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CHEM Trust comments on the EU Commission's roadmap for a Chemicals Strategy for Sustainability

CHEM Trust welcomes the opportunity to comment on the European Commission roadmap for a Chemicals Strategy for Sustainability. CHEM Trust supports the Commission's overall Zero Pollution Ambition for a toxic-free environment and clearly, an ambitious chemicals strategy is crucial for this aim.

The large volume of chemicals on the market and the multiple concerns related to the massive production and use of chemicals demand more effective legislation. Precautionary and preventative measures are needed in particular to address environment and health impacts from endocrine disruptors, cumulative effects of chemical mixtures, harmful exposure from consumer products including food contact materials packaging as well as extremely persistent chemicals. CHEM Trust, as part of a coalition of NGOs submitted comprehensive proposals on a future chemicals policy to the Commission in November 2019¹. In our view chemical pollution deserves a long-term vision and concrete plan with ambitious timelines to effectively and urgently reduce the exposure of people and environment to toxic chemicals. The European Green Deal is the ideal opportunity to set coherent and ambitious long-term targets as well as specific immediate actions.

It is very important that the roadmap's aim of reducing the length and complexity of supply chains, decreasing dependency on imports and achieving strategic autonomy for essential products will go hand in hand with reducing pollution and strengthening the EU's industrial and regulatory potential to develop safer solutions, made in Europe, replacing hazardous substances. Certain industrial chemicals can have negative effects on the immune system of people and wildlife thus increasing the vulnerability towards infectious diseases and pandemics. Therefore the EU's chemical strategy for sustainability should include swift action to identify and phase out chemicals that disrupt the immune system and other hazardous chemicals that weaken our health. New efficient policies and approaches must ensure that we use chemicals wisely so the costs to environment and health do not outweigh the benefits. We need a chemicals strategy which will be a real game changer.

CHEM Trust regards the following seven points as priorities for the new strategy:

1. Protect EU-citizens and the environment from Endocrine Disrupting Chemicals (EDCs)
2. Address the reality of combined exposure to multiple sources of chemicals

3. Speed up the phase-out of problematic chemicals and avoid regrettable substitution by adopting a grouping approach
4. Use the "One substance - One assessment" approach to deliver quicker protection for people and wildlife
5. Phase out the use of PFAS and other very persistent chemicals
6. Develop new efficient legislation on food contact materials to protect consumers and the environment
7. Ensure the development of a clean circular economy

1) Protect EU citizens and the environment from endocrine disrupting chemicals (EDCs)

The Chemicals Strategy for Sustainability should include an action plan with specific measures and timelines to minimise exposures to EDCs. This was missing in the 2018 EC Communication although scientific reports have already shown years ago that exposure to EDCs may lead to serious impacts on human health and the environment and that exposure in early life is especially critical and may lead to serious effects even in the next generations. EU research has shown that these substances are ubiquitously found in the general population and in the environment.^{2,3} The existing EU regulation on different kinds of chemical substances and products are not consistent when it comes to protection from EDCs: the EU Commission's REFIT assessments of its chemicals regulations over the past years have clearly identified gaps and inconsistencies of the EU regulatory framework on EDCs. Although they are covered by REACH, the Biocidal Products Regulation and the Plant Protection Regulation only a few EDCs have been identified and controlled until now. As described in our CHEM Trust submission to the Fitness Check⁴ we therefore need better implementation of existing laws but also new and effective EU regulation on EDCs across legislations to adequately protect citizens and the environment.

Therefore, we propose the following elements to be included in the Chemical Strategy:

- **A cross cutting regulatory framework for EDCs** to identify and control them across all relevant legislations aiming at establishing coherent and effective protection. The best approach would be to have an identification system for EDCs that will lead to regulatory consequences in each of the specific legislative systems.
- **Horizontal criteria for identification that include 2 categories of EDCs**, i.e. Cat. 1: ED (known and presumed) and Cat. 2: **Suspected EDC**. Although, the EU has finally established criteria for identification of endocrine disrupting biocides and plant protection products these cannot be directly applied to other legislations due to the lack of safety data for other chemicals. Further, the criteria require a too high burden of proof so there is a need to ensure that also those substances for which there are substantial data on endocrine disrupting properties will not be overlooked by the authorities but will be identified as suspected endocrine disruptors.

