Union authorisation of biocidal products

Biocides Stakeholders' Day

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Overview

- Introduction: procedure, actors and timelines
- Dossier format
- Summary of product characteristics
- Advantages

What is Union authorisation?

- Authorisation given by the EU Commission, valid on the entire Union market
- For single biocidal products or product families with similar conditions of use across EU
- Excluded:
  - Products containing substances fulfilling the exclusion criteria
  - Products to control rodents, birds, fish, and other vertebrates (PTs 14, 15, 17 and 20)
  - Antifouling products (PT 21)

When is it applicable?

Pre-defined phase-in periods according to Article 42(1):

1. Step

1 September 2013:

PT 1, 3, 4, 5, 18 and 19

BP containing new active substances

2. Step

1 January 2017:

PT 2, 6 and 13

3. Step

1 January 2020:

All remaining PTs (beside those excluded)

Who are the actors?

- **Applicant:**
  - **Pre-submission** of a draft summary of product characteristics (SPC) to ECHA for eligibility check
  - **Submission** of application including SPC via R4BP to ECHA
- **Evaluating Competent Authority:**
  - **Validation and evaluation** by evaluating competent authority chosen by applicant
  - Provides and updates the product assessment report (**PAR**) and the SPC

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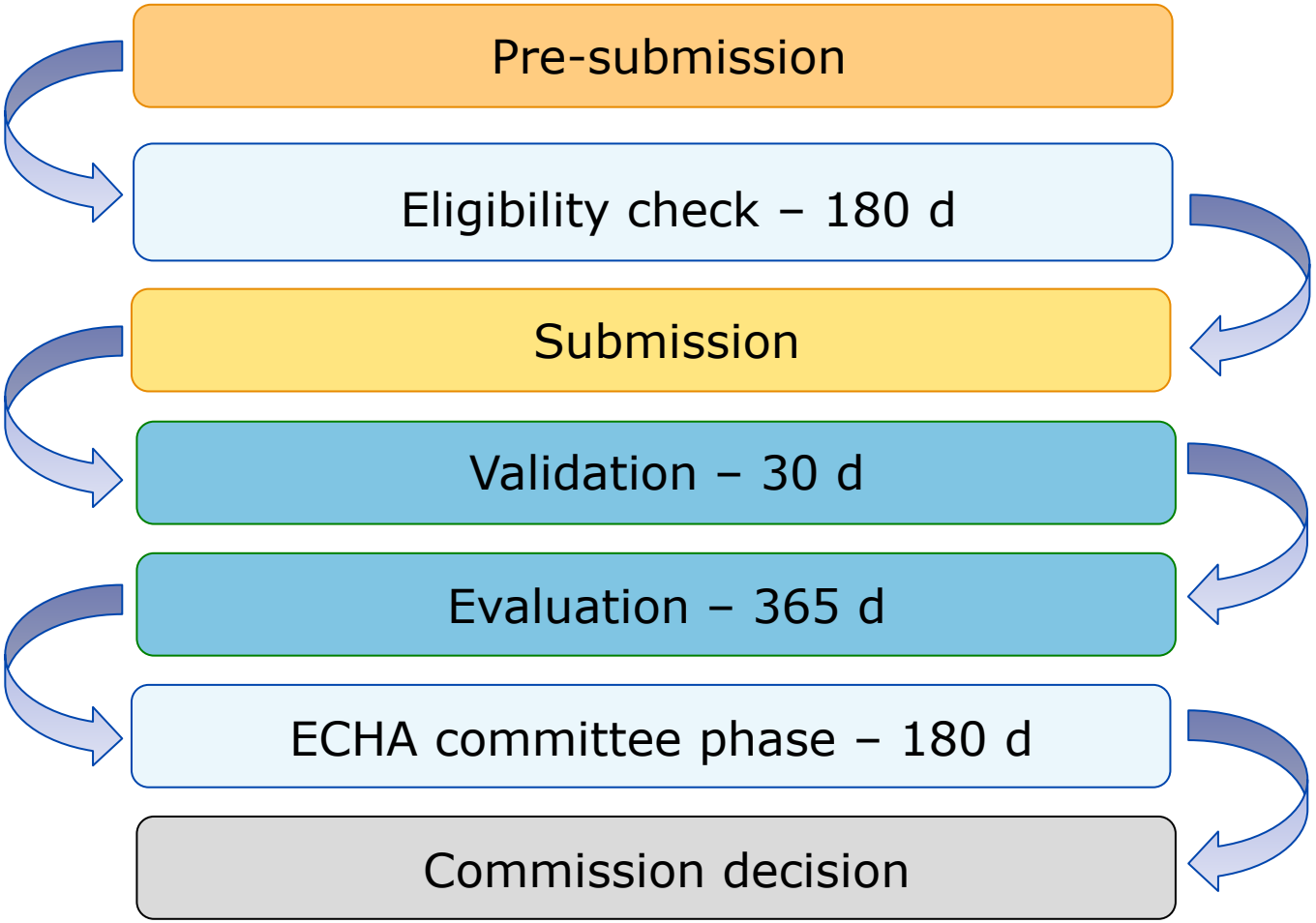
- **ECHA**:
  - **Eligibility check**: ECHA coordinates verification/confirmation of similar condition of use as per Art 43(1), scope within the BPR and correct product type(s) allocation.
  - **Committee phase**: Peer-review in the Biocidal Products Committee (supported by the ECHA Secretariat) resulting in the ECHA opinion
- **Commission:**
  - Takes the decision for authorising the product on the entire EU market

