



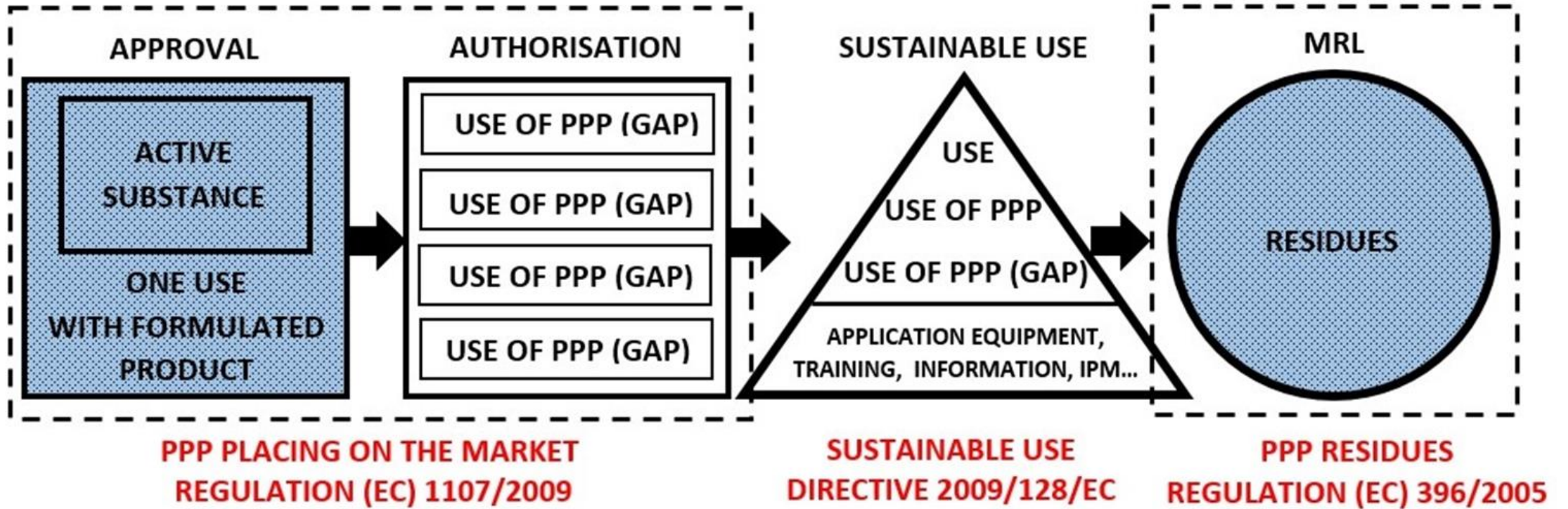
Pesticides Regulatory Framework Approval process for active substances and plant protection products

Türkiye-EU cooperation

Brussels, 20 December 2023

Eric Liégeois, European Commission, DG SANTE E.4

Pesticides are highly regulated in the EU



Two-Steps Procedure to be placed on the market

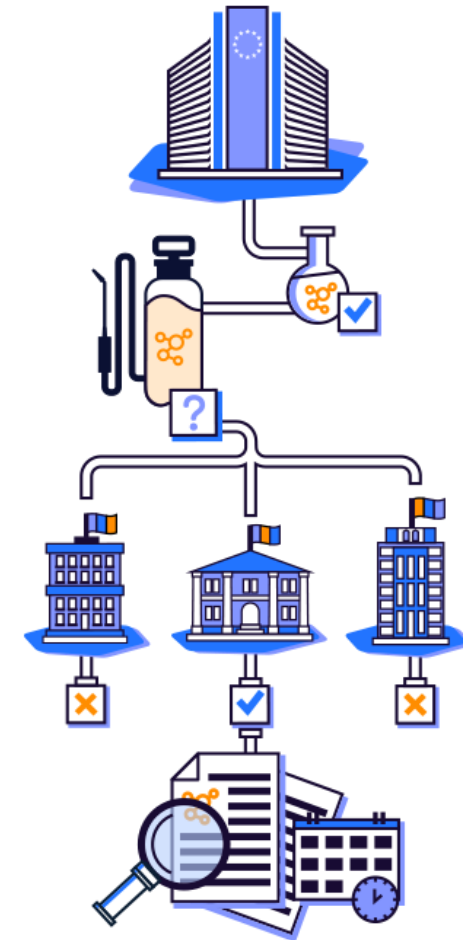
- **Step 1: The Active Substance** present in one representative plant protection product demonstrating its efficacy against one pest in one crop (one GAP) needs to be evaluated at EU level and considered as not presenting any unacceptable risk (**ONE SAFE USE**).

