ALLEN & OVERY

The European Commission's Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment

1. Introduction

Nearly 20 years after the European Commission (the **EC**) set out its first strategic approach to the management of chemicals in the European Union[1] (the **EU**), it adopted the new **EU Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment**[2] (the **Strategy**). The Strategy is part of the EU's zero pollution ambition, one of the key commitments of the European Green Deal[3], and was published by the EC on 14 October 2020.

The Strategy maps out the EC's new, long-term vison for the EU's chemical policy. Its main aim is twofold, ie (i) to boost innovation for safe and sustainable chemicals, and (ii) to strengthen, simplify and consolidate the existing EU chemicals legal framework[4] in order to protect citizens, and address environmental and health concerns. It consists of both regulatory and non-regulatory initiatives.

The reasons for revision are both macroeconomic and regulatory. On the one hand, the global production of chemicals is set to double in 2030 and, as the majority of such production take place outside Europe, it is critical to create an innovative EU chemical industry to boost economic growth and increase EU's competitiveness at the global level. On the other hand, recent evaluations of the current chemicals legislation exposed a number of inconsistencies across the different pieces of legislation as well as protection gaps against the current scientific evidence[5].

We discuss in more detail some of the key issues addressed by the Strategy, and actions to take.

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[1] The **EC's White Paper, Strategy for a future Chemicals Policy**, Brussels, 27 February 2001, COM(2001) 88 final.
[2] Communication from the EC 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*, Brussels, 14 October 2020, COM(2020) 667 final.
[3] Communication from the EC: **The European Green Deal**, Brussels, 11 December 2019, COM(2019) 640 final.
[4] Chemicals in the EU are currently regulated by approximately 40 pieces of legislation.
[5] The Strategy builds in particular on the findings of recent evaluations of the current legislation on chemicals, including (i) the Commission General Report on the operation of REACH and review of certain elements (REACH REFIT) of March 2018; (ii) the **fitness check of the most relevant chemicals legislation** (excluding REACH) and identified challenges, gaps and weaknesses (Fitness Check of non-REACH chemicals legislation) of June 2019; (iii) the Commission's Communication on the 'implementation of the circular economy package: options to address the interface between chemical, product and waste legislation' of January 2018, (iv) the ongoing Fitness Check on endocrine disruptors, and (v) the 'Study for the strategy for a non-toxic environment of the 7th Environment Action Programme'.

2. Key issues

2.1 Non-toxic material cycles

In its **new Circular Economy Action Plan**[6], the EC identified a number of areas of concern, where further action is to be taken. These include the need to

1. develop solutions for high-quality sorting and removing contaminants from waste;
2. develop methodologies to minimise the presence of substances that pose problems to health or the environment in recycled materials and articles made thereof;
3. cooperate with industry to develop harmonised systems to track and manage substances of very high concern (**SVHCs**) and other relevant substances, and to identify those substances in waste;
4. propose amendments to the annexes to the Regulation on Persistent Organic Pollutants[7]; and
5. improve the classification and management of hazardous waste so as to maintain clean recycling streams.

The EC found that the lack of adequate information on the chemical content of products hampers the creation of a well-functioning market for secondary raw materials and the transition to safer materials.

In order to move towards toxic-free material cycles, substances of concern in products and recycled materials must be minimised and legacy substances in waste streams must be properly addressed.

Based on these findings, the EC determines that it must:

– minimise the presence of substances of concern in products, prioritising products with the highest potential for circularity;

– ensure the availability of information on chemical content and safe use, by introducing information requirements, and tracking the presence of substances of concern through the whole life cycle of products and materials, particularly by (i) resorting to the new ECHA's SCIP database[8], and (ii) developing products' passports;

– ensure that authorisations and derogations from restrictions for recycled products under REACH are exceptional and justified;

– support investments in sustainable innovations that can decontaminate waste streams, increase safe recycling and reduce the export of waste; and

– develop methodologies for chemical risk assessment.

2.2 Strengthening the EU legal framework to address environmental and health concerns

(a) The protection of consumers, vulnerable groups and workers from the most harmful chemicals

Over the past decades, the exposure of citizens to carcinogenic substances has been reduced by applying a "generic approach to risk management". In other words, carcinogenic products have been generally banned from most consumer products and for uses that expose vulnerable groups, while allowing limited exemptions under conditions that are clearly defined by law.

In the Strategy, the EC announces its intention to

– firstly, extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or endocrine system[10], or are persistent and bio accumulative; and

– secondly, launch a comprehensive impact assessment to define the modalities and timing for extending such approach to other chemicals, including those affecting the immune, neurological or respiratory systems and chemicals that are toxic to a specific organ.

In the meantime, while the generic approach to risk management is not (yet) in place, the EC intends to prioritise these chemicals for restrictions for all uses (instead of regulating them one by one).

The EC also announces its intention to:

– Ensure that childcare articles and products for children (other than toys) are subject to the same level of protection as toys (through the mandatory requirements of the General Product Safety Directive[11] and REACH).

