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Regulatory Proposal

PRO2024-05

Reclassification of the group of formulants Nonylphenol ethoxylates (NPEs) to List 1 – Formulants of Toxicological Concern

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Executive summary

The Pest Management Regulatory Agency (PMRA) is proposing to reclassify the group of formulants Nonylphenol ethoxylates (NPEs) from List 2-Potentially Toxic Formulants with a High Priority for Testing to List 1-Formulants of Toxicological Concern and subsequently add it to the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* based on risks to the environment, as described in Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. This regulatory proposal serves as notice to registrants and other interested parties and is being distributed for information and for public comment. After consideration of comments received, a final decision will be published.

Background

NPEs are present in pesticides as formulants. They are surfactants that are currently classified as List 2 formulants. The PMRA identified NPEs as a priority formulant for re-assessment and potential reclassification.

Regulatory Directive DIR2006-02 outlines Health Canada's Pest Management Regulatory Agency (PMRA) policy on the regulation of formulants contained in pest control products. In this context, a formulant is defined as any substance or group of substances other than the active ingredient that is intentionally added to a pest control product to improve its physical characteristics. Based on DIR2006-02, adjuvants are formulants that are sold and used separately for in-tank mixing by the end-user. Adjuvants intended to directly improve efficacy or enhance biological performance of pest control products are also subject to registration and re-assessment under Health Canada's re-evaluation program. Decisions on acceptability or continued acceptability of adjuvants that are part of the NPE chemical group will take into account the approach for NPEs as formulants. The PMRA ensures that information on formulations and identification of formulants are accurate and meet current standards. In addition to data/information required for an individual formulant, data (for example, acute toxicity, efficacy) may also be required on the end-use formulation containing the formulant. Through the implementation of the Formulants Policy, the PMRA ensures that formulants in registered pesticides that meet the policy's criteria for toxicity are eliminated or replaced with less hazardous alternatives, or that registrants provide scientific information to demonstrate their safety under conditions of use. The PMRA also encourages the use of the least toxic formulants available that are appropriate to the formulation. These outcomes are aligned with the Minister of Health's primary objective under the *Pest Control Products Act* to prevent unacceptable risks from the use of pest control products to human health and the environment. Existing formulants in registered pest control products in Canada have been assigned to one of five lists that are ranked in order of concern based on the categorization criteria provided in Section 3.0 of Regulatory Directive DIR2006-02. List 1 consists of formulants of toxicological concern, that is, formulants that have been identified as being of significant concern with respect to their potential adverse effects on health and/or the environment. Formulants that have been determined to be potentially toxic based on either structural similarity to List 1 formulants or data suggestive of toxicity are identified as List 2 formulants (potentially toxic with a high priority for testing). Formulants of lower concern are identified as List 4A (formulants of minimal toxicological concern) or 4B (formulants of minimal concern under specific conditions of use). Formulants not meeting any of these criteria are identified as List 3 formulants. If further information on the

toxicity of a formulant becomes available, formulants are reassessed. If the reassessment determines that the formulant is of toxicological concern, the formulant is reclassified to List 1 under the Formulants Policy and subsequently added to the [List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part I](#), which entails that their identity and concentration in pest control products are not protected as confidential business information and are made available to the public. Formulants reassessed and not meeting criteria for reclassification to List 1 under the PMRA Formulants Policy are reclassified to either List 4A or 4B. Pest control product formulants and their associated list number is posted on the [Open Government Portal](#) as the [PMRA List of Formulants](#).

Reassessment of nonylphenol ethoxylates (NPEs)

Regulatory history

NPEs were assessed by Environment and Climate Change Canada (formerly Environment Canada) and Health Canada under the Priority Substance List Program (PSL), and on June 23, 2001, a final decision was published in Canada Gazette (vol. 135, no. 25). Based on this assessment, NPEs were declared "toxic" to the environment under section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA) and added to the List of Toxic Substances, Schedule 1 of the same Act. Subsequently, a risk management strategy¹ was published, identifying the four sectors contributing to the highest releases of NPEs to the environment: use of soap and cleaning products (56%), followed by the use of textile processing aids (18%), pesticides (8%), and pulp and paper processing aids (5%). The risk management actions presented had the environmental goal of achieving ambient concentrations in Canadian waters that do not exceed the draft Canadian Water Quality Guidelines of 1.0 µg/L NP TEQ (nonylphenol toxic equivalent) for freshwater and 0.7 µg/L NP TEQ for marine waters, such that no adverse effects to aquatic organisms are likely to occur. The overall risk management objective was to achieve a 95% reduction of NPEs released by three of the four major sectors (together representing approximately 80% of the total NPE releases in Canada), with the fourth (in other words, pesticides, contributing to 8% of estimated releases) being regulated under the *Pest Control Products Act*. Voluntary reductions were already in progress for the pulp and paper sector (contributing to 5% of the estimated releases) at the time the risk management strategy was published in 2004. Environment and Climate Change Canada noted that it was expected that the PMRA would manage pesticide releases.

The PMRA initially adopted a voluntary reduction strategy, which involved notifying registrants when their products contained more than 1% w/w NPEs and encouraging replacement of the NPE component.

¹ Environment Canada (2004). *Risk Management Strategy for Nonylphenol and its Ethoxylates Under CEPA (1999)*, 11 pp. (En14-139-2004)

Current status

In 2022, Environment and Climate Change Canada published a report² that assessed the effectiveness of the risk management actions that are in place for NPEs. The report indicates that, overall, the risk management strategy was meeting its intended objectives; NPE releases were reduced by more than 95% in the three major sectors that were assessed (soap and cleaning products, textile processing aids, and pulp and paper processing aids).

