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POSITION PAPER

FEEDBACK ON THE

EU TAXONOMY - REVIEW OF CLIMATE AND ENVIRONMENTAL DELEGATED ACTS

DEZEMBER 2025

The Austrian Federal Economic Chamber, Wiedner Hauptstraße 63, 1045 Vienna, Austria, is registered in the European Union Transparency Register – ID Number: 10405322962-08.

The Austrian Federal Economic Chamber is the legal representative of the entire Austrian business community and represents all Austrian companies – some 540,000 businesses drawn from the areas of Crafts and Trade, Industry, Commerce, Banking and Insurance, Information and Consultancy, Tourism and Leisure, Transport and Logistics. 99,6 % of our members are SME.

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IN GENERAL

The Austrian Federal Economic Chamber (WKÖ) welcomes the European Commission's initiative to improve the clarity, usability, legal certainty, and cost-effectiveness of the EU Taxonomy. The criteria of the delegated acts must be revised for their practicality and, above all, their feasibility coherence between the EU Taxonomy and other legislation.

The revision should ensure better alignment with related EU legislation, simplify and clarify criteria. Overlaps or contradictions must be eliminated. We call for a full harmonization of European requirements with uniform thresholds. A coherent framework is needed which aligns, the reporting obligations under the CSRD (Corporate Sustainability Reporting Directive), climate, environmental, and energy legislation, and the requirements of financial market regulation with the EU Taxonomy. Only in this way can a practical and efficient sustainability framework be achieved.

Clarify and simplify the technical screening criteria, especially the Do No Significant Harm (DNSH) components. European companies are still struggling to comply with the complex and burdensome requirements of the EU Taxonomy. The criteria demand technical knowledge that exceeds the capabilities of many companies. More precise definitions, streamlined requirements, and clearer, more accessible guidance - including on what qualifies as sufficient evidence for DNSH compliance - are needed to ease reporting burdens and lessen businesses' dependence on external consultants.

Offer businesses practical support and standardized templates. Companies require clear guidance, illustrative examples, and digital tools to understand the requirements and demonstrate Taxonomy alignment. Sector-specific, standardized templates can further reduce administrative effort and help harmonize rules. In the financial sector, the question often arises as to which external confirmations of customer information are necessary (e.g., sworn declarations, external expert opinions, certificates, official confirmations, energy performance certificates, etc.). Thus, legal certainty for the data they receive (i.e. official permits) is necessary. Energy performance certificates should also be more closely aligned with the data requirements of the EU Taxonomy.

Consider minimum Social Safeguards (MSS) criteria fulfilled for EU companies and for all activities carried out within the EU, provided there are no indications that EU law has been violated. Evidence of compliance with the MSS (the procedure that is currently required for demonstrating Taxonomy alignment) should only be required when the company operates outside the EU. Many European SMEs that operate within the EU legal framework are already subject to comprehensive EU regulations. Therefore, requiring the same evidence for MSS compliance for their activities inside the EU creates unnecessary administrative burdens without adding significant value. This approach would allow banks to use European SMEs for KPIs e.g. GAR (green asset ratio) calculations, while still ensuring that MSS standards are met for activities outside the EU, where regulatory oversight may vary.

Companies need planning and investment security. For companies that have spent years intensively preparing for the requirements of the EU Taxonomy and have invested significant resources in implementation, it must be ensured that the specific substantive provisions do not lead to dilution or substantive erosion. The efforts already made by companies and the trust in reliable sustainable regulation must not be counteracted.

IN DETAIL

- **Inconsistencies with the EU Emissions Trading System (EU ETS).**

There is a l*ack of alternative emission calculation methodologies*. The TSC refer to EU Emissions Trading System (EU ETS) benchmarks for many economic activities under the EU Taxonomy through footnotes (e.g. "calculated in accordance with Regulation (EU) 2019/331"). However, not all plants or processes relevant to these economic activities are covered by the EU ETS (it covers only specific high-emitting processes).

Since many branches of the industry sector are highly complex, some of its eligible activities (e.g. chemicals produced as by-products) are not covered by the TSC using the specific EU-ETS boundaries. Therefore, some of these activities cannot be assessed and must automatically be reported as not Taxonomy-aligned.

We recommend clarifying (via FAQs or other instruments) that activities with TSC, that include a reference to the EU ETS, are Taxonomy-eligible when the plant relevant to the activity in question 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).

