GR

ORIGINAL SUBMISSION

000003

Heart Blend Foods LLC

July 15, 2005

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

To whom it may concern:

Heart Blend Foods LLC is submitting a GRAS Notification in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substance Generally Recognized as Safe (GRAS); the GRAS proposal). The subject of this notice is plant sterol esters.

The attached notice informs FDA that Heart Blend Foods LLC has concluded, through scientific procedure, that plant sterol esters at 1.0 g per 8 fl. oz. serving are GRAS for use in coffee brewed from plant sterol ester enriched ground coffee.

Three copies of the notice are attached.

Please contact me with any questions at the address below or at 609-273-4466

Sincerely,

William C. Franke, PhD
President
Heart Blend Foods LLC
14 Silvers lane
Cranbury, NJ 08512

GRAS Notification

Use of Plant Sterol Esters in Ground Roasted Coffee

Submitted by

Heart Blend Foods LLC
14 Silvers Lane
Cranbury NJ 08512

July 15, 2005

Table of Contents

1. Introduction

An estimated 105 million American adults have total blood cholesterol values of 200mg/dL or higher according to the National Health and Nutrition Examination Survey III, conducted by the CDC/National Center for Health Statistics, Atlanta. Adults with total cholesterol levels of 200 to 239mg/dL are considered at risk (borderline) for heart disease, while those (about 37 million) with levels of 240mg/dL, or greater, are at high risk.

Americans have been encouraged to reduce their blood cholesterol levels by exercising more and eating a healthy diet. Many Americans are reluctant or can't afford to take drugs, thus there is interest in foods products that help reduce cholesterol levels.

A number of food products containing plant sterols and plant sterol esters have been introduced into the US market since 1999 when the FDA did not object to Lipton's Expert Panel's conclusion that plant sterol esters are GRAS (generally recognized as safe) and in 2000 when FDA authorized a health claim about the role of plant sterol esters in reducing the risk of CHD for foods containing at least 0.65 g of plant sterol esters per serving. Among them are spreads, dressings, chews, orange juice and yogurt.

In order for foods containing plant sterol esters to be truly effective in reducing cholesterol, they must be consistent with dietary advice, compatible with lifestyle and food habits, widely available, good tasting, economical and consumed on a daily basis.

Coffee fits with the eating habits, lifestyle and needs of the target consumer. It is consumed on a daily basis, is low in calories and fat and is low in cost, thus is an ideal food vehicle to deliver plant sterol esters. The American Heart Association allows moderate consumption of coffee as part of its heart healthy diet recommendations. The National Cholesterol Education Program (NCEP) Guidelines now recommend plant sterol esters, as part of the new Therapeutic Lifestyle Change Diet. Heart Blend Foods LLC has developed technology that allows coffee brewed from ground coffee to be enriched with plant sterol esters without impacting taste or acceptability.

The subject of this Notification is Heart Blend Foods' LLC conclusion that plant sterol esters in coffee brewed from ground coffee, at a level to deliver 1.0 g plant sterol esters per 8 fl. oz. serving is GRAS (generally recognized as safe). This conclusion is based on scientific procedures.

2. CLAIM

Heart Blend Foods LLC has concluded that plant sterol esters in coffee brewed from ground coffee, at a level to deliver 1.0 g plant sterol esters per 8 fl. oz. serving, is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act because the notifier has determined that such use is GRAS. The GRAS determination is based on scientific procedures.

3. NOTIFIER

Heart Blend Foods LLC
14 Silvers Lane
Cranbury NJ 08512

William C. Franke, PhD
President

4. SUBSTANCE

Plant Sterol Esters are the subject of this Notification. Plant sterol esters manufactured and sold by ADM (Archer Daniels Midland, Decatur, IL) under the brand name Cardio-Aid ^{TM}–S (ADM product code 040087) is an example of a commercially available plant sterol esters.

5. CONDITIONS OF USE

Plant sterol esters will be incorporated into roasted ground coffee that, when brewed according to package directions, will yield a plant sterol ester-enriched coffee beverage containing 1.0 g plant sterol esters per 8 fl oz serving. Depending upon the particular roast and grind of the coffee, the amount of ground coffee used per serving can range from approximately 5 to 10 grams per 8 fl oz serving. The plant sterol ester content of the enriched ground coffee will range from approximately 17% to 9 %on the weight of the plant sterol ester enriched coffee or 20% to 10% on the weight of the coffee, respectively. The final concentration of the plant sterols esters in the ground coffee will be such that, on a brewed coffee basis, the plant sterol ester content will be 0.43% w/v, assuming 100% extraction. In practice the extraction efficiency will be approximately 85%, but for the safety determination 100% will be assumed to provide the most conservative exposure assessment.

The product is intended to lower serum cholesterol and the target population is adults concerned about their serum cholesterol level. The heaviest consumers of coffee are

adults age 40+. This target market coincides with the population most concerned about serum cholesterol levels.

6. BASIS FOR GRAS DETERMINATION

The basis for the GRAS determination is scientific procedures. GRAS Notices and Agency Response Letters GRN , 000048, 000053, 000061, 000112 and Food Master File 000625 are incorporated by reference. Agency Response Letters are attached in Appendix 10.1 The Notifier notes also that there has been safe, widespread consumer use of plant sterol esters and free plant sterols in foods in the US, Europe and Australia (e.g.Unilever's Pro-Activ and Take Control spreads, Minute Maid's Heartwise orange juice)

All the data that forms the basis of Heart Blend Foods LLC's determination that plant sterol esters are safe for their intended use in coffee brewed from ground coffee is presented in this notification, has been previously reviewed by the Agency (e.g. GRN 000061 and FMF 00625), or is publicly available in the scientific and trade literature.

To the best of the Notifier's knowledge there are no substantiated reports of adverse reactions to plant sterol esters

7. DETAILED INFORMATION ABOUT THE SUBSTANCE

7.1 Prior GRAS Notifications

Detailed information about plant sterol esters is contained in FMF 00625 and GRAS Notice GRN 000061.

The substance was the subject of a prior GRAS Notice (GRN 000061) and the agency issued a Response Letter (April 18, 2001) indicating that the agency had no questions at that time regarding ADM's conclusion that plant sterol esters are GRAS for the intended use in spreads, dressings for salad, yogurt-type products, health drinks, and health bars. The product specification sheet and certificate of analysis for a typical commercially available plant sterol ester (ADM'sCardioAid-S) can be found in Appendix 10.2 and 10.3.

7.2 Updated Review of the Literature

A review of the literature from Jan 2000 to June 2005 was conducted to determine if any relevant published studies (References1-18) might impact on the original safety assessment and GRAS determinations (FMF 00625 and GRN 00061). Based on the review of the literature, the Notifier has concluded that the original safety assessment remains valid.

8. DETAILED SUMMARY FOR THE DETERMINATION THAT PLANT STEROL ESTERS AT 1.0 g PER 8 FL. OZ. SERVING ARE SAFE FOR USE IN COFFEE BREWED FROM PLANT STEROL ENRICHED GROUND COFFEE.

8.1 Background

As noted above, the Agency had no questions regarding ADM's conclusion that plant sterol esters are safe in a number of different food applications, including health drinks (GRN 000061). Heart Blend Foods LLC considers plant sterol ester-enriched coffee to be a healthy drink, based on its cholesterol-lowering benefit. Coffee is low in fat, carbohydrates and sodium and high in antioxidants, making it an excellent vehicle to deliver plant sterol esters. In fact the American Heart Association allows moderate coffee consumption as part of its heart-healthy diet recommendations.

A plant sterol ester/emulsifier blend will be applied to cooled roasted whole beans then ground, evenly distributing the plant sterol ester throughout the ground coffee. There is little concern about oxidation of the phytosterols during grinding or storage and during consumer preparation the maximum time (2 hours) and temperature (80°C) exposure will result in negligible phytosterol oxide formation (References 10,13,16).

8.2 Consumer preparation and information

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The consumer will be instructed to use 1 or 2 rounded tablespoons of plant sterol enriched coffee (depending upon roast, grind and blend) per 8 fl oz water and use an automatic drip coffee maker equipped with a "permanent" filter (e.g. wire mesh or nylon) or a spunbonded polyester coffee filter.

A typical paper coffee filter will trap the plant sterol esters in the filter and little or none will pass into the filtered coffee beverage. The consumer will be instructed to use a "permanent" type coffee filter (e.g. wire mesh or nylon) or a nonwoven spunbonded polyester coffee filter to allow the extracted plant sterols to pass through the filter and be delivered in the brewed coffee. This requirement serves to help limit the exposure of plant sterol enriched coffee beverage to consumers who actively seek to increase their intake of plant sterols.

The product will be positioned specifically for its cholesterol-lowering benefit. Brand name, brand positioning, premium price, product information and directions for preparation will all serve to inform consumers and increase awareness about the presence of plant sterol esters in the product. The requirement to use a wire mesh filter will limit consumption predominately to home brewed coffee because wire mesh filters are not commonly used in commercial food service operations. Thus the exposure assessment will focus on coffee brewed at home.

The following additional statements will be included in product literature and on the website: "Each serving of Heart Blend ™ Coffee provides 0.65g g of plant sterol esters. Should be used in moderation as part of a heart healthy diet, low in fat, saturated fat,

cholesterol, sodium and high in fruits and vegetables." The product is not intended for use by children or pregnant or lactating woman except on the advice of a physician."

