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Health Canada's Proposal to Enable the Use of L-Lysine Monohydrochloride in Certain Processed Snack Foods

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: NOP/ADP-0032

May 13, 2019

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* (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 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. The requested maximum level of use is 0.8% calculated as L-lysine.

Although “processed snack foods” is a term that is intended to refer to multi-ingredient snack foods that are comprised of individual bite-sized pieces, such as crackers, hard pretzels, chip-type products, tortilla chips, etc., the snack foods of primary interest to the petitioner are processed dried potato-dough-based products and processed wheat flour-dough-based products. Hence, snack foods such as pretzels, crackers, tortilla chips, corn chips, and potato chips made from sliced potatoes were not considered as part of this proposal.

Health Canada has determined that information related to the safety and efficacy of L-lysine monohydrochloride supports the uses of this additive as shown in the table below. Therefore, it is the intention of Health Canada to modify the [List of Permitted Additives with Other Accepted Uses](#) by adding the following entry to the list.

Proposed Modification to the *List of Permitted 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 dried potato dough-based snack foods; Processed wheat flour dough-based snack foods | To inhibit acrylamide formation | 0.8% calculated as L-Lysine |

* As this proposed provision is for a food additive and a technical function each of which have not previously appeared in the [Lists of Permitted Food Additives](#), an amendment to the Schedule

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in the [Marketing Authorization for Food Additives with Other Accepted Uses](#) is also required. The steps for amending this Schedule are being taken following a separate procedure. Further details are available in the [Notice of Intent to Issue Food Marketing Authorization](#).

Rationale

Health Canada's Food Directorate assessed L-lysine monohydrochloride for use to inhibit acrylamide formation as requested by the petitioner. The assessment considered information related to chemistry, microbiology, nutrition, and toxicology, including the efficacy of L-lysine monohydrochloride in inhibiting acrylamide formation.

Test results for L-lysine monohydrochloride demonstrated reduced acrylamide formation in a potato-based processed product and a multigrain-based processed product made with this additive at a level of 1%¹ compared to the same product made without the additive.

Health Canada did not identify any toxicological or nutritional safety concerns with this use of L-lysine monohydrochloride. L-lysine is an essential amino acid as it cannot be synthesized by the body and therefore must be obtained from the diet. The available safety data indicate that the additional lysine from the proposed use of L-lysine monohydrochloride would be unlikely to lead to any nutritional concerns related to L-lysine. Individuals who need to follow a diet reduced in lysine will be able to identify processed snack foods that have been made with L-lysine monohydrochloride since the additive will need to be declared in the list of ingredients in accordance with the general food ingredient labelling requirements.

The results of the premarket assessment support the safety of L-lysine monohydrochloride when used in the foods at the level set out in the table above. The Department is therefore proposing to enable the use of this additive as 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.

Implementation and Enforcement

¹ A level of 1% L-lysine monohydrochloride is equivalent to a level of 0.8% L-lysine.

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The proposed change will be effective the day on which it is published in the [List of Permitted Additives with Other Accepted Uses](#). This will be announced via a Notice of Modification (NOM) that will be published on the [Canada.ca website](#). The publication of this NOM will be contingent on the publication of the amendment to the Schedule² of the [Marketing Authorization for Food Additives with Other Accepted Uses](#) in the *Canada Gazette*, Part II.

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

For additional information or to submit comments related to this proposal, please contact:

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If communicating by e-mail, please use the words “**L-lysine monohydrochloride (NOP-0032)**” in the subject line of your e-mail. Health Canada is able to consider information received by **July 26, 2019**, 75 days from the date of this posting.

² See the [Notice of Intent to Issue Food Marketing Authorization](#).