### EU Regulatory Issues and Lessons Learnt from a Registrant's perspective

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### Overview

- 1. Core beliefs of EU policy making and key drivers of the EU pesticides policy
- 2. Trends in EU pesticides authorization
- Exporting EU Standards Mirror Clauses & MRLs
- Towards Sustainable Food Chains The upcoming sustainable food systems regulation
- 5. Business as usual or fundamental re-think possible implications of Russia's invasion in Ukraine on agricultural and pesticides policy



EU Pesticides
 Policy – Core
 Beliefs and Key
 Drivers





# Core Beliefs of European Food Policy Making

- Climate change and biodiversity losses are the core challenges for mankind that need to be addressed immediately and radically
- The EU has achieved food security and high standards of food safety already
- "Feeding a fast-growing world population remains a challenge with current production patterns. Food production results in air, water and soil pollution, contributes to the loss of biodiversity and climate change, and consumes excessive amounts of natural resources, while an important part of food is wasted"
- "Current food consumption patterns are unsustainable from both health and environmental points of view. While in the EU, average intakes of energy, red meat, sugars, salt and fats continue to exceed recommendations, consumption of whole-grain cereals, fruit and vegetables, legumes and nuts is insufficient."





### Key Drives of EU Pesticides Policies

- **Pesticides Authorization:** the precautionary principle and hazardbased approaches drive developments in pesticides authorization and thus pesticides availability for EU growers
- Pesticides Use Key Objectives:
  - Minimizing the use of chemical pesticides
  - Promoting and incentivizing the development and use of alternatives to chemical pesticides
- The EU's global ambition on pesticides: EU considers its pesticides policies as gold standard and aims at exporting it to other parts of the world



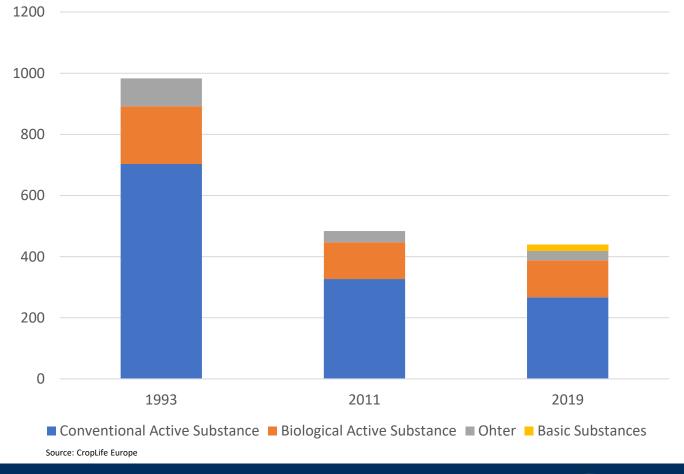
2. Trends in EUPesticidesAuthorization





# Availability of Active Substances in the EU

Number of active substance available to EU growers







# Availability of Active Substances in the EU

- Clear net loss in the number of chemical active substances approved.
- Net result in biocontrol active substances barely positive; increase in basic substances (e.g. vinegar)
- Particularly sharp decline in availability of insecticides new chemical and non-chemical substances not compensate loss of old ones
- Dozens of active substances will expire soon as not supported for renewal; thus the number of approved active substances will be further reduced.
- We are getting close to a tipping point where there will be no
  effective treatments or controls for some pests and diseases in
  Europe. Real problems exist already with lack of means to control
  invasive alien species (e.g. Xylella Fastidiosa vector control)
- Substantial increase of emergency authorizations as a result of limited availability of fully authorized active substances (EU Harmonized Risk Indicator 2 shows an increase of 55% compared to the baseline period 2011-2013)





### Possible new challenges & opportunities under the Green Deal

- Further *legislation on hazardous chemicals* expected impact on authorization of pesticides to be anticipated
  - Export ban for pesticides banned in the EU
  - Chemicals Regulation REACH: Further restrictions/hurdles expected (PFAS, Reach Group Restrictions of CMRs, Neurotoxicants, Mixture Assessment Factor)
  - New Hazard Categories in CLP (ED, Mobility)
- Giving a boost to innovation in agriculture may constitute opportunities
  - New legislation on gene editing
  - New guidelines to facilitate the authorization of biologics
  - Promotion of digital tools in agriculture and plant protection



3. Exporting EU Standards – Mirror Clauses and MRLs





### Mirror Clauses – Setting the Scene

- Mirror Clauses **Definition** 
  - Guarantee that imported products are produced under the exact same sanitary, phytosanitary, welfare and environmental standards as those imposed on domestic products within the European Union.
  - This *includes processes* and *production methods* that are not necessarily linked to the product properties (e.g. deforestation free products)
- Mirror Clauses *Rationale for implementation* 
  - Instrument to achieve a transition towards sustainable global food systems in accordance with EU thinking
  - Unilaterally implemented EU standards can deteriorate the competitiveness of EU agriculture. Mirror clauses would thus help to provide a level playing field.



