



Endocrine Disruptors: EU legislation and policy

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Context and background

1990s: *Concerns about endocrine disruptors start to appear*

1999: *Community Strategy for endocrine disruptors - implemented over 20 years – action and progress in fields of research, regulation, international cooperation*

2013-2016: *Two European Parliament's resolutions on endocrine disruptors; Council conclusions on the protection of human health and the environment through the sound management of chemicals; 7th Environment Action Programme*

2017: *Commission establishes criteria to identify endocrine disruptors under the legislation on pesticides and biocides*

2018 Commission Communication on endocrine disruptors



Outlines strategic approach
to endocrine disruptors for
years to come.

How EU legislation addresses endocrine disruptors

- **Progressive update of EU body of laws on chemicals in the past decades** - EU legislation for all chemicals is today recognised as among the most protective in the world
- The **EU approach is based on:**
 - High-level scientific advice from the relevant EU risk assessment bodies
 - Risk management decisions by Commission (and Member States) taking into account precautionary principle
 - Enforcement of legislation by Member States

How EU legislation addresses endocrine disruptors

- The Commission has **taken action** against endocrine disruptors (e.g. restrictions, bans) in line with different legal requirements:
 - Specific provisions included in the legislation on **pesticides, biocides**, chemicals in general (**REACH regulation**), **medical devices** and **water**
 - General requirements of the legislation (e.g. **food contact materials, cosmetics**) – case-by-case regulatory action

How EU legislation addresses endocrine disruptors

- 2018 Communication states that to realise full potential of EU legislation, the Commission is currently working on different **actions**, such as:
 - **Aiming to develop a horizontal approach for identification** of endocrine disruptors across EU legislation building on the criteria developed for pesticides and biocides
 - **Updating data requirements** in the legislation to improve identification of endocrine disruptors
 - Assessing how to **improve communication through the supply chain** for endocrine disruptors under REACH (Safety Data Sheets)

A comprehensive approach

Action: Launch of a **Fitness Check**

DRIVERS

Stakeholder views that legislation in some areas is not adequate to protect human health and wildlife

Differences in legal provisions and regulatory approaches

MAIN OBJECTIVES

Assess if legislation delivers its objective to protect human health and the environment by minimising exposure to EDs
(Effectiveness question)

Assess whether legislation delivers its objective in a coherent way across regulatory sectors
(Coherence question)

- **Cross-cutting look** at approach to endocrine disruptors in **> 30** pieces of legislation, building on scientific evidence and data collected and analysed by the Commission through broader evaluations covering main areas of the chemical policy
- Attention to legislation which **does not contain** ED specific provisions; e.g. toys, cosmetics and food contact materials

An inclusive approach

Actions:

- Organisation of an **Annual Forum on endocrine disruptors** with all interested stakeholders
- Commitment to **step up support** to the work of **international organisations** (OECD in particular)
- Explore possibilities for the inclusion of endocrine disruptors in the existing **international system for classification of chemicals**
- Launch of a **one-stop shop web portal** on endocrine disruptors

Implementation Actions 2018 Communication

Action: Fitness Check - Consultation Strategy

➤ *Ensure that views from all interested parties are considered in the evaluation.*

➤ *3 Surveys:*

✓ Stakeholders consultation (businesses, public authorities, academia, research organisations, civil society organisations, and experts in the field of endocrine disruptors) **(Closed 31st January 2020)**

✓ Public consultation (designed from a citizen's perspective) (closing 9th March 2020)

✓ Small and Medium-sized Enterprises (SMEs) (conducted by European Enterprise network) (in progress)

Implementation Actions 2018 Communication

Action: Fitness Check

Tasks	
Roadmap (preparation and feedback)	completed
Methodology development	completed
Preliminary analysis of current situation & mapping of provisions	completed
Answer to evaluation questions (1 st evidence stream)	completed
ED Forum 8th November 2019	completed
Stakeholder orgs survey - closed 31 st January 2020	completed
Public survey – open until 8 th March 2020	in progress
SME survey – in progress	in progress
Analysis and answer to evaluation questions (2 nd evidence stream from stakeholder input)	planned
Submission to EC Inter-service steering group (ISSG)	planned
Final report for submission to Regulatory Scrutiny Board	Q2 2020

Implementation Actions 2018 Communication

First Annual Forum held on 8 November 2019

- More than 150 participants including policymakers, regulators, scientists, public and private stakeholders, to exchange information, identify challenges and build synergies

- Programme
- Video recordings
- Forum Report



- **Second Annual Forum** will be held on **20-21 October 2020** – more information in the coming months

Implementation Actions 2018 Communication

One-stop shop web portal on endocrine disruptors
launched on 14 November 2019

- https://ec.europa.eu/info/policies/endocrine-disruptors_en

Single access point to information on endocrine disruptors

Implementation Actions 2018 Communication

Action: Assessing how to improve the communication through the supply chain for endocrine disruptors under REACH (Safety Data Sheets)

- Update of Safety Data Sheets (REACH Annex II) to include information on endocrine disrupting properties was adopted in REACH Committee meeting of 20 November 2019

Implementation Actions 2018 Communication

Action: Updating data requirements in the legislation

Biocidal Product Regulation

- Of biocidal active substances (**BPR Annex II**)
- Of biocidal products (**BPR Annex III**)

Extensive consultations to prepare a Delegated Act amending data requirements in Annex II and III. Draft Delegated Act will be published in early 2020 for feedback and then Commission will adopt it.

