

Understanding EU and GB Biocidal Product Registration Routes:

Strategic Considerations and Common Pitfalls

Dr Helen Pye,

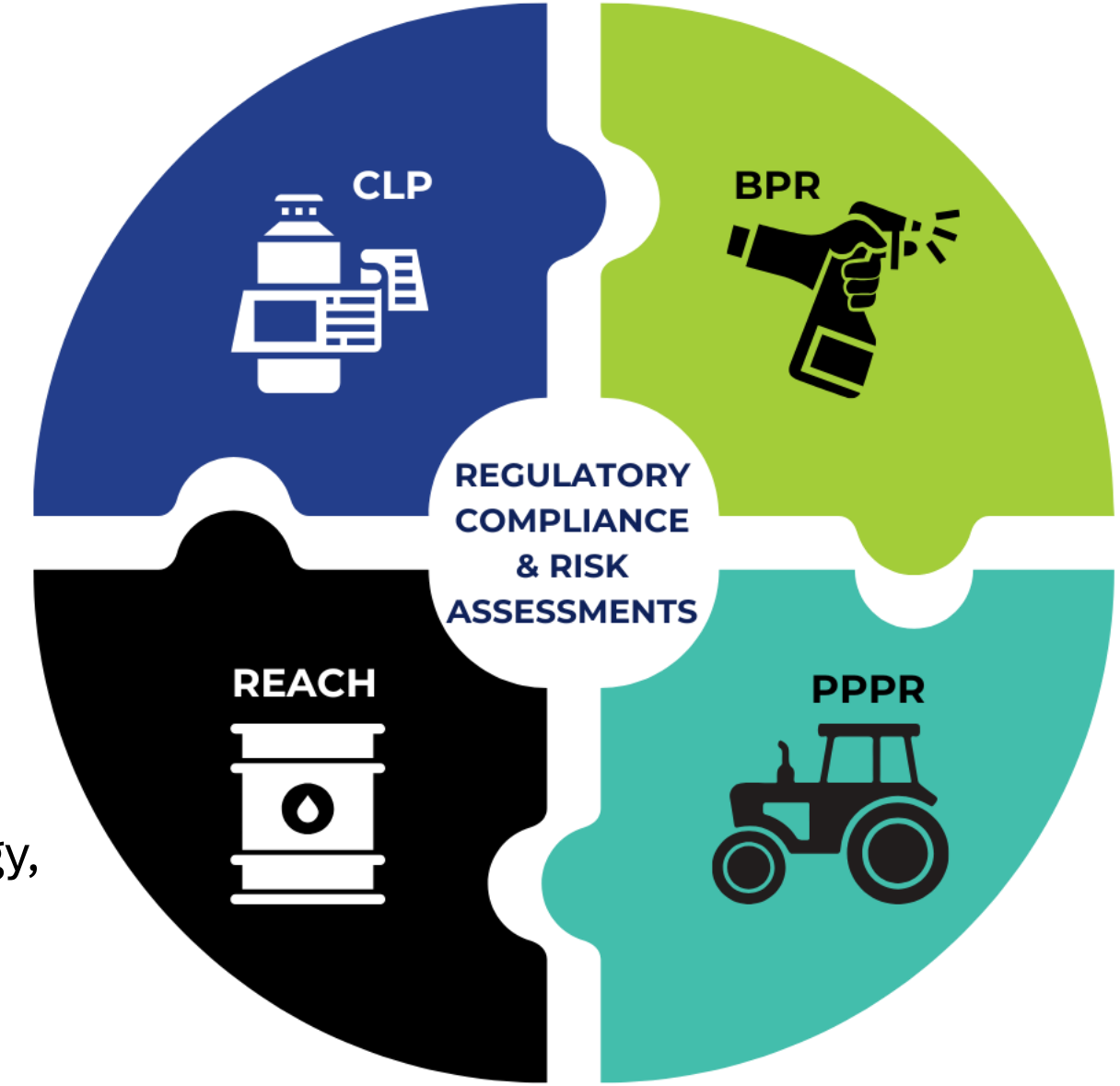
Senior Biocide Consultant, Enviresearch

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WHO ARE ENVIRESEARCH

- Offices in both UK and Portugal
- Regulatory and risk assessment services
- Multidisciplinary team - scientists and regulatory consultants
- Specialists in chemistry, analytical methods, environmental fate, ecotoxicology, residues and efficacy.



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WHAT IS THE BPR?

- 2013 - Biocidal Products Regulation (applicable to all EU member states)

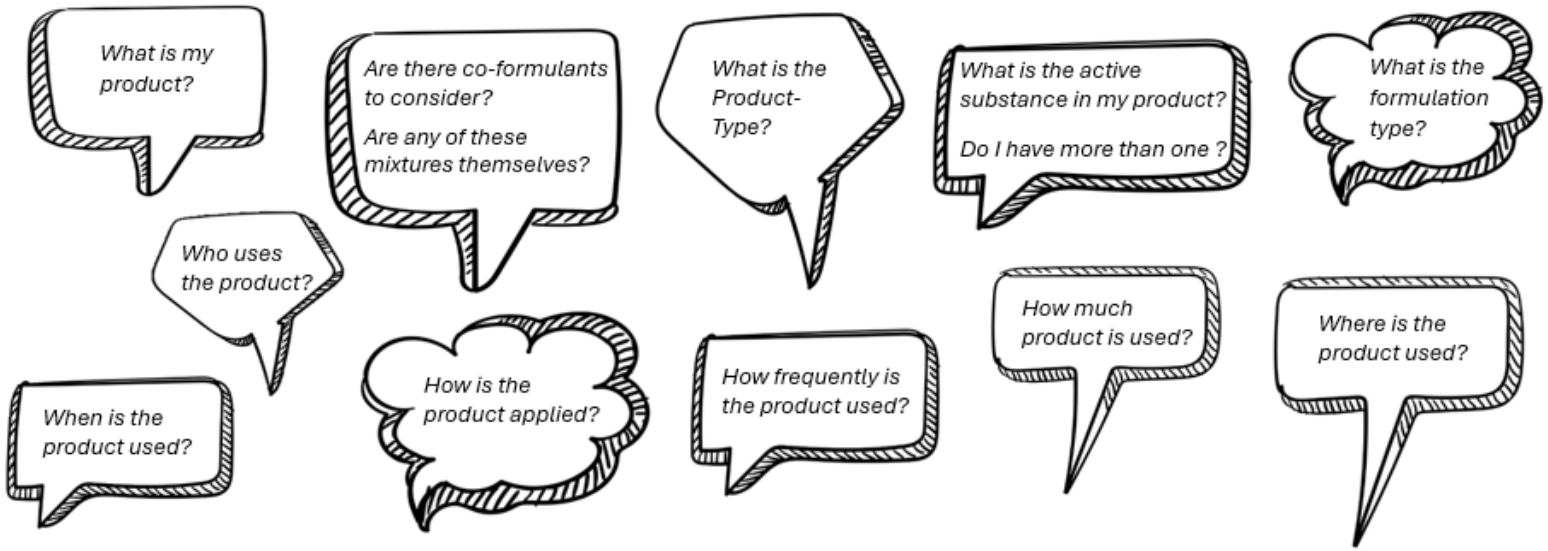
- Dual aspect
  - Active Substance review programme
  - Biocidal Product approval

