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Biocide Product Authorisation Requirements

Biocidal Product Symposium
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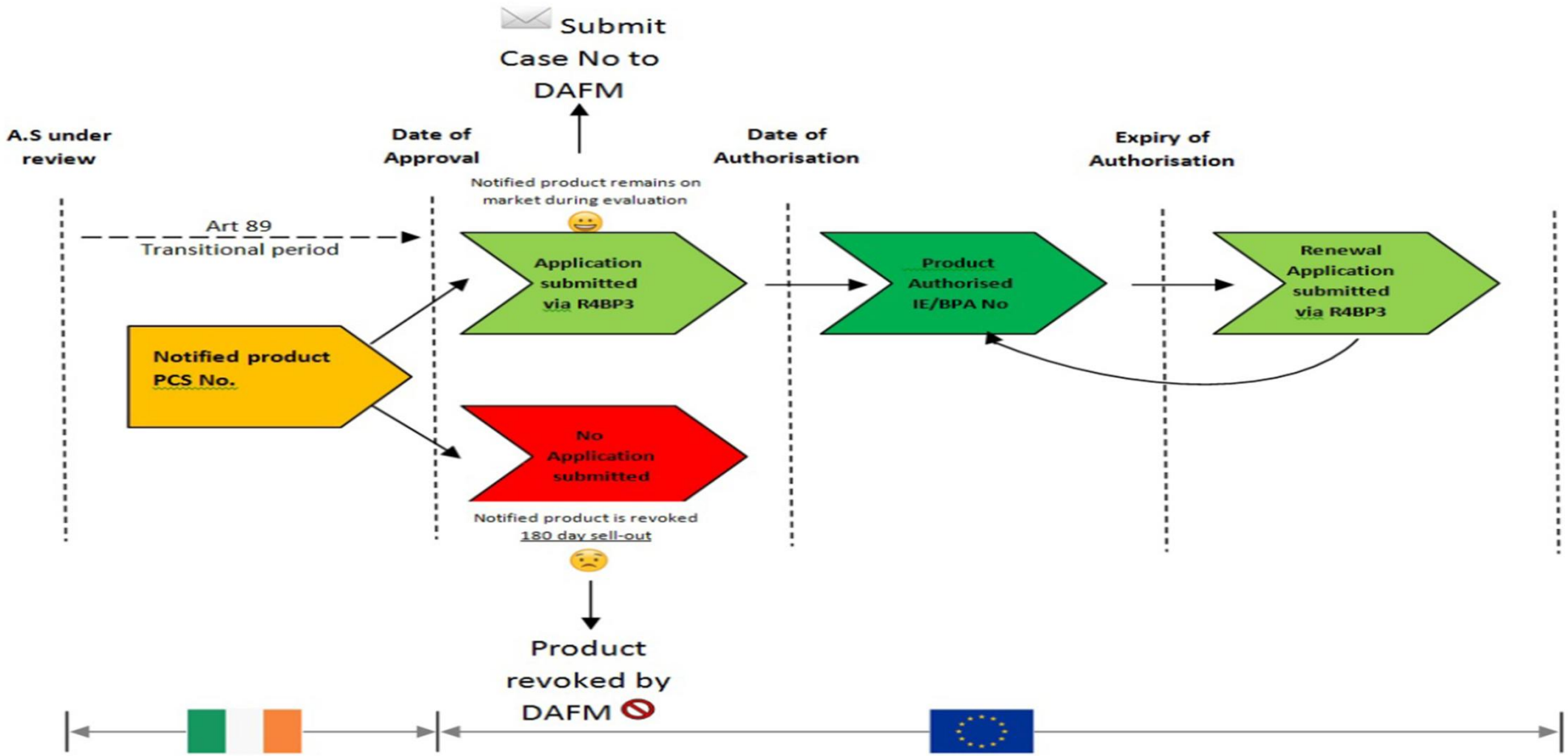
Authorisation Requirements

- Timelines
- Procedures
- Types of authorisation
- Renewals
- Changes to authorisations
- Fees

Timelines


Submit Case No to DAFM
A.S under review
Date of Approval
Date of Authorisation
Expiry of Authorisation
Notified product remains on market during evaluation
Art 89
Transitional period
Application submitted via R4BP3
Product Authorised IE/BPA No
Renewal Application submitted via R4BP3
Notified product PCS No.
No Application submitted
Notified product is revoked
180 day sell-out
Product revoked by DAFM

Timelines
Existing Active Substances

- Regulation published approving the active substance
- 18 months to 2 years later – the actual approval date.

