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

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

Version 3.0
July 2019

Application Form for Biocidal Product Notification

Product Name	
Active Substance(s)	
Product type	

Please fully complete <u>all sections</u> in this application form

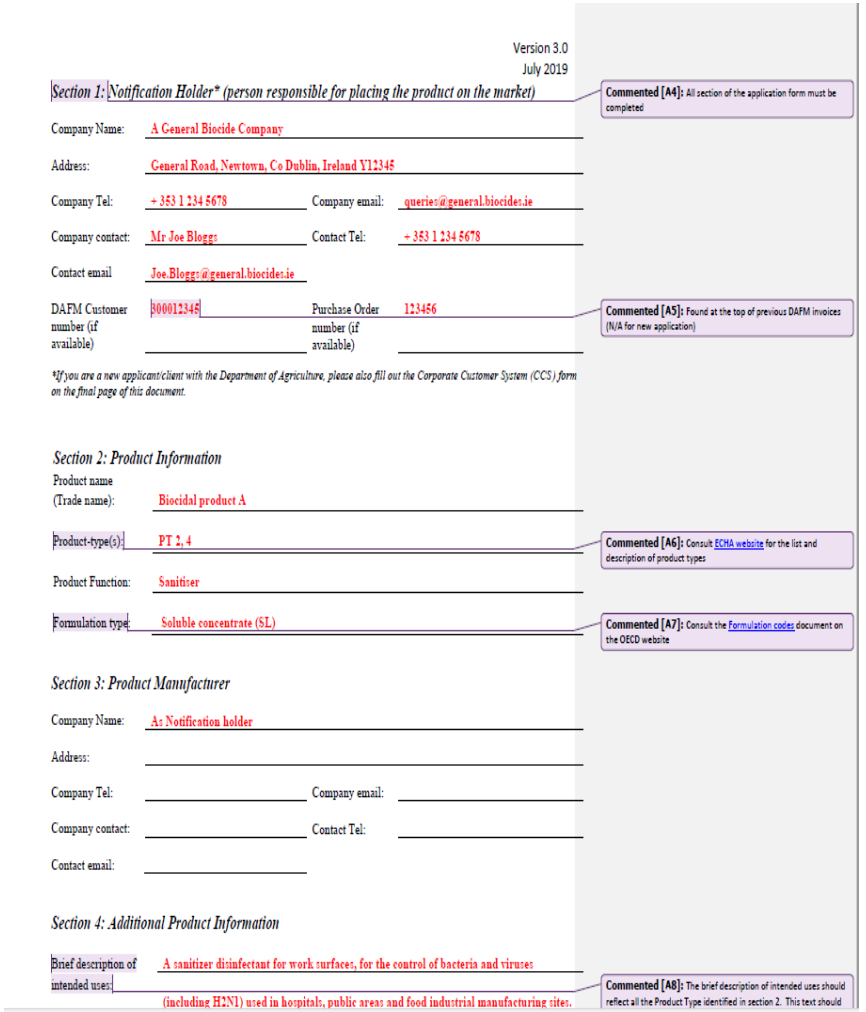
Application Check List – The application <u>MUST</u> include items 1-5. New customers <u>MUST</u> also include item 6. If any of these items are missing, the application will be rejected and sent back to applicant for re-submission.

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**



Version 3.0
July 2019

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

Company Name: A General Biocide Company

Address: General Road, Newtown, Co Dublin, Ireland Y12345

Company Tel: + 353 1 234 5678 Company email: queries@general.biocides.ie

Company contact: Mr Joe Bloggs Contact Tel: + 353 1 234 5678

Contact email Joe.Bloggs@general.biocides.ie

DAFM Customer number (if available) 300012345 Purchase Order number (if available) 123456

**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): Biocidal product A

Product-type(s): PT 2, 4

Product Function: Sanitiser

Formulation type: Soluble concentrate (SL)

Section 3: Product Manufacturer

Company Name: As Notification holder

Address:

Company Tel: Company email:

Company contact: Contact Tel:

Contact email:

Section 4: Additional Product Information

Brief description of intended uses: A sanitizer disinfectant for work surfaces, for the control of bacteria and viruses (including H2N1) used in hospitals, public areas and food industrial manufacturing sites.

