Opinion of the European Economic and Social Committee on 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — Chemicals Strategy for Sustainability — Towards a Toxic-Free Environment'

(COM(2020) 667 final) (2021/C 286/30)

Rapporteur: Maria NIKOLOPOULOU

Co-rapporteur: John COMER

Referral European Commission, 28.10.2020

Legal basis Articles 192(1) and 304 of the Treaty on the Functioning of the

European Union

Section responsible Section for Agriculture, Rural Development and the Environment

Adopted in section 15.4.2021
Adopted at plenary 27.4.2021
Plenary session No 560

Outcome of vote

(for/against/abstentions) 242/1/7

# 1. Conclusions and recommendations

- 1.1. The EESC supports the Commission's objective of moving towards a toxic-free environment and ensuring that chemicals are produced in a way that maximises their positive contribution to society and reduces the environmental impact.
- 1.2. A definition of what uses of chemicals are 'essential' is needed, and a clearly outlined methodology for how to make chemicals 'safe and sustainable by design'. In this context, we emphasise that 'substances of concern' must be identified, evaluated and classified in the most comprehensive, unambiguous and simplified manner so that industry can adapt.
- 1.3. The EESC compliments the Commission on its view that the EU should be a global frontrunner in the production and use of safe and sustainable chemicals and highlights the importance of assuring a level playing field in international trade deals for companies, and measures for a just transition for all EU citizens.
- 1.4. In order for the strategy to be successful, people's and industry engagement is required, as well as innovative ways of thinking, coupled with transparency and involvement in the decision-making process.
- 1.5. The strategy aims to extend the generic approach to risk management to consumer products containing hazardous chemicals such as carcinogenic, mutagenic or endocrine disruptors. However, to make it easier for industry to adapt, the balance between generic and risk assessments needs to be ensured.
- 1.6. The EESC calls for proper and consistent labelling to be mandatory, with enforcement for the whole supply chain, including products containing nanomaterials.
- 1.7. The EESC welcomes the effort to strengthen the EU's strategic autonomy, especially in terms of chemicals used for health applications, and wishes to see the same effort in other sectors and calls for a revision of EU Industrial Policy to be considered, with a view to relocating part of the key chemicals production in the EU countries.

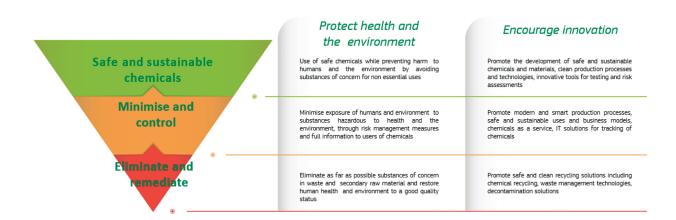
- 1.8. The EESC stresses the importance of tackling the lack of availability of chemical data so as to boost innovation, consumers' trust and conduct proper impact assessments. It is vital to have accessible and reliable databases for research results to review the industrial property rights and patents that limit access to data, and to strengthen the principle of 'no data-no market'.
- 1.9. The EESC considers that addressing chemical mixtures is a relevant step forward in the risk assessment of chemicals. However, more research and development is crucial to cover the actual gaps of knowledge and put forward the assessment and management of chemical mixtures.

# 2. Commission's proposal

- 2.1. This strategy is an opportunity to reconcile the societal value of chemicals with human health and the limits of our planet, responding to the legitimate aspirations of EU citizens for a high level of protection from hazardous chemicals, and to promote EU industry as a global frontrunner in the production and use of safe and sustainable chemicals.
- 2.2. To strive for a toxic-free environment, a new hierarchy in chemicals management is established, which includes the use of safe and sustainable chemicals, the minimisation or substitution of substances of concern with a chronic effect on human health and the environment, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products.

