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Health Canada Proposal to Improve Food Colour Labelling Requirements – February 2010

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

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Canada 

Background

Health Canada is currently in the latter stages of developing regulations to improve the labelling of “priority” food allergens (for example peanuts, eggs, soy, milk, etc.), gluten sources and added sulphites on prepackaged foods having a list of ingredients. Health Canada’s next efforts to improve food labelling will focus on food colours. Health Canada is currently planning to change the regulations governing how food colours are labelled in Canada as described below. Letters inviting comments on the proposal have been sent to various food manufacturers and citizens who have previously contacted Health Canada on this subject. Through the current internet notification, Health Canada is inviting comments from any interested Canadian citizens, representatives of food manufacturing companies, and other stakeholders on the proposal. Additional details on the proposal, and how to provide comments, are provided in the following sections.

Current Canadian Requirements for Labelling Food Colours

The majority of pre-packaged foods in Canada are required to carry a list of all ingredients, including food additives, on the product label. Since food colours are regulated as “food additives” in Canada, they too must be identified in the ingredient list of foods containing them. The food colours that are permitted as food additives in Canada are listed in Table III of section B.16.100 of the Food and Drug Regulations (the Regulations).

Although the Regulations require that food colours be declared in ingredient lists of pre-packaged foods, section B.01.010 (3)(b) of the Regulations provide food manufacturers with the choice of declaring added colour(s) by either their common name or simply as “colours”. The exceptions are tocino and longaniza sausages. The ingredient lists of tocino and longaniza must specifically identify the name of the colours contained therein, annatto in the case of tocino, and annatto, allura red, and/or sunset yellow FCF in longaniza, as per sections B.14.031 (i) and B.14.032 (d)(xvi) of the Regulations. Therefore, except in the case of these two types of sausage, manufacturers currently have the choice of labelling using either the specific common name of the colour or the general term “colour.”

Summary of Past Health Canada Scientific Evaluations which Provide a Health-Based Rationale in Support of Improved Labelling of Food Colours

Health Canada scientists reviewed available literature data on possible adverse effects induced by the ingestion of foods containing added colours. Of the colours approved for use in Canada as well as in many other countries worldwide, the following colours were reported in some countries (although not in Canada) to be associated with adverse reactions:

- cochineal extract derived from the dried female insect body, *Coccus cacti* and its major component carmine;
- annatto (aqueous or oil-based extracts of annatto seeds); and
- synthetic colours containing an azo-type chemical structure (-N=N-), including tartrazine and sunset yellow FCF.

Despite occasional, individual reports in some countries of adverse effects associated with these colours, they have not been designated priority allergens according to the criteria defined by the international scientific expert body, JECFA (the Joint World Health Organization/Food and Agriculture Organization of the United Nations Expert Committee on Food Additives). The JECFA's criteria are also used by Health Canada to identify priority allergens. Despite the small number of reports of adverse effects, including allergic reactions, associated with the ingestion of food colours in the general population, Health Canada considers that it would be prudent to identify the presence of specific colours on food labels and thereby enable consumers to make more informed choices which could contribute to further reduction of allergic or other adverse reactions.

In addition to reports on allergic reactions, a United Kingdom team of psychologists and paediatricians recently reported in the scientific journal *Lancet* (McCann, D. et al., November 03, 2007) that there may be a link between the ingestion of mixtures of certain food additives and hyperactivity in schoolchildren. Despite a lack of consensus on conclusions derived from this study, the [UK Food Standards Agency](#) proposed that manufacturers voluntarily remove the colours sunset yellow, quinoline yellow, carmoisine, allura red, tartrazine and Ponceau 4R from food and beverage formulations (quinoline yellow, carmoisine and Ponceau 4R are not permitted for use in Canada).

Health Canada scientists reviewed the results of the UK study and agreed with the conclusions of the UK Committee on Toxicology that the results of this study are consistent with, and add weight to, previous published reports of behavioural changes occurring in children following consumption of particular food additives which included a number of azo food colours. Health Canada also noted the inconsistencies in the results between the two mixtures of food colours and between age groups, and the small observed effect relative to the degree of variation in effect between individuals, which suggested that conclusions could not be drawn regarding possible changes that might be observed at the population level. 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. The results of the UK study became more consistent when analyzed on the basis of the dose of azo food colours received by the two age groups and with the two food additive mixtures. Due to the multiple factors affecting susceptibility to the effects of azo colours, susceptibility would differ widely with the individual. It is therefore proposed that clear labelling of food colours is the best option for risk management of behavioural effects attributable to food colouring agents. Improved labelling provides consumers the choice of avoiding specific components in their diet.

Labelling Requirements in Other Jurisdictions

International Recommendations of the Codex Alimentarius Commission:

The United Nations Codex Alimentarius is a compilation of international food standards elaborated by Codex member states. Codex Standard 1-1985, last amended in 2008, is the General Standard for the Labelling of Pre-packaged Foods. It recommends in section 4.2.3.3 that food additives be labelled by their functional class titles (e.g., “colour” for colouring agents) together with the specific name or a recognized numerical identifier as required by national legislation. The International Numbering System (INS) is a registry that assigns unique numbers to individual food additives, including colours. This registry of food additives is maintained by one of the Codex Committees, namely the Codex Committee on Food Additives (CCFA).

