Notice of Modification to the List of Permitted Preservatives to Enable the Addition of Potassium Lactate and Sodium Lactate to Standardized Meat Products and Poultry Meat Products

Notice of Modification – Lists of Permitted Food Additives
Reference Number: NOM/ADM-0001

November 20, 2012
Summary

Food additives are regulated in Canada under the *Food and Drug Regulations* and associated Marketing Authorizations (MAs). All permitted food additives and their conditions of use are listed in the *Lists of Permitted Food Additives*.

Food additives must be of suitable quality, must be effective for their intended purpose, and, when used according to the Lists, must not pose a hazard to the health of the consumer.

Health Canada has received two food additive submissions that together seek approval to add potassium lactate and sodium lactate to cooked and uncooked meat products and poultry meat products to control the growth of pathogenic and spoilage bacteria during refrigerated storage. Health Canada had previously approved the use of these additives in cooked meat and poultry meat products under an Interim Marketing Authorization (IMA). The modification to the *List of Permitted Preservatives* set out in the table below includes the food additive provisions from the IMA and extends the use of both additives to standardized uncooked meat and poultry meat products.

The results of Health Canada’s evaluation of available data support the safety and efficacy of both potassium lactate and sodium lactate when used for this purpose on these foods. Therefore, Health Canada has modified the *List of Permitted Preservatives* by adding the following entries to Part 2 of the *List*:

**Modifications to the List of Permitted Preservatives: Part 2 – Class 2 Preservatives**

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted in or Upon</th>
<th>Column 3 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>P.2.1</td>
<td>Potassium Lactate</td>
<td>(1) Injection or cover solution for the curing of poultry meat or poultry meat by-product; Prepared meat; Prepared meat by-product; Prepared poultry meat; Prepared poultry meat by-product; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle or cover pickle employed in the curing of preserved meat or preserved meat by-product; Sausage</td>
<td>(1) Good Manufacturing Practice</td>
</tr>
</tbody>
</table>

Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch
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<table>
<thead>
<tr>
<th>S.2.2</th>
<th>Sodium Lactate</th>
<th>(1) Injection or cover solution for the curing of poultry meat or poultry meat by-product; Prepared meat; Prepared meat by-product; Prepared poultry meat; Prepared poultry meat by-product; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle or cover pickle employed in the curing of preserved meat or preserved meat by-product; Sausage</th>
<th>(1) Good Manufacturing Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(2) Solid cut meat; Solid cut poultry meat</td>
<td>(2) Good Manufacturing Practice provided that: (a) i) when sold as a cooked product, the solid cut meat or solid cut poultry meat contains a meat protein content of not less than 12 per cent; ii) when sold as an uncooked product, the solid cut meat or solid cut poultry meat contains a meat protein content of not less than 10 per cent; (b) a bone or a visible fat layer is not included in any calculation used to determine meat protein content for the purposes noted in (a) i) and (a) ii) above; and (c) the potassium lactate is not used in the fluids of a chill tank in which a whole or any part of a dressed poultry carcass is placed.</td>
<td></td>
</tr>
</tbody>
</table>
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<table>
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<th>(2) Solid cut meat; Solid cut poultry meat</th>
<th>(2) Good Manufacturing Practice provided that:</th>
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<td></td>
<td><em>(a)</em> i) when sold as a cooked product, the solid cut meat or solid cut poultry meat contains a meat protein content of not less than 12 per cent;</td>
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<tr>
<td></td>
<td></td>
<td>ii) when sold as an uncooked product, the solid cut meat or solid cut poultry meat contains a meat protein content of not less than 10 per cent;</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(b)</em> a bone or a visible fat layer is not included in any calculation used to determine meat protein content for the purposes noted in <em>(a)</em> i) and <em>(a)</em> ii) above; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(c)</em> the sodium lactate is not used in the fluids of a chilling tank in which a whole or any part of a dressed poultry carcass is placed</td>
</tr>
</tbody>
</table>

**Rationale**

Health Canada’s Food Directorate has completed a premarket safety and efficacy assessment of two food additive submissions related to the use of potassium lactate and sodium lactate. The assessment considered toxicological, microbiological and nutritional aspects of the use of these additives in meat and poultry meat products.

The Food Directorate has concluded that the available data demonstrate the efficacy of lactates as antibacterial agents against spoilage and pathogenic microorganisms in cooked and uncooked meat products and poultry meat products when used at levels of 2% to 4%. Lactates may also exert a synergistic antimicrobial effect when combined with the additive sodium diacetate in certain meat and poultry meat products. Lactates are therefore effective in extending the shelf-life of, for example, treated cooked meat and poultry meat products to several weeks depending on the product. The addition of lactates to cooked and uncooked meat and poultry meat products would contribute to enhancing the safety and shelf-life of meat and poultry meat products available for sale in Canada.
While the average sodium intake is currently above the Tolerable Upper Intake Level in Canada, no particular concerns have been raised for the general population with respect to sodium or potassium intake from the use of potassium lactate and sodium lactate on meat and poultry meat products described above. In June 2012, Health Canada released its Guidance for the Food Industry on Reducing Sodium in Processed Foods, which includes guiding benchmark sodium reduction levels for approximately 100 broad food categories. As this current modification to the List of Permitted Preservatives covers both potassium lactate and sodium lactate, the food industry will have the option of using these substances at ratios that will assist them to meet the guiding benchmark levels while ensuring that the intended technical effect as antimicrobial preservatives is not compromised.

