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International environmental policy and governance issues

# Information on the implementation of paragraph 22 of resolution 5/7 on the sound management of chemicals and waste, updating the report entitled *State of the Science of Endocrine Disrupting Chemicals 2012*

### Note by the secretariat

1. In paragraph 22 of resolution 5/7 on the sound management of chemicals and waste, the United Nations Environment Assembly of the United Nations Environment Programme (UNEP) requested the Executive Director of UNEP to, among other things, subject to the availability of resources, and in cooperation with the World Health Organization (WHO), update the report entitled *State of the Science of Endocrine Disrupting Chemicals 2012*<sup>1</sup> prior to the sixth session of the Environment Assembly.

2. The annex to the present note provides an update on progress made in the implementation of the request, outlining the overall approach and proposed process for developing an updated report. It also includes an overview of work conducted by the Organisation for Economic Co-operation and Development, UNEP and WHO of relevance to endocrine-disrupting chemicals. The annex has not been formally edited.

<sup>\*</sup> UNEP/EA.6/1.

<sup>&</sup>lt;sup>1</sup> State of the Science of Endocrine Disrupting Chemicals 2012 (United Nations Environment Programme and World Health Organization, 2013).

#### Annex\*

Information on the implementation of paragraph 22 of resolution 5/7 on the sound management of chemicals and waste, updating the report entitled *State of the Science of Endocrine Disrupting Chemicals 2012* 

# I. Introduction

1. In paragraph 22 of its resolution 5/7 on the sound management of chemicals and waste, the United Nations Environment Assembly (UNEA) of the United Nations Environment Programme (UNEP) requested the Executive Director of UNEP to, inter alia, subject to the availability of resources, and in cooperation with the World Health Organization (WHO), update the report entitled State of the Science of Endocrine Disrupting Chemicals 2012 prior to the sixth session of the Environment Assembly.

2. In response to this request, UNEP and WHO have initiated a process to develop this report, in close collaboration with OECD. As financial means to support the work are expected to be available in 2024 from the European Union, the updating of the report, including convening of expert consultations, is foreseen to take place in 2024 and 2025, with the report to be released ahead of the seventh session of the United Nations Environment Assembly.

3. The present report aims to provide an update on progress made in the implementation of the above-mentioned request from UNEA, outlining the overall approach and proposed process to develop the updated report (section II). It also includes an overview of the work conducted by OECD, UNEP and WHO of relevance to endocrine disrupting chemicals (EDCs) over the recent years (appendix).

#### Background

4. At its third session in 2012, the International Conference on Chemicals Management (hereinafter referred to as "the Conference") adopted a resolution including EDCs as an Emerging Policy Issue of global concern under the Strategic Approach to International Chemicals Management (SAICM)<sup>1</sup>. The Conference recognized the potential adverse effects of endocrine disruptors on human health and the environment as well as the need to protect humans and ecosystems and their constituent parts. It also stressed the particular needs of developing countries and countries with economies in transition. Amongst others, the Conference considered that information dissemination and awareness-raising on EDCs were particularly relevant and that improving the availability of and access to information on such chemicals was a priority, calling for the implementation of cooperative actions in this regard. Responding to the request by the Conference, a joint plan of work with the participation of OECD, UNEP and WHO was developed, with each organization taking on relevant tasks.

5. In 2013, UNEP and WHO published the "State of the science of endocrine disrupting chemicals 2012"<sup>2</sup>. The report identified, amongst others, concerns, including evidence in humans, laboratory animals, and wildlife that exposure to EDCs can result in adverse effects. The report further highlighted that an important focus should be on reducing exposure.

6. At its fourth session in 2015, the Conference, amongst others, invited UNEP and WHO to address the needs identified by developing countries and countries with economies in transition by generating and disseminating information on EDCs<sup>3</sup>.

