

Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments by FDA Due by February 10, 2016 – Extended to May 10, 2016

Note: All comments will be made available to the public.

Document:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm>

In Canada, the Canadian Food Inspection Agency (CFIA) administers and enforces the regulatory requirements that prohibit foods from being labelled in a false and misleading manner. While the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* provide the overarching rule that regulated parties must comply with, the CFIA has developed interpretive guidance on what could be considered compliant. Guidance on method of production claims, which include use of the term “natural”, is available on CFIA website:

<http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=2>. There is also guidance under consultation specifically related to certain method of production claims for meat, poultry and fish: <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=9#s3c9>.

From a broader perspective, the CFIA is also completing the Food Labelling Modernization initiative to develop a more modern food labelling system that responds to current and future challenges. This could impact how claims such as “natural” are assessed for compliance with regulatory requirements.

We continue to hear from regulated parties that continued harmonization with the United States is important and as such, we are hereby providing the CFIA perspective on the use of the term “natural” for foods. The CFIA remains available to further discuss or provide clarification to our answers.

Below are answers to the specific questions outlined in the FDA consultation.

1. Should we define, through rulemaking, the term “natural?” Why or why not?

Natural is a term that can have a number of meanings, depending on the food it is applied to. Canada does not have specific regulations for natural claims, but applies the law that prohibits sale of foods that are advertised or labelled in a manner that is false, misleading, or likely to create an erroneous impression. As mentioned above, we have interpretive guidance to support this.

Recently the CFIA has proposed to explore with stakeholders, particularly consumers and industry about increasing the roles they could play in improving compliance of the products they sell. Results of the survey are not available at this time, but a PDF copy of the survey is available at <http://www.inspection.gc.ca/food/labelling/labelling-modernization-initiative/consultations/collecting-feedback/eng/1378236636065/1378236761342>.

While this is an area still under consideration and engagement and no decisions have been made, it provides an alternative approach to specific regulations. In the proposed approach, industry and consumers, including their associations, can have a more active role in the definition, management and resolution of consumer values type of claims, with government oversight only as required, for example in areas of fraud and misrepresentation, or market disruption.

Companies, associations, or third parties could manage the maintenance of the claims and

- be proactive in developing policies on new claims,
- communicate the meaning of the claim to consumers, and
- follow up with respect to consumers and company to company complaints.

Government could enhance the current guidance material to provide clear criteria for developing truthful and not misleading claims, the process to develop claims (including engagement), and clear definition of “consumer values” claims. It can assist consumers in understanding their role or the purpose of the consumer values claim and the impact of this claim on them.

In summary, the responsibilities for the government in the proposed framework could be over federal food regulations as well as interacting with consumers and industry. Whereas industry would be responsible for ensuring that the food they sell is compliant with all legislation, and communicating with consumers and government.

Additionally, when developing new regulations, we are moving towards outcome-based regulations wherever possible. Rulemaking on specific claims such as “natural”, may limit the possibility for innovation by industry in the future.

2. Should we prohibit the term “natural” in food labeling? Why or why not?

The use of claims on food labels, such as the term “natural”, help consumers make informed decisions based on the criteria that is important to them (health, social, environmental).

3. If we define the term “natural,” what types of food should be allowed to bear the term “natural?”

Currently in Canada, a food or ingredient of a food that is represented as natural is expected:

- not to contain, or to ever have contained, an added vitamin, mineral nutrient, artificial flavouring agent or food additive.
- not to have any constituent or fraction thereof removed or significantly changed, except the removal of water. For example: the removal of caffeine.
- not to have been submitted to processes that have significantly altered their original physical, chemical or biological state (i.e. maximum processes).

Examples of maximum processes can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=8>.

Current Canadian guidelines on the use of the term "natural" can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=2>.

Current Canadian guidelines on the use of the term "natural" on meat, poultry and fish products can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=9#s3c9>.

Note that some food additives, vitamins and mineral nutrients may be derived from natural sources. Some of these ingredients may be regarded as natural ingredients, in which case the acceptable claim would be that the food contains "natural ingredients". The processes used to produce the ingredient should not significantly alter its original physical, chemical, or biological state.

4. Should only raw agricultural commodities be able to bear the term? Why or why not? Section 201(r) of the FD&C Act defines the term "raw agricultural commodity" as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing."

Currently in Canada, the term "natural" may be used on commodities that have been minimally processed, such as peeled, chopped or degermed.

Examples of minimum processes can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=7>.

5. Should only single ingredient foods, e.g., bottled water or bagged spinach, be able to bear the term? Why or why not?

Currently in Canada, provided that the final food meets the three criteria outlined in the response to item 3, multi-ingredient foods may bear the claim "natural". Multi-ingredient foods produced with all natural ingredients may also claim "natural ingredients".

