

Notice of Modification to the *List of Permitted Preservatives* to Enable the Use of Modified Vinegar in Various Meat and Poultry Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0176

November 08, 2021





Summary

Food additives are regulated in Canada under Marketing Authorizations (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 Lists of Permitted Food Additives 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.

The food industry has for some time been interested in using modified vinegar to control microbial growth in certain foods. Modified vinegar can contain one or more of potassium acetate, potassium diacetate, sodium acetate and sodium diacetate. These substances, when used on their own, are permitted for use as preservatives in various meat and poultry products¹.

The results of the Food Directorate's evaluation of available scientific data support the safety of modified vinegar for use in the same meat and poultry products where these individual preservatives are already permitted. As a result, the Department published Health Canada's Proposal to Enable the Use of Modified Vinegar as a Preservative in Certain Meat and Poultry Products and Preparations. The proposal was published on December 22, 2020, and was open to the public for comment for 75 days. The comments Health Canada received are summarized in the section "Notification – Summary of Comments and Health Canada's Responses".

One comment was a request to authorize modified vinegar in pumping pickle, cover pickle and dry cure. This request was consistent with earlier information received by the Department to the effect that modified vinegar can be indirectly added to raw meat products as part of a brine or marinade.

There is a standard for pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product set out in B.14.009 of the Regulations. Including pumping pickle, cover pickle and dry cure in the new entry M.3 would allow modified vinegar to be a component in these standardized ingredients and indirectly added to preserved meat and preserved meat by-product. The same conditions of use would apply whether modified vinegar is added directly to foods, or indirectly through pumping pickle, cover pickle or dry cure. Since in both cases the maximum level of use of potassium or sodium diacetate applies to the final foods, the outcomes of the safety assessment remain unchanged.

Therefore, Health Canada has agreed to also permit the use of modified vinegar in pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product.

The other information that was submitted to Health Canada as a result of this Notice of Proposal did not further change the Department's decision about modified vinegar. Since the conclusions of the evaluation remain as described in the publication, with the exception of permitting the use of modified vinegar in pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat byproduct, Health Canada has enabled the uses of modified vinegar by adding the entries shown in the table below to Part 2 of the *List of Permitted Preservatives*.

¹ Part 2 of the List of Permitted Preservatives: potassium acetate (item no. P.01), sodium acetate (item no. S.01), potassium diacetate (item no. P.2.01) and sodium diacetate (item no. S.2.1).

Modification to Part 2 of the List of Permitted Preservatives²

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
M.3	Modified vinegar (a liquid or spray-dried mixture containing acetic acid and one or more of potassium acetate, potassium diacetate, sodium acetate or sodium diacetate, prepared by adding potassium bicarbonate or sodium bicarbonate, potassium carbonate, or potassium hydroxide or sodium hydroxide to vinegar)	(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 product; Sausage	(1) Good Manufacturing Practice (the total amount of potassium diacetate or sodium diacetate added to the food, from all sources, not to exceed 0.25% of final product weight).
		(2) Pumping pickle, cover pickle or dry cure employed in the curing of preserved meat or preserved meat by-product	(2) Good Manufacturing Practice (the total amount of potassium diacetate or sodium diacetate added to the cured preserved meat or the cured preserved meat by-product, from all sources, not to exceed 0.25% of final product weight).
		(3) Unstandardized preparations of (a) meat and meat by- product (Division 14); and (b) poultry meat and poultry meat by-product (Division 22)	(3) Good Manufacturing Practice (the total amount of potassium diacetate or sodium diacetate added to the food, from all sources, not to exceed 0.25% of final product weight).

Consequential Modification

In addition, the conditions of use for potassium diacetate (item P.2.01) and sodium diacetate (item no. S.2.1) were modified so that the total amount of potassium diacetate or sodium diacetate added to a food, if used

² The modification presented in this document differs slightly from the proposed modification published on December 22, 2020 as part of *Health Canada's Proposal to Enable the Use of Modified Vinegar as a Preservative in Certain Meat and Poultry Products and Preparations* (NOP/ADP-0036). It was updated to reflect the comments received by Health Canada during the consultation period.

in combination with modified vinegar that contains either of these additives, does not exceed 0.25% of final product weight.

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of modified vinegar for use as an antimicrobial preservative in various meat and poultry products. The Department concluded that information related to allergenicity, chemistry, microbiology, nutrition, and toxicology supports the safety of modified vinegar for use as shown in the table above, and technical information indicates this food additive can have a bacteriostatic effect against certain bacteria. Therefore, the Department has enabled the use of modified vinegar as a preservative by adding to Part 2 of the *List of Permitted Preservatives* the new item number and its corresponding entries shown in the above table. However, there are multiple factors that can influence the microbial safety of a food, and food manufacturers and processors should identify optimal conditions for any controls, including preservatives such as modified vinegar, that are used to achieve a microbiologically safe food.

