

# CropLife EUROPE

## Dealing with MRLs in the EU - State of Play, Trends and Opportunities

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# Today's talk



## Green Deal landscape

## The Farm to Fork policy space

- Ambitions in a nutshell
- Bringing vision into legislation
- The industry views and activities
- MRL deletion process

## Transparency regulation to amend General Food Law

## REFIT on EU legislation on plant protection products and pesticides residues



# CropLife Europe ...



- ...represents an industry offering **highly innovative, R&D-driven wide range of agricultural solutions** in Europe
  - 22 companies; 32 national associations; 26,000 people in the sector
- ...advocates **policies and legislation that foster innovation**
  - giving Europe's farmers the tools they need to help meet the world's growing food demand in a sustainable way
- ...promotes good agricultural practices through **the complementarity of its solutions**
  - ensuring safe and affordable food; safeguarding water; enhancing biodiversity; protecting the health of farmers and the public



# Green Deal landscape



# Key Strategies under the EU Green Deal Overview

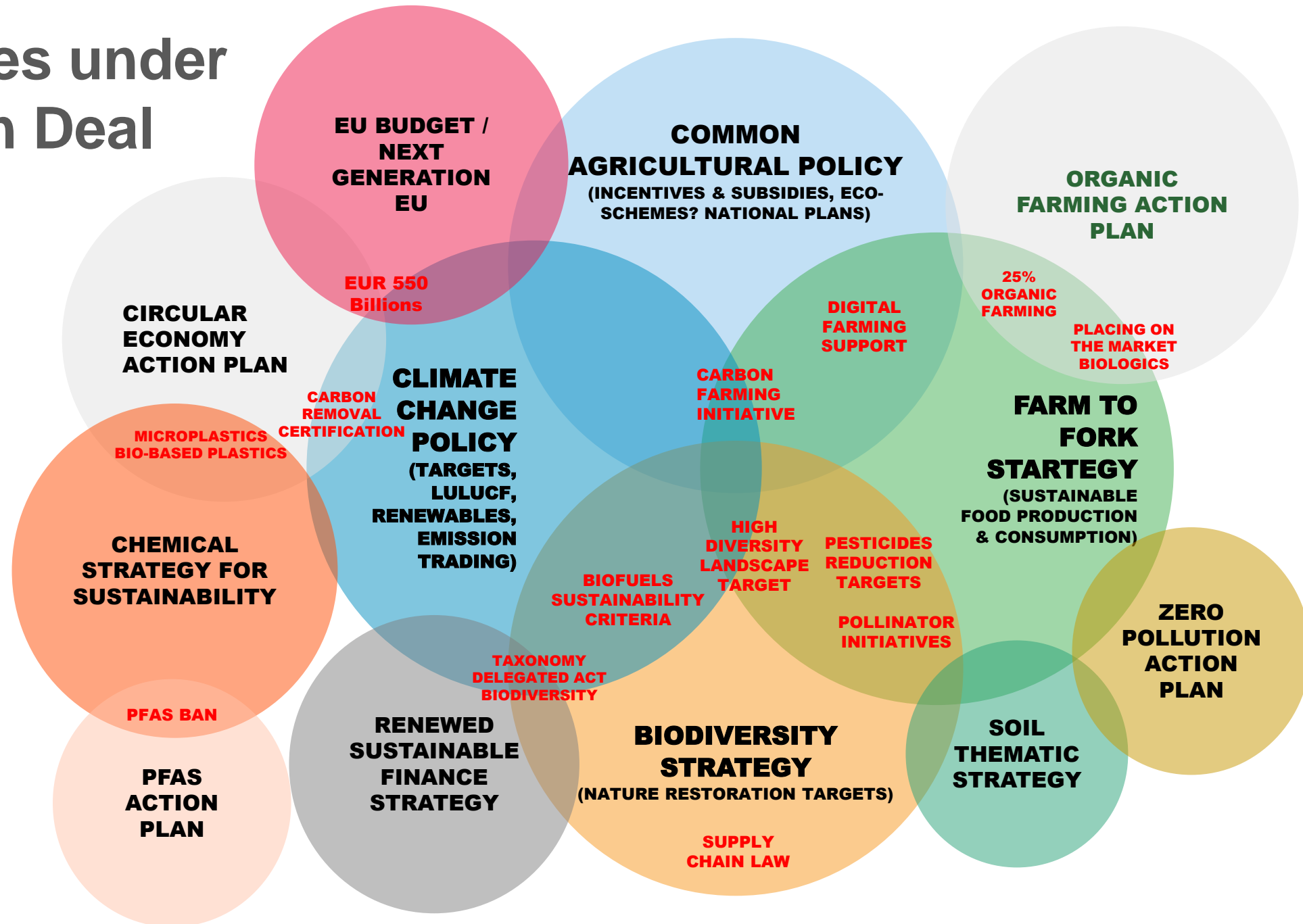
