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

5th PCD Biocides Symposium

Product Authorisations - moving from Article 89 to Authorisations

29th May 2025

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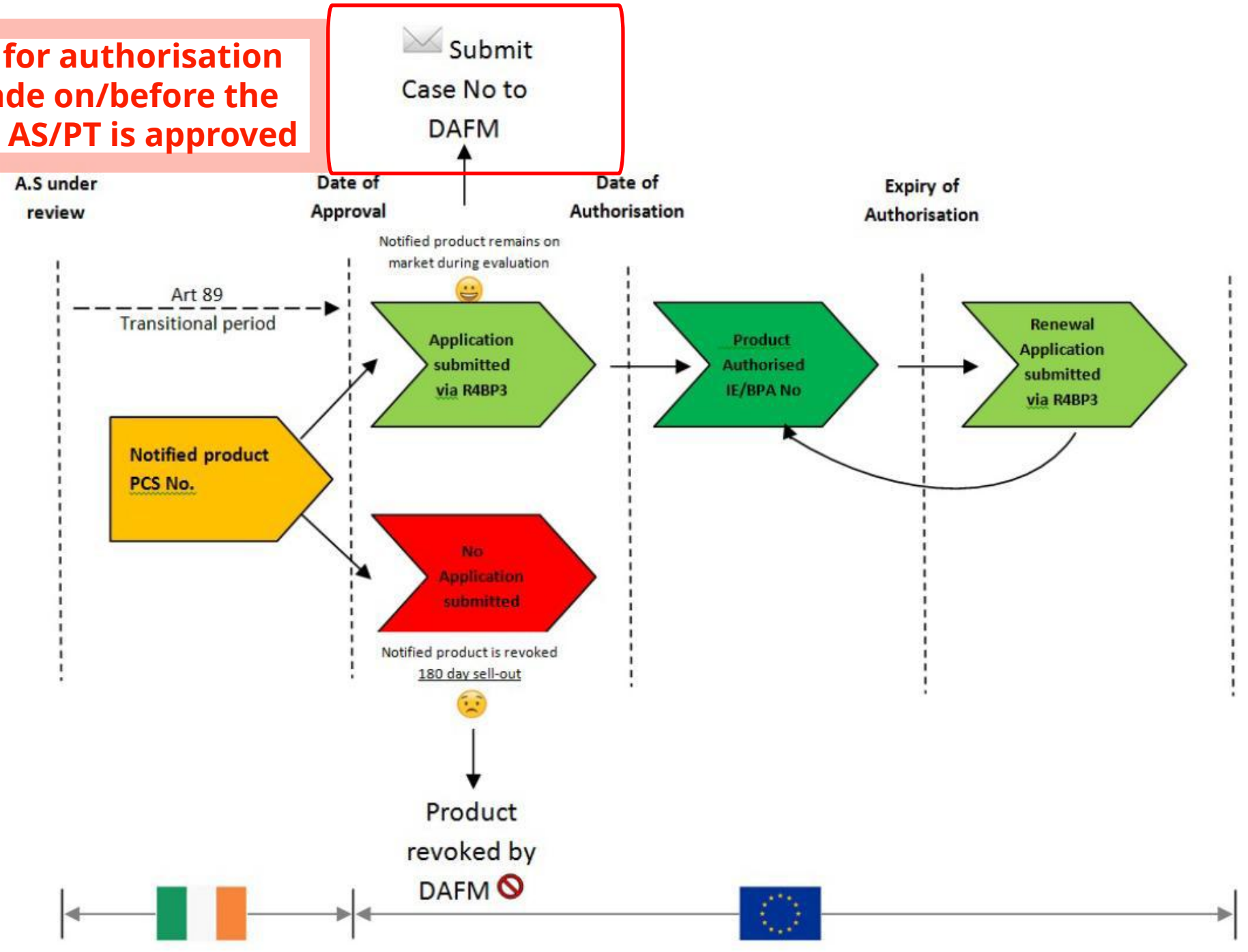
Pesticide Registration & Controls Divisions
Department of Agriculture, Food & the Marine

Outline

- Article 89 to Authorisation
- Granting Authorisation
- Other Options
- Fees
- Lessons Learned/Challenges
- Label review
- Annual Fees

Application for authorisation must be made on/before the date the last AS/PT is approved



