

HEAL's response to the EU Commission's proposed roadmap 'Towards a more comprehensive framework on endocrine disruptors'



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The Health and Environment Alliance (HEAL) welcomes the opportunity to comment on the European Commission's proposed roadmap "Towards a more comprehensive framework on endocrine disruptors"ⁱ. In HEAL's view, a comprehensive European approach to address the health and societal challenges of endocrine disrupting chemicals (EDCs) that reduces exposure is long overdue and an absolute necessity.

From a legal point of view, the seventh Environment Action Programme (EAP)ⁱⁱ adopted in 2013 already makes the minimisation of exposure to EDCs a priority objective, including addressing safety concerns related to EDCs across legislations and their combination effects. Moreover the December 2016 Environment council conclusions invite the European Commission to update the 1999 EU endocrine disruptors strategy as appropriateⁱⁱⁱ.

The significant increase in the relevant scientific knowledge providing evidence on the link between EDC exposure and a series of serious health conditions – including but not limited to reproductive disorders, cancers such as breast cancers or prostate cancers, behavioural disorders such as autism or ADHD – since the 1999 strategy was released should guide the European Commission's effort in building a new strategy. This new strategy should place measures to reduce citizens' exposure to EDCs at its core in order to truly make a difference in terms of health and societal gains.

INITIAL FRAMING

We are puzzled at the framing proposed by the European Commission under this roadmap, which suggests to update and replace the 1999 "strategy" by a "framework on endocrine disruptors". The latter seems less ambitious and appropriate than a fully-fledged strategy. We also note that this constitutes a change of language in comparison to the European Commission's July 2017 communication, which mentions that *"the adopted criteria will provide a stepping stone for further actions to protect health and the environment by enabling the Commission to start working on a new strategy to minimise exposure of EU citizens to endocrine disruptors, beyond pesticides and biocides"*^{iv}. We would welcome clarifications about the reason for this distinction and urge the European Commission to uphold an ambitious approach that builds a new strategy that places measures to truly reduce citizens' exposure to EDCs at its core.

Moreover we are ill-at-ease with the Commission's framing of its own actions so far in the area of EDCs under this term, which gives a misleading impression that significant progress has been achieved and that remaining issues are independent of its own actions (e.g. "Despite significant progress having been achieved since then [1999] in understanding endocrine disruptors, societal concerns remain high";

"The current Commission has paid special attention to endocrine disruptors, and this has resulted in the development of a number of initiatives since 2014"). We would like to remind the Commission of its own delay in presenting identification criteria for ED biocides and pesticides, resulting in a condemnation at the European Court of Justice. Swifter action on these criteria would have allowed the Commission to take steps to identify EDCs and reduce exposure to these in other areas at an earlier stage, thereby contributing to an overhaul of the 1999 strategy and enhanced protection for citizens' health.

INITIATIVE AIMS

In light of the above, we are surprised and regret that the reduction of exposure to EDCs (and related gains for human health and the economy) is not explicitly mentioned in the aims of the roadmap. Comprehensive EU action on EDCs should indeed make such a reduction central to its action, including as a way to reduce the economic costs of the health conditions associated to current levels of exposure^v. We are concerned that the roadmap aims hereby presented ("addressing the gaps in knowledge", "linking science and regulation", "cooperating on the global scene") do not take this element into account. The proposed aims will be of little concrete added-value to citizens and society unless they are not associated to a clear objective and related

measures of exposure reduction. Should the Commission fail to address this objective, it will breach the commitments made under the seventh EAP and not deliver on the Council 2016 requests. This might also jeopardise the ability to deliver in relation to the legal basis referred to in the roadmap itself (articles 114 and 191 of the Treaty of the Functioning of the European Union^{vi}) and the better regulation principles.

CONTENTS OF THE NEW INITIATIVE

In order for the new initiative to reach the objective of truly reducing citizens' exposure to EDCs, HEAL considers that the European Commission should fully embrace and include the eight proposals for action developed by the EDC Free Europe Coalition in May 2018^{vii} (the full proposals can be found in the annex at the end of this document).

1. Consider public health and precaution as the cornerstones of a new EU EDC Strategy;
2. Enhance public awareness of EDCs – connect it with the EU's work on protecting citizen's health;
3. Improve regulation: Increase the control of the use of EDCs across all sectors;
4. Reduce our EDC daily cocktail: Replace the substance-by-substance approach by including all possible sources of exposure to multiple chemicals;
5. Speed up testing, screening and identification of EDCs;
6. Work towards a clean 'Circular economy' and a non-toxic environment: Avoid toxic substances such as EDCs in products from the start;
7. Enhance European market leadership for safer substitution with no regrets and promotion of innovative solutions;
8. Monitor the health and environmental effects of single, groups and mixtures of ED substances to capture all sources of EDC exposure 'across the board' and respond swiftly to minimise them.

