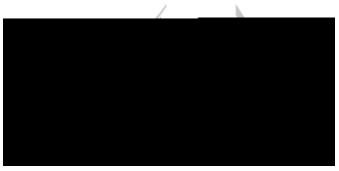

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1. SUSTAINABLE CHEMICALS FOR THE GREEN AND DIGITAL TRANIs3(R)5(A)-f3(IO(R)5NTBT/F5

Nevertheless, in order to develop and deploy the sustaina

A more coherent, predictable and stronger regulatory framework, combined with non-regulatory incentives, will drive the necessary innovation, deliver increased protection, while enhancing the competitiveness of the European chemical industry and its value chains. To ensure a level playing field between EU and non-EU players, the EU must ensure **full enforcement** of its rules on chemicals both internally and at its borders, and promote them as a gold standard worldwide, in line with our international commitments.

The **COVID-19 pandemic** has not only added to the urgency to protect human and planetary health but it has also made us aware that manufacturing and supply chains have become increasingly complex and globalised for some critical chemicals, such as those to produce pharmaceuticals. The EU must strengthen its **open strategic autonomy** with **resilient value chains** and diversify sustainable sourcing for those chemicals that have essential uses for our health and for achieving a climate-neutral and circular economy.

This strategy highlights the areas where the Commission wants to make greater progress, in **close concertation with stakeholders** to fine-tune these objectives as part of rigorous impact assessment processes building on the ample evidence already gathered on the performance of existing legislation[17]. The Commission will establish a **high**

Figure: The toxic-free hierarchy ±a new hierarchy in chemicals management

This strategy sets a pathway towards implementation of this vision through actions to support innovation for safe and sustainable chemicals, strengthen the protection of human health and the environment, simplify and strengthen the legal framework on chemicals, build a comprehensive knowledge base to support evidence-based policy making, and set the example of sound management of chemicals globally.

2.1. Innovating for safe and sustainable EU chemicals

The transition to chemicals that are **safe and sustainable by design** is not only a societal

support, as well as advice and assistance in particular for SMEs, and requires a concerted effort from all: authorities, businesses, investors and researchers.

Regulatory tools[22] need to be exploited to **drive and reward**

safer materials and products is being slowed down by a number of issues, in particular the **lack of adequate information on the chemical content** of products[27]. Consumers, value chain actors as well as waste operators therefore cannot make informed choices.

To move towards toxic-free material cycles and clean recycling and ensure that ³5HF\FOHG LQ WKH (8 becomes a benchmark worldwide, it is necessary to ensure that **substances of concern in products and recycled materials** are minimised. As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where a derogation to this principle may be necessary. This would be under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact on consumer health and the environment, and where the use of recycled material compared to virgin material is justified on the basis of a case by case analysis.

Regulatory actions need to go hand-in-hand with increased investments in **innovative technologies** to address the presence of **legacy substances in waste streams,** which could in turn allow to recycle more waste[28]. This is particularly important for certain plastics and textiles. Sustainable innovations and technologies will have to be developed for this purpose. Technologies such as chemical recycling could also have a role but only if they ensure an overall positive environmental and climate performance, from a full life cycle perspective.

NON-TOXIC MATERIAL CYCLES

The Commission will:

- minimise the **presence of substances of concern in products** by introducing requirements, also as part of the Sustainable Product Policy Initiative, giving priority to those product categories that affect vulnerable populations as well as those with the highest potential for circularity, such as textiles, packaging including food packaging, furniture, electronics and ICT, construction and buildings;
- ensure availability of **information on chemical content and safe use**, by introducing information requirements in the context of the Sustainable Product Policy Initiative and tracking the presence of substances of concern through the life cycle of materials and products[29];
- ensure that **authorisations and derogations** from restrictions for recycled materials under REACH are exceptional and justified;

2.1.3. Greening and digitalising the production of chemicals

Chemical production is one of the most polluting, energy and resource-intensive sectors and is closely integrated with other energy-

essential applications for society through EU funding and investment mechanisms[37].