From National Article 89 Measures to BPR Authorisation

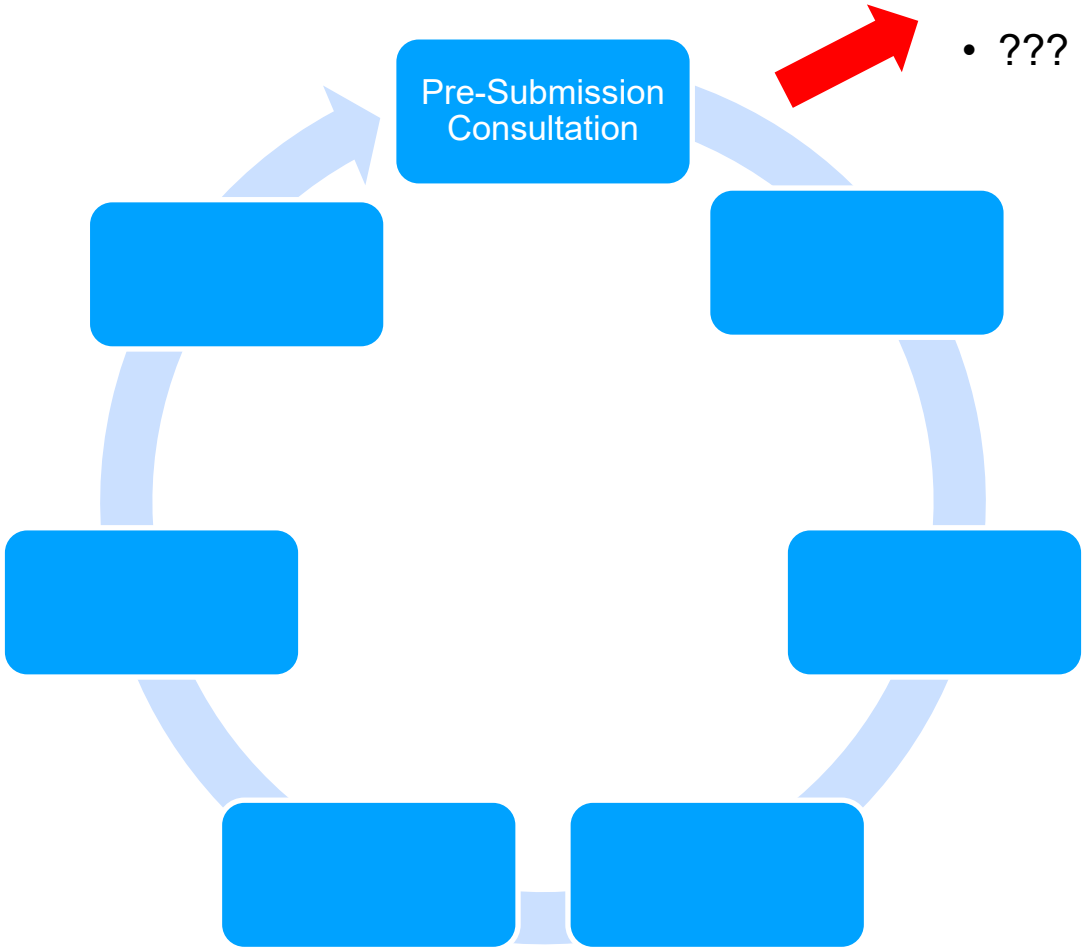
Limited data requirements

- Composition, packaging, labelling, SDSs

To full data packages

- Phys.chem properties
- Human health/tox. properties,
- Environmental properties, fate and behaviour
- Efficacy

National Authorisation and Mutual Recognition



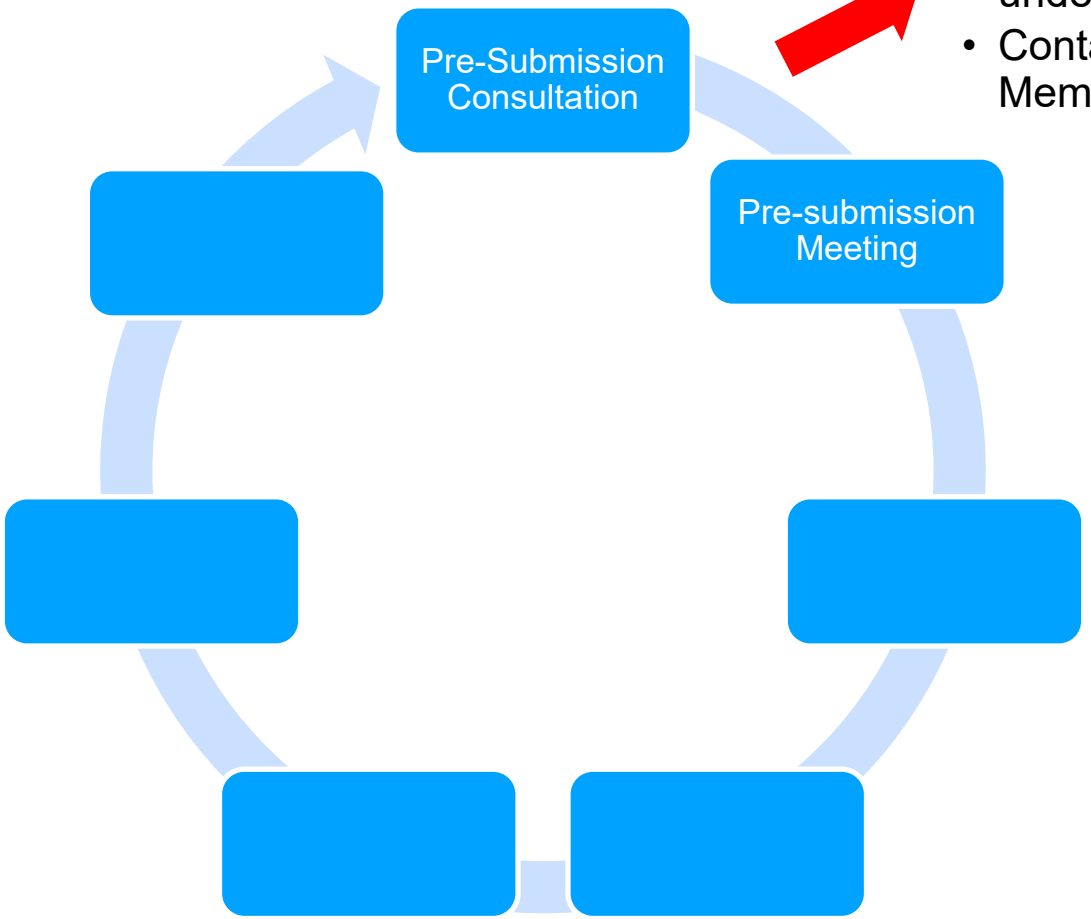
Pre-Submission Consultation

- In line with Annex 3 of the BPR, an intending applicant must initiate a pre-submission consultation with the Irish Competent Authority before an application for authorisation is made.

