EUROPEAN
COMMISSION

Brussels, 14.10.2020
SWD(2020) 248 final

COMMISSION STAFF WORKING DOCUMENT

Synopsis report summarising the feedback received in the context of the Chemicals Strategy for Sustainability

Accompanying the document

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} - {SWD(2020) 225 final} - {SWD(2020) 247 final} - {SWD(2020) 249 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}

EN   EN

1.   INTRODUCTION

This report covers feedback and input from citizens and administrations, associations and other organisations (hereinafter 'stakeholders') as regards the Commission roadmap[1] on the Chemicals Strategy for Sustainability (hereinafter 'the Strategy'), which was published on the 'Have your say' portal[2]. It also provides a broader overview of other feedback of relevance for the Strategy provided by stakeholders in previous public consultations.

The Commission initiated its work to develop the Strategy following the European Green Deal[3] call for the simplification and strengthening of existing chemical legislation in order to better protect human health and the environment against hazardous chemicals, encourage innovation for the development of safe and sustainable alternatives and to increase global competitiveness. The Strategy is the first initiative under the European Green Deal's objective of the zero pollution ambition for a toxic-free environment.

For the purpose of this report, the assessment of the feedback to the roadmap of the Strategy has been structured following the five main pillars of the Strategy: strengthening health and environmental protection, boosting safe and sustainable chemicals, simplification of the legal framework on chemicals, providing a comprehensive and transparent knowledge base, and inspiring chemicals management globally.

2.   BACKGROUND AND PREVIOUS CONSULTATIONS

The Chemicals Strategy for Sustainability builds on a number of reviews, studies and Staff Working Documents prepared by the Commission services, as well as on contributions from several stakeholders. Brief summaries of the outcome of previous consultations are provided below, while stakeholders' feedback as obtained in the public consultation on the Roadmap is presented in Section 3 of this report.

In particular, when developing the Strategy the Commission has taken into consideration the main findings of the following documents, as well as the feedback provided by stakeholders during their preparation:

- The 'Communication on the implementation of the circular economy package: options to address the interface between chemical, products and waste legislation' (adopted in January 2018)[4];
- The 'Commission General Report on the operation of REACH and review of certain elements', also known as the second REACH review (adopted in March 2018)[5];
- The Commission Report on 'Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses' (adopted in June 2019)[6];
- Other targeted consultations as well as the Staff Working Documents (SWD) accompanying the Strategy:

---

[1] European Commission, Roadmap on the Chemicals Strategy for Sustainability.
[2] European Commission, Better Regulation Portal.
[3] COM(2019) 640.
[4] COM(2018) 032.
[5] European Commission, Second General Report on the operation of REACH.
[6] COM(2019) 264.

- on Poly- and perfluoroalkyl substances (PFAS);
- the progress report on the assessment and management of combined exposures to multiple chemicals and associated risks;
- the Fitness Check on endocrine disruptors;
- the review of a number of provisions under article 138 of REACH; and
- a synopsis report, summarising contributions received by external stakeholders.

The Strategy also builds on various additional contributions from stakeholders not covered in the abovementioned documents, including in particular:

- Council Presidency information note on the 'Policy conference "REACH Forward" Brussels, 1 June 2016' (published in June 2016)[7]
- Council Conclusions on 'Protection of human health and the environment through the sound management of chemicals' (adopted in December 2016)[8]
- Special Eurobarometer survey on Chemical Safety (published in June 2017)[9]
- Council Conclusions on 'Towards a Sustainable Chemicals Policy Strategy' (adopted in June 2019)[10]
- Outcome of the high-level EU Chemicals Policy 2030 conference (published in June 2019)[11]
- European Parliament Resolution on the 'Chemicals Strategy for Sustainability' (adopted in July 2020[12]), as well as other previous Resolutions on chemicals

2.1. SPECIAL EUROBAROMETER ON CHEMICAL SAFETY

A Eurobarometer survey on chemical safety[13] was carried out from 26 November to 5 December 2016, consisting of face-to-face interviews with 27 929 citizens from all EU Member States. The results of this survey painted a mixed picture of public awareness of, and confidence in, the safety of chemical products.

Around two-thirds of EU citizens were, to different extent, concerned about being exposed to hazardous chemicals in their daily life, including a quarter who were 'very much' concerned. At least half in every Member State are concerned. Less than half of respondents said they feel well informed about the potential dangers of the chemicals contained in consumer products, although there were considerable variation between Member States. In general, respondents in northern Europe tended to feel better informed, especially in the Nordic countries, while those in southern Europe tended to feel less well informed. There are two main sources of information used by the public on the potential dangers of chemicals: product labels and the media.

---

[7] Council of the European Union, Presidency information note on 'Policy conference "REACH Forward".
[8] Council of the European Union, Conclusions on 'Protection of human health and the environment through the sound management of chemicals'.
[9] European Commission, Special Eurobarometer 456.
[10] Council of the European Union, 'Conclusions on 'Towards a Sustainable Chemicals Policy Strategy'.
[11] Ministry of Environment and Food of Denmark and European Commission, EU chemicals policy 2030 - report.
[12] European Parliament, Resolution on the Chemicals Strategy for Sustainability.
[13] European Commission, Special Eurobarometer 456.

Two in three respondents said that if they asked whether a product contains particularly hazardous chemicals, the seller was required by law to provide them with this information. Only a small minority did not think this was the case. Awareness and comprehension of hazard pictograms was tested. Awareness and comprehension was quite high for certain pictograms, especially for the 'flammability' pictogram. However, only one in five said that they had seen the serious health hazard pictogram before, and just one in six knew the meaning of the exclamation mark pictogram.

Almost half of respondents thought that chemical products were safe for human health and the environment, although perceptions of safety varied considerably between Member States. At the same time, half of respondents said that the current level of regulation and standards in the EU was not high enough and should be increased.

