

Mandate of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes

Ref.: OL OTH 120/2025

(Please use this reference in your reply)

25 September 2025

Excellency,

I have the honour to address you in my capacity as Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, pursuant to Human Rights Council resolution 54/10.

In this connection, I would like to bring to the attention of your Excellency's Government information I have received concerning the **proposal for a regulation of the European Parliament and of the Council amending the below three regulations (referred to as "Omnibus package on chemicals")**¹:

- Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging of substances and mixtures ("CLP Regulation");²
- Regulation (EC) No. 1223/2009 on Cosmetic Products ("Cosmetic Products Regulation");³ and
- Regulation (EU) 2019/1009 on EU Fertilizing Products ("Fertilizing Products Regulation").⁴

Background

In her political guidelines for the European Commission's 2024-2029, European Commission President von der Leyen's emphasized sustainable prosperity and strengthening competitiveness by streamlining business operations, among others.⁵ The 2025 Single Market Strategy supports this commitment by aiming to reduce red tape, lower costs, and improve productivity, while maintaining the ambition on the climate

¹ Regulation of the European Parliament and of the Council 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

² Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006

³ Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast)

⁴ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No. 1107/2009 and repealing Regulation (EC) No. 2003/2003

⁵ https://commission.europa.eu/document/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en

and sustainability, and social responsibilities.⁶

Following those commitments, on 9 July 2025, the European Commission presented its proposal on the Omnibus package on chemicals which aims at simplifying and streamlining certain requirements and procedures for chemical products identified as particularly burdensome by industry and authorities. The proposal argues that these provisions would benefit from regulatory streamlining and modernization, which would make chemical legislation more efficient and cost-effective for industry, while at the same time ensuring a high level of protection of human health and the environment. The Omnibus package has been formally transmitted to both the European Parliament and the Council of the European Union for consideration and negotiation.

CLP Regulation

The objectives of Regulation (EC) No. 1272/2008 (the CLP regulation) are 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 EU the United Nations' Globally Harmonised System (GHS) and establishes legally binding hazard identification and classification rules.

The CLP regulation was recently amended by Regulation (EU) 2024/2865 which came into force on 10 December 2024. Many of its provisions were scheduled for implementation in 2026 and 2027, with transitional allowances in place. However, the European Commission has proposed to delay the mandatory application of several key provisions to 1 January 2028.⁷ To ensure legal clarity and to avoid having different application dates for the same type of obligations imposed on businesses, the proposal also adjusts the transitional provisions, extending the period during which companies can voluntarily apply the new rules.

Among the amendments in the proposal,⁸ I am particularly concerned about articles relating to the formatting of labeling allowing for derogations from labelling requirements for small packaging, especially for very small containers under 10 ml (Article 29(2) and section 1.5.2.4 of Annex I). The amendment to Article 29(2) will allow economic operators to provide less information on the label for packaging containing smaller quantities of chemical substances or mixtures without the need to prove that this packaging is either in such a shape or form or is so small that it is impossible to meet full labelling requirements. Moreover, the amendment deletes minimum requirements concerning the dimensions of labels and pictograms for packages not exceeding 0,5 litres and packages greater than 0,5 litres but not exceeding 3 litres, introduced with Regulation (EU) 2024/2865 to ensure that labels on substances and mixtures are legible.

Furthermore, I am concerned about the proposed amendment relating to advertisement and online sales of chemicals sold to the general public (Article 48 and 48a). In order to allow consumers to make an informed decision, information on the

⁶ COM(2025)500 - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - The Single Market: our European home market in an uncertain world

⁷ COM(2025)526 - Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2024/2865 as regards dates of application and transitional provisions

⁸ See supra note 1

hazards of a substance or mixture needs to be available upfront during advertisement.

Cosmetic Products Regulation

Regulation (EC) No. 1223/2009 on cosmetic products applies to all cosmetic products made available on the EU market either manufactured in the EU or entering the EU market from third countries. The regulation impacts manufacturers, importers, distributors, and consumers by ensuring that all cosmetic products in the EU are safe for use and that the rules for selling them are consistent across countries.

Article 15 of the Cosmetic Products Regulation establishes that substances which have been classified as carcinogenic, mutagenic or reprotoxic (CMR) in Annex VI to the Regulation are prohibited for use in cosmetic products, unless an exemption has been granted.

