EUROPEAN COMMISSION



Brussels, 10.06.2021 C(2021) 4285 final

Dear Speaker,

The Commission would like to thank the Riksdag for its Opinion on the Communication on the Chemicals Strategy for Sustainability {COM(2020) 667 final}.

The Commission thanks the Riksdag for the consistent political support given in the past years on the objective of a toxic-free environment and welcomes the support for the ambition and actions announced in this Strategy. The Strategy is the first delivery of the EU's zero-pollution ambition for a toxic-free environment in the context of the European Green Deal, which will be complemented by a Zero Pollution Action Plan in the coming weeks.

The aim of this Strategy is to strengthen health and environmental protection and at the same time to contribute to improving the competitiveness of European Union's industry, support the socio-economic recovery from the COVID-19 pandemic and the European Union's open strategic autonomy. For this, the Commission has indeed proposed not only a number of legislative initiatives, but also a series of supportive actions. The Commission is grateful that this is so positively acknowledged by the Riksdag.

The Commission also takes due note of the views and recommendations expressed by the Riksdag. The Commission would like to emphasise that this Strategy is based on a number of policy evaluations on the European Union chemicals legislation that it has carried out in the last years. Those evaluations clearly show that the European Union has a very advanced and protective regulatory framework on chemicals, based on a world-class knowledge base on chemicals. At the same time, they brought to our attention a number of gaps, weaknesses and challenges that we aim to address through the actions announced in the Strategy in order to fully achieve EU policy objectives. In addition to this, in preparing the various proposals for legislative changes announced in the Strategy, the Commission will of course adhere to its Better Regulation principles.

The Commission would also like to thank Sweden for its support to the ambition of the Strategy during the preparation of the Council Conclusions adopted in March under the

Portuguese Presidency. Such Council Conclusions will be very helpful for the Commission in the practical implementation of the announced actions.

The Commission is now fully committed to the implementation of the Strategy. We have published – in an Annex to the Strategy – an ambitious timeline for the various actions, which takes into account the time needed to carry out the necessary impact assessments, in line with available resources in the Commission. Nevertheless, the Commission fully understands the wish of the Riksdag to speed up some of the actions and will do its utmost to deliver the various proposals and start the non-legislative actions without undue delay.

In response to the more technical comments, the Commission would like to refer the Riksdag to the attached annex. The Commission hopes that the clarifications provided in this reply address the issues raised by the Riksdag and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Maroš Šefčovič Vice-President Virginijus Sinkevičius Member of the Commission

<u>Annex</u>

As regards the points to which the Riksdag has drawn the Commission's particular attention, the Commission would like to make the following comments:

Phasing out substances of very high concern: The Commission is committed to ensure that chemicals legislation becomes more preventive in tackling the most harmful substances. This is why the Strategy announces proposals to extend the generic approach to risk management across relevant legislation, in particular to ensure that the most harmful chemicals are not present in consumer products and the vulnerable groups are not exposed to them. Our evaluations have shown that the generic approach to risk management is simpler, generally faster and provides clear signals to all actors on the types of chemical substances where innovation should be prioritised by the industry. This is further explained in the Staff Working Document SWD(2019) 199 final/2, accompanying the report of the Commission on the findings of the Fitness check of the most relevant chemicals legislation (except REACH) and identified challenges, gaps and weaknesses. The concept of generic risk management – as proposed – will still allow for the use of these most harmful chemicals where proven essential for society. Work has started in the Commission and with the competent authorities for REACH and Classification, Labelling and Packaging (CARACAL) to define this concept further, based on the definition provided by the Montreal Protocol. The Commission will soon launch targeted workshops and consultations to define criteria and potential application of the concept across relevant legislation, with all interested stakeholders.

The Commission agrees with the Riksdag that the grouping approach can ensure that the EU can take the necessary risk management actions much faster, more effectively and with fewer resources. The European Chemicals Agency is currently developing this concept.

The Commission would also like to point out that the work on restrictions of per- and polyfluorinated alkyl substances (PFAS) under Regulation (EC) No 1907/2006 (REACH) is already ongoing. The Commission has requested the European Chemicals Agency to start working on a restriction dossier for firefighting foams — a common source of PFAS. The Commission is confident that the European Chemicals Agency will be able to deliver this work by October 2021, after which the Commission can start preparing — if appropriate — the respective proposal and discuss it with Member States. In addition, five Member States, including Sweden, have announced their intention to prepare a restriction dossier for PFAS more generally. The Commission hopes that the first general analysis will be finalised soon, so that the dossier can be submitted to the European Chemicals Agency late 2021/early 2022.