2.2. Stronger EU legal framework to address pressing environmental and health concerns

Although the (8¶V DSSURDFK WR FKHPLFDOV PDQDJHPHQW KDV and environmental exposures to certain problematic substances, ongoing and emerging health and environmental concerns call for a **strengthening of the legal framework** to rapidly respond to scientific findings, making it more coherent, simple and predictable for all actors. In particular, the **REACH and CLP Regulations** should be reinforced DV (8¶V **cornerstones for regulating chemicals**, and be complemented by **coherent approaches to assess and manage chemicals** in existing sectorial legislation, especially that regulating

People and other living organisms are daily exposed to a **wide mix of chemicals originating from various sources**. Significant progress has been made in recent years to close some knowledge gaps on the impact of the combination effect of those chemicals. However, the safety of chemicals in the EU is usually assessed through the evaluation of single substances, or in some cases of mixtures intentionally added for particular uses, without considering the combined exposure to multiple chemicals from different sources and over time[49]. For people, the combination effects of chemicals may intensify in closed environments. Some pieces of legislation[50] require to assess the cumulative exposure to the same chemical from different sources. Explicit requirements to take into account the impact of **unintentional mixtures** is generally lacking, currently existing for the protection of workers[51]. The pesticides and biocides legislation require to consider cumulative and synergistic effects[52]. For pesticides, progress has been made in developing a targeted methodology, and work will be accelerated so that existing provisions can be fully implemented[53].

To adequately address the combination effect of chemical mixtures, legal requirements need to be consistently in place to ensure that risks from simultaneous exposure to multiple chemicals are effectively and systematically taken into account across chemicals-related policy areas. As it is currently not realistic nor economically feasible to specifically assess and regulate an almost infinite number of possible combinations of chemicals, scientific consensus is emerging that the effect of chemical **mixtures needs to be taken into account and integrated more generally into chemical risk assessments**.[54] In parallel, targeted methodologies could be further developed and explored for specific policy areas.

CHEMICAL MIXTURES

The Commission will:

- assess how to best introduce in REACH (a) **mixture assessment factor(s)** for the chemical safety assessment of substances;
- introduce or reinforce provisions to take account of the **combination effects in other relevant legislation,** such as legislation on water, food additives, toys, food contact material, detergents and cosmetics;
- improve the assessments of the **mixtures used in the manufacture of tobacco** and related products by using where possible existing EU agencies[55].

2.2.3. Towards zero chemical pollution in the environment

Hazardous chemicals and their complex interaction with other environmental stressors can have **long-term and large-scale environmental** impacts on the terrestrial and marine environment. They can contribute to the reduction of ecosystem resilience, leading to rapid declines in animal populations and, ultimately, to extinctions[56], as well as impacting human health and wellbeing, not least through the possible presence of contaminants in the food chain. It is estimated that 2.8 million potentially contaminated sites exist in the EU, mainly from waste disposal and treatment, posing a significant environmental hazard for terrestrial and aquatic ecosystems and affecting the productivity of soils[57]. The current regulatory and policy framework struggles to take this into account and needs to be strengthened.

CHEMICAL POLLUTION IN NATURAL ENVIRONMENT

The Commission will:

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Chemical safety assessments are being initiated under various pieces of legislation, by various actors and at different points in time, and they are carried out by various EU agencies[65], scientific committees[66], expert groups or Commission departments. Stakeholders and the general public struggle to keep track of regulatory processes and resulting decisions. µ2QH VXEVWDQFH RQH DVVHVVPHQW initiation and prioritisation of the safety assessments are done in a coordinated, transparent and to the extent possible synchronised manner taking into account the specificities of each sector. When an assessment is proposed under one piece of legislation, full account shall be taken of the planning under other pieces of legislation, so that coordinated action is ensured. This could be most HIILFLHQWO\ GRQH E\ EXLOGLQJ RQ WKH VXFFHVV RI WKH existing mechanism in place under REACH and CLP[67]. To avoid duplication of work, early agreement on the problem definition will be key, favouring the assessment by groups of substances with structural or functional similarities. The use of available resources and expertise shall be optimised, through a clear **allocation of responsibilities** as well as good cooperation among all actors.

