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Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* to Modify the Level of Use of Lecithin as an Emulsifying Agent in Infant Formula

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0044]

February 13, 2015

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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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 MA's 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's Food Directorate received a query regarding the maximum level of use for lecithin in infant formula which led to a review of the regulatory history of this particular food additive provision.

In both official languages, Item L.2 of the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* on Health Canada's website indicates that lecithin is permitted for use in infant formula at a maximum level of 0.03%. The same listing occurs in Table IV of Division 16 of the official version of the *Food and Drug Regulations* (FDR) on the website of the Department of Justice.¹

In the course of the review, the Food Directorate found that the intended maximum level of use for lecithin in infant formula had been 0.3% as consumed, not 0.03% as consumed. This was reflected in the English version of the initial amendments to permit this additive use² as well as the consultation document supporting the regulatory amendments³. However, subsequent regulatory amendments changed the maximum level of use from 0.3% to 0.03%.

Consequently, Health Canada is modifying the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) to enable the use of lecithin, in infant formula, at a level of 0.3% as consumed.

1 The Food Additive Tables in Division 16 of the *Food and Drug Regulations* will be rescinded as a result of the creation, in 2012, of the Lists of Permitted Food Additives. These lists are published on Health Canada's website and have the force of law as they are incorporated by reference into Marketing Authorizations.

2 *Canada Gazette Part II*, Vol. 110, No. 22, SOR/1976-751

3 Health Protection Branch, Information Letter No. 414, *Principles of Proposed Infant Formula Regulations*, February 22, 1974

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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
L.2	Lecithin	(3) Infant formula	(3) 0.3% as consumed

Rationale

Health Canada's Food Directorate reviewed the regulatory history of Item L.2 of the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* and determined that the level of use of lecithin should be 0.3% as consumed, as was originally intended.

The Department has therefore modified the use of lecithin as described in the above table.

Other Relevant Information

The Codex General Standard for Food Additives (GSFA) provides for the use of lecithin (INS 322 i) in a wide variety of foods, including food category 13.1.1 Infant formulae, at a maximum level of use of 5,000 mg/kg (or 0.5%), on the ready-to-eat basis.

Implementation and Enforcement

The above modification came into force **February 13, 2015**, the day it was published in the [*List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*](#).

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 permitted food additive including lecithin. 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 "**Lecithin**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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