The TSC could give reporting undertakings the option to assess the activity as non-eligible by adding the following to the existing relevant footnotes:

(x) Calculated in accordance with Regulation (EU) 2019/331. When the product benchmarks set out in Regulation 2019/331 are not applicable to the specific manufacturing process, the undertaking may assess the economic activity as non-eligible.

Alternatively, the EU Taxonomy should include alternative emission calculation methodologies for manufacturing processes which are not covered under the EU ETS.

- **Third-party verification of quantified life-cycle GHG emissions**

The Taxonomy Regulation requires quantified life-cycle GHG emissions verified by an independent third party. As per the current interpretation, the LCA assessment and the third-party verification are required at product-level on a yearly basis.

Many industry companies can produce thousands of products aligned with the EU Taxonomy and are required to have a LCA assessment verified by an independent third party for each of them, which represents a significant cost and is extremely time-consuming.

According to the ISO 14044 LCA standard, a critical review is always required but may be carried out by a qualified internal or external expert. A costly third-party critical review by a panel of interested parties is required only when the results of an LCA are intended to be used for comparative assertions disclosed to the public, such as in marketing materials. Moreover, many activities or products covered by specific EU legislation within the Taxonomy already refer to a verified methodology approved by the EU.

In addition, some undertakings use software for LCA calculations. Those software tools are often verified by a third party. The ISO standard allows LCA to be calculated using a software and to be verified externally. In such cases, it does not make sense to require a LCA for each product that is individually verified by a third party. Third-party verification for the entire system/software should be sufficient and is in accordance with ISO.

The EU Taxonomy should also allow for this option in order to reduce the compliance burden and costs.

We recommend adding the following wording to the existing third-party verification requirement:

(x) Quantified life-cycle GHG emissions are verified by an independent third party or calculated with third-party certified Product Carbon Footprint (PCF) automation tools.

Please find below the detailed demands of WKÖ regarding the different technical screening criteria:

On **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

3.3. MANUFACTURE OF LOW CARBON TECHNOLOGIES FOR TRANSPORT

The following points are cited as technical screening criteria that are intended to make a substantial contribution to climate change mitigation:

> *(c) urban, suburban and road passenger transport devices, where the direct (tailpipe) CO_2 emissions of the vehicles are zero;*
>
> *(e) personal mobility devices with a propulsion that comes from the physical activity of the user, from a zero-emissions motor, or a mix of zero-emissions motor and physical activity;*
>
> *(f) vehicles of category M1 and N1 classified as light-duty vehicles ([80]) with:*
>
> *(i) until 31 December 2025: specific emissions of CO_2, as defined in Article 3(1), point (h), of Regulation (EU) 2019/631 of the European Parliament and of the Council ([81]), lower than 50 g CO_2/km (low- and zero-emission light-duty vehicles);*
>
> *(ii) from 1 January 2026: specific emissions of CO_2, as defined in Article 3(1), point (h), of Regulation (EU) 2019/631, are zero;*
>
> *(h) vehicles of categories N2 and N3, and N1 classified as heavy-duty vehicles, not dedicated to transporting fossil fuels with a technically permissible maximum laden mass not exceeding 7,5 tonnes that are 'zero-emission heavy-duty vehicles' as defined in Article 3, point (11), of Regulation (EU) 2019/1242 of the European Parliament and of the Council ([84]);*
>
> *(i) vehicles of categories N2 and N3 not dedicated to transporting fossil fuels with a technically permissible maximum laden mass exceeding 7,5 tonnes that are zero-emission heavy-duty vehicles', as defined in Article 3, point (11), of Regulation (EU) 2019/1242 or 'low-emission heavy-duty vehicles' as defined in Article 3, point (12) of that Regulation;*

All of these criteria are based exclusively on "zero-emission engines" or "zero-emission" vehicles. These assessment criteria are based on the provisions of Regulation (EU) 2019/631 setting CO_2 emission performance standards for new passenger cars and Regulation (EU) 2019/1242 setting CO_2 emission performance standards for new heavy-duty vehicles.

