A P I D

Zonal Authorisation Procedure – Improvements and Developments

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Institute for Plant Protection Products

BOG 4

Break Out Group 4 (out of 5)

Implementation of new scientific and technical knowledge - Guidance Documents

- New a.s. data post (renewal of) approval introduced into the product dossier

- Latest scientific knowledge (in terms of Guidance Documents)

New a.s. data post (renewal of) approval introduced into the product dossier

- Confirmatory information will be introduced by COM to a less and less extent
- More and more issues shifted to „MS may pay particular attention to“, which means to be addressed at product level (zRMS)
- Many of those are to dealt with at EU level rather than on zonal level:

  - Relevance assessment of groundwater metabolites (tox and fate)
  - Relevance assessment of metabolites in food of plant and animal origin
  - Residue definition

New a.s. data post (renewal of) approval introduced into the product dossier

- GD on the evaluation of new a.s. data post (renewal of) approval (GD SANCO 10328/2004) was amended and noted at SCoPAFF (October 2021)

  - Lack of transparency
  - Lack of predictability
  - Lack of traceability
  - Increase of delays
  - Unclear as regards what to be assessed when
  - Unclear procedure

New a.s. data post (renewal of) approval introduced into the product dossier

- Which data to be assessed?

  - New a.s. data needed to support uses that were not covered by the representative use(s) in the dossier supporting the EU approval/renewal
  - New a.s. data to demonstrate safe use when risk mitigations are not enough to address the risk
  - New a.s. data to address data gaps listed in EFSA Conclusion on Pesticides Peer review (EFSA conclusion) and reflected in the Review Report (RR) and listed in the approval regulation under the points "*MS may particular attention to2*

New a.s. data post (renewal of) approval introduced into the product dossier

- Which data NOT to be assessed?

  - New a.s. data to avoid risk mitigation and/or to reduce risk mitigation measures (to be further discussed)

  - All data gaps mentiones in the EFSA conclusion which are not mentioned in the Review Report and/or approval / renewal Regulation

New a.s. data post (renewal of) approval introduced into the product dossier

- Procedure?

  - One zRMS on behalf of all zones

  - dRR (commenting period for all MS and applicant)

  - EFSA not part of the game

  - Traceability: confirmatory information table to be extended

New a.s. data post (renewal of) approval introduced into the product dossier

- Follow up / ToDos?

  - Amendment of the GD (PAI group)

  - Confirmatory information list to be amended (PAI group)

  - Timeframe: End of 2024?

Latest scientific knowledge (in terms of Guidance Documents)

- Use of GD for applications from that time concluded at SCoPAFF (implementation date)

Option 1

Latest scientific knowledge (in terms of Guidance Documents)

- Use of GD for applications from that time taken for a note at SCoPAFF

Option 2

Latest scientific knowledge (in terms of Guidance Documents)

- Use of GD for applications from that time made publically available (EFSAs homepage)

Option 3

Latest scientific knowledge (in terms of Guidance Documents)

- Mixture of all the 3 options

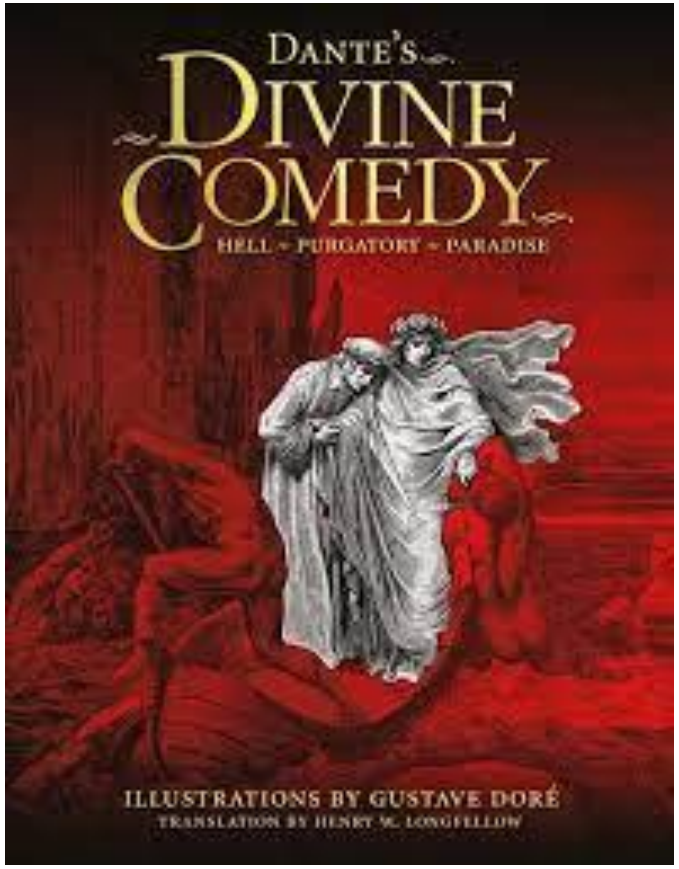
Option 4

Latest scientific knowledge (in terms of Guidance Documents)

- Follow-up

  - Further discussions at PAI

  - European court decision



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