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SUMMARY OF CONSULTATIONS AND COMMENTS RECEIVED ON PROPOSED REVISIONS TO FOOD AND DRUG REGULATIONS ON PREPACKAGED WATER AND ICE

Health Canada and the Canadian Food Inspection Agency

April 2009

Summary of Consultations and Comments Received on Proposed Revisions to Food and Drug Regulations on Prepackaged Water and Ice

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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1. BACKGROUND AND CONTEXT

Bottled water and prepackaged ice have a long history of safety. To date, there have been no documented outbreaks related to bottled water or prepackaged ice in Canada.

In Canada, bottled water and prepackaged ice are foods that are regulated under the *Food and Drugs Act*. The existing requirements for the safety of bottled water include microbial standards, limits on specific chemical contaminants, as well as labelling requirements to allow consumers to make informed decisions about the products they buy.

Since the coming into force of these requirements in the early 1970's, scientific knowledge of the impact of certain chemical and radiological contaminants and microorganisms on human health has evolved. There have also been changes to industry practices and standards, consumer preferences and expectations, and developments in the regulatory framework of Canada's trading partners. These factors have highlighted the need to improve and modernize the federal regulations and policies governing the sale of bottled water and prepackaged ice.

While these products have an excellent safety record in Canada, the Government wishes to ensure that the regulations are up to date with the latest science in order to provide the safest and highest quality products possible. As a result, since 2002, Health Canada and the Canadian Food Inspection Agency (CFIA) have undertaken various consultations on proposed regulatory revisions related to the sale of bottled water and prepackaged ice to ensure the continued safety and quality of these foods sold in Canada. Comments were sought on requirements specified under Division 12 and Division 15 of Part B of the *Food and Drug Regulations* (FDR) as well as labelling requirements and policies applicable to bottled water and prepackaged ice outlined under the *Consumer Packaging and Labelling Act* (CPLA) administered by the CFIA.

The results of these consultations will be used to help develop revised policies that will lead to publication of regulatory amendments through the usual Canada Gazette process.

2. CONSULTATIONS TO DATE

Public opinion research and focus groups were conducted at the beginning of 2002 to guide the development of a discussion paper released in August 2002. The paper "MAKING IT CLEAR - Renewing the Federal Regulations on Bottled Water: A Discussion Paper" outlined proposed revisions to the regulations and labelling requirements for bottled water and prepackaged ice. The document included six chapters that detailed current and proposed requirements on the categorization of bottled water products, microbiological, chemical and

radiological standards for bottled water and prepackaged ice, and labelling provisions. Stakeholders were invited to respond to sixty-one (61) questions on the detailed proposals. They could provide their responses in writing or could respond directly via the Health Canada website.

The discussion document was sent to 1,059 individuals and groups that represented producers, importers, distributors, industry associations, provincial and territorial governments, special interest groups, health professionals, academics and consumers. When the comment period closed at the end of January 2003, a total of thirty-seven (37) responses had been received from industry and/or industry associations (16), subject experts (5), individual consumers (5), health professionals (4), provincial/territorial governments (4), federal departments (2) and one (1) consumer association. While some stakeholders responded to all the questions, others submitted comments only on specific issues or topics of interest.

Health Canada hosted a workshop in May 2003 to focus the discussion on the proposed revisions to the microbiological requirements for bottled water and provide stakeholders with an additional opportunity to document their position on the proposed requirements on total aerobic bacteria and *Pseudomonas aeruginosa.*

In 2005, targeted consultations were conducted on a new proposed maximum allowable concentration (MAC) for arsenic in drinking water and its application to bottled water. Comments were also sought on proposed labelling rules for the naming of surface water and prepared water.

Since 2006, ongoing discussions have been held with various stakeholders as a result of inquiries related to the sale of bottled water products in Canada. A targeted consultation was conducted on the proposed revisions to radiological requirements for drinking water under the *Guidelines for Canadian Drinking Water Quality* and its applicability to bottled water. In 2008, the CFIA completed a review of comments on proposed revisions to the labelling requirements. A summary of proposed amendments was developed and presented to industry stakeholders for discussion during the Fall of 2008. The present document summarizes stakeholders' comments received as of November 2008.

3. SUMMARY OF COMMENTS

3.1 Classification of Bottled Water

There was clear support for the proposal to classify bottled water as either Water Represented by Its Origin or Prepared Water. Most stakeholders agreed that a bottled water product would have to meet specific criteria in order to be classified

as a Water Represented by Its Origin and could only be subjected to permitted treatments. Respondents also supported the proposal that all other bottled water products not meeting the criteria for Water Represented by Its Origin would fall under the Prepared Water category.

