FAQ - Notification of Biocidal products

Contents

Date: 06/01/2020

This information is current at the time of publishing.

Q1. Do I have to change my address because of Brexit?

A. The BPR states that the authorisation holder must be based in the EU. Our interpretation is that notified products under Art 89 do not require a modification to amend the address to an EU address. We are awaiting confirmation from the Commission, Pesticide Control Division (PCD) of the Department of Agriculture Food and the Marine (DAFM) will contact companies if a change of notification holder is required. If a change is required, we will circulate a template for this purpose and we will be able to complete these changes quickly, but we hope that this won't be necessary.

For authorisations, a change will be required to amend the authorisation holder to an EU address; this can be carried out by applying for a change through R4BP3.

Q2. Can one company be notification holder, and another pay the annual fees?

A. Yes, both companies need to be set up on the DAFM Corporate Customer System (CCS), the notification holder is the person legally responsible for the product and the account holder is the person that pays all fees (both the original notification, any modifications and the annual fees). Only the account holder will receive an invoice for fees unless specified to PCD. We can organise to have both names and addresses on the invoice of the notification holder and the account holder.

Date: 06/01/2020
This information is current at the time of publishing.

Q3. What do I need to do to allow me to make my product available on the market for sale and use in Ireland?

A. You need to carry out the following checks on the ECHA website to determine the status of the active substance in your product. http://echa.europa.eu/information-on-chemicals/biocidal-active-substances;

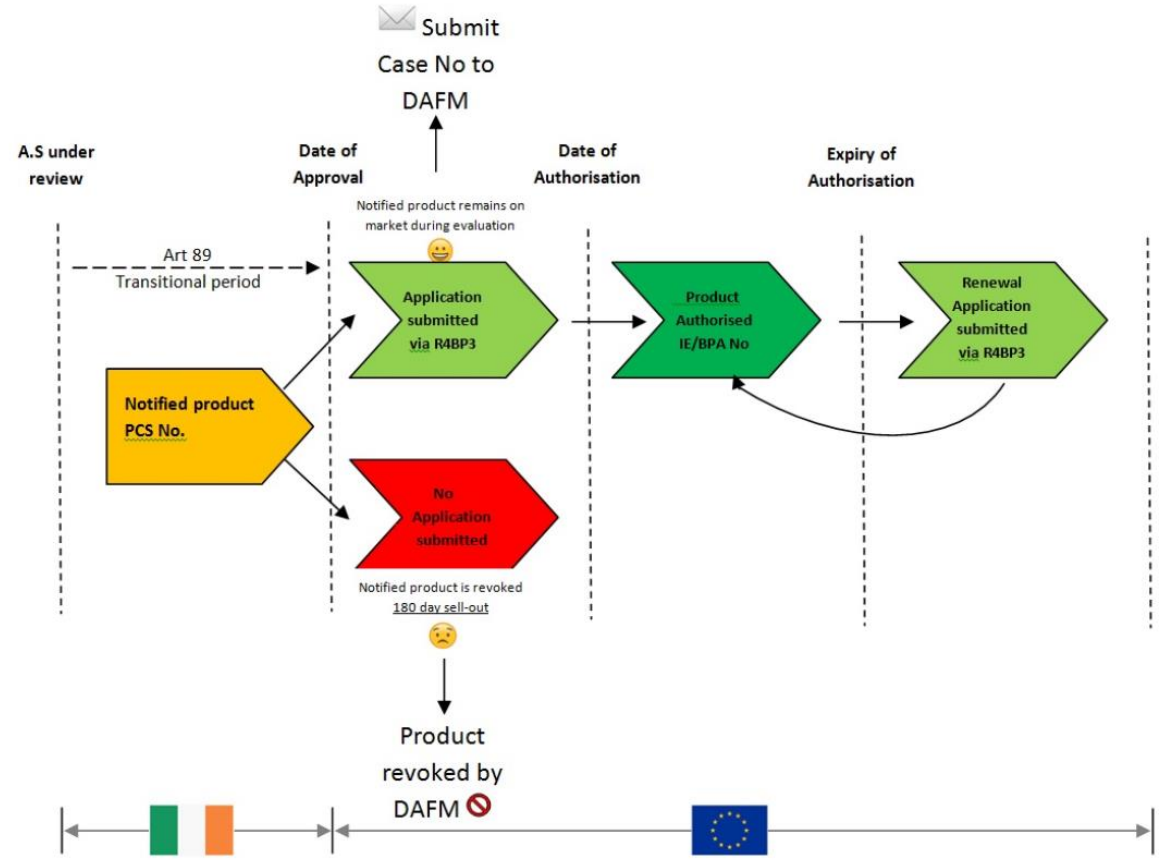
1. Is the active substance (AS) in my product supported, search by the CAS No of your AS.
2. Is the AS supported for the correct product type (PT) based on the intended use of my product?
3. What is the status of the active substance in the review programme? See below description of how the status impacts the next steps I need to take.
4. Check the Art 95 list of suppliers to ensure I purchase the AS-PT combination in my product from one of these suppliers.

