



Health
Canada

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Votre santé et votre
sécurité... notre priorité.

Bureau of Chemical Safety Food Directorate

Bureau d'innocuité des produits chimiques Direction des aliments

Health Canada reviews comments received on the proposed changes to current food colour labelling regulations for prepackaged foods

A PAHO/WHO Collaborating Center for
Food Contamination Monitoring



World Health
Organization

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Notre Mission

Veiller à ce que les produits chimiques ne soient pas présents dans les aliments à des niveaux pouvant entraîner des effets néfastes sur la santé des canadiennes et des canadiens.

Our Mission

To ensure chemicals are not present in foods at levels that may cause adverse health effects to Canadians.

Canada

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Background

On February 18, 2010, Health Canada's Bureau of Chemical Safety, Food Directorate distributed a letter to various food manufacturers and to citizens who had previously contacted Health Canada on the subject of food colours. The purpose of this letter was to invite comments on Health Canada's proposal to amend the regulations governing how food colours are labelled in Canada. In addition to this invitation, an [open call for comments](#) was made available from February 18th to May 3rd 2010 through Health Canada's website.

Current labelling regulations require that food additives, including food colours, be declared in the list of ingredients on the label of prepackaged foods. However, section B.01.010 (3)(b) of the *Food and Drug Regulations* (FDR) provides manufacturers with the choice of declaring food colours by their common name or simply by the generic term "colour"¹. Health Canada has proposed to [amend the current labelling regulations](#) so that food colours would be required to be identified on labels by their common name and/or by a numerical identifier. These changes are being proposed due to reports of potential adverse health effects associated with the consumption of certain food colours, as well as requests by consumers that more information be made available when making food selections.

As a result of this consultation, more than 130 responses were received from various stakeholders including consumers, health professionals, food organizations, health organizations, and members of the food industry.

Summary of Comments

The majority of comments received by Health Canada supported the proposal to eliminate the current option of including only the term "colour" on the ingredients list to declare the addition of a colour to a food product. Many comments noted that the proposed amendments to the food colour labelling regulations will improve transparency and contribute to improving the health of Canadians.

Health Canada proposed two possible options as replacements to the current labelling requirements:

- (1) Require labelling of all food colours by their individual common name or a numerical identifier (such as the International Numbering System used by the Codex Alimentarius Commission or the "E" number system used in Europe); and
- (2) Require labelling by the individual common name of all synthetic colours that do not occur in nature and that must undergo a certification process, as well as the natural colours cochineal, carmine, and annatto. All remaining natural colours could be permitted to be identified either by the generic term "colour" or by their common name.

¹ The Regulations specify exceptions for tocino and longaniza sausages for which permitted food colours must be declared by their common name as per sections B.14.031 (i) and B.14.032 (d)(xvi).

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Overall, both options proposed by Health Canada received considerable support. However, almost all who supported option (2) suggested that colours not required to be identified by their individual name or by a numerical identifier be identified by the generic term “natural colour” rather than just “colour” since, under option (2), all colours that could be identified by the generic term would be natural colours.

While almost all responses were supportive of identifying some or all colours by more than just a generic term, varied opinions on how colours should be identified on ingredient lists were received. Some responses indicated that the common name would be the most recognizable format to consumers, while others believed that a numerical identifier would be clearer and easier for consumers to identify specific colours. Many responses indicated that no matter how the colours are to be identified (name or number or both), the terms “natural” or “synthetic” should also be included. Below is a summary of the comments received from various stakeholders along with Health Canada’s response to those comments.

(1) Comments on Health Canada’s two proposed options to improve food colour labelling requirements:

Option 1 - *Require labelling of all food colours by their individual common name or a numerical identifier (e.g. such as the International Numbering System used by the Codex Alimentarius Commission or the “E” number system used in Europe);*

Option 2 - *Require labelling by the individual common name of all synthetic colours that do not occur in nature and that must undergo a certification process as well as the natural colours cochineal, carmine, and annatto. All remaining natural colours could be permitted to be identified either by the generic term “colour” or by their common name.*