The following procedures will be followed.

- ✓ A completed Work Request Form for the evaluation of a biocidal product or product family must be submitted to PRCD biocide-authorisations@agriculture.gov.ie.
- ✓ PRCD will provide a decision on the work request as soon as possible after submission.
- ✓ If the work request is accepted by PRCD, a pre-submission meeting will be organised.

National Authorisation and Mutual Recognition



- No capacity to undertake evaluation
- Contact another Member State

Pre-Submission Meeting

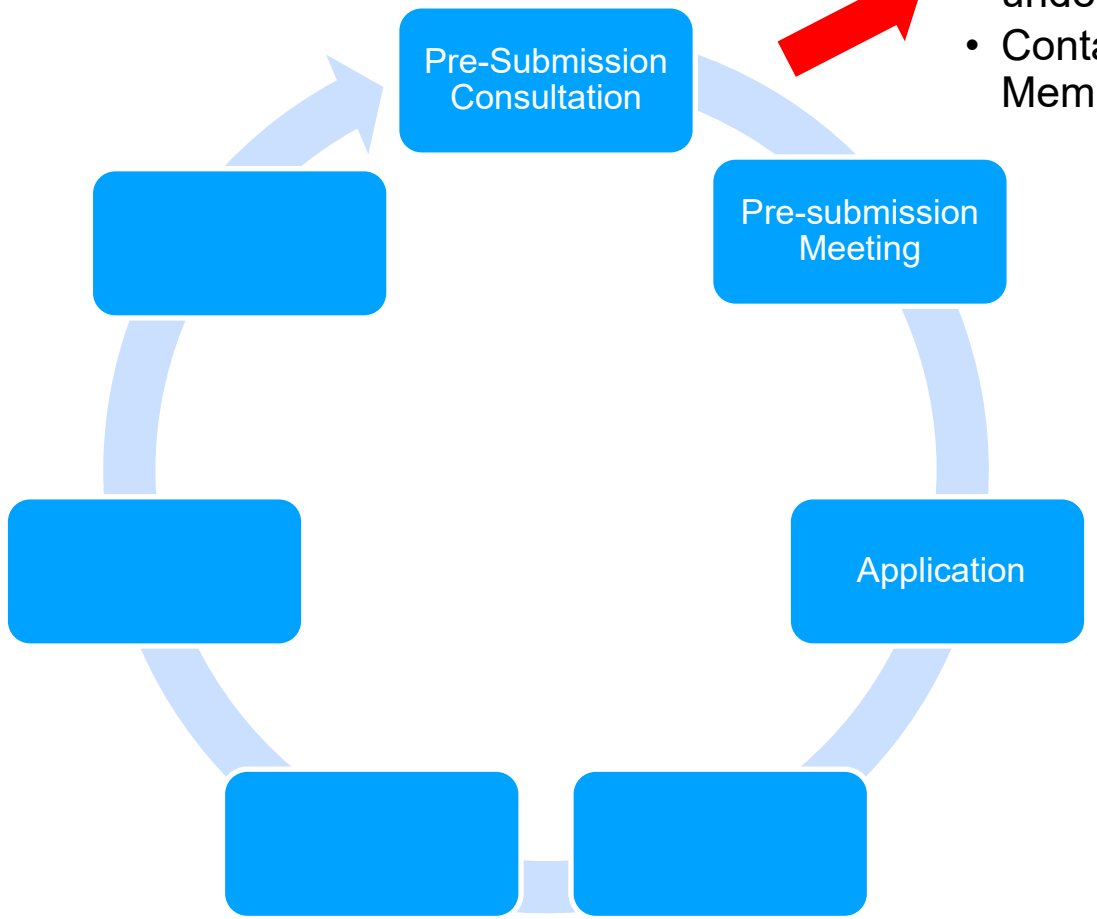
- An opportunity for you to provide further information to the evaluation team on the product/family dossier to be submitted.
- An opportunity for us explain in further detail the evaluation process, timelines, and ask specific questions on the dossier.

Preparation: Intending applications will need to prepare a presentation covering the following areas:

- General Overview
- Chemistry
- Mammalian Toxicology
- Environmental Fate & Behaviour/Environmental Chemistry
- Ecotoxicology
- Efficacy

Important: Highlight any known data gaps (if any) in the dossier and the steps being undertaken to address them.