The following health claim will appear on the label of Heart Blend™ plant sterol ester enriched coffee "Plant Sterols and Heart Disease" "Foods containing at least 0.65g per serving of plant sterols, consumed with meals for a daily total intake of at least 1.3g, as part of diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of Heart Blend™plant sterol ester enriched coffee contains at least 0.65g of plant sterols per serving."

8.3 Exposure Assessment

Heart Blend Foods contracted with Exponent to conduct an independent assessment of potential intake of plant sterols from home brewed coffee and to calculate total dietary exposure based on EDI's previously not objected to by the FDA. Exponent's assessment is attached in Appendix 10.4

8.3.1 Dietary Intake Assessment Method

Exponent estimated the potential dietary intake of plant sterols from home brewed coffee using Exponent's Foods and Residue Evaluation Program (FARE™) version 7.79, and food consumption data from the United States Department of Agriculture's (USDA) Continuing Survey of Food Intakes by Individuals (CSFII). The CSFII consumption data used were collected from 1994 through 1996 and 1998 for the Supplemental Children's Survey data (USDA, 1995, 1996, 1998). Because the target foods for enrichment were from home use only, we used the eating locations reported in the CSFII survey to estimate intakes from coffee brewed at home only ("Eaten at home" and "Taken from home but eaten away [e.g. brown-bag lunch]").

Provided the ingredient/contaminant of interest does not have the potential to cause acute toxicity or teratogenic effects, it is appropriate to average exposures over a longer period than one day. Therefore, Exponent used each respondent's food consumption averaged over the two days of the CSFII survey. For example, if someone reported consuming 100 grams of bread on day 1 and 150 grams of bread on day 2, his/her 2-day average bread consumption would be 125 grams ([100+150]/2). A two-day average frequently overestimates long-term (chronic) intake; however, only two nonconsecutive days' worth of food consumption data are available in the most recent CSFII survey database. Although the 1989-91 CSFII included food consumption diaries on three nonconsecutive days, which might better support estimation of chronic daily intake, Exponent believes that rapidly evolving trends in diet and the pace of introduction of new foods call into question the representativeness of the older data for today's consumers. Although more recent survey data are available (NHANES 1999-2002), they are limited to only a single day of food consumption. Exponent therefore uses the 1994-96, 1998 CSFII data in our assessments.

8.3.2 Existing GRAS uses of plant sterols

FDA had no questions concerning two GRAS notices for the use of plant sterols in seven broad food groups (GRN000061 and GRN 000112). These GRAS food uses are summarized in Table 1. In general, all of the food uses proposed in the first notice (GRN000061) were also included in the second notice (GRN 000112).

Table 1. Summary of Approved and Proposed Food Uses of Sterols

	Prior GRAS notices	**Proposed**
GRN000061 (ADM)	**GRN 000112 (Phoenix/Teriaka)**	**Heart Blend Foods**
spreads	margarine and vegetable based spreads	
yogurt type products	milk-based juice beverages	
health drinks	ice cream & non standardized ice cream products	
	cream cheese and cream cheese like products	
health bars	snack bars/health bars	
dressings for salads	mayonnaise, salad dressings	
vegetable oil spreads		
	white breads-rolls-buns and comparable nonstandardized white bread products	
		ground coffee for brewing

8.3.3 Food selection and plant sterol enrichment

The focus of the current analysis is home brewed coffees only, therefore cappuccino, instant coffee and Mexican coffees were excluded (see list of foods below for foods included in analysis). Two use rates of plant sterol esters were proposed; 0.85 g sterol esters per 8 oz of coffee (as consumed) and 1.0 g sterol esters per 8 oz of coffee (as consumed). The two previous GRAS notifications were expressed on a "plant sterols" basis; therefore, the proposed enrichment of coffee with plant sterol esters was converted to a "plant sterols" basis to be consistent with prior intake assessments. In order to convert enrichment levels to "plant sterols" we assumed that plant sterol esters are composed of 60% plant sterols resulting in 0.5 g sterols per 8 oz of coffee and 0.6 g sterols per 8 oz of coffee.

$$\frac{0.85\ g\ sterol\ esters}{8\ oz\ coffee} \times \frac{60\ g\ sterols}{100\ g\ sterol\ esters} = \frac{0.5\ g\ sterols}{8\ oz\ coffee}$$

8.3.4Estimated Daily Intake

The estimated daily intakes (EDI) of sterols from the previous GRAS notifications are summarized in Table 2. The most recent notification submitted by Phoenix/Teriaka (GRN 00012) demonstrated that enrichment of 7 food groups with plant sterols at a rate of 0.75 g/serving resulted in per capita mean consumption of 1.6 g/day at the mean (3.6 g/day at the 90th percentile). The FDA noted that "...the per capita intake estimated by Teriaka is comparable to the 'eaters only' intake estimated by FDA" indicating that nearly

everyone in the US population consumed at least one of the foods selected for fortification by Teriaka (i.e 100% consumers).

Table 2. Existing approved uses and Sterol Consumption in the US

	Prior GRAS notices	
	GRN000061 (ADM)	**GRN 000112 (Phoenix/Teriaka)**
Fortification level	1.65 g/serving (1 g sterol equivalent/serving)	0.75 g sterols/serving
EDI (mean)	5.5 g/day (users)	1.6 g/day (per capita)[1]
90th percentile	10.6 g/day (users)	3.6 g/day (per capita)

[1] FDA noted in GRN , "...the per capita intake estimated by Teriaka is comparable to the 'eaters only' intake estimated by FDA"

The current analysis was conducted using two fortification levels (0.5 g and 0.6 g of plant sterols per serving of coffee) for the US population on a per capita and per user basis. Only 30% of the US population reported consuming brewed coffee that was eaten at home or taken from home but eaten away as compared to 38% of the population who reported consuming these same beverages from any location. This indicates that the majority of consumers of the selected foods eat them at home.

The lower plant sterol enrichment level resulted in per user intakes of 1.1 g/day at the mean and 2.1 g/day at the 90th percentile. A small increase in enrichment level to 0.6 g plant sterols per serving of home brewed coffee resulted in 1.4 g/day at the mean and 2.5 g/day at the 90th percentile (users only).

Table 3. Average daily sterol[1] consumption from home brewed[2] coffee US population

Use Level for Coffee		Mean (g/day)	90th Percentile (g/day)	Unweighted N	% Consumers in the US
0.5 g PS/serv[2]	**Per Capita**	0.33	1.1	4182	30%
	Per User	1.1	2.1		
0.6 g PS/serv	**Per Capita**	0.40	1.3		
	Per User	1.4	2.5		

[1] Enrichment of coffee was proposed at two levels, 0.85 g sterol esters per 8 oz. of coffee and 1.0 g of sterol esters per 8 oz of coffee. Assuming that plant sterols contain 60% plant sterol esters, these two fortification levels are equivalent to 0.5 g plant sterols and 0.6 g plant sterols per 8 oz of coffee.
[2] CSFII Reported Consumption Locations include "Eaten at home" and "Taken from home but eaten away (e.g. brown-bag lunch)"

The details of the most recent GRAS notification submitted by Phoenix/Teriaka (GRN 000112) were not available at the time of this report; therefore total exposure to plant sterols based on current and proposed uses can only be estimated. Given that nearly everyone in the US population reported consuming at least one of the foods in the GRN 000112 submission, and only 30% of the US population reported consuming a home

brewed coffee in the CSFII survey, a conservative approach would be to assume that consumers of the foods included in GRN 000112 also drink home brewed coffee containing plant sterols. A conservative estimate of exposure for users would be to sum 2.5 g plant sterols/day (90th percentile from home brewed coffee) and the 3.6 g/day user 90th percentile exposure from GRN 000112, resulting in approximately 6.1 g plant sterols per day for the highly exposed consumer.

8.3.5 Children and Teenagers

Heart Blend Foods LLC has estimated intake of coffee by children and teenagers based on estimates of food intake contained in the USDA NFS Report No. 96-5 "Foods Commonly Eaten in the United States"- Quantities Consumed per Eating Occasion and in a Day, 1994-96 by Helen Smiciklas- Wright et al. 2002. The pertinent tables are included in Appendix 10.5.

The mean consumption of coffee by children 2-5 years of age is about 0.33 servings of coffee per day (80g/d) and is not consumed on a daily basis. Therefore consumption of plant sterol esters from coffee for children would be negligible. Teens consume about 1.5 servings of coffee per day but are not concerned about blood cholesterol levels and would be very unlikely consumers of this product

8.4 Acceptable Daily Intake (ADI)

Heart Blend Foods notes that an acceptable daily intake (ADI) of 130 milligrams/kilogram/day (as the free sterol) was set by Lipton's GRAS panel for vegetable oil sterol esters and not objected to by the FDA. Since the target consumer for plant sterol enriched coffee is mature adults, Heart Blend Foods believes an ADI of 9.1 grams per day (as the free sterol) for a 70 kg person is appropriate.

8.5 Conclusion

Since the EDI for highly exposed consumers is less than the ADI for adults and children's intake from coffee is negligible, Heart Blend Foods LLC has concluded that plant sterol esters are GRAS for use in home brewed coffee at a level of 1.0g per 8 fl. oz. serving. The consumer exposure assessment conducted by Exponent and the previously referenced GRAS Notifications not objected to by FDA support this conclusion.