Comments	Health Canada’s consideration
<ul style="list-style-type: none"> • Most stakeholders were in favour of identifying all added colours in foods by their common name or numerical identifier as this provides the most information to consumers when selecting foods. • Others felt it was necessary to identify only synthetic colours by their common name/numerical identifier. This way food colours associated with potential adverse health effects are more clearly identified. • Many stakeholders supportive of option (2) suggested a slight modification whereby natural colours could be identified by the term “natural colour” rather than just “colour”. 	<p>The proposed amendments to food colour labelling aim to provide consumers with as much information as possible when making food choices. Although potential adverse reactions to food colours have been linked primarily to synthetic colours, there may be some individuals who are sensitive to certain natural colours. Consequently, a requirement to declare all synthetic and at least some natural colours by name or number will assist a broader segment of the Canadian population to make appropriate food choices. Listing natural colors by their name or number is not expected to negatively affect consumers’ ability to identify synthetic colours that may be associated with adverse health effects in sensitive individuals.</p>

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<ul style="list-style-type: none"> • Other stakeholder comments on the two options included: <ul style="list-style-type: none"> ⇒ Identification of natural colours is not necessary since there is a lack of evidence that natural colours cause adverse health effects. ⇒ Labelling of natural colours by name could raise unnecessary concerns as new names may lead consumers to conclude that new additives are present. ⇒ Labelling all colours by name or number will help facilitate the problem of identifying colours that are not permitted in Canada. ⇒ A clearer identification of colours in food would help certain cancer patients who must adhere to a specific diet and avoid particular substances while undergoing treatment. 	<p>Health Canada notes that an amendment requiring identification of all colours on labels would be of assistance in ensuring the compliance of food products both domestic and imported, with Canadian regulations.</p>
<ul style="list-style-type: none"> • If option (2) were adopted, would the three natural colors to be identified by name or number be required to go through a certification process similar to that which synthetic colours must undergo? 	<p>Sections B.06.004 and B.06.005 of the <i>Food and Drug Regulations</i>, currently require certification only for synthetic colours. At this time, Health Canada is not proposing any amendments to require that the natural colours, cochineal, annatto, and carmine, be certified. However, all three natural colours will continue to be required to meet applicable food-grade specifications.</p>
<ul style="list-style-type: none"> • Some stakeholders supporting option (2) suggested removing the specific labelling of annatto due to a lack of evidence that it may cause adverse health effects, and that the specific labelling of annatto may create undue concerns about its safety. 	<p>Although there is not a strong body of scientific literature on possible sensitivities to annatto, cochineal, or carmine, Health Canada considers that the few reports that have been documented support the proposal for them to be labelled. The concerns with these natural food colours pertain to their potential to cause an allergic reaction in certain individuals. Annatto is derived from achiote trees (<i>Bixa orellana</i>) of the tropical Americas. The annatto extract contains the carotenoid pigment bixin. Allergic reactions could occur due to either bixin contamination or residual seed proteins to which some individuals develop a hypersensitivity. Cochineal colours (cochineal, carminic acid, carmine) are obtained from an</p>

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	<p>extract of the insect <i>Coccus cacti</i>. It is possible that proteins present in these food colours could cause an allergic reaction. However, the structure of the protein and the role of protein-bound carminic acid in the allergic reaction are unknown.</p> <p>Requiring the identification of all colours on the label will also align food colour labelling requirements with the labelling requirements for all other substances regulated as food additives (all other food additives must be declared by their full name).</p>
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(2) Other options suggested by stakeholders:

Comments	Health Canada's consideration
<ul style="list-style-type: none"> Some stakeholders have proposed banning the use of all synthetic food colours or synthetic food colours that have been shown to cause adverse health effects. Conversely, some stakeholders believe there is insufficient evidence to support any change to the current regulations. A few stakeholders requested clarification on why Health Canada stated in its proposal that "clear labelling of food colours is the best option for risk management of behavioural effects attributable to food colouring agents." 	<p>Health Canada has reviewed the available data from scientific literature on possible adverse effects caused by consuming foods that contain added colours. Although specific areas of study relevant to behavioural effects and allergenicity are under review, the general toxicological data is supportive of safety, whether the food colours are natural or synthetic, that are permitted for use in Canada when used according to the provisions within the <i>Food and Drug Regulations</i>. However, to enable consumers to make informed food choices, especially those who may have sensitivities to certain food colours, Health Canada considers that enhanced labelling of food colours would achieve this objective.</p>

