Notification Process, the requirements and common mistakes

Brian Murphy
Biocide Enforcement and Product Notifications
12th March 2020
Overview

• Process for Notification of a new product & Trivial Amendments

• Application form and the Biocidal Product Register

• Common issues with applications

• The application queue

• Biocide Notifications Procedure

• Useful links
Product Notification: First Steps

1. Check the **Online register**
   - Duplication of product names is prohibited

2. Check the ECHA Active Substance **review programme**
   - Check the status or date of approval for the AS/PT combination

3. Consult our ‘**How to Guide**’
   - Mock application form explains how the form must be filled out

4. Consult the **FAQ document**
   - The FAQ is updated regularly

5. Once these steps are complete begin preparing a Notification application
Product Notification: Requirements

Applications should include:

• A fully complete application form
• Safety data sheets for the Active Substance(s) and all co-formulants
• Safety data sheet for the product
• Letter of Access or Supply for the Active Substance(s)
• Draft Irish Label
• Completed CCS Form*

*A completed CCS form is required for all new applicants so we can set them up on our system.
Received Product Notification Applications

• All notification applications must be sent to: biocide-notifications@agriculture.gov.ie

• Biocide Notifications will acknowledge receipt of the application and issue a tracker number

• At the same time an Invoice is issued
  • €300 fee applies

• Only when the invoice is paid will an application be considered for processing

• Applications completed on a first come first served basis
Evaluation of a Notification Application

• When processing an application
  • Data is evaluated
  • Added to our database in a specific format

• An application under query email is generated outlining:
  • Data gaps
  • The PCS number to be added to the final label
  • +/- other comments/ further information

• Reminder emails are issued
  • In the previous 3 months the average processing time was 11 weeks

• Applications are rejected if the data is not submitted
  • Require re application and new notification fee
Trivial Amendments

• Similar process for Trivial Amendments
  • Acknowledgement and Invoice

A Trivial Amendments is required if a change is made to any part of the application form*
• €300 fee applies

*Changes to the distributor company and/or Account holder
Trivial Amendment Submission Requirements

• Products that have been notified in the **previous 3 years**
  • Application form with the completed section(s) where the change(s) is made
  • OR resubmit the previous application form with the amendment highlighted in **RED**
  • Updated label/SDS/Letter of Access or Supply if necessary

• Products notified for **more than 3 years**
  • Will require a full application (as a new notification)
  • To complete our records

• This will be requested at processing – Application Under Query email
Changes that don’t require a fee

• Label or SDS update
  • Change of classification
  • Update to artwork
    • Change of colour scheme/Picture

• Changes to the Distribution Company or the Account Holder will be considered updates
  • Specific form available on the website
  • CCS form
Application Form Available Since July 2019

Application Form for Biocidal Product Notification

<table>
<thead>
<tr>
<th>Product Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Substance(s)</td>
<td></td>
</tr>
<tr>
<td>Product type</td>
<td></td>
</tr>
</tbody>
</table>

Please fully complete **all sections** in this application form

Application Check List – The application **MUST** include items 1-5. New customers **MUST** also include item 6. If any of these items are missing, the application will be rejected and sent back to applicant for re-submission.

1. Draft Irish label(s) (CLP/Article 69 of BPR compliant)
2. REACH compliant Safety Data Sheet(s) for the active substance(s)
3. REACH compliant Safety Data Sheet(s) for the product
4. REACH compliant Safety Data Sheet(s) for co-formulant(s)

Consult the [Mock Completed Application Form](#)
Application Form Explained

- **Section 1:** Notification holder = Entity responsible for making the product available for sale and use
  - CCS form for new companies
- **Section 2:** Product Information
  - Product type = ECHA website
  - Formulation type = OECD website
- **Section 3:** Product Manufacturer = Product formulator
- **Section 4:** Additional Product Info
  - Clarify the exact product uses
- **Section 5:** Labelling
Application Form Explained

• Section 6: **Packaging Information**
  - Pack type – exact description
  - Packaging material
  - Pack size

• Section 7: **Primary Distributor** = name and address of the Irish central distribution point(s) & **Marketing Company**

• Section 8: **Account holder** = Entity responsible for paying the notification fee and annual fees
  (CCS form for new customers)
Application form Explained

• Section 9: **Active Substance Manufacturer** = must be listed on the Article 95 list