Figure

The toxic-free hierarchy — a new hierarchy in chemicals management



# 2.3. The strategy focuses on five main goals

- 2.3.1. Innovate for safe and sustainable EU chemicals. Proposed measures include, among others, developing EU safe and sustainable-by-design criteria for chemicals; introducing legal requirements on the presence of substances of concern in products through the initiative on sustainable products and making amendments to EU legislation on industrial emissions to promote the use of safer chemicals by EU industry.
- 2.3.2. Strengthen the EU legal framework to address pressing environmental and health concerns. The actions proposed are geared towards the protection of consumers and workers to avoid the presence of the most harmful chemicals in all consumer products, e.g. food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles. Specific attention will be devoted to chemicals that can cause cancers, gene mutations, affect the reproductive or the endocrine system or are persistent and bioaccumulative. This approach will eventually apply to chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ. Until the generic approach to risk management is in place, substances with all the above-listed hazards will be prioritised for restrictions for all uses and through grouping, instead of regulating them one by one.

- 2.3.3. Simplify and consolidate measures to improve the legal framework. The proposal includes the establishment of a 'one substance, one assessment' process to coordinate the hazard/risk assessment of chemicals across chemical legislation, to strengthen the governance of the European Chemicals Agency and increase the sustainability of its financing model. In addition, the strategy proposes targeted amendments to the REACH (Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (the Regulation on classification, labelling and packaging) to be carried out in line with the better regulation principles and subject to evaluations and impact assessments, as appropriate.
- 2.3.4. Build a comprehensive knowledge base on chemicals. An EU early warning and action system for chemicals will be developed to ensure that EU policies address emerging chemical risks as soon as they are identified by monitoring and research; and to create a framework of indicators to monitor the drivers and impacts of chemical pollution and measure the effectiveness of chemicals legislation.
- 2.3.5. Set the example for a global sound management of chemicals. These actions will aim to support the capacity-building of third countries in chemicals assessment and management and to ensure that hazardous chemicals banned in the EU are not produced for export.

#### 3. General comments

3.1. Over the past 50 years, chemicals have become central to our way of life, making a positive contribution to our culture and to the progress of society as a whole, with its growing population. At the same time, chemicals – both synthetic and naturally occurring ones – can have hazardous properties posing a risk to human health and the environment.

Despite this, humanity is increasingly dependent on them. According to the UN, chemicals output will grow seven times faster than the global population between 1990 and 2030.

- 3.2. We should all agree to the laudable objective of a toxic-free environment and no matter how difficult it is to achieve it, there is no excuse for not trying to move forward. The EESC welcomes the Commission's intention to establish a **high-level roundtable** with all stakeholders for this purpose.
- 3.3. Large quantities of hazardous chemicals continue to leak into the environment, from many sources, such as treated or untreated domestic and industrial wastewater discharge, landfill, incineration and manufacturing processes etc., and can spread through air, soil and water, where they do serious damage (1).
- 3.4. There are many legacy issues due to chemical contamination. For example, PBDEs (Polybrominated diphenyl ethers) and other flame retardants migrate easily from the products they are added to, such as polyurethane foam, and then contaminate air and dust. Although many harmful PBDEs have been banned, they remain in the environment due to their persistence and extensive use.
- 3.5. When replacing such hazardous chemicals, we need to be sure that the impact of the replacement is a significant improvement. For example, palm oil biodiesel, which contributes to deforestation, might be worse for the environment than using fossil fuels.
- 3.6. Moreover, regulators need to be aware of and avoid attempts at replacing one hazardous chemical with chemicals that have similar hazardous properties. For instance, PFAS should be dealt with as a group rather than on an individual basis. New research suggests that some alternatives to legacy PFASs may be no safer (²).

<sup>(1)</sup> Joyce Msuya, deputy director of the UN Environment programme.

<sup>(2)</sup> EU news alert issue 517, 22.11.2018.

