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Health Canada's Proposal to Enable the Use of *Lactococcus lactis* DSM 11037 as an Oxygen Scavenger in Certain Modified Atmosphere-Packaged (MAP) and Vacuum-Packaged Preserved Meat Products

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0021]

September 20, 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 a food additive submission seeking approval for the use of a preparation containing a live culture of the non-genetically modified bacterium *Lactococcus lactis* (*L. lactis*) DSM 11037 as an oxygen scavenger in certain modified atmosphere-packaged (MAP) or vacuum-packaged non-shelf-stable cured meat products.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of *L. lactis* DSM 11037 for this purpose. Therefore, Health Canada intends to modify the [List of Permitted Food Additives with Other Generally Accepted Uses](#) by adding the entries to the list as set out in the table below.

Proposed modification to the *List of Permitted Food Additives with Other Generally 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.01	<i>Lactococcus lactis</i> DSM 11037	Modified atmosphere-packed preserved meat (Division 14); Modified atmosphere-packed preserved meat by-product (Division 14); Modified atmosphere-packed preserved sausage; Vacuum-packed preserved meat (Division 14); Vacuum-packed preserved meat by-product (Division 14); Vacuum-packed preserved sausage	Oxygen scavenger	Good Manufacturing Practice

*Addition of table entry will require publication in *Canada Gazette*, Part II, of an [amendment to the Marketing Authorization for list 8](#).

Rationale

Health Canada's Food Directorate has completed a pre-market safety and efficacy assessment of *L. lactis* DSM 11037 when used as described in the table above. The assessment considered microbiological, toxicological and chemical aspects of the proposal.

L. lactis bacteria have a long history of safe use in food. The subspecies *lactis* is essential in the manufacture of cheese and other fermented milk products such as buttermilk and sour cream. *Lactococcus lactis* DSM 11037 is a single strain culture that was obtained by selecting for a mutation in a wild type strain of *L. lactis* subspecies *lactis*.

L. lactis DSM 11037 has a high oxygen consumption capacity and a very low acidification profile compared to the wild type strain of *L. lactis* subspecies *lactis*. As a result, *L. lactis* DSM 11037 can be used to stabilize the oxygen level throughout the shelf-life of preserved meat products that are packaged in Modified Atmosphere Packaging (MAP) or that are vacuum-packed. MAP and vacuum packaging displaces or removes oxygen within the packaging. *L. lactis* DSM 11037 is intended to be used in MAP or vacuum-packaged preserved cured meat products that have a red colour due to added nitrites. The bacterial culture helps to maintain exceptionally low oxygen levels in the package in order to try to slow or prevent colour fading of the preserved meat that would otherwise result from photo-oxidation.

The bacterial culture is to be sprayed onto the surface of non-shelf-stable cooked preserved meat products just prior to packaging and it is mixed in with other ingredients during the preparation of uncooked preserved sausage. The meat products are then either MAP or vacuum packaged. This includes products such as cooked hams, gourmet hotdogs, red meat bologna, mortadella sausage, beer sausage, cooked cervelat and chipolata sausage. All of the meat products that are included in this proposal are subject to compositional standards set out in Division 14 of the *Food and Drug Regulations*.

The information that the Food Directorate evaluated supports the safety of *L. lactis* DSM 11037 when used for this purpose under the conditions set out in the table above. The petitioner described the process for ensuring the continued genetic and physiological integrity of the microorganism, provided the microbial specifications that are used to control for the purity of each batch of *L. lactis* DSM 11037, and submitted information indicating that the microorganism is not resistant to a suite of antibiotics and that there are no transposable genetic elements linked to antimicrobial resistance. Based on its lineage, *L. lactis* DSM 11037 is not considered to be pathogenic and results of testing indicate it does not produce biogenic amines in foods to which it is added.

Other Relevant Information

The petitioner informed the Food Directorate that the *L. lactis* DSM 11037 preparation complies with the general requirements on food safety laid down in regulations in the European Union (EU), including regulations on microbiological criteria for foods, and that the preparation is sold in the EU for use in non-shelf-stable meat products packaged in modified atmosphere packaging or vacuum packaging for the purpose of preventing discolouration of the meat.

Implementation and enforcement

The proposed changes to the [List of Permitted Food Additives with Other Generally Accepted Uses](#) will be effective the day on which they are published in this List on Health Canada's website. This will be announced via a Notice of Modification that will also be published on [Health Canada's website](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the food-related aspects of the *Food and Drugs Act* and its associated regulations.

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 word "*Lactococcus lactis*" in the subject line of your e-mail. Health Canada is able to consider information received by **December 3, 2016**, 75 days from the date of this posting.