9. REFERENCES

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Appendix 10.1

U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000048

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

November 27, 2000

Steven D. McCurry, Ph.D.
Cargill Incorporated
15407 McGinty Road West, MS110
Wayzata, MN, 55391-2399

Re: GRAS Notice No. GRN 000048

Dear Dr. McCurry.

The Food and Drug Administration (FDA) is responding to the notice, dated June 1, 2000, that you submitted 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)). FDA received the notice on June 2, 2000 and designated it as GRAS Notice No. GRN 000048. In a letter of October 24, 2000, you provided additional clarifying information.

The subject of your notice is vegetable oil phytosterol esters. The notice informs FDA of the view of Cargill Incorporated (Cargill) that vegetable oil phytosterol esters are GRAS, through scientific procedures, for use as an ingredient in vegetable oil spreads, dressings for salads, bars, and yogurt.

The main sterol components of the ingredient vegetable oil phytosterol esters are beta-sitosterol, campesterol, and stigmasterol. These components of vegetable oil phytosterol esters already are present as ingredients in other vegetable oil based spreads, dressings for salads, bars, and yogurt that have a similar intended use. Your notice describes the manufacturing process for vegetable oil phytosterol esters, in which sterols are esterified with vegetable oil fatty acids. The sterols are mostly derived from soy The fatty acids are derived from soy, canola, sunflower or other vegetable oils. After the esterification reaction, adsorbents are used to remove trace components and color bodies, and the ingredient is subjected to vacuum stripping and filtration. Your notice includes food grade specifications for vegetable oil phytosterol esters, including a specification for lead of less than 0.1 milligrams/kilogram.

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Your notice describes a series of published studies conducted with free phtytosterols, vegetable oil sterol esters, or plant stanol esters. In general, you rely on the similarity of vegetable oil phytosterol esters to the test articles in these published studies to determine that these studies establish the safety of vegetable oil phytosterol esters. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, you commit to notify the agency if additional relevant information (i.e., changes in exposure, adverse events, or new scientific data) becomes known with respect to the safety of vegetable oil phytosterol esters.

Cargill views the ingredient vegetable oil phytosterol esters as an additional ingredient choice for manufacturers of currently marketed products that contain an enhanced level of phytosterol esters. For this reason, Cargill considers that the marketing of its ingredient would not change the cumulative dietary intake of phytosterol esters compared to what already is marketed.

Your notice includes the findings of a panel of individuals (Cargill's GRAS panel) who evaluated the data and information that are the basis for Cargill's GRAS determination. Cargill considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. The clarifying information that you provided in your letter of October 24, 2000, included an addendum to the report of this GRAS panel.

In its original report, Cargill's GRAS panel concludes that the composition of vegetable oil phytosterol esters is equivalent to that of another marketed ingredient (i.e., vegetable oil sterol esters, also known as plant sterol esters), which was the subject of a previous submission to FDA.[1] Cargill's GRAS panel reported that FDA had evaluated vegetable oil sterol esters for use in vegetable oil spreads, dressings for salads, bars, and yogurt. However, as you discussed by telephone in July, 2000, with Dr. Linda Kahl of the Office of Premarket Approval, FDA's evaluation of the intended use of vegetable oil sterol esters was limited to its use in vegetable oil spreads (Ref. 1) FDA's evaluation of the intended use of two related ingredients (i.e., plant stanol esters and tall oil phytosterols)[2] likewise was limited to their use in spreads (Refs. 2 and 3). Thus, at the time that you submitted your GRAS notice, FDA had only evaluated dietary exposure to plant sterol and stanol esters from their consumption in spread. This consumption would be approximately 3 grams of plant sterols or plant stanols per person per day (which is equivalent to approximately 5 grams of plant sterol esters or plant stanol esters per person per day). At that time, FDA had not evaluated the implications, if any, of the cumulative dietary exposure to plant sterol esters or plant stanol esters as a result of their use in food products such as dressings for salads, bars, and yogurt.

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Your October 24 letter acknowledges that FDA's previous evaluation of the use of plant sterols and stanols, in free or esterified form, was limited to the use of these ingredients in spreads. Your October 24 letter also discusses an interim final rule that FDA issued, after FDA received your notice, to authorize a health claim for plant sterol/stanol esters (65 FR 54685; September 8, 2000). FDA authorized this health claim for plant sterol esters when used in spreads and dressings for salads, and for plant stanol esters when used in spreads, dressings for salads, and snack bars. In this interim final rule, FDA acknowledged receipt and consideration of information regarding the use of plant sterol esters and plant stanol esters in a broader array of food categories than spread. FDA also concluded that the health claim petitioners had met the burden to demonstrate, to FDA's satisfaction, that the use of plant sterol esters and plant stanol esters in this broader array of food categories is safe and lawful. In your view, the interim final rule makes clear that the primary source of data and information that FDA relied on in reaching this conclusion was the data and information that FDA evaluated regarding the use of these ingredients in spreads. Likewise, Cargill's GRAS panel primarily relied on data and information that supported the use of these ingredients in spreads. Thus, it is Cargill's view that the original report of its GRAS panel is consistent with the views expressed by FDA in the interim final rule authorizing a health claim.

Based on the information provided by Cargill, as well as other information available to FDA, the agency has no questions at this time regarding Cargill's conclusion that vegetable oil phytosterol esters are 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 vegetable oil phytosterol esters. As always, it is the continuing responsibility of Cargill 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 Office of Premarket Approval's homepage on the Internet (at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.

2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.

3. Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

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[1]In a submission dated January 11, 1999, Lipton informed FDA of its view that vegetable oil sterol esters are GRAS for use in spreads at a level up to 20 per cent.

[2]In a submission dated February 18, 1999, McNeil Consumer Healthcare informed FDA of its view that plant stanol esters are GRAS for use in spreads at a level of 1.7 grams of plant stanol esters per serving of spread. In a GRAS Notice dated January 28, 2000 (GRN No. 000039), Novartis Consumer Health, Inc. informed FDA of its view that tall oil phytosterols are GRAS for use in spreads at a level of up to 12 percent.

U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000053

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

December 20, 2000

Maury M. Bandurraga, Ph.D.
The Procter & Gamble Company
Winton Hill Technical Center
6071 Center Hill Avenue
Cincinnati, OH 45224

Re: GRAS Notice No. GRN 000053

Dear Dr. Bandurraga:

The Food and Drug Administration (FDA) is responding to the notice, dated July 17, 2000, that you submitted 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)). FDA received the notice on July 24, 2000 and designated it as GRAS Notice No. GRN 000053.

The subject of your notice is phytosterol esters. The notice informs FDA of the view of The Procter & Gamble Company (P&G) that phytosterol esters are GRAS, through scientific procedures, for use as an ingredient in vegetable oil, at a level up to 13.3 per cent by weight, for home use applications such as baking, frying, and salad dressings.

You obtain the phytosterol esters from Cargill, who submitted a GRAS notice for its ingredient in June, 2000 (GRN 000048). Your notice describes the identity and composition of the ingredient produced by Cargill. Your notice includes food grade specifications for phytosterol esters, including a specification for lead of less than 0.1 milligrams/kilogram.

000021

The major components of phytosterol esters are beta-sitosterol, campesterol, and stigmasterol. These components already are present in currently marketed ingredients. These products include "vegetable oil sterol esters," which are marketed by Lipton in Take Control™ brand spread, "plant stanol esters," which are marketed by McNeil Consumer Healthcare in Benecol™ brand spread, and "tall oil phytosterols" which are marketed by Novartis Consumer Health, Inc. in Phytrol™ brand spread. FDA had previously evaluated these ingredients when consumed in spread (Refs. 1

through 3). Consumption would be approximately 3 grams of plant sterols or plant stanols per person per day (which is equivalent to approximately 5 grams of plant sterol esters or plant stanol esters per person per day) when following specific label directions recommending consumption of multiple servings per day of the spread. You estimate that the expected additional consumption of phytosterol esters, at the 90th percentile level, from your proposed use in vegetable oil would range from approximately 750 milligrams per person per day to approximately 2100 milligrams per person per day.

Your notice describes an unpublished study demonstrating the stability of phytosterols during typical home cooking conditions. You conclude that no significant new oxidized species were formed by heating the vegetable oil containing phytosterol esters compared to standard vegetable oil. Your notice also describes a series of published studies conducted with free phytosterol, vegetable oil sterol esters, plant stanol esters, or tall oil phytosterols. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, you mention that P&G plans, as for any new product, to conduct the firm's usual post-market evaluation of consumer acceptance and use for this new product and to share with FDA any information on product usage and exposure that materially changes the GRAS determination presented in your notice.

Your notice includes the findings of a panel of individuals (P&G's GRAS panel) who evaluated the data and information that are the basis for P&G's GRAS determination. P&G considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. In its report, P&G's GRAS panel concludes that the composition of the ingredient that P&G would add to vegetable oil is equivalent to the ingredient "vegetable oil sterol esters" that is marketed by Lipton in its Take Control™ brand of vegetable spread. In its report, P&G's GRAS panel considered additional phytosterol intake from the consumption of P&G's vegetable oil product compared to the consumption of phytosterol esters contained in currently available spreads and assessed phytosterol stability during typical home cooking conditions.

Based on the information provided by P&G, as well as other information available to FDA, the agency has no questions at this time regarding P&G's conclusion that phytosterol esters are 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 phytosterol esters. As always, it is P&G's continuing responsibility to ensure that food ingredients that P&G 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 Office of Premarket Approval's homepage on the Internet (at http://vm.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.

