

**Submitted to regulations.gov Docket EPA-HQ-OA-2021-0403-0001 - Draft Fiscal Year 2022-2026  
Strategic Plan for the Environmental Protection Agency**

November 12, 2021

The Endocrine Society appreciates the opportunity to comment on the Fiscal Year (FY) 2022-2026 Draft Environmental Protection Agency (EPA) Strategic Plan. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. The Endocrine Society's membership consists of over 18,000 scientists, physicians, educators, nurses, and students in more than 100 countries. Society members represent all basic, applied and clinical interests in endocrinology. Included among our members are the world's leading experts on the health effects of endocrine-disrupting chemicals (EDCs).

We enthusiastically support the goals of the strategic plan and welcome EPA's commitment to action on critical issues such as climate change and environmental justice. We also welcome EPA's strategic approach to ensuring that children and other vulnerable populations are accounted for to ensure the health and wellbeing of individuals in all communities across the lifespan. Decades of scientific evidence has confirmed that proper identification, assessment, and regulation of EDCs throughout our environment will be essential to these and other objectives described in the strategic plan. In our comments, we offer several recommendations for improving the strategic plan to better accomplish the ambitions goals described therein.

**EPA Needs a Comprehensive and Strategic Approach to Endocrine Disruption**

Decades of peer-reviewed scientific research has documented the widespread ecological and human health effects of EDCs<sup>1</sup>; consequently, endocrine disruption is a threat to each of the goals of the strategic plan. For example, emerging evidence suggests that climate change will increase the incidence and severity of many diseases and public health issues that are linked to EDCs, compounding the effects of chronic exposure to these chemicals<sup>2</sup>. Often, these same diseases contribute to health disparities driven in part by disproportionate chemical exposure<sup>3</sup>. These effects are expected to be further magnified for pregnant women, children, and vulnerable

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<sup>1</sup> Gore AC, 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>

<sup>2</sup> Stewart PM, et al., Environmental Pollution, Climate Change, and a Critical Role for the Endocrinologist. *JCEM*. dgab721, <https://doi.org/10.1210/clinem/dgab721>

<sup>3</sup> Ruiz D, et al., Disparities in Environmental Exposures to Endocrine-Disrupting Chemicals and Diabetes Risk in Vulnerable Populations. *Diabetes Care*. 2018 Jan; 41(1): 193–205. Published online 2017 Nov 15. doi: 10.2337/dc16-2765



communities which may have limited means to adapt to climate change and already experience disproportionate exposures to chemical hazards. The overall impact on environmental justice communities, where multiple environmental stressors converge in complex scenarios with preexisting health disparities, may be severe and will require urgent action by EPA in collaboration with federal partners.

Given the unique features of EDCs and their links to the goals in the strategic plan, we are disappointed that endocrine disruption is not mentioned in the text. This omission is even more striking, given the global urgency to evaluate the effects of endocrine disruption in the context of multinational strategies to assess chemicals<sup>45</sup>. To ensure that EPA does not miss opportunities to reduce ecological and public health harms from exposure to EDCs, the final strategic plan should:

- Call for climate adaptation plans that explicitly include reducing harms from EDCs through better chemical regulation.
- Call for multidisciplinary research projects that evaluate interrelated aspects of climate change, chemical and other environmental exposures, and endocrine health.
- Call for opportunities to revise chemical assessment processes that consider the endocrine-related impacts on environmental justice communities.

#### **EPA Should Adopt More Effective and Efficient Approaches to Chemical Assessments**

We remain concerned that the expanding universe of chemicals in commerce is outpacing efforts to screen and identify hazardous substances. Current regulatory approaches are inadequate to assess chemicals in commerce for their effects on endocrine systems; for example, guideline studies often fail to include the most sensitive endpoints and with consideration for low-dose or nonmonotonic effects that are often observed for endocrine disruption<sup>6</sup>. Better engagement with academic scientists with expertise in the fundamental mechanisms of endocrine signaling and consequences to disrupted signaling will help address some of these barriers and improve chemical assessments with effective endocrine-relevant endpoints. For example, researchers have developed effective systematic review methodologies<sup>7</sup> that can specifically be applied to endocrine

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<sup>4</sup> [https://ec.europa.eu/environment/strategy/chemicals-strategy\\_en](https://ec.europa.eu/environment/strategy/chemicals-strategy_en)

<sup>5</sup> <https://www.foodpackagingforum.org/news/resolution-on-edcs>

<sup>6</sup> Demeneix B, et al., Thresholds and Endocrine Disruptors: An Endocrine Society Policy Perspective. *Journal of the Endocrine Society*, Volume 4, Issue 10, October 2020, bvaa085, <https://doi.org/10.1210/jendso/bvaa085>

<sup>7</sup> Vandenberg LN, et al., A proposed framework for the systematic review and integrated assessment (SYRINA) of endocrine disrupting chemicals. *Environ Health*. 2016 Jul 14;15(1):74. doi: 10.1186/s12940-016-0156-6.



disruptors. Furthermore, a consensus statement identified key characteristics of endocrine disruption that could be applied to screening and assessment programs at EPA<sup>8</sup>.

