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Results of the Consultation on
Modifications to Health Canada's Policy
“Managing Health Risk Associated with the Consumption
of Unpasteurized Fruit Juice/Cider Products”

October 12 – December 16, 2005

Bureau of Microbial Hazards
Food Directorate
Health Canada

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Summary

Health Canada issued *Consultation on Modifications to Health Canada's Policy "Managing Health Risk Associated with the Consumption of Unpasteurized Fruit Juice/Cider Products"*, for comment between October 12 and December 16, 2005.

The consultation document was distributed to fruit juice/cider producers and their industry associations, federal, provincial and territorial government agencies responsible for food safety, consumer associations, academia and associations for health professionals. The consultation was also open to the general public via the Health Canada website. Ninety-one responses were received, and all groups were represented (Industry, Federal, Provincial, and Territorial (FPT) government, Consumers and Academia/Health Professionals). Responses represent the opinions of the respondent only and are not considered representative of the respondent's respective group (i.e., FPT Government, Juice Industry, Consumers, etc.).

Support for mandatory labelling of unpasteurized juices as 'unpasteurized' was high for all respondent types. All FPT government respondents and 79% of respondents from the juice industry supported mandatory labelling.

Opinions regarding the inclusion of cautionary labelling including an educational statement were divided according to respondent type. While 92% of FPT government respondents were in favour of cautionary labeling, 78% of juice producers were against. Three options were presented, and there was little consensus on which is the most appropriate. Many respondents felt that the statements given in the consultation should be reworded.

It is critical that such cautionary labelling is read, understood and not misinterpreted by consumers, including those that are not fluent in English or French. Focus groups may be necessary to develop the appropriate wording if it is decided to include an educational statement on the label. Several recommendations for rewording the statements were submitted in response to the consultation and are being considered by the Policy Team.

Some industry respondents questioned whether the risk from unpasteurized juice and cider warrants a mandatory educational label when compared to other foods. Industry respondents also pointed out that labels are already crowded with all the requirements in two languages and many producers have just re-designed their labels to comply with nutritional labelling requirements. It was felt by some that the educational statements being considered were not complete because they do not describe the low risk posed by the product and are lacking information on the Code of Practice for the Production and Distribution of Unpasteurized Apple and other Fruit Juice/Cider in Canada. Consumers' understanding of pasteurization, or lack thereof, was used to argue both for and against an educational statement.

Many distribution points for educational materials were suggested. However, some respondents stated that mandatory pasteurization is the only effective way to protect susceptible groups and the population in general, while others felt that labels should stand alone, without an educational

campaign. Comments specific to the Code of Practice have been forwarded to the Canadian Food Inspection Agency for review.

Fifty-nine percent of respondents agreed with the definition of pasteurization as a 5- \log_{10} reduction of the most resistant pathogen of concern that would apply to both thermal and non-thermal treatment/technologies, while only 10% of respondents disagreed with the definition. Many respondents felt that more guidance was needed to help juice/cider producers understand the definition and the conditions required to achieve a 5- \log_{10} reduction using heat and non-thermal technologies. Also, more specifics in terms of the technique, cost and verification of the available processes was wanted by some producers. Many responded that although non-thermal technologies should be recognized as equivalent to pasteurization, they should be referred to by a different term.

Next Steps

Based on results of the consultation, the low percent of households aware of the risks, and the high consumption of unpasteurized juice by children under the age of 6, Health Canada will further investigate the introduction of mandatory labelling as 'unpasteurized' and cautionary labelling with an educational statement that includes reference to boiling the juice as a safety measure for unpasteurized fruit juices, ciders and vegetable juices. Health Canada will also investigate developing and conducting an education campaign on the risks of unpasteurized juices and ciders, and risk reduction measures that can be adopted by consumers.