At the same time, respondents were more likely to think that product safety has improved in the last 10-15 years than to say it has deteriorated. They were also inclined to think that products manufactured in the EU contained safer chemicals than those imported from outside the EU, although three in ten said that none of the products were safe.

There were varying perceptions of who currently has responsibility for ensuring the safety of chemicals contained in consumer products in the EU. There were also different views on who should have this responsibility. Three in ten respondents thought this responsibility lies among multiple actors (i.e. EU authorities, national authorities or manufacturers), while more than four in ten respondents thought that this responsibility should lie with more than one actor.

Overall, the survey findings indicated the need to better inform EU citizens about the safety of chemical products, and to clarify the concerns that many of them have.

2.2. PUBLIC CONSULTATION SUPPORTING THE SECOND REACH REVIEW

The REACH Regulation[14] mandates the Commission to publish every five years a general report on the operation of the Regulation, focused on its state of implementation. The review is based on reporting from Member States and the European Chemicals Agency (ECHA), as well as on input from stakeholders. For the preparation of the second REACH review, an open public consultation took place from 28 October 2016 to 28 January 2017, where 453 replies were received[15]. An SME panel[16] was also carried out through the Europe Enterprise Network in order to gather views on relevant issues for Small and Medium Enterprises (SME).

In general, stakeholders recognised that REACH was overall adequate to address most of the current challenges posed to it but a number of gaps and weaknesses were recognised. A few

---

[14] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. *OJ L 396, 30.12.2006, p. 1–849*

[15] More information can be found here: European Commission, Second REACH review, Annex II.

[16] European Commission, Final Summary Report on the SME panel.

stakeholders considered that these would require a revision of the Regulation, while most pointed to the need to improve its implementation.

Businesses mentioned legal stability and certainty as a key issue, considering predictability an important driver for business decisions. They acknowledged the positive effects of REACH in terms of making information available to ensure safe use of chemicals and stressed the need to reduce burden and costs (in particular for SMEs) and to minimise negative impacts on innovation and competitiveness of EU industry; and they expressed support for risk-based approaches. They also highlighted the importance of a level playing field and harmonised enforcement, including at the EU borders. Coherence between REACH and other chemical legislations was another area where businesses showed concern.

NGOs considered that REACH could deliver a higher level of protection of human health and environment, but that its potential had not been fully developed. In particular, they pointed at poor quality of registration dossiers and insufficient information on safe use of chemicals flowing through the supply chain and for consumers. They also considered that the authorisation and restriction provisions are excessively burdensome and lengthy, leading to slow progress in substitution and phasing-out of hazardous chemicals. Due to such deficiencies, it was their shared view that general principles underlying REACH such as the 'no data, no market', the shift in the burden of proof or the precautionary principle were not being applied in practice.

Most public authorities shared the view that REACH had succeeded in improving the management of chemical risks, but also raised concern on the deficiencies related to its implementation. Most Member States expressed doubts about the quality of data generated by industry, in their view insufficient to decide on the need for regulatory risk management measures and thus making the shift of the burden of proof incomplete. Some authorities acknowledged the challenges faced by SMEs in complying with REACH requirements. Some Member States did not favour re-opening REACH, proposing actions to improve implementation within the existing framework, while others proposed actions outside such framework to increase the speed of regulatory measures and minimise negative impacts.

Trade unions considered REACH as a positive development, making companies better informed about the risks posed by chemicals and helping to improve risk management and the safety of those workers using chemicals, also beyond the chemical industry.

The SME panel consisted of a specific questionnaire tackling SME related issues in relation to the information sources, existing support mechanisms and effects of REACH, and their relation with authorities. Registration and testing as well as substitution of substances of very high concern (SVHCs) were the main cost factors indicated by the companies. The main challenges reported were the complexity of the Regulation, the obligation to communicate information in the supply chain as well as the access to data. Opportunities and benefits of REACH appeared in relation to the reduction of risks to workers and the environment, as well as to the substitution of hazardous substances. Administrative burden and market distortions

4

in favour of larger companies were also reported. Respondents also demanded more guidance and training tailored to the needs of SMEs, including support by authorities.

2.3. PUBLIC CONSULTATION SUPPORTING THE FITNESS CHECK OF THE CHEMICALS LEGISLATION (EXCL. REACH)

An open public consultation took place from 4 March to 27 May 2016, where 356 replies and 21 position papers were received. In addition, targeted consultations and workshops were organised and two Eurobarometer surveys (see section 2.1 for more information on the survey on chemical safety) were prepared. Stakeholders were consulted on five evaluation criteria, the main findings being the following:

Effectiveness: The EU chemicals legislation was considered to be moderately effective in reaching its goal of protecting human health by all stakeholder groups. Regarding environmental protection, citizens and businesses considered it mostly effective, while public authorities considered it moderately effective and NGOs and consumer associations only slightly effective. Citizens, businesses and public authorities considered the EU chemicals legislation as mostly effective in ensuring a well-functioning internal market, while civil society considered it moderately effective. A particular concern pertained to inconsistent enforcement by Member States. The main reasons for lower effectiveness were that the legislation is not adapted to issues at stake or that legislation is not effectively implemented.

Efficiency: Costs derived from EU chemical legislation, particularly for SMEs but also for bigger companies and public authorities, were considered an important factor. On the other hand, the main benefits generated by the chemicals legislation were considered to be reducing the damage to the environment and reducing the exposure to toxic chemicals of consumers, citizens and workers.

Coherence: Industry associations and companies as well as civil society representatives considered the chemicals legislation internally inconsistent, although public authorities and citizens were more ambivalent. SMEs also had more nuanced opinions. All stakeholders agreed that the chemicals legislation contains gaps, missing links and has overlaps (except NGOs on the latter). Although such issues were indeed identified, further analysis of position papers presented by stakeholders showed that inconsistencies most often affect specific aspects of functioning of some pieces of legislation while not compromising the functioning of the whole framework.

