CropLife EUROPE

Evolution of data and scientific requirements

Human Health

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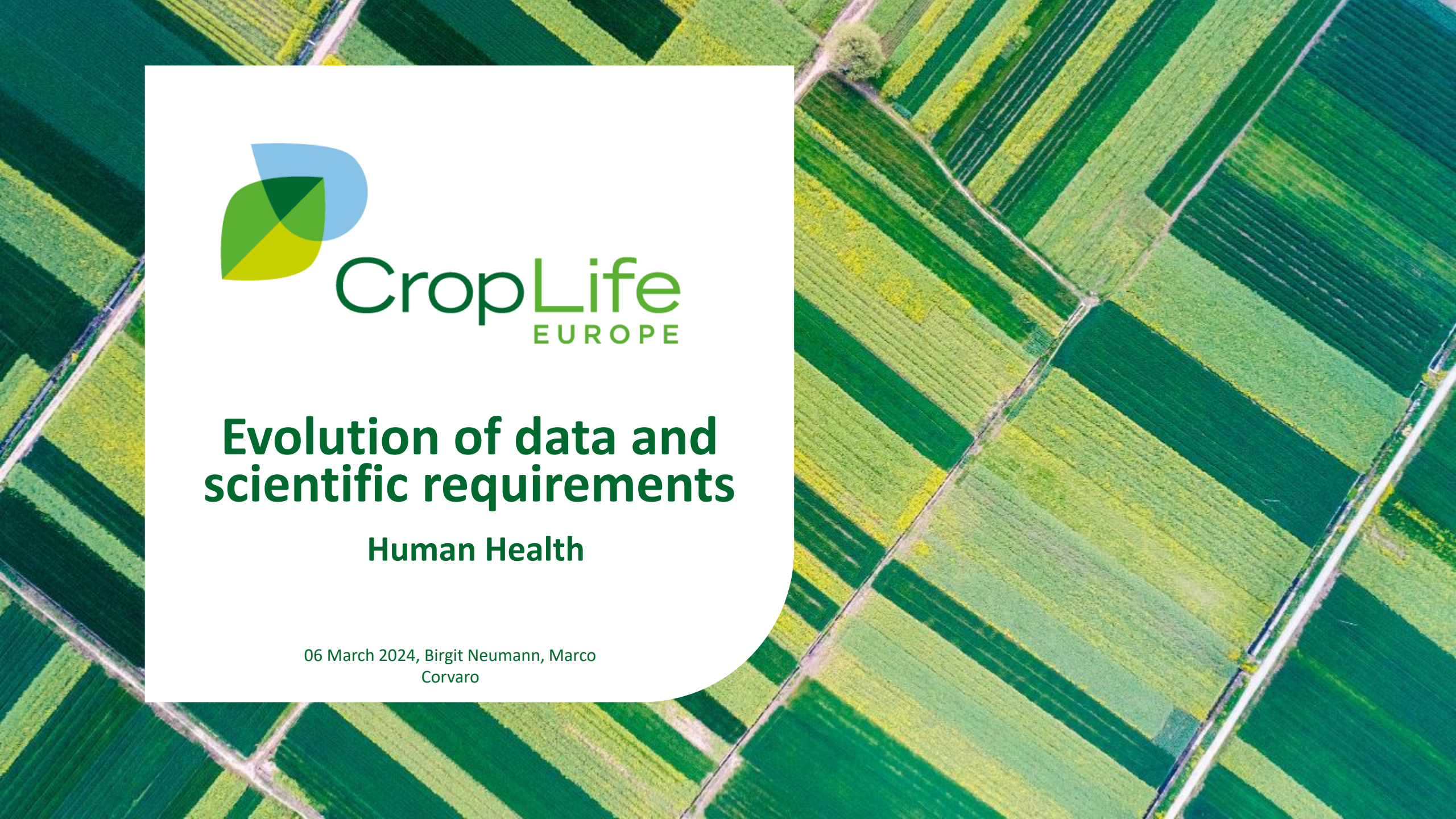

