Canadian Friends of Freedom Organization Steps Up To the Codex Challenge

Written by Friends of Freedom
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Friends of Freedom Submission for Codex meetings in Bonn, Germany on November 1st to 4th, 2004

Addressed to the Canadian Codex Contact office in Health Canada, relating to the CCNFSDU - Codex Committee for Nutrition and Foods for Special Dietary Uses, and to CCFL - Codex Committee for Food Labeling.

To: Canadian delegation for Codex Committee on Nutrition and Foods for Special Dietary Uses (NFSDU)

From: The Friends of Freedom, Inc.

Date: Monday, 20 September 2004

THE FRIENDS OF FREEDOM, INC., a mixed stakeholder, non-partisan, political and legal action organization dedicated to preserving the rights of all Canadians to access substances that promote health through natural means that also serves as an umbrella organization advocating on behalf of like-minded associated groups across Canada submits the following comments on behalf of its 100,000 Canadian members and supporters and on behalf of associated groups in response to the request for stakeholder comments in preparation for the November committee meeting of the Codex Committee on Foods and Nutrition for Special Dietary Uses.

Nothing in this submission should be deemed to express or imply that The Friends of Freedom concedes the authority of the federal government of Canada to act in this manner as the agent authorized by Canadian law to speak on behalf of or vote on behalf of either the provinces or the citizens of Canada.

Nothing in this submission should be deemed to express or imply that The Friends of Freedom acknowledges or concedes that the federal government of Canada acted lawfully in promulgating the regulations concerning natural health products contained in *Canadian Gazette,Part II, Volume 137, Number 13*.

BACKGROUND AND INTRODUCTION:

THE RELATIONSHIP BETWEEN THE NEW CANADIAN REGULATORY MODEL AND CODEX:

On 5 June 2003, the Governor General in Council, acting on the recommendation of the Minister of Health, published a new series of regulations purporting to govern the manufacture, sale, and licensure of natural health products in *Canadian Gazette, Part II, Volume 137, Number 13, pages 1532-1607*. Within those regulations were contained inter alia the decision to treat natural products as drugs (although couched in public relations language as 'the third category,') the decision to treat Canadians unequally based on ethnicity by preserving free access for the few while denying free access to the many, increasing the cost of those products that remain, wiping out the vast majority of small, medium sized and cottage producers who created this industry in Canada and who presently generate an estimated $ 4.3 billion in retail sales revenue annually, while transferring control over these products to 'licensed medical doctors' for purposes of clinical trials and control of the marketplace in Canada to large, principally foreign-based, transnational pharmaceutical companies.

In promulgating these regulations, the federal government of Canada and Health Canada breached a series of promises made by the federal government of Canada to its citizenry in pledges made both within and outside of the Codex context.

At the Codex Alimentarius Commission, 22nd session, 1997, the Canadian delegate said: "Our citizens view access to these products as a right." And equally importantly, Canada said at that meeting that there was no scientific basis to justify restricting consumer access to these products.

"The delegation of Canada..expressed objection to the development of the guideline [vitamins and minerals] in the framework of Codex... The development of international guidelines in this area would negatively affect the rights of consumers to use these products and there was no scientific basis for such restrictions.." [emphasis added]

Report of the Codex Alimentarius Commission, 22nd Session, Geneva, 23-24 June 1997

paragraph 110

Outside of Codex but in related pledges, the former Canadian Minister of Health promised that access to these products would be preserved within a new 'third category' that would not be a drug category. Similar pledges were made in the context of a parliamentary review of the status of natural health products.

Where Canada sees its new regulations in relation to the Guidelines for Vitamin and Mineral Supplements, presently in the final stages of preparation at Step 7.

Whether the draft guidelines are finalized as expected or abandoned, the Canadian government sees its new regulatory package as immune to any effect under international law whether within the WTO adjudication system or elsewhere, e.g., within NAFTA.

At Codex, the word food is specifically defined as excluding "substances used only as drugs." Through incorporation by reference, this definition carries over into the SPS and TBT agreements that form the basis for WTO adjudications and define the parameters of Codex authority as an international reference standard setting body. Thus Canada sees itself as immune from any effect of such vitamin and mineral guideline. And, Canada has said as much.

"NHPs are drugs at the level of the Food and Drug Act."

Canadian Gazette, Part II, previously cited, page 1573

"NHPs which, by definition and regulatory authority, are now a separate category from foods.

"Therefore, Codex requirements for foods will have no relevance to NHPs in Canada."