**12 Non-Binding Communications**

**7 Strategies Published**

**4 Key Targets: Pesticides, GHG, Agricultural Land, Organic Farming**

**To Date: +/- 20 Pieces of Legislation will be revised by Co-Decision & Comitology in the coming 12 months**

**More to Come with Chemical Strategy for Sustainability, Soil Strategy, Forest Strategy, Zero Pollution Action Plan**



# The Farm to Fork policy space



# The Farm to Fork policy space

## *Ambitions in a nutshell*



### Process

- 2020 Farm to Fork and Biodiversity Strategy published
- EU strategy means beginning of the process.
- Nothing has been decided yet, nothing is mandatory for the time being.**
- No EU legislative process will be launched right now** but Council (EU Member States) and the European Parliament are providing comments. This will influence the legislative proposals.
- 2022-2025** legislative proposals concerning pesticides expected;
- The EU Commission playing with different options.

### Key elements for the EU

- Chemical pesticide reduction in use and risk by 50%;
- 50% reduction of the use of hazardous pesticides;
- 25% of EU agricultural land to be under organic production models by 2030;
- 10% of farmland to be set aside for non-productive measures;
- The digitalisation of EU agriculture mentioned as a key facilitator to reach the announced targets.
- New innovative techniques and biotechnology playing a role in increasing sustainability of EU Agriculture

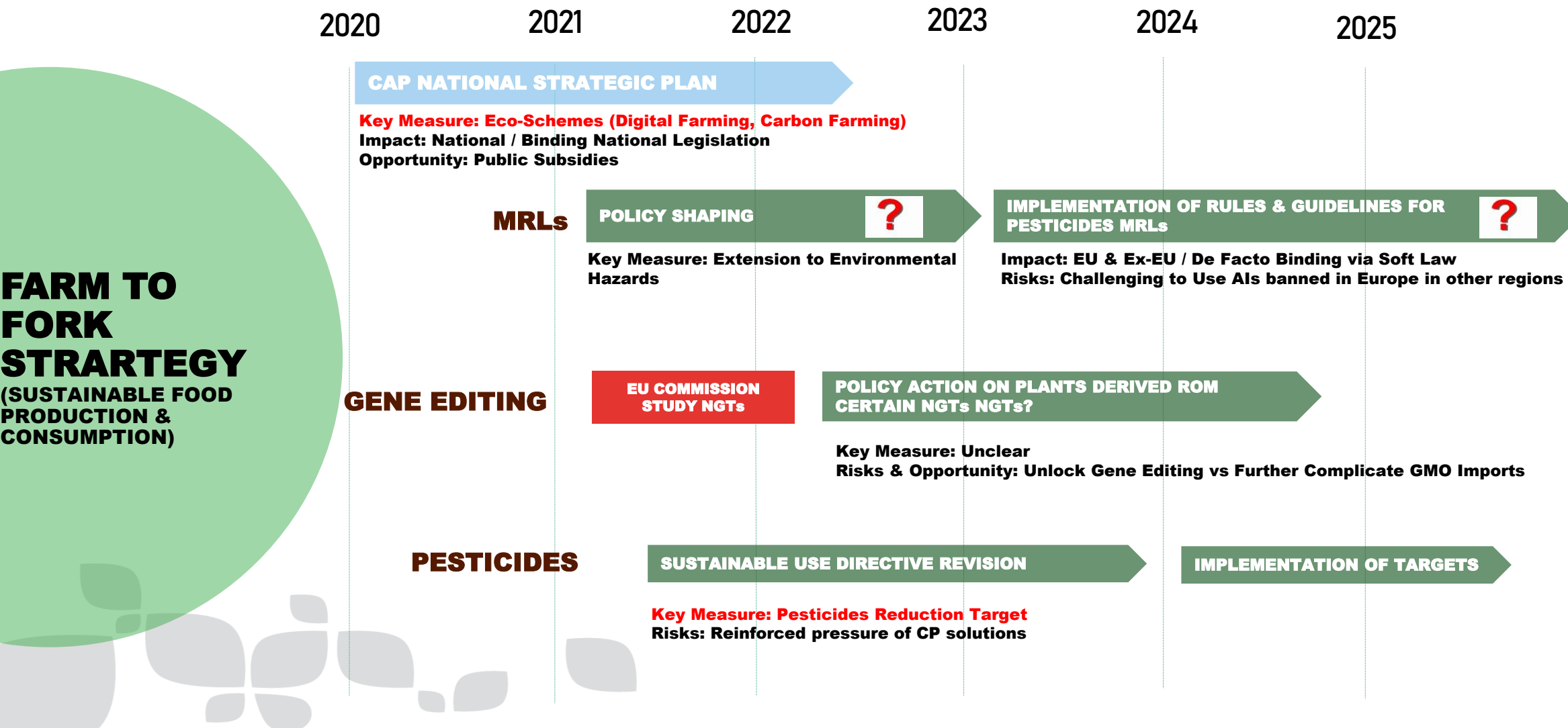
### Key elements for 3<sup>rd</sup> countries

