

## ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work in order 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 make available any relevant information that they may have.

<b>TITLE OF THE INITIATIVE</b>	Towards a more comprehensive EU framework on endocrine disruptors
<b>LEAD DG – RESPONSIBLE UNIT</b>	SG E1
<b>LIKELY TYPE OF INITIATIVE</b>	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions
<b>INDICATIVE PLANNING</b>	Q3 2018
<b>ADDITIONAL INFORMATION</b>	-

This Roadmap is provided for information purposes only and its content might change. 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 Roadmap, including its timing, are subject to change.

### A. Context, Problem definition and Subsidiarity Check

<b>Context</b>
<p>Endocrine-disrupting chemicals ("endocrine disruptors") are substances that alter the functions of the hormonal system in animals and humans and consequently cause adverse effects.</p> <p>As of the 1990s, awareness of endocrine disruptors grew and so did public and political interest. In the EU, the Commission adopted a "<a href="#">Strategy for endocrine disruptors</a>" in 1999 setting out a number of actions with the overall goal of minimising exposure.</p> <p>Despite significant progress having been achieved since then in understanding endocrine disruptors, societal concerns remain high. In this context, in 2017, when working with Member States on the criteria to identify endocrine disruptors in the areas of pesticides and biocides, the Commission <a href="#">announced</a> that it would start working on a comprehensive framework on endocrine disruptors. With this initiative, the Commission will deliver on its commitment and, at the same time, will address relevant concerns of the European Parliament and the Council<sup>1</sup>.</p> <p>The initiative will take account of evaluations/fitness checks currently being carried by the Commission on subjects related, to different extents, to endocrine disruptors (e.g. on <a href="#">chemical legislation</a> or on <a href="#">pesticides</a>).</p>
<b>Problem the initiative aims to tackle</b>
<p>In the past decades, scientific evidence has increasingly confirmed the link between exposure to endocrine disruptors and human diseases or negative impacts on wildlife<sup>2</sup>. Scientific progress, also stimulated by significant funding allocated by the EU in the context of its research programmes, has brought consensus on a number of issues, including the definition of "endocrine disruptor"<sup>3</sup> and the particular sensitivity to endocrine</p>

<sup>1</sup> See for example the European Parliament's resolutions of 14 March 2013 (P7\_TA(2013)0091) and 8 June 2016 (P8\_TA(2016)0270), the Council conclusions on the protection of human health and the environment through the sound management of chemicals (19.12.2016) and Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 (OJ L 354, 28.12.2013, p. 171)

<sup>2</sup> Reviews of the extensive literature on endocrine disruptors and reports on the subject include for example: Kortenkamp et al. (2011), [State of the art assessment of endocrine disruptors](#); United Nations Environment Programme/World Health Organisation (2012), [State of the science of endocrine disrupting chemicals](#); Organisation for Economic Co-operation and Development (2012), [Detailed review paper on the state of the science on novel in vitro and in vivo screening and testing methods and endpoints for evaluating endocrine disruptors](#); European Environmental Agency (2012), [The impacts of endocrine disruptors on wildlife, people and their environments](#); European Food Safety Authority (2013), [Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment](#); Joint Research Centre (2013), [Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disruptors Expert Advisory Group](#)

<sup>3</sup> "An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations" (definition provided in

disruptors of organisms in their developmental phase. It is now also generally accepted that endocrine disruptors can interfere with the endocrine system in different ways ("modalities") and some of these are relatively well known<sup>4</sup>. There is also increasing evidence showing that exposure to a combination of endocrine disrupting substances may have a supplementary impact ("cocktail effect") and produce an adverse effect at concentrations at which individually no effect has been observed.

In parallel with scientific progress, in the past decades the EU has progressively updated its body of laws regulating chemicals and, in this context, has specifically tackled endocrine disruptors. Today a comprehensive set of legislative measures is in place, based on the precautionary principle, to provide a high level of protection of citizens and the environment from risks caused by exposure to all chemicals, including those with endocrine disrupting properties. Specific provisions on endocrine disruptors are included in the legislation on pesticides and biocides, chemicals in general ("REACH Regulation"), medical devices and water. Other pieces of legislation can address endocrine disruptors even if there are no specific provisions for these substances (e.g. legislation on food contact materials or cosmetics). The current Commission has paid special attention to endocrine disruptors, and this has resulted in the development of a number of Commission initiatives since 2014 (e.g. the adoption of criteria to identify endocrine disruptors in the areas of pesticides and biocides, the budget allocated to research on endocrine disruptors under Horizon 2020, but also broader initiatives, like that on [transparency and sustainability of risk assessment under food law](#) which, if supported by Parliament and Council, will allow the commissioning of independent verification studies that could prove useful for some aspects of the assessment of endocrine disruptors).

