



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Notice of Modification to Remove “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat” and “Solid cut poultry meat that contains phosphate salts or water” From the List of Foods that are Permitted to Contain Transglutaminase in the *List of Permitted Food Enzymes*

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0086]

February 15, 2017

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.

Transglutaminase is an enzyme that can be used to bind together small pieces of meat into larger “formed” meat products. It was first approved for such use in 2007. In response to concerns that were subsequently raised about the possibility of microbial contamination in the interior of certain types of formed meat products that look like whole cuts of meat but which are actually made from smaller pieces of meat and a binding agent (such as transglutaminase), Health Canada revisited its safety evaluation of transglutaminase. The specific concern was not with the safety of transglutaminase itself, but rather with the possibility of consumers cooking certain types of formed meat products to a medium rare state even though these products are labelled “formed”. Cooking to a medium rare state would not be sufficient to destroy any pathogens at the interior of the product.

Health Canada concluded that such concerns were founded and therefore, in July 2016, Health Canada posted a notice of a proposal, titled [Notice of Health Canada's Proposal to Remove "Solid cut meat with or without added phosphate salts" From the List of Foods that are Permitted to Contain Transglutaminase in the List of Permitted Food Enzymes - Reference Number: NOP/AVP-0020](#). The intended effect of this proposal was to prevent the preparation of formed beef, veal, or lamb products that have the appearance of intact cuts of meat. The proposal was open for public comment for 75 days. Health Canada received three comments expressing concerns in response to the proposal, as described further below. No new scientific information was submitted that changed the conclusion of the safety evaluation that the transglutaminase is itself acceptable for use as a food enzyme.

Upon analysing the comments submitted, Health Canada’s Food Directorate concluded that preventing the use of transglutaminase in the preparation of formed beef, veal, or lamb products that have the appearance of intact cuts of meat was not the appropriate risk mitigation measure to follow. Rather, the Food Directorate will be exploring, as a separate project, alternative strategies such as product labelling for addressing the concerns about possible microbial contamination at the interior of certain types of formed meat products. As such, the food additive provisions will continue to allow the use of transglutaminase in these types of meat products.

In the course of the review of this issue, the Directorate also determined that the use of transglutaminase in formed meat and poultry products is accommodated by the existing

Notice of Modification to Remove “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat” and “Solid cut poultry meat that contains phosphate salts or water” From the List of Foods that are Permitted to Contain Transglutaminase in the *List of Permitted Food Enzymes*

provisions for its use in “Prepared meat”, “Prepared meat by-product”, “Prepared poultry meat”, and “Prepared poultry meat by-product”. Therefore, the provisions for the use of transglutaminase in “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat” and “Solid cut poultry meat that contains phosphate salts or water” are not necessary. These food categories have therefore been removed from the List as indicated below. These are corrective modifications that have no impact on the foods in which transglutaminase has been accepted for use.

Corrective Modifications to the *List of Permitted Food Enzymes*

Sub-item T.01(8) in the [*List of Permitted Food Enzymes*](#) has been removed and new sub-items T.01(11) and (12) have been added. These new sub-items replicate the food categories that were previously listed under T.01(8) with the exception of the three food categories that were identified as unnecessary:

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or upon	Column 4 Maximum Level of Use and Other Conditions
T.01	Transglutaminase	<i>Streptoverticillium mobaraense</i> S-8112	(8) [Removed, 2017-02-15, (See NOM/ADM-0086)]	
			(9) Bread; Flour; Whole wheat flour	(9) Good Manufacturing Practice
			(10) Unstandardized bakery products	(10) Good Manufacturing Practice

Notice of Modification to Remove “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat” and “Solid cut poultry meat that contains phosphate salts or water” From the List of Foods that are Permitted to Contain Transglutaminase in the *List of Permitted Food Enzymes*

			(11) Brawn; Headcheese; Meat by-product loaf; Meat loaf; (naming the prepared meat or prepared meat by-product) with (naming the non-meat ingredients); Prepared meat (Division 14); Prepared meat by-product; Preserved meat (Division 14); Preserved meat by-product; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product; Sausage	(11) Good Manufacturing Practice
			(12) Prepared poultry meat; Prepared poultry meat by-product; Preserved poultry meat; Preserved poultry meat by-product	(12) Good Manufacturing Practice

In addition, a corrective modification has been made to the [List of Permitted Food Enzymes](#) in which the food item “prepared poultry meat” had been mistakenly reported as “sous-produits de viande de volaille préparée” instead of “viande de volaille préparée”.

Rationale

Health Canada previously evaluated a food additive submission requesting amendment of the *Food and Drug Regulations* (FDR) to allow for the use of the enzyme transglutaminase from *Streptoverticillium mobaraense* S-8112 as a binding agent in certain prepackaged poultry products and meat products including “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat” and “Solid cut poultry meat that contains phosphate salts or water”.

The results of the evaluation supported the safety of transglutaminase as a food additive at levels consistent with Good Manufacturing Practice (GMP) in various prepackaged meat and poultry products and an Interim Marketing Authorization (IMA) was issued on November 24, 2007,

Notice of Modification to Remove “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat” and “Solid cut poultry meat that contains phosphate salts or water” From the List of Foods that are Permitted to Contain Transglutaminase in the *List of Permitted Food Enzymes*

enabling the requested uses of this food enzyme. The provisions reflected in the IMA were later added to the [*List of Permitted Food Enzymes*](#) that is incorporated by reference in the *Marketing Authorization for Food Additives That May Be Used as Food Enzymes*.