- 3.7. The EESC is concerned that decontamination actions to restore human health and the environment may not be sufficient, especially for essential chemicals for which toxic-free alternatives are not available yet or require long-term development process, as well as those phased-out chemicals that are still a matter of great concern due to their persistence in the environment. As there are still great efforts to adopt decontamination strategies, the EESC is looking forward to seeing the upcoming 'Zero pollution action plan'.
- 3.8. The EESC calls for proper and consistent labelling to be mandatory for the whole supply chain, with enforcement, for products containing nanomaterials (toys, biocides, clothes, pesticides, drugs, paints, childcare products, etc.).
- 3.9. The EESC also wonders if the timeline for the several actions to be held in parallel is realistic and feasible, considering industry's need to adapt to the transition gradually without severe negative social and economic consequences. Moreover, the capacity building of authorities needs to be reinforced; this is essential for the successful implementation of the planned updated policies.
- 3.10. Some aspects are missing or not sufficiently explained in the strategy, such as the estimated energy balance of the suggested chemical transition, and the consequences for workers and big and small companies in Europe. The European Structural and Investment Funds should dedicate financial resources to ensure effective implementation of the strategy.

### 4. Specific comments

- 4.1. Innovating for safe and sustainable EU chemicals
- 4.1.1. It is agreed that the transition to **safe and sustainable-by-design criteria for chemicals** is a social and economic imperative, in order to facilitate the green and digital transition of EU industry. This will be an enormous challenge and the necessary research is potentially very costly and will offer some competitive advantages. However, some job losses and economic losses might ensue, as not all companies might be able to adapt and not all workers to be reskilled/upskilled. Therefore, financial and incentive measures are crucial to achieve a just transition, with special reference for workers to keep their jobs or have a viable alternative, support investments and innovative business models.
- 4.1.2. Measures to ensure complete adaptation for workers, such as the incentivisation and funding of re-skilling and specialisation training in order to prevent job losses, are not specified. It is also concerning how the geo-allocation of industry sectors will determine the impact of the strategy. Industries located in peripheral areas should be taken into consideration, as well as the high rate of SMEs participating in the sector.
- 4.1.3. The concept of 'safe and sustainable-by-design' that will be developed causes concerns among stakeholders. For this reason, its definition and the appropriate skills to boost their production should involve the criteria of all the relevant actors.
- 4.1.4. The process for registration, evaluation and authorisation for chemicals is complex and requires specialisation, which is sometimes challenging for SMEs and usually entails high compliance and administrative costs. To facilitate the fulfillment of registration and regulatory risk management processes in REACH and CLP, the process should be simplified or training for non-experts could be incentivised.
- 4.1.5. Novel and cleaner industrial processes and technologies will reduce the environmental footprint of chemicals production, improve market readiness and achieve the Sustainable Development Goals and the overarching European Green Deal. Assessment guidelines and sharing of best practices on the design and implementation of cleaner industrial processes and technologies would make such a transition possible. The best available technologies need to be considered.

- 4.1.6. The Commission aims to minimise the presence of substances of concern in **recycled materials**, by introducing requirements and information on chemical content and safe use as part of the **Sustainable Product Policy Initiative**. The use of recyclable materials should not allow the use of hazardous chemicals in higher concentrations to remain (3). 'Substances of concern' must be identified, evaluated and classified in the most comprehensive, unambiguous but also simplified manner so that industry is enabled to adapt.
- 4.1.7. These measures will increase the **confidence** of consumers and producers for recycled products. The lack of adequate information on the chemical content of products produced by recycled materials is an issue and data protection restrictions could pose problems in this area.
- 4.1.8. The strategy announces increased investment in innovative technologies. This is a great opportunity to **foster research in the field of valorisation of industrial waste products, particularly from agri-food waste**, the great potential of which has been hampered by insufficient investment.

However, **legal requirements for products from agri-food waste valorisation** are almost neglected in both the 'Farm to Fork' and sustainable chemicals strategies. For instance, the presence of pharmaceutical residues in treated animal manure for fertilisation, the re-use of treated waste-water for crop irrigation and the residues of pharmaceuticals and pesticides, herbicides and insecticides in optimised food waste are matters of particular concern, as these bioactive substances might spread throughout the environment, triggering adverse effects on ecosystems. They should, therefore, be identified, evaluated and regulated. Human populations might be affected not only via exposure but also through consumption, as these substances may bioaccumulate and bio-magnify along the food chain.