- MRL/IT policy - adding complexity to the current already unpredictable and complex policy
- How new products developed using NGTs will be assessed/regulated
- Green diplomacy
- Sustainable food systems (expected in 2023)
  - What impact on the current the GMOs import authorisation process



# EU Farm to Fork Strategy

*Bringing visions into legislation*





# The political environment surrounding MRLs/IT



## *The EU regulatory and policy environment on MRLs/ ITs is challenging*

- ✓ **Misperception on the nature of MRLs:** still referred to as safety standards and not trade standards;
- ✓ **EU Commission – regulators:** lack of predictability on schedule, timing and transitional measures;
- ✓ **European Parliament** objecting to packages of MRLs/ ITs – proposed and endorsed by regulators on sound science - with legal consequences for the global supply chain; excessive use of precautionary principle;
- ✓ **Member States:** tend towards protectionism and lack of political ownership so far;
- ✓ **NGOs:** increased attention and public pleas on MRLs and residues – mixing with Plant Protection Products (PPPs) export ban issue.

## **Advocacy shift**

- ✓ Absence of European farmers from the debate and action (moving towards positioning against ITs – seeking 'fair conditions')
- ✓ Green diplomacy: European Union aspires to be a global sustainability leader introducing legislative projects impacting third countries globally;
- ✓ Downstream supply chain and Third countries

# MRLs Regulation implementation

## *Industry position – our asks*

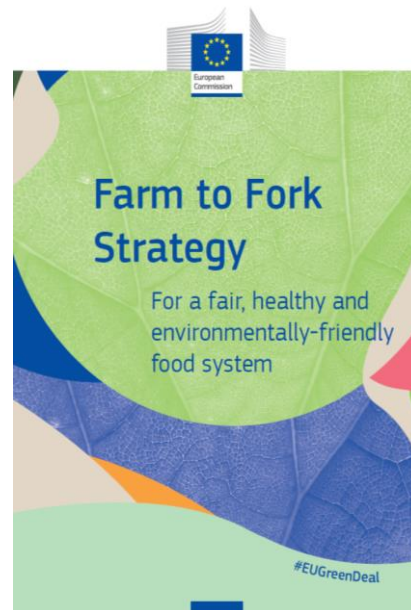
- **EU MRL setting should always be based on Risk Assessment:** EU should continue to ensure ITs evaluations are conducted through risk assessment predictability and defined clear timelines for IT evaluation (**PROCESS**) - *necessary to comply with international standards, including the WTO SPS agreement*
- **Any deletion of MRLs following non-renewal of Plant Protection Products approvals:**
  - should not apply to global trade facilitating MRLs that are safe, set on the basis of risk assessment and based on evaluated Codex MRLs or set as ITs authorized in Third countries;
  - EU should maintain all EU MRLs provided there is commitment to apply for an IT, including after EU uses MRLs are deleted, until a decision of an IT is made (**AVOID VACUUM/BRIDGE THE GAP**)
- **Where legitimate risk-based MRL reduction is foreseen:**
  - Unjustified and avoidable trade disrupting gaps in available and safe MRLs should be avoided by aligning with upcoming MRL or IT review processes
  - Adequate **transition periods** must be put in place to allow predictability and sufficient time for trading partners and the agri-food chain to adapt as well as maintaining marketing of food which was legally placed on the market;

# Farm to Fork and Biodiversity Strategies

## – Green Deal

*2020 Adding complexity to MRLs and IT Policy*

- Commission “will reflect on options of **including environmental aspects** in the risk assessment regarding ITs of substances no longer approved in the EU, while still respecting WTO legislation”
- The EU will seek to ensure that there is an ambitious sustainability chapter in all EU bilateral trade agreements
- EU Green Diplomacy to encourage the adoption of European standards outside the EU**



