

March 30, 2021

Dr. Marcos A. Orellana
Special Rapporteur on Toxics and Human Rights
OHCHR-UNOG
Avenue Giuseppe Motta 48
CH-1202 Geneva, Switzerland

Dear Dr. Orellana,

The Endocrine Society appreciates the opportunity to provide a submission to inform the upcoming thematic report on the right to benefit from scientific progress and its applications. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. Our membership of over 18,000 includes researchers who are advancing our understanding of the effects of exposures to chemicals that interfere with hormone systems, also known as endocrine-disrupting chemicals (EDCs). EDCs have been demonstrated by abundant scientific evidence and confirmed by international consensus to cause significant adverse health effects in humans. Strong evidence exists for a causative role for EDCs in metabolic disorders such as obesity and diabetes, female and male reproductive health disorders, hormone-sensitive cancers including breast cancer and prostate cancer, thyroid disease, and developmental neurological and neuroendocrine effects¹.

Despite this evidence, barriers to the effective translation of scientific information on the health effects of EDCs to policy and regulatory action remain. In addition to advancing the latest science on endocrine systems and EDCs, our members have experience working at the science-policy interface and detailed knowledge of the challenges that communities, scientific organizations, and governments face in delivering the benefits of scientific knowledge to the public. We strongly support the human right to benefit from scientific progress and its applications. Our comments describe several barriers to the effective translation of scientific knowledge into regulatory action and identify opportunities for the UN to pursue so all communities may benefit from scientific information on EDCs.

Barrier: Unequal resource allocations disadvantages independent and community groups

The use of scientific information in the public interest requires effective strategies to translate scientific information about the health effects of hazards into restrictions or guidance on the use of hazardous substances. Such strategies require resources, both financial and human; one barrier to the

¹ A.C. Gore et al., EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, *Endocrine Reviews*, Volume 36, Issue 6, 1 December 2015, Pages E1–E150, <https://doi.org/10.1210/er.2015-1010>.



effective and unbiased dissemination of research results is the concentration of such resources among specific actors, often including regulated industries. We are concerned that the existing system to develop, promulgate, and enforce regulatory decisions often involves greater representation from regulated interests relative to the communities impacted by pollution or scientists generating knowledge about the health effects of chemical pollution. This may be in part because representatives of the scientific community, including professional associations like the Endocrine Society often must volunteer their time and effort to present independent expertise and guidance to regulatory agencies or contribute to discussions related to chemical safety. The time and effort involved in such contributions reduces availability for teaching, research, or other activities for which academic scientists are generally compensated and influence retention and promotion decisions.

Often, regulated entities deploy resources to advance their interests outside of the regulatory process itself by casting doubt on established scientific findings. The Endocrine Society's members dedicate substantial time and effort to the development of scientific resources and information based on peer-reviewed academic literature. However, chemical industry associations have launched websites with resources designed to manufacture doubt about well-established scientific consensus positions, sometimes using similar logos, color schemes, and imagery to present themselves as professional scientific organizations. This creates confusion about the scientific consensus surrounding endocrine disruption and diminishes the voice of scientific experts who are actively publishing research and generating new knowledge in this field. Disinformation campaigns are ubiquitous and prevent individuals and communities from accessing appropriate scientific information that would help them better control their exposures and reduce personal health hazards. Such campaigns can also obstruct regulatory activity that would benefit public health, as has been shown for the case of EDCs in the European Union².

Free diffusion of scientific information requires mechanisms to support the participation of scientists in education and policymaking at all levels. **We encourage the UN to explore systems and modalities that empower community and academic scientists to participate in such activities.** Remote participation in meetings and ad hoc participation by specific subject matter experts may reduce barriers due to travel or schedule conflicts for academic researchers. Financial support for the participation of scientists or representatives from community groups should also be considered to ensure a diversity of perspectives and participation from under-resourced institutions or communities.

² Stéphane Horel and Stéphane Foucart, *Perturbateurs endocriniens : ces experts contestés qui jouent les semeurs de doute.* *Le Monde*, June 22, 2020.



Barrier: Insufficient mechanisms and safeguards to prevent and address conflicts of interests

While overt disinformation campaigns distort science and influence public opinion, regulatory agencies may also be captured by regulated entities through the distortion of scientific information. Conflicts of interest (COI) throughout regulatory processes are often underreported or undisclosed, with different agencies and systems having different standards and rules for monitoring, disclosing, and managing COI. In the extreme, this can lead to regulatory agencies that rely principally on science that is promoted by conflicted stakeholders. Conflicts of interest can also be generated through industry/academic partnerships. In an environment of limited government spending on investigator-initiated research, such relationships are often necessary to allow research groups to continue to operate; however, they can also introduce bias that may influence the design of research studies and/or the reporting of results.

