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Strategic Approach to International Chemicals Management

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Item 5 (b) (i) of the provisional agenda*

Implementation towards the achievement of the 2020 goal of sound chemicals management: emerging policy issues and other issues of concern: proposal on environmentally persistent pharmaceutical pollutants as a new emerging policy issue

Nomination for new emerging policy issue: environmentally persistent pharmaceutical pollutants

Note by the secretariat

I. Introduction

1. One of the functions of the International Conference on Chemicals Management, as set out in paragraph 24 (j) of the Overarching Policy Strategy of the Strategic Approach to International Chemicals Management, is to focus attention and call for appropriate action on emerging policy issues as they arise and to forge consensus on priorities for cooperative action.

2. The modalities for considering emerging policy issues are set out in the annex to resolution II/4, on emerging policy issues, of the International Conference on Chemicals Management. The modalities provide that the process will be open and transparent, it will be facilitated by the secretariat, and it will provide for the participation of all stakeholders.

3. Environmentally persistent pharmaceutical pollutants have been nominated as a new emerging policy issue for consideration by the Conference at its fourth session by the Ministry of Environment of Peru, the Ministry of Housing, Land Planning and Environment of Uruguay and the International Society of Doctors for the Environment.

4. The proponents completed a questionnaire on the nomination of emerging policy issues, setting out why environmentally persistent pharmaceutical pollutants should be considered to be an emerging policy issue. They included a short description of the issue explaining how, in their view, it met the definition of an emerging policy issue. They also provided information aimed at facilitating the assessment of the issue against the criteria set out in paragraph 2 (b) of the annex to resolution II/4.

5. The issue of environmentally persistent pharmaceutical pollutants was considered by the Open-ended Working Group at its second meeting, held in Geneva from 15 to 17 December 2014.

6. The Working Group requested that further work be undertaken on the issue in a contact group with a view to its submission for consideration by the International Conference on Chemicals Management at its fourth session.

* SAICM/ICCM.4/1.

7. Subsequently, the co-chair of the contact group presented a conference room paper setting forth an amended proposal. The Working Group endorsed the proposal for consideration by the International Conference on Chemicals Management at its fourth session. The proposal as endorsed by the Working Group is contained in document SAICM/ICCM.4/INF/15. It is presented therein as submitted, without formal editing.

II. Proposed cooperative actions on the issue

8. The submission from the proponents states that pharmaceuticals comprise one of the few groups of chemicals specifically designed to be slowly degradable or even non-degradable, to resist chemical degradation during passage through a human or animal body. They present a special risk, therefore, when they or their active metabolites or degradants enter, persist or disseminate in the environment. In the proposal of the proponents, the term "environmentally persistent pharmaceutical pollutants (EPPP)" is used as an abbreviation for the above defined substances.

9. The submission further suggests cooperative actions, or options for such actions, to be considered in moving forward on the nominated emerging issue, including a rationale explaining how the proposed actions would address the nominated emerging issue.

10. The proposed actions are summarized by the secretariat below:

(a) To raise awareness of the issue as a global problem, of its adverse effects on the environment and of its potential adverse effects on human health;

(b) To support the decision-making process;

(c) To initiate work to reduce the introduction of chemicals of pharmaceutical origin in the environment, promoting cost-effective and measurable prevention measures;

(d) To improve understanding of their risk to human health and the environment and encourage cooperative action on the part of all stakeholders;

(e) To consider implementing capacity-building programmes and technical cooperation activities to support Strategic Approach stakeholders in responding to the issue;

(f) To promote monitoring in order to support decision-making processes, prioritization of actions and the development of guidance and training tools within relevant sectors;

(g) To encourage the exchange of information through the clearing house of the secretariat and at regional meetings, workshops, training sessions, webinars and other mechanisms.

11. The proponents have prepared a summary of information against the criteria listed in paragraph 2 (b) of the annex to resolution II/4 (see annex).