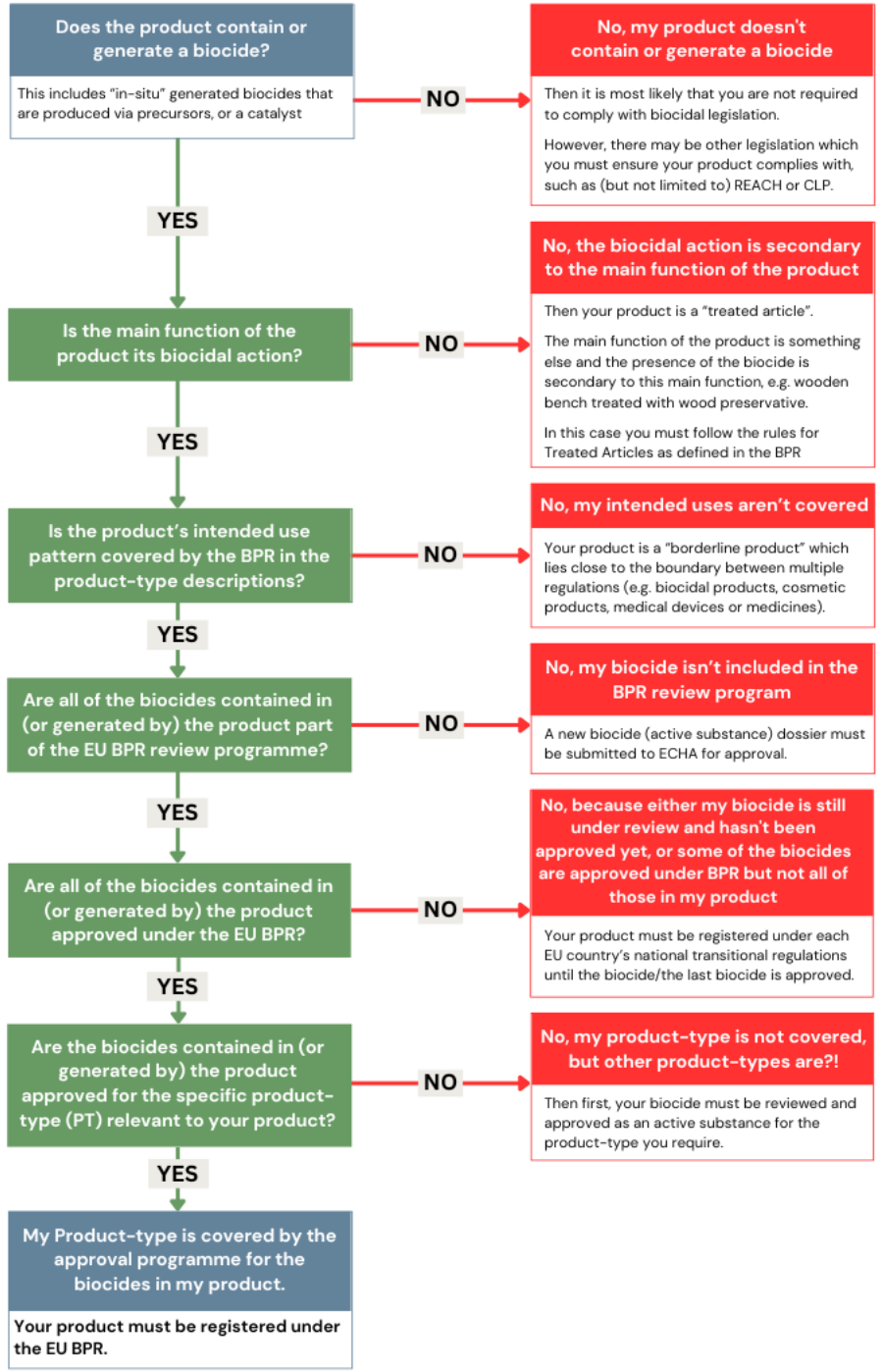
- Aims to ensure end users of the products are protected
  - No unacceptable risks to users or bystanders
  - No unacceptable risks to the environment
  - Efficacious for users and remain so during shelf life



BPR DECISION TREE

- The outcome of each question determines the appropriate route to market





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PRODUCT REGISTRATION STRATEGY

- Transitional/pre-BPR
- Union Authorisation
- Simplified Authorisation
- Same Biocidal Product (SBP)
- National Authorisation