000022

2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.

Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

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Content last updated by saw/pmg on 2001-JAN-5
Hypertext last updated by saw/pmg on 2001-JAN-5

000023

U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000061

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

April 18, 2001

Mark W. Empie, Ph.D.
Vice President Regulatory and Scientific Affairs
Archer Daniels Midland Company
1001 North Brush College Road
Decatur, IL 62521

Re: GRAS Notice No. GRN 000061

Dear Dr. Empie:

The Food and Drug Administration (FDA) is responding to the notice, dated November 22, 2000, that you submitted on behalf of Archer Daniels Midland (ADM) 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)). FDA received the notice on November 27, 2000 and designated it as GRAS Notice No. GRN 000061. In a letter of February 28, 2001, you provided additional clarifying information.

The subjects of the notice are plant sterols and plant sterol esters. The notice informs FDA of the view of ADM that plant sterols are GRAS, through scientific procedures, for use as an ingredient[1] in vegetable oil spreads, dressings for salad, health drinks, health bars, and yogurt-type products at a level of 1 gram per serving, and as a raw material in the manufacture of plant sterol esters for use as an ingredient in the same foods at a level of 1.65 grams (i.e., 1 gram sterol equivalent) per serving. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, ADM commits to provide production and sale data, for the purpose of monitoring usage of plant sterols and plant sterol esters, if FDA requests such data in the future.

000024

The main sterol components of the ingredients plant sterols and plant sterol esters are beta-sitosterol, campesterol, and stigmasterol. ADM describes the manufacturing processes for plant sterols and plant sterol esters, in which the plant sterols are esterified with vegetable oil fatty acids. The sterols are derived from oil seeds such as corn, palm, soy, rape and sunflower. The fatty acids are preferentially derived from soy, sunflower, safflower, and canola; but corn, peanut, cottonseed and palm may also be used as sources. ADM's notice includes food grade specifications for plant sterols and

plant sterol esters, including a specification for lead of less than 0.1 parts per million.

ADM intends to provide to its customers plant sterols and plant sterol esters for incorporation into spreads, dressings for salad, yogurt-type products, health drinks, and health bars. ADM estimates that a total daily consumption of plant sterols for an individual who would consume all the listed products and conventional food sources of plant sterols (i.e., 0.25 grams of phytosterols per day) would be up to 5.5 grams at the mean level and up to 10.6 grams at the 90th percentile level.

ADM considers that the ingredients plant sterols and plant sterol esters are similar to the ingredient vegetable oil sterol esters, which is marketed by Lipton and which FDA previously evaluated for use in vegetable oil based spreads (Ref. 1). In ADM's view, Lipton's submission of January 11, 1999, presents a thorough evaluation of the available literature. This literature was evaluated by a panel of individuals (Lipton's GRAS panel) whom Lipton considered qualified by scientific training and experience to evaluate the safety of substances added to food. ADM notes that several relevant studies that were not publicly available at the time of Lipton's submission have now been published. Because the publicly available information draws on studies that included both sterol esters and free sterols, ADM concludes that this literature supports the safety of both of its ingredients.(2)

ADM notes that Lipton's GRAS panel set an acceptable daily intake (ADI) for vegetable oil sterol esters of 130 milligrams/kilogram/day (as the free phytosterol), equivalent to 9.1 grams per day for a 70 kg person. ADM discusses the rationale that Lipton's GRAS panel used to set this ADI.

ADM notes that its own estimated daily intake (i.e., 10.6 grams per day at the 90th percentile level) exceeds the ADI set by Lipton's GRAS panel by 16 percent. ADM discusses the rationale for its own conclusion that dietary exposure to plant sterols and plant sterol esters from ADM's proposed uses remains within a safe range. To a large extent, ADM relies on consumers' previous exposure to a drug product (i.e., *Cytellin*) marketed by Eli Lilly as a treatment for hypercholesterolemia during the 1950's to 1980's. The primary component of *Cytellin* (beta-sitosterol) was the same as the primary component of plant sterols. More than 1800 people participated in clinical studies conducted with *Cytellin* to assess effects on blood cholesterol levels, with no reported adverse effects. Individuals who used the marketed drug typically consumed dosages ranging from 9 to 30 grams per day. More recently, plant sterols as the esters have been the subject of additional studies and there has been general consumption in the United States. For all of these reasons, ADM considers that the ADI set by Lipton's GRAS panel is a conservative number.

Based on the information provided by ADM, as well as other information available to FDA, the agency has no questions at this time regarding ADM's conclusion that the ingredients plant sterols and plant sterol esters are 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 plant sterols or plant sterols esters. As always, it is the continuing responsibility of ADM 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 Office of Premarket Approval's homepage on the Internet (at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

000025

References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.

2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.

3. Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

4. Letter dated November 27, 2000, from Alan Rulis of FDA to Steven D. McCurry.

5. Letter dated December 20, 2000, from Alan Rulis of FDA to Maury M. Bandurraga.

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(1)In describing the intended use of plant sterols and plant sterol esters, ADM asserts that plant sterols contribute nutritive value. ADM's assertion raises an issue under section 403(r) of the Federal Food, Drug, and Cosmetic Act, which lays out the statutory framework for a health claim. Under 21 CFR 101.14(b)(3)(i), the substance that is the subject of a health claim must contribute taste, aroma, or nutritive value, or any other technical effect listed in 21 CFR 170.3(o), to the food and must retain that attribute when consumed at the levels that are necessary to justify a claim. Whether plant sterols and plant sterol esters contribute nutritive value within the meaning of 21 CFR 101.14(b)(3)(i) is the purview of the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) in FDA's Center for Food Safety and Applied Nutrition. The Office of Premarket Approval neither consulted with ONPLDS on this labeling issue nor evaluated the information in ADM's notice to determine whether it would support ADM's view that plant sterols and plant sterol esters contribute nutritive value.

(2)FDA has evaluated the data and information supporting the safety of similar ingredients when consumed in vegetable oil based spread and additional product categories, including dressings for salads, bars, yogurt, or vegetable oils for home use applications such as baking, frying, and salad dressings (Refs. 2-5).

Content last updated by lsk on 2001-APR-24
Hypertext last updated by lsk on 2001-APR-24

000026

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
February 4, 2003

Agency Response Letter
GRAS Notice No. GRN 000112

C. K. Gund, Ph.D.
Phoenix Regulatory Associates
21525 Ridgetop Circle, Suite 240
Sterling, VA 20166

Re: GRAS Notice No. GRN 000112

Dear Dr. Gund:

The Food and Drug Administration (FDA) is responding to the notice, dated August 15, 2002, that you submitted on behalf of Teriaka Ltd. (Teriaka) 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 August 19, 2002, filed it on August 19, 2002, and designated it as GRAS Notice No. GRN 000112.

The subject of the notice is phytosterols. The phytosterols would be added to food as a component of a fatty mixture (either a vegetable fat mixture, a vegetable oil mixture, or an anhydrous milk fat mixture). The notice informs FDA of the view of Teriaka that phytosterols are GRAS, through scientific procedures, for use as an ingredient in margarine and vegetable-based spreads (margarine-like); yogurt and yogurt-like products; milk-based juice beverages; ice cream and non-standardized ice cream products; cream cheese and cream cheese-like products; snack bars (health bars); salad dressing, mayonnaise, French dressing, and dressings for salads; and white breads, white rolls and buns, and comparable non-standardized white bread products.

Teriaka describes the products it manufactures containing phytosterols as vegetable fat mixtures with phytosterols, vegetable oil mixtures with phytosterols, or anhydrous milk fat mixtures with phytosterols, depending on the fat used to produce the sterol-enriched ingredient. The phytosterols that Teriaka uses are either from vegetable oils (soybean, cottonseed, corn, sunflower seed, canola, or peanut) or tall oil extracted from pine trees (*Pinus pinaster* and *Pinus syvestris*). Teriaka notes that the vegetable oil phytosterols that it processes into a fatty mixture are the subject of a previous GRAS notice, i.e., GRN 000061 Teriaka notes that the tall oil phytosterols that it processes into a fatty mixture predominantly contain beta-sitosterol, beta-sitostanol, campesterol, and campestanol and compares the composition of these tall oil phytosterols with that of the tall oil phytosterols that are the subject of a previous GRAS notice, i.e., GRN 000039.

000027

Teriaka describes the manufacture of the tall oil phytosterols that it processes into a fatty mixture. Phytosterols are produced from raw tall oil pitch, which is produced from pine trees as a by-product of the kraft pulping process and is composed of the neutral non-lignin, non-cellulosic portion of the pine

trees. The raw tall oil pitch is distilled to give fatty acids, rosin acids, and tall oil pitch. The tall oil pitch is then extracted with alcohol and heated to give primary phytosterol crystals. After cooling, these crystals are washed with water and filtered to separate them from the tall oil residues. The phytosterols are recrystallized, filtered, dried under vacuum, and then milled and sieved to obtain the required crystal size. Teriaka provides specifications for the tall oil phytosterols and for the fatty mixtures that contain phytosterols. Teriaka estimates that per capita intake of phytosterols from use in fatty mixtures would be 1.6 grams per person per day (g/p/d) at the mean and 3.6 g/p/d at the 90th percentile.(1)

In its notice, Teriaka discusses published studies addressing the safety of acute, sub-chronic, and chronic intakes of phytosterols and the potential for genotoxic, reproductive, or developmental effects of phytosterols. Teriaka also discusses published studies addressing the metabolism of plant sterols in animals, the effect of phytosterols on sex hormones in animals and humans, the effect of phytosterols on fat soluble vitamins and carotenoids, and the safety of the cumulative intake of plant sterols. Teriaka notes that most of these studies were discussed in previous GRAS notices and Food Master Files submitted to FDA by other manufacturers (i.e., GRN 000039, GRN 000048, GRN 000053, GRN 000061, FMF 000625, and FMF 000626). Teriaka concludes that its ingredients containing either vegetable or tall oil phytosterols are safe for their intended use.