National Authorisation and Mutual Recognition

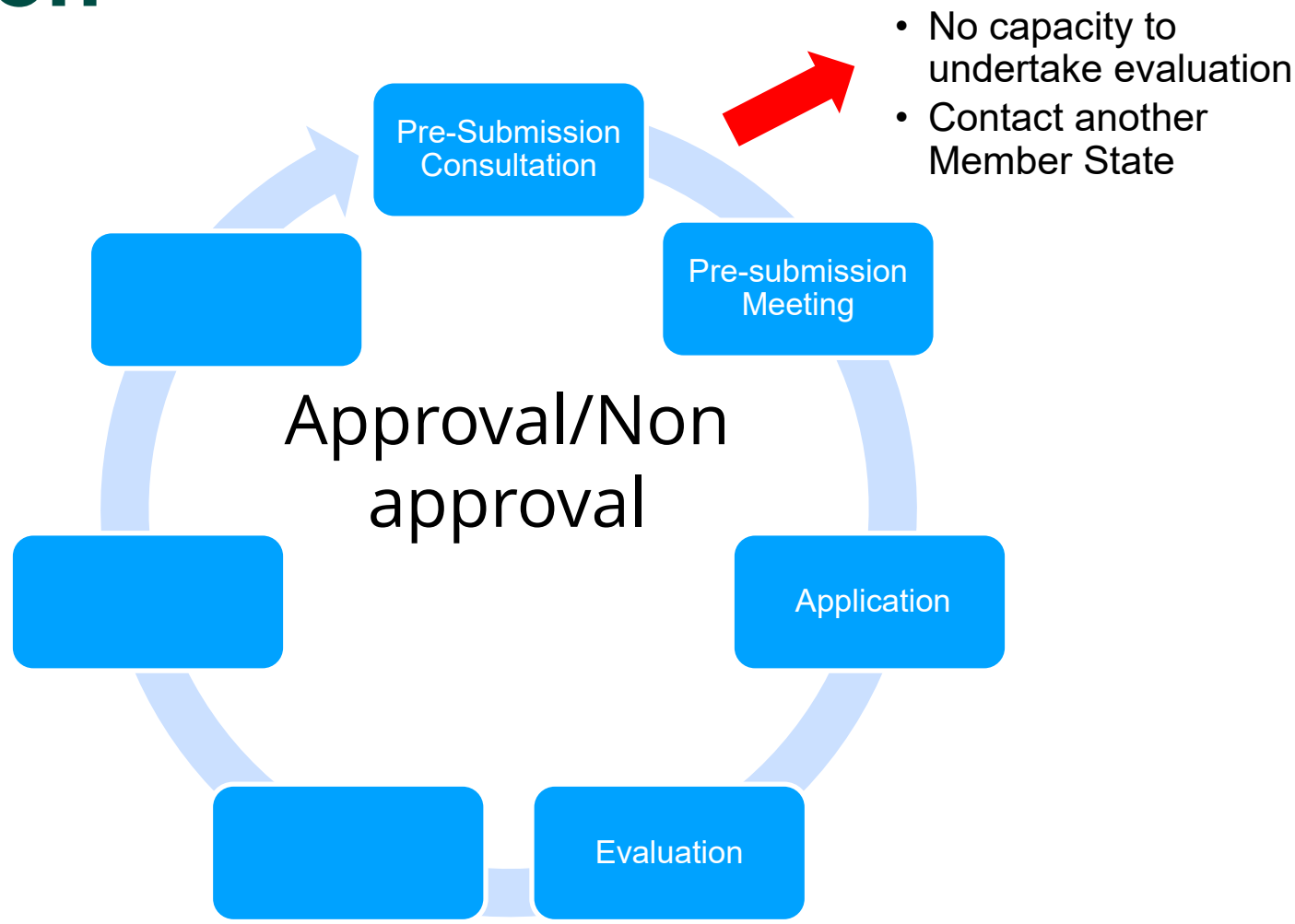


- No capacity to undertake evaluation
- Contact another Member State

Application

- NA-APP or UA-APP application for Authorisation
- Requirements as listed per Article 20
  - *Dossier or letter of access for the product satisfying the requirements outlined in Annex III*
  - *Summary of Product Characteristics (SPC)*
  - *Dossier or letter of access for the product satisfying the requirements outlined in Annex II for each active substance in the product.*
- Ensure the dossier is complete!
- List all MS's for mutual recognition in parallel (NA-MRP)
- Fees payable to PRCD before the evaluation can commence
- Cannot make multiple applications across MS's.

