CropLife EUROPE

EU situation – Regulatory challenges

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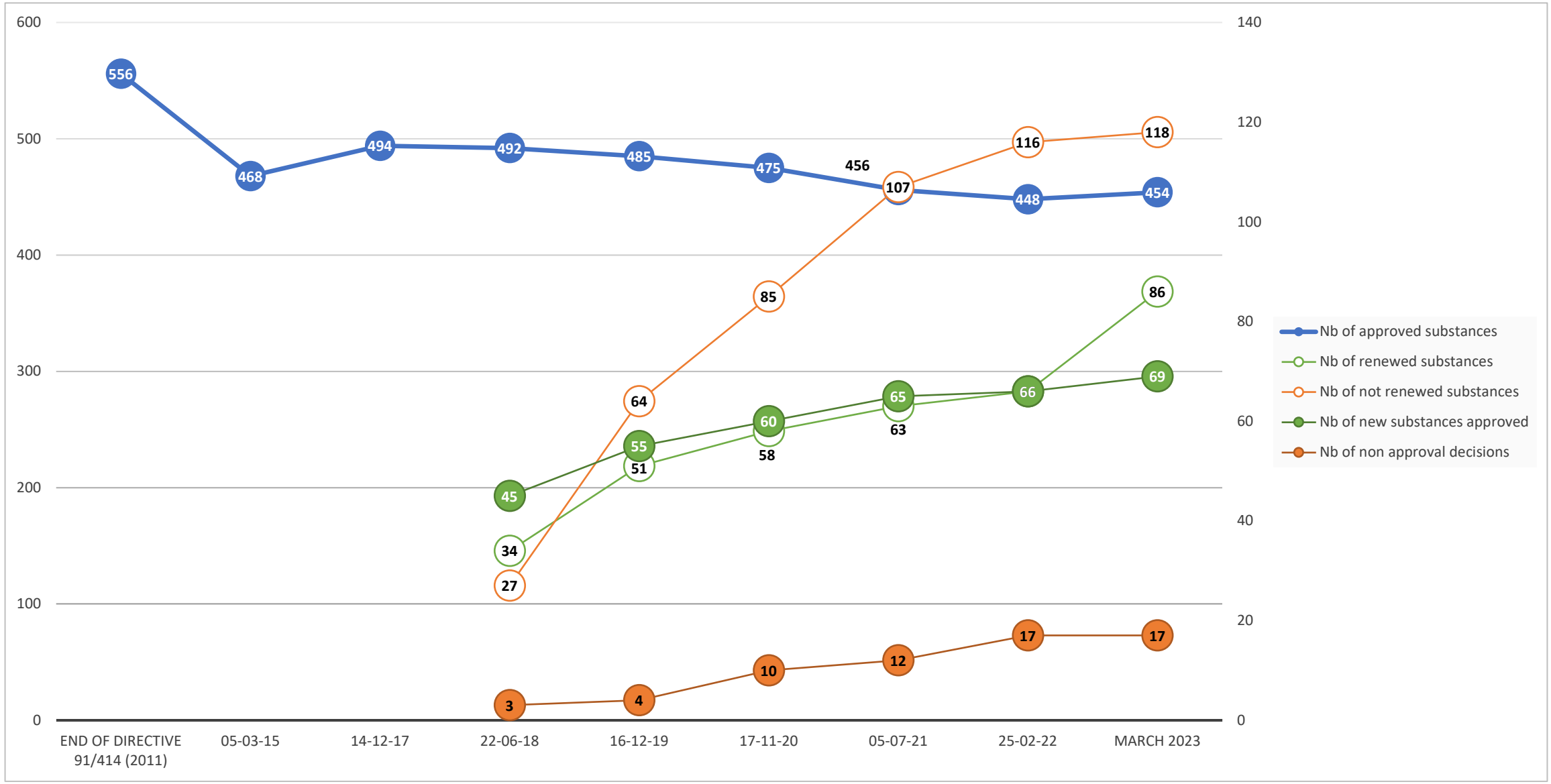
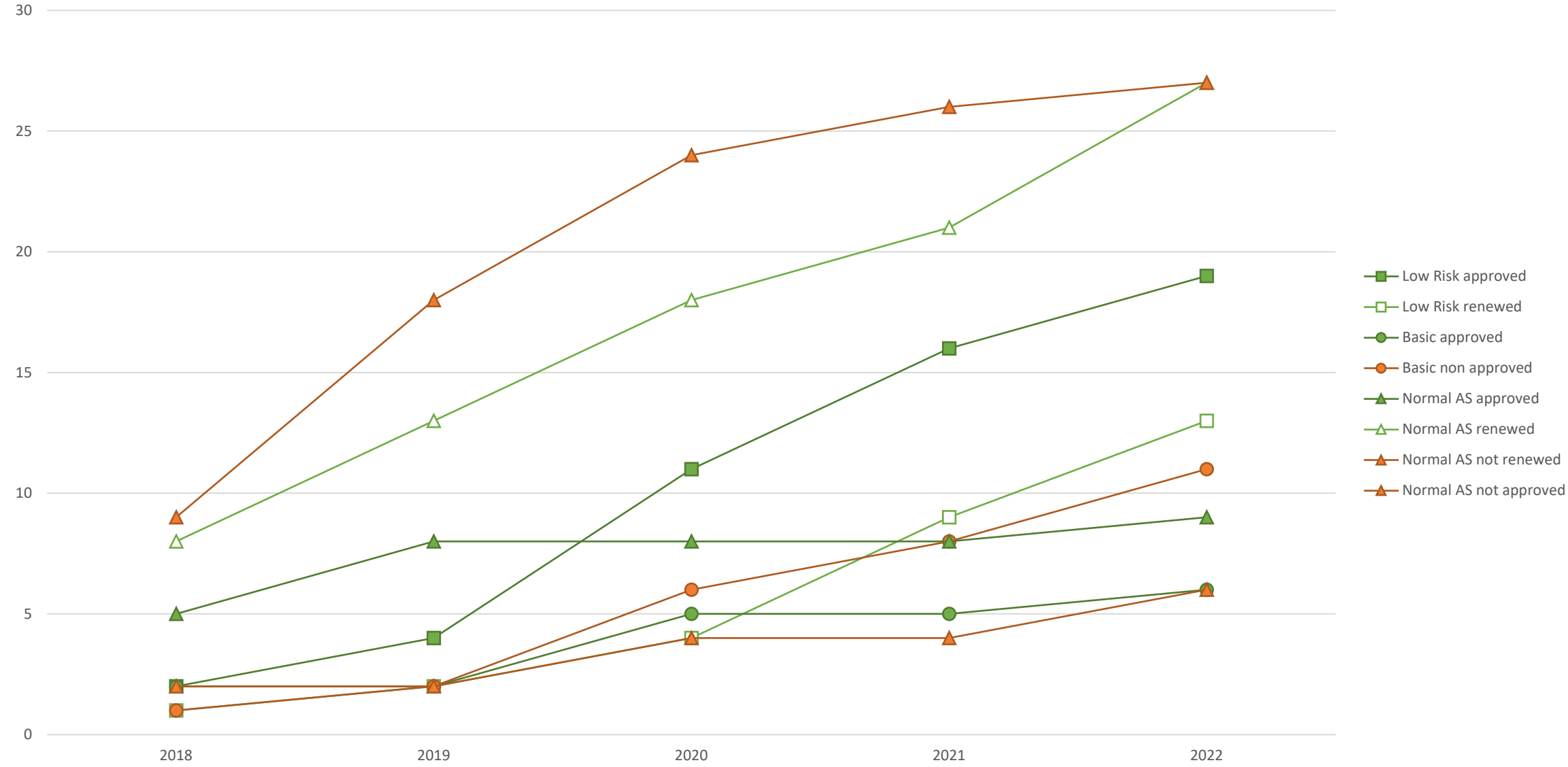
Evolution of availability of Substances in the EU