EU GB GB&EU

Information **Advantage**

Limitation **Consideration**

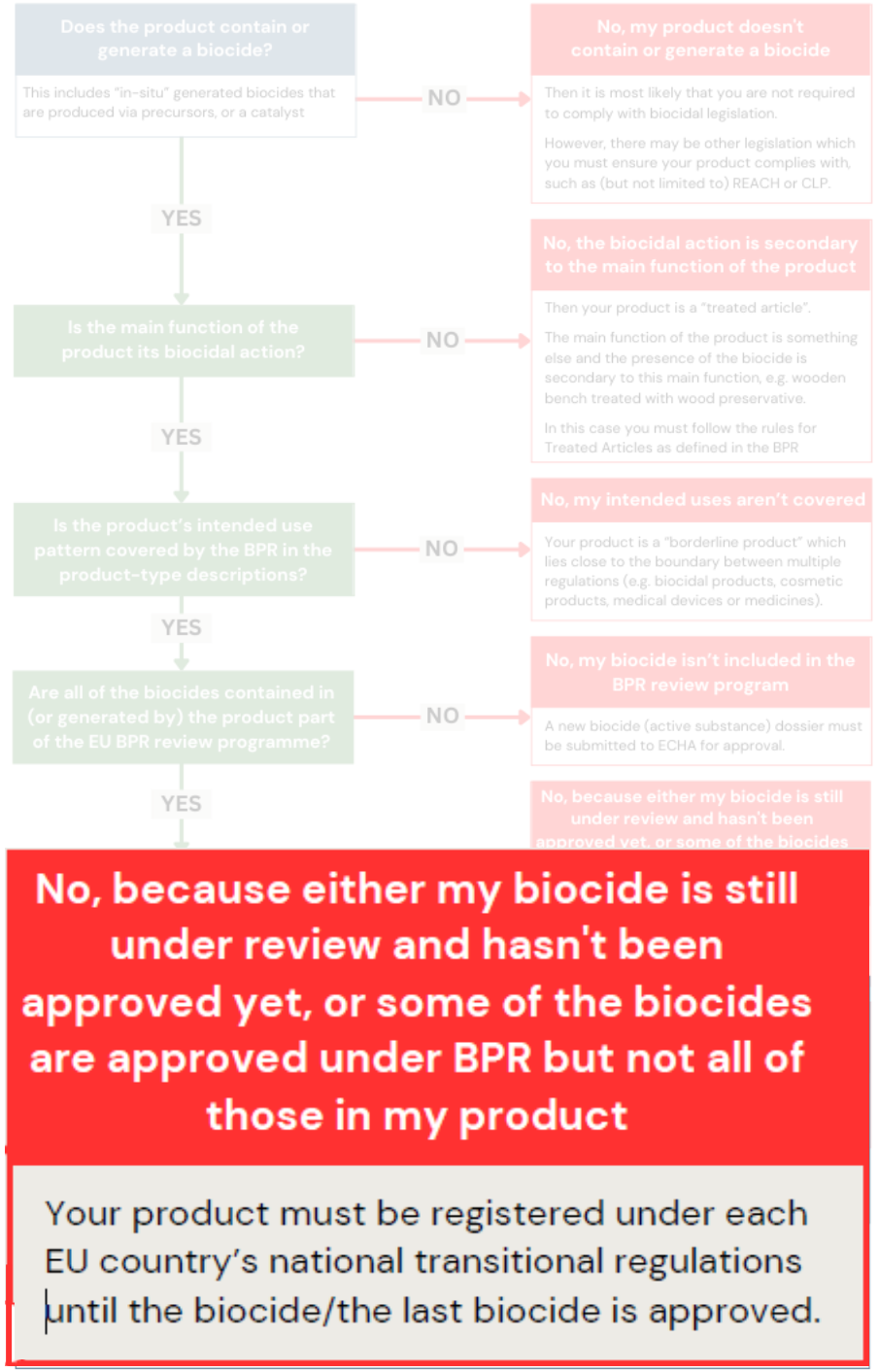


BIOCIDAL PRODUCT: ROUTE TO MARKET - TRANSITIONAL MEASURES (Art. 89)

My product:

- ✅ contains a biocidal active substance (or more than one!)
- ✅ the main function of the product is its biocidal action
- ✅ the use pattern is covered by a BPR Product Type
- ✅ the active substance(s) are included in the review programme
- ⛔ all contained active substances are approved

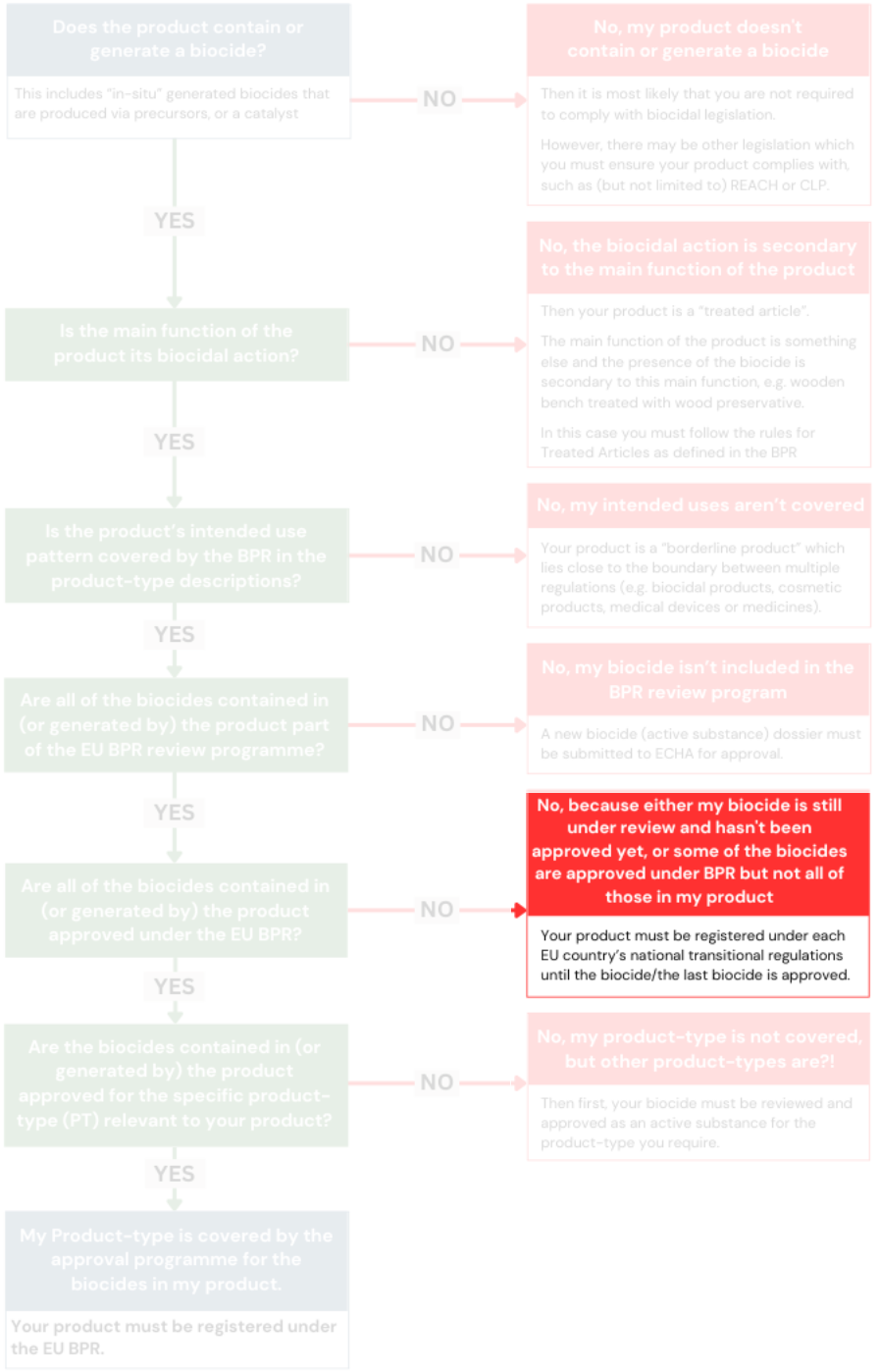
→ **product is regulated under Transitional Measures**



GB&EU

TRANSITIONAL MEASURES (Art. 89)

- ℹ️ Pre-existing national registration route (before BPR)
- ✅ Mandatory
- ⛔ Country-by-country, requirements vary greatly
  - No obligations – quick, low/no cost €0, basic dataset
  - Full evaluation – slow, high cost (€300- €22,000++), full dataset
- ⚠️ Translations
- ⚠️ Annual fees
- ⚠️ Volume declarations
- ⚠️ PCN, CLP, REACH, Art 95, advertising requirements
- ⛔ Valid until last AS is approved and BPR applies
  - Submit a BPR dossier in time to maintain market access!