- **Improved identification of EDCs through more information/data requirements in REACH, BPR and PPPR.** Currently, it is very difficult to identify EDCs because of the lack of (or inadequate) information very often the necessary information to make a clear conclusion is missing. Therefore, there is a need for updating the information/data requirements to include a systematic screening for endocrine disrupting properties (also at low tonnage levels) and for relevant tests to detect health-related endpoints – an update much more comprehensive than the current processes on updating the BPR and REACH annexes foresees.⁵
- **Strict control of all EDCs and ban of EDCs and suspected EDCs in consumer products** for daily use including food contact materials, toys and cosmetics. A more precautionary approach is needed to reflect the specific uncertainties related to EDCs, e.g. the timing of exposure, sensitive windows under development, low dose effects and effects in the next generations and at the same time the ubiquitous exposure of citizens and the environment. EDCs should be considered default as non-threshold substances and as substances of particular concern in line with PBTs. Many EDCs act at low doses and show non-monotonic dose-responses and this and the joint effects from exposure to other EDCs should be taken into consideration in the assessments and risk management, e.g. by grouping of substances with similar effects.
- **Transparency in processes and easy access to information on EDCs and suspected EDCs.** There is a need for transparency of status of assessments within the EU. Therefore, official lists of EDCs and suspected EDCs should be publicly available to facilitate the substitution to less harmful substances in the supply chains and in support of the consumers to take informed choices.
- **Transition measures to swiftly identify EDCs and suspected EDCs** to protect vulnerable groups and the next generations until the cross-cutting regulatory framework is in place and functioning.

2. Address the reality of combined exposure to multiple sources of chemicals

European citizens are exposed to hundreds of chemicals from multiple sources including from food, consumer products, household dust and drinking water and likewise the environment is polluted by multiple different substances.⁶ Scientific research has shown that **mixtures are a real-world issue, with mixtures of chemicals creating combination effects** even if each individual chemical is present at levels below which it is known to cause an effect. However, **current safety assessments of chemicals mainly focus on single substances.**

We need updated legislation which is able to manage the fact that we are exposed to multiple chemicals at the same time. **A very useful tool for a solution is the application of a mixture assessment factor.** More details on our proposals for a pragmatic way forward can be found in our joint NGO paper.⁷

EU decision makers have neglected this topic for many years. Now it is high time to take these decisions in the context of the upcoming Chemical Strategy for Sustainability and the European Green Deal.

The chemicals strategy should:

- **Establish a cross-cutting approach** to address mixture toxicity and take account of the cocktail effect to be applied under all relevant EU laws.
- **Use a consistent, generic mixture assessment factor** to protect human health and the environment against combined exposure to chemical mixtures across the different pieces of EU legislation.
- **Take combination effects systematically into account in risk assessment**, including by using an additional mixture assessment factor by default in prospective risk assessment.
- **Speed up the substitution of SVHCs** and other harmful substances to minimize exposure of the general population, especially vulnerable groups, workers and the environment.

3. Speed up regulation of harmful chemicals and avoid regrettable substitution by adopting a grouping approach

To avoid regrettable substitution, hazardous chemicals should be regulated more often via a grouping approach rather than by regulating each substance one by one (or by using only too narrow groups). For example, CHEM Trust's toxic soup report⁸ predicted how (banned) Bisphenol A might be replaced with the legal Bisphenol S, and recent studies have shown that such **regrettable substitution** has in fact happened⁹.

The REACH Review¹⁰ showed a need to improve the restriction process and to implement the precautionary principle. It also acknowledged the need to scale up the concept of grouping of chemicals, where relevant, to **improve regulatory efficiency, avoid regrettable substitution and avoid delayed protection** of environment and health from harmful groups of chemicals such as the PFAS, the bisphenols and phthalates.

The term "grouping" can be understood in many ways including mainly as *assessment* of chemicals in groups. We find it important to be clear that there is also a need for *regulating* chemicals in groups. No doubt, even a move towards assessing more chemicals in groups may well speed up regulatory processes, but it is important that the actual restrictions implemented under REACH and other laws will cover broader groups of chemicals in the future.

The chemicals strategy for sustainability should include the following steps:

- Make grouping the **default approach** for regulatory processes under REACH and other relevant legal acts including any kind of restrictions of use, classification and labelling as well as for designation of substances as SVHCs. Grouping should be aiming at speeding up regulatory action and avoiding regrettable substitution by e.g. ensuring that a restriction covers all relevant similar substances.

- Identify **important problematic chemicals groups** for which group restrictions should be established as soon as possible. These are e.g. the PFAS (see below), the bisphenols, the phthalates and other groups of chemicals where there is growing evidence of regrettable substitution, e.g. Brominated flame retardants.
- As the first **significant steps**, efficient group restrictions on PFAS and bisphenols should be developed under REACH.

4. Use the "One substance - One assessment" approach to deliver quicker protection for people and wildlife

There is a need for more coherence in the hazard assessment of chemicals, in particular for EDCs. However, it is currently **unclear how the proposed 'One substance – One assessment' approach will be taken forward**. It is definitely important to improve transparency and reduce overlaps and double work as was seen e.g. with the bisphenol assessments by ECHA and EFSA¹¹.