• Section 10: **Product Specifications**
  • Wipe Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Identity of Active Substance in the product</th>
<th>CAS No</th>
<th>Purity of active substance (g/kg)</th>
<th>Content of active substance in the product (as a quantity) units = g/kg, g/L etc.</th>
<th>Content of active substance in the product (as %) units = w/w OR %v/v</th>
<th>Manufacturer of AS</th>
<th>SDS Attached Yes/No</th>
<th>Letter of access (LoA) or supply Attached Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 4</td>
<td>AS 1</td>
<td>123-11-3</td>
<td>500 g/kg</td>
<td>200 g/kg</td>
<td>20.0 % w/w</td>
<td>A Chemical company</td>
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<td>yes</td>
</tr>
<tr>
<td>2, 4</td>
<td>AS 2</td>
<td>456-45-0</td>
<td>1000 g/kg</td>
<td>11.48 g/kg</td>
<td>1.148 % w/w</td>
<td>ACME Chemical company</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Identity of Co-formulants (other than AS) in the product</th>
<th>Trade name if applicable</th>
<th>CAS No</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 co-formulant in the product (as %) units = w/w OR %v/v</th>
<th>Substance of concern Yes/No</th>
<th>SDS Attached Yes/No</th>
<th>Manufacturer of the co-formulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-formulant 1</td>
<td>n/a</td>
<td>768-78-3</td>
<td>Colour</td>
<td>3.5 g/kg</td>
<td>0.7 % w/w</td>
<td>no</td>
<td>no</td>
<td>X company</td>
</tr>
<tr>
<td>Co-formulant 2</td>
<td>n/a</td>
<td>004-05-4</td>
<td>Solvent</td>
<td>78.653 g/kg</td>
<td>78.652 % w/w</td>
<td>yes</td>
<td>yes</td>
<td>Y company</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td>1000.00 g/kg</td>
<td>100.000 % w/w</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

* Where the application is for a bicomodal product generated in situ from 1 or more precursor products, please add an additional specification table for each precursor product.
Common Issues with the Application Form

• Sections left blank
  • All sections **must be completed**
  • Form is formatted to match our database

• No active substance purity figure included

• Section 10: Formulation table
  • Content of the RED column not adding up to 1000.00
  • Content of the GREEN column not adding up to 100.00
  • Active substance content not presented as the pure active substance
  • Active substance impurity not included as a co-formulant
  • Active substance content not **identical** to the product label
  • CAS numbers on the application form not matching the review programme
Other common Issues

• Incorrect SDSs attached
  • The Safety Data Sheet (SDS) quotes a different CAS no to the application form/review programme
  • The SDS quotes the incorrect Product name or Active Substance name
  • DPD classifications are out of date
  • CLP link between the section 2 of the SDS and the Label
  • Required PPE not specified

• Letter of access or supply
  • Approved AS require a letter of access to the Active substance dossier
  • Where the AS is still in review a letter of supply will suffice
  • Confirmation must show link back to the Article 95 Company
    • Intermediary companies
Labelling issues

Elements **missing** from submitted labels

- Exact name and content of each active substance
  - Exactly as it appears on the application form
- The approval number
  - Must be indelible ink
- The name and address of the **Notification holder**
  - Other company names can appear in addition, if required
- Direction for use of the product
- User category details
- CLP classification as per the Product SDS (section 2)
- The following text is missing:
  
  ‘Use Biocides Safely and Sustainably. It is illegal to use this product for uses or in a manner other than that prescribed on this label’
Labelling Issues (2)

It is the **responsibility of the notification holder** to label in accordance with Art 69 of the Biocidal Product regulation

- Labels are not approved at notification – Checked on inspection

- Some labels mislead the risk associated with the product

- Prohibited phrases
  - ‘Non toxic’
  - ‘Natural’
  - ‘Harmless’
  - ‘Low-risk biocidal product’
  - Phrases of a similar indication

- Biocidal products should not be packaged in a way in which they may be mistaken for Food and shall not be attractive to children

An Roinn Talmhaíochta, Bia agus Mara │ Department of Agriculture, Food and the Marine
Packaging Issues: CLP

• Products classified as Corrosive and available to the general public
  • Child resistant fastenings
  • Tactile warnings

• Identification of non compliant products on inspection will result in product removal/market recall

More information is available below
• ECHA website:  

• HSA website:  
  https://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/CLP_info_sheet.pdf
The Application Queue

• The application queue had been very long
  • Staffing and recruiting issues

• Allowing reminder emails and excessive time to submit data

• Queue has now shortened
  • No longer continuing the same level of reminders
  • Applications are being rejected to prevent additional delays
# Application Queue

