Union Authorisation

Role (and support) of the Member States

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ECHA Biocides Stakeholders Day, 1 September 2015

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Outline of presentation

- **Biocidal Product Regulation**
- **Ctgb**
- **Union Authorisation and the role of Member States**
  - **Union vs National Authorisation**
  - **Applications for UA**
  - **Same biocidal products**
- **Ctgb pre-submission support**
- **BPR Workload**

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Biocidal Product Regulation

- **Regulation EU 528/2012**
  a binding legislative act across EU
- **September 2013**
- **Important role for ECHA**

- **Harmonised, clear and strict procedures**
  - **Short timelines**
  - **Responsibilities are well described**
- **New procedures:**
  - **Union Authorisations**
  - **Same Biocidal Products**
  - **Biocidal Product Families**

ECHA
EUROPEAN CHEMICALS AGENCY

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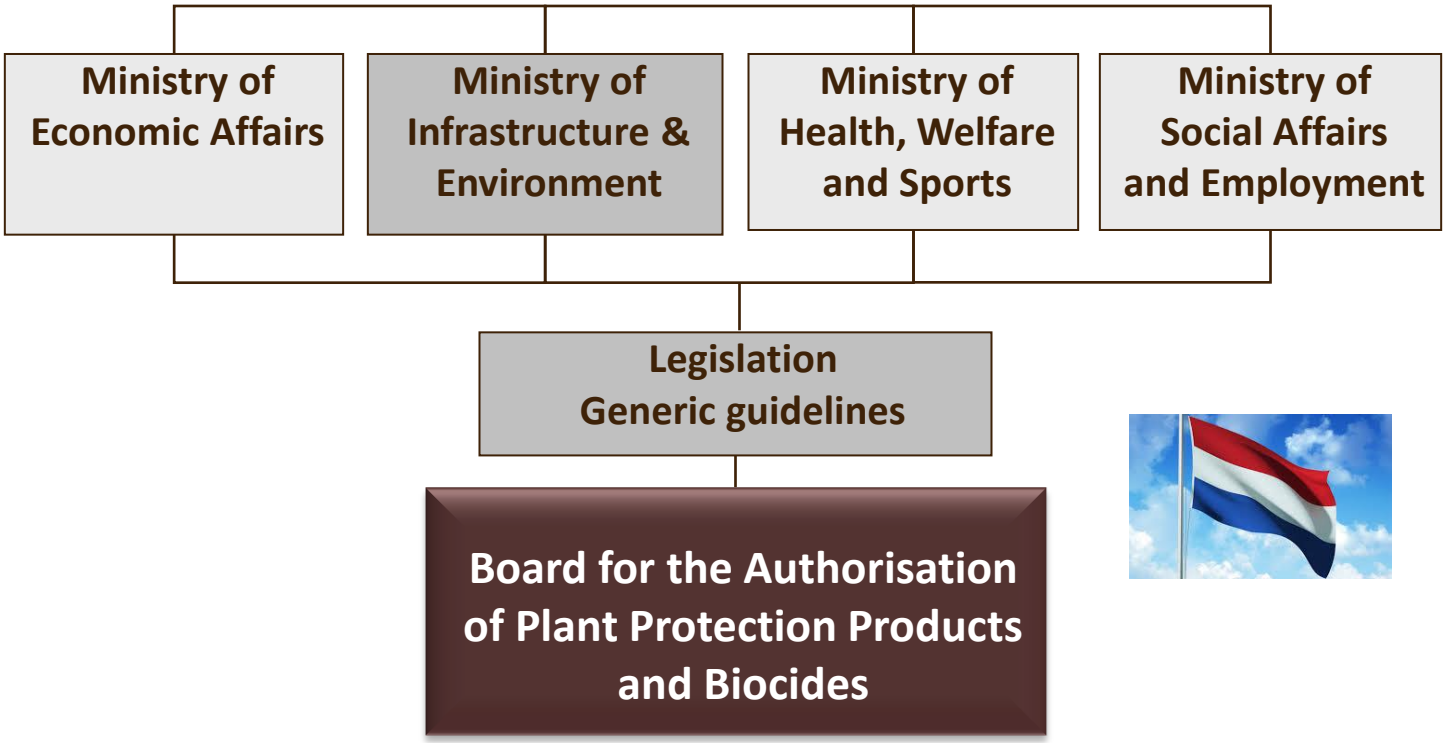
Organisation chart of Ctgb