Relevance: Stakeholders from all groups considered that not all relevant considerations are taken into account in regulatory decision-making on risk management. Regarding the way the EU legislative framework addresses emerging areas of concern, opinions varied: slightly (civil society), moderately (citizens and public authorities) and mostly (industry associations and companies) sufficiently.

EU added value: Businesses, public authorities and civil society considered the chemicals legislation to have a high level of added value, while citizens considered the added value to be moderate.

2.4.   Public consultation on the Options to address the Interface between Chemicals, Products and Waste

An open public consultation run from 23 July to 29 October 2018 and in total 461 replies and 40 position papers were received. Feedback on four main issues identified by the Commission were sought and summarised in a report published in March 2019[17].

Issue 1: Insufficient information on substances of concern in products and waste. Regarding the concept of 'substances of concern', two tentative definitions of the term were proposed, with one referring to SVHCs and to hazardous substances classified for chronic effects in CLP[18] Annex VI, and the other definition referring to SVHCs, persistent organic pollutants and substances restricted under REACH and other sectorial (product) legislation. The latter seemed to give rise to a greater level of agreement from stakeholders, although industry and business associations were critical about both proposed definitions. Overall, stakeholders welcomed the development of compulsory information systems, observing that it would be useful to waste operators and industry. Some respondents expressed uncertainties regarding the framework for implementation and the real benefits of introducing such a system. The development of sector-specific approaches was highly supported across all stakeholder categories, as they were regarded as effective in addressing the particularities of each value-chain. There was also strong support for the option to subject imported products to the same rules applied to those products produced within the EU, and attention was drawn to the related risks from uncontrolled e-commerce.

Issue 2: Substances of concern in recycled products. Stakeholders raised concerns regarding the issue of legacy substances. Businesses in general supported the use of waste streams containing legacy substances only when a safe use of the recovered material can be guaranteed and defended a case-by-case approach. Recycling industries and trade associations raised concerns about the costs associated with recycling of products that contain legacy substances and the obstacles involved. Some NGOs proposed that the Commission should adopt ambitious measures to avoid recycling legacy substances. Regarding how legislation should apply to primary and secondary raw materials, NGOs were of the opinion that the same requirements should apply, while most businesses supported the use of different standards for primary and secondary materials so as not to jeopardise the viability of recycling activities. By contrast, other businesses argued that the use of the same rules for primary and secondary materials would facilitate compliance with specific product legislation such as the Restriction of Hazardous Substances (RoHS)[19] and Ecodesign Directives[20].

Issue 3: Harmonised end-of-waste criteria. The majority of stakeholders expressed their concerns on the lack of harmonised end-of-waste rules across the EU. NGOs supported the

---

[17] European Commission, Summary report on the public consultation on the main issues identified in the Commission's Communication on the interface between chemical, product and waste legislation.

[18] 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. *OJ L 353, 31.12.2008, p. 1–1355.*

[19] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. *OJ L 174, 1.7.2011, p. 88–110.*

[20] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products. *OJ L 285, 31.10.2009, p. 10–35.*

option that recovered materials should reach the end-of-waste status through REACH registration of the recovered substances, whereas businesses highlighted that the removal of the REACH registration exemptions for recovered substances was not a viable solution, as it would create additional administrative burden for recyclers. In addition, businesses advocated for the inclusion of obligations and/or exemptions under REACH to facilitate recycling of waste.

Issue 4: Difficulties in applying waste classification methodologies. Businesses called for harmonised waste classification as well as for better enforcement and implementation of rules governing this matter at EU level. They had, however, divergent views on the practicality of alignment between the rules for classification of waste under the Waste Framework Directive[21] and those for substances/mixtures under CLP. The use of bioavailability as an element to be considered in hazard classification of waste raised different opinions and concerns among the stakeholders.

2.5. HIGH-LEVEL 'EU CHEMICALS POLICY 2030' CONFERENCE

Some 300 stakeholders, including more than 50 speakers and contributors, attended the high-level EU Chemicals Policy 2030 conference, which took place in June 2019. Six thematic sessions were held and are summarised below.

Session 1: Promoting green and sustainable chemistry. In general, there was alignment among stakeholders on goals and what needs to be done to overcome barriers to innovation. It was a shared view that regulation alone will not drive green and sustainable chemistry and that there is a need for policy that incentivises R&D and commercialisation across the value chain. Participants called for development of a set of clear, flexible and science-informed criteria for green and sustainable chemistry.

Session 2: Chemicals in a circular economy. There was general support to the progressive phasing-out of substances of concern. Businesses stressed the need for an EU chemicals framework that maximises the value of materials without compromising safety, including by use of risk-based approaches. Harmonisation of end-of-waste criteria was strongly supported by industry. All stakeholders supported that appropriate information is shared across value chains to ensure safe use and recycling.

Session 3: Improving the regulatory framework. There was a shared vision of a coherent, harmonised and transparent EU chemicals and products policy. To achieve this, governance mechanisms to bring together regulators across chemical sectors should be established, data requirements and risk assessment methodologies should be standardised across legislation and EU chemical safety databases should be fully connected and inter-operable.

Session 4: Knowledge building, monitoring and early warning. The collective vision was to protect more effectively human health and the environment through establishment of early warning systems targeting key chemicals and sensitive species and by creation of a

---

[21] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste. *OJ L 312, 22.11.2008, p. 3–30.*

formalised science-policy interface to ensure better uptake of scientific findings into policy decisions.

Session 5: Smarter communication, better protection and lower costs. The group's vision was to have safe and sustainable products placed on the EU market and that consumers should have access to simple, understandable, harmonised and science-based information, which empowers them to make informed decisions and builds trust in products. There should be very strong enforcement of the EU chemicals legislation, thus creating a level playing field, including for online commerce.

Session 6: Global challenges – sustainability, innovation and competitiveness. It was a shared vision that the EU policy should shape the global policy and governance towards sustainability, safety and innovation. In particular, industry envisioned a globally harmonised risk management system on chemicals and waste – where approaches and methodologies for hazard assessment and risk management of chemicals are aligned and shared - and that an integrated approach and sustainable products should be the main business model. ˊThe same high standards should apply for chemicals, products and waste irrespective of origin.