### Key facts

- Environmental factors mentioned in non-binding documents (Farm to Fork and Biodiversity Communication)
- Environmental factors considered within the **‘other legitimate factors’** of the 2018 EU policy on MRLs and IT and stemming from Regulation 396/2005 (Art.14)
- So far EU Commission does not intend to modify Regulation 396/2005 (MRLs) – subject to REFIT process
- COM intends to start including environmental factors in the risk assessment for MRLs/IT directly on specific active substances - no precedent yet (as of January 2021)



# Environmental Aspects not covered by current MRL regulation (Reg. 396/2005)



Importe... Commis...  
**import**...  
respecting... standards and obligations. To address the global threat of antimicrobial resistance, the Commission has adopted a Regulation (EU) 2019/1022 on the importation of food and feed of animal origin from third countries. The Regulation sets out the conditions for importation while ensuring that the products meet the same standards as those required for products produced in the EU.

**environmental aspects**

// Fate and behavior in the environment: Soil, Water, Air



// Ecotoxicological studies regarding non-target species (birds, vertebrates, aquatic Organisms, arthropods, soil meso- and macrofauna etc.)



**≠** **⚡**

„Public Health Reasons“ (consumer / dietary risk assessment)

*Not compatible with current MRL-regulation (EU 396/2005)*

- // MRL-setting focuses on comprehensive consumer risk assessment
- // Current data requirement do not include environmental data
- // Only “public health reasons” mentioned as exemption from IT-MRL

# Industry activities and milestones



- EU MRL Policy raised at political level (in addition to technical level)
- Inconsistent EU policy approaches raised at WTO re development and environment
- EU heavily challenged during WTO Trade Policy Review



- Alliances built with like-minded countries and food value chain stakeholders
- Virtual MRL & trade conference held with African Union and USDA on African-wide coordination on a science-based approach to pesticide MRLs
- CropLife International's EU Renewal Monitor released: providing transparency and predictability
- Supported US International Trade Commission investigation



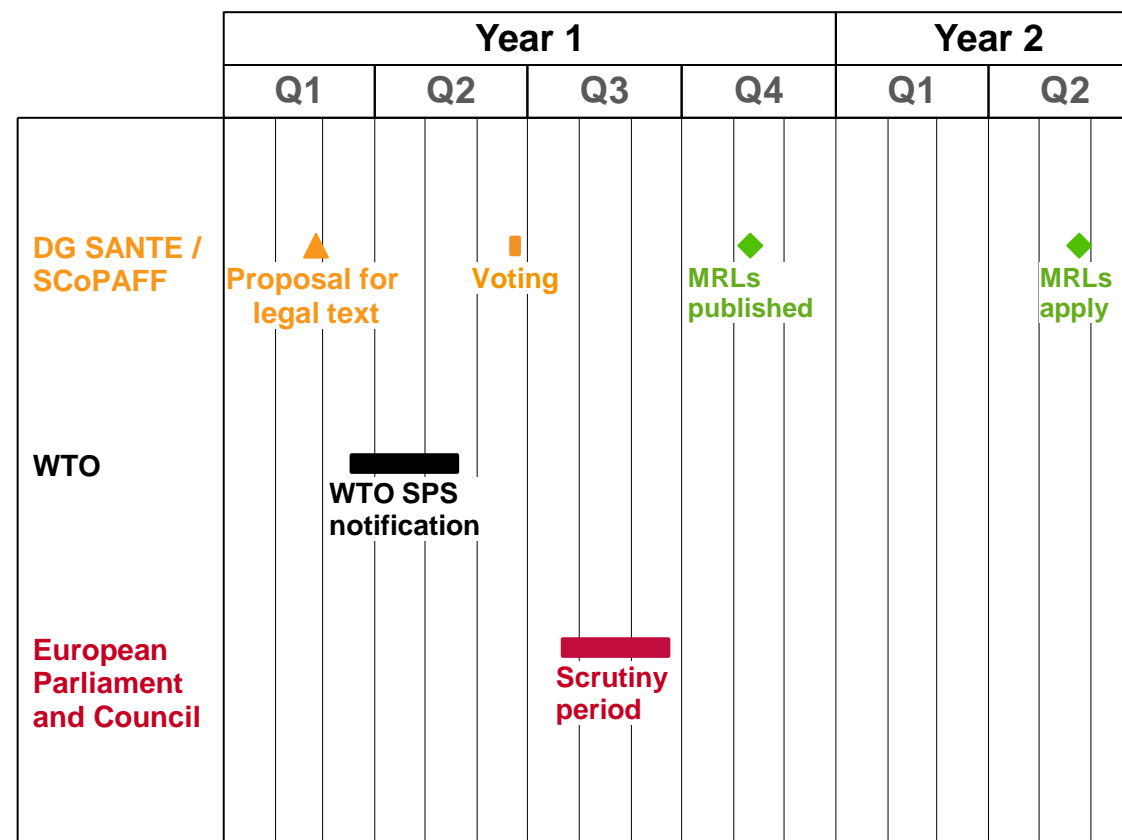
- Decisions based on EU cut-off policy continue to be delayed
- Political problem won't be solved with technical solutions:
  - Health, Trade, Secretariat General, and other Directorates Generals stimulated inter-directorate dialogue
  - Need for holistic approach acknowledged
- EP decreased support to objections on MRLs / ITs, letter from non-EU countries' growers to Members of European Parliament (MEPs)



