Subject: EU Reply to Communication of UN Special Procedures regarding the EU "Omnibus package on chemicals"

Ref.: OL OTH 120/2025

The European Union would like to thank the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes for his communication of 25 September 2025 concerning the proposed Chemicals Omnibus Package and, in particular, the legislative proposal amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products ([1]).

In order to provide a reply as pertinent as possible, the replies below reflects information provided by European Commission Directorates General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) and for Environment (DG ENV).

The European Union's regulatory framework governing chemicals sets a high benchmark in the development of chemicals legislations around the world. The European Union (EU) remains fully committed to ensuring a high level of protection of human health and the environment from the adverse effects of hazardous chemicals.

The proposed amendment of the CLP Regulation

The Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ('CLP Regulation') seeks to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and certain articles. The CLP Regulation implements in the European Union the United Nations' Globally Harmonised System (GHS), which addresses classification of chemicals by types of hazard and proposes harmonised hazard communication elements, thus ensuring that information on physical hazards and chemicals toxicity is available in order to enhance the protection of human health and the environment during the handling, transport and use of these chemicals. Currently, the Commission is working on the implementation in the CLP Regulation of the GHS revisions 8 to 10; leading by example across the globe in ensuring that workers and users have access to comprehensive information on physical hazards and toxicity from chemicals to enhance the protection of human health and the environment during the handling, transport and use of chemicals.

The provisions of the Chemicals Omnibus amending the CLP Regulation were prepared with full respect to the GHS principles and recommendations. Specifically, for the labelling of the small packaging, the GHS provides for a possibility for the competent authorities to allow certain label elements to be omitted from the immediate container for certain hazard classes/categories where the volume of the substance or mixture is below a certain amount ([2]). Furthermore, in accordance with GHS rules, "*where the volume of a hazardous substance or mixture is so low […] and the competent authority has determined, that there is no likelihood of harm to human health or the environment, then the label elements may be omitted from the immediate container*". The existing labelling derogations for small packaging (125 ml and less) in section 1.5.2 of Annex I to the CLP Regulation were

([1]) COM(2025)531 final, https://single-market-economy.ec.europa.eu/publications/simplification-certain-requirements-and-procedures-chemical-products_en

([2]) Section 1.4.10.5.4.4 of GHS, ST/SG/AC.10/30/Rev.10.

developed in accordance with the abovementioned GHS provisions and are applicable only to certain hazard classes and categories and certain (low) volumes of the substances or mixtures. Additional derogations from labelling requirements were introduced by the Regulation (EU) 2024/2865 for substances and mixtures in a very small packaging (10 ml and below). These provisions and their impact on human health and the environment were analysed in the accompanying impact assessment ([3]).

The provisions of the Chemicals Omnibus with regard to the labelling of small packaging seek to facilitate the application of abovementioned provisions and clarify the derogation for 10 ml packaging adopted by the Regulation (EU) 2024/2865. The scope of the derogations still remains limited to low volumes and certain hazard classes, in line with the principles of UN GHS, thus seeking to ensure a high level of protection of human health and the environment. The elements that should be provided on the label are also clearly defined in section 1.5.2 of Annex I to the CLP Regulation.

Contrary to what is stated in your letter, the Chemicals Omnibus does not delete or modify existing minimum requirements concerning the dimensions of labels and pictograms. Instead, the Chemicals Omnibus seeks to simplify the formatting rules laid down for labelling of hazardous chemicals by the Regulation (EU) 2024/2865, particularly on mandatory minimum font sizes and line spacing, as these were identified being particularly burdensome and costly for industry. At the same time, to ensure a high level of protection of human health and the environment, the Chemicals Omnibus lays down general legibility requirements and requires labels to be clearly and indelibly marked, to stand out clearly from the background and to be of such a size and be spaced in such a way that will allow them to be easily read – in line with the currently applicable legibility provisions laid down in the CLP Regulation and UN GHS principles.