3. FEEDBACK ON THE ROADMAP ON THE CHEMICALS STRATEGY FOR SUSTAINABILITY

Stakeholders had the opportunity to provide their feedback on the roadmap for the Strategy during 6 weeks, from 9 May to 20 June 2020. During this period, 424 contributions were received via the Better Regulation portal, while 17 ad hoc contributions were received by the Commission services via email or letter.
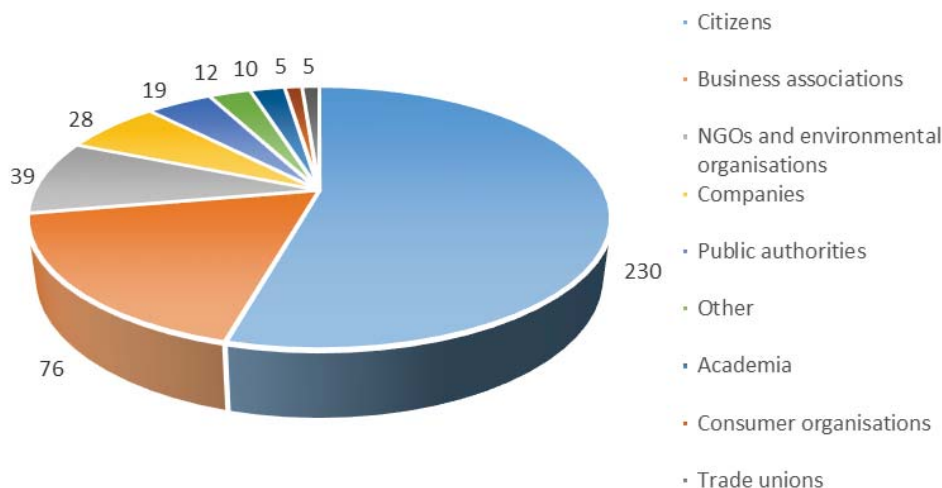

Figure 1: distribution of feedback received by user type.

The stakeholders represented a great variety of sectors. Over half of the respondents were citizens, followed by business associations (18 %), NGOs (8 %), companies (7 %) and public authorities (4 %). Other stakeholders, including academia, environmental and consumer

organisations and trade unions represented 8 % of respondents. Figure 1 offers more disaggregated data on user types. French citizens sent 200 almost identical responses[22].

3.1.   GENERAL COMMENTS

Several stakeholders provided general comments regarding the state of play of chemicals legislation or the scope of the Strategy. Some of them, in particular public authorities, referred to the health impacts of exposure to hazardous chemicals and the associated societal costs, which according to the information provided by them amount to billions of Euro annually. Other stakeholders, in particular NGOs, built on this issue by pointing at the costs to society of exposure in particular to endocrine disruptors and carcinogenic substances at the workplace. Businesses mentioned the need for an impact assessment of the Strategy and careful consideration of the consequences of any change in the existing regulations.

There was overall support among public authorities and NGOs, citizens and consumer associations for a Strategy designed as a cross-cutting programme to achieve a toxic-free environment by contributing coherently to other EU policies. A number of public authorities consider that chemicals management is an integral part of environmental sustainability and that the Strategy should contribute to achieving the Sustainable Development Goals (SDGs), climate neutrality, use of renewable resources and circularity. Stakeholders also mentioned the importance of complementarity with other major Commission initiatives under the European Green Deal, such as Circular Economy, Farm-to-Fork, Biodiversity Strategy, Beating Cancer Plan and Pharmaceuticals Strategy.

Some respondents considered that stronger links to other pieces of chemicals legislation should be in the scope of the Strategy, e.g. the biocidal and plant protection products legislation[23], including Integrated Pest Management. Some stakeholders also referred to the growing importance of bio-based chemicals and asked for them to be covered by the Strategy.

Businesses emphasised the key role of the chemical and pharmaceutical industry regarding health and environmental protection as well as sustainable solutions to achieve the goals of the European Green Deal. It was a generalised concern among industry and certain citizens that the lack of Impact Assessments in the context of the Strategy might have large and negative consequences. Some stakeholders argued for the preparation of SME-centred impact assessments.

Most citizens were concerned about exposure to chemicals in everyday products and the failure, in their opinion, to achieve sound management of chemicals. In this regard, some respondents proposed to establish a hierarchy of actions and address essential and non-essential uses. Many stakeholders, particularly NGOs and citizens, also referred to the need to implement better the polluter pays principle by introducing a fee on chemicals, while others

---

[22] For the purposes of this report, these responses have been aggregated and considered as only one feedback.
[23] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market; and Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

pleaded for lower fees to increase competitiveness. Animal welfare NGOs suggested the Commission to commit to phasing-out the use of animal testing.

Finally, many respondents from different stakeholder groups suggested putting more emphasis on nanomaterials, while others proposed to advance towards a full ban on certain materials and products like flame retardants or plastics.

3.2. STRENGTHENING THE EU LEGAL FRAMEWORK TO ADDRESS PRESSING HEALTH AND ENVIRONMENTAL CONCERNS

Although it was not included in the roadmap, some stakeholders showed support for the development of a toxic-free hierarchy for chemicals, pointing at the precautionary principle and to the need to apply it on a case-by-case basis. Other stakeholders were against such a hierarchy as, in their opinion, it is not based on scientific findings and would be contrary to the current combination of hazard and risk approaches.

Public authorities, and particularly many Member States, stressed the need to speed up the phasing out of substances of concern, including groups of substances, by introducing restrictions that would only exempt essential uses. In particular, they mentioned the presence of SVHCs in consumer products as a possible focus of future restrictions. Businesses in general defended maintaining the current legislative framework, while exploring certain changes such as on harmonised classification for metal alloys or on nanomaterials.

