

A stylized graphic of a plant or cluster of leaves in the top left corner, composed of various colored shapes (red, blue, yellow, green) in shades of green, yellow, and blue.

Biopesticides: towards ambitious and fit-for-purpose EU policies

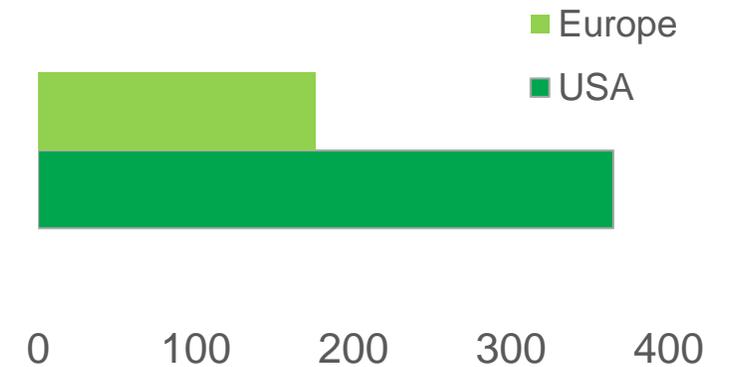
Our ambition

Industry responsibility and commitment to develop solutions that are:

- Effective and innovative
- Safe
- Sustainable

CLE member companies are actively developing new solutions:

- Conventional chemistry
- Classical biopesticides
- Novel biopesticides



Number of natural substances

Ambitious Industry ✓ innovation lagging behind the US

Are we fit-for-purpose?

Case-studies on possible biopesticide innovation with unclear defined regulatory requirements.



	Classical biopesticides			Novel biopesticides		
	Micro-organism (living)	Semiochemical	Botanical	Dead-cell and Fermentation material	RNA-i	Neuropeptides
Definition	Any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material	Substances emitted by plants, animals and other organisms for purpose of intra- or inter-species communication	one or more components found in plants	Dead microbes containing the same components as the living product or broth/extract with the substances without vegetative cells or spores	RNAi is RNA interference, a naturally-occurring process involving RNA that takes place in the cells of plants, animals, and humans.	Peptide-based insecticides that selectively disrupt specific physiological processes in target species, and by this reduce survival and /or reproduction
How regulated (EU)	EC Reg. 1107 & (still) Reg. 283/2013, Part B	EC Reg. 1107 & (still) Reg. 283/2013, Part A But mainly guidance documents		EC Regulation 1107 & Regulation 283/2013, Part A		
Environmental exposure	Based on literature data and environmental factors	Background level comparable		Identical to 'current' microorganisms containing products	Rapid degradation rates	Expected low due instability
Manufacturing pathway	Fermentation	Synthetic or biological		Biological: Identical to "living version"	Synthetic or biological	Synthetic or biological
Mode of action & specificity	Multiple	Botanicals: multiple Semiochemical: specific		Multiple and almost identical to microorganism.	Species-specific alteration of a vital function	Species-specific alteration of a vital function
Fit-for-purpose	Yes fit-for-purpose Execution can be better	Yes fit-for-purpose Execution can be better		Not fit-for-purpose		

Partly, unclear how to register innovative actives of some of our case-studies!

Case studies conclusions

- Innovation is not limited to these case studies.
- Exciting new technologies such as **peptides** and **fermentation products** are being developed. But because of the lack of a clear regulatory pathway and expertise at authority level, this new innovation is not reaching the farmers.
- For the industry it is uncertain about the ability to secure registration in Europe (reliability on regulatory timelines), and EU farmers suffer because they are at a competitive disadvantage compared to other regions of the world where those technologies are supported.



Innovative biopesticides can be made accessible to farmers

Biopesticides and Europe



- **Evolution**

- A timely implementation of existing EU regulation can help foster development and approval of effective and safe biopesticides as well as additional tailored-made data requirements & guidance and center of expertise

- **Innovative biochemicals**

- We pursue a fit-for-purpose regulation where biochemicals such as peptides, antibodies, enzymes, RNAi, etc., not yet on the EU market, can have tailored scientific-regulatory pathways which are clear for applicants and authorities.