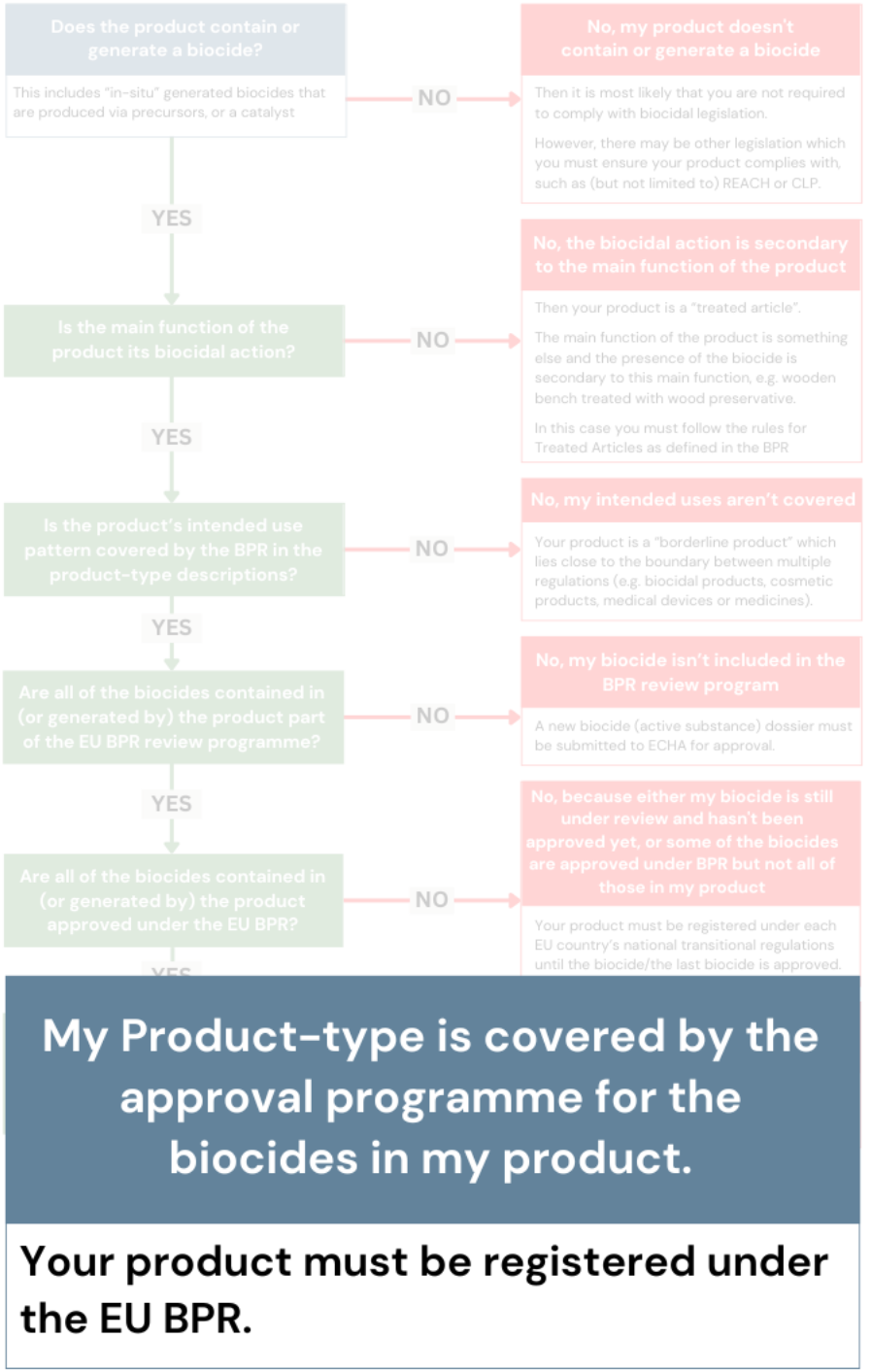
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BIOCIDAL PRODUCT: ROUTE TO MARKET – FULL BPR SUBMISSION

My product:

- ✅ Contains a biocidal active substance (or more than one!)
- ✅ The main function of the product is its biocidal action
- ✅ The use pattern is covered by a BPR Product Type
- ✅ The active substance(s) are included in the review programme
- ✅ All contained active substances are approved
- ✅ Active substances are approved for my Product Type

→ **product regulated under BPR**



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EU/GB

PRODUCT REGISTRATION STRATEGY

⚠ Different registration routes:

- Union Authorisation
- Simplified Authorisation
- Same Biocidal Product
- National Authorisation

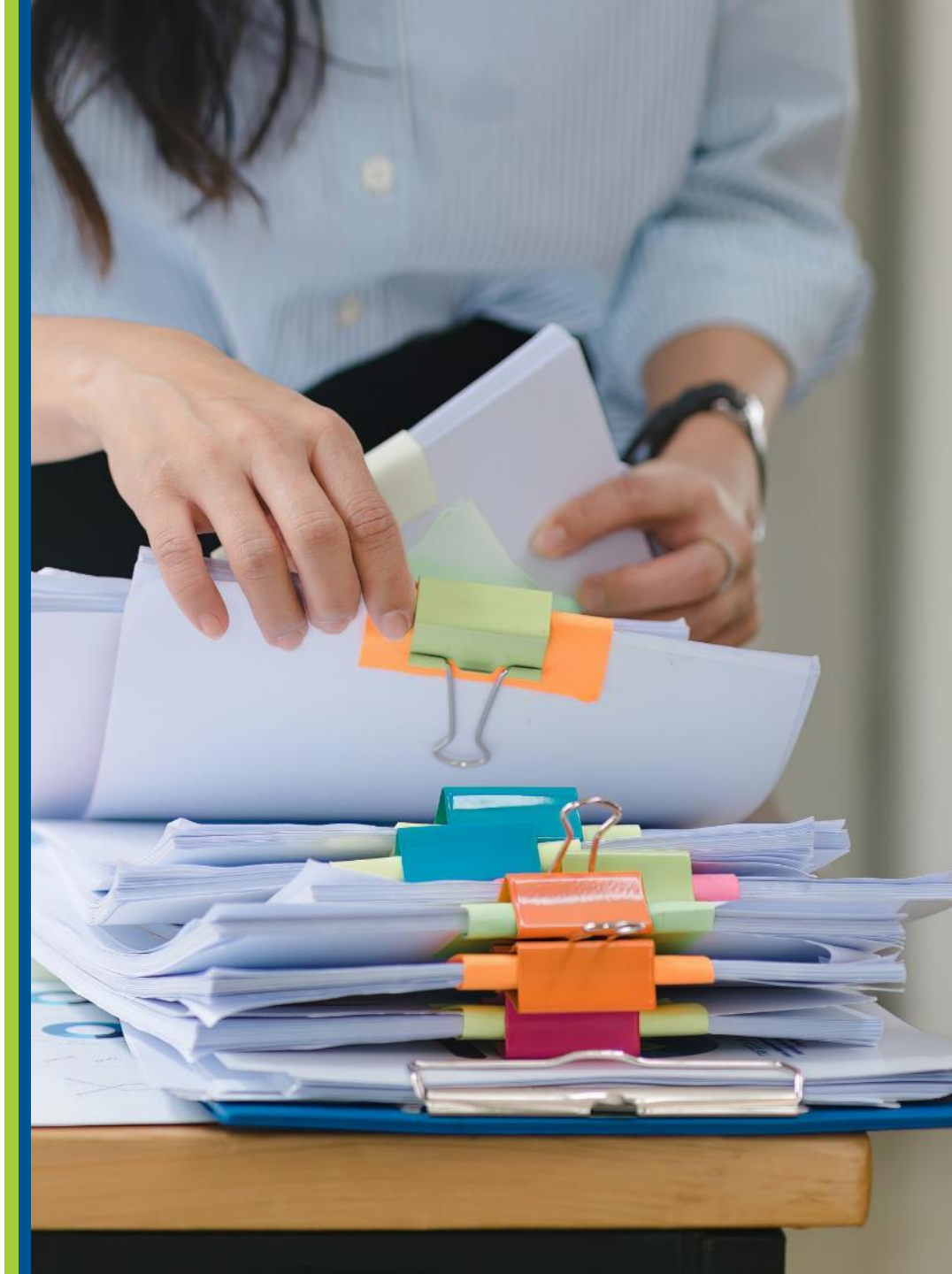
ℹ Pre-submission meeting with evaluating competent authority

