Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

EU process of evaluation and decision-making

[active substance review]

Legal framework in the EU – Overview

- **Active substances assessed on community level**
  - List of approved active substances
- **Plant protection products subject to an authorisation**
  - Authorisations granted by Member States
  - worksharing and mutual recognition
- **Harmonisation of**
  - Data requirements
  - Decision criteria
  - Packaging and labelling rules
- **Maximum residues levels (MRLs) established on community level**

Active substances: Evaluation & decision on EU level

Active substances are assessed on community level on the basis of harmonised

- data requirements (regulations 283/2013 + 284/2013)
- evaluation principles (EU guidance documents)
- decision-making criteria (regulation 1107/2009)

establishing

- general acceptability of an active substance to be used in plant protection products
- EU level restrictions, mandatory for all member states

Main features of the a.s. review

- **work-sharing:**
  - each member state to evaluate a number of active substances according to their capacity [rapporteur member state – RMS]
  - co-RMS

- **transparency for applicant and public**

- **open peer review of the RMS's evaluation:**
  - all MS, EFSA and third parties (applicant, public) can comment

- **public access to documents [except study reports, CBI]**

- **prescribed process and timelines**

- **central co-ordination by EFSA**

Main steps in the process (1)

Submission of a dossier by an applicant

Evaluation by the Rapporteur Member State
Preparation DAR or RAR (Draft Assessment Report or Renewal Assessment Report)

12 months

Commenting period
Comments from Member States, EFSA, applicant and public

2 – 3 months

Main steps in the process (2)

EFSA Peer Review

Consultations on expert level (EFSA Experts‘ Meetings),
co-ordinated by the European Food Safety Authority (EFSA)
Preparation EFSA Conclusion

4-5 months
[stop–the–clock]

Consultations on EU-level with all 27 Member States,
European Commision and EFSA
(Standing Committee on the Food Chain and Animal Health)

6-8 months

Decision on the approval according to
Regulation (EC) No 1107/2009

Documents prepared in the process (1)

Document	Prepared by	Content
Dossier	Applicant	Study reports Summaries of studies Overall assessment Reference lists [OECD Dossier Guidance]
DAR (Draft Assessment Report) RAR (Renewal Assessment Report)	RMS (Rapporteur Member State)	Summaries of studies Detailed and overall assessment Proposed decision Reference lists [OECD Monograph Guidance]
Reporting table	RMS, applicant, EFSA	Compilation of all comments Responses to each comment by RMS & applicant Conclusion on each item by EFSA

Documents prepared in the process (2)

Document	Prepared by	Content
Evaluation table	RMS, EFSA	Further discussion of items open from reporting table Comments from RMS and expert meetings Conclusion by EFSA
Peer Review Report	EFSA	Detailed reports from Experts‘ meetings Compilation of all comments, reporting and evaluation tables (for public)
EFSA Conclusion	EFSA	Comprehensive report on the properties of the active substance, the outcome of the risk assessment, critical areas of concern and data gaps. Submitted to the European Commission
List of endpoints	RMS, EFSA	Tabular listing of the outcome of the assessment Studies & exposure calculations Harmonised active substance endpoints, to be used in subsequent PPP assessments

Documents prepared in the process (3)

Document	Prepared by	Content
Review Report	European Commission	Comprehensive summary, description of the complete process (Applicant, dossier submission, identity of the active substance, results of the scientific assessment, toxicological reference values ADI, AOEL, ARfD, possible restrictions and risk manangement options, proposal for a decision on approval/non-approval)
Commission Implementing Regulation	European Commission	Decision of the European Commission on the approval/non-approval Published in the „Offical Journal“ of the EU

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 1, 1.3.1 Name and address of applicant(s)	NOT (Task Force) - 13.05.2009: BASF, BAYER Crop Science [BCS] references should be added as applicant for carbendazim Annex I renewal	**RMS:** Addressed in final draft of the DRAR.	Addressed.
1(2)	Vol. 4, C.1.0.1	EFSA: It is not clear why the reference source would be the one used for the previous annex I inclusion as it is this very specification which we now need to define to current standards. We are reviewing the specification and there should be a full check against supporting batch data and tox and ecotox data and if necessary after this process a new reference specification should be derived.	**NOT (Task Force) - 14.12.2009:** Compilation of samples and available profile used in the tox and ecotox studies where presented in Document J. **RMS:** The approach taken is in compliance with the legal requirements as given in Regulation 737/2007. Furthermore EFSA's interpretation (for other substances) that the scientific and technical knowledge has been changed since the first inclusion is arguable. Our understanding is that no changes have been harmonised with regard to the data requirements or the scientific and technical knowledge since the first inclusion.	Data gap: A reliable specification should be proposed that is based on the available batch data. Once this has been done for the reference source then equivalence checks can be done. See also 1(6) The argumentation from the RMS is unclear. If it were correct that scientific and technical knowledge had not changed then why would tox and ecotox have to consider it.

