

# CropLife EUROPE

**Scientific Guidance Documents and their impact on innovation**

**Anne Alix**

**7<sup>th</sup> & 8<sup>th</sup> March 2023**

# From Scientific Guidance Documents to dossier content

- ▶ 38 technical guidance documents (EFSA, Commission)
  - ▶ 10 guidance documents under revision/new guidance documents
  - ▶ Av 300 studies for an active substance dossier, 150 for a preparation dossier for national registrations
- The European risk assessment is recognized as the most conservative globally, enabling to achieve the high level of safety required by the regulation, for everyone's benefit



# Yet, the challenges are many

## **Perception of lack of protectiveness from the public, with few exceptions:**

- Frequent update of the risk assessment (incl. guidance documents)
- Complexity and conservatism with limited use of high tier risk assessments
- The EFSA workplan on guidance document updates reflects this expectation
- But communication is essential

## **Race against the clock on dossiers completeness:**

- Availability vs implementation date of guidance documents
- Management of public and political expectations

## **Alignment with national risk assessments:**

- Developed to better reflect national/regional conditions
- Realism vs time and resource consuming

## **Additional drivers of change: Green Deal and related policy strategies**



# The Green Deal and the future of agriculture



## **Sustainable Use Regulation:**

- Use and risk reduction of PPP, through a broad toolbox of alternatives
- Integrated Pest Management

## **Nature Restoration Regulation:**

- Increase of biodiversity in, amongst others, agriculture ecosystems and consequences on the risk assessment

## **Sustainable Food Systems:**

- Crop diversification and self-sufficient national production systems
- Expected pressure on production systems and agriculture ecosystems

## **Technology and optimization of practices:**

- Diversification of application technologies towards observation, monitoring, diagnosis and precision



# Innovation, driving crop protection industries since 1950



## 🌱 Active substances:

- additional MoA, increased selectivity through thorough screening processes, and thus reduced application rates
- average application rates dropped from 1,200, 1,700, and 2,400 grams of active ingredient per hectare for fungicides, insecticides, and herbicides in 1950ies, to 100, 40, and 75 grams per hectare respectively by the 2000s, i.e. 95%)

## 🌱 Research and partnership in biopesticides development:

- €1.75 billion invested today, commitment to €4 billion by 2030

## 🌱 Digital and Precision agriculture, including precision applications:

- New application technology and Farm Management Systems, Applications for support services etc
- €2.15 billion invested today, commitment to €10 billion into innovation in precision and digital technologies by 2030

## 🌱 How can the risk assessment reflect this?

- EFSA system-based risk assessment could prioritize updates

# What does our regulatory and risk assessment framework need to better reflect?

- ▶ **Evolution of crop protection and pesticide use resulting from policies and technological development**
  - Precision applications
  - Risk mitigation measures
  - IPM
- **Commission's work on finalizing a compendium on risk mitigation measures**
- **Commission's work on the identification of uses with potential low environmental impact**
- **First workshop on digital and precision applications**
- **These are first steps towards addressing the needs and informing risk assessment adaptations**

# What does our regulatory and risk assessment framework need to better reflect?

- ▶ **Understanding biopesticides' role in crop protection**
  - Clear vision on the potential of biopesticides in Europe
  - Risk assessment context-adapted
- **Commission's work on biopesticides**
- **Commission's work on the identification of uses with potential low environmental impact**
- **First step towards addressing the needs and informing risk assessment adaptations**



# What does our regulatory and risk assessment framework need to better reflect?



- **Change of crop protection needs resulting from changes in food production systems alongside climate change**
  - Clear understanding of needs in crop protection at country and local levels, through continuous monitoring pests and agro pedo climatic conditions
  - Clear understanding of the potential of preventative measures, including NGTs
- **Commission's efforts on regulatory developments on NGTs**
- **Development of Observation and diagnosis technologies such Farm Management Systems (include number of tools identified by D&PA)**
- **First step towards effective IPM in the future**



# CLE joint research projects

- **5 ongoing projects on human health risk assessment**
  - Facilitating studies interpretation, read across, meta-analysis, risk assessment
  - Risk reduction (CTS)
- **8 ongoing projects in environmental exposure and effects:**
  - Environmental Exposure estimates, environmental and effect modelling, interpretation of laboratory and field studies
- **2 projects on precision applications: spray and groundwater modelling**
- **Digital Label Compliance project (€1.15 M in 2023, cnt'd in 2024)**
- **Close Transfer System**
- **15 new proposals and program extensions in 2023**

➤ **Budget: €1.5 M on top of companies individual investments**

A decorative graphic in the bottom left corner consisting of several overlapping, semi-transparent grey leaf shapes of various sizes and orientations.

# Digital agriculture and Precision Applications: workshop 21 & 22 Feb



- ▶ 31 participants (CLE, Commission (JRC, SANTE and AGRI), EFSA, Member States, CEMA, COPA COGECA, Fresenius)
- ▶ Objective: gather a first inventory of precision application and precision equipment on the basis of views and visions across stakeholders, to identify needs and priorities, and exchange on way forward
- ▶ “EU Task Force on Precision Applications” (title in progress)
  - Report under finalization, call for volunteers



# 6 tasks identified

Task 1: inventory of equipment and corresponding aims of treatment  
Define rating scales, performances, classes in 2D and 3D crops

Task 2: design uses and how they should appear in a GAP table: aim of treatment, area treated, type of equipment (volume and risk reduction classes), biology

Task 3: implications for RA and RM

Task 4: risk assessments (regulatory authorities, EFSA)

Task 5. Risk management and precision application compendium



Crop	MS	F, G or I	Pests or groups of pests controlled	Formulation	Application method	Stage	Application rate	Remarks
Cereals Use 1	All	F	Broadleaf weeds	Liquid for low volume application	Precision spray after scouting (ground sprayer) Inward spray only at the edge of the field and risk mitigation measures to reduce spray drift Where scouting indicates wide spread of weeds to control, the scenario does not apply.	Pre / post emergence	Solution prepared for 0.5 mg/m <sup>2</sup> Localized spray enables application on weed spots (>50% volume reduction)	Spray is driven by confirmed presence of weed, using directed spray.
Cereals Use 2	All	F	Broadleaf weeds	Liquid for low volume application	Ultra localized applications (plant by plant detection and spray) Where scouting indicates wide spread of weeds to control, the scenario does not apply.	Pre / post emergence	Solution prepared for 0.5 mg/m <sup>2</sup> Ultra localized spray on weeds only (>95% volume reduction)	Spray is driven by confirmed presence of weed, using ultra localized sprayer

Use category	Potential change in the risk assessment for				Potential RMM for			
	Surface water	NTA	Non dietary	etc	Surface water	NTA	Non dietary	etc
Ex: spot application post emergence herbicide								
Ex:								
Ex:								

Use of FMS, integrated tools (weather, maps, landscape, biodiversity data)

“Enhanced”  
Use reduction  
Risk reduction  
IPM

# Conclusions and perspectives



- ▶ **Our risk assessment is extremely robust and protective**
- ▶ **Improving the risk assessment (accuracy, robustness, protection, workability) is possible, but this should reflect and today's agricultural needs and agricultural practice**
- ▶ **Safety does not only depend upon risk assessments: innovation can (and does) improve safety**
- ▶ **Communication on innovation and the robustness of the regulatory system will be critical**



Thank you for  
your attention

