Tunney's Pasture
Ottawa, Ontario
K1A 0L2

March 18, 1998

TO ALL INTERESTED PARTIES

Subject: Nutrient Content Claims

The purpose of this letter is to present Health Canada's proposed revisions to the compositional criteria for nutrient content claims. Attachment 1 to this letter describes the considerations taken into account in developing these revised proposals and Attachment 2 presents the revised proposals.

In January 1996 Health Canada and Agriculture and Agri-Food Canada published a Consultation Document on Nutrient Content Claims. A summary of responses and a list of outstanding issues were sent to stakeholders in August, 1996. Copies of this summary can be obtained from this office or by accessing the Health Canada Website at http://www.hc-sc.gc.ca/datahpb/datafood.

The 1996 Consultation Document proposed that the compositional criteria for nutrient content claims be harmonized where feasible with those of the United States. While Health Canada takes into account the potential economic and trade implications of regulatory decisions, its position is that health and safety issues must take precedence. This is consistent with the provisions of the Technical Barriers to Trade (TBT) agreements under both the WTO and NAFTA wherein members maintain their rights to establish standards to ensure an adequate level of health protection.

In a letter dated April 24, 1997, Health Canada announced its decision to revise the compositional criteria for the claim "fat-free". The letter also indicated that, whereas the revised claim "fat-free" was introduced as a guideline under the Canadian Food Inspection Agency's Guide to Food Labelling and Advertising, it was Health Canada's intention that all nutrient content claims would be regulated in the future.

Your comments are requested on the revised proposals. Comments received

until June 1, 1998 will be considered in developing proposals for regulatory amendments respecting nutrient content claims for pre-publication in the *Canada Gazette* Part I. All interested stakeholders will have further opportunity to comment on the proposals at that time. A notice of the date of pre-publication will be posted on the Health Canada Website once it is known.

Comments on the attached documents should be addressed to

Ms. Christina Zehaluk (2203A)
Nutrition Evaluation Division
Food Directorate, Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario, K1A 0L2

FAX: (613) 941-6636
E-MAIL: christina_zehaluk@hc-sc.gc.ca

Yours truly.

George M. Paterson, Ph.D.
Director General
Food Directorate

Attach.

Attachment 1

NUTRIENT CONTENT CLAIMS

Food Directorate, Health Protection Branch
Health Canada
March, 1998

SUMMARY

This document contains revised proposals for the compositional and labelling requirements for nutrient content claims.

The following are highlights of the revised proposals:

- "Free" with respect to nutrients would be defined as nutritionally insignificant in relation to current dietary recommendations. This is in line with the U.S. definition for "free". Current Canadian rounding rules for nutrients will continue to apply when a food carries a "free" claim with respect to a nutrient.
- "Low" claims would be based on reference amounts* as well as labelled serving size and would include a density criterion for foods with reference amounts of 30 g or 30 mL or less. A modification of the term "low" with an adjective denoting that the food contains an amount that is lower than low, e.g. "very low", "ultra low" would require that the criteria for free, with respect to the subject nutrient, be met.
- The claim "(naming the percentage) fat-free" would be allowed for foods meeting the compositional criteria for "low fat" and the claim "100% fat-free" would be allowed for foods meeting the compositional criteria for "fat-free" and containing less than 0.5 g fat per 100 g and no added fat.
- Compositional criteria for the claim "free" of saturated fatty acids would be revised to decrease the levels of both saturated and *trans* fatty acids.
- Revised compositional criteria for comparative claims for saturated fatty acids would ensure that there is a significant reduction in both saturated and *trans* fatty acids.
- Claims for *trans* fatty acids and omega-3 and omega-6 fatty acids would be allowed.
- The claim "light" would be allowed only for foods that meet the criteria for either "reduced fat" or "reduced energy".
- The current Canadian compositional criteria for protein claims would be retained until the issues

around appropriate methodology for protein quality in different foods have been resolved.

- The current Canadian compositional criteria for dietary fibre would be retained.
- At this time, implied nutrient content claims would continue to be handled on a case by case basis by the Canadian Food Inspection Agency.
- The current criteria for the use of the term "healthy" on labels of or in advertisements for foods would be retained (Guidelines for Health Information Programs Involving the Sale of Foods, Health Canada, 1995). This policy would remain as a guideline.
- The following claims: "carbohydrate reduced", "calorie-reduced", "low calorie", "sugar-free" and "low sodium" would not be restricted to products meeting the definition of "food for special dietary use".
- Specially formulated foods meeting the compositional criteria for energy/calorie, sugar and sodium claims could continue to be represented for special dietary use if they meet the regulatory definition for "food for special dietary use". The term "diet" or "dietetic" would be restricted to foods for special dietary use that meet compositional criteria for and were labelled as "free", "low" or "reduced" in energy/calories or "sugar-free".

Health Canada intends that the compositional criteria for nutrient content claims will be the subject of regulations.

The comments received on the attached proposals will be considered in developing final proposals for regulatory amendments for pre-publication in the Canada Gazette Part I.

* Reference amounts for foods were published in the Guide to Food Labelling and Advertising available from the Canadian Food Inspection Agency or on the Internet at HTTP://WWW.CFIA-ACIA.AGR.CA

INTRODUCTION

A letter sent by this Division to stakeholders in August 1996, identified a number of issues that remained outstanding following the January 1996 Consultation Document on Nutrient Content Claims (1996 Consultation). A copy of this letter, which also included a summary of comments received on the 1996 Consultation, is available from this office or by accessing the Health Canada Website at http://www.hc-sc.gc.ca/datahpb/datafood. The issues that were identified included the following:

1• the basis for **"free" claims**, i.e. nutritional insignificance versus "0";

2• **"low" claims**: the need for a density criterion, i.e. per 50 g in the case of foods with a reference value of 30 g or 30 mL or less and the basis for the claim, i.e. per reference amount and per serving;

3• **claims for saturated fatty acids**: the restriction on *trans* fatty acids;

4• **cholesterol claims**: the maximum level of total fat;

5• the basis for **"light" claims**, i.e. claim to be applicable only to foods that are reduced in total fat or energy;

6• **"sugar-free"**: the inclusion of energy restriction or statements indicating that a product is not "energy-free" or "low energy" or "reduced in energy" unless the food meets the criteria for one of these claims;

7• **"no added sugar"**: the potential for individuals with diabetes to confuse with "sugar-free";

8• **"lightly salted"**: the potential for consumers to confuse with "low sodium";

9• **protein claims**: acceptable methodologies for determining protein quality;

10 • **implied nutrient content claims**: the application of the proposed principles.

In addition to the above, the question of whether Canada should harmonize with the U.S. or adopt international standards elaborated by the Codex Alimentarius Commission, was an issue raised by several stakeholders.

This document contains a discussion of the issues identified above. Revised proposals for nutrient content claims are presented in Attachment 2, *"Revised Proposals for Nutrient Content Claims"*. There is no discussion presented of those claims where the comments on the 1996 Consultation indicated general agreement with the proposal.

The 1996 Consultation presented compositional criteria for 35 nutrient content claims and proposed to harmonize with the U.S. respecting the compositional criteria as well as certain mandatory accompanying information for 20 of these claims. The proposals presented in this document and in the attached *Revised Proposals for Nutrient Content Claims* result in the compositional criteria for 14 nutrient content claims becoming consistent with those of the U.S. Of the remaining claims, the criteria proposed for "low" claims will be consistent with those of the U.S. except in the case of foods which have a labelled serving that is larger than the reference amount and where the criteria for the claim are not met on the basis of the labelled serving size. Criteria proposed for claims for dietary fibre and for "light" will be less strict than under the U.S. system. Compositional criteria proposed for "low" and comparative claims respecting saturated fatty acids and for cholesterol claims are stricter than those under the current U.S. system. The criteria proposed for claims for saturated fatty acids, and for cholesterol, all include a restriction on *trans* fatty acids.

INTENT TO REGULATE CLAIMS

As had been indicated in previous consultations with stakeholders, it is Health Canada's intent that all nutrient content claims be regulated to ensure consistency in their application.

TRADE AND INTERNATIONAL ISSUES

While Health Canada takes into account the potential economic and trade implications of regulatory decisions, its position is that health and safety issues must take precedence. This is consistent with the provisions of the Technical Barriers to Trade (TBT) agreements under both the WTO and NAFTA.

BUSINESS IMPACT

The claim "fat-free" was dealt with on a priority basis because it included issues that were both health and trade related and were of interest to stakeholders in all sectors. Resolution of these issues was also seen as being applicable to other nutrient content claims.

In the case of the claim "fat-free", the issue was one where the Canadian definition was being liberalized to bring it in line with that of the U.S. which had been in effect since 1994. It was considered that this liberalization would increase the availability of foods labelled "fat-free" for Canadian consumers. Some stakeholders had expressed concern that adoption of the U.S. criteria would give U.S. manufacturers and large multi-nationals who had existing products meeting the new definition an unfair advantage over Canadian manufacturers. The economic and trade impact analysis carried out by Agriculture and Agri-Food Canada indicated that aligning the Canadian criteria to U.S. standards would result in more two-way trade with the United States and have a small but positive impact on Canadian industry overall. Some Canadian firms would benefit from easier access to the U.S. market while no negative impact on employment was expected even in the short-run.

CODEX

At its 22nd session in June 1997, the Codex Alimentarius Commission adopted compositional criteria for claims respecting energy, fat, saturated fat, cholesterol, sugars and sodium. These are based on a per 100 g or per 100 mL amount. However, the Codex Committee on Nutrition and Foods for Special Dietary Uses has agreed to consider the use of serving sizes as the basis for compositional criteria for nutrient content claims. Generally, the compositional criteria for claims under the Codex system are stricter than those proposed in this document and those of the U.S.

"FREE" CLAIMS

1996 Proposal:

In the 1996 Consultation it was proposed to adopt the U.S. method of defining "free" with respect to nutrients.

Discussion:

Under the current Canadian system, "free" claims are intended to designate foods which are practically free of energy (calories) or a nutrient. In addition, in Canada, "sugar free" has been defined as a food that was practically free of sugar and energy thus qualifying as a "free" food for diabetic diets.