- **Ctgb is the independent legal entity for authorisation and a semi-autonomous rate-controlled agency**
- **No enforcement**

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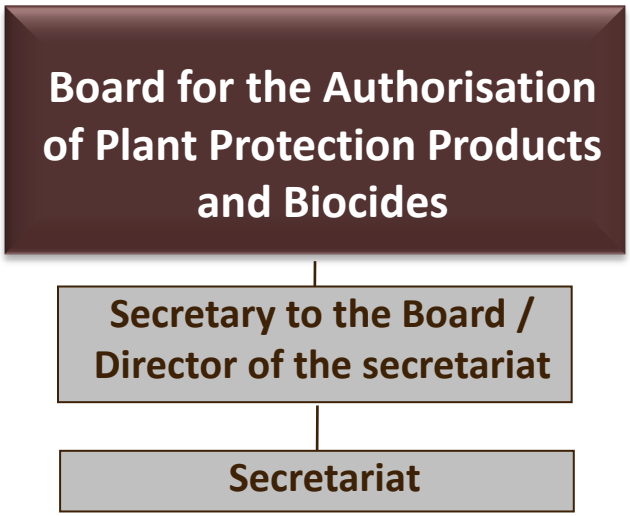
Relation Board and Secretariat



The Secretariat is responsible for the assessment of applications, and drafting the advice to the Board

- **120 staff; Hourly fee €118,- (2015)**

The Board discusses this advice and:

- **adopts or rejects the advice or**
- **asks for clarification of certain issues**

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Union Authorisation (UA)

- **Authorisation given by the European Commission, valid on the entire Union market**
- **For single Biocidal Products or Product Families**
- **Excluded:**
  - **Products containing substances fulfilling the exclusion criteria (Article 5 of BPR)**
  - **Products to control rodents, birds, fish, and other vertebrates (PTs 14, 15, 17 and 20)**
  - **Antifouling products (PT 21)**

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The actors

- **Applicant:**
  - **Submission** of application via R4BP
- **Evaluating Competent Authority (eCA):**
  - **Validation and evaluation**
  - eCA chosen by the applicant (CA-agreement)
- **ECHA:**
  - **Pre-submission phase**: eligible for UA?
  - **Committee phase**: Peer-review by MS
- **European Commission (COM):**
  - **Decision** for authorising the product

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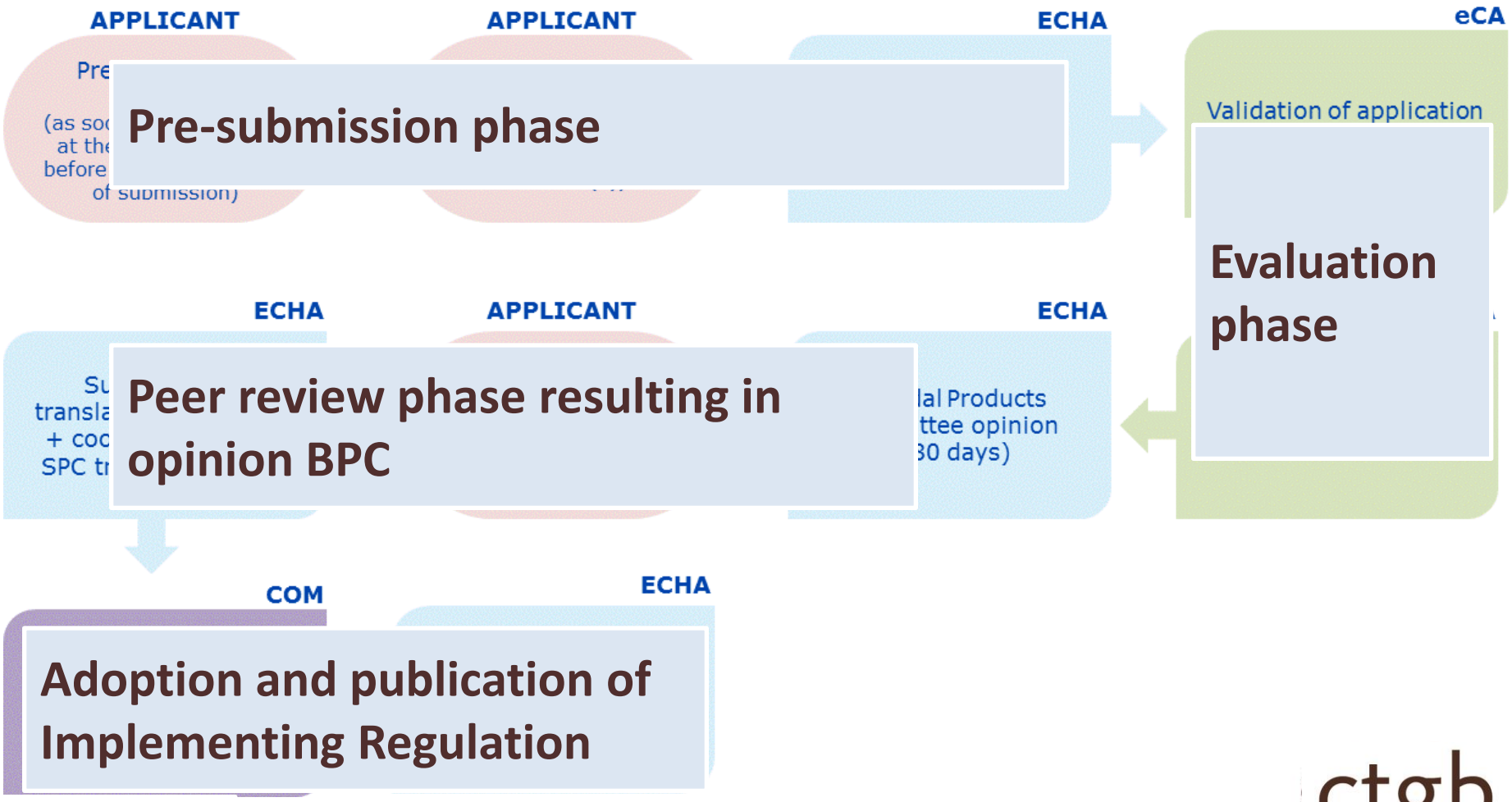
Procedure UA