Status of AS/PT	**What this means**	**Next Steps**
Initial Approval in Progress	This AS/PT is still under evaluation and a decision has not been made at EU level yet. Your product falls under national rules (Art 89 of the BPR) whilst the evaluation is in progress. You must submit a notification application which must be completed prior to making the product available on the market for sale and use in Ireland	Details of the application process are identified in the 'Notifications - How To Guide' on the following link: http://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/nationalnotificationapplications/ Regularly check the ECHA website to identify changes to the status of the AS/PT, when the AS/PT is approved, you must submit a dossier on or before the date of approval to maintain your product on the market. If you are unable to generate a dossier, you should start discussions with your suppliers as soon as possible and come to an agreement that they will support your product at authorisation in their dossier. They will become authorisation holder and you will be a marketing company for your trade name.
Approved (approval is for a	This AS/PT was evaluated at EU level and approved. The Implementing Regulation	There is typically ~18 months from the date of publication of the approval decision and the "date of approval". This gives time to

period of 5, 7 or 10 years. The AS and the products will be re-reviewed every 5, 7 or 10 years depending on the safety of the product).	published by the Commission identifies a 'Date of Approval'. This is the date by which a dossier must be submitted to Ireland for authorisation via R4BP3. Please note, if a notification was not submitted to Ireland on or before the date of approval, no product can be made available on the market in Ireland UNTIL the product is authorised which can take up to 3 years. There will be a market freeze until authorisation if you have not complied with the transitional rules.	prepare your dossier and contact Member States to request them to act as rapporteur member state (RMS). An application for authorisation must be submitted via R4BP3 on or before the date of approval to the RMS and an application for mutual recognition in parallel (MRP) is submitted to the other concerned Member States (CMS). Your notified product only remains on the market if an authorisation application is submitted on the date of approval, the trade name of your notified product must be identified in the summary of product characteristics (SPC). During the preparation of your dossier, if you identify that you need to make changes to your product, it is critical that you amend your notified product before the date of approval to match the product in the dossier. <u>If the notified product is not identical to the product in the dossier, the notified product will be revoked on the date of approval.</u>
Not Approved	This AS/PT was not approved and is illegal for use in a Biocidal product	Check other substances in the review programme for the PT of interest to guide you in selecting an alternative AS to reformulate your product.

Figure 1 shows a visual representation of what is required to maintain your biocidal product on the market long term – from a notified product through to authorisation and renewal.

Figure 1: Product Life Cycle



Q4. What is required to submit a national notification to receive a PCS number?

A. Applicants must submit the following documents, they must be fully complete with no blanks. Incomplete applications will be rejected and will need to be resubmitted;

Step 1 – submit the following documents, see below document completed to aid you in completion of your application.