Under the U.S. system, "free" refers to a level of energy or of a nutrient that is nutritionally trivial and physiologically inconsequential. Under the U.S. system, the frequent consumption of a food labelled "free" in energy or in a nutrient would have an insignificant impact within the total diet on the consumption of energy or the subject nutrient. The average number of servings of food and beverages consumed per day, according to information from dietary surveys has been estimated to be 20. As an example, 10 servings of a food labelled "Calorie free" would provide less than 50 kilocalories (approximately 2.5% of energy on a 2000 kilocalorie diet); 10 servings of foods labelled "fat-free" would provide 4 g or less of fat (less than 2% of energy on a 2000 kilocalorie diet); 20 servings of foods labelled "sodium free" would provide less than 100 mg of sodium, an insignificant amount even in diets that are reduced in sodium.

In general, respondents to the 1996 Consultation supported adoption of the proposals for "free" claims based on the premise that "free" is nutritionally insignificant. However, the consumer sector indicated that they considered that "free" should only be used when the food contains none of the nutrient., i.e. free = 0.

Based on additional consultations and data from consumer research, it was decided that, for the purpose of nutrient content claims, "free" could appropriately be defined as an amount that was nutritionally insignificant in the context of a total diet. However, based on the consumer research, it was decided to retain the Canadian system of rounding for the purpose of nutrient content declaration. Under this system the declaration of macronutrients such as fat is required to the nearest 0.1 g in the case of amounts less than 10 g; the energy value is declared rounded to the nearest whole number when expressed in Calories (Calories or Cal), and when expressed in kilojoules, to the nearest whole number for values less than 10 kJ and to the nearest 10 kJ for values of 10 kJ or more. This is different from the U.S. system where amounts of macro-nutrients that meet the definition for "free" are declared as "0".

Conclusions:

- "free" with respect to nutrients be defined as nutritionally insignificant in relation to current dietary recommendations; please see the attached "Proposed Regulations for Nutrient Content Claims" for the compositional criteria for "free" claims for specific nutrients;

- current Canadian rounding rules for nutrients apply when a food carries a "free" claim with respect to a nutrient, i.e.

    - the energy value of the food be rounded to the nearest whole number when expressed in Calories (Calories or Cal), and when expressed in kilojoules, to the nearest whole number for energy values less than 10 kJ and to the nearest 10 kJ for energy values of 10 kJ or more;

- the content in the food of protein, fat, fatty acids and of carbohydrate and its constituents, be rounded to the nearest 1/10 of a gram for quantities less than 10 g and to the nearest whole number for quantities of 10 g or more.

"LOW" CLAIMS: DENSITY CRITERION AND BASIS FOR CLAIMS

1996 Proposal:

In the 1996 Consultation it was proposed that the compositional criteria for "low" claims be based on the "reference amount" of a food (i.e. an amount that represents amounts of food consumed at a single eating occasion) **and** include a density factor for foods with reference amounts equal to or less than 30 g or 30 mL. It was further proposed to require the disclosure of the compositional criteria for a nutrient content claim in close proximity to the claim where the declared serving size for a food differed from the reference amount and the food met the compositional criteria for a nutrient content claim only on the basis of the reference amount but not on the basis of the declared serving size. As an alternative to the disclosure statement it was proposed to include the labelled serving size as part of the criteria for "low" claims.

Discussion:

The principles used to define "low" for the purpose of nutrient content claims are the same for Canada and the United States. "Low" claims are intended to designate foods containing a distinctly low but not inconsequential amount of a nutrient. It is therefore important that consumers understand that foods carrying "low" claims are not intended to be consumed freely in numerous servings if the intake of the nutrient that is the subject of the claim is to be limited. Properly used, "low" nutrient content claims should assist consumers in assembling a prudent diet in which the nutrient that is the subject of the claim is limited.

Under both the current Canadian and the U.S. systems for nutrient content claims, "low" claims include a density criterion to prevent "low" claims for foods with a small reference amount or serving size but with a high content of the nutrient or food component in question. A similar density criterion for "free" claims is not considered necessary because the criterion for "free" is so low that even frequent consumption of foods labelled "free" would not contribute significant amounts of the nutrient that is the subject of the claim.

Those respondents commenting on this proposal generally supported the proposal that criteria for "low" claims should be based on **both** the reference amount and the serving size such that disclaimers would not be necessary when the criteria for a claim were met on the basis of a reference amount but not on the basis of a labelled serving size. In general, stakeholders do not favour the use of disclaimers on labels indicating that these are confusing to consumers and onerous for the manufacturer who has limited label space.

Density criterion: Some respondents suggested that the proposed density criterion for "low" claims would not be necessary when the claim was based on both the reference amount and the labelled serving size. Although the requirement that "low" claims be based on both a reference amount and a serving size would ensure that the criteria for a "low" claim would always be met by the labelled serving size, it cannot be used to replace the density criterion which is intended

to prevent "low" claims for foods with a small reference amount or serving size but with a high inherent content of the nutrient or food component in question. For example, the density criterion for a "low fat" claim limits the fat content in foods with reference amounts equal to or less than 30 g or 30 ml to 6%. If the density criterion was deleted, foods with reference amounts equal to or less than 30 g or 30 mL could contain in excess of 6% fat, depending on the reference amount. With no density criterion, foods with reference amounts of 20 g (crackers) could contain up to 15% fat; foods with reference amounts of 15 g or 15 ml (e.g. table cream (18% BF), evaporated whole milk, olives) up to 20% fat. Health professionals have indicated that to describe these foods as "low fat" would be inconsistent with nutrition education programs and consumers' perceptions.

Conclusion:

As discussed above, it is proposed to include labelled serving size as well as reference amount as the basis for "low" claims. However, the inclusion of the "per labelled serving size" criterion for "low" claims can not replace the density criterion. It is important to note here that current definitions for "low" claims for nutrients include density criteria. Please see the attached revised proposals for further details.

It is also proposed that a modification of the term "low" with an adjective denoting that the food contains an amount that is lower than low, e.g. "very low", "ultra low" would require that criteria for "free", with respect to the subject nutrient, be met. This is in line with guidelines that currently exist, e.g. " very low fat" must meet the same criteria as "fat-free" (Guide to Food Labelling and Advertising, Canadian Food Inspection Agency).

CLAIMS FOR FAT: "FAT-FREE", "100% FAT-FREE" and "(NAMING THE PERCENTAGE) FAT-FREE"

1996 Proposal

The 1996 Consultation also proposed to adopt the U.S. definitions for the claims "fat-free", "100% fat-free" and "(naming the percentage) fat-free".

Discussion:

1. "fat-free": Health Canada announced its decision on the claim "fat-free" in April 1997 in a letter to stakeholders which is available on the Health Canada Website. The definition proposed in the 1996 Consultation was adopted and is consistent with that of the U.S. The revised definition is, at this time, a guideline in the Guide to Food Labelling and Advertising, Canadian Food Inspection Agency.

2. "100% fat-free" and "(naming the percentage) fat-free": Currently in Canada these claims are not permitted. The definition proposed in the 1996 Consultation for the claim "!00% fat-free" was stricter than that for "fat-free" (i.e. "100 % fat-free" = less than 0.5 g fat per reference amount and per labelled serving and less than 0.5 g fat per 100 g and no added fat) because of the further qualification of "fat-free" by the "100%" designation. The proposed definition for "(naming the percentage) fat-free" restricted this claim to foods that met the criteria for the claim "low fat".

The claim "(naming the percentage) fat-free" is considered to imply that a food has a small amount of fat; the claim would be considered misleading if it appeared on a food that was not low in fat.

Although the majority of respondents had no comments on these two claims, the health sector commenting on these proposals indicated their concern that the claims "100% fat-free" and "(naming the percentage) fat-free" were potentially misleading and of little use to the consumer. Certain of the food industry had similar concerns, more so about the latter claim than about the former.

Conclusions:

- the claim "(naming the percentage) fat-free" be allowed as proposed for foods meeting the compositional criteria for "low fat"; Health Canada considers that this claim will not mislead in view of its restriction to foods meeting criteria for "low fat";

- the claim "100% fat-free" be allowed as proposed for foods meeting the compositional criteria for "fat-free" and containing less than 0.5 g fat per 100 g and no added fat; it is considered that this claim would not be misleading in view of the additional criteria beyond those for "fat-free";

Please see the attached revised proposals for further details.

CLAIMS FOR SATURATED FATTY ACIDS

1. INCLUSION OF A CRITERION FOR *TRANS* FATTY ACIDS

1996 Proposal:

The 1996 Consultation proposed restrictions on the *trans* fatty acid content as part of the compositional criteria for claims for saturated fatty acids.

Discussion:

Of those commenting on the inclusion of a *trans* criterion in the definitions for claims for saturated fatty acids, several of the food industry sectors as well as the health sector expressed their support whereas some other sectors of the food industry objected to the inclusion of a criterion restricting the *trans* fatty acid content of foods carrying claims for saturated fatty acids. Those objecting indicated that there were insufficient scientific data to support the need for this restriction.

Claims for the saturated fatty acid content of foods are intended to assist consumers in choosing foods for a diet that will reduce risk of coronary heart disease as set out in the Nutrition Recommendations for Canadians (Health and Welfare Canada, 1989). In research conducted by the National Institute of Nutrition, consumers indicated that claims respecting saturated fatty acids meant that a product was "good for you" (*Consumer Use and Understanding*

of Nutrition Information on Food Package Labels, 1992). In the same research study, consumers also stated that they consider the claim "cholesterol free" on a food label to mean that the food is "good for your heart".

Well controlled clinical or intervention studies have shown that dietary *trans* fatty acids, relative to *cis-unsaturated* fatty acids, raise plasma low-density lipoprotein (LDL) cholesterol levels. A direct relationship exists between serum LDL cholesterol levels and risk of coronary heart disease. Clinical studies also have indicated that dietary *trans* fatty acids increase serum lipoprotein (a) levels which are also associated with risk of heart disease. In addition, some studies have indicated that dietary *trans* fatty acids reduce serum high-density lipoprotein (HDL) cholesterol levels which are negatively associated with risk of coronary heart disease; dietary saturated fatty acids do not lower HDL levels. A number of epidemiological or observational studies have also provided evidence for a relationship between intake of *trans* fatty acids and risk of coronary heart disease.