The CO_2 fleet limits for passenger cars and commercial vehicles are currently being revised. The EC proposal to amend the CO_2 fleet limits for passenger cars and commercial vehicles was announced as part of the so-called automotive package for December 10, 2025. The EU's current CO_2 fleet targets for 2030 and the planned ban on combustion engines in 2035 are central pillars of the EU's climate policy. However, changes occurred and thus the current CO_2 regulation, with its target of 0 g/km in 2035, must be revised. The focus is purely on zero-emission vehicle technology. As part of the review of CO_2 fleet limits, alternative climate-neutral drive systems should also be recognized. If a van reduces its CO_2 emissions to zero through verifiable renewable fuels or other technologies, this should be taken into account in the regulatory framework. Such a technology-neutral approach would promote innovation and could enable practical solutions, particularly for specific areas of application (e.g., long trailer journeys or very heavy vehicles). Even the Commission

itself writes in its call for comments in the run-up to the public consultation that achieving the climate neutrality targets by 2035 requires a technology-neutral approach in which e-fuels play a role. The Commission also wants to pay more attention to hybrid drive systems. It is therefore urgently necessary to adjust the assessment criteria within the EU Taxonomy, with its current focus on zero-emission technology, and to anticipate the development towards a technology-neutral approach in the transport sector.

Specifically, Article (h) "The restriction that vehicles must not be 'intended for the transport of fossil fuels'" is opposed as it has no effect on the vehicle per se. This also applies to similar restrictions in the context of shipping.

3.14. MANUFACTURE OF ORGANIC BASIC CHEMICALS

The current TSC penalizes electrification efforts in favour of crackers using fossil gas technologies. It 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 a future-oriented chemical industry. The strict reference to the calculation methodology of the EU ETS therefore diminishes the importance of the use of green electricity and removes one of the most important levers for the sustainable transformation of the chemical industry.

On the contrary, Taxonomy should push this sector towards sustainable projects by recognizing the consumption of green electricity (including with guarantees of origin).

It is recommended to include the following footnote:

(x) For the manufacture of High Value Chemicals (HVC) via steam cracking, the indirect emissions from electricity consumption within the system boundaries of steam cracking shall be calculated with the average life-cycle GHG emissions of the electricity used. Life-cycle GHG emissions are calculated using Recommendation 2013/179/EU or, alternatively, using ISO 14067:2018 or ISO 14064-1:2018.

This was also recommended by the EU Platform on Sustainable Finance in their March 2025 report.

3.17. MANUFACTURE OF PLASTICS IN PRIMARY FORM

The impracticability of the TSC regarding mechanical and chemical recycling is viewed critically. A theoretical full manufacture with 100 % recyclates does not reflect reality.

Mechanically recycled products and production lines are already implemented. But in many cases the products exhibit recycled shares below 100 % - not only because of market expectations but also to adjust product performance to application-specific requirements by adding virgin material.

Chemically recycled products may be derived from production processes where, due to technical feasibility, co-feeding of primary fossil and/or renewable feedstocks is required, and some chemical components may also not originate from recycled streams (e.g. oxygen).

Under the current TSC, alignment is only possible if 100 % of the input comes from recycling, which means that a product using, for example, 1 or 99 % of recycled input would not be aligned. Furthermore, any proportion of recycled input is not supported, which is inconsistent with other relevant EU legislation, such as the Plastic Packaging Regulation. On the contrary, Taxonomy should encourage a progressive increase in the proportion of recycled input in the production process.

It is recommended to include the following footnote in paragraphs a) and b):

(x) For manufacturing processes mixing fossil and recycled feedstocks (including co-processing), only the fraction of production attributable to plastic waste feedstocks shall be considered aligned.

Alternatively, the TSC could set a minimum threshold of recycled content, following the approach in other EU Taxonomy economic activities (e.g. manufacture of plastic packaging goods).

A revision of the feasibility of the TSC in this economic activity was also recommended by the EU PSF in their March 2025 report.

Additionally, this activity mainly refers to the product; the relevance of upstream processes such as pre-treatment facilities or chemical recycling leaves room for interpretation. A clear reference that pre-treatment facilities are also relevant under this activity would be useful. Chemical recycling should be addressed in more detail.

4.18. CO-GENERATION OF HEAT/COOL AND POWER FROM GEOTHERMAL ENERGY
4.22. PRODUCTION OF HEAT/COOL FROM GEOTHERMAL ENERGY

A key concern for our companies regarding geothermal energy is that the current Delegated Regulation stipulates life-cycle GHG emissions of <100g CO_2e/kWh for geothermal energy. This does not apply to solar or wind energy, meaning geothermal is disadvantaged. The additional burden of cost and time for a life-cycle analysis should not be underestimated. In the future, the threshold is even expected to be reduced to zero.

