

## A QUICK-FIX MECHANISM TO BOOST A RESILIENT TRANSFORMATION



### A/ Starting point: The industrial competitiveness and transformation at risk

The political cycle 2019-24 has set Europe on the transformation path to 2050. The **Green Deal** could become the core brand of the EU and put Europe's economy at the forefront of technological progress. Another overarching political goal is the strengthening of the **resilience of the domestic industry**. The chemical and pharmaceutical sector is highly supportive to both goals and expects many new business opportunities to emerge.

However, we see an **increasing mismatch between these intentions and economic realities. Europe's industrial competitiveness faces a fast and drastic deterioration.** To take the example of the German chemical industry: In the years 2022 and 2023, total production structurally decreased by more than 20 (!) percent, mainly affecting basic chemicals which are essential for building derivatives and value chains. In the same period, the domestic sector's investments in Germany shrunk to 9 billion euros while investments abroad rose by 25 percent to around 12 billion euros. There is a double threat of failure: **Europe will miss the sustainability goals and lose its innovative domestic industry.**

**One primary reason for this situation** (next to high energy costs and geopolitical tensions) **is the current regulatory environment.**<sup>1</sup> According to a recent survey, more than **86 percent of VCI companies feel massively held back by regulatory requirements**, and costs from bureaucracy meanwhile amount to circa 5 percent of the total turnover, i.e. corresponding to **12.5 billion euros per year solely for the German chemical and pharmaceutical sector.** The complexity of legal texts, inconsistencies, a tendency to micro-manage, and the lack of incorporating business considerations are a real burden for the EU's green transformation and resilience targets.

### B/ Omnibus for the chemical industry: The way to a sectoral quick-fix mechanism

A turnaround is needed to prevent the (further) exodus of transition projects and to narrow – and possibly, in the mid-term, to invert – the growing gap between the EU and other leading regions in

<sup>1</sup> See notably [1st half 2024: Sunshine and Rain | VCI](#) and [Studie zum Standort Deutschland](#)  
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the world. To set smart incentives for innovation and investment, a **screening exercise of EU legal texts is to be performed with the objective to spot and correct provisions and clauses hindering the industrial transformation.**

**We therefore support the suggestion of an omnibus procedure to be presented in the very first weeks of the new term:**

- (I) The **European Commission should examine existing legislation** – or legislation soon to become effective – for contradictions and shortcomings as regards the promotion of the objectives mentioned above. **The chemical industry and companies should be consulted and contribute to this exercise.**
- (II) **An early reach-out to the Council and the European Parliament** shall ensure broad support within the institutions and build a joint understanding for later negotiations. The institutions should agree – in pre-negotiations – about the character, the rules and general content before the launch of such targeted proposals.
- (III) This initial screening and assessment should **result in an Omnibus or a “Package of Measures”** – a series of separate legislative or policy proposals forming a sectoral package for the chemical industry.

For procedural reasons and to avoid legal confusion as the proposal will deal with different policy fields and consequently different legal competences, it is preferable to opt for such a **package of measures or several smaller – vertical – omnibuses.** This approach could lead to a cluster approach based on policies on e.g. chemicals, circularity, energy, hydrogen, finance & reporting, pharma & health, etc. Such a clustered procedure would also lower the risk of possible delay, denaturalisation or failure – in comparison to one large omnibus where the failure of one measure would endanger the entire exercise. **A prioritisation should be established according to the feasibility of the required policy action** (see next chapter).

This package is to be presented to the Council and the European Parliament with high priority in this new term.

The **idea of revising existing legislation is gaining ground among high-level policymakers.** In recent months, political support has been expressed either explicitly referencing to an omnibus – like in Enrico Letta’s report “Much more than a market” (p. 130), at the joint press conference of economic ministers of Germany, France and Italy (8 April 2024) and in post-election strategy papers of political groups in the European Parliament (EPP and Renew) – or indirectly notably in the May Council conclusions on the future of industrial policy. The Political Guidelines of Ursula Von der Leyen (July 2024, p. 7) spell out the objective: “We will make proposals to simplify, consolidate and codify legislation to eliminate any overlaps and contradictions while maintaining high standards.” **The Commission President has confirmed her intention at the Budapest summit and in the Strasbourg plenary in November 2024 by calling for an omnibus procedure to simplify policies and reduce bureaucracy and burdens.**

**It is very important to stress** – and as mentioned above: The clear objective of this exercise is to **enable and accelerate the transformation** by augmenting legal clarity, addressing complexity and regulatory burden and, hence, improving business conditions. **In this sense, an omnibus is a precondition for a successful transition and resilient Europe,** and does not imply reaching a lower level of ambition in the field of climate and environment policies by 2050.

### C/ Let's be more specific: List of detailed case studies

The following section presents **almost 50 specific examples of major obstacles for German chemical and pharmaceutical companies** related to provisions in EU legal texts. Such policy measures were listed that create **inconsistency of rules** (opposition of targets within and between legislation or leading to unintended consequences), lead to **disproportionate burden for business** or have **highly challenging implementation** as consequence. In each case study, we present the respective challenges and impact before proposing concrete policy solutions.

**Five levels of policy action can be identified ranked according to the feasibility of the measure:**

- (1) **Immediate change possible:** The Commission can take action on its own and without delay, because the measure is within its own powers, or the Commission can propose modifications via comitology procedures.
- (2) **Ongoing legislative file:** The Commission proposal is in the co-decision process with the possibility by the Commission or the co-legislators to propose adjustments. A possible option is the transfer to second reading to relaunch talks and correct unfavourable developments.
- (3) **Upcoming revision:** Introduction of changes by using existing revision clauses, with the possibility to extend the initially intended scope of the revision. It could be considered to bring forward revision dates, if those are too far in the future.
- (4) **Real omnibus (OLP):** Many obstacles that are hampering the transformation and business success are embedded in legal texts. Inserting specific amendments in existing legislation will require an orchestrated approach and close coordination between the institutions via a “real omnibus” (OLP; ordinary legislative procedure). While more time might be needed for setting up such a mechanism, the positive impact of such changes will be substantial and very beneficial.
- (5) **Addressing principles:** These modifications concern broader policy principles and general developments with impact on the competitiveness of the chemical and pharmaceutical industry. A general policy debate involving stakeholders is needed to address these points.

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## **(1) IMMEDIATE CHANGE POSSIBLE**

### Cluster Chemicals

#### **1.1. CLP – Font size and formatting rules for labels in revised legislation**

**Concerned legislation/policies:** Revised CLP Regulation (Classification, labelling, packaging) 2024/2865 (revising Regulation 1272/2008)

**Issue:** In the previous CLP Regulation, label elements were required to be in “such size and spacing as to be easily read” with no legally binding font size prescribed, except the required dimensions for the labels and hazard pictograms. In the revised version, minimum font sizes and further requirements are introduced, which result in various technical, operational, and practical challenges as well as additional costs.

#### **Main challenges:**

(1) A mismatch with international rules becomes evident. As the font size used for safety and other instructions, pictograms and net weight has to follow ISO international standards, different font sizes will apply on one label, also causing conflicts for available space.

(2) Today, it is common practice to display text in different languages. The new minimum font size requirements will lead in many cases to the impossibility to print multiple languages on one label. This will particularly cause legal concerns in countries with multiple official languages like Belgium. In the case of “character-rich” languages (like German) current label formats might not be sufficient to display even one single language. Fewer languages on a label will result in constant redesigning, reformatting, reprinting, and most importantly, relabelling operations to accommodate the shipping planning to different destinations. Where Made-to-Stock with multilingual labels enable a lot of flexibility today, the change of font size minimum requirements will lead to much higher inventory costs and a need to relabel articles upon shipment.

(3) Finally, many practical reasons arise: Containers used (drums, Intermediate Bulk containers, vials) are also of ISO standards and more space to affix a bigger label is not an option (limited metal plating, width of stacked cardboard boxes, etc.). Expect big increase of manual handling and costs, as well as resulting troubles at the filling centres. Fold out labels are not an option where shrink wrap is used for palletized freight. In many cases, no solution has been identified (for larger containers), some pilot projects foresee use of 24-pages booklet labels (!!!) to display all required information.

**Impact:** The change of font size could lead to partly reorganising company-internal production and logistics. And the new rules challenge the internationally harmonised standards and, thus, will disrupt extra-EU commerce. There is also a risk of creating a contradiction with the objectives of the PPWR, as an augmented minimum font size could, in some cases, result in the making of larger packaging formats with larger labels.

Finally, the calculated financial costs for the German sector (based on estimations provided by larger members) to adopt the new rules could exceed 1 billion (!) Euro. This number stands in stark contrast to the expected 25.66 million Euros additional recurrent (annual) administrative costs for the entire CLP implementation, as estimated by the European Commission.<sup>2</sup>

#### **Change recommended:**

A dedicated analysis should be initiated to establish an appropriate formatting for the labels, taking into account technical constraints for both manufacturers and exporters of chemicals to the EU.

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<sup>2</sup> See European Commission Annual Burden Survey 2022, p. 27

Upon completion of a proper study on the label formats, Annex I section 1.2.1 should be revised via a comitology process. The new minimum font sizes and other formatting rules (background colour, line spacing) should give industry the necessary flexibility.

## 1.2. CLP – Classification challenges of particulate substances (dust)

**Concerned legislation:** Revised CLP Regulation (Classification, labelling, packaging) 2024/2865 (revising Regulation 1272/2008)

**Issue:** Dusts have regularly been receiving incorrect hazard classification due to their physical properties rather than hazard profile, which leads to erroneous effects on the downstream value chain. Dusts (or technically ‘particulates’) are systematically assessed by regulatory authorities as part of harmonised classifications according to CLP. This requirement is regularly leading to questionable results, specifically with regard to the hazard class ‘Specific organ toxicity – repeat exposure’ (‘STOT RE’). Said hazard classification is problematic as only a small or non-existent part of the particles of the end product placed on the market is respirable and thus responsible for the adverse health effects. As such, the classification of dust/particles as ‘STOT RE’ should not be derived from their particle effects instead of their intrinsic hazard.

### Main challenges:

The faulty hazard classification stems from the fact that current inhalation studies on particles set a guidance value of 200 mg/m<sup>3</sup> (as set in Annex I Tables for guidance values ‘STOT-RE’). Yet, said value leads to saturation of lung clearance (lung overload) in any setting, regardless of the hazard property of the tested substance.

Thus, the results of said studies should not lead to automatic classification as ‘STOT RE’ for particles. Regulators must rather provide a solution that ensures safe production and use of particles, by ensuring that non-intrinsic, physical properties are not considered in the regulatory process of harmonized classification. A change in the threshold value for the testing would also contribute to animal welfare, as (animal) testing currently requires test subjects to be exposed to particle concentrations of up to 200 mg/m<sup>3</sup>.

**Impact:** As a result, many classifications are misleading and do not reflect real exposure risks. This is severely impacting the availability and use of substances in particulate form. A classification as ‘STOT RE’ has strong downstream effects in sectoral legislation where the use of ‘STOT RE’ substances is restricted, as well as on the handling of particles in the workplace (for occupational health and safety of workers).

**Change recommended:** To make CLP also workable for particulate substances and to determine whether a classification is warranted we are suggesting the following changes:

- (1) Clarify the CLP requirements of Annex I, section 3.9 on STOT RE in a way that the composition and form of a material as placed on the market is decisive for hazard classification and not the behavior of an artificially manipulated material in an unrealistic and non-representative form.
- (2) Adjust CLP Annex I, section 1.1.1 about expert judgement, specifically related to particulate substances. The goal should be to prevent erroneous and tedious classification of dusts which exhibit no or very low intrinsic toxicity and are generally at the low end of the water solubility range (PSLT substances) – especially since their particle effects on the lung are well-known and independent of the chemical nature of the dust.
- (3) Establish a decision process (e.g. adjust the relevant guidance for CLP) on how to distinguish general health effect applicable to all particles/dusts from potential “systemic” chemical effects of a specific substance.

Cluster Circularity

**1.3. ESPR – No Ecodesign requirements for chemicals and polymers**

**Concerned legislation:** Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of Ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC

**Issues:** The selection of which product groups are to be regulated as a priority under the Ecodesign Regulation takes place via the Ecodesign working plan, to be published in March 2025. The ESPR is currently set to regulate both the presence of chemicals in products for inter alia safety reasons, as well as regulating chemicals and an (intermediate) product group. Furthermore, discussions with the Commission suggest that polymers will form an own priority product group.

**Main challenge:** The working plan for the priority working group is currently being developed by the Commission. The Commission has indicated that both chemicals and polymers are expected to be included as intermediates in the priority product groups. The inclusion of polymers or chemicals as a priority product group is highly problematic, as both chemicals and polymers are heterogeneous substances/materials, hence used in a very extensive variety of products, and cannot be regulated with overarching sustainability requirements under the Ecodesign Regulation.

**Impact:** Regulating chemicals and polymers, as product groups, under the ESPR could have detrimental impacts on the availability and performance of the various substances and materials, as these are highly heterogeneous and are tailored to specific applications. The ESPR is simply not the right mechanism to deal with such large commodity groups.

**Change recommended:** Chemicals (including polymers) should not be prioritized in any workplan under the new Ecodesign Regulation. The Commission must clearly establish in the ESPR Working Plan that chemicals and polymers will not be included in the future.

In a second step, with the aim to increase legal certainty and via amending the legal text (see also corresponding point in section (4) “Real Omnibus”): Article 18(5) should not reference chemicals.

**1.4. PPWR – Derogations for pallet straps and wrappings (Transport Packaging)**

**Concerned legislation/policies:** Packaging and Packaging Waste Regulation (PPWR), awaiting final adoption and entry into force.

**Issue:** The revision of the PPWR seeks to foster a European circular economy by making all packaging reusable or recyclable by 2030. Article 29 of the final text proposes targets for the reuse of transport packaging of 40% for 2030 and 70% for 2040. However, from 2030 onwards, these obligations are to apply to 100% of the packaging intended to deliver products to another operator within the same Member State, as well as to products intended to be delivered between any site on which the economic operator performs its activity within the EU. This is to apply to pallets, foldable plastic boxes, trays, plastic crates, immediate bulk containers, pails, drums, canisters, as well as flexible formats and pallet wrappings and straps for stabilization.

**Main challenges:**

(1) Beyond the physical impossibility to reuse stretch films, the reuse rates for transport packaging between (chemical manufacturing) sites could pose a significant threat to human and environmental safety, as they often are in contact with hazardous substances. For most companies, the most

effective transport packaging system is already in place, including highly functioning reuse and recycling systems where these make sense.

(2) Neither the reuse rates for transport packaging of the initial Commission proposal, nor the significantly higher targets of the inter-institutional agreement have been subject to an appropriate impact assessment. It has not been assessed to what extent mandatory targets could contribute to the reduction of the impact of packaging on the environment.

(3) Rather, these targets are bound to create a discrimination within the EU single market (mandatory targets for packaging transported within a Member State), health and safety hazards, as well as an increased environmental footprint linked to the transport of said packaging.

**Impact:** As it is not technically possible to reuse these pallet wrappings and strapping bands for the same purpose, they are therefore recycled in practice and form an important basis for fulfilling the current recycling targets and future recycled content quotas. Another problem is the extension of the reuse quotas to "sales packaging for the transport of products" provided for in the compromise. The extension of the reuse quotas to "sales packaging for the transport of products" dilutes the sensible and proven distinction between sales and transport packaging and leaves it unclear which packaging formats are meant.

