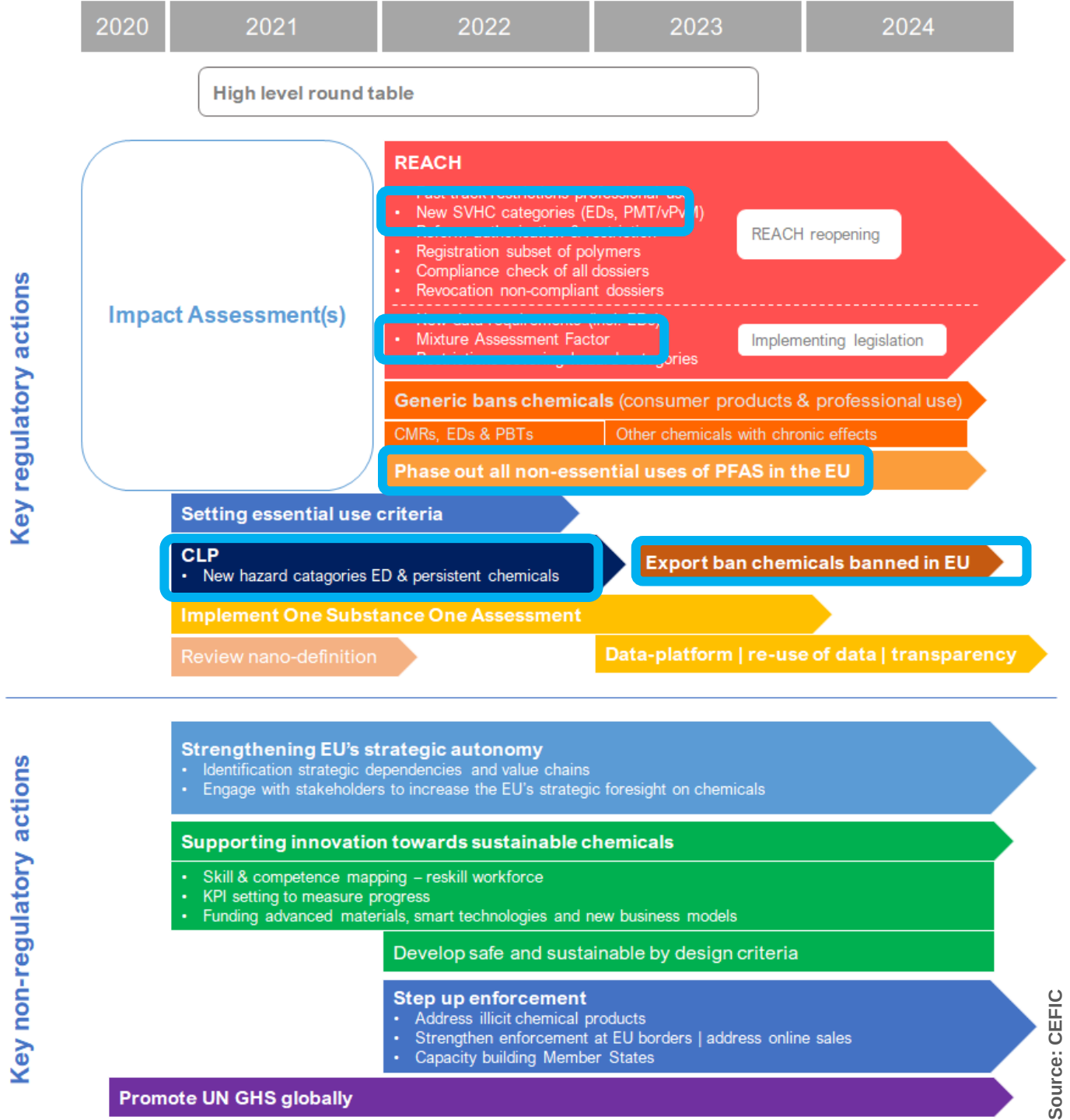
# Chemical Strategy for Sustainability

## Impacts on Plant Protection Products

# Massive Workplan

- Several initiatives are already delayed
- The workload for COM is massive and not everything will be done before the next COM/EP in 2025



# Key initiatives under CSS affecting Plant Protection Products

- Proposal to revise the CLP regulation and **introduce new hazard classes**
- Introduction of a **Mixture Assessment Factors**
- Development of an **Essential Use** concept
- Proposals linked to **Group Restrictions**
- Proposal to set up an **Export Ban** for substances not approved in the EU
- Proposal to expand **Generic Risk Approach** under REACH ?

# New Hazard Classes into a revised CLP regulation

- **COM wants to include new hazard classes into the Classification and Labelling Regulation:** not based on adverse effects but on modes of action or properties
  - Endocrine Disruption
  - New way of calculating Persistence (PBT/vPvB), new Mobility criteria (PMT/vPvM)
- **Co-formulants affected (via REACH) and Active ingredients affected by new Persistence calculations and the new Mobility criteria if translated in the PPP framework**
- **Industry position:**
  - A minimum of 62.9% of AIs are expected to be classified as vPvM or PMT (CLE survey on 200+ AIs)
    - Majority of PPP classified as mobile although demonstrated in experimental studies and model simulations that they will not reach drinking water sources.
  - Higher tier assessment options are essential (including a Weight of Evidence) to go beyond the simplistic approach taken for REACH and should be included in the upcoming CLP annex revision, or if not when the Mobility concept will be looked at under the PPP regime.
- **Timing: legislative proposal in October 2022**