The EU Taxonomy requirement for a life-cycle assessment (LCA) for geothermal facilities should be removed in order to improve the bankability of geothermal projects. Requiring an LCA puts geothermal heat projects at a disadvantage compared with other technologies, such as wind or solar, which are already defined as sustainable. It adds time and costs for geothermal developers, without improving environmental outcomes. Removing the LCA requirement would allow private investment to flow more quickly into clean-heating projects and would help to improve the conditions for project financing.

5.12. UNDERGROUND PERMANENT GEOLOGICAL STORAGE OF CO_2

The requirement that suitable leakage detection systems must already be implemented may not fully reflect the realities of project development timelines. In practice, such systems are typically integrated at a later stage, after planning and permitting processes are completed. We would welcome a more flexible interpretation that accounts for the phased nature of implementation while still ensuring environmental protection.

6.3. URBAN AND SUBURBAN TRANSPORT, ROAD PASSENGER TRANSPORT
6.5. TRANSPORT BY MOTORBIKES, PASSENGER CARS AND LIGHT COMMERCIAL VEHICLES
6.6. FREIGHT TRANSPORT SERVICES BY ROAD
6.10. SEA AND COASTAL FREIGHT WATER TRANSPORT, VESSELS FOR PORT OPERATIONS AND AUXILIARY ACTIVITIES

The following DNSH criterion is defined under "(5) Pollution prevention and control": *"For road vehicles of category M, tyres comply with external rolling noise requirements in the highest populated class and with Rolling Resistance Coefficient (influencing the vehicle energy efficiency) in the highest two populated*

classes as set out in Regulation (EU) 2020/740 and as can be verified from the European Product Registry for Energy Labelling (EPREL).”

This criterion is difficult to apply in practice. Gathering the information necessary to meet this criterion poses a huge challenge for Taxonomy assessments of motor vehicles and leads to the inability to complete Taxonomy assessments. Therefore, removing this criterion would generate significant improvements in the practical application of the Taxonomy.

7.1. CONSTRUCTION OF NEW BUILDINGS
7.2 RENOVATION OF EXISTING BUILDINGS

It is very difficult to meet the DNSH for climate targets “(4) Transition to a circular economy”, and “(5) Pollution prevention and control”. For Taxonomy compliance, detailed information about the materials/substances used must be obtained or certain technical tests conducted.

9.1. CLOSE-TO-MARKET RESEARCH, DEVELOPMENT AND INNOVATION’:

The requirement that R&D&I activities must demonstrate their greenhouse gas mitigation potential in a relevant environment (at least TRL 6) could unintentionally restrict support for innovations at an earlier development stage with high transformative potential. Furthermore, linking to TRL 6 is not directly relevant for P&L structures and adds administrative complexity when aligning innovation activities with Taxonomy criteria. A more flexible and proportionate approach could help ensure promising technologies are not overlooked due to procedural thresholds.

On **COMMISSION DELEGATED REGULATION (EU) 2023/2486** of 27 June 2023 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 the sustainable use and protection of water and marine resources, to the transition to a circular economy, to pollution prevention and control, or to the protection and restoration of biodiversity and ecosystems and for determining whether that economic activity causes no significant harm to any of the other environmental objectives and amending Commission Delegated Regulation (EU) 2021/2178 as regards specific public disclosures for those economic activities

ANNEX II: 1.1 MANUFACTURE OF PLASTIC PACKAGING GOODS

Consideration of Post-Industrial Recyclates (PIR): In order to achieve the objectives pursued by the Regulation in the field of Manufacture of plastic packaging goods, a comprehensive assessment of the entire manufacturing process is rightly called for. The current Taxonomy Regulation sets out minimum shares of post-consumer recyclates (PCR). However, post-industrial recyclates (PIR) also make a substantial, measurable and – in many cases – more stable contribution to the circular economy. Their systematic and explicit consideration under the Taxonomy Regulation is therefore warranted.

PIR often exhibit higher material purity, lower contamination levels, and broader applicability without downcycling compared to PCR. By contrast, PCR is not suitable for all technical applications, and its quality deteriorates with each recycling loop.