- **Data requirements for micro-organisms**

- CLE looks forward to have it implemented rapidly with possible follow-up on the return of experience.
- To plan feedback sessions on lessons learnt by the authorities after use of the Secondary Metabolites Guidance Document for microbial dossiers.

- **Expertise hub**

- New technologies are triggering new questions. We believe a specific EU level group should be able to gather questions and issue common interpretations (e.g., the current DG SANTE Biopesticide Working Group)

Exploring parallel streams

- We welcome the BTSF program!
- We welcome updates of the current regulatory systems
- While technical capacity/capabilities is being built, we suggest to start a discussion with EFSA, Commission, CRD, and EU MS on:
 - The creation of **specialised sections** – with authority experts on biopesticides (like in the US EPA) within the EFSA Pesticide Unit
 - The **decoupling within PRAPER meetings** of biopesticides from other substances.
 - Precedent already set in Q1 2020 with [Pesticide Peer Review Experts' meeting Microorganisms - March 2020](#)
 - Allocation of a **fixed part of the SCoPAFF agenda to biopesticides**, avoiding any hold up after publication of EFSA conclusions.
 - Clarity on **what can be called a Biopesticides** in the EU

* BTSF: Better Training for Safer Food

What is the NZ view on Biopesticides capacity/expertise ?

Digital and Precision agriculture

New opportunities

➤ The EU Green Deal and Farm 2 Fork Strategy reflect societal demands to extend the regulatory framework to select more sustainable farming practices, addressing in particular climate change and biodiversity objectives.

→ To deliver this will require innovative enabling tools.



New opportunities

➤ **Digital and Precision Agriculture tools will be key to delivering on these objectives, by completing the farmers' tool-box with the solutions needed to more efficiently plan, execute, and document farming operations, and ultimately to produce food and feed more sustainably.**

→ **Crop Life Europe calls upon policy-makers and food chain partners to support EU farmers in this endeavour by establishing a dedicated stakeholder forum tasked with generating data and documentation whilst removing existing roadblocks to increase the adoption of Digital and Precision Agriculture tools.**