The Nutrition Facts table that appears on pre-packaged products includes mandatory declaration of the amount of sodium per serving and the percent contribution of that serving to the daily value for sodium. Companies using the potassium form of the food additive are strongly encouraged by Health Canada to voluntarily include the amount of potassium, as well as the percentage of the daily value for potassium, in the Nutrition Facts table in order to provide information to assist consumers in making informed choices.

The requested level of use for potassium lactate and sodium lactate, which are salts of lactic acid, was originally 2% to 4% for both cooked and uncooked meat and poultry meat products. In the case of uncooked products this was revised to 3%. The Food Directorate concurs with the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which has assigned an Acceptable Daily Intake (ADI) of “Not Limited” to lactic acid. Since the need for a numerical ADI has not been identified, and in the case of solid cut meat and solid cut poultry meat, minimum protein requirements are being set as a condition of use, Health Canada is authorizing the use of these additives at a maximum level consistent with Good Manufacturing Practice. The actual level of use will be self-limiting as the flavour of the product is expected to be affected at use levels greater than 3% to 3.5%.

Adding sodium lactate and potassium lactate to the List of Permitted Preservatives allows for the addition of a Class 2 (antimicrobial) preservative to some meat and poultry meat products that have traditionally not contained preservatives. To address nutritional concerns raised by the possibility of protein dilution due to the addition of lactate solutions to solid cut meat and solid cut poultry meat, conditions of use pertaining to minimum protein content are included in column 3 of the List of Permitted Preservatives. These conditions must be met when potassium lactate or sodium lactate are used in or upon either solid cut meat or solid cut poultry meat.

Based on the results of the safety assessment, Health Canada’s Food Directorate scientists consider that the data demonstrate that potassium lactate and sodium lactate are safe food additives under the conditions of use that were evaluated. The Department is therefore enabling the use of potassium lactate and sodium lactate as described in the above table.
Other Relevant Information

In the Codex Alimentarius General Standard for Food Additives (GSFA), potassium lactate (International Numbering System [INS] for food additives INS 326) and sodium lactate (INS 325) are listed in Table 3, which is the table listing those food additives that may be used in foods in general, unless otherwise specified, in accordance with good manufacturing practice. Table 3 provides for the use of potassium lactate and sodium lactate in processed meat, poultry and game products in whole pieces or cuts, and processed comminuted meat, poultry and game products. There is no Codex provision for the use of lactates with fresh meat, poultry and game.

In the United States, the Food and Drug Administration has affirmed the status of potassium lactate and sodium lactate as Generally Recognized as Safe (GRAS) when they are used in accordance with current good manufacturing practice. In addition, both lactates have also been cleared by the United States Department of Agriculture’s Food Safety and Inspection Service to inhibit microbial growth on various meat and poultry products.

Australia and New Zealand permit potassium lactate and sodium lactate to be added to a variety of foods in accordance with Good Manufacturing Practice, including processed meat, poultry and game products in whole cuts or pieces and processed comminuted meat, poultry and game products. Australia and New Zealand do not permit lactates to be added to raw meat, poultry and game.

In the European Union, potassium lactate and sodium lactate may be added to a variety of foods following the quantum satis principle, i.e. in accordance with good manufacturing practice, in the minimum amount needed for the intended purpose, and provided that they do not mislead consumers. Potassium lactate and sodium lactate are also permitted in prepackaged preparations of fresh minced meat following the quantum satis principle.

The Canadian Food Inspection Agency (CFIA) was consulted and had no objection to the use of potassium lactate and sodium lactate in cooked and uncooked meat and poultry meat products. However, the CFIA emphasized the importance of adequate labelling for certain products. In this regard, Health Canada’s Food Directorate intends to consider future regulatory amendments that would require protein content labelling of solid cut meat or solid cut poultry meat to which lactates have been added.

Implementation and Enforcement

The above modification comes into force the day on which it is published in the List of Permitted Preservatives.

The CFIA is responsible for compliance and enforcement of the Food and Drugs Act and its associated regulations with respect to foods.
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**Contact Information**

For additional information or to submit information related to this modification to the *List of Permitted Preservatives*, please contact:

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E-mail: bcs-bipc@hc-sc.gc.ca

If communicating by E-mail, please use the words “**potassium lactate and sodium lactate**” in the subject box of your e-mail.