Demonstrable advantages of PIR include:

- reduced energy consumption when compared with primary production;
- savings of fossil resources when compared with primary production;
- lower CO_2 emissions;
- the preservation and utilisation of established industrial material loops.

A functioning circular economy depends on the availability and use of all technically and ecologically viable secondary raw material streams. Exclusive recognition of PCR would neglect significant industrial return flows.

Moreover, PCR-based requirements render processing companies—particularly SMEs—dependent on collection and sorting infrastructures, which are entirely outside their operational control. As the availability and quality of PCR cannot be assured by processors themselves, such requirements risk creating competitive distortions, increasing disproportional compliance costs, inhibiting innovation, and thereby potentially causing production to be relocated outside the EU. A PCR-focused approach would also lead to quality degradation, reduced product safety, and increased downcycling pressure, which would directly contradict the aims of the Taxonomy Regulation.

By enabling the material reuse of PIR, precisely those outcomes sought by the taxonomy—waste prevention, resource conservation, and strengthening of circularity—are achieved. PIR therefore constitutes a significant contributing factor and should accordingly given due consideration within the technical screening criteria.

The substance exclusions listed under Annex II, 1.1 / 3. must be considered critically from the perspective of plastic converters. The EU Taxonomy is intended to provide harmonised criteria determining when an economic activity is considered “environmentally sustainable” and operates as a steering mechanism for directing financial flows towards sustainable activities. It is not intended to introduce additional product requirements or manufacturing-process restrictions for individual market participants. Product safety and chemical restrictions are already comprehensively regulated under existing EU legislation, including REACH and CLP.

The substance-related prohibitions therefore appear systemically unsuitable an disproportionate in the context of the Taxonomy-Regulation. A reference to existing regulatory frameworks would be adequate and more coherent. Furthermore, the breadth of the exclusion list lacks objective justification. It fails to distinguish adequately between the intrinsic hazard characteristics of a substance and the actual risk posed when incorporated into a polymer matrix in the final product. As a result, substances may be excluded without an assessment of their concrete relevance or risk within the specific production process.

Taking into account, that plastic manufacturers are predominantly downstream users, the extensive substance exclusions risk is likely to impose disproportionate burdens along the entire value chain and may create additional obligations that exceed their practical and legal sphere of influence. SMEs would be confronted with significant documentation requirements and increased administrative and financial effort. Furthermore, manufacturing companies are often unable to evaluate the properties of the materials themselves and depend entirely on information provided by their suppliers. This situation may unduly restrict access to sustainable finance without achieving the intended environmental benefits of the taxonomy.

In effect, the current approach of excessive substance exclusion in Annex II, 1.1 / 3 creates a regulatory barrier that is disproportionate and insufficiently calibrated. The exclusions are systemically foreign to the

taxonomy framework, excessively broad, and likely to lead to competitive disadvantages for European manufacturers—especially SMEs—due to additional documentation burdens and compliance uncertainties.

ANNEX II: 3.1. CONSTRUCTION OF NEW BUILDINGS

(I) It is very difficult to meet are DNSH for climate targets "(4) Transition to a circular economy", and "(5) Pollution prevention and control". For taxonomy compliance, detailed information about the materials/substances used must be obtained or certain technical tests conducted.

(II) Key contribution criteria include "the three heaviest material categories: bricks, tiles, and ceramics."

> *(4) … The operator of the activity must ensure that the three heaviest material categories used in the construction of the building, measured as mass in kilograms, comply with the following maximum quantities of primary raw materials used:*
>
> *(a) for the combined total of concrete, natural or agglomerated stone, a maximum of 70 % of the material comes from primary raw material;*
>
> *(b) for the combined total of brick, tile, ceramic, a maximum of 70 % of the material comes from primary raw material;*
>
> *(c) for bio-based materials a maximum of 80 % of the total material comes from primary raw material;*
>
> *(d) for the combined total of glass, mineral insulation, a maximum of 70 % of the total material comes from primary raw material;*
>
> *(e) for non-biobased plastic, a maximum of 50 % of the total material comes from primary raw material;*
>
> *(f) for metals, a maximum of 30 % of the total material comes from primary raw material;*
>
> *(g) for gypsum, a maximum of 65 % of the material comes from primary raw material.*

(III) DNSH criteria for the climate target "Pollution prevention and control"

Here, separate testing must be carried out to ensure that building components and materials used in the construction that may come into contact with occupiers contain less than 0,06 mg of formaldehyde per m3 of test chamber air after testing in accordance with the conditions specified in Annex XVII to Regulation (EC) No 1907/2006 and less than 0,001 mg of other carcinogenic volatile organic compounds of categories 1A and 1B per m3 of test chamber air after testing in accordance with CEN/EN 16516 (90) or ISO 16000-3:2011 (91) or other equivalent standardised test conditions and determination methods.