The Commission has noted in its proposal that changes to Article 15 do not affect the current approach that the hazard-based harmonized classification of a substance as CMR category 1 or 2 triggers its prohibition in cosmetic products, unless a derogation request is submitted, and the derogation criteria are met. I am, however, concerned about weakened safeguards preventing the use of CMRs in cosmetics. In particular, the proposed amendment would allow selling products that contain CMRs for years longer than is currently permitted.

Fertilizing Products Regulation

The general objective of the Regulation (EU) 2019/1009 was to incentivize large scale fertilizing products production in the EU from domestic organic or secondary raw materials by creating a regulatory framework granting such fertilizing products easier access to the internal market.

The amendment seeks to remove the requirement that all substances incorporated into an EU fertilizing product, on their own or in a mixture, except polymers, shall be registered pursuant to REACH Regulation (EC) No. 1907/2006. In absence of any specific requirements under the Fertilizing Products Regulation, the general REACH provisions, including the relevant gradations depending on quantity, would apply to substances used in EU fertilizing products.

I am concerned that the amendment would weaken safety controls related to substances used in fertilizers. As noted by the Special Rapporteur on the right to food in his communication concerning the European Union's Common Agricultural Policy Simplification Package (OTH 78/2025, 12 June 2025) fertilizers negatively impact soil depletion, water and air pollution, biodiversity loss, and overall public health.

Environment and human rights impact assessment

I am concerned that there has not been a full impact assessment of the proposed omnibus package. In relation to the impact assessment, the Commission's proposal itself notes⁹:

⁹ https://single-market-economy.ec.europa.eu/document/download/ebed9e83-9e40-4b0c-8439-2d3f2af190ae_en?filename=COM_2025_531_1_EN_ACT_part1_v4.pdf, pg. 10

“Given the need to urgently put forward a proposal to address the identified problems in order to reduce administrative burden and excessive costs for businesses it has not been possible to prepare a full impact assessment.”

On the basis of the information available, it is expected that the amendments would entail significant cost savings for industry and for authorities. No detrimental impacts to human health and the environment are expected. The removal of certain obligations under the three pieces of legislation will not compromise the high level of protection ensured by the overall EU legal framework for chemical substances and products. At the same time, certain environmental benefits can be expected from the proposed amendments.” However, I am concerned that due to the lack of a full impact assessment, there has not been an opportunity to evaluate the potential detrimental human rights and environmental impacts.

Consultations

The Commission is obligated under the Treaty on European Union and EU Better Regulation principles to ensure evidence-based and participatory decision-making. This means that the Commission must independently assess any proposals submitted in terms of their impact, including on human rights and the environment.

In preparation of the proposal, the Commission consulted stakeholders in three Reality Checks, on 7 and 16 May 2025. The workshop on the CLP regulation on 16 May reportedly included 450 participants, mostly representing industry interests. Only a handful of consumer and environmental NGOs took part, which undermines the credibility of the process. NGOs have raised concern that the accelerated timeline for the chemicals omnibus package is an intent to fast-track legislative amendments without a proper impact assessment or stakeholder consultation.¹⁰

While I appreciate the objective of simplification, reducing regulatory burdens and economic efficiency, I would like to underline that there is a high risk that the proposed Omnibus package on chemicals, as currently drafted, may negatively impact human rights, including the rights to health and a healthy environment, reversing recent improvements and creating legal uncertainty for businesses that have already invested in compliance. It is possible to simplify EU regulations while respecting and protecting human rights. In this regard, I am also concerned that public input, especially from those potentially affected, has been bypassed, and the impact assessment draws mainly on data provided by industry. In this context, it is important to address the concerns raised by civil society, including by ensuring the right to participation.¹¹ I also note that some groups in the European Parliament have expressed concern that the European Commission’s proposal prioritizes industrial interests and rolls back vital health and environmental protections across several key areas of EU chemicals legislation. They further expressed concern that the proposal counters the precautionary principle and is likely to increase exposure to hazardous chemicals for both people and the environment by making it easier to use carcinogens in cosmetics; weakening hazard labelling requirements for products sold to the public; and reducing safety controls on substances

¹⁰ <https://eeb.org/wp-content/uploads/2025/06/NGO-Comments-CLP-Simplification-May2025.pdf>