- A fully completed application form, see below for documents
- REACH compliant SDS for the active substance(s)
- REACH compliant SDS for the product
- REACH compliant SDS for EACH co-formulant(s)
- Draft product label compliant with Art 69 of the BPR 528/2012 and CLP Regulation.
- Letter of access for active substances (that are approved on the ECHA review programme) and a letter of supply for active substances still in progress, on the ECHA review programme

Date: 06/01/2020
This information is current at the time of publishing.

from your manufacturer on the Article 95 list. Very Important - the letter must name each specific product trade name.

Useful links below, please also consult our 'Notifications How to Guide' on our website:

1. Blank Biocidal Product notification form
2. Mock completed Biocidal Product application form – example
3. Biocidal product types
4. Formulation codes

Step 2 **–** The product is placed in the application queue, and the invoice will be sent to the appropriate party, this may take several weeks. Applications will be processed on a first come first served basis only when the invoice is confirmed as paid. If you are a new customer of DAFM please ensure that you have completed a CCS form so we can set your company up on our accounts system and issue an invoice.

CCS Customer Registration Form

Please submit the CCS in an editable format as we must add addition information before your company can be added to our system

Step 3 – you will receive a query email containing your PCS No

- Once a PCS No is received via email, a final product label containing the PCS No must be submitted to complete the application. The application is ONLY complete when the final product label is submitted to PCD displaying the PCS number. Your product can ONLY be made available on the market for sale and use in Ireland AFTER it is available on the public register. You will receive an automated email from the register to inform you that your application is complete. Please note, the label is not approved, it is the responsibility of the notification holder to correctly label their product. On inspection if the product is not compliant with Art 69 of the BPR, your product will be removed from sale. A full market recall will be required and all products will need to be re-labelled prior to returning product to sale.

Q5. What are product-types or PTs?

A. Product-types abbreviated to PT. There are 22 PTs outlined and described in Annex V of the Biocidal Products Regulation, see below pdf, each defining specific uses for the product. The active substances (AS) are reviewed at EU level for specific uses or PT's. After evaluation, the specific AS/PT combination receives an approval or non-approval. A product must contain an AS in the review programme for the correct PT to support their product claims. Please consult the ECHA website for a list and description of the different product types

Q6. Where can I find details of the fees?

A. Please refer to our website for the most up to date fees. On the date of printing the fees were €300 per product notification. A trivial amendment will also incur a fee of €300. http://www.pcs.agriculture.gov.ie/fees/

Q7. Is there an annual fee and if so, how does it work?

A. Yes, there is an annual fee to maintain products on the register. The fee is not charged in the calendar year of notification but is charged each subsequent year. The fee is currently €225 for professional (and amateur) products and €125 for amateur only products. An invoice is issued in Q4 of the year and must be paid by 31st of December. Failure to pay the annual fee will result in automatic revocation of the product(s) on the 31st December of the year the invoice was issued. No new product can be supplied onto the market after this date; existing product can be phased out over 180 days. There is a late fee penalty option available for companies to pay if they want to re-instate their products, please contact PCD in Q1 to get information on this. Late fees can only be issued in the subsequent year after revocation. After this time a new product application must be submitted and you will receive a new PCS No, only on publication of the notification on the register, can this new product be made available on the market for sale and use in Ireland.

Type of Product	**Fee (payment by 31-Dec)**	**Late Fee (Payment after Dec)**
Amateur Use Product	€125	€225
Professional Use Product	€225	€425
Amateur and Professional Use Product	€225	€425

Q8. How do I submit the notification application?

A. Submit the fully completed application form along with the necessary supporting documents to biocide-notifications@agriculture.gov.ie. Applications are added to an application queue and are dealt with and processed on a first come first served basis. The notification documents should be attached as .pdf files, as we are unable to download external content. Applications sent to any other email address will result in a longer processing time.

These is no facility to fast track applications.

Q9. When should I apply for a new notification (PCS number) under Art 89?

A. A company should apply at least six months before they intend on placing the product on the market in Ireland. Product can only be made available on the market after completion of the notification. The application queue will vary in length depending on the volume of applications received.

An application can be made up to the date of approval of the active substance/Product-type combination in the product. When processing applications after the date of approval, PCD will require the Case Number of the authorisation application for this trade name, if this trade name/formulation is not included on the SPC which forms part of the dossier, the notification application will be rejected. The application will be placed in the queue and processed on a first come first served basis. The product can only be placed on the market after completion of the notification and the details are available on the public register.

Q10. Can I submit a notification if one active substance in my product is past the date of approval and the others have not?

A. Yes, a notification application can be submitted on or before the date of approval of the last active substance product type combination in the product. Once all active substance/product type combinations in a product are past their respective dates of approval, notification applications can no longer be accepted for that product. An application for authorisation must be submitted on or before the date of approval of the last substance/product type combination in the product to maintain the notified product on the market during evaluation of the dossier. Failure to submit a dossier for authorisation on or before the date of approval will result in revocation of your notified product on the date of approval of the last active substance/product type combination.

Q11. Are there any other requirements notification/authorisation holders must comply with?

A. All notification and authorisation holders must submit the information of their products to the National Poisons Information Centre of Ireland, http://www.poisons.ie/page.asp?pageId=24

Q12. We are generating a new product that falls under transitional rules and it will be ready to launch in 3 weeks-time, can we place it on the market then?

A. No, only products notified to PCD listed on the public register can be made available on the market for sale and use, the product label must contain a PCS No. The product details must match the details on the product register. It is important to submit a high-quality application well in advance of your product launch to ensure your product is approved for sale and use in Ireland by the necessary date.

Date: 06/01/2020
This information is current at the time of publishing.

Q13. I have changed my product artwork; do I have to inform PCD? If so, is there a fee involved?

A. Yes, the most up to date version of the label artwork should always be submitted to PCD. Labels are available on our public register, which are available to the end-user and these labels are used for enforcement and checked during inspections. The details on the product label on sale must be identical to the information supplied to PCD and available on the public register. If a product is identified upon inspections with different information on the label to that on our register, the product will be removed from sale, a full market recall should be carried out until the product is compliant. There is no fee for updating label artwork.

Q14. I want to make a change to my notified product, what do I have to do?

A. A trivial amendment application must be submitted**.** Submit the application form containing the updated details of the product along with a cover letter. This is placed in the application queue and dealt with on a first come basis. Any changes to the notified product that require a change to the notification form and database will incur a fee. Please note, once the trivial amendment is complete, only the product detailed on the register can be sold. You must manage your stock to ensure that the product on sale and the product on the register are identical.

Q15. What is the fee for trivial amendments to notified products?

A. A trivial amendment fee is €300.

Q16. If I apply for a trivial amendment, can I keep my existing PCS Number?

A. Amended products may retain their existing PCS Number ONLY in the following circumstances:

- Product Name Change
- Minor Formulation Change

  A minor formulation change could for example be a change to some of the co-formulants and/or a slight variation in the level of active substance, generally to within +/- 10% of the original content. This is provided the change does not alter the classification of the finished product.

- Change of Notification/Account holder / Manufacturer / Substance Supplier

Please note that once the trivial amendment is complete and the register has been updated, the product on sale must be identical to the register as the biocidal products listed on the register is the approved product. This will require careful management of stock.

Q17. What happens if the modification to the formulation is greater than that described in the minor formulation change above?

A. This would be considered a new product and would require a different trade name and a new application. This new product trade name/formulation would receive a unique PCS number which must be displayed on the product label prior to making available on the market for sale.

Q18. What do I have to submit for a trivial amendment?

A. The requirements are:

- Cover letter in the email identifying the change to be made to the product
- Amended Notification Form (only required to fill in the information that will be changing, if you submitted the original application on the old form, a full new application form will be required)
- Product SDS (if applicable)
- Co-Formulant SDS (if applicable)
- Amended Label (if applicable)
- Fee

  PLEASE NOTE - One TA submitted per email.