National Authorisation and Mutual Recognition

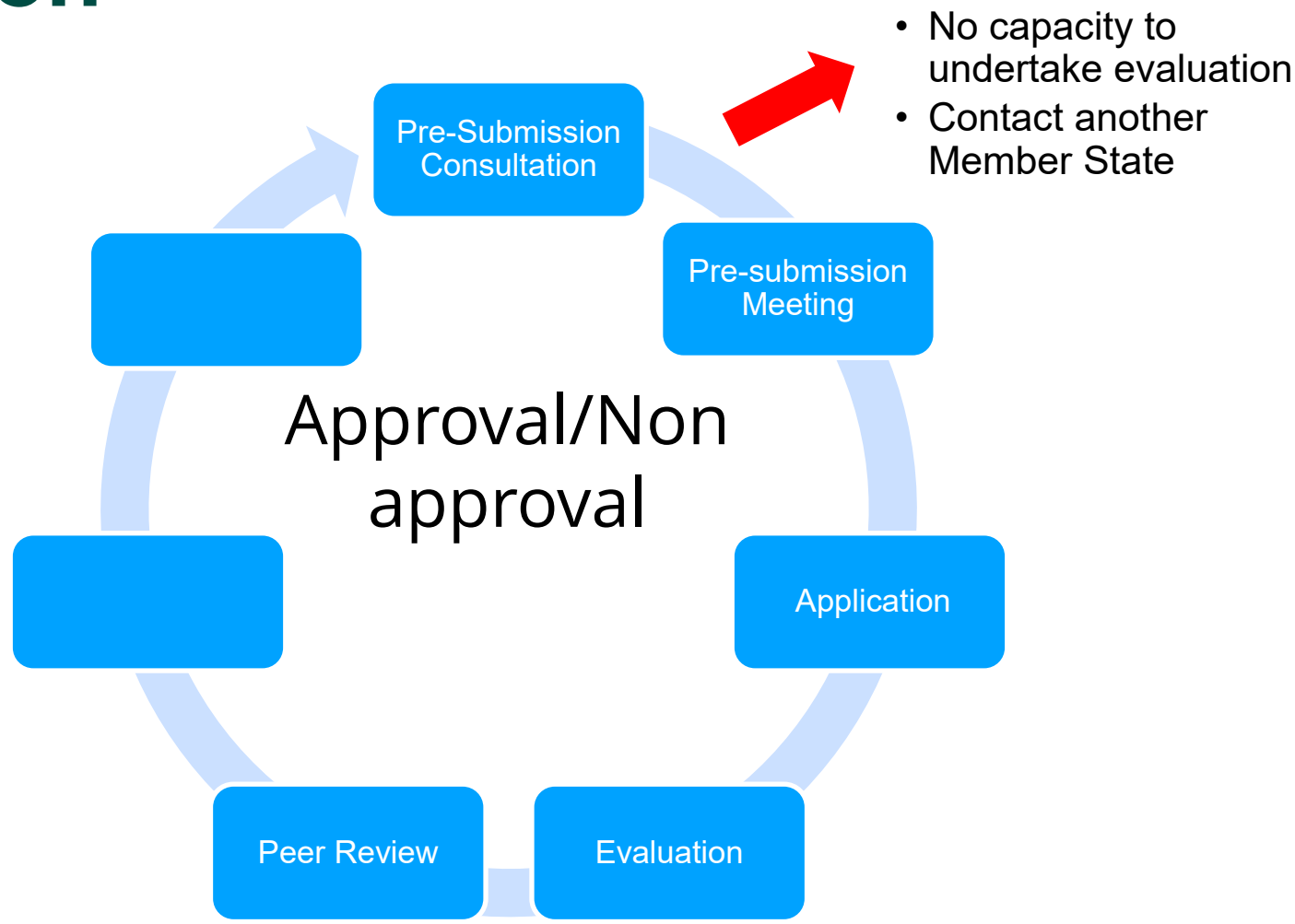


- No capacity to undertake evaluation
- Contact another Member State

Evaluation

- Joins the application queue
- Validation – 30 days after acceptance of the application
- 90 days to re-submit any missing data/information
- Technical sift – qualitative checks carried by evaluation team
- Stop the clock (shall not exceed 180 days)
- We have the right to reject the application if data/information is not submitted on time.
- Approval/Non-Approval Decision

National Authorisation and Mutual Recognition



- No capacity to undertake evaluation
- Contact another Member State

Peer Review for Mutual Recognition

- Article 32 – "…authorise the BP under the same terms and conditions."
- Timeline - 102 days

Step	MR Phase	Days
Step 1	cMS commenting period	40
Step 2	RefMS provides RCOM, and "Updated draft SPC"	14
Step 3	Bilateral discussions RefMS-cMSs	20
	cMS to comment on refMS responses	10
	RefMS to reply to cMS comments	5
	cMS to comment further on refMS responses	5
Step 4	RefMS provides final draft PAR, final draft SPC and final RCOMs	10
Step 5	cMSs agree or indicate disagreement	6
Step 6	Record of the SPC and PAR in R4BP3	2
Step 7	Submission of formal referral by cMSs	10

- Agreement/disagreement on the authorisation among c'MSs

National Authorisation and Mutual Recognition

- No capacity to undertake evaluation
- Contact another Member State

Referral to Co-Ordination Group

- Referrals to CG under Article 35
- *Follow Procedure: 'Resolving disagreements on mutual recognition, renewal, changes, simplified notification and Article 48 procedure: working procedure for the Coordination Group (CG)'*
- Timeline: 60 days
- BPR Coordination Group - ECHA

Steps
Acceptance by CG
Distribution of documents by CG
Commenting/Bi-Lateral Discussions
CG Discussions (if applicable)
Additional Meeting (if required)

- Delays product authorisation, time consuming for authorities, ECHA
- Approval/Non approval or referral to the Commission

National Authorisation and Mutual Recognition

- No capacity to undertake evaluation
- Contact another Member State

Referrals to Commission under Article 36

- RMS notifies Commission of the disagreement
- cMS's and applicant also informed.
- Commission may request an opinion from ECHA.
- Commission will request written comments from the applicant >> 30 days
- Discussion at SCBP >>Implementing Act adopted by the Commission
- rMS/cMS will have 30 days to grant approval/non approval.
- Further delays authorisation, time consuming for all involved

