General Policy for Biocide Authorisation Applications to the Irish Competent Authority:

Mutual Recognitions

Same Biocidal Products

Change Applications

September 2026

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1. Overview

The purpose of this document is to outline the general policy of the Irish Competent Authority for Biocides (IE CA) for applications for mutual recognition, same biocidal products and change applications under the Biocidal Products Regulation (EU) No 528/2012 (BPR).

1.1. Relevant Regulations and Legislation

Biocidal Products Regulation (EU) No 528/2012 (BPR): Biocidal Products Regulation (EU) No 528/2012

Same biocidal product applications: COMMISSION IMPLEMENTING REGULATION (EU) No 414/2013

Changes of biocidal products: Implementing regulation - 354/2013 - EN - EUR-Lex

Transposition of above into Irish Law and specific conditions of authorisation for biocidal products in Ireland: S.I. No. 427/2013 - European Union (Biocidal Products) Regulations 2013.

1.2 Register for Biocidal Products (R4BP3)

The Register for Biocidal Products (R4BP3) is an information system established and maintained by European Chemicals Agency (ECHA) in accordance with Article 71 of the BPR with the aim of ensuring that the BPR processes are managed. R4BP3 provides appropriate functions that allow the exchange of information between industry and authority users (ECHA, MSCAs and Commission). R4BP3 is used to record and communicate the decisions on authorisations taken by Member States and at Union level (see Article 71(6) of the BPR). R4BP3 consists of two main independent applications, one for all the authority users and one for industry users. All mutual recognition and change applications must be submitted through R4BP3. All additional communication and documentation (SPC's and product labels) related to an application must be submitted under the relevant case on R4BP3.

Further information:

ECHA guide for making applications on R4BP3: https://echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation.

ECHA guide on how to prepare an SPC: https://echa.europa.eu/documents/10162/17242/best_practice_spc_iluclid_preparation_en.pdf

ECHA technical support: https://echa.europa.eu/contact/technical-support

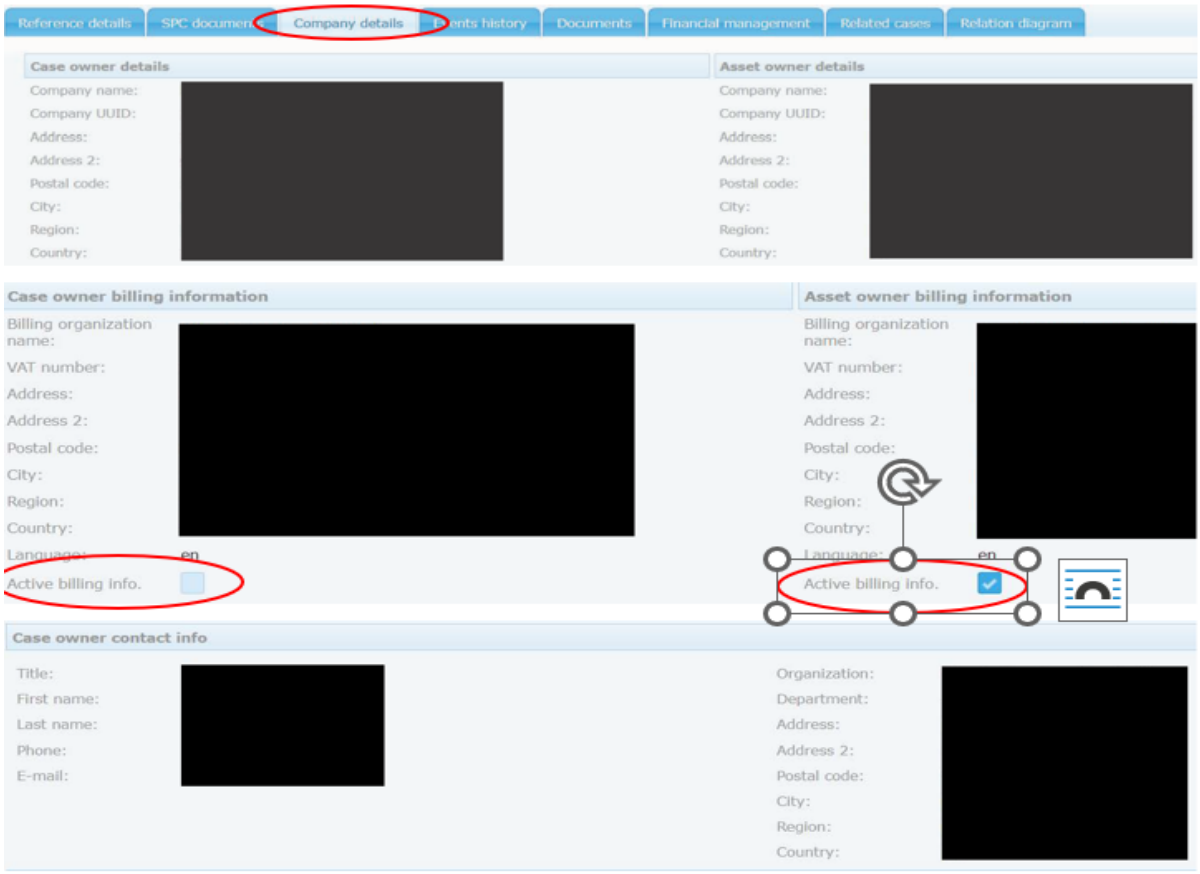
2. The procedures for receipt and payment for applications:

