January 2021 – PCD Advice on Revised Registration Requirements for Biocidal Products and Plant Protection Products (PPPs)

This document is issued by the Pesticide Control Division (PCD), the competent authority for biocides and plant protection products in Ireland, to advise companies placing biocide and plant protection products on the Irish market of their of their obligation to notify product to the Irish National Poisons Information Centre (NPIC), obligations with respect to Unique Formulation Identifiers and product Safety Data Sheets (SDS).

Changes to the Notification Procedure to the National Poisons Information Centre for Biocides and PPPs

Biocidal products and plant protection products (PPPs) classified under the CLP Regulation (EC) No 1272/2008 with respect to physical and health hazards must be notified to the Irish National Poisons Information Centre (NPIC) in Beaumont Hospital, Dublin. For example, if the product label has any of the CLP pictograms GHS 02, GHS 03, GHS 05, GHS 06, GHS 07, GHS 08 then the product must be notified to NPIC before being placed on the Irish market. Previously this was done by notifying the product directly to NPIC.

From 1st January 2021, Annex VIII to the CLP Regulation '*harmonising information relating to emergency health response'* makes it a legal obligation for submission of information using a new harmonised format. New biocidal products and plant protection products (PPPs) which classify with respect to physical and health hazards, being placed on the Irish market for use by consumers and professionals must be notified to NPIC through the European Chemicals Agency (ECHA) Notification Portal
Products must be notified to the national poisons centre in each member state in which the products will be placed on the market.
Following a successful notification, companies will receive a submission report confirming the NPIC notification for each mixture notified.

Details on the notification requirements and the entity responsible for the notification can be found at the following links:

National Poisons Information Centre of Ireland

ECHA - Steps for industry - Poison Centres

Note 1:

Products already on the Department of Agriculture, Food and the Marine (DAFM) biocidal or PPP registers which have been notified to the Irish NPIC prior to 31st December 2020 can avail of a transition period. Such notifications will remain valid until 1 January 2025 or until changes are made to the product (e.g. changes to the mixture composition, toxicological properties, hazard classification or product identifiers/name). If a biocidal product or PPP product is on the market prior to January 2021 and it has not previously been notified to the Irish NPIC, then a notification must be submitted through the ECHA submission portal. Furthermore, companies may voluntarily notify existing products through the on-line portal before the end of the transition period.

Unique Formulation Identifier (UFI)

The Unique Formula Identifier (UFI) is a code that will be required both in the submission of information to NPIC and on labels of products which classify with respect to physical and health hazards. From 1st January 2021, products which classify as hazardous must have a UFI code printed or affixed to the product label. This is applicable for new products to be placed on the market or for existing products where certain changes occur (see note 2 below). The UFI is a 16 character alphanumeric code. When placed on the product label, the acronym 'UFI' must be in capital letters, followed by a colon and the 16-character alphanumeric code. The code is divided into four blocks, each separated by a hyphen.
For example: **UFI: N1QV-R02N-J00M-WQD5**

To create a UFI for a product, the company's VAT number (or 'company key', in specific cases) and a mixture-specific formulation number will be required. Entering these two numbers into ECHA's UFI Generator online tool will provide the UFI code. It is possible to assign a UFI for each unique formulation/mixture, regardless of how many products are marketed with that formulation. However, all products labelled with the same UFI need to share the same formulation composition.

Link to UFI Generator Tool

Note 2: When a product undergoes a formulation change, for example, if a component is added, deleted or substituted, or if the concentrations of components change beyond the allowed variation range, then a new UFI will need to be generated. Both the new formulation and UFI must be notified to the NPIC via the on-line European Chemicals Agency (ECHA) notification portal. In addition, the change in formulation must be notified to/applied for with the Pesticide Control Division (PCD).

Safety Data Sheets (SDS)

In accordance with the provisions of Annex II of REACH, it is still obligatory to include a poisons centre emergency number in Section 1.4 of a product SDS. For the Irish NPIC, it should be stated that the emergency number is available from 8am to 10pm every day. It is also possible for companies to include their own emergency number in this section if so desired. **The NPIC emergency number cannot be used on an SDS until the mixture has been notified to the NPIC.**
With the exception of unpackaged mixtures there is no obligation to include the UFI in the SDS. However, it may be included voluntarily and if so should be provided in Section 1.1.

Link to NPIC - SDS Advice

In Summary

Listed below are the additional data/information which must be submitted to the Pesticide Control Division before new products will be placed on DAFM official registers from January 2021.

- Proof of notification of the product to the Irish NPIC i.e. the submission report generated from the ECHA database (or where relevant, a declaration that notification is not required for the particular product).
- Copy of proposed final product labels with a valid UFI (where applicable) printed or affixed. (Labels should not be printed until accepted by the Pesticide Control Division).
- REACH compliant Safety Data Sheet (SDS) for the product which includes the NPIC emergency telephone number in Section 1.4.

All of the above requirements are also applicable in the following scenarios:

- When applications are made for formulation changes to products which are already on the DAFM registers and which are subject to the NPIC requirements.
- When applications are made to change the trade name of a product which are already on the DAFM registers and which are subject to the NPIC requirements.
- When the hazard classification of the product with respect to physical or health aspects are changed.
- When relevant new toxicological information that is required in Section 11 of the SDS becomes available on the hazardous properties of the mixture or its components.

Link to NPIC FAQ Document: Poisons Centre - Ireland FAQ

Link to ECHA Guidance Document on UFIs: UFIs in Brief

Link to ECHA Poisons Centre Questions and answers: Q & As - Poison Centres

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