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Review of the Regulatory Approach for Personal Insect Repellents Containing Plant-Derived Essential Oils

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Canada 



As part of Health Canada's ongoing commitment to regulatory modernization, the purpose of this document is to notify registrants, pesticide regulatory officials, stakeholders, and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) will conduct a review of the current approach to the regulation of personal insect repellents containing plant-derived essential oils.

This review, by PMRA, will include a consultation with an external advisory panel composed of scientific experts in the field. Following this expert consultation, comments will be solicited from the public, industry, and other stakeholders on a proposed regulatory approach before finalizing the regulatory framework.

The PMRA is responsible for administering the *Pest Control Products Act*. Under the Act, pesticides must be assessed before they are sold or used in Canada in order to determine that they do not pose unacceptable risks to humans or the environment and have value when used according to the label instructions. This assessment applies to both conventional chemical pesticides and non-conventional substances used as pesticides, for example biological organisms and plant extracts, which include personal insect repellents containing plant-derived essential oils.

The PMRA has developed guidelines that provide a tiered approach and corresponding data and information requirements¹ specifically for non-conventional pest control products. However, insect repellents containing plant-derived essential oils, although derived from natural sources, are applied directly to the skin and the nature of exposure is different from other types of non-conventional pesticides. Therefore, additional work is needed for plant-derived essential oils to determine that the existing data requirements are appropriate for the protection of human health or whether an alternate approach could be used. In recent years, a number of non-conventional pesticides have been approved by the PMRA (including some personal insect repellents containing soybean oil and eucalyptus oil) and this experience will be used to inform the review of the regulatory framework.

While this review is being conducted, manufacturers of currently registered personal insect repellents containing plant-derived essential oils will be permitted to remain on the market for sale and use. For personal insect repellents containing citronella oil specifically, only those products which have met the allowable concentration limit for the contaminant of concern (methyl eugenol) may remain on the market for sale and use during this time.

The review is expected to be completed and published for consultation in 2016.

¹ Regulatory Directive, DIR2012-01, Guidelines for the Registration of Non-Conventional Pest Control Products, 22 February 2012.