In our view this new approach will **only be a positive step, if it leads to quicker decisions on harmful chemicals** and more effective protection of human health and the environment. However, it could rather become an obstacle and slow down decisions if too many parties have to agree and nothing can move forward. We suggest the concept shall be closely linked with increased efforts towards harmonised classification and labelling and with a **generic risk assessment** approach. This is described in more detail below, in point 6 on food contact materials (FCM) and should be used across legislations. In addition, the REACH regulation should be strengthened by adding further categories of substances to the list of SVHCs such as neurotoxicity, immunotoxicity, vPvM and PMT and expanding the scope of article 68,2, so that e.g. persistent chemicals or other substances with harmful environmental effects are not allowed for widespread dispersive use.

It is important for the Commission to make it clear that:

- The aim of a 'One substance – One assessment' approach is to identify and share hazard data under different legal acts such as REACH, FCM pesticides and toys and then decide on respective risk management measures in the different sectors.
- Even if a substance has been "assessed", there may well be important endpoints which still needs to be established.
- 'One substance – One assessment' should not contradict the grouping approach and force the assessment of substances one by one.
- It is very important that the assessments should be updated as new evidence emerges, as the science on hazardous properties is constantly advancing. Anything that attempted to freeze this process to create one 'official assessment' would be unacceptable.
- The assessments have to include all available evidence ensuring that studies from academia and independent scientists are not disregarded.

5. Phase out the use of PFAS and very persistent chemicals

Scientists have argued for decades that high persistence in itself is a major concern.¹² Very persistent (vP) chemicals accumulate in the global environment and have the potential to reach critical concentrations at which negative unexpected effects can be triggered. Moreover, **contamination will take generations to reverse** after emission have ceased, putting future generation at risk. vP chemicals are also of particular concern in the context of developing a safe and sustainable circular economy as they may accumulate in recycled material.

However, as reported in the 2017 sub-study on very persistent chemicals for the strategy for a non-toxic environment,¹³ the current EU legislation is insufficient to prevent the build-up of very persistent substances in the environment as it *“does not provide an adequate way to systematically control substances on the basis of their persistent properties”*.

In the current EU regulatory framework, persistent chemicals are usually regulated under the combined categories of PBT and/or vPvB. Recently, under REACH certain very persistent and mobile perfluorinated chemicals have been identified as SVHCs giving rise to an equivalent level of concern.¹⁴

These chemicals belong to the PFAS family (Per- and polyfluorinated alkyl substances). The PFAS group is made of over 4,700 substances, all very persistent¹⁵. Regulating all PFAS with the current approach would take decades, allowing these very persistent substances to further build-up in the environment. A **PFAS group restriction is the only way** to ensure high level of protection to human health and the environment from exposure to these chemicals and put an end to a never-ending spiral of regrettable substitution.

Five EU Member States are currently working on a proposal to restrict all PFAS in all non-essential uses. However, the concept of **non-essential use is not currently defined** in the EU legislation. Its definition will be critical in succeeding to limit to the strict minimum emissions of these vP substances in order to minimise exposure of future generation and prevent further irreversible contamination of drinking water. The PFAS currently restricted under REACH such as PFOA benefit from many derogations which are not justified by the absence of alternatives. This means the current EU regulatory approaches to address the pervasive contamination with PFAS need to be strengthened and accelerated.

Therefore, the EU Chemical Strategy should draw up an EU action plan on PFAS that includes:

- **Phasing out all very persistent chemicals** in order to efficiently protect human health and the environment and ensure a safe and sustainable circular economy.
- **Restricting PFAS chemicals as a group** with as few exemptions as possible.
- Taking EU leadership in advocating for the **global regulation of PFAS as a group under the Stockholm Convention**.

6. Develop new legislation on food contact materials to protect consumers and the environment

In March 2020, 33 international scientists published a joint consensus statement¹⁶ expressing deep concern about the current use of chemicals in food contact materials (FCM). Following up on this

more than 200 NGO have signed a declaration of concern¹⁷. To ensure that these concerns are adequately addressed, the chemicals strategy for sustainability must clearly **support the aim of the Farm to Fork Strategy¹⁸ of revising the EU legislation on Food Contact Materials**. The new legislation should be based on the five key principles for a new policy¹⁹ developed in 2019 by key NGOs, and take inspiration from the most effective legal instruments to protect humans and the environment adopted under other EU regulations, including REACH.

The Farm to Fork strategy seem to link the issue of safe FCM with the circular economy agenda. However, in our view, the need for improved **legislation for FCM is not only a matter of ensuring a toxic free circular economy**. The use of harmful chemicals in FCM that migrate into our food is a basic public health issue, and the use of PFAS and other substances that may harm the environmental in FCM is problematic even without a circular economy.