Commented [A4]: All section of the application form must be completed

Commented [A5]: Found at the top of previous DAFM invoices (N/A for new application)

Commented [A6]: Consult ECHA website for the list and description of product types

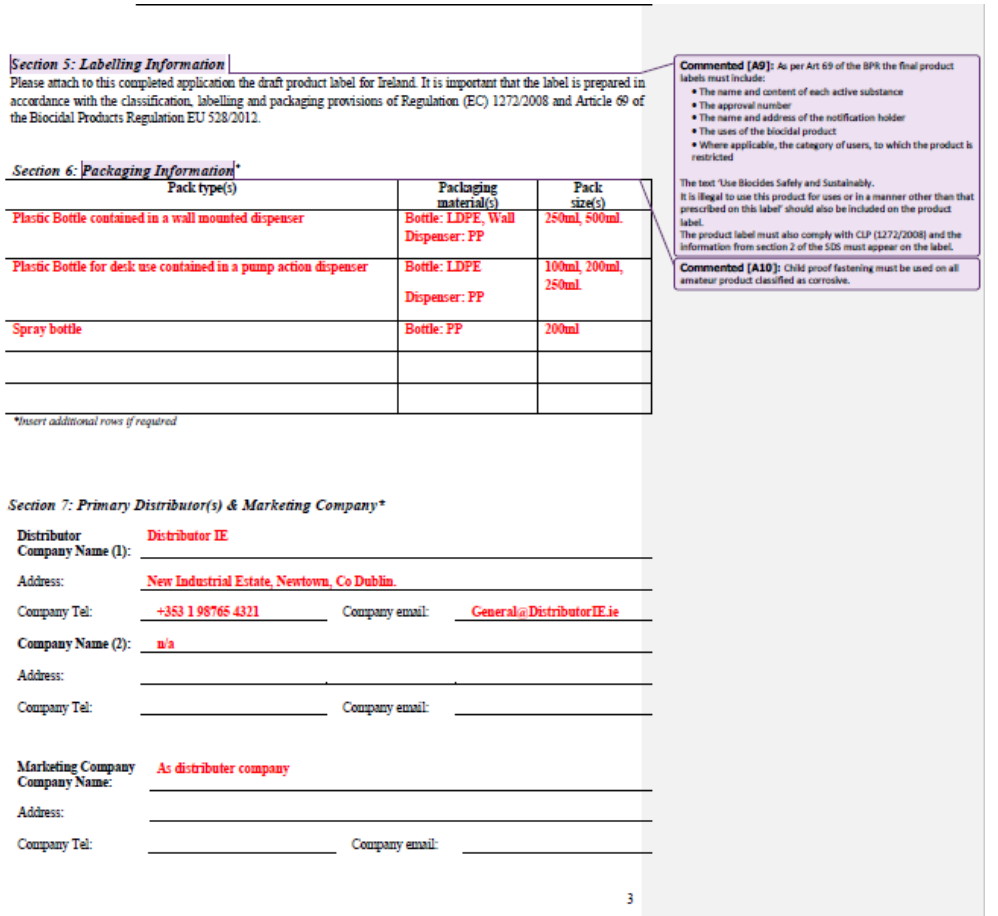
Commented [A7]: Consult the Formulation codes document on the OECD website

Commented [A8]: The brief description of intended uses should reflect all the Product Type identified in section 2. This text should

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)



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.

*Section 6: Packaging Information**

Pack type(s)	Packaging material(s)	Pack size(s)
Plastic Bottle contained in a wall mounted dispenser	Bottle: LDPE, Wall Dispenser: PP	250ml, 500ml.
Plastic Bottle for desk use contained in a pump action dispenser	Bottle: LDPE Dispenser: PP	100ml, 200ml, 250ml.
Spray bottle	Bottle: PP	200ml

**Insert additional rows if required*

*Section 7: Primary Distributor(s) & Marketing Company**

Distributor Company Name (1): Distributor IE

Address: New Industrial Estate, Newtown, Co Dublin.

