Contents

1.0 Objectives of this Document: ................................................................. 3

2.0 Introduction ....................................................................................... 4

3.0 Application Information ................................................................. 5

   3.1 General Application Information .................................................. 5
       3.1.1 Types of Notification Application ....................................... 5
       3.1.2 Submission of the Application ............................................. 6
       3.1.3 Fees .............................................................................. 6

   3.2 The Application Form ................................................................ 6

   3.3 Filling out an Application Form .................................................. 8
       Section 1: Notification Holder .................................................... 8
       Section 2: Production Information ............................................. 8
       Section 3: Product Manufacturer .............................................. 9
       Section 4: Use Information ......................................................... 9
       Section 5: Labelling Information ............................................... 10
       Section 6: Packaging Information ............................................. 10
       Section 7: Primary Distributor(s) .............................................. 10
       Section 8: Active Substance manufacturer ................................ 11
       Section 9: Active Substance and Co-Formulant Information ....... 12

   3.4 Accompanying Documentation .................................................. 13
       3.4.1 Safety Data Sheets (SDS) .................................................. 13
       3.4.2 Biocidal Product Label (draft) .......................................... 13
       3.4.3 Article 95 Compliance (List of active substance and product suppliers) ........................................... 14
       3.4.4 Corporate Client System Form ......................................... 14

   3.5 Corporate Client System (CCS) Form (worked example) ............... 15

4.0 Application Procedure (What happens when an application is received?) ........................................... 16

   4.1 Application Process .................................................................. 16
   4.2 Procedural Flow Diagram .......................................................... 17
1.0 Objectives of this Document:
The aim of this document is to act as guidance on product notification for applicants wishing to place biocidal products on the market in Ireland for sale and use. In addition, the objectives of this guidance are to:

- To explain notification
  - What is Notification?
  - Why is Notification required?
  - Who does Notification apply to?
  - When should products be notified?

- To provide information to applicants on the completion of the notification application form.

- To inform companies about what supporting documentation is required when submitting an application for product notification.

- To explain the procedure followed when an application is received.
2.0 Introduction

Notification of biocidal products applies only to products prior to the EU approval of active substances for a given product-type. As such, biocidal products containing the active substances supported in the EU-level Review Programme of existing active substances for the given product-type must be notified in Ireland under the National Notification System provided under S.I. 427 of 2013.

Why must products be notified?

Biocides are designed to be biologically active in order to control unwanted or harmful organisms. As a result biocidal products can pose risks to humans, non-target animals and the environment. Therefore, notification is required to identify and control biocidal products placed on the market in Ireland in order to minimise these risks to humans, non-target animals and the environment prior to authorisation under Regulation (EU) No 528/2012.

What is Notification?

Notification is the national transitional system of registering biocidal products in Ireland. Notification is simplified notification procedure and is mandatory under Irish legislation, Statutory Instrument (S.I.) 427/2013, before the placing of biocidal products on the market by any person wishing to sell or use biocidal products.

Who does Notification apply to?

Notification applies to those persons placing biocidal products on the Irish market for sale and use. Under S.I. 427 of 2013 those persons are defined as a Notification Holder:

“notification holder” means the person who is responsible for the notification to the Minister that a biocidal product is placed on the market for sale and use”

Notification holders are normally the legal owner of the product and can include active substances manufacturers, product manufacturers or distributors. In some cases, where companies are represented by consultants it may be the consultant that is responsible for the notification of their client’s products but the company legally owns the notification.

When should products be notified?

Biocidal Products are required to be notified before they are placed on the Irish market. No product can be legally sold on the Irish market before notification. Notified products on the market in Ireland must have a PCS Number on the label to show that it is notified with the Department of Agriculture Food and the Marine. The PCS Number takes the form – PCS 90000 and must be indelibly printed on the label or packaging of the biocidal product.
3.0 Application Information

The Department of Agriculture, Food and the Marine (DAFM), Pesticide Controls Division (PCD) is the competent authority for biocidal products in Ireland. Applications for notification of biocidal products are to be submitted to DAFM-PCD prior to placing on the market for sale and use.

3.1 General Application Information

3.1.1 Types of Notification Application

There are two types of application for the notification of biocidal products under S.I 427 of 2013 in Ireland, these include:

- Application to notify a biocidal product
- Application for changes to a notified biocidal product (trivial amendment)

Applications must be made for all biocidal products that contain active substances supported under the EU Review Programme for Existing Active Substances and are within scope of the Biocidal Products Regulation (EU) 528/2012.

