects or toxicity of the lycopene treatment was encountered during the study duration. Lyc-O-Mato® tomato extract was also administered for eight weeks at approximately 15 mg lycopene/day to grade-1 hypertensive patients ($n=31$). It was well tolerated, and resulted in significantly decreased systolic and diastolic blood pressure ($P<0.01$ and $P<0.05$, respectively) (Engelhard *et al.*, 2006). Clark *et al.* (2006) administered lycopene at up to 120 mg/day (dose-escalating Phase I/II trial of 15, 30, 45, 60, 90, and 120 mg/day) to patients for one year, which did not result in any discernible response in serum PSA levels in biochemically relapsed prostate cancer patients ($n=36$). Toxicity was mild, with one patient discontinuing therapy because of diarrhea. Plasma lycopene levels significantly increased during the first three months, and then plateaued for all six dose levels.

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[12] A pre-cancerous lesion in the oral cavity, in which a white patch or plaque on the oral mucosa develops that cannot be scraped off and cannot be attributed to any diagnosable disease, but tobacco consumption is always present (Singh *et al.*, 2004).

5. CONCLUSION

We, the Expert Panel, have individually and collectively critically evaluated information generated since the first GRAS review summarized in this amendment for the GRAS dossier (Dossier in support of the Generally Recognized As Safe (GRAS) status of Lyc-O-Mato® Powder as a food ingredient). This information is consistent with that provided in the initial GRAS determination and fully supports the GRAS status of Lyc-O-Mato® Powder. We conclude that the use of Lyc-O-Mato® Powder as an ingredient when added to medical foods is Generally Recognized As Safe by scientific procedures. It is our opinion that other qualified experts qualified by scientific training and experience to evaluate the safety of food and food ingredients would concur with these conclusions.

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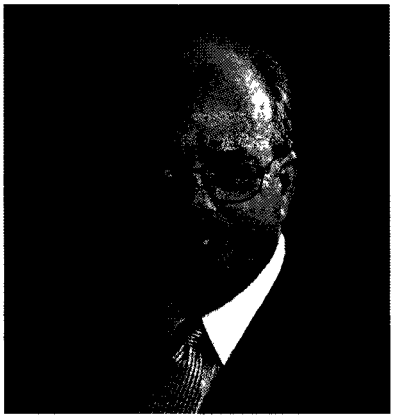

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Burdock Group **1988-Present**
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Dr. Burdock is an internationally recognized authority on the safety of food ingredients, personal care products, and dietary supplements. He has more than twenty years experience dealing with regulatory issues related to product safety and risk assessment. As the President of Burdock Group, Dr. Burdock provides safety and toxicity information on food, food and feed additives, drug excipients, and contaminants to a varied client list, including Fortune 100 corporations, start-up companies, law firms, and trade associations. This information may be in the form of confidential reviews, regulatory petitions, Generally Recognized As Safe (GRAS) self determinations, GRAS notifications, product contamination, and litigation support. As a leading scientist in the food industry, Dr. Burdock is sought by scientific publishers to author journal articles and edit reference books on food additives, flavor ingredients, and regulatory matters and by clients to comment on proposed regulations or respond to communications from regulatory agencies including the FDA and the USDA.

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Dr. Burdock managed the FEMA scientific programs, coordinated the research activities of the testing laboratories, and communicated with external consultants and allied industry committees working with FEMA. As the primary scientific liaison, Dr. Burdock guided member companies with the preparation of submissions to the FEMA Expert Panel for GRAS review, alerted Expert Panel and Association members to scientific developments in the food and flavor industry, and identified

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Shulton Research Division, American Cyanamid Corporation **1984-1986**
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Dr. Burdock directed the Product Safety section, Microbiological Research Services, the Clinical Evaluation Laboratory and the Product Evaluation Center. As the senior toxicologist, he was responsible for the toxicological laboratories and microbiologic safety of products applied to the test groups in clinical evaluation laboratories and for those products released for public use. Dr. Burdock served as a corporate member of the Pharmacology/Toxicology Committee and the Cosmetic Ingredient Review Subcommittee of the Cosmetic, Toiletries and Fragrance Association. He represented the Consumer Products Division on toxicology issues within the corporation, and externally, with vendors, government agencies, and trade associations.

Hazleton Laboratories America, Inc. **1979-1984**
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As a Study Director, Dr. Burdock designed and managed toxicological oversight for compliance with regulatory requirements, quality assurance, budgetary monitoring, testing of pharmaceuticals, food additives, pesticides, and evaluated the performance of subcontractors. He negotiated program design and individual toxicity study requirements for the registration of substances with FDA, EPA, and other regulatory agencies. Dr. Burdock supervised two laboratory sections -Teratology/Reproduction and Sub-Chronic Rodent Toxicology.

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G.A. Burdock and B. Magnuson (2006) Small threat? *World of Food Ingredients. Pp 61-62.*

G.A. Burdock, I.G. Carabin and J.C. Griffiths (2006). The Importance of GRAS to the Functional Food and Nutriceutical Industries *Toxicology* 221: 12-27.

G.A. Burdock and J.C. Griffiths (2006). Aflatoxin basics: Penicillins deadly cousin – past and present. Petfood Industry Pp. 28-29.

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I.G. Carabin and **G.A. Burdock**. (2005) Overweight and obesity in the United States – an overview. *Update: Food and Drug Law, Regulation and Education* 42(9), 2004: 1513-29.

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M.G. Soni, **G.A. Burdock**, H.G. Preuss, S.J. Stohs, S.E. Ohia, D. Bagchi (2004) Safety assessment of (-)-hydroxycitric acid and Super CitriMax®, a novel calcium/potassium salt, *Food and Chemical Toxicology* 42, 1513-1529

G.A. Burdock, and I.G. Carabin. (2004) Warning letters, recalls and elixir of death. *Nutritional Outlook* p. 20 – 26.

G.A. Burdock. (2003) Sensory deception: the science of making foods more palatable. *Functional Foods and Nutraceuticals* p. 34-36.

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G.A. Burdock. (2002) Chapter 3: Status and safety assessment of foods and food ingredients produced by genetically modified microorganisms. In *Biotechnology and Safety Assessment.* Third Edition. (J.A. Thomas and R. Fuchs, Eds.) Elsevier Science, New York. P. 39-83.

M.G. Soni, **G.A. Burdock**, S.L. Taylor, and N. Greenberg. (2002) Evaluation of the health aspects of methyl paraben: a review of published literature. *Food and Chemical Toxicology*. 2002 10: 1335-73.

F. Kotsonis, **G.A. Burdock,** and W.G. Flamm. (2001) Chapter 31: Food Toxicology. In: *Toxicology: The Basic Science of Poisons*. 7th edition C.D. Klaassen (Ed.) Pergamon Press, New York. P. 1049-1088

G.A. Burdock. (Ed.) (2002) *Fenaroli's Handbook of Flavor Ingredients*. Fourth Edition. CRC Press, Boca Raton, FL. 1834 pp.

G.A. Burdock. (2002) Regulation of flavor ingredients. In: *Nutritional Toxicology*. Second Edition. Target Organ Toxicology Series. (F. Kotsonis and M. Mackey, Eds.). Taylor and Frances, New York. p. 316-339.

G.A. Burdock, I.G. Carabin, and M.G. Soni. (2001) Safety assessment of beta-nitropropionic acid: A monograph in support of an acceptable daily intake in humans. *Food Chemistry* 75(1): 1-27.

M.G. Soni, **G.A. Burdock**, S.L. Taylor, and N. Greenberg. (2001) Safety assessment of propyl paraben. *Food and Chemical Toxicology* 39:513-532.

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M.G. Soni, S.A. White, W.G. Flamm, and **G.A. Burdock.** (2001) Safety evaluation of dietary aluminum. *Regulatory Toxicology and Pharmacology* 33:66-79.

M.G. Soni, H. Kimura, and **G.A. Burdock.** (2001) Chronic studies on diacylglycerol oil in rats. *Food and Chemical Toxicology* 39:317-329.

I.G. Carabin, **G.A. Burdock,** and C. Chatzidakis. (2000) Safety assessment of *Panax* ginseng. *International Journal of Toxicology* 19:293-301.

G.A. Burdock and W.G. Flamm. (2000) Review article: Safety assessment of the mycotoxin cyclopiazonic acid. *International Journal of Toxicology* 19:195-218.

G.A. Burdock, W.G. Flamm, and I.G. Carabin. (2000) Toxicity and mutagenicity studies of DN-50000® and RP-1® enzymes. *Food and Chemical Toxicology* 38:429-442.

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J.A. Trutter, F.E. Reno, **G.A. Burdock,** and D.W. Korte, Jr. (1984). Fertility study with a candidate antimalarial drug in the rat. *Journal of the American College of Toxicology* 3:172.

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J.C. Kapeghian, **G.A. Burdock,** and L.W. Masten. (1980). The effect of the route of administration of microsomal enzyme induction following repeated methadone administration in the mouse. *Biochemical Pharmacology* 28:3021-3025.

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G.A. Burdock, R. B. Hackett, and L.W. Masten. (1976). Dose-response relationship of oral methadone administration and liver microsomal enzyme activity. *Federation Proceedings* 35:469.

J.D. Catravas, I.W. Waters, **G.A. Burdock,** and W.M. Davis. (1975). Haloperidol and propanolol in the treatment of acute amphetamine intoxication in the dog. *Toxicology and Applied Pharmacology* 33:185.

REPORTS

G.A. Burdock. (1993). High Dose Irradiation of Food. Report submitted to the Food Safety Unit, World Health Organization.

W.G. Flamm, P. Lombardo, A. Forbes, W. Nichols, J.B. Little, **G.A. Burdock,** and J.A. Flamm. (1992). Review of the wholesomeness of irradiated food. Report submitted to the Food Safety Unit, World Health Organization.

Dr. Burdock was the author of numerous technical reports while serving as a consultant and a scientist for the Flavor and Extract Manufacturers' Association, Hazleton Laboratories and American Cyanamid. The content of these reports is proprietary and confidential to the sponsoring organizations.

EDITORIAL REVIEW

Regulatory Toxicology and Pharmacology. (1997 to present) Elsevier Science. Manuscript reviews.

Journal of Agricultural and Food Chemistry. (1998 to present) American Chemical Society. Manuscript reviews.

Bee World. (1999 to present) International Bee Research Association. Manuscript reviews.

Italian Journal of Food Science. (1999 to present) Istituto di Industrie Agrarie, University of Perugia Manuscript reviews.

Journal of Agricultural Research. (1999 to present) Agricultural Research Service. Manuscript reviews.

Food and Chemical Toxicology. (1999 to present) Elsevier. Manuscript reviews.

International Journal of Toxicology. (2000 to present) Taylor & Francis. Manuscript reviews,

Update (2005) Food and Drug Law Institute. Editorial Board Member.

INVITED PRESENTATIONS AND ABSTRACTS

G.A. Burdock. Functional Foods: Session I – Functional Foods – What are they? Who wants them? Who regulates them? 4th Inventages Life Venture Summit, Great Exuma, Bahamas, June, 2007.

G.A. Burdock. Functional Foods: Session II - How can Functional Ingredients be Added to Food? 4th Inventages Life Venture Summit, Great Exuma, Bahamas, June, 2007.

G.A. Burdock. Functional Foods – Session IV – Getting to market: Costs, timelines and frequent mistakes. 4th Inventages Life Venture Summit, Great Exuma, Bahamas, June, 2007.

G.A. Burdock. Practical applications of toxicology. University of Mississippi School of Pharmacy, University, MS, May, 2007.

G.A. Burdock. Nanotechnology and Nanotoxicology of Food and Feed Ingredients. Alltech International Feed Industry Symposium, Lexington, KY, May 23, 2007.

G.A. Burdock. Food and Supplement Nanotechnology. Nutracon, Anaheim, CA, March, 2007.

G.A. Burdock. Food Toxicology: An Applied Science. University of Florida, Nutritional Science Department. Gainesville, FL, February, 2007

G.A. Burdock. Nanotechnology: Implications for food and food ingredients. Annual ILSI Meeting. Cancún, México, January, 2007.

G.A. Burdock. Conventional Foods as "Functional Foods," FDA Public Hearing. Washington, DC, 2006.

G.A. Burdock. Nanotechnology in Food and Nanotoxicology. Nano4Food Conference. Atlanta, GA, 2006.

G.A. Burdock. New Dietary Ingredient Notifications. Council of Responsible Nutrition (CRN). Boston, Mass, 2006

G.A. Burdock. Nanotoxicology: a small science or the (big) science of small things? Institute of Food Technologists (IFT). Orlando, FL, 2006

G.A. Burdock. Nutraceuticals & Functional Foods – Strategies for Moving Forward. Nestlé Foods Technical Centre. Lausanne, Switzerland, June, 2006.

G.A. Burdock. Qualified Health Claims: A Critical Juncture. 2005 Institute of Food Technologists Annual Meeting and Food Expo. New Orleans, LA, 2005.