Finally, a new European EDC strategy should commit to anchor its proposed measures to better identify EDCs and reduce exposure in the latest scientific developments. EDC science is fast evolving; researchers are publishing new evidence on EDCs on a weekly basis. While knowledge gaps remain (e.g. on the exact mode of action of some substances, or the assessment of the cocktail effect), there is enough scientific evidence to take policy action and even global consensus on the urgency to do so^{viii}. For instance, the knowledge on some key principles by which EDCs act (such as nonmonotonic dose-responses, low-dose effects,

and developmental vulnerability) has evolved a lot over the last years^{ix}. The European Commission has a responsibility to guarantee that EU legislation relies on the latest scientific knowledge to make decisions to identify substances, regulate them across legislations and sources of exposure. A new strategy must provide legislators with the flexibility to integrate this new knowledge and to use it in the most health and environment protective ways in case where uncertainties remain, in full compliance with the precautionary principle, which is a cornerstone of EU treaties.

By way of illustration of the fast moving pace of the EDC research and the need to adapt our regulatory framework to it in a precautionary way, here we have added an extra set of resources:

- The Collaborative on Health and Environment (CHE) webinar series to discuss EDC science and its implications
<https://www.healthandenvironment.org/our-work/webinars/che-edc-strategies-partnership>
- Member states' work on EDCs to inspire EU action:
 - France ongoing work for a second national strategy:
<https://www.ecologique-solidaire.gouv.fr/rapport-devaluation-du-plan-national-daction-sur-perturbateurs-endocriniens-gouvernement-engage>
 - Belgium senate information report on EDCs in view of a national EDC strategy:
<https://www.senate.be/www/webdrive.r?MltabObj=pdf&MlcolObj=pdf&MlnamObj=pdfid&MltypeObj=application/pdf&MlvalObj=100663866>
 - Danish report towards a non-toxic future:
http://en.mfvm.dk/fileadmin/user_upload/ENGLISH_FVM.DK/Focus_on/Chemicals_and_waste/13215_MF_Kemikonferencen_Rapport_A4_PRINT.pdf
 - Sweden strategy for a non-toxic environment (including on EDCs):
<http://www.swedishepa.se/Environmental-objectives-and-cooperation/Swedensenvironmental-objectives/The-national-environmentalobjectives/A-Non-Toxic-Environment>

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About the Health and Environment Alliance (HEAL):

The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 70 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

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Promoting environmental policy that contributes to good health

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- ^{vi} Article 114(3) of the TFEU mentions: "The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts". Article 191(1) mentions "Union policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment, protecting human health".
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EU has the obligation to protect its people and the environment from all harm caused by endocrine disrupting chemicals

Our eight demands for an EU EDC strategy

Why we are concerned

Endocrine disrupting chemicals (EDCs) are increasing our chances of getting serious and potentially lethal diseases and health disorders as highlighted by experts from the World Health Organization (WHO) [1], scientists from the Endocrine Society [2], and others. In these reviews of scientific literature, impacts from EDCs have been linked to reproductive and fertility problems such as drastically falling sperm rates, as well as hormone dependent cancers such as breast and prostate cancers. Neurological impairments including autism and IQ loss as well as metabolic changes including obesity and diabetes have also been associated with exposures to EDCs [3, 4]. In wildlife, there is further evidence of reproductive and developmental harm linked to impairments in endocrine function in a number of wildlife species: EDCs have been associated with changes in immunity and behaviour as well as skeletal deformities [5].

A growing body of science underpins the ways in which some people are more vulnerable than others to the health impacts of endocrine disruption, even in small doses, with effects sometimes appearing decades later. The time during development in the womb and during early childhood has been found to be a particularly sensitive window of exposure and has raised serious concerns among health professionals. In 2015 over 100 national societies of obstetricians and gynaecologists from around the world called on policymakers to prioritise reducing exposures as an important means of disease prevention [6].

Avoiding EDCs is not a choice that a person can make anymore [7]. EDCs are found everywhere in our daily lives: from high-profile substances, such as the bisphenols used in the making of certain plastic bottles and can linings, and restricted phthalates that are still found in one out of five toys [8]; the flame retardants used in sofas; the pesticides sprayed on and ending up in our food; and the antimicrobial biocides found in cleaning products. They are nearly everywhere, both at home and in the workplace. The

nonprofit research institute the Endocrine Disruption Exchange (TEDX) lists over 1,400 potential EDCs [9], the WHO mentions over 800 EDCs [10], and many more suspected EDCs still need to be investigated.