  An update to a label/SDS is not considered a trivial amendment but should be submitted to PCD to update our records, this does not incur a fee. Only amendments that require updating the current information displayed on the Register incur a fee.

Q19. When can I place my product undergoing a trivial amendment on the market? When is it legal for sale and use?

A. The product can only be placed on the market for sale and use after the trivial amendment is complete and a product label with the PCS Number is on file. The product placed on the market must always match the Biocidal Product register, this will require careful stock management.

Q20. What is Article 95 (Letter of Access (LOA))?

A. A LOA is access to the active substance dossier, this allows you to use some of the data to read across to the product when generating your own product dossier. This is required for all products after the date of approval for the active substance. A letter of supply is sufficient for active substances where their evaluation is in progress in the ECHA Active Substance review programme, this must name the active substance and CAS No.

Date: 06/01/2020
This information is current at the time of publishing.

All notification holders must submit proof of purchasing their active substance from a manufacturer on the ECHA Article 95 list. All product notifications require this confirmation.

In some cases, you may be purchasing your active substance from a company not listed on the ECHA article 95 list. In this situation your supplier may be acting as a 'middle man' and purchasing the active substance from an Art 95 approved manufacturer. You must provide a letter from the Art 95 supplier saying they are supplying the 'name of the middle man' with the Art 95 substance, without this letter, we cannot complete your notification.

Please refer to the information on our website for details on Article 95 compliance:

http://www.pcs.agriculture.gov.ie/biocides/activesubstances/activesubstancesuppliersarticle95list/

ECHA Art 95 list:

http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

Q21. My supplier is not on the Article 95 list, what does this mean for my products?

A. Your notification application cannot be accepted or processed. Contact your active substance supplier to ensure they are procuring the active substance from an approve Art 95 listed manufacturer. You will have to change your active substance supplier to comply with the Art 95 requirements before you can make your product available on the market for sale and use. A list of these can be found on the ECHA website.

Q22. I have a product with more than one active substance (AS); one of the substances has an approval decision, what is required of me on the date of approval? Do I have to submit an authorisation application which includes a full product dossier?

A. An application for authorisation is required on or before the date of approval of the last AS PT combination**.** If your product contains at least one active substance still in progress, no authorisation application is required at this time. The implementing regulation containing the date of approval is generally published 18 months in advance of the date of approval. It is important to contact a MS as soon as the approval decision Implementing Regulation is published to get agreement to act as rapporteur member state (RMS) and to ensure your RMS of choice has the resources to evaluate your product. Notification holders should regularly review the statuses on their active substances in the ECHA review programme.

You MUST submit the product dossier on or before the date of approval of the last active substance/product type combination in the product. However, if your product contains multiple

actives, a full letter of access (LoA) to the active substance dossier or an equivalent dossier under Article 20(1)(a)(iii) is required on the date of approval of that AS/PT. If a LoA is not submitted the notified product will become revoked and will receive 180 day phase out.

Q23. Do I have to provide any additional information to PCD after notification?

A. Yes, on an annual basis, details of the quantities of this product (by pack size) manufactured in Ireland, imported into Ireland and/or exported from Ireland must be submitted to the Irish Competent Authority for Biocides by 31 January of the following year.

On the date of approval, the case number for the authorisation application should be submitted to maintain your notified product on the market after the date of approval.

Q24. I have an approval under National Legislation in another member state, e.g., I have a HSE Number, can I use this in Ireland?

A. No, each member state has their own National Legislation and companies must apply to each member state in which they wish to market the product. The requirement in Ireland for products containing an active substance with the status 'in progress' and up to the date of approval, is a national notification application. Details of the application process can be found here:

http://www.pcs.agriculture.gov.ie/biocides/biocidalproducts/nationalnotificationapplications/.

Q25. What does notification holder mean?

A. The notification holder is the person legally responsible for making the product available on the market for sale and use. The notification holder is generally the product formulator, however, a product formulator can provide the confidential information on the product to a third party and allow them to become the notification holder.