A Fresh Start, Final Report ONHP Transition Team, Section 7.2 Codex Alimentarius

Why do we bother? A legitimate question given Canada's interpretation of the domestic effect of vitamin and mineral guidelines to be adopted at Codex:

We at The Friends of Freedom believe that freedom is a totality. Thus anything we can do promote and protect the freedom of others benefits them and us. This is especially true in the light of efforts toward globalized harmonization of regulatory standards

Indeed, Canada has already announced its intention to aggressively push for global harmonization of others to its anti-consumer, anti small and medium sized enterprises model.

"... Canada will need to ensure that its NHP status is secure within international agreements..other countries which regulate their NHPs as foods or pharmaceuticals will engage in trade within these parameters."

A Fresh Start, cited above, Section 7.2

Being pragmatic, the announced framework for discussion at Codex NFSDU:

Under the Codex committee system, a committee chair has wide latitude to control the scope of discussion and to determine when consensus has been reached. We understand that chairman Grossklaus has announced his intention to keep the discussion of the draft guideline strictly focused on brackets, that is undecided porticos of the text.

Accordingly, our discussion focuses on those areas.

DRAFT GUIDELINES FOR VITAMINS AND MINERAL SUPPLEMENTS at Step 7:

Paragraph 3.1.2

The sources of vitamins and minerals may be from either [natural] or synthetic sources....

Recommendation:

We recommend removal of the brackets and addition of the bracketed material to the text so that the phrase reads:

"may be from either natural or synthetic sources.."

Rationale:

Canada in its new regulations supports the maintenance of natural sources for vitamins and minerals. (See page 1570 and page 1575, *Canadian Gazette, Part II,* previously cited.)

In this instance, Canada's stated view is the correct one. For some consumers the distinction between natural and synthetic sources is a vital one due to allergy, past toxic chemical exposure and bioavailability issues.

In addition, Canada cannot keep its pledge to protect Chinese herbal practitioners and their sources of supply, if it does not support creation of an international guideline that recognizes the value of natural sources should the guideline later be expanded to include herbal and botanical products.

Paragraph 3.2

"Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set taking into account:

(a) Upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) The daily intake of vitamins and minerals from other dietary sources. [When the maximum levels are set due account should be taken to the reference intake value of vitamins and minerals for the population.]

Recommendation:

We recommend deleting the bracketed language.

Rationale:

Actual diets consumed, as opposed to theoretical diets postulated (based on extrapolations from out of date studies of limited populations), differ widely based on a variety of factors. In fact, total diet studies. the scientific basis for actual diet consumption determinations are in their infancy in terms of real world application. See, for example, *Food Safety Consultation, GEMS/Food, Total Diet Studies, Report of the 2nd International Workshop on Total Diet Studies*, 4-15 February 2002. [N.B.; We are aware that the focus of this report is on non nutritive substances within foods. Nevertheless, the point remains that these studies have not been done widely nor on a global scale. Much work needs to be done to apply these studies to: nutritional aspects of foods consumed coupled with determination of the specific needs of individuals and groups.] .

Canada has represented itself to the world as a proponent of science based rules and risk assessment based on sound science. It would be highly inappropriate for Canada to use a back door approach to setting ULs on a non-scientific basis as a method for avoiding its consumer protection and fair trade obligations as a Codex member and as a member of the WTO and as a signatory to various regional trade integration and bilateral trade agreements.

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS, at Step 4:

Since the proposed standard is at a very early stage, our comments are general.

Recommendation One:

We recommend that Canada recommend that NFSDU seek a WTO opinion on the ramification and effects of this standard in general.

Rationale:

In the past delegates to committees that have not obtained expert guidance at an early stage have wasted much time worrying on the record, during meetings, about the legal effect of guidelines. Delegates who are uncertain about the application of a standard tend to resist standard development.

Recommendation Two:

Since we presume from the language of the text as proposed so far, that its primary application is intended to fall under the TBT and that its primary goal is to prevent fraud in claims, we propose the following framework for discussion:

-That fraud be understood to mean the knowing misrepresentation of a material fact and/or the representation as fact of a thing not true based on a reckless disregard for the consequences of that misrepresentation

- That it be clearly understood that fraud can come in many forms as for example, in a representation that a food is safe based on extrapolation of data from consumption patterns studies in 1940 transmuted into an RDA and then preserved as an RDI.

And that such pseudoscientific representation can be very fraudulent compared to,for example, centuries of reporting of safe traditional usage.

The framework for presentation of claims should include:

Claims based on well designed clinical studies, claims based on reports of decades and/or centuries of safe usage, that traditional claims encompass all forms of traditional usage whether Western or Asia or other and that accumulated documented cases of individual reports be deemed an appropriate basis for claims. The framework could include transition language so that as better data becomes available, regulatory authorities could phase out certain bases for claims.