The Commission decides about the approval (or not) of the active substance.

- **Step 2: The Plant Protection Products** (containing this active substance) are then evaluated by the **Member States** taking into account local climatic, soil and agronomic conditions for all other pests and crops where the product is deemed effective (several GAPs).

Each Member State decides for their own territory to deliver (or not) an authorisation for the plant protection product(s).

- **Both steps** require a factual **evidenced risk assessment** and call for decision about the management of risks potentially identified during the assessment.



Who is doing what in these two steps process?



INDUSTRY

Develops active substance/product

Carry out studies to support risk assessment

„No data – no market“

Apply for approval a EU level and authorisation



MEMBER STATES (MS)

Rapporteur MS does the initial assessment of the dossier presented by industry

Other MS expert peer-review the initial report.

Each MS vote the approval (or not) of the active substance in Standing Committee

MS then deliver authorisation for plant protection products



EFSA

Organises peer-review process for each active substance, sets reference values and concludes the risk assessment.

„Develops guidance for risk assessment.

Proposes Maximum Residues Limits (consumer exposure)



EUROPEAN COMMISSION

Transform EFSA conclusions on risk assessment into a proposal for decision regarding approval (or not) of active substance (risk management).

Organise the Standing Committee and vote by MS (qualified majority)

Manage expert groups, develops guidance document, provides support

Some figures concerning active substances

In 2001 EU counted 979 active substances

Today we have:

1. 451 active substances approved and
2. **946 NOT approved.**
3. 18 active substances are currently processed.
4. 66 are pending for a decision

More info in :

[Implementing Regulation \(EU\) No 540/2011](#)

And in our EU Pesticide Database.

Search Active substances, safeners and synergists

European Commission > Food Safety > Plants > Pesticides > EU Pesticides database > Active substances

Search options

Type

Nothing selected

Status

Nothing selected

Legislation

Nothing selected

Authorised in 

Nothing selected

Active substances, safeners and synergists (1484 matching records)

Export Active substances

Filter results...

