ENDOCRINE SOCIETY
Hormone Science to Health

February 23, 2021

Stella Kyriakides
Commisisoner, Health and Food Safety
Rue de la Loi / Wetstraat 200
1049 Brussels, Belgium

Dear Commissioner Kyriakides,

Science-based policies for EU actions on endocrine disruptors: SCCS and EFSA draft opinions

On behalf of the Endocrine Society and our European Union EDC Task Force, I write to raise an issue related to the science of endocrine disruption which, in our view, could seriously impact the EU's ability to protect public health by setting appropriate limits for EDCs. Upon review of recent draft opinions by the Scientific Committee for Consumer Safety (SCCS) and European Food Safety Agency (EFSA), we find that conclusions relevant to EDCs drawn in these opinions are not based on current science and could therefore result in less effective regulatory policies.

Following careful review by members of the Endocrine Society with expert scientific knowledge of hormonal systems and endocrine biology, we prepared formal responses to the SCCS draft opinion on the safety of resorcinol, and the EFSA Scientific Committee Opinion on the biological plausibility of non-monotonic dose responses (NMDRs) and their impact on risk assessment. These were submitted in December 2020 and February this year. In addition to specific scientific problems and corrections related to the latest endocrine science, we were surprised to note that the opinions failed to reflect important international scientific consensus publications on EDCs, in particular:

- The consensus paper following from the expert meeting hosted by the German Federal Institute for Risk Assessment (BfR) in Berlin, Germany on 11-12 April 2016[1]
- The Endocrine Society's Second Scientific Statement on EDCs, published in 2015[2]

In the case of the EFSA draft opinion on non-monotonic dose responses (NMDRs) and their impact on risk assessment, our detailed comments conclude that "*without substantial revision, adoption of the opinion will result in the use of restrictive criteria that will limit the ability of regulatory agencies to make health protective decisions".* We hope the comments will support EFSA in re-evaluating its

[1] Solecki et al., Arch Toxicol. 2017 Feb;91(2):1001-1006. doi: 10.1007/s00204-016-1866-9. Epub 2016 Oct 6.
[2] Gore et al., Endocrine Reviews, Volume 36, Issue 6, 1 December 2015, Pages E1–E150, https://doi.org/10.1210/er.2015- 1010

2055 L Street NW
Suite 600
Washington, DC
20036
T. 202.971.3636
F. 202.736.9705
endocrine.org

scientific information in order to accurately reflect the state of science of NMDRs and their relevance to regulatory assessment of EDCs. Our scientists welcome the opportunity to meet the EFSA working group on NMDRs to discuss these issues.

The Society's response to the SCCS draft opinion on Resorcinol, a chemical which has been previously identified as an EDC by ECHA's Member State Committee[3] based on a detailed scientific assessment[4] and international definitions, raised similar concerns. The draft opinion refers for example to an outdated paper of 2011, which has been superseded by the EU EDC criteria debate[5] and international scientific consensus statement of 2017[6], none of which were referenced. The SCCS draft opinion's lack of recognition of NMDRs as established features of hormone biology and key characteristics of endocrine disrupting action was also of serious concern.

We take this exceptional step of raising these technical and scientific issues with you in the interests of ensuring that EU regulatory measures on endocrine disruptors are fully science-based and can protect human health in the most effective way.

We request your assistance to secure a meeting with the relevant technical Committees and Commission services so that these issues can be fully discussed with our expert member scientists before the current draft opinions are finalized.

Sincerely,

Barbara Demeneix, PhD, DSc
Chair, EDC Advisory Group
Endocrine Society

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[3] https://echa.europa.eu/et/-/resorcinol-not-identified-as-a-substance-of-very-high-concern
[4] https://echa.europa.eu/et/registry-of-svhc-intentions/-/dislist/details/0b0236e1825f3720

[5] https://ec.europa.eu/health/endocrine_disruptors/process_en (accessed 23 Feb, 2021)
[6] Solecki et al., Arch Toxicol. 2017 Feb;91(2):1001-1006. doi: 10.1007/s00204-016-1866-9. Epub 2016 Oct 6.