- Non-science factors prevented in Codex decision making
- Codex Strategic Plan and Codex workplans shaped
- Focused advocacy to ensure the continuation of Codex' work during pandemic
- Coalition for an Enhanced Codex

# Timelines in case of MRL deletions

- MRLs based on EU uses for active substances which are no longer approved in the EU will be deleted and set to default level (in general 0.01 mg/kg).
- The MRL deletion process includes several steps, including WTO SPS notification.
- It takes usually 1 year from the WTO SPS notification until default MRLs apply





# Transparency Regulation to amend General Food Law

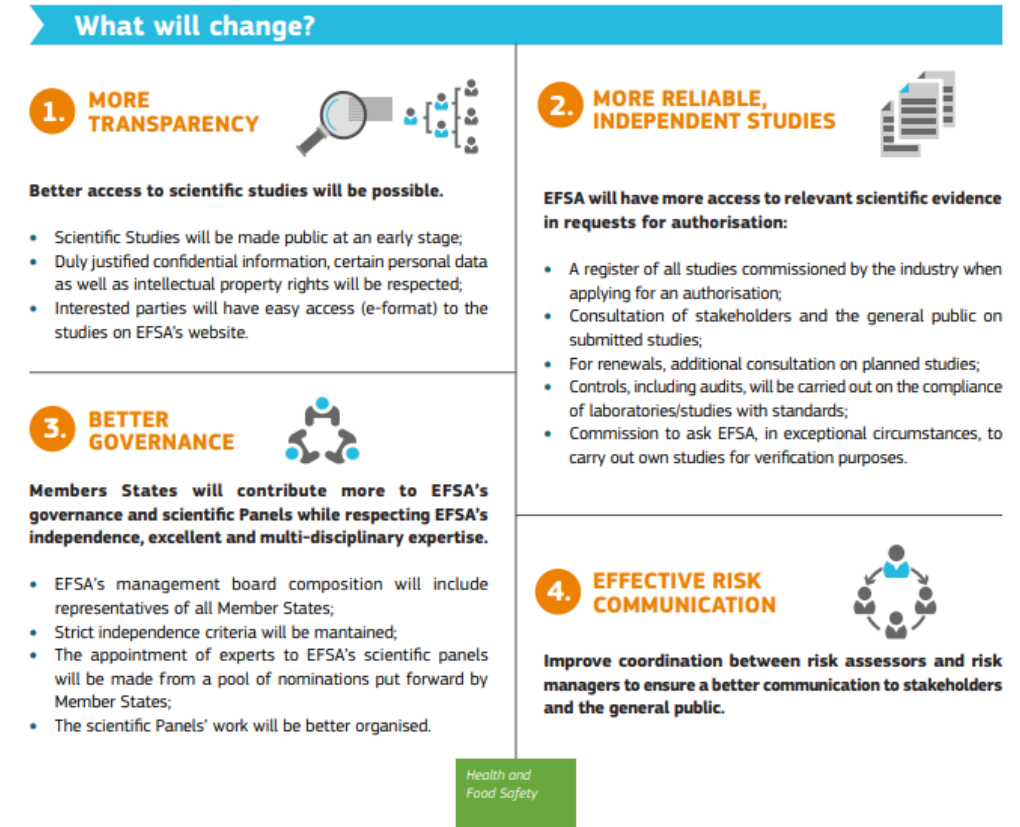




# Transparency Regulation to amend General Food Law



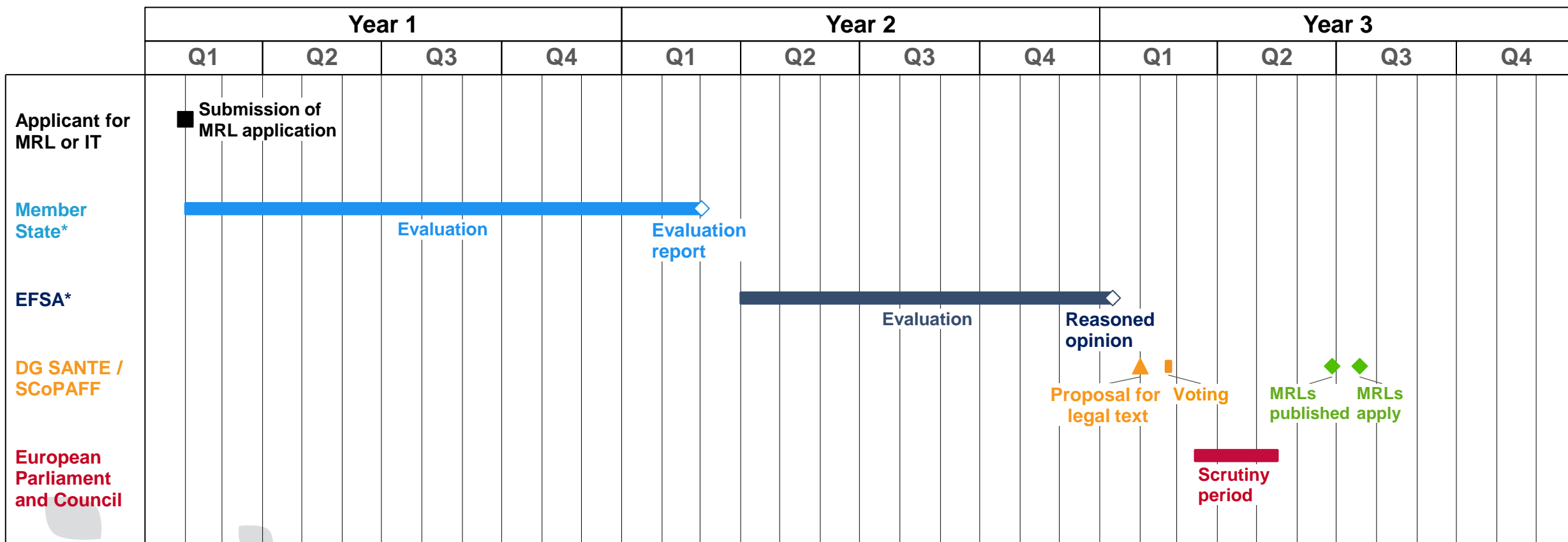
- Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain mainly amends Regulation (EC) No 178/2002 (aka the General Food Law) and became applicable on 27 March 2021.
- As the regulation introduces many changes to the process, submission format and communication, EFSA developed and published practical arrangements documents which are binding means to interpret and implement the legal framework provided by the Transparency Regulation.
- The Practical Arrangements can be found on [EFSA's dedicated webpage](https://efsa.europa.eu/en/food-safety/food-safety-communication/food-safety-communication-practical-arrangements).



Excerpts from DG SANTE's factsheet on transparency regulation:  
[https://ec.europa.eu/food/sites/food/files/gfl\\_transparency\\_comm\\_proposal\\_20180410\\_factsheet\\_en.pdf](https://ec.europa.eu/food/sites/food/files/gfl_transparency_comm_proposal_20180410_factsheet_en.pdf)