### Mirror Clauses – State of Play

- State of Play
  - EU Commission report on rational and legal feasibility of mirror clauses requested by Member States and European Parliament in June 2021
  - Leaked version available since earlier this month. Official publication to be expected for June 2022
- Leaked Report's major conclusions:
  - Try to achieve higher standards at multilateral level. (e.g. Codex)
  - Continue to include ambitious environmental targets and sustainability chapters into trade agreements and get them considered in bilateral cooperation
  - Take measures autonomously on the basis of case by case evaluations





# Mirror clauses in practice – Environmental factors in MRL setting

- <u>Starting Point:</u> 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" (Farm to Fork Strategy)
- <u>Regulatory approach</u>: Including environmental factors in the risk assessment for MRLs/IT for specific active substances. No change of EU MRL regulation planned.
- <u>Test case:</u> MRLs for clothianidin and thiamethoxam
  - Legal proposal setting MRLs/ITs for clothianidin and thiamedoxam apparently under preparation.
  - WTO notification required
  - Proposal needs support from a qualified majority of Member States
  - Large time span between publicly announcing the plan for lowering the MRLs and presentation of the proposal hints at intensive discussion at EU Commission level
- <u>Justification</u>: Addressing a global environmental concern (protection of pollinators)





### Mirror clauses – Gowan's perspective

- We support the ambition of the EU Green Deal to tackle environmental challenges, but think multilateral fora, not non-tariff barriers to trade are the correct way to achieve this.
- Maximum Residue Levels are a trading standard and not an appropriate tool to be used to tackle environmental challenges outside the EU:
  - Grower's needs to protect their crops are different around the world. Pesticides not used in the EU might be necessary in other geographies
  - Non-EU countries have sophisticated risked-based authorization systems for pesticides that might come to different conclusions on acceptable environmental risks than the more hazard-based assessments of the EU
- It is difficult to understand how the EU can aim at a de facto ban of certain active substances (e.g. clothianidin and thiamethoxam) in third countries, while simultaneously allowing emergency authorizations for these active substances within the EU.



4. Sustainable Food Chains — Towards a new EU Sustainable Food Systems (SFS) Regulation





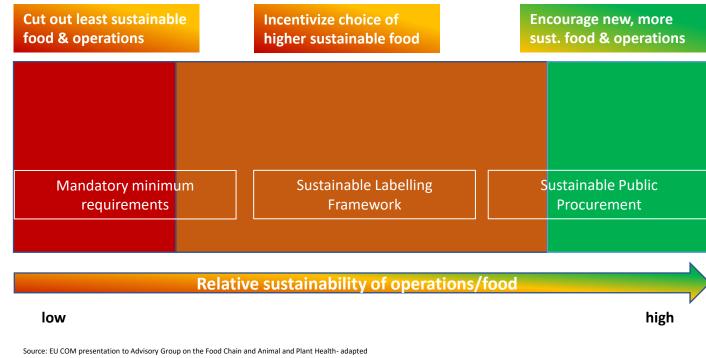
### SFS - Goals and State of Play

- Objective: SFS aims to make the EU food system sustainable and to integrate sustainability into all food-related policies by establishing general principles and objectives, together with the requirements and responsibilities for all actors in the EU food system
- State of Play
  - Public Consultation ongoing (28<sup>th</sup> April to 21<sup>st</sup> July 2022)
  - Legislative proposal expected in Q4 2023
- Why it is relevant for growers in non-EU countries?
  - Food produced outside the EU and imported to the EU might be in scope
  - Certain processes and production methods might be considered as not sustainable





### SFS – What's on the Menu (I)







### SFS – What's on the Menu (II)

- Commission Impact Assessment will look into different intensities of measures (status quo, voluntary measures, regulatory options) and geographical scopes (EU, beyond EU)
- Examples of possible far-reaching policy/legislative options:
  - Elimination of the least sustainable food system operations/products by setting minimum sustainability requirements for operations and products produced and placed on the market in the EU (imports included)
  - Development of a mandatory harmonized EU sustainability label for all EU and imported food product





### SFS – Gowan Perspective

- Gowan supports the plans on sustainable food systems provided they remain science-based and take equally into account all three dimensions of sustainability (people, planet and profits)
- Gowan supports a comprehensive impact assessment, that should take into account the impact in the EU and at global level
- Truly sustainable food systems need a highly productive and resource efficient and environmentally friendly agriculture
- Sustainable food systems are open to new technologies and innovation, including innovative chemical pesticides, that help achieving greater sustainability.
- Food Chain players both from the EU and from third countries need to engage to ensure and to shape what we think are sustainable food systems



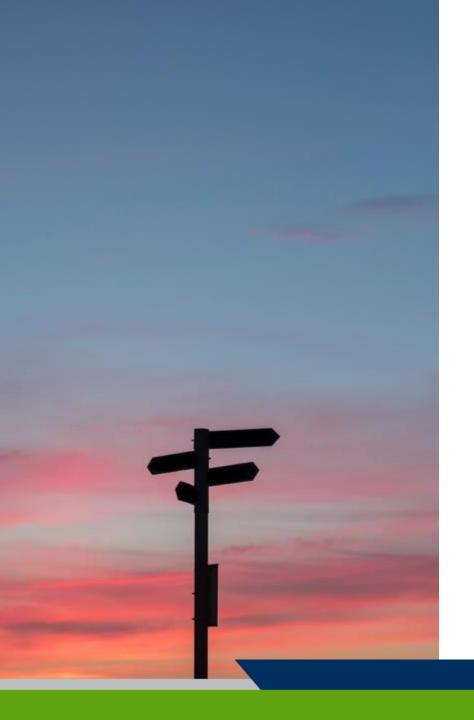
5. New Realities – New Thinking?





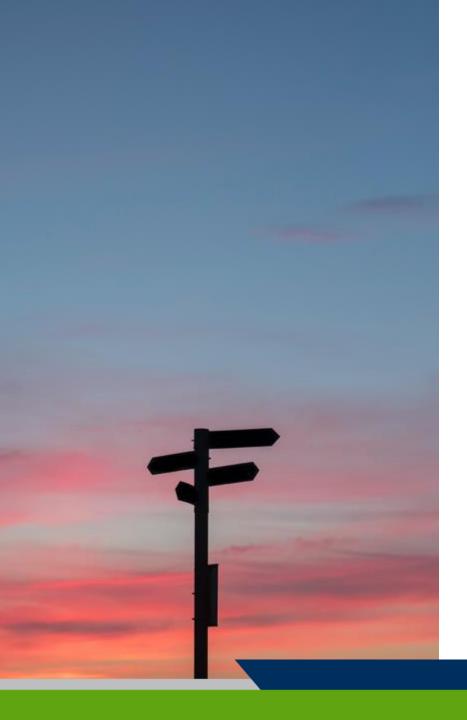
#### The New realities

- Russia's unjustified war against Ukraine re-emphasizes the vulnerability of global food systems:
  - Inflation has risen substantially in the EU. Inflation in the EURO area is currently at a record high of 7,5%, with significantly higher inflation in some countries (e.g. Estonia 19%, the Netherlands 11%). Increasing energy and food prices are the main drivers.
  - Food security at EU level is probably actually not at risk but food affordability is likely to become an issue and current supply cannot satisfy the current demand for single products (e.g. sunflower oil)
  - High dependency on grain imports from Ukraine and Russia of some non-EU countries e.g. in the Middle East or Africa may lead to supply deficits and higher food prices. This brings back memories of the Arab Spring, which was triggered by rising bread prices and ultimately led to violence, war and refugee flows into the EU in many southern and eastern Mediterranean countries.



## ... and their perception in EU Policy Making

- Increasing fears that rising inflation and possible new migration flows will lead to political instability
- Analysis that global food systems are highly vulnerable and that the expected effects of Russia's invasion of Ukraine are significant for the EU and other parts of the world widely shared amongst policy makers. Conclusions drawn however very different:
  - Some policy makers want to stick to an unchanged Green Deal agenda. They think food security in the EU is not at risk. Changes in food consumption and reduced food waste are key to ensure food security.
  - Others continue to support the Green Deal objectives but believe that effective short-term measures need to be taken that allow the full production potential of EU agriculture to be realized.



#### Conclusions

- 1. Global food security is at risk and the full production potential of EU agriculture is needed. Extensification of EU agriculture is therefore not a solution. The EU needs sustainable increases in agricultural productivity.
- 2. Restricting the use of certain technologies in agriculture (e.g. the use of pesticides or fertilizers) requires the *availability of equally efficient* and effective technological alternatives. Otherwise, productivity losses in EU agriculture may increase the vulnerability of global food systems. Current EU policy developments make this risk seem real.
- 3. Technological innovations in crop protection, fertilization and plant breeding are key drivers for achieving sustainable food systems. The EU should *focus* more *on enabling* such *innovations*. This also includes the creation of a technology-open and innovation-friendly social environment.
- **3.** Science should guide EU policy action. This is especially true for risk assessments for pesticides authorization,
- 5. The EU activities on Sustainable Food Systems and Mirror Clauses have the potential to disrupt international trade. In the current situation, however, additional trade conflicts are the last thing we need.





### Thank you for your attention!

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