Chemicals Omnibus and Chemicals Action Plan: the EU's deregulation trend prioritises corporate interests over citizens' health.

ESPE – ESE – Endocrine Society Joint Statement

The European Society for Paediatric Endocrinology (ESPE), the European Society of Endocrinology (ESE) and the Endocrine Society represent scientists and clinicians dedicated to advancing the understanding, prevention, diagnosis, and treatment of hormone-related disorders across all life stages.

We would like to express our concern about the European Commission's proposed *Chemicals Omnibus*[i] and *Chemicals Action Plan*. Under the guise of simplifying chemical legislation and strengthening industry's competitiveness, these proposals risk significantly weakening consumer protection and putting human health and the environment at risk.

I – Endocrine Disrupting Chemicals (EDCs) and Carcinogenic, Mutagenic and Reprotoxic (CMR) Substances

There are over 350,000 synthetic chemicals in the world[ii] and the United States alone produce an average of 1500 new substances a year[iii]. More than 50 chemicals are known EDCs[iv] and more than a thousand are "suspected EDCs" based on their probable endocrine-interfering properties[v]. Many of these synthetic chemicals are encountered by people in their daily lives, for example cosmetic products, but overall significantly less than 1% of these substances have undergone safety assessments.

While EDCs are defined by the impacts on the endocrine system rather than specific endpoints, many endocrine EDCs can also be CMR substances:

- **Carcinogenicity**: EDCs can contribute to cancer by mimicking or interfering with hormonal activity. Many chemicals listed by the US National Cancer Institute as carcinogens[vi] are also known EDCs;
- **Mutagenicity**: Some pesticides and industrial chemicals have both endocrine-disrupting and mutagenic effects[vii].
- **Reproductive toxicity**: EDCs such as phthalates, PFAS, BPA (Bisphenol A), TCS (Trichlorosilane), and DES (Diethylstilbestrol) interfere with reproductive hormones and are linked to infertility[viii];

Taking into account the collective effects of both classes of hazardous chemicals, CMR substances and EDCs are associated with numerous adverse health effects related to cancer, infertility, obesity, diabetes, and disorders of the immune system and neurodevelopment – all non-communicable disorders whose incidence is increasing across Europe.

Additionally, they also have a disproportionate economic impact. CMR hazards and cancer-related costs are estimated in Europe alone at €199 billion annually[ix], while the remediation costs of EDCs

such as PFAS are estimated at €100 billion. The latter does not include additional healthcare costs, which are estimated to be between €52-84 billion annually[x].

II – Risks of simplifying the Cosmetic Products Regulation (CPR)

Cosmetic products are used daily by people of all ages across Europe. In France, for example, the average number of cosmetic products used daily is 18 for pregnant women, and 6 for children under three years of age[xi,xii]. A recent breakthrough publication underlines that the use of various care and cosmetic products by pregnant women, infants and adolescents can result in exposure that exceeds the half-maximal genotoxic effect doses (EC_{50}) by a factor of 100,000[xiii]. In addition, this publication also reveals that many cosmetic products contain undeclared or forbidden chemicals, among them EDCs and CMRs.

Exposure to hazardous substances during these sensitive stages of development, or also during the preconception period, for both women and men, is particularly concerning, as it can have lifelong and even inter- and transgenerational negative health consequences.

Given the widespread use of cosmetics by vulnerable groups, it is essential that the CPR ensures the highest level of protection against harmful chemicals, for both current and future generations.

In this regard, we are particularly concerned with the following proposed modifications to Article 15 of the CPR:

- **Derogation criteria (art 15(2))**: We do not support the proposed simplification of derogation criteria, which would eliminate key safeguards without reducing the administrative burden of companies. In particular, removing the requirement for compliance with food safety standards poses significant risks for young children, who may accidentally ingest cosmetic products (e.g. through hand-to-mouth behaviour). Without this requirement, substances that are not safe to ingest might be used in cosmetics intended for young children, increasing their risk of contamination.
- **Natural complex substances (art. 15(6))**[xiv]: We disagree with the proposal to treat synthetic and natural complex substances differently regarding their CMR content. The origin of a substance does not affect its toxicity, and thus this origin should not be considered under Article 15. In fact, exempting natural complex substances, even in small quantities, from CMR restrictions could be harmful.
- **Route of exposure (art. 15(5))**: We strongly oppose limiting bans to substances classified as CMRs through dermal exposure alone. Many cosmetics can also be inhaled or ingested, especially by children. This proposal would overlook the real-world routes of exposure and significantly undermine health protections.

III – The Chemicals Action Plan

We support the proposal for a universal restriction of PFAS, while appreciating that an essential use approach may be necessary for specific applications. “Essential” means that PFAS should only be utilised in those uses that are necessary for health or safety, or are critical for the functioning of

society, where no alternatives are available[xv]. Secondly, the half-life or the time required for a PFAS substance to reduce to half of its initial value should be taken into account for all regulatory measures.

We are firmly convinced that a ban of PFAS in consumer products like cosmetics, food contact materials and outdoor clothing would be a first important step towards a ban in all consumer products.

ESPE, ESE and Endocrine Society experts remain available to work with the EU institutions towards an effective regulatory framework on cosmetic products that does not harm consumers' health.

Furthermore, we will reinforce our strategic efforts to disseminate information on these high-priority health issues. This will involve not only the continued use of their annual congresses and official scientific journals to inform and engage the professional and research communities, but also the implementation of coordinated communication strategies across mainstream and digital media platforms. These actions aim to enhance public awareness and policy engagement, with a particular focus on safeguarding the health of vulnerable groups, notably children and pregnant women.