Original slide from Anne Chapelle & Jean-Claude Malet (DGAL France) continued for 2022/2023

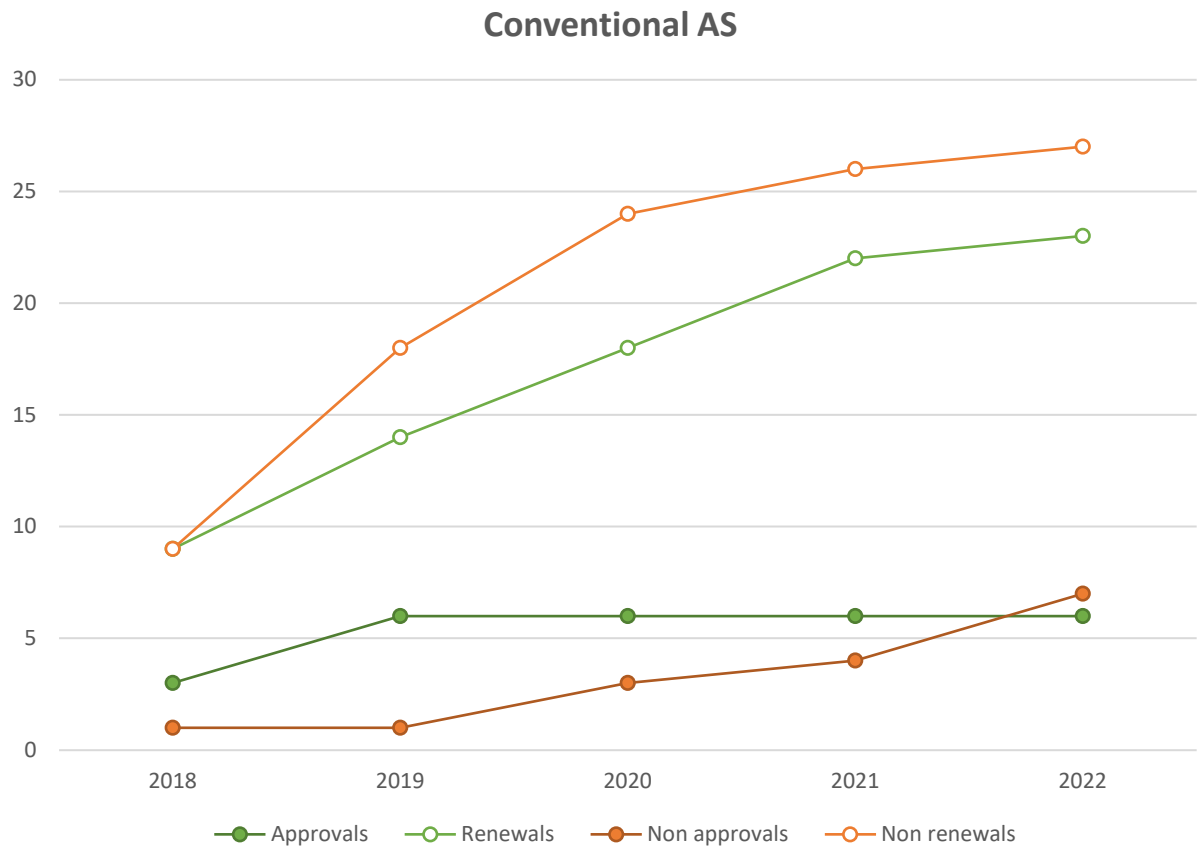
SCoPAFF decisions since 2018

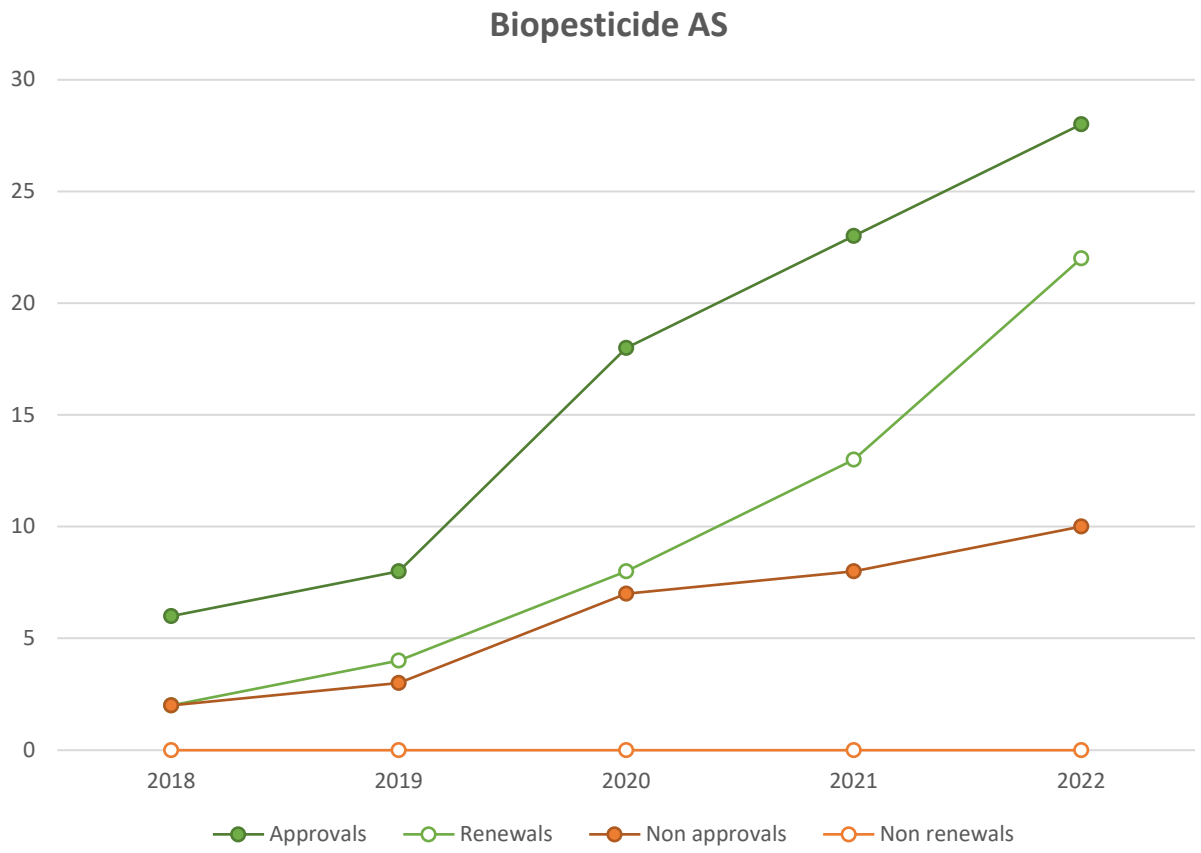
Per regulatory categories



SCoPAFF decisions since 2018

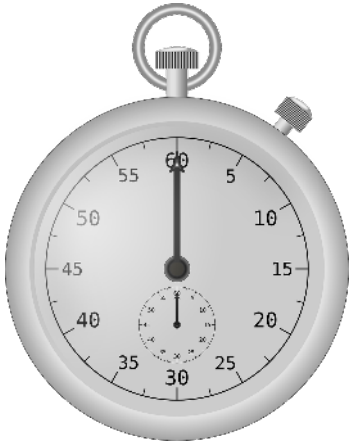
Per technologies





Decision making and delays

- **Estimation that for dossiers submitted since 2014, more than 250 decisions need to be taken.**
- **No real progresses on derogations possibilities**
- **Further delays created by the Transparency Regulation implementation**
- **Risk Mitigation Measures at AS level**
  - Range of Measures is available: acceptance in the decision-making process and risk assessment needed to accelerate uptake and recognition by society
  - Update of the inventory ongoing at COM level, to facilitate implementation, communication and regulatory process
  - Links to risk assessment (e.g., how to get out of worst-case assumptions via precision application)
  - Feeds into the Green Deal and objectives of Risk Reduction
- **Lots of substances under ED Stop the Clock**



Experience with ED criteria

- **Experience being gained by all actors on the implementation of the criteria. However, we see:**
  - No proper weight of evidence applied in practice.
  - Stepwise testing approaches not implemented: lower tier tests often disregarded and request for higher tier studies.
  - Extremely complex new field: various assessors with different understanding !

    → Questioning risk management decisions consistency and predictability for applicants

- **Need for a Risk Managers group to align on:**
  - Outcome quality checks, experience sharing
  - Interpretation limits
  - How to further build dedicated expertise

Chemical Strategy for Sustainability

Example of initiatives affecting PPPs

New Hazard classes into CLP

- Delegated act introducing PMT/vPvM and ED now published
- Question remain what does a PMT/vPvM classification would mean under the PPP regime

PFAS restriction proposal

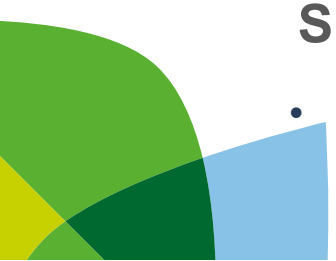
- Proposal now submitted to ECHA. Contains several derogations
    - Clarifications are needed when it comes to intermediates
- Proposes reporting obligations to ECHA
- Calls on the Commission to reinforce persistence assessments in dedicated regulations
- No derogation for packaging
- Estimated application not before Q2 2025 (+18 months transition period)

Export ban

- Proposal being prepared by the European Commission, for hazardous chemicals.
- Public consultation end April - COM impact assessment by end summer – proposal in Q3.

Challenges around co-formulants

- **Increased uncoordinated requests for detailed information**
- **Issue with National lists of co-formulants –** the new Reg 1107/2009 annex III population mechanism goes in the right direction of harmonisation
- **Undue pressures on whole formulations by some stakeholders:**
  - The extensive data package on the components of a formulation includes all necessary information to allow for a complete risk evaluation.
  - On top of the regular re-evaluation process, mechanisms and safeguards allow for constant evaluation and data generation, targeted monitoring or even rapid reaction of authorities if needed.
- **Alternative co-formulant suppliers**
  - Different interpretations of the SANCO “non-significant change” guidance.
- **Unforeseen impact of several EU Chemical Strategy for Sustainability initiative on availability and extra workload:**
  - E.g., Mixture allocation factor / Generic Risk Approach



Zonal system and product authorisation

- **We welcome the upcoming stakeholder workshop in Q4 2023 !**
- **A great opportunity to gather all actors to:**
  - Harmonize approaches within a zone as much as feasible
  - Work on eliminate unjustified national requirements
  - Make better use of interzonal options
  - Use technology to increase efficiency
  - Introduce ‘fit for zonal process’ test - regulations, guidance documents and IT systems
  - Clear appropriate rules instead of pragmatic workarounds

  → And address the resource issue amongst authorities…

Conservatism in scientific evaluations

Case of technical guidance documents

- **Recently released or upcoming guidance will have a large impact on resources at Member States authority level, and at applicant level.**
  - Increased complexity
  - Increased conservatism
  - Increased time to generate, understand and process risk evaluations – despite software tools supposed to help !
  - Not always with demonstration that previous versions led to lack of protection
- **Will further accentuate applicants' tendency to focus resources on core uses and drop others**

Get ready for:

- *Revised EFSA Birds and Mammals GD*
- *EFSA PEC soil modelling framework GD*
- *New version of the EFSA pollinator GD*
- *Water Treatment by-products*

