Don´t think twice, it´s alright

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Institute for Plant Protection Products

Content

- New actives data post approval
- Follow up Workshop on Zonal Evaluation

New actives data post approval

- 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

- GD on the evaluation of new a.s. data post (renewal of) approval was amended and noted at SCoPAFF (October 2021)
- New procedure established – which means further delay of Article 43 assessments (and Article 33?)
- 1 MS assesses the data on behalf of all MS (as a matter of principle the RMS for the active´s approval)

- Involvement of EFSA (only if List of Endpoints to be amended) and COM (Review Report to be amended if necessary)

- Other issues which are not human health based (e.g. metabolites in terms of ecotox)?

- Data gaps in EFSA conclusion which are not mentioned in the Renewal Regulation – in principle for the next renewal of the active (groundwater metabolites if higher application rates compared to representative uses?)

- Assessment format: addendum to D(R)AR

- At the moment: focus on consumer risk (metabolites, residue definition)
- Commenting period for MS, applicants and EFSA
- If no changes in the relevant end points obvious (after assessment by the RMS) -> no need to await the next steps before product registration
- Priority by the RMS in order to minimise delays
- Only open points to be considered (NO re-evaluation of already agreed issues, no additional data to be introduced)

- Further amendment needed in order to
  - Avoidance additional delays (analogy to confirmatory information possible?)
  - Transparent procedure
  - Cover more than consumer risk issues (metabolites)
  - Ecotox (even in cases of product data)?
  - Data submitted before October 2021 (assessment at zonal level and later revision of the D(R)AR – pending on later data submission?)
  - Keep on track of data provided and assessed
  - …
- MS (DE, IT, SE) already volunteered

OR

Follow up Workshop on Zonal Evaluation

Dublin 1

„Dublin 2“ / Braunschweig 1

- Organising Committee already established
- Date: November 2023
- Braunschweig, Campus BVL
- Plenary sessions and outbreak groups
- MS, COM, EFSA, Industry (other stakeholder?)
- Face to face (no hybrid and/or online format)
- Focus on products and product registration process

- Topics to be collected
  - PAI / izSC
  - Zonal Committees
  - Industry (COM letter to CropLife, ECCA, IBMA)
- Possible topics
  - New actives data post approval
  - IUCLID and product application
  - Co-formulants
  - Quality of dossiers
  - Low risk products
  - Article 33 and 45 interpretations
  - Article 43 and ED
  - …

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