Health Canada's Proposal to Revise Permitted Uses of the food additives Methyl Paraben, Propyl Paraben and their Sodium Salts in Various Foods

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/ADP-0033]

November 15, 2019

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* (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.

The Food Directorate is proposing changes to the paraben food additive entries that appear in Part 2 of the *List of Permitted Preservatives*, based on:

- Health Canada identifying parabens as a priority for safety assessment, both in the Food Directorate and as part of the third phase[1] of the Government of Canada's Chemical Management Plan[2] (CMP);
- the Food Directorate's review of the paraben listings and updated toxicological opinion on parabens;
- a determination that the existing permitted conditions of use for the parabens could result in exposures that may exceed the acceptable daily intake for these food additives; and
- consultation with food industry stakeholders who identified that the parabens are used in fewer food categories and at lower levels than currently permitted.

The objective of the proposed modification to the *List of Permitted Preservatives* is to ensure that approved food additive uses of parabens are up to date and reflective of actual uses by the food industry in foods sold in Canada. Therefore, it is the intention of Health Canada to modify Part 2 of the *List of Permitted Preservatives* to revise the food categories and maximum levels for methyl-*p*-hydroxybenzoate (methyl paraben), propyl-*p*-hydroxybenzoate (propyl paraben), and their sodium salts (sodium salt of methyl-*p*-hydroxybenzoic acid and sodium salt of propyl-*p*-hydroxybenzoic acid) in the *List of Permitted Preservatives*, as shown in the table below.

Proposed Modification to Part 2 of the *List of Permitted Preservatives*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
M.1		**(1) [Removed, 20YY-MM-DD, (See NOM/ADM-01XX)]**	
		(2) [Removed, 20YY-MM-DD, (See NOM/ADM-01XX)]	

[1] List of substances in the third phase of CMP (2018-2020): December 2018 update: https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/cmp-third-phase-update.html

[2] Additional details about the Chemicals Management Plan are available at: https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan.html

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
	Methyl-*p*-hydroxybenzoate (Methyl Paraben)	(3) Antifoam preparations	(3) 5,000 p.p.m. calculated as *p*-hydroxybenzoic acid. If any combination of propyl-*p*-hydroxybenzoate or the sodium salts of methyl-*p*-hydroxybenzoic acid or propyl-*p*-hydroxybenzoic acid is used, the total amount not to exceed 5,000 p.p.m., calculated as *p*-hydroxybenzoic acid.
		(4) Aqueous colour formulations for use in chewing gum, unstandardized carbonated and flavoured beverages, unstandardized confectionery, or unstandardized frozen concentrated beverages	(4) Good Manufacturing Practice. The total amount of methyl-*p*-hydroxybenzoate in the finished beverage or food not to exceed 10 p.p.m. If used in combination with its sodium salt, the total amount not to exceed 10 p.p.m., calculated as methyl-*p*-hydroxybenzoate.
		(5) Aqueous colour formulations for use in marinades	(5) Good Manufacturing Practice. The total amount of methyl-*p*-hydroxybenzoate in the finished food not to exceed 40 p.p.m. If used in combination with its sodium salt, the total amount not to exceed 40 p.p.m., calculated as methyl-*p*-hydroxybenzoate.
		(6) Enzyme preparations	(6) 5,000 p.p.m. calculated as *p*-hydroxybenzoic acid. If any combination of propyl-*p*-hydroxybenzoate or the sodium salts of methyl-*p*-hydroxybenzoic acid or propyl-*p*-hydroxybenzoic acid

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
			is used, the total amount not to exceed 5,000 p.p.m., calculated as *p*-hydroxybenzoic acid.
P.5	**Propyl-*p*-hydroxybenzoate (Propyl Paraben)**	**(1) [Removed, 20YY-MM-DD, (See NOM/ADM-01XX)]**	
		(2) [Removed, 20YY-MM-DD, (See NOM/ADM-01XX)]	
		(3) Antifoam preparations	(3) 5,000 p.p.m. calculated as *p*-hydroxybenzoic acid. If any combination of methyl-*p*-hydroxybenzoate or the sodium salts of methyl-*p*-hydroxybenzoic acid or propyl-*p*-hydroxybenzoic acid is used, the total amount not to exceed 5,000 p.p.m., calculated as *p*-hydroxybenzoic acid.
		(4) Aqueous colour formulations for use in chewing gum or unstandardized confectionery	(4) Good Manufacturing Practice. The total amount of propyl-*p*-hydroxybenzoate in the finished food not to exceed 20 p.p.m. If used in combination with its sodium salt, the total amount not to exceed 20 p.p.m., calculated as propyl-*p*-hydroxybenzoate.
		(5) Aqueous colour formulations for use in marinades	(5) Good Manufacturing Practice. The total amount of propyl-*p*-hydroxybenzoate in the finished food not to exceed 40 p.p.m. If used in combination with its sodium salt, the total amount not to exceed 40 p.p.m., calculated as propyl-*p*-hydroxybenzoate.
		(6)	(6)