2.1. Receiving & invoicing an application

Once an application is received on R4BP3 it is added to our internal application queue and invoiced in line with Article 80 (2) of the BPR, as per the company details linked to the case. Applications will remain on hold until the invoice has been paid in full. The application may be rejected where fees are not paid within 30 days of invoicing. Information on fees is available on our website through the following link: https://www.pcs.agriculture.gov.ie/fees/.

Please ensure company details are correctly included and updated on R4BP3. It is the responsibility of the applicant to ensure company details are maintained accurately and ensuring the correct company name is included in each of the sections i.e. case owner, asset owner and billing information. Ensure active billing information is selected for the entity to be invoiced as per the screenshot below. Please ensure all contact information is populated including name(s) and at least one email address.

Screenshot of Company details page on R4BP3:



The case/asset owner indicated for 'active billing info' needs to be registered on our internal accounting system for invoicing and contact purposes. A Company Registration form (CCS form) will be issued on receipt of an application on R4BP3 and **must** be completed and returned immediately to enable invoicing of the application. Any delay in submitting a completed CCS form will delay the invoicing process and future processing of the application.

A CCS form can be downloaded from our website https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/authorisationapplications/.

3. Biocidal product labels

3.1. Marketing status of the product/trade name(s) in Ireland

a) Where the product/trade name(s) are to be placed on the market immediately after authorisation:

Final label(s) must be **reviewed and approved** by the IE CA if the product/trade name(s) are to be placed on the market in Ireland **immediately** after authorisation. This is in line with Condition 6 of the Product Authorisation outlined below. The final label should include all artwork as it will appear on the market. Product labels must be submitted through correspondence on R4BP3 under the relevant case and will not be accepted through email.

Condition 6 of Authorisation:

"6. A printed copy of the Irish label in accordance with the Annexes of this authorisation must be submitted to the Irish Competent Authority for Biocides prior to any product being made available on the market in Ireland. All product labels must carry the authorisation number of the form: IE/BPA 70XXX."

b) Where the product/trade name(s) are NOT to be placed on the market immediately after authorisation:

If the product/trade name(s) are **NOT** going to be placed on the market in Ireland **immediately**, it may be authorised as "Not Marketed" on the Certificate of Authorisation and on our Authorised Biocidal Product Register. Information on the marketing status can be included in the supporting document or in correspondence to IE CA on R4BP3.