3.1.1 Water Represented by Its Origin

Stakeholders supported the proposed five (5) criteria for the classification of bottled water as Water Represented by Its Origin. While stakeholders supported the principle of restricting the treatments permitted for Water Represented by Its Origin, there was no clear consensus on whether the regulations should include a list of permitted treatments. Some stakeholders supported an outcome-based requirement that would indicate the effect of the treatment rather than identify a specific process. Other stakeholders preferred the option of a general prohibition for the use of any treatments that would significantly alter the composition of products falling into the category of Water Represented by Its Origin.

3.1.2 Differentiation of Water Represented as Mineral Water or Spring Water

Mineral water and spring water are standardized bottled water products under the current regulatory framework. Stakeholders generally supported the maintenance of the current requirement that these bottled water products originate solely from an underground source. Some stakeholders also requested that the regulations allow blending of waters from more than one underground source to be included in this category. There was support for a differentiation of these products based on a total dissolved solids (TDS) criterion. Some stakeholders expressed concerns regarding the proposed 500 milligrams per litre (mg/L) TDS maximum limit for products represented as spring water because it would not be compatible with labelling requirements applicable in Quebec province or in other countries, such as United States.

3.1.3 Surface Waters

The discussion document presented two approaches for the regulation of surface waters, such as glacier and iceberg waters. The majority of respondents supported the inclusion of surface waters within the Water Represented by Its Origin category provided that these waters met the criteria. However, several stakeholders expressed the opinion that, based on current knowledge, it would be unlikely that surface waters could comply with all the proposed criteria of Water Represented by Its Origin, particularly the criterion on the microbiological safety at the source.

A majority of stakeholders preferred one of the two proposed definitions for glacier water, namely that “glacier water is water obtained from glacial melt water, which, at the collection point, has the same consistent composition of

major minerals and characteristics as the glacial stream at the point it emerges from the glacier". A majority of respondents supported the inclusion of definitions for other types of surface waters, such as iceberg water. While the majority of respondents supported that surface waters are unlikely to meet all the criteria for Water Represented by Its Origin, they were of the opinion that manufacturers should be allowed to use statements regarding their origin, e.g., "derived from a glacier", on the label. Some stakeholders suggested requirements that should be met in order to allow such statements.

3.1.4 Prepared Water

A general consensus was expressed for the proposed use of the term "Prepared Water" for this alternate category of bottled water. Various labelling requirements for these foods were proposed and stakeholders' responses are covered below under the section "Regulatory Issues Related to Labelling". Respondents were generally opposed to the inclusion of water with added flavours and/or colours in the proposed category "Prepared Water".

3.2 Microbiological Quality Requirements

The discussion document outlined proposed microbiological requirements for bottled water, water used to manufacture prepackaged ice and prepackaged ice. All bottled water would be required to meet standards for total aerobic bacteria (100 per 1 ml), coliform bacteria (0 per 100 ml) and *Pseudomonas aeruginosa* (0 per 100 ml). Requirements for total aerobic bacteria and coliform bacteria were proposed for water used to manufacture prepackaged ice and for prepackaged ice. Many stakeholders did not support keeping criteria for total aerobic bacteria and adding a new criterion for *Pseudomonas aeruginosa* in the regulations. In addition, many concerns were expressed regarding the official methods proposed to be used for determining compliance with the microbiological requirements presently referenced in Division 12 of the FDR.

In May 2003, the government hosted a workshop to further discuss these issues. External experts and one Health Canada official presented their views and supporting data on the proposed approach. The workshop also provided an opportunity to discuss the proposed revisions to official methods and their incorporation in the FDR. The views received during this focussed consultation can be summarized as follows:

1. On the proposed retention of the regulatory requirement for total aerobic bacteria count:
    - concerns with the potential for confusion over enforcement activities should this requirement remain;
    - no recalls have been initiated by the CFIA based solely on high counts in total aerobic bacteria;

- the 24-hour limit for testing is unrealistic, particularly for imported products;
- total aerobic bacteria count should become a guideline, an indicator of good manufacturing practices, and should also apply to prepackaged ice.

2. It was suggested by many participants that a “zero tolerance” for *Escherichia coli* be specified in the regulations in addition to the current requirement on total coliform count.

3. On the proposed inclusion of *Pseudomonas aeruginosa* in the FDR:
   - while this microorganism may cause temporary, non life-threatening adverse health effects, there is no clear consensus on whether or not it can be considered a gastrointestinal tract pathogen;
   - *Pseudomonas aeruginosa* should be an indicator of good manufacturing practices (not a health indicator) and remain a guideline;
   - concerns regarding the proposed revised official method for the determination of this microorganism in bottled water.