(3E)-dec-3-en-2-one

PENDING

(4Z-9Z)-7,9-Dodecadien-1-ol

NOT APPROVED

(E)-10-Dodecen-1-yl acetate

NOT APPROVED

(E)-11-Tetradecen-1-yl acetate

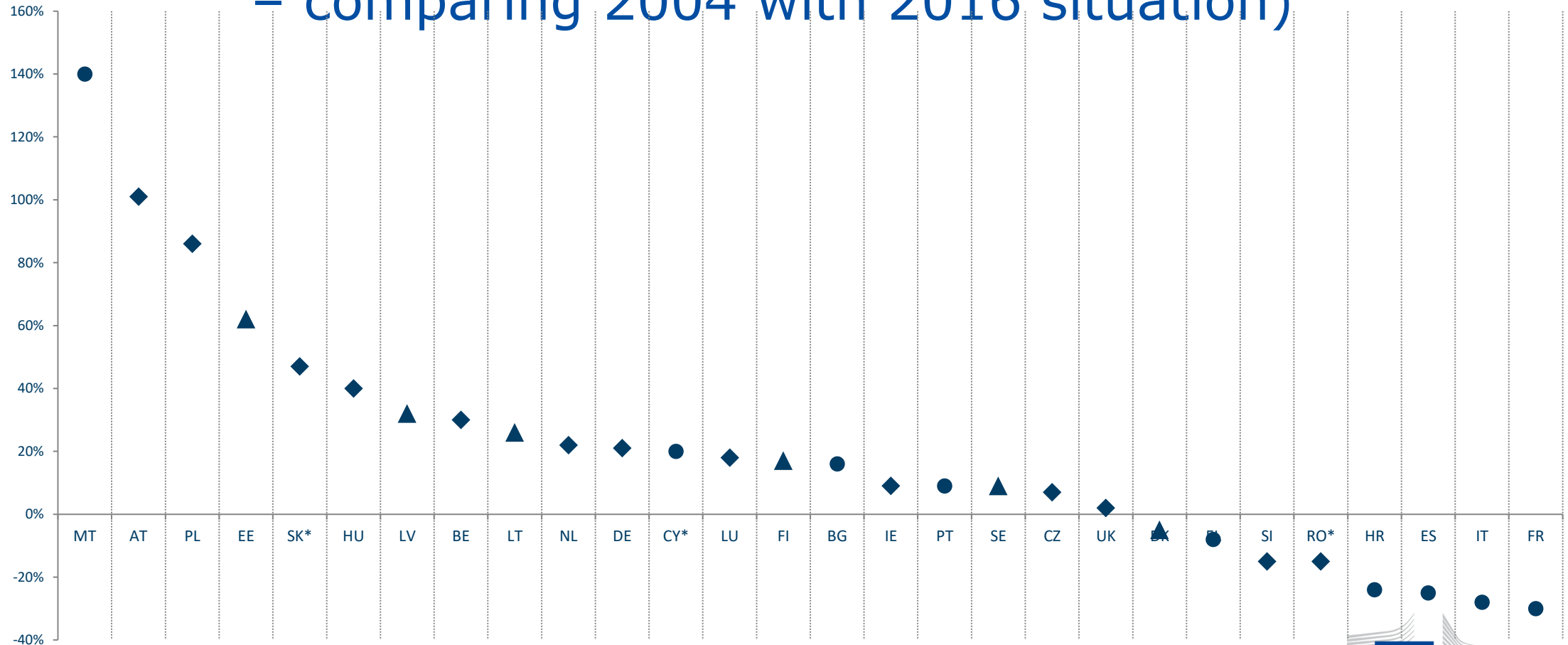
APPROVED

Expiry of Approval : 30/08/2037

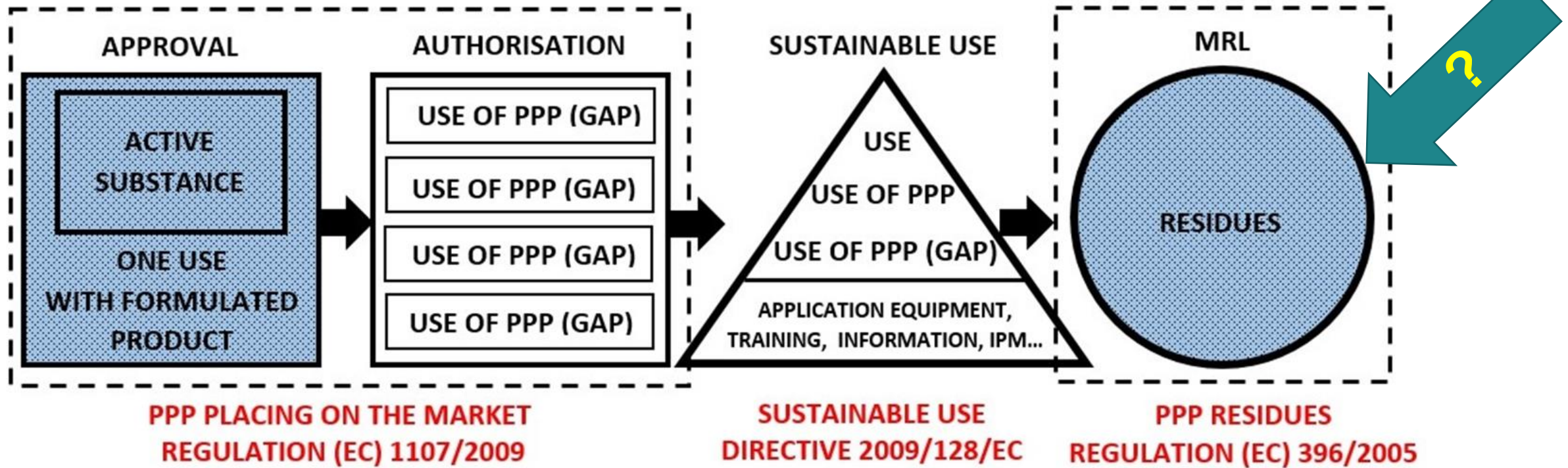


European
Commission

Availability of Plant Protection Products (decrease at MS level – comparing 2004 with 2016 situation)



Withdrawal of Pesticides – consequences on residue levels?



