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Health Canada's Proposal to Remove Ethylene Oxide from the List of Permitted Food Additives with Other Accepted Uses

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0025]

June 1, 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* (FDR). 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. The food additive provisions in the FDR and the MAs are regulations that Health Canada's Food Directorate administers under the authority of the *Food and Drugs Act* (FDA).

A food additive provision for the use of ethylene oxide as a fumigant on whole or ground spices was established under the authority of the FDA on October 5, 1971. Subsequently, in 1976, the use of ethylene oxide was registered under the authority of the *Pest Control Products Act* (PCPA) for restricted use to sterilize and fumigate spices. Despite the existence of the food additive provision for ethylene oxide, Health Canada considers that the regulation of fumigants is appropriately placed under the authority of the PCPA. Ethylene oxide meets the regulatory definition of a pest control product under the PCPA when used for the purpose of fumigation.

The food additive provision and the conditions of registration as a pesticide have historically been complementary. However, a re-evaluation of the safety of ethylene oxide that was concluded by the Pest Management Regulatory Agency (PMRA) and a subsequent consultation led to the implementation, in 2013, of changes to the instructions of use for ethylene oxide as a registered pesticide and highlighted the need to remove the food additive provision for ethylene oxide, which currently appears in the [List of Permitted Food Additives with Other Accepted Uses](#) on Health Canada's website.

Since the PCPA is the appropriate Act for managing the use of ethylene oxide as a fumigant, Health Canada intends to modify the [List of Permitted Food Additives with Other Accepted Uses](#) by removing the entry for ethylene oxide from the List.

Proposed 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
E.2	Ethylene Oxide	[Removed, YYYY-MM-DD, (See NOM/ADM-XXXX)]		

Rationale

Currently, the use of ethylene oxide as a fumigant on spices is enabled under two pieces of legislation, the FDA and PCPA. Under the FDA, there is a food additive provision that permits the use of ethylene oxide at levels consistent with Good Manufacturing Practice on "whole or ground spice (except mixtures containing salt)" provided that residues of ethylene chlorohydrin,

a reaction by-product, do not exceed 1500 parts per million (ppm). Ethylene oxide is also currently registered under the PCPA as a fumigant for use on similar foods, namely on “whole or ground spices and other processed natural seasonings (except mixtures to which salt has been added)”, with the exception of basil, at a maximum application rate of 500 mg active ingredient/L chamber volume (500 ppm ethylene oxide).¹

Health Canada considers that the use of ethylene oxide as a fumigant meets the regulatory definition of a pest control product and therefore is appropriately regulated under the PCPA. Removal of the food additive provision for ethylene oxide will mean that the approved conditions of use of ethylene oxide will reside solely under the PCPA.

Therefore, Health Canada intends to remove the food additive entry for ethylene oxide, item E.2, from the [List of Permitted Food Additives with Other Accepted Uses](#). This modification to the List will result in a single, consistent, appropriate and up-to-date regulatory framework for administering the use of ethylene oxide as a fumigant on spices.

Implementation and Enforcement

The proposed change will be effective the day on which it is published in the [List of Permitted Food Additives with Other Accepted Uses](#). This will be announced via a Notice of Modification which will be published on [Health Canada's Website](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the food-related aspects of the FDA and its associated regulations. The PCPA is administered by the PMRA.

Contact Information

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

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If communicating by e-mail, please use the words “**ethylene oxide**” in the subject line of your e-mail. The comment period for this proposal is open until **August 15, 2017**, 75 days from the date of this posting.

¹ In 2013, as a result of the PMRA's re-evaluation of ethylene oxide, basil may no longer be treated with ethylene oxide, as per the conditions of registration. Also, the maximum application rate was reduced, from 1500 to 500 mg active ingredient/L chamber volume. See: “Re-evaluation Decision RVD2013-02, Ethylene Oxide” 19 December 2013. Available at: http://www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/decisions/rvd2013-02/rvd2013-02-eng.pdf