G.A. Burdock. Why Efficacy Trials for Dietary Supplements? Association of Clinical Research Professionals 2005 Conference and Exhibition – North America. Orlando, FL. 2005.

G.A. Burdock. Dietary Supplements and a Method for Determining Safety and Efficacy. Botanical Dietary Supplements: Scientific Perspectives and Public Health Pitfalls Congressional Science Briefings. Washington, DC. 2005.

G.A. Burdock Approving Preservatives: Not a 'Natural' Process. International Symposium on Natural Preservatives in Food Systems. Princeton, NJ. 2005.

G.A. Burdock. Regulatory Issues and the Effect on Your Bottom Line. South Florida Regional Chapter, Institute of Food Technologists. Fort Lauderdale, FL. 2004.

G.A. Burdock. The Dichotomy of Structure Function Claims. Food and Drug Law Institute, Qualified Health Claims Conference. 2004.

G.A. Burdock. Qualified Health Claims and the Role of Independent Experts (and a few other items). 2004 Institute of Food Technologists Annual Meeting and Food Expo. Las Vegas, NV. 2004.

G.A. Burdock. Premarket Notification for New Dietary Ingredient Notifications, Public Meeting. Food and Drug Administration/Center for Food Safety and Nutrition. College Park, MD. 2004.

G.A. Burdock. Efficacy Assessment of Functional Ingredients by Independent Experts. Institute of Food Technologists. Chicago, IL. 2003.

G.A. Burdock. When Accidents Happen – Risk Assessment for the Processing Plant. American Meat Institute. Chicago, IL. 2003.

G.A. Burdock. The GRAS status of Pycnogenol®. Vitafoods International. Geneva, Switzerland. 2003.

G.A. Burdock. Risk Assessment at the Processing Plant. Food Safety Inspection Service, U.S. Department of Agriculture. Washington, DC. 2003.

G.A. Burdock. Hot Topics (Dietary Supplements). Food and Drug Law Institute, Washington, DC 2003.

G.A. Burdock. Overview: Nutraceuticals, Dietary Supplements and Functional Food Ingredients. American College of Toxicology 23rd Annual Meeting. Hershey, PA. 2002.

G.A. Burdock. Pycnogenol®. SupplySide East International Trade Show and Conference. Seacacus, NJ. 2003.

G.A. Burdock. When Accidents Happen – Risk Assessment for the Processing Plant. American Meat Institute, Chicago, IL July, 2002.

G.A. Burdock. Safety Assessment of Foods Derived From Biotech Crops. 42nd Annual Meeting of the Society of Toxicology. Nashville, TN. 2002.

G.A. Burdock. Dietary Supplements at a Crossroads. Food and Drug Law Institute Food Week. Washington, DC. 2002.

G.A. Burdock. Determining the Safety of a Dietary Supplement (Ingredient). Food and Drug Law Institute. Washington, DC. 2002.

G.A. Burdock. Safety Assessment of Botanicals. Worldnutra 2002 3rd Annual International Conference and Exhibition on Nutraceuticals and Functional Foods. San Diego, CA. 2002.

G.A. Burdock. Safety Assessment of Botanicals. ILSI Workshop on Principles for the Safety Assessment of Botanicals and Botanical Preparations in Food and Food Supplements. Marseille, France. 2002.

G.A. Burdock. Ephedra, Is It As Toxic As Reported? 43rd Annual Meeting of the American College of Toxicology. San Antonio, TX. 2002.

G.A. Burdock. The Line Between Generally Recognized As Safe (GRAS) and Dietary Supplements. Toxicology Forum, Aspen, CO. 1999.

G.A. Burdock. DSHEA, GRAS and Functional Foods: Regulatory and Safety Criteria. American Chemical Society. 224th ACS National Meeting. Boston, MA. 2002.

CONTINUING EDUCATION

Clinical Pathology-The Granddaddy of Biomarkers. Society of Toxicology 44th Annual Meeting and Toxexpo. New Orleans, LA. March, 2005

Herbals and Dietary Supplements in Athletic Performance Enhancement: Fact vs. Fiction. Society of Toxicology 43rd Annual Meeting and Toxexpo. Baltimore, MD. March, 2004.

The Safety Assessment of Proteins: Applications to Agricultural Biotechnology. Society of Toxicology 43rd Annual Meeting and Toxexpo. Baltimore, MD. March, 2004.

Choice and Application of Classical, Population or Physiologically-Based PK for Chemical Assessment and Pharmaceutical Development. Society of Toxicology 42nd Annual Meeting and Toxexpo. Salt Lake City, UT, March,2003.

Medicinal Herbals and Dietary Supplements. Society of Toxicology 42nd Annual Meeting and Toxexpo. Salt Lake City, UT, March, 2003.

Dietary Supplement Use in the Elderly. American College of Nutrition Continuing Education Program. NIH Campus, Bethesda, MD. January, 2003.

International Regulatory Approval of Ingredients and Dietary Supplements. Institute of Food Technologists Annual Meeting. Chicago, IL. July, 2003.

Labeling of FDA Regulated Foods. Institute of Food Technologits. Orlando, FL. February, 2001.

Dietary Ingredients or Drugs? Food and Drug Law Institute. Washington, DC. July, 2000.

Reproductive Toxicology. American College of Toxicology – 20th Annual Meeting, Washington, DC. November, 1999

PROFESSIONAL ACHIEVEMENT AND RECOGNITION

Institute of Food Technologists, *Toxicology and Safety Evaluation Division*, (2006 Member at Large); Professional Member (2004 to present).

Society of Toxicology, *Food Safety Specialty Section*, (2005 – 2006 Vice President, 2004 – 2005 Vice President-Elect).

International Society of Regulatory Toxicology and Pharmacology (2005 - 2006 President; 2004 – 2005 Past Vice-President; Councilor)

FDA Advisory Committee Member, *Additives and Ingredients Subcommittee*. 2004 to present.

CURRICULUM VITAE
Clare M. Hasler
August-2007

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EDUCATION:

M.B.A.	2003	University of Illinois at Urbana-Champaign
Ph.D. (dual)	1990	Human Nutrition/Environmental Toxicology, Michigan State University
M.S.	1984	Nutrition Science, The Pennsylvania State University
B.S.	1981	Human Nutrition, Michigan State University

PROFESSIONAL APPOINTMENTS:

2005-Present	Board of Directors, Chiquita Brand International, Inc.
2004-Present	Executive Director, Robert Mondavi Institute for Wine and Food Science, University of California, Davis
1999-2003	Adjunct Assistant Professor of Pharmacognosy, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago
1997-2003	Assistant Professor, Division of Nutritional Sciences, University of Illinois at Urbana-Champaign
1998-1999	Co-Leader, Strategic Research Initiative on Food Safety and Functional Foods, Council for Food and Agricultural Research (C-FAR)
1992-1997	Visiting Assistant Professor, Department of Human Nutrition and Dietetics, University of Illinois at Chicago
1992-1996	Visiting Assistant Professor, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois at Chicago
1992-1997	Visiting Assistant Professor, Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign
1992-2000	Director, Functional Foods for Health Program, University of Illinois
1990-1992	Post-Doctoral Fellow, Laboratory of Cellular Carcinogenesis and Tumor Promotion, National Cancer Institute, National Institutes of Health

PROFESSIONAL ASSOCIATIONS:

American Association for Cancer Research
American Association of Cereal Chemists
American Association for the Advancement of Science
American Nutraceutical Association

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American Society for Nutritional Sciences
Gamma Sigma Delta
Institute of Food Technologists
Penn State Alumni Association
University of Illinois College of Business Alumni Association
Sigma Xi, The Scientific Research Society
Cal Aggie Alumni Association

OFFICES HELD IN PROFESSIONAL SOCIETIES:

2003-Present	American Association for the Advancement of Science (AAAS), Electorate Nominating Committee, Section on Agriculture, Food and Renewable Resources
2003-2004	Chair, American Society for Nutritional Sciences, Nutrition Education Research Interest Section

PROFESSIONAL AWARDS AND RECOGNITION:

2007	The Executive Leadership and Management Institute at Stanford
2007	Outstanding Alumni Award, Michigan State University, Department of Food Science and Human Nutrition
2005-2008	Institute of Food Technologists, Distinguished Lecturer
2000	Recognition of Service Award, American Dietetic Association
1999	Experiment Station Committee on Organization and Policy/Academic Committee on Organization and Policy (ESCOP/ACOP) Leadership Development Program
1999	Meritorious Service Award, United Soybean Board
1998	Author, Institute of Food Technologists' Scientific Status Summary on Functional Foods
1998	"Top 25 Food Influential"(Mover and Shaker Award), Self Magazine
1997	Friend of Agriculture Award, Illinois Soybean Association
1996	Emerging Leaders Award, Michigan State University, College of Human Ecology, Centennial Alumni Celebration

EDITORIAL ACTIVITIES:

2006-Present	Advisory Editor, Food Science and Technology Bulletin: Functional Foods
2004-Present	Editorial Board, Nutrition & the M.D.
2002-2004	Associate Editor, Applied Biotechnology, Food Science and Policy
2002-Present	Editorial Board, Current Topics in Nutraceutical Research
2000-Present	Editorial Board, Ingredients, Health & Nutrition
1999-2001	Editorial Board, Journal of Food Science, Food Chemistry & Toxicology Section
1998-Present	Editorial Board, Journal of the American Nutraceutical Association
1998-Present	Editorial Board, Taste for Life
1997-Present	Editorial Board, Journal of Medicinal Food
1996-Present	Editorial Board, Journal of Nutraceuticals, Functional and Medical Foods
1993-2003	Editor, Functional Foods for Health Program ALERT, University of Illinois

ADVISORY BOARD ACTIVITIES:

2007-Present	Reliv, Scientific Advisory Board
2005-Present	Hannaford Brothers Co., Scientific Advisory Board
2005-2006	Internal Advisory Board, UC Davis Cancer Center's Disparities and Outreach Research and Education
2004-Present	Almond Board of California, Nutrition Subcommittee
2003-Present	Cranberry Marketing Institute, Scientific Advisory Board
2003-Present	Publicis Dialog Nutrition Research Center, Scientific Advisory Board
2002-Present	Mushroom Council, Scientific Advisory Board
2002-Present	Dietary Supplement Health and Information Bureau, Scientific Advisory Board
2001-Present	Naturemade Vitamins, Women's Wellness Advisor
2001-Present	Sherbrooke Capital, Scientific Advisory Board
2001-2002	Nutripharma, Scientific Advisory Board
2000-Present	American Council on Science and Health, Board of Scientific & Policy Advisors
2000-2001	NutritionGrocer.com, Scientific Advisory Board
1999-2001	Campbell Soup Company, Scientific Advisory Board
1998-2002	Centrum Center for Nutrition Science, Scientific Advisory Board
1998-2001	AgeWave/LifeSpring, Scientific Advisory Board

OTHER PROFESSIONAL ACTIVITIES:

2005-Present	Participant, Danone Institute International, Functional Foods and Health Claims Global Initiative
1998-Present	Expert Resource, International Food Information Council (IFIC) Foundation Media Guide on Functional Foods
2005	Expert Panel Member, GRAS Status Determination of a Food Extract, Burdock Consulting Group
2004	Expert Panel Member, GRAS Status Determination of an Herbal Extract, Burdock Consulting Group

RESEARCH AND PROGRAM SUPPORT:

Dr. Hasler attracted over $3 million in research funding between 1996 and 2002

Campus Research Board: *"Effect of Soy on Markers of Cardiovascular Disease Risk in African-American Women."* $14,000, **CM Hasler** (PI), 2002-2003.

Illinois Soybean Program Operating Board: *"Enhancing StratSoy as a Source of Information On Soybean Utilization and Health Benefits."* $15,000, S Thompson, **CM Hasler** (Co-PI), Karl Weingartner, 2001-2002.

United States Department of Agriculture: *"Component Interactions for Efficacy of Functional Foods."* $2,400,000, E. Jeffery, **C Hasler** (Director of Outreach/Education), MA Smith, J Erdman, R MacDonald, 2000-2004.

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Illinois Soybean Program Operating Board: *"Effects of Soy Protein Consumption in African-American Women with Mild Hypercholesterolemia."* $113,300, **CM Hasler** (PI), 2000-2003.

Illinois Soybean Program Operating Board: *"Enhancing StratSoy as a Source of Information on Soybean Utilization and Health Benefits."* $30,000, S Thompson, P Khanna, **CM Hasler** (Co-PI), 2000-2001.

United Soybean Board: *"Soy Health Claim Communication."* $7,500, **CM Hasler** (PI), 1999-2000.

University of Illinois, Office of the Provost: *"Acquisition of an HPLC-MS to Facilitate Functional Foods Research."* $150,000, **CM Hasler**, (PI), 1999.

Council for Food and Agricultural Research: "Strategic Research Initiative on Food Safety and Functional Foods." $148,800, **CM Hasler** (PI), 1998-1999.