EDCs end up in all of us – children and adults alike – contaminating our bodies without our consent or knowledge. Human biomonitoring samples of urine, hair and blood across Europe are starting to demonstrate the extent of that internal pollution. In France, over 20 EDCs were found in women tested for the presence of these chemicals in 2015 [11]. The European Biomonitoring Initiative has included many EDCs and potential EDCs in its priority list and the results will be used to inform policy decisions on specific substances [12].

Most importantly, EU laws regulating EDCs are not protecting us – the ones that are supposed to do so are patchy, not properly implemented and leave huge gaps where EDCs are not regulated at all such as in cosmetics, toys, textiles, furniture and food packaging and in other articles that we come into contact with every day.

What we want

In 2017 the EU Commission committed to bring out a new integrated strategy on EDCs which is supposed to cover *'for example toys, cosmetics and food packaging'* [13. 14]. Previous attempts to update the existing EU Community Strategy on EDCs from 1999 with recent scientific advances and actions to tackle the problem was derailed by intense industry lobby in 2013 as documented by the investigation *'Toxic Affair'* [15].

We are calling on EU Commission President Jean-Claude Juncker to bring out a fully-fledged strategy before the summer of 2018. This would include a concrete action plan aiming for a high level of protection for human health, especially vulnerable groups, and the environment. Tangible activities should have clear targets, a timeline and a reasonable budget. This would be an opportunity for reconnecting the EU's agenda with citizens' demands for better public health protection on EDCs as illustrated by widely supported petitions developed and supported by the EDC-Free campaign partners in 2017. The first one was delivered to member states with almost half a million signatures in July [16], and the second one with over 300,000 signatures in October [17].

An EU EDC strategy could also support and build on efforts by progressive countries, such as France [18], Sweden [19] and Denmark [20], which are already implementing actions on EDCs. Belgium has just announced the launch of a national action plan on EDCs [21]. It should be in the interest of the European Commission to promote harmonisation when it leads to an equal and high level of protection for all EU citizens, and supports the avoidance of barriers to trade within the European single market. Today, a clear

EU commitment is needed to reduce people's exposure to EDCs in a more comprehensive way throughout Europe.

This is not only a unique opportunity to increase well-being by preventing diseases, but it can also contribute to reducing the rising costs associated with EDC-related illnesses, as showed by a study evaluating the bill at a staggering 163 billion Euros a year for Europe [22], even though its scope covered only a few, rather than all, EDC-related illnesses. This is also an opportunity for policy coherence and for the EU to set a regulatory framework that builds the foundations for a truly non-toxic circular economy by encouraging industrial innovation through safer substitution. Considering that our exposure to preventable environmental chemicals is estimated to result in health costs worth 10% of global GDP [23], there is a real business case for promoting safe substitution to toxic EDCs through a comprehensive EU strategy for action.

We need a comprehensive action plan that effectively prevents further impacts on health and ends wildlife loss associated with EDCs. It needs to set out legal actions for eliminating exposure and to contribute towards meeting the 2030 commitments set out in the Sustainable Development Goals to "substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water, and soil pollution and contamination" [24].

The EU EDC Strategy must reflect the most recent advances in science and draw the logical conclusions from them by complementing existing obligations in the EU regulatory context. The following identifies the eight crucial elements that the EDC strategy needs to include to enable the EU to effectively protect health and the environment against EDCs.

Essential elements of an EU Endocrine Disrupting Chemicals Strategy

1. Consider public health and precaution as the cornerstones of a new EU EDC Strategy

Protect those who are most vulnerable. Reduce exposures to children to prevent suffering from EDC-related diseases and the spiralling costs associated with treating them. Build on and expand the short-, medium- and long-term actions from the 1999 EU EDC strategy and augment their effectiveness [25].

2. Enhance public awareness of EDCs – connect it with the EU's work on protecting citizen's health

A recent Eurobarometer survey found that two out of three European citizens are concerned about exposure to chemicals in their daily lives through food, air, drinking water and consumer products or other items, as well as in the workplace. Less than half of the same group felt well informed about the potential dangers of chemicals [26]. A Europe-wide campaign to raise awareness on EDCs is needed.

Specific focuses of such a campaign should include:

- Informing parents before and during pregnancy, and families in general, about ways to minimise exposures in everyday life.
- The dissemination of good practice for exposure reductions and health advice connected to grassroots and local agendas and the creation of a bank of success stories showing how the EU is making a difference.
- Information and training materials for medical, health and educational professionals and multiplier groups so that they can advise the public on reducing their exposures.
- A response to consumers' concerns and the provision of tools for traceability and the right to know for chemicals in products.