Prior to placing the product on the market product labels must be reviewed and approved by the IE CA in line with Condition 6 of the authorisation. Product labels must be submitted

through correspondence on R4BP3 under the relevant approved case and will not be accepted through email.

3.2. Labelling requirements for biocidal products in Ireland

All points addressed under Article 69 of the BPR and the information should be included on the product label exactly as prescribed in the relevant sections of the SPC, but not limited to, the details outlined below:

- Section 1: The exact trade name as listed on the SPC. The tradename for the product must read top to bottom uninterrupted by marketing claims or additional words.
- Section 2: Exact name and concentration of the active substance(s), and type of formulation.
- Section 3: The CLP classification as prescribed in the SPC should be included in a separate text box with pictograms, signal word, hazard statements and precautionary statements (as required).
- The IE/BPA No. 7XXXX must be placed in the bottom right-hand corner of the CLP information text box in bold writing.
- Section 4 & 5: Authorised use details included in the SPC and all information outlined in the following sections:
  - 4.1; 4.1.1; 4.1.2; 4.1.3; 4.1.4; 4.1.5;
  - 5.1; 5.2; 5.3; 5.4; 5.5;
  - 6 (if applicable).
  - In particular risk mitigation measures must be included on the product label or an accompanying leaflet.
- The formulation batch number or designation and the expiry date relevant to normal conditions of storage. The expiry date must be clearly included in a date format for the end user e.g. DD/MM/YYYY or MM/YYYY. A date of manufacture and shelf-life will not suffice.
- A valid UFI code (See link to NPIC* FAQ Document: Poisons Centre - Ireland FAQ) (See link to other NPIC guidance also Industry / Manufacturers - National Poisons Information Centre of Ireland , Product Registration - National Poisons Information Centre of Ireland)
- "Special Labelling Provisions for Ireland" (outlined below) must be included on the product label.

- 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.
- Poison Information:
  For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-809 2166), retain the label for reference.

*Please note there may be additional requirements prescribed in the "Special Labelling Provisions for Ireland" for different product types.

For further information on labelling requirements for the IE CA, please refer to our website through the following link: https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/

4. Processing Mutual Recognition applications

The following steps outline the procedure followed by the IE CA when processing mutual recognition applications:

Step 1. Reference Application is Approved (For Parallel applications only).

Step 2. If necessary, a request is sent to the applicant to submit an updated draft SPC & product labels (up to 4-weeks for submission)

Step 3. Review Submitted documents – For in sequence applications, peer review/commenting will be initiated with the rMS if necessary.

Step 4. Request any amendments if required (up to 2-week for submission)

Step 5. Approve/non-approval decision

Note: Incomplete applications lead to longer processing times, which results in a longer application queue. Applications may be rejected where no information/documentation is received within the specified time periods. There will be no refund of fees paid in the case of rejection of an application by IE CA. Where additional time is required to submit requested documentation, please notify the IE CA through correspondence on the relevant case on R4BP3.

4.1. Mutual Recognition and Same Biocidal Product in Parallel applications

Once the reference application (NA-APP) is approved, the applicant should promptly resubmit an updated draft Summary of Product Characteristics (SPC; i6z) to the IE CA aligned with the text from the final approved SPC in the reference Member State (rMS). Draft product labels including artwork (in pdf format) should be submitted to the IE CA for review and approval.

Section 3 above outlines the specific requirements for biocidal product labels in Ireland.

4.2. Mutual Recognition and Same Biocidal Product in Sequence applications

The SPC (i6z) submitted with an in-sequence application (NA-MRS/NA-BBS) should be aligned exactly with the Reference Member State (rMS) at the time of application. Draft product labels including artwork (in pdf format) should be submitted to the IE CA for review and approval. Section 3 above outlines the specific requirements for biocidal product labels in Ireland.