7. In 2016, responding to its commitment to the Conference (under resolutions III/2 of 2012 and IV/2 of 2015), UNEP commissioned the International Panel on Chemical Pollution (IPCP) to develop three overview reports on EDCs. The reports included: a review of worldwide initiatives to identify EDCs and potential EDCs; an overview of current scientific knowledge on the life cycles, environmental exposures, and environmental effects of selected EDCs and potential EDCs; and existing national, regional, and global regulatory frameworks<sup>4</sup>.

<sup>\*</sup> The annex has not been formally edited.

<sup>&</sup>lt;sup>1</sup>Resolution III/2: Emerging policy issues, Part F Endocrine-disrupting chemicals

<sup>&</sup>lt;sup>2</sup> UNEP and WHO (2013). State of the science of endocrine disrupting chemicals 2012

<sup>&</sup>lt;sup>3</sup> Resolution IV/2: Existing emerging policy issues, Part E Endocrine-disrupting chemicals

<sup>&</sup>lt;sup>4</sup> https://www.unep.org/resources/report/overview-reports-endocrine-disrupting-chemicals-and-potential-edcs

8. At its 76<sup>th</sup> session in May 2023, the World Health Assembly adopted resolution WHA76.17 requesting the Director-General to work jointly with UNEP to update the report entitled "State of the Science of Endocrine Disrupters 2012".

9. At its fifth session held in September 2023 in Bonn, Germany, the Conference decided that all existing SAICM emerging policy issues and issues of concern, including EDCs, should transition on an interim basis to "issues of concern" as part of the Global Framework on Chemicals<sup>5</sup>. At its next session, the International Conference of the Framework will determine their path in moving forward within the context of the framework.

# II. Approach in updating the 2012 State of the Science of Endocrine Disrupting Chemicals

10. As per the mandate set forth in paragraph 22 of UNEA resolution 5/7 and WHA 76.17, UNEP and WHO initiated a process to update the report entitled State of the Science of Endocrine Disrupting Chemicals 2012, in close collaboration with OECD. The updated report is proposed to be released as a joint UNEP and WHO publication ahead of the seventh session of UNEA.

11. The final report is proposed to be circulated along with a summary and key findings document, to further allow dissemination and uptake. It will be made available to UNEA in response to the mandate set out in resolution 5/7, and shared through UNEP and WHO networks and those of partner organizations.

#### A. Scope of the report

12. Regarding the scope of the report, it is proposed that it encompasses latest scientific development for selected key end points, also covering new areas of relevance such as assessment of exposure, evaluation, and substitution of EDCs. The following key elements are expected to be considered and further expanded as deemed necessary: definitions, existing initiatives, status of scientific knowledge on the life cycles, environmental exposures, and environmental effects, impacts on human health and ecosystems; non-traditional pathways; EATS (estrogen, androgen, thyroid, and steroidogenesis) and non-EATS evaluation; examples of recent policy and regulatory initiatives at regional and national levels, relevant voluntary initiatives in key sectors, with a focus on major uses/sources of releases, as well as associated economic and social aspects, including in terms of efforts to estimate benefits of action and costs of inaction.

#### B. Establishment of an expert working group

13. To guide and support the process, it is proposed to establish a working group, composed of representatives from relevant backgrounds and expertise. Expertise sought may include, but not be limited to toxicology, endocrinology, ecotoxicology, epidemiology, ecology, environmental science, risk assessment, regulatory issues, and social and economic sciences.

14. It is proposed that members be selected following a call for expression of interest, on the basis of a set of criteria to ensure in particular representativeness from relevant backgrounds and allow gender as well as geographic/regional balanced and comprehensive participation. The size of the group will be kept moderate to ensure efficiency and streamlined communication, while allowing flexibility for the leveraging of specific expertise as needed. UNEP's Chief Scientist Office, as well as participating organizations of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) and other relevant UN agencies as appropriate, will be invited to participate and contribute to the group's deliberations.

