Follow up to the European Parliament non-legislative resolution on a comprehensive European Union framework on endocrine disruptors

1. **Resolution tabled pursuant to Rule 123(2) of the European Parliament's Rules of procedure**

2. **Reference numbers:** 2019/2683(RSP) / B8-0241/2019 / P8_TA-PROV(2019)0441

3. **Date of adoption of the resolution:** 18 April 2019

4. **Competent Parliamentary Committee:** None

5. **Brief analysis/assessment of the resolution and requests made in it:**

The European Parliament considers that the EU framework on endocrine disruptors is not adequate to address the threat to human health and the environment due to exposure to these substances (**paragraph 1**).

The European Parliament calls on the Commission to take action to minimise overall exposure of humans and the environment to endocrine disruptors and treat these substances in the same way as carcinogens, mutagens and substances toxic for reproduction (**paragraphs 2 and 3**). In particular, it calls on the Commission to develop by June 2020 a horizontal definition of known, presumed and suspected endocrine disruptors, based on the one by the World Health Organisation (**paragraph 4**), and to accompany it with proper guidance documents (**paragraph 5**). Also by June 2020, the Commission should make proposals to introduce more protective rules on endocrine disruptors in the legislation on cosmetics, toys and food contact materials (**paragraphs 6 to 8**).

The European Parliament calls on the Commission to further promote research (**paragraph 15**), accelerate test development and validation (**paragraph 9),** regularly update data requirements in the relevant legislation (**paragraph 10**), take mixture effects and combined exposure into account in the relevant legislation (**paragraph 11**) and ensure adequate bio-monitoring of endocrine disruptors **paragraph 13**). Also, the European Chemicals Agency (ECHA), the Commission and the Member States should better implement the REACH Regulation as regards endocrine disruptors by the end of 2019 (**paragraph 12**). Finally, the European Parliament calls on the Commission to adopt as soon as possible an overall strategy for a non-toxic environment (**paragraph 14**).

6. **Response to the requests and overview of the action taken, or intended to be taken, by the Commission:**

While the Commission agrees with the Parliament that, in order to make further progress and maintain the necessary high level of protection, there is a need to step up the EU approach regarding endocrine disruptors, it stresses that in the past twenty years, the EU has made significant progress in understanding and regulating these substances. EU legislation is today recognised as among the most protective in the world.

The Commission considers that the Communication '*Towards a comprehensive European Union framework on endocrine disruptors*' (COM(2018) 734 final), adopted last November, provides a sound framework in which to take work on these substances forward.

In the Communication, the Commission confirmed its commitment to protect EU citizens and the environment from endocrine disruptors, with the goal to minimise overall exposure. The Communication outlines the Commission's strategic approach to deal with these substances and announces a number of concrete actions to be implemented across policy

areas in the future. These include: a cross-cutting Fitness Check to analyse the coherence of the relevant legislation; further support to research; an annual stakeholder Forum; a one-stop shop web portal; stepping up the support to international organisations, in particular the Organisation for Economic Co-operation and Development, and exploring possibilities for the inclusion of endocrine disruptors in the existing international system for classification of chemicals.

The Commission is also committed to stepping up the implementation of existing policies on endocrine disruptors in a number of areas. By way of example, the Commission has amended Regulation (EU) No 844/2012 governing the renewal process for active substances in pesticides to facilitate the assessment in all ongoing evaluation procedures of whether the active substances meet the criteria adopted in 2018 to identify endocrine disrupting substances. Similar steps have been taken in the relevant procedural guidance for the assessment of all substances used in biocidal products.

In the area of cosmetics, as announced in the '*Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products with regard to substances with endocrine-disrupting properties*' (COM(2018) 739 final), the Commission has established a priority list of potential endocrine disruptors in cosmetic products that are not already covered by the bans laid down in the Cosmetics Regulation for their subsequent risk assessment. This list has been published and safety evaluations of these substances will be progressively carried out based on scientific evidence collected through a call for data that is open until mid-October 2019. The Commission will then take regulatory measures to ban or restrict these substances in cosmetic products if necessary.