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		Aqueous colour formulations for use in unstandardized carbonated and flavoured beverages	Good Manufacturing Practice. The total amount of propyl-*p*-hydroxybenzoate in the finished beverage not to exceed 10 p.p.m. If used in combination with its sodium salt, the total amount not to exceed 10 p.p.m., calculated as propyl-*p*-hydroxybenzoate.
		(7) Enzyme preparations	(7) 5,000 p.p.m. calculated as *p*-hydroxybenzoic acid. If any combination of methyl-*p*-hydroxybenzoate or the sodium salts of methyl-*p*-hydroxybenzoic acid or propyl-*p*-hydroxybenzoic acid is used, the total amount not to exceed 5,000 p.p.m., calculated as *p*-hydroxybenzoic acid.
S.4	**Sodium Salt of Methyl-*p*-hydroxybenzoic acid**	**Same foods as listed for Methyl-*p*-hydroxybenzoate**	**Same levels and conditions as prescribed for Methyl-*p*-hydroxybenzoate**
S.5	**Sodium Salt of Propyl-*p*-hydroxybenzoic acid**	**Same foods as listed for Propyl-*p*-hydroxybenzoate**	**Same levels and conditions as prescribed for Propyl-*p*-hydroxybenzoate**

This proposal is expected to have no impact on the food industry given that the food categories as shown in the above table were developed based on responses from the food industry. For some food categories in which parabens may currently be legally used, there was either no reports received of actual use of parabens or there was clear indication from the industry that parabens are not used; hence, these food categories were not further considered. In addition, the food categories corresponding to subitems (3) to (7) are considered to be currently included in the broad food listing of "unstandardized foods" (subitem (2)).

Although the proposed maximum level of use (MLU) of 5,000 parts per million (ppm) calculated as *p*-hydroxybenzoic acid in antifoam preparations and enzyme preparations is higher than the

currently permitted level of use of 1,000 ppm in foods as per the Part 2 of the *List of Permitted Preservatives*, this MLU will result in significantly lower levels of parabens in the finished food or food ingredient manufactured with such preparations. The original MLU was based on the direct addition of parabens to those foods in order to preserve the finished food itself. In contrast, the propose us of parabens in the antifoam or enzyme preparations is to preserve these preparations themselves rather that the finished food prepared with them.

Consequential Modification to Part 2 of the *List of Permitted Preservatives*

A consequential modification will also be required to Part 2 of the *List of Permitted Preservatives*, as shown in the table below, to remove duplication in the listing of Items M.1 and M.2, Methyl-*ρ*-hydroxy Benzoate and Methyl Paraben, respectively, and Items P.5 and P.6, Propyl-*ρ*-hydroxy Benzoate and Propyl Paraben, respectively. Synonymous names for the same compound should not appear separately as different Item numbers in the same List, and reflect an unnecessary redundancy. Instead, the synonyms will appear in parentheses under the lowest Item number, M.1 and P.5, as shown in the table above.

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
M.2	**[Removed, 20YY-MM-DD, (See NOM/ADM-01XX)]**		
P.6	**[Removed, 20YY-MM-DD, (See NOM/ADM-01XX)]**		

Rationale

The Food Directorate identified the parabens as a priority for safety assessment, committing itself to a review of the existing listings and toxicological database for the parabens, as well as to an evaluation of paraben exposure from their use as food preservatives in foods sold in Canada.

Consultation with the food industry and information in the literature indicate that the use of parabens in food preservations has declined. Overall, there is minimal use of parabens by the food industry in foods sold in Canada, and the use levels in finished foods are low.

The Food Directorate completed a re-evaluation of the potential exposure to parabens from their use as a preservative in foods at their existing maximum levels of use as per Part 2 of the *List of Permitted Preservatives*. It was estimated that, if the parabens were used at these maximum levels of use in all foods identified according to the listings for parabens[3], exposures for certain

[3] The exposure assessment included the following unstandardized foods: baked goods, including cakes (especially fruit cakes), pie crusts, and pastries (non-yeast); icings, toppings and fillings (especially fruit, jellies, and creams); beverages such as soft-, fruit-, and energy- drinks; alcoholic beverages; creams and pastes; snack foods such as tortilla chips; fruit products such as fruit salads; sauces, syrups and sweet sauces; frozen dairy products; sugar

age groups could potentially exceed the established Acceptable Daily Intake (ADI) for parabens[4]. Exposure was further estimated based on the levels of parabens presently in use, as identified by the food industry[5]. The Food Directorate concluded that there is no safety concern based on these current reported uses by industry. Health Canada is therefore proposing to revise the use of methyl- and propyl- paraben, and their sodium salts as described above.