What are the timelines?



Dossier format for application: IUCLID 5.5

- Study summaries
  - Former Doc III for active substance, substance of concern and biocidal product to be compiled in IUCLID templates
  - Study reports to be attached to the respective template
- Assessment documents to be attached in section 13 of IUCLID
  - Former Doc II
  - Overall summary and conclusion
- Letter of Access can be submitted instead of the mentioned documents at any level.
- SPC, Technical Equivalence assessment decision (if available) to be appended to the IUCLID dossier.

Summary of Product Characteristics (SPC)

Requirement for application for UA (Article 20 of BPR)

- **At the time of application** → submitted in one of the official languages of the Union accepted by the eCA
- **At the time of submission by eCA to ECHA** → proposal ECHA: submitted in English

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- **30 days after the BPC opinion:**
  - applicant to prepare SPC in all official languages of the Union
  - submitted by ECHA in all official languages of the Union to COM, where ECHA coordinates the check of the SPC translations

Predicted number of BPC opinions
(DG-ENV February 2013)

	Legal Time limit (days)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Approval of new active substances	270	0	0	2	5	5	5	5	5	5	5
Approval of existing active substances (RP)	270	0	50	50	50	50	50	50	50	50	50
Renewal of active substance approvals	270 (full) 90 (partial)	0	2	3	3	0	0	1	8	12	12
Union authorisation of biocidal products	180	0	**5**	**12**	**23**	**77**	**79**	**76**	**131**	**143**	**162**
Amendments of Union authorisations	90	0	0	0	0	**1**	**2**	**4**	**12**	**20**	**27**
Disagreement mutual recognition	120	0	30	30	30	30	30	30	30	30	30
Total		**0**	**87**	**97**	**111**	**162**	**167**	**166**	**236**	**259**	**286**

Foreseen advantages of Union authorisation

- Facilitates the making available of biocidal products with similar conditions of use on the EU market
- Simplifies procedures for economic operators targeting several Member State markets
- Reduces the overall administrative burden
- *Single authorisation* for the entire Union market will have a positive impact on product availability.

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- *Fixed deadlines* will provide more certainty for applicants.
- *Harmonised procedures* will improve consistency in the dossiers' assessment.

Thank you

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