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Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* to Enable the Use of Polysorbate 80 in Seasonings and Rice-Based Ready-to-Eat Cereals

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0060]

September 15, 2015

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations*. Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on Health Canada's website. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada received a food additive submission seeking approval for the use of polysorbate 80 (polyoxyethylene (20) sorbitan monooleate) in seasonings at levels consistent with Good Manufacturing Practice. The purpose of using this additive is to help disperse the spice oleoresins in the seasonings, which are intended for use in a variety of standardized meat and poultry products. Residues of polysorbate 80 are not expected to exceed 0.15% in the final food product containing the seasoning. The residues of polysorbate 80 in the finished product containing the seasoning would not exceed 0.15%.

In addition, the Department received a separate food additive submission seeking approval for the use of polysorbate 80 in rice-based ready-to-eat cereals. In this application, the additive aids in solubilizing and dispersing tocopherols throughout the cereal dough during the manufacturing process and also helps to reduce product breakage. The maximum level of use of polysorbate 80 is 0.1% in the final cereal product.

Polysorbate 80 is already permitted for use in Canada as an emulsifier in several standardized and unstandardized foods, at levels ranging from 10 ppm to 0.5%. The results of Health Canada's evaluation of available scientific data support the safety of polysorbate 80 when used in seasonings and in rice-based ready-to-eat cereals as requested by the petitioners. Therefore, Health Canada has modified the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) to extend the use of polysorbate 80 by adding the entries shown below to the list.

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Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Maximum Level of Use and Other Conditions
P.2	Polyoxyethylene (20) Sorbitan Monooleate (Polysorbate 80)	(22) Seasonings for use in boneless (naming the poultry), brawn, canned (naming the poultry), headcheese, prepared meat (Division 14), prepared poultry meat, or preserved meat (Division 14)	(22) Good Manufacturing Practice. Residues of polysorbate 80 must not exceed 0.15% in the finished food containing the seasoning preparation
		(23) Rice-based ready-to-eat cereals	(23) 0.1%

Rationale

Health Canada's Food Directorate has completed a pre-market safety assessment of the requested uses of polysorbate 80. The assessment considered the toxicological and technical aspects of these uses of this additive, and found that the requested uses are acceptable from a food safety perspective. Therefore, the Department has enabled the requested uses of polysorbate 80 as set out in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as polysorbate 80, which do not have specifications set out in the Regulations, meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC). The FCC is a compendium of standards for purity and identity for food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

Implementation and Enforcement

The above modification came into force September 15, 2015, the day it was published in [*List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*](#).

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The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including polysorbate 80. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**polysorbate 80**" in the subject line of your e-mail.

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