<table>
<thead>
<tr>
<th>Application date</th>
<th>Tracker No</th>
<th>Company Name</th>
<th>Invoice Issued</th>
<th>Invoice Paid</th>
<th>Product Name</th>
<th>Processer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/01/2019</td>
<td>1234</td>
<td>Company A</td>
<td>Y</td>
<td>2/09/2020</td>
<td>Hand sanitiser</td>
<td></td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1235</td>
<td>Company B</td>
<td>Y</td>
<td>28/01/2020</td>
<td>Germ killer</td>
<td></td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1236</td>
<td>Company C</td>
<td>Y</td>
<td>11/02/2020</td>
<td>Wood preserver</td>
<td></td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1237</td>
<td>Company D</td>
<td>Y</td>
<td>18/02/2020</td>
<td>Insect repellent</td>
<td></td>
</tr>
</tbody>
</table>

**Week 1** - All applications are received and added to the queue, invoices are issued
## Application Queue

<table>
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</thead>
<tbody>
<tr>
<td>1/01/2019</td>
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<td>Company A</td>
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<td>Hand sanitiser</td>
<td></td>
</tr>
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**Week 4-** Company B pays the invoice
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<td>Hand sanitiser</td>
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**Week 5** - Company B’s application is claimed and processing begins - an application under query email is sent
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<tr>
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<td>Insect repellent</td>
<td></td>
</tr>
</tbody>
</table>

**Week 6** - Company C pays the invoice, Company B has not responded so Company C processing begins.
## Application Queue

<table>
<thead>
<tr>
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<th>Tracker No</th>
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<td>Insect repellent</td>
<td></td>
</tr>
</tbody>
</table>

**Week 7** - Company D pays the invoice but Company B & C have submitted poor quality applications, additional time and correspondence takes up time which delays starting Company D’s application.
## Application Queue

<table>
<thead>
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<th>Tracker No</th>
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<td>Insect repellent</td>
<td></td>
</tr>
</tbody>
</table>

**Week 8 to 11** - Still unable to find time to start Company's D application due to follow-up with other companies, continued emails and phone calls.
## Application Queue

<table>
<thead>
<tr>
<th>Application date</th>
<th>Tracker No</th>
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<td>11/02/2019</td>
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<td>1/01/2019</td>
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<td>Y</td>
<td>18/02/2019</td>
<td>Insect repellent</td>
<td></td>
</tr>
</tbody>
</table>

**Week 13** - Company C submits the correct information and the product is notified
**Application Queue**

<table>
<thead>
<tr>
<th>Application date</th>
<th>Tracker No</th>
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<td>Company D</td>
<td>Y</td>
<td>18/02/2019</td>
<td>Insect repellent</td>
<td>XX</td>
</tr>
</tbody>
</table>

**Week 14** - Company D is claimed and processing begins – They read the guidance, all the information is correct and an application under query email is sent to request the final label
### Application Queue

<table>
<thead>
<tr>
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<td>Company D</td>
<td>Y</td>
<td>18/02/2019</td>
<td>Insect repellent</td>
<td>Complete</td>
</tr>
</tbody>
</table>

**Week 16** - Company D submit the product label and the product is notified
## Application Queue

<table>
<thead>
<tr>
<th>Application date</th>
<th>Tracker No</th>
<th>Company Name</th>
<th>Invoice Issued</th>
<th>Invoice Paid</th>
<th>Product Name</th>
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<tbody>
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<td>Y</td>
<td>28/01/2019</td>
<td>Germ killer</td>
<td>Complete</td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1236</td>
<td>Company C</td>
<td>Y</td>
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<td>Wood preserver</td>
<td>Complete</td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1237</td>
<td>Company D</td>
<td>Y</td>
<td>18/02/2019</td>
<td>Insect repellent</td>
<td>Complete</td>
</tr>
</tbody>
</table>

**Week 18** - Company B submits the requested information and the product is notified
## Application Queue

<table>
<thead>
<tr>
<th>Application date</th>
<th>Tracker No</th>
<th>Company Name</th>
<th>Invoice Issued</th>
<th>Invoice Paid</th>
<th>Product Name</th>
<th>Processor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/01/2019</td>
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<td>1/01/2019</td>
<td>1235</td>
<td>Company B</td>
<td>Y</td>
<td>28/01/2019</td>
<td>Germ killer</td>
<td>Complete</td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1236</td>
<td>Company C</td>
<td>Y</td>
<td>11/02/2019</td>
<td>Wood preserver</td>
<td>Complete</td>
</tr>
<tr>
<td>1/01/2019</td>
<td>1237</td>
<td>Company D</td>
<td>Y</td>
<td>18/02/2019</td>
<td>Insect repellent</td>
<td>Complete</td>
</tr>
</tbody>
</table>