This testing must be carried out at a specific stage of construction/renovation; it is not directly enshrined in law, which in turn makes implementation difficult and prevents third-party companies, including banks, from collecting this data from customers.

Reasoning (I, II, III): Although we are aware of the importance of such criteria for supporting the circular economy and for preventing and reducing environmental pollution, the criteria are difficult to implement in practice, both at the undertaking/operator level (higher standards entail higher costs for companies; a competitive advantage cannot yet be derived from them) and for financial institutions that are interested in supporting these efforts and want to have a higher number of taxonomy-aligned activities in their KPIs (can publish higher GARs).

These criteria (substantial contribution criteria for the climate target of "transitioning to a circular economy" and DNSH for the climate targe "Pollution prevention and control") should therefore be revised. A positive revision would mean:

1. Simplification – fewer or less detailed criteria
2. Development of standardized/clear processes on the basis of which proof of compliance with these criteria can be obtained
3. Anchoring directly in the legal framework for the construction industry to collect.

ANNEX II: 3.1. CONSTRUCTION OF NEW BUILDINGS 3.2. RENOVATION OF EXISTING BUILDINGS

The proposed thresholds of 20 % for new buildings (4. c) and 10 % for renovations (5. c) are not achievable for wood, as secondary wood streams are highly underdeveloped. Reasons include the long lifespan of wood products, lack of recycling infrastructure, limited technological options for structural products, scarce end-of-life solid wood, and the absence of a secondary raw material market. Therefore, we call for a market-based approach.

Alternatively, at least a 50 % share of reused, recycled, or sustainably sourced renewable materials overall should be targeted. Sustainably sourced renewable materials must be recognized as equivalent to recycled and reused materials.

DNSH Requirements (Pollution Prevention & Control): These criteria must be harmonized with the updated REACH provisions on formaldehyde and VOC emissions. New limits stipulate 0.062 mg/m³ for furniture, wood-based materials, and vehicle interiors, and 0.080 mg/m³ for all other products. Separate or stricter Taxonomy limits would create unnecessary bureaucracy without additional environmental benefit. Moreover, VOC emissions from wood decrease over time, so reused wood components should be assessed based on their actual condition. DNSH requirements must not hinder reuse or high-quality recycling, as this would undermine the EU's circular economy goals.

Therefore, the following is demanded:

- Realistic and practical requirements for secondary materials that consider the specific characteristics of wood.
- Recognition of sustainably sourced renewable materials as equivalent circular inputs.
- Harmonization of DNSH criteria with existing EU regulations to ensure legal certainty and proportionality.
- Targeted support for SMEs to help them meet rising requirements.

ANNEX III: 1.1 MANUFACTURE OF ACTIVE PHARMACEUTICAL INGREDIENTS 1.2 MANUFACTURE OF MEDICINAL PRODUCTS

The current Technical Screening Criteria (TSC) for these activities do not reflect how pharmaceutical research and development operate in practice. As currently designed, the criteria risk disqualifying novel or transformative therapies from alignment, regardless of their sustainability benefits.

Based on the current TSC, the activity on manufacturing of active ingredients medicinal products can – in summary – only be assessed as Taxonomy-aligned if the active ingredient and any other ingredients are naturally occurring, biodegradable, or mineralized; 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.

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 non-biodegradable options in the same therapeutic areas.

Effectively preventing the Taxonomy-alignment of such manufacturing does not add incentives to their development and/or improvement!

The EU Taxonomy needs to develop workable significant contribution criteria for the pharmaceutical sector. 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 have to be persistent to be effective.

Without revision, the EU Taxonomy may inadvertently deter investment in Europe's life science ecosystem. By creating barriers for environmentally beneficial yet scientifically complex activities, the current model may delay the introduction of innovative treatments, increase development costs, or push research and manufacturing outside of the EU.

