New active substances

Biocides Stakeholders' Day

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BPD to BPR:
What will change?

Biocides approval: 2-step process

	Old: Directive	New: Regulation
Step 1	**Active substance approval** Responsible: Commission Inclusion in **Annex I to Directive 98/8/EC**	**Active substance approval** Responsible: Commission Inclusion in **Union list of approved active substances**
Step 2	**Product authorisation** Responsible: • Member State Competent Authority	**Product authorisation** Responsible: • Member State Competent Authority • **Commission**
		Basis for Commission decision making: Agency opinion

New provisions: exclusion criteria and candidates for substitution

- An active substance fulfilling **exclusion criteria** will not be approved (unless Art. 5[2] conditions are fulfilled)
- If an active substance is **candidate for substitution**

  ➔ Biocidal product is subject to comparative assessment
- 60-day public consultation by ECHA:
  - Third parties to provide relevant information
  - Mainly information on available substitutes expected

New provisions: exclusion criteria and candidates for substitution 2

- Explicit evaluation of the criteria in Competent Authority Report
- Major influence on applicant: **need for certainty**
- Only the final outcome of assessment will confirm whether criteria are met
- Alignment of the biocide processes with:
  - Committee for Risk Assessment
  - PBT expert group

Dossier structure

- Dossier and competent authority report:
  - Structure agreed at BPC-2
  - Template expected to be agreed at BPC-3
- New Regulation elements included
- Simplified structure; repetition avoided

IUCLID data set

Data for active substance + evaluating competent authority annotations

Data for representative biocidal product + evaluating competent authority annotations

Appendices:
- Reference lists
- Confidential data and information

IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

Competent authority report

Assessment report (AR)

1. Overall conclusions of the assessment report

2. Assessment of the active substance in the biocidal product

Part A – Effects

Part B – Exposure assessment

Part C – Risk characterisation

Part D - Appendices:
- Listing of end points
- List of terms and abbreviations
- List of intended uses
- Reference lists (incl. data owner, confidentiality claim)

Conclusion

1. Overall conclusion in the context of Regulation (EU) No 528/2012 (BPR)

2. Opinion

ECHA EUROPEAN CHEMICALS AGENCY R4BP 3.0

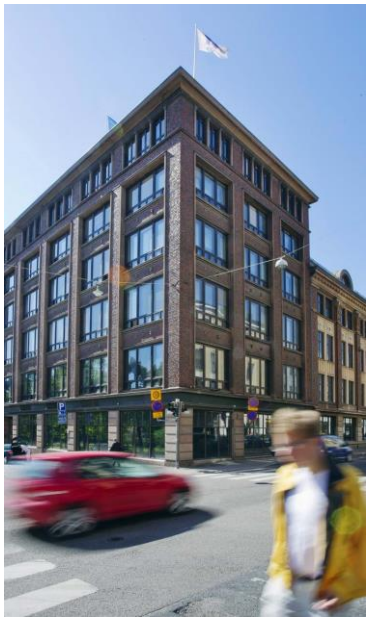
Active substance approval process

Evaluation of an application

- Validation by ECHA
- Completeness check by evaluating competent authority
- Evaluating competent authority evaluation: time limit of one year
  - Possible to stop the clock (request for further information)
- Applicant commenting period
  - 30-day period before submission of the competent authority report

Evaluation: ECHA involvement

- Problem identification
  - Possibility of upstream working group discussions
  - Possibility of upstream tasks for adhoc working groups
- Ensuring timeline
- Identifying candidates for substitution
  - Preparations for public consultation
- Requests for additional information (stopping the clock)
  - Role as mediator



Peer review process – main steps

Competent authority report

Public consultation
Only if candidate for substitution

Commenting phase
MSCAs, applicant

Working group discussions

Efficacy | Phys-chem + analytical methods | Human health | Environment

Follow-up

Biocidal Products Committee

Commission decision making

Faster active substance approval

All new applications:

- One year evaluation stage
- 270 days for opinion forming
- Possibility of stopping the clock during evaluation
  - Up to 180 days; more if justified by the nature of the data requested or by exceptional circumstances
- **Overall:** around two years from submission of application to BPC opinion
  - Followed by COM implementing act

Applicant participation

During evaluation:

- 30 days commenting period before competent authority report submission
- Informal discussions should take place before this

Applicant participation 2

During peer review: all stages

- Participation in commenting period
- Preparation for working group discussion
- Working group discussion
  - Also stakeholder organisations
- Follow-up + preparing the draft opinion
- Observer in Biocidal Products Committee discussion
  - Also stakeholder organisations

Conclusions

- 2-step approval remains
- New procedures, new provisions (e.g. substitution and exclusion criteria)
- Active substance approval becomes faster
- Applicant participation at all stages of peer review
- Participation of stakeholder organisations in Committee and working group meetings

Thank you

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