– Define criteria for essential uses, to ensure that the most harmful chemicals are only allowed if their use is necessary for health or safety, or is critical for the functioning of society, and if there are no alternatives that are acceptable from an environmental and health standpoint[12].

– Extend the level of protection granted to consumers under REACH to professional users.

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A new Circular Economy Action Plan, For a cleaner and more competitive Europe*, Brussels, 11 March 2020, COM(2020) 98 final.
[7] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast).
[8] ECHA's SCIP database was launched on 28 October 2020. It is the database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts) established under the Waste Framework Directive 2008/98/EC. As from 5 January 2021, companies supplying articles containing SVHCs on the candidate list in a concentration above 0.1% w/w on the EU market will have to submit information on these articles to the European Chemicals Agency (**ECHA**). The SCIP database will ensure that this information is available to waste operators and consumers throughout the entire lifecycle of articles and materials.
[9] 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.
[10] See also further below.
[11] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

The Strategy pays special attention the exposure of humans and the environment to endocrine-disrupting chemicals and the need to adopt a preventive generic approach to risk management across legislation with respect to endocrine disruptors. REACH does not qualify endocrine disruptors automatically as SVHCs; instead, based on Article 57(f) of REACH they can be identified as SVHCs on a case-by-case basis, provided there is scientific evidence of probable serious effects to human health or the environment in a way "*which give rise to an equivalent level of concern*" to (other) SVHCs.

In this respect, the EC's **Fitness Check on Endocrine Disruptors**[13] identified the following two aspects to be of particular concern:

– the need for an horizontal approach to the identification of endocrine disruptors: harmonised criteria for the identification of endocrine disruptors should be established and held valid across relevant legislations in order to increase legal certainty and avoid substances to be identified as endocrine disruptors under one piece of legislation and not under another one; and

– inconsistent regulatory approaches under different legislation: endocrine disruptors are variably regulated under the current legal framework, with certain pieces of legislation banning them, others subjecting them to authorisation and others simply not addressing them.

The Strategy proposes to (i) establish legally binding hazard identification of endocrine disruptors, (ii) to classify them under the CLP Regulation[14], and (iii) accordingly include them in Article 57 REACH as an independent category. This would mean these substances could be included in the Candidate List for authorisation as and for themselves, without the need to punctually prove characteristics and levels of concern similar to those of other SVHC categories.

(b) The protection of people and the environment from the combination effects of mixtures

The 'Fitness Check of non-REACH chemicals legislation' highlighted how existing assessment processes are not designed to identify combination effects of chemical mixtures. Under current chemicals legislation, risk assessments are carried out on a substance-related and use-related basis, without considering potential risks resulting from the combination of substances with other chemicals (the so-called "combination effect" or "cocktail effect").

The Strategy proposes to assess how to best introduce in Annex I of REACH mixture assessment factors for the chemical safety assessment of substances, and to introduce or reinforce legal requirements to take into account the combination effect in other relevant legislation. Notably, the Annex to the Strategy mentions the planned introduction and/or reinforcement of relevant provisions under the Environmental Quality Standards Directive[15] or the Ground Water Directive[16], the Food contact materials Regulation[17], the Food additives Commission Regulation[18], the Detergents Regulation[19], the Toy Safety Directive[20] and the Cosmetic Products Regulation[21] in 2022.

[12] The concept of "essential use" was introduced by the Montreal Protocol on Substances that Deplete the Ozone Layer. However, the scope of chemicals covered by the EU chemicals regulatory framework is much broader, and it will be challenging to develop a generic definition of "essential use(s)", that would bring added value to the authorization and restriction process that currently already exists under REACH, whilst ensuring their homogenous application across all relevant EU legislation. Annex I to the Strategy indicates that the EC plans to define criteria for "essential uses" for 2021-2022. The Strategy introduces the concept of "essential use" as an exception to the generic approach to risk management, to be extended to the most dangerous chemicals in consumer products. Therefore, it is reasonable to assume that the criteria for "essential uses" will be incorporated in the amendments to the legislations for which such an extension in planned, namely: REACH, the Food Contact Materials Regulation, the Cosmetic Products Regulation and the Toy Safety Directive.

[13] Commission Staff Working Document, *Fitness Check on endocrine disruptors*, Brussels, 14 October 2020, SWD(2020) 251 final.

[14] 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.

[15] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council.

[16] Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration.

[17] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

[18] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

[19] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents.

[20] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

[21] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).

(c) Towards zero chemical pollution in the environment

The 'Fitness check of non-REACH chemicals legislation' also highlighted how hazardous chemicals can result in long-term and large-scale environmental damages, such as ecosystem losses, animal extinctions, food-chain contamination. It exposed significant gaps in the capacity of the current chemicals legislation to account for those issues. Furthermore, it identified bottlenecks, *inter alia*, in relation to:

– inconsistency of risk management decisions in the various pieces of legislation regarding endocrine disruptors, substances that are persistent, bio-accumulative and toxic (**PBTs**), substances that are very persistent and very bio-accumulative (**vPvB**) and substances fulfilling the classification criteria for specific target organ toxicity substances;

– knowledge gaps on the impact of hazardous chemicals on the environment, resulting both in inadequate communication to consumers and in legislative inaccuracy; and

– the (lack of) information on the level of compliance with the existing EU chemicals legislation, particularly with respect to consumer products, and cooperation among the relevant EU agencies.