Stimulating safe design and non-toxic material cycles for innovative circular economy: The Commission attaches great importance to the ongoing work on safe and sustainable by design, which shall allow to catalyse the shift to chemicals, materials and products which are inherently safe and sustainable, along their full lifecycle. The Commission is currently putting in place the framework for developing further the concept of safe and sustainable chemicals, closely in line with the ongoing work under the Circular Economy

Action Plan and in particular the upcoming initiative on sustainable products. The Commission is finalising a study to map all the relevant concepts and initiatives upon which the concept should build, in particular those related to green and sustainable chemistry promoted in the EU as well as internationally. The involvement of stakeholders will be key in developing implementable criteria, and this is why the Commission intends to establish an inclusive EU network of experts and stakeholders to enable multidisciplinary design processes. This framework was presented to the stakeholders in a first stakeholders' workshop on 18 March.

As announced in the Strategy, the Commission will also develop a strategic Research and Innovation agenda for chemicals. This will steer funding and investments opportunities in order to achieve the objectives of the Strategy, and will also foster multidisciplinary research and digital innovations for advanced tools, methods and models, and data analysis capacities to also move away from animal testing.

Addressing deficiencies in the EU's chemicals legislation: The Commission is fully committed to ensuring high protection of health and environment from hazardous chemicals, and a number of upcoming legal proposals aim to strengthen chemicals legislation in this direction, in particular to address the most harmful chemicals like endocrine disruptors and persistent chemicals, as well as the combination effect of chemicals. In particular, we will look how to upgrade REACH and the Classification, Labelling and Packaging Regulations to reach the objectives of this Strategy. This will ensure — for instance — that sufficient information on chemicals manufactured or imported into the EU is generated, that substances of concern are rapidly identified and, where needed, phased-out from problematic uses. In this exercise, we will also look at sectoral chemicals legislation, such as toys, cosmetics, or food contact materials.

All new legal proposals will follow the Commission's Better Regulation guidelines, including an impact assessment and a consultation process with stakeholders. We plan to publish the Inception Impact Assessment Roadmaps for the revisions of REACH and Classification, Labelling and Packaging Regulations in the coming weeks, and they will stay open for 4 weeks for public consultations. More targeted consultations and discussions will also take place afterwards.

The Commission would also like to stress the importance it attaches to the enforcement of EU legislation. As said in the Communication already, stepping up implementation and enforcement of chemicals legislation is urgently needed to ensure compliance for the production and placing on the market of chemicals, as well as for their release and disposal. This should also help establish a better level playing field, and is therefore important for the competitiveness of the EU's chemicals industry. The implementation of the new market surveillance Regulation, as well as the forthcoming measures to reinforce the EU Customs Union and the revision of the General Products Safety Directive will strengthen enforcement both within the single market and at the EU's external borders, including by exploiting the opportunities offered by the digital technologies.

Chemical issues need to be integrated into the Commission's other strategic initiatives: The Chemicals Strategy integrates the main objectives of the European Green Deal into a holistic vision and roadmap. In particular, this strategy represents the necessary first step towards EU's zero pollution ambition and the related targets defined in the biodiversity and farm to fork strategies, laying the foundations for the upcoming zero pollution action plan and contributing to the success of the Europe's beating cancer plan. The strategy is also complementary to the European industrial strategy, the recovery plan for Europe, the circular economy action plan, and other Commission's strategies and initiatives such as the pharmaceuticals strategy, the beating cancer plan, the hydrogen strategy and the batteries initiative. The Commission as a whole is highly committed to achieving the goals of the Strategy across policy areas, and internal coordination is fully in place to ensure coherence and alignment of the upcoming initiatives announced under the various Commission strategies.

Acting globally for a new agenda for chemicals and waste after 2020: The Commission recognises the fragmentation of the international instruments to ensure the sound management of chemicals, and is fully committed to promote efforts to step up the ambition globally, reflecting the ambition defined in the Strategy also internationally. The Commission fully appreciates Sweden's ongoing effort and commitment to promote a high level of protection internationally, also by giving greater scope to the toxic-free ambition in international organisations and in the EU's free trade agreements.