# Mixture Assessment Factors

- **Concept will be introduced in the REACH regulation revision:**
  - *“to ensure the risks from simultaneous exposure to multiple chemicals are effectively and systematically taken into account.”*
- **Possible impact: Co formulants mainly but could be used in the future to look at Active Ingredients**
  - This would be a very blunt instrument – precedent setting – compared to what EFSA is already doing on multiple exposure
  - Adding an extra arbitrary safety factor would affect many risk assessments negatively.
- **Industry position:**
  - MAF should not be used for any chemicals as it is too simplistic and does not reflect any reality when it comes to uses.
  - Consideration of higher tier data is also essential to provide refinements to such simple tool.
- **Timing: legislative proposal end 2022**

# Essential Use concept

- **Concept will be introduced in the REACH regulation revision:**
  - Ensuring that the most harmful chemicals are only allowed *if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from an environmental and health standpoint.*
- **A consultant is helping the Commission in framing by organizing consultations/workshops/interviews with stakeholders.**
  - PPPs identified as “necessary for health and safety” in their documentation.
  - Last stakeholder workshop led to a flurry of comments/questions (500+ participants) – drowning the organizers and providing no clarity on the criteria, the possible process or entities involved in the end.
- **Industry position:** Reg 1107/2009 already embeds the concept of essential use: layers of hazard/risk assessments, risk managements elements and post authorisation safeguards.
- **Timing: legislative proposal end 2022 (delayed ?)**

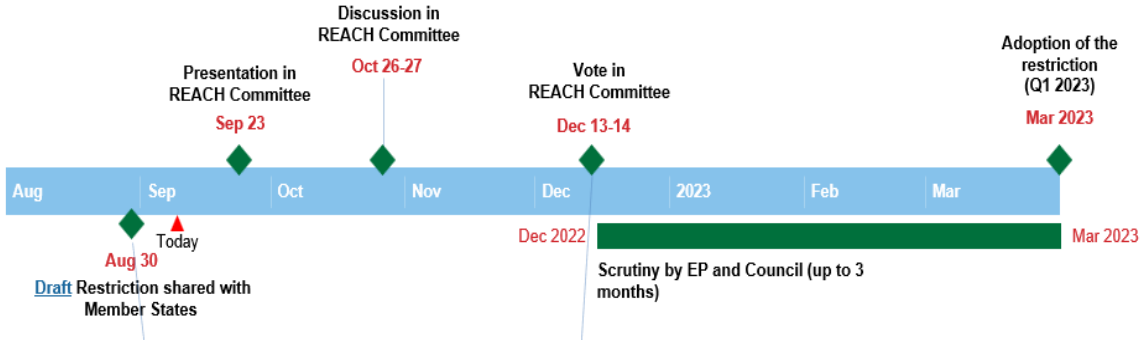
# New group restrictions
## PFAS case

- **Restriction proposal to the manufacture, marketing and use of all per- and polyfluoroalkyl compounds (PFAS) over concerns on high persistence**
  - Proposal being prepared by 5 MS (NL/DK/SW/NO/DE)
- **Possible impact: current definition used could put several AIs in scope = direct ban?**
- **Industry position:**
  - Persistency is not a concern for currently authorised Ais or their metabolites. The assessment framework prevent “forever chemicals” to enter the market
  - Several legislations with thorough ERA should be out of scope of this restriction proposal (e.g., PPP, Animal Health products, Pharmaceuticals)
- **Timing: submission of the proposal to ECHA in January 2023**

# Export ban

- **CSS text says:**
  - *"Lead by example, and, in line with international commitments, ensure that hazardous chemicals banned in the European Union are not produced for export, including by amending relevant legislation if and as needed"*
  - The approach is supported by the Council (all Member States) and the European Parliament
- **Possible impact: non-authorised / renewed Active Ingredients cannot be produced/exported from the EU**
- **Industry position:**
  - AIs produced in Europe can respond to very different needs in other regions (crops, pests, diseases) which would not have even been looked at by the EU (different uses submitted).
  - EU need to respect its International trade commitments
- **Timing: legislative proposal in 2023**

# Intentionally added microplastics COM proposal




- **Biodegradability -** CLE should advocate biodegradability to be focused on the most relevant compartment only (e.g., soil for plant protection products).
- **Transition Period -** CLE should advocate for 11 years for plant protection products, seed treatment and coatings, which is a more realistic timeline to carry out reformulation and obtain a re-authorization. 8 years for plant protection products and 5 years for seed coatings is extremely optimistic.
- **Progress review -** CLE should advocate to ensure a medium-term progress review is included in the proposal to see how the search for effective replacements is evolving. The measures proposed for agricultural products would be appropriate only if degradable alternatives with at least similar functionality would become available in the medium term.
- **Enforceable size limit –** CLE supports a lower size limit for enforcement of at least 0.1µm, in line with ECHA's proposal. In conjunction with this, the limit must be able to be measured reliably to ensure compliance and enforcement.

# Cumulated Impacts ?

- COM is not doing any cumulative impact assessment.
- Only the Chemical Industry association (CEFIC) has been doing such exercise on a high level (multi sectors)
- CropLife Europe is working on assessments for key initiatives.
- Foreseen impact is high on availability of solutions for farmers

→ Issue is so far under the radar of many authorities – at national level but also EU level !

# What does it mean on top of the Farm to Fork impact ?