California Prune Board: *"Assessing the Cholesterol Lowering Effects of Prune Puree in Human Subjects."* $86,848, **CM Hasler** (PI), P Bowen, E Emeson, 1998-1999.

Council for Food and Agricultural Research: *"Amount of Soy Protein Needed to Lower Cholesterol."* $45,980, **CM Hasler** (PI), S Potter, R, 1998-1999.

Illinois Soybean Program Operating Board (ISPOB): *"Evaluation of the Use of the StratSoy "Ask an Expert" Website by Consumers."* $23,350, **CM Hasler** (PI), 1998-1999.

United Soybean Board: *"Soy Protein Health Claim."* $200,000, **CM Hasler** (contract manager), 1997-1999.

Council for Food and Agricultural Research: *"Amount of Soy Protein Needed to Lower Cholesterol."* $93,760, SM Potter, **CM Hasler** (Co-PI), R Weigel, 1997-1998.

College of Agricultural, Environmental and Consumer Sciences, Value-Added Program: *"Stimulating Functional Foods Research at the University of Illinois."* $25,000, **CM Hasler** (PI), 1997-1998.

Council for Food and Agricultural Research: *"Stimulating Functional Foods Research at the University of Illinois."* $80,000, **CM Hasler** (PI), 1996-1998.

RESEARCH PUBLICATIONS:

1. Wansink, B, S Sonka, **CM Hasler**. Front-label health claims: when less is more. *Food Policy* 29: 659-667, 2004.

2. Rah, JH, **CM Hasler,** JE Painter, KM Chapman-Novakofski: Applying the theory of

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planned behavior to women's behavioral attitudes on and consumption of soy products. *Journal of Nutrition Education and Behavior* 36:238-244, 2004.

3. De Mejia, EG, T Bradford, **C Hasler**: The anticarcingenic potential of soybean lectin and lunasin. *Nutrition Reviews* 61: 239-246.

4. Pelletier S, S Kundrat, **CM Hasler**: Functional food consumption trends in Illinois: Positive effects of an educational program. *Journal of the American Dietetic Association*, 102:1297-1299, 2002.

5. Teixeira, SM, SM Potter, R Weigel, S Hannum, JW Erdman, Jr., **CM Hasler**: Effects of feeding 4 levels of soy protein for 3 and 6 weeks on blood lipids and apolipoproteins in mildly hypercholesterolemic men: *American Journal of Clinical Nutrition* 71:1077-1084, 2000.

6. Wool, DL, AG Kanfer, J Michaels, S Thompson, **CM Hasler**: Evaluating the relevance of a web based "ask an expert" feature: Stratsoy and soy and human health queries: *Journal of Applied Communications* 84:7-22, 2000.

7. Arjmandi, BH, R Birnbaum, NV Goyal, MJ Getlinger, S Juma, L Alekel, **CM Hasler**, BW Hollis, JL Drum, SC Kukreja: The bone modulating effect of soy protein in ovarian hormone deficiency is related to its isoflavone content. *American Journal of Clinical Nutrition* 68:1364S-1368S, 1998.

8. Getlinger, MJ, BH Arjmandi, NV Goyal, L Alekel, **CM Hasler**, BL Drum, SC Kukreja: The role of soy protein with normal or reduced isoflavone content in reversing ovarian hormone deficiency induced bone loss in rats. *American Journal of Clinical Nutrition* 68: 1358S-1363S, 1998.

9. **Hasler, CM**: Narrowing the gap between food and drugs. *Cereal Foods World* 42: 462-463, 1997.

10. Hayashi, T, **CM Hasler**, SY Oh, BV Madhukar, CC Chang, JE Trosko: A human kidney epithelial cell culture as an in vitro model to study chemical modulation of intercellular communication. *In Vitro Toxicology* 9:3-17, 1996.

11. **Hasler, CM**, G Acs, PM Blumberg: Specific binding to protein kinase C by ingenol and its induction of biological responses. *Cancer Research* 52:202-208, 1992.

12. **Hasler, CM**, JE Trosko, MR Bennink: Incorporation of n-3 fatty acids into cell phospholipids inhibits gap junctional intercellular communication. *Lipids* 26:788-792, 1991.

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13. Madhukar, BV, CC Chang, **CM Hasler**, D de Feyter, SY Oh, B Lockwood, JE Trosko: Characterization of an *in vitro* human kidney epithelial system to study gap junctional intercellular communication. *In Vitro Toxicology* 4:630-640, 1991.

14. **Hasler, CM**, MR Bennink, JE Trosko: Inhibition of gap junction-mediated intercellular communication by α-linolenate. *American Journal of Physiology* 216 (Cell Physiol. 30): C161-C168, 1991.

15. **Hasler, CM**, MA Frick, MR Bennink, JE Trosko: TPA-induced inhibition of gap junctional intercellular communication does not involve free radical production. *Toxicology and Applied Pharmacology* 103:389-398, 1990.

16. **Hasler, CM**, H Rothenbacher, DJ Mela, PM Kris-Etherton: Exercise attenuates diet-induced arteriosclerosis in the adult rat. *Journal of Nutrition* 117:986-993, 1987.

17. **Hasler, CM**, H Rothenbacher, DJ Mela, PM Kris-Etherton: The effect of exercise and hyperlipemic diet on aortic histopathology in the rat. *Atherosclerosis* 52:279-286, 1984.

INVITED REVIEWS, POSITION PAPERS, LAY PUBLICTIONS, LETTERS TO EDITORS, BOOK FOREWARDS, EDITORIALS:

1. Tapsell, L, Nestel P, Inge K, Fazio V, **Hasler CM**, Bowerman S: Herbs and Spices—An Integral part of the daily diet. A Position Paper compiled by leading nutrition experts from Australia and the United States in conjunction with the National Centre of Excellence in Functional Foods (NCEFF), Australia, August 2006.

2. **CM Hasler**, A Bloch, C Thomson: Position of the American Dietetic Association: functional foods. *Journal of the American Dietetic Association* 104: 814-826, 2004.

3. **Hasler, CM**: Functional foods: Benefits, concerns, and challenges—A position paper from the American Council on Science and Health. *Journal of Nutrition* 132: 3772-3781, 2002.

4. **Hasler, CM**: The cardiovascular effects of soy products. *Journal of Cardiovascular Nursing* 16 (4): 50-63, 2002.

5. **Hasler, CM**, A Moag-Stahlberg, D Webb: Guidance for dietitians on how best to evaluate the safety efficacy and quality of nutraceuticals, functional foods and their ingredients. *Journal of the American Dietetic Association* 101: 733-736, 2001.

6. **Hasler, CM**, S Kundrat, D Wool: Functional foods and cardiovascular disease: *Current Atherosclerosis Reports* 2: 467-475, 2000.

7. **Hasler, CM**: The changing face of functional foods: *Journal of the American College of*

Nutrition, 19(5): 499S-506S, 2000.

8. Unnevehr, LJ, **CM Hasler**: Health claims and labeling regulation: How will consumers learn about functional foods? *AgBioforum* 3(1): 262-265, 2000.

9. Teixeira, SR, S Hannum, JW Erdman, Jr., SM Potter, **CM Hasler**: There is still more to learn about soy (letter to the editor). *American Journal of Clinical Nutrition* 72:1588-1589, 2000.

10. **Hasler, CM,** JB Blumberg: Introduction. Symposium on phytochemicals: biochemistry and physiology. *Journal of Nutrition* 129: 756S-757S, 1999.

11. Thomson, C, A Bloch, **CM Hasler**: Position of the American Dietetic Association: functional foods. *Journal of the American Dietetic Association* 99: 1278-1285, 1999.

12. **Hasler, CM**: Strain-independent variation of phytoestrogen content in soybeans mitigates significance of variation in genetically modified varieties (letter to the editor). *Journal of Medicinal Food* (letter to the editor) 2:279-280, 1999.

13. **Hasler, CM**: Probiotics and prebiotics: where are we today? (Foreward). *British Journal of Nutrition* 80: S195, 1998.

14. **Hasler, CM**, SC Finn: Soy: Just a hill of beans? *Journal of Women's Health* 7: 519-521, 1998.

15. Unnevehr, L, MR Ward, **CM Hasler**: Regulating health claims on food products: The balance between consumer choice and consumer protection. *Choices*: First Quarter (March): 26-30, 1998.

16. **Hasler, CM**: A new look at an ancient concept. *Chemistry & Industry*, Feb 2nd, (No.3): 84-89, 1998.

17. **Hasler, CM**: Scientific status summary. Functional foods: their role in disease prevention and health promotion. *Food Technology* 52: 63-70, 1998.

18. **Hasler, CM**: Functional foods: the western perspective. *Nutrition Reviews* 54: S6-S10, 1996.

BOOKS EDITED:

1. **Hasler, Clare M**: *Regulation of Functional Foods and Nutraceuticals: A Global Perspective*, Iowa State Press/Institute of Food Technologists Press, 2005.

BOOK CHAPTERS:

1. **Hasler, CM**, S Kundrat: Soy isoflavones as functional ingredients in women's health. In:

Phytoestrogens and Health. Sarwar G, G Gilani, J Anderson (Eds.), AOCS Press, Champaign, IL, Chapter 2, pp. 32-50, 2002.

2. **Hasler, CM**: Functional foods. In: *Present Knowledge in Nutrition*, 8th Edition. Bowman, B, R Russell (Eds.), ILSI Press, Washington, D.C., Chapter 64, pp. 740-749, 2001.

3. **Hasler, CM**: Eggs as a functional food: technology update. In: *Egg Nutrition and Biotechnology*. Sim JS, S Nakai, W Guenter (Eds.), CAB International, Wallingford, U.K, Chapter 19, pp. 243-251, 2000.

4. **Hasler, CM**: Plants as medicine: The role of phytochemicals in optimal health. In: *Phytochemicals and Phytopharmaceuticals.* Shahidi F, S-T. Ho (Eds.). AOCS Press, Champaign, IL, Chapter 1, pp. 1-12, 2000.

5. **Hasler, CM**: Foreward. In: *Functional Foods: Biochemical & Processing Aspects.* Mazza G (Ed.), Technomic Publishing Inc., pp. xi-xiv, 1998.

6. **Hasler, CM**: Phytochemicals: biochemical markers of ingestion, absorption and metabolism using flaxseed as a model. In: *Nutraceuticals--Designer Foods III: Garlic, Soy and Licorice*. Lachance PA (Ed.), Food & Nutrition Press, Inc., pp. 39-43, 1997.

7. **Hasler, CM**, M Cullum: Functional foods in chiropractic. In: *Advances in Chiropractic.* Vol. 4. Mosby-Year Book, Inc.: pp. 601-637, 1996.

8. **Hasler, CM**, RL Huston, EM Caudill: The impact of the Nutrition Labeling and Education Act on functional foods. In: *Nutrition Labeling Handbook.* Shapiro R (Ed.), Marcel Dekker, Inc., pp. 471-493, 1995.

9. Trosko, JE, BV Madhukar, **CM Hasler**, CC Chang: Modulated intercellular communication: consequence of extracellular molecules triggering intracellular communication. In: *Eicosanoids and Other Bioactive Lipids in Cancer and Radiation Injury*. Honn, KV, LJ Marnett, S Nigam, TL Walden, Jr., (Eds.), Kluwer Academic Publishers, Boston, pp. 285-295, 1991.

BOOK REVIEWS:

1. **Hasler, CM**: Nutraceuticals (Rapport L, Lockwood B, Eds.). American Journal of Clinical Nutrition 77 (4) :996-997, 2003.

2. **Hasler, CM**: Essentials of Functional Foods (Schmidl MK and Labusa TP, Eds.). *Food Technology* 55 (7): 87, 2001.

3. **Hasler, CM**: Functional Foods--Designer Foods, Pharmafoods, Nutraceuticals (Goldberg I, Ed.). *American Journal of Clinical Nutrition* 64:255, 1996.

BULLETINS, REPORTS, CONFERENCE PROCEEDINGS:

1. Hodgins ME, Fitzpatrick F, Newton I, Bailey R, **Hasler C**, Mellentin J: *Strategic Analysis of Geo-Market Penetration for Canadian Functional Foods and Nutraceutical Products and Ingredients*. February, 2004.

2. Childs N, **CM Hasler**, L Pike, F Shahidi, B Watkins, ME Camire: Nutraceuticals for Health Promotion and Disease Prevention. *Council for Agricultural Science and Technology Issue Paper*. Number 24, October 2003.

3. **Hasler CM**: Where do functional foods fit in the diet? National Agricultural Biotechnology Council (NABC) Report 14 on *Foods for Health,* 2002.

4. **Hasler, CM** (Editor): Functional foods: Trends in global market, scientific and regulatory development. *University of Illinois Functional Foods for Health Program*, 2001.

5. **Hasler, CM**: Public health implications of the soy protein health claim. *Soy Connection* 8 (No. 1), Winter 1999-2000: 1-3.

6. **Hasler, CM**: Functional foods for health. *The Quest* (University of Illinois Cooperative Extension Service Bulletin, Knox County Unit), p. 2, March, 1997.