Company Tel: +353 1 98765 4321 Company email: General@DistributorIE.ie

Company Name (2): n/a

Address:

Company Tel: Company email:

Marketing Company Company Name: As distributer company

Address:

Company Tel: Company email:

3

Commented [A9]: As per Art 69 of the BPR the final product labels must include:
- The name and content of each active substance
- The approval number
- The name and address of the notification holder
- The uses of the biocidal product
- Where applicable, the category of users, to which the product is restricted

The text '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' should also be included on the product label.
The product label must also comply with CLP (1272/2008) and the information from section 2 of the SDS must appear on the label.

Commented [A10]: Child proof fastening must be used on all amateur product classified as corrosive.

Application form Explained

- Section 9: **Active Substance Manufacturer** = must be listed on the Article 95 list
- Section 10: **Product Specifications**
  - Wipe Information

*Section 10: Product Specification continued. **

Product type	Identity of Active Substance in the product	CAS No	Purity of active substance (g/kg)	Content of 'active substance' in the product (as a quantity) units = g/kg, g/L etc	Content of active substance in the product (as a %) units = w/w OR %v/v	Manufacturer of AS	SDS Attached Yes/No	Letter of access (LoA) or supply Attached Yes/No
2, 4	AS 1	123-12-3	500 g/kg	200 g/kg	20.0 % w/w	A chemical company	yes	yes
2, 4	AS 2	456-45-6	1000 g/kg	11.48 g/kg	1.148 % w/w	ACME 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 (as a quantity) units = g/kg, g/L etc	Content of co-formulant in the product (as a %) units = w/w OR %v/v	Substance of concern Yes/No	SDS Attached Yes/No	Manufacturer of the co-formulant
Co formulant 1	na	789-78-9	Colour	2 g/kg	0.2 % w/w	no	no	X company
Co formulant 2	na	654-65-4	Solvent	786.52 g/kg	78.652 % w/w	yes	yes	Y company
Total				1000.00 g/kg	100.000 %w/w			

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*

Commented [A11]: Purity must be a specific figure not a range. This can be obtained from the AS manufacturer

Commented [A12]: 'Active substance' content: the amount of active including in the product. Any impurities should be included in the co-formulants section
This value must be on the product label

Commented [A13]: Applications can only be accepted if the red column adds up to 1000 and the green column adds up to 100.
Red: (200+11.48+2+786.52=1000.00)
Green: (20+1.148+0.2+78.652=100.000)

Product Registration System

Bia agus Mara
Department of Ag
Food and the Mari

Home | Biocides | Products | Active Substances | Companies | Admin | Help | Exit

Application Details

Section 1

Business ID [redacted]

Name [redacted]

Address [redacted]

Email(s) [redacted]

Application No PCS [redacted]

Application Type NOTIFICATION

Status Notified

Generate Certificate Of Free Sale: Generate

Product Details

Section 2 & 4

Product/Brand Name [redacted]

Approval Type
IE Notification (under National rules)

Annual Fee
Yes

Intended Use [redacted]

Active Substances [redacted] - 0.5(% w/w) (PT3);

Application Date [redacted]

Formulation code
Other liquids to be applied undiluted [AL]

Non-professional Use
Yes

Section 6

Section 3

Section 7

Section 8

Specification *Total: 100.00000(% w/w)* | Packaging | Companies | Product Documents | Tracking

Product Active Substances

Section 9 & 10

PT	Substance Name		Purity(g/kg)	Content(g/kg)	Content(% w/w)	SDS	LOA	Manufacturers	Ac
PT3	[redacted]		200.0000	5.0000	0.50000	[redacted]	[redacted]	[redacted]	

Product Co-formulants

Identity	Trade Name	Cas No	Function	Content(g/kg)	Content(% w/w)	SVHC	SDS	Manufacturer

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

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:

https://echa.europa.eu/regulations/clp/labelling/specific-labelling-and-packaging-situations

- 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

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer

Week 1- All applications are received and added to the queue, invoices are issued

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	
1/01/2019	1236	Company C	Y		Wood preserver	
1/01/2019	1237	Company D	Y		Insect repellent	