Objectives of the MRL Regulation (396/2005)

- *Ensure a harmonised high level of consumer protection (public health > crop protection):*
 - **No unacceptable risk to humans**
 - **MRL set at lowest achievable level consistent with critical Good Agricultural Practices (cGAPs)**
 - **Protecting vulnerable groups (children, unborn)**
- *Trade facilitation:*
 - **Free circulation of food and feed in EU**
 - **Provisions for third countries (imports into EU)**
- *Transparency and predictability*

New MRLs established based on

- GAPS in EU – **No authorisation = No GAP → Lowering of MRLs to LOQ**
- GAPS in Third Countries ("import tolerances")
- Codex Alimentarius standards

Same level of stringency in assessment, same data requirements, same timelines for assessment

MRLs valid for

- Commodities from EU and Third Countries:
same MRL for all food and feed on the EU market

The EU political context (>2019)



Farm to Fork Strategy: Pesticide reduction targets by 2030

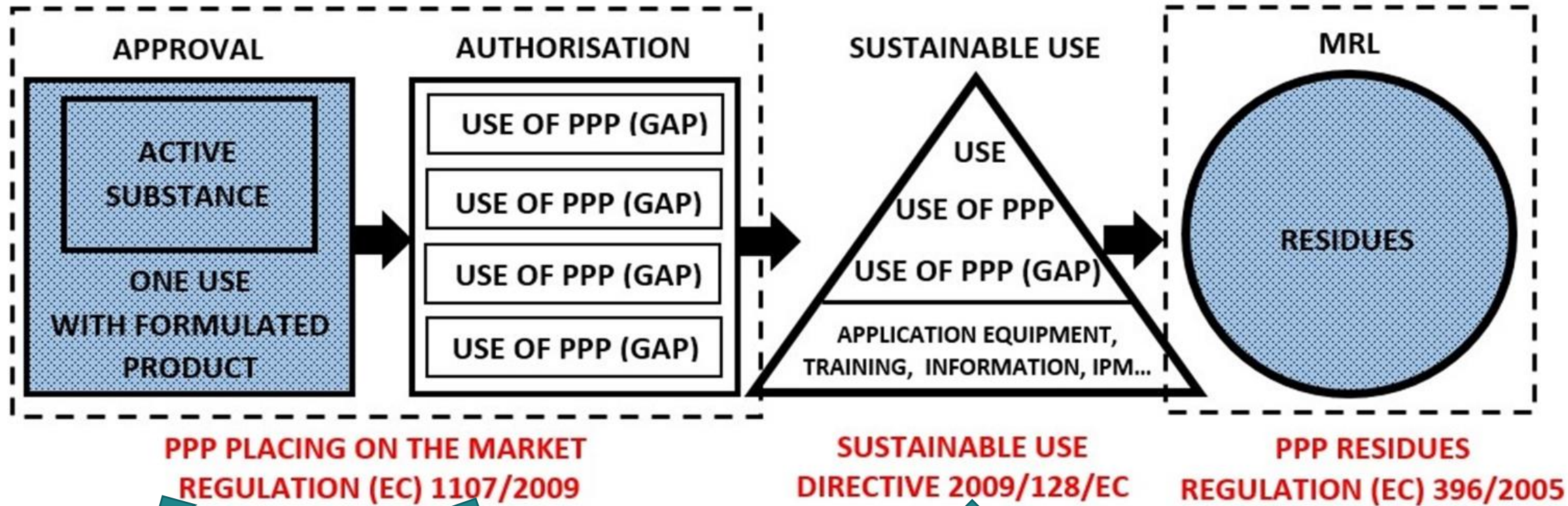


Reduce by 50% the overall use and risk of chemical pesticides



Reduce use by 50% of more hazardous pesticides

Options to fulfill F2F objectives



OPTION 1

« Enrich » the products' portfolio with more low-risk actives and PPPs.

OPTION 2

- « Make the use of PPP possible only as last resort » (via IPM)
- De-risk the « last-resort » use of pesticide (use conditions, machines, digital/precision = risk mitigation)

Less Hazardous Pesticides

- Scientific Endocrine Disruptors' criteria - implemented since 2018
- Unacceptable co-formulants list (Annex III) and rules and criteria for identifying additional unacceptable co-formulants (Regulation 574/2023)
- Reach restrictions (PFAS under discussion, applicable to co-formulants).
-
- New CLP criteria – besides PBT, ED, Mobile,...