Risk of not complying with the requirements of PPWR due to impossible and impractical obligations: Further, reuse quotes linked to transport between companies within a Member State and between company locations are concerning due the fact that packaging quantities reported by companies are to be published by the Member States (Art. 31(6)), as this allows details conclusions to be drawn about the business activities of individual companies.

**Change recommended:** Amendments need to be achieved via a delegated act. Clear derogations for pallet straps and wrappings should be introduced via delegated acts as set under Article 29(18).

### 1.5. SUPD – Support investment and upscaling of chemical recycling technologies

**Concerned legislation:** Implementing act 2023/2683 on the recycled content of PET beverage bottles, supplementing Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment.

**Issues:** The Single Use Plastics Directive (SUPD) introduced targets for recycled content in plastic beverage bottles. By 2030, single use plastic beverage bottles are to contain at least 30% recycled content, by 2040 at least 40% recycled content. An adopted implementing act sets a calculation methodology for mechanically recycled content. In order to take into account recycled content from complementary recycling technologies other than mechanical one (e.g. from chemical or biotechnological recycling), the Commission is currently in the process of drafting an implementing act with coherent rules on the application of a chain of custody mass balance model with fuel-use exempt as defined in ISO 22095-2020 (Chain of custody – General terminology and models). This implementing act was expected in January 2022. However, still no draft has been proposed by the Commission.

**Main challenges:** The implementing act on recycling technologies other than mechanical one is to function as a blueprint for implementation of a chain of custody mass balance model with fuel-use exempt in other European legislations. Industry is waiting for clarification in this important question for 36 (!) months.

**Impact:**

(1) Without this implementing act, the roll-out of recycling technologies other than mechanical recycling will be severely hindered, and the expected €8 billion in investments will not take place in the EU.

(2) It is also worth to mention that chemical recycling is an innovation area in which Europe is leading the global technology development, but that this leadership role is at risk because of the hesitant legal framework. Mainly China is catching up quickly.

(3) Furthermore, multiply producers of contact-sensitive packaging and bottles will not be able to comply with mandatory recycled content targets as set in the Packaging and Packaging Waste Regulation.

**Change recommended:** We suggest the Commission to table within the coming weeks an amendment to the current Implementing act 2023/2683 to establish a chain of custody mass balance model with fuel-use exempt for recycled content in PET beverage bottles.

## Cluster Hydrogen

### 1.6. RED II (two) – Rigid criteria for RFNBO production

**Concerned legislation:** Renewable Energy Directive (RED II), delegated regulation 2023/1184 (Art. 27(3) RED II)

**Issue:** Strict rules regarding the production criteria of RFNBO (especially additionality and time correlation) are impractical and effectively hinder electrolysis investments thus significantly slowing down the market ramp up.

**Impact:** Of the 10 GW of electrolysis capacity planned by 2030 in Germany, for example, final investment decisions have so far only been made for 0.3 GW. Only 0.15 GW is currently in operation.

#### **Change recommended:**

Amend the existing RED II Delegated Act:

- Extend current deadlines for additionality and temporal correlation. Ideally, a more pragmatic approach should be chosen reducing complexity and strengthening the role of green PPA and guarantees of origin.
- Move forward the review date of the impact assessment of the union methodology (currently 1 July 2028) at least to 1 July 2026 (see Art. 27 (6) RED III).

### 1.7. Low-carbon hydrogen (LCF) – Delegated Act hinders scale-up of production

**Concerned policy:** (Draft) Delegated Act deriving from Art. 9 (5) of Directive (EU) 2024/1788 (“Low Carbon Fuels DA”, deriving from Gas Directive)

**Issue:** Advancing emissions reductions in high-temperature heat applications and for industrial feedstock relies critically on the scale-up of the EU’s hydrogen economy. Low-carbon hydrogen has a central role to play in that economy: It can be produced in a baseload profile that matches industrial demand patterns and remains cost-competitive over renewable hydrogen. A combination of renewable and low-carbon hydrogen can moreover drive the EU’s hydrogen economy to scale faster than a technology specific approach would.

#### **Main challenges:**

(1) Green hydrogen, given high electricity costs and restrictive framework conditions, will remain significantly more expensive than gray or low-carbon hydrogen in the medium term. Currently, the production of renewable hydrogen in the EU is approximately twice as expensive as production from fossil sources.

In a future liquid hydrogen market, additional costs would arise from imports, reconversion and associated energy losses, network transport, as well as price differences induced by quotas. Therefore, the European Commission should prioritize measures to reduce overall hydrogen costs and improve the competitiveness of hydrogen production and industrial usage.

(2) For the time being, a lack of regulatory clarity still inhibits the further scale-up of low-carbon hydrogen production and consumption in the EU. In addition, preferential regulatory incentives in favour of renewable hydrogen distort the competitive playing field with low carbon hydrogen that complies – by definition – with the same GHG emissions reductions threshold. The regulatory regime should be developed in such a way that it facilitates complementarity between different types of hydrogen, rather than competition. The current draft DA does not address these issues.

**Change recommended:**

We urge the Commission to:

- Prioritise the use of supplier specific, certified upstream methane emissions values (where available).
- Open the accounting of non-RFNBO compliant electricity emissions to supplier-specific emission values (instead of grid average)
- Carbon captured from industrial sources should be fully eligible to be utilized in low-carbon fuel, provided the above emissions threshold is respected. The proposed flexibility should also be enabled in the Delegated Act 2023/1185.

Cluster Finance and reporting

**1.8. Taxonomy and ETS eligibility – Many white spots**

**Concerned legislation:** Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives.

**Issue:** The EU Taxonomy is grappling with a range of usability issues regarding the reference to EU Emission Trading System (ETS). One of these issues is the unfair treatment of economic activities that are Taxonomy eligible but can never be aligned due to the Technical Screening Criteria (TSC) set out by the regulation not being applicable to that activity.

**Main challenges:** The Technical Screening Criteria (TSC) for many economic activities under the EU Taxonomy reference EU Emissions Trading System (EU ETS) benchmarks through footnotes, e.g. “Reflecting the average value of the 10% most efficient installations...” and “Calculated in accordance with Regulation (EU) 2019/331”. However, not all plants or processes relevant to these economic activities are always covered by the EU ETS. The EU ETS only covers specific high emitting processes described in detail by Guidance Document nr. 9 on the harmonised free allocation methodology for the EU-ETS post 2020. As the chemical industry is highly complex, some of its eligible activities (e.g., chemicals produced as by-products) are not covered by the TSC with the specific EU-ETS boundaries. Therefore, some of these activities cannot be assessed and must generally be reported as not taxonomy-aligned.

For example, the manufacture of soda ash in a caprolactam production network (3.12. Manufacture of soda ash) is not covered by the EU ETS (see guidance document nr. 9, exemption on p. 178). Hence,

under the current rules it is impossible to screen this activity and consequently for this activity to be taxonomy aligned, but it is nonetheless eligible. There is no apparent environmental logic behind this as the issue stems from misalignment of the TSC, i.e. a lack of data.

This uncoherent situation does also apply to notably: CCM/CCA 3.7. Manufacture of cement, 3.12. Manufacture of soda ash, 3.14. Manufacture of basic organic chemicals, 3.16. Manufacture of nitric acid.

**Impact:** Redressing the inconsistency of TSC with regard to ETS benchmarks will result in more accurate and therefore comparable Taxonomy reporting as well as a reduced administrative burden.

**Change recommended:**

(1) A straightforward way to resolve this usability issue would be for the Commission to clarify (in an FAQ or other instrument) that activities with TSC including a reference to the EU ETS, are taxonomy eligible when the plant relevant to this activity is indeed within the specific ETS system boundaries. This would result in more targeted and accurate reporting leading to greater comparability between figures across companies and industries. This would also be in line with the rationale to address high-emitting processes first (i.e., those covered by the EU ETS). In addition, a generally applicable materiality principle is necessary to increase comparability. This is currently not firmly established at all companies.

(2) Certificates from non-European countries for non-European activities/production assets should also fulfil the technical screening criteria/ criteria for substantial contribution as long as they are comparable to the European standard. DNSH criteria for chemicals should reference to existing chemicals legislation which would also define thresholds of concentration. Without those thresholds the definition is up to individual companies and auditors which creates legal uncertainty.

### 1.9. Taxonomy and ETS – Disadvantaging electrification

**Concerned legislation:** Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives

**Issue:** We have identified an inconsistency in relation to the EU ETS for the activity CCM 3.14 Production of basic organic chemicals and in particular high-value chemicals (HVC) by steam cracking. Due to the direct link between the TSC and the EU ETS (EU 2019/331), the sector-specific guidelines must be followed. Regarding the ETS calculation for steam crackers, the relevant guidelines require companies to calculate the emissions for steam cracking with a standardized CO<sub>2</sub> backpack for the electricity used. Regardless of where and how the electricity is generated, emissions are reported using a standardized rucksack of 0.376 kg CO<sub>2</sub>/kWh). Under the current EU ETS, this is necessary to compare the performance of operating cracker plants.

**Main challenge:** In the context of the taxonomy, this strict rule is absolutely detrimental to innovative processes such as the electrification of steam crackers or other chemical processes. Any innovative chemical process technologies that utilize electrification using green/renewable electricity will even be penalized with a higher CO<sub>2</sub> value with respect to this strict calculation rule where fuel and electricity are interchangeable. As a result, some chemical industry efforts to electrify HVC or similar production processes are classified as unaligned. The current taxonomy reporting therefore penalizes electrification efforts in favor of crackers using fossil gas technologies.

**Impact:** This limits the chemical industry in the electrification of production processes and ignores the benefits of renewable green electricity. Electrification and access to affordable renewable and low-carbon energy are fundamental to climate neutrality and the chemical industry of the future. The strict reference to the calculation methodology of the EU ETS therefore diminishes the importance of the use of green electricity and closes off one of the most important levers for the sustainable transformation of the chemical industry. The sustainable transformation from fossil production processes to low-emission processes with renewable electricity is even negatively evaluated by this criterion, as every higher electricity consumption increases the GHG emissions calculated according to the ETS system.

This leads to a significant discrepancy between the company's efforts to mitigate climate change and the recognition of the activity 3.14 Production of organic raw materials. We therefore see a compelling need to revise these criteria for a significant contribution to align them with the actual change in the chemical industry. We call for a better definition that makes it possible to include the positive effects of renewable energies in the specific calculation. The strict requirement to follow the for calculating GHG emissions should be supplemented. It must be ensured that the reduction of GHG emissions using electricity from renewable energy sources is also applicable, visible and recognized in this criterion.

**Change recommended:** We suggest the following change in wording in the respective delegated act: “Where the GHG emissions are calculated in accordance with Regulation (EU) 2019/331, and organic chemicals in scope are produced using renewable electricity, the fixed factor for electricity given by the regulation (EU) 2019/331 should be adjusted to the specific factor of the renewable electricity”.

#### 1.10. Taxonomy – Unclear links with chemicals, pharma and agriculture

**Concerned legislation:** Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088 (Text with EEA relevance).

**Issue:** It is positive to aim to clarity and transparency in environmental sustainability through the EU Taxonomy. However, some implementation issues need to be resolved and no new activities should be introduced before the root problems of the EU taxonomy have been resolved.

#### **Main challenges:**

(1) The Delegated Act on pollution prevention and control sets reporting obligations for the pharmaceutical sector on manufacture of medicinal products (Annex III, Technical Screening Criteria, TSC, 1.2). The EU Taxonomy regulation as it has been proposed will only provide a limited representation of the commitments to environmental sustainability from innovative pharmaceutical companies because the aspects addressed by the alignment criteria applicable to the pharmaceutical industry prove to be very limiting in that regard. The TSC outlined in chapter 1.2 of Annex III are not aligned with the pharmaceutical industry's purpose.

(2) The disclosure of taxonomy-related OpEx (operating expenditure) is less relevant than turnover and CapEx (capital expenditure): Companies sustainability profile is primarily defined by their taxonomy-related turnover data followed by their CapEx figures (including CapEx plans). Furthermore, other EU initiatives like the Green Bond standard or the recently announced taxonomy-aligned benchmark are connected with "green" turnover and CapEx but have no connection with OpEx.

**Impact:** Based on the current alignment criteria, the activity of manufacturing of a pharmaceutical preparation can – in summary – only be assessed as Taxonomy-aligned if the active ingredient and any other ingredients are naturally occurring, biodegradable or mineralised and if the new active

ingredient or medicinal product can be deemed an appropriate substitute for an existing ingredient or product which is not biodegradable. However, substitution itself is limited in the same therapeutic area or substance class.

In other words, the taxonomy-alignment of a pharmaceutical preparation will depend on the clinical development history and subsequent scope of the marketing authorization for potential competitor products. Manufacturing of products for previously untreated therapeutic areas can never be taxonomy-aligned because they cannot fulfil the requirement of being a substitute in the first place. For products that significantly improve treatment options for patients, taxonomy alignment depends on the availability of pre-existing nonbiodegradable options in the same therapeutic areas. Effectively disallowing such manufacturing to be taxonomy-aligned does not add incentives to their development and/or improvement.

**Change recommended:**

(1) The application of the EU taxonomy should be voluntary, as the benefits and demand only exist in certain sectors. The TSC for pharmaceutical production need to provide a realistic incentive to increase sustainability. Focusing only on the biodegradability of an active pharmaceutical ingredient may be counterproductive, as by nature, certain pharmaceuticals must be persistent to be effective.

(2) Given that OpEx is cumbersome to calculate and adds little value to financial market participants, this disclosure should be voluntary. Looking at the TSC in the field of agriculture, we recommend creating incentives across all agricultural systems to transition to more sustainability due to the sector's significant potential to contribute to the four key environmental objectives climate change mitigation and adaptation, biodiversity and environmental impact reduction. Outcome-based criteria that assess the sustainability impact of agricultural practices and that account for land use change, greenhouse gas emissions and implications on natural habitats for biodiversity need to be set. Furthermore, the potential of digital farming in supporting the transition to more sustainability should be recognised.

**1.11. Taxonomy and the description of renewable feedstock – Disadvantaging inorganic raw materials**

**Concerned legislation:** Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021, supplementing Regulation (EU) 2020/852, establishes technical screening criteria to determine if economic activities contribute substantially to climate change mitigation or adaptation without causing significant harm to other environmental objectives.

**Issue:** We identified an inconsistency in the description of activity CCM 3.17 (Production of plastics in primary form). While renewable feedstock is defined as biomass, industrial biowaste, or municipal biological waste, inorganic raw materials that do not alter natural balances or are returned via the biological cycle (e.g., air, water, sodium chloride) are excluded from consideration as renewable raw materials.

**Main challenges:** The description of activity CCM 3.17 refers to the manufacture resins, plastics materials and non-vulcanisable thermoplastic elastomers, the mixing and blending of resins on a custom basis, as well as the manufacture of non-customised synthetic resins. The economic activities in this category could be associated with NACE code 20.16 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

An economic activity in this category is a transitional activity as referred to in Article 10(2) of Regulation (EU) 2020/852 where it complies with the technical screening criteria set out in this Section

**Impact:** Currently, inorganic raw materials whose extraction from nature does not change the balance or are returned via the biological cycle are not being taken into consideration in the context of renewable raw materials (examples: air, water, sodium chloride, ...) and therefore cannot contribute to the CO2 reduction ambitions. This discourages investments and creates uncertainty regarding the contribution of related projects to climate protection.