Those food industry members utilizing the parabens have indicated that there are no known preservative substitutes for the remaining identified paraben uses. Scientific evidence has demonstrated that the parabens are particularly effective in the more alkaline end on the neutral pH range (above a pH of 6.5) as broad-spectrum antimicrobial agents.

Although the proposed food categories are more restrictive than those currently appearing in Part 2 of the *List of Permitted Preservatives*, removing those food categories where the parabens are no longer used will add greater specificity to the listings and reflect current uses. Potential exposures associated with the proposed maximum levels of use were confirmed to be well below the ADI for all age groups.

Based on the results of the safety assessment, Health Canada's Food Directorate recommends that the use of methyl-*p*-hydroxybenzoate (methyl paraben) and propyl-*p*-hydroxybenzoate (paraben paraben), and their sodium salts (sodium salt of methyl-*p*-hydroxybenzoic acid and sodium salt of propyl-*p*-hydroxybenzoic acid) be revised as described above.

Other Relevant Information

International Comparison

The food categories and maximum levels proposed by the Food Directorate are generally in line with those established by regulatory bodies who have more recently assessed permitted parabens maximum levels in food. Differences that exist between international regulations and those that the Food Directorate is proposing are the following: (1) the Food Directorate's recent assessment of the latest toxicological evidence; (2) the specific parabens that are allowed in foods (methyl- and ethyl- paraben are permitted in the European Union and by the Codex General Standard for Food Additives (GSFA); (3) the food categories in which they are permitted (more extensive in U.S.A. and Codex GSFA); and (4) the levels of parabens in finished foods (higher concentrations in general are permitted in finished foods by other authorities, with the exception of enzyme preparations where concentrations are lower in the European Union).

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substitutes; candies and sweets; and coffee extracts. These are unstandardized foods in which parabens may have been used in the past.

[4] The current ADI for methyl- and propyl-paraben and their sodium salts is 0-10 mg/kg bw.

[5] Responses received from food industry stakeholders in reply to the Food Directorate's call for data on August 31, 2017.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an ADI of 0-10 mg/kg bw for the parabens in 1974. The ADI represented the sum of methyl-, ethyl- and propyl paraben, and their sodium salts, since they are commonly used in combination. In 2006, the JECFA removed propyl paraben from this group ADI, based on a toxicological study[6] suggesting that this ADI was not appropriate for propyl paraben[7] and, in part, on recommendations from the European Food Safety Authority (EFSA) in 2004[8] which were based on the same study. To date, neither authority has re-assessed the parabens.

The difference in specific parabens allowed between Canada, the EU and the Codex GSFA is the result of the Food Directorate's assessment of new toxicological evidence on the parabens, which does not support the conclusions made by JECFA and EFSA in their respective assessments. Therefore, the Food Directorate includes propyl paraben in its ADI for the parabens and considers that current propyl paraben uses by the food industry are acceptable from a food safety perspective. Contrary to the EU and Codex GSFA, the Food Directorate has never received a request from the food industry for approval of its use in foods sold in Canada and therefore ethyl-paraben is not currently permitted.

Concentrations of the parabens measured in food in other countries also suggest that the use of parabens in food is limited, with actual levels in the finished foods being in the low parts per million (ppm) range.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in Part 2 of the *List of Permitted Preservatives*. This will be announced via a Notice of Modification that will be published on the Government of Canada's Website.

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

For additional information or to submit comments related to this proposal, please contact:

Bureau of Chemical Safety, Food Directorate

[6] Oishi, S. (2002), *Food and Chemical Toxicology*, 40(12):1807-1813.
[7] Evaluation of certain food additives and contaminants (Sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 940, 2006; and WHO Food Additives Series, No. 58, 2006.
[8] EFSA (2004) Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a Request from the Commission related to para hydroxybenzoates (E214-219). Question number EFSA-Q-2004-063. Adopted on 13 July 2004.

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If communicating by e-mail, please use the words "**parabens (NOP-0033)**" in the subject line of your e-mail. Health Canada is able to consider information received by **January 28, 2020,** 75 days from the date of this posting.