CropLife EUROPE

Industry experiences in the on-going active substance evaluation process

Dr Martyn Griffiths, Chairman Crop Protection Reg Policy Team

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General Food Law (GFL)
-implementation very challenging

- **Dossier format IUCLID**
  -companies investing specific additional resources
  -MS need to understand how to retrieve the information
- **Study Notification**
  -a new step to bring trust into the process
  -Preparation short notice as the database is not available yet
- **Disclosure of information**
  -industry supports the transparency initiatives
  -questions still on how exactly will be the dissemination, open-EFSA platform not yet available

New renewal regulation (2020/1740)
-implements GFL provisions

- Croplife Europe supports the development
- We appreciate updates to AIR4 & 5 program documents
- We welcome the **new provision** of a draft EFSA conclusion, and the opportunity to provide further data
- It is clear from the provisions that **preparation** for renewal submissions **need to be made much earlier**
  -at least 5 years before submission
  -very challenging for Candidates for Substitution
- **Special attention to the Completeness check** due to study notification & additional justifications for confidentiality

Endocrine disruption

- **Weight of evidence (WoE) not considered enough**
  -significant additional vertebrate testing required
- Major lack of capacity for tox & ecotox studies and delays for ongoing studies
- Availability of draft EFSA conclusion would be advantage to prepare for renewal of product authorisations
- **Limited feedback from ED reviews**
  -regulation of ED properties a major area of uncertainty
- Positive development with acceptance of embryo studies (XETA)

Safeners

- CropLife Europe supports considering safeners as new substances under a new EU framework
- CropLife Europe supports that safeners should be aligned with approval periods currently in place for basic substances
- First applications under a new work program should only take place at least 5 years after process and data requirements are clearly set
- Data requirements should be adapted based on their nature and function

Seed treatment (ST) Guidance

- **Application of risk assessment and legislation relating to ST is not consistent in MS**
- **Smarter implementation is needed, ST guidance can help to achieve harmonization**
- **Birds and Small Mammals risk assessment is a key regulatory hurdle**
  - Refinement steps require acceptance of WoE-approach: overall low acceptance of refinement approaches by MSs

Challenges impact chemical and low risk/Biologics substances equally

Seed treatment Guidance

- **<u>Dust</u> is also becoming a critical issue with a little basis for a tiered approach to dust RA**
  -Very conservative, and leaves very little scientific options for refinement
  -Off-crop exposure is independent of the a.s.-in-crop rate and exclusively driven by sowing rate
  -Heubach test doesn't represent dust particle spectrum generated in field sowing experiments

Working groups involving regulators, EFSA and industry should be promoted wherever possible.

Take home messages

- Challenging preparation for peak of renewal submissions in 2021 with implementation of GFL
- Still significant uncertainties for evaluation of endocrine disrupting properties
- **Continued depletion of Toolbox for EU farmers**
  -Time to market delays leading to significant increase of emergency authorisations
  -Innovation rate (chemicals/biologics) not sufficient especially insecticides

Thank you for your attention