Australia/New Zealand:

Colours approved for use in foods in Australia and New Zealand are listed in Standard 1.3.1 of the Australia New Zealand Food Standards Code. Standard 1.2.4 sets out labelling requirements for food ingredients, including colours and other food additives. Colours must be declared by the name of their functional class, that is, “colour” followed by either the colour’s full name or its numerical identification code, as provided in Schedule 2 of Standard 1.2.4. The food additive Code numbers used by Australia and New Zealand are aligned with Codex Alimentarius International Numbering System (INS) registry numbers. The Australia/New Zealand authorities are not currently planning to change labelling requirements in response to the UK studies on child behaviour and the ingestion of certain food additive (including colour) mixtures, and have noted that the intake of synthetic colours in Australia/New Zealand is much lower than that tested in the UK study.

European Union (EU):

In the EU, the list of approved colours is outlined in the European Parliament and Council Directive 94/36/EC of June 1994. Certain modifications to this Directive were introduced in subsequent years; e.g., the colour Red 2G was delisted in 2007 because of safety concerns (Commission Regulation No 884/2007). This colour has never been allowed for use in Canada.

Council Directive 79/112/EEC of 18 December 1978 outlines the labelling rules for foodstuffs. All food additives, including food colours, have to be declared by their functional category (colour) followed by either the full name of the additive or its European food additive E number (e.g., colour riboflavin or colour E101). All foods must be labelled in the national language of the appropriate European state. The EU Colour Directive does not distinguish between “natural” and “artificial colours”.

In response to the recent studies on child behaviour and the ingestion of food additive (including colour) mixtures, the European Food Safety Authority (EFSA) has not advised any specific action until further proof of any adverse reactions induced by food colours becomes available. Nonetheless, the European Union issued a new Regulation (EC) of the European Parliament and of the Council of 16 December 2008 on Food Additives (No. 1333/2008), which will be in effect starting July 20, 2010. This regulation requires that the synthetic colours sunset yellow (E110), quinoline yellow (E104), carmoisine

(E122), allura red (E129), tartrazine (E102), and Ponceau 4R (E124) be labelled by their common names or E numbers in the list of ingredients along with the following warning statement: “may have an adverse effect on activity and attention in children”.

The United States:

The Food and Drug Administration (FDA) is responsible for regulating all food colours in the US. Colours are classified as either “certifiable” or “exempt from certification”. Certifiable colours are synthetic and do not occur in nature. Manufacturers must analyse each batch of synthetic colour to ensure safety and quality (a similar certification process also exists in Canada). Certifiable colours, once certified, are designated FD&C (“Food, Drug and Cosmetics”). The US exempts from certification, colours derived from natural sources, mainly plant, but sometimes animal or mineral. These colours may be obtained as natural extractives or synthesized in the laboratory as nature-identical. They may be labelled by their specific common name or using the term “colour added” or “artificial colour” or an equally informative statement. The term “natural colour” is not allowed in order to avoid an erroneous interpretation that the colour is a natural constituent of that food and was not added. Food ingredients (for example a fruit juice) used for colouring purposes are exempt from such labelling. Spices that are also used for colouring purposes must be declared accordingly, that is, labelled “spice and colouring”. Labelling requirements for colours are defined in sub-part 101.22 of Title 21 of the US Code of Federal Regulations (CFR).

Since the enactment of the Nutrition Labeling and Education Act in 1993, all certified food colours must be labelled by their specific name, e.g. Red 40, Yellow 5, etc.

There is one exception to the labelling requirements for colours that are exempt from certification. Under the FDA rule issued on January 5, 2009, the colours cochineal extract and a related colour, carmine will have to be declared by their common name on all foods containing them (Federal Register, January 5, 2009). This rule will be effective on January 5, 2011.

The list of approved food colours in the US, both certified as well as exempt, is found in Parts 73 and 74 of Title 21 of the CFR.

Health Canada’s Proposal

Several major national jurisdictions require that at least synthetic colours be declared on food labels by their functional class “colour” and their common name. In many countries worldwide all food colours have to be displayed by their individual name or by a numerical identifier that is nationally recognised. Health Canada will be proposing changes to improve the labelling of food colours sold in Canada.

Some possible options for colour labelling include:

- ***Require labelling of all food colours by their individual common name or a numerical identifier (e.g. a Colour Identification number);***

- *Require labelling by the individual common name of all synthetic colours that do not occur in nature and have to undergo a certification process as well as the natural colours cochineal, carmine and annatto (each of which have been associated with allergic or sensitivity responses). All remaining natural colours could be permitted to be identified either by the generic term “colour” or by the common name.*

In order to adopt the most appropriate path forward for food colour labelling, Health Canada intends to consult on the issue with a large number of stakeholders.

After the close of the comment period, all comments received will be examined and regulatory amendments on colour labelling will be drafted and formally proposed through publication in the Canada Gazette Part I (CG Part I). Following the subsequent public consultation period, which always follows publication of any proposed regulation in CG Part I, and consideration of any additional comments, the final regulatory amendment will be published in the Canada Gazette Part II.

Please note that a transition period will be granted to allow time for manufacturers who do not already label colours by their common name, to alter their food labels or formulations to be compliant with the amended labelling regulations. The length of this transition period will be determined taking into consideration comments from stakeholders.

How to Provide Comments

Health Canada has directly contacted various stakeholders by letter and invites comments from any interested citizen by **May 03, 2010**. Comments may be submitted by mail at the address shown below or by Email at the following address: bcs-bipc@hc-sc.gc.ca. Please use the words “Food Colour Labelling” in the subject box.

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ADDITIONAL INFORMATION

For more information on this initiative, please contact the [Chemical Health Hazard Assessment Division](#).