Some stakeholders also brought up other issues, such as the possibility of introducing the principle of extended producer responsibility (EPR), along with new fiscal instruments (including a border tax for SVHC substances), and a revision of the food contact materials legislation. Some businesses called for delayed applications of certain obligations, such as CLP classifications and adaptations to technical progress.

Generally, NGOs considered that the overall exposure to chemicals of concern should be effectively reduced, including by phasing out SVHCs and setting more stringent Binding Occupational Exposure Limits. The protection of vulnerable groups was another issue considered a priority by the majority of stakeholders.

3.2.1. Addressing endocrine disruptors

The majority of respondents from exposure to endocrine disruptors in the EU, which amounted to between EUR 157 and 270 billion annually. They supported an effective and coherent cross-sectoral system for identification and listing of endocrine disruptors, including suspected ones, to minimise exposure, use generic risk assessment to ban them (both confirmed and suspected) in all types of consumer products and to ensure consistent protection level for vulnerable groups. Animal welfare NGOs called for new approaches avoiding the need for animal tests for identification of endocrine disruptors instead of using multigenerational animal tests.

Academia stated that exposure to endocrine disruptors has been associated with a number of neurological, metabolic and reproductive effects and that action should focus on, in particular, vulnerable groups.

3.2.2. Addressing combination effects

Although there was generalised support for actions on mixtures, the different stakeholder groups differed in the suggested actions. Public authorities that provided views considered that combination effects should be addressed in all relevant chemicals and emissions legislation by introducing a pragmatic solution. Some Member States considered that in REACH, a generic mixture assessment factor could be generally applied in risk or safety assessments, except in cases where justified by specific use patterns or lifecycles.

Businesses noted that intentionally produced mixtures are already regulated under CLP and REACH. For unintentional mixtures, they suggested to identify relevant cases where risk assessment of individual chemicals have shown to be not sufficient and develop specific risk management procedures for these scenarios. Impact of the cocktail effect needs to be studied in detail with all stakeholders with the aim of developing constructive proposals based on well-established scientific knowledge. In view of this, most of the businesses considered that a mixture assessment factor is not the right solution. Some companies pointed at the work done by the European Food Safety Authority as a good practice, in particular with its 'Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals'.

NGOs, trade unions and consumer associations supported unambiguously the use of a generic mixture assessment factor across different pieces of legislation as an adequate solution for addressing mixtures. Daily exposure to mixtures of chemicals should be minimised to avoid cocktail effects, especially in vulnerable groups.

Respondents from academia agreed that the evaluation of the risk of exposure to combinations of chemicals is a major challenge and called for strengthening the legal basis and introducing intermediate measures in line with precautionary approaches, pointing concretely at a mixture assessment factor.

3.2.3. Addressing chemicals in the environment

A broad majority of stakeholders from all groups supported action on chemicals affecting the environment, in particular regarding Per- and Polyfluoroalkyl Substances (PFAS). However, there were different views regarding the scope of the actions on these substances and on the need for grouping approaches (rather than individual, per substance approaches) for chemicals of concern.

Most public authorities called for speeding up identification of Substances of Very High Concern (SVHCs), considering that new hazard classes should be added to the SVHC definition, including persistent and mobile substances. According to their feedback, a grouping approach should be implemented to avoid regrettable substitution and ensure coherent, adequate, consistent and highly protective measures. They also overwhelmingly called for the Commission to develop an EU action plan for addressing PFAS, for which only essential uses should be allowed. For nanomaterials, some public authorities considered that a harmonised and legally binding definition should be developed followed by registration requirements set out in an independent legal cross-cutting instrument.

11

Many businesses emphasised that persistent chemicals should be regulated if a risk is identified. Others were supportive of the restriction of PFAS, particularly businesses affected by possible contamination from these chemicals. Many businesses also stated that potential mobility is not in their opinion suitable to inform on exposure. A few businesses complained about EU policies being contradictory, as some substances are restricted due to environmental concerns while they are at the same time essential for batteries and electrical vehicles important for addressing climate change. Water-related businesses called for better control of micro-pollutants at source.

NGOs supported regulating very persistent chemicals including, but not only, PFAS, in all relevant chemical legislation. They proposed to ban all non-essential uses of persistent chemicals and chemicals that accumulate in the environment and to phase out all chemicals that are persistent, mobile and toxic.

Both NGOs and academia considered that manufactured nanomaterials and nanoparticles should be better evaluated with the aim of assessing their safety. Academia also stated that highly persistent organic chemicals, in particular when also bioaccumulative or mobile, must be limited as much as possible. In particular, the production and use of the group of PFAS need to be brought under strict control, and only uses that are essential for society should be allowed.

3.3. SAFE AND SUSTAINABLE INNOVATION

Stakeholders from all groups welcomed the focus on safe innovation and economic recovery presented in the roadmap. Many respondents considered issues such as increased investment in R&D, eco-design, faster substitution and competitiveness of EU companies as vital for the green and digital transition. Some respondents presented new ideas, such as chemical leasing, increased support from EU funds, development of horizontal criteria for sustainability and extended exemptions for product and process-oriented research and development.

The majority of stakeholders supported action at EU level to increase the strategic autonomy of the Union in the production of essential chemicals, although there was disagreement regarding their extent and focus. Stakeholders generally agreed on the need to use this opportunity to improve the overall sustainability of the chemical sector.

3.3.1. Safe and sustainable by design

Regarding the development of safe and sustainable by design criteria, stakeholders generally welcomed this idea and in many cases offered expertise and support to the Commission. Some stakeholders provided examples of other criteria being developed at industrial level, such as in the automotive industry. The creation of an EU substitution centre to put in practice these criteria was also recommended by a broad variety of stakeholders from all groups. Some stakeholders requested the Commission to take into consideration bio-based chemistry and the cascade use of biomass when developing criteria.