7. **Hasler, CM**, D Nice, R Witwer: Bioactive ingredients for grain-based products. *Teltech Technology Dossier Service. Teltech Resource Network Corporation*, September, 1996.

8. **Hasler, CM**: Oat beta-glucan, coronary heart disease risk, and health claims. *Scan's PULSE*, American Dietetic Association Publication for Sports, Cardiovascular, and Wellness Nutritionists. Vol. 15 (No.4):1-4, Fall 1996.

9. **Hasler, CM**: Soybeans and Human Health. *International Soybean Program (INSTOY) Soybean Processing and Utilization Course*, 1996.

10. **Hasler, CM**, RS Witwer: The application of bioactive ingredients in cold, non-carbonated, non-dairy beverages. *Teltech Technology Dossier Service, Teltech Resource Network Corporation*, May, 1996.

11. **Hasler, CM**: Phytoestrogens and breast cancer. *Y-ME Hotline* 56: 1-2, March/April, 1996.

12. **Hasler, CM**: Soybeans and Human Health. *Proceedings of the Twenty-Fifth Soybean Seed Research Conference*, pp. 61-67, 1995.

13. **Hasler, CM**: Phytochemicals in Disease Prevention. *Nutri-News*, Mosby-Year Book, Inc.: 1-4, 1995.

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14. **Hasler, CM**: Scientists debate method for identifying human carcinogens. *Illinois Research* 35, Fall: 10, 1993.

15. **Hasler, CM**: New weapon in the war against chronic disease. *Illinois Research* 35, Spring/Summer: 21-23, 1993.

INVITED LECTURES AND PRESENTATIONS:
The following are selected presentations since 1997 and do not include numerous industry-related or regional presentations. Dr. Hasler has given more than 400 regional, national and international presentations since 1992.

International [Selected]:

Guelph Food Technology Center: *"Global Product Trends in Functional Foods."* Toronto, Ontario, Canada, April 18, 2006 **(Keynote Speaker).**

BASF: *"An Overview of Health and Nutrition Trends."* Speyer, Germany, September 15, 2005 **(Keynote Speaker).**

Richardson Centre for Nutraceutical and Functional Foods: *"Global Trends in Functional Foods and Nutraceuticals Research."* Winnipeg, Manitoba, Canada, May 28, 2003 (Keynote Speaker).

ILSI SE Asia Symposium on Functional Foods: *"Functional Food Science—Global Overview."* Beijing, China, November 25, 2002.

Agricultural Biotechnology International Conference: *"Active Molecules From Plants: Naturally Existing Phytochemicals,"* Saskatoon, Saskatchewan, Canada, September 16, 2002.

Nutraceuticals and Functional Foods Institute, Laval University: *"Functional Foods: Then, Now and the Future,"* Quebec, Canada, January 28, 2002.

University of the West Indies, Department of Chemistry: *"Functional Foods: Trends in Global Scientific and Regulatory Development,"* Kingston, Jamaica, December 12, 2001.

Swedish Center of Excellence and Innovation in Functional Foods, Functional Foods–Where Academy and Market Meet: *"Functional Foods: Then, Now and the Future,"* Göteborg, Sweden, May 3, 2001 **(Keynote Speaker).**

American Overseas Dietetic Association Annual Conference: *"Functional Foods Now: Current Science,"* Alicante, Spain, March 23, 2001.

Soy and Health Symposium 2000: *"Soybeans--A Global Trend: From Traditional to*

Functional Food," Manila, Philippines, November 17, 2000.

New Zealand Nutrition Foundation: *"Soy as a Functional Food for Heart Health,"* Auckland, New Zealand, October 10, 2000.

South East Asia Soyfood Symposium 2000: *"Soybeans–From Traditional to Functional Food, a Global Trend,"* Bangkok, Thailand, September 4, 2000.

10th World Congress on Food Science & Technology: *"Cholesterol Lowering Margarine as a Functional Food,"* Sydney, Australia, October 4, 1999 **(Plenary Speaker).**

Pan American College of Agriculture: *"Functional Foods: Research, Market & Regulatory Update,"* Zamorano, Honduras, May 24, 1999.

Global Development and Opportunities in Functional Foods and Nutraceuticals Conference: *"Research Initiatives on Functional Foods in the U.S."* Copenhagen, Denmark, October 30, 1998, Chair, Pacific Rim Session.

Royal Society of Medicine: "*The Public Health Implications of Lycopene*," London, England, May 28, 1998.

Fifth North American Chemical Congress: *"Plants as Medicine: The Role of Phytochemicals in Optimal Health,"* Cancun, Mexico, November 17, 1997.

The University of Alberta: "*Where are We Now in Functional Foods for Health?"* Edmonton, Canada, September 5, 1997.

Guelph Food Technology Center: *"Functional Foods Research at the University of Illinois,"* Toronto, Canada, May 5, 1997.

National [Selected]:

Long Island Section of the Institute of Food Technologists: "*Nectar of the Gods: Wine as a Functional Beverage in Disease Prevention and Health Promotion."* Mineola, NY, June 5, 2006.

Oregon Section of the Institute of Food Technologists: "*Nectar of the Gods: Wine as a Functional Beverage in Disease Prevention and Health Promotion."* Salem, OR, May 10, 2006.

The Procter & Gamble Company: *"Functional Foods and Nutraceuticals in Health and Wellness."* Cincinnati, OH, February 7, 2006.

Chicago Section of the Institute of Food Technologists: "*Nectar of the Gods: Wine as a Functional Beverage in Disease Prevention and Health Promotion."* Chicago, IL, October 10, 2005.

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Colgate-Palmolive: *"Bioactive Ingredients in Health & Wellness."* New Brunswick, NJ, September 13, 2005.

International Association of Food Technologists: *Wine: Enjoying the Health Benefits from Grape Fermentation."* New Orleans, LA, July 19, 2005.

Florida Dietetic Association: *"Functional Foods: Opportunities and Challenges."* Fort Meyers, FL, July 11, 2005.

California League of Food Processors: *"Functional Foods and the Robert Mondavi Institute for Wine and Food Science at UC Davis."* Sacramento, CA, February 1, 2005.

California Tomato Growers Association: *"Tomatoes as a Functional Food in Disease Prevention Optimal Health."* Modesto, CA, January 19, 2005.

Southern California Food Industry Conference (SFICS): *"Functional Foods Overview and Current Research."* Orange, CA, January 12, 2005.

WorldNutra 2004: *"Recent Research Implications on Health: Soy or Wine?"* San Francisco, CA, November 8, 2004.

American Nutraceutical Association: *"The Role of Soy in Preventing Chronic Disease: Review and Guidelines for the Clinical Procedure."* Memphis, TN, October 23, 2004.

Nutrition Council of California Indian Clinics, *Functional Foods in Reducing Risk of Heart Disease and Diabetes."* Sacramento, CA, June 16, 2004.

Western Arts Leadership Institute, "*Wine, Food Sciences and Quality of Life – Realizing a Vision at UC Davis."* Squaw Creek, CA, May 17, 2004.

Northern California Institute of Food Technologists, *"Hot Topics in Health and Nutrition"* Oakland, CA, May 4, 2004.

Eastern Kentucky University: *"Functional Foods."* Richmond, KY, March 3, 2004.
University of Las Vegas: *"Wine and a Heart Healthy Lifestyle."* Las Vegas, NV, April 29, 2004.

New Jersey Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Whippany, NJ, May 13, 2003.

Louisiana Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Baton Rouge, LA April 24, 2003.

Food and Drug Administration Grand Rounds Workshop on Functional Foods: "*Academic Research Trends in Functional Foods.*" Washington, DC, April 8, 2003.

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Texas Dietetic Association: *"Functional Foods: Challenges and Opportunities for Evaluating Emerging Science."* Houston, TX, April 4, 2003.

Soyfoods 2003: *"Marketing Soy to Health Professionals."* Miami, FL, February 26, 2003.

4th Annual Alternative & Complementary Medical Therapies: *"Phytochemicals in Chronic Disease Prevention—Stopping Cancer with Food."* Chicago, IL, December 15, 2002.

ADA 85th Annual Meeting: *"Bioavailability and Biotransformation of Isoflavones: An Alternative to HRT?"* Philadelphia, PA, October 22, 2002.

Soyfoods 2003: *"Public Health Implications of Dietary Supplement Health Claims—Soy Protein."* Chicago, IL, July 11, 2003.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality?"* State College, PA, June 19, 2002.

Foods for Health 14th Annual National Conference, National Agricultural Biotechnology Council (NACB): *"Where Do Functional Foods Fit in the Diet?"* University of Minnesota, Minneapolis, MN, May 20, 2002.

ADA 84th Annual Meeting, Nutrition in Complementary Care Practice Group: *"Soy for Your Heart, Your Bones & Weight Management,"* St. Louis, MO, October 21, 2001.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality?"* Hershey, PA, May 31, 2001.

National Research Council Public Workshop, Opportunities in Agriculture: A Vision for USDA's Food and Agricultural Research in the 21st Century: *"Functional Foods: Impact on Health and Society,"* Washington, D.C., May 22, 2001.

Society of Toxicology: *"From Dietary Supplements to Drugs: Indole-3-Carbinol & Phenethyl Isothiocyanate,"* San Francisco, CA, March 26, 2001, Session Co-Chair.

St. Louis Section of the Institute of Food Technologists: *"Functional foods: Consumer, Regulatory, Market and Research Update,"* St. Louis, MO, February 6, 2001.

Penn State College of Medicine: *"Functional Foods in Cancer Chemoprevention: Fantasy or Reality,"* Harrisburg, PA, June 1, 2000.

Rachel Schemmel Endowed Lecture in Clinical Nutrition, Michigan Dietetic Association: *"Functional Foods,"* Grand Rapids, MI, May 11, 2000.

University of North Carolina Public Health Nutrition Update Conference: *"Functional*

Foods," Chapel Hill, NC, April 28, 2000.

Simmons School for the Health Sciences: *"Functional Foods,"* Boston, MA, April 4, 2000.

ADA 82nd Annual Meeting: *"Functional Foods 1999: What Does the Latest Science Say and Why Should We Care?"* Atlanta, GA, October 28, 1999.

Memorial Sloan-Kettering Cancer Center: *"Functional Foods and Cancer Prevention,"* New York, NY, April 30, 1999.

The Pennsylvania Food Industry--Strengthening Partnerships for Growth: *"Nutraceuticals: A Regulatory Challenge,"* Harrisburg, PA, March 31, 1999.

The Pittsburgh Conference (PITTCON): *"Functional Foods for Cardiovascular Health,"* Orlando, FL, March 8, 1999.

American Association of Cereal Chemists/IFT Short Course on Functional Foods: *"Botanicals as Functional Foods,"* Orlando, FL, March 4, 1999.

ADA 81st Annual Meeting, Flaxseed in Human Nutrition Symposium: *"Introductory Remarks,"* Kansas City, MO, October 20, 1998, Presiding Officer.

Nebraska Dietetic Association: *"Phytochemicals & Functional Foods,"* Omaha, NE, April 23, 1998.

Oklahoma Dietetic Association: *"Functional Foods: Soy,"* Oklahoma City, OK, April 14, 1998.

University of Oklahoma, Department of Nutritional Sciences: *"Soy as a Functional Food,"* Oklahoma City, OK, April 14, 1998.

Oklahoma State University, Department of Nutritional Sciences: "Functional Foods: Therapies for the 21st Century," Stillwater, OK, April 13, 1998.

Oregon Dietetics Association: "*Functional Foods,"* Portland, OR, March 23, 1998.

IFT (Maryland Section): *"Functional Foods: The Future of Food Technology,"* Baltimore, MD, January 15, 1998.

American Dietetic Association (ADA) 80th Annual Meeting and Exhibition: *"Functional Foods: Therapies of the Future?"* Boston, MA, October 27, 1997.

Institute of Food Technologists (IFT) Annual Meeting: *"Introduction--Prebiotics and Probiotics: Where are We Today?"* Orlando, FL, June 18, 1997, Symposium Co-Chair.

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Oklahoma City Dietetic Association Spring Convention: *"Phytochemicals,"* Oklahoma City, OK, April 16, 1997.

Food Update: *"Narrowing the Gap Between Food and Drugs,"* Tampa, FL, April 7, 1997.

Ohio State University Extension, 64th Annual Food and Dairy Industries Conference: *"Functional Foods and Disease Prevention: Fantasy or Reality?"* Columbus, OH, April 2, 1997, Meeting Co-Chair.

THESES/GRADUATE STUDENTS DIRECTED:

(b)(6) *"The Effects of Soy Protein Consumption on Blood Lipids in Hypercholesterolemic African-American Women"*. M.S. Thesis, 2003.

(b)(6) *"Effect of soy on Blood Pressure in African-American Women."* M.S. (non-thesis), 2003.

(b)(6) *"Evaluation of the Educational Program "Keeping Your Heart Healthy With Functional Foods" With Cardiac Rehabilitation Patients."* M.S. Thesis, 2002.