Rapporteur: DE

1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

No.	Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the PRAPeR Expert Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
	Section 1 Open points: ***2*** Points for clarification: ***0*** Data gaps: ***11*** Expert consultation: ***0***		Not applicable	Not applicable	
	Data gap: 1.1 A reliable specification should be proposed that is based on available batch data. Once this has been done for the reference source then equivalence checks can be done. See also 1(6) The argumentation from the RMS is unclear. If it were correct that scientific and technical knowledge had not changed then why would tox and ecotox have to consider it. See reporting table 1(4)	DE: There is again a misunderstanding. The new scientific knowledge is linked only to the toxicological risk assessment of the relevant impurity DAP. Based on this a new (lower) maximum limit was proposed by tox (evaluation of an Ames test). Consequently, it is proposed to amend the reference specification as included in Annex I accordingly.	Not applicable	Not applicable	Data gap: A reliable specification should be proposed that is based on the available batch data. Once this has been done for the reference source then equivalence checks can be done. The argumentation presented by the RMS is not correct it does not say anywhere in 737/2007 that physchem should ignore the specifiifcation but tox and ecotox can still change it. Also 737/2007 does not apply to carbendazim as it is not named in this regulation.

rapporteur DE

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	DAR: 16-07-2009	**Carbendazim**

Ecotoxicology

Effects on non-target species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	Endpoint (mg/kg bw/day)	Endpoint (mg/kg feed)
Birds ‡				
Colinus virginianus	as	Acute	LD_{50} > 2250	-/-
Anas platyrhynchos	as	Short-term	LDD_{50} = 615	LC_{50} ~ 5000
Anas platyrhynchos	as	Long-term	NOEL = 26.4	NOEC = 212
Mammals ‡				
Dog	as	Acute	LD_{50} > 5000	-/-
Rat	as	Long-term	NOEL = 22.5	-/-

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Cereals, 2 × 100 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	5.406	> 416	10

Risk management at EU level (1)

- **The EU approval decision of an active substance**

  - establishes the reference specification: max. content of impurities, relevant impurities
  - sets reference values such as ARfD, ADI, AOEL (=> list of endpoints)
  - may request confirmatory information to be submitted by a certain date: frequently used; type of requested data range from validation of an analytical method to the full set of tests on endocrine disruption

Risk management at EU level (2)

- **The EU approval decision of an active substance**

  – may indicate issues to which member states have to pay particular attention when assessing products with different use conditions
  – may impose mandatory restrictions, such as upper limits of use rates, crops and/or use conditions for which products shall not be authorised, etc.
  – may be granted for less than the regular 10-year period (candidates for substitution)
  – may be granted for up to 15 years (e.g., ‘low risk’ substances)

Risk management at EU level (3)

- **The EU approval decision of an active substance**

  – is a somewhat strange hybrid because it is about the active substance

  – and therefore makes use of hazard-based decision-making criteria

  – BUT makes also use of the risk assessment for at least one PPP and 'representative uses' as a means to conduct a risk-based assessment against risk-based decision-making criteria

Risk management at EU level (4): Criteria

- **Risk-based criteria: safe uses (human health, environment, groundwater) for at least one PPP**

- **Substances which meet certain hazard-based criteria must normally not be used in plant protection products**
- **CMR cat. 1A&1B, POP, PBT, vPvB, endocrine disruption**
- **CMR as defined in Regulation (EC) 1272/2008 – CLP**
- **POP, PBT, vPvB as defined in Regulation (EC) 1907/2006 - REACH**
- **Endocrine Disruptors:**
  - Transitional regime based on C/R classification
  - Specific scientific criteria

Results of the EU active substance review

- Active substances, which had been on the market in the Member States before the deadline 25 Juli 1993 were called existing active substances
- Review programme for EAS initiated 1993
- ~ 1000 active substances, divided in 4 groups (list 1 – 4)
- EAS review programme finalised in December 2009
- 316 substances approved, 641 not approved or not defended
- Currently stepwise re-examination of old EU approval decisions after 10 years (programmes AIR 1, 2, 3 etc. = Annex I Renewal)
- 200 new active substances, 147 approved, 13 not approved, 40 ongoing

Thank you for your attention!

Questions?

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