Based on the information provided by Teriaka, as well as other information available to FDA, the agency has no questions at this time regarding Teriaka's conclusion that phytosterols added as a component of a fatty mixture are GRAS under the conditions of their intended use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of phytosterols. As always, it is the continuing responsibility of Teriaka to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In the notice, Teriaka states its intention to use phytosterols in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. 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. If you have any questions about the use of phytosterols in standardized foods that would be marketed in the United States, you should contact the staff in Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS), Division of Standards and Labeling Regulations, HFS-820, 5100 Paint Branch Parkway, College Park, MD 20740. You can reach this division by telephone at (301) 436-2375. The Office of Food Additive Safety (OFAS) neither consulted with ONPLDS on the use of phytosterols in standardized foods nor evaluated the information in your notice to determine whether your use of phytosterols is permitted by the applicable standards of identity.

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).

Sincerely,

Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

000028

[1]FDA normally considers exposure to an ingredient only for eaters of foods containing the ingredient. For these phytosterols, the per capita intake estimated by Teriaka is comparable to the "eaters only" intake estimated by FDA.

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Content last updated by amd/pmg on 2002-MAR-12
Hypertext updated by amd/rxm/pmg on 2002-MAR-19

000029

Appendix 10.2

CardioAid™-S

ADM product code 040087
Technical Data Sheet

DESCRIPTION:

CardioAid™-S is a creamy white to pale yellow paste having a bland flavor and odor. CardioAid™-S is produced by esterifying vegetable oil sterols with food grade rapeseed oil fatty acids. Sterol esters are structurally similar to cholesterol. In studies, phytosterol esters have been found to reduce the absorption of dietary cholesterol which can impact serum cholesterol levels. [J. of Nutr., 107:1139-1146 (1977); Can. J. Physiol. Pharmacol., 75:217-227(1997)]. CardioAid™-S is GRAS (Generally Recognized As Safe) for use in vegetable oil spreads, dressings for salad, health drinks, health bars, and yogurt-type products. The FDA has allowed the following health claim, for products containing CardioAid™-S, ***"Foods containing at least 0.65 grams per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ____ grams of plant sterol esters."*** CardioAid™-S can be formulated into cosmetics such as skin creams, lipsticks, soap and hair care products.

Typical Chemical and Physical Properties

Appearance:	Creamy white to pale yellow solid
Flavor and Odor	Bland
Melting Range	25-30° C
Total sterols	56% minimum
Beta-sitosterol (% of total sterols)	80% maximum
Beta-sitostanol (% of total sterols)	15% maximum
Campesterol (% of total sterols)	40% maximum
Campestanol (% of total sterols)	5% maximum
Stigmasterol (% of total sterols)	30% maximum
Brassicasterol (% a of total sterols)	3% maximum
Other sterols and stanol s (% of total sterols)	3% maximum
Cholesterol, (% of total sterols)	Max. 1.0%
Acid value	Max. 1.0 mg KOH/g
Peroxide value	Max. 5.0 meq/kg
Moisture	Max. 0.1%

Status

CardioAid™-S is kosher and pareve.

Storage and Shelf-Life

CardioAid™-S can be stored refrigerated for a maximum of 6 months.
CardioAid™-S can be stored frozen for a maximum of 12 months.

Packaging

10 kg pail	(ADM Code 040087-5P)
190 kg drum	(ADM Code 040087-5K)

CS-002-040316

RUN-DATE: 04/25/05
RUN-TIME: 08:16:27

M PROCESSING - NUTRACEUTICALS
3700 EAST DIVISION

DECATUR IL 62526

****
*** ARCHER DANIELS MIDLAND ***
*** CERTIFICATE ***
*** OF ANALYSIS ***
****

** SHIPTO **
767741 HEARTBLEND FOODS
14 SILVERS LN
CRANBURY NJ

* CUSTOMER PO# VERBAL BILL ADM ORDNO # 113096 *INVOICE # 113096 1034
PRODUCT CD: 040087 CUSTOMER PRODUCT CD:
PRODUCT DESC:CARDIOAID-S
LOTNO: PER0205500 TEST DATE: 02/24/05 DATE OF EXPIRY: 02/24/06
SHIP DATE: 04/25/05 CARNO:
SHIP FROM: DECATUR ,IL
MANUFACTURE DATE: 02/24/05
QTY 1 NET WEIGHT 10.000 K
CONTAINER CD: 6G 10KG PL

*

TEST	ASSAY RESULTS			
LAB NUMBER	022B5			
TOTAL STEROLS (TS)	59.2	%		
CHOLESTEROL (%TS)	0.4	%		
BRASSICASTEROL (%TS)	2.4	%		
CAMPESTEROL (%TS)	26.3	%		
CAMPESTANOL (%TS)	1.1	%		
STIGMASTEROL (%TS)	18.3	%		
SITOSTEROL (%TS)	44.1	%		
SITOSTANOL (%TS)	3.9	%		
OTHER STEROLS (%TS)	3.4	%		
ACID VALUE	0.2	MG	KOH/G	
ACIDITY	0.04	ML	0.1N	NAOH
PEROXIDE VALUE	0.0			
MOISTURE %	0.0000			

*
THIS PRODUCT IS TESTED PERIODICALLY TO ENSURE IT MEETS THE FOLLOWING CRITERIA:
HEAVY METALS < 10 PPM, LEAD < 2 PPM
OVI CONTENT COMPLIES WITH USP STANDARDS
*
COUNTRY OF ORIGIN: USA

CHRIS SCHUETTE

QC MANAGER

000031

Appendix 10.4

Exponent®

EXTERNAL MEMORANDUM

TO: Bill Franke
FROM: Kim Smith
DATE: June 27, 2005
PROJECT: Sterols-Home Brewed Coffee
SUBJECT: Preliminary Results

Dietary Intake Assessment: Methods

Exponent estimated the potential dietary intake of plant sterols from home brewed coffee using Exponent's Foods and Residue Evaluation Program (FARE™) version 7.79, and food consumption data from the United States Department of Agriculture's (USDA) Continuing Survey of Food Intakes by Individuals (CSFII). The CSFII consumption data used were collected from 1994 through 1996 and 1998 for the Supplemental Children's Survey data (USDA, 1995, 1996, 1998). Because the target foods for enrichment were from home use only, we used the eating locations reported in the CSFII survey to estimate intakes from coffee brewed at home only ("Eaten at home" and "Taken from home but eaten away [e.g. brown-bag lunch]").

Provided the ingredient/contaminant of interest does not have the potential to cause acute toxicity or teratogenic effects, it is appropriate to average exposures over a longer period than one day. Therefore, Exponent used each respondent's food consumption averaged over the two days of the CSFII survey. For example, if someone reported consuming 100 grams of bread on day 1 and 150 grams of bread on day 2, his/her 2-day average bread consumption would be 125 grams ([100+150]/2). A two-day average frequently overestimates long-term (chronic) intake; however, only two nonconsecutive days' worth of food consumption data are available in the most recent CSFII survey database. Although the 1989-91 CSFII included food consumption

diaries on three nonconsecutive days, which might better support estimation of chronic daily intake, Exponent believes that rapidly evolving trends in diet and the pace of introduction of new foods call into question the representativeness of the older data for today's consumers. Although more recent survey data are available (NHANES 1999-2002), they are limited to only a single day of food consumption. Exponent therefore uses the 1994-96, 1998 CSFII data in our assessments.

Existing GRAS uses of plant sterols

FDA had no questions concerning two GRAS notices for the use of plant sterols in seven broad food groups (GRN000061 and GRN 000112). These GRAS food uses are summarized in Table 1. In general, all of the food uses proposed in the first notice (GRN000061) were also included in the second notice (GRN 000112).

Table 1. Summary of Approved and Proposed Food Uses of Sterols

	Prior GRAS notices	Proposed
GRN000061 (ADM)	GRN 000112 (Phoenix/Teriaka)	Franke
spreads	margarine and vegetable based spreads	
yogurt type products	milk-based juice beverages	
health drinks	ice cream & non standardized ice cream products	
	cream cheese and cream cheese like products	
health bars	snack bars/health bars	
dressings for salads	mayonnaise, salad dressings	
vegetable oil spreads		
	white breads-rolls-buns and comparable nonstandardized white bread products	
		ground coffee for brewing

Food selection and plant sterol enrichment

The focus of the current analysis is home brewed coffees only, therefore cappuccino, instant coffee and Mexican coffees were excluded (see list of foods below for foods included in analysis). Two use rates of plant sterol esters were proposed; 0.85 g sterol esters per 8 oz of coffee (as consumed) and 1.0 g sterol esters per 8 oz of coffee (as consumed). The two previous GRAS notifications were expressed on a "plant sterols" basis; therefore, the proposed enrichment of coffee with plant sterol esters was converted to a "plant sterols" basis to be

consistent with prior intake assessments. In order to convert enrichment levels to "plant sterols" we assumed that plant sterol esters are composed of 60% plant sterols resulting in 0.5 g sterols per 8 oz of coffee and 0.6 g sterols per 8 oz of coffee.

$$\frac{0.85\ g\ sterol\ esters}{8\ oz\ coffee} \times \frac{60\ g\ sterols}{100\ g\ sterol\ esters} = \frac{0.5\ g\ sterols}{8\ oz\ coffee}$$

Results

The estimated daily intakes (EDI) of sterols from the previous GRAS notifications are summarized in Table 2. The most recent notification submitted by Phoenix/Teriaka (GRN 00012) demonstrated that enrichment of 7 food groups with plant sterols at a rate of 0.75 g/serving resulted in per capita mean consumption of 1.6 g/day at the mean (3.6 g/day at the 90th percentile). The FDA noted that "...the per capita intake estimated by Teriaka is comparable to the 'eaters only' intake estimated by FDA" indicating that nearly everyone in the US population consumed at least one of the foods selected for fortification by Teriaka (i.e 100% consumers).