1.0 Distribution of the Consultation

The consultation document was directly distributed by mail or e-mail to:

- 185 producers of unpasteurized and pasteurized fruit juice (117 Ontario, 40 Western, 28 Atlantic)
- 16 industry associations
- 37 consumer associations,
- members of the Food Directorate Unpasteurized Juice Policy Team,
- the Federal/Provincial/Territorial Committee on Food Safety Policy,
- the Canadian Food Inspection System Implementation Group and
- the Federal/Provincial/Territorial Agri-Food Inspection Committee
- Food Directorate Executive Risk Management Committee and
- the Food Directorate Regional Liaison Officers.

Le ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec (MAPAQ) distributed the document to 56 individuals/groups in Quebec.

The consultation document was available on the Health Canada website from October 12, 2005 to December 16, 2005, with links from the main Health Canada web page and several food safety-related pages. The consultation was also mentioned on the Food Safety Network.

2.0 Quantitative Summary of Responses

Please note that due to the way participation was solicited, responses represent the opinions of the respondent only and cannot be considered representative of the respondent's respective group (i.e., FPT Government, Juice Industry, Consumers, etc.).

Respondents by Type, based on self-identification:

Federal Government (Hlth, Ag, Inspectn)	10
Provincial/Territorial (Hlth, Ag, Inspectn)	17
Not specified	10
<i>TOTAL FPT Government</i>	<i>37</i>
Pasteurized Juice Producers	10
Unpasteurized Juice Producers	19
Industry Associations	6
Not specified or both	6
<i>TOTAL Juice Industry</i>	<i>41</i>
Consumers	11
Consumer Associations	0

<i>TOTAL Consumers</i>	<i>11</i>
Academia	1
Health Professional	1
<i>TOTAL Academia/Health Professional</i>	<i>2</i>

OVERALL TOTAL	91
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The following is a summary of the responses to each question.

Question 1: Should unpasteurized fruit juice/cider carry a mandatory label indicating the product is unpasteurized? *Please select one of the following*

- Yes, labels indicating the product is unpasteurized should be made mandatory
- No, labels indicating the product is unpasteurized should remain voluntary

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>
FPT Gov, incl Public Health	36	0
Unpast. and past. Industry	31	8
Consumers	10	1
Academia/Health professionals	2	0
Total (n=88):	79	9
	<i>90%</i>	<i>10%</i>

Question 2: Is an Information label with the word “Unpasteurized” sufficient to inform consumers of the potential health risks, or should the label carry an Educational statement as well? *Please select one of the following*

- Information labels with the word “Unpasteurized” are sufficient
- Labels should have both Information and Educational statements

<u>Type of Respondent</u>	<u>Info</u>	<u>Both</u>
FPT Gov, incl Public Health	3	33
Unpast. and past. Industry	31	9
Consumers	3	8
Academia/Health professionals	0	2
Total (n=89):	37	52
	<i>42%</i>	<i>58%</i>

Question 3: Should an Educational statement become mandatory, please select the statements that should or should not be included. These statements could be used in conjunction with the word “Unpasteurized”. You may select “Yes” for more than one option for a combination of statements.

Please select for each statement either Yes(Y), No(N), or Undecided(U):

a) “This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness especially in children, the elderly and persons with weakened immune systems” (statement currently used on U.S. labels)

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>	<u>Undecided</u>
FPT Gov, incl Public Health	20	6	4
Unpast. and past. Industry	6	28	4
Consumers	4	4	2
Academia/Health professionals	0	1	1
Total (n=80):	30 38%	39 49%	11 14%

b) “Product should be boiled before giving to young children, the elderly or people with weakened immune systems”

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>	<u>Undecided</u>
FPT Gov, incl Public Health	11	10	2
Unpast. and past. Industry	8	19	10
Consumers	3	4	3
Academia/Health professionals	1	0	1
Total (n=72):	23 32%	33 46%	16 22%

c) “This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness especially in children, the elderly and persons with weakened immune systems unless boiled”

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>	<u>Undecided</u>
FPT Gov, incl Public Health	20	11	2
Unpast. and past. Industry	8	25	5
Consumers	6	3	1
Academia/Health professionals	1	1	0
Total (n=83):	35 42%	40 48%	8 10%

Question 5: Do you agree with the definition of juice/cider pasteurization as a 5-log₁₀ reduction of the most resistant pathogen of concern that would apply to both thermal and non-thermal treatment/technologies?