The chemicals strategy should help ensure that:

- Harmonised implementing measures and **positive lists** for chemicals in FCM are developed for all materials. These positive lists should be developed based on a two-phased approach similar to the one recently adopted under the Drinking Water Directive²⁰
- A **generic risk assessment** approach is adopted for the most hazardous chemicals. As soon as certain hazardous effects, such as CMR, EDC, PBT, PMT and DNT, are identified under other regulations, the use in FCM should be restricted via a fast track procedure.
- The migration of chemicals from food contact articles – **including Non-Intentionally Added Substances (NIAS)** - must be assessed and controlled.

7. Ensure a clean circular economy

We support the Commission's aim in the Roadmap that the zero-pollution for a toxic-free environment must complement biodiversity protection and moving towards a climate-neutral and circular economy.

In order to achieve complementarity, the European Commission needs to:

- Specify how the circular economy action plan will support zero-pollution and a toxic-free environment.
- Create a market for and public trust in a clean material cycle by establishing a system of traceability for hazardous substances in products and materials and ensuring full transparency. This requires in particular an effective SCIP database to this extent.
- Start a **clean cycle of materials and products** by phasing out the continued use of hazardous substances **without creating new exemptions for secondary materials**, via the approaches set out above using grouping and applying mixture assessments, adding further hazard categories and establishing consistent restrictions across products and materials, including all food contact materials.
- Identify effective solutions for addressing the challenges of hazardous chemicals in recycling processes. This requires **proper implementation the EU's waste framework policy**, in particular applying the waste management hierarchy and enforcing hazardous waste management rules to **ensure that hazardous substances are not further spread in our technosphere** and to prevent building up a liability for future

generations. Preference has to be given to solutions which are available on the market now to avoid procrastination and lock in situations, like we have seen for lead in PVC.

¹ Towards a non-toxic environment. NGO chemicals policy asks of the new Commission, November 2019: <https://eeb.org/library/towards-a-non-toxic-environment-ngo-chemical-policy-asks-of-the-european-commission/>

² <https://www.hbm4eu.eu/>

³ <https://www.solutions-project.eu/>

⁴ <https://chemtrust.org/eu-urgent-action-edcs/>

⁵ https://chemtrust.org/wp-content/uploads/Final-CHEM-Trust-comments-follow-up-to-CASG-ED1_February-2020.pdf

⁶ <https://chemtrust.org/chemical-mixture-effects/>

⁷ https://chemtrust.org/wp-content/uploads/Final-NGO-comments-mixtures-CARACAL-CA_MS_34_2020.pdf

⁸ From BPA to BPZ a toxic soup? How companies switch from a known hazardous chemical to one with similar properties and how regulators could stop them. CHEM Trust, March 2018.

<https://chemtrust.org/toxicsoup/>

⁹ Report from ECHA on the use of BPS in thermal paper. June 18 2020: https://echa.europa.eu/-/bisphenol-s-has-replaced-bisphenol-a-in-thermal-paper?utm_source=social&utm_medium=Twitter.com&utm_campaign=Bisphenol

¹⁰ REACH Review, 2018; https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

¹¹ Why a group restriction on the bisphenols is long overdue. CHEM Trust, May 2020

https://chemtrust.org/bisphenol_group/

¹² Why is high persistence alone a major cause of concern? Cousins, I.T. et al., 2019. Environmental Science: Processes & Impacts, 21, pp. 781-792. <http://doi.org/10.1039/C8EM00515J>

¹³ Study for the strategy for a non-toxic environment of the 7th EAP. Sub-study d: Very Persistent Chemicals. Goldenman et al., 2017. <https://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20d%20very%20persistent%20subst.%20NTE%20final.pdf>

¹⁴ Identification of HFPO-DA and PFBS as substances of very high concern (SVHC). CHEM Trust, 2019. https://chemtrust.org/wp-content/uploads/CHEM-Trust_PFAS-consultations-responses_November-2019_updated-Jan2020.pdf

¹⁵ PFAS – the ‘forever chemicals’, Invisible threats from persistent chemicals. CHEM Trust, 2019.

https://chemtrust.org/wp-content/uploads/PFAS_Brief_CHEMTrust_2019.pdf

¹⁶ Impact of Food Contact Materials on human health: a consensus statement:

<https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-0572-5>

¹⁷ A Declaration of Concern and call to action regarding plastic, packaging and human health:

https://zerowasteurope.eu/wp-content/uploads/2020/03/Declaration_Of_Concern_3March2020.pdf

¹⁸ Commission’s Farm to Fork Strategy: https://ec.europa.eu/food/farm2fork_en

¹⁹ Read about the five key principles for a reform of the EU FCM legislation: <https://chemtrust.org/5-key-principles-fcm/>

²⁰ Information about the positive list under the Drinking Water Directive, ECHA, 2020:

<https://echa.europa.eu/-/echa-starts-work-on-making-drinking-water-safer>