(b)(6) *Effect of Prune Concentrate on Mammary and Colon Carcinogenesis."* M.S. Thesis, 2002.

(b)(6) *"Effect of Prune Fiber on Blood Lipids in Human Subjects."* M.S. Thesis, 2000.

(b)(6) *"Evaluation of the Use of the StratSoy "Ask an Expert" Website by Consumers."* M.S. Thesis, 1999.

GRADUATE STUDENT EXAMINING COMMITTEES:

Dr. Hasler participated on approximately 30 MS and PhD examining committees between 1997 and 2003.

TEACHING ACTIVITIES:

While at the University of Illinois, Dr. Hasler developed three courses on the topic of functional foods:

- Food Science and Human Nutrition (FSHN) 495: *Physiologically Active Functional Foods: Science, Regulation and Business Issues* (Fall 1996, 1998, 2000). A 1-unit graduate course designed for extramural MS students in the Chicago area who are employed full-time in the food industry.

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- Nutritional Science (NS) 410: *Functional Foods and Cardiovascular Health* (Fall 2001). A 0.25 unit graduate course taught every other year and which covers the scientific and regulatory issues related to a variety of functional foods for heart health.
- NS 410: *Phytomedicinals and Human Health* (Fall 1998). A 0.25 unit graduate course related to the scientific and regulatory principals of the major botanicals in the marketplace.

Dr. Hasler also team taught (Spring 2000, 2001, 2002) or taught (Spring 2003) FSHN 496: *Graduate Seminar in Functional Foods*. This course is designed to enhance student presentation skills and involves the critical review of a research paper and a comprehensive review of a functional foods topic.

REVIEW PANELS:

2002-2003	USDA National Research Initiative Competitive Grants Program, Improving Human Nutrition for Optimal Health
2001-2003	National Institutes of Health, Office of Dietary Supplements, Annual Bibliography of Scientific Advances in Dietary Supplement Research

MEDIA RELATIONS ACTIVITIES:

Dr. Hasler has participated in numerous radio, print and television interviews, including being featured on CNN, Lifetime and Dateline NBC's feature story, *Foods of the Future* on December 31, 1999.

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CURRICULUM VITAE

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Born: June 29, 1928 Iron River, MI, USA
Married: (b)(6)
Children: (b)(6)

EDUCATION

1948 B.S. University of Southern California, Los Angeles, CA
1950 M.S. University of Southern California, Los Angeles, CA (Biochemistry and Nutrition)
1953 Ph.D. University of Southern California, Los Angeles, CA (Biochemistry, with Harry J. Deuel, Jr.)

PROFESSIONAL EXPERIENCE

1953-55 U.S. Public Health Service Post-doctoral Fellow; Harvard University (with George Wald)
1955-56 National Council to Combat Blindness Post-doc. Fellow; Harvard University (with George Wald)
1956-60 Instructor, Lecturer, Department of Biology, Harvard University
1960-64 Assistant Professor, Department of Pharmacology, Tufts University School of Medicine (TUSM)
1964-67 Associate Professor, Department of Pharmacology, TUSM
1967-69 Associate Professor, Department of Biochemistry, TUSM
1969-70 Professor, Department of Biochemistry, TUSM
1970-87 Professor, Department of Biochemistry and Pharmacology, TUSM
1973 Visiting Professor, Department of Physiology/Anatomy, University of California, Berkeley, CA
1981-82 Research Associate, Boston Veterans Administration Medical Center
1987-2000 Professor, Department of Biochemistry, Tufts University School of Medicine
1993-present **Scientist, USDA Human Nutrition Research Center on Aging, Tufts University**
2000-present **Professor Emeritus, Department of Biochemistry, Tufts Univ. School of Medicine**

RESEARCH INTERESTS

Function and metabolism of carotenoids, including antioxidant and anticarcinogenic actions and metabolism to retinoic acid and apocarotenoids. Role of carotenoids in primate macula. Analysis of tissue carotenoids. Biological oxidant damage, and mechanisms of lipophilic and hydrophilic protection.

EDITORIAL BOARDS

1984-1986 Journal of Free Radicals in Biology and Medicine
1984-1986 Advances in Free Radical Biology and Medicine
1987-1994 Free Radical Biology and Medicine
1993-2003 Archives of Biochemistry and Biophysics

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1994-2002	Free Radical Research
1997-present	Environmental & Nutritional Interactions
2002-present	Nutrition Reviews

PUBLICATIONS (see attached listing)

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PROFESSIONAL SOCIETIES

1948	American Association for the Advancement of Science (Fellow, 1966)
1949	Society of the Sigma Xi
1951	American Chemical Society
1951	New York Academy of Sciences
1959	American Society for Biochemistry and Molecular Biology
1972	American Society for Photobiology
1982	Society for Free Radical Research
1988	The Oxygen Society (2003: Society for Free Radical Biology and Medicine)
1988	International Society for Nutrition and Cancer
1993	European Retinoid Research Group
1994	International Carotenoid Society
1998	American College of Nutrition (Fellow, 1998)
1999	International Society for Coenzyme Q Research

PROFESSIONAL ACTIVITIES/HONORS

1950	Phi Sigma Award in the Biological Sciences, University of Southern California
1952	Phi Lambda Upsilon
1966	Fellow, American Association for the Advancement of Science
1967-1968	President, Tufts University Chapter, Society of the Sigma Xi
1975-1981	Secretary-Treasurer, American Society for Photobiology
1978	Organizing Committee, Fifth International Symp. on Carotenoids and Vitamin A, Madison, WI
1980	Co-Chairman, Workshop on Biological Chemiluminescence, American Society for Photobiology, Colorado Springs, CO
1981	Chairman, 1st Gordon Research Conference on "Oxygen Radicals in Biology and Medicine" Ventura, CA
1981-1984	Teaching Award, Tufts University School of Medicine
1982-1983	President, American Society for Photobiology
1984	Treasurer, Ninth International Congress on Photobiology, Philadelphia, PA
1987	Organizing Committee, Fourth International Congress on Oxygen Radicals, La Jolla, CA
1987	Chairman, Eighth International Symposium on Carotenoids, Boston, MA
1988-1991	Council, The Oxygen Society
1989-2000	Executive Committee, International Society for Nutrition and Cancer
1990	Lottie Arnrich Lecturer, Dept of Food & Nutrition, Iowa State University, Ames, IA May 1. 1990
1992	Chairman, 1st Gordon Research Conf. on "Chemistry and Biology of Carotenoids", Oxnard, CA
1993	Co-Chair, New York Academy of Sciences Conference on "Carotenoids in Human Health ", San Diego, CA
1993	Honorary Member, The Vitamin Society of Japan
1993	Distinguished Faculty Award, Tufts University School of Medicine
1994	Fellow, The Oxygen Society
1994	Co-Chair, Second International Conference on "Antioxidant Vitamins and ß-Carotene in Disease Prevention", October 10-12, Berlin, Germany
1994-1999	President, New England Free Radical/Oxygen Society
1995	Co-Chair, FASEB Summer Research Conference on "Antioxidant Nutrients in the Cellular Biology of Health and Disease", Saxtons River, VT
1995-1996	Secretary-General, The Oxygen Society
1996-1998	Advisory Committee, International Antioxidant Research Centre, King's College, London
1997	Mordechai Avron Memorial Lecturer, Nikken Sohonsha Corp., Gifu and Tokyo, Japan, 2/21/97
1997	Award Lecturer, American College of Nutrition, New York, NY September 27, 1997
1997-1999	Chair, Panel on Antioxidants and Related Nutrients, Food & Nutrition Board, Inst. of Med./NAS

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1998	Fellow, American College of Nutrition
1998	Dozor Visiting Professor, Ben-Gurion University of the Negev, Beer-Sheva, Israel
1999	Visiting Scholar, Linus Pauling Institute, Oregon State University, Corvallis, OR
1999	Honorary Member, Oxygen Club of California
1999	Lars Ernster Lecture, Oxygen Club of California 1999 World Congress, Santa Barbara, CA
2000	Robert S. Harris Lecture, Massachusetts Institute of Technology, Cambridge, MA
2001	National Associate, National Academy of Science/National Research Council
2002	Chair, Committee on the Examination of the Evolving Science for Dietary Supplements, Food & Nutrition Board, IOM/NAS
2003-2007	Member, Food Advisory Committee, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety, FDA
2003-2007	Chair, Nutrition Subcommittee, Food Advisory Committee, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety, FDA

RESEARCH TRAINEES: PRE-DOCTORAL		PRESENT POSITION
1964-1967	(b)(6) "Chemical and Biochemical Reduction of Carotenoid Epoxides"	Professor, Banting & Best Dept. of Medical Research University of Toronto, Toronto, Canada
1967-1974	(b)(6) "The Concentration, Turnover, Exchange & Enrichment of Cholesterol in Mitochondria and Mitochondrial Fractions"	Private Practice of Medicine New York, New York
1968-1974	(b)(6) "Mechanism of Photodynamic Oxidation and Lysis of a Model Membrane System (Liposomes)"	Associate Professor Department of Medicine Univ. of Texas, San Antonio, TX
1973-1980	(b)(6) "Kinetic and Structure-Function Studies Concerning Human Myeloperoxidase	Senior Scientist Seradyne.1200 S. Madison Avenue Indianapolis, IN
1987-1991	(b)(6) "Characterization of Tissue Carotenoids, Their Breakdown Products, and Relationship to Biological Metabolites"	Assistant Professor University of Massachusetts Lowell, MA

RESEARCH TRAINEES: POST-DOCTORAL		PRESENT POSITION
1963-1965	(b)(6)	Associate Director (Retired), National Institute of Nutrition Hyderabad, India
1964-1968	(b)(6)	Assoc. Professor (Med), Channing Laboratory Harvard Medical School, Boston, MA
1966-1967	(b)(6)	Consultant, New York, NY
1971	(b)(6)	Chairman, Environmental Sciences Program

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		University of Massachusetts, Boston, MA
1972	(b)(6)	Director, Dermal & Ocular Branch Division of Toxicology, Food & Drug Administration, Washington, DC
1977	(b)(6)	Research Associate, Sylvius Laboratoria, Univ. of Leiden, Leiden, The Netherlands
1979-1989	(b)(6)	Scientist, Duracell Technology Center, Needham, MA
1988	(b)(6)	Professor, Nutrition Physiology Institute für Physiologie, Veterinary Faculty University of Leipzig. D-7010, Leipzig, FRG
1990-1992	(b)(6)	Institute of General Pathology Catholic University, Rome. Italy
1996-1999	(b)(6)	USDA HNRCA, Boston, MA
1999-2003	(b)(6)	University of Milan, Milan, Italy

RESEARCH TRAINEES - UNDERGRADUATES/MEDICAL STUDENTS

1964-1966	(b)(6)	TUSM, 1968
1966-1967		TUSM, 1968
1973-1974		Tufts University, 1973
1974	(b)(6)	Tufts University, 1974
1974		, Tufts University, 1974
1974	(b)(6)	, Tufts University, 1974
1974		, Tufts University, 1974
1974		TUSM, 1977
1974	(b)(6)	, Hampshire College, 1975
1974-1975		Tufts University, 1975
1975-1976	(b)(6)	, Tufts University, 1979
1977-1978		Tufts University, 1979
1979-1980	(b)(6)	, Tufts University, 1981
1980		, Tufts University, 1980
1980	(b)(6)	, Oberlin College, 1981
1980		Tufts University, 1981
1983-1984	(b)(6)	Tufts University, 1984
1983-1984		, TUSM, 1987
1984-1985		, Tufts University, 1985
1988-1989	(b)(6)	Tufts University 1990
1991		, Wellesley College 1992

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FACULTY ACTIVITIES

TUFTS UNIVERSITY SCHOOL OF MEDICINE

1963-1966	Pre-Clinical Curriculum Study (Director)
1963-1967	Curriculum Committee
1967-1969	Faculty Medical Education Group
1968-1971	Committee on Extended Educational Opportunity (Chairman)
1968-1969	Health Information Sciences Committee
1969-1970	Advisory Committee on Medical Education
1970-1972	Committee on Faculty Affairs
1973-1978	Committee on Educational Affairs
1974-1975	Fringe Benefits Subcommittee, Faculty Affairs Committee
1974-1975	Admissions Committee
1977	Medical Bylaws Committee
1978-1979	Faculty Affairs Committee (Chairman)
1979-1981	Budgetary Advisory Subcommittee, Faculty Affairs Committee
1979-1981	Boston Tuition Scholarship Benefits Committee
1980-1983	Curriculum Coordinator, Year I
1980-1983	Student Promotions Committee
1981-1982	Ad Hoc Committee on Student Performance Evaluation
1981	Special Program Development Committee
1981-1983	Library and Educational Spaces Planning Subcommittee
1981-1986	Curriculum Committee
1982-1983	Committee on the Teaching of Nutrition at TUSM (Co-Chairman)
1982-1985	Ad Hoc Grievance Committee
1982-1983	Basic Science Appointment, Promotion and Tenure Committee
1983-1985	Task Force on Curriculum Planning
1983-1985	Faculty Advisor
1984-1987	Course Director, Biochemistry
1984-1987	Faculty Affairs Committee
1985-1987	Curriculum Committee Sub-Committee on Curriculum Planning and Implementation
1985-1990	Problem-Based Learning Committee
1988-1989	Curriculum Committee
1989-1992	Faculty Affairs Committee (Chairman, 1990-1992)
1991-1992	Self-Study Sub-Committee on Governance and Administration, LCME, (Chairman)
1992-1993	Steering Committee, RWJ Foundation Generalist Physician Initiative Program
1993-1994	Member, Faculty Senate
1994-1995	Member, Core Curriculum Collaborators Group
1994-1996	Member, Faculty Prizes/Awards Committee
1996-1998	Self-Study Sub-Committee on Governance and Administration, LCME