COORDINATE AND SIMPLIFY ACTIONS ACROSS EU CHEMICAL LEGISLATION

The Commission will:

- use a single µ3XEOLF $FWLYLWLHV &RRUGLQDWLRQ

concerned;

- establish a **coordination mechanism** within the Commission to agree and synchronise, to the extent possible, actions across chemical legislation as regards hazard identification/classification and risk assessment and oversee the process WRZDUGV µRQH VXEVWDQFH RQH DVVHVVPHQ
- rationalise the use of expertise and resources by proposing the **reattribution of technical and scientific work** on chemicals performed under the relevant pieces of legislation to European agencies, including work of the SCHEER and SCCS[69];
- make a proposal to strengthen the **governance of the EƬTƷreuroee micels Agkec**

- review the **definition of nanomaterial**[77] and ensure its coherent application across legislation using legally binding mechanisms;
- develop a **common open data platform** on chemicals[78] to facilitate the sharing, access and re-use of information on chemicals coming from all sources;
- promote reuse and harmonisation of **human and environmental health-based limit values**[79] among EU risk assessors and managers through a centralised and curated EU repository;
- establish tools and practices to ensure that relevant **academic data** is easily and readily accessible for safety assessments and is suitable for regulatory purposes;
- enable EU and national authorities to commission **testing&va9t**

2.4.2. A strengthened chemical science-policy interface

Substantial efforts have been put in place to improve the **scientific understanding of the impacts of chemicals** on health and the environment[99]. Monitoring the presence of chemicals in humans and ecosystems is key to improve the understanding of their impact, and should be further promoted, including to understand the links between chemicals and gender[100]. In partnership with Member States, the Commission will **continue to foster research and (bio-)monitoring** to understand and prevent chemicals-related risks and drive **innovation in chemical risk assessment and regulatory science** through its future framework programme for research and innovation**.**

Despite a strong EU policy for the **protection of animals used for scientific purposes**, adopted 10 years ago, which makes full replacement of animal testing its ultimate goal, animals are still required to be used systematically for testing in the field of chemicals[101]. **Safety testing and chemical risk assessment** need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.

SCIENCE-POLICY INTERFACE

The Commission will:

- establish and update a **research and innovation agenda for chemicals**, driven by a EU-level Coordination Group, that would also promote the regulatory uptake of research findings;
- foster multidisciplinary research and digital innovations for **advanced tools, methods and models, and data analysis capacities**[102] to also move away from animal testing;
- provide financial support for **EU-wide human and environmental (bio)monitoring capacities**, complementing ecosystem monitoring initiatives[103];
- develop an **EU early warning and action system for chemicals**[104] to ensure that EU

2.5. Setting the example for a global sound management of chemicals

The **production, use and trade of chemicals** are growing in all regions of the world. World [106] chemicals value added production is expected to double by 2030. Chemical-intensive sectors like construction, automotive and electronics are

INTERNATIONAL LEADERSHIP

The EU will:

- step up its **international advocacy**

This is key to avoid duplication of work, save resources and support international standards. The existing knowledge base and **experience of EU agencies**, within their mandate and resources, shall also be put to the benefit of EU international policies and leadership.

COOPERATION WITH THIRD COUNTRIES

The EU will:

- promote the sound management of chemicals through international cooperation and partnerships, in **bilateral, regional and multilateral fora**, including through cooperation with Africa[119], as well as cooperation with neighbours and other partners to support their capacity to assess and manage chemicals in a sound manner;
- lead by example, and, in line with international commitments, ensure that **hazardous chemicals banned in the European Union are not produced for export**, including by amending relevant legislation if and as needed;
- promote **due diligence** for the production and use of chemicals within the upcoming initiative on sustainable corporate governance.

3. CONCLUSIONS

This strategy is an opportunity to **reconcile the societal value of chemicals** with human **health and planetary boundaries** as well as to **support industry** in producing safe and sustainable chemicals. It is also an opportunity to respond to the legitimate aspirations of EU citizens for a high level of protection from hazardous chemicals and to promote the EU industry as a global frontrunner in the production and use of safe and sustainable chemicals.

7KLV VWUDWHJ\ UHSUHVHQWV WKH ILUVW VWHS WRZDUGV WKH **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 (XURSH¶V EHDWLQJ FDQFHU SODQ 7KH European Industrial \ LV DOV strategy[120], the recovery plan for Europe[121], the circular economy action plan, and other European Green Deal strategies and initiatives such as the pharmaceuticals strategy, the hydrogen strategy and the batteries initiative.

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