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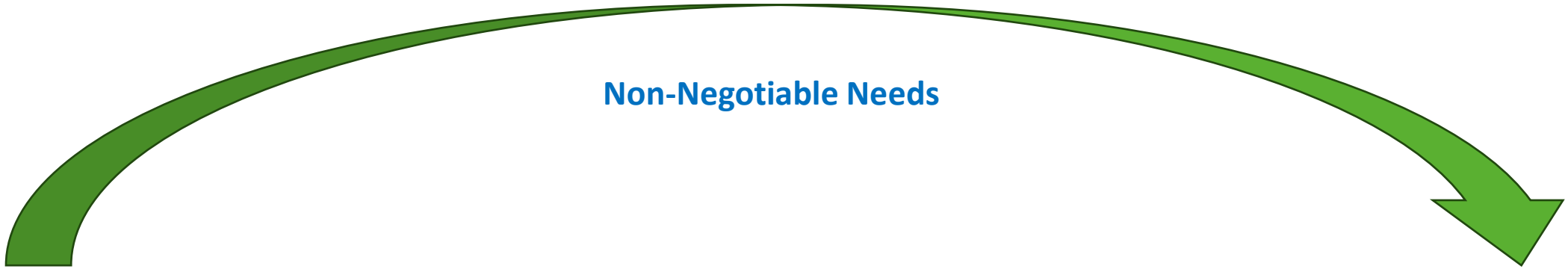
Evolution of data and scientific requirements

Human Health

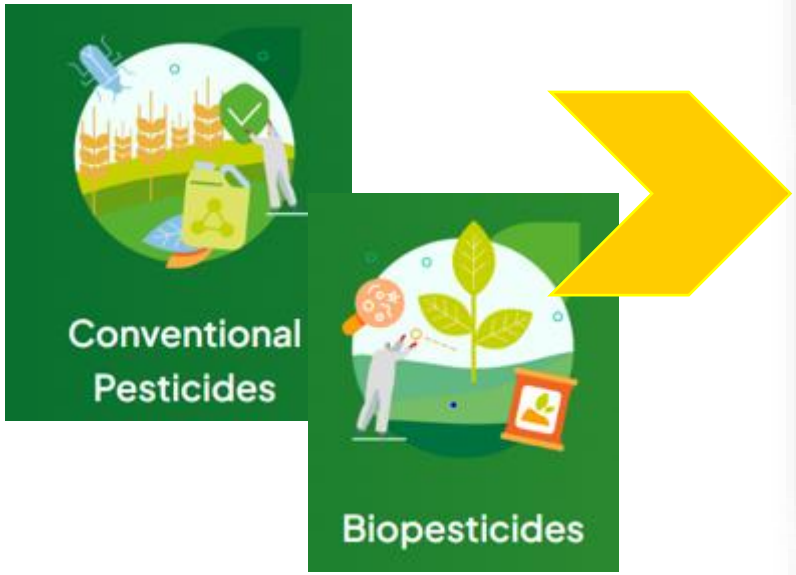
06 March 2024, Birgit Neumann, Marco Corvaro