- 4.1.9. Substances considered of concern cause confusion among stakeholders. An explanation of what kind of requirements are to be introduced and the timeline for implementation would be helpful so as to understand the impact of this measure on current material cycles.
- 4.1.10. The estimated energy balance of the suggested chemicals transition is a matter of concern. Given that the main required transformations for green material cycles are heavily endothermic processes (e.g. separation, recycling, decontamination, chemical conversion), the energy demand is expected to increase. Besides, the carbon footprint from manufacturing chemicals needs to be reduced, as it is usually an energy-intensive process.
- 4.1.11. Hydrogen has great potential for this purpose, both as an energy source and as a chemical reduction agent in targetable processes (e.g. to replace carbon as a reductor). However, hydrogen fuel cells still rely on expensive and environmentally costly platinum. There is a need for fundamental chemical research to find alternatives to platinum.
- 4.1.12. The Commission envisages more resilience in the supply and **sustainability** of chemicals used in **essential applications** for EU society by making the EU less dependent and increasing strategic foresight for chemicals. Increasing the resilience of chemicals used in health applications will mark considerable progress for the EU market and industry of chemicals used in healthcare. We need to know how these measures would apply to other chemicals of essential use.
- 4.1.13. Products made with raw materials imported from non-EU countries, for instance, REE, acquired through ore mining activities that pose environmental and health hazards, have become critical to several modern technologies, ranging from defence systems, mobile phones and televisions to LED light bulbs and wind turbines. Thus, the question arises as to what strategies will be put in place to tackle the dependency on other essential substances, for which production processes rely on supply from non-EU countries.

<sup>(3)</sup> EESC opinion on the 'Implementation of EU environmental legislation in the areas of air quality, water and waste' (OJ C 110, 22.3.2019, p. 33).

- 4.1.14. The EESC also wonders how the 'safe and sustainable-by-design' approach will be applicable to non-EU suppliers, which have their own chemicals regulations. Since the limits of these criteria for the production of chemicals have not yet been established, it is not clear whether the principle and the assessment measures would apply to raw material sources, regardless of their origin. It remains unclear how the proposed measures will be interlinked and balanced with different existing policies in non-EU countries involved in EU chemicals value chains.
- 4.1.15. The EESC therefore suggests that the EU Industrial Strategy be reviewed and that consideration be given to incentivising the return of chemicals production to EU countries. This will not only boost the EU's strategic autonomy but it will also create new quality jobs and facilitate the achievement of the chemicals strategy.
- 4.2. Stronger EU legal framework to address environmental and health concerns
- 4.2.1. The EESC welcomes the Commission's aim to extend the generic approach to risk management. Nevertheless, given that some products will be restricted, it is necessary to ensure consistency between generic and specific risk assessments in all chemicals, so as to enable industry to gradually adapt.
- 4.2.2. The EESC also welcomes the use of grouping to address PFAS regulation and endorses that the extent to which grouping strategies are adopted might need to be scaled up in order to increase the efficiency and effectiveness of the legislation (4).
- 4.2.3. The strategy will propose new hazard classes and criteria in the CLP Regulation to fully address environmental toxicity, persistency, mobility and bioaccumulation. It is important that the evaluation of chemicals' adverse effects on the environment and the allocation of different hazard classes to chemicals are performed on a comprehensive and transparent basis. The classification criteria should be defined in detail, so as to anticipate potential concerns about other products under development.
- 4.2.4. The introduction of endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances as categories of (Substances of Very High Concern) SVHC requires relying on comprehensive and transparent assessment and evaluation. Moreover, greater coherence between the SVHC identified in REACH and other European legislation (e.g. the EU Water Framework Directive) is needed.
- 4.2.5. The strategy mainly focuses on EDCs and PFAS, and also addresses pesticides, biocides, pharmaceuticals, heavy metals, plasticisers and flame retardants as hazardous substances. However, other chemicals of concern, such as nanomaterials, are barely mentioned. Though they are included in the REACH, the revision of the definition is pending and their regulation remains insufficient (e.g.: the lack of regulation of releases of nanomaterials into the environment, no restriction on their placing on the market, transparency and the establishment of an EU register to ensure their traceability from manufacture to consumers).
- 4.2.6. Given the widely documented evidence of the risks associated with some families of substances, the EU should not only restrict but sometimes even ban the use of already identified EDCs such as bisphenol, and phthalates –this also applies to chemicals with no nutritional utility in food products, such as nanomaterials.
- 4.2.7. Measures to promote and facilitate the substitution of SVHC and other hazardous compounds could be implemented through a financial mechanism (bonus/malus).