Authorisation

- Authorisation under 19(1) or 19(5)
- Article 37 (Derogation)
- Authorisation for up to maximum of 10 years or up to the expiry of authorisation in the rMS.
- Candidate for substitution - 5 years

Article 19(1)

- Safe use(s) identified.
- The Biocidal Product is sufficiently effective
- No unacceptable effects on:
  - *Target Organism(s)*
  - *Humans*
  - *Environment*
- No unacceptable properties - Phys/Chem, Tox, or Ecotox

Article 19

Conditions for granting an authorisation

1. A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

(a) the active substances are approved for the relevant product-type and any conditions specified for those active substances are met;

(b) it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

(i) the biocidal product is sufficiently effective;

(ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

(iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— the fate and distribution of the biocidal product in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— the impact of the biocidal product on non-target organisms,

— the impact of the biocidal product on biodiversity and the ecosystem;

(c) the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

(d) the physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product;

(e) where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [1], Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food [2], Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [3], Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin [4] or Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed [5];

(f) where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately.

2. The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

(a) realistic worst case conditions under which the biocidal product may be used;

(b) the way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

(c) the consequences of use and disposal of the biocidal product;

(d) cumulative effects;

(e) synergistic effects.

3. A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 20.

[1] OJ L 37, 13.2.1993, p. 1.
[2] OJ L 338, 13.11.2004, p. 4.
[3] OJ L 70, 16.3.2005, p. 1.
[4] OJ L 152, 16.6.2009, p. 11.
[5] OJ L 140, 30.5.2002, p. 10.

Article 19(5)

- Authorisation where there is unacceptable risk to humans, animals and the environment
- Disproportionate negative impact on society if not authorised
- Subject to appropriate risk mitigation measures to ensure exposure to humans, animals and the environment are minimised.

5. Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met.

Article 37 Derogation from Mutual Recognition

- Refuse authorisation or
- Adjust the terms and conditions of an authorisation
- Such a measure can be justified on the grounds of:
  - *Protection of the environment*
  - *Public policy/security*
  - *Human, animal or plant health*
  - *Protection of National Treasures*
  - *Target organism(s) not present in harmful quantities.*

Article 37

Derogations from mutual recognition

1. By way of derogation from Article 32(2), any of the Member States concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:

(a) the protection of the environment;

(b) public policy or public security;

(c) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;

(d) the protection of national treasures possessing artistic, historic or archaeological value; or

(e) the target organisms not being present in harmful quantities.

National Authorisations (NA-APP)

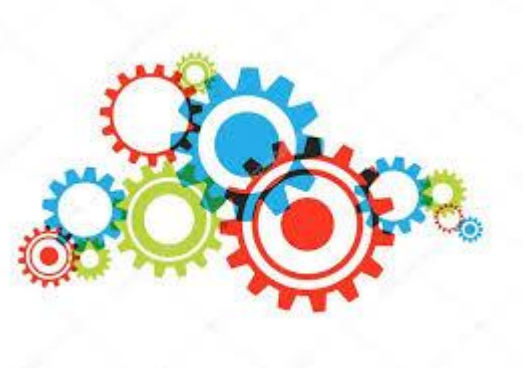
Lessons Learned from on-going and completed applications:

- Validation – Full sections of the dossier not completed
- Technical Sift: Poorly compiled dossier: incomplete/missing studies >> Delays evaluation.
- Products claims – we have to be able to evaluate all claims!!

- Its not the responsibility of the CA to make an evaluation work for the data submitted!
- CA's are not in a position to advise on product formulation or claims!
- Evaluation doesn't automatically assume authorisation!

Challenges – MR Process

- Harmonisation
  - *Member state agreement on assessment and risk management*
- Timelines
  - *Dossier submission to decision making and vote >10 years*
- Moving goalposts
  - *Change in data requirements, guidance, new information, etc.*
- Expertise and knowledge
  - *Applicants, MS competent authorities and evaluators*
- Other regulatory regimes (e.g. CLP, REACH)