The Commission has carefully considered all the issues raised by the European Parliament in its resolution and would like to offer the following observations.

Horizontal definition (paragraphs 4 and 5) and changes to the legislation on cosmetics, toys and food contact materials (paragraphs 6 to 8)

The legislative measures constituting the EU legal framework regulating chemicals have been developed at different points in time and have, in certain cases, different specific objectives. This has resulted in different approaches to endocrine disruptors, depending on the sector being regulated, and has raised questions as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent.

The Commission agrees that there should be coherence in the treatment of endocrine disruptors across different policy areas. However, before proposing changes to the legislation, there is a need to see whether and what changes are necessary. Regulating the same substance differently as a function of the use made of it does not in itself mean that the approach is incoherent.

For this reason, one of the actions announced in the Communication '*Towards a comprehensive European Union framework on endocrine disruptors*' is a cross-cutting Fitness Check of all the relevant EU legislation applicable to endocrine disruptors. The Fitness Check will assess whether the existing legislation delivers on its objectives, and will focus on the coherence of the different approaches to endocrine disruptors in different sectors.

The Fitness Check will address specifically the two aspects mentioned by the European Parliament in its resolution: the absence of horizontal criteria to identify endocrine disruptors in the different legal frameworks and the different regulatory consequences for substances identified as endocrine disruptors depending on the policy area in which they are regulated. Furthermore, the Fitness Check will pay special attention to the three pieces of legislation spelled out by the European Parliament in the resolution, namely those regulating toys, cosmetics and food contact materials, taking into account that these products constitute an important source of exposure for vulnerable consumers. The Fitness Check will build on

data collected and analysed in the context of relevant evaluations, such as the ongoing one on the Food Contact Materials legislation (to be finalised in the first quarter of 2020).

The Commission services have already started work on the Fitness Check, with the goal to finalise it in 2020. Its outcome will feed into the reflection on whether legislative changes are needed.

Research promotion (paragraph 15) and test development (paragraph 9)

EU decision-making is evidence-based and the Commission agrees on the importance to provide continued support to research on endocrine disruptors to constitute a strong basis for effective policy-making.

Since 1999, the European Union's Framework Programmes for Research and Technological Development have allowed to fund over 50 relevant projects for an amount of over EUR150 million from the EU. These projects have improved our understanding of the endocrine mechanism of action, the identification of adverse effects on human health and wildlife from exposure to endocrine disruptors, and the development of tools for identification of endocrine disruptors and exposure assessment. The Commission allocated further EUR 50 million under Horizon 2020, allowing the funding of eight projects on new testing methods for endocrine disruptors.

In addition to research funded under Horizon 2020, a special effort was made in recent years to further improve the availability of test guidelines for identification of endocrine disruptors and address the testing weaknesses identified at EU and international level, under the auspices of the Organisation for Economic Co-operation and Development.

In the Communication '*Towards a comprehensive European Union framework on endocrine disruptors*', the Commission committed to continue ensuring the necessary support to research on endocrine disruptors in its future framework programme for research and innovation, Horizon Europe, building on the work under the current framework programme, Horizon 2020. Particular attention should be paid to areas where knowledge gaps on endocrine disruptors still exist, and where more scientific evidence can best support improved policies. One of these areas is that of test developments. Once the negotiations on the Commission's proposal for Horizon Europe are finalised, the Commission will be able to look more in detail into the question and be more precise in its strategic programming documents.

As regards testing, the Commission has also committed to stepping up its support to the work of relevant international organisations, in particular the Organisation for Economic Co-operation and Development. The Commission will carry out work to ensure that priorities for test method development are agreed, in order to fully support the implementation of the Communication's strategic approach to endocrine disruptors. The Commission will ensure that its experts, in particular in the Joint Research Centre, continue to provide high quality work in the area. The Commission will also encourage the Member States to dedicate the appropriate resources to test method developments and validation.