Please select one of the following

Yes No Do not know

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>	<u>Do not know</u>
FPT Gov, incl Public Health	29	2	6
Unpast. and past. Industry	20	4	14
Consumers	1	3	6
Academia/Health professionals	1	0	1
Total (n=87):	51 59%	9 10%	27 31%

Question 6: Under Appendix 2, Health Canada provided an example of how we believe that a 5-log₁₀ reduction can be achieved using heat and time (or temperature and time) treatments. Is this type of guidance sufficient for you to apply it in your operation?

Please select one of the following

Yes No Do not know

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>	<u>Do not know</u>
FPT Gov, incl Public Health	22	1	11
Unpast. and past. Industry	17	9	13
Consumers	1	0	9
Academia/Health professionals	0	0	2
Total (n=85):	40 47%	10 12%	35 41%

Question 7: For non-thermal technologies such as ultra-violet light, high pressure processing, ohmic heating, etc., is this definition of pasteurization suitable and does it provide the basis to verify that pasteurization has been achieved?

Please select one of the following

Yes No Do not know

<u>Type of Respondent</u>	<u>Yes</u>	<u>No</u>	<u>Do not know</u>
FPT Gov, incl Public Health	17	3	16
Unpast. and past. Industry	15	4	20
Consumers	2	0	8
Academia/Health professionals	1	0	1
Total (n=87):	35 40%	7 8%	45 52%

3.0 Summary of Responses and Comments

3.1 MANDATORY LABELLING AS “UNPASTEURIZED”

Support for mandatory labelling of unpasteurized juices as ‘unpasteurized’ was high for all respondent types. All federal, provincial and territorial government responses (36/36) and 79% (31/39) of responses from the juice industry are in support of mandatory labelling. Many respondents commented that mandatory labelling is a minimum requirement for informed consumer choice, with many agreeing that it should be part of the common name (e.g., “Unpasteurized Apple Juice”). Also, it was felt by many respondents that any education or communication campaign efforts would be insufficient without labelling. However, some respondents see mandatory labelling as a promotion tool, with the view that unpasteurized juice is healthier.

Some respondents questioned why the Code of Practice for the Production and Distribution of Unpasteurized Apple and other Fruit Juice/Cider in Canada (referred to as the ‘Code of Practice’) is not mandatory. Several respondents (6) from FPT governments feel that pasteurization of all juices should be mandatory. This would eliminate the need for an education/communication campaign that, in the end, may not effectively protect susceptible populations. Another concern is the impact on inspectors to enforce a regulation, based on the widespread and geographically dispersed production and selling-points of unpasteurized fruit juice/cider.

Several comments were made with respect to the scope of the proposed labelling changes. The exclusion of unpasteurized vegetable juices was questioned, given that vegetables are often grown in or near the ground and have a higher pH than fruit juices. Therefore the risks are considered equivalent, or higher. Some felt that there should be no exceptions, including juice intended for further processing, and that loop-holes such as the sale of bulk juice where the purchaser supplies their own jug should be addressed. In comparison, one industry respondent was pro-mandatory labelling except for direct sales on-site and at farmer’s markets. There were several comments concerning the labelling of pasteurized juices, some stating that perhaps it should also be mandatory and others commented that the label should be more descriptive of the type of treatment (e.g., UV light treated vs. heat treated). It was clear, based on the comments, that there was some confusion regarding the scope of the proposed labelling and the definition of the term ‘juice/cider’. Any regulations would have to clearly define the type of products affected and this would have to be clearly communicated to industry and inspection personnel.

3.2 INCLUSION OF A CAUTIONARY/EDUCATIONAL STATEMENT ON THE LABEL

The following statements were provided for comment:

- a) This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness especially in children, the elderly and persons with weakened immune systems. (*statement currently used on U.S. labels*)

- b) Product should be boiled before giving to young children, the elderly or people with weakened immune systems.
- c) This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness especially in children, the elderly and persons with weakened immune systems unless boiled.