Upgrading the Risk Mitigation toolbox

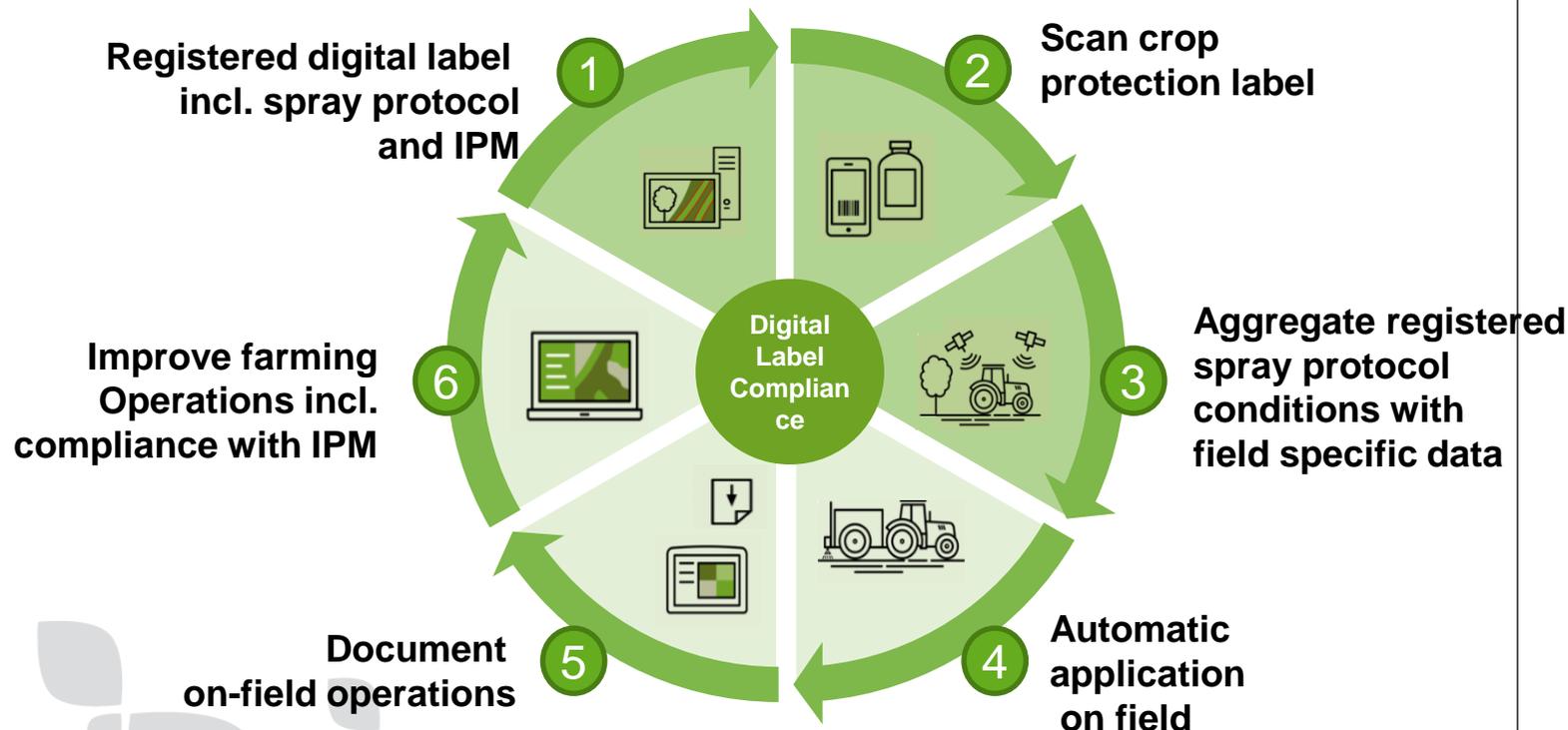


- Range of Risk Mitigation Measures (RMM) available
- Significant progress in application technology and digital sciences in recent years
 - Update of the inventory ongoing at COM level, to facilitate implementation, communication and regulatory process
 - Links to risk assessment guidance documents (e.g., how to get out of worst case assumptions via precision application)
 - Ongoing data generation:
 - E.g., Commission (DG AGRI) sponsored PhytoDron project in Spain
 - E.g., CropLife Europe exploring data generation projects in areas like Ground Water Assessment or Drift measurement
- Acceptance of RMM in the decision making process and risk assessment is needed to accelerate uptake and recognition by society
- Feeds into the Green Deal and objectives of Risk Reduction



Digital Label Compliance at a glance

The Digital Label Compliance concept is a six-step process:



Scope:

- Cross-industry concept open to all relevant stakeholders
- All Plant Protection Products
- All EU Member States
- All farmers including high-tech adopters with digital ag and precision application equipment and low-tech adopters without these technologies
- Pre-competitive - legal compliance
- Elements of CP application in relation to Integrated Pest Management (IPM)