- Fees ~ €1000-€5000
- Mutually agreeable plan, don't over or under submit

ℹ Submission via R4BP3 platform

✅ Changes allowed:

- Admin - no change to properties/efficacy €300-€1200
- Minor - limited reassessment €1500-€26,800
- Major - extensive reassessment €5000-€76,000



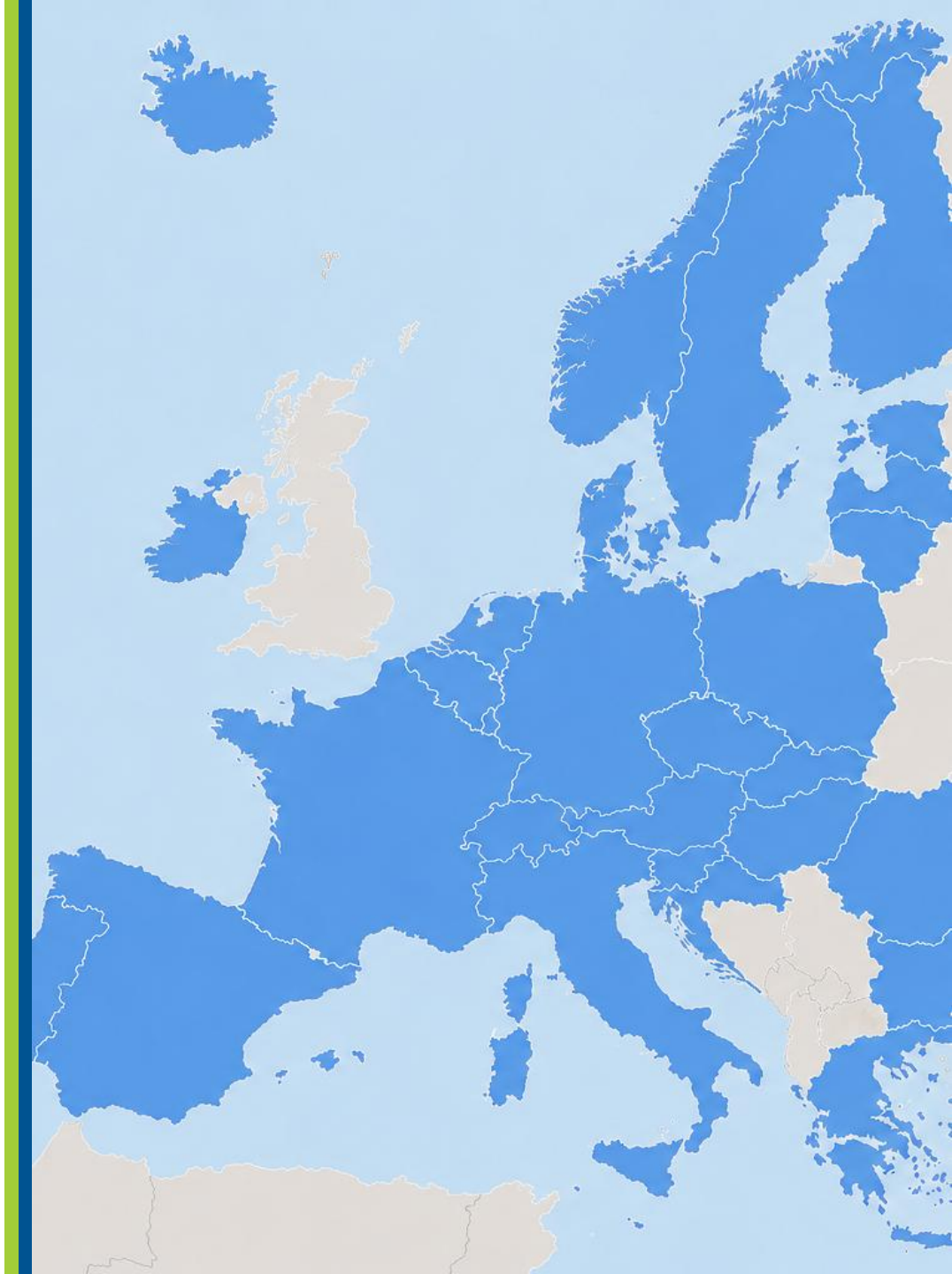
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EU

UNION AUTHORISAION

- ✅ Gain market access across all EU MSs via single application.
- ⛔ Specific exclusions
  - not PT14, 15, 17, 20, 21
- ⚠️ Choose eCA - capacity issues
- ⚠️ Full evaluation and full data set
- ⚠️ Time: uncertain ~1-2 years+
- ⛔ Fees: Expensive!
  - ECHA fee €95,600 plus annual fee €11,950
  - ✅ Verified SMEs can get a reduction of 20-60%
  - eCA fee €40,000- €133,000
  - Renewals €10,000- €75,000
- ⚠️ Translations into ~27 languages