TUFTS-NEW ENGLAND MEDICAL CENTER

1963	Committee on the Role of the Basic Scientist in the Medical Center, (Chairman)
1968-1969	Audio-visual Task Force
1970-1971	Advisory Committee on Minority Opportunity and Planning
1982-1984	Board of Directors, Women's Resource Center

TUFTS UNIVERSITY

1966-1968	Policy and Program Committee, Graduate School of Arts and Sciences
1967-1973	Molecular Basis of Biological Phenomena Program (Chairman)
1968-1971	Committee on Equal Educational Opportunity, Faculty of Arts and Sciences

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1968-1970	Faculty Representative, Trustees Committee on Honorary Degrees
1970-1971	University-wide Committee on Equal Employment Advancement
1970-1971	Committee on Educational Planning
1978-1979	Advisory Committee on University Investments
1986-1987	Faculty Representative, Trustees Academic Affairs Committee
1993-1999	University-wide Benefits Advisory Committee

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SACKLER SCHOOL OF GRADUATE BIOMEDICAL SCIENCES

1983-1984 Faculty Secretary
1983-1987 Nominating Committee (Chairman)

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

1964-1965 Curriculum Committee

JEAN MAYER HUMAN NUTRITION RESEARCH CENTER ON AGING AT TUFTS UNIVERSITY

1995-2000 Promotions Committee

TEACHING EXPERIENCE

HARVARD UNIVERSITY

1956-1960 Biology 191 (Experimental Biochemistry)
1956-1960 Undergraduate Advisor, Department of Biology
1958 Biology 190 (General Biochemistry, with George Wald)

TUFTS UNIVERSITY SCHOOL OF MEDICINE

1960-1967 Pharmacology
1967-1999 Biochemistry (Course Director, 1984-1987, 1994)
1968-1986 Neuropharmacology
1974-1979 Biochemistry of Disease
1980-1985 Principles of Pharmacology
1985-1991 Problem-Based Learning Facilitator
1990 Nutrition and Medicine Facilitator

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

1960-1966 Pharmacology
1966-1968 Basic Health Sciences
1968-1988 Pharmacology
1984-1993 Biochemistry

TUFTS UNIVERSITY SCHOOL OF VETERINARY MEDICINE

1979-1985 Biochemistry
1980-1985 Neuropharmacology
1980-1985 Pharmacology

TUFTS UNIVERSITY GRADUATE SCHOOL OF ARTS AND SCIENCES

1960-1967 Graduate Pharmacology
1970 Mitochondrial Membranes and Bacterial Envelopes (BCM 294)
1972 Energy Flow in Biological Systems (BCM 214)
1974, 1978 Metabolic Pathways (BCM 213)
1978, 1982 Membranes (BCM 211)
1981- 1982 Advanced Biochemistry (BCM 223)

TUFTS UNIVERSITY SACKLER SCHOOL OF GRADUATE BIOMEDICAL SCIENCES

1984 Membranes (BCM 221)
1984-1999 Graduate Biochemistry (BCM 223)

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1985 Recent Advances in Neurochem. and Neuropharm. (BCM 220)
1995 Free Radicals in Biology & Medicine (BCM 293)

TUFTS UNIVERSITY SCHOOL OF NUTRITION

1991, '93, '99 Dietary Antioxidants and Degenerative Diseases (Nutrition 291-DA)

SCIENTIFIC CONFERENCES AND MEETINGS: INVITED PARTICIPATION

1. Invited Speaker: The Lipoprotein Nature of Rhodopsin Symposium on "Visual Mechanisms" (Sponsored by National Institutes of Health) Bethesda, Maryland, September 11-12, 1957.

2. Invited Speaker: The Role of Carotenoid Pigments as Protective Agents against Photosensitized Oxidations in Chloroplasts. Symposium on "Biochemistry of Chloroplasts" NATO Advanced Study Institute, Aberystwyth, Wales, U.K., August 5-9, 1965.

3. Invited Speaker: A Biochemical Basis for Carotenoid Function in Green Plants and Algae. Joint Japan-U.S. Seminar on "Carotenoid Biosynthesis and Related Topics" National Science Foundation/Japan Society for the Promotion of Science, Kyoto, Japan, November 29 - December 1, 1965.

4. Invited Speaker: Carotenoid De-epoxidation Reactions. Conference on "Photosynthetic Pigments" in honor of Harold H. Strain, Argonne National Laboratory, Argonne, Illinois, November 7-8,1968.

5. Invited Speaker: Minority Programs at Tufts University School of Medicine. Conference on "Minority Groups in Professional Schools" American Personnel and Guidance Association, Las Vegas, Nevada, March 30 - April 2, 1969.

6. Invited Participant: Minority Enrollment at Tufts University School of Medicine. Conference on "The Impact of Cultural and Economic Background on Programs to Recruit Negroes for Medicine" Macy Foundation, Princeton, NJ, April 13-16, 1969.

7. Invited Speaker: Evolution of Photosensitive Pigments in Microbes. Colloquium on "Photosynthetic Organisms: Origin and Evolution on Early Earth" 123rd meeting of the American Association for the Advancement of Science, Boston, MA, December 26, 1969.

8. Invited Speaker: The Protective Function of Carotenoid Pigments against Aerobic Photosensitivity. Colloquium on "Molecular Mechanisms of Photodynamic Action with and without Molecular Oxygen" VIth International Congress on Photobiology, Bochum, W. Germany, Aug. 21-25, 1972.

9. Sigma Xi Lecturer: Function of Carotenoids. University of Rhode Island, Kingston, RI, October 10, 1973.

10. Invited Speaker: Photosensitization and Protection of Biomembranes and Model Systems. Colloquium on "Photochemistry of Biomembranes" at the 2nd Meeting of the American Society for Photobiology, Vancouver, British Columbia, Canada, July 24, 1974.

11. Theme Speaker: Light and Life: Biochemical Responses to Light. New England Association of Chemistry Teachers 36th Summer Conference, St. Anselem's College, Manchester, New Hampshire, Aug. 20-24, 1974.

12. Invited Speaker: Singlet Oxygen Production in Biological Systems, Workshop on "The Role of Oxygen in the Production of Excited States in Biological Systems" Photobiology Group, Biophysical Society, Philadelphia, PA, February 18, 1975.

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13. Invited Speaker: Damage and Protection against Singlet Oxygen. Workshop on "Free Radical Damage and Protection" Bioenergetics Group, Biophysical Society Seattle, WA, February 24, 1976.

14. Invited Speaker: Cellular Damage Initiated by Visible Light. Symposium on "The Survival of

Vegetative Microbes" Society for General Microbiology, Cambridge, England, April 5-8, 1976.

15. Invited Speaker: Non-Photosynthetic Functions of Carotenoids. Discussion. Meeting on "The Biochemical Functions of Terpenoids in Plants" The Royal Society, London, England, January 26-27, 1978.

16. Invited Speaker: Carotenoid Protection against Oxidation. Fifth International Symposium on "Carotenoi and Vitamin A" Madison, WI, July 24-28, 1978.

17. Invited Participant: Joint Seminar on "Chemi- and Bio-energized Processes" Universidade de Sáo Paulo, Sáo Paulo, Brazil, August 5-7, 1978.

18. Invited Speaker: Cholesterol Oxidation by Either Polymorphonuclear Leukocyte or by Isolated Myeloperoxidase. International Conference on "Chemi- and Bio-energized Processes" Guaruja, Estado de Sáo Paulo, Brazil, August 8-10, 1978.

19. Invited Speaker: Carotenoid Pigments: Multiple Mechanisms for Coping with the Stress of Photosensitized Oxidations. Conference on "Strategies of Microbial Life in Extreme Environments" Dahlem Konferenzen, Berlin, Fed. Rep. Germany, November 20-24, 1978.

20. Invited Speaker: Is Singlet Oxygen Involved in Biological Chemiluminescence? Symposium on "Biological Basis of Chemiluminescence" American Society for Photobiology, Colorado Springs, CO, February 21, 1980.

21. Invited Speaker: Photosensitized Damage. Round Table on "Sensitized Photooxidation of Biomolecules" International Conference in Oxygen and Oxy-Radicals in Chemistry and Biology, Austin, TX, May 25-29, 1980.

22. Invited Speaker: Molecular Bases for Cellular Damage Initiated by Photosensitized Oxidations. Round Table on "Endogenous and Exogenous Inhibitors and Sensitizers. Fundamental Aspects" 8th International Congress on Photobiology, Strasbourg, France, July 20-25, 1980.

23. Invited Speaker: Interaction of Oxygen and Oxyradicals with Carotenoids Symposium on "Photochemical Toxicity" Food and Drug Administration, Bethesda, MD, March 16-17, 1981.

24. Invited Speaker: Possible Participation of Singlet Oxygen in Biological Systems. Symposium on "Radicals and Excited States in Biological Systems" Seventh International Biophysics Congress and Third Pan-American Biochemistry Congress, Mexico City, Mexico, August 24-28, 1981.

25. Invited Speaker: In vivo Analysis of UV-B Formation of 5.6-a-Epoxy- cholesterol. 2nd NCI/EPA/NIOSH Collaborative Workshop on "Progress on Joint Environmental and Occupational Cancer Studies" Rockville, MD, September 9-11, 1981.

26. Invited Speaker: The Biological Implications of Singlet Oxygen Production. Table Ronde Roussel Uclaf on "New Concepts of Free Radicals in Chemistry and Biology" Paris, France, October 22-23, 1981.

27. Invited Speaker: Photosensitization. Singlet Oxygen Damage and Cancer. "International Workshop on Photobiology" Cheju, Korea, May 25-June 1, 1982.

28. Invited Speaker: Introduction to Photobiology and Photosensitization. Symposium on "Photobiology" Chosun University, Gwang Ju, Korea, June 2, 1982.

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29. Invited Speaker: Free Radicals as Possible Mutagens and Carcinogens. Symposium on "Free Radicals

and Cancer" Council for Tobacco Research, New York, NY, June 21, 1982.

30. Invited Speaker: Mutagenic and Carcinogenic Effects of Oxygen Radicals Symposium on "Possible Roles of Free Radicals in Aging" Gerontological Society of America, Boston, MA, Nov. 21, 1982.

31. Invited Speaker: Biology and Photobiology of Singlet Oxygen 3rd International Conference on Oxygen Radicals, Munich, FRG, July 10-15, 1983.

32. Invited Speaker: Comparison of the Oxidant Mechanisms of Myeloperoxidase and UV-B Irradiation EMBO Workshop on "Oxidative Enzymes-Damage and Consequences" Grottoferrata, Italy, October 2-7, 1983.

33. Public Lecture: New Findings on the Role of Provitamin A in Health and Disease. Institute for Research on Aging, University of California, San Diego, CA, September 13, 1984.

34. Invited Speaker: The Action of Carotenoids In vitro as Compared to their Function In vivo. Symposium on "Nutrition and Disease: Cancer" Helicon Foundation, San Diego, CA, September 15, 1984.

35. Invited Speaker: Detection and Biological Function of Active Oxygen Species School Lecture, American Society for Photobiology, New Orleans, and LA, June 27, 1985.

36. Invited Speaker: The Unique Singlet Oxygen Quenching Properties of Carotenoids. FASEB Summer Research Conference on "Micronutrients Retinoids" Saxtons River, VT, June 22-27, 1986.

37. Invited Speaker: Mechanisms of Inactivation of Oxygen Species by Carotenoids. 2nd International Conference on Anticarcinogenesis and Radiation Protection, National Bureau of Standards, Gaithersburg, MD, March 9-12, 1987.

38 Invited Speaker: Beta-carotene and Cancer: Overview and Rationale. VNIS Health Communications Conference: Beta-Carotene, Boca Raton, FL, April 11-12, 1987.

39. Invited Speaker: Overview of Carotenoids in Medicine. Eighth International Symposium on Carotenoids, Boston, MA, July 26-31, 1987.

40. Invited Speaker: Enzymic and Pigment Protection from Photodynamic Damage. FEMS/Society for Applied Bacteriology Symposium on "Homeostatic Mechanisms in Micro-organisms." Warwick University, Coventry, UK, September 14-18, 1987.