Currently in Canada, the use of the term "natural" on water is restricted to mineral or spring water which does not have its composition modified through the use of chemicals and meets the Natural criteria, outlined in item 3, in all other ways, such as how it is processed, and may be described as "Natural Mineral Water". More information on the use of the term "natural" on water can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/prepackaged-water-and-ice/eng/1392050209634/1392050277168?chap=9#s14c9>.

6. If multi-ingredient foods should be able to bear the term, what type(s) of ingredients would disqualify the food from bearing the term? Please explain why such disqualification would be warranted.

Currently in Canada, if multi-ingredient foods contain and added vitamin, mineral nutrient, artificial flavouring agent or food additive or if they are produced or processed using ingredients that do not meet the "natural" criteria (see criteria outlined in item 3), they may not use the term "natural".

7. We are interested in any data or other information to suggest that consumers associate, confuse, or compare the term "natural" with "organic" (the USDA Agricultural Marketing Service administers the National Organic Program, which enforces laws and regulations regarding certified organic foods). We are interested in data and other information about consumers' understanding of foods labeled "natural" versus "organic." Is the term "natural" on food labels perceived by consumers the same way as "organic?" Or is "natural" perceived by consumers to be "better" (or not as good as) "organic?" Please provide consumer research or other evidence to support your comment.

The Government of Canada commissioned EKOS Research Associates to conduct a survey of Canadians about their understanding and acceptance of labelling practices.

As a result a Public Opinion Research Report was published in 2012. This survey included questions to examine the view of Canadians on "natural" and "organic". While asked, unprompted, about "natural", there was no mention of "organic". However, when asked, unprompted, to list their reasons for purchasing organic foods, 57 per cent responded the exclusive use of natural ingredients.

More research would be necessary in order to determine if foods labelled "natural" are perceived by consumers to be the same, better, or not as good as "organic".

A copy of the report is available at <http://amicus.collectionscanada.ca/porr-rrp-bin/Main/BasicSearch?l=0&id=956747.1472217&v=1&coll=28>, enter POR 038-11 in the report no. search field.

8. If we were to revise our policy regarding the use of the term “natural” or engage in rulemaking to establish a regulatory definition for “natural,” should certain production practices used in agriculture, for example, genetic engineering, mutagenesis, hybridization, the use of pesticides, or animal husbandry practices, be a factor in defining “natural?” Why or why not?

Certain production practices could be a factor to define the term “natural”. Currently in Canada, the guidance relevant to this area is that processes should not significantly alter the food’s original physical, chemical, or biological state.

Canada is aware that there is an interest in animal husbandry practices when it comes to the use of a “natural” claim, however a policy has not been completed on the subject at this time.

Currently in Canada, the use of pesticides or genetic engineering is not evaluated for the use of a “natural” claim.

9. We are interested in any data or other information to suggest that consumers associate, confuse, or compare the term “natural” with “healthy.” We have a regulation that defines the term “healthy” when used as an implied nutrient content claim with specific conditions related to the food's nutrient profile that must be met in order to use the term on the label or in labeling of a food (see 101.65(d)). We are interested in data and other information about consumers' understanding of foods labeled “natural” versus “healthy.” Is the term “natural” on food labels perceived by consumers the same way as “healthy?” Or is “natural” perceived by consumers to be “better” (or not as good as) “healthy?” Do consumers view “natural” and “healthy” as synonymous terms? Please provide consumer research or other evidence to support your comment.

The Government of Canada commissioned EKOS Research Associates to conduct a survey of Canadians about their understanding and acceptance of labelling practices.

As a result a Public Opinion Research Report was published in 2012. This survey included questions to examine the view of Canadians on “natural”. When asked, unprompted, to explain their understanding of the term “natural”, respondents provided a number of interpretations, with the plurality (30 per cent) suggesting that a “natural” product is derived from natural ingredients. One in five (20 per cent) feel that natural products are not processed or modified in any way, and one in seven believe that “natural” implies no preservatives (16 per cent), no pesticides or herbicides (14 per cent), or no artificial

flavours or colours (13 per cent). In these responses there is no comparison of the term "natural" with "healthy".

A copy of the report is available at <http://amicus.collectionscanada.ca/porr-rrp-bin/Main/BasicSearch?l=0&id=956747.1472217&v=1&coll=28>, enter POR 038-11 in the report no. search field.

In Canada, general health claims are permitted on foods when the message being transmitted is in line with the dietary recommendations outlined in Canada's Food Guide. The word "healthy" refers to the healthy eating patterns recommended by Eating Well with Canada's Food Guide. The use of the word "healthy" on a food that does not meet the recommendations of Canada's Food Guide could be misleading. More information on the claim "healthy" can be found here:

<http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=11#s24c11>

10. Should manufacturing processes be considered in determining when a food can bear the term "natural?" For example, should food manufacturing processes, such as drying, salting, marinating, curing, freezing, canning, fermenting, pasteurizing, irradiating, or hydrolysis, be a factor in defining "natural?"

Currently in Canada, food or ingredient of a food that is represented as "natural" should not have been submitted to processes that have significantly altered their original physical, chemical or biological state (i.e. maximum processes). Examples of maximum process that may disqualify a food or ingredient of a food from using the term "natural" can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=8>.