Updates to data requirements (paragraph 10)

The Commission agrees on the importance to update data requirements in the different legislative frameworks to improve identification of endocrine disruptors. Data requirements are specifically laid down under the legislation on pesticides, biocides and REACH.

The Commission is in the process of updating the data requirements for active substances and other co-formulants used in biocidal products to ensure that application dossiers contain the necessary information to decide on whether the substances meet the criteria for the identification of endocrine disruptors. In the same vein, guidelines describing the methods to use to satisfy the data requirements for applications for active substances used in pesticides are being revised.

Under REACH, the review of March 2018 (COM(2018) 116 final) noted that the standard information requirements of REACH provide already some but limited information on endocrine disruption. The Commission intends to work towards an update of the data requirements, which depend on the production or import volume. Such a review of data requirements will likely assess whether currently required tests should include further endpoints as well as how we can integrate latest developments on test methods and screening strategies to better identify endocrine disrupting properties.

Other sectoral legislations make use of the data on hazard properties gathered under REACH or obtained from other sources. These are assessed by the relevant scientific bodies of the EU, which provide guidance on what scientific information is needed for their assessments. This guidance is regularly updated.

Mixture effects and combined exposure (paragraph 11)

Exposure to mixtures and how to tackle these in risk assessment and risk management is a clear recognised challenge that goes beyond endocrine disruptors.

From a scientific perspective, the Commission has funded relevant projects under Horizon 2020. The European Food Safety Authority is finalising specific methodologies to assess mixtures. In the Communication '*Towards a comprehensive European Union framework on endocrine disruptors*', the Commission highlighted that this will indeed be an area where research should further develop and the Commission will support that.

From a regulatory perspective, already now, combined exposure can be taken into account if the adverse effects are based on the same endocrine mode of action. For example, the Commission has recently restricted uses of four phthalates present in a variety of consumer products taking also into account consumers' combined exposure to them.

Bio-monitoring of endocrine disruptors (paragraph 13)

The 'European Human Biomonitoring Initiative' – HBM4EU - includes substances of concern for endocrine disruption. Within the framework of this large-scale initiative, the past and current exposures of the European populations to chemicals, including those with endocrine-disrupting properties, are being investigated in various European regions and in different exposure settings. This will contribute to the development of the necessary knowledge basis for analysing long-term exposure to these substances.

As regards presence in the environment, the Commission has included three endocrine disruptors in the "watch list" of substances of the Commission Implementing Decision (EU) 2018/840 for which Union-wide monitoring data should be gathered.

REACH implementation (paragraph 12)

The REACH Regulation provides powerful tools to regulate endocrine disruptors.

REACH allows already to identify endocrine disruptors based on the definition of the World Health Organization and 14 substances have already been identified under REACH as endocrine disruptors (out of 197 substances identified as substances of very high concern so far). Two endocrine disruptors are subject to authorisation requirements (listed in Annex XIV). Several substances with known or suspected endocrine disrupting properties are on the list of restricted substances (Annex XVII), although not necessarily because of those hazard properties. Furthermore, 86 substances are currently being assessed for their endocrine disrupting potential under the Substance Evaluation procedure.

ECHA published in April 2018 the latest progress analysis on the identification of substances of very high concern. Based on ECHA's databases and other information, ECHA considered 377 substances as being potentially endocrine disruptors. The majority of those substances were at the time of assessment not available on the EU market or not registered. In total 99 substances have been regulated. The report further indicated that all known and

relevant substances with endocrine disrupting properties were either regulated or included in the on-going work.

Strategy for a non-toxic environment (paragraph 14)

In the past years, the Commission has dedicated significant resources to the preparation of a number of important documents in the chemicals area.

In 2018, in addition to the Communication on endocrine disruptors, the Commission finalised its second REACH review and adopted a Communication on options to address the interface between chemical, product and waste legislation (COM(2018) 32 final). The Fitness Check of all chemicals legislation excluding REACH is expected to be finalised in June 2019.

These documents together will provide a comprehensive assessment of the situation in the chemicals area and will allow the Commission to decide on the next steps.