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. For modified vinegars manufactured with potassium bicarbonate, potassium carbonate or potassium hydroxide, the name "modified vinegar" does not indicate the presence of potassium. For this reason, Health Canada strongly encourages industry to voluntarily declare the total amount of potassium in a food manufactured with one of these modified vinegars, as well as the percentage of the "daily value" for potassium, in the Nutrition Facts table. This is to alert individuals following a low potassium diet to the presence of potassium in foods made with one of these modified vinegars.

This potassium declaration will become mandatory for most prepackaged foods as a result of amendments to the Regulations published in *Canada Gazette* Part II on December 2, 2016.³ For foods that are not prepackaged when offered for sale, such as foods prepared in a grocery store for sale from a specialty counter, Health Canada strongly encourages the seller to make the nutrition information about the food, including its potassium content, available to consumers.

Food additives such as modified vinegar are required to meet food-grade specifications set out in Part B of the Regulations or, if there are none in Part B, the specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC) or the *Combined Compendium of Food Additive Specifications*. The FCC 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.

There are no specifications for modified vinegar in any of these sources. However, industry informed Health Canada that the bases used in the manufacture of modified vinegar meet FCC or JECFA specifications, and that modified vinegar is manufactured under strict quality control standards and good manufacturing practices, and is considered to be of food grade quality.

³ <u>Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Other Labelling Provisions and Food Colours), Canada Gazette Part II, Vol. 150, No. 25, SOR/DORS/2016-305.</u>

Notification – Summary of Comments and Health Canada's Responses

Health Canada received comments from nine stakeholders, all from industry,⁴ following the publication of *Health Canada's Proposal to Enable the Use of Modified Vinegar as a Preservative in Certain Meat and Poultry Products and Preparations* (Reference number: NOP/ADP-0036) on December 22, 2020. Health Canada, in collaboration with the Canadian Food Inspection Agency (CFIA), is replying as summarized in the table below.⁵

Summarized Comments	Summarized Responses
Requested clarification on the authority of Health Canada and the CFIA.	Health Canada is the federal authority regulating the safety and nutritional value of food in Canada. The CFIA is responsible for determining compliance with all food labelling requirements.
Requested clarification on the scope of the proposal.	Health Canada proposed to regulate modified vinegar as a food additive (preservative) permitted in certain cooked or raw (as permitted by their standard) standardized meat and poultry products and certain unstandardized meat and poultry products as described in MOP-0036 .
Requested clarification on the foods not covered by the proposal, or requested that Health Canada extend the use of modified vinegar to other standardized	File a food additive submission with Health Canada for consideration to be given to extending the use of modified vinegar to other foods.
meat and poultry products, certain standardized foods (e.g. pumping pickle, cover pickle and dry cure) and unstandardized foods.	Health Canada committed to give further consideration to the request to allow modified vinegar in pumping pickle, cover pickle and dry cure as the safety of use of modified vinegar has been assessed for the types of meat product in which these ingredients would be added. Further to this consideration, Health Canada has agreed to permit the use of modified vinegar in pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product.
Supported Health Canada's initiative to regulate modified vinegar as a food additive.	Noted position.
Agreed with Health Canada's characterization of modified vinegar, its	Noted position.

⁴ Six industry associations (from which three associations presented a joint response), two ingredient suppliers and one consultant on behalf of a food manufacturer.

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⁵ The hyperlinks to the "Nature, natural – Method of production claims on food label" guidance, to the "Marketing Authorization for Food Additives That May Be Used as Preservatives" and to the "standard of identity" were not included in the original communications. They were added to the summarized comments and responses for clarity purposes. The CFIA is revising the above referenced guidance.