Q26. What does account holder mean?

A. The account holder is the person responsible to feeing the fees associated with the notification, this include the initial notification fee and subsequent annual fees.

Q27. What does marketing company mean?

A. The marketing company is the company that markets the product on behalf of the notification holder. The notification holder and marketing company can be the same company or two different companies.

Date: 06/01/2020
This information is current at the time of publishing.

Q28. My biocidal product has been notified, is there anything else required of me?

A. Your application must be kept up to date and any amendments made to the product must be processed prior to making the change to the product. You must submit all revisions of your SDS to the National Poisons Centre and pay an annual fee to maintain your product on the market. Your label must be compliant with Art 69 of the BPR and reflect the classification in your product SDS. You should know your requirements as the notification holder; product notification is only a transitional measure and step 1 of maintaining your biocidal product on the market. Depending on the date(s) of approval of the active substance(s) contained in your product, an authorisation application is required on or before the date of approval of the last active substance product type combination contained in the product. Please see Q3 and figure 1 above.

Q29. The date of approval is approaching for the last active substance in my product. I want to continue selling this product in Ireland, what should I do?

A. An authorisation application must be submitted on or before the date of approval of the last active substance product type combination contained in your product. The authorisation application must be submitted via R4BP3. Once the product authorisation is submitted the subsequent case number received must be send to the DAFM to maintain the notified product on the market during the evaluation of the dossier. The notified product must be identical to the product outlined in the authorisation application and named in the summary of product characteristics (SPC). The case number will maintain the notified product on the market for up to 3 years or until the authorisation application is complete, whichever comes first.

Dates of approval are published on the ECHA review programme ~18 months in advanced, this gives companies enough time to prepare and submit their authorisation applications. More information on the requirements for authorisation and the associated fees can be found on the DAFM website.

Failure to make an authorisation application and submit the case number to DAFM on or before the date of approval will result in your notified product being revoked. Authorisation applications made after the date of approval will result in a market freeze of your product until the authorisation process is complete.

Q30. My biocidal product has been identified as non-compliant during an inspection of a wholesale/retail store. The wholesaler/retailer has informed me that my product is not correctly registered and has been removed from sale, what do I do?

A. Consult the biocidal product register to check if the details on the register are current and correct as the details on the register reflect the approved product and only this product can be made available on the market for sale and use in Ireland. If the register is not correct, you must submit a trivial amendment prior to placing the product back on the market. If the register is correct, the label needs to be updated to reflect the register and Art 69 of the BPR and the product must be relabelled prior to placing product back on the market.

Action required:

1. Submit trivial amendment to update the register to match the product on the market (usually the result of the product being changed without notifying the Department of Agriculture Food and the Marine).
2. Amend the product label so it matches the register.

You must contact this office to rectify the issue(s) before the product can return to sale.

Q31. Acronyms and explanations

AS – Active Substance

BPR – Biocidal Product Regulation

CAS number – unique identifier assigned to chemical substances

CCS – Corporate Customer System

CLP – Classification Labelling and Packaging

CMS – Concerned Member State

DAFM – Department of Agriculture Food and the Marine

ECHA – European Chemicals Agency

HSE – Health and Safety Executive: UK competent Authority for Biocides

IE/BPA number – Approval number granted by PCD for an authorised product

LoA – Letter of Access

MRP – Mutual Recognition in Parallel

PCD – Pesticide Control Division: Division within DAFM and Competent Authority for Biocides in Ireland

PCS number – Approval number granted by PCD for a notified product

PT – Product Type

R4BP3 – Portal operated by ECHA for authorisation applications

Date: 06/01/2020
This information is current at the time of publishing.

REACH – Registration, Evaluation, Authorisation and Restrictions of Chemicals

RMS – Reference Member State

SDS – Safety Data Sheet

SPC – Summary of Product Characteristics

TA – Trivial Amendment