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Evaluation phase

- **Basically similar to National Application:**
  - **Physical – chemical properties**
  - **Efficacy**
  - **Human toxicology**
  - **Environment**
- **Validation** **30 days**
- **Evaluation** **365 days (max)**
- **Stop the clock** **180 days (max)**
- **Review by applicant** **30 days**

- **Draft PAR and SPCs to ECHA**

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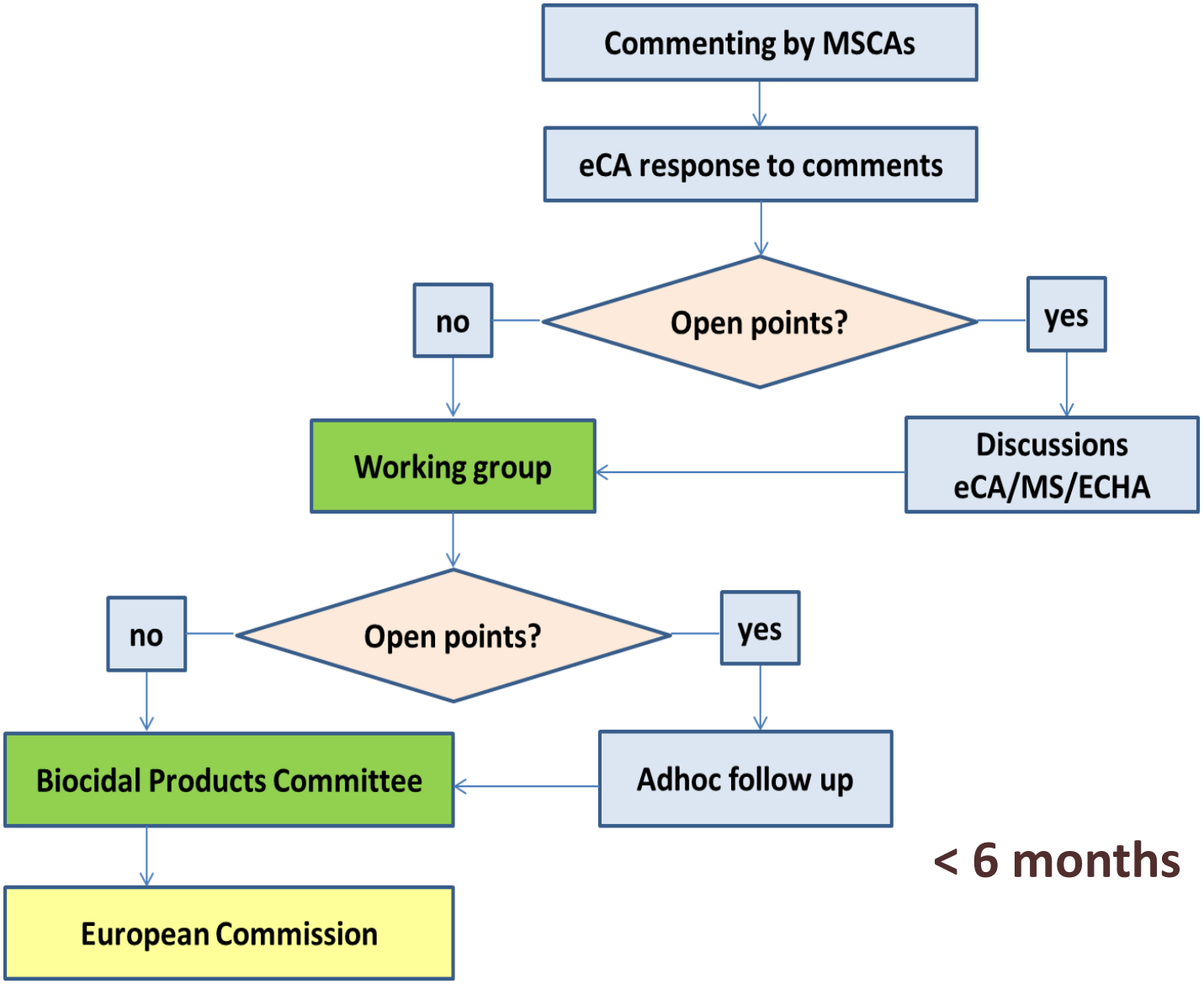
Peer Review phase of UA



