Notice of Modification to the List of Permitted Food Additives with Other Accepted Uses to Enable the Use of Copper Sulphate in Preserved Duck Eggs

Notice of Modification – Lists of Permitted Food Additives
Reference Number: [NOM/ADM-0106]

October 6, 2017
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 by Health Canada 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 copper sulphate in the manufacture of preserved duck eggs (also known as century eggs, 100-year-eggs, or 1000-year-old eggs¹). The copper sulphate is to be added to the alkaline soaking solution used to manufacture preserved duck eggs in such quantity that the content of copper in the edible portion of the finished preserved egg does not exceed 0.0005%. The maximum limit of 0.0005% copper in the edible portion of the finished egg is for copper from all sources, including copper sulphate.

The manufacturing process for preserved duck eggs involves soaking the raw eggs in an alkaline solution for a period of time. The eggs are removed from the soaking solution, dried and packaged with the shell on. The addition of copper sulphate to the soaking solution is intended to improve consistency in achieving the desired characteristics of the finished product.

Copper sulphate is already permitted for use in Canada as a fining agent in wine.

The results of Health Canada’s evaluation of available scientific data support the safety of copper sulphate for use in the processing of preserved duck eggs. Therefore, Health Canada has modified the List of Permitted Food Additives with Other Accepted Uses to extend the use of copper sulphate by adding the entry shown below to the list.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted in or Upon</th>
<th>Column 3 Purpose of use</th>
<th>Column 4 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.17</td>
<td>Copper Sulphate</td>
<td>(2) Preserved duck eggs</td>
<td>(2) In the alkaline soaking solution to assist in the preservation process</td>
<td>(2) 0.0005%, calculated as copper, in the edible portion of the finished product</td>
</tr>
</tbody>
</table>

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of the requested use of copper sulphate. The assessment did not identify any chemical, nutritional, microbiological or toxicological food safety concerns with this use of this additive. Therefore, Health Canada has enabled the requested use of copper sulphate by modifying the *List of Permitted Food Additives with Other Accepted Uses* as shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as copper sulphate 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

The above modification came into force October 6, 2017, 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 copper sulphate. 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 "copper sulphate" in the subject line of your e-mail.

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