3. Improve regulation: Increase the control of the use of EDCs across all sectors

- Make a plan with timetables to implement suitable EDC criteria in all relevant EU laws to identify and reduce exposures to EDCs.
- Address missed deadlines first, like the 2015 one for cosmetics and obvious loopholes like toys, food packaging regulations. Commit to addressing other relevant EU legislation and sources of exposure, such as public procurement, worker's exposure, textiles, etc. and deliver on the 7th EAP commitment [27].
- Support the implementation of the EU Plastics Strategy by banning the presence of EDCs in plastics in particular as the presence of EDCs can hinder recyclability and negatively affect the value of recyclates.
- EDCs should be regulated with the presumption that no safe threshold for exposure can be set with sufficient certainty [28].
- EDCs should be regulated by using group approaches based on similar structures and similar properties to avoid regrettable substitution [29].
- Implement and enforce, efficiently and ambitiously, the existing regulatory obligations controlling the use of EDCs. This includes speeding up the inclusion of EDCs in the REACH candidate list of substances of very high concern and the adoption of measures to limit exposure, such as REACH restrictions or REACH authorisation. Currently only 12 substances have been identified as EDCs under REACH.
- Accelerate the assessment of EDCs to implement restrictions on them in pesticides and biocides.
- Create new sectorial laws to ensure robust protection in priority for consumer products. For most consumer products, e.g. textiles, child care articles, plastics there is no specific provision addressing EDCs.

4. Reduce our EDC daily cocktail: Replace the substance-by-substance approach by including all possible sources of exposure to multiple chemicals

- Prioritise the identification and regulation of the most problematic groups of hormone disrupting chemicals and swiftly act on known co-exposures to harmful chemicals from various sources (e.g. indoor air pollution, dust, food contact materials).

- Move from a single substance risk assessment to cumulative assessments for chemicals acting on the same adverse outcome and similar chemicals [30]. Sweden and Denmark are looking at this issue in the context of their national work [31].
- Respond more swiftly to early warning signals from new scientific findings about potential health or environmental damages in re-approvals and authorisations of substances. When concerns show up in one chemical use, a risk evaluation should automatically be triggered across legislative ‘silos’ to fully assess the impact of cumulative exposures and to ensure swift action in the absence of full scientific certainty.

5. Speed up testing, screening and identification of EDCs

- Update test requirements with new and updated screens and test methods in all relevant EU laws so that data gaps will be closed and EDCs can be identified. The EU should systematically make industry responsible for providing sufficient evidence to demonstrate safety.
- Prioritise data collection on potential EDCs and draw up lists to communicate to consumers and business alike.
- Improve the screening and testing guidelines used to identify EDCs and address data gaps.

6. Work towards a clean ‘Circular economy’ and a non-toxic environment: Avoid toxic substances such as EDCs in products from the start

- Need to have full traceability to avoid finding EDCs in recycled materials.
- Need to have producer responsibility. Each company should be obliged to inform consumers about the chemical content of their products, including the packaging.
- Need to have the same level of protection from EDCs for primary and secondary materials [32], which means that when an EDC is banned from a virgin material, it should be banned from recycled materials as well, contrary to current practice.

7. Enhance European market leadership for safer substitution with no regrets and promotion of innovative solutions

- Support initiatives that guide companies to move away from EDCs. Some examples can be found at chemsec.org – market place, the ‘dating platform’ for companies trying to meet a provider of safer alternatives.
- Limit and avoid the use of pesticides in agriculture and the management of green or urban areas and set specific targets for an overall reduction of pesticide use in line with the Sustainable Use of Pesticides Directive (2009/128/EC).
- Encourage communication campaigns at a national level in order for citizens to be 1) more mindful about chemical use in their daily lives, in particular during pregnancy and with children, 2) to have the right to know about EDCs in products.

8. Monitor the health and environmental effects of single, groups and mixtures of ED substances to capture all sources of EDC exposure ‘across the board’ and respond swiftly to minimise them

- Ensure sufficient focus on investigating chemicals of new and emerging concern which are used as replacements for banned chemicals in the context of the EU Human Biomonitoring Initiative [33].
- Develop sensitive test methods with new endpoints such as chemicals interfering with brain development and ensure they are appropriately considered within the regulatory evaluations.

EDC-Free Europe is a coalition of public interest groups representing more than 70 environmental, health, women’s and consumer groups across Europe who share a concern about hormone disrupting chemicals (EDCs) and their impact on our health and wildlife. Campaign partners include trade unions, consumers, public health and healthcare professionals, advocates for cancer prevention, environmentalists and women’s groups:





DES Daughter Network

Because Social Media increases Awareness and brings the DES Community Together



* This organisation endorses this EDC-Free Europe statement on an EU EDC Strategy but is not an official campaign partner.

Contact the campaign: email info@env-health.org or visit www.edc-free-europe.org

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