4.3. Considerations for in-sequence applications (NA-MRS/NA-BBS)

- Consider any change applications (NA-ADC/NA-MIC/NA-MAC) that may be on-going in the rMS that may impact the NA-MRS/NA-BBS application submitted to the IE CA. Any changes will thereafter be required on the Product Authorisation in the IE CA in line with Article 32 (2):
  "Without prejudice to Article 37, all Member States receiving applications for mutual recognition of a national authorisation for a biocidal product shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions."
- Consider if a renewal (NA-RNL) has been submitted to the rMS before the NA-MRS/NA-BBS application is approved in the IE CA. If so, a renewal application must be submitted to the IE CA following the product authorisation.
- Authorisation holders should inform the IE CA (as the rMS) if an NA-MRS application is to be submitted to another Member State.

5. Processing a change application (NA-MIC, NA-MAC, NA-ADC)

The following steps outline the procedure followed by the IE CA when processing change applications:

Step 1. Reference Application Approved (For parallel & grouped applications only).

Step 2. If necessary, a request is sent to the applicant to submit an updated draft SPC & product labels (up to 4-week for submission)

Step 3. Review Submitted documents

Step 4. Request any amendments if required (up to 2-week for submission)

Step 5. Approve/non-approval decision

Note: Incomplete applications lead to longer processing times, which results in a longer application queue. Applications may be rejected where no information/documentation is received within the specified time periods. There will be no refund of fees paid in the case of rejection of an application by IE CA. Where additional time is required to submit requested documentation, please notify the IE CA through correspondence on the relevant case on R4BP3.

5.1. NA-MIC & NA-MAC

a) Where IE CA are the reference member state (rMS)

Applicants should ensure that all relevant documents are submitted with a change application including:

- An updated draft SPC (i6z);
- A completed supporting document including a detailed description of the change requested. Applicants should ensure all concerned member states are included in the supporting document.
- All additional studies/data should be added to the IUCLID dossier for the product. No study/data should be submitted by R4BP3.

The IE CA will update the PAR as required and manage the peer review process with all concerned member states. The PAR will be sent to the applicant for review for a period of up to 30 days prior to the peer review process commencing.

Where product label amendments are required, labels should be submitted to the IE CA for review and approval immediately after the case has been approved on R4BP3. Please refer to section 3 above which outlines the specific requirements for biocidal product labels in Ireland.

b) Where IE CA are a concerned member state (cMS)

Once the reference application is approved the Authorisation holder should promptly resubmit an updated SPC (i6z) to the IE CA aligned with the final approved reference SPC. The IE CA will partake in the peer review process as indicated by the rMS. Draft product labels including artwork (in pdf format) should be submitted to the IE CA for review and approval, if label amendments are required. Please refer to section 3 above which outlines the specific requirements for biocidal product labels in Ireland.

5.2.NA-ADC

a) Where IE CA are the reference member state (rMS)

Applicants should ensure that all relevant documents are submitted with a change application including an updated draft SPC (i6z), a completed supporting document including a detailed description of the change requested, along any other relevant documentation. The IE CA will update the PAR as required.

Where additional trade names are being added to the authorisation or label updates are required, draft product labels including artwork (in pdf format) should be submitted to the IE CA for review and approval at the time of application to avoid delays. Please refer to section 3 above which outlines the specific requirements for biocidal product labels in Ireland.

b) Where IE CA are a concerned member state (cMS)

Grouped Application:

Applications made under a grouped submission will only be processed following the decision by the rMS in line with Article 32 of the BPR. Applicants should submit a draft SPC to the IE CA at the time of application. Any further amendments that may occur during the processing of the reference application should be reflected by resubmitting an updated SPC to the IE CA.

Individual Application to IE CA:

Applicants should ensure that all relevant documents are submitted with a change application including an updated draft SPC (i6z), a completed supporting document including a detailed description of the change requested, along any other relevant documentation.

Where additional trade names are being added to the authorisation or label updates are required, draft product labels including artwork (in pdf format) should be submitted to the IE CA for review and approval **at the time of application** to avoid delays. Please refer to section 3 above which outlines the specific requirements for biocidal product labels in Ireland.