Opinions regarding the inclusion of a cautionary statement were divided according to respondent type. While 92% of FPT government respondents were in favour of a cautionary statement, 78% of juice producers were against the inclusion of such a statement. Most of the consumer respondents were in favour of a cautionary statement, but due to the small number of consumer responses (11), and the way participation was solicited, this cannot be considered a representative response for consumers in general. Many government respondents want to have mandatory microbiological criteria in addition to a mandatory cautionary statement.

The main question from industry is whether the risk is sufficient to justify a cautionary statement and/or an education campaign. The safety of Canadian-produced juice/cider compared to other foods should be considered.

A concern voiced by one industry association is the number of mandatory labelling changes put forward recently by Health Canada, and the impact on industry. Many producers have just re-designed their labels to comply with nutritional labelling requirements. Producers and industry associations pointed out that labels are already crowded with all the requirements in two languages. Many producers felt that education should be provided through other means, such as public schools, fact sheets at point of purchase, etc., and not on the label. Some unpasteurized juice producers feel that mandatory labelling, especially with an educational component, is unnecessary for those producers who follow the Code of Practice. Some producers found the statements to be unnecessary as consumers are already informed, more frightening than educational, and not representative of the low risk presented by the product. If producers feel that the educational statement is negative, compliance may be decreased. The impact on inspection/enforcement resources must be considered.

3.3 TYPE OF CAUTIONARY / EDUCATIONAL STATEMENT

There was little consensus as to which statement, or type of statement, is the most appropriate. Government respondents tended to prefer statements 'a' and 'c' (20% responded 'yes' to both 'a' and 'c', compared to 11% for 'b'). Industry respondents were the most opposed to statement 'a', which provides consumers with information about potential risks without information about appropriate actions to reduce the risks (i.e., option to boil). Respondents from industry were least opposed to statement 'b', which advises consumers to boil the product before giving to susceptible groups.

Many respondents felt that the statements are flawed. Some felt that there should be more instruction surrounding boiling (time and temperature), microwaving and cooling. Others felt that the statements are misleading because all people are susceptible to illness from *E. coli* O157, *Salmonella* and *Cryptosporidium*, not just the high-risk groups. Some respondents, especially from industry, felt that the cautionary statements are not complete because they don't describe the low risk presented by the product, or the steps producers have taken to minimize the risk (e.g., adherence to the Code of Practice). Some producers felt that the educational statements should not be mandatory for those who follow the Code of Practice, or that there should be some way, such as a symbol, to indicate that a producer is adhering to the Code of Practice. It is clear that to be able to capture all the above information in a label statement is unreasonable and may prove to be ineffective. There was another group of respondents who felt that short and simple statements are best.

Some producers would like guidance on where they can send their product for pathogen testing, in order to be able to inform their consumers that their cider has tested negative.

3.4 EDUCATION CAMPAIGN

Several of the respondents felt that education should be limited to the label, either because they viewed past education campaigns as ineffective, or because the risk does not justify a resource-intensive education campaign. One respondent felt that the costs/benefits of an education campaign should be evaluated against the costs/benefits of assisting willing unpasteurized juice producers in implementing pasteurization processes. In the end, consumers may be unwilling to change their views or purchasing habits.

Those respondents who felt that some form of education campaign beyond the label is necessary recommended a number of distribution points. To reach susceptible groups, written materials (pamphlets, fact sheets or articles) should be distributed to health professionals, old age/retirement homes and their cooks/nutritionists, daycares and other early childhood centres, prenatal clinics, doctors' offices and other health units, magazines targeted at parents, retirees and other susceptible groups and at schools. One respondent pointed to the fact that vehicles to disseminate advice already exist in the form of health professionals for susceptible groups. The distribution of materials at the point of sale, such as fall or county fairs, farmers' markets and grocery stores was also recommended. Education through the school curriculum as part of science units, or the inclusion of information on unpasteurized foods in an educator tool-kit was mentioned.