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NATIONAL AUTHORISAION

⚠ Choose an eCA

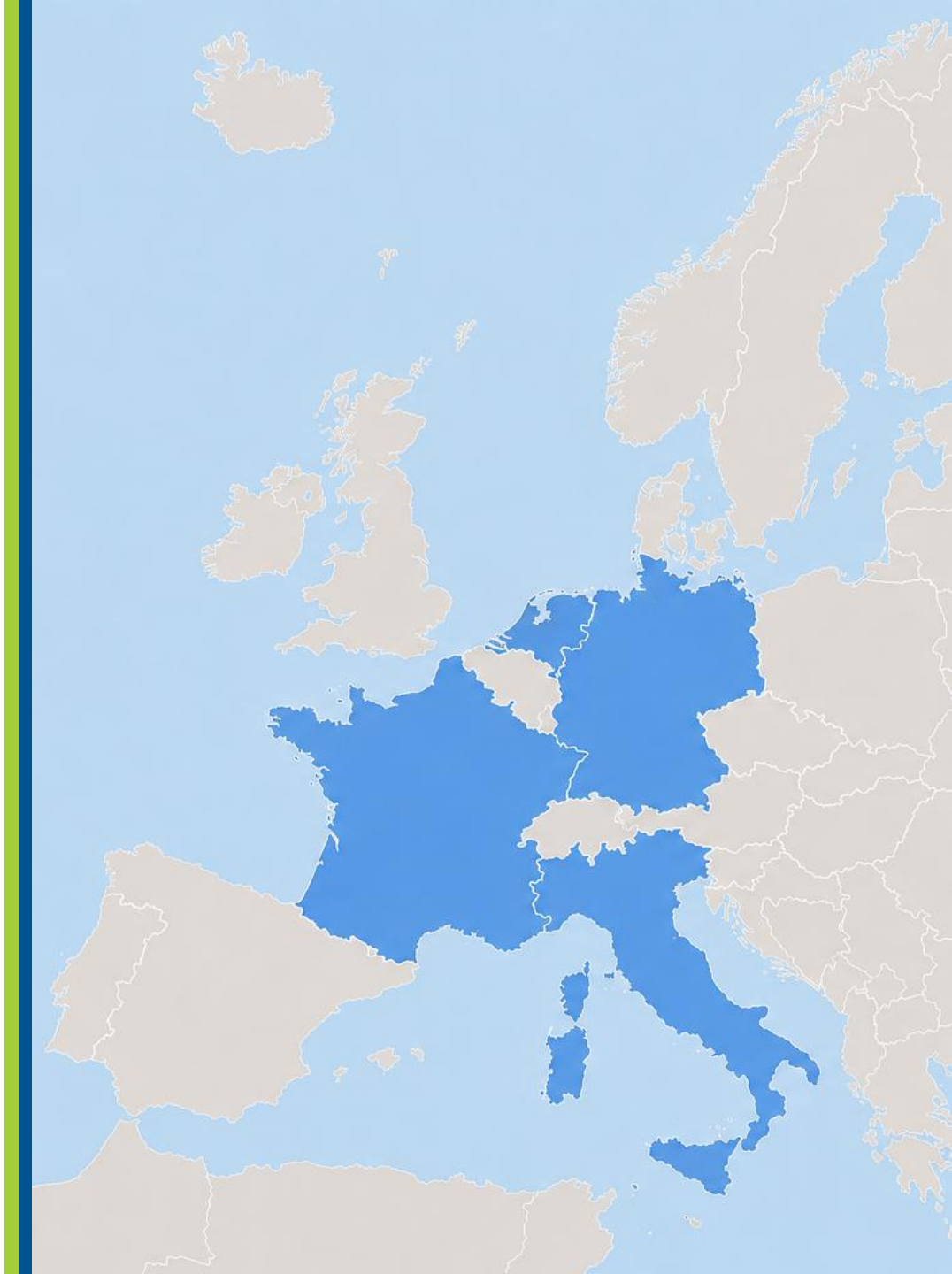
ℹ Mutual recognition

⚠ Fees:

- ECHA fee €837 per cMS
- eCA fee €20,000-€113,000
- cMS fee €8000-€57000

⛔ Country specific extras

- Germany, Hungary, Portugal



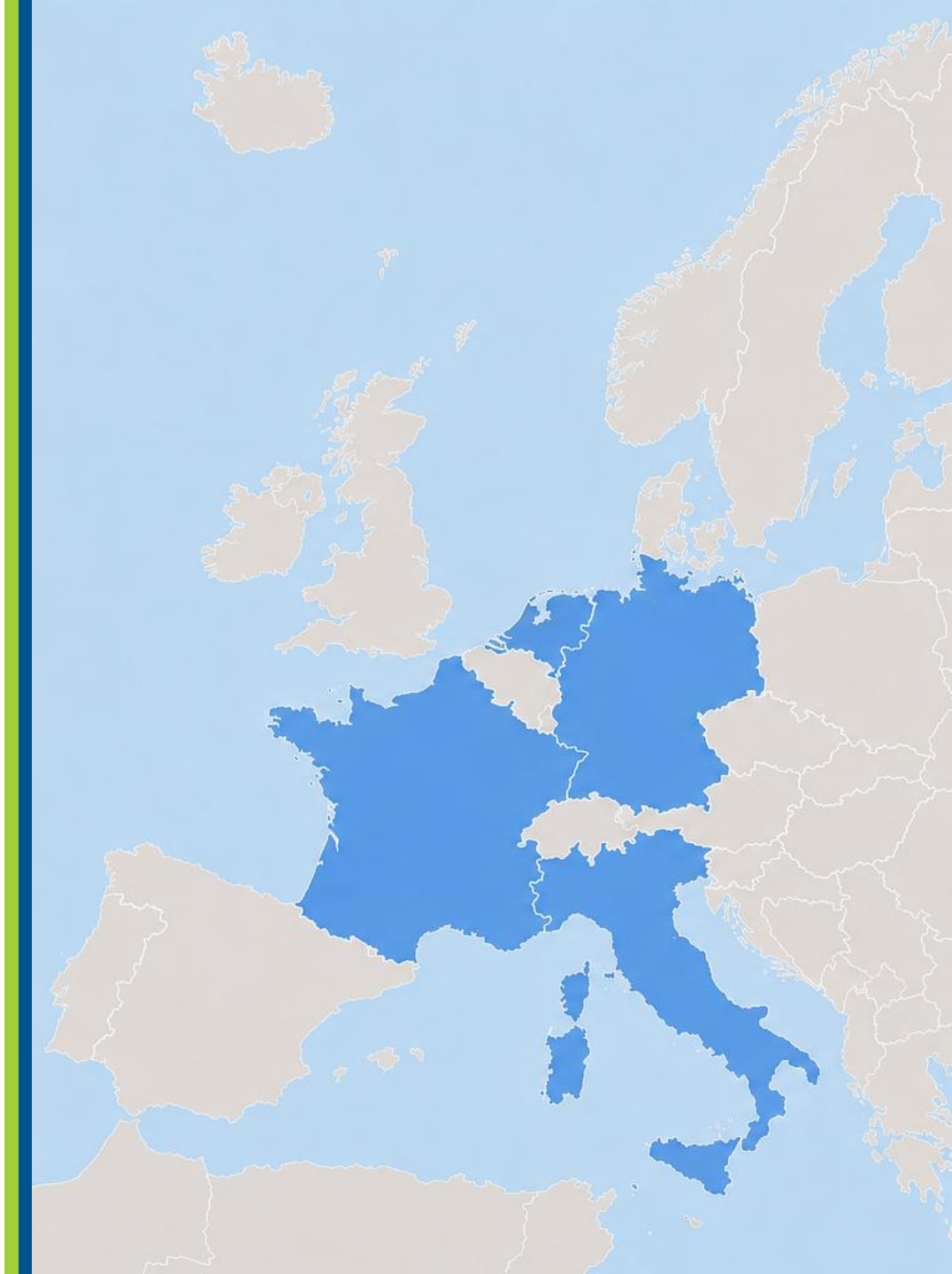
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EU