During the Fall of 2008, further discussions were held with the industry and the following proposal, originally presented at the 2008 annual meeting of the Canadian Bottled Water Association, was introduced by the Health Canada’s Bureau of Microbial Hazards:

- It was proposed to revoke the total aerobic bacteria standard from the regulations and keep the criteria as a guideline in the Health Canada’s Standards and Guidelines for Microbiological Safety of Food - An Interpretive Summary (the Interpretive Summary), to be applied to all bottled waters and not just for “water in sealed containers”. The total aerobic bacteria guideline would also apply to ice and water used to make ice and would be used to determine good manufacturing practices.
- It was proposed to keep the criteria for coliform bacteria presently found in the regulations, except that the number of sample units would be reduced from 10 to 5 for consistency with other bottled water standards in Division 12. This criterion would also apply to ice and water used to make ice.
- It was proposed to have a “zero tolerance” for *Escherichia coli* in the regulations for all bottled water. Analysis of coliform bacteria would proceed in order to determine counts of fecal coliform bacteria and *Escherichia coli*. This criterion would also apply to ice and water used to make ice.
- It was proposed to have a “zero tolerance” for *Pseudomonas aeruginosa* which would represent a Health Risk 3, as published in the Interpretive Summary. This guideline would apply to all bottled water.

- It was proposed to have a “zero tolerance” for *Aeromonas hydrophilia* which would represent a Health Risk 3, as published in the Interpretive Summary. This guideline would apply to all bottled water.

Overall, there was strong agreement with the proposed criteria for coliform bacteria and *Escherichia coli* and less so for total aerobic bacteria, *Pseudomonas aeruginosa* and *Aeromonas hydrophilia*. No comments were provided on the criteria for ice as no representatives from the ice industry were present.

3.3 Chemical and Radiological Requirements

The government proposal included two sets of maximum limits for chemical and radiological contaminants in bottled water. While Prepared Water would be required to comply with the MACs for chemical contaminants in the *Guidelines for Canadian Drinking Water Quality*, maximum limits for Water Represented by Its Origin would be specified in the FDR. The majority of respondents supported the adoption of only one set of requirements for all bottled water products sold in Canada. Maximum limits for other chemical contaminants were recommended for inclusion in the proposed regulations because these standards appeared in an industry association code used by their members. A recommendation was also made for the inclusion of regulatory requirements on monitoring of products that would apply to all manufacturers of bottled water sold in Canada.

During the additional consultation of 2005, stakeholders were asked to express their views on the proposed lowering of the MAC for arsenic from 10 parts per billion (ppb) to 5 ppb in the *Guidelines for Canadian Drinking Water Quality* and the feasibility of applying this proposed requirement to all bottled water products. Objections were expressed to this lower limit of 5 ppb for arsenic in bottled water for the following reasons:

- based on up to date scientific evidence, a 10 ppb maximum limit for arsenic in bottled water would not pose a health hazard to consumers;
- a 10 ppb limit would be compatible with WHO guidelines for drinking water and Codex standards for natural mineral waters and bottled/packaged drinking waters (other than natural mineral waters);
- a 10 ppb limit for arsenic would also be compatible with the requirement established by the US Environmental Protection Agency for drinking water quality and with the US Food and Drug Administration rule for arsenic levels in bottled water products sold in the USA.

A targeted consultation was conducted in 2006 on proposed revisions to the radiological requirements for drinking water specified in the *Guidelines for*

Canadian Drinking Water Quality and their direct application to the requirements for bottled water sold in Canada. No response was received on this consultation.

3.4 Regulatory Issues Related to Labelling

3.4.1 Common Name

Various options on regulating the common names for the proposed categories of bottled water were presented in the discussion document. For Water Represented by Its Origin, the two options were: the establishment of mandatory common names or the optional use of common names specified in the regulations. The discussion document presented both regulatory and non-regulatory options for common names of Prepared Water. The regulations could establish mandatory common names based on the TDS content, or a list of designated common names which would not be based on TDS content. If not specified in regulation, bottlers could use any reasonable common name that is considered accurate and does not mislead the consumer. The submitted comments supported the establishment of mandatory common names for Water Represented by Its Origin. However, there was no consensus on any of the options proposed for Prepared Water.

In 2005, further targeted consultations were conducted with the industry on the proposed approach to allow "naming the source" Prepared Water to be used for surface water, such as glacier prepared water or iceberg prepared water, if the product as sold does not differ significantly from its source based on the TDS content. While respondents agreed with the proposal regarding glacier prepared water, they objected to the criterion related to the TDS content. There was no clear consensus on an approach to allow the use of the name "iceberg" on prepared water or other names that would identify other surface water resources.