Other vehicles such as the Internet, ads on TV, the radio and newspapers were mentioned by many of the respondents. A presentation by Health Canada at fairs and markets, attaching additional information to containers and delivery of materials to all households were other suggested options.

Information about the Code of Practice, treatment methods (e.g., UV light) and health benefits should be included in the educational material. A focus on informing producers and retailers

(instead of consumers) on the Code of Practice, storage conditions and other ways to minimize risk was recommended. Another suggestion was to work with producers to encourage pasteurization (including UV). One industry association stated that they have worked closely with their provincial government to inform producers and increase the use of good manufacturing practices.

3.5 DEFINITION OF JUICE/CIDER PASTEURIZATION

Fifty-nine percent of respondents agreed with the definition of pasteurization as a 5-log₁₀ reduction of the most resistant pathogen of concern that would apply to both thermal and non-thermal treatment/technologies, while only 10% of respondents disagreed with the definition.

Non-thermal treatment, e.g., UV, was said to be affordable and a viable option for smaller producers, although some disagreed. In general, response was favourable to include non-thermal treatments in the definition of pasteurization. Several industry and government respondents would like to distinguish between thermal and non-thermal treatments on the label, or use a term other than 'pasteurized' since it traditionally refers to heat treatments.

One government respondent stated that a 5-log₁₀ reduction may be insufficient in some circumstances and that a maximum level of pathogens (microbiological criteria) should be set as a bench mark for inspectors to use to determine compliance. On the other hand, another government respondent felt that more support is required for the 5-log₁₀ reduction and felt that it may be excessive. They cite three references on concentrations of verotoxigenic *E. coli* in fecal matter.

3.6 GUIDANCE TO INDUSTRY ON THERMAL PASTEURIZATION

Forty-seven percent of respondents stated that the guidance provided was sufficient, but 41% stated that they do not know. In the consultation document, guidance was provided for pasteurization using heat treatments, however the smaller producers may not be using heat pasteurization due to the higher equipment costs compared to UV pasteurizers. Many respondents felt that more guidance was needed to help juice/cider producers understand the definition and the conditions required to achieve a 5-log₁₀ reduction using heat and non-thermal technologies. Also, more specifics in terms of the technique, cost and verification of the process was wanted by some producers.

Some government and industry respondents want approved time-temperature combinations in table form, which will be more user-friendly for producers. Also, the pH of the cider should be included as a parameter in the requirements related to time-temperature combinations. One respondent asked if there will be an educational component for producers regarding other factors that may influence pasteurization, such as pH. They also stated that producers should be required to produce machine-printed readouts confirming that the product has been subjected to the pasteurization conditions.

3.7 GUIDANCE TO INDUSTRY ON NON-THERMAL PASTEURIZATION

Forty percent of respondents said that the definition of pasteurization is suitable and it provides the basis to verify that pasteurization has been achieved. Fifty-two percent of respondents stated that they do not know.

Many respondents stated that non-thermal technologies should be recognized as equivalent to pasteurization, but should be referred to by a different term (e.g., cold pasteurization, UV treated). There were questions surrounding UV treatment and its ability to be effective on product with high amounts of suspended solids, especially citrus juices that have high pulp contents. Also, one respondent questioned UV light's effectiveness against *Cryptosporidium*, as compared to *E. coli*.

4.0 Next Steps

Based on results of the consultation, the low percent of households aware of the risks, and the high consumption of unpasteurized juice by children under the age of 6, Health Canada will further investigate the introduction of mandatory labelling as 'unpasteurized' with a cautionary statement that includes reference to boiling the juice as a safety measure for unpasteurized fruit juices, ciders and vegetable juices. Health Canada will also investigate developing and conducting an education campaign on the risks of unpasteurized juices and ciders, and risk reduction measures that can be adopted by consumers.

Further consultation will occur as these recommendations are being implemented.