¹¹ <https://www.clientearth.org/media/aupjcz42/letter-to-the-ec-chemicals-omnibus-fin.pdf>

used in fertilizers.¹²

I would therefore like to bring to your attention human rights concerns related to the proposed amendments, with the aim of ensuring that alignment with international human rights standards is fully integrated into the ongoing negotiations. Respect for human rights lies at the core of the just transition to a chemically safe circular economy. The regulation of chemicals is closely linked to the effective enjoyment of human rights, as states have a duty to prevent harm by ensuring that toxic substances do not endanger people's life, health, safety, or environment. Exposure to hazardous chemicals can compromise the full enjoyment of human rights and constitute violations of international human rights norms and standards, including the right to life, the right to the highest attainable standard of health, the right to a clean, safe, healthy and sustainable environment, the right to adequate food and the right to clean water.

The right to a healthy environment has been recognized by the Human Rights Council (A/HRC/RES/48/13), the General Assembly (A/RES/76/300) and the International Court of Justice (Advisory Opinion of 23 July 2025). The right to live in a non-toxic environment is a substantive element of the right to a clean, healthy, and sustainable environment.

International environmental law and human rights law also mandate meaningful and informed participation, including in environmental decision-making. The right to participation is reflected in human rights instruments such as the International Covenant on Civil and Political Rights, the UN Declaration on the Right to Development, the Human Rights Council Guidelines on participation ([A/HRC/39/28](#)), and the UN Framework Principles on human rights and the environment ([A/HRC/37/59](#)) as well as environmental instruments such as the Aarhus Convention, which the European Union is party to. I encourage you to hold extensive, in-depth dialogue and active consultations that would allow concerned individuals, communities and civil society organizations to take full part in a full impact assessment, and guarantee access to information.

Simplicity and efficiency should not come at the expense of retrogressive measures or the health of the population, especially those that are the most vulnerable to toxics and pollution such as children. Weakening the current regulatory framework would be a step backward when it comes to environmental standards, hence a potentially retrogressive measure as per the Framework Principles on Human Rights and the Environment, which set out basic obligations of States under human rights law as they relate to the enjoyment of a safe, clean, healthy and sustainable environment. More specifically, principle 11 provides that “States should establish and maintain substantive environmental standards that are non-discriminatory, non-retrogressive and otherwise respect, protect and fulfil human rights”. Additionally, as noted by the Committee on Economic, Social and Cultural Rights (CESCR), “any deliberately retrogressive measures [which would impact the realization of the rights of the Covenant] would require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources” (general comment No. 3, para. 9). In my view, there is no compelling justification to explain the above-mentioned measures.

¹² <https://socialistsanddemocrats.eu/newsroom/commissions-chemicals-package-gift-corporate-interests-expense-public-health>

The principle of non-retrogression is fundamental not only to international human rights and environmental law, but also European Union law. The Omnibus package on chemicals seems to contradict Article 37 of the Charter of Fundamental Rights of the European Union, Article 3 of the Treaty on the European Union and Article 191 of the Treaty on the Functioning of the European Union, which require an improvement of the quality of the environment.

The proposal also seems to conflict with rights set out in the Charter of Fundamental Rights of the European Union, including the rights to health and environmental protection. Additionally, it undermines the European Union's credibility as a global leader in green policy and the rule of law. The European Union has played a leading role at the global level in advancing a strategic vision on environmental policies, including on chemicals. Given the European Union's role in promoting human rights globally, I encourage it to continue to lead by example and ensure that its legislation complies with international human rights norms and standards relating to chemicals.

As it is my responsibility, under the mandate provided to me by the Human Rights Council, to seek to clarify all cases brought to my attention, I would be grateful for your observations on the following matters:

1. Please provide any additional information and/or comment(s) you may have on the above-mentioned observations.
2. Please provide your observations on how the EU intends to ensure compatibility of the proposed omnibus package with international human rights norms and standards, highlighted in the present communication.
3. Please provide information on any steps that have been taken or are planned to ensure meaningful and informed participation in the development of the proposed omnibus package.

This communication, as a comment on pending or recently adopted legislation, regulations or policies, and any response received from your Excellency's Government will be made public via the communications reporting [website](#) after 48 hours. They will also subsequently be made available in the usual report to be presented to the Human Rights Council.

Please accept, Excellency, the assurances of my highest consideration.

Marcos A. Orellana
Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes