An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

National Notifications under Art 89

- David McKearney
- Pesticides Controls Division, Notifications and Enforcement
- 29th May 2025

Contents

- A high-level overview of the BPR
- Two stage process of Biocidal Product Registration
- Early engagement with biocidal product consultants for authorisation
- An overview of the notifications process including,

- Validation step
- Common issues identified
- Application form explained

Biocidal Product Regulation (BPR)

- The Biocidal Products Directive 98/8/EC was repealed in 2012 by the Biocidal Products Regulation (EU) No 528/2012, it is implemented under Irish Law by: –S.I. 427 of 2013
- All biocidal products require an Irish registration prior to making available on the market for sale and use
- “Making available on the market” means any supply of a biocidal product or a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge.

What is a biocidal product?

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the **intention** of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, **any harmful organism** **by any means** other than mere physical or mechanical action,
- any substance or mixture, **generated** from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Product Types (PT's)

- The Biocidal Products Regulation (BPR) controls the sale and use of biocidal products in ROI. There are 22 different product types (PTs) which are split into 4 groups.

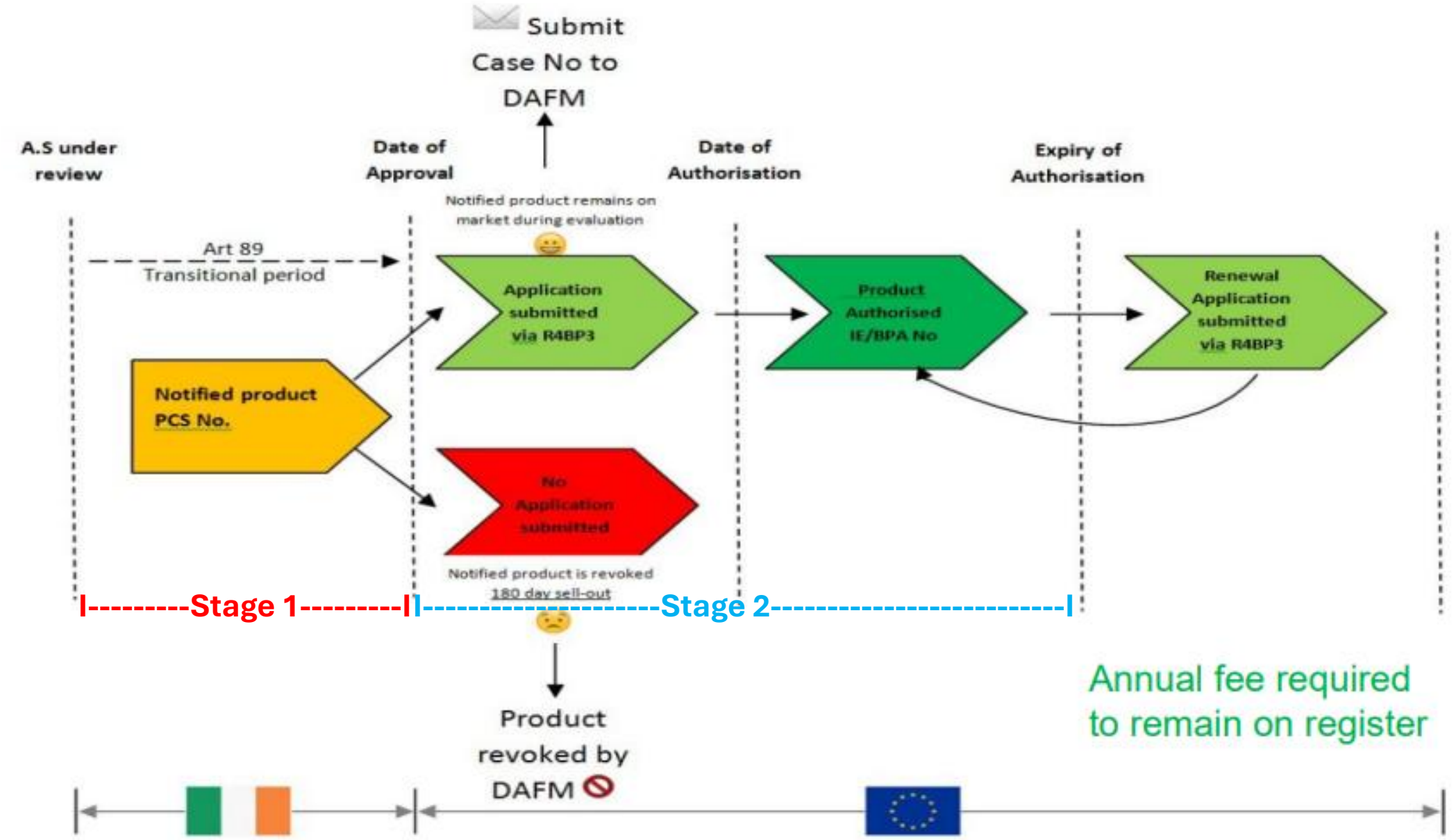
PT01 – PT05	Products used as disinfectants
PT06 – PT13	Products used as Preservatives
PT14 – PT20	Products used in Pest Control
PT21 – PT22	Other - Antifouling paints/Embalming Agents

https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

The 2 Stage Process

- **Stage 1** – The existing Active Substances (AS's) are evaluated at EU level (review programme). The review has been extended until December 2030.
- While the AS/PT combination is 'in progress' **or** if the assigned 'Date of approval' (DOA) has not yet passed, products can avail of the transitional period (article 89) known as Notifications (PCS numbers)
- **Stage 2** – When the AS/PT combination is approved at EU level, for the product to remain on the market under transitional measures, a **valid dossier must be submitted** for evaluation with a view to full authorisation.
- Once the product has been evaluated and authorised the transitional product is revoked, and the PCS No. is replaced by an IE/BPA No. or EU No.

Product Lifecycle



Next steps?

Different options available

- Prepare an authorisations dossier yourself in-house
- Hire a consultant to submit an authorisation on your behalf
- Form a taskforce or a consortium
- Become a marketing company

Notifications Process – Article 89

Requirements

- A fully complete notification application form
- Safety data sheets for the Active Substance(s) and SDS for each co-formulant
- Safety data sheet for the product itself
- Letter of Access **or** a letter of Supply for the Active Substance(s)*
- Draft Irish Label
- Unique tradename
- Completed CCM Form **

Submission Validation step

- Added in February 2024
- Incomplete/incorrect documentation submitted was causing huge delays and an inefficient use of time.
- Only fully completed submissions with all required documentation are accepted.
- Applications deemed incomplete following validation are **rejected** and **must be resubmitted by the applicants**
- Common issues identified on rejected applications include; incomplete/outdated application forms, insufficient proof of article 95 compliance, missing SDS's

Notification Submission Validation criteria

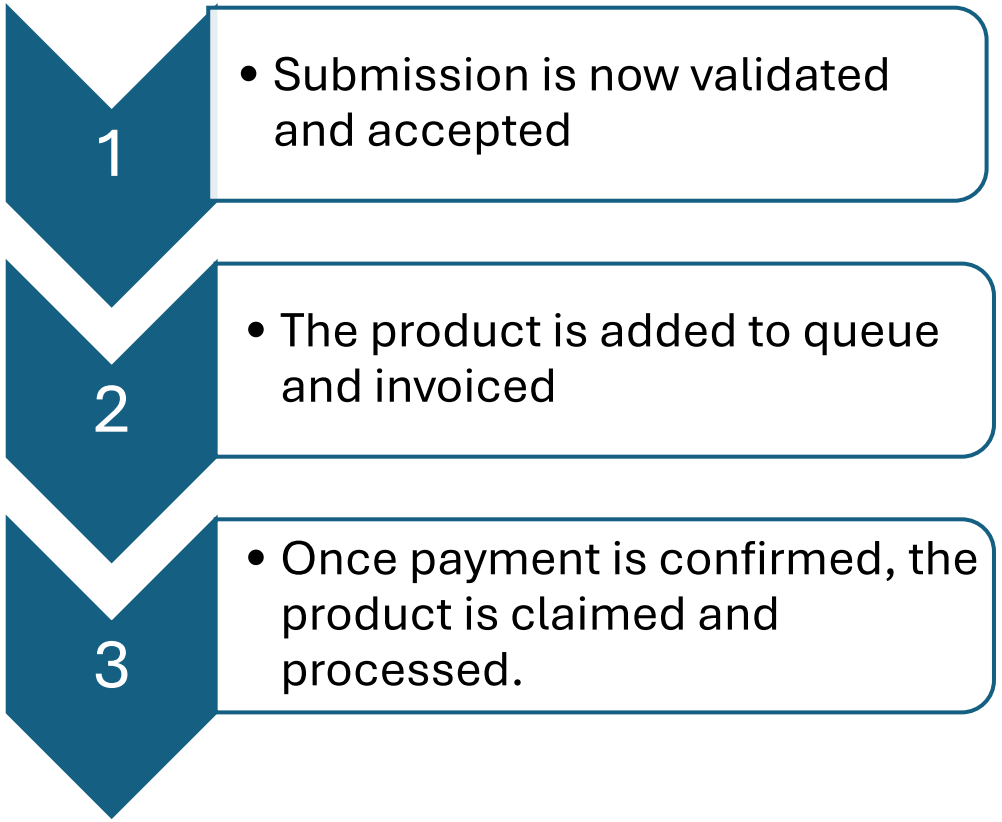
Task	Complete (Y/N)
Is the Active Substance(s) (AS) in the review programme?	
Is there a Date of Approval (DOA), if so, was the application submitted before the DOA?	
Current version of application submitted (December 2024)?	
Are all sections of the application form fully completed?	
Formulation adds up to 1000.00 and 100.00 % exactly?	
Draft Label submitted?	
SDS for each AS submitted?	
SDS for all co-formulants submitted?	
SDS for biocidal product submitted?	
LoA submitted for each AS?	
Unique trade name?	
CCS form (if applicable)	
Initial and date on completion	

Validations Continued

- The validation step, has been extremely positive for our team and notification holders
- Notifications queue wait time in 2020 – 9 Months
- Wait time in 2024 **prior** to validations step – 4-6 months
- Current wait time following addition of validation step – 3/4 weeks if paid
- Quality of applications have improved
- Beginning of the validation step had approx. 75% application rejection >> 20% rejected now

**This allows the applicants who submit good quality applications to enter the market as quickly as possible **

Steps following validation



Applications paid sooner are claimed and completed sooner

Last 50 new & TA applications took on average 65 Days from receipt of application to payment and 30 days to complete once paid.

Issues that cause delays during the notification process

- Incorrect labels
  1. Missing PCS number
  2. Missing mandatory statements
  3. Directions for use/ product claims are not in line with the PT description or the BPR
  4. AS concentration on the label is different to the application form
- Product SDS missing the NPIC information (If applicable - UFI)
- Images of fruit/food on product labels

Food on labels update

Updated Guidance on food on labels of biocidal products. Details to be circulated via Biocides Newsletter next week

For Authorised products

- **No food images allowed** on authorised products

For Notified products

- **No food images allowed** on notified products which **classify**
- A max of 1 small food item allowed on notified products which do not classify under CLP.

Changes that don’t require a fee

- Label or SDS updates which may include..
    1. Change of classification
    2. Update to artwork
    3. Change of colour scheme/pictures
    4. Addition of a UFI code to the product (legal requirement under CLP Reg 1272/2008 since January 1st 2025).

Application Form Explained (1)

December 2024

Section 1: Notification holder = Company responsible for the product making the product available for sale and use.

Section 2: Product Information

- Product Function
- Product type = ECHA website
- Formulation type = OECD website
- UFI code

- Section 3: Product Manufacturer of the Biocidal Product

Section 1: Notification Holder* (person responsible for placing the product on the market)

Company Name:	**A Biocide Company**		
Address:	**General Inner Road, Dublin, T12 Q34**		
Company Tel:	**+12345678**	Company email:	support@biocidecompany.ie
Company contact:	**Mr Joe Bloggs**	Contact Tel:	
Contact email	Joebloggs@biocidecompany.ie		
DAFM Customer number (if available)	**12345678**	Purchase Order number (if available)	**PO9876**

**If you are a new applicant/client with the Department of Agriculture, please also fill out the Corporate Customer System (CCS) form on the final page of this document.*

Section 2: Product Information

Product name (Trade name):	**Biocide Product**
Product-type(s):	**PT2**
Product Function:	**Disinfectant**
Formulation type: *(AL, SL, etc.)*	**AL**
UFI Code (if known):	**UFI: QW12-ER34-TY56**

Section 3: Product Manufacturer

Company Name:	**AS NOTIFICATION HOLDER**		
Address:			
Company Tel:		Company email:	
Company contact:		Contact Tel:	
Contact email:			

Application Form Explained (2)

- Section 4: Additional Product Info.

- Clarify the exact uses

(Fogging/Misting require tox. Reports)

- Section 5: Labelling Information

- listed on page 12 of the application

- Section 6: Packaging Information

- Pack type - exact description
- Packaging material
- Pack size

Section 4: Additional Product Information

(Each PT listed in section 2 must be described, 1800 Characters Max)

Brief description of intended uses: **Used for the disinfection of toilets and sinks and other bathroom surfaces only**

For amateur use:	Yes	X	No		For professional use:	Yes	X	No	
For indoor use:	Yes	X	No		For outdoor use:	Yes		No	X
For Fogging/Misting Use^:	Yes		No	X	Toxicology report attached:	Yes		No	X

Please note that if you answered '**Yes**' above, and the product is intended to be applied via a fog or a mist, a ^toxicology report **must** be submitted for a risk assessment to be carried out for that use.

If necessary, please specify the use area further:

Section 5: Labelling Information

Please attach to this completed application the draft product label for Ireland. 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 EU 528/2012. See final page for specific labelling requirements which must be on the final label submitted to complete the notification.

Section 6: Packaging Information*

Pack type(s)	Packaging material(s)	Pack size(s)
Plastic Bottle with child resistant plastic cap	Bottle - HDPE Cap - HDPE	750ml, 1000ml

Application Form Explained (3)

- Section 7A: Primary Distributor = name and address of the Irish central distribution point(s)
- Section 7B: Marketing Company
- Section 8: Account holder = Entity responsible for paying the notification fee and annual fees

Section 7a: Primary Distributor(s)

Distributor Company Name (1): **Irish Distributor Company**

Address: **Newtown Road, Monaghan A12 NM23**

Company Tel: +353 1234 5678 Company email: **Queries@IrishDisCom.ie**

Company Name (2): **n/a**

Address:

Company Tel: Company email:

**Insert lines for each distributor, if required*

Section 7b: Marketing Company

Marketing Company Company Name: **Same as Distributor company**

Address:

Company Tel: Company email:

*Section 8: Account Holder (company responsible for paying the notification and annual fees) **

Company Name: **As Notification Holder**

Address:

Company Tel: Company email:

Company contact: Contact Tel:

Contact email

DAFM Customer number Purchase Order number

** If the company named here is a new applicant/client with the Department of Agriculture, please also fill out the Corporate Customer System (CCS) form on the final page of this document.*

Application Form Explained (4)

- Section 9: Article 95 Listed Active Substance Manufacturer
- Section 10: Product Specifications

Section 10: Product Specification continued. *

Please specify units below in the content of "Active Substance" (previously known as technical content) columns in red and green

For information on using the correct units, please refer to the table on page 10 of this document - 'Common Issues Identified'.

Product type (PT)	Identity of Active Substance in the product (as Listed on the review programme)	CAS No	Purity of active substance (g/kg)	Content of "active substance" in the product	Units g/kg, g/L etc.	Content of "active substance" in the product (as a %) units = w/w OR %v/v	Units %w/w, %w/v, Etc.	Manufacturer of AS	SDS Attached Yes/No	Letter of access (LoA) or supply Attached Yes/No
PT02	Active substance 1	1234-56-78	800g/kg	100	g/kg	10%	w/w	Chemical Company	yes	yes

Identity of Co-formulants (other than AS) in the product	Trade name (if applicable)	CAS No	Function of the co-formulant	Content of co-formulant in the product	Units g/kg, g/L etc.	Content of co-formulant in the product (as a %) units = w/w OR %v/v	Units %w/w, %w/v, Etc.	Substance of concern Yes/No	SDS Attached Yes/No	Manufacturer of the co-formulant
Co-Formulant 1	CoForm®	12-34-56	Surfacant	800	g/kg	80%	w/w	no	yes	X Company
Co-Formulant 2	FormCo®	65-43-21	Solvent	100	g/kg	10%	w/w	no	yes	Y Company
Total				1000		100				

NB: the total quantities for the pink and green columns must add up to 1000.00g/Kg and 100.00%, respectively.

** Where the application is for a biocidal product generated in situ from 2 or more precursor products, a separate application form is required.*

Key Take Home Messages

- The registration of biocidal products is a 2-stage process
- The notifications phase is the transitional period used to facilitate the lead into the authorisation process.
- Early engagement with the authorisation process is key.
- The validations step in the notifications has greatly reduced wait times for notifying products and raising overall compliance rates.
- Make yourself familiar with the common issued identified so you can avoid them.

- Queries on any of these topics discussed today can be emailed directly to Biocides@agriculture.gov.ie

Thank you for listening!