The Applications for biocidal product notification outlined above are relevant to all the different types of biocidal products that include:

- Individual biocidal products or product ranges (NB: an application form is required for each product in the range)
- Biocidal products where the active substance is released (e.g. formaldehyde releasers) or is generated in situ by precursor chemicals (e.g. chlorine dioxide).
- Biocidal products where the active substance is generated in situ or released by a device (e.g. ionisation, electrolysis).
- Treated articles with a primary biocidal function (e.g. mosquito nets impregnated with a biocide).

Application for product notification must be made before the biocidal product(s) are placed on the market for sale and use.

Further information on National Notification Applications can be found on the DAFM-PCD website.
3.1.2 Submission of the Application

All applications for biocidal product notification are to be submitted electronically to DAFM-PCD through the email:

biocide-notifications@agriculture.gov.ie

3.1.3 Fees

All applications for notification under S.I. 427 of 2013 are subject to a fee. Information on fees can be accessed via the DAFM-PCD website.

If a Purchase Order (PO) Number is required on the invoice this must be supplied with the application.

Notified biocidal products are also subject to Annual Registration Fees (ARF) on 31\textsuperscript{st} December of each year. The Notification Holder responsible for notifying the products is also responsible for the payment of the Annual Registration Fees.

Please Note: Where fees (notification, trivial amendment and ARF fees) are not paid within the given deadline the notified product will be cancelled and revoked from the market.

3.2 The Application Form

The first step in the notification process involves completion of the application form for either:

- notification of a new biocidal product(s) or;

There are nine sections to complete requiring information on amongst other aspects the product and its specification, the active substance(s), product uses, product labelling and classification (if required).

All sections must be completed. A worked example is provided in Section 3.2 of this guidance document.

Supporting document, described in Section 3.3 of the guidance document, must also be provided with the application.

The application form for a biocidal product notification can be found at the DAFM-PCD website.
• trivial amendment of an existing notified biocidal product.

The relevant section or sections of the notification application form that relate to the change or changes to be made on the biocidal product must be completed.

Worked examples of each section are provided in Section 3.2 of this guidance document.

Applicants may also need to submit additional updated or new supporting documents (see Section 3.3) where the changes made to the notified product have an impact on the data held on the product record.

Where the applicant is updating company and/or contact details the applicant must submit an updated CCS Customer Registration Form (see Section 3.5)

The application form for a change to a notified biocidal product (trivial amendment) can be found at the DAFM-PCD website.
3.3 Filling out an Application Form

Section 1: Notification Holder
This is where the applicant fills out their company details. The applicant is the notification holder as described in Statutory Instrument 427 of 2013. New applicants are required to complete a Corporate Customer System form. An example CCS form can be found at section 3.4 on page 14 of this document.

Example:

![Example of Section 1: Notification Holder](image)

Section 2: Production Information
The notification holder must provide the required information about the product that is being notified/amended.

Example:

![Example of Section 2: Production Information](image)

A full list of product types can be found in Annex 5 of the Regulation of Biocidal Products 528 of 2012.

A full list of formulation types can be found with this document.
Section 3: Product Manufacturer

In this section the company details of the product manufacturer are filled in. State ‘As Notification Holder’ if the manufacturer is the same company as the notification holder.

Example:

![Section 3: Product Manufacturer](image)

Section 4: Use Information

The notification holder must describe what the product is designed to do and also if the product is designed to be used by amateurs or professionals.

Example:

![Section 4: Use Information](image)
Section 5: Labelling Information
Please attach to applications the draft product label for Ireland (see Section 3.4). It is important that the label is prepared in accordance with the classification, labelling and packaging provisions of Regulation (EC) 1272/2008 and Article 69 of the Biocidal Products Regulation.

Section 6: Packaging Information
The packaging on the product should be described in this section. This includes packaging type, packaging material(s) and packaging size(s).

Example:

<table>
<thead>
<tr>
<th>Section 6: Packaging Information*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack type(s)</td>
</tr>
<tr>
<td>Plastic Bottle contained in a wall mounted dispenser</td>
</tr>
<tr>
<td>Plastic Bottle for desk use contained in a pump action dispenser</td>
</tr>
</tbody>
</table>

* Insert additional rows if required

Section 7: Primary Distributor(s)
The details of the company/companies used to distribute the product must be filled in here if they are different to the notification holder.