Table 2. Existing approved uses and Sterol Consumption in the US

	Prior GRAS notices	
	GRN000061 (ADM)	**GRN 000112 (Phoenix/Teriaka)**
Fortification level	1.65 g/serving (1 g sterol equivalent/serving)	0.75 g sterols/serving
EDI (mean)	5.5 g/day (users)	1.6 g/day (per capita)[1]
90th percentile	10.6 g/day (users)	3.6 g/day (per capita)

[1] FDA noted in GRN , "...the per capita intake estimated by Teriaka is comparable to the 'eaters only' intake estimated by FDA"

The current analysis was conducted using two fortification levels (0.5 g and 0.6 g of plant sterols per serving of coffee) for the US population on a per capita and per user basis. Only 30% of the US population reported consuming brewed coffee which was eaten at home or taken from home but eaten away as compared to 38% of the population who reported consuming these same beverages from any location. This indicates that the majority of consumers of the selected foods eat them at home.

000034

The lower plant sterol enrichment level resulted in per user intakes of 1.1 g/day at the mean and 2.1 g/day at the 90th percentile. A small increase in enrichment level to 0.6 g plant sterols per serving of home brewed coffee resulted in 1.4 g/day at the mean and 2.5 g/day at the 90th percentile (users only).

Table 3. Average daily sterol[1] consumption from home brewed[2] coffee US population

Use Level for Coffee		Mean (g/day)	90th Percentile (g/day)	Unweighted N	% Consumers in the US
0.5 g PS/serv[2]	**Per Capita**	0.33	1.1	4182	30%
	Per User	1.1	2.1		
0.6 g PS/serv	**Per Capita**	0.40	1.3		
	Per User	1.4	2.5		

[1] Enrichment of coffee was proposed at two levels, 0.85 g sterol esters per 8 oz. of coffee and 1.0 g of sterol esters per 8 oz of coffee. Assuming that plant sterols contain 60% plant sterol esters, these two fortification levels are equivalent to 0.5 g plant sterols and 0.6 g plant sterols per 8 oz of coffee.
[2] CSFII Reported Consumption Locations include "Eaten at home" and "Taken from home but eaten away (e.g. brown-bag lunch)"

The details of the most recent GRAS notification submitted by Phoenix/Teriaka (GRN 000112) were not available at the time of this report; therefore total exposure to plant sterols based on current and proposed uses can only be estimated. Given that nearly everyone in the US population reported consuming at least one of the foods in the GRN 000112 submission, and only 30% of the US population reported consuming a home brewed coffee in the CSFII survey, a conservative approach would be to assume that consumers of the foods included in GRN 000112 also drink home brewed coffee containing plant sterols. A conservative estimate of exposure for users would be to sum 2.5 g plant sterols/day (90th percentile from home brewed coffee) and the 3.6 g/day user 90th percentile exposure from GRN 000112, resulting in approximately 6.1 g plant sterols per day for the highly exposed consumer.

USDA CSFII Food Codes Included in Analysis

92100000 COFFEE, NS AS TO TYPE
92100500 COFFEE, REGULAR, NS GROUND/INSTANT
92101000 COFFEE, GROUND
92101500 COFFEE, BREWED, EQUAL PARTS REG & DECAFFEINATED
92101700 COFFEE, MADE FROM GROUND, REGULAR, FLAVORED
92111000 COFFEE, DECAFFEINATED, NS AS TO GROUND OR INSTANT
92111010 COFFEE, DECAFFEINATED, MADE FROM GROUND
92130000 COFFEE, PRE-SWEETENED W/SUGAR, PRE-LIGHTENED
92130010 COFFEE, PRE-LIGHTENED, NO SUGAR
92130020 COFFEE, PRESWEETENED W/ SUGAR
92150000 COFFEE & CHICORY, NS AS TO GROUND OR INSTANT
92152000 COFFEE & CHICORY, MADE FROM GROUND
92153000 COFFEE, REGULAR, W/ CEREAL (INCLUDE W/ BARLEY)
92153100 COFFEE, DECAFFEINATED, W/ CEREAL (INCLUDE W/BARLEY)
92191250 COFFEE, DRY, ACID NEUTRALIZED (INCLUDE KAVA)

Foods Commonly Eaten in the United States

Quantities Consumed Per Eating Occasion and in a Day, 1994-96

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ABSTRACT

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This report contains estimates of food intakes by individuals residing in households in the entire United States. The estimates were based on information obtained from 14,262 non-breast fed individuals ages 2 and above who provided 2 days of dietary intake information in the 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII 1994-96), conducted by the U.S. Department of Agriculture. Food intake data were collected by in-person interviews from 1994 through 1996.

This report includes 2 sets of tables with food intake estimates tabulated by sex and age. Table Set 1 provides estimates for the percentage of persons who consumed 111 foods and food groups and the quantities consumed per eating occasion. Table Set 2 provides estimates for the quantities of 96 foods and food groups eaten per individual in a day.

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Introduction

The purpose of this report is to provide estimates of quantities consumed by users of specified foods during an eating occasion and during a day. Unlike traditional published mean intakes (see appendix C), the data in these tables are based on users of the specified food only rather than on all individuals in the survey - both users and nonusers of the food. Estimates provided are (1) means and percentiles of quantities consumed during an eating occasion and (2) means and percentiles of quantities consumed during a day.

Data such as these are important for many purposes, including development of food guidance programs and education materials, assessments related to food marketing and labeling, food safety exposure assessments, risk assessments, and development of dietary assessment tools. For example, mean and median intakes, as well as distributions of intakes, can be useful in reassessing appropriate serving sizes for dietary guidance. Quantities consumed at the upper percentiles may facilitate risk assessment related to dietary contaminants from particular foods, while distributions of intake may be more useful for microbial risk assessment.

The data are provided in two sets of tables. Set 1 (tables 1.001 to 1.111) provides estimated amounts of foods consumed by users at a single time, while Set 2 (tables 2.001 to 2.096) provides estimated amounts of foods consumed by users on a single day. For both sets of tables, food intake estimates are tabulated for individuals by sex and age.

The report is a result of a collaborative effort by The Pennsylvania State University and the Agricultural Research Service. It is based on data from 14,262 individuals ages 2 and over collected in the 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII), conducted by the U.S. Department of Agriculture (USDA 1998). The survey provides estimates of food intakes by individuals residing in households in a nationally representative sample of the United States.

This report is the latest in a series of reports on the same subject (Pao and Burk 1975, Pao et al. 1982, Krebs-Smith et al. 1997). The first of these provided data on the amounts consumed in a day and per eating occasion, as well as the frequency of consumption, of 49 foods or groups of foods, based on a survey conducted in 1965. The second provided similar data on the frequency and quantities of 200 foods eaten over a 3-day period, based on a survey conducted in 1977-78. Both of these reports were limited in the ability to quantify individual foods consumed as ingredients of mixed foods. The third report (Krebs-Smith et al. 1997) provided data based on a survey conducted in 1989-91. That report benefited from two important methodological advances. First, the mixed foods reported in the survey were disaggregated via recipe files so that the components of these foods could be placed with similar foods whenever preferable. Second, there were advances in the statistical analysis methods and software, which account for the complex

sample and non-response adjustments. These advances resulted in better estimates of population parameters and their variances.

This report provides reasonable comparability to the 1989-91 report despite some methodological differences. These differences include a different distribution of sample persons by sex-age categories, specifically young children and the elderly. Other differences are mainly due to improvements in dietary data collection procedures and to modifications and updates to the food databases. Also, this report is based on 2 days of dietary data whereas the previous report was based on 3 days. Although there were no significant changes in the tables or foods included in each table, 4 new tables were added in Set 1 and 1 new table was added in Set 2 to capture the consumption of milk consumed with cereal.

METHODS

Data Collection and Processing

Data Collection. Data were collected from January 1994 to January 1997 by Westat, Inc., Rockville, MD under contract with the USDA. Two 24-hour dietary recalls separated by 3 or more days were completed by 95 percent of the participating sample persons. Details of the design of the CSFII 1994-96 sample and data collection protocols are described elsewhere (Tippett and Cypel, eds. 1998).