More concretely, public authorities considered that both innovation and competitiveness of the chemicals industry will depend on its ability to integrate concepts like safe-by-design,

green chemistry and new business models into the production and use of chemicals. They supported the idea of products being designed and produced in a way that preserves resources and prevents negative impact, also enabling non-toxic material cycles. They also suggested taking into consideration the economic, social, societal and environmental impacts in an integrated approach.

Businesses called for a Strategy that supports the industry's green and sustainable transition through a progressive and gradual process. Among the ideas presented, incentives and policies like *tax breaks* or research and development credits as well as establishing harmonised definitions of 'safe' and 'sustainable' were mentioned. They suggested to avoid substances of concern in the design phase and to employ a holistic approach also considering circular economy and resource efficiency in a robust eco-design policy. They called for the Commission to bear in mind that production of many non-hazardous substances require the use of reactive (hazardous) starting materials that can be handled safely in an industrial environment. According to this view, the sustainability of a chemical should be assessed holistically taking into account the specific uses during the entire lifecycle.

NGOs, trade unions and consumer associations supported developing criteria for the safe-by-design concept and establishing economic incentives to support substitution, clean production, and frontrunner companies. They also considered that boosting innovation should not necessarily lead to placing more chemicals on the market. Academia promoted the shift to non-hazardous and renewable alternatives to prevent hazardous chemicals from being used in materials in the first place. The Commission should provide a framework securing that front-runners with proactive business models can achieve competitive advantages.

3.3.2. *Safe products and non-toxic material cycles*

Stakeholders gave a lot of attention to the issue of circular economy and proposed different solutions to the main issues identified within the roadmap and the Communication on the interface between chemical, products and waste legislation. There was overwhelming agreement on the need to tackle chemical content in products, particularly in imported products, as well as on the final ambition of ensuring clean waste streams.

Public authorities strongly supported moving towards non-toxic materials cycles with increased resource efficiency and reduced energy intensity and a transition to renewable raw materials. In their view, the performance of recycling processes should be improved with a view to reducing or controlling the content of hazardous chemicals in the recycled material, removing legacy chemicals from the material cycles once identified. A well-functioning internal market for high-quality and non-toxic secondary raw materials should be created. A network of regional authorities considered the use of sustainable and renewable biomass for production of bio-based products as an example where the EU could allocate funds for innovation.

Businesses called for an EU harmonisation of end-of-waste criteria to facilitate the recycling of materials and facilitate compliance with product legislation. In general, they defended a holistic and balanced approach on circular economy, resource efficiency and chemical

content in products to increase recycling, including research on options for decontamination of waste streams and chemical recycling. Some businesses expressed the view that recycling should be prioritised and that it should be part of the risk assessments of chemicals. Businesses provided conflicting views regarding information on chemicals in recycled material, some of them considering it essential for enhancing the EU market for secondary raw materials, while others believing that full tracking is not feasible. They generally called for avoidance of substances of concern in the design phase and employing a holistic approach also considering circular economy and resource efficiency in a robust eco-design policy.

NGOs asked to introduce broad restrictions with reduced possibilities for derogations for recycled materials. They also suggested that substances of concern should be eliminated from the production of virgin materials and products to avoid their presence in waste, while strongly advocating for equal requirements for recycled and virgin materials under chemical legislation.

3.3.3. Strategic autonomy

In view of the COVID-19 crisis, there was generalised support for the idea of increased autonomy of the Union regarding the production of certain essential chemicals. The role of certain chemicals in the protection of human health was also highlighted. However, many stakeholders considered it necessary to ensure that such autonomy is based on sustainability and respects the environmental objectives of the Union.

Businesses were especially keen on supporting actions to increase production in the EU, including repatriation of chemical production. They considered that there is a need to strengthen Europe as a location for chemical production. NGOs found it important that decreasing dependency of imports and achieving industrial autonomy for essential products go hand in hand with reducing pollution and strengthening the potential to develop safer solutions and replacing hazardous chemicals.

3.3.4. Post COVID-19 recovery

Stakeholders welcomed the idea of contributing to the recovery of the industry producing and using chemicals after the crisis, seeing it as an opportunity for the overall transition to a more sustainable sector. Many respondents highlighted the importance of competitiveness and innovation to ensure that the environmental and climate objectives of the Commission are achieved.

Businesses considered that the COVID-19 crisis has demonstrated the global interconnection of the chemicals supply chain, which emphasises the need for global standards and greater EU independence. Some businesses considered that the location and relocation of industries in Europe is not attractive to companies due to the high regulatory burden of registration and approval of pharmaceuticals and biocides. Some respondents favoured the introduction of specific funding for the recovery and transition of the chemicals sector, and others in addition proposed the development of a system similar to the carbon border adjustment in order to decrease the import of SVHCs in products.

3.4. **SIMPLIFICATION OF THE LEGAL FRAMEWORK**

The importance of increasing coherence and simplifying the legal framework was stressed in many contributions. Among the main issues identified, stakeholders mentioned the importance to have the same rules for imported and EU produced articles, to improve certain processes (for example, authorisation under REACH), to reduce administrative burdens, to establish stronger links between different EU chemical legislations and to increase synergies with other political priorities. The objectives of the Strategy were strongly supported, particularly the idea of advancing towards a 'one substance, one assessment' approach and improving enforcement of existing legislation.

Some public authorities stressed that a long-term sustainable funding and resourcing of ECHA should be secured corresponding to the activity level required, e.g. by establishing an annual fee for registrants. They also considered that the interface between REACH and Occupational Safety and Health legislation needs clarification with the aim to improve protection of workers from exposure to hazardous chemicals.

Several businesses were of the view that risks relating to occupational use of chemicals are better addressed under the Occupational Safety and Health legislation than under the REACH authorisation provisions; therefore, the interface between these two pieces of legislation should be clarified and more binding occupational exposure limits should be adopted. Some businesses emphasised that REACH and the RoHS directive should remain separate, but acknowledged that the RoHS process could be improved by drawing on different aspects of the REACH authorisation system.

