How to do a successful Union authorisation application

Biocides Stakeholders’ Day

26 September 2017

Chiara Pecorini
Biocides Assessment Unit
European Chemicals Agency
Overview

1. How did the process go so far
2. What is important for successful applications
3. Where are we heading to
Overview

1. How did the process go so far
2. What is important for successful applications
3. Where are we heading to
Steps and actors in the process

- Preparatory discussions
- Pre-submission consultation
- Submission of application
- ECHA acceptance
- Validation and evaluation
- Biocidal Products Committee opinion
- Commission decision

Overall timeline: at least 2.5 years
Applications in the ECHA’s pipeline

- Union authorisations (UA)
- Same biocidal products

- About 90% product families
- Disinfectants (>70%), insecticides and preservatives

Update 18 September 2017
How did the process go so far (1/2)

Pre-submission
• 92% of UA applications with pre-submission
• 95% of positive outcomes
• 93% of outcomes with additional comments

Submission and checks by ECHA
• Overall, smooth submissions of applications
• In general, applications passed ECHA checks
How did the process go so far (2/2)

Validation and evaluation
• Effective cooperation with evaluating authorities
• 3 evaluations submitted to ECHA

BPC opinion
• 3 working group discussions so far
• 2 BPC opinions foreseen in December 2017
Overview

1. How did the process go so far

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Tips for pre-submission

• Discuss technical or methodological questions with your evaluating authority
• Describe clearly the uses in the Summary of Product Characteristics (SPC)
• Justify that co-formulants do not contribute to efficacy
• Make a pre-submission at the latest 6 months before the intended date of submission
Requirements for pre-submission

**Mandatory**
- ☑ SPC (English; .xml)
- ☑ Supporting document

**Recommended**
- ☑ Agreement signed by the evaluating authority

**Where relevant**
- ☑ Overview of the family

Tips for Union authorisation applications

• **Discuss** with the evaluating authority to prepare a good quality dossier
• Have your **SME status** verified before submission
• **Apply** as early as possible before the deadline
• **Monitor** your case in R4BP 3
• Pay attention to **deadlines**
  • Payment of the fees
  • Resubmission of requested information
Requirements for UA applications

**Mandatory**
- ✔ IUCLID dossier
- ✔ SPC (English; .xml)
- ✔ Agreement signed by the evaluating authority
- ✔ Outcome of pre-submission consultation or rationale about similar conditions of use

**Where relevant**
- ✔ Overview of the family
- ✔ Supporting document for provisional authorisation

Tips for same product

• New possibilities after amendments to Same Products Regulation
• Only administrative changes accepted

Examples of administrative changes relevant for same product applications
• Change of the name of the product
• Addition of trade names
• Different authorisation holder
Requirements for same product

**Mandatory**
- ✔ Reference case number
- ✔ SPC (English; .xml)
- ✔ Supporting document

**Where relevant**
- ✔ Letter of access

Ensure consistency between supporting document and SPC

Union authorisation


# ECHA procedures

## Timelines for the peer review of Union authorisations applications

As indicated in section 3 of the Working procedure for Union authorisation applications, the dates given below are the actual binding dates for each step. The first column “Step Ref” refers to the steps given in the working procedure.

<table>
<thead>
<tr>
<th>Step Ref</th>
<th>Step description</th>
<th>Actors</th>
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<th>Process flow 1.8</th>
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<th>Sentence code</th>
<th>Sentence</th>
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<td>N-19</td>
<td>If discharging to municipal sewage treatment plant, provide the required onsite wastewater removal efficiency of [XX (%)]</td>
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<tr>
<td>N-20</td>
<td>Freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.</td>
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<td>N-21</td>
<td>Hazardous to bees. Do not apply close to blooming plants/cultures.</td>
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<tr>
<td>N-22</td>
<td>Do not apply near bodies of surface water or in the area of water protection zones. [where relevant provide for appropriate distance stipulations]</td>
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</table>

**SPC FIELD**

- 4.1 Where relevant, an exact description of the authorised use
- 4.1 Field(s) of use
- 4.1 Application rate(s) and frequency
- 4.1 Pack sizes and packaging material
- Instructions for use
- Risk mitigation measures
- Particulars of likely or indirect effects, aid instructions and emergency measures to protect the environment


**Linguistic review of the translations of the summary of product characteristics (SPC) for Union Authorisation applications**

R4BP 3.9

- New functionalities for Union authorisation
  - Grouped administrative changes
  - Notification of unexpected or adverse effects
Overview

1. How did the process go so far
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Outlook to 2018

First Union authorisations granted

First same product authorisations granted

18 BPC opinions adopted

Fine-tuning the process in light of experience
Conclusions

• Making the process as effective as possible
  • More templates and procedures available
  • More experience acquired by all the actors
  • Cooperation as the key to success
  • Continuous improvement thanks to your feedback
Thank you

chiara.pecorini(at)echa.europa.eu

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