Against this background, the EC proposes in its Strategy to:

– introduce new hazard classes and criteria in the CLP Regulation (to include endocrine disruptors and PBTs and vPvBs, and assessing the need for specific criteria for immunotoxicity and neurotoxicity (proposals are currently planned for 2021);

– amend Article 57 of REACH to include endocrine disruptors, persistent, mobile and toxic (**PMT**), very persistent and very mobile (**vPvM**) substances in the list of SVHCs (proposals planned for 2022), thus broadening the number of substances subjectable to authorisation and delivering on the REACH REFIT's call for more efficient and comprehensive authorisation processes;

– to mainstream environmental concerns in safety risk assessments, eg by increasing registration requirements under REACH to certain polymers of concern;

– to address the impact of pharmaceutical products on the environment in the upcoming pharmaceuticals strategy for Europe;

– to support decontamination solutions in terrestrial and aquatic environments; and

– to strengthen rules on chemical contaminants in food.

Further, the EC proposes to phase out Per- and polyfluoroalkyl substances (PFAS), unless they are proved essential for society, in order to address their severe effects on soil and water and on human health. According to the Strategy, they should be banned from all uses and assessed based on a group approach under relevant legislation on water, sustainable products, food, industrial emissions and waste. Research and funding for their substitution are also to be scaled up.

2.3 Simplification and consolidation of the legal framework

(a) One substance, one assessment

The Strategy proposes to introduce the 'one substance, one assessment' rule to simplify and coordinate the assessment procedure across chemicals legislation. Under current rules, safety assessments are carried out by different actors, at different times and under different pieces of legislations. As a result, substances can be subject to several regimes/classifications, which in turn hampers the efficiency of the circular economy. For instance, the same substance can be considered hazardous as a product but not as waste. Such inconsistencies have been exposed by both the REACH REFIT Report and the 'Fitness Check of non-REACH chemicals legislation'[22].

The 'one substance, one assessment' rule, which should be established as of 2021, aims to ensure that safety assessments are carried out only once for substances which are considered for different uses and by different legislations. Once an assessment is initiated or priorities are set under a certain legislation, authorities planning to examine the same substance under a different legislation will need to take full account of the planning under other pieces of legislation, so that coordinated action is ensured.

In order to do so, the EC will

– use the Public Activities Coordination Tool (**PACT**), a tool that is already used under REACH and CLP to provide information on ECHA and/or Member State Competent Authority activities;

– set up an expert working group of Member States, EC services and EU Agencies (such as the European Food Safety Authority, ECHA, the European Medicines Agency and the European Environment Agency) to discuss initiatives across chemical legislation, taking into account the specificities of each sector;

– make the switch from a substance-to-substance assessment to a group approach, whereby substances with similar properties, hazards or functions will be assessed together in order to accelerate procedures[23];

– develop a common open data platform on chemicals to facilitate the sharing, access and re-use of information on chemicals from all relevant sources; and

– extend principle of open date and transparency principles to the chemicals legislation.

(b) Zero tolerance for non-compliance

In spite of current (enforcement) efforts, it appears that only one third of the existing REACH registration files are fully compliant. In addition, imported articles and online sales constitute an additional challenge. Therefore, the EC has found that implementation and enforcement of chemicals legislation is urgently needed to ensure compliance at every life-stage.

It will, amongst others,

– require the compliance of all REACH registration dossiers and revoke registration numbers in case of non-compliance;

– propose to carry out audits in the Member States to ensure compliance and enforcement, and use infringement procedures if necessary;

– specifically target areas of high risk of non-compliance (such as online sales);

– extend the scope of action of the European Anti-Fraud Office for coordination and investigation to prevent the circulation of illicit chemicals in the EU; and

– promote an enhanced use of EC IT platforms to be used for the exchange of information on enforcement on chemical legislation and explore the use of digital tools.

Whilst an enhanced use of the (existing) tools and platforms can definitely contribute to a smooth(er) exchange of relevant information, it remains to be seen how such information is to be used by the (enforcement) officials of the various Member States, and how an uniform enforcement policy will be achieved.

The implementation of the new market surveillance Regulation[24] and announced measures to reinforce the EU Customs Union[25] are expected to strengthen enforcement within the EU market and at the EU's external borders, but penalties for infringements remain the responsibility of the individual Member States.

[22] The 'Fitness Check of non-REACH chemicals legislation' reported consistent overlaps of tasks among different agencies resulting in multiplied and un-aligned decisions, and called for better convergence of conclusions.
[23] Grouping was suggested in the 'Fitness Check of non-REACH chemicals legislation' and legislative proposals under the Strategy are now planned for 2022.
[24] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.
[25] According to the Strategy, a study is currently ongoing on how to integrate REACH requirements into customs processes. The results of this study are, at the time of writing this contribution, still unknown/not published yet.