Notice of Modification to the *List of Permitted Firming Agents* to Enable the Use of Potassium Aluminum Sulphate in Salted Jellyfish

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0167

May 20, 2021





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* (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 the Canada.ca 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's Food Directorate received a food additive submission seeking approval for the use of potassium aluminum sulphate as a firming agent in salted jellyfish, at a maximum level of use of 100 parts per million (ppm)¹. While the submission was specific to the hydrated form of this additive (potassium aluminum sulphate dodecahydrate), the Food Directorate's safety evaluation both the hydrated and anhydrous form (potassium aluminum sulphate anhydrous). On an "as aluminum" basis, this level is equivalent to 6 ppm for potassium aluminum sulphate dodecahydrate and 11 ppm for potassium aluminum sulphate anhydrous.

Potassium aluminum sulphate is already permitted for use as a firming agent in pickles and relishes, sea urchin roe, and unstandardized foods.

The results of the Food Directorate's evaluation of available scientific data support the safety of potassium aluminum sulphate, both the hydrated and anhydrous form, when used in salted jellyfish as set out in the table below. Therefore, Health Canada has modified the <u>List of Permitted Firming Agents</u> to extend the use of potassium aluminum sulphate by adding the entry shown below to the list.

Modification to the List of Permitted Firming Agents

Item	Column 1	Column 2	Column 3 Maximum Level of Use and Other Conditions
No.	Additive	Permitted in or Upon	
P.1	Potassium Aluminum	(4)	(4)
	Sulphate	Salted Jellyfish	11 p.p.m. calculated as aluminum

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of potassium aluminum sulphate for use as firming agent in salted jellyfish. The assessment concluded that information related to allergenicity, chemistry, microbiology, nutrition, and toxicology support the safety of potassium aluminum sulphate for its requested use. Therefore, the Department has enabled the requested use of potassium aluminum sulphate by adding to the <u>List of Permitted Firming Agents</u> the new entry shown in the above table.

¹ Based on the hydrated form.

Other Relevant Information

Food additives and other ingredients generally must be declared in the list of ingredients on the label of prepackaged foods sold in Canada. Salted jellyfish treated with potassium aluminum sulphate will need to have the potassium aluminum sulphate declared in the list of ingredients. This will alert individuals following a low potassium diet to the presence of the additive in this food. Health Canada is also strongly encouraging industry to voluntarily declare the total amount of potassium, as well as the percentage of the "daily value" for potassium, in the Nutrition Facts table on prepackaged foods. This declaration will become mandatory in accordance with amendments to the *Food and Drug Regulations* that will change nutrition labelling requirements, published on December 2, 2016².

The Food and Drug Regulations require that food additives such as potassium aluminum sulphate that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications set out in the most recent edition of 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, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **May 20, 2021**, the day it was published in the <u>List of Permitted</u> <u>Firming Agents</u>.

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 new scientific information on the safety in use of any permitted food additive, including potassium aluminum sulphate. Anyone wishing to submit new scientific information on the use of this additive or to submit inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "potassium aluminum sulphate (NOM-0167)" in the subject line of your e-mail.

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 $^{^2}$ Canada Gazette, Part II, Vol. 150, No 25, December 14, 2016. SOR/DORS/2016-305: $\underline{\text{http://gazette.gc.ca/rp-pr/p2/2016/2016-12-14/html/sor-dors305-eng.html}}$