More Low-risk Pesticides: Activities on micro-organisms used in PPP

New Regulations on MO

- Four implementing Regulations
- Applicable as from Nov 2022

Two Communications from the European Commission

- List recommended test methods/ guidance documents
- Support dossier-preparation
- Not legally binding
- Endorsed in March 2023
- Additional database of useful guidance documents

Explanatory notes + dRR

- Support understanding of the new EU Reg
- Support dossier-preparation
- Harmonise risk assessment and risk management
- Not legally binding
- Endorsed at PAFF October
- dRR also endorsed

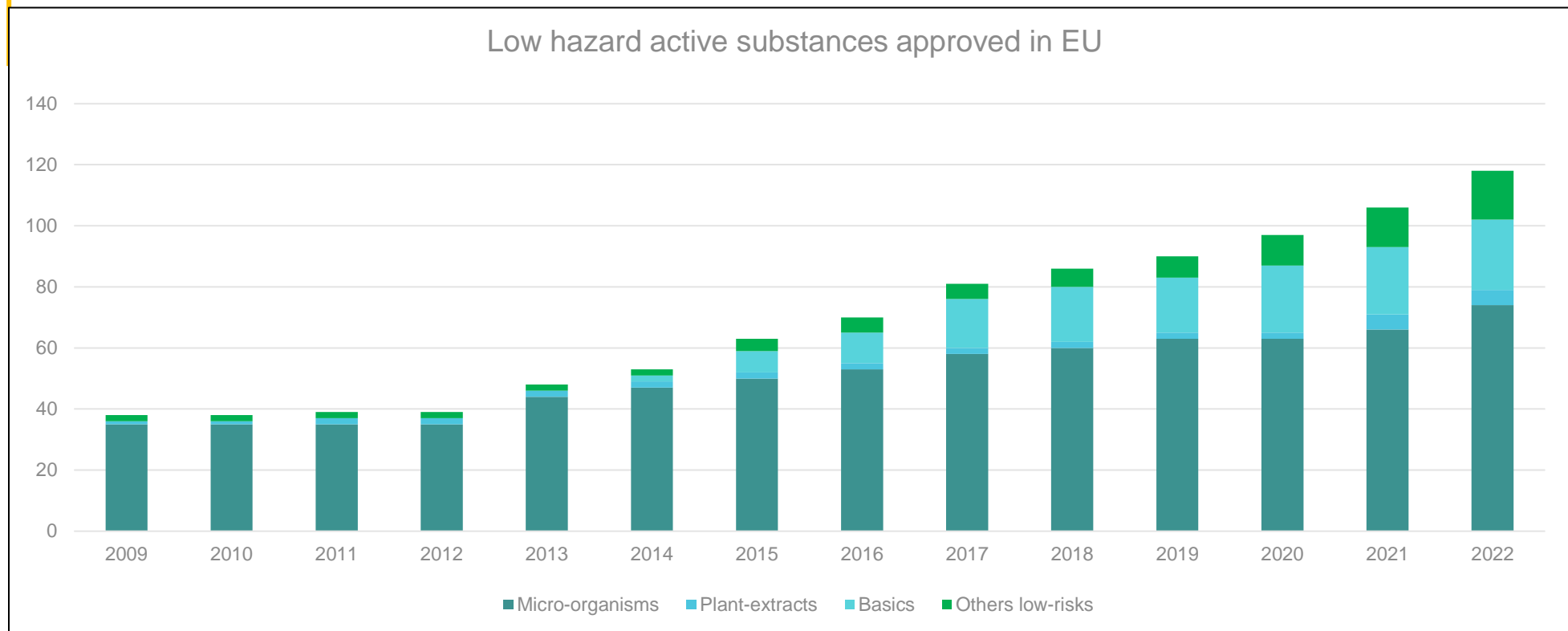
Tools

- IUCLID
- New test methods (OECD)
- Consensus documents on MO species
- Background level on MO species

Completed/available

On-going

What about the low-risk substances today?



