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Active substance evaluation process

Member State experience and feedback

Experiences so far with 1107/2009 in DE

- **Fortunately agreed procedures, responsibilities, reporting (Registration Report) and language (English) but**
  - Reporting requirements are more time consuming than expected
  - Processes of active substance approval and authorisation of products are not well connected
  - Loss of important active substances/uses lead to more emergency authorisations and problems with minor uses
- **Ideally, assessment and decision criteria are harmonised but**
  - Both are not fully harmonised in critical areas
  - Partly, GD development don’t meet requirements of MS
  - Existing approvals with old endpoints extended for long time
  - New approvals are not granted although no substantial risks were identified

Problems in MS

- High workload and adminstrative burden in MS; timelines are not met
- The number of court cases in DE increases
- DE was sentenced to accept the decisions of other MS
- When DE is cMS, only Art. 36 (3) is allowed for rejection
- Even if no complete dRR/RR (legal/administrative requirements) is available, DE should accept the evaluation of zRMS
- Inconsistent regulatory decisions lead to public discussions and frustration amongst PPP-users (e.g. GAP, RMM)
- Extension of a.s. approval period lead to extension of authorisations without new evaluations
- Number and area of emergency authorisations increases
- Grower associations complain about lack of tools for plant protection

DCG and HLM

- **At European level, a forum of Designated National Authorities (DNA) to address issues at a strategic level is needed.**
  - No structures for rapid exchange/agreements at a **strategic level before**
  - Since 2020 Northern and Southern Zone participate in the DCG (Directors Consultation Group)
- **Meeting of DCG with COM and EFSA/COM**
  - Address specific needs of DNA together at EU-level
  - Goal: improve the communication between MS, EFSA and COM
  - **High-level-meeting (HLM) December 2020**

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Improving the process of active a.s. approval

- **Points of discussion in HLM**
  - REFIT
    - availability of enough active substances for effective plant protection
    - low risk substances
    - Timelines
  - Capacities of CA and partnership
  - Data gaps in approval procedure
  - Guidance Documents – priority setting and feasibility
  - RMM in approval procedure
  - GFL, IUCLID and IT-collaboration

Development of GDs

- **Priority setting**
  - Planning for guidance development is partly unclear for MS
  - Needs and capacities of MS should be considered

- **Feasibility check**
  - The guidance documents are becoming increasingly scientific driven, focused on active substance approval and leave room for interpretation which hampers harmonisation. This does not benefit the feasibility of the guidances especially for PPP authorisation.
  - The competent authorities propose to include a feasibility check in the process of development of guidances.

EFSA conclusion – COM approval decision

- **Peer review often results in considerable amount of open points:**
  - Data gaps identified for the representative uses
  - Issues that could not be finalized
  - Critical areas of concern
- **EFSA-Conclusion should separate identified risks in substantial ones based on full assessment and preliminary due to a lack of data**
- **At the time of approval identified problems partly not solved or no approval – lead to data gaps**

Data Gaps

- **Data gaps on active substance level and impact on product authorisation process**
  - The gradual changes in the EFSA approach towards renewal of active substances and the way it has been dealt with by SCoPAFF significantly affects the work at the MS level for product authorisations.
  - Increase in the number of data gaps within crucial aspects of the evaluation of active substances. Leaving these data gaps to be resolved at MS level in the context of product authorisation is a strategy with important drawbacks
  - Risk characterisation is often not balanced and proportional
  - Too much room for not warranted critical interpretation

Risk Mitigation Measures

- **Risk mitigation measures (RMM) stipulated in product authorisation process nearly not considered in a.s. approval procedure**
- **Huge amount of RMM in use by MS; COM/MS project to structure/harmonise RMM underway**
- **For approval only additional RAssessment-scenarios including typical mitigation measures needed (one safe use concept)**
- **To ease implementation RMM should be grouped according to degree of risk reduction**
  - Classes with defined mitigation factors (comparable with approaches for drift-reducing technique 50, 75, 90 etc. %)
- **MS/applicants should provide scientific evidence for effectiveness of RMM – plausibility check must be possible**
- **Overall subsidiary principle important regarding RMM**

Take Home Message

- **Over the last ten years a lot of progress have been made as regards work-sharing amongst EFSA, COM and MS**
- **But there are still major short-comings in procedures leading to high work-load in DNAs**
- **High Level Meeting of EFSA, COM and MS for strategic discussions and balancing of interests was established**
- **Items like matching of as-approval and product authorisation, RMM in approval procedure, GD-development, collaboration in IT-approaches, availability of effective and safe measures for plant protection, … are under discussion**
- **Improvement of procedures under discussion and solution for problems were identified**

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Thank you for your attention!

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Example : Use of Risk Mitigation Factor (RMF)

Risk assessment of non-target arthropods via spray-drift :

efsa European Food Safety Authority

results in TER 0.25 → TER 10 (protection goal)
RMF of 40 needed.

→ No acceptable risk?
→ Check for Risk Mitigation Measures

Member States

Acceptable risk could be demonstrated by a combination of risk mitigation measures (tool box):

- 90 % drift reducing nozzles (RMF 10)
- 5 m buffer zone (RMF 4.8)
- Anti hail net (RMF 2)

Source: Wikimedia - Bauer Karl 2010

5 m Buffer plus 90 % drift reduction nozzles sufficient to prove safe use – approval possible!