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About the European Society for Paediatric Endocrinology
The European Society for Paediatric Endocrinology (ESPE) is an international society registered in Europe that promotes the highest levels of clinical care for infants, children and adolescents with endocrine problems throughout the world, including in less advantaged areas. At the EU level, it works with the EU and partner organisations to create a healthier environment for children and adults.

To find out more about ESPE, please visit **eurospe.org.**

About the European Society of Endocrinology
The European Society of Endocrinology (ESE) provides a platform to develop and share leading research and best knowledge in endocrine science and medicine. Through the 50 National Societies involved with the ESE Council of Affiliated Societies (ECAS) and partnership with specialist endocrine societies, ESE and its partners jointly represent a community of over 20,000 European endocrinologists.

ESE and its partner societies work to promote knowledge and education in the field of endocrinology for healthcare professionals, researchers, patients and the public. ESE informs policymakers on health decisions at the highest level through advocacy efforts across Europe. Find out more: **www.ese-hormones.org.**

About the Endocrine Society
Endocrinologists are at the core of solving the most pressing health problems of our time, from diabetes and obesity to infertility, bone health, and hormone-related cancers. The Endocrine Society is the world's oldest and largest organisation of scientists devoted to hormone research and physicians who care for people with hormone-related conditions.

The Society has more than 18,000 members, including scientists, physicians, educators, nurses, and students in 122 countries. To learn more about the Society and the field of endocrinology, visit our site at **www.endocrine.org**. Follow us on X (formerly Twitter) at **@TheEndoSociety** and **@EndoMedia**.

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REFERENCES

[i] An omnibus is a legislative proposal which introduces changes in several pieces of legislation, usually on the same broad topics. The Chemicals omnibus proposed by the European Commission would see changes introduced to the Classification, Labelling and Packaging Regulation, the Cosmetic Products Regulation and the Fertilizer Products Regulation.

[ii] Wang Z, Walker GW, Muir DCG, Nagatani-Yoshiida K. Toward a Global Understanding of Chemical Pollution: A First Comprehensive Analysis of National and Regional Chemical Inventories. *Environmental Science & Technology*. 2020 Mar; 3;54(5):2575-2584. doi: 10.1021/acs.est.9b06379

[iii] Naidu R, Biswas B, Willett IR, Cribb J, Kumar Singh B, Paul Nathanail C, Coulon F, Semple KT, Jones KC, Barclay A, Aitken RJ. Chemical pollution: A growing peril and potential catastrophic risk to humanity. *Environment International*. 2021 Nov; 156:106616. doi: 10.1016/j.envint.2021.106616

[iv] https://echa.europa.eu/da/ed-assessment

[v] Endocrine Society. Common Endocrine Disrupting Chemicals and Where They Are Found. https://www.endocrine.org/topics/edc/what-edcs-are/common-edcs

[vi] U.S. National Cancer Institute. Cancer-Causing Substances in the Environment. https://www.cancer.gov/about-cancer/causes-prevention/risk/substances

[vii] Min Choi S, Dong Yoo S, Mu Lee B. Toxicological characteristics of endocrine-disrupting chemicals: developmental toxicity, carcinogenicity, and mutagenicity. *J Toxicol Environ Health B Crit Rev.* 2004 Jan-Feb; 7(1):1-24. doi: 10.1080/10937400490253229

[viii] Dutta S, Sengupta P, Bagchi S, Chhikara BS et al. Reproductive toxicity of combined effects of endocrine disruptors on human reproduction. *Frontiers in Cell and Developmental Biology*. 2023 May; 12;11:1162015. doi: 10.3389/fcell.2023.1162015

[ix] Hofmarcher T, Lindgren P, Wilking N, Jönsson B. The cost of cancer in Europe 2018. *European Journal of Cancer*. 129 (2020) 41-49. https://doi.org/10.1016/j.ejca.2020.01.011

[x] Calatayud JM, et al. The forensics of the plastic industry disinformation campaign to defend PFAS. *The Forever Lobbying Project.* 2025 Jan. Available from: https://foreverpollution.eu/lobbying/the-disinformation-campaign/

[xi] Marie C, Garlantézec R, Béranger R, Ficher AS. Use of Cosmetic Products in Pregnant and Breastfeeding Women and Young Children: Guidelines for Interventions during the Perinatal Period from the French National College of Midwives. *Journal of Midwifery & Women's Health*, 67, S99-S112. https://onlinelibrary.wiley.com/doi/10.1111/jmwh.13428

[xii] Ficheux AS, Dornic N, Bernard A, Chevillotte G, Roudot AC. Probabilistic assessment of exposure to cosmetic products by French children aged 0-3 years. *Food Chem Toxicol*. 2016; 94: 85-92. https://doi.org/10.1016/j.fct.2016.05.020

[xiii] Morlock GE, Zoller L. Fast unmasking toxicity of safe personal care products. *Journal of Chromatography*, July 2025; 1752, 465886. https://doi.org/10.1016/j.chroma.2025.465886

[xiv] Natural Complex Substances are a heterogeneous family of substances that are notably used as ingredients in several products, including cosmetics. The compositions of natural complex substances vary widely and hundreds to thousands of compounds can be present at the same time.

Mattoli L, Leucchini C, Fiordelli V, Burico M, Gianni M, Zambaldi I. Natural complex substances: From molecules to the molecular complexes. Analytical and technological advances for their definition and differentiation from the corresponding synthetic substances. *Phytochemistry*, November 2023; 113790. https://doi.org/10.1016/j.phytochem.2023.113790

[xv] Juliane G, Cousins IT, Wang Z, et al. Information Requirements under the Essential-Use Concept: PFAS Case Studies. *Environ Sci Technol.* 2022; 56(10):6232–6242. https://pubs.acs.org/doi/10.1021/acs.est.1c08254