Week 4- Company B pays the invoice

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y		Wood preserver	
1/01/2019	1237	Company D	Y		Insect repellent	

Week 5 - Company B's application is claimed and processing begins - an application under query email is sent

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**XX**
1/01/2019	1237	Company D	Y		Insect repellent	

Week 6 - Company C pays the invoice, Company B has not responded so Company C processing begins

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**XX**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	

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

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**XX**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	

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

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**Complete**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	

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

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**Complete**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	**XX**

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

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**XX**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**Complete**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	**Complete**

Week 16 - Company D submit the product label and the product is notified

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y		Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**Complete**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**Complete**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	**Complete**

Week 18 - Company B submits the requested information and the product is notified

Application Queue

Application date	Tracker No	Company Name	Invoice Issued	Invoice Paid	Product Name	Processer
1/01/2019	1234	Company A	Y	14/07/2019	Hand sanitiser	
1/01/2019	1235	Company B	Y	28/01/2019	Germ killer	**Complete**
1/01/2019	1236	Company C	Y	11/02/2019	Wood preserver	**Complete**
1/01/2019	1237	Company D	Y	18/02/2019	Insect repellent	**Complete**

Week 24 - Company A pays the invoice

Application Queue

- Timelines for the current example

	Payment length	Processing length	Total length
Company A	24 weeks	-	-
Company B	4 weeks	14 weeks	18 weeks
Company C	6 weeks	7 weeks	13 weeks
Company D	7 weeks	2 weeks	16 weeks

- 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

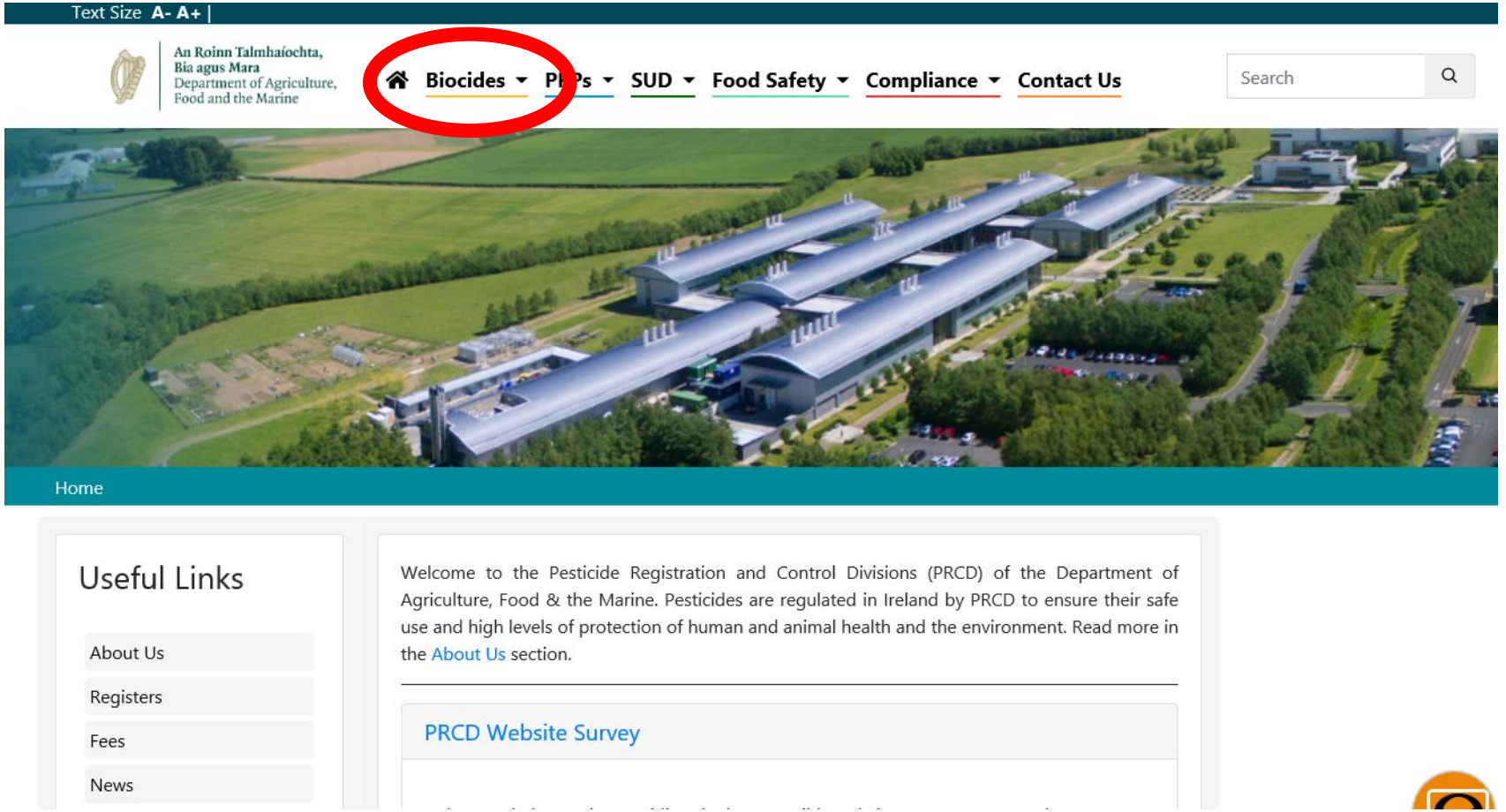
- Applications to be acknowledged and invoices issued within 2 - 4 weeks of submission
  - Time for invoice payment & time to allow processing begin
  - Unpaid invoice will be cancelled and the application rejected