NATIONAL AUTHORISATION

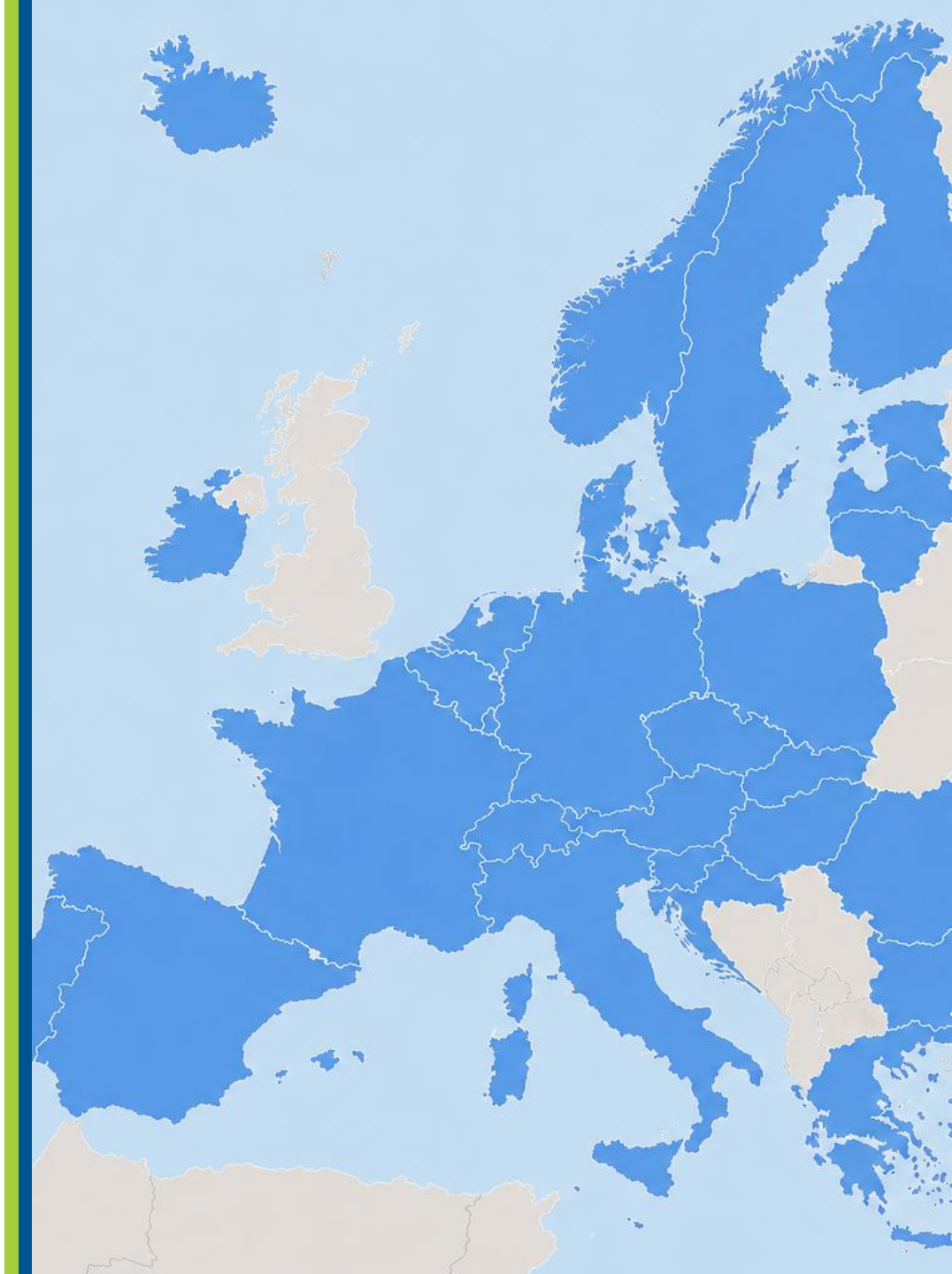
- Mutual recognition in parallel
  - ℹ️ At submission
  - ✅ Simultaneous approvals across chosen MS
  - ✅ Potentially faster process to all markets
  - ⛔ Wait for all cMS to review and agree (or not)
  - ⚠️ ~1-2 years plus 5 months for all cMS – delays!

- Mutual recognition in sequence
  - ℹ️ After approval
  - ✅ Additional cMS can be chosen as needed
  - ⚠️ ~1-2 years plus 5 months per cMS – delays!
  - ⛔ Can be more expensive



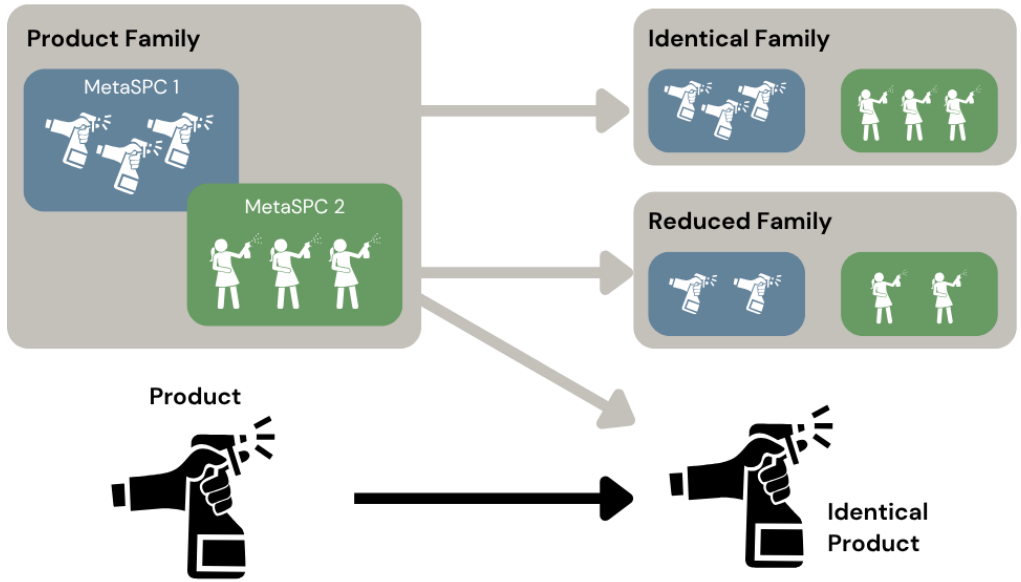
SIMPLIFIED AUTHORISATION (Art. 25)

- ✅ Covers all EU countries, choose eCA
  - No mutual recognition required, 30 day notification
- ⛔ Specific criteria:
  - All AS contained appear in Annex I (low risk)
  - Product is efficacious
  - Product does not contain any substance of concern
  - Product does not contain nanomaterials
  - No personal protective equipment (PPE) required
- ✅ Time: 90 – 180 days
- ⚠️ Fees: ECHA €0, eCA €2050- €24,700
- ⚠️ Notification to cMS: €800- €1000