(3) Comments on how to declare individual colours in the list of ingredients:

Comments	Health Canada's consideration
<ul style="list-style-type: none"> Stakeholder opinions on how colours should be identified in the ingredients list were divided. Some supported declaring the common name of the colour, others were in favour of using a numerical identifier, and some believed the common name and a numerical identifier should be required. Recommendations were also made to give manufacturers the choice of using either the 	<p>Health Canada will continue to consider these comments as it works to determine the most appropriate approach for labelling colours to ensure consumers are able to easily make informed food choices.</p>

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<p>name or a number.</p> <ul style="list-style-type: none"> • Numerical identifier will be difficult to recall at the point of sale. Common names will be easier for consumers to remember. • Numerical identifiers have been successfully used in Europe for several years (“E number” system). • Individual names will be confusing to consumers – consumers may be uncomfortable with unfamiliar names in the ingredients list. • Identification by number will require sustained education and awareness efforts. 	
<ul style="list-style-type: none"> • Many stakeholders believed it was equally important to insert the terms “natural” or “synthetic” in front of the name or numerical identifier. 	<p>Health Canada recognizes that consumers would like to know whether added colours are “natural” or “synthetic”. There is currently no regulatory definition for these terms and their use may even lead to confusion. The term “synthetic” generally means that the compound does not occur naturally. The term “natural”, when used in reference to colour, means it is derived from a natural source (plant, animal or mineral). Natural colours may be obtained as natural extractives or synthesized in the laboratory as nature-identical. The term “natural” does not imply that the colour preparation is a natural food or ingredient as outlined in the existing labelling policies for “natural” in the CFIA’s Guide to Food Labelling and Advertising (Section 4.7 GFLA). The CFIA advises that a food or an ingredient must meet these guidelines in order to use the claim “natural”.</p>
<ul style="list-style-type: none"> • It was suggested that, if the common name is used, Health Canada should provide a reference (e.g. website) to information on potential health effects for each colour. • It was suggested that, if a numerical identifier is used, Health Canada should use an internationally recognized system and provide a reference (e.g. website) to a listing of the colours that correspond to each number with information on potential health effects. 	<p>Health Canada will provide the necessary information, including any required reference material regarding changes to food labelling requirements, to enable consumers to make an informed choice.</p>
<ul style="list-style-type: none"> • Adopt a system that identifies food colours 	<p>Health Canada will continue to consider food</p>

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<p>by their certified names (e.g. FD&C Red No. 40 or Red 40).</p> <ul style="list-style-type: none"> • Harmonize food colour labelling requirements in Canada with those implemented in the United States (certified names). • Provide manufacturers with the option of using either the certified names or common names without having to declare both. 	<p>colour labelling requirements in other jurisdictions and aims to achieve harmonization with internationally adopted best practices where suitable.</p>
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(4) Transition period for manufacturers and alignment with other regulatory labelling changes proposed by Health Canada:

Comments	Health Canada's consideration
<ul style="list-style-type: none"> • Food industry members have suggested that Health Canada provide a transition period of at least 2 years and up to 5 years in order to implement changes to comply with the proposed regulatory requirements for food colour labelling. • Industry members have also requested that any amendments to the food colour labelling regulations coincide with other food labelling changes proposed by Health Canada such as the priority food allergen labelling initiative. 	<p>Health Canada will endeavour to provide sufficient time to food manufacturers to implement the necessary label changes with minimal burden. Health Canada will also strive to align the implementation of other regulatory amendments that affect labelling changes where possible.</p>

(5) Regulatory labelling exceptions for standardized alcoholic beverages:

Current labelling regulations in Canada do not require a list of ingredients for standardized alcoholic beverage products. However, some standards of identity in Division 2 of the Food and Drug Regulations allow for the use of certain colours in alcoholic beverages.