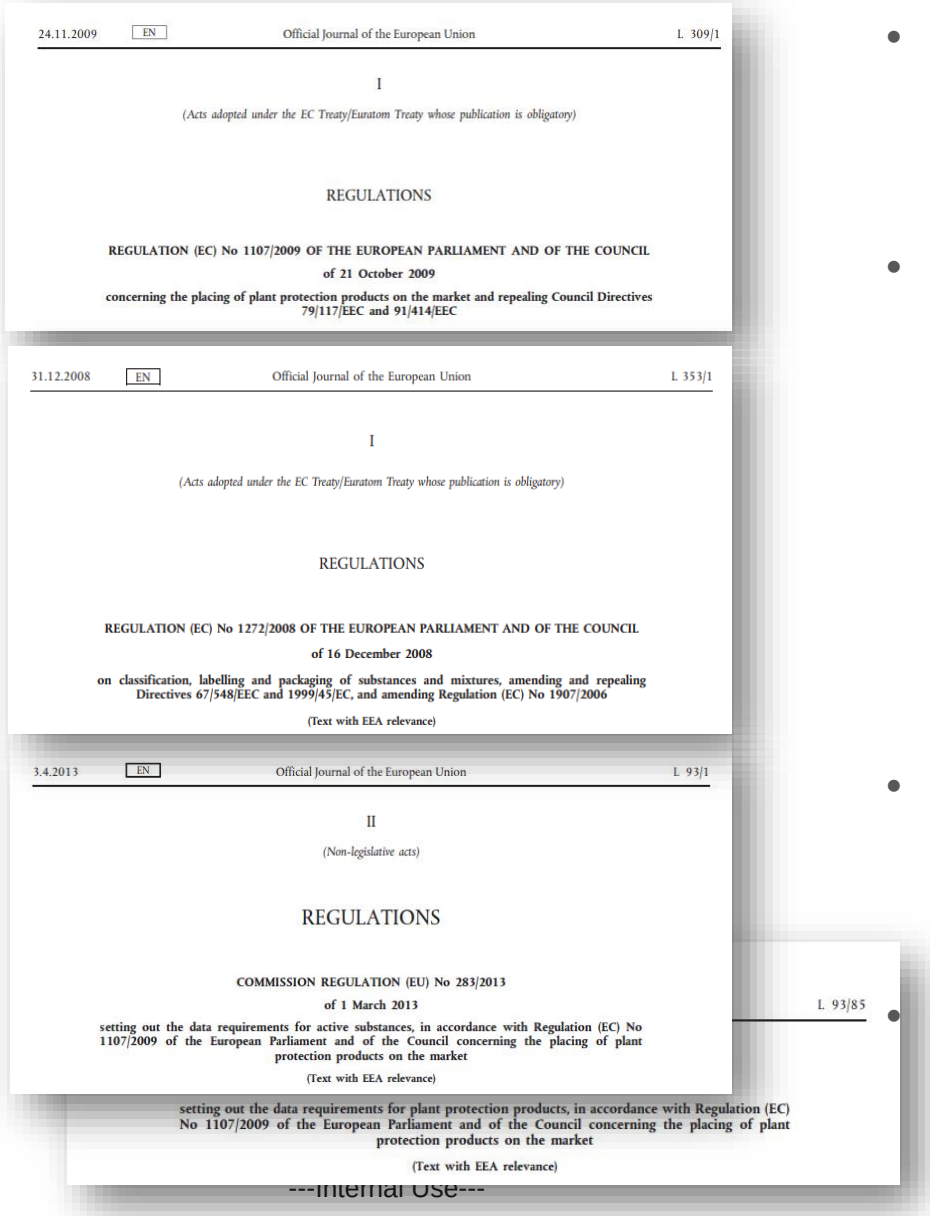
Setting the scene

Background: Agricultural crop protection (conventional and biological) and safety sciences are undergoing huge advancements. The adequacy of current regulatory frameworks to accommodate implementation of innovation and perspectives for possible future approaches are debated within in the session.



Current Regulatory System





24.11.2009 EN Official Journal of the European Union L 309/1

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009
concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

31.12.2008 EN Official Journal of the European Union L 353/1

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
(Text with EEA relevance)

3.4.2013 EN Official Journal of the European Union L 93/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 283/2013
of 1 March 2013
setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
(Text with EEA relevance)

L 93/85

setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
(Text with EEA relevance)

- **Regulation (EC) No 1272/2008**: CLP
- **Regulation (EC) No 1107/2009:** assessment and approval criteria of conventional pesticides, safener, synergists, microbials based on hazard-based cutoffs and risk assessment
- **Regulation (EC) No 283/2013:** data requirements for active substances, microbials
- **Regulation (EC) No 284/214:** data requirements for products

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Current intricate data requirements; however, assessment moving to based on weight of evidence


3.4.2013 EN Official Journal of the European Union L 93/1

II

(Non-legislative acts)

REGULATIONS

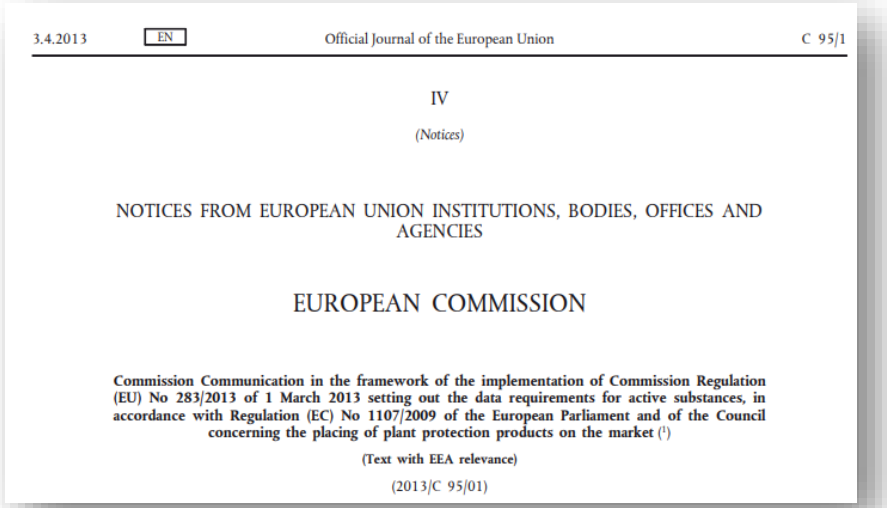
COMMISSION REGULATION (EU) No 283/2013

of 1 March 2013

setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

Regulation (EC) No 283/2013: sets out data requirements for active substances, microbials