Food Coding and Editing. Food survey intake data processing was facilitated by Survey Net, a computer-assisted food coding and data management system tailored specifically to the questions, quality control needs, and data processing needs of the CSFII 1994-96. It contains three central databases:

1. a food coding database containing food descriptions and food measures with corresponding gram weights,
2. a predefined recipe data base
3. the Survey Nutrient Database (not used in analyses of this report)

In preparation for the CSFII 1994-96, the food coding database used for CSFII 1989-91 was expanded and updated to capture important food processing and nutritional information that was to be collected during the food intake interviews. Some expanded food groups were vegetables; infant formulas; baby foods; margarines, spreads, and butters; fast-food sandwiches; and home-prepared soups. Ethnic foods and new foods reported during the course of the survey or during NHANES III were added to all food groups. Another change in the food database that impacts this report was the expansion of the list of food measures and their corresponding weights in grams. These included cubic inch weights of meats, fluid weights of beverages, and dimensions for raw fruits and vegetables.

Food codes in the database of Survey Net were chosen to match the descriptions of the foods eaten by the

sample persons. Once a matching food description was found and selected, Survey Net provided a list of common household measures appropriate for that food. Food descriptions and quantities not present in the food coding database were resolved by ARS.

Survey Net automatically performed gram weight checks of food quantities entered against maximum and minimum values established by ARS for each food. This weight check allowed coders to correct entry errors immediately. Coders recorded any questions regarding their food and quantity selections in a notepad within Survey Net, which coding supervisors then reviewed and answered.

Combination codes. Greater flexibility and specificity in food coding was possible through the use of combination codes. Combinations were often instances of one food being added to another, such as margarine to toast or milk to cereal. Other combinations are foods made up of several components that are relatively easy to describe and quantify separately, such as sandwiches and salads. Still another type of combination is a mixed dish where two or more food codes linked together in a food combination present a more precise picture of what was eaten by the respondent than if a single food code is used, such as coding a frozen meal when the meat or vegetable was not eaten. Foods coded separately but eaten in combination at the same eating occasion were assigned a common sequential combination number and were classified with a categorical combination type. There were 11 combination types: beverage, cereal, bread/baked product, salad, sandwich, soup, frozen meal, ice cream/frozen yogurt, vegetable, fruit, and other mixture.

The presence of combination codes in the CSFII94-96 data set may be useful in planning analyses, especially those related to salads, sandwiches, or foods combined "at the table" such as cereal and milk or corn chips and salsa. A familiarity with the different ways a food mixture might be reported, recorded, and coded into the food coding database would provide insights into the analysis of food consumption patterns, reported frequencies, and mean intakes of various foods. This report contains four new tables that describe the intake of milk with cereal, generated with the aid of combination codes.

Analysis

Comparability of analysis. A major objective in planning this report was to mirror the analysis conducted with the CSFII 1989-91 data (Krebs-Smith et al. 1997). The same criteria were applied in disaggregating recipes and in selecting and grouping foods. The criteria that a food be reported by at least 7 percent of the population was relaxed slightly in order to provide continuity between the reports. The percentage of individuals reporting a food or food group is presented in the tables. The statistical analyses were conducted using the most current versions of software designed to account for complex sample designs and the sampling weights were applied to produce population estimates as was done in

preparing the 1989-91 report. As noted in the introduction, the difference in the number of days of intakes reported in 1989-91 and in 1994-96 should be considered in comparing percentages of individuals reporting a food between the two reports.

Disaggregation of mixed foods. Many of the foods in the CSFII data set are mixed foods – that is, foods composed of more than one ingredient, such as sandwiches and soups. As in the previous report (Krebs-Smith et al. 1997), mixed foods were disaggregated so that the individual ingredients could be grouped together with similar foods that were reported separately. Therefore, weights of foods consumed as ingredients of mixed foods could be combined with weights of foods reported separately in order to complete the data for each table. This approach provides a more thorough representation of the consumption of many foods especially for the tables on quantities consumed in a day. The types of mixed foods from which ingredients were extracted are identified in the Table Notes section of this report. For example, the definition for Pasta (Table 1.019) includes all pasta whether reported separately or as part of a mixed dish.

Selection and grouping of foods for tables. Foods were selected for inclusion in this report based on the percentage of persons who reported eating them in the survey. The criterion was that a minimum of 7 percent of the population age 2 years and over be users of a food. The percentage was determined to provide estimates for most sex and age groups without reservation as to their statistical reliability. (See below for discussion of reporting guidelines.)

Four new tables were added to Table Set 1 and include fluid milk with cereal, whole milk with cereal, low fat milk with cereal and skim milk with cereal. There was also one new table added to Table Set 2, fluid milk with cereal. These new tables were included because of the high consumption of these food mixtures.

Similar foods were grouped together in the same table if their gram weights for a given household measure were approximately the same. So, for example, many kinds of rice are grouped together in one table because the weight per cup is approximately the same for all, while raw tomatoes and tomato sauce are separated into different tables because their weights per ½ cup are different. As a result, the gram weight data in the tables, when considered together with the volume/weight equivalents, can be translated into estimates of common measures.

Statistical procedures. Table Set 1 provides data on the means and percentiles consumed during an eating occasion per user of the food. These values represent all relevant reports by each person consuming the food.

Table Set 2 provides data on means and percentiles of total quantities consumed by consumers during a single day. The purpose of these tables is to reveal daily intakes. To maximize the number of individuals included, but not allow frequent consumers more weight than

infrequent consumers, only a single day on which the food was reported was included for each individual. If a respondent reported the food only on 1 of 2 days, that day of intake was selected for analysis. If the food was reported on both days, one of the two days was randomly selected.

While some foods may be eaten in discrete common units, it is assumed that the underlying distributions of most food intake data are continuous. Therefore, quantities consumed at various percentiles were estimated using a linear interpolation method.

Appendix A shows the calculations used in deriving the estimates. Means, standard errors, quantities consumed at various percentiles, and estimates of percent of persons using a food at least once in a 2-day period were calculated using SUDAAN, version 7.5.1 (Shah 1997). SAS, version 6.12 (SAS Institute 1996) was used in preparing the data and controlling the calls to SUDAAN and in the generation of the tables. Coefficients of variation (CVs), though not provided in the tables, were generated using SUDAAN and examined, along with relevant sample sizes, to determine whether or not to flag a particular value. See rules used for flagging estimates below.

Reporting guidelines. Data presented in this report follow the guidelines issued in a joint policy statement on variance estimation and statistical reporting standards prepared by a USDA/National Center for Health Statistics Analytic Working Group (Federation of American Societies for Experimental Biology 1995). The guidelines call for an estimate to be flagged when the reliability of the estimate might be affected by a small sample size or high variability relative to the mean. The guidelines (listed below) for determining when a small sample size might affect the reliability of an estimate take into account the effect of the sampling method on estimation through a "broadly calculated" design effect. The variance inflation factor (VIF) has been used in this role, where VIF = 1 + CV^2, and CV is the coefficient of variation of the full set of sampling weights. For 2-day respondents of CSFII 1994-96, the VIF = 1.60.

Asterisks are used in the tables to flag estimates that may tend to be less statistically reliable than those that are not flagged. The rules used for flagging estimates are as follows:

1. An estimated mean is flagged when it is based on a cell size of less than 30 times the average design effect or when its coefficient of variation (CV) is equal to or greater than 30 percent. The CV is the ratio of the estimated standard error of the mean to the estimated mean, expressed as a percentage.

2. An estimated proportion (percent) that falls above 25 percent and below 75 percent is flagged when it is based on a cell size of less than 30 times the average design effect (VIF) or when the CV is equal to or greater than 30 percent.

3. An estimated proportion of 25 percent or lower or 75 percent or higher is flagged when the smaller of np and n(1- p) is less than 8 times the VIF,

where "n" is the cell size on which the estimate is based and "p" is the proportion expressed as a fraction.

The rules for flagging percentiles follow the rules used with proportions with the exception that the CV of the percentile is not considered. The following table provides the minimum sample sizes for the presentation of the percentiles in these tables without flags:

	Minimum sample size
5th percentile	256
10th percentile	128
25th percentile	52
50th percentile (median)	48
75th percentile	52
90th percentile	128
95th percentile	256

The survey design and operations report (Tippett and Cypel, eds. 1998) provides additional information on the sample design and weighting. Appendix A provides additional statistical notes.

How to use the data in tables. The explanations for the symbols used and the sections providing the description of foods in each of the table sets (Table Notes) should be consulted before using any of the tables. They provide details about how to interpret the data and whether all uses of a food, or only a selection, are included.

Table Set 1 represents quantities of food eaten during an eating occasion. This information was intended to be useful when considering serving sizes for food guidance, for food labeling purposes, and for development of dietary assessment tools. These tables include foods reported separately and foods eaten as part of mixed foods, but generally only if the ingredient of the mixture would tend to be eaten in an amount equivalent to the portions reported separately.

Table Set 2 was designed to address the needs of dietary assessments in the food safety, marketing, nutrition education, and other arenas which consider the amount of food consumed during an entire day. Therefore, these tables include more foods for which every kind of use is represented because the total consumption of a food is of interest. In summary, Table Set 1 generally includes foods eaten separately or readily identifiable in mixtures, such as the eggs in potato salad or peanut butter on a sandwich, whereas Table Set 2 generally includes uses similar to those just mentioned as well as ingredient uses, such as the peanut butter and eggs contained in cookies.

The two main sets of tables present amounts of foods consumed over short periods of time by consumers only during the 3-year period, 1994-1996. Appendix B presents data from the same survey as average amounts consumed per day by the target population, including both consumers and nonconsumers.