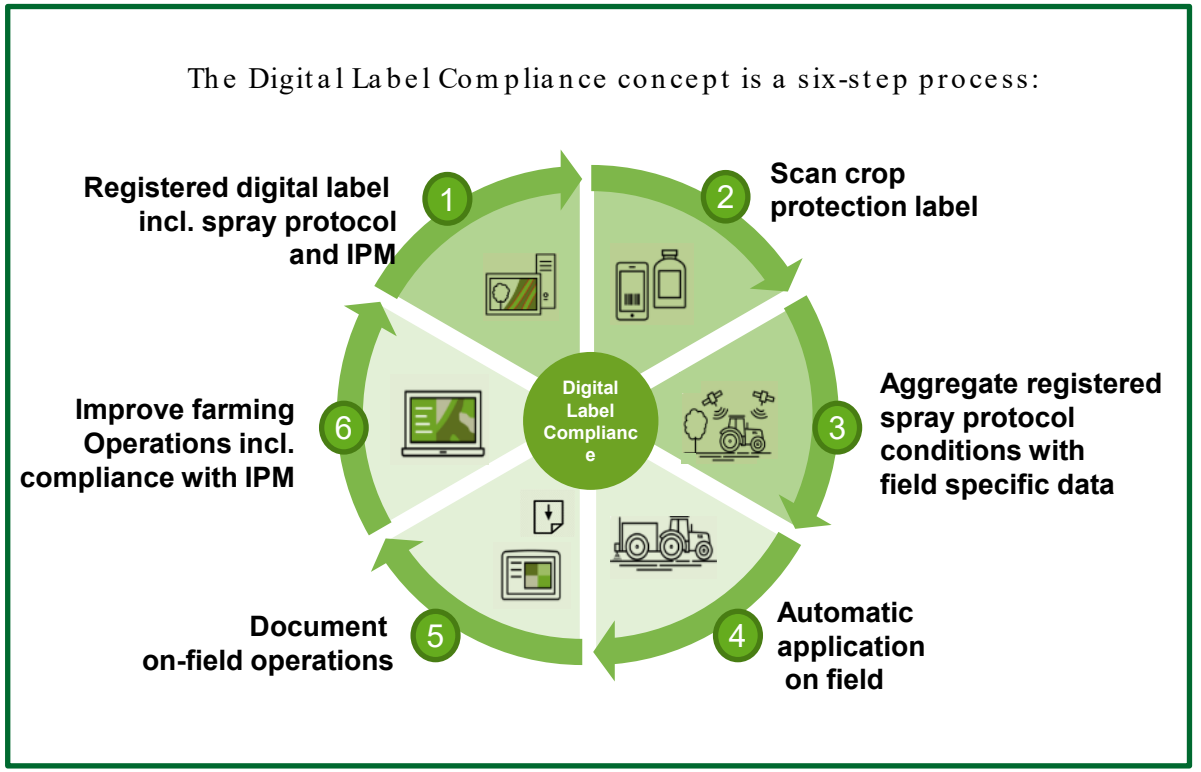
Conservatism in scientific evaluations

Industry proposals

- Have evaluation supporting documents also **developed** and **tested** by their end-users.
- Get **MS agreement on mandates** content before triggering development work.
- Make sure the content is **fit for purpose**
- **Shift away from totally unrealistic worst-case assumptions** adding up through risk assessment schemes.
- **Involve stakeholders further**: more than just once with a short public consultation.
- Connect with regulatory science approaches taken in other developed OECD countries.

Further uptake of Digital and Precision Agriculture

- **Tools will be key to delivering on the Green Deal objectives.**
- **Crop Life Europe calls upon establishing a dedicated stakeholder forum to:**
  - Generate relevant data and documentation and remove existing roadblocks to increase the adoption of Digital and Precision Ag tools.
- **Cross-Industry concept on Digital Label Compliance**
  - Paradigm-shift from elabels to smart elabels & pro-active compliance recommendation allowing for more realism in risk assessments



- **Drones:** taking them further than scouting activities - new data available and first cases appearing in certain Member States

How to further encourage Biopesticides

- **Need for timely implementation of existing EU regulation**
- **Positive move made with the new Micro-Organism data requirements.** Now what's next ?
  - **Novel technologies are also waiting to enter Europe** (e.g., peptides, antibodies, RNAi based products)
  - Clarity on how these will be assessed is also needed for applicants.
  - Having a guidance document addressing most of the questions for these novel biochemicals would help.
- **Reinforce technical expertise and capacities in evaluating authorities**
- **Provide clarity on what can be considered a biopesticide**
- **Have risk managers be creative to support more biopesticide solutions reaching EU conventional and organic growers.**
  - E.g., preliminary authorisations ? Low Risk status presumption ?

Some extra hurdles

- **Problematic implementation of the Transparency rules**
  - Adaption of the EFSA practical arrangements needed
  - Stock taking exercise needed before expanding the rules to other areas
- **Indirect effect of other legislations on PPP availability**
- **EU regulatory divergence from global partners**