Conclusion:

It is the position of Health Canada that the current scientific literature, including data from very recent studies, as well as recommendations made by authoritative bodies, support the need for the proposed restriction on *trans* fatty acids when claims are made respecting saturated fatty acids, particularly in the Canadian context. Please see the Appendix to this Attachment for a discussion of the health effects of *trans* fatty acids.

2. "FREE" CLAIM FOR SATURATED FATTY ACIDS"

1996 Proposal:

The 1996 Consultation proposed that "free" of saturated fatty acids be defined as "less than 0.5 g of saturated fatty acids and less than 0.5 g of *trans* fatty acids per reference amount and per labelled serving of food".

Discussion:

The major objection to this proposal was from a portion of the food industry who objected to the inclusion of the criterion for *trans* fatty acids in this definition. There were no specific comments on the proposed levels of either saturated fatty acids or *trans* fatty acids with the exception of respondents who objected, in general, to the concept that "free", with respect to a nutrient, was not "zero".

Since the 1996 Consultation, the proposed levels of saturated fatty acids and of *trans* fatty acids in the criteria for the claim "free" of saturated fatty acids have been re-considered taking into account dietary guidance and analytical methodology. The results of new scientific literature on the effects of dietary saturated and *trans* fatty acids has also been considered.

As indicated above, it has been agreed that in Canada, as in the U.S., "free" with respect to nutrients would be defined as nutritionally insignificant in relation to current dietary

recommendations. The proposed definition for "free" of saturated fatty acids, i.e. "less than 0.5 g of saturated fatty acids and less than 0.5 g of *trans* fatty acids per reference amount and per serving of food", would result in foods so labelled providing amounts of saturated fatty acids and of *trans* fatty acids that may not be considered nutritionally insignificant in terms of Nutrition Recommendations.

Nutrition Recommendations for Canadians, recommend that the Canadian diet provide less than 30% of total energy as total fat with less than 10% of total energy from saturated fat. Thus, the recommended level of saturated fat in the diet is 1/3 of that of total fat. It is therefore reasonable, barring analytical difficulties, that "free of saturated fatty acids" be defined as containing saturated fatty acids in an amount that is 1/3 the amount for fat in the definition "fat-free".

Specific Canadian recommendations with regard to *trans* fatty acid intake do not exist with exception of the recommendation that their intake not be increased (Nutrition Recommendations, The Report of the Scientific Review Committee, Health and Welfare Canada, 1990). However, in view of data from scientific studies that indicate that *trans* fatty acids may have an adverse effect on risk of coronary heart disease at even lower levels of intake than for saturated fatty acids, it is considered that the level of restriction should be of at least the same magnitude.

Conclusion:

As discussed above, it is proposed that the compositional criteria for the claim "free of saturated fatty acids" include a restriction on both saturated and *trans* fatty acids. The following compositional criteria are proposed, based on the ratio of saturated fatty acids to fat in Nutrition Recommendations: "Less than 0.2 g of saturated fatty acids and less than 0.2 g of *trans* fatty acids per reference amount and per labelled serving."

These levels are within the limit of detection for foods including those with large serving sizes. Please see the attached revised proposals for further details.

3. "REDUCED in SATURATED FATTY ACIDS"

Proposal:

The 1996 Consultation proposed the following definition for the comparative claim for saturated fatty acids: "at least 25% less saturates and *trans* fatty acids combined per reference amount and reference food not low in saturates".

Discussion:

There were no specific comments received on this claim other than from those objecting to the inclusion of the restriction on *trans* fatty acids.

Reduction of dietary saturated fatty acid intake is one of the Nutrition

Recommendations for Canadians. A claim respecting the reduction of saturated fatty acids should be similar to other comparative claims for nutrients in requiring a significant minimum reduction of the nutrient that is the subject of the claim. The additional inclusion of the criterion for *trans* fatty acids is in line with the above discussion.

Conclusion:

In view of the above, it is proposed to change the definition for the comparative claim for saturated fatty acids from that proposed in 1996 to "at least 25% less saturates and, where present, at least 25% less *trans* fatty acids unless the *trans* fatty acid content is less than 0.2 g per reference amount and per labelled serving, per reference amount and the reference food not low in saturates". Please see the attached revised proposals for further details.

CLAIMS FOR *TRANS* FATTY ACIDS

In 1995 in a letter to stakeholders, Health Canada indicated that it would authorize claims for the *trans* fatty acid content of foods under a Letter of Temporary Marketing Authorization. A copy of this letter can be obtained from this office or by accessing the Health Canada Website.
The letter indicated that claims respecting *trans* fatty acids would be be restricted to the following:

- The claim "contains no *trans* fatty acids" if a food contained no more than 0.1 g of *trans* fatty acid per 100 grams and its content of saturated fatty acids was not increased;

- A comparison claim with respect to the *trans* fatty acid content if the *trans* fatty acid content of the food was reduced by a minimum of 25% and 1 gram per serving and its content of saturated fatty acids was not increased. Comparison claims would be permitted only between a food that has had its *trans* fatty acid content modified and an unmodified food.

Discussion:

Health Canada considers that claims for the *trans* fatty acid content of foods will be useful to the consumer in following Nutrition Recommendations which state that current levels of *trans* fatty acids in the diet should not be increased as well as guidance from authoritative bodies, based on data from scientific studies, which suggests that the *trans* fatty acid content of the diet should be reduced. In addition, it is envisaged that the availability of claims for *trans* fatty acids may encourage the manufacture of foods with lower levels of *trans* fatty acids and discourage the use of partially hydrogenated oils.

Proposal:

It is proposed that the claims "*trans* fatty acid-free" (free of *trans* fatty acids) and "reduced in *trans* fatty acids" be allowed on food labels and in food advertising. With respect to

the claim "*trans*-free", it is proposed that this be defined as "less than 0.2 g of *trans* fatty acids per reference amount and per labelled serving of food and the food meets the criteria for "low in saturates". The restriction on *trans* fatty acids in this definition is the same as that in the definition for the claim "free of saturated fatty acids". In order to encourage the use of claims for *trans* fatty acids and thus to encourage the reduction in the use of partially hydrogenated fats, it was considered that a similar restriction was not required for saturated fatty acids. However, in view of the association of *trans* fatty acids and coronary heart disease, it was considered that foods carrying a claim respecting the absence of *trans* fatty acids should also be required to be restricted in saturated fatty acids. It was also decided that foods carrying the claim "free of *trans* fatty acids" should meet the criteria for "low in saturated fatty acids".

It is proposed that the claim "reduced in *trans* fatty acids" would be allowed when the *trans* fatty acid content of a food has been reduced by a minimum of 25% and by a minimum of 1 gram per reference amount when compared to the reference food and the content of saturated fatty acids not increased in comparison to the reference food.

In line with the above proposals, the Food and Drug Regulations would need to be amended to provide for the declaration of the *trans* fatty acid content of foods.

Please see the attached revised proposals for further details.

CLAIMS FOR *OMEGA-3 AND OMEGA-6* POLYUNSATURATED FATTY ACIDS

In 1995 in a letter to stakeholders, Health Canada indicated that it would authorize claims for the omega-3 (n-3) and omega-6 (n-6) polyunsaturated fatty acid content of foods under a Letter of Temporary Marketing Authorization. A copy of this letter can be obtained from this office or by accessing the Health Canada Website. The letter indicated that claims respecting omega-3 and omega-6 polyunsaturated fatty acids would be be restricted to the following:

- A claim that a food is a source of omega-6 polyunsaturates would be permitted if the food contained at least 2 g of omega-6 polyunsaturates per serving.
- A claim that a food is a source of linoleic acid would be permitted if the food contained at least 2 g of linoleic acid per serving.
- A claim that a food is a source of omega-3 polyunsaturates would be permitted if the food contained at least 0.3 g of omega-3 polyunsaturates per serving.
- A claim that a food is a source of alpha-linolenic acid would be permitted if the food contained at least 0.3 g of alpha-linolenic acid per serving.
- No claims would be permitted at this time for gamma-linolenic acid, arachidonic acid, eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA) because these are not essential nutrients in the diet and recommended intakes have not been established for them.

Discussion:

Health Canada considers that claims for the omega-3 and omega-6 polyunsaturated fatty acid content of foods will be useful to the consumer in following Nutrition Recommendations which include recommended intakes for omega-3 and omega-6 fatty acids.

Proposal:

It is proposed that the claim "source of" be allowed for omega-3 and omega-6 polyunsaturated fatty acids as well as for linoleic acids and alpha-linolenic acid as indicated above with the exception that the basis for the claims will be both reference amounts and labelled serving sizes.

It is also proposed that the Food and Drug Regulations be amended to provide for the declaration of the omega-3 and omega-6 polyunsaturated fatty acids and of the alpha-linolenic acid fatty acid content of foods. Provision already exists under the Regulations for the declaration of linoleic acid.

CHOLESTEROL CLAIMS: MAXIMUM LEVEL OF FAT

1996 Proposal:

The 1996 Consultation proposed that the compositional criteria for "cholesterol free" claims also include a restriction on the total fat content of the food. The proposed maximum level of total fat for foods carrying cholesterol claims, not more than 5 g fat per reference amount and per serving, was based on prior consultations with stakeholders. The United States requires the disclosure of the total fat content in close proximity to the cholesterol claim if a food contains more than 13 g fat per reference amount and per labelled serving or per 50 g if the reference amount of the food is 30 g or less or 2 tablespoons or less.

Discussion:

Claims for the cholesterol content of foods are intended to assist consumers in choosing foods for a diet that will reduce the risk of coronary heart disease. However, the Nutrition Recommendations for Canadians (Health and Welfare Canada, 1990) also state that "the evidence linking saturated fat intake with elevated blood cholesterol and the risk of heart disease is among the most persuasive of all diet/disease relationships" and that "a reduction in total fat intake is an important way to reduce the intake of saturated fat".