< 6 months

Union Authorisation granted

- **Implementing regulation**

  The Commission shall, at the request of a Member State, decide:

  - to adjust certain conditions specifically for a MS

  - decide that a UA shall not apply in a MS

- **Authorisation number: EU-1234567-0001**

- **Application for adm/minor/major changes to ECHA**

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Union vs National: procedures

Union Authorisation

- Apply at ECHA, select eCA
- Validation within 30 days
- 12 month for evaluation
- Peer review (~6 month)
- Authorisation granted by COM
- Products are allowed in EU

Nat.Auth. + Mutual recognitions

- Apply at eCA and CMSs
- Validation within 30 days
- 12 month for evaluation
- CMSs Peer review (~3 month)
- Authorisation granted by eCA and CMSs involved
- Products are allowed in eCA and CMSs

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Applications for Union Authorisation

- **Slow start**
- **Update 28 August 2015:**
  - **UA applications submitted in R4BP3**
  - **Ctgb: eCA for 6 applications**
- **First applications:**
  - **Iodine (and PVP Iodine), Octanoic acid**
  - **Date of approval: 1 September 2015**
- **All applications are Biocidal Product Families**

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Same Biocidal Products

- **An authorisation is sought for a product that is identical to an authorised product (= the reference product)**
- **Regulation (EU) 414/2013**
- **Private label companies**

- **Letters of Access to dossier of reference product and active substance**
- **When relevant: administrative changes**

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UA and Same Biocidal Product

- **The applicant (e.g. private label) for SBP submits application to ECHA pending the UA**
- **The reference product can be:**
  - **a single product**
  - **a Biocidal Product Family (BPF)**
  - **a single product from a BPF** ***(implementation pending)***
- **The applicant becomes Union Authorisation holder (?)**

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UA and Same Biocidal Products (2)

Work around (unwanted?) for private label

- **Application UA Biocidal Product Family**
  - **Product X is a family member**

- **Application (in parallel to UA):**
  - **National Authorisation of the single Product X**
  - **Application based on full LoA**

Commission proposal:

- **Amendment of the SBP regulation**
- **The applicant for SBP can apply at national level**
- **CA agreement, implementation pending**

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Pre-submission support

- Application proces
  - Pre-submission
    - Pre-submission support
      - Website
      - Service desk
      - Request For Meeting
  - Validation
  - Evaluation

- Symposia
- Workshops

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BPR Workload Challenge

Ctgb approach to accommodate industry demands

- **Workload forecast**
  - **Close contact with industry and consultants**
  - **eCA agreements**
    - **Optimize resources management**

- **Pre-submission support**
  - **Improve quality and completeness of dossiers**
    - **Optimize workflow management**

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Thank you for your attention

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