Notice of Modification to the List of Permitted Food Additives with Other Accepted Uses to Enable the Use of Lactococcus lactis DSM 11037 as an Oxygen Scavenger in Certain Modified Atmosphere-Packaged (MAP) or Vacuum-Packaged Preserved Meat Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: [NOM/ADM-0095]

Santé

Canada

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Bureau of Chemical Safety Food Directorate Health Products and Food Branch













Summary

Food additives are regulated in Canada under <u>Marketing Authorizations</u> (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 <u>Lists of Permitted Food Additives</u> 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 bacterium *Lactococcus lactis* (*L. lactis*) DSM 11037 for use 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 when used for this purpose. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published a *Notice of Proposal to Enable the Use of L. lactis DSM 11037 as an Oxygen Scavenger in Certain Modified Atmosphere-Packaged (MAP) and Vacuum-Packaged Preserved Meat Products on September 20, 2016, requesting comments. The comment period was open for 75 days, during which no new scientific information about this additive was submitted to the Department in response to this publication. Since the conclusions of the evaluation remain as described in the Notice of Proposal, Health Canada has modified the <i>List of Permitted Food Additives with Other Accepted Uses* as indicated below.

Modification to the List of Permitted Food 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.01	Lactococcus lactis DSM 11037	Modified atmosphere-packed preserved meat (Division 14); Modified atmosphere-packed preserved meat by-product; Modified atmosphere-packed preserved sausage; Vacuumpacked preserved meat (Division 14); Vacuum-packed preserved meat by-product; Vacuumpacked preserved sausage	Oxygen scavenger	Good Manufacturing Practice

Rationale

Health Canada's Food Directorate assessed the safety and efficacy of *L. lactis* DSM 11037 for its requested use in certain modified atmosphere-packaged (MAP) or vacuum-packaged non-shelf-stable cured meat products.

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 displace or remove 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, thereby slowing or preventing colour fading of the preserved meat that would otherwise result from photo-oxidation.

L. lactis bacteria have a long history of safe use in food. Data was submitted to support the safety in use of L. lactis DSM 11037 from both a microbiological and molecular biological perspective. Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of L. lactis DSM 11037 when used under the conditions set out in the table above. The Department has therefore enabled the use of L. lactis DSM 11037 as described in the table.

Other Relevant Information

The Food and Drug Regulations require that food additives such as L. lactis DSM 11037 that do not have specifications set out in Part B of the Regulations meet the most recent 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 is prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and published by the Food and Agriculture Organization of the United Nations.

Notification – Summary of Comments

In response to the <u>Notice of Proposal to Enable the Use of L. lactis DSM 11037 as an Oxygen Scavenger in Certain Modified Atmosphere-Packaged (MAP) and Vacuum-Packaged Preserved Meat Products</u>, published on September 20, 2016, Health Canada did not receive any comments during the 75-day comment period.

Implementation and Enforcement

The above modification came into force **May 3, 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 *L. lactis* DSM 11037. 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 "*Lactococcus lactis* DSM 11037" in the subject line of your e-mail.

Bureau of Chemical Safety, Food Directorate

251 Sir Frederick Banting Driveway Tunney's Pasture, PL: 2202C

Ottawa, Ontario, K1A 0L2 E-mail: <u>bcs-bipc@hc-sc.gc.ca</u>