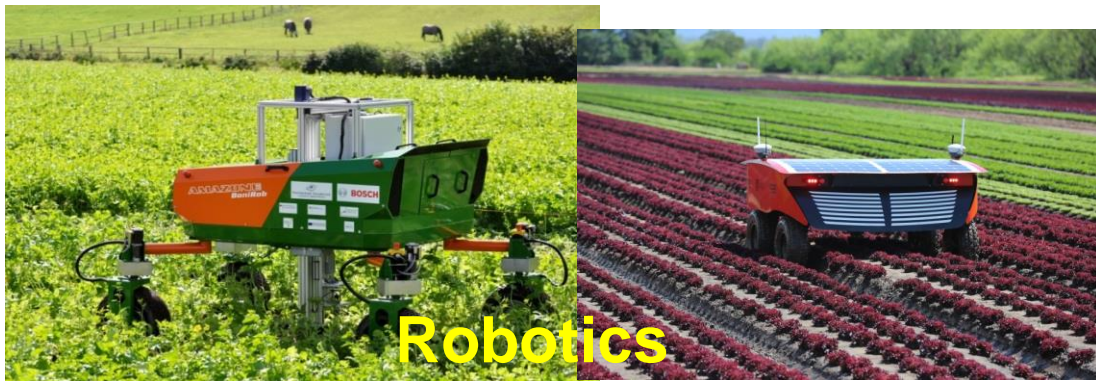
Today “Low risk” substances:

- Micro-organisms
- Pheromones
- Plant extracts
- + basic substances

In the future:

- RNAi
- Peptides
- Antibodies

Reducing Risks with innovative application techniques



Special machines

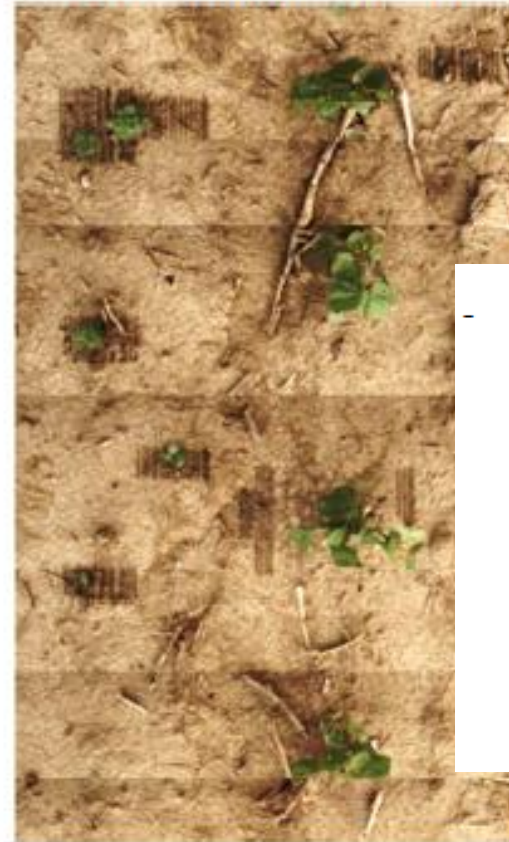
Moyens permettant de diminuer le risque de dérive de pulvérisation
Aide à l'identification des matériels

Digital Technologies : applying pesticides only on the target pests

Sense & Decide: Blue River's deep learning process identifies subtle differences between crops (green) and weeds (red)