**Policy changes recommended:** In addition to bio-based raw materials, inorganic raw materials whose extraction from nature does not change the balance or are returned via the biological cycle should also be listed under the footnote 155 of Commission Delegated Regulation (EU) 2021/2139 in the context of renewable raw materials (examples: air, water, sodium chloride, ...).

#### 1.12. Corporate Sustainability Reporting Directive (CSRD) – ESRS Set 1 overly complex

**Concerned legislation:** Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting.

**Issue:** The new CSRD reporting requirements are accompanied by a significant expansion of the scope of application for companies. This poses challenges for companies that are first-time adopters and SMEs which will also be indirectly subject to the reporting requirements in the future. But also large companies that have already fallen under the NFRD are finding it difficult to meet the requirements.

##### Main challenge:

(1) Previously, NFRD obligated parties had to report on 250 data points. Now it is over 1,100 data points for the own operations as well as value chain activities. To be able to report on a single data point, countless metrics have to be used. The value chain data is particularly difficult to obtain, as the chemical and pharmaceutical industry works with a lot of different suppliers and customers around the world. To obtain the data from tier 2 and subsequent tiers is often impossible, as value chains are highly complex and widespread.

(2) In addition, some ESRSs are not clearly defined (e.g. ESRS E5-5 DR 37 (d) total quantity and percentage of non-recycled waste), which leads to legal uncertainties. Another challenge arising from some data points is that conclusions can be drawn about production volumes and market behaviour (e.g. ESRS E2-5 DR 34 on the total amount of substances of concern generated, used or procured in production). Moreover, the implementation guidelines provided by EFRAG, the standard setter, are currently still confusing, as some of them contain definitions that differ from those in ESRS Set 1.

**Impact:** The CSRD extends the existing sustainability documentation and reporting obligations and overburdens the companies. Especially in times of a shortage of skilled workers, many ESG experts are tied up in fulfilling reporting obligations, which are lacking for the transformation to a sustainable future. The costs for companies are also extremely high: For reporting according to the European Sustainability Reporting Standards (ESRS), the Commission estimated EUR 1 700 million in one-off costs and EUR 1 700 million in annual recurring costs. The real costs are likely to be much higher.

##### Change recommended:

The ESRS needs to be revised:

(1) The focus should be on requirements that offer real decision-making relevance in the financial sector and thus support the financing of the transformation, e.g., ESRS E1 climate and the aims to reduce GHG emissions as well as ESRS E1 own workforce. In contrast, the topic ESRS E4 biodiversity and ecosystems should be deleted as the database is not relevant for the financial sector, data availability is not given and science-based metrics do not exist. Further, the topic ESRS S2 workers

in the value chain should also be deleted as the database is not relevant for the financial sector and data availability is not given since data protection issues exist.

(2) In addition, the EU Commission should limit the request for data on the value chain only for requirements relevant to decision-making and to tier 1. The chemical industry often works with suppliers from emerging economies, where comprehensive environmental and social data is often difficult to obtain. Restricting this to tier 1 analyses could significantly improve feasibility.

(3) The EU Commission should clarify ambiguously defined ESRS: e.g. ESRS E5-5 DR 37 (d) Total amount and percentage of non-recycled waste; ESRS E3 AR 6, 7, 15 data points of the LEAP approach, some of which are mandatory although the approach is voluntary; ESRS S1 and S2 dealing with contractors; S1-16 DR 97 (a)+(b) Reporting of unadjusted gender pay gap and annual total remuneration rate. We recommend that no further implementation guidelines is developed before these corrections take place.

(4) Disclosure requirements should allow reporting according to local definitions and legislation since uniform global reporting is difficult. (e.g. Definition of “hazardous waste” as per ESRS Glossary: “Waste which displays one or more of the hazardous properties listed in Annex III of Directive 2008/98/EC (*EU Waste Framework Directive*)”).

(5) The application of materiality principles in the calculation, e.g., analysis of the environmental relevance of sites, should be permitted.

### 1.13. **CSRD – National implementation of the subsidiary exemption**

**Concerned legislation:** Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting (Text with EEA relevance)

**Issue:** Article 19a(3) and Article 29a(3) of Directive 2013/34/EU exempt all subsidiary undertakings from the obligation to report non-financial information where such undertakings and their subsidiary undertakings are included in the consolidated management report of their parent undertaking, provided that the report includes non-financial information reported pursuant to that Directive.

**Main challenge:** While the national implementation process has not been finalized, some Member States (e.g. Hungary) seem to consider deviating from the rule to exclude subsidiary undertakings; i.e. subsidiary exemption potentially would not be applicable in some Member States.

**Impact:** The need to prepare one or more subsidiary CSRD reports including the double materiality analysis at national level, in addition to the group level report would significantly add the reporting burden for companies. Different rules in different member states would additionally create legal uncertainty in the Single Market.

**Change recommended:** The implementation of the exemption for subsidiary reporting should be harmonized across Member States. The Commission should therefore further support and monitor the correct transposition of the CSRD in the Member States.

### 1.14. **CSRD – Refrain from sector-specific standards**

**Concerned legislation:**

DIRECTIVE (EU) 2022/2464 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting.

**Issue:** We welcome the postponement of the introduction of the sector-specific standards by two years to 2026. Before introducing new standards, it is crucial to evaluate the effectiveness of ESRS Set 1. A clear understanding of its implementation – how it is managed and its impact on large companies – is essential before considering sector-specific standards.

**Main challenge:**

(1) Companies likely need more than two years to implement ESRS Set 1. In addition, the relevant topics are already included in the sustainability report through the materiality assessment. There is therefore no need for detailed sector-specific standards.

(2) Currently, sector-specific standards map directly to NACE codes, requiring companies operating across multiple sectors to report separately for each. This poses a challenge, as larger companies often produce products under different NACE codes.

**Impact:** The ESRS Set 1 – by itself – overburdens the companies with bureaucracy and thus weakens the global competitiveness and resilience of the EU (see previous point on ESRS complexity). For many requirements, it is already questionable whether they will have a steering effect.

Further detailing of the data points with sector-specific standards would create massive supplementary compliance costs for companies: According to initial assessment by a number of companies, the additional workload (in hours) is in the range of 50-100 percent (!) compared to the current implementation of the first set of ESRS.

**Change recommended:** The European Commission's current goal of reducing the reporting burden of EU companies by 25% in order to improve competitiveness (mentioning the CSRD as example). Consequently, no new further reporting burden should be added, meaning that no sector-specific standards should be developed.

**1.15. CSRD – Limit the SME Standard**

**Concerned legislation:** DIRECTIVE (EU) 2022/2464 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting.

**Issue:** The CSRD extends the existing sustainability reporting obligation. It is to be expected that this will be accompanied by an increase in data requests from companies about their own location in the value chain. As a result, SMEs in the value chain will increasingly be indirectly included in the sustainability reporting obligation (trickle-down effect). VSME are voluntary sustainability reporting standards for small and medium-sized enterprises (SMEs). These standards are supposed to help non-listed SMEs meet the increasing demand for sustainability data from their business partners across the value chain, demanded by the CSRD and ESRS.

**Main challenge:** The data required by the VSME is still too demanding for SMEs, which may have to fulfil a total of 28 disclosure requirements if all modules are used. Furthermore, the standard will only be accepted if stakeholders recognise it as the only market standard for sustainability issues and do not demand more data from SMEs (value chain cap).

**Impact:** SME, including the German *Mittelstand*, are heavily affected by the CSRD and similar sustainability legislation because of trickle down effects. This is likely one reason why, according to a recent VCI study, 86 percent of members indicate that “regulation” is the main obstacle for investing in Germany and Europe.

**Change recommended:**

- (1) The scope of the VSME should be reduced by a delegated act so that SMEs are not overburdened, and the data request should remain limited to the relevant data.
- (2) A value chain limitation in the form of the VSME (basic module) must be anchored in the CSRD itself.

Cluster Pharma and health

**1.16. Health Technology Assessment (HTA) – Fragmented landscape**

**Concerned legislation:** Regulation (EU) 2021/2282 and upcoming implementing acts

**Issue and main challenges:** Health technology developers often face the difficulty of submitting the same type of information and evidence to different Member States (MS). The HTA landscape is highly fragmented in terms of data, analysis, and methodologies that are required for national submission. The duplication of submissions and consideration of different timings for submission across MS constitute a significant administrative burden for HT developers.

**Impact:**

- HTA agencies often reach different conclusions on the medical impact of new pharmaceuticals, even though the data studied is predominantly the same for all markets. This is because HTA agencies adopt different approaches for information and methodological requirements, as well as when rating and interpreting this data. The fragmentation contributes to impeding and distorting market access, leading to a lack of business predictability, higher costs and, in the long run, negative effects on innovation.
- For companies, this means duplicative administrative work. The HTA coordination group guideline — together with the draft Implementing Act, which restricts developers' involvement and contains unrealistic data requirements and unworkable timelines — indicates that the JCA project is at real risk. In turn, the EU's competitiveness as a region for ATMPs is in danger, and ultimately, rare disease patients could see fewer transformative treatment options available in the EU.
- For agencies, this means sometimes inability to conclude on the basis of the evidence provided, because the evidence was generated for other purposes and does not fit national requirements.
- For patients, this means unnecessary trials, potential delays, and access restrictions because of methodological misalignment (rather than the intrinsic properties of products).

**Change recommended:**

Through implementing legislation:

- Given the intention of the HTA Regulation to harmonize processes and accelerate patient access, an EU-wide HTA is recommended to avoid duplication of HTA at national level. A streamlined process should be in place when selecting the PICOs to avoid duplication at Member State level.
- HTA should be an independent process but should not exclude or minimize the involvement of other stakeholders. All stakeholders can be part of the discussion whilst the actual assessment remains independent.

- Systematic involvement of all stakeholders, including Health Technology Developers (HTDs), will add significantly to the timely delivery of high- quality EU HTA. JSC and JCA should include the perspectives of clinical and scientific experts and patients.
- Disease specific guidance should be developed and applied in the context of JSC/JCA that acknowledge nuances of different therapeutical areas (e.g., the ability or inability to conduct RCTs, endpoints, comparators, magnitude of clinical benefit, and the regulatory context).

### 1.17. **Clinical trials – Regulatory divergence in Member States**

**Concerned legislation:** Medical Device Regulation (MDR) (2017/745 EU) and Directive (2011/24/EU)

**Issue:** This divergence refers to differences in regulatory requirements, standards, and procedures among the different Member States.

#### **Main challenges:**

Divergences in regulatory requirements, standards, and procedures for clinical trials among the different Member States. Some key aspects include:

- Member States are not implementing the In Vitro Diagnostic Regulation (IVDR) & Medical Device Regulation (MDR) in the context of clinical trials in a harmonised way. Some of these issues can be addressed through the already foreseen revision of the EU MDR.
- Approval of clinical trials with medicines containing Genetically Modified Organisms (GMOs) in addition to the approval of clinical trials by regulatory authorities. The initiation of a clinical trial with an investigational medicinal product that consists of or contains a GMO is currently a lengthy and complex process in Europe due to the fragmentation of GMO application procedures and data requirements implemented by each EU Member State.
- Divergent access to information on clinical trials and the trials themselves. Although many patients would be interested in entering a clinical trial, only a small minority of patients could benefit from clinical trials (3-5%) due to several challenges.

#### **Impact:**

- Increased costs for sponsors to run clinical trials due to diverging compliance requirements in the different Member States.
- The fragmented landscape for GMO applications poses challenges when sponsors attempt to coordinate with clinical trial applications and their harmonisation under the European Clinical Trials Regulation.
- Delayed and reduced collaboration in R&D due to divergences in clinical trials approvals for cross-border trials, as well as reduced attractiveness for international companies, leading to delays for patients to access clinical trials and innovative medicines in Europe, and international pharma companies launching clinical trials outside of Europe.

#### **Change recommended:**

- (1) Through the revision of the MDR: Harmonization of implementation of IVDR & MDR in Member States, creation of coordination process for NCAs and development of clarifying guidelines
- (2) Through secondary/implementing legislation: Harmonization of existing regulatory standards in the CTR across Member States and facilitation of regular collaboration across National Competent Authorities to ensure future harmonization.
- (3) Enable cross-border access to trials for patients when there is no option for them to join a clinical trial in their own country.

EU-X-CT leadership proposed a six-point action plan to enhance access to cross-border clinical trials in Europe:

- Define minimal ethics committee requirements.
- Develop recommendations for industry and academic sponsors as well as contract research organisations (CROs).
- Formulate guidelines for investigators and clinical trial sites.
- Clarify cost coverage responsibilities of health insurance companies and payers.
- Determine liability insurance coverage parameters.
- Increase awareness among patients and treating physicians.
- Exemption of clinical trials for Cell & Gene Therapies from the GMO legislation framework.

### Cluster Promoting Batteries

#### **1.18. Batteries Regulation – Declaration of the carbon footprint of batteries**

**Concerned legislation:** EU Batteries and Batteries Waste Regulation; and thereof Draft Commission Delegated Act (DA) supplementing Regulation (EU) 2023/1542 of the European Parliament and of the Council by establishing the methodology for the calculation and verification of the carbon footprint of electric vehicle batteries.

**Issue:** The EU Battery Regulation was adopted on 12 July 2023. One of the most important elements is the declaration of the carbon footprint of the batteries. Through article 7 of the legislation, the Commission was mandated to adopt a delegated act on the carbon footprint calculation methodology, based on the existing 'product environmental footprint' (PEF) methodology. The use of the PEF-methodology was recommended by the Commission in an official Recommendation. On 30 April 2024, the Commission published a draft DA for the calculation of the carbon footprint of batteries.

**Main challenges:** The draft text for the delegated act on calculating the carbon footprint of batteries contains significant inconsistencies with regards to electricity modelling (section 2.4). It requires economic operators on the battery value chain to use the national average energy mix. The impact of such a delegated act is that the use of the 'average national energy mix' could potentially severely disincentivize companies from investing in local renewable energy production, and would render existing power purchasing agreements (PPAs) virtually worthless.

#### **Impact:**

(1) Contractual instruments (in particular PPA's linked to EACs) are a critical and valuable lever for decarbonization, particularly in a well-functioning electricity market such as the EU's. A lack of recognition for these instruments puts Europe at a competitive disadvantage for EU battery manufacturers, who are already struggling with high energy costs in comparison to other global jurisdictions.

(2) This issue is not only relevant from the perspective of honouring the principles of an EU single market for energy, but also it puts EU competitiveness at severe risk, as it could potentially impact battery investments in Europe.

**Change recommended:** The Delegated Act should be aligned with the EU-PEF [C(2021)9332] and GBA GHG Rulebook Rule Set 2 (Physically Modelled Approach). Allow for contractual instruments in general, as stated in JRC guidance options on electricity, provided that adequate protection against

double counting is in place. Establish a positive list / “white list” for jurisdictions that fill minimum quality requirements and where contractual agreements are acceptable in CO2 counting. Establish a strong definition for renewable energy acceptable in carbon footprint declarations (e.g. following REDII).