Subsequent to the initial safety evaluation, concerns about the possibility of microbial contamination in the interior of formed meat products that look like whole cuts of meat but which are actually made from smaller pieces of meat and a binding agent (such as transglutaminase) were raised, on the basis that such products if not properly cooked could pose a health risk. There are no concerns about the safety of transglutaminase itself. Health Canada’s Food Directorate considered, from a microbial perspective, the safety of such food products and concluded that formed beef, veal, and lamb products, if cooked medium rare by consumers as though they were indeed an intact cut of meat, could present microbiological concerns. There is not a corresponding concern about other types of formed meat products that may also look like an intact piece of meat (e.g., chicken breast, ham, pork loin) because the recommended internal cooking temperatures for these types of intact products are also appropriate for the corresponding formed products.

In July 2016, as a result of these conclusions, Health Canada posted a notice of the Department’s proposal, titled [*Notice of Health Canada's Proposal to Remove "Solid cut meat with or without added phosphate salts" From the List of Foods that are Permitted to Contain Transglutaminase in the List of Permitted Food Enzymes - Reference Number: NOP/AVP-0020*](#). The proposal was open for public comment for 75 days. Health Canada received three comments expressing concerns in response to the proposal, as described below. No new scientific information was submitted that changed the outcome of the safety evaluation of the enzyme transglutaminase.

Upon analysing the comments that were submitted, Health Canada’s Food Directorate concluded that preventing the use of transglutaminase in such formed meat products is not an appropriate measure for addressing the concerns that were identified. Rather, the Food Directorate will be exploring, as a separate project, alternative strategies such as product labelling for addressing the concerns about possible microbial contamination at the interior of certain types of formed meat products. Therefore, the food additive provisions will continue to allow the use of transglutaminase in these types of meat products.

In the course of the review of this issue, the Directorate also determined that the use of transglutaminase in formed meat and poultry products is accommodated by the existing provisions for its use in “Prepared meat”, “Prepared meat by-product”, “Prepared poultry meat”, and “Prepared poultry meat by-product”. Therefore, the provisions for the use of transglutaminase in “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat”, and “Solid cut poultry meat that contains phosphate salts or water” are not necessary. As a consequence, the provisions for the use of transglutaminase in these foods have been removed from the List as shown in the table above. These are corrective modifications that have no impact on the foods in which transglutaminase has been accepted for use.

Notification – Summary of Comments

Three comments were received in response to the [Notice of Health Canada's Proposal to Remove "Solid cut meat with or without added phosphate salts" From the List of Foods that are Permitted to Contain Transglutaminase in the List of Permitted Food Enzymes - Reference Number: NOP/AVP-0020.](#)

Comments were submitted in response to the proposal by three stakeholders: the company that originally sought approval for the use of transglutaminase in meat manufacturing, an industry organization, and the United States Government. The industry stakeholders expressed the opinion that preventing the use of the enzyme transglutaminase to manufacture certain types of formed meat products would be discriminatory because there are other binders that are available for producing formed meat. The scientific rationale for the proposal was questioned based on the claim that to date, there have been no reported cases of contamination in meat formed with the transglutaminase enzyme. It was also suggested that the reduction of microbial contamination at the interior of the product or of cross-contamination could be achieved through the application of HACCP¹ in meat processing establishments. It was further suggested that it would be appropriate to focus on proper handling and processing of raw meat products, work on consumer education, and implement “enhanced labelling requirements” that provide proper cooking instructions for formed meat products made with solid cut meat. Finally, the United States Government asked if Canada would consider other means of achieving the same level of protection, drawing attention to the possibility of using labels that display a safe handling statement instructing the end user how to properly cook the product.

Health Canada responded that it has decided to continue to allow the use of transglutaminase in formed meat products, recognising that there are other binders available to prepare the same products, but that it would be exploring other measures for addressing the concerns about possible microbial contamination at the interior of formed products that have the appearance of intact cuts of beef, veal, or lamb. The provisions for the use of the enzyme transglutaminase in formed meat products will remain in the *List of Permitted Food Enzymes*, and are accommodated under the existing provisions for its use in “Prepared meat”, “Prepared meat by-product”, “Prepared poultry meat”, and “Prepared poultry meat by-product”. Consequently for house-keeping purposes, corrective modifications have been made to the List to remove the food categories “Solid cut meat with or without added phosphate salts”, “Solid cut poultry meat”, and “Solid cut poultry meat that contains phosphate salts or water” from the transglutaminase listing (item T.01 of the *List of Permitted Food Enzymes*), as these food categories are considered redundant.

¹ HACCP stands for Hazard Analysis and Critical Control Points.

Implementation and Enforcement

The above modifications came into force on **February 15, 2017**, the day they were published in the [*List of Permitted Food Enzymes*](#). 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 of any permitted food additive, including transglutaminase. 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 “***transglutaminase as a binding agent***” 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 0L2E-mail: bcs-bipc@hc-sc.gc.ca