Act: Only weeds are sprayed and not the crop

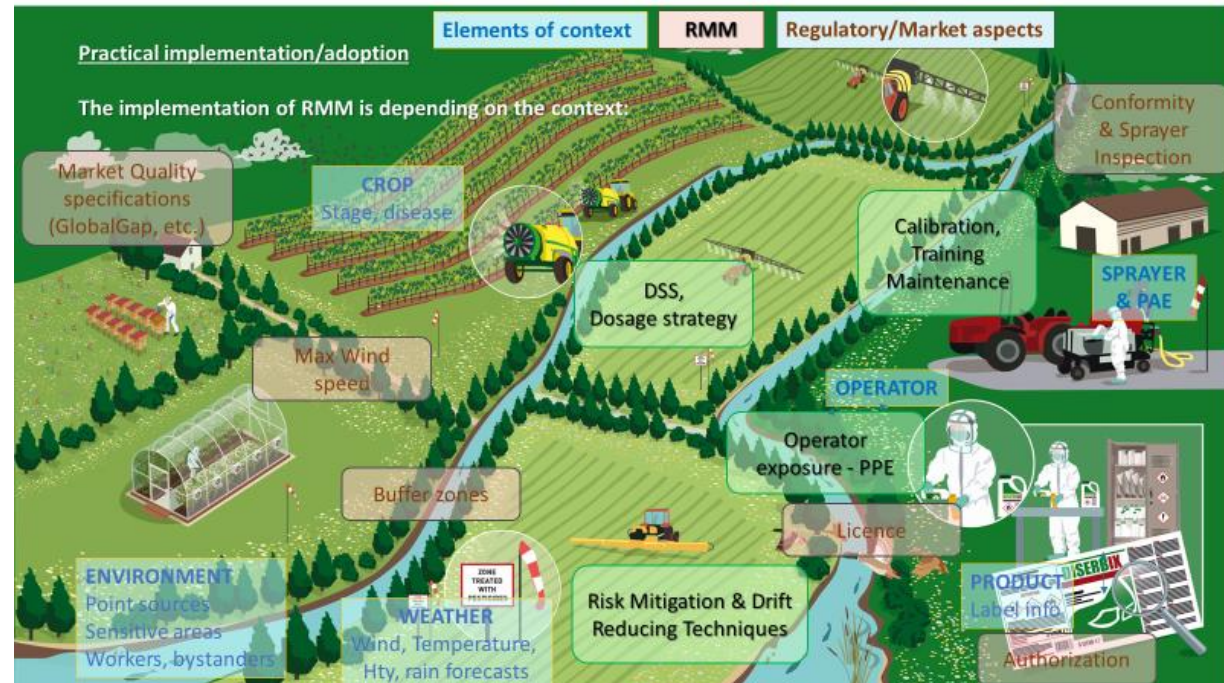
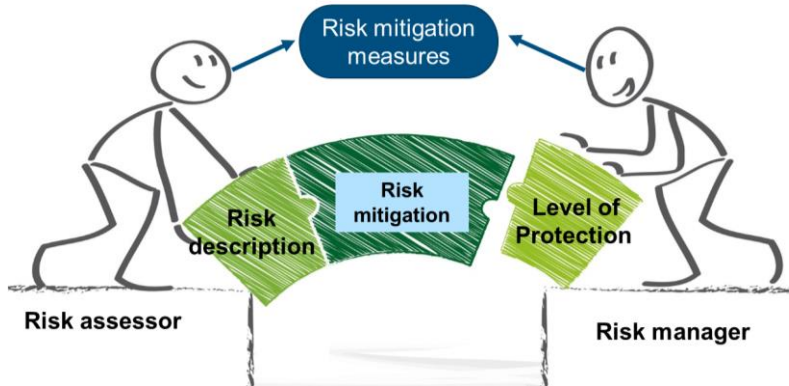


How to consider such innovative techniques in the regulatory risk assessment and decision making?

- Strengths
 - Reduced chemical usage
 - 50-90% reduction
 - Differentiation of target
 - Utilization of non selective herbicide in non gmo crop
 - No preliminary work required

“Horizontal work”: compendium conditions of use/Risk Mitigation Measures (RMM)

- Adapting conditions of use/risk mitigation measures :
 - Relevant for making pesticide use scenario (GAP) less risky



Some EU perspectives

- **Pesticides policy in EU is evolving:**
 - New political objectives: Green Deal, Farm2Fork, IPM, bio-control based solutions first
 - New elements in the risk assessment (ED, ...): less chemical hazardous active substances
 - New types of active substances: MO, semiochemicals, plant extracts, RNAi, Peptides,...
 - New types of application techniques: digital and precision techniques
- **Calling for more creativity in the risk assessment approach:**
 - Problem formulation
 - Need to know approach

How can we cooperate?

- **Audits' Recommendations**

- Compliance with EU standards as laid down in Regulation (EC) No 396/2005
- Ensure that RASFF notifications are followed up rapidly and effectively to ensure compliance with EU standards
- Ensure that samples of produce for export to the EU are analysed in laboratories with sufficient scope to achieve effective controls of MRLs

- **Helping TK regulators:**

- Better Training for Safer Food modules
- Other assistance needed?

Thank you for your attention!

For further information:

<https://ec.europa.eu/food/plant/pesticides>

Disclaimer

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