A fundamental revision of the TSCs is recommended.

ANNEX VI: 2.1 HOTELS, HOLIDAY, CAMPING GROUNDS AND SIMILAR ACCOMODATION

Taxonomy-reporting accommodation activities, if located in a protected area, can only carry out their economic activity in a taxonomy-compliant manner if they control access to this protected area (e.g., through tickets). This is something that the accommodation activities cannot realize, but only the owner of the protected area, to which the accommodation activity does not belong. Such criteria must be removed to make taxonomy alignment realistic and practical.

On Appendix C: Delegated Regulations (EU) 2021/2139 ("Climate Delegated Act") and (EU) 2023/2486 ("Environmental Delegated Act") as regards the DNSH criteria for pollution prevention and control

The changes adopted on Appendix C as regards the deletion of paragraph f) bis[1] is welcomed. However, Appendix C still remains as one of the main challenges for the chemical industry as it is directly linked to their core economic activities.

[1] ANNEX to the COMMISSION DELEGATED REGULATION (EU) .../... amending Commission Delegated Regulation (EU) 2021/2178 as regards the simplification of the content and presentation of information to be disclosed concerning environmentally sustainable activities and Commission Delegated Regulations (EU) 2021/2139 and (EU) 2023/2486 as regards simplification of certain technical screening criteria for determining whether economic activities cause no significant harm to environmental objectives (see Annex XII – not in force until it is published in the Offical Journal)

Appendix C should not go beyond the requirements and definitions set out in the REACH Regulation (EU) 1907/2006, which sets clear and widely adopted rules for restricting certain chemicals in specific processes and constitutes "the standard" for chemical compliance in the EU. Compliance with the REACH Regulation should already be considered as not doing significant harm (DNSH) to the Pollution Prevention and Control (PPC) objective. This approach would also be in line with Article 19(1)(k) of the EU Taxonomy Regulation (EU) 2020/852, which requires that the technical screening criteria (TSC) must "be easy to use and be set in a manner that facilitates the verification of their compliance".

Paragraph 1: Heading

The current interpretation of "use" prevents alignment of (the manufacturing of) substances (e.g. chemical precursors key for the transition towards a sustainable economy) that fulfil both the substantial contribution and the DNSH criteria but require the involvement of restricted substances during the manufacturing process that are not present in the final product nor in contact with it (e.g. intermediates, substances required for fuel/combustion, etc.). In most cases, these types of emissions are covered by the DNSH criteria to the pollution prevention and control (PPC) objective, which refer to the relevant BAT-AEL values.

Removing the word "use of" in the heading is recommended: "The activity does not lead to the manufacture, placing on the market or presence in final product or final output of:''

Paragraph 1 (f)

The REACH Regulation includes a very specific interpretation of 'strictly controlled conditions' in relation to intermediates (i.e. Art. 17 and Art. 18). The concept of 'under controlled conditions' is therefore unclear in the context of Appendix C and risks leading to divergent and excessively stringent interpretations, ultimately hampering data comparability. The suggested wording, also referred to in the REACH Regulation, still acknowledges the importance of establishing adequate measures to ensure the proper management of the substances in question while providing more certainty and clarity to reporting undertakings.

The clarifications in this regard provided in the recently published EC FAQs on EU Taxonomy increase the burden on companies given the excessive evidence required. According to question 136, companies would have to prove that the risk assessment has been carried out and the risk management measures have been put in place for each substance (both at local and global level) to minimise the exposures and emissions of the substance that give rise to serious risks from both a human health and environmental perspectives during the use phase.

Deleting the term "under controlled conditions" in paragraph 1 (f) is recommended:

> *"substances, whether on their own, or in mixtures or in an article, in a concentration above 0,1 % weight by weight (w/w), and meeting the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and that were identified in accordance with Article 59(1) of that Regulation for a period of at least 18 months, except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market and ~~that they are used under controlled conditions~~* ***provided procedural and controlled technologies are used to minimise emission and any resulting exposure".¶***

Provisions should also be introduced to clarify how companies should report cases in which resources have been allocated to substitute critical substances, but the substitution process is still ongoing at the moment of the reporting (i.e. the suitable alternative is not yet implemented at industrial scale). An action plan with clearly allocated resources for substitution should enable undertakings to meet the DNSH criteria.

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