- 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

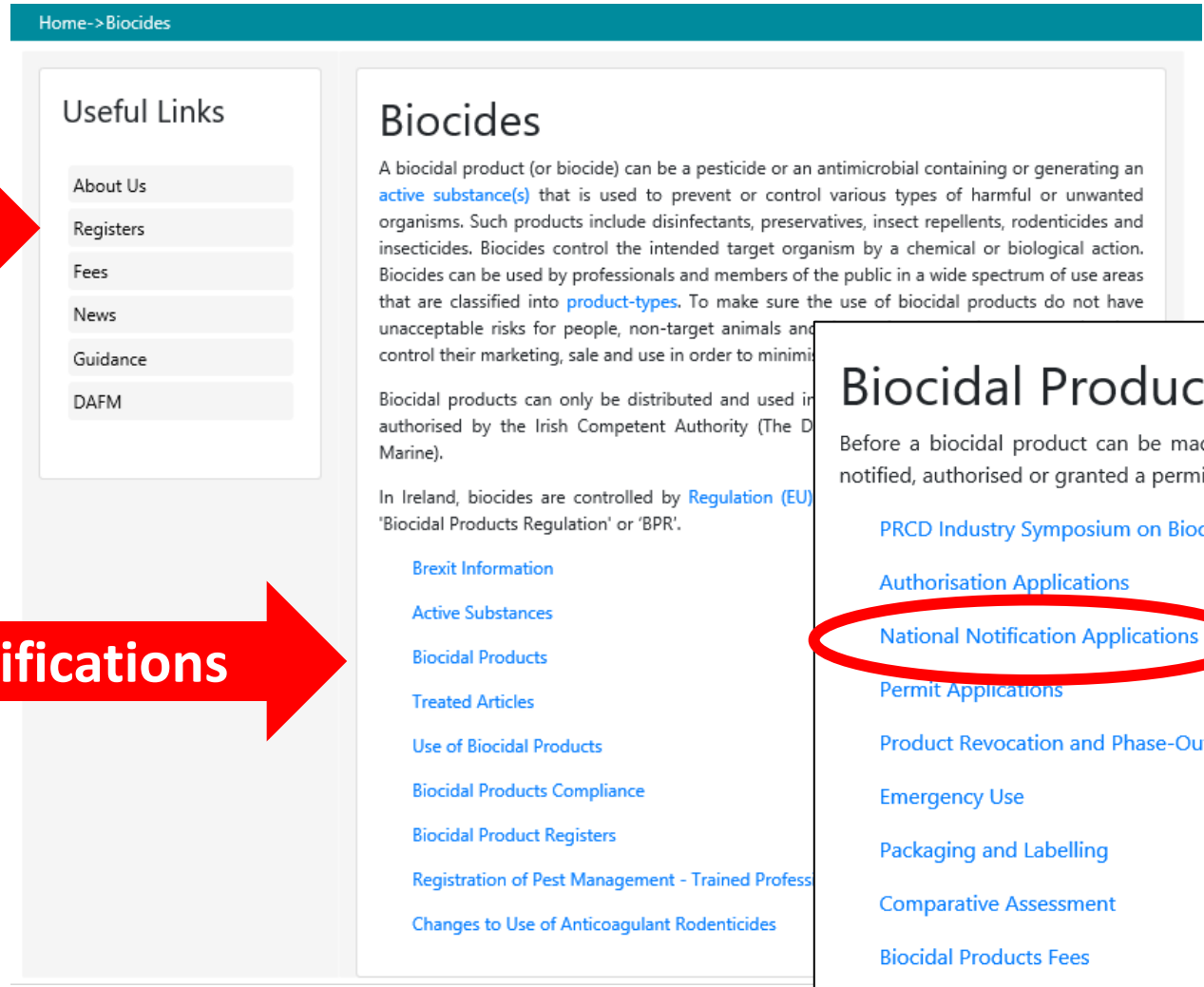


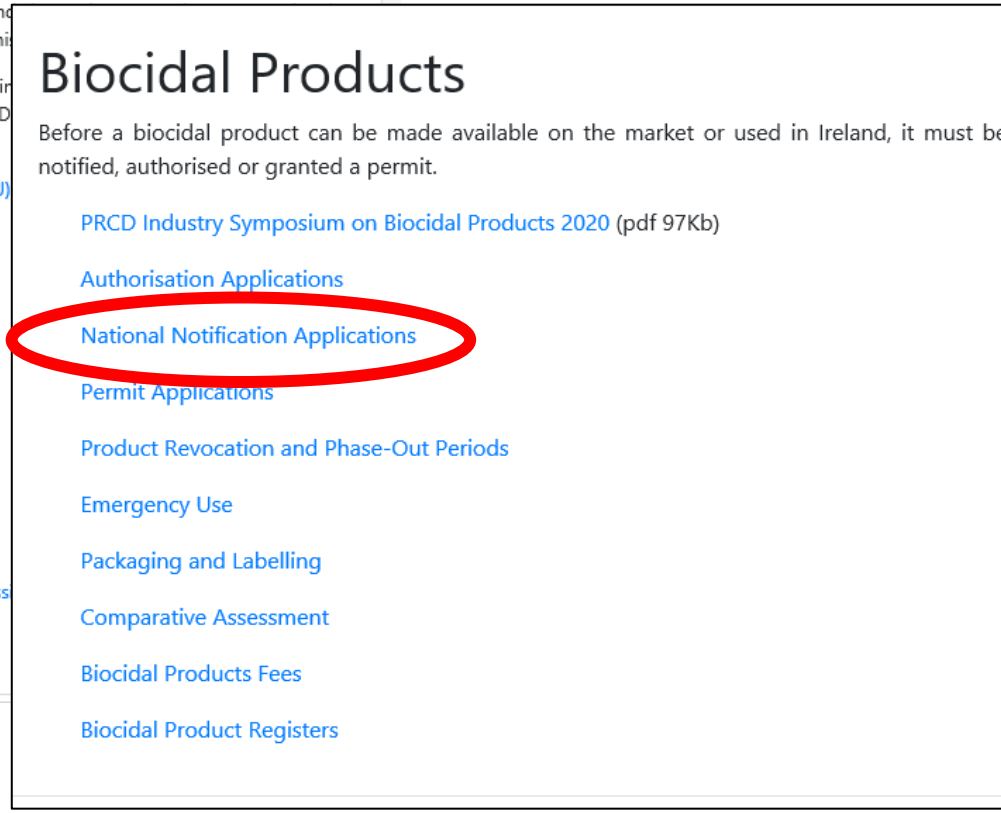
Documents of Interest: PRCD Website