#### 1.19. **Batteries – Ongoing CLP classification of Lithium salts as toxic for reproduction**

**Concerned policy:** Proposal for a harmonised classification of three lithium salts under the CLP Regulation 1272/2008

**Issue:** Three Lithium salts – essential for notably the manufacturing of rechargeable lithium-ion batteries, building insulation products and certain pharmaceutical applications – are currently undergoing (since 2022) a harmonized classification process under CLP as toxic for reproduction, highest category (1A). The intention and timing of this proposal are putting at risk the shift to electric mobility and many Green Deal objectives.

The reassessment by the ECHA RAC which ended in March 2024 did not change the initial classification proposal (Cat 1A – developmental toxicity; Cat 1B – fertility) for the three Lithium salts. RAC seems to weigh toxicological evidence in a different manner as compared to toxicologists from several non-EU authorities, the industry and academia.

The RAC opinion will be sent to the EU Commission (DG GROW and DG ENV), who will pass it to CARACAL for discussion. The timing of these discussions will depend on when Commission will start the drafting of the next ATP (end of the year) but considering the proposal has to go through CARACAL, WTO and scrutiny by the EP and Council, we may expect the publication in Annex XI of the CLP by the end of 2025. Anticipating a transition period of 18 months, the new classification and labelling could enter into force by mid 2027.

#### **Main challenges:**

(1) A harmonised classification under CLP would automatically result in regulatory actions under REACH, possibly leading to restrictions or authorisation. And, as a consequence of a legal cascade effect, a classification would trigger a series of legal measures, such as alternative risk management measures under the CMRD (Carcinogens Mutagens Reprotoxic Directive), the Water Framework and Ambient Air Quality Directives, knowing that alternative risk management measures will take many years to be defined.

(2) With such a harmonised classification the EU would act unilaterally and increase incoherence with the situation outside the EU where a different classification is handled. Argentina, Australia, UK and US expressed explicit disagreement with the EU classification proposal.

**Impact:** A harmonised classification of these lithium salts as toxic for reproduction would represent a massive obstacle to the achievement of Green Deal and the EU’s resilience targets, notably the ramping up of European battery supply chains and the legal goals set by the Batteries Regulation 2023/1542. The pending procedure creates legal uncertainty and negatively impacts investment decisions – noting that the EU Strategic Action Plan on Batteries (2018) estimated an EU battery market worth up to EUR 250 billion a year, served by at least 10 to 20 Gigafactories.

**Change recommended:** We call on the Commission to refrain from including a 1A classification for lithium carbonate, lithium chloride and lithium hydroxide in the ATP proposal.

#### Cluster Solutions for agriculture

## 1.20. Sustainable use of pesticides – Drone-based application of plant protection products

**Concerned legislation:** Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

**Issue:** Article 9 of Directive 2009/128/EC prohibits aerial spraying of plant protection products.

**Main challenges:** As this is a generalized ban on aerial application it covers all types of aerial spraying, including drone-based application, thus hindering the development of drone technology for precision application of pesticides. Drone technology applied in pesticides application allow for the targeted application of plant protection products, contributing to optimized input use and reduced risks to human health and the environment. Article 9 of Directive 2009/128/EC allows Member States to provide for derogations to allow aerial spraying under certain conditions. This has resulted in fragmentation within the EU, with several Member States setting up different national frameworks to provide for such derogations for drone-based application. This has also resulted in illegal use in countries where no workable framework for drone-based application was in place. Furthermore, allowing the use of a certain technology only by derogation, and upon a case-by-case evaluation, provide for a cumbersome procedure which disincentive the use at scale of such technology.

**Impact:** The lack of a harmonised EU framework allowing the use of drone technology for pesticides application risks depriving private operators of the incentives and business case needed to invest in this technology for use in agriculture in the EU. Drone-based application will be further developed in other geographies, which benefit from a more pragmatic framework.

### **Change recommended:**

- (1) The European Commission should provide guidance to Member States on a set of a harmonized criteria they could adopt nationally to grant derogations based on current Member States best practices.
- (2) In the long-run, we propose amending Article 9 of Directive 2009/128/EC accordingly and setting up technical criteria for allowing drone-based application via secondary legislation (i.e. implementing act).

## (2) ONGOING LEGISLATION

### Cluster Pharma and health

#### 2.1. **Pharma package – Increase protection of intellectual property**

**Concerned legislation:** Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

**Issue:** Industry faces a big challenge with the protection of intellectual property (IP) in the healthcare sector of the European Union. This is exemplified by the European Commission's proposal to cut Regulatory Data Protection (RDP) by 2 years at a time when the European Council (March 2023) asked with expressive words to strengthen, rather than cut incentives for research and innovation.

#### **Main challenges:**

RDP is vital to every company, regardless of their location. Whether the company is US or European based, RDP is essential to ensuring a medicine is launched in a timely way in Europe:

- While RDP is the last layer of protection for (estimated) one in three medicines, it will be factored into the R&D decision-making process of all of medicines.
- Sufficient RDP is especially important for advanced, complex therapeutics with a long or difficult development time.
- RDP is vital in helping to address unmet medical need (UMN) for patients with no treatment options or where treatment is limited, and has applied to medicines for cardiovascular disease, HIV, cancer, and rare diseases.

#### **Impact:**

Where R&D happens is determined by a wide range of factors. Companies decide where to carry out R&D considering considerations such as, where science is strongest, the stability and predictability of the intellectual property framework, fiscal incentives, data and technology available, manufacturing capabilities, and the ability to get the medicines used by patients.

- Research has shown that reducing RDP in Europe would cost the region 2 billion Euros a year in lost R&D investment.
- Weakening RDP would see Europe lose out on the R&D of about 50 of 225 expected new treatments over the next 15 years – medicines which may not be researched elsewhere. Europe could also see 16 million years of life lost (YLL) through increased mortality and premature death because of this lost innovation.
- The numbers are worse for Small and Medium-sized Enterprises (SMEs), with only 1 out of 10 RDP reliant projects remaining economically viable, simultaneously reducing access to medicines for thousands of patients.
- The proposal's estimations also fail to recognize the savings made by innovative medicines in other parts of the system. Advances in the treatment of Hepatitis C (first- and second-generation direct-acting antivirals) has led to significant savings for healthcare systems across Europe over a 20-year horizon: 45m Euro in Romania, 65m Euro in Italy, 275m Euro in Spain.
- Decisions to weaken RDP in Europe at a time when the region has seen a 25% decline in R&D investment over two decades and a reduction of its share of clinical trials from around 25% to

19% over the same period, will negatively impact all Member States with a life science footprint.

**Change recommended:**

The general pharmaceutical legislation revision is still in Council negotiations. The below suggestions could still be reached within the Council mandate or later during interinstitutional negotiations.

The main objectives are: Strengthen, rather than weaken current RDP measures, with a minimum 8-year baseline. And, do not link RDP to conditions which the industry cannot reasonably fulfil.

The regulatory data protection period shall be ten years from the date when the marketing authorisation for that medicinal product was granted. For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.

Subject to a scientific evaluation by the relevant competent authority, the data protection period shall be prolonged by:

- One year, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application or subsequent variation that the medicinal product addresses an unmet medical need at least in one of its indications
- One year, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application or subsequent variation use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;

In the case of a conditional marketing authorisation granted the prolongation referred to in the first subparagraph, point (b), shall only apply if, during the regulatory data protection period the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.

Any reference to the prolongation of the data protection period linked to medicinal products supplied in Member States should be removed.

## **2.2. Pharma Package – Reconsider choices re antimicrobial resistance & prescription criteria of antivirals and antifungals**

**Concerned legislation:** Revision of the EU General Pharmaceutical Legislation – Regulation 726/2004 and Directive 2001/83/EC

**Issue:**

- The proposal to restrict access to common antifungal and antiviral non-prescription medicines by making them subject to prescription could result in the restriction of access to commonly used non-prescription medicines.
- Non-prescription antivirals and antifungals (mostly topical products) are helping people to take timely action and avoid aggravation of some common self-manageable conditions such as skin warts, dandruff and athlete's foot.
- We strongly support the public health objective of combating antimicrobial resistance (AMR). The primary concern in AMR lies in bacterial resistance to antibiotics associated with common infections, coupled with the inappropriate prescription and overuse of antibiotics where they prove ineffective, such as in the empirical prescription of antibiotics and their use for viral infections.

- Antibiotics demonstrating a confirmed risk of AMR should only be available with a prescription, tied to a definitive diagnostic approach. This should not apply to common antivirals and antifungals.
- Non-prescription antiviral and antifungals have defined indicated usages and are often used in lower doses and via topical routes of administration. There is no evidence that non-prescription medicines are associated with AMR.

**Main challenges and impact:**

- Shifting readily available non-prescription antivirals and antifungals to prescription-only status increases costs for consumers, reduces patient access to effective self-care solutions, and disincentivizes development and innovation in the self-care sector. This disproportionately impacts smaller companies lacking the resources to navigate complex prescription procedures and marketing regulations.
- Blanket prescription status to these medicinal products would have an unintended negative impact on the accessibility of self-care products and add an additional burden to patients and national health system resources.
- Transforming medicines from prescription to non-prescription status represents a noteworthy innovation in the self-care sector. It is pivotal in-patient care as it broadens the spectrum of non-prescription treatments and liberates healthcare professionals away from dealing with conditions that can be adequately self-diagnosed and self-treated.

**Change recommended:**

Amend the Art. 17, Art 4, Art 51 (e, f) & Art 55 of the Directive in the following way:

- Prescription status of antimicrobial products should be restricted to those products for which an AMR risk has been confirmed as a public health threat (like antibiotics). This risk-based approach allows the continued availability of non-prescription antivirals and antifungals that do not pose a significant AMR risk.
- Simplify the regulatory pathway for non-prescription medicines and establish clear criteria for reclassification, reducing administrative burdens and promoting innovation in the self-care sector. This could be implemented via a delegated act focusing on simplified registration and post-market surveillance requirements.
- Enhance transparency by clearly defining criteria for AMR risk assessment and product reclassification. The development of comprehensive guidance documents and public consultations can ease compliance and minimize uncertainty for companies, especially smaller players.

Cluster Solutions for agriculture

**2.3. New genomic techniques (NGT) – Augment ambition to match scientific progress**

**Concerned legislation:** Ongoing negotiation of Regulation on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

**Issue:** The Commission concluded that there are strong indications that the current Union GMO (genetically modified organism) legislation is not fit to regulate NGT (new genome techniques) plants obtained by targeted mutagenesis or cisgenesis, and products (including food and feed) derived from them and that that legislation needs to be adapted to scientific and technical progress in this area. The Commission has therefore adopted in 2023 a proposal for Regulation on plants obtained

by certain new genomic techniques and their food and feed, in response to the challenges presented in its study.

**Main challenges:** As presented, the proposed Regulation is a step in the right direction (in that NGT plants that meet certain criteria would be treated like conventional plants and exempted from the requirements of the GMO legislation), but more future adaptations of the legislation are needed to enable the full potential of this technology for agriculture. The current proposal is limited to very few, specific techniques only, and due to its precautionary approach risks being outdated by the time all implementing and secondary legislation is in place. In addition, an adequate IP protection of innovations based on NGT technologies must be maintained.

**Impact:** The application of disproportionate regulatory oversight to NGTs is not conducive to the development of innovative products that are potentially beneficial for breeders, farmers, food business operators, consumers and the environment. These problems affect numerous operators across the agri-food system, especially breeders, the agricultural biotechnology innovation and research sector, farmers, biobased industry and consumers, traders and national authorities. In addition, outside the Union, various third countries have already taken measures on NGTs, adapting the degree of regulatory oversight to the specific nature of NGT plants and products made from them. The Union risks being excluded to a significant extent from the technological developments and economic, social and environmental benefits that these new technologies can potentially generate, if its regulatory framework is not adapted to NGTs. In turn, this would lead to less strategic autonomy for the Union.

**Change recommended:**

(1) The current IP system for protecting innovative plant traits should apply to NGTs in the same way as it does for any other technical innovation. The European Parliament's suggested new Art. 4a that foresees exclusion from patentability of NGT plants, plant material, arts thereof, genetic information and the process features they contain shall not be patentable is unacceptable. As with any research-intensive activity, NGT traits will mostly be developed in countries benefiting from a strong IP framework. Some NGT traits will emerge without patents but the plants which need the most scientific research will not arrive in Europe, for example, gene editions for breakthrough traits that will specifically tackle the problems of European farmers, like standing up to droughts and new pests. This, in turn, will impact European farmers as they become significantly less competitive to farmers from countries which do foster innovative NGTs.

(2) A future-proof regulation for NGT plants requires a flexible regulatory approach including provisions to consider future innovations as in other advanced regulatory frameworks. The system should not be tied to the use of specific techniques as suggested in Art. 3(2) since they continue to evolve more rapidly than policy. Rather, focusing on the characteristics of the new plants is an opportunity to realign regulatory frameworks with sound risk analysis principles, considering a tiered approach and case-by-case evaluation. Science is advancing rapidly; therefore, regulatory frameworks need periodic reviews and regular adaptations considering scientific and technological progress. The Union's regulatory framework should be adapted to make NGTs subject to the appropriate regulatory oversight. This includes provisions to adjust the NGT legislation considering continuously evolving scientific and technological advancements in plant breeding. The legislation and especially the "equivalence criteria" need to be kept up to date.

(3) A more appropriate criterion for establishing equivalence with conventional plants is the absence of foreign DNA. The current proposal of a limit of 20 modifications as laid out in Annex I (1) is more restrictive than that of most third countries. This would restrict for example the developments of resistance and tolerance to abiotic stresses (e.g. droughts) traits, which are complex and impacted by many genes.

(4) The proposed verification process to establish equivalence with conventional plants conducted by national authorities as proposed by the Commission, will cut red tape and significantly reduce costs of commercialisation of NGT plants. The proposal however leaves the system open to potentially be misused. One comment submitted by a Member State or the Commission during the verification process as set out in Art. 6 (7) risks prolonging and politicising the process and increases uncertainty and costs.

### Cluster Sustainability

#### **2.4. EU Deforestation Regulation – Burdensome rules**

**Concerned legislation:** EU Deforestation Regulation (EUDR) 2021/0366 (file is open gain)

**Issue:** The EUDR aims to reduce the EU's impact on global deforestation and forest degradation by promoting the consumption of deforestation-free products. However, the implementation is posing major problems – for both competent authorities and economic operators. The additional 12-month phase-in period is urgently needed to help companies and authorities to prepare adequately. Industry from various sectors has warned of this challenge from the beginning.

#### **Main challenges:**

(1) Without a country benchmarking system and the resulting automatic categorisation as standard risk countries (*cf.* Article 29, EUDR), companies in countries that would actually be classified as low-risk (such as Germany) are burdened with considerable additional reporting obligations.

(2) There is ambiguity regarding the documentation required to prove compliance with the legislations of producing countries, as stipulated in Article 9. This extends to wide requirements for geolocation data, compliance proof and segregated commodity flows, which impose a significant economic burden on both external producers and smallholders in origin countries. Additionally, achieving EUDR compliance requires a considerable data infrastructure for multiple actors along the value chains, oftentimes resulting in reliance on different solution providers and further obstacles to efficient data sharing along the value chain (always provided that suppliers are willing to share data in the first place).

(3) The EUDR does not contain clear rules for in-scope intermediate products, which were produced from out-of-scope commodities. Intermediate products are common in the chemical and pharmaceutical production and are not intended to be placed on the market but used for an intercompany production of products out of scope of the EUDR. Any regulation of intermediates should be excluded from the EUDR.