  "A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements".
- On or before the approval date of the active substance an application for authorisation must be received
- For products containing more than 1 AS then the application must be made on the latest date of approval

Timelines
Existing Active Substances

HAS ADOPTED THIS REGULATION:

Article 1

Cypermethrin is approved as an active substance for use in biocidal products of product-type 18, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 August 2018.

For the Commission
The President
Jean-Claude JUNCKER

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
Cypermethrin	IUPAC Name: Cypermethrin *cis:trans* 40:60; (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate EC No: 257-842-9	≥ 92 % w/w Isomeric ratio: *cis:trans* 40:60	1 June 2020	31 May 2030	18	The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.

Procedure

- Submission of product dossier and Summary of product characteristics
- Data access to active substance and product
  - *Own data or Letters of Access (LOA)*

- Active substance supplier from Article 95 list

Procedure

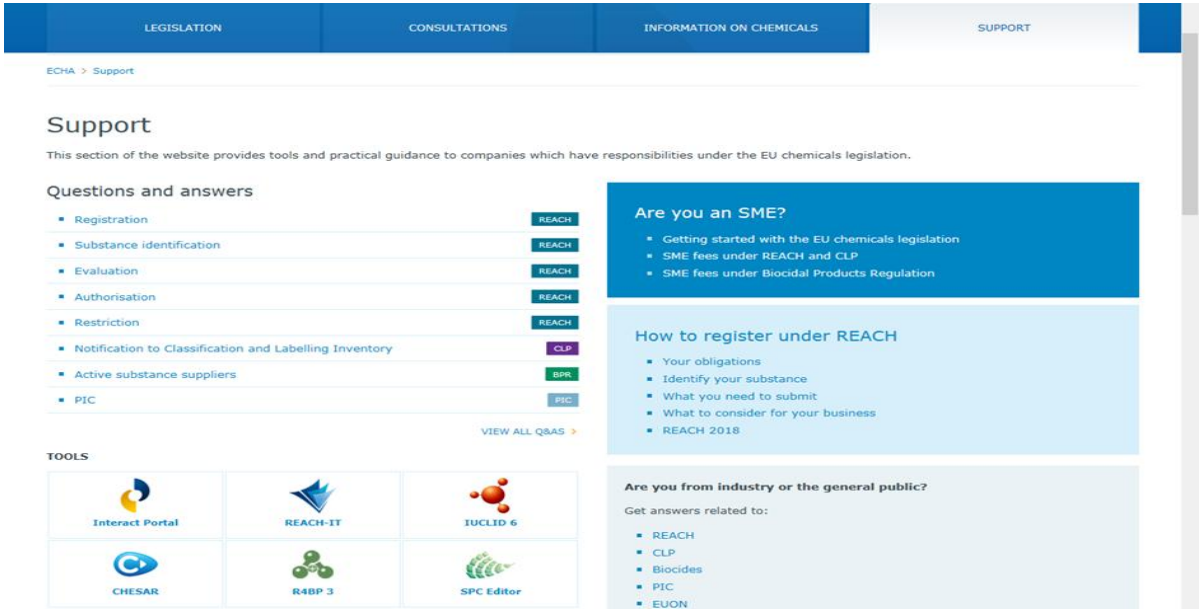
- **Considerations**
  - Cost of submission
  - Experience of regulatory affairs and submissions
  - Access to data
  - Range of products
  - Consolidation, task force options
  - Authorisation holder vs marketing company

Procedure

- Identify the type of authorisation that you can apply for.
  - ***Simplified authorisation***
  - ***National authorisation +/- mutual recognition***
  - ***Union authorisation***

Procedure

- Identify and contact an evaluating member state that will evaluate your product application
- Make application to MS through R4BP3



Authorisation Types

National Authorisation (Article 29, 30)

- If for Ireland only or if for Ireland and mutual recognition (MR) to other member states
- Application through R4BP3
- Dossier submitted through IUCLID software
  - *ECHA guidance available on their website and YouTube channel*
  - *Fees payable to member states (and ECHA if going for MR)*