Pervasive COI prevent the full and unbiased utilization of all scientific information to benefit public health, denying the public the full human rights afforded by scientific progress. **Systematic approaches to the identification and management of COI need to be developed and applied to local, national, and international regulatory decision-making processes.** This includes developing internationally recognized processes to ensure that national and international regulatory bodies do not themselves become sources of disinformation. Where appropriate, penalties should exist for failing to disclose relevant COI.

To ensure that academic scientists have sufficient financial resources to preclude relationships that may present COI, **robust, sustainable publicly funded support for investigator-initiated research must be championed by national governments and international groups.** Funding programs should be projected to increase with inflation, and consider the resources required for publishing scientific work. We note that the well-intentioned trend towards open access publishing has shifted more of the costs of publication onto researchers themselves, further stretching already limited budgets and creating unintended barriers to distribution of data and results. For example, researchers may be forced to publish in a journal that is less expensive, but less relevant to their field of study, preventing their research from reaching the appropriate audience. Or they may be forced to publish in a “predatory” journal with less stringent editorial controls and peer-review processes.

Barrier: Unequal exposures disproportionately impact communities

While acknowledging that all demographic sectors bear risks due to EDC exposure, such risks are not distributed uniformly. There exist numerous examples where pollution has been concentrated in specific regions where land is inexpensive. This has resulted in disparate impacts on specific communities, such as “Cancer Alley” in Louisiana³; contamination of Fayetteville North Carolina

³ Tristan Baurick, Lylla Younes and Joan Meiners, [Welcome to “Cancer Alley,” Where Toxic Air Is About to Get Worse](#). The Times-Picayune and The Advocate, Oct. 30, 2019.



and Parkersburg, West Virginia by per- and polyfluoroalkyl substances (PFAS)⁴⁵; air pollution along the Houston Texas ship channel community⁶; and chlordecone (Kepone) poisoning in the French islands of Martinique and Guadeloupe⁷. Entire countries may also bear different risks due to the displacement of hazard, for example by shipping plastic waste to under-resourced countries⁸. The health effects of EDC exposures include cancer, fertility loss, and neurodevelopmental issues across generations. These chronic health effects also play a role in exacerbating disparities in mortality due to public health crises such as COVID-19⁹. Impacts are further magnified when industry creates an economic dependence to gain support from impacted communities at both the grassroots and political level. As an example, EDCs can cause declining sperm counts and increased incidence of endometriosis and other reproductive health disorders; consequently, increased use of reproductive health technologies will be necessary to achieve pregnancy¹⁰. Because these procedures are expensive, the health and economic inequalities experienced by impacted communities are further exacerbated, with profound impacts on the right to benefit from scientific progress and other fundamental rights (referenced in the call for submissions).

Traditionally, companies and governments have paid closer attention to short term economic effects and immediate toxic effects. The concept of endocrine disruption requires us to think about longer timeframes where exposures during development, or cumulative exposures, may cause the development of disease later in life. Such timeframes raise important questions about the rights of health, body integrity, and autonomy for pregnant women, children, and future generations in the context of chemical exposures. Regulatory agencies have taken steps to address vulnerability or susceptibility of subpopulations to chemical exposures; however, there are opportunities to improve upon these processes. **For example, agencies could prioritize chemical reviews and regulation based in part on different exposure profiles for environmental justice communities. Additionally, it is imperative that regulatory agencies acknowledge that biological sex is an important variable that may result in different responses to toxicants between men and women.** We note with concern that the US Food and Drug Administration (FDA) requires that for

⁴ Sharon Lerner, [The Teflon Toxin: How DuPont Slipped Past the EPA](#). *The Intercept*, August 20, 2015.

⁵ John Henderson, [GenX in water supply causing stress for residents who live near Chemours plant](#). *The Fayetteville Observer*, August 14, 2020.

⁶ Lauren Elliott, [These Houston residents dream of moving to where the air is clear](#). Reuters, January 3, 2020.

⁷ [Thousands protest in Martinique against 'insecticide impunity' in chlordecone case](#). RFI, March 1, 2021.

⁸ Hiroko Tabuchi and Michael Corkery. [Countries Tried to Curb Trade in Plastic Waste. The U.S. Is Shipping More](#). NY Times, March 12, 2021.

⁹ Kimberly A. Terrell and Wesley James. Racial Disparities in Air Pollution Burden and COVID-19 Deaths in Louisiana, USA, in the Context of Long-Term Changes in Fine Particulate Pollution. Environmental Justice, September 2, 2020. <http://doi.org/10.1089/env.2020.0021>.

¹⁰ Shanna H. Swan and Stacey Colino. *CountDown*. Simon & Schuster, 2021.



an observed effect to be toxicologically relevant, it must occur in both sexes¹¹. This requirement is not supported by abundant scientific evidence demonstrating that males and females often have different responses to biological perturbations or stressors¹². In general, assessments involving vulnerable populations or different exposure profiles should be used as a floor to set a fundamental standard that can be applied generally, to ensure widespread protection consistent with the precautionary principle.

Barrier: Lack of transparency and access to information

For scientific information to achieve the maximum benefit to the public, consumers (including businesses downstream in the supply chain) must have access to knowledge generated that is accessible, transparent, and in plain language. Consumer products are increasingly chemically complex and used in the context of other sources of exposure. A more thoughtful approach to product labelling standards and information disclosure may therefore be required to provide consumers with information that they need to make informed choices. Such information should include not only lists of ingredients, but access to information about potential health effects. **Laws governing the disclosure of confidential business information (CBI) should be carefully examined in light of the possibility that CBI could be used as a loophole to avoid disclosure of unsafe ingredients.**

While the disclosure of scientific information about the health effects is a necessary first step, consumers should be empowered to evaluate products and take action to minimize their risk without detailed scientific expertise or access to scientific literature. Consumers should not be asked to read and evaluate professional scientific literature in order to receive accurate information about health effects. **Governments and regulatory agencies should explore the use of labelling programs (e.g., SaferChoice¹³) and other strategies to give consumers rapid, actionable guidance on the safety of products.**

A more accurate knowledge of the totality of health effects will also require updates to the regulatory system and better engagement with academic scientists. Commonly used guideline studies, such as the rodent uterotrophic assay, may be less sensitive than other methods and unable to capture the contribution of chemicals to ensemble or mixture effects^{14,15}. Better collaboration

¹¹ Federal Register: 69620-69626 (7 pages) 21 CFR 73 Docket No. FDA-2018-C-4464 Document Number: 2019-27173.

¹² A. Bhargava et al., Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement. *Endocrine Reviews*, 2021; bnaa034, <https://doi.org/10.1210/endrev/bnaa034>

¹³ <https://www.epa.gov/saferchoice>.

¹⁴ Helen Tinwell and John Ashby. Sensitivity of the immature rat uterotrophic assay to mixtures of estrogens. *Environ Health Perspect*. 2004 Apr; 112(5): 575–582.

¹⁵ C.M. Markey et al., The mouse uterotrophic assay: a reevaluation of its validity in assessing the estrogenicity of bisphenol A. *Environ Health Perspect*. 2001 Jan;109(1):55-60. doi: 10.1289/ehp.0110955.



between regulators and academics will more rapidly translate new scientific information for greater public benefit; however, it requires a willingness for regulatory agencies to be adaptable and open to new systems and approaches. For example, we applaud the aims and goals of the CLARITY-BPA study to reduce barriers between the US FDA and grantees funded by the National Institutes of Health (NIH), but we were disappointed that the FDA prematurely released a statement on the safety of BPA that did not take into account the totality of effects found in the academic studies^{16,17}.

Additionally, our members report that manufacturers may not provide appropriate chemical standards at the necessary levels of purity for independent scientists to reproducibly evaluate effects.

We urge the UN to promote ways to reduce cultural barriers that exist between scientists and regulators – mutual understanding, collaboration, and validated resources will better promote scientific progress and the diffusion of research results.

In conclusion, the Endocrine Society welcomes and supports the upcoming thematic report on the right to benefit from scientific progress and its applications. We are encouraged by opportunities to improve the science-policy interface to accelerate the translation of scientific research to provide more access to consumers and better health-protective measures by regulatory agencies. In the context of EDCs, we assert that the right to science is inextricably linked to other rights illustrated in the call for submissions, including the right to health, the right to life, right to body integrity, and right to education. Our members stand ready to serve as a resource to you in the development of your report and implementation of actions arising from the report. If we can be of further assistance, please contact Joe Laakso, PhD, Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

Carol H. Wysham, MD
President, Endocrine Society

¹⁶ G. S. Prins et al., CLARITY-BPA academic laboratory studies identify consistent low-dose Bisphenol A effects on multiple organ systems. *Basic Clin Pharmacol Toxicol*. 2019 Aug;125 (Suppl 3):14-31. doi: 10.1111/bcpt.13125.

¹⁷ <https://www.endocrine.org/news-and-advocacy/news-room/2018/endocrine-society-experts-express-concern-with-fda-statement-on-bpa-safety>