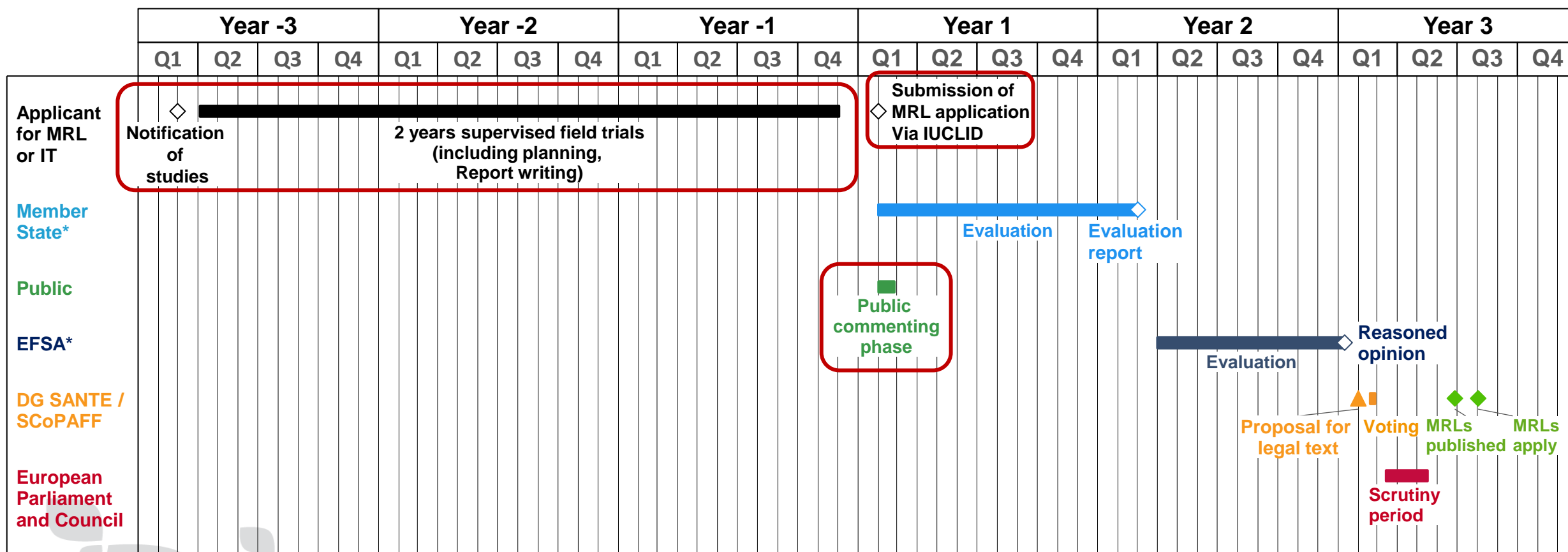
# EU MRL setting process until March 2021



\*average timelines as observed from EU MRL applications in the last years.

# EU MRL setting process as of April 2021

## - including notification of studies



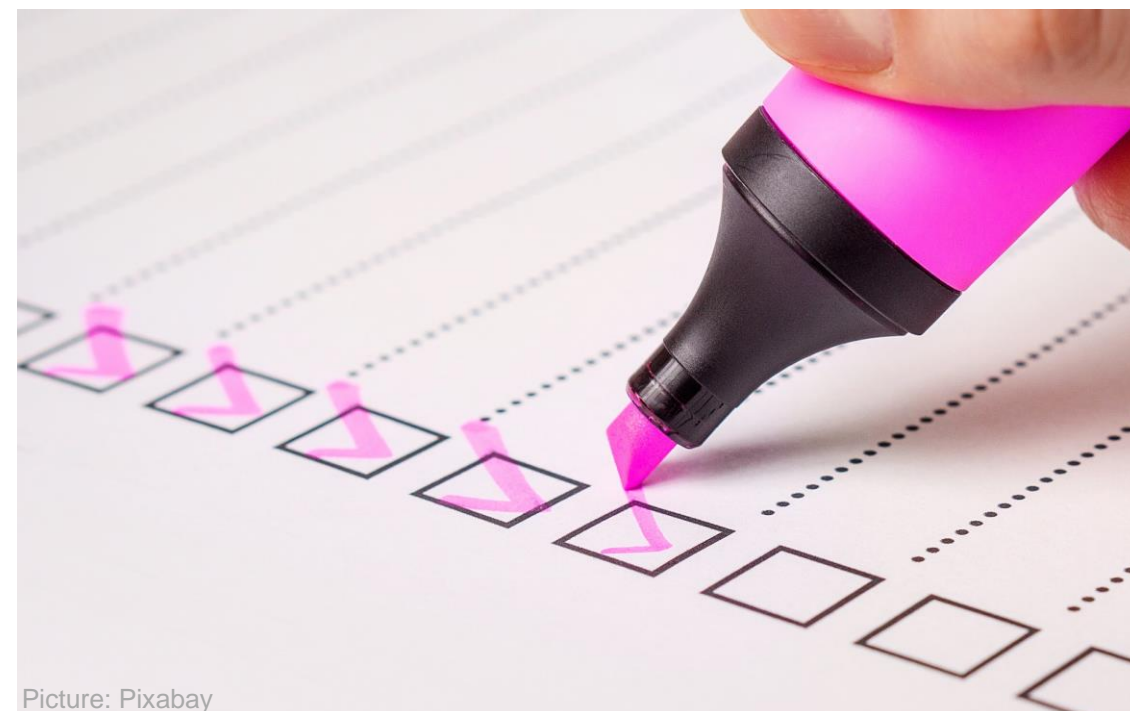
\*average timelines as observed from EU MRL applications in the last years.