While the EU policy and legal framework can be considered as one of the most protective globally, concerns of European citizens on endocrine disruptors remain high<sup>5</sup>. This is due to a number of factors including:

- Science on endocrine disruptors progresses quickly, but there are a number of scientific aspects that are not entirely understood yet and this scientific uncertainty amplifies citizens' concerns about whether controls are adequate. By way of example, it remains difficult to ascertain the specific role of endocrine disruptors in the development of human diseases (due to confounding factors such as nutrition or lifestyle). Questions remain open on the applicability of basic toxicology principles to endocrine disruptors (e.g. can a safe threshold be fixed below which endocrine disruptors have no negative effects?) and on complex issues like the cocktail effect of endocrine disruptors. Further work is also needed on the development of testing methods.
- The relevant measures of the EU legal framework on chemicals have been developed at different points in time, and this has sometimes resulted in different approaches to endocrine disruptors, depending on the policy area being regulated. Furthermore, implementation of the different legislative measures does not run at the same pace. This has raised questions on whether the EU legal framework regulating endocrine disruptors is sufficiently coherent.
- Endocrine disruption is a subject of extraordinary complexity and EU citizens demand clear and comprehensive information they can rely on.

#### **Basis for EU intervention (legal basis and subsidiarity check)**

A coherent framework of different policies is the appropriate way to deal with endocrine disruptors. In this context, the legal basis for the initiative is multiple, depending on the policy area (e.g. Article 114 TFEU on the approximation of laws for the functioning of the internal market or Article 191 TFEU on environment). These are areas of shared competence between the EU and Member States.

The EU has already taken action in a number of fields with regards to endocrine disruptors. The initiative will follow up on the existing situation, taking stock of progress achieved so far and identifying areas where further action would need to be taken in the future. In this context, the EU framework on endocrine disruptors would continue to remain compliant with the subsidiarity principle. The role of Member States would also be recognised and coordinated actions will be envisaged as appropriate.

#### **B. What does the initiative aim to achieve and how**

The initiative will take the form of a Communication in which the Commission will present the comprehensive framework of EU policies on endocrine disruptors, in the context of the Commission's continued commitment to protect EU citizens and the environment from dangerous chemicals.

The Communication will provide a comprehensive picture of where we stand today, highlighting the different facets of the issue and taking stock of the progress achieved in the EU in the past twenty years as regards scientific knowledge, policy and legislation and international cooperation. The Communication will also outline

2002 by the International Programme on Chemical Safety, a joint programme of various UN Agencies, including the World Health Organisation, in the publication [Global Assessment of the state-of-the-science of Endocrine Disruptors](#))

<sup>4</sup> Oestrogen, androgen, thyroid hormone or steroidogenesis

<sup>5</sup> See for example the different petitions tabled to the European Parliament which led to the organisation of a [hearing on endocrine disruptors](#) on 22 March 2018 or the more than 27 000 replies provided to the [online public consultation](#) organised by the Commission in 2015 in the context of the preparation of the measures establishing criteria to identify endocrine disruptors under the legislation on pesticides and biocides

areas where further action would need to be taken in the future. In this context, the Communication may include the following types of actions:

- Addressing the gaps in knowledge, for example by fostering research activities in specific areas, encouraging data gathering and data sharing;
- Linking science and regulation, by ensuring that the EU legislative framework is adequately implemented and remains fit for purpose;
- Cooperating on the global scene, for example by continuing supporting the work of the Organisation for Economic Co-operation and Development (OECD) in the development of testing methods.

The Commission will also look into communication activities that could be carried out both at EU and national level to provide to citizens the information and advice they need on endocrine disruptors.

## **C. Better regulation**

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

The Communication will build on the outcome of the consultation activities carried out by the Commission in the context of the different policies of relevance for endocrine disruptors developed so far (e.g. the consultations carried out during the preparation of the Commission measures setting criteria for identifying endocrine disruptors in the areas of pesticides and biocides, or in the context of the Fitness Check of chemical legislation).

Furthermore, this roadmap will be published for stakeholders' feedback for four weeks.

Additional consultation activities could be announced in the Communication itself as a result of specific actions described therein.

### **Evidence base and data collection**

An important body of evidence exists on endocrine disruptors and a number of scientific reports have become available since 1999 (see section A of the roadmap). Many of these reports were published by EU agencies, EU Scientific Committees, or in the context of activities co-ordinated or commissioned by the Commission. Furthermore the Communication will build on all the evidence that has been collected by the Commission services in the context of the different policies of relevance for endocrine disruptors developed so far (e.g. the Impact Assessment accompanying the Commission's measures setting criteria for identifying endocrine disruptors in the areas of pesticides and biocides).

The Communication will also take account of a number of on-going evaluations/fitness checks that are relevant for endocrine disruptors (e.g. chemicals legislation or pesticides).

An Impact Assessment will not be necessary for the development of the initiative, given that its purpose is to take stock of the current situation in a comprehensive way and outline the next steps. If/when necessary, in line with Better Regulation principles, Impact Assessments will be conducted before developing future specific actions that will be announced in the Communication.