**Week 24** - Company A pays the invoice
Application Queue

• Timelines for the current example

<table>
<thead>
<tr>
<th></th>
<th>Payment length</th>
<th>Processing length</th>
<th>Total length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company A</td>
<td>24 weeks</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Company B</td>
<td>4 weeks</td>
<td>14 weeks</td>
<td>18 weeks</td>
</tr>
<tr>
<td>Company C</td>
<td>6 weeks</td>
<td>7 weeks</td>
<td>13 weeks</td>
</tr>
<tr>
<td>Company D</td>
<td>7 weeks</td>
<td>2 weeks</td>
<td>16 weeks</td>
</tr>
</tbody>
</table>

• Multiplying this example
  • 22 product types
  • Over 5000 products currently on our register
  • Approximately 800 applications received annually
Expectation...

Application submitted

Biocide Notifications request updated label with PCS number

Applicant submits documents as requested

Application completed and product notified
... vs Reality

Application submitted

Applicant submits some more data

Applicant submits the data but contains numerous errors

Poor quality information submitted

Applicant submits documents as requested

Biocide Notifications request additional data

Biocide Notifications request outstanding data

Biocide Notifications requests clarifications

Biocide Notifications set deadline for application rejection

Application is completed and product notified
New Timelines for Notifications

• Applications to be acknowledged and invoices issued within 2 - 4 weeks of submission
  • Time for invoice payment & time to allow processing begin
  • Unpaid invoice will be cancelled and the application rejected

• During processing “Applications Under Query” is issued with a max 3 week deadline to submit outstanding data
  • Guidance included in the query email

• After 3 weeks a Final Reminder email issued with a 1 week deadline for outstanding data

• Applications are being rejected after 4 weeks
  • No response or failure to submit the requested data
Documents of Interest: PRCD Website

Biocides Page of the PRCD Website

Useful Links
- About Us
- Registers
- Fees
- News
- Guidance
- DAFM

Biocides
A biocidal product (or biocide) can be a pesticide or an antimicrobial containing or generating an active substance(s) that is used to prevent or control various types of harmful or unwanted organisms. Such products include disinfectants, preservatives, insect repellents, rodenticides and insecticides. Biocides control the intended target organism by a chemical or biological action. Biocides can be used by professionals and members of the public in a wide spectrum of use areas that are classified into product types. To make sure the use of biocidal products do not have unacceptable risks for people, non-target animals and the environment, their marketing, sale and use are controlled by legislation.

Biocidal products can only be distributed and used in the Republic of Ireland if they are authorised by the Irish Competent Authority (The Department of Agriculture, Food and the Marine).

In Ireland, biocides are controlled by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 20 June 2019 on biocidal products (the Biocidal Products Regulation) or BPR.

- Brexit Information
- Active Substances
- Biocidal Products
- Treated Articles
- Use of Biocidal Products
- Biocidal Products Compliance
- Biocidal Product Registers
- Registration of Pest Management - Trained Professionals
- Changes to Use of Anticoagulant Rodenticides

Biocidal Products
Before a biocidal product can be made available on the market or used in Ireland, it must be notified, authorised or granted a permit.

- PRCD Industry Symposium on Biocidal Products 2020 (pdf 97Kb)
- Authorisation Applications
- National Notification Applications
- Permit Applications
- Product Revocation and Phase-Out Periods
- Emergency Use
- Packaging and Labelling
- Comparative Assessment
- Biocidal Products Fees
- Biocidal Product Registers
Documents of Interest: PRCD Website

Useful Links

About Us
Registers
Fees
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Guidance
DAFM

National Notification Applications

Before the EU approval of active substances for a given product-type, 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.

Before a biocidal product may be placed on the Irish market, an application for product notification must be submitted. This must be followed by submission of the biocidal product register before the product can be placed on the market. Applications for product notification and changes to a national notification can be submitted electronically to the Department of Agriculture, Food and the Marine: biocide-notifications@agriculture.gov.ie

Guidance on Applications

- Mock Completed Form
- FAQ

Document requirements for a notification

- Notifications - How to Guide
- Application to notify a biocidal product
- Application for changes to a biocidal product (trivial amendment)

Product updates & Trivial amendments
Useful Links

• Notification Guidance – ‘How to Guide’

• PRCD Product Notification page
  http://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/nationalnotificationapplications/

• Notified Biocidal Product Register
  https://publicapps.agriculture.gov.ie/prs/home

• ECHA Active Substance Review Programme
  https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

• Article 95 list of compliant Active Substance Manufacturers
  https://echa.europa.eu/information-on-chemicals/active-substance-suppliers