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# Health Canada's Proposal to Enable the Use of Potassium Acetate and Potassium Diacetate as Preservatives in Meat and Poultry Products

**Notice of Proposal – *Lists of Permitted Food Additives***

**Reference Number: [NOP/AVP-0017]**

**June 07, 2016**

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

## 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 MAs 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 received two food additive submissions, one seeking approval for the use of potassium acetate and potassium diacetate and the other seeking approval for the use of potassium acetate only. These additives are intended for use as class 2 (i.e., antimicrobial) preservatives in a variety of meat and poultry products. The maximum levels of use for potassium acetate and potassium diacetate are Good Manufacturing Practice (GMP) and 0.25% of the final product weight, respectively. Potassium diacetate in particular, which has a defined maximum level of use of 0.25%, could be used in combination with sodium diacetate which is already permitted for use in the same foods and same maximum levels of use. Therefore, the maximum levels of use for each of potassium diacetate and sodium diacetate would also need to be set on the basis of their potential combined use.

The results of Health Canada's evaluation of the available scientific data support the safety and efficacy of potassium acetate and potassium diacetate when used in meat and poultry products as requested by the petitioners. Therefore, it is the intention of Health Canada to modify the *List of Permitted Preservatives* by adding the entries shown below to the list.

**Proposed Modification to Part 2 of the *List of Permitted Preservatives***

| Item No. | Column 1 Additive | Column 2 Permitted in or upon | Column 3 Maximum Level of Use and Other Conditions |
|---|---|---|---|
| P.01 | Potassium Acetate | (1) Brawn; Headcheese; Meat by-product loaf; Meat loaf; Potted meat; Potted 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- | (1) Good Manufacturing Practice |

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|---|---|---|---|
| | | product; Sausage<br><br>(2)<br>Unstandardized preparations of<br>(*a*) meat and meat by-product (Division 14); and<br>(*b*) poultry meat and poultry meat by-product | <br><br>(2)<br>Good Manufacturing Practice |
| P.2.01 | Potassium Diacetate | (1)<br>Brawn; Headcheese; Meat by-product loaf; Meat loaf; Potted meat; Potted 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; Sausage<br><br>(2)<br>Unstandardized preparations of<br>(*a*) meat and meat by-product (Division 14); and<br>(*b*) poultry meat and poultry meat by-product | (1)<br>0.25% of final product weight. If used in combination with sodium diacetate, the total not to exceed 0.25% of final product weight.<br><br>(2)<br>0.25% of final product weight. If used in combination with sodium diacetate, the total not to exceed 0.25% of final product weight. |

In addition, the following modification would be required to Part 2 of the *List of Permitted Preservatives* as a result of this submission:

| **Item No.** | **Column 1 Additive** | **Column 2 Permitted in or upon** | **Column 3 Maximum Level of Use and Other Conditions** |
|---|---|---|---|
| S.2.1 | Sodium Diacetate | (1)<br>Brawn; Headcheese; Meat by-product loaf; Meat loaf; Potted meat; Potted meat by-product; Prepared meat; Prepared meat by-product; Prepared poultry meat; Prepared poultry meat by-product; Preserved meat; | (1)<br>0.25% of final product weight. If used in combination with potassium diacetate, the total not to exceed 0.25% of final product weight. |

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|---|---|---|---|
| | | Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Sausage<br><br>(2)<br>Unstandardized preparations of<br>(a) meat and meat by-product (Division 14); and<br>(b) poultry meat and poultry meat by-product<br><br>(3)<br>Prepared fish or prepared meat (Division 21); Preserved fish or preserved meat (Division 21)<br><br>(4)<br>Unstandardized preparations of<br>(a) meat (Division 21); and<br>(b) fish | <br><br><br><br>(2)<br>0.25% of final product weight. If used in combination with potassium diacetate, the total not to exceed 0.25% of final product weight.<br><br>(3)<br>0.25% of final product weight<br><br>(4)<br>0.25% of final product weight |

## Rationale

Health Canada's Food Directorate completed a pre-market safety and efficacy assessment of potassium acetate and potassium diacetate. The assessment considered microbiological, toxicological, nutritional and chemical aspects of these additives when used as described above.

The efficacy data that was provided for a variety of meat and poultry products as part of the two submissions demonstrated that the combined use of potassium acetate and potassium diacetate could control or reduce bacterial load, including the presence of *Listeria monocytogenes*. The results of studies presented in the scientific literature as well as past Health Canada evaluations of sodium acetate and sodium diacetate were considered to support the potential for potassium acetate and potassium diacetate to act as antimicrobial preservatives when used individually.

Potassium acetate dissociates in the gastro-intestinal tract and forms acetic acid (and the potassium ion). Potassium diacetate similarly dissociates in the gastro-intestinal tract to release potassium ion, acetic acid, and acetate. For both additives, the toxicological evaluation is based on potential exposure to acetic acid. No toxicological concerns associated with exposure to

acetic acid as a result of the proposed uses of potassium acetate or potassium diacetate were identified. The safety of the sodium salts of these additives, sodium acetate and sodium diacetate, was previously established by Health Canada and both appear in the *Lists of Permitted Food Additives*.

No nutritional concerns for the general population were identified regarding the potential contribution to dietary intake of potassium from the use of these two additives. There are individuals however with impaired renal function causing improper excretion of potassium and individuals who take certain medications who must control their intake of potassium. Current food labelling requirements allow the presence of added potassium-containing food additives in foods to be identified.

Based on the results of the premarket evaluation, Health Canada's Food Directorate considers that the requested uses are acceptable from a food safety perspective. Therefore, the Department is proposing to enable the requested uses of potassium acetate and potassium diacetate as set out in the above table.

## Other Relevant Information

Permitting the use of potassium acetate and potassium diacetate will provide the food industry with alternatives to sodium acetate and sodium diacetate, thereby helping to reduce the amount of added sodium in the final food product.

The proposed uses of these additives in Canada are similar to permitted uses of potassium acetate and/or potassium diacetate in Australia and New Zealand, Europe, and the United States of America. The Codex General Standard for Food Additives contains provisions for the use of potassium acetate only as a preservative at a maximum level of use consistent with GMP in a variety of meat and poultry products.

There are general labelling provisions requiring the declaration of ingredients, including food additives, in pre-packaged foods sold in Canada. In the case where a food product that is not pre-packaged contains added sodium-containing ingredients such as sodium acetate or added potassium-containing ingredients such as potassium acetate, Health Canada recommends that manufacturers or retailers, as the case may be, voluntarily make information regarding the presence and amount of added sodium and potassium available to consumers to assist those individuals who for health reasons may need to monitor their dietary intake of sodium or potassium.

With respect to pre-packaged products that are required to carry a Nutrition Facts table (NFt), the NFt includes the mandatory declaration of the amount of sodium per serving and the percent contribution of that serving to the "daily value" for sodium. Companies using potassium-containing ingredients such as potassium acetate 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 NFt in order to provide information to assist consumers in making informed

choices. Health Canada recently published a regulatory proposal that would make it mandatory to include potassium in the NFt[1].

## Implementation and Enforcement

The proposed change will be effective the day on which it is published in the *List of Permitted Preservatives*. This will be announced via a Notice of Modification which will be published on Health Canada's Website.

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 "**potassium acetate and/or potassium diacetate**" in the subject line of your e-mail. Health Canada is able to consider information received by **August 20, 2016**, 75 days from the date of this posting.

1 *Canada Gazette*, Part I, Volume 149, No. 24, June 13, 2015 (http://gazette.gc.ca/rp-pr/p1/2015/2015-06-13/html/reg1-eng.php)