What should not be done here would be to formulate a pseudo-precautionary principle that allows regulators to avoid the time limitations on precautionary measures contained in current international agreements.

Reply from:
Santina Scalzo
Manager, Codex Program Services
Office of Ron Burke, Codex Contact Point for Canada

Hi Trueman:

This is further to our conversation on draft proposals that are currently being developed for consideration at the upcoming Codex Committee on Nutrition and Foods for Special Dietary Uses. I have to admit that based on our conversation I needed some time to track all the documents that are currently out for stakeholder consultation as I wasn't sure if your interest is strictly with the CCNFSDU and/or the Codex Committee on Food Labeling (CCFL) as well.

I have summarized below what is currently out for comments for both of these Committees, in an effort to provide clarity for you to be able to pull together your organization's comments. Please note anytime you submit comments on any draft texts out for review, our job in the Codex office is to ensure it is dispersed to the appropriate technical expert/Head delegate for that Committee who has the responsibility to review and consider all comments received in the development of a Canadian position. In the case of CCNFSDU Health Canada has the lead and the Head delegate is Christina Zehaluk. In the case of CCFL, the Canadian Food Inspection Agency has the lead and the Head delegate is Greg Orriss. Of course when there are cross-issues both CFIA and HC will be involved in the development of Canadian positions.

As regards CCNFSDU, the following documents were circulated in May for comments by August 13:

1. CL 2004/20-NFSDU:
- Proposed Draft Revised Standard for Infant Formula [and Formulas for Special Medical Purposes intended for Infants]
- Section B: Formulas for Special Medical Purposes intended for Infants.

2. CL 2004/21-NFSDU:
Comments on the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Children (CAC/GL 10-1979 (amended 1983, 1991)).

These three proposals were circulated in early July for comments by August 16th:

3. CX/NFSDU 04/3-Add.1:
Agenda Item 3: Proposals for a Definition and Methods of Analysis for Dietary Fibre Content - Prepared by a drafting group led by France and Sweden

Regarding agenda item 3 above, "Part B Containing Provisions on Dietary Fibre" of the "Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents" is also on the CCNFSDU agenda. Comments were requested on this through the distribution of the report of the last session (25th) of the CCNFSDU in November 2003 (ref: Alinorm 04/27/26, CL 2003/42-NFSDU, Appendix II).

4.CX/NFSDU 04/9:
Agenda Item 8: Proposed Draft Recommendations on the Scientific Basis of Health Claims (at Step 3) - Prepared by France

5. CX/NFSDU 04/11:
Agenda Item 10: Discussion Paper on Definition for Trans Fatty Acids - Prepared by Malaysia and Denmark.

Most recently, the following was circulated for comments by early September:

6. CL 2004/36_GEN:
This Circular Letter is a compilation of draft standards and texts that were reviewed and adopted at Step 5 of the Codex process by the 27th Session Codex Alimentarius Commission (held in July 2004) with the understanding that the CCNFSDU would do a review and take into consideration written comments submitted to the Commission. Therefore, the following three CCNFSDU issues were circulated for review and comments:

- Draft Guidelines for Vitamin and Mineral Supplements (ref: Alinorm 04/27/26; para. 61; Appendix IV)
- Draft Standard for Infant Formula (Section A) (ref: Alinorm 04/27/26; para. 100; Appendix V), and
- Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children (ref: Alinorm 04/27/26; para. 130; Appendix VI)

All of the above issues are on the agenda for the upcoming CCNFSDU and it would be appreciated if you could provide us with your comments by September 20th, 2004 at the latest. For your convenience I have attached a copy of the provisional agenda.

If you wish to attend the CCNFSDU as an observer with the Canadian delegation, you need to advise our office. An invitation to the meeting including a list of hotels and a registration form was also circulated to our stakeholders on July 22nd. I will resend you a copy of the e-mail and attachments. Please fill out the registration form and return it to our Codex Canada mailbox: codex_canada@hc-sc.gc.ca.

As regards the CCFL, the report of the 32nd Session (Alinorm 04/27/22; CL 2004/22-FL) was circulated in May and comments were requested on the following issues for consideration at the next CCFL session to take place in Malaysia (May 2005):

1. Proposed Draft Amendment to the Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods: Proposed Draft Revised Annex 2 - Permitted Substances (para. 76, Appendix VIII).

2. Proposed Draft Amendment to the General Standard for the Labeling of Prepackaged Foods: Quantitative Declaration of Ingredients (para. 109, Appendix VII).

3. Proposed Draft Guidelines for the Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labeling Provisions (para. 93, Appendix VI).

Comments are requested by November 1, 2004.

Best regards,

Santina Scalzo