Summarized Comments	Summarized Responses
use, and the choice of the term "modified" in the additive common name.	
Opposed Health Canada's initiative to regulate modified vinegar as a food additive and were of the opinion that modified vinegar should not be considered as a substance different from "vinegar".	Noted position.
Questioned Health Canada's characterization of modified vinegar, its use, and the choice of the term "modified" in the additive common name.	Modified vinegar, which can contain one or more of potassium acetate, potassium diacetate, sodium acetate, sodium diacetate, and unreacted vinegar, is different than vinegar (i.e. water and acetic acid) as described in Division 19 of the Regulations. Since modified vinegar's main components are, on their own, regulated as food additives in Part 2 of the <i>List of Permitted Preservatives</i> , Health Canada has proposed to regulate its use as a food additive (preservative) permitted in the same foods and with the same conditions of use as potassium acetate, sodium acetate, sodium diacetate. The term "modified vinegar" accurately communicates to consumers that it is no longer vinegar but a different, vinegar-derived product.
Proposed other terms to be considered as an alternative common name or for use as synonyms as the term "modified" was considered inaccurate or misleading.	The suggested synonyms (i.e. low acid vinegar, neutralized vinegar and buffered vinegar) are not considered acceptable options for the common name. These terms do not correctly describe the product and are likely to create an erroneous impression with consumers due to the chemical modifications involved, which are more than simply a buffering action and a change in pH.
Opposed the term "low-acid vinegar" as it refers to an already-existing product. Emphasized that any synonym should communicate that "vinegar" has indeed been modified.	Noted position.
Requested clarification on labelling requirements.	The additive itself (i.e. "modified vinegar") must be declared in the list of ingredients, with no mention of the individual substances that go into production of the food additive.
	If the <u>standard of identity</u> for a meat or poultry product allows the use of a preservation method (e.g., the standards that apply to bacon, chopped ham, beef wiener), there is no requirement to label this food as "preserved". However, when the standard of identity for a meat or poultry meat

Summarized Comments	Summarized Responses
	product does not allow for the use of a preservation method (e.g., blood sausage), then the common name must refer to the use of the treatment or process (e.g., preserved blood sausage).
Highlighted differences in food additive- related requirements between the Food Standards of the Food and Drug Regulations (Regulations) and the Canadian Standards of Identity (CSID) incorporated by reference in the Safe Foods for Canadians Regulations (SFCR).	The <u>SFCR's CSID</u> are more detailed on certain aspects than the Regulations food standards and vice-versa. Should there be inconsistency for a food between the SFCR and the Regulations, industry should rely on the requirements set out in <u>Health Canada's Lists of Permitted Food Additives</u> , where it is specified which food additives are permitted in foods, with their associated limits and conditions.
Suggested expanding the proposed listing by adding an entry for powdered (dry) modified vinegar.	To provide regulatory clarity to industry and further transparency to consumers, the proposed List entry for "Modified vinegar" already includes a description of what this ingredient is and how it is made and specifies it can be used in its liquid form or as a spray-dried mixture.
Requested clarification on the permitted maximum level of use.	In Part 2 of the <i>List of Permitted Preservatives</i> , modified vinegar is permitted to be added at levels consistent with Good Manufacturing Practice (GMP), as defined in the Marketing Authorization for Food Additives That May Be Used as Preservatives, but there is a requirement that if the modified vinegar contains potassium diacetate or sodium diacetate, the total amount of potassium diacetate or sodium diacetate added to the food, from modified vinegar singly or in combination with potassium diacetate (item P.2.01 of Part 2 of this List) or sodium diacetate (item S.2.1 of Part 2 of this List), must not exceed 0.25% of the final product weight.
Suggested to include modified vinegar in Column 3 ("Maximum level of use and other conditions") in Part 1 of the List of Permitted Preservatives under item A.1 (acetic acid), and in Part 2 of this List under items P.01 (potassium acetate) and S.01 (sodium acetate), as these substances are also components of modified vinegar.	The entry for acetic acid in Part 1 of the <u>List of Permitted Preservatives</u> is for a different purpose of use (curing) than modified vinegar (antibacterial). Potassium acetate and sodium acetate, which are listed in Part 2 of the list, are permitted for use as antibacterial preservatives at levels consistent with GMP. Since they do not have numerical maximum levels of use, it is not necessary to specify a distinct condition of use in their respective List entry for when they are used in combination with modified vinegar.
Requested clarification on compliance requirements.	Industry must be able to demonstrate that the use of any food additive complies with the regulations using suppliers' specifications, internal calculations, laboratory expertise or another reliable method.
Expressed concern that, based on CFIA's guidance Nature, natural - Method of production claims on food labels, foods containing modified vinegar would not	The CFIA is revising its guidance on "Natural" claims to incorporate an outcome based approach to the use of this claim. The update to the guidance will be posted on the CFIA website in Fall 2021.

Summarized Comments	Summarized Responses
be allowed to carry a "Natural" claim on their label.	
Suggested to allow two transition periods, one year apart. The first would be to allow suppliers to bring their labels into compliance. The second to allow manufacturers to modify their products, if necessary, and bring their labels into compliance.	Regulated parties should contact the CFIA to discuss the compliance date for labelling related to modified vinegar following the date Health Canada publishes the Notice of Modification for modified vinegar.

Implementation and Enforcement

The above modification came into force **November 08, 2021**, the day it was published in Part 2 of the <u>List of Permitted Preservatives</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 modified vinegar. Anyone wishing to submit an inquiry or new scientific information on the use of this additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "modified vinegar (NOM-0176)" in the subject line of your e-mail.

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