Comments	Health Canada's consideration
<ul style="list-style-type: none"> • Some stakeholders have expressed concerns over how the proposed food colour labelling amendments may affect alcoholic beverages. • New European regulations that came into effect in July 2010, require the labelling of certain synthetic food colours. However, alcoholic beverages are exempt from those new requirements in Europe. 	<p>At this time, Health Canada is not proposing changes to the current labelling requirements for alcoholic beverages. Therefore, standardized alcoholic beverages will not be required to provide a list of ingredients. However, unstandardized alcoholic beverages are currently required to have a complete list of ingredients. The proposed amendments for food colour labelling requirements will apply to all products already subject to mandatory ingredient labelling.</p>

(6) Warnings for certain synthetic food colours:

Comments	Health Canada's consideration
<ul style="list-style-type: none"> Some stakeholders suggested that when added to a food, certain synthetic food colours should be accompanied with a warning that these food colours may be associated with causing adverse reactions in children. 	<p>Based on the general toxicological data currently available, Health Canada is not currently considering warning labels on prepackaged foods containing certain synthetic colours.</p>

(7) Which foods will be affected by the new food colour labelling regulations?

Comments	Health Canada's consideration
<ul style="list-style-type: none"> A number of responses inquired whether specific foods would be affected by the amendments and whether foods from the food service industry (restaurants, cafeteria, etc) would also be affected. There was a concern regarding how this initiative will impact products regulated as natural health products. One response also asked if the changes will apply to all prepackaged foods (e.g. oranges in a plastic bag). 	<p>The proposed amendments to food colour labelling requirements will apply to those prepackaged foods sold in Canada that are already required to carry an ingredient label. This initiative will not change any of the permitted uses of food colours.</p> <p>Natural health products are subject to requirements under the <i>Natural Health Products Regulations</i>. This proposal will only impact products that are classified as foods.</p>
<ul style="list-style-type: none"> Some concerns were raised as to whether food colours will have to be declared and identified when part of a flavour preparation or as a component of another ingredient in food. 	<p>The proposed amendments to food colour labelling requirements are not meant to change the existing requirements and exemptions that apply to component declaration.</p>
<ul style="list-style-type: none"> Some stakeholders expressed the desire to apply the proposed food colour labelling changes (i.e. identification by name or numerical identifier) to other food additives and ingredients such as flavours and spices. 	<p>Labelling requirements for flavours and food ingredients such as spices and seasonings are outside the scope of the present proposal.</p>

(8) Statement on effects of azo food colour component:

“Health Canada has since found information suggesting a mechanism by which the azo food colour component of the tested food additive mixtures could affect the availability of neurotransmitters in the brain and thus influence behaviour”.

Comments	Health Canada's consideration
<ul style="list-style-type: none"> A few stakeholders requested more information regarding the above statement made by Health Canada in its initial proposal. 	<p>The information described above as being found by Health Canada is not from a recent or new study. Rather, this is a reference to earlier studies on the action of azo dyes on a group of</p>

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	<p>enzymes, called sulfotransferases, found in the human body. In laboratory studies, some azo dyes have been shown to inhibit some of the sulfotranferases, which are responsible for inactivating chemicals that can act as neurotransmitters, such as dopamine and norepinephrine. If azo dyes interfered with the inactivation of these chemicals, their activity in the body, including the brain, could theoretically be affected. It should be noted however that this is only a hypothesis and it has not been tested. Furthermore, some naturally occurring compounds (such as phenolics found in fruit juices) were also found to inhibit sulfotransferases, but are not known to have an effect on neurotransmitters.</p>
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(9) Requirements as a result of certain colours being associated with allergies:

Comments	Health Canada’s consideration
<ul style="list-style-type: none"> • A concern was raised by one stakeholder regarding expectations for processing facilities and supply chains handling foods containing those colours that may be associated with allergic reactions. 	<p>Although there have been occasional, individual reports in some countries of adverse effects associated with certain colours, at this time, these colours have not been designated “priority” allergens in Canada and therefore are not subject to any requirements specific to priority allergens.</p>

Next Steps

Health Canada will continue to take these comments under consideration when updating its proposal to enhance food colour labelling requirements. The relevant proposed regulatory changes will be developed and published for consultation in Part I of the *Canada Gazette*.

This work has been undertaken by Health Canada's Food Directorate in accordance with its commitments through the Government of Canada's [Food and Consumer Safety Action Plan](#) to help modernize and strengthen Canada's safety system for food.