

## FITNESS CHECK ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

<b>TITLE OF THE FITNESS CHECK</b>	Fitness Check on Endocrine Disruptors
<b>LEAD DG – RESPONSIBLE UNIT</b>	DG JRC – Directorate F – Health, Consumers and Reference Materials Unit F3 – Chemical Safety and Alternative Methods
<b>INDICATIVE PLANNING</b>	Planned start date: Q1 2019 – Planned end date: Q2 2020
<b>ADDITIONAL INFORMATION</b>	<a href="https://ec.europa.eu/health/endocrine_disruptors/overview_en">https://ec.europa.eu/health/endocrine_disruptors/overview_en</a>

**The Roadmap is provided for information purposes only. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the document, including its timing, are subject to change.**

### A. Context, purpose and scope of the evaluation

#### Context

Endocrine disruptors are chemical substances that can alter the functioning of the endocrine (hormonal) system and negatively affect the health of humans or animals. The EU response to endocrine disruptors has developed in the past twenty years, in line with the actions outlined in the [Community Strategy for endocrine disruptors](#) (1999). Significant progress in understanding and regulating endocrine disruptors has been made since then, and the EU is today recognised as one of the global leaders in dealing with these chemicals.

A variety of EU legal measures address the risks from exposure to hazardous chemicals, with some pieces of legislation having specific provisions for endocrine disruptors (i.e. the legislation on [chemicals in general \(REACH\)](#), [plant protection products](#), [biocides](#), [water](#) and [medical devices](#)). Other pieces of legislation consider them like other hazardous substances and regulate them via general provisions that aim to ensure the protection of human health and the environment from the exposure to such substances. Collectively, these measures aim to ensure a high level of protection of human health and the environment, while ensuring the smooth functioning of the internal market. EU action on endocrine disruptors relies on high-level scientific advice from the EU risk assessment bodies, such as the Scientific Committee on Consumer Safety, European Chemicals Agency or the European Food Safety Authority. Following the risk assessment, the Commission, in its role of risk manager, then takes the final decision together with Member States.

EU measures that cover endocrine disruptors have been developed at different points in time and have, in certain cases, different specific objectives. This has resulted in different approaches for managing endocrine disruptors, depending on the sector being regulated. While regulatory measures have allowed protective action to be taken against these substances (e.g. by introducing bans or restrictions to their use), questions are regularly raised by stakeholders on the overall coherence of the EU legal framework.

On 7 November 2018, the Commission adopted its Communication "[Towards a comprehensive EU framework on endocrine disruptors](#)", updating the Strategy of 1999. The Communication confirms the Commission's commitment to protect EU citizens and the environment from endocrine disruptors. It outlines a number of actions to step up the EU approach in order to further progress and maintain the expected high level of protection. In particular, in order to address the concerns on the coherence of the EU legal framework, the Communication announces the launch of a cross-cutting Fitness Check on endocrine disruptors. While evaluations or Fitness Checks of relevance for endocrine disruptors (see section B) have already been carried out or are under way, a systematic analysis of the coherence of relevant provisions on endocrine disruptors across the EU legal measures has not yet been completed. This will therefore be a particular focus of this Fitness Check.

#### Purpose and scope

The Fitness Check will contribute to the assessment of whether EU chemicals legislation delivers its objective to protect human health and the environment by minimising the overall exposure to endocrine disruptors.