NGOs pointed at the inconsistencies of the regulatory framework for chemicals in products and defended a new focus on vulnerable groups while agreeing that simplification should not come at the detriment of the level of protection.

3.4.1. *One substance, one assessment*

Stakeholders from all user groups supported a 'one substance, one assessment' approach, with businesses calling for it to be based on the strongest possible scientific data. Public authorities supported the establishment of a network of European agencies to carry out independent studies of potentially hazardous substances through a single evaluation platform. Some Member States considered that in order to ensure a consistent hazard identification, this process should be separated from regulation of the uses and that the CLP is an appropriate tool for that, adding new hazard categories. Public authorities supported the 'one substance, one assessment' approach but mentioned that this requires access to reliable data on uses of chemicals and the likely exposures to them. Furthermore, the implementation of the 'one substance, one assessment' approach should not lead to lower protection standards, but to better protection of vulnerable groups, which should be defined.

Businesses also called for a harmonised method for assessing substance properties, welcoming the 'one substance, one assessment' approach. They suggested limiting it to hazard assessment and that the strengths of the various EU agencies should be considered with ECHA taking care of hazard assessment, while other agencies or scientific bodies should

conduct exposure and risk assessments within their specific remit and expertise. Grouping assessment could be promoted, in the opinion of some businesses, based on the established read-across assessment framework. The use of alternative methods for filling data gaps needs to be accelerated for reducing the dependence of animal testing. Businesses strongly advocated for the development of mandatory regulatory management option analyses before developing proposals for regulation of chemicals and that proposals should be accompanied by robust impact assessment or risk-benefit analysis.

NGOs suggested that the 'one substance, one assessment' should include all available evidence, including studies from academia and independent scientists; and that the use should not lead to delays in regulating harmful chemicals, nor lower the protection level. They also supported allowing the use of grouping approaches for assessing and regulating chemicals and defended that, when there is scientific uncertainty, the precautionary principle should be used. Animal welfare NGOs considered that existing barriers to the use and acceptance of non-animal methods for regulatory purposes should be addressed, and that the use and acceptance of exposure-based waivers for adaptation should be increased. Academia supported the 'one substance, one assessment' approach, mentioning that the scope of the approach needs to be further identified, for example, whether it is restricted to hazard assessment or risk assessment covering the whole lifecycle.

3.4.2. *A more simplified, coherent and predictable approach to manage risks*

Respondents mainly provided their views on simplification and predictability in relation with the REACH and CLP Regulations. Chemical risk management was one of the areas where stakeholders showed more divergence in opinions. While some groups defended extending protection for certain vulnerable groups, others considered the current approach to risk management fit for purpose.

Public authorities providing views, supported simplification and strengthening of the chemicals *acquis* building on the precautionary principle and better protecting citizens, in particular vulnerable groups. In their opinion, the REACH instruments, particularly restriction and authorisation, should be more balanced and effective in eliminating substances of concern, especially by assessing groups of substances and restricting all but essential uses. New hazard classes should be introduced in the CLP Regulation for endocrine disruptors, for persistent, bioaccumulative and toxic substances and for very persistent and very bioaccumulative substances.

Businesses recognised REACH as the backbone of chemicals legislation and emphasised the need for a stable regulatory environment employing a risk-based approach for an effective and proportionate risk management. The wider sustainability impacts (climate, circularity) should be taken into account in selection of risk management measures. The procedures for deciding on authorisation applications under REACH could be streamlined by postponing the deadlines for application giving more time to phasing out the use instead of having to apply for authorisation. Finally, most businesses emphasised that the CLP Regulation should remain aligned with the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and new hazard classes should be first introduced in the UN GHS.

NGOs called for exempting only essential uses from restrictions under REACH. They also defended speeding up the identification and phasing out substances of concern, including SVHCs, and include more hazard classes as SVHCs. NGOs strongly supported the use of generic approaches to risk management to ensure coherent application and protection across EU legislation for critical hazard categories. Animal welfare NGOs supported using exposure assessment and biomonitoring for protecting human and environmental health instead of excessive animal testing. Academia considered that the current limitations of the socio-economic analyses must be recognised, in particular as regards assessing future environmental costs, impact on ecosystem services and resilience of ecosystems.

3.4.3. Zero tolerance for non-compliance

Almost all stakeholders from all groups shared similar views with regard to enforcement, considering that strengthening it, particularly at borders, is a key element to ensure the proper implementation of EU chemicals legislation.

Public authorities considered that sufficient resources should be allocated for enforcement activities and that this should be homogenous across legislation. Some Member States were in favour of the creation of a European control force with legal means for imposing sanctions, including control of e-commerce. Public authorities also considered that the import of goods not compliant with EU standards should be prevented. Businesses called for urgent action on enforcement in order to ensure a level playing field and avoid unfair competition from incompliant imports. NGOs also supported better enforcement, including through the strengthening of the 'no data, no market' provisions, harmonised sanctions for non-compliance and increased access to information and participation from consumers.

3.5. KNOWLEDGE BASE

Stakeholders in general considered it important to address existing knowledge gaps on chemicals, as well as to improve access to and sharing of existing data. Some respondents considered it necessary to centralise more data on chemicals, while the transition towards non-animal testing was strongly supported by certain stakeholders from academia and NGOs.

3.5.1. Improved access to and sharing of data

Stakeholders focused their attention on issues such as the tracking of chemicals through the lifecycle of materials and products, the inclusion of polymers in the existing registration scheme under REACH, the use of animals for testing, the communication of information on SVHCs through supply chains and the data requirements for registration of chemicals produced in low tonnage under REACH.

Public authorities suggested making easily available information on data profiles and dates for expected update of registration dossiers available on the ECHA website; and registering potential hazardous polymers. They also supported the introduction of a lifecycle traceability system of substances of concern in materials and products that can also provide information to waste operators. Along with this, they supported the development of product passports and tools for consumers to be informed about the presence of SVHCs and other chemicals in products. They considered it essential that REACH registrations are compliant to ensure a

level playing field and that a transparent and solid basis is available for chemicals management. Some Member States mentioned that a mandatory regular update of dossiers should be required and non-compliance should lead to revocation of registration numbers. The REACH evaluation procedures should be more efficient and all hazards should be clarified under substance evaluation to improve subsequent risk management.

