Product authorisation - Follow up to the ZAPID workshop

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Parallel Session 2

Zonal System – Realization of efforts and complexity

- **Without the zonal system, the level of technical complexity would be impossible to manage for authorities and applicants**

- **Differences still exist between countries in key items ➔ National requirements – technical and procedural**
  - Farmers' use patterns
  - Mitigation options
  - Interpretation of legislation and guidance

- **Zonal guidance documents – call for:**
  - up to date with possibility for applicants to comment before implementation
  - distinction between zonal and national requirements and how to address them (core vs national addenda)

- **Timelines for product authorizations not kept (CLE survey 2022, MS/COM report 2022) ➔ how to manage increasing workload?**
  - Complexity of scientific guidance documents
  - Active substance data (data gaps, issues that could not be finalized…)
  - Art. 43 following active substance renewal after ED stop-the-clock
  - Increased data requests (co-formulants, microplastics,…)

ZAPID workshop = Kickstart event

- **ZAPID workshop, Germany December 5th-7th**
- **8 years since previous zonal workshop**
- **EU Commission, Efsa, Member States, Industry representatives**
- **5 Break-out groups working on key challenges**
  - **BOG1: legal requirements / delays, BOG2: harmonization in decision making**, BOG3: digital platforms, **BOG4: implementation of new scientific and technical knowledge (GD)**, BOG5: low risk, bioPPP and non-chemical PPP
  - Concrete proposals made
  - First outcome: ZAPID WS report, with clear action table, to be published on EU Commission website
- **Post-workshop follow-up and next steps?**

CLE priorities: Tackling delays

- **Common responsibility to monitor product authorisation timelines**
- **Clear advice from ZAPID workshop participants on the need for priority setting at EU level**
- **MS concern on complexity of assessment methodologies**
  - Pilot: set up an ‘excellence network’, with CA experts on specific GD, refinements, etc. to assist CAs with issues that need specialized knowledge
  - Feasibility check GDs during development of guidance documents and before finalization. Criteria needed for feasibility
- **Dossier quality**
  - Openness on bottlenecks perceived by CAs
  - Clear distrust between MS evaluations
  - Relevance and remit of pre-submission meetings and completeness check

CLE priorities: Harmonising zonal decision making

- **Mutual recognition**
  - Limited willingness/possibilities in some Member States to further reduce national requirements
    - Proposal to publish National requirements on a centralized location, i.e. DG SANTE pesticides webpage
  - National evaluation in the frame of a MR limited to “specific environmental and agricultural circumstances” complying with Article 36(3)
  - Increase trust between Member States
    - When acting as zRMS: increase transparency on how conclusions are reached, respect agreements made at zonal level, evaluate for all cMS ➔ keep in mind the zonal partners

- **To be further discussed: Possibilities of harmonization on procedural aspects to improve the zonal system** at each stage, most of them based on good practices already in place at member state level

CLE priorities: Implementation of new scientific and technical knowledge - Guidance Documents

- **Data gaps in Efsa conclusion and uses not included as representative uses triggering need for active substance data in product dossier**
  - **Targeted re-opening of Guidance document on active substance data post-Approval -** GD SANCO 10328/2004 ➔ PAI, with proposal for a pilot before adoption
  - **Proposal to extend the list of confirmatory data to include the new a.i. data** and clarify who will assess them, and make the assessment available
- **Uncertainty remains:** different MS interpretation of applicability of guidance document (published, endorsed, noted?)

Let’s transform proposals into concrete actions

- Unique opportunity to have all stakeholders around the same table and discuss key challenges
- Need for transparent and traceable implementation plan + call for integrated plan in each EU forum discussion (e.g. standing item in zonal steering committees, in PAI, in SCoPAFF, in EFSA PSN…)"
- Communication between Competent authorities and industry is crucial to improve the product registration scheme - Zonal workshop to be organized more frequently (every 3 years)