Biocides Page of the PRCD Website

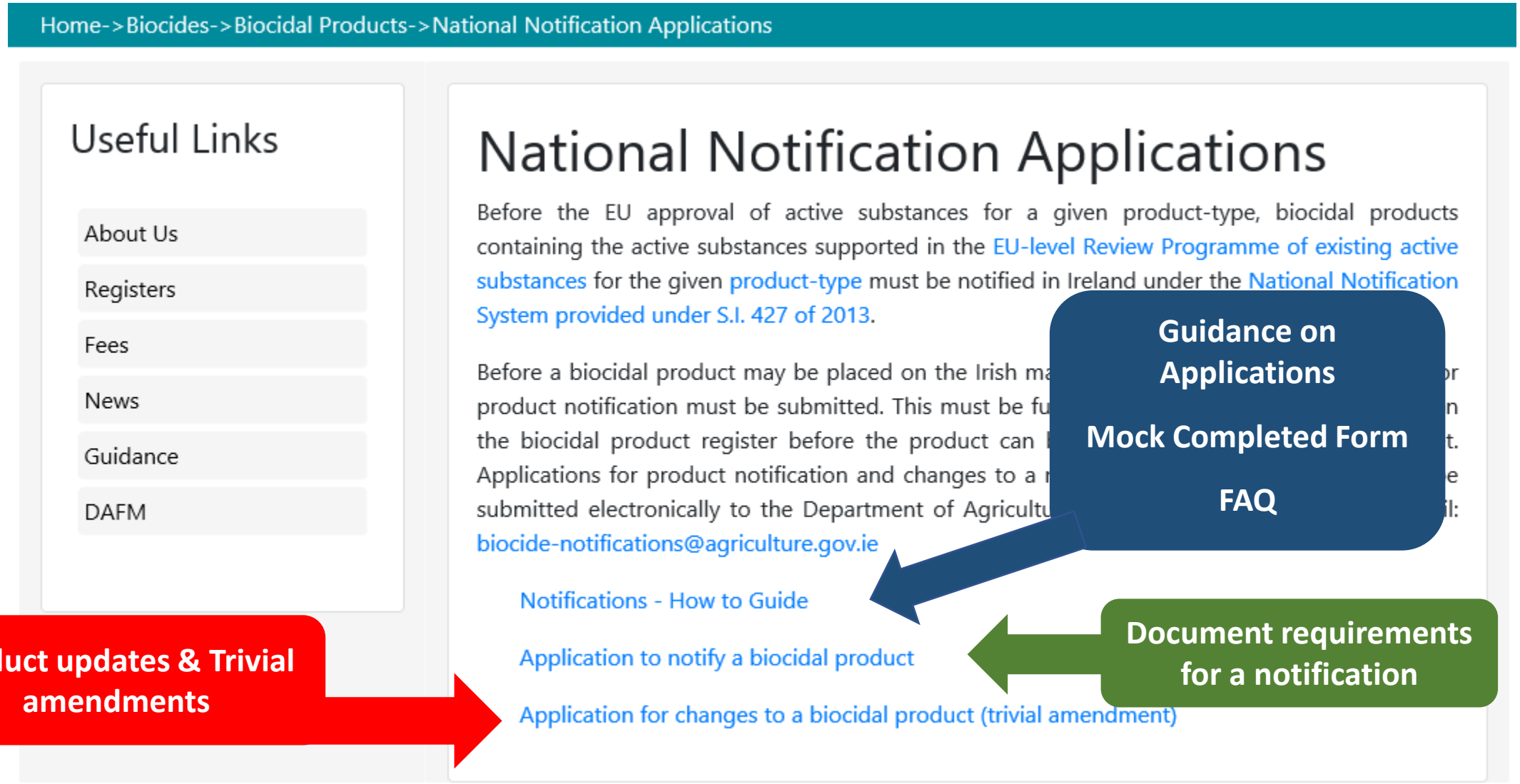
Register

Info on Notifications





Documents of Interest: PRCD Website



Useful Links

- Notification Guidance – ‘How to Guide’

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

- 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