3.4.2013 EN Official Journal of the European Union C 95/1

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (1)

(Text with EEA relevance)

(2013/C 95/01)

- Supplemental to Reg. (EC) 283/2013: COM Communication and numerous guidance for the generation of data, their evaluation and specific assessments needs
- Interdependence of different studies, results, information needed to support WoE approaches (example ED)

Some observations:

- Box-checking list of requirements with limited opportunity for testing strategy discussion and targeted testing
- Animal intensive programs
- Specific assessment needs not identified in regulation
- Individual active substance approval isolated from product approval
- Risk envelopes possibilities, limited application
- Risk benefit analysis?

Is our current regulatory system fit to accommodate innovation and targeted safety assessments?

❖ **Food Production & Crop Protection Innovation and Life-Cycle Management:**

- New technologies to be addressed, e.g. diversity of biologic solutions, precision/digital technologies, less exposure, targeted and integrated solutions

❖ **Innovative Scientific tools for safety assessment promoted by EU and international research programs and agencies:**

- New tools for data generation; non-animal testing options; modeling; ability to evaluate larger data sets, … etc.

- **Upcoming Regulatory Changes in EU Safety Legislation:**
  - Changes in safety regulation (e.g. OSOA; NGRAroute and «need to know»-based assessments; with increased use of tiered approaches and testing triggers)

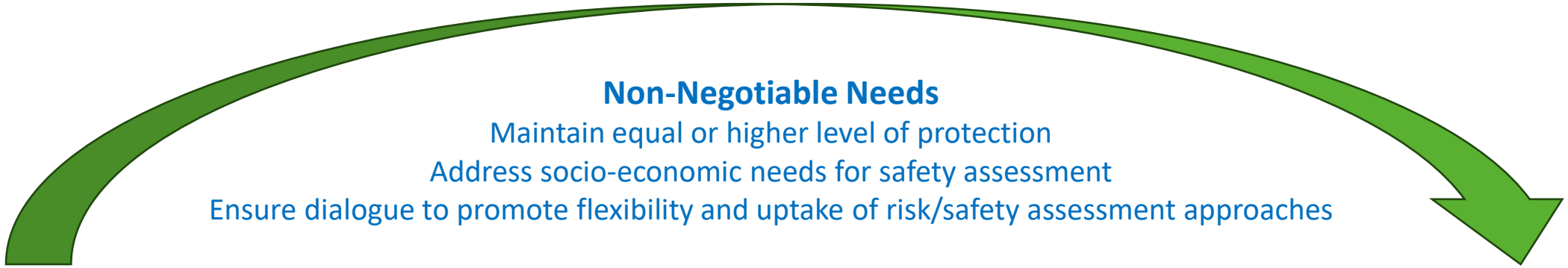
Foundational

❖ **Non-negotiable:**

- Maintain equal or higher level of protection
- Address socio-economic needs for safety assessment
- Ensure dialogue to promote flexibility and uptake of risk/safety assessment approaches
- Reliability/validity of methods

Bringing it all together

Debate point: is the current regulatory frameworks adequate to accommodate implementation of fast-paced innovation in agriculture and safety science?



Current Safety Assessment Paradigm

- Box-ticking list of requirements
- Animal intensive programs
- Assessment needs not identified in regulation
- No dialogue opportunity for testing strategies
- Active substance approval isolated from products
- Risk envelopes use limited
- Risk benefit analysis?

Upcoming changes: where next?

- New technologies in Food Production & Crop Protection
- New scientific tools for safety assessment
- Upcoming Regulatory Changes in EU Safety Legislation

Thank You

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Charge Questions for the panel/moderator

- Conceptual - What flexibility on data requirements and registration process is needed for a regulatory framework to empower future agricultural technologies and advancements in safety science?

- Conceptual - What are resources-benefits of a system based on a critical “need to know”-based information requirement?
  - How can such a concept provide regulatory certainty and predictability in terms of outcomes and timelines for all stakeholders?

- What procedural mechanisms can enable a robust regulatory process that supports the implementation of innovation (agriculture/safety) and incentivizes stakeholder trustful dialogue?
  - Additional dialogue opportunities exists in other regulatory framework (for example but not limited to: data package pre-assessment, data call-in and risk envelopes across all available formulations at renewals, … etc.)