Example:

<table>
<thead>
<tr>
<th>Section 7: Primary Distributor(s)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name (1):</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Company Tel:</td>
</tr>
<tr>
<td>Company Name (2):</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Company Tel:</td>
</tr>
</tbody>
</table>

* Insert lines for each distributor if required
Section 8: Active Substance manufacturer

The details for the active substance manufacturer must be completed in this section for each manufacturer of each active substance contained in the product.

The active substance supplier in the product must be included on the Article 95 list (Section 3.4.3).

Example:

<table>
<thead>
<tr>
<th>Active Substance (I):</th>
<th>Ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company name:</td>
<td>ACME Chemical Company</td>
</tr>
<tr>
<td>Address:</td>
<td>New Road, Oldtown, Co Cork</td>
</tr>
<tr>
<td>Company Tel:</td>
<td>00 353 2 123456</td>
</tr>
<tr>
<td>Company email:</td>
<td><a href="mailto:sales@acmechemicals.ie">sales@acmechemicals.ie</a></td>
</tr>
</tbody>
</table>

* Insert additional rows if required
Section 9: Active Substance and Co-Formulant Information

This is where the applicant specifies information in relation to the active substance(s) and co-formulant(s) where they classify. Please note: The total quantities for the pink and green columns must add up to 1000 and 100, respectively.

<table>
<thead>
<tr>
<th>Identity of Active Substance in the product</th>
<th>Trade name (if applicable)</th>
<th>CAS No</th>
<th>Manufacturer of AS</th>
<th>Function of the co-formulant</th>
<th>Content of co-formulant in the product (as a quantity) units - g/kg, g/L etc</th>
<th>Content of active substance in the product (as a %) units - w/w or %v/v</th>
<th>SDS Attached Yes/No</th>
<th>LoA Attached Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol 64-17-5 No N/A ACME Chemical Company 999.99 100.0g/l 1.0 %v/v Yes Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colour Red Red 1234 1234-123 The Big Dye Company Dye 2.00g/l 0.20 No Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purified Water N/A 77-32-18-5 Waterworks Ltd Solvent 878.0g/l 87.80 No Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerin N/A 58-81-5 The Big Glycerin Co Ltd. Humectant 20.0g/l 2.00 No Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.

*Where the application is for a biocidal product generated in situ from 2 or more precursor products, please add an additional specification table for each precursor product.
3.4 Accompanying Documentation

In addition to a completed application other information and documents are also required. These must be submitted with the application for notification or revised versions must be provided where a change to an existing notification is made that requires revisions to supporting information/documents.

3.4.1 Safety Data Sheets (SDS)

SDSs include information about the properties of the substance or mixture, its hazards and instructions for handling, disposal and transport and also first-aid, fire-fighting and exposure control measures. The format and content of the safety data sheets are specified in the REACH Regulation 1907/2006.

Safety Data Sheets (SDS) must be provided with the application for:

- the active substance(s) contained in the product; and
- for the biocidal product(s); and
- for a co-formulant(s) in the biocidal product that contributes to the classification of the product or are a substance of concern (SoC) or are Substance of Very High Concern (SVHC).

The SDS should be updated without delay if new information becomes available on the hazards or the need for more stringent risk management measures.

Guidance on the compilation of Safety Data Sheets can be found on the ECHA website.

3.4.2 Biocidal Product Label (draft)

The draft biocidal product label(s) that will be used in Ireland must also be provided. The biocidal product labelling must provide the information specified in Article 69 of the Biocidal Products Regulation (EU) 528/2012.

The specified information contained in Article 69 can be obtained from the Biocidal Products Regulation.

Additionally, if the product classifies (e.g. flammable, corrosive, toxic) the labelling of the product must be carried out in line with the CLP Regulation (EC) 1272/2008.

Guidance on the labelling of products in accordance with the CLP Regulation can be found on the ECHA website.
The PCS number must also be displayed on the label and packaging. This can only be done once it has been issued by DAFM-PCD. On receipt of the PCS number the applicant must supply the final label that has the PCS number displayed on the product label.

3.4.3 Article 95 Compliance (List of active substance and product suppliers)

From 1 September 2015, a biocidal product consisting of, containing, or generating a relevant substance, for a given product-type cannot be notified if the substance supplier or product supplier is not included in the Article 95 list.

The Article 95 list is published by ECHA and can be downloaded from their website by applicants to determine if their source of active substance or product supplier is compliant with Article 95.

The purpose of this list is to "ensure the equal treatment of persons placing active substances on the market" and all applications for biocidal product notification in Ireland must submit documentation showing Article 95 compliance.