Regarding advertisements and distance sales, the Chemicals Omnibus lays down the requirement for distance sales offers aimed at general public to provide all label elements required by the CLP Regulation to provide consumers with all hazard information upfront before making a purchase. At the same time, the advertisements, differently from distance sales offers, are promotional communications and constitute neither placing on the market nor the offer to buy. The Chemicals Omnibus thus requires advertisements of chemicals to encourage customers to read the label and product information by including the sentence '*Always read the label and product information before use*'. The full hazard information will always be available to consumers on the label of the product in accordance with the applicable requirements of the CLP Regulation, which follow UN GHS labelling principles. The labels can be consulted before the purchase – either in a physical shop or in the distance sales offer in case of the distance sales – allowing consumers to make an informed decision.

The proposed amendment of the Cosmetic Products Regulation

Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetic Products Regulation' or 'CPR') remains one of the most protective legal frameworks for consumer products globally. Its primary objective is – and will continue to be – the highest level of protection of human health, while allowing the free movement of cosmetic products in the EU internal

([3]) Commission Staff Working Document impact assessment report accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, SWD/2022/435 final.

market. The EU framework has served as a model for many jurisdictions specifically because of its stringent health-protection provisions, including the prohibitions of carcinogenic, mutagenic or reprotoxic ('CMR') substances at EU level.

The changes proposed in the Omnibus VI Simplification regarding the CPR are strictly technical and procedural in nature. They would not alter the essence of the existing safety regime for cosmetic products, nor would they weaken any substantive provision that protects consumers. All core mechanisms ensuring safety – the obligation of a responsible person, mandatory safety assessment by a qualified safety assessor, the cosmetic product safety report, notification in the Cosmetic Product Notification Portal, and the positive and negative lists in the Annexes – remain fully unchanged. Whenever a concern arises regarding the safety of an ingredient, the Commission continues to request an independent assessment by the Scientific Committee on Consumer Safety (SCCS) and to act on its advice without delay. The rigorous, precautionary management of risks to human health therefore should remain intact.

Article 15 of the CPR establishes one of the strictest regimes in the world for CMR substances. Where a substance receives a harmonised classification as CMR category 1A, 1B or 2 under the CLP Regulation, it is prohibited for use in cosmetic products unless a derogation request is submitted and all derogation criteria are fulfilled. The Omnibus VI proposal preserves this approach. It only introduces clearer rules on when products must be withdrawn from the market. The CPR will therefore continue to contribute decisively to the removal of CMR substances from consumer products placed on the EU market, unless the strict derogation criteria are met.

It should also be recalled that the CPR was agreed upon by the legislators sixteen years ago, at a time when far fewer substances were classified as CMR and when the pace of scientific and technological development was markedly different. Today, hazard classification is more frequent and more comprehensive, which is in itself an expression of scientific progress and improved vigilance. Since then, several hundreds of CMR substances have been prohibited in cosmetic products, and the EU is banning several dozens of them each year. This evolution, however, has highlighted the need to ensure that the procedural sequence between classification, the SCCS assessment (where relevant), regulatory action and market enforcement operates smoothly and predictably, especially for smaller businesses. The proposed amendments respond to this implementation need while ensuring the high level of protection afforded to consumers. The proposed adjustments concern only the clarity and predictability of procedural timelines. Transitional measures remain limited, proportionate and pragmatic. Consumer health will remain the decisive factor in all regulatory follow-up.

Reformulation, relabelling and withdrawal of products are complex processes involving both authorities and operators. These steps can only be initiated in a legally secure environment where the sequence of decisions is transparent. The limited procedural adjustments proposed do not compromise consumer safety; on the contrary, they support effective and timely enforcement of the prohibitions already enshrined in Article 15

While the proposal aims to modernise procedures, the CPR remains the most protective legal framework for cosmetics globally, particularly regarding CMR substances. The Commission would welcome comparable health-protective mechanisms in other jurisdictions.

The proposed amendment of the Fertilising Products Regulation

Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products ('Fertilising Products Regulation') aims at creating a single market for fertilising products that comply with harmonised requirements and at promoting the circular economy and reducing waste. It applies in conjunction with other pieces of EU legislation that together ensure the safety of consumers, workers and other EU residents as well as the protection of the environment.