While not explicitly mentioned in the strategic plan, we also note with concern that new approach methodologies (NAMs) have recently been prioritized by the agency to reduce animal testing without a clear vision and public understanding for how these methods can or will be implemented in a regulatory context. We assert that more effective use of in vivo assays along with in vitro assays could reduce the number of animals used in testing – for example by using grouping approaches to evaluate chemicals with similar structure/function. Because of uncertainty regarding the effectiveness of NAMs in relation to existing methodologies, when in vitro assays are used they should only be used to indicate a hazard or for screening purposes; the results should not be used to remove a hazard from consideration.

Additionally, we are pleased to see that EPA plans to expand the Safer Choice program, but again it will be important to ensure that the agency work with endocrine experts to develop criteria for endocrine disruption for the alternatives assessment. Including criteria that more explicitly include sensitive endocrine endpoints will ensure that products identified by the Safer Choice criteria protect pregnant women, children, and all individuals throughout the lifespan, reduce endocrine-related impacts on wildlife, and advance environmental justice.

To enable more effective and efficient approaches to chemical assessments, the strategic plan should:

- Commit to engagement with independent and academic scientists with relevant discipline-specific expertise and with attention to avoiding conflicts of interest.
- Prioritize the development of more sensitive assays (including in vitro and in vivo methods) paired with techniques that inform their use to capture important effects that can currently only be identified in intact animals.
- Establish a clear plan for chemical assessment and risk management, including expansion of the Safer Choice program with the involvement of endocrine scientists, that will achieve the agency's stated environmental justice goals by reducing disproportionate chemical exposures and impacts in communities.

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<sup>8</sup> La Merrill MA, et al., Consensus on the key characteristics of endocrine-disrupting chemicals as a basis for hazard identification. *Nat Rev Endocrinol*. 2020 Jan;16(1):45-57. doi: 10.1038/s41574-019-0273-8. Epub 2019 Nov 12.



## **EPA Should Re-Envision the Endocrine Disruptors Screening Program**

A fundamental hurdle facing the EPA in the achievement of important public health and ecological goals related to endocrine disruption is the inability of the Endocrine Disruptors Screening Program (EDSP) to properly capture the effects of chemicals on the endocrine system. Indeed, a recent report by the EPA Office of Inspector General confirmed that the EDSP “has not implemented Section 408(p)(3)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to test all pesticide chemicals for endocrine-disruption activity.”<sup>9</sup> This failure is even more troubling, given that the effects of chemicals on endocrine systems are now known to affect other endocrine pathways beyond those mandated in the 1996 update to the FFDCA. As described above, this failure will have enormous consequences for all populations but in particular for children, pregnant women, and other vulnerable populations, with disproportionate effects on communities with higher levels of exposure<sup>10</sup>.

As an overarching recommendation, we therefore urge EPA to consider adding an objective in the plan to re-envision the EDSP taking into account all effects on endocrine systems. As a fundamental consideration, the EDSP should validate the program using accurate test cases that are consistent with the latest scientific information on chemicals.

Thank you very much for considering the Endocrine Society’s comments. Our members stand ready to work with the EPA towards completion of the goals of the plan. If we can be of any further assistance, please contact Joe Laakso, PhD, Director of Science Policy at [jlaakso@endocrine.org](mailto:jlaakso@endocrine.org).

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<sup>9</sup> [https://www.epa.gov/system/files/documents/2021-07/epa\\_oig\\_20210728-21-e-0186.pdf](https://www.epa.gov/system/files/documents/2021-07/epa_oig_20210728-21-e-0186.pdf)

<sup>10</sup> James-Todd TM, et al., Racial/ethnic disparities in environmental endocrine disrupting chemicals and women’s reproductive health outcomes: epidemiological examples across the life course. *Curr Epidemiol Rep.* 2016 Jun; 3(2): 161–180. Published online 2016 Mar 31. doi: 10.1007/s40471-016-0073-9