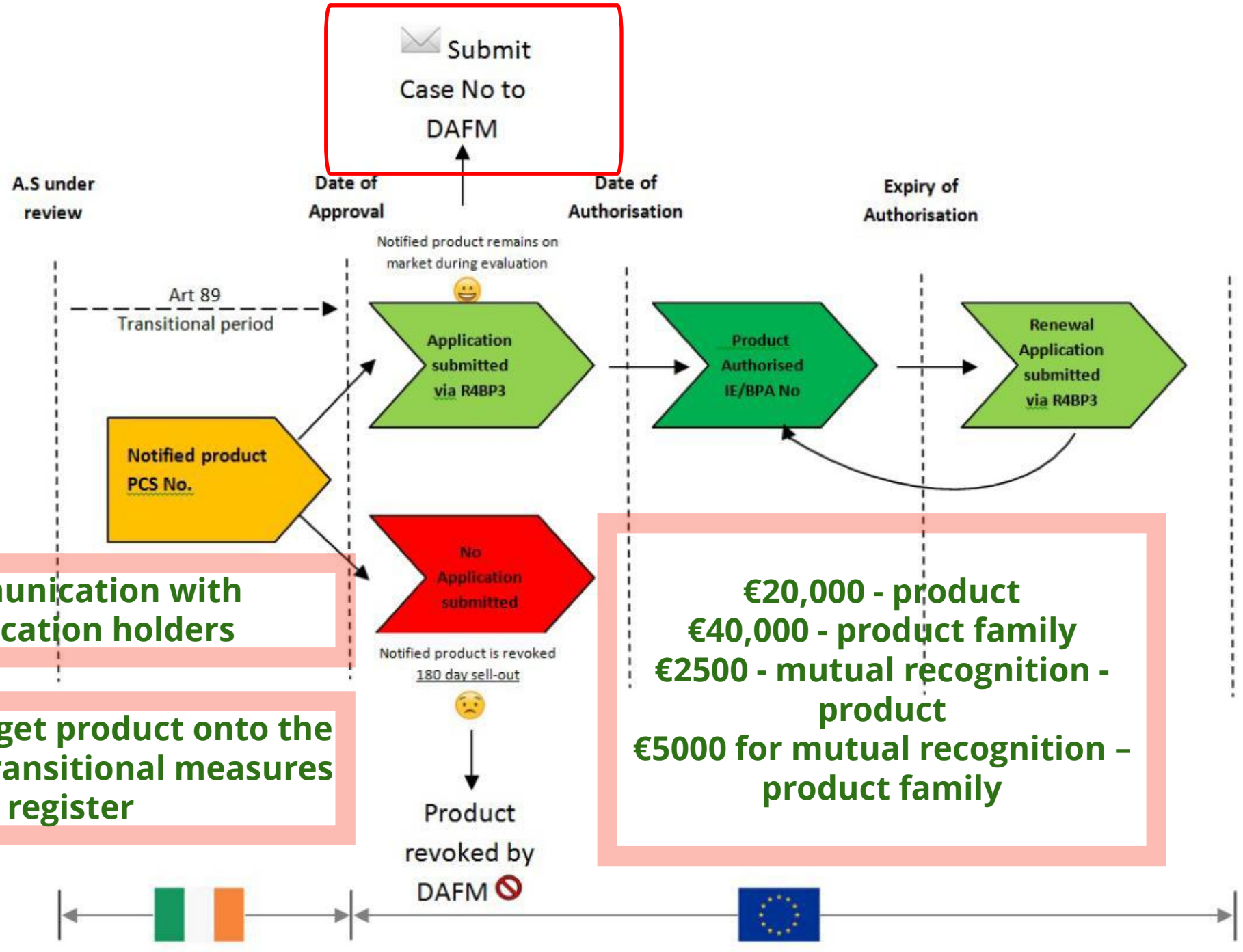


Renewal of Authorisations (NA-RNL)

- In line with Article 31, a renewal applications must be received at least 550 days before the expiry of the authorisation.
- Full or partial evaluation
- Ensure rMS and all cMS's are listed.
- Extension of authorisation can be granted under Article 31(7)

Other Authorisation Options

- Union Authorisation (UA-APP)
  - *Access to all MS markets*
  - *Costly*
- Same Biocidal Product (NA-BBP or NA-BBS)
  - *Must be identical composition to an authorised product*
  - *Possible cost effective option to enter biocide market*
  - *May be costly to purchase a letter of access to an authorised product*
- Parallel Trade Permits
  - *Parallel trade permits are designed for identical biocidal products allowing products to be made available on the market in one Member State (Member State of Origin) if the biocidal product is identical to a biocidal product already authorised in the Member State of Introduction (rMS).*
  - *Possible cost effective option (€500) to enter the biocide market.*


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
Communication with Notification holders
€300 fee to get product onto the 'Notified' transitional measures register
€20,000 - product
€40,000 - product family
€2500 - mutual recognition - product
€5000 for mutual recognition – product family