Implementation Actions 2018 Communication

Action: Updating data requirements in the legislation

Update of REACH Annexes to include data requirements on endocrine disruption

- Formation of a subgroup of the Competent Authorities for REACH and CLP (CARACAL) on endocrine disruptors (CASG-ED)
- Mandate for the CASG-ED presented in CARACAL meeting of 6/7 November 2019
- First meeting of CASG-ED: **7 February 2020**

Implementation Actions 2018 Communication

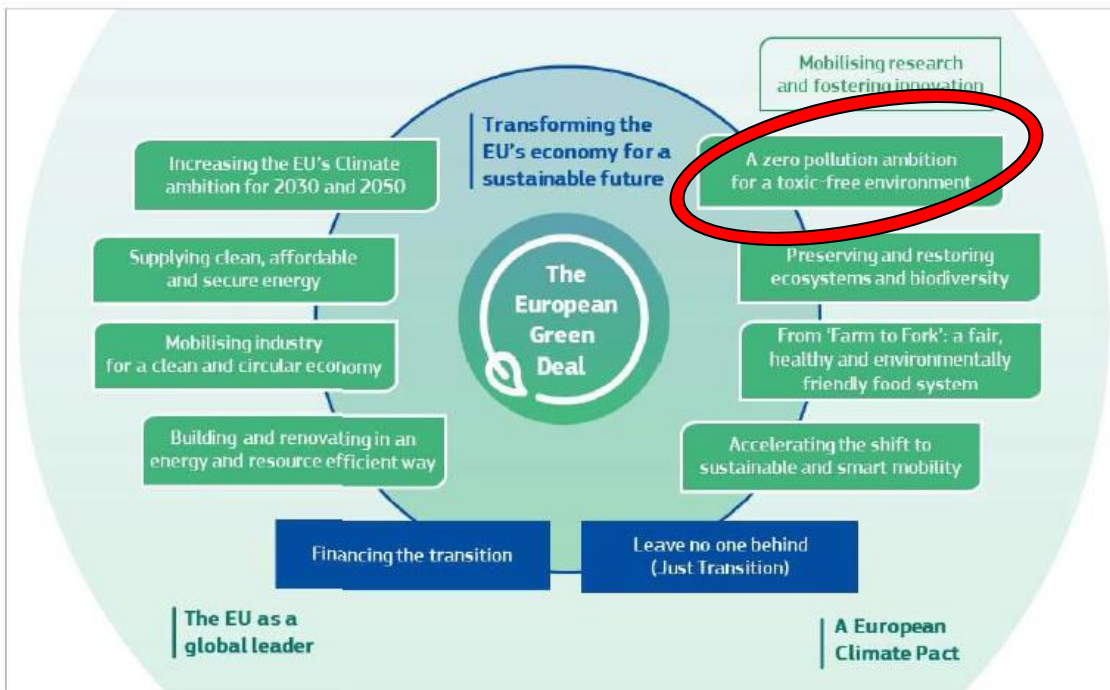
Action: Explore possibilities for the inclusion of endocrine disruptors in the existing international system for classification of chemicals

- Commission started working with Member States towards the inclusion of endocrine disruptors in the existing international system for classification of chemicals (GHS) and in the CLP Regulation.
 - > EU-wide and global solution to the identification of ED
- Workplan: discussion in CASG-ED on **7 February 2020**

Risk assessment of substances with potential ED properties in cosmetics

- On 7 November 2018, the Commission adopted a review of Regulation (EC) No 1223/2009 on cosmetic products regarding substances with endocrine disrupting properties
- Commitment to establish a priority list of potential EDs not yet regulated under the Cosmetics Regulation for further assessment by Scientific Committee on Consumer Safety (SCCS)
- A list of 14+14 substances was consolidated (group A high priority, group B lower priority). Call for data on 14 Group A substances: 16 May – 15 October 2019 - 16 contributions received
- Preliminary evaluation of quality of submitted information was carried out and SCCS's capacity taken into account
- First wave of mandates for 5 substances prepared by Commission and submitted to the SCCS for risk assessment – mandates in process of being adopted by SCCS and to be published early February with a 9-month deadline. Other substances to be assessed subsequently

New Commission The European Green Deal



“To ensure a toxic-free environment, the Commission will present a chemicals strategy for sustainability”... “In parallel, the regulatory framework will need to rapidly reflect scientific evidence on the risk posed by **endocrine disruptors** [...]”



**Thank you for your
attention**