The Fitness Check will be an essential tool to assess the coherence of the relevant EU legislation. It will include an analysis of how different provisions in different legal instruments interact, identifying potential gaps or inconsistencies. It will also assess, to the extent possible, EU legislation's effectiveness, efficiency, relevance and EU added-value. It will pay particular attention to legislation that does not contain specific provisions for endocrine disruptors, such as the legislation on toys, cosmetics and food contact materials. A specific focus will be on

whether the different pieces of legislation take into account the protection of vulnerable population groups that are particularly sensitive to endocrine disruptors (such as the foetus or adolescents) when assessing and regulating such substances. Overall, it will help assess whether legislation is fit for purpose and analyse whether there is potential to improve the regulatory efficiency. More generally, it will feed into the reflection on whether legislative changes are necessary to achieve the EU's objectives. Two points in particular deserve special attention:

#### **Horizontal approach to the identification of endocrine disruptors**

Criteria for identifying endocrine disruptors have been recently established under the legislation on plant protection products and biocides. However, EU legislation in other fields does not contain such criteria. It has been argued that criteria for the identification of endocrine disruptors should be laid down in the legislation, and that the same criteria should apply across the relevant pieces of EU chemicals legislation for reasons of legal certainty and in order to avoid the potential risk that a substance is identified as an endocrine disruptor under one piece of legislation and not under another one.

#### **Regulatory consequences for endocrine disruptors**

Different regulatory approaches exist in different pieces of legislation for substances that have endocrine disrupting effects. In some pieces of legislation, endocrine disruptors cannot in principle be authorised for use. There are very limited derogation possibilities. In other pieces of legislation, endocrine disruptors can be subject to authorisation requirements or restrictions. Other pieces of legislation do not mention endocrine disruptors specifically but consider them like other substances and regulate them via general provisions aimed at protecting against the risks of exposure to hazardous substances.

The Fitness Check will assess the situation in the EU today and compare it with the situation in 1999 (when the first Strategy on endocrine disruptors was adopted). The international dimension will also be assessed, taking into account the impact of EU provisions on products imported into the EU.

### **B. Better regulation**

#### **Consultation of citizens and stakeholders**

The Commission will consult a broad range of stakeholder groups as well as citizens to ensure that all interested parties can provide their views. The different consultation activities will aim to contribute to the analysis of the coherence of the EU framework, as well as, to the extent possible, its effectiveness, efficiency, relevance and EU added-value. The main stakeholders identified are: public authorities (within and outside the EU), economic operators (within and outside the EU) in both the chemicals industry and downstream industries (with a focus on SMEs), workers, industry associations, trade unions, farmers, NGOs, consumer associations, international organisations, academia/research institutes/think tanks, consumers and, more generally, citizens. We will carry out both public and targeted consultations. More specifically:

- We plan a Public Consultation in Q4 2019. It will be accessible on the Commission's central consultation web page [Have your Say](#) for 12 weeks in 23 EU languages. It will be possible to reply in any of the 24 official EU languages.
- We plan to consult key stakeholders and public authorities through targeted consultations, as appropriate.

In addition, we will organise the first meeting of the Annual Forum on endocrine disruptors, announced in the Communication "*Towards a comprehensive EU framework on endocrine disruptors*", in Q4 2019.

A synopsis report, summarising the results of all consultation activities will be published on the consultation page once all consultation activities are closed.

#### **Data collection and methodology**

The Fitness Check will build on scientific evidence and the data already collected and analysed by the Commission on the topic, in particular in the context of relevant finalised and on-going evaluations. These are in particular: the [REACH REFIT evaluation](#); the [REACH Review on the authorisation route of substances with endocrine disrupting properties according to REACH Art. 138\(7\)](#); the [Fitness Check of the most relevant chemicals legislation \(excluding REACH\)](#); the [REFIT evaluation of the legal framework on pesticides](#); the [evaluation of the 7th Environment Action Programme](#); the [Fitness Check of the water legislation](#); the [evaluation of the legislation on food contact materials](#); the [evaluation of the legislation on toy safety](#); and the recent [review of the legislation on cosmetics](#) with regard to endocrine disruptors. Findings from the [impact assessment](#) on the criteria to identify endocrine disruptors in the areas of pesticides and biocides will also be taken into account. These sources of evidence will be complemented with findings from the scientific literature, reports from EU Agencies and Scientific Committees, and the consultation activities.