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Notice of Modification to the *List of Permitted Food Additives with Other Accepted Uses* to Enable the Use of L-Lysine Monohydrochloride in Certain Processed Snack Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: NOM/ADM-0140

November 6, 2019

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Notice of Modification to the *List of Permitted Food Additives with Other Accepted Uses* to Enable the Use of L-Lysine Monohydrochloride in Certain Processed Snack Foods

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (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 the Canada.ca 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 food additive submission seeking approval for the use of L-lysine monohydrochloride to inhibit acrylamide formation in processed snack foods made from dough where the primary ingredient is either dried potatoes or wheat flour.¹ The requested maximum level of use is 0.8% in the finished snack food, calculated as L-lysine.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of L-lysine monohydrochloride when used as requested by the petitioner. Since this is a food additive that was not previously permitted for use in Canada, [Health Canada's Proposal to Enable the Use of L-Lysine Monohydrochloride in Certain Processed Snack Foods \[Reference Number: NOP/ADP-0032\]](#) was published on May 13, 2019. The proposal was open to the public for comment for 75 days. No new scientific information was submitted to the Department as a result of this Notice of Proposal. Since the conclusions of the evaluation remain as described in the publication, Health Canada has enabled the requested uses of L-lysine monohydrochloride by adding the entry shown in the table below to the [List of Permitted Food Additives with Other Accepted Uses](#).

Modification to the *List of Permitted Food Additives with Other Accepted Uses*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Purpose of Use	Column 4 Maximum Level of Use and Other Conditions
L.5	L-Lysine Monohydrochloride	Processed snack foods based on dried potato dough; Processed snack foods based on wheat flour dough	To inhibit acrylamide formation	0.8% calculated as L-Lysine

¹ There is a standard of identity and composition for flour in section [B.13.001](#) of the *Food and Drug Regulations* that prescribes that flour shall be a food prepared from wheat.

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Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of L-lysine monohydrochloride for inhibiting acrylamide formation in processed snack foods made from either dried potato or flour dough. The Food Directorate's assessment concluded that L-lysine monohydrochloride is effective for its requested use and that information related to chemistry, microbiology, nutrition, and toxicology supports the safety of this additive for such use. Therefore, the Department has enabled the requested use of L-lysine monohydrochloride by adding to the [*List of Permitted Food Additives with Other Accepted Uses*](#) the new entry shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as L-lysine monohydrochloride that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade specifications set out in the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. The *Combined Compendium of Food Additive Specifications*, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations.

Notification – Summary of Comments

No comments were received in response to [*Health Canada's Proposal to Enable the Use of L-Lysine Monohydrochloride in Certain Processed Snack Foods*](#) [Reference Number: NOP/ADP-0032], published on May 13, 2019.

Implementation and Enforcement

The above modification came into force **November 6, 2019**, the day it was published in the [*List of Permitted Food Additives with Other Accepted Uses*](#).

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 L-lysine monohydrochloride. 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

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electronically, please use the words "**L-lysine monohydrochloride (NOM-0140)**" in the subject line of your e-mail.

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