15. Terms of reference will be developed, articulating the structure and membership of the group, its functions, and responsibilities as well as its operating modalities, in line with relevant guidelines on conflict of interest and quality assurance. The group's anticipated main tasks will be to provide inputs on the overall proposed approach and methodology, including scope, outline of the update report and key milestones for the conduct of the work, provide guidance on relevant scientific data to be collected, as well as its quality and suitability, and review the draft versions of the report. Online and face to face consultation meetings will be organized and facilitated by UNEP in cooperation with WHO. Intersessional exchanges with the group will happen, as necessary.

<sup>&</sup>lt;sup>5</sup>Resolution V/5: Emerging policy issues and issues of concern

## C. Identification and engagement of experts

16. The identification and engagement of experts to be part of the working group as well as the report's author(s) will be undertaken by UNEP and WHO in close collaboration, considering the scope and outline of the report as well as established criteria.

17. Experts and author(s) taking part in this work will be required to abide to the relevant provisions of the lead organizations, UNEP and WHO as appropriate, including to prevent any actual, potential, or perceived conflicting interests, ensure respect of any required confidentiality and copyrights for the sake of the publication.

18. The report will also be circulated for external and peer review, and received comments considered in the subsequent review and finalization of the report.

# Appendix

# Report on relevant activities by OECD, UNEP and WHO

# I. Activities conducted by OECD

1. The OECD has been actively standardising methodologies for testing and assessment of chemicals for endocrine disruption for the last three decades. A large number of new and updated Test Guidelines have been adopted that contain ED specific endpoints informing the mode of action or the adverse effects on human health and wildlife. Guidance material has been developed over the years for various purposes: 1) for how to conduct the assays and 2) interpret the data in the context of weight-of-evidence, culminating in 2018 with the revision of the Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption.

2. Since 2019, a couple more in vitro Test Guidelines using zebrafish embryo models for testing estrogen and androgen pathways have been published (TG 250, TG 251<sup>1</sup>). Some in vitro Test Guidelines for human health have been updated or corrected in their data interpretation procedures (TG 456, TG 455, TG 458<sup>2</sup>). In addition, a detailed review paper describing retinoid effects on development and reproduction, along with candidate methods to detect chemicals that disrupt retinoid signaling, was published in 2021 (No. 343 in the Series on Testing and Assessment). The Advisory Group on Endocrine Disrupters Testing and Assessment (EDTA AG) met in May and October 2021 virtually, to keep pace with progress with European-funded projects of the EURION cluster and deliverables that might come out for regulatory applications and method standardisation, and progress with other on-going activities. One of such activities was the EU-NETVAL (European Union-Network of Validation Laboratories) that leverage knowledge on a number of in vitro assays addressing the thyroid pathways, also described in the OECD Thyroid Scoping Document in 2014 (No. 207 in the Series on Testing Assessment). That activity, launched in 2017 came to completion in 2022.

3. In the course of 2022, the OECD established an Expert Group on Thyroid Disruption Methods, harvesting the results of the EU-NETVAL efforts and assessing individual assays for their status of validation and readiness for Test Guideline development. Five assays were assessed in the period Q3 2022-Q1 2023, another set of five assays were assessed in Q2 2023 until Q4 2023. Assessment reports will be compiled and published by OECD, while the background material on the assays including intra-laboratory report is made available via the EU tracking system TSAR<sup>3</sup>.

4. In September 2022 and September 2023, the OECD participated in the fourth and fifth EU Stakeholders' forum on Endocrine Disrupters<sup>4</sup>. The Forum is an annual event and brings together scientists and public and private stakeholders with expertise on endocrine disruptors to exchange information and best practices, identify challenges and build synergies. Issues associated with but not limited to shortage of financial resources for methods' validation and standardisation were on the agenda, as the European Union has adopted the new Classification, Labelling and Packaging Regulation including two new hazard classes for endocrine disrupters in human health and in the environment.