III. Possible action by the International Conference on Chemicals Management

12. The issue of environmentally persistent pharmaceutical pollutants, following its consideration by the Open-ended Working Group at its second meeting, is proposed for consideration by the Conference as a new emerging policy issue, taking into account the current work on existing emerging policy issues and the relevance of the issue to the overall orientation and guidance for achieving the 2020 goal of the sound management of chemicals (SAICM/ICCM.4/6).

13. The Conference may wish to review the proposal to designate environmentally persistent pharmaceutical pollutants as an emerging policy issue (see SAICM/ICCM.4/INF/15); and in so doing consider

(a) Adopting the issue as an emerging policy issue;

(b) Recommending ways of addressing environmentally persistent pharmaceutical pollutants but not as an emerging policy issue.

14. Should the nominated issue be adopted as an emerging policy issue, the Conference may wish to adopt a resolution along the following lines:

The Conference,

Recalling the goal of the Plan of Implementation of the World Summit on Sustainable Development, as set out in paragraph 23, of ensuring that by 2020 chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health,[1]

Recognizing that pharmaceuticals are used in both animal and human health care,

Recognizing also the potential adverse effects of environmentally persistent pharmaceutical pollutants on human health and the environment, and the need to protect humans and ecosystems and their constituent parts that are especially vulnerable, as set forth, inter alia, in paragraph 14 (b) of the Overarching Policy Strategy of the Strategic Approach,

Mindful of the scope of the Strategic Approach and the work being done by other international bodies,

1. *Agrees* that international cooperation is crucial to build awareness and understanding and promote action on environmentally persistent pharmaceutical pollutants as an emerging policy issue;

2. *Considers* that information dissemination and awareness-raising on environmentally persistent pharmaceutical pollutants are particularly relevant and that improving the availability of and access to information on such chemicals is a priority;

3. *Recognizes* the current knowledge gaps on exposure to and the effects of environmentally persistent pharmaceutical pollutants;

4. *Decides* to implement cooperative actions on environmentally persistent pharmaceutical pollutants with the overall objective of increasing awareness and understanding among policymakers and other stakeholders;

5. *Invites* Governments and other stakeholders to generate and share information to fill the identified knowledge gaps;

6. *Invites* [relevant international bodies] within their respective mandates as part of their programmes of work, to lead and facilitate cooperative action on environmentally persistent pharmaceutical pollutants in an open, transparent and inclusive manner;

7. *Requests* all interested stakeholders and organizations to provide support, including expertise, financial and in-kind resources, on a voluntary basis, for such cooperative action, including by participating in developing and making available relevant information and guidance;

8. *Invites* [relevant international bodies and other Strategic Approach stakeholders] to report, through the secretariat, on the cooperative action on environmentally persistent pharmaceutical pollutants to the Conference at its fifth or any other session as decided upon by the Conference.

15. If the nominated issue is not considered to be an emerging policy issue, the Conference may wish to recommend other ways in which the issue may be addressed, such as by:

(a) Disseminating information about the issue through the Strategic Approach website;

(b) Including the issue as a topic for regional meetings, workshops or webinars;

(c) Forwarding the issue to other forums or individual stakeholders with relevant mandates for their consideration;

(d) Highlighting the issue as a possible priority for Strategic Approach stakeholders.

[1] *Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August–4 September 2002* (United Nations publication, Sales No. E.03.II.A.1 and corrigendum), chap. I, resolution 2, annex.

Annex

Information provided by the proponents against the criteria listed in paragraph 2 (b) of the annex to resolution II/4

(a) Magnitude of the problem and its impact on human health or the environment, taking into account vulnerable subpopulations and any toxicological and exposure data gaps

1. Chemicals of pharmaceutical origin present in the environment are a global issue. This has recently been demonstrated by a database on the worldwide occurrence of chemicals of pharmaceutical origin in the environment (www.pharmaceuticals-in-the-environment.org/en/home/dok/2.php). The database covers at least 71 countries in all five United Nations regional groups. It indicates that in total 631 different chemicals of pharmaceutical origin (or their transformation products) have been detected in the environment, including antibiotics, analgesics, lipid-lowering drugs, oestrogens and many other therapