European Society of Endocrinology

The voice for endocrinology

Re: Evaluation and Fitness Check Roadmap – Ares(2019)3752914

The European Society of Endocrinology (ESE) is at the centre of Europe's endocrine community. It is our vision to shape the future of endocrinology to improve science, knowledge and health. Through our direct membership and through the ESE Council of Affiliated Societies (ECAS), ESE represents more than 20 000 endocrinologists across Europe and beyond.

The below comments represent the view of ESE on the draft roadmap of the European Commission towards a fitness check for EU legislation on Endocrine Disrupting Chemicals (EDCs) and do not necessarily represent the views of the institutions the experts are affiliated to.

These comments were developed by the ESE's EDC Working Group:

Chair:
Prof Josef Köhrle (Germany)

Members:
Dr Anna-Maria Andersson (Denmark)
Prof Barbara Demeneix, (France)
Prof Evi Diamanti-Kandarakis (Greece)
Prof Jorma Toppari (Finland)
Prof Luca Chiovato (Italy)
Prof Majorie B.M. van Duursen (Netherlands)
Prof Manuel Tena-Sempere (Spain)
Prof Salvatore Benvenga (Italy)

European Society of Endocrinology
Starling House, 1600 Bristol Parkway North, Bristol, BS34 8YU, UK **Tel** +44 1454 642247 **info@euro-endo.org www.ese-hormones.org**

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ESE Comments

In brief ESE:

Welcomes

- The initiative by the European Commission (EC) to perform a fitness check in the area of EDCs
- The focus on population groups that are particularly sensitive to endocrine disruptors (such as foetuses or adolescents)
- The special attention for toys, cosmetics and food contact materials

Calls for

- Concrete timelines including ambitious deadline for the completion of the different components of the fitness check across all sections
- Clarification whether the Forum is part of the "consultation activities" or should be perceived as a separate activity
- The immediate implementation of concrete measures to tackle EDCs and reduce the exposure to EDCs in the EU without further delay based on the already available scientific evidence
- A central role for independent scientific (academic) studies or analysis
- The inclusion of EU legislation for buildings, building materials, clothing, interior trims and upholstery, textiles, cosmetics, personal care products and certain medical devices related products
- The fitness check should consider the critical windows of susceptibility of exposure during development, both for humans and environmental animal species
- Enforcing the precautionary principle and a renewed commitment that EDCs will not be authorised unless exposures are negligible
- Adopting regulatory measures in all sectors to cover risk of combined exposures to EDCs appropriately in and across the EU legislation
- Close legal loopholes and scientific gaps for this area

Background

ESE Welcomes the Fitness Check

As outlined in its statement from November 2018(1), ESE, in principle, **welcomes the initiative by the European Commission (EC) to perform a fitness check for EDCs** as long as the check does not lead to delayed actions by the EC in this area. ESE acknowledges the need to immediately close the current legislative loopholes and gaps of knowledge that permit the use of alternative EU laws to "rehabilitate" a compound initially identified as an EDC under another EU legislation. Currently, the practical definitions of EDCs are, for example, not the same in the EU biocide vs. the EU pesticide regulations. **ESE also supports the focus of the fitness check on population groups that are particularly sensitive to endocrine disruptors (such as foetuses or adolescents).**

Concerns about the timing

ESE is worried about the duration of the fitness check; **the current roadmap does not provide any concrete timelines including ambitious deadline for the completion of the different components of the fitness check.** To date, only a stakeholder consultation has been announced (for Q4 of 2019) and consequent actions or an overall deadline for the completion of the fitness check has not been published.

Unclear role EDC Stakeholders Forum

It is also not clear from the text how the EDC Stakeholders Forum, scheduled in the same period as the consultation, will feed into the fitness check (if at all). ESE urges the EC to **clarify whether the Forum is part of the "consultation activities" or should be perceived as a separate activity?**

Concrete measures need to be implemented without further delay

In line with the European Parliament resolution(2) and the Conclusions of the Environment Council(3), **ESE urges the European Commission to start implementing concrete measures to tackle EDCs** and reduce exposure of humans, animals and the general environment to EDCs **in the EU without further delay.** The EC could already start closing some of the identified legislative loopholes based on the widely available scientific evidence. In particular the study on EDCs from March 2019, commissioned by the European Parliament and written by Prof Barbara Demeneix and Dr Rémy Slama, provides a good overview of many shortcomings in EU policies and legislation for EDCs and provides sufficient scientific basis for immediate action(4).

Independent science should be at the centre of the Finess Check

In terms of data collection and methodology, ESE is of the opinion that the aforementioned study by Prof Demeneix and Dr Slama and other **independent studies or analysis (e.g. Kortenkamp et Al (5), Gore et Al (6), outcomes of the 41st meeting of the European Thyroid Association (7), World Health Organisation (8), Diamanti-Kandarakis et Al** (9)) **should be at the centre of the fitness check**. The data presented in these independent studies should at least receive the same consideration as data already collected and analysed by the Commission in an earlier stage.

Broader scope of the Finess Check needed

With regards to the scope of the fitness check, **ESE strongly welcomes the focus of the fitness check on toys, cosmetics and food contact material.** In addition to these key areas, **ESE urges the EC to consider the fitness check to also cover current EU legislation and policies on construction products**, especially Regulation 305/2011 which lays down harmonised conditions for the marketing of construction products(10).

While more prevalent in the past, building materials[1], interior trims and upholstery, textiles, medical devices, cosmetics and personal care products continue to contain EDCs (11).

Another area worth to consider for inclusion in the fitness check is textile and clothing (12) (13) (14) . This potential source of EDC exposure is particularly relevant due to the potential long-term direct contact with the skin and wash out into the environment[2].

[1] As building materials are incorporated in permanent structures, it may take decades/generations to get rid of these materials again once they are used. They may consequently pose a threat for making the EU a toxic free environment within the foreseeable future. We should avoid a repetition of past events. For example, in the 60'ies and 70'ies PCB was being used in large quantities in many different products. We continue to pay the price today for the lack of caution maintained at that time in the form of continuous health impact on the wider population, the costs of rebuilding those constructions and the problem of discarding PCB containing waste

[2] Perfluorinated compounds, such as Gore-Tex, are a key threat due to their longevity. These chemicals end up in our environment and thereby affect human and animal life. Exposure is ubiquitous as exemplified by high contamination of arctic areas.

Critical window of susceptibility of exposure should be taken into consideration

The fitness check should consider the critical windows of susceptibility of exposure, e.g. during development, both for humans and environmental animal species. As is commonly known, the consequences of exposure very much depend on the timing of the interaction with the EDCs during the different life stages of humans and animals.

Precautionary principle should be enforced

ESE calls on the Commission to enforce the precautionary principle and have the roadmap include a statement that EDCs will not be authorised unless exposures are negligible. There is concern that the current legislative criteria for the identification of EDCs for biocides and plant protection products will only qualify a small number of substances. In addition, the current lack of test methods and missing information in registration dossiers with respect to EDCs actions lead to delayed decision-making. Suspected EDCs ma consequently end up in a grey legislative area which could lead to their (continuous) usage if producers/distributors/suppliers may take advantage of gaps of knowledge or loopholes in current EU legislation

Cocktail effect must be a key part of the Fitness Check

Finally, the fitness check should identify whether the risk of combined exposures to EDCs are addressed appropriately in and across various sectors of the EU legislation relevant for this area. This would be in line with the important step the EC made in its Communication from November 2018(14) by acknowledging the adverse effects that a mixture of EDCs, or the "cocktail effect", could cause even if the EDCs individually might have no harmful consequences at very low concentrations.

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