5. A French public-private partnership for the validation of ED assays (PEPPER platform), created in 2019 to speed up the validation and standardisation of methods at the OECD level, is actively sponsoring the validation of mechanistic methods for testing endocrine disrupting properties of chemicals. Five project proposals have been included in the OECD Test Guidelines workplan (3 in 2022 and 2 in 2023); the PEPPER platform will aim at validating assays addressing novel pathways beyond estrogen and androgen, where the toolbox of methods is already well developed<sup>5</sup>.

6. The OECD is actively participating in the UN Globally Harmonised System for Classification and Labelling of Chemicals (UN GHS) discussions on potential hazards of interest, including endocrine disrupting chemicals (EDCs). In July 2023, the UN GHS Sub-Committee of Experts

<sup>&</sup>lt;sup>1</sup> https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems\_20745761

 $<sup>^{2}\</sup> https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects\_20745788$ 

<sup>&</sup>lt;sup>3</sup> https://tsar.jrc.ec.europa.eu/

<sup>&</sup>lt;sup>4</sup> https://environment.ec.europa.eu/events/fifth-annual-forum-endocrine-disruptors-2023-10-19\_en

<sup>&</sup>lt;sup>5</sup> https://ed-pepper.eu

approved a mandate to the OECD for reviewing the state of the science and analyse gaps in the existing hazard classes for the identification and classification of  $EDCs^6$ .

# II. Activities conducted by UNEP

7. Following the release in 2013 of the report "State of the Science of Endocrine Disrupting Chemicals – 2012" together with WHO, UNEP continued to advance work on the issue.

8. In 2016, UNEP commissioned the International Panel on Chemical Pollution (IPCP) to develop a set of three overview reports on EDCs. These reports covered: (i) worldwide initiatives to identify EDCs and potential EDCs; (ii) review of existing national, regional, and global regulatory frameworks that address EDCs; (iii) overview of the current knowledge on chemicals identified as EDCs and selected potential EDCs<sup>7</sup>. The reports were developed in close collaboration with a UNEP Advisory Group on EDCs, which had been established by UNEP in 2014 to provide strategic and policy advice on approaches related to the implementation of its activities concerning environmental exposure and impact of EDCs<sup>8</sup>.

9. UNEP, together with WHO, has been invited by the OECD to participate in the ad hoc expert group supporting the work in response to the request from the UN GHS Sub-Committee of Experts to review the state of the science and analyse possible gaps in the existing hazard classes for the classification of EDCs. This work is ongoing and is to be presented in December 2024 to the UN GHS sub-committee.

10. Since November 2023, UNEP is also partnering with the Geneva Graduate Institute in the context of an applied research project related to EDCs, with a particular focus on approaches to protect human health and the environment along value chains as well as efforts in quantifying costs of inaction. The final report of the project is expected to be finalized in June 2024.

### Complementarity with other existing efforts

11. Other recent work led by UNEP contribute to the further development of knowledge on the issue of EDCs.

12. In 2020, in response to UNEA resolution 4/8, UNEP developed an Assessment Report on Issues of Concern<sup>9</sup> with the aim to inform the international community about the current situation of specific chemicals and waste issues of concern, based on a review of published evidence. The report covered nineteen issues of concern : eleven for which emerging evidence of risks had been identified by the report entitled Global Chemicals Outlook II<sup>10</sup> and eight identified as emerging policy issues or other issues of concern by ICCM. Issues include EDCs, as well as phthalates, BPA, and PFAS, among others.

13. In 2022, at its resumed fifth session, UNEA recognized the need to take further action to reduce or eliminate the risks associated with the chemicals and waste issues discussed in the Assessment report. The Executive Director of UNEP was requested through resolution 5/7 to seek views from Member States and other stakeholders on priorities for further work, building on existing measures and initiatives, and on potential further international action on the issues discussed in the Assessment Report. The resolution also requests the preparation of a summary analysis, taking into account the views received. In response to this request, UNEP conducted in 2023 a consultation process to gather views from Member States and other stakeholders, which included a call for written inputs and a global consultation meeting. The final report will be made available on the UNEP website for consideration by UNEA at its sixth session<sup>11</sup>.

<sup>&</sup>lt;sup>6</sup> https://unece.org/transport/documents/2023/04/working-documents/potential-hazard-issues-andtheir-presentation <sup>7</sup> www.unep.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/scientificknowledge-endocrinedisrupting

<sup>&</sup>lt;sup>8</sup> Members of the Advisory Group were invited by the members of the SAICM bureau. Individual experts were also invited to become members based on expertise, previous work, and special interest on EDCs. Further information may be found here: https://www.unep.org/explore-topics/chemicals-waste/what-we-do/emergingissues/advisory-group-endocrine-disrupting

<sup>&</sup>lt;sup>9</sup> UNEP (2020). An Assessment Report on Issues of Concern: Chemicals and Waste Issues Posing Risks to Human Health and the Environment.

<sup>&</sup>lt;sup>10</sup> UNEP (2019). Global Chemicals Outlook II: From Legacies to Innovative Solutions: Implementing the 2030 Agenda for Sustainable Development.

<sup>&</sup>lt;sup>11</sup> https://www.unep.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/issues-concern

14. In 2023, in cooperation with the secretariat of the Basel, Rotterdam and Stockholm conventions and with financial support from the Governments of Norway, Sweden and Switzerland, UNEP released the 2023 "Chemicals in plastics: a technical report"<sup>12</sup>. The report provides the state of knowledge on chemical-related issues of plastic pollution and their adverse impacts and includes an overview of chemicals of concern based on their hazardous properties, which also include endocrine disruption. The report, along with a "Summary and key findings" was also made available to the second session of the Intergovernmental Negotiating Committee on Plastics to inform negotiators<sup>13</sup>.

15. In cooperation with WHO, UNEP is initiating the execution of a project entitled "Global best practices on emerging chemical policy issues of concern under the Strategic Approach to International Chemicals management (SAICM) (EDCs, Environmentally Persistent Pharmaceutical Pollutants (EPPPs))" funded by the Global Environment Facility (GEF). The project has two substantive outputs, first the development of a global toolkit on pharmaceutical residues in the environment, and second the prioritization of EPPPs and EDCs emissions pathways from manufacturing and wastewater. Among other things, the project will address the scientific and policy barriers preventing robust action on EPPPs and EDCs by promoting coordinated action by UNEP and WHO to develop global best-practice protocols and policy guidance to facilitate prompt action at key life cycle "hotspots", including manufacturing facilities.

### III. Activities conducted by WHO

16. In May 2023, the World Health Assembly through resolution WHA76.17 requested WHO to work jointly with UNEP to update the report entitled State of the Science of Endocrine Disrupting Chemicals 2012. WHO has completed a mapping of evidence on the health effects of endocrine disrupting chemicals (EDC) to assist planning the work on the update of the report. This work has resulted in a transparent methodology for mapping and querying all published literature on the health effects of EDCs from 1975 to December 2022 to determine the main health outcomes and chemical classes reported in the literature. A qualitative comparison of these main health outcomes and chemical classes with those described in 2012 has also been carried out. With a more than two-fold increase in research output occurring over the last 10 years, together with a large number of systematic reviews and substantial international initiatives on exposures, WHO is currently working to make a proposal for the prioritisation of health outcomes for further investigation and review.

<sup>&</sup>lt;sup>12</sup> UNEP and Secretariat of the Basel, Rotterdam and Stockholm Conventions (2023). Chemicals in plastics: a technical report.

<sup>&</sup>lt;sup>13</sup> Document UNEP/PP/INC.2/INF/5: Chemicals in Plastics - A Technical Report, available at https://wedocs.unep.org/bitstream/handle/20.500.11822/42421/Chemicals.pdf