Health professionals have expressed concerns about the appearance of cholesterol claims for foods that contain significant amounts of fat. The contention is that these claims are potentially misleading because consumers choose these foods in the belief that they will be of benefit to them. Research indicates that consumers consider foods carrying the claim "cholesterol free" to mean that the food is "good for your heart" and that it contains less fat and is low in saturated fat (National Institute of Nutrition's CONSUMER USE AND UNDERSTANDING OF NUTRITION INFORMATION ON FOOD PACKAGE LABELS, July 1992).

In view of the above concerns, the Health Protection Branch proposed in 1993 (Canada Gazette Part I, September 4, 1993) that the definitions for the terms, "cholesterol free" and "low cholesterol" be changed by incorporating a restriction on the total fat content consistent with that required for a food to be described as "low fat" (not more than 3 g of fat per serving and 0.15 g of fat per g dry matter). A total fat restriction was considered to resolve both the issue of the claim appearing on foods containing significant amounts of fat and the issue of the replacement of saturated fatty acids with *trans* fatty acids. Comments received on the 1993 proposal suggested that the total fat limit should be raised to 5 g per serving to allow the claim to be carried on a greater number of foods including liquid vegetable oils and that the limit on saturated fatty acids be re-introduced. This was therefore the proposal that was put forward in the January 1996 Consultation Document on Nutrient Content Claims.

Of those commenting on this proposal, respondents from some of the food industry as well as the health and consumer sector indicated that the maximum proposed fat level was too high and proposed that foods carrying cholesterol claims should meet the compositional criteria for "low fat" foods.

Conclusion:

It is proposed that the compositional criteria for cholesterol claims require that foods carrying these claims meet the criteria for "low fat" and "low saturates". The above discussion respecting *trans* fatty acids is equally applicable to cholesterol claims. Please see the attached revised proposals for further details.

"LIGHT" CLAIMS

1996 Proposal:

The criteria for the nutrient content claim "light" proposed in the 1996 Consultation Document on Nutrient Content Claims included a 1/3 reduction in fat for products containing 50% or more energy from fat or a 1/3 reduction in either fat or energy/calories for products with less than 50% of energy from fat. The proposal was consistent with the 1992 research findings of the National Institute of Nutrition *Consumer Use and Understanding of Nutrition Information on Food Package Labels* which showed that the majority of consumers interpret "light" to mean lower in fat (58%) or containing fewer calories (41%). It was also consistent with the Calorie Control Council's 1990 report *Americans Find "Light" to their Liking* which suggests that controlling energy/calories (85% of respondents) and fat (83% of respondents) were two of the major reasons for the use of "light" products. The proposal would eliminate the use of the term "light" with reference to all other nutrients.

Discussion:

There was objection to the January 1996 proposal from all sectors for various reasons. Although some of the food industry indicated that they supported the status quo, i.e. "Light" allowed with reference to energy or other nutrients with a 25% reduction, other industry respondents who did not object to limiting "light" to a reduction in energy or fat objected to the 33% reduction instead of the current 25%. Some respondents from the health sector stated that "light"

should refer to energy reduction only since this is the consumer perception of "light". Some respondents also indicated that "light" should not be allowed with reference to sensory or physical characteristics as consumers misunderstand that type of claim.

Conclusion:

In view of consumer perceptions with respect to light, application of this term to nutrients other than fat and to energy is not considered appropriate. However, since Canadian consumers are currently familiar with the term "light" referring to a 25% reduction, it is proposed to retain this level of reduction instead of the higher 33 1/3%. Please see the attached revised proposals for further details.

"SUGAR-FREE"

1996 Proposal:

The 1996 Consultation proposed two different options for the claim "sugar-free". One option was adoption of the U.S. criteria, less than 0.5 g sugars per reference amount of food and per labelled serving, and the mandatory statements "not calorie free", "not low in calories" or "not reduced in energy" unless the food met the criteria for these statements and was so labelled. The second option included a specific energy restriction (not more than 10 kilocalories per reference amount and per labelled serving) as well as the restriction on sugars, i.e. less than 0.5 g sugar per reference amount and per labelled serving. The second option was less restrictive than the current definition for "sugar-free" which restricts the claim to carbohydrate-reduced foods that provide, except for chewing gums, not more than 1 kilocalorie per 100 grams or millilitres of food.

Discussion:

The industry sector did not generally support the inclusion of an energy criterion for this claim; other respondents did not generally support the proposal to raise the energy maximum from 1 kcal per 100 g or mL to 10 kcals per reference amount and per labelled serving. As for other claims, there was also very little support for the use of disclaimers in the case of the "sugar-free" claim.

Canadian consumers suffering from diabetes are familiar with the fact that foods labelled as "sugar-free" are also "free" foods in terms of energy. A major re-education program for this very large consumer group with special needs would be required if the definition of "sugar-free" were changed to eliminate the current energy restriction.

Conclusion:

It is proposed to retain an energy restriction for the claim "sugar-free". In view of the proposed change to the definition of "energy free" from not more than 1 kilocalorie per 100 grams or millilitres to less than 5 kilocalorie per reference amount and per serving, this same energy restriction will also be applicable to foods labelled "sugar-free". Chewing gums labelled "sugar-free" will continue to be exempted from the energy requirement for this claim. Please see

the attached revised proposals for further details.

"NO ADDED SUGAR"

1996 Proposal

The Consultation Document proposed that the compositional criteria for this claim remain virtually unchanged. It was proposed however that the claim should be accompanied by the mandatory statements "not calorie free", "not low in calories" or "not reduced in energy" unless the food met the criteria for these statements and was so labelled.

Discussion

The industry sector generally supported the compositional criteria but not the requirement for the accompanying statements respecting energy. The health sector was split in its support; some expressed concern that the claim may be potentially dangerous for persons with diabetes who may consider the food to be "sugar-free"; others stated that the claim should include disclosure of the sugar source in the foods and should be accompanied by disclaimers such as "not sugar free" and "not calorie-free".

The National Institute of Nutrition's research study *"Consumer Use and Understanding of Nutrition Information on Food Package Labels"* (January 1992) indicated that the majority of respondents (60%) did not understand the claim "no added sugar". Of the respondents, 22% stated that "no sugar added" meant that there is no sugar in the food and 28% stated that it meant that the product contained "only natural sugar".

The claim "no sugar added" (or "unsweetened") has a long history of use in Canada. When the claim is used, the label is required to carry a declaration of the sugars content (all mono and disaccharides) of the food. The claim "no sugar added" is not generally considered to have a health basis.

Conclusion

In view of the potential for this claim to mislead and the fact that a large number of consumers do not understand the claim, it is proposed that the claim be accompanied by the statement "not sugar-free". Please see the attached revised proposals for further details.

"LIGHTLY SALTED":

1996 Proposal

The 1996 Consultation Document proposed that the claim "lightly salted" be defined as "at least 50% less sodium than normally added to the reference food and the reference food must not be "low sodium". In addition it was proposed that the claim should be accompanied by the statement "not low in sodium" unless the food met the criteria for low in sodium, and by a statement indicating the percent, fraction or amount of difference in sodium or salt content.

These proposed compositional criteria are consistent with those of the U.S. , and are stricter than the current Canadian criteria which require a minimum 25% reduction in added sodium or salt.

Discussion

Some respondents indicated that the claim "lightly salted" should be synonymous with "reduced sodium". Other respondents were concerned that consumers would confuse this claim with "low sodium".

Conclusion

It is proposed to amend the definition for "lightly salted" as presented in the 1996 Consultation Document. The mandatory accompanying information will require the statement "not low in sodium" unless the food is "low in sodium" and is so labelled. The accompanying information is considered essential to properly position foods carrying this claim. Please see the attached revised proposals for further details.

PROTEIN CLAIMS

1996 Proposal

The 1996 Consultation Document proposed to adopt the U.S. criteria for protein claims. The U.S. criteria, except for foods for infants under 1 year of age, are based on a "corrected amount of protein" determined using the protein digestibility corrected amino acid score (PDCAAS). Current Canadian criteria are based on protein quality determined using the protein efficiency ratio (PER).

Discussion

Some objection was expressed to the proposed use of the "corrected amount of protein" instead of the PER to measure protein quality. The objection was based on the fact that the PDCAAS underestimates the quality of very high quality protein sources (e.g. milk, egg, meats and fish) which may have an impact particularly when these are used as complementary sources of protein (e.g. milk with cereal). The latter is due to the fact that the PDCAAS considers values greater than 100 to be equal to 100. The PDCAAS also fails to fully account for the possible adverse effects of anti-nutritional factors. Furthermore, the PDCAAS assumes that supplemental amino acids have complete biological efficiency which may not be true in the case of poorly digestible low quality proteins (Sarwar, G., *The Protein Digestibility-Corrected Amino Acid Score Method Overestimates Quality of Proteins Containing Antinutritional Factors and of Poorly Digestible Proteins Supplemented with Limiting Amino Acids in Rats*, J. Nutr 127:758-764, 1997).

Conclusion

In view of the above concerns, it is proposed to retain the current Canadian criteria

for protein claims until the issues related to methodology are resolved. Please see the attached revised proposals for further details.

IMPLIED NUTRIENT CONTENT CLAIMS

It is proposed at this time that implied nutrient content claims will continue to be handled on a case by case basis by the Canadian Food Inspection Agency.

FOODS FOR SPECIAL DIETARY USES

1996 proposal

The 1996 Consultation proposed that the claims "carbohydrate-reduced", "calorie-reduced", "low calorie", "sugar-free" and "low sodium" would no longer be restricted to products meeting the definition of "food for special dietary use"[1] under the Food and Drug Regulations.

It was further proposed that specially formulated foods meeting the compositional criteria for energy/calorie and for sodium claims could continue to be represented for special dietary use if they met the regulatory definition for "food for special dietary use", carried the appropriate claim for energy/calories or sodium and were labelled in accordance with the requirements set out under Division 24 of the Food and Drug Regulations.

Discussion

There was general support from respondents for this proposal.