<sup>(4)</sup> EC Study for the strategy for a non-toxic environment of the 7th Environment Action Programme.

- 4.2.8. It is a relevant step forward in the risk assessment of chemicals of concern that mixtures are given special attention and the EESC welcomes the fact that both intentional and unintentional mixtures will be addressed. However, the remaining knowledge gaps on the toxicity and exposure to mixtures and the large number of chemicals in use lead to proposals such as the systematic use of the Mixture Assessment Factor (MAF) for single chemicals, to address unintentional mixtures. The reliability of MAF in chemical risk assessment raises concern, as this is not a scenario-specific factor. The EESC, therefore, strongly subscribes to the priorities and recommendations on research and development pointed out in the report (SWD(2020) 250 (5)) so as to effectively assess and manage chemical mixtures.
- 4.3. Simplifying and consolidating the legal framework
- 4.3.1. The EESC embraces the 'one substance, one assessment' approach to be considered for the efficient safety assessment of chemicals.
- 4.3.2. This will simplify and speed up the approval process, which will benefit producers and will facilitate the research and development of alternative toxic-free substances. However, the different impacts of the same substance in different circumstances and also in mixtures should not be dismissed.
- 4.3.3. Some 30 % of alerts regarding dangerous products on the market involve risks due to chemicals and only one third of the registration files of the chemical substances registered by industry under REACH are fully compliant with the information requirements.
- 4.3.4. The zero-tolerance approach to non-compliance and the proposed actions to step up the implementation and enforcement of chemicals legislation are welcome. It is strongly recommended, that the principle of 'No data, no market' is properly implemented, instead of having unregulated products and chemicals on the markets.
- 4.3.5. Moreover, data on chemical substances approved for the market should be updated at regular intervals by the same registrants, as REACH is insufficient on certain aspects. According to the Chemical Evaluation Report (6), 64 % of the substances under evaluation (126 out of 196) lacked the information to demonstrate the safety of the chemicals marketed in Europe.
- 4.3.6. Almost 90 % of the products considered dangerous are imported from outside the EU. Global chemicals production is projected to continue to increase. It is likely that the EU and OECD countries will concentrate on developing and manufacturing technologically advanced chemical products, such as speciality and life-science chemicals. Africa, the Middle East and Asia will likely produce high volumes of 'commodity'-type chemicals. This will pose enormous problems for the EU in terms of border controls and economic competitiveness. Measures will be required to ensure a level playing field for EU companies in free trade agreements.
- 4.3.7. The EESC welcomes the measures to strengthen the EU's border controls and cooperation with online direct sales platforms.
- 4.4. A comprehensive knowledge base on chemicals
- 4.4.1. As the EU **lacks a comprehensive information base on all substances**, proposals for actions to improve availability of chemical data are welcome as long as they are effective.
- 4.4.2. From the industry's point of view, the questionable patents system makes it impossible to reveal all aspects of patented products on the market.

<sup>(5)</sup> Commission Progress report on the assessment and management of combined exposures to multiple chemicals (chemical mixtures) and associated risks.

<sup>(6)</sup> European Environmental Bureau: https://eeb.org/chemical-evaluation-report-achievements-challenges-and-recommendations-after-a-decade-of-reach/