5.3. Considerations for change applications

The Authorisation holder should ensure the updated draft SPC incorporates the change requested that is also reflected exactly as outlined in the supporting document. Ensure any changes made in the SPC are limited to the change that is requested in the supporting document.

For example, for the addition of a trade name, please ensure that the exact trade name is included in the supporting document and the exact trade name is also included in the relevant section of the SPC. There should be no other amendments made to the draft SPC.

In line with condition 2 of the authorisation applicants must inform the IE CA where any amendments are made to the original authorisation in another Member State.

"Condition 2:

The requirements and conditions, specified in the Annexes, of this authorisation may not be altered without prior approval of modifications by the Irish Competent Authority for Biocides in Ireland. Where any amendments are made to the original authorisation in another Member State, the Irish Competent Authority for Biocides in Ireland must be informed by the Authorisation Holder."

5.4. Cancellation of an authorisation/Removal of trade names

An applicant can cancel an authorisation by submitting an NA-CCL application on R4BP3.

If removing trade name(s) from an authorisation this must be done by submitting an NA-ADC application on R4BP3. Applicants must ensure all of the trade names to be removed are correctly listed on the supporting document and removed from the draft SPC submitted as part of the application.

The date the NA-ADC/NA-CCL application is approved by the IE CA is the date of revocation. A period of grace for the sell-out and use up of existing stocks will apply in line with Article 52 of the BPR from the date of revocation. No new stock should be placed on the market from the date of revocation.

5.5. Transfer of a National Authorisation (NA-TRS)

Where the authorisation holder is changing legal entity an NA-TRS application should be submitted. An updated CCS form needs to be submitted to allow PCD to update our internal accounts system. This will be requested on receipt of an application on R4BP3. A CCS form can be downloaded from our website https://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/authorisationapplications/.

Updated product labels should be submitted for review and approval by the IE CA reflecting the new authorisation holder details. Please refer to section 3 above which outlines the specific requirements for biocidal product labels in Ireland.

6. Annual Registration fees (ARF)

All trade names listed on an authorisation are subject to ARF in line with the condition of authorisation below. It is the responsibility of the authorisation holder to ensure the billing information is correct for the invoicing of ARF.

"Annual Registration Fees (ARF) for the maintenance of the product on the Register of Biocidal Products are payable to the Irish Competent Authority for all trade names listed on this certificate of authorisation. Following authorisation, ARF shall be paid by the 31st December of the following year and each year thereafter. This authorisation will be cancelled if ARF are not paid in due time."

7. Common SPC issues

Discrepancies between the reference SPC and draft IE SPC requires SPC documents to be resubmitted causing delays in processing applications. As per Article 32 of the BPR outlined in Section 4.3 above, mutual recognition applications can only be authorised under the same terms and conditions as per the rMS.

Some common issues found that delays processing of mutual recognition and change applications are outlined below.

7.1. Discrepancies between Reference SPC and draft IE SPC

Please ensure information included in the draft SPC for IE market area is identical to the reference SPC, for example H statements, target organisms. Examples included below are unacceptable and will require amendments before the application can be processed.

a) Variances in target organisms:

Reference SPC:

Target organism(s) (including development stage)	Scientific name: Lasius niger Common name: Black Garden Ant Development stage: All development stages

Draft IE SPC:

Target organism(s) (including development stage)	Scientific name: Lasius niger Common name: ants Development stage: adults

*Common name and development stage not corresponding.

b) Variances in H Statements:

Reference SPC:

Hazard statements	H360D: May damage the unborn child. H373: May cause damage to organs (blood) through pr olonged or repeated exposure ..

Draft IE SPC:

Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure.