SAME BIOCIDAL PRODUCT

- ℹ️ Duplicate of a National or Union authorisation
- ⚠️ Use original approving eCA
- ⚠️ Must be **IDENTICAL**
  - Except trade names or manufacturing site
- ⛔ Tied to someone else's approval
- ⚠️ Cost: Letter of Access to full dataset
- ✅ Fees: €300- €19,500
- ✅ Time: short - 60-90 days



ONGOING RESPONSIBILITIES

- ⚠ **Poison Centre Notification (PCN)**
  - Applicable to any substance or mixture with human or physical hazard
  - Submission fees and annual maintenance fees
- ⚠ **Annual declarations -** volume/tonnage & fees
- ⚠ Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**)
  - Compliant SDS
  - Co-formulant tonnages and registered suppliers
- ⚠ Classification, Labelling and Packaging of Chemicals (**CLP**) Regulation
  - Product labels
- ⚠ **Renewals**: start 550 days before expiry



EU/GB DIVERGENCE

- ⛔ Legal entities:
  - GB submissions must have a GB legal entity
- ℹ️ Duplication of
  - dossiers and submissions
  - Active Substance lists
  - Art 95 lists to check
- ℹ️ Variation in
  - data requirements
  - assessment approach
- ⚠️ Northern Ireland – EU law, GB administration



EU/GB CONVERGENCE

- ℹ️ Sanitary and Phytosanitary (SPS) agreement negotiations:
  - ✅ GB BPR could be aligned with EU BPR
  - ⛔ Impacting product authorisation, labelling, supply chains and operational practices
  - ⛔ Unknown transition - planning product authorisations, renewals, or regulatory strategy over the coming years
- ⚠️ Formalised PCNs in GB to come?



GB&EU

BEES RISK ASSESSMENT

- ⚠ EU - February 2026
- ⚠ GB - February 2027
- ⛔ Product submissions and renewals for approved AS
  - Quantitative risk assessment for bees
- ⚠ PT18 arthropod control (insecticide/acaricide)
  - Reach flowering vegetation or pollinator habitats
  - AS has an insecticidal MoA
- ℹ Applicants must demonstrate low risk to bees:
  - Identify which exposure routes
  - Tiered risk assessment
  - Identify which studies are required
  - Evaluate existing toxicity and residue data
  - Exposure modelling
  - Practical risk management measures and label proposals



EU

DRINKING WATER ASSESSMENT

⚠ New drinking water treatment requirements
- 1 April 2026
- Biocidal product authorisations and active substance renewals

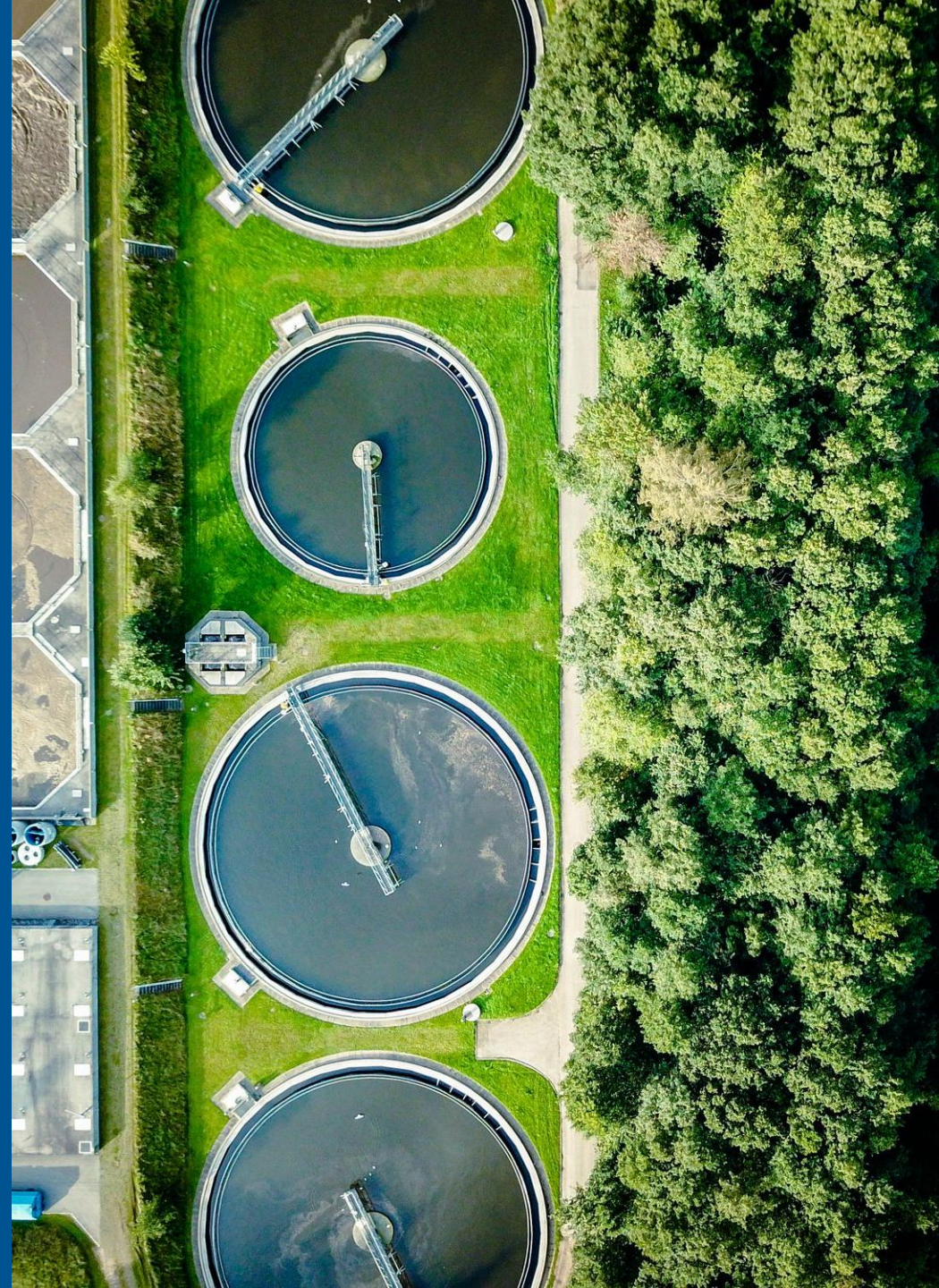
- Water treatment processes transform AS and their metabolites and SoC into new compounds

→ transformation products (TPs) in surface and groundwater

ℹ New environmental risk assessment screening steps:
- TPs formed identified, quantified, and assessed for toxicological relevance

⛔ Potential further obligations:
- Higher-tier modelling
- Commissioning laboratory studies

⚠ Early-stage review of your AS, PT and use patterns



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TAKE HOME MESSAGES

- Know your product
- Plan well in advance
- Be patient
- Be flexible
- Communicate
- Be aware



Thank you for listening!

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