The PMRA also conducted a performance assessment to evaluate the impact of the voluntary reduction notices on the use of NPE formulants and adjuvants. Based on release information presented in the risk management strategy document (pesticide contribution of 8% of 18000 tons in 1998/1999) and sales data available for 2020, it was estimated that there has been an overall reduction of 37% in the environmental release of NPEs from pest control products. From 2003 to 2020, approximately 80 products have replaced NPEs in their formulations, and a 30% reduction in the number of products containing NPEs was observed. As of 2020, less than 400 products contained NPEs, representing about 5% of all registered products. Furthermore, 30% of the current products containing NPEs are also available in an NPE-reduced or NPE-free formulation. The analysis of sales data from 2008 to 2020 revealed that there was a 15% decrease in sales of products containing NPEs as formulants; however, there was an overall 43% increase in the use of NPE-based adjuvants, with an initial 65% decrease from 2008 to 2013 followed by a 310% increase from 2013 to 2020. Although some progress has been made, a voluntary approach towards the reduction of NPEs in pesticides has not been sufficient to reach the 95% reduction goal set out by Environment and Climate Change Canada.

Proposed reclassification conclusion

NPEs are substances of variable chain length, which impacts their ecotoxicity and persistence. The transformation of NPEs in the environment involves a stepwise removal of ethoxy functional groups from the chemical structure. This results in the formation of intermediate biotransformation products that are shorter-chain NPEs and NPE-carboxylates, as well as nonylphenol (NP). Although the NPEs with longer ethoxylate chains are nonpersistent in the environment and undergo a rapid primary biodegradation, their transformation products are considerably more persistent.³ Following further examination of the fate and ecotoxicity of NPEs under the continuous oversight approach, the PMRA has concluded that the overall residues of NPEs meet the persistence criteria for List 1 formulants as set out in Regulatory Directive DIR2006-02. Shorter chain NPEs and NPs were reported to have a lethal concentration of less than one part per million for aquatic toxicity^{3,4}, which meets the ecotoxicity criteria for List 1 formulants as set out in Regulatory Directive DIR2006-02. Therefore, the PMRA concludes that residues of NPEs meet the criteria for classification as List 1 formulants due to concern with respect to the potential adverse effects on the environment from both NPEs and their transformation product, NP.

² Environment and climate Change Canada (2022), *Performance Measurement Evaluation for Risk Management of Nonylphenol and Its Ethoxylates, eco-component*, 35 pp. (En14-489/2022E-PDF)

³ Canadian Water Quality Guidelines for the Protection of Aquatic Life- Nonylphenol and its Ethoxylates

⁴ *Priority Substances List Assessment Report for Nonylphenol and its Ethoxylates* (2001). Environment Canada and Health Canada, EN40-215/57E.

Reclassification proposal under DIR2006-02

According to Regulatory Directive DIR2006-02, when a formulant is proposed for reclassification to List 1, registrants will be advised and given an opportunity to comment through a regulatory proposal document. This regulatory proposal serves as notice to registrants and other interested parties that the PMRA is proposing the reclassification of NPEs to List 1 under the Formulants Policy.

Given that NPE residues meet the definition of List 1 formulants, it is concluded that the risk to the environment related to their use is unacceptable. Therefore, the PMRA is proposing to reclassify NPEs from List 2 (potentially toxic formulants with a high priority for testing) to List 1 (formulants of toxicological concern), and consequently apply the regulatory actions for List 1 formulants as set out in Regulatory Directive DIR2006-02. This decision would implicate all pest control products containing NPEs. Alternatives to NPEs that have a better environmental profile are available for substitution in pesticide formulations.

This proposed decision means that, should the PMRA's reclassification of NPEs to List 1 be finalized following a review of comments received, as per Regulatory Directive DIR2006-02 registrants may either (i) opt for voluntary discontinuation of any pest control products containing NPEs within 4 months of the date of final notification of reclassification and discontinue sales, or (ii) retain the pest control product but substitute an alternative to NPEs, including submitting information demonstrating that the formulant used for substitution has no unacceptable health or environmental risks and that the product is still efficacious with the new formulant. Within 16 months of notification of reclassification, registrants would need to submit an application to amend their registered product. In addition, until a substitution of NPEs is made, a label disclosure (via printed labels or over-stickering) would be required within four months of notification on any products in the hands of registrants. Further details are outlined in Regulatory Directive DIR2006-02, section 4.3 Regulatory Action on Pest Control Products That Contain List 1 Formulants under part (a) Options for Registered Products with Future List 1 Formulants (except those subject to the Montreal Protocol) and part (b) Disclosure of List 1 Formulants on Product Labels.

Finally, as stated in Regulatory Directive DIR2006-02, applications submitted to register new products or to amend existing products containing NPEs would not be accepted, unless information or data to specifically support the safety of the product containing NPEs accompanies the application.

Next steps

Health Canada's PMRA is inviting interested Canadians to submit their views on the proposed reclassification of NPEs to List 1 and subsequent addition to the *List of Formulants and Contaminants of Health or Environmental Concern*. Health Canada will consider all comments received before finalizing its position. Please provide your comments and include the following information:

- Title of this consultation document;
- Your full name and organization;
- Your phone number; and
- Your complete mailing address or email address.

Any amendments to the PMRA List of Formulants (posted on the [Open Government Portal](#)) and to the [List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern](#), Part I would be published and associated regulatory actions would be implemented based on Regulatory Directive DIR2006-02.

Written comments on this proposal will be accepted up to 60 days from the date of this publication. Please forward all comments to PMRA Publications. (Contact information can be found on the cover page of this document.)