Documentation to be submitted as part of the notification application can be either:

- Letter of supply from the active substance or product supplier; or
- Letter of access from the active substance or product supplier

Guidance and further information on the ECHA list of active substance and product suppliers (Article 95 List) can be obtained from the ECHA website.

3.4.4 Corporate Client System Form

The Corporate Client System (CCS) form is to be completed and submitted as part of the application for:

New applicants/clients of DAFM-PCD

Existing applicants/clients are updating company, financial and/or contact details as part of a trivial amendment application.

The CCS form can be downloaded from the DAFM-PCD website. A worked example CCS form can be found in Section 3.5.
3.5 Corporate Client System (CCS) Form (worked example)

Example:

<table>
<thead>
<tr>
<th>*VAT No: IE1234567J</th>
<th>And/or *CRO No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>*COMPANY NAME: ChemLtd</td>
<td></td>
</tr>
<tr>
<td>TRADING NAME:</td>
<td></td>
</tr>
<tr>
<td>*NATIONALITY: Irish</td>
<td>*LANGUAGE: English</td>
</tr>
<tr>
<td>EMPLOYER NO:</td>
<td>CONTACT NAME:</td>
</tr>
<tr>
<td>*POSTAL ADDRESS:</td>
<td>BUSINESS ADDRESS (if different)</td>
</tr>
<tr>
<td>201 TownPark Avenue</td>
<td></td>
</tr>
<tr>
<td>Ballylane Road</td>
<td></td>
</tr>
<tr>
<td>Dublin</td>
<td></td>
</tr>
<tr>
<td>Eircode/Postcode/ZIP code:</td>
<td></td>
</tr>
<tr>
<td>Telephone No: 01-123-321</td>
<td></td>
</tr>
<tr>
<td>Fax No:</td>
<td></td>
</tr>
<tr>
<td>Mobile No:</td>
<td></td>
</tr>
<tr>
<td>Email Address: <a href="mailto:info@chemltd.ie">info@chemltd.ie</a></td>
<td></td>
</tr>
</tbody>
</table>

If you are agreeable to have remittance advices and other correspondence issued this email address please tick X

If your business is liable for Professional Services it is subject to Withholding Tax. If your business relates to either the Construction, Forestry or Meat Processing Industries payments are subject to Relevant Contracts Tax.
Please tick the relevant box below.

Withholding Tax X Relevant Contract Tax □

CURRENT BUSINESS ID OR ROLE WITH DEPARTMENT:

Signature: Joe Bogg

Date: 13/06/16

*Any field denoted by an asterisk is mandatory and must be completed

This form was issued by Pesticide Controls Division and must be completed fully and returned to this Division. NOTE: Please submit bank details if you intend to receive payments from Department Agriculture, Food and the Marine
4.0 Application Procedure (What happens when an application is received?)

4.1 Application Process

1. The Applicant submits an application to the Pesticide Controls Division of the Department of Agriculture. This application should include all the required documentation listed in Section 3.4.

2. The application is checked to ensure that the application is valid. Initial checks determine whether the product is in scope of the Biocidal Products Regulation and the active substance(s) are supported under the EU Review Programme for the correct product-type.

3. When the application is deemed to be valid the product is notified or the amendment is accepted. In the case of new applications a PCS number is then assigned to the product and sent to the applicant (Notification Holder). In the case of trivial amendments the Applicant will be informed that the changes are accepted by email. In addition, the fee for notification or the trivial amendment is also issued to the notification holder.

4. For product notification the invoice is sent to the Applicant along with a request to submit the final label(s) containing the PCS number and any other outstanding information that may be required (e.g. Article 95 compliance, SDSs).

5. The notification holder must submit a final label (with PCS number), pay for the notification and/or any other information outstanding from the application within four months. If these requirements are not satisfied within four months the application will be rejected.

6. When the notification/trivial amendment fee is paid, the final/updated label and any other relevant information/documentation is provided the product file is then finalised.

7. A Notification Document is issued by email to the notification holder and the product details are uploaded on to DAFM-PCD’s “Register for Notified Biocidal Products in Ireland”.
4.2 Procedural Flow Diagram

1. An application for notification is made by the notification holder

2. Initial checks are made: A B.P? A Supported A.S.?
   - NO: Application Rejected
   - YES: Product notified with issue of the PCS number and invoice

3. A request is made for payment, final label (with PCS No.) and any additional outstanding information

4. Applicant must submit a final label and also pay for the notification within 4 months
   - NO: Application Rejected
   - YES: Notification record finalised

5. The Notification Document is issued. The product details are uploaded to Register.