(4) Obligations within the EUDR cannot be fulfilled or lead to bureaucratic burden in cases of:

- intercompany transfer of in-scope commodities or products,
- shipment of samples from in-scope commodities,
- distribution of flyers or advertising materials.

(5) According the EUDR there is no possibility to exchange reusable wood packaging (pallets) between different locations/legal entities within one company, to return them as a deposit or to transport them for reconditioning, repair or recycling. As pallets in connection with a product does not subject to the EUDR, such packaging does not have any due diligence statements. Moreover, pallets are standardised transport packaging and has no labelling of its origin. Reusable packaging actively contributes to a circular economy in the EU and should not be bureaucratically burdened.

**Impact:** Without a revision (not extension) of Annex I, a level playing field is not guaranteed, which would lead to increased transportation and logistics costs and exclude small farmers and trading partners from the supply chain. In addition, the EUDR leads to a (oftentimes) non-efficient reorganization of internal and external processes for EU-based companies (e.g., to achieve transparency, supplier relations need to be adjusted, and the inclusion of intercompany transactions further reduces supply chain and sourcing resilience). As the EUDR rules are often impractical and bureaucratic, some companies are likely to switch to fossil commodities, which is not in the sense of the industrial transition!

**Policy recommendation:**

- (1) The EUDR should become as practicable as possible to increase the use of sustainable biogenic resources.
- (2) Reduction of administrative burden for traders is essential. Traders along the value chain should be excluded from the requirements of the EUDR as the initial operator has already provided the required documentation.
- (3) The handling of continuous treatment processes or process-related mixing should be reduced to data reporting for processes within the last month and/or mass balancing should be permitted.
- (4) Practicable rules should be established: Products for own use within a company (even at different locations) should be excluded from the scope. The transportation of empty transport packaging of any kind within a company (also at different locations) should be excluded from the scope of application. Any regulation of intermediates, any shipment of samples from in-scope – commodities, any distribution of flyers or advertising materials should be excluded from the EUDR.

### **(3) UPCOMING REVISIONS**

#### Cluster Energy and Climate

##### **3.1. Emission Trading System (ETS) – Missing incentivisation of CCU**

**Concerned legislation:** Revised EU Emission Trading System (ETS) Directive; Carbon Removal Certification Framework (EU) 2024/3012; Implementing Regulation (EU) 2024/2493 on GHG Monitoring and Reporting, derived from ETS Directive; Delegated Regulation (EU) 2024/2620 (“CCU Delegated Act” based on Art. 12 (3) b EU-ETS Directive)

**Issue:** Moving away from a linear model and transitioning to a regenerative circular growth model is essential to keep resource consumption within planetary boundaries and is therefore one of the main key targets of the EU Green Deal. However, the EU ETS is causing obstacles to reach this ambitious climate target by not incentivizing the recycling of CO<sub>2</sub>, even though the scenarios show that the climate target cannot be met without such recycling. One of the ways to successfully recycle CO<sub>2</sub> is the technical process of Carbon Capture and Utilization (CCU) – a procedure that is not incentivised in current existing EU legislation.

##### **Main challenges and impact:**

(1) CCU allows fossil resources to remain in the ground: The carbon which is needed as a raw material for the production of chemical products (e.g. plastics) is used from recycled CO<sub>2</sub> instead of virgin fossil fuel or gas. In other words: if we recycle CO<sub>2</sub>, then we do not need to extract fresh crude oil/natural gas for this amount of carbon, and this amount of carbon can thus remain in the ground. This CO<sub>2</sub> may arise from industrial processes (cement or waste incineration) that will occur even after full transformation, or can be captured from the air. Hence, CCU means CO<sub>2</sub>-recycling and is a contribution to climate protection.

While carbon used as material in chemicals is not priced, chemicals based on CCU have to bear the higher cost of CO<sub>2</sub>-priced carbon. This puts CCU at a disadvantage compared to CCS (carbon capture + storage).

(2) The current wording of Article 12 (3 b) inhibits the promotion of CCU products produced by the chemical industry via CO<sub>2</sub>-recycling. This is because the installation producing and capturing CO<sub>2</sub> – without emitting it, and then selling it to another installation that produces the CCU product, has to surrender ETS allowances for the captured CO<sub>2</sub>. The reason for this mandatory payment is that we currently have no equal legal treatment of CCU and CCS. The CO<sub>2</sub>-pricing of the CO<sub>2</sub> that is temporarily bound in the CCU product (e.g. a plastic) has to be the waste incineration plant. Therefore, the change of Article 12 (3b) has to be done together with the full integration of municipal waste incineration into ETS. Currently, municipal waste incineration is only monitoring and reporting their emission, but not surrendering allowances for it – in other words, not paying for it. Any change in this legislation is currently only foreseen from 2028 on. The pricing at the waste incineration then triggers carbon capture at this installation which subsequently captures the CO<sub>2</sub>, which then can be further used by other market participants, e.g. the chemical industry.

Furthermore, the biogenic share in waste leads to negative emissions. In the future, tradable negative emissions certificates will create business models. If integrated into the EU ETS, this could also help mitigate the certificate shortage anticipated in the EU ETS by the late 2030s.

##### **Change recommended:**

- Recognition of CCU in **EU-ETS Directive** (equal to CCS): In Article 12(3)b delete "in such a way that they have become permanently chemically bound in a product so that they do not enter

the atmosphere under normal use, including any normal activity taking place after the end of life of the product.” This change should be inserted when ETS is being revised in July 2026.

- Equally in the EU-ETS Directive: inclusion of municipal waste by deleting the term “municipal” in both Annex I, paragraph 5 (5) and the table / activities column (and therefore deleting this exemption)
- The Delegated Act deriving from Art. 12(3)b (**Delegated Regulation (EU) 2024/2620**) equally needs to be amended: Currently, only industrially produced CO<sub>2</sub> volumes processed into durable CCU products (e.g., carbonates for the construction sector) are exempt from the certificate surrender obligation. CCU fuels must and should continue to be priced under EU ETS I and not under the transport sector/ ETS II. CCU must not be subject to double pricing. Therefore, a distinction between CCU materials (e.g., polymers) and CCU fuels is necessary. This Delegated Act therefore needs to link ETS pricing to the obligation of energy taxes. This provides a clear distinction between CCU materials (polymers) and CCU fuels: products that are not fuels are not subject to energy taxes. To avoid double pricing of carbon (which would occur if one prices both municipal waste incineration and the generation of CCU materials), this serves as a suitable differentiation factor between CCU materials and CCU fuels.
- Under this approach, CCU materials would be priced at the end of their lifecycle during waste incineration, thus closing the circular economy loop.
- Linking the **Framework on Carbon Removals** with the EU-ETS is key to bring this missing link for a European circular economy to success: Emissions captured within the boundaries of the ETS-installation, and which have undergone the verification process in a recognized certification scheme (Article 1, 1(b), and Article 13 of CFRR) should be eligible for deduction from the compliance of EUAs of the respective ETS-installation
- Change of wording in Art. 49 of **Implementing Regulation (EU) 2024/2493** on GHG Monitoring and Reporting, derived from ETS Directive: CO<sub>2</sub> volumes that are created but subsequently captured and incorporated into products should no longer require EU ETS certificates. This has already been the case for CCS since 2013: CO<sub>2</sub> volumes from ETS installations that are captured and geologically stored do not require the ETS installation operator to surrender certificates. Thus, CCS and CCU would be treated equally.

### 3.2. ETS – Revise Market Stability Reserve (MSR) as obstacle

**Concerned legislation:** Revised EU Emission Trading System (ETS) Directive

**Issue:** The Market Stability Reserve (MSR) is a main feature of the EU ETS and began operating in January 2019. The reserve is supposed to address the current surplus of allowances and to improve the system's resilience to major shocks by adjusting the supply of allowances to be auctioned. However, MSR has – from a certain standpoint – shown to be unnecessary and counter-productive.

**Main challenges:** The MSR leads to rising EUA (ETS allowances) prices by a mechanism to reduce the auction volumes of EU ETS allowances and by a mechanism to delete them. This aggravates the problem of a non-liquid EUA market post-2040. A deletion of Article 1 (5) phrase 3 would at least delete the enacted doubling of the intake-rate until 2030 of the MSR and as such help to reduce the effect of the MSR.

**Change recommended:** Deletion of Article 1 (5) phrase 3, as part of the 2026 revision

### 3.3. ETS – Exaggerated auditing related to energy efficiency

**Concerned legislation:** Revised EU Emission Trading System (ETS) and link to revised Energy Efficiency Directive (EED) EU/2023/1791)

**Issue:** Energy efficiency is high on the political agenda. Therefore, the EED requires certain industrial plants to undergo audits. As part of these audits, numerous recommendations for making their facilities more efficient are made to the companies. In the latest revision of the ETS Directive, the worst-performing companies are penalized by reducing their free allocation, if they do not implement these recommendations.

**Main challenges:** Audit obligations are simply not needed because the objective of energy efficiency is inherently part of the ETS system, as strict performance benchmarks force less efficient companies to buy more allowances on the market for compliance.

**Impact:** The parallelism and mix of policy tools create unnecessary duplication of efforts and lead to pointless bureaucracy. In some cases, energy efficiency conditionalities could even hinder companies' efforts to reduce greenhouse gas (GHG) emissions as new technologies often require increased energy inputs; i.e. decarbonisation often means electrification. Hence, efforts in decarbonisation may lead to more electricity consumption.

**Change recommended:** Cancellation of the following conditionalities: the climate neutrality plan and energy efficiency obligations in Art. 10a of the ETS Directive. As part of the 2026 ETS revision

### 3.4. ETS – Making International Certificates usable to avoid shortage in the system

**Concerned legislation:** EU Climate Law and Emission Trading System (ETS)

**Issue:** Article 6 of the Paris Agreement provides for international certificates. At COP 29, significant agreements were reached on this topic. In the past (until the middle of the 3rd trading period), international certificates could be used in the EU ETS to meet surrender obligations.

**Main challenges:** In the interest of global cost efficiency, these new international certificates should also be usable for surrender obligations. For this to happen, not only the EU ETS Directive but also the EU Climate Law must be amended.

**Change recommended:**

- EU ETS Directive: add new article(s) that allow the use of international certificates.
- EU Climate Law: amend Art. 1 to allow the use of international certificates

### 3.5. ETS – Avoiding Carbon Leakage by implementing a “safety net”

**Concerned legislation:** EU Climate Law and Emission Trading System (ETS)

**Issue:** The EU Emission Trading System (ETS) currently foresees a phase-out of free certificates (i.e. net-zero) by 2039 already.

**Main challenge:** This ambition can only materialise if the price conditions and the availability of low-carbon energy and infrastructure respond to the needs and demand of the sector.

**Change recommended:**

A regular monitoring must evaluate if the increasing gap between ideal scenarios – as established by the Fit-for-55-Package – and market realities can be closed. If not, corrective measures must be taken before the end of the 2024-29 term in the form of an ETS “safety net” by adjusting the quantity of certificates and free certificates. The ETS revision in 2026 should serve this purpose.

### 3.6. CBAM – Complex and ineffective architecture

**Concerned legislation:** CBAM (Carbon Border Adjustment Mechanism) Regulation (EU) 2023/956 in relation the EU Emissions Trading System (ETS)

**Issue:**

(1) CBAM is the EU's tool to put a price on the carbon emitted during the production of carbon intensive goods ('embedded' carbon) that are entering the EU so as to ensure the carbon cost of imports is equivalent to the carbon cost of domestic production. The Regulation also aims at stimulating equivalent climate policy efforts outside of the EU and thereby create a level-playing between EU and non-EU producers. The gradual introduction of the CBAM is goes hand in hand with the phase-out of the allocation of Free Allowances under the ETS.

(2) The current goods covered and the related greenhouse gas emissions are cement, iron and steel, aluminium, ammonia, fertilizers, hydrogen and electricity. A targeted expansion to organic chemicals and polymers will be examined in a report in 2025. At the same time, the aim is to transfer all ETS sectors to the CBAM by 2030. A large majority of the sector is opposed to such an extension, given the high complexity of chemical value chains.

(3) The ETS has proven to be a smart tool for reducing emissions at acceptable societal cost. In addition, effective carbon leakage prevention – the intention of CBAM – is crucial for the industry's transition. However, CBAM requires substantial enhancements to effectively meet its objectives, indeed, a major revision is required – also in view of a possible extended scope in the future.

**Main challenges:**

(1) Only basic goods are covered by CBAM. Downstream products such as derivatives of ammonia and hydrogen – originating from the EU – will carry the full EU carbon cost thus losing their carbon leakage provision while downstream products imported into the EU will not carry the equivalent carbon cost and will thus have an undesired competitive advantage in the EU. For a CBAM to work effectively, negative effects along the value chain must be omitted in order to avoid circumvention possibilities, causing carbon leakage.

(2) Moreover, exports of EU goods covered by CBAM are also losing free allowances and thus competitiveness and market shares while no alternative carbon leakage provision has been established to address export competitiveness.

(3) The administration of the CBAM system is – by its nature – highly cumbersome and authorities have failed so far to provide sufficient guidance and support. The data requirements are extremely broad and almost impossible to fulfil, especially for products based on global value chains. To just take the example of products suppliers (from third countries): They are hesitant to agree that their personal data is captured in the CBAM registry. Often they are not able or willing to provide the information on emissions or do not understand the format of the Excel collection tool (which far too complicated).

(4) Ammonia is a high-volume basic chemical, notably as a basis for nitrogen fertilizers, key to food production, but is also used as starting material for the manufacture of numerous chemical and even medicinal products. The intention of policymakers is to avoid carbon leakage of ammonia production linked to the manufacturing of fertilizers, neglecting the impact of CBAM on ammonia as a feedstock for chemical value chains, i.e. significantly augmenting the price level for downstream uses while these uses do not require carbon leakage protection.

**Change recommended:**

CBAM will be revised in 2026:

(1) Need for a general revision of CBAM: The EU offers an attempt to level the global playing field, yet the current proposed CBAM mechanism still does not cover 3 key issues highlighted by the chemical industry to effectively prevent carbon leakage:

- Negative effects along the value chain to be omitted
- Export competitiveness to be addressed
- Mechanism (administrative burden) must be feasible, effective and efficient; de minimis thresholds have to be raised significantly and the use of default values has to be extended significantly as well

Before inclusion of other chemicals with their complex processes and value chains can be considered, we need to jointly develop effective solutions addressing the export competitiveness gap, reducing negative effects on downstream parts of value chains, and efficient functioning.

(2) Lowering of the CSCF (Article 10 ETS Directive: the share of allowances to be auctioned shall be 57%), exemption of non-CBAM-protectable sectors (like chemicals) from the CSCF (as addition to Article 10 ETS). If in total all ETS installation apply for more EUA than the Commission allocates to budget of free of charge free allowances, the cross sectoral correction factor (CSCF) occurs for every application on free allowances. The option of a CSCF is necessary for the Commission, as the budget of free certificates is restricted to 57% of the total volume of allowances (the so called “cap”). We suggest exempting CBAM-Products from the CSCF – in case the CSCF occurs - in the next allocation period (2026-2030).

### 3.7. Electricity market design (EMD) – No bidding zone review

**Concerned legislation:** Electricity market design (EMD)

**Issue:** In order to achieve the Renewable Energies target set out in the RED III and secure green and affordable energy for the chemical industry, large volumes of investments needs to be made. In order to invest, investors need planning security.