Authorisation Types

National Authorisation (Article 29, 30)

- Individual authorisation required in each MS in which it is intended to market the product
- Product evaluation by 1 MS with mutual recognition by the others
- Authorisation usually lasts for 10 years
  - *5 years for products containing active substances which are candidates for substitution*

Authorisation Types

National Authorisation (Article 29, 30)

- Product to be evaluated by the MS within 365 of having validated the application.
- Acceptance and validation – up to 60 days
- **Minimum** of 425 days from date of application until final decision on authorisation (or not)
- Evaluating member states can ‘stop the clock’ to request additional data/ information

Authorisation Types

Mutual Recognition (Article 33, 34)

- MR In Parallel – Apply in all concerned MSs at same time as submitting for national authorisation
- Once approved by refMS – cMS has minimum of 120 days to process and approve

Authorisation Types

Mutual Recognition (Article 33, 34)

- MR In Sequence– Apply in concerned MSs after initial national authorisation granted
- Once application received – cMS has minimum of 180 days to process and approve
- If cMSs don't agree with refMS – appeal/referral possible through ECHA Co-ordination Group
- Possible to refuse MR through Article 37

Authorisation Types

Simplified Authorisation (Article 25)

- Encourage the use of less harmful products
- **Eligible if**

1. AS in Annex I of BPR

   E.g. food additives, traditional substances of natural origin, pheromones, CO_2, N_2

2. Contains no substances of concern
3. Contains no nanomaterials
4. Is sufficiently effective
5. No PPE required

Authorisation Types

Simplified Authorisation (Article 25)

- Shorter evaluation time (120 days)
- Less data required
- Lower fees
- No mutual recognition necessary (single EU authorisation)
- **Must** be notified to MS 30 days before placing on the market. (May be some national requirements on labelling etc in some MSs)

Authorisation Types

Union Authorisation (Article 41-43)

- Similar conditions of use across the EU
- PTs 14, 15, 17, 20 and 21 not eligible
- Active substances meeting the exclusion criteria not eligible
- 1 evaluating MS – 1 single authorisation – No MR or national authorisations required
- COM regulation published

Authorisations

Comparative assessment (Article 23)

- Products containing an AS that is a candidate for substitution
- Product compared with other authorised biocidal products, non-chemical means of control and prevention methods with regard to risks they pose and benefits from their use
- Approved for maximum of 5 years

Authorisations

From National Notification to Authorisation

- **Necessary** to apply for authorisation
- Existing product remains on the market until evaluation for authorisation completed
- No application received on date of approval
  - *Product can only be placed on market for 180 days after*
  - *Existing stocks to be used within 365 days of date of approval*
- No authorisation granted
  - *Product can only be sold for 180 days after decision of the MS*
  - *Existing stocks to be used within 365 days of date of approval*

Renewal of Approvals

- Necessary to apply for renewal of product once AS is renewed
- Application to be made at least 550 days before expiry date of current authorisation
- Applicable for national authorisations mutual recognitions, unions authorisations
- Applications made as before

Changes to authorised products

3 main categories

- Administrative changes (Prior notification)

  Change in product name

  Transfer of authorisation

  Change in authorisation holder name or address

  Addition of AS manufacturer, location or identity

Administrative changes (No prior notification)

Change in admin. details of authorisation holder

Change in formulator, location or identity, additional formulator

Classification change to comply with Reg. 1272/2008

Changes in some conditions of use

Changes to authorised products

3 main categories

- Minor changes (Prior notification)
  - Composition change
  - Changes in some conditions of use
  - Change to shelf life or conditions of storage
  - Change to pack sizes
- Major changes (Prior notification)
  - Change in admin. details of authorisation holder
  - Change in formulator, location or identity, additional formulator
  - Classification change to comply with Reg. 1272/2008
  - Changes in some conditions of use

Fees

- National authorisation
  - *€20,000 to €40,000 (single product vs family)*
- Mutual recognition
  - *€2,500 to €5,000*
- Simplified authorisation
  - *€5,000 to €10,000*
- Renewals as above
- Changes
  - *€300 to €10,000 (administrative modification vs major change to product family)*

(Fees correct as of 1st March 2020)

Thank You

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