Biocidal Product Authorisation

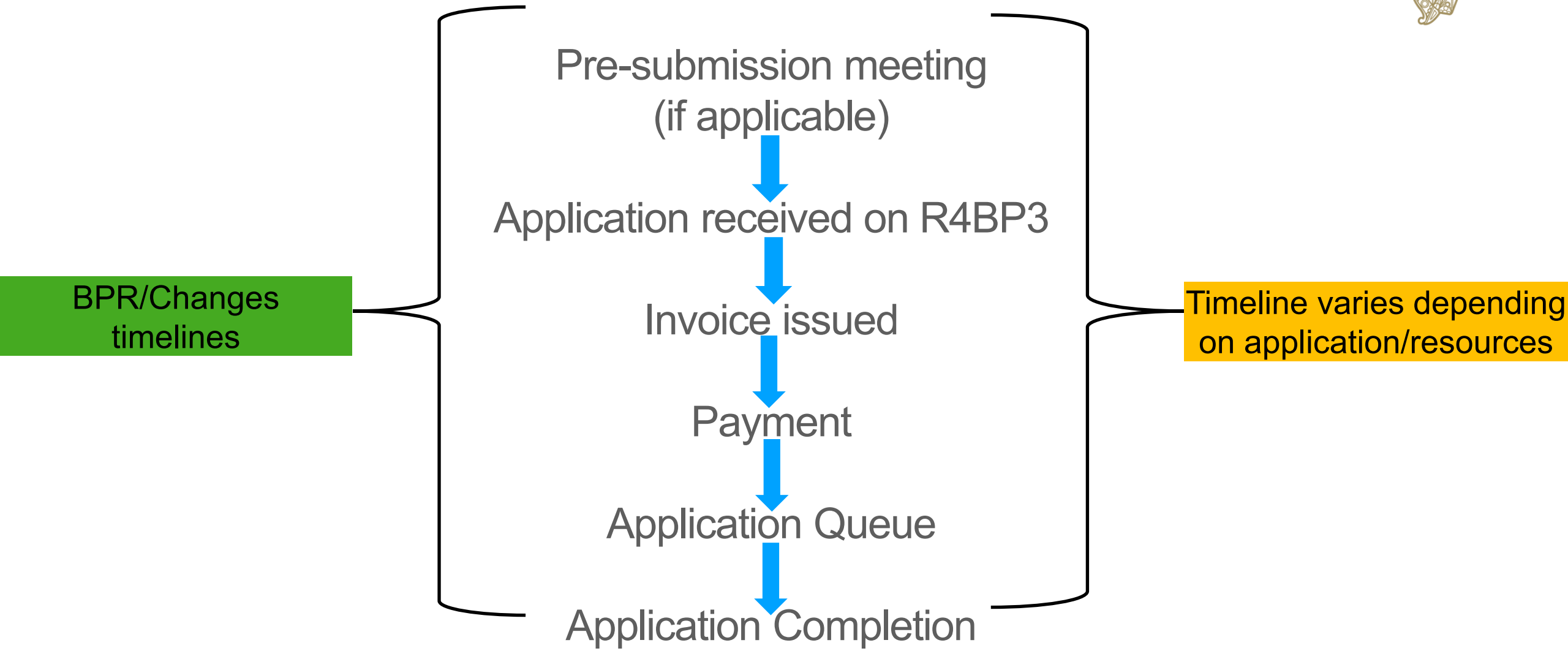
- Simplified Authorisation procedure (single product) **€5,000**
- Simplified Authorisation procedure (product family) **€10,000**
- Same biocidal product (single product) **€300**
- Same biocidal product (product family) **€1,300**
- Union Authorisation (single product) **€75,000**
- Union Authorisation (product family) **€150,000**

Changes to Authorised Products

• Administrative changes (NA-ADC)	**€300**
• Transfer of product authorisation (NA-TRS)	**€300**
• Minor change (NA-MIC)	**€1,500**
• NA-MAC single product (ref MS)	**€5,000**
• NA-MAC product family (ref MS)	**€10,000**
• NA-MAC (Product and family) - cMS	**€2,000**
• SA-MAC (Simplified Auth single product) – ref MS	**€2,500**
• SA-MAC (Simplified Auth product family) – ref MS	**€5,000**
• SA-MAC (Simplified Auth product and family) - cMS	**€1,000**

- **No grouping fee available in the current fee structure**

Processing applications



Advertising and Labelling – Enforcement

Conditions of authorisation on the certificate:

(1) Product may not be made available on the market or used in the Republic of Ireland unless it complies with the Annexes of this authorisation.

(4) All product made available on the market in Ireland must comply with the classification, labelling and packaging requirements established in: Article 69 of Regulation (EU) No 528/2012; the Chemicals Act 2008 (as amended) transposing Regulation (EC) No 1272/2008; and the classification, labelling and Safety Data Sheet information detailed in the Annex II to this certificate.

(5) All biocidal products advertised must comply with Article 72 of Regulation (EU) No 528/2012.

(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

Common Issues– Label Review

Common issues:

- Labels submitted with no/partial text from the SPC
- No directions for use or not made fully clear to the user.
- Claims/uses/target species that haven't been authorised.
- Information outlined in Article 69(2) is missing.

What's needed?

- ✓ Use description as per the SPC (authorised uses, users; target species; application rate, application method etc.,); full directions for use including risk mitigation measures and disposal instructions
- ✓ Only authorised uses/PT's and claims can be on the label
- ✓ Text on the SPC has to be transposed exactly onto the label - no deviation
- ✓ Follow Article 69 of the BPR.
- ✓ Cannot assume that a user (i.e., amateur or professional) knows how to use your product!
- ✓ No Misleading words like Safe, Organic, Green, Bio, Eco, Nature

Causes significant delays in processing applications!

Annual Registration Fees

- All products on the biocidal product registers in Ireland are subject to annual registration fees.
  - *Amateur use products (non professional)* ***€125***
  - *Professional, Trained Professional and Industrial use products* ***€225***
  - *Late Fees or re-instatement on the register (non professional)* ***€225***
  - *Late Fees or re-instatement on the register (Professional +)* ***€425***
- Failure to pay means an immediate revocation from the register.
- Very small number of authorised products revoked for not paying fees
- Industry: Annual review of what products are on the Irish Market
- Usual NA-ADC applications to remove trade name(s)

PRCD - Home

https://www.pcs.agriculture.gov.ie

Sign in

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BIOCIDES

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- Changes to Use of Anticoagulant Rodenticides

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Useful Links

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Listen

Welcome to the Pesticide Registration and Control Divisions (PRCD) of the Department of Agriculture, Food & the Marine. Pesticides are regulated in Ireland by PRCD to ensure their safe use and high levels of protection of human and animal health and the environment. Read more in the About Us section.

PCS.AGRICULTURE.GOV.IE

Thank you for your attention!

- **E-mail:** Mervyn.Parr@agriculture.gov.ie

Biocides (Helpdesk):
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