*H360D is missing from the draft SPC

c) Correct changes being applied to NA-ADC applications

For example, where a new trade name is being added please ensure the trade name is added correctly and no other trade names are removed unless required:

Original Authorised SPC with 3 trade names:

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	PRODUCT A PRODUCT B PRODUCT C

*In some instances, the applicant may submit the SPC as such without the addition of the new trade name

Example of an SPC submitted with the new trade name with a trade name removed by accident:

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	PRODUCT A PRODUCT C NEW TRADE NAME

SPC submitted with the new trade name as requested with no other changes to the SPC:

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	PRODUCT A PRODUCT B PRODUCT C NEW TRADE NAME

Note: Please ensure that the exact trade name is included in the SPC as per the supporting document. There should be no other amendments made to the draft SPC.

d) Document names on IUCLID SPC

Document names is a new field that was introduced with the implementation of IUCLID to maintain consistency between related applications and **cannot be changed.**

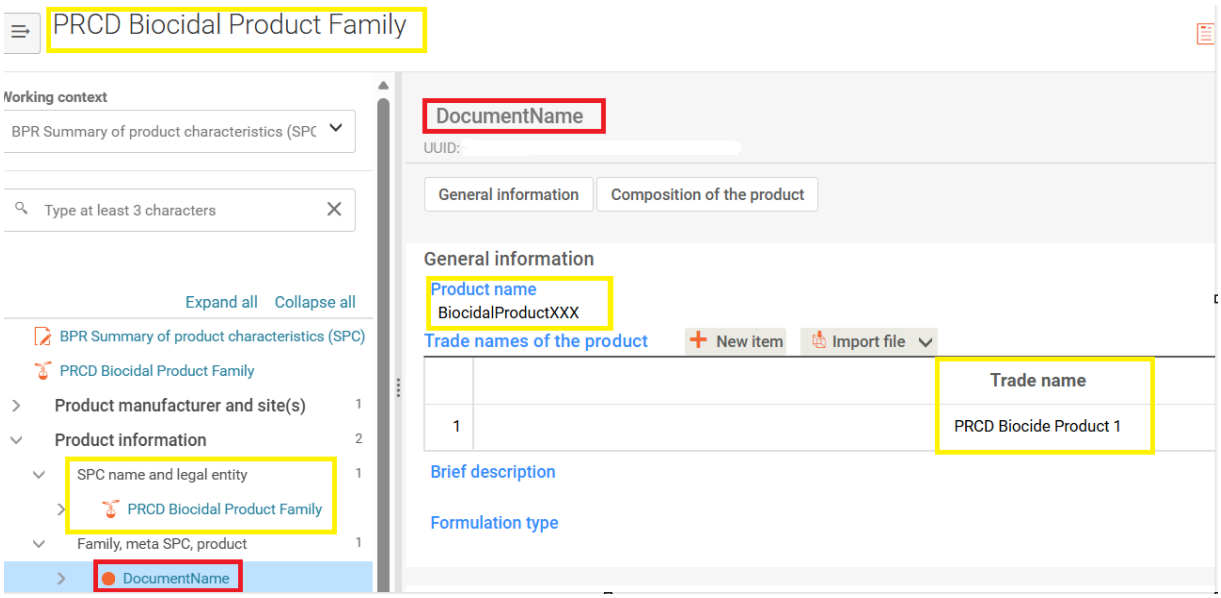
Please note, the document name **is not related to the product name or trade name**. it is merely to enable R4BP3 to ensure that there is a correlation between a reference and related applications, e.g., mutual recognitions, renewals, changes on request or same biocidal product applications.

In order to ensure that the related biocidal product(s) are identical to the related application, an SPC should be provided with the same document name(s) describing the biocidal product as available in the reference application.

If you need to identify the original document name(s) available in a SPC dossier also available in IUCLID, you can refer to the names available in the SPC tree structure of the reference SPC.

As per the screenshot below, the document name (highlighted in red) should be identical to the reference SPC.

The SPC name, Product name and Trade names can be unique to the product.



Further information on this topic can also be found on the ECHA Support Q and A 2054 found through the following link: https://echa.europa.eu/support/qas/?ids=2054.