11. Should the term "natural" only apply to "unprocessed" foods? If so, how should "unprocessed" and "processed" be defined for purposes of bearing the claim? If the term natural should include some processing methods, what should those methods be? In making determinations related to processing, should one look at the process to make a single ingredient of a food, or does one evaluate the process done to the formulated finished food product (or both)?

Currently in Canada, provided that the final food was not subject to a process that significantly alters its original physical, chemical or biological state and that the other two criteria are met, the final food may bear a "natural" claim. Processes affecting the natural character of a food with a minimal physical, chemical or biological change could still be permitted on foods using the term "natural".

Examples of maximum processes can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=8>

Examples of minimum processes can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=7>.

Additionally, multi-ingredient foods produced with natural ingredients could claim "natural ingredients".

12. The current policy regarding use of the term "natural" hinges in part on the presence or absence of synthetic ingredients. For example, under the current policy synthetic forms of Vitamin D would not be used in a food claiming to be "natural," whereas naturally sourced Vitamin D (e.g., from salmon or egg yolks) could be. Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as "natural?" Please explain your reasoning.

Currently in Canada, the "natural" status of ingredients depends on how they are processed (e.g. whether they were subjected to minimal/maximal processes) and whether they are synthesized or contain additives. Ingredients that are synthesized or contain additives, or that have been subject to significant processing may not be described as "natural" (see criteria outlined in item 3).

For example, currently in Canada, steviol glycosides are not considered to be a natural ingredient due to its significant processing and the types of solvents used for its extraction and purification.

Some ingredients, such as food additives, vitamins and mineral nutrients, may be derived from natural sources and be minimally processed, in which case they may be described as "natural" ingredients. While these ingredients can be described as "natural", the food itself should not because it contains added components.

13. What can be done to ensure that consumers have a consistent and accurate understanding of the term "natural" in food labeling to ensure that it is not misleading?

Whether the use of the term "natural" in food labelling is defined through rulemaking or a policy, the criteria that will be used to determine if a product can bear such a claim should be made publicly available in clear plain language. Consumer education of what the term "natural" entails when used on a food label could also be undertaken either by industry or government officials. Currently in Canada, the Canadian Food Inspection Agency has a Food Labelling for Consumer webpage with Factsheets and Interactive Tools to assist consumers in understanding food labels; this can be found at <http://www.inspection.gc.ca/food/labelling/food-labelling-for->

consumers/eng/1400426541985/1400455563893. Consumers are also encouraged to contact industry on the products they purchase to understand the claims being made and/or request for product information.

In Canada, the results of the Food Labelling Modernization initiative will inform how claims such as "natural" will be managed, taking into account the role of industry, consumer, and government.

14. What are the public health benefits, if any, of defining the term "natural" in food labeling? Please provide supporting data and other information to support your comment.

The CFIA has no comments.

15. Should "natural" have some nutritional benefit associated with it? If so, what should be the benefit? What nutrients should be considered? What data are available to support the association between "natural" and a given nutritional benefit, and/or between "natural" and certain nutrients?

In Canada, the criteria for determining if a food or ingredient of a food can use the term "natural" is based on how they are processed and whether they are synthesized or contain additives. Labels and advertisements should not convey the impression that "Nature" has, by some miraculous process, made some foods nutritionally superior to others or has engineered some foods specially to take care of human needs.

16. How might we determine whether foods labeled "natural" comply with any criteria for bearing the claim?

The manufacturer or importer of the food product should have documentation supporting the use of the term "natural" on the food product. Documentation could be ingredient records or processing spread sheets. This documentation could be used to verify the products compliance with any criteria established for bearing the "natural" claim.

Additional comments:

17. Currently in Canada, substances that impart flavours that have been derived from a plant or animal source, may be claimed to be "natural". As well, any additive, such as preservatives and solvents added to a flavour preparation to have a technological effect solely on the flavour, does not modify the "natural" status of the flavouring material itself. However, the addition does alter the natural status of the food to which it has been added, even though it need not be declared as an ingredient on the food label. In other words, such foods may not be claimed to "contain only natural ingredients".

Furthermore, acids, bases, salts and sweeteners may be used to impart sour, bitter, salty and sweet tastes in conjunction with natural flavours. They are not considered to alter the "natural" status of the flavouring material itself. For example, citric acid is not a flavour but acts only as an acidulant when used in conjunction with natural flavours.

Note, however, that while the flavour remains "natural", such acids, bases, salts or sweeteners have an effect on the foods to which the flavour preparation is added. Therefore, the list of ingredients of such foods must declare acids, bases, salts or sweeteners that are present by their proper common names.

The status of enzymatic flavours, processed flavours, reaction flavours or nature-identical flavours are examined on a case-by-case basis.

18. Currently in Canada, the use of the word "natural" in a trademark name may be subject to the same criteria outlined in item 3.