The number of persons in the sample, provided on each table, represents both users and non-users of the food.

Below that, on Table Sets 1 and 2, are the estimated percentages of persons using the food at least once in 2 days, on 1 of 2 days, and on 2 of 2 days. For each group of persons, the latter 2 percentages total to the percentage using the food at least once in 2 days (any differences due to rounding). For example, about 93 percent of all persons over age 2 used total yeast bread (Table 2.001) at least once in 2 days, with 28 percent of persons using it on 1 of the 2 days and 65 percent of persons using it on both days.

The quantities consumed per eating occasion (Table Set 1) and in a day (Table Set 2) are quantities consumed by users only and are reported in terms of gram weights. The weights can be translated into common household measures using the conversions on the tables and in the table notes. For example, it is estimated that among all consumers of white bread age 2 and older, the mean quantity consumed during an eating occasion (Table 1.001) is 50 g, or about 2 slices. The median value is estimated to be 46 g, that is, it is estimated that half the population consuming white bread has 46 g or less per eating occasion, while the other half has 46 g or more. The conversion of household measures to gram weights are reflective of those used in the 1994-96 survey and do not reflect changes in the market or in methodology since that time.

Appendix B contains estimates of mean quantities of foods consumed per person per day for all individuals, that is, consumers and nonconsumers, over all days. Although an individual's usual (that is, long-run average) daily intake cannot be estimated, each of these means is an estimate of the population's (or subpopulation's) mean usual daily intake. For example, the estimated mean usual daily intake of total white bread is 50 g, while that of total yeast bread is 63 g. The difference in these values is in part a reflection of the wider variety of breads and range of uses included in total yeast bread and in part a reflection of the greater percentage of persons using total yeast bread than white bread.

Appendix C provides the minimum and maximum values of foods for which percentiles could not be interpolated in Table Sets 1 and 2 because the sample size was too small or because too many reports were of exactly the same magnitude.

Limitations of the Data

The data, which are represented in the various tables, are subject to the following limitations. Respondents frequently were not expected to or could not provide recipes for mixed foods they had eaten, necessitating the use of standard recipes. Therefore, the foods represented in the tables are, in part, based on assumptions about the types and quantities of ingredients consumed as part of mixed foods. In addition, occasionally the ingredients of mixed foods were coded as individual foods to address unusual ingredient combinations. Therefore, even though a table description may state that the table includes only particular foods if reported separately and not as part of mixed foods, this may include some foods which were consumed as part of mixed foods. However it is assumed this would have a minor impact on the results presented here because of the low frequency of occurrence.

Many of the tables in Set 2 represent the intake of all forms of a particular food, including those that are raw and cooked. Sometimes the gram weight of a particular household measure varies for different forms of the food. For example, one half cup of raw onions weighs 80 grams, while one half cup of cooked onions weighs 108 grams. The gram weights presented will be influenced by the relative contribution of the different forms of the food and do not represent the raw commodity weights. Finally, the data are subject to the kinds of errors which are common to all food intake data - imprecision in the quantities reported due to such factors as an inability to estimate portions precisely and imperfect memory. However, the survey procedures were designed to minimize these types of errors.

Table 1.076. Coffee: Percentage of persons using food in 2 days and quantities consumed per eating occasion.

Statistic	All individuals age 2 and over	Age (years) and sex									
		2-5	6-11	12-19		20-39		40-59		60 and older	
		Males and females	Males and females	Males	Females	Males	Females	Males	Females	Males	Females
Number in sample	14,262	2,109	1,432	696	702	1,543	1,449	1,663	1,694	1,545	1,429
Percent of persons using						%					
at least once in 2 days	45.4	0.9	1.8	7.5	5.1	45.8	43.6	72.5	71.0	80.8	76.6
on 1 of 2 days	11.0	0.9	1.4	4.5	4.1	15.9	14.7	14.1	14.1	11.6	12.2
on both days	34.5	0.0 *	0.4 *	3.0	1.0 *	29.8	28.9	58.4	56.9	69.2	64.4
Quantity consumed per eating occasion (8 fluid ounces = 237 g)						g					
Mean	463	79 *	198 *	326 *	346 *	536	476	536	458	408	359
SEM	10	12 *	24 *	28 *	37 *	21	19	18	15	11	12
5th percentile	178	---	---	123 *	96 *	195	177	184	178	175	178
10th percentile	218	---	76 *	215 *	121 *	229	179	237	219	209	207
25th percentile	237	30 *	108 *	236 *	202 *	238	235	268	238	237	237
50th percentile	355	52	169	244	238	391	329	403	355	316	273
75th percentile	476	104 *	238 *	355 *	439 *	552	476	590	477	474	414
90th percentile	799	119 *	297 *	463 *	594 *	931	815	947	787	710	592
95th percentile	1,066	119 *	---	474 *	---	1,369	1,179	1,267	1,066	918	714

* Indicates a statistic that is potentially unreliable because of small sample size or large coefficient of variation.
# Indicates a percentage that is greater than 0 but less than 0.05 or a mean, SEM, or percentile that is greater than 0 but less than 0.5.
--- Indicates a percentile that could not be estimated.
Note: See "Table notes."
Source: USDA's Continuing Survey of Food Intakes by Individuals, 1994-96, 2 days.

0000048

Table 1.077. Coffee, with Caffeine: Percentage of persons using food in 2 days and quantities consumed per eating occasion.

Statistic	All individuals age 2 and over	Age (years) and sex									
		2-5	6-11	12-19		20-39		40-59		60 and older	
		Males and females	Males and females	Males	Females	Males	Females	Males	Females	Males	Females
Number in sample	14,262	2,109	1,432	696	702	1,543	1,449	1,663	1,694	1,545	1,429
Percent of persons using						%					
at least once in 2 days	40.8	0.9	1.5	7.3	4.7	44.4	41 8	67.7	62.5	66.9	60.9
on 1 of 2 days	11.6	0.9	1.1	4.3	3.9	15.8	15.2	16.2	14.3	15.2	12.9
on both days	29.3	0.0 *	0.4 *	3.0	0.9 *	28.6	26.6	51.5	48.2	51.7	48.0
Quantity consumed per eating occasion (8 fluid ounces = 237 g)						g					
Mean	469	80 *	193 *	327 *	355 *	535	476	536	451	423	370
SEM	10	12 *	28 *	29 *	40 *	22	19	18	15	12	14
5th percentile	178	---	---	123 *	95 *	179	177	178	177	177	177
10th percentile	217	---	69 *	213 *	117 *	229	179	237	217	207	207
25th percentile	237	30 *	102 *	236 *	200 *	238	233	254	237	237	237
50th percentile	355	54	145	238	238	395	317	403	355	317	296
75th percentile	477	106 *	227 *	355 *	450 *	551	474	590	505	474	467
90th percentile	829	119 *	310 *	464 *	595 *	931	824	947	775	710	592
95th percentile	1,130	119 *	---	474 *	---	1,361	1,178	1,257	1,063	936	755

* Indicates a statistic that is potentially unreliable because of small sample size or large coefficient of variation.
# Indicates a percentage that is greater than 0 but less than 0.05 or a mean, SEM, or percentile that is greater than 0 but less than 0.5.
--- Indicates a percentile that could not be estimated.
Note: See "Table notes."
Source: USDA's Continuing Survey of Food Intakes by Individuals, 1994-96, 2 days.

000049

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Table 1.078. Coffee, Decaffeinated: Percentage of persons using food in 2 days and quantities consumed per eating occasion.

Statistic	All individuals age 2 and over	Age (years) and sex									
		2-5	6-11	12-19		20-39		40-59		60 and older	
		Males and females	Males and females	Males	Females	Males	Females	Males	Females	Males	Females
Number in sample	14,262	2,109	1,432	696	702	1,543	1,449	1,663	1,694	1,545	1,429
Percent of persons using						%					
at least once in 2 days	8.8	#	0.3 *	0.2 *	0.5 *	3.0	4.8	12.6	15.5	24.0	25.9
on 1 of 2 days	4.2	#	0.3 *	0.2 *	0.5 *	1.9	3.5	6.6	7.4	8.5	10.5
on both days	4.6	0.0 *	0.0 *	0.0 *	0.0 *	1.1	1.4	6.0	8.1	15.5	15.4
Quantity consumed per eating occasion (8 fluid ounces = 237 g)						g					
Mean	360	59 *	227 *	296 *	237 *	382 *	380	417	393	334	310
SEM	12	0 *	29 *	0 *	#	40 *	41	22	29	15	13
5th percentile	134	---	---	---	---	131 *	118 *	133 *	133	150	125
10th percentile	178	---	---	---	---	192 *	166 *	177	178	179	178
25th percentile	237	---	---	---	---	237 *	226	224	232	237	237
50th percentile	253	---	---	---	---	289	252	304	294	238	238
75th percentile	427	---	---	---	---	376 *	462	477	474	385	355
90th percentile	592	---	---	---	---	579 *	683 *	701	577	571	474
95th percentile	714	---	---	---	---	837 *	892 *	966 *	930	701	684

* Indicates a statistic that is potentially unreliable because of small sample size or large coefficient of variation.
# Indicates a percentage that is greater than 0 but less than 0.05 or a mean, SEM, or percentile that is greater than 0 but less than 0.5.
--- Indicates a percentile that could not be estimated.
Note: See "Table notes."
Source: USDA's Continuing Survey of Food Intakes by Individuals, 1994-96, 2 days.

Submission End