During the Fall of 2008, further discussion was undertaken with the industry on proposed options for naming prepared waters. There was general agreement that common names that describe the final product (such as "demineralized water" or "carbonated water") should be mandatory. With respect to "naming the source" prepared waters, consensus was reached that source declaration, including glacier and other surface waters, may be made if the following criteria are met:

- the source declaration reflects the place of collection
- the source is indicated on the label, as for water represented by its origin
- the water may be treated for potability but must retain the essential compositional character of the water at the source
- the water does not pass through a municipal supply system

3.4.2 Declaration of Total Dissolved Solids, Fluoride and Mineral Content

Stakeholders were consulted on the mandatory declaration of the TDS content of bottled water, the method for determining the TDS and the units to express TDS

and mineral ion content on the label. Respondents supported the proposal to specify in regulation that TDS content be determined using the method published in *Standard Methods for the Examination of Water and Waste Water.* There was also support for expressing the TDS and mineral ion content of bottled water in units of mg/L.

With respect to the declaration of TDS, two options were presented: mandatory declaration of TDS content only for Water Represented by Its Origin or mandatory declaration of TDS content for all bottled water products. A majority of stakeholders supported the mandatory declaration of the TDS on all bottled water products. Some respondents suggested alternative approaches to the proposed amendments, including the recommendation that the TDS declaration be voluntary on all bottled water products. Should TDS be mandatory for all products, it was suggested to allow its declaration in ranges rather than using absolute numbers because of natural variations throughout the year in the TDS content of the water at the source for Water Represented by Its Origin.

The proposal included minor changes to the requirements regarding the fluoride declaration. There was support for the proposal to eliminate the mandatory declaration of total fluoride ion content on prepackaged ice. Stakeholders also supported the approach to permit declaration of total fluoride content on another location than the principal display panel. Although some respondents believed that the declaration of total fluoride content should only be mandatory if it has been added, the majority supported the proposal for mandatory declaration of the fluoride content on all bottled water products, as is the case currently.

While the declaration of the mineral ions would remain optional, it was proposed that conditions would be established in regulation for this declaration. There was support for the proposal that all constituent mineral ions be listed together on the label with equal prominence and concentrations expressed in mg/L and that no nutritional benefits would be claimed for any of the minerals.

3.4.3 Source Declaration

In the discussion paper, it was proposed to make the source declaration mandatory for Water Represented by Its Origin and optional for prepared water that is treated in accordance with the criteria permitted for Water Represented by Its Origin. The location identifier would include the “source”, local government unit and province for domestic products and names of the region and country for imported products. It was also proposed to require that bottled water obtained from a municipal water system carry the statement “From a public/municipal water distribution system” on the label unless the water had undergone a significant change as a result of treatments or additions, so that it no longer resembles the water in the source. Three options to characterize “significant change” were proposed, for example that the water would be treated to reduce the TDS content to 10 mg/L or less (demineralized water). However, there were

objections to this proposed declaration statement with many respondents, who preferred that the municipal source be identified.

The majority of respondents supported the mandatory declaration of the source for Water Represented by Its Origin and the optional declaration of the source for Prepared Water treated in accordance with the criteria permitted for Water Represented by Its Origin. No consensus was obtained on how specific the location should be on the label. Some stakeholders wanted the identifier to be more detailed while others thought that indicating the region and province was sufficient.

3.4.4 Addition of Ozone and Carbon Dioxide

To avoid a duplicate declaration of ozone addition, it was proposed to require its declaration only in the list of ingredients when it was added to any bottled water, whether the list appears on the principal display panel or elsewhere on the label. There was support for this proposal although several respondents questioned the need for listing ozone as an ingredient since it is no longer detectable in the product after 48 hours.

On the addition of carbon dioxide to mineral water, changes were proposed to the regulations to bring them in line with the Codex General Standard for Bottled/Packaged Drinking Waters (Other Than Natural Mineral Waters) (Codex Stan 227-2001). All comments received on this issue were in support of the proposal to 1) make it mandatory for all bottled water to include the terms “carbonated” or “sparkling” in the common name of the product if it spontaneously and visibly releases CO_2, in any amount, when uncapped under normal atmospheric conditions; 2) permit spring water and mineral water to use the modifier “naturally” in the common name if the added CO_2 comes from the same source as the water and is re-injected into the water at the same level as it was present originally; 3) permit spring water and mineral water to be described as “fortified with carbon dioxide” if CO_2 from the source is added to the bottled water so that it’s concentration in the final product is at least 20% greater than at the source.

3.4.5 Declaration of Treatment

In order to provide consumers with more information about the treatment of bottled water, two labelling options were presented in the discussion paper. The first was the voluntary declaration of treatments by naming the treatment as part of common name for all bottled water products. The second option was the mandatory declaration of treatments on the label of all bottled water products with some exceptions. Treatments permitted for Water Represented by Its Origin or chlorination followed by removal of by-products would be exempt from label declaration under this option. The majority of respondents supported the mandatory declaration of treatments on the principal display panel. Many respondents noted that the list of treatments presented in the discussion document was incomplete.