Contrary to other EU product legislation, the Fertilising Products Regulation allows other fertilising products to be made available on the market in accordance with national laws of the Member States. Manufacturers of fertilising products may opt for placing their products on the market according to national rules. In this case, Regulation (EC) No 1907/2006 (REACH) applies to those national products, including the registration requirements depending on tonnage.

The Fertilising Products Regulation sets out registration requirements for substances used in EU fertilising products that are significantly more extensive for substances manufactured or imported in low volumes than what is required under the REACH Regulation and applicable to substances used in all other products in the EU, including in national fertilising products. Given the flexibility offered to manufacturers to choose their way to the market, these can circumvent the higher registration requirements and other requirements laid down in the Fertilising Products Regulation by placing their products on national markets according to national rules. In many Member States, national rules for fertilising products are quite limited and only general REACH requirements apply.

However, broad single market access of safe and economically viable fertilising products and especially plant biostimulants, which stimulate plant nutrition and make crops stronger, reducing the use of plant protection products, is more efficient by complying with the Fertilising Products Regulation.

Therefore, the Chemicals Omnibus seeks to remove the extended REACH registration requirement for substances in EU fertilising products. However, the prohibition of placing on the market a product that presents a risk to human, animal or plant health, regardless of whether the risk results from non-compliance or aspects not covered by the Fertilising Products Regulation, would remain (see Article 4(1) and(2) of the Fertilising Products Regulation). Manufacturers would still be required to carry out an analysis and assessment of risks with regard to their product (see Annex IV, Part II, all Modules, point 2.1. of the Fertilising Products Regulation). In addition, once more fertilising products are marketed as EU fertilising products, as expected from this legislative amendment, more fertilising products on the internal market would comply with the stringent rules of the Fertilising Products Regulation, including its safeguards for contamination of soils, water and pollution.

Besides the safety rules in the Fertilising Products Regulation, general REACH obligations would still apply to substances used in EU fertilising products, as they apply to other substances in the EU. Under REACH, manufacturers, importers and downstream users will still be obliged to ensure the safe use of substances that they manufacture, place on the market or use. Where Member States or the Commission consider that a certain substance used in an EU fertilising product poses a risk to human health or the environment that is

not adequately controlled, they must initiate the preparation of a restriction dossier in accordance with Article 69 REACH. If the concern is well-founded and it is concluded that the risk needs to be addressed on an EU-wide basis, the substance can be banned for the use in (EU) fertilising products under REACH.

Finally, other European Union legislation will continue ensuring food safety, notably Regulation (EU) 2023/915 on maximum levels for certain contaminants in food and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, ensuring a high level of protection of consumers and public health.

***

During the preparation of the proposal, the Commission consulted stakeholders in three 'Reality Checks', one for each regulation to be amended. The 'Reality Checks' were organised seeking a broad participation of all relevant actors, including Member States' competent authorities, consumer associations, civil society organisations, and economic operators. Furthermore, all interested actors were given a possibility to provide written feedback after these meetings. All comments and suggestions expressed during and after these 'Reality Checks' were carefully analysed and taken into account by the European Commission.

In light of the above, the European Commission considers that the proposal respects the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union and adheres to the principles recognised therein, including the rights to health and environmental protection. Nothing in the proposal constitutes a retrogressive measure within the meaning of international human-rights instruments. Rather, the changes preserve the existing high level of protection and enhance regulatory robustness in view of the evolving scientific landscape. Furthermore, the reduction of administrative burden on companies should lead to societal gains in terms of wealth creation, employment and innovation. In addition, the proposed amendments would reduce the amount of paper-based documentation and decrease the need for relabelling and repackaging, thus also reducing the amount of waste, with positive impacts on the environment.

Please note, that the points made above are based on the initial proposal presented by the Commission, which is currently in the legislative process involving both the European Parliament and the Council.