

April 29, 2010

Bureau of Chemical Safety  
251 Sir Frederick Banting Drive  
Health Canada, Tunney's Pasture  
Address Locator: 2203B  
Ottawa, Ontario K1A 0L2

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

To Whom It May Concern:

On behalf of the International Association of Color Manufacturers (IACM), I am pleased to submit the following comments in response to the Health Canada Proposal to Improve Food Color Labeling Requirements (February 2010). IACM is the trade association that represents color additive manufacturers and their customers that manufacture foods, drugs and cosmetics.

With the exception to the reference of annatto, IACM would support Health Canada's proposal that would:

“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. All remaining natural colours could be permitted to be identified either by the generic term “color” or by the common name.”

As you are aware, the United States Food and Drug Administration (FDA) allows for certified (“synthetic”) color additives to be listed within the ingredient statement by specific or abbreviated name such as “FD&C Red No. 40” or “Red 40.” Color additives exempt from certification (“natural” colors) may be listed as “artificial color,” “artificial coloring,” or by their specific common or usual names such as “caramel coloring” and “colored with beet juice.” (21 CFR 101.22(k) (1) and (2), 21 CFR 74) More recently, the US FDA issued a final rule that would also require specific labeling of cochineal extract or carmine (21 CFR 73.100). This was in response to the body of research that has indicated that cochineal extract or carmine can provoke allergic responses in a very small subset of the population.

IACM suggests the adoption of Health Canada's proposal as detailed above with the addition of language that would allow artificial colors to be labeled using their certified names as an alternative option to common names. Health Canada should be consistent with the CDN Food and Drug Regulations pertaining to the naming and labeling of colors permitted for use in drugs (C.01.040.2) that are also permitted for use in foods. These regulations list colors via their common names yet also recognize and declare the certified names of those colors.

Cosmetic regulations in Canada require all ingredients to be declared in detail on the product label including individual colors. The CDN cosmetic regulations permit manufacturers to use INCI (International Nomenclature Cosmetic Ingredient) to name ingredients on the label (Regulations 21.2(1)). In an analogous manner, industry should have the option of labeling food colors using either their common or certified names without having to declare both. In some cases consumers may be more likely to recognize certified names (e.g., FD&C Red No. 40) versus a common name (e.g. Allura Red) which has been the labeling preference used by the pharmaceutical industry in Canada for various reasons, including consistency with other regulatory markets. Additionally, certified names can sometimes be shorter than common names and therefore provide a useful alternative when space is limited on bilingual labels.

IACM also supports Health Canada's granting of a transition period to allow time for manufacturers to alter food labels to be compliant with amended labeling regulations.

IACM anticipates that adoption of Health Canada's proposal as detailed above would align the color additive labeling requirements in Canada with those currently in place in the United States. This measure would further facilitate trade between the two countries and ease barriers resulting from conflicting regulatory labeling requirements. Uniformity in color labeling would be beneficial to both consumers and the food and beverage industry.

IACM does not support specific labeling requirements for annatto. The US FDA does not require the specific declaration of the presence of annatto color additives in food because there is not appropriate scientific support for such a requirement. To date there are only anecdotal published reports of allergic responses to annatto, and the only larger-scale studies that have been reported were flawed or did not yield conclusive results.<sup>1</sup> Drawing specific attention to annatto extract may result in undue concern about this safe color additive. Additionally, the current labeling provisions in Canada are sufficient to assist individuals that may have general concerns about their potential sensitivity to food colors and other additives. IACM strongly believes that the rationale for any ingredient labeling requirement should be supported by strong, conclusive scientific evidence. Therefore, we believe that specific labeling requirements for annatto should not move forward until scientific data firmly support such a measure.

We are grateful for the opportunity to comment on this proposal and would be happy to provide any additional information.

Sincerely,



Ellen Gardner  
Executive Director

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<sup>1</sup> Reviewed in Lucas, C.D., Hallagan, J.B., Taylor, S.L. (2001) The role of natural color additives in food allergy. [Adv Food Nutr Res.](#) 2001;43:195-216.