- 4.4.3. From the scientific point of view, limited free-of-charge open science hampers the free exchange of knowledge and the combination of efforts and investment. Scientific data protection rules, industrial property rights not sufficiently well-founded are constraining the accessibility of all relevant chemical data, and hence innovation.
- 4.4.4. The conflicts of data accessibility should be addressed and solved by including measures to broaden the data available and to improve its quality. For instance, a mechanism could be created in which industries that import manufacturing nanomaterials, finance independent research on nanomaterials risk, where there is a lack of scientific knowledge.
- 4.4.5. The Commission aims to **continue to foster research and (bio-)monitoring** to understand and prevent chemicals-related risks and drive innovation in chemical risk assessment and regulatory science.
- 4.4.6. To facilitate innovation through research, worker participation and financial support should also be devoted to optimise best practices in the transfer of knowledge, both industrial and scientific, ensuring free and easy access to reliable databases. Furthermore, access to innovation should be made available to every actor concerned by the EU chemicals industry.
- 4.4.7. Measures to foster innovation in **safety testing** and chemical risk assessment reducing animal testing are appreciated, especially considering the advances in research and cutting-edge novel methods developed (e.g. *in vitro* assays) that will improve the quality, efficiency and speed of chemical hazard risk assessments.
- 4.4.8. It is essential to ensure more transparency in decision-making. Many important matters are discussed in closed meetings, which causes confusion among EU citizens about the actions taken by the EU to limit their exposure to hazardous chemicals. Also, the raw data on which evaluations and decisions are made (ECHA & EFSA) (7) must be available. There is a need to ensure more transparency on the decisions and positions of Member States regarding chemical substances on the market.
- 4.5. Setting the example for a global sound management of chemicals
- 4.5.1. In view of its global impact, the EESC is pleased to see that among the actions to **promote safety and sustainability standards outside the EU**, the Commission is committed to ensuring that **hazardous chemicals banned in the EU are not produced for export**.. However, it remains unclear how remaining pieces of legislation to be developed and harmonised will apply globally. The banning of products for export may affect industry in other countries for which the ambition of the chemicals strategy does not apply. It is not clear how the effects on non-EU industries will be handled, as former producers and exporters of a specific product.
- 4.6. The overuse of chemicals in healthcare

There should be much more research in developing policies on disease prevention with a special focus on the immune system. The objective must be a positive attitude towards a healthy lifestyle, enabling people to use fewer chemical treatments when appropriate. All chemical treatments should be directed to those for whom that they are essential avoiding overuse.

- 4.7. Chemicals in agriculture
- 4.7.1. The negative impacts of pesticides used in agriculture on the environment need to be reduced without causing a decline in the quality of food production or compromising food security within the EU.
- 4.7.2. The current European Research Alliance, which is tasked with finding and testing organic alternatives to synthetic chemicals in agriculture, needs to be adequately funded. Investment should be focused on biological organic pesticides. Financial support should be also increased to foster research and innovation on natural-based plant growth promoters and plant protectors. For instance, the inherent bioactivity of certain natural compounds metabolised by rhizobacteria may be used as plant protectors against external pathogens.

<sup>(7)</sup> Acronyms ECHA (European Chemicals Agency) & EFSA (European Food Safety Authority).

- 4.7.3. A much more targeted use of chemical fertilizers is desirable and this should result in lower chemical fertilizer usage. Further research is needed to develop alternatives so that adequate food production continues and that farmers receive adequate incomes.
- 4.7.4. Further environmental and health risk assessments are required to evaluate whether the use of biotechnology and genetic engineering could help develop alternatives to chemical fertilizers and pesticides.
- 4.7.5. If no other viable alternatives are presented, a significant reduction in the use of pesticides will either increase production costs and/or lead to lower yields. Therefore, the questions of the economic burden for producers and consumers and the food imports from non-EU countries need to be looked at.
- 4.7.6. The new EU Biodiversity Strategy for 2030 is highly ambitious, as it is projected to transform at least 30 % of Europe's land into a network of actively managed and protected areas. It should prove a major contribution to biodiversity, to nature restoration and help underpin the sustainable Chemicals Strategy in the agricultural sector.
- 4.7.7. In this sense, special efforts should be taken to better protect biodiversity and especially pollinators from pesticides. For instance, the EFSA Guidance document on the risk assessment of plant protection products on bees has big loopholes. It must integrate data on chronic toxicity, effects of pesticides on larvae and data on acute toxicity for bees and other pollinators.
- 4.7.8. For the Chemicals Strategy to be successful, we must have significant support from the general public and a real culture change in our approach to chemicals usage, climate change and environmental pollution.

Brussels, 27 April 2021.

The President of the European Economic and Social Committee Christa SCHWENG