The claims "low calorie", "sugar-free" and "low sodium" are equally valid whether applied to foods that have been specially formulated to meet the criteria for the claims or those foods which inherently meet the criteria, e.g. most vegetables are inherently "low sodium". Furthermore, it is generally accepted that claims such as "calorie-reduced", "low calorie" and "low sodium" are useful to consumers choosing foods in line with healthy eating guidelines as well as consumers on special diets.

The claim "carbohydrate-reduced" was used in the past to identify foods recommended for carbohydrate-reduced diets which were used for the dietary management of diabetes. However, carbohydrate restriction per se is no longer part of the dietary guidance in the management of diabetes; although diets for persons with diabetes are individualized,

---

[1] "food for special dietary use" means a food that has been specially processed or formulated to meet the particular requirements of a person
(a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or
(b) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods
(Section B.24.003 of the Food and Drug Regulations)

carbohydrate is a significant component. We are unaware of other legitimate special dietary uses for "carbohydrate-reduced" foods.

With respect to the claim "sugar-free", it is apparent from comments received that foods so identified can be considered to be foods for special dietary use for the dietary management of diabetes. It is therefore proposed that the claim "sugar-free" also continue to be used as a claim for special dietary use provided pertinent requirements under Division 24 of the Food and Drug Regulations are met.

Conclusion

Please see the attached revised proposals for further details.

USE OF THE TERMS "DIET" OR "DIETETIC"

1996 Proposal

The 1996 Consultation proposed that the terms "diet" or "dietetic" should be restricted to foods which meet compositional criteria for and are labelled as "free", "low" or "reduced" in energy/calories and to "foods for special dietary use" as defined under Division 24 of the Food and Drug Regulations and so represented.

Discussion

Although there was some support for the proposal from the very few respondents who commented, some in the health sector indicated that the terms "diet" or "dietetic" are vague and of little use to consumers. It was also stated that persons with diabetes may confuse "dietetic" with "diabetic".

In view of the latter comment, it is proposed to restrict the use of the terms "diet" and "dietetic" to foods that meet compositional criteria for and are labelled as "free", "low" or "reduced" in energy/calories or "sugar-free".

Conclusion

Please see the attached revised proposals for further details.

COMPARATIVE CLAIMS (E.G. "REDUCED", "LESS", "LOWER", "MORE")

The 1996 Consultation proposed to make the criteria for comparative claims consistent with those of the U.S. The new definitions retain the current relative difference in the nutrient that is the subject of the claim between the foods being compared. However, instead of specifying an absolute minimum difference in addition to the relative difference for claims indicating a reduction of a nutrient, the new proposed definition will require that the reference food not meet the criteria for a "low" claim respecting the subject nutrient. There was general agreement with this proposal. Please see the

attached revised proposals for further details.

REFERENCE AMOUNTS FOR FOODS FOR NUTRIENT CONTENT CLAIMS

The letter sent to stakeholders in April 1997 included a table of reference amounts for foods for the purpose of nutrient content claims. These have been included in the Guide to Food Labelling and Advertising (Canadian Food Inspection Agency). Since reference amounts of foods will form the basis of regulated nutrient content claims it is required that they also be regulated.

DEFINITIONS FOR NUTRIENTS

It is proposed to include definitions for the following nutrients as proposed in the 1996 Consultation Document under the Food and Drug Regulations:

- energy/total calories
- sugars
- total

Please see the attached revised proposals for details.

REFERENCE FOODS

Please see the attached revised proposals for details respecting reference foods for the purpose of comparative nutrient content claims including the claim "light".

LABELLING

As had been indicated in discussions with stakeholders, Health Canada is carrying out a review of nutrition labelling. At this time, current requirements will continue to apply, i.e. declaration of only that nutrient which is the subject of the claim (exceptions, cholesterol, fatty acids and sodium).

APPENDIX

Health Effects of Trans Fatty Acids

Trans fatty acids and coronary heart disease

A number of controlled clinical or dietary intervention studies indicate that *trans* fatty acids in partially hydrogenated fats have detrimental effects on indices of coronary heart disease risk, such as plasma levels of low density lipoprotein cholesterol (LDL-C) and high density lipoprotein cholesterol (HDL-C) and lipoprotein (a) (1-9).

Compared to diets containing fat with higher levels of oleic or linoleic acids (the naturally occurring cis-unsaturated fatty acids), diets high in *trans* fatty acids from partially hydrogenated fats increase the level of plasma LDL-C (1-7). A strong association has been demonstrated between plasma LDL-C and the rate of coronary heart disease.

When *trans* fatty acids replaced saturated fatty acids, levels of plasma LDL-C were not found to be significantly different or were lower than LDL-C levels on diets containing saturated fatty acids (4-9).

In contrast to diets high in saturated fatty acids, however, diets high in *trans* fatty acids lowered plasma HDL-C. Thus, the effect of *trans* fatty acids on the ratio of total cholesterol to HDL-C appears to be more unfavourable than the effects of equivalent amounts of saturated or other dietary fatty acids. A high ratio of total cholesterol to HDL-C is now recognized as a strong risk factor for coronary heart disease. In addition, the effect of *trans* fatty acids on HDL-C increases with the amount consumed (3).

Another plasma protein considered a risk factor for coronary heart disease is lipoprotein(a) (10). Evidence exists from a number of published studies that *trans* fatty acids can raise lipoprotein(a) (1,2,5,9). In contrast to *trans* fatty acids, saturated and natural *cis*-unsaturated fatty acids tend to lower lipoprotein(a).

Several epidemiologic studies have reported positive associations between dietary *trans* fatty acids and incidence of coronary heart disease (11-16). However, two epidemiological studies that examined the relationship between the adipose tissue concentrations of *trans* fatty acids and risk of acute myocardial infarct (17) or sudden cardiac death (18), found no associations, although generally the adipose tissue concentrations of *trans* fatty acids reflect dietary intake.

The above epidemiological studies together with the clinical or intervention studies strongly indicate that higher intakes of *trans* fatty acids are associated with an increased risk of coronary heart disease.

Trans fatty acids and early human development

Two human studies have suggested a possible adverse effect of *trans* fatty acids on the growth and essential fatty acid balance of infants. Studies in Germany (19) and in the Netherlands (20) reported an inverse correlation between birth weight and the *trans* fatty acid content in plasma lipids. There was also a significant negative correlation between plasma n-6 and n-3 long-chain polyunsaturated fatty acids (LCPs) and *trans* fatty acids. In addition the Netherlands study found a positive correlation between levels of maternal plasma *trans* fatty acids and the *trans* fatty acid content of fetal tissue.

A preliminary report from the United States (21) suggests that higher maternal plasma *trans* fatty acids, as well as cis positional isomers of unsaturated fatty acids, are linked to poorer LCP status in the infant at birth.

LCPs, which are important constituents of cell membranes, are key in the development of the central nervous system (22, 23). *Trans* fatty acids may compete for the same enzyme systems that are responsible for the synthesis of LCPs from their dietary precursors (24, 25).

Trans fatty acids in the Canadian Diet

The possible adverse effects of *trans* fatty acids on serum lipoproteins and on the early development of infants should be of particular concern to Canadians. Two recent studies suggest that there is a higher consumption of *trans* fatty acids in Canada than in other countries.

In one study, adipose tissue fat from 12 adult Canadians was found to contain 6.3% *trans* fatty acids (26). This value is higher than those reported for the United States (27) and for Britain (28), and is three times higher than those reported for eight European countries and Israel in the EURAMIC study (17). The concentration of *trans* fatty acids in adipose tissue is generally considered to reflect dietary intake.

In the second study, the *trans* fatty acid content from breast milk samples from 198 Canadian women averaged 7.2% of milk fat and ranged from 0.1 to 17.2% (29). Such high levels of *trans* fatty acids have not been reported in human milk from other countries (30). Based on the level in breast milk, the mean intake of *trans* fatty acids for Canadians was estimated to be 8.4 g per day and in some individuals, the intake could be as high as 39 g per day (31).

Partially hydrogenated vegetable oils, which are used in the production of margarine and commercial shortening are the prime sources of *trans* fatty acids in the Canadian diet. In 1995, 973 000 metric tonnes (MT) of edible oils were deodorized in Canada, of which 53% was hydrogenated for the production of margarine (153,000 MT) and commercial shortening (353,000 MT) (32).

In 1995 Health Canada determined the *trans* content and the fatty acid composition of 109 margarine brands, covering the entire Canadian market (33). The average total *trans* content of the margarines was about 21% but some margarine brands contained as much as 46% *trans* fatty acids. In 33 margarine samples the *trans* content was more than 30% and the linoleic acid content was below the 5% level recommended to Health Canada by the Ad Hoc Committee on the Composition of Special Margarines (34). The same Committee also recommended that margarines contain less than 1% trans-trans fatty acids.

Canadian commercial shortenings are usually made from partially hydrogenated canola oil and may contain up to 50-55% *trans* fatty acids. These shortenings are presently used by major fast-food chains and french-fries manufacturers for deep fat frying. Also, partially hydrogenated shortenings are used in the production of many baked products. As a consequence, high levels of *trans* fatty acids are present in many common foods in Canada. A study conducted by Health Canada in 1991 (35) found the following levels of *trans* fatty acids in Canadians foods: french fries, 33% (of total fatty acids); breads 16%; hamburger buns 26%; cakes 10-26%; candies/chocolates 11%; cereals 9-34%; cookies 8-39%; crackers 14-35%; donuts 28-33%; muffins 16-24%; pizza 22-28%; potato chips 30-40% and corn chips 30-34%. As was the case for margarines, the products high in *trans* fatty acids were lower in essential fatty acids. In this same study (35) it was observed that food items labelled as "cholesterol free" and or "low in saturated fat" contained very high levels of *trans* fatty acids . At present the Canadian consumer lacks readily accessible information on the *trans* fatty acid content of foods.

Statements from authoritative bodies

Food and Agriculture Organization / World Health Organization (FAO/WHO) of the United Nations

In 1993, the FAO/WHO convened a joint expert consultation on the role of dietary fats and oils in human nutrition which made the following recommendations about *trans* fatty acids (36):

a) Consumers should substitute liquid oils and soft fats for hard fats to reduce both saturated fatty acids and *trans* isomers of unsaturated fatty acids.

b) Food manufacturers should reduce the levels of *trans* isomers arising from hydrogenation.

c) Where there is a possibility of deficiency of essential fatty acids during pregnancy and lactation, a high level of *trans* fatty acids should be avoided.

d) Governments should limit the claims concerning the saturated fatty acid content of foods which contain appreciable amounts of *trans* fatty acids, and should not allow foods that are high in *trans* fatty acids to be labelled as being low in saturated fatty acids.

e) It would be inappropriate to suggest an advantage of a food in reducing the risk of heart disease if it contained other components that clearly increase the risk of heart disease.

Codex Alimentarius Commission (FAO)

The Codex Committee on Nutrition and Foods for Special Dietary Uses has included the following statement in the conditions for nutrient content claims: *"In the case of the claim for "low in saturated fat, trans fatty acids should be taken into account where applicable. This provision consequentially applies to foods claimed to be "low in cholesterol" and "cholesterol free"."*(37)

American Heart Association

The American Heart Association (38) has recently stated that, based on current clinical and epidemiological data respecting *trans* fatty acids "it is prudent at this point to recommend that naturally occurring unhydrogenated oil be used when possible and attempts made to substitute unhydrogenated oil for hydrogenated or saturated fat in processed foods. Additionally, the recommendation to substitute softer for harder margarines and cooking fats seems justified."

The Danish Nutrition Council

In 1995 the Danish Nutrition Council made the following conclusions and recommendations (39):

Conclusions:

a) Consumption of *trans* fatty acids from margarine is equally, or perhaps more, responsible for the development of arteriosclerosis than saturated fatty acids.

b) Both the fetus and breast-fed baby are exposed to *trans* fatty acids in relation to mother's consumption. A couple of recent studies suggest a possible restrictive influence of the *trans* fatty acids on the weight of the fetus.

Recommendations:

a) The consumption of *trans* fatty acids should be reduced as much as possible.

b) The content of *trans* fatty acids in all types margarines should be reduced to 5% or lower.

c) The Danish Nutrition Council encourages all producers of margarine and margarine-containing foods to produce products that can be labelled as "free of *trans* fatty acids".

REFERENCES

1. Lichtenstein, A.H., L.M. Ausman, W. Carrasco, et al. Hydrogenation Impairs the Hydrogenation Effect of Corn Oil in Humans. Hydrogenation, Trans Fatty Acids, and Plasma Lipids. *Arterioscler. Thromb. 13*: 154-161 (1993).

2. Mensink, R.P., P.L. Zock, M.B. Katan, and G. Hornstra. Effect of Dietary Cis and Trans Fatty Acids on Serum Lipoproteins Levels in Humans, *J. Lipid Res. 33*:1493-1501 (1992).

3. Zock, P.L., M.B. Katan and R.P. Mensink. Dietary trans fatty acids and lipoprotein cholesterol (Letter) *Am. J. Clin. Nutr. 61*: 617 (1995).

4. Mensink, R.P. and M.B. Katan. Effect of Dietary Trans Fatty Acids on High-Density and Low-Density Lipoprotein Cholesterol Levels in Healthy Subjects. *N. Eng. J. Med. 323*:439-445 (1990).

5. Nestel, P., M. Noakes, B. Belling, et al. Plasma Lipoprotein Lipid and Lp(a) Changes with Substitution of Elaidic Acid for Oleic Acid in the Diet. *J. Lipid Res. 33*:1029-1036 (1992).

6. Zock, P.L. and M.B. Katan. Hydrogenation Alternatives: Effects of Trans Fatty Acids and Stearic Acid Versus Linoleic Acid on Serum Lipids and Lipoproteins in Humans, *J. Lipid Res. 33*:399-410 (1992).

7. Judd, J.T., A. Clevidence, R.A. Muesing et al. Dietary Trans Fatty Acids: Effects on Plasma Lipids and Lipoproteins on Healthy Men and Women. *Am. J. Clin. Nutr. 59*:861-868 (1994).

8. Aro, A., M. Jauhiainen, Partanen R., et al. Stearic acid, *trans* fatty acids, and dairy fat: effects on serum and lipoprotein lipids, apolipoproteins, lipoprotein(a), and lipid transfer proteins in healthy subjects. *Am. J. Clin. Nutr. 65:*1419-1426 (1997).

9. Almendingen, K., O. Jordal, P. Kierulf et al. Effects of Partially Hydrogenated Fish Oil, Partially Hydrogenated Soybean Oil and Butter on Serum Lipoproteins and Lp(a) in Men. *J. Lipid Res. 36*:1370-1384 (1995).

10. Brown, S.A. J.D. Morrisett, E. Boerwinkle et al. The relation of lipoprotein(a) concentrations and apolipoprotein(a) phenotypes with asymptomatic atherosclerosis in subjects of the Atherosclerosis Risk in Communities (ARIC) Study. *Arterioscler. Thromb. 13:*1558-1566 (1993).

11. Siguel, E.N. and R.H. Lerman. Trans-Fatty Acid Patterns with Angiographically Documented Coronary Artery Disease. *Am. J. Cardiol. 71*:916-920 (1993).

12. Willett, W.C., M.J. Stampfer, J.E. Manson et al. Intake of Trans Fatty Acids and Risk of Coronary Heart Disease Among Women. *Lancet 341*:581-585 (1993).

13. Ascherio, A., C.H. Hennekens, J.E. Burling et al. Trans-Fatty Acid Intake and Risk of Myocardial Infarction. *Circulation 89*:94-101(1994).

14. Kromhout, D., A. Menotti, B. Bloemberg, et al. Dietary Saturated and Trans Fatty Acids and Cholesterol and 25-year Mortality from Coronary Heart Disease: the Seven Countries Study. *Prev. Med. 24*:308-315 (1995).

15. Hu, F.B., M.J. Stampfer, .E. Manson et al. Dietary fat intake and the risk of coronary heart disease in women. *New Eng. J. Med. 337*:1491-1499 (1997).

16. Pietinen, P., A. Ascherio, P. Korhonen et al. Intake of Fatty Acids and Risk of Coronary Heart Disease in a Cohort of Finnish Men. *Am. J. Epidemiol. 145*:876-887 (1997)

17. Aro, A., A.F.M. Kardinaal, I. Salminen et al. Adipose Tissue Isomeric Trans Fatty Acids and the Risk of Myocardial Infarction in Nine Countries: the EURAMIC study. *Lancet 345*:273-278 (1995).

18. Roberts, T.L., D.A. Wood, R.A. Riemersma et al. Trans Isomers of Oleic and Linoleic Acids in Adipose Tissue and Sudden Cardiac Death. *Lancet 345*:278-282 (1995).

19. Decsi, T., and B. Koletzko. Do Trans Fatty acids Impair Linoleic Acid Metabolism in Children? *Ann. Nutr. Metab. 39*:36-41 (1995).

20. Houwelingen, A.C.v. and G. Hornstra. Trans Fatty Acids in Early Human Development. *World Rev. Nutr. Diet 75*:175-178 (1994).

21. Ayagari, A., J.M. Peeples and S.E. Carlson. Relationship of isomeric Fatty Acids in Human Cord Blood to N3 and N6 Status. *Ped. Res. 39*:304A (1996).

22. Uauy, R., P. Peirano, D. Hoffman et al. Role of essential fatty acids in the function of the developing nervous system. *Lipids 31*: s167-176 (1996).

23. Innis, S. Essential fatty acids in growth and development. *Prog. Lipid Res. 30*:39-103 (1991).

24. Berdeaux, O. J.L. Sébédio, J.M. Chardigny et al. Effects of *trans* n-6 fatty acids on the fatty acid profile of tissues and microsomal metabolism in the rat. *Grass. Aceit. 47*:86-99 (1996).

25. Blond, J.P., J.M. Chardigny, J.L. Sébédio and A. Grangirard. Effects of dietary 18:3(n-3) *trans* isomers on the □6 desaturation of □ -linolenic acid. *J. Food Lipids 2*: 99-106 (1995).

26. Chen, Z.Y., W.M.N. Ratnayake, L. Fortier, R. Ross, and S.C. Cunnane, Similar Distribution of Trans Fatty Acid Isomers in Partially Hydrogenated Vegetable Oils and Adipose Tissue of Canadians, *Can. J. Physiol. Pharmacol. 73*:718-723 (1995).

27. Hudgins, L.C., J. Hirsh, and E.A. Emken, Correlation of isomeric fatty acids in human adipose tissue with clinical risk factors for cardiovascular disease. *Am. J. Clin. Nutr. 53*:474-482 (1991).

28. Roberts, T.L., D.A. Wood, R.A. Riemersma, P.J. Gallagher, and F.C. Lampe, Trans Isomers of Oleic and Linoleic Acids in Adipose Tissue and Sudden Cardiac Death. *Lancet 345*:278-282 (1995).

29. Chen, Z.Y., G. Pelletier, R. Hollywood, and W.M.N. Ratnayake, Trans Fatty Acid Isomers in Canadian Human Milk. *Lipids 30*:15-21 (1995).

30. Emken, E.A., Trans Fatty Acids and Coronary Heart Disease Risk; Physiochemical Properties,

Intake, and Metabolism. *Am. J. Clin. Nutr. 62*:659S-669S (1995).

31. Ratnayake, W.M.N., and Z.Y. Chen, *Trans* Fatty Acids in Canadian Breast Milk and Diet, in Development and Processing of Vegetable Oils for Human Nutrition, edited by R. Przybylski and B.E. McDonald, AOCS Press, Champaign, IL, 1995, pp. 20-35.

32. Domestic Production of Deodorized Oils and Fats, Catalogue 32-006, Vol. 46, No. 12, Statistics Canada, Ottawa, Canada. 1996.

33. Ratnayake, W.M.N., G.R. Pelletier, R. Hollywood, S. Bacler and D. Leyte. *Trans* Fatty Acids in Canadian Margarines: Recent trends, submitted for publication in *J. Am. Oil Chem. Soc.* (1998).

34. Minister of Supply and Services Canada. Report of the Ad Hoc committee on the Composition of Special Margarines. Ottawa. (1980).

35. Ratnayake, W.M.N., Hollywood, E. O'Gradey and G.R. Pelletier. Fatty Acids in Some Common Food Items in Canada. *J. Am. Coll. Nutr. 12*:651-660 (1993).

36. Food andAgriculture Organization of the United Nations. Fats and Oils in Human Nutrition, Report of a Joint Expert Consultation, FAO Food and Nutrition Paper 57, 1994.

37. Food and Agriculture Organization of the United Nations and the World Health Organization. Codex Alimentarius Commission. Report of the Twentieth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. Alinorm 97/26 (1996).

38. American Heart Association. *Trans* Fatty Acids, Plasma Lipid Levels, and Risk of Developing Cardiovascular Disease. *Circulation 95*:2588-2590 (1997).

39. Stender, S., J. Dyerberg, G. Holmer, L. Ovesen, and B. Sandstrom. The Influence of Trans Fatty Acids on Health: A Report from the Danish Nutrition Research Council, *Clinical Science 88*:375-392 (1995).

REVISED PROPOSALS FOR NUTRIENT CONTENT CLAIMS

Food Directorate, Health Protection Branch
Health Canada

March 1998

1. ENERGY

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free ("energy free", "calorie free")	• Less than 5 Cal per reference amount* and per labelled serving
Low ("low calorie", "low in energy")	• Not more than 40 Cal per reference amount and per labelled serving and not more than 40 Cal per 50 g of food if its reference amount is 30 g or 30 mL or less • **Prepackaged meals and main dish entrées**: not more than 120 Cal per 100 g of product
Comparison ("reduced", "less", "fewer")	• Not less than 25% fewer Cal per reference amount than reference food and the reference food must not meet the criteria for "low in energy" • **Prepackaged meals and main dish entrées**: not less than 25% fewer Cal per 100 g than reference food and reference food must not meet the criteria for "low in energy" • ***Accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in energy value indicated adjacent to the most prominent comparative claim.

* Reference amounts for foods were published in the Guide to Food Labelling and Advertising available from the Canadian Food Inspection Agency or on the Internet at HTTP://WWW.CFIA-ACIA.AGR.CA

2. FAT

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free	• Less than 0.5 g fat per reference amount and per labelled serving • **Prepackaged meals and main dish entrées**: Less than 0.5 g fat per reference amount and per labelled serving or per labelled serving where no reference amount is indicated.
Low	• Not more than 3 g fat per reference amount and per labelled serving and not more than 3 g fat per 50 g if the reference amount of the food is 30 g or 30 mL or less • **Prepackaged meals and main dish entrées**: not more than 3 g fat per 100 g and not more than 30 % of the energy in the food from total fat
"100% fat-free"	• Must meet the criteria for "fat-free" and must contain less than 0.5 g fat per 100 g and must contain no added fat
"(stating the percentage) fat-free"	• Must meet the criteria for "low fat"
Comparison ("reduced", "less", "fewer")	• At least 25% less fat per reference amount than reference food and the reference food must not meet the criteria for "low fat" • **Prepackaged meals and main dish entrées**: At least 25% less fat per 100 g than the reference food and the reference food must not meet the criteria for "low fat" • ***Accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in fat content indicated adjacent to the most prominent comparative claim.

3. SATURATED FAT

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free	• Less than 0.2 g saturated fatty acid and less than 0.2 g *trans* fatty acids per reference amount and per labelled serving • **Prepackaged meals and main dish entrées**: Less than 0.2 g saturated fatty acids and less than 0.2 g *trans* fatty acids per reference amount and per labelled serving or per labelled serving where no reference amount is indicated
Low	• Not more than 2 g saturated and *trans* fatty acids combined per reference amount and per labelled serving and per 50 g if reference amount is 30 g or 30 mL or less, and not more than 15% of energy from saturated and *trans* fatty acids combined per reference amount and per labelled serving • **Prepackaged meals and main dish entrées**: Not more than 2 g saturated and *trans* fatty acids combined per 100 g and not more than 15% of energy from saturated and *trans* fatty acids combined
Comparison ("reduced", "less", "fewer")	• At least 25% less saturated fatty acids and, where present, at least 25% less *trans* fatty acids unless the *trans* fatty acid content is less than 0.2 g per reference amount and per labelled serving, per reference amount than reference food and the reference food must not meet the compositional criteria for "low in saturated fatty acids" • **Prepackaged meals and main dish entrées**: At least 25% less saturated fatty acids and, where present, at least 25% less *trans* fatty acids unless the *trans* fatty acid content is less than 0.2 g per labelled serving where no reference amount is indicated, per 100 g than reference food and reference food must not meet the compositional criteria for "low in saturated fatty acids" • ***Accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in saturated fatty acid content indicated adjacent to the most prominent comparative claim.

4. *TRANS* FATTY ACIDS

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free	• Less than 0.2 g *trans* fatty acids per reference amount and per labelled serving and meets the compositional criteria for "low in saturates". • **Prepackaged meals and main dish entrées**: Less than 0.2 g *trans* fatty acids per reference amount and per labelled serving or per labelled serving where no reference amount is indicated, and meets the compositional criteria for "low in saturates".
Comparison ("reduced", "less", "fewer")	• At least 25% and at least 1 gram less *trans* fatty acids per reference amount than reference food and the content of saturated fatty acids not increased in comparison to the reference food. • **Prepackaged meals and main dish entrées**: At least 25% and at least 1 gram less *trans* fatty acids per 100 g than reference food and the content of saturated fatty acids not increased in comparison to the reference food. • ***Accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in *trans* fatty acid content indicated adjacent to the most prominent comparative claim.

5. OMEGA-3 (n-3) and OMEGA-6 (n-6) POLYUNSATURATED FATTY ACIDS

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Source of omega-3 polyunsaturated fatty acids; source of omega-3 polyunsaturates	• A minimum of 0.3 g of omega-3 polyunsaturates per reference amount and per labelled serving. • **Prepackaged meals and main dish entrées**: A minimum of 0.3 g of omega-3 polyunsaturates per 100 g.
Source of alpha-linolenic fatty acid	• A minimum of 0.3 g of alpha-linolenic acid per reference amount and per labelled serving. • **Prepackaged meals and main dish entrées**: A minimum of 0.3 g of alpha-linolenic acid per 100 g.
Source of omega-6 polyunsaturated fatty acids; source of omega-6 polyunsaturates	• A minimum of 2 g of omega-6 polyunsaturates per reference amount and per labelled serving. • **Prepackaged meals and main dish entrées**: A minimum of 2 g of omega-6 polyunsaturates per 100 g.
Source of linoleic fatty acid	• A minimum of 2 g of linoleic acid per reference amount and per labelled serving. • **Prepackaged meals and main dish entrées**: A minimum of 2 g of linoleic acid per 100 g.

6. CHOLESTEROL

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free	• Less than 2 mg cholesterol per reference amount and per labelled serving and meets compositional criteria for "low fat" and for "low in saturates" • **Prepackaged meals and main dish entrées**: Less than 2 mg cholesterol per reference amount and per labelled serving or per labelled serving where no reference amount is indicated and meets compositional criteria for "low fat" and "low in saturates"
Low	• Not more than 20 mg cholesterol per reference amount, per labelled serving and per 50 g of food if reference amount is 30 g or 30 mL or less and meets compositional criteria for "low fat" and "low in saturates" • **Prepackaged meals and main dish entrées**: Not more than 20 mg cholesterol per 100 g and meets the compositional criteria for "low fat" and "low in saturates"
Comparison ("reduced", "less", "fewer")	• At least 25% less cholesterol per reference amount than reference food and meets the compositional criteria for "low fat" and "low in saturates" and reference food not a "low cholesterol" food • **Prepackaged meals and main dish entrées**: At least 25% less cholesterol per 100 g than reference food and meets criteria for "low in saturates" and "low fat" and reference food not a "low cholesterol" food • ***Accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in cholesterol content indicated adjacent to the most prominent comparative claim.

7. SODIUM

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free	• Less than 5 mg sodium per reference amount and per labelled serving • **Prepackaged meals and main dish entrées**: less than 5 mg sodium per reference amount and per labelled serving or per labelled serving where no reference amount is indicated
Low	• Not more than 140 mg sodium per reference amount and per labelled serving and per 50 g if reference amount is 30 g or 30 mL or less • Except in the case of salt substitutes, no added sodium salts • **Prepackaged meals and main dish entrées**: not more than 140 mg sodium per 100 g
Very low	• Not permitted
Comparison ("reduced", "less", "fewer")	• At least 25% less sodium per reference amount than reference food and reference food must not meet compositional criteria for "low in sodium" • **Prepackaged meals and main dish entrées**: At least 25% less sodium per 100 g than reference food and reference food must not meet compositional criteria for "low in sodium" • ***Accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in sodium content indicated adjacent to the most prominent comparative claim.
Light in sodium	• Not permitted

Unsalted (without added salt; no salt added)	• No salt or other sodium salts added during processing and no ingredients containing sodium or salt • The reference food is normally processed with salt or other sodium salts • ***Accompanying information:*** Unless food is "sodium free" and is so labelled, claim to be accompanied in close by statement "not sodium free".
Lightly salted	• At least 50% less sodium than normally added to the reference food and reference food does not meet the compositional criteria for a "low sodium" food • ***Accompanying information:*** Unless food is "low in sodium" and is so labelled, claim to be accompanied in close proximity by the statement "not a low sodium food"; the identity of the reference food and the percent, fraction or amount of difference in sodium/salt content indicated adjacent to the most prominent comparative claim.

8. SUGAR

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
Free	• less than 0.5 g sugars per reference amount and per labelled serving **and**, with the exception of chewing gum, meets definition for "free of energy" • "sugars" is defined as the sum of all free mono and disaccharides
Low	• not permitted
No added sugar	• no sugar or other ingredients containing sugars added in processing or packaging and no ingredients with added sugars and sugars content not increased through some other means such as the use of enzymes except where the functional effect is not to increase the sugar content of the food • the reference food has added sugars • ***accompanying information***: Unless food is "sugar free" and is so labelled, claim to be accompanied in close proximity by the statement "not sugar free".
Comparison ("reduced", "less", "fewer")	• At least 25% less sugars per reference amount than reference food • **prepackaged meals and main dish entrées**: At least 25% less sugars per 100 g than reference food • ***accompanying information:*** The identity of the reference food and the percent, fraction or amount of difference in sugars content adjacent to the most prominent comparative claim.

9. DIETARY FIBRE

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
"contains", "source of" "made with"	• A minimum of 2 g dietary fibre per reference amount and per labelled serving when a specific fibre source is not mentioned **or** a minimum of 2 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned • **prepackaged meals and main dish entrées:** must contain at least one food that meets criteria for "source of dietary fibre"
"high source", "high in"	• A minimum of 4 g dietary fibre per reference amount and per labelled serving when a specific fibre source is not mentioned **or** a minimum of 4 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned • **prepackaged meals and main dish entrées**: must contain at least one food that meets criteria for "high in dietary fibre"
"very high source" "very high in" "rich in fibre"	• A minimum of 6 g dietary fibre per reference amount and per labelled serving when a specific fibre source is not mentioned **or** a minimum of 6 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned • **prepackaged meals and main dish entrées**: must contain at least one food that meets criteria for "very high in dietary fibre"
comparison ("more", "higher")	• A minimum of 2 g dietary fibre per reference amount and per labelled serving **and** a minimum 25% increase in dietary fibre • **prepackaged meals and main dish entrées**: at least one food that meets criteria for "source of dietary fibre" **and** a minimum 25% increase in dietary fibre per 100 g; ***accompanying information*:** The identity of the reference food and the percent, fraction or amount of difference in dietary fibre content indicated adjacent to the most prominent comparative claim.

10. LIGHT/LITE

PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
• meets criteria for "reduced energy" or "reduced fat" • **prepackaged meals or main dish entrées**: meet definition for "low fat" or "low calorie" • **"Light" in reference to sensory or physical characteristic:** label must identify sensory or physical characteristic • **"Light" in reference to any other nutrients than fat** (e.g. sodium (salt), sugar, etc.): not permitted ***accompanying information:*** • A statement of the % or fraction or amount of reduction for calories or fat or both depending on the reduction to meet the criteria for the claim • **prepackaged meals and main dish entrées**: an indication whether product meets "low in calories" or "low in fat" or both • **for physical or sensory attributes**: indication of which attribute product is "light" in e.g. "light in texture", "light in flavour". The above information must appear immediately adjacent to the most prominent "light" claim

11. PROTEIN

Current compositional criteria for protein claims will be retained until the issues around appropriate methodology for protein quality in foods have been resolved. There is some overlap between the current Canadian criteria and those of the U.S. although the basis for the claims are different ("protein rating" in Canada; "corrected protein" in the U.S.).

CLAIM	PROPOSED COMPOSITIONAL AND SPECIFIC LABELLING REQUIREMENTS
"source of", "contains", "good source", "high"	protein rating[1] at least 20 **or** protein rating of at least 20 per 30 g of breakfast cereal with 125 mL of milk ***prepackaged meals and main dish entrées:*** must contain a food that meets the definition of "source of protein"
" excellent source of", "very high"	protein rating at least 40 ***prepackaged meals and main dish entrées:*** must contain a food that meets the definition of "excellent source of protein"
Comparison ("more", "higher")	protein rating at least 20 and at least 25% increase in protein per RDI compared to the reference food and more protein per serving ***accompanying information:*** the identity of the reference food and the amoun or fraction) difference in protein in close proximity to the most prominent co

[1] protein rating = PER (protein efficiency ratio) of protein multiplied by g protein in RDI of food

12. IMPLIED NUTRIENT CONTENT CLAIMS

It is proposed at this time that implied nutrient content claims will continue to be handled on a case by case basis by the Canadian Food Inspection Agency.

13. USE OF THE TERM "HEALTHY"

The current criteria for the use of the term "healthy" on labels of or in advertisements for foods will be retained. This policy will remain as a guideline under the Guide to Food Labelling and Advertising (Canadian Food Inspection Agency)

14. REFERENCE AMOUNTS FOR FOODS

A letter sent to stakeholders by Health Canada, dated April 25, 1997, contained a list of reference amounts for foods for the purpose of nutrient content claims. This list has been included in the Guide to Food Labelling and Advertising (Canadian Food Inspection Agency). It is now intended to include this list of reference amounts under the Food and Drug Regulations.

15. REFERENCE FOODS

CLAIM	PROPOSED CRITERIA
"reduced", "less", "fewer", "added" "more"	*i)* The reference food must not meet the compositional criteria for "low" for the nutrient that is the subject of the claim. *(ii)* For the claims "reduced" and "added", the reference food must be a similar food. For the claims "less", "fewer" or "more", the reference food may be either a similar food or a dissimilar food within the same food group of Canada's Food Guide To Healthy Eating that can be substituted in the diet, e.g. potato chips and pretzels; cheese and milk. *(iii)* The reference food may be the same as that provided for "light" (a product that is representative of the type of food that includes the product that bears the claim) or it may be the manufacturer's regular product or that of another manufacturer. *iv)* The reference food must be described so that it can be easily identified by consumers.

"Light"	*(i)* The reference food must not meet the compositional criteria for "low energy" if "light" refers to energy reduction or for "low fat" if "light" refers to fat reduction. *(ii)* If "light" is part of the common name, the reference food must be the same named food not described as "light", e.g. "Light Potato Chips" vs. "Potato Chips". *(iii)* If "light" is not part of the common name, the reference food may be the same named food not described as "light" or another similar food, e.g. "Cream Cheese Product" vs. "Cream Cheese". *(iv)* The reference food must be representative of the type of food that includes the product that bears the claim. *(v)* The nutrient value for the reference food must be representative of a broad base of foods of that type, e.g., •value in representative, valid data base; •average top 3 national (regional) brands; •market leader, if representative ; or •minimum level in standard for class of foods, if applicable, and if representative of the class *(vi)* The reference food must be described so that it can be easily identified by consumers.

16. SINGLE SERVING CONTAINERS

It is proposed that sub section B.01.002A of the Food and Drug Regulations will be amended as follows:

(1) For the purposes of this Part, a serving of stated size of a food shall be

(a) declared on the basis of the food as offered for sale;
(b) expressed
(i)in grams, where the net quantity of the food is declared on the label by weight, and
(ii)in millilitres, where the net quantity of the food is declared on the label by volume; and
(c) where the food is packaged in a container that could reasonably be construed as containing a single serving of the food, equal to the net quantity of the food.

(2) Notwithstanding subsection (1), where the reference amount of the food is less than 100 g or 100 mL and where the container contains less than 200% of the reference amount for that food, the entire container shall be labelled as one serving.

(3) The reference amount of a food referred to in subsection (2) is found in Table of section B.01.xxx.

17. DEFINITIONS

ENERGY/TOTAL CALORIES: calculated in any one of the following ways:

A. using specific Atwater factors (Table 13 in Energy Value of Foods -Basis and Derivation by A.L. Merrill and B.K. Watt, United States Department of Agriculture (USDA) Handbook No. 74, 1973)

B. using the general factors 4, 4 and 9 calories per gram of protein, total carbohydrate and total fat, respectively, as described in USDA Handbook No. 74, pgs 9-11

C. using the general factors of 4, 4 and 9 per gram of protein, total carbohydrate less the amount of insoluble dietary fibre, and total fat, respectively

D. using bomb calorimetry data and subtracting 1.25 calories per gram protein to correct for incomplete digestibility as described in USDA Handbook No.74, pg 10

E. using data for specific foods or ingredients accepted by the Health Protection Branch

SUGARS: sum of all free mono- and disaccharides

FAT/TOTAL FAT: total lipid fatty acids expressed as triglycerides

SATURATED FATTY ACIDS/ SATURATES: all fatty acids containing no double bonds

***TRANS* FATTY ACIDS**: unsaturated fatty acids where one or more of the double bonds are in a "*trans*" configuration.

18. ROUNDING RULES

- The energy value of the food, shall be rounded to the nearest whole number when expressed in Calories (Calories or Cal), and when expressed in kilojoules, to the nearest whole number for energy values less than 10 kJ and to the nearest 10 kJ for energy values of 10 kJ or more.
- The content in the food of protein, fat and carbohydrate, shall be rounded to the nearest 1/10 of a gram for quantities less than 10 grams and to the nearest whole number for quantities of 10 grams or more.
- The content in the food of cholesterol shall be rounded to the nearest milligram.
- The content in the food of sodium shall be rounded to the nearest whole number.

19. FOODS FOR SPECIAL DIETARY USES AND THE USE OF THE TERMS "DIET" AND "DIETETIC"

It is proposed that the following definitions will be deleted from Division 24 of the Food and Drug Regulations: "carbohydrate reduced", "calorie-reduced", "low calorie", "sugar-free" and "low sodium" and will appear with other nutrient content claim definitions in Division 1 of the Regulations. The result of the proposed amendment will be that these claims will not be restricted to products meeting the definition of "food for special dietary use"[2] under the Food and Drug Regulations.

It is also proposed that specially formulated foods meeting the compositional criteria for energy/calorie, sugar and sodium claims may continue to be represented for special dietary use if they meet the definition for "food for special dietary use" in Division 24 of the Regulations and are labelled in accordance with the requirements set out therein. The term "diet" or "dietetic" will be restricted to foods for special dietary use that meet compositional criteria for and are labelled as "free", "low" or "reduced" in energy/calories or "sugar-free".

20. PROVISION FOR DECLARATION OF *TRANS* , OMEGA-3, OMEGA-6 AND ALPHA-LINOLENIC FATTY ACID CONTENT

It is proposed to amend section B.01.303 of the Food and Drug Regulations to make provision for the declaration of *trans,* omega-3 polyunsaturated, omega-6 polyunsaturated and alpha-linolenic fatty acid content of a food in g as part of the total fat content of a food. The declaration of any one of these fat components would require the declaration of total fat, saturates, monounsaturates and polyunsaturates.

---

[2] "food for special dietary use" means a food that has been specially processed or formulated to meet the particular requirements of a person
(a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or
(b) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods
(Section B.24.003 of the Food and Drug Regulations)