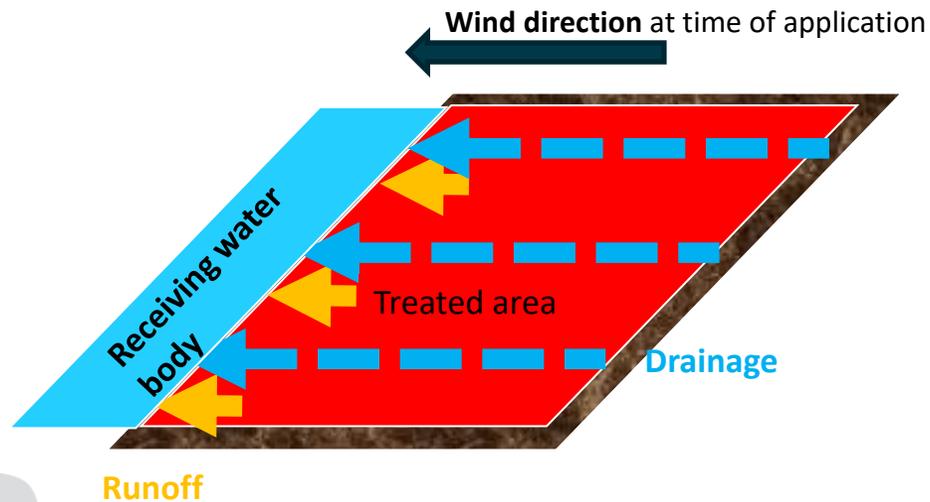
Potential future scope:

- Advanced IPM recommendations

Towards risk assessments for precision applications

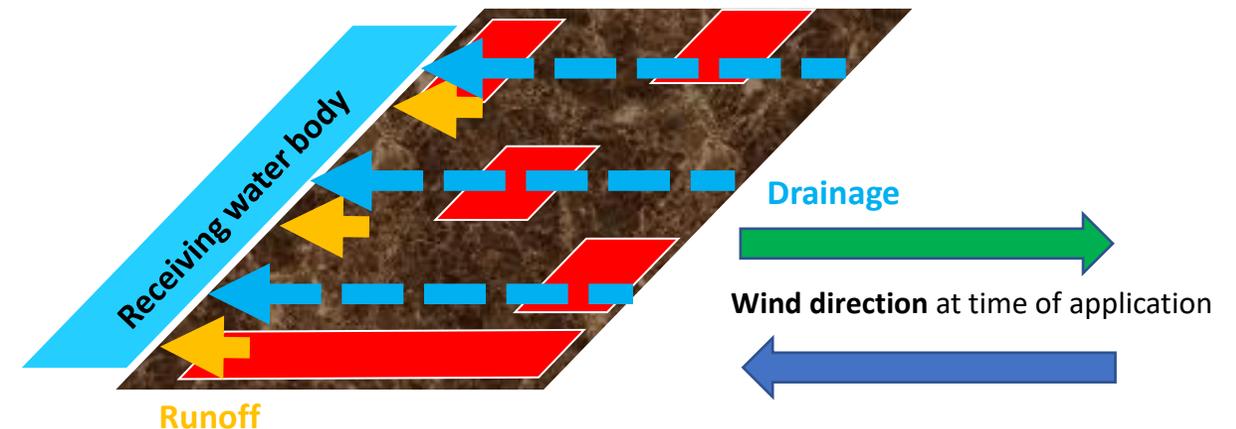
• broadcast application:

- Typical field sprayer
- Broad application
- Overall worst-case for exposure



• Spot application:

- Position and rate of application based on disease pressure and environmental conditions as defined in digital label
- Real-time adaption of risk mitigation
- Realistic exposure assessment



General application example:
Support grower in driving within allowed speed limits as stated on label

DLC as paradigm-shift from elabels to smart elabels & pro-active compliance recommendation allowing for more realism in risk assessments

- DLC will provide machine-readable labels following one standard
- DLC concept can support real time data collection for record keeping and aid compliance
- Conditions of use will be read directly by the machine – aim is to provide the grower with industry-aligned real-time pro-active recommendation on compliant PPP usage
- DLC will provide the link between regulatory data and farming practice
- Data generated enable better assessment of actual pesticide use and the development of more accurate risk calculation tools
- CLE is working on case studies on which to build adapted exposure scenarios and move towards field-specific risk assessments
- Collaboration with stakeholders from industry, academia, authorities, and growers on DLC concept, and on risk assessment tools