**Notification of studies and submission via IUCLID applies to Import Tolerances as well!**

# Other important changes for MRLs / ITs from the transparency regulation

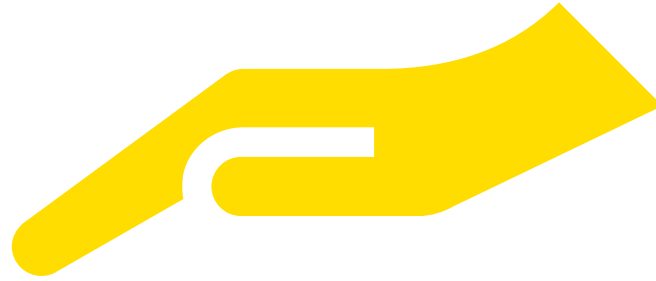


- Submissions of MRLs / Import tolerance applications need to be done to OpenEFSA Portal via IUCLID software.
- Data on metabolism in the areas of residues and mammalian toxicology (if needed) generated with the MetaPath composer software should be submitted as part of the IUCLID dossier
- A detailed MRL application manual is available at the following link  
[MRL Application manual | Zenodo](#)



Picture: Pixabay





# REFIT on EU legislation on plant protection products and pesticides residues



# REFIT – What is it?



Picture: Pixelcreatures @ Pixabay


- Evaluations and Fitness Checks are tools that are used to implement the Regulatory Fitness and Performance programme (REFIT).
- REFIT is a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose'; that regulatory burdens are minimised and that all simplification options are identified and applied.
- Starting in November 2016, the Commission has conducted a REFIT Evaluation of the EU legislation on plant protection products and pesticides residues in order to assess if the regulations meet the needs of citizens, businesses and public institutions in an efficient manner.

# REFIT - Outcome



## The evaluation found that

- stakeholders from across the spectrum consider that the regulatory requirements for pesticides in the EU are among the strictest in the world.
- Both regulations provide for the protection of human health and the environment and are generally effective, although implementation can be further improved.

 **Efficiency stands out as the critical area requiring attention. Due to a lack of resources and capacity in Member States, most of the procedures set out in the Regulations suffer from severe delays**



Brussels, 20.5.2020  
COM(2020) 208 final

### **REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL**

**Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products  
on the market and of Regulation (EC) No 396/2005 on maximum residue levels of  
pesticides**

{SWD(2020) 87 final}

# REFIT – Way forward



■ The immediate focus for follow-up of this evaluation will be on improving the implementation of the existing legislative framework. Sixteen areas have been identified where implementation in the short and medium term could be improved

■ Among the 16 identified areas are;

- Improved implementation of the cut-off criteria
- Cumulative risk assessment
- Promote sustainable plant protection, low-risk solutions and efficient risk mitigation
- Using green diplomacy to promote our green agenda for pesticides



Picture: geralt @ Pixabay



## Three Key Takeaways

1. MRLs are not a stand-alone policy – they are part of a bigger ambition.
2. This means the industry is working in a very complex policy space. At the moment a lack of visibility on the intentions/policy approaches further complicates MRL work.
3. The industry is doing its utmost through engagement, at all levels, and there is more we want to (and can) do together.

**Thank you very much for your attention**





# Glossary



- **CAP: Common Agricultural Practice**
- **COM: European Commission**
- **CP: Crop Protection**
- **DG SANTE: Directorate-General for Health and Food Safety of the European Commission**
- **EFSA: European Food Safety Authority**
- **EU: European Union**
- **GMO: Genetically Modified Organism**
- **IT: Import Tolerance**
- **IUCLID: International Uniform Chemical Information Database**
- **Member State: Member State of the European Union**
- **MRL: Maximum Residue Limit**
- **NGTs: New Genomic Techniques**
- **PPP: Plant Protection Products**
- **REFIT: Regulatory Fitness and Performance programme**
- **SCoPAFF: Standing Committee on Plants, Animals, Food and Feed**
- **USDA: U.S. Department of Agriculture**
- **WTO SPS: World Trade Organisation – Sanitary and Phytosanitary measures**