Businesses considered that the use of labels for communication to consumers is complicated and that communication on hazards and safe use of chemicals can take advantage of new digital technologies. Some mentioned that supply chain communication should be improved to collect and make available relevant data for risk assessment and selection of adequate risk management measures. Waste managers and recyclers emphasised transparency on chemicals in materials for sustainable recycling, while other businesses emphasised that information on the presence of a chemical does not imply knowledge on related risks.

NGOs advocated full chemical transparency in supply chains and towards consumers and workers, including by strengthening the obligations in Articles 7 and 33 of REACH. According to them, safety testing of chemicals should be carried out by independent laboratories. Animal welfare NGOs called for modern approaches for assessing and managing the potential toxicity of chemicals; and to incorporate validated non-animal methods in the information requirements. Academia supported traceability of chemicals along the supply chains and that consumers should be informed so that they can make informed purchasing decisions.

3.5.2. Science-policy interface

There was extended criticism among businesses and part of academia regarding the way the Roadmap referred to the Eurostat indicator on the production and consumption of hazardous chemicals, which they considered misleading as it was giving the false impression that the hazardousness of chemicals corresponds to a risk for people and the environment. Other stakeholders focused on issues such as biomonitoring and early warning systems for chemical threats.

Public authorities suggested that research and problem-driven monitoring of effects of chemicals should be developed and linked to green and sustainable substitution; and that research on the effects of chemicals on species, biodiversity, ecosystem resilience and impact of climate change is required. The development of suitable indicators for measuring the impact of chemicals on health and the environment is also needed, in their view. Furthermore, they supported the development of an early warning system to identify new emerging chemical risks fuelled by data from multiple sources.

NGOs supported better early warning approaches. Animal welfare NGOs called for urgent investment in next generation, animal-free approaches.

Academia called for increased involvement of scientists from universities in the development of new methods, in particular testing and assessment methods. The current proposal for a candidate Partnership for the Assessment of the Risk from Chemicals was seen as an important opportunity for increased collaboration.

3.6. GLOBAL SOUND MANAGEMENT OF CHEMICALS

Stakeholders agreed to consider global governance as important to avoid different regulatory requirements among countries. Some respondents called for the Commission to promote high European standards internationally and ensure fair competition between European and non-European players.

3.6.1. International leadership

Public authorities considered that the EU should actively contribute to international activities to achieve a holistic approach to the sound management of chemicals and waste. The Union should contribute to a more sustainable global products policy and promote the highest international standards related to health and the environment.

Businesses emphasised the need for a coherent implementation of the UN GHS and for support to the development of the Strategic Approach to International Chemicals Management (SAICM) as a foundation for sustainable chemicals management and emphasised the value of the chemical industry's Responsible Care programme.

NGOs supported promoting an ambitious international framework as successor to SAICM with roadmaps, targets, milestones and indicators. They also suggested rapidly listing brominated dioxins under the Stockholm Convention and withdrawing all existing exemptions for substances under the convention, as well as strengthening the Minamata Convention.

3.6.2. Promoting standards outside the EU

Public authorities favoured adequate measures to prevent both imports and exports of chemicals banned or severely restricted in the EU in order to achieve a level playing field and a high level of protection. In this regard, the Strategy should aim to address or restrict import of articles produced using non-authorised chemicals into the EU. Furthermore, ambitious standards should be promoted at international level to ensure safe management of chemicals and preserve European competitiveness.

Businesses suggested that in order to safeguard innovation, the introduction of an SVHC border adjustment mechanism could be investigated to promote greener technologies outside the EU. This would reward investors by ensuring a level playing field.

NGOs suggested promoting the highest standards for the protection of human health and the environment globally and ensuring that REACH provisions apply to exported products. They also defended avoiding double standards.

3.6.3. Cooperation with third countries

Businesses suggested that the Strategy should support capacity building for chemical management (infrastructure, know-how) outside the EU, in particular in emerging regions. This could be achieved through cooperation, sharing of best-practices and providing tools (e.g. the International Council of Chemicals Association Toolbox).

NGOs suggested supporting the implementation of the legislation based on REACH in developing countries and countries with economies in transition.

4. SUMMARY AND CONCLUSIONS

Overall, citizens and stakeholders expressed very strong support for the preparation of the Chemicals Strategy for Sustainability. They considered the chemicals sector as an important part of the European economy that should be transformed and protected, and the chemicals legislation as a comprehensive set of rules that needs to be adapted to new challenges while ensuring high levels of protection of health and the environment as well as the competitiveness of the European industry.

There was a general agreement on the need and scope of certain actions, including the horizontal identification of endocrine disruptors; the definition of 'safe and sustainable by design' criteria; the transition towards non-toxic material cycles; introducing the 'One Substance, One Assessment' approach; the use of alternative non-animal studies and scientific publications; the need for more coherence between different pieces of legislation; the improvement of enforcement at EU level, including the import of products; the introduction of traceability systems for substances of concern and an early warning system to identify new emerging chemical risks; and an increased international dimension for the Union on chemicals.

Nevertheless, there was also diversity of positions regarding other issues, such as the need to include biocides and pesticides in the scope of the Strategy; the scope of restrictions on endocrine disruptors; the approach to address combination effects of mixtures and use of a mixture assessment factor; the possibility of providing derogations in restrictions for recycled materials containing legacy substances; the scope of the 'one substance, one assessment' approach and the use of various risk assessment approaches under different pieces of legislation; and the establishment of mandatory regulatory management options analyses.

The feedback provided on the Commission roadmap for the Strategy has been used to inform policy-making and to develop concrete actions in the Chemicals Strategy for Sustainability.