41. Invited Speaker: The Evidence for the Role of Carotenes in Preventive Health Symposium on "Carotenes in Food and Health" Department of Food Science and Office of Continuing Professional Education, Rutgers, The State University of New Jersey, Iselin, NJ, December 3, 1987.

42. Invited Speaker: Carotenoids as Chemopreventive Agents. Third International Conference on "The Prevention of Human Cancer: Chemoprevention" Arizona Cancer Center, Tucson, AZ, January 12-15, 1988.

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43. Invited Speaker: Theoretic and Experimental Basis for Anti-carcinogenic Effects of Retinoids. Workshop on "Emerging Role of Retinoids in the Treatment of Aging and Skin Cancer" Miami, FL, March 11-13, 1988.

44. Invited Speaker: Experimental Studies on Carotenoids and Cancer in Animal Models. Symposium on "The Biological Actions of Carotenoids" American Institute of Nutrition, Las Vegas, NV, May 1-6,

1988.

45. Invited Speaker: Biological Functions of Carotenoids and Retinoids. Symposium on "Biology of Human Skin Aging" American Academy of Dermatology, Philadelphia, PA, May 18-20, 1988.

46. Invited Speaker: Membrane Antioxidants. Conference on Biological Membranes in Cancer Cells, New York Academy of Sciences, Torgiano, Italy, June 13-18, 1988.

47. Invited Speaker: Pigment and Enzymic Protection Against Photodynamic Damage. Tenth International Congress of Photobiology. Jerusalem, Israel, October 31 1988.

48. Invited Speaker: Cancer Prevention: Animal and In vitro Studies. International Conference on "Anti-Oxidant Vitamins and Beta-Carotene in Disease Prevention" British Nutrition Foundation, London, U.K. October 2-4, 1989.

49. Invited Speaker: Carotenoid Metabolism. Workshop on "Carotenoids" FASEB Annual Meeting, Washington, DC, April 1, 1990.

50. Invited Speaker: Carotenoids and Cancer. Symposium on "Nutrition Related Cancer Research: An Interdisciplinary Update" Nutrition Council at Tufts, Boston, MA, April 25, 1990.

51. Invited Speaker: Carotenoid Function. Workshop on "Carotenoids" FASEB Annual Meeting, Atlanta, C April 20, 1991.

52. Invited Speaker: Role of Carotenoids. Seminar on "Recipe for Cancer Prevention: Food Issues for the 1990s" American Cancer Society and Nestlé Beverage Company, New York, NY, June 12, 1991.

53. Invited Speaker: Mechanisms of Action of Antioxidants. Conference on Molecular and Comparative Nutrition, US-Japan Malnutrition Panel, Bethesda, MD, July 22-24, 1991.

54. Invited Participant: National Heart, Lung and Blood Institute Workshop on "Antioxidants in the Prevention of Human Atherosclerosis" Bethesda, MD, September 5-6, 1991.

55. Invited Speaker: Carotenoids in Cellular and Animal Systems: Effects on Mutagenesis, Carcinogenesis and Age-related Diseases. Symposium on "Free Radicals and Aging" Society for Free Radical Research (Europe), Paris, France, September 26-28, 1991.

56. Invited Speaker: Conversion of Carotenoids to Retinoids. Symposium on "Retinoids: New Trends in Research and Clinical Applications" Palermo, Italy, October 21-24, 1991.

57. Invited Speaker: Beta-Carotene - Animal Data. Symposium on "Vitamins and Cancer Prevention" Pennington Biomedical Research Center, Baton Rouge, LA, October 30 November 1, 1991.

58. Invited Speaker: Carotenoids as Biological Antioxidants. Symposium on "Active Oxygens, Lipid Peroxides and Antioxidants" 5th International Congress on Oxygen Radicals, Kyoto, Japan, November 17-21, 1991.

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59. Invited Speaker: Excentric Cleavage Mechanism(s) for Carotenoid Metabolism. Gordon Research Conference on "Chemistry and Biology of Carotenoids" Oxnard, CA, March 9-13, 1992

60. Invited Speaker: Nutritional Factors an Their Influence on Mutagenicity and Malignant Transformation. Tobacco and Health Research Institute, University of Kentucky Symposium on "Tobacco Smoking and Nutrition: Influence of Nutrition on Tobacco Associated Health Risks" Lexington, KY,

September 14-16, 1992

61. Invited Speaker: Excentric Cleavage of Carotenoids. New York Academy of Sciences Conference on "Carotenoids in Human Health" San Diego, CA, February 6-9, 1993.

62. Invited Speaker: Antioxidant Effects of Carotenoids. International Conference on "Critical Aspects of Free Radicals in Chemistry, Biochemistry and Medicine" Vienna, Austria, February 14-17, 1993.

63. Invited Speaker: Antioxidant Properties of Carotenoids. The Kurashiki Symposium for Medical Science, Kurashiki, Japan, May 21-22, 1993.

64. Invited Speaker: ß-Carotene: Disease Prevention and Its Health Impact. Japan Vitamin Society, Gifu City, Japan, May 25-27, 1993.

65. Invited Speaker: Function, Actions, and Associations of Carotenoids. Tenth International Symposium on Carotenoids, Trondheim, Norway, June 20-25, 1993.

66. Invited Speaker: Antioxidants: Classification and Mode of Action. Symposium on "Antioxidants and Disease Prevention: Biochemical, Nutritional, and Pharmacological Aspects" Stockholm. Sweden, June 30-July 3, 1993.

67. Invited Speaker: Carotenoid Metabolism. Symposium on "Retinoids: New Trends in Research and Clin Applications" Genoa, Italy, October 4-7, 1993.

68. Invited Speaker: The Effects of Carotenoids on Cells. Workshop on "Cell Proliferation and Differentiation: Modulation by Free" Rome, Italy, October 8, 1993.

69. Invited Discussant: Antioxidant Nutrients. Symposium on "Nutritional Assessment of Elderly Populations: Measure and Function" Boston, MA, October 11-13, 1993.

70. Invited Speaker: Clinical and Experimental Studies of ß-Carotene and Cancer. FDA Public Conference on Antioxidant Nutrients and Cancer and Cardiovascular Disease. Washington, DC, November 1-3, 1993.

71. Invited Speaker: Recent Research Findings on Beta-Carotene. Henkel Symposium on Vitamin E Palm Beach, FL, June 7-8, 1994.

72. Invited Speaker: Comments on Antioxidant Vitamins and ß-Carotene. "Second International Conference on Antioxidant Vitamins and Beta Carotene in Disease Prevention" Berlin, Germany, October 10-12, 1994.

73. Invited Speaker: Plant Carotenoids and Related Molecules - Important Dietary Antioxidants. Symposium on "Free Radicals and Oxidative Stress - Environment, Drugs and Food Additives" Biochemical Society, Brighton, U.K., December 14-16, 1994

74. Invited Speaker: Antioxidants and Their Role in Human Health. 22nd Annual Texas Human Nutrition Conference, "Health Claims for Foods and Nutrients" Texas A & M Univ., Tyler, TX, February 3, 1995.

75. Plenary Lecture: An Overview of the Functions and Actions of Carotenoids: A Personal Perspective. 2nd Gordon Research Conference on Carotenoids, Ventura, CA February 5-9, 1995.

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76. Invited Speaker: Carotenoids as Biological Antioxidants. 2nd Symposium on Vitamins and

Biofactors, San Diego, CA February 15-19, 1995.

77. Invited Speaker: Overview of Carotenoids. USAID Workshop on the Bioavailability and Bioconversion of Carotenoids. Washington, DC April 4-5, 1995

78. Invited Speaker: Functions of Carotenoids. FASEB Summer Conference on Antioxidant Nutrients in the Cellular Biology of Health and Disease, Saxtons River, VT August 17-21, 1995

79. Invited Speaker: Biological Effects of Radicals on Carotenoids, 6th European Society for Photobiology, Cambridge, UK September 2-9, 1995.

80. Invited Speaker: Low Molecular Weight Antioxidants; You are What You Eat, Oxygen '95 Free Radical School, Annual Meeting of the Oxygen Society, Pasadena, CA November 17, 1995

81. Invited Speaker Carotenoids: Structure and Function, Workshop on "Potential Effects of Reducing Carotenoid Levels on Human Health" Department of Nutrition, Harvard School of Public Health, Boston, MA January 17th, 1996

82. Invited Speaker Metabolism and Mechanism of Action of Antioxidants, The Toxicology Forum, Givens Institute, Aspen, CO, July 9, 1996.

83. Invited Speaker Are the Oxidative Breakdown Products of Carotenoids Evidence of Antioxidant Action or the Generation of Biologically Active Molecules? VIII Biennial Meeting, International Society for Free Radical Research, Barcelona, Spain October 4, 1996

84. Invited Speaker ß-Carotene and Disease: A Causal Relationship? Oxygen '96, Annual Meeting of the Oxygen Society, Miami □Beach. FL November 22, 1996

85. Invited Lecturer: Natural and Synthetic Carotenoids: Their Actions in Biology. 5th Mordechai Avron Memorial Lecture, Gifu and Tokyo, Japan, Nikken Sohonsha Corp., February 21 and 23, 1997

86. Invited Speaker: Overview of Lycopene, Carotenoids and Disease Prevention, International Symposium on the Role of Lycopene and Tomato Products in Disease Prevention, American Health Foundation/Tomato Research Council, New York, NY, March 3, 1997

87. Invited Speaker: Hypothetical Health Benefits Of ß-Carotene And Other Carotenoids, Society of Toxicology, Cincinnati, OH, March 11, 1997

88. Invited Lecturer: The Properties of Carotenoids that Define Their Actions (June 1) and The Actions of Carotenoids in Biology and Medicine (June 3), NATO Advanced Study Institute on Free Radicals, Oxidative Stress and Antioxidants. Pathological and Physiological Significance, Antalya, Turkey, May 24-June 4, 1997

89. Invited Speaker: Carotenoids and Chronic Degenerative Diseases, International Conference on Nutrition and Cancer, Irvine, CA July 16-July 19, 1997

90. Invited Speaker: The Antioxidant and Biological Properties of the Carotenoids, 7th Congress of the International Association of Biomedical Gerontology, Adelaide, Australia, August 15-August 18, 1997

91. Invited Speaker: Biochemistry of Carotenoids: Actions and Functions. American College of Nutrition Award Lecture, American College of Nutrition Annual Meeting, New York, NY, September 26-28, 1997

92. Invited Speaker: Measurement of Carotenoids, WORKSHOP on Quantitative Methods for Determination of Hydroxyl Radicals, Oxidation of Biological Molecules and Antioxidants, The Oxygen Society, San Francisco, CA, November 20-24, 1997.

93. Invited Speaker: Actions of Carotenoids, Oxygen Club of California, Santa Barbara, CA, February 7, 1998

94. Plenary Lecture: Carotenoids in Health and Disease, Gordon Research Conference on Oxygen Radicals in Biology, Ventura, CA, February 12, 1998

95. Invited Speaker: Role of Carotenoids in Health and Disease, The First Regional Meeting on Medical Sciences: "The Roles of Free Radicals in Health and Disease" Jerusalem and Amman, March 22-27, 1998

96. Invited Speaker: Activity of ß-Carotene Oxidation Products, European Conference on Biomedical Research and Peace, Paralimni, Cyprus, October 17-21, 1999

97. Invited Speaker: What is the Scientific Evidence for Establishing Carotenoids as Recommended Nutrients? Symposium on Dietary Antioxidants: the New Dietary Reference Indices; The Oxygen Society, New Orleans, LA, November 21, 1999

99. Invited Speaker: The Relationship Between Antioxidant and Chronic Disease Symposium on Dietary Reference Intakes, Experimental Biology '00, San Diego, CA April 17, 2000

100. Invited Speaker Carotenoids, Smoking and Cancer, 3rd International Conference on Antioxidants and Free Radicals in Health and Disease, Vancouver, BC, Canada July 23, 2000

101. Invited Speaker: Antioxidants and Chronic Diseases: How Much Science is Enough? Symposium on Dietary Reference Intakes, American Dietetic Association, Denver, CO October 18, 2000

102. Invited Speaker: Antioxidants and Chronic Diseases, Symposium on Dietary Reference Intakes, American Public Health Association, Boston, MA Nov. 13, 2000

103. Invited Speaker: Carotenoids in Health and Disease, Robert S. Harris Lecture, Massachusetts Institute of Technology, Cambridge, MA March 15, 2001

104. Invited Speaker Possible Biologic Mechanism for the Protective Role of Xanthophylls, Symposium on Lutein and Macular Degeneration, FASEB Meeting, Orlando, FL, April 1, 2001

105. Invited Speaker: Carotenoid Research in the Past and Present Millennia, CARIG Lecturer, EB'01 Conference, Orlando, FL, April 2, 2001

106. Invited Speaker: Possible Biologic Mechanism for the Protective Role of Xanthophylls in Age-Related Macular Degeneration, American Society of Nutritional Sciences (EB'01), Orlando, FL, April 1, 2001

107. Invited Speaker: Dietary Carotenoids: What do They Do? PAX Mechanisms Conference, Cambridge, MA, September 30, 2001

108. Invited Plenary Lecturer Historical Critical Evaluaiton of free Radical and Antioxidant Research Oxygen Club of California, Santa Barbara, CA, March 8, 2002

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109. Invited Speaker: Health Benefits of Carotenoids, Helmut Sies Festschrift, L'Abbaye de Royamount,

Royamount, France, July 15, 2002

110. Invited Speaker: Dietary Carotenoids Modify Human Plasma Lipid Oxidizability, International Society for Free Radical Research Meeting, Paris France, July 16-20, 2002

111. Invited Plenary Lecturer Human Requirements for Fat-Soluble Vitamins, XIIth European Meeting on Fat-Soluble Vitamins, Rieti, Italy March 13-15, 2003

112. Invited Speaker: Overview of Lutein and Zeaxanthin, Advisory Committee, National Eye Institute, May 17, 2004

NORMAN I. KRINSKY, Ph. D. PUBLICATIONS

A. Peer Reviewed Journal Articles (99)

1. Ganguly, J, Krinsky, NI, Mehl, JW and Deuel, HJ Jr, Studies of the Distribution of Vitamin A as Ester and Alcohol and of Carotenoids in Plasma Proteins of Several Species. Arch. Biochem. Biophys. 38:275-282 (1952).

2. Krinsky, NI and Ganguly, J, Intracellular Distribution of Vitamin A Ester and Vitamin A Alcohol in Rat Liver. J. Biol. Chem. 202:227-232 (1953).

3. Ganguly, J and Krinsky, NI, Absence of Relationship between Vitamin A Alcohol Levels in Plasma and Liver of Rats. Biochem. J. 54:177-181 (1953).

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September 19, 2007

Laura Tarantino, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

09-24-07 P04:35 RCVD

RE: Lyc-O-Mato® Powder GRAS Notification (GRN 000163) Amendment

Dear Dr. Tarantino:

1. Introduction

As representative of the notifier, LycoRed Ltd. [LycoRed Natural Products Industries, Ltd.], Hebron Road – Industrial Zone, P.O. Box 320, Beer Sheva – 84102 Israel; Burdock Group, by this letter, is providing the Food and Drug Administration (FDA) a notice of intention to market tomato pulp powder (Lyc-O-Mato® Powder), the subject of a prior Generally Recognized As Safe (GRAS) notification (GRN 000163),[1] as an ingredient to be added to products that have been previously determined as medical foods.[2,3] This addition of tomato pulp powder to medical

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[1] See attached copy of the Notification Letter.

[2] 21 CFR 101.9(j)(8) Nutrition labeling of food. Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if: (i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube; (ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; (iv) It is intended to be used under medical supervision; and (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

food products does not increase the Estimated Daily Intake in the general population, and is supported by the safety studies cited in the previous GRAS notification (GRN 000163).

2. History of regulatory activity of tomato powder

The FDA has previously reviewed the GRAS status of tomato pulp powder for use in baked goods, ground meat products, meat analogues (vegetable protein-based), dairy products, soups, and sauces (GRN 000163). The GRN 000163 letter, dated August 8, 2005, acknowledged that the Agency had no further questions concerning the determination that the substance was GRAS for these uses. The Agency also stated in that letter that the common and usual name for the notified substance was tomato pulp powder. The substance trade name, Lyc-O-Mato® Powder, is composed of tomato pulp, containing lycopene, proteins, sugars, dietary fibers, lipids, and other carotenoids. The specifications for tomato pulp powder have not changed from the original notification.

A GRAS Notification amendment letter submitted September 15, 2006 informed FDA of LycoRed's determination that the addition of tomato pulp powder to other foods (*i.e.*, beverages) is GRAS while acknowledging that the use of tomato pulp powder in some of the foods listed in GRN 000163 was impractical and nonviable in the marketplace and therefore did not contribute to lycopene exposure. FDA replied on January 26, 2007[4] and indicated that the agency had no questions at that time regarding LycoRed's conclusion that tomato pulp powder is GRAS under the intended conditions of use.

3. Consumption of tomato powder

Tomato pulp powder (as indicated in GRN 000163 and the Amendment to this GRAS dated September 15, 2006) is intended to be used to increase the consumption of lycopene in the diet of the general population when incorporated into the foods identified in GRN 000163, according to food codes given in the U.S. Department of Agriculture (USDA) 1994-1996, 98 Continuing Survey of Food Intakes by Individuals (CSFII, 94-96, 98). Those codes have been used to calculate the Estimated Daily Intake (EDI) values for lycopene consumption (Table 1). Other GRAS Notices concerning lycopene have been filed with the FDA, but due to the self-limiting nature of lycopene (*i.e.*, an undesirable red color or tomato-like taste), lycopene from more than one source would not likely be added to a food product. GRN 000163 identified the Acceptable Daily Intake (ADI) of lycopene at 120 mg/day.

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[3]Because there is no specific deficiency, disease, syndrome or symptom arising from an absence of lycopene, the addition of lycopene, in and by itself, cannot render a food a "medical food" simply as the result of its addition to the food. In this GRAS Notification, tomato extract of lycopene is to be added to foods already determined to be medical foods.

[4] See attached copy of the FDA response letter to the GRN000163 Amendment.

Table 1. Current lycopene intake, predicted lycopene intake following supplementation of selected foods at the levels indicated in GRN 000163 and total lycopene intake (predicted + current) for individuals consuming selected supplemented foods

Lycopene intake from:	*Per* Person (mg/day) Mean	90th Percentile
A. Consumption from food containing lycopene naturally	6.1[a]	13.7
B. Possible maximum consumption with Lyc-O-Mato® Powder as an added ingredient to food [b]	15.3	28.9
C. Lycopene consumed as a color additive[c]	5.3	9.2
D. Total from conventional food (current + added)	26.7	51.8
E. Potential dietary supplement use	30	60
F. Potential total lycopene from all sources (food + dietary supplements)	56.7	111.8

[a] Levels calculated using consumption values from CSFII 1994-1996 (CSFII 1994-96, 2000) and food lycopene concentrations from Holden *et al.*, 1999, for foods with naturally-occurring lycopene that were consumed by individuals that also ate the target foods.
[b] GRN 000163 indicated that the mean consumption of lycopene from Lyc-O-Mato® Powder as an added ingredient was 20.0 mg/day, with a 90th percentile consumption at 35.9 mg/day. Submission of a GRN 000163 Amendment altered the mean and 90th percentile consumption of lycopene from the proposed foods to 15.3 and 28.9 mg/day, respectively.
[c] GRN 000163

4. Proposed new use of tomato powder as an ingredient in products previously determined to be medical foods

Lycopene is a natural constituent of the typical US diet, with mean lycopene consumption from the target foods stated in GRN 000163 at approximately 6 mg/day.[5] The available information indicates that current commercial enteral formulas do not provide lycopene to patients comparable to that which would be derived from a typical diet (Olmedilla *et al.*, 1996). LycoRed, Inc. intends to market tomato pulp powder as an ingredient for addition to products previously determined as medical foods.

The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods are in some cases, the sole source of calories and nutrients for a patient, but as often as not, certain medical foods are consumed as caloric and nutritive supplement (*i.e.*, may be taken to supplement the typical diet), as a result of the patient not eating or being able to eat normally due to the patient's specific disease or condition.[2]

The addition of tomato powder to products previously determined as medical foods intended to supplement the patient's diet was evaluated and determined GRAS by scientific procedures

[5] GRN 000163 Notification.

when added to medical foods at a level not to exceed 3 mg/100 kcal or 36 mg of lycopene/day.[6] While there is no question that patients receiving such a medical food as a sole source of nutrition would not exceed the ADI of lycopene because of the absence of other lycopene sources, the Expert Panel determined supplemental uses to the typical diet to also be consistent with the safe use of lycopene for the following reasons:

- The original lycopene consumption calculation (see Table 1 above), indicating a potential total consumption of lycopene from all sources was 56.7 mg/day (mean) and 111.8 mg/day (90th percentile). This total stipulated that consumption from food [*i.e.*, as a natural constituent of foods, as an added ingredient (with limitations to specific foods) and as a color additive] was 26.7 mg/day (mean) and 51.8 mg/day at the 90th percentile. The Expert Panel reasoned that if a patient is receiving medical food to supplement his/her caloric intake, it is unlikely that the patient will be consuming enough conventional food to achieve the mean or 90th percentile intakes of lycopene.
- This total (above, 56.7 and 111.8 mg/day lycopene) also assumed an exaggerated consumption of lycopene as a dietary supplement at 30 mg/day (mean) and 60 mg/day (90th percentile). Because medical foods are administered under supervision of a physician, the Expert Panel reasoned that patients who receive medical food to supplement their caloric and nutritive intake would be unlikely to consume dietary supplements, at least to the extent of the exaggerated estimates identified above.
- Lastly, the only documented effect of over-consumption of lycopene is a skin color change and to this extent, lycopene is self-limiting. In addition, because a patient consumes medical foods under the supervision of a physician, the physician, as a trained observer, would notice the skin color change, investigate this phenomenon and subsequently caution the patient about over consumption of lycopene.

5. Additional information in the scientific literature developed since the original GRAS (GRN 000163)

Tomato powder is composed of the same substance previously notified, and reference is made to the original GRAS submission (GRN 000163). Summaries of safety data relevant to lycopene consumption are also referenced in GRN 000163 as a general recognition of safety. From the time of the first GRAS notification, additional preclinical and clinical studies have been published that evaluate the effects of lycopene or tomato extract consumption. Those studies are summarized in the attached GRAS 163 Amendment document. No adverse effects were noted in any of the preclinical or clinical studies published since the original GRAS submission. The Expert Panel that initially evaluated the available information on the tomato oleoresins and concluded that tomato powder was GRAS by scientific procedures for supplementing the diet with lycopene, was requested to reassess the GRAS status of tomato powder in light of the proposed use as an ingredient in products previously determined as medical foods. The Expert Panel evaluated information generated since the first GRAS review, and found that this information is consistent with that provided in the first GRAS determination and fully supports the GRAS status of tomato powder for use as an ingredient in products previously determined to be medical foods, as indicated in the attached GRAS dossier Amendment document.

[6] The energy content of a supplemental product is typically in the range of 200 – 400 kcal *per* serving, with a suggested intake of 1 to 3 servings *per* day, depending on the product. The maximum daily intake of lycopene from products previously determined as medical foods taken as a supplement to the typical diet would be 36 mg/day.

6. Conclusion

In consideration of the facts and reasoning presented above, it is concluded by the GRAS Expert Panel that that the use of tomato powder at a level not to exceed 3 mg/100 kcal or 36 mg of lycopene/day as an ingredient in products previously determined as medical foods, remains consistent with the safety data cited in GRN 000163.

The GRAS notification is based on published, generally available and accepted scientific data, information, methods and principles, as well as experience based on common use in foods. LycoRed has determined that the use of tomato powder (*i.e.*, Lyc-O-Mato® Powder) as an ingredient to supplement medical foods with lycopene, is GRAS, and therefore, exempt from the premarket approval requirements of the U.S. Food, Drug and Cosmetic Act.

Sincerely,

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George A. Burdock, PhD.
Diplomate, American Board of Toxicology
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October 12, 2007

Laura Tarantino, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

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[5] GRN 000163 Notification.

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5. Additional information in the scientific literature developed since the original GRAS (GRN 000163)

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[6] The energy content of a supplemental product is typically in the range of 200 – 400 kcal *per* serving, with a suggested intake of 1 to 3 servings *per* day, depending on the product. The maximum daily intake of lycopene from products previously determined as medical foods taken as a supplement to the typical diet would be 36 mg/day.

6. Conclusion

In consideration of the facts and reasoning presented above, it was concluded by LycoRed Ltd., that the use of tomato powder at a level not to exceed 3 mg/100 kcal or 36 mg of lycopene/day as ingredients in products previously determined as medical foods, is generally recognized as safe (GRAS), and remains consistent with the safety data cited in GRN 000163. LycoRed Ltd. bases its conclusion of GRAS status and assumes responsibility for this conclusion following close consultation with, and based on, the opinion of an Expert Panel (in compliance with the definition and description of Expert Panel actions in section 201(s) of the Federal Food Drug and Cosmetic Act) and, whose opinion is attached to this Notification.

The GRAS notification is based on published, generally available and accepted scientific data, information, methods and principles, as well as experience based on common use in foods. LycoRed Ltd. has determined that the use of tomato powder (*i.e.*, Lyc-O-Mato® Powder) as an ingredient to supplement medical foods with lycopene, is GRAS, and therefore, exempt from the premarket approval requirements of the U.S. Food, Drug and Cosmetic Act.

Sincerely,

(b)(6) 12 OCT 2007

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