**Main challenge:** As a follow-up to the Electricity Market Design dossier, ACER is currently reviewing the European electricity bidding zones. However, a split of the uniform bidding zone of Germany and Luxembourg would lead to significant planning uncertainty, thus preventing urgently needed investments in renewable generation.

**Change recommended:** The Commission should oppose restructuring the current uniform bidding zone of Germany and Luxembourg in the upcoming review.

## (4) REAL OMNIBUS

### Cluster Chemicals

#### 4.1. CLP – Short label update deadlines in revised legislation

**Concerned legislation/policies:** Revised CLP Regulation (Classification, labelling, packaging) 1272/2008

**Issue:** Under the revised CLP regulation, the update requirements for labels have been changed to a period of six months in Article 30 in cases where substances or mixtures need to be assigned a new hazard class or a more severe classification, or if new supplementary information is required on the label.

**Main challenges:** This timeline is too short, in particular for complex value chains that involve several mixture formulators downstream, and inconsistent with current practices which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages.

**Change recommended:** Consistent with current rules, we recommend that the timeline for all label updates should be 18 months. This is also the usual timeline for ATPs when CLH becomes mandatory for specific substances including when new classification of substance(s) are more severe. Article 30 of the CLP Regulation should thus be changed to allow 18 months for the re-printing of all labels for each value chain stakeholder.

#### 4.2. CLP – New Advertisement rules in revised legislation

**Concerned legislation/policies:** Revised CLP Regulation (Classification, labelling, packaging)

**Issue:** Under the revised CLP regulation, the rules under Article 48 stipulate that advertisements for a mixture classified as hazardous or covered by Article 25(6) “shall indicate the hazard pictograms, signal words, hazard statements and supplemental EUH statements set out in Annex II. “

Any advertisement for such a mixture for sale to the general public shall, in addition, state: “Always follow the information on the product label.”

**Main challenges:** Under the previous CLP text, hazard information for advertisements for mixtures only had to be communicated where a contract for purchase could be concluded without having sight of the label. The new rules will mandate the full communication of hazard information for all advertisements, including supermarket leaflets, TV and radio commercials and social media advertisements, including advertisements as short as 3 seconds.

**Impact:** These rules are an unnecessary burden for industry and in fact counterproductive for sustainability efforts:

- The detergents and home care sector has a well-established safe use record and low incident rates, all of which do not suggest that intensified hazard communication is needed.
- More highly concentrated products such as laundry detergents will be overly discriminated because they may have a more severe CLP classification although in fact the product is more sustainable than its non-compacted competition.
- Product categories being regulated under CLP (such as detergents) will be discriminated against non-CLP regulated categories (such as cosmetics) because the quantity of hazard phrases could make detergent products less attractive, for instance on supermarket leaflets.

- The sheer implementation of these new rules will be next to impossible for cases such as very short and fast-paced social media clips, which don't allow for the inclusion of such complex information in such a short-form clip.

**Change recommended:** Reintroduce the text of the previous version of Article 48 CLP (which was targeted at a clear scenario, i.e. the intended purchase of the product in a case where the consumer could not visualise the label and the respective hazard information.)

#### Cluster Circularity

#### 4.3. **ESPR – Chemicals regulation via the backdoor**

**Concerned legislation:** Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products (ESPR), amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC

**Issues:** Within the ESPR's final legislative text, the definition of substances of concern in Article 2(27)a-d includes substances classified as SVHC, certain substances classified under CLP Annex VI, and substances regulated under the POPs Regulation. These substances are primarily relevant to health and safety (which should be regulated by REACH instead), including the CLP classes pertaining to water toxicity 1-4 and specific target organ toxicity. In addition, in the Article 2(27), the text proposed that substances are considered a substance of concern (SoC) if they “negatively affect” (rather than the preferred terminology ‘impede’) the re-use and recycling of materials in the product in which they are present.

The issue arises through the broad definition of SoCs which will be relevant for information and performance requirement within the different delegated and implementing acts for each product (group). In addition, the current provisions then require the entirety of the SoCs to be tracked in the Digital Product Passport (DPP) by default throughout the entire life cycle of the products, instead of just the SoCs present in the end product. This will create significant burdens along the value chain.

#### **Main challenges:**

(1) The text creates many screening and disclosure obligations which are difficult to fulfil and are partly contradicting. For example, economic actors must disclose SoCs when they are present in the manufacturing process, as opposed to the end product. It also requires disclosure of SoCs at the waste stage. This creates significant administrative burden, as operators will have to disclose substances used in various manufacturing processes.

(2) In addition, the text proposes that performance requirements (based on the product parameter set out in Annex I, point (f)) shall not restrict the presence of substances in products for reasons relating primarily to chemical safety. However, the establishment of performance requirements shall also, where appropriate, reduce significant risks to human health or the environment. This reaffirms the REACH via backdoor scenario, whereby many definitions aimed at restricting substances that should be regulated within REACH are cropping up in product related legislations (including in ESPR but also PPWR, Green Claims, Waste Framework Directive, Detergents Regulation).

**Impact:** ESPR creates a parallel track to REACH, resulting in duplication and legal unclarity. From a practical point of view, given the chemicals value chain's complexity and the sheer amount of chemicals classified in the listed hazard classes (around 4000), these requirements pose significant tracking and tracing challenges, and unnecessary administrative burden.

#### **Change recommended:**

Via amending the legal text:

- Article 2(27) definition of substances of concern should limit restricting substances based on their relevance to circularity only. Therefore, all references to hazard classes which are primarily relevant to health and safety should be omitted. This article should also omit vague terminology in the sense that permits ESPR to restrict substances based on whether they make reuse or recycling 'complicated', 'costly', or whether they 'negatively impact' reuse or recycling. Negatively impact should be replaced with 'impede';
- Article 5(14)c is highly subjective and should be omitted, as olfactory properties are bound to be different in recycled materials than virgin materials;
- Article 6 should omit reference to establishment of performance requirements to reduce significant risks to human health or the environment, as this is REACH-via-the-backdoor.
- Annex I should remove any reference to performance requirements being linked to reduction of risks to human health or the environment;
- Annex I should also omit reference to ESPR being allowed to restrict substances relevant to circularity present in manufacturing process, and rather should focus on substances present in an end product that may impede circularity, thus taking a more holistic approach;
- Recital 31 should change the wording "included by default" to "included where relevant".
- Article 18(5) should not reference chemicals, to ensure polymers or chemicals do not fall, as product categories, under the ESPR.

#### 4.4. **Transport Packaging in PPWR – Impossible objectives**

**Concerned legislation/policies:** Packaging and Packaging Waste Regulation (PPWR)

**Issue:** The revision of the PPWR seeks to foster a European circular economy by making all packaging reusable or recyclable by 2030. Article 29 of the final text proposes targets for the reuse of transport packaging of 40% for 2030 and 70% for 2040. However, from 2030 onwards, these obligations are to apply to 100% of the packaging intended to deliver products to another operator within the same Member State, as well as to products intended to be delivered between any site on which the economic operator performs its activity within the EU. This is to apply to pallets, foldable plastic boxes, trays, plastic crates, immediate bulk containers, pails, drums, canisters, as well as flexible formats and pallet wrappings and straps for stabilization.

**Main challenges:**

(1) Beyond the physical impossibility to reuse stretch films, the reuse rates for transport packaging between (chemical manufacturing) sites could pose a significant threat to human and environmental safety, as they often are in contact with hazardous substances. For most companies, the most effective transport packaging system is already in place, including highly functioning reuse and recycling systems where these make sense.

(2) Neither the reuse rates for transport packaging of the initial Commission proposal, nor the significantly higher targets of the inter-institutional agreement have been subject to an appropriate impact assessment. It has not been assessed to what extent mandatory targets could contribute to the reduction of the impact of packaging on the environment.

(3) Rather, these targets are bound to create a discrimination within the EU single market (mandatory targets for packaging transported within a Member State), health and safety hazards, as well as an increased environmental footprint linked to the transport of said packaging.

**Impact:** Not technically possible to reuse these pallet wrappings and strapping bands for the same purpose. They are therefore recycled in practice and form an important basis for fulfilling the current recycling targets and future recycled content quotas. Another problem is the extension of the reuse quotas to "sales packaging for the transport of products" provided for in the compromise. The extension of the reuse quotas to "sales packaging for the transport of products" dilutes the sensible and proven distinction between sales and transport packaging and leaves it unclear which packaging formats are meant. Risk of not complying with the requirements of PPWR due impossible and impractical obligations. Further, reuse quotes linked to transport between companies within a Member State and between company locations are concerning due the fact that packaging quantities reported by companies are to be published by the Member States (Art. 31(6)), as this allows details conclusions to be drawn about the business activities of individual companies.

**Legal change recommended:**

In addition to a delegated act to exempt pallet wrappings and stretch film from reuse quotas (see section (1)), a detailed impact assessment on the de facto 100% reuse quotas for transport packaging should be launched. A revisit of said target should be considered by amending the text.

#### 4.5. **PPWR – Avoid unfair treatment of Biobased Materials**

**Concerned legislation:** Packaging and Packaging Waste Regulation (PPWR)

**Issue:** The legislation could create competing markets between biobased materials and recycled content by allowing both materials to contribute to the same recycled content targets for plastic packaging.

**Main challenges:** The current Packaging and Packaging Waste Regulation sets targets for recycled content in plastic packaging via Article 7. The current text states that three years after entry into force, the Commission should present a report on the state of play of biobased feedstock which can be accompanied by a legislative proposal to allow for these recycled content targets to be met with biobased feedstock (Article 8). However, the option of potentially meeting recycle usage quotas for plastic packaging with bio-based raw materials can lead to market competition between the two raw materials and co-existing technologies. Every option is necessary for the industry to meet both the net zero and circularity objectives under the EU Green Deal. Recycled content and biobased feedstock both have an equally important but distinctly individual role to play thereby encouraging existing technologies, but also innovative ones.

**Impact:** An unfair competition would have the effect of further weakening both markets, which are currently still emerging as alternatives to fossil-based feedstocks. Instead, separate quotas should be created in order to avoid negative impacts on both markets.

**Change recommended:** Article 8(2)(c) should be deleted entirely.

### Cluster Hydrogen

#### 4.6. **RED III (three): Rigid Green Hydrogen Rules**

**Concerned legislation:** Renewable Energy Directive (RED III)

**Issue:** Hydrogen plays an essential role in chemical production, both as a raw feedstock and as a fuel. Chemical processes require an immense demand for hydrogen already exclusively for feedstock/material use (e.g. German chemical industry demand for hydrogen is 1.1 million t/a). Most of this demand arises intrinsically (mainly for ammonia production) and as a byproduct in other

processes (e.g. chlorine alkali electrolysis). These quantities cannot be directly substituted with green hydrogen.

**Main challenges:**

(1) The new 42% RFNBO target from REDIII must be seen in this light. This is a very ambitious target for the chemical industry, especially as most feedstock use is part of highly integrated industrial processes and cannot be substituted by electrolysis based RFNBO.

(2) One must acknowledge on top that there will not be enough RFNBO available in the foreseeable future, nor can it be offered at competitive prices. The use of RFNBO is also being promoted in the RED and other regulations such as the ReFuel Aviation and FuelEU Maritime for the various transport sectors. This further creates competition for a very scarce and expensive good between industries with widely differing price sensitivities.

(3) Green hydrogen (RFNBO) is not expected to be cost-competitive, at least not in the near term. Industries exposed to international competition will be challenged with the additional costs deriving from the mandated use of green hydrogen in production processes. As also acknowledged by the European Commission, an early uptake of green hydrogen would have to be accompanied by supporting measures for industry, as part of an overarching industrial policy.

**Change recommended:**

(1) In order to strengthen the role of low carbon hydrogen in the market ramp-up and to make the quota realistically achievable, low carbon hydrogen should be excluded from the calculation of the quota's denominator by adding "low carbon hydrogen" in a new Art. 22 a) iv). This would give the member states more flexibility in achieving the targets and promote a technology-neutral approach.

(2) Another simple and pragmatic approach to the problem is to slightly adjust the very ambitious targets by specifying new percentages in Article 22a of the directive. We propose realistic alternatives of 30% by 2030 based on the German Hydrogen Council's recommendation. If the adjustment of the targets is considered too far-reaching, at least a review clause must be included in the same article: in 2025, the targets and reality should be compared through an honest assessment, and the quotas adjusted based on this impact assessment.

Further policy changes in Article 22a of the RED III are recommended to make achieving the targets more feasible:

(3) Extend the granted derogations for RED III Art. 22a RFNBO quota also to co-products: To make the RED III Art. 22a RFNBO industry quota more feasible, the derogations granted in Art. 22a (1) should be extended from by-product H2 to "by-product and co-product" H2.

Equally implemented in Art. 22a should be the commitment for the Commission to provide a framework for supporting the up-take of RFNBO in industry at Union level, in conjunction with the possibility for national level support. This framework should: contribute to the achievement of the industry target for RFNBO consumption on Member State level; be compatible with the principles of the internal market; take into account geographical differences in the production cost of RFNBO.

Cluster Environment policies

**4.7. IED – Burdensome Environmental Management Systems and performance values**

**Concerned legislation/policies:** Industrial Emissions Directive (IED)

**Issue:** The revised IED includes a binding Environmental Management System (EMS, Article 14a) with a chemical inventory as well as binding environmental performance level values (EPLV) for energy,

waste generation and water (Article 15). Companies should implement an EMS for each installation and audit it regularly. Under the new IED, the EMS would be binding and would become an integral part of the permits requirements as any other Best Available Technique conclusions in BREFs (BAT Reference documents). Although EMS exist already at the sites level according to ISO requirements, they would have to be revised entirely due to new EMAS driven requirements. For this reason, SMEs in particular will have to cope with additional administrative burden, engage new EMAS certification, especially because they often do not have a certified EMS.

**Main challenges:**

(1) As the new EMS becomes binding, it becomes de facto a permit pre-requisite. This could delay the permitting process if the timescale of obtaining a certified EMS would not be decoupled from the obtention of a permit for new installation, or, even worse, if an audited EMS with findings could lead to a permit suspension until findings are lifted.

(2) These changes under the IED mean a considerable amount of extra work and additional bureaucracy for operators of industrial plants. Approval procedures will be considerably longer.

**Impact:** As the new EMS becomes binding, it becomes de facto a permit pre-requisite and will impact 6000 industrial sites across the EU. This could delay the permitting process (extension from 1 year to almost 2 years) or, even worse, if an audited EMS with findings could lead to a permit suspension until findings are lifted.

**Change recommended:**

With regard to Art. 14a the following legal changes are needed:

- Companies that have already an EMS for their sites (e.g. an EMS according to ISO 14001, energy management system according to ISO 50001 or EMAS) should be able to use the documentation as far as possible to prove the requirements of the IED EMS.
- The matrix certification established in practice with recertification audits every three years should be taken into account in EMS auditing in accordance with the IED. It must be possible for companies to harmonize their audit cycles, for example according to ISO 14001 and the IED, by means of sufficient implementation regulations (see below).
- The provision on inclusion of the chemical inventory into EMS should ideally be deleted. Existing EU legislation (mainly REACH) is providing a pertinent risk assessment for chemicals so that a further chemicals inventory is only creating additional reporting. Or second best: Limit the chemicals inventory to “Substances of Very High Concerns” (SVHCs) instead of “hazardous substances”.

With regard to Art. 15 the following requirements should be changed:

- When implementing the bandwidths for environmental performance, realistic bandwidths, that vary from one industrial installation to another should be selected. It is important to consider individual performance of every industrial installation.
- The requirement to prove the lowest achievable emissions will increase the permitting process complexity and duration. Changes to existing installations need a simple process to apply for derogation.
- Environmental performance values in accordance with Art. 15 Para. 3a, which are specified to operators in the form of “binding ranges”, must relate to very specific installations/parts of installations. In individual categories of environmental performance values (e.g. for water or energy consumption, but also for the use of raw materials), ranges can also only apply to certain product categories or manufacturing processes. This should be taken into account

in the plant-specific (BAT) administrative provisions, also from the point of view of proportionality. Upcoming BREFs will be critical.

- Mandatory ranges for environmental performance as regard to article 15(4) should be non-binding. Representing limit values as ranges is not legally systematic and will come with numerous questions. It is unclear what legal consequences will arise if the values are exceeded or not met.
- In order to avoid setting in motion an excessive regulatory and monitoring process for the authorities and operators, a very cautious and measured approach should be taken here. This is another reason why it is necessary to involve the affected sectors at an early stage when setting the environmental performance values.

With regard to Art. 27d the following legal changes are needed:

- Remove the provisions concerning the transformation plan to eliminate additional reporting requirements. Since the application of Deep Transformation and the development of INCITE already provide incentives for decarbonization and the circular economy, the transformation plan does not add value.

#### 4.8. AAQD – More time for new air quality targets for industrial sites

**Concerned legislation/policies:** Ambient Air Quality Directive (AAQD)

**Issue:** In the revised directive the EU sets strict targets for nitrous oxide (NO<sub>x</sub>) as well as for fine dust particles PM. In the proposal text, limit values instead of guidelines have been set for SO<sub>x</sub>, NO<sub>x</sub>, PM. However, it is not mentioned, that air quality is essentially based on the interaction of various sources and sectors. It also varies from day to day and season to season. Therefore, exceedances may occur in some cases. Still, these exceedances have become increasingly smaller over the years. This is also shown by analyses by the German Federal Environment Agency. In 2006, for example, around 55% of the measuring stations exceeded the dust value; today it is just under 1%. This means that a guideline value would be better in order to maintain a certain 'flexibility'.

**Main challenges:** In order to comply with new set values, all air pollution control plans must be revised and (massive) measures taken at the same time. Moreover, the timeframe set for achieving medium air quality standards (2030) is too tight. Extending the deadline to 2040 for achieving medium air quality standards allows the chemical industry more time for developing and implementing efficient pollution control technologies, ensuring thorough adjustment of air quality control plans.

**Impact:** The revision of air pollution control plans will need to be implemented, which will take many resources from local authorities. Increased requirements for detailed documentation and regular reporting on emissions and compliance measures will be burdensome. This involves substantial administrative effort and can divert resources from core business activities. Moreover, air quality limit exceedance may lead to a potential problem for expansions of industrial sites.

**Change recommended:** Industry requires more time to prepare for the new targets, therefore limit values in the Annex I for PM<sub>2,5</sub> and Nitrogen dioxide (NO<sub>2</sub>) should be set for 2040 instead of 2030.

#### 4.9. UWWTD – Quaternary treatment and extended producer responsibility

**Concerned legislation:** Directive concerning urban wastewater treatment (UWWTD; recast)

**Issue:** The final legislative text introduces quaternary treatment to be applied to treatment plants treating a load of over 150.000 population equivalent (p.e.), in some areas even 10.000 p.e. from 2033

on to eliminate micropollutants. The proposal also added the Article 9 on extended producer responsibility (“EPR”) for producers who place products listed in Annex III on the market, in its current version these are only pharmaceuticals and personal care products. This would require them to cover various costs unless the quantity of the products to be placed on the market is below one ton per year or do not generate micropollutants in wastewaters at the end of their life.

**Impact:**

(1) The financial burden of the quaternary treatment is substantially underestimated by the European Commission: in Germany alone, costs of €30 to 48 billion (!!!) will be incurred over 20 years (according to an analysis by VCI member companies). These high costs will be solely distributed among the pharmaceutical and cosmetic industries.

(2) Additionally, there is a lack of specifications on how the design of an EPR scheme in water law could look like in practice, and the implementation would require plenty of time and increased bureaucracy – linked with a significant lack of clarity and transparency. Furthermore, these additional costs will have negative impacts on providing medical care with generic drugs to the population.

(3) In the highly regulated pharmaceutical market, the planned EPR levy system will result in various drugs disappearing from the market. For cosmetic products the costs for consumers may raise significantly in cases, where certain substances defined here as micropollutants are needed for a specific function of a product. In no case will the optional national co-financing of up to 20% of the EPR costs be sufficient to circumvent this detrimental market dynamic.

**Change recommended:**

(1) In Art. 9 paragraph 1 a), the term "at least 80 %" should be improved to a more appropriate value, such as "maximum 80%". Additionally, operational costs should be removed from Article 9a. In practice, the quaternary treatment stage in a wastewater treatment plant will not be fully distinguishable from the rest of the operations in terms of operating costs. For clear cost separation—which is also legally required—only the investment costs but not the operational costs, should be covered by the EPR.

(2) In Art. 9 paragraph 2 a), the tonnage should be increased, for example, to 5 tons, in order to spare small manufacturers – usually these are SMEs -, who do not bring many of the affected products to market, from excessive bureaucratic effort.

(3) Furthermore, in the entire Art. 9, the term “substance” should be replaced by the term “micropollutants” in order to gain legal certainty and clarity in the implementation process.

Cluster Industrial policy

**4.10. NZIA – Widen the definitions in Net-Zero Industry Act**

**Concerned legislation:** Net-Zero Industry Act (NZIA)

**Issue:** The NZIA has extremely high ambitions and has been labelled the European response to the US Inflation Reduction Act. NZIA is supposed to strengthen the European manufacturing capacity of net-zero technologies and overcome barriers to scaling up the manufacturing capacity in Europe. The narrow scope of the legislation – reflecting a silo thinking – will not allow value chains to support the uptake of the technologies promoted in the NZIA.

**Main challenge:**

(1) The definition of net zero technologies (Article 3(1)b) now includes final products as well as specific components or machines that are mainly used for the production of these products. However, the materials (chemicals) required for this are disregarded. Most goods that are manufactured in Europe rely on enabling chemicals, needed for a wide range of functions. Chemicals are at the heart of Europe's major value chains (e.g. ultrapure water production), including wind turbines, solar panels, electronics, construction materials, automotive, and many more.

(2) Still, if materials (chemicals) would get included, another hurdle would remain in that sense that producers would have to prove that their products actually flow into a subsidized net-zero technology in order to receive funding. Such proof is extremely complex and burdensome to deliver and would only lead to partial funding, as it's not the entire new project/installation that would be in scope but only part of it i.e. part of the supply chain of a net-zero technology.

**Impact:** The fact that the chemical industry is not fully considered to be a part of the value chain will create a two-tier-economy across Europe and will hamper competitiveness among different industrial sectors. With the isolated focus on end products and components, the entire upstream value chain, including chemical precursors, cannot benefit directly from the new provisions and risks being left out in future funding opportunities referencing the NZIA. This is neglecting the existing interdependencies in the underlying value chains of these technologies. The picked winners labelled 'strategic' net-zero technologies, as well as their applications, are not standalone. They depend on multiple supplies from EU's upstream material flows and of complex manufacturing value chains.

In the worst case, the real value creation of manufacturing will take place outside of Europe, even risking further relocation effects, which in turn would remain dependent on foreign exports, with only the final products being assembled in Europe. Instead, also chemical production capacities in the EU need to grow to meet emerging demand and contribute to reducing emissions in other sectors in Europe (we need not only green electrons but also green molecules!). As a general rule, if European manufacturers are to meet at least 40 percent of the EU demand for "net-zero technologies" by 2030 then equally the chemical production capacities have to grow equally by 40 percent at least.

**Change recommended:**

Wording should be added following Article 3(1)a: "‘net-zero technologies’ means all technologies identified under Article 3a, which are final products, specific components, materials or specific machinery primarily used for the production of those products."

Wording in Art. 2 should be deleted: "This Regulation shall apply to energy intensive industry decarbonisation projects when those are part of the supply chain of a net-zero technology and reduce emission rates of CO<sub>2</sub>-eq of industrial processes significantly and permanently to an extent which is technically feasible, except for Articles 3c, 19, 20 and 21." Recital 9(a) should also be adapted accordingly.

Pharma and health

**4.11. European Health Data Space – Fix definition, electronic data derogations and IP**

**Concerned legislation:** European Health Data Space, Regulation COM(2022)197

**Issue:**

- Vague definitions (e.g. ‘non-personal electronic health data’, ‘health data holder’) will lead to inconsistent interpretation of what and who the EHDS applies to.
- The ambiguous minimum categories of electronic data for secondary use will generate unprecedented risks to the protection of personal data, IP and security of ICT systems.

- The opt-out scheme for secondary data use and public derogations will undermine the need to protect patient safety and avoid health data biases and disparities in other scientific research contexts.
- The weak rules on IP governance do not provide the same level of protection and control for rights holders as existing legal safeguards aimed at protecting scientific and technological potential.
- The technologically inaccurate rules on electronic health record (EHR) systems and products claiming interoperability with EHR systems will cause uncertainties about compliance obligations for manufacturers and healthcare providers. National derogations will lead to an increasingly fragmented legal landscape across the EU.

**Main challenges and impact:** The EHDS will set back health R&I in the EU, weaken the global competitiveness and resilience of the EU's health and life sciences sector, and disrupt European health ecosystems:

- The protection of IP rights is an essential incentive that compensates innovators in their trial-and-error efforts while attempting to advance health R&I over time. IP is crucial to protect scientific, technological, and business information where there is a legitimate interest in keeping them confidential (including from governmental bodies, such as health data access bodies).
- By removing adequate and effective control by data holders, the EHDS makes it easy to identify and scrape information about competitors' trade secrets and protected databases. This will damage the EU's health sector.
- The lack of safeguards will hinder access for patients and providers to state-of-the-art healthcare innovations in the EU.

Increased risks and uncertainty will drive up costs not only for researchers and innovators in the EU, but also for Member States that need to procure innovative healthcare solutions.

**Change recommended:**

- Clear definitions of terms like 'electronic health data', 'electronic health data holder' and 'electronic health record system'
- Amend Article 33a to signify that the health data holder should not be obliged to make available health data for secondary use in case of being under protection of intellectual property rights; would harm the data holder due to risks undermining its scientific or technological potential; or making it available would lead to an act of competition by the data user that is contrary to honest practices in industrial matters
- The opt-out mechanism should have a limited, but well-defined, consistent and transparent scope

Cluster Promoting Batteries

**4.12. Batteries – Insufficient interplay between different waste legislations**

**Concerned legislation:** EU Waste Framework Directive & List of Waste, and the EU Waste Shipment Regulation

**Issue:** Faster progress is needed to meet the EU resource-efficiency targets, ensure sustainable use of materials and enhance strategic autonomy, notably by increased recycling. Today, we see

however a missing interplay between the Waste Framework Directive and the EU Waste Shipment Regulation.

**Main challenges:**

(1) The current EU legislative framework, specifically the regulatory environment set by the EU Waste Framework Directive & List of Waste, and the EU Waste Shipment Regulation, does not yet provide sufficient guidance on the rules governing the classification and shipment of the materials in the battery recycling loop. It is – for instance – unclear whether the product or (hazardous) waste classification is applicable to end-of-life lithium-ion batteries as well as intermediates of recycling such as battery production waste and black mass.

(2) The views on the proper classification of these materials differ dramatically across EU Member States. Austria and some states in Germany, for instance, are currently classifying certain types of spent batteries as waste. Spain decided that lithium-ion batteries (LIB) should be considered as Amber list in the Basel Convention. Other Member States consider black mass as a product mix, product substance or waste, depending on oftentimes diverging criteria applied after pre-treatment. Moreover, as end-of-life lithium-ion batteries and intermediates of recycling do not fulfil the end-of-waste criteria laid out in Article 6 of the Waste Framework Directive, they cannot be classified as a “product” by companies in some Member States.

**Impact:** This lack of common interpretation (due to a failed policy integration at EU-level), causes extensive problems of circulation of goods and waste within the Single Market, and creates significant uncertainty for EU recyclers.

**Change recommended:**

The main changes needed are:

- (a) Inclusion of harmonized waste codes (“hazardous waste”) in the EU List of Waste for waste lithium-ion batteries, battery production waste and black mass;
- b) harmonization of shipment rules for hazardous waste as part of the revision of the Waste Shipment Regulation;
- c) establishment of a fast-track notification procedure for pre-consented recycling facilities as part of the revision of the Waste Shipment Regulation.

Such improvements could be effectively achieved via targeted amendments of the Waste Framework Directive and List of Waste Regulations:

- clarify that materials generated during the end-of-life lithium-ion battery recycling process, such as black mass and battery, module and cell waste, are strictly classified as “waste” and therefore cannot be considered as “product”;
- clarify that, based on the assessment of the chemical properties of their components, some of the materials such as black mass are classified as “hazardous waste”;
- include a specific absolute “hazardous waste” European Waste Codes (EWC) in the EU List of Waste for the black mass;
- when implemented, these regulatory solutions, aimed at clearly classifying waste lithium-ion batteries, battery production waste and black mass as “hazardous waste” as well as clarifying, harmonizing and enforcing their shipment rules, would help remove the grey areas and leave no room for dispute. This would ensure that the battery waste generated in Europe remains in Europe and that it is handled with full respect to high European EHS standards;

- to reduce unnecessary delays and the associated safety risks, we propose that the “hazardous waste” classification is accompanied by an accelerated (fast-track) notification procedure for pre-consented recycling facilities.

### Cluster Solutions for agricultural

#### **4.13. Crop protection – Highly difficult approval (including biopesticides)**

**Concerned legislation:** Regulation 1107/2009 on the placing of plant protection products on the market

**Issue:** For all innovative products: Currently timelines to approval and market (often far) exceed those prescribed in the legislation, leading to delays in getting new innovations to market. It takes up to 11 years for a single product to be processed through the regulatory system before finally arriving on the market. Even for new biological solutions, despite regulatory timelines prescribe approval timelines of 2.5 to 3.6 years, their approval takes anywhere from 5 to 10 years.

Following the CJEU ruling on cases C-308/22, 309/22 and 310/22, there is now increased uncertainty about the product approval process for new and existing crop protection products in EU Member States. The ruling opens the door for individual Member States to diverge from EU and zonal approval processes, causing greater Single Market fragmentation and potentially creating more inequality between Member States in terms of available crop protection products for farmers.

#### **Main Challenges:**

(1) For biopesticides, the specificities of these technologies are not adequately addressed within the framework of Regulation 1107/2009: Currently there are no tailored guidance documents for certain categories of biopesticides (e.g. natural substances), hampering their timely assessment. There is a lack of clarity on if/how novel technologies such as peptides, RNAi technology, fermentation products are covered under the framework creating uncertainty among applicants and delaying their submission in the EU.

(2) There is insufficient and unbalanced expertise on biopesticides within Member State authorities and EFSA. Very few Member States are currently equipped to accept new biopesticide applications, and those which are, are overburdened.

**Impacts:** Long time to market for crop protection innovation (whether conventional or biological) negatively affects the competitiveness of EU agriculture, with numerous crop protection solutions being removed from the farmers toolbox without being replaced by effective alternatives. This produces negative implication for EU growers' competitiveness vis-à-vis other geographies, where farmers can access crop protection innovation much faster due to shorter timelines.

This also results in a less attractive innovation environment, which can disincentivise investment in crop protection innovation for the European market. The extended timelines new crop protection solutions to reach the market threatens the return on investment, thereby creating uncertainty and barriers for developers, which includes significant numbers of SMEs and startups.

Following the CJEU ruling mentioned above, greater uncertainty and in the product approval process for crop protection products in EU Member States creates greater uncertainty about return on investment for innovative solutions. Increasingly fragmented decision-making means there will be differences in the availability of crop protection products across EU Member States. This will impact the competitiveness of farmers in some Member States vis-à-vis their EU neighbours.

#### **Change recommended:**

For all innovative products:

- Ensuring legally prescribed timelines are met would already offer a significant improvement on the status quo. This would provide guarantees for businesses and farmers concerning return on investment and access to technology respectively.
- Introducing regulatory paths to accelerate time to market for all crop protection innovation.
- Measures to protect the principle of mutual recognition and ensure as much Single Market harmonization as possible. This will ensure all EU farmers can access novel and existing crop protection solutions and offers greater regulatory predictability for industry.

For biopesticides, the situation could be improved via modifications to Regulation 1107/2009 and adoption of additional guidance documents/measures:

- Fit-for-purpose data requirements for all categories of biopesticides (following improved data requirements for micro-organisms)
- Increasing or ‘reactivating’ regulatory paths to make biopesticides available to farmers quicker, such as through Mutual Recognition or provisional approvals of products whilst they undergo assessment (Article 30 Regulation 1107/2009)
- Introducing sufficiently flexible, future-proof definitions and requirements within 1107/2009 to offer a clear regulatory pathway for novel technologies such as peptides, RNAi technology, fermentation products.
- Boosting expertise on biopesticides within Member State authorities and EFSA. This can improve assessment times and dialogue with applicants – and could be achieved through training of Member State experts and the creation of a dedicated unit/team within EFSA.

Precise regulatory changes:

- Definition: ‘Biopesticides are active substances as defined by Regulation (EC) No 1107/2009, that are derived from nature, either naturally occurring or synthesized and functionally identical to their naturally occurring counterparts.’

- Provisional authorisation Article 30(new):

‘Provisional authorisations for plant protection products containing solely active substances exerting biological control’

1. By way of derogation from Article 29(1) point (a), Member States may authorise, for a provisional period not exceeding three years, the placing on the market of plant protection products containing solely active substances that exert biological control which have not yet been approved, provided that:

(a) the draft assessment report has been submitted to the Commission as set out in Article 11(1);

(b) pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses;

(c) the Member State concludes that the active substance(s) that exert biological control is expected to satisfy the requirements of Article 4(2) and (3) and that the plant protection product is expected to satisfy the requirements of Article 29(1), points (b) to (h), and fulfils the requirements set out in Article 29(3);

(d) where deemed relevant by the Rapporteur Member State, maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

#### **4.14. GMO directive – Lengthy approval and authorisation**

**Concerned legislation:** Directive 2001/18 EC GMO directive / Commission Implementing Regulation (EU) No 503/2013

**Issue:** The current GM (genetically modified) authorisation process is slow and does in most cases not meet the legally set deadlines. The EU approach differs considerably from other jurisdictions.

**Main challenges:** Most delays in the GM product authorisation process in the EU occur during the phase known as risk assessment. During this period, EFSA evaluates the impact of the GM product on human and animal health, and on environmental safety. For new products, the legal timeline to conduct the risk assessment is six months. But the reality is different: it takes EFSA on average more than four years to conduct a risk assessment. This is despite continuous advancement of scientific understanding and nearly 30 years of data generated to support the safety of GMOs.

The EU Comitology process can be completed in 6 months. However, the average is 9 months. There is no reason for the Comitology process to exceed the minimum when there are no underlying issues. The risk assessment (RA) of a stack product starts when all the singles included in the stack are positively risk assessed. The average Stack RA timeline has increased in the past 4 years, now making stack RA longer on average than RA for single products. A majority of countries do not require a RA for stacks when the single events have been risk assessed or have a streamlined stack process, making the EU an outlier with stack policies.

**Impact:** Delays and uncertainty in the authorization process of GM products are costly for food and feed chain operators and not justified on safety grounds.

**Change recommended:**

(1) We call for an efficient and predictable authorization process for the import of GM Crops into the EU respecting legally foreseen timelines for the authorization. Since the first large-scale introduction of GM crops in 1996, there has been a vast accumulation of experience with risk assessment and authorisation processes for GM crops. This experience can be used to identify those attributes of regulatory systems that, while ensuring human and animal health and environmental safety, enable other public policy goals, such as food security, to be met. For example, the regulatory data needed to support product authorizations can be streamlined by the use of derogations as foreseen by Art 5.2 in Reg 503/2013.

(2) Call for a general revision of the current rules: it is time for policy makers and regulators to assess their existing regulatory and authorisation systems to ensure the framework appropriately evaluates safety while balancing the needs of agricultural stakeholders and maximizing the overall benefits to society.

(3) Regarding international best practices: There is no scientific rationale to regulate GM products combined with traditional breeding methods (stack products). Simplified procedures should be considered for conventional breeding stacks of individual GM products previously deemed safe by EFSA; such an approach has been implemented since 2014 by Japanese regulatory authorities for GM crop import applications; depending on a categorical classification assigned to the previously approved, single traits, breeding stacks containing these traits are now exempt from, or subject to a simplified risk assessment. Several other global regulatory authorities use a simplified process to risk assess breeding stacks (e.g. the Philippines, Paraguay), or have deemed their regulation is not necessary when the safety assessments of the single events were positively concluded (e.g. Australia/New-Zealand, Canada, the USA (USDA and FDA), Vietnam).

#### 4.15. CSDDD – Legal uncertainties and exaggerated obligations

**Concerned legislation:** Corporate Sustainability Due Diligence Directive (CSDDD)

**Issue:** The aim of the CSDDD is to foster sustainable and responsible corporate behaviour in companies' operations and across their global value chains. Despite these good intentions many conceptual and practical provisions are likely to hinder a smooth implementation by both authorities and economic operators.

**Main challenges:**

(1) Apart from the harmonization of the central due diligence requirements of Articles 8(1), 8(2), 10(1) and 11(1) via Article 4, there is no full harmonization of the obligations.

(2) Moreover, introduction of civil liabilities creates uncertainties for the industry. The scope of application in many cases goes far beyond the actual sphere of influence of companies within their value chains and networks. For very large companies for instance, even the total number of Tier-1 suppliers can exceed 50.000. It is fairly impossible to go beyond this sphere of influence and being held responsible with regards to human and environmental rights in all levels of the supply chain. To ensure that compliance with the requirements does not become almost impossible, industry initiatives must be recognized as an essential means of implementing the directive within the framework. We see such provisions as a great opportunity for greater acceptance of supply chain regulation in practice, which will help SMEs in particular to implement it.

(3) Reporting obligations must be synchronized with the obligations in other sustainability legislation, such as the CSRD, Battery Regulation, Forced Labour Ban Regulation, etc. There should be one consistent process that companies are required to follow in terms of safeguarding due diligence and respectively reporting on them.

**Impact:** The huge legal uncertainty and incalculable risk for companies due to the envisaged introduction of the civil liability will most probably lead to the withdrawal of companies from high-risk regions and markets. Companies will be faced with up to 27 different national frameworks due to the fact that as a directive, the CSDDD leaves too much space for additional regulation and "goldplating" as well as for national interpretation and implementation.

**Change recommended:**

(1) A full re-evaluation of the final text within the next EU legislature should be done, notably aiming for maximum harmonization of obligations for companies and avoiding that national goldplating leads to fragmentation within the European Market. Unnecessary reporting must be avoided: The requirements related to the Climate Transition Plan are already part of the CSRD and should be removed.

(2) A clear limitation to direct suppliers (similar to the German Supply Chain Law) and the exclusion of downstream activities from the due diligence obligations are to be established,; e.g. introduction of the concept of substantiated knowledge for adverse impacts in Tier-N; Art. 3 (1) lit. g in connection with Art. 1(1): § 9 (3) Lieferkettensorgfaltspflichtengesetz (LkSG, Act on Corporate Due Diligence Obligations in Supply Chains) could serve as a blueprint. According to § 9 (3) LkSG an enterprise is obliged to take measures, if it has actual indications that suggest that a violation of a human rights-related or an environment-related obligation at indirect suppliers may be possible (substantiated knowledge).

(3) Consideration of existing, proved sector initiatives such as Chemie<sup>3</sup> or Together for Sustainability as sector-specific solutions. Definition in Art. 3 (1) lit. g. Initiatives are mentioned throughout the

whole directive, but no procedure for "Recognition of supply chain due diligence schemes" like in Art. 8 of the Conflict Minerals Regulation is provided. Art. 8 of the Conflict Minerals Regulation could serve as a blueprint as we suggested in the legislative process of the CSDDD.

(4) Align implementation timeline of CSDDD and CSRD: As per today, some companies will have to report under the CSRD only in 2028 but earlier under CS3D while there is connected content. In addition, overlaps in the transformation plans should be eliminated. This can also be applied to the other laws that also require such plans, including ETS and IED).

(5) Guidelines and implementing legislation should be adopted at least two years before compliance with legislation becomes mandatory or the transition period should be extended. If the process is not started or finalised in time and delays become apparent, the entry into force of the directive must be postponed accordingly - legal uncertainties and costs such as the short-term postponement of the EU Deforestation Regulation must be avoided.

#### 4.16. CSRD – Auditor Standard and “reasonable assurance”

**Concerned legislation:** DIRECTIVE (EU) 2022/2464 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting.

**Issue:** The CSRD mandates sustainability reports to undergo limited assurance audits. However, a uniform audit standard does not currently exist. For reasonable assurance, Article 26(a) requires the Commission to develop relevant standards by October 2028, following feasibility assessments for auditors and companies. Extending to reasonable assurance prematurely would impose unnecessary administrative and financial burdens.

**Main challenge:** Auditors across Germany and the EU apply varying audit depths, leading to inconsistencies. Companies face liability risks and reputational damage from publicized sanctions by the complaints office, even if suspicions are unconfirmed. Furthermore, auditors are also navigating liability concerns during the early implementation phase, which compounds challenges for companies already overburdened by extensive sustainability reporting obligations.

**Impact:** The CSRD extends sustainability reporting obligations significantly overburdening companies. Collecting and processing data demands considerable time and resources. Additionally, inconsistent audits and potential sanctions may result in reputational harm, regardless of fault, while auditors are learning to navigate liability concerns.

#### **Change recommended:**

(1) A first step is to introduce an auditing standard as quickly as possible. Therefore, the depth of the audit should be reduced by OLP in the first years of implementation until the standard is widely used.

(2) Susceptibility to abuse can be solved, for example, by introducing a confidentiality clause for the complaints office. This can be enforced, for example, by not sanctioning the auditor.

(3) In future, testing with limited certainty should be sufficient, and no extension to adequate certainty in terms of cost and effort versus benefit is required. A usability study should be carried out before a test is performed to obtain reasonable assurance.

(4) Simplifying the audit and focussing on core aspects:

- Adjust audit depth: In the first few years, compliance with the sustainability reports should primarily be checked for gross deviations instead of carrying out detailed audits. This ensures that auditors and companies can gain experience without detailed audits becoming a major burden.

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- Example: An audit structure that initially focuses only on the major risks and does not go into the smallest details could reduce both audit costs and the workload.
- Proposal for addition: Introduction of a 'learning time approach' that limits the scope of the audit in the early years and focuses on basic aspects of compliance.

## **(5) ADDRESSING PRINCIPLES**

### **5.1. Trade policy and legislation – Negative effects of mirror clauses**

**Concerned legislation:** Tendency in different acts & free trade agreements (FTA)

**Issue:** The concept of mirror clauses (application of EU production standards to imports) has seen increased attention recently in the context of the farmers' protests across the EU.

**Main challenges:** Calls for mirror clauses or similar have come from national governments, the European Parliament, as well as European political parties in the run up to the EP elections – often specifically targeting the use of plant protection products (PPPs) no longer authorized in the EU. There are also recent examples where several Member States and the European Parliament plenary have rejected safe MRL/IT proposals; the cumulative impact of this could be similar to the outcome sought via such mirror clauses.

**Impact:** Mirror clauses are blunt instruments which fail to take into consideration that growers around the world work under different agronomic conditions and face different pest and climatic pressures. Introducing mirror clauses formally into FTAs or 'substance-by-substance' via MRL/IT proposals could limit the ability of ex-EU growers' – including smallholders in the global south – to manage pests or access an important export market, with associated economic, social and environmental consequences. This is likely to either increase costs of production or lower export volumes to the EU, which in turn can also impact the competitiveness of the EU-based food industry – which relies on many raw materials from outside the EU (such as animal feed, cocoa, tropical fruits, spices, tea, coffee etc). Lastly, it is important to note that lowering or blocking the setting of individual MRLs/ITs for non-scientific reasons can be considered an unjustified restriction of market access, a breach of WTO rules, and risks jeopardising Europe's relations with its trading partners.

**Change recommended:** The MRL regulation should be maintained and implemented on the basis of risk (i.e. setting safe MRLs based on a consumer risk assessment). Aside from not yielding to demands for mirror clauses in FTAs, one key solution is to keep crop protection solutions available on the EU market and to ensure crop protection innovations reach the market in a timely fashion. This ensures EU farmers can remain competitive and avoids the perception of a lack of a level playing field and associated political rejections of MRL proposals.

### **5.2. EU Economic Security Strategy – Adverse effects on biotechnology research**

**Issue:** The expansion of specific de-risking tools must be carried out with a sense of proportion and requires precise analysis and justification.

**Main challenges:** It is unreasonable to support, by principle, an introduction to limitations on outbound investment. Only in exceptional cases, where serious security concerns are effectively proven this could be a last resort measure. The private sector should be consulted to ensure that the measures adopted are effective whilst fully preserving the EU's global competitiveness.

**Impact:** With biotechnology being identified as one of the four technology areas that are considered highly likely to present the most immediate risks for the EU's Economic Security, the impact could be significant. The biotechnology and life science industry are highly distributed, multidisciplinary, and international, which limits the identification, adoption and influence of specific biotechnologies to meet economic security needs.

**Change recommended:** Any measures foreseen under the Protect Pillar must not unnecessarily harm or contradict the objectives set out under the Promote Pillar.

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Careful definition of the scope (concepts and criteria) for risk and resilience on biotechnologies considering respective operational factors from R&D to manufacturing (incl. cross-border activities, data-sharing mandates).

Risk assessment on present and future vulnerabilities (threats/ actors) of biotechnologies, the degree of likelihood and options for risk mitigation.

Analysis of socio-economic benefits of biotechnologies contributing to the EU's efforts towards global food security and health and transition to circularity - Ensure relevant assessments are well balanced within the three-pronged approach under ESS ("promote", "protect" and "partner") and coherent with existing policies on biotechnology.

Any "de-risking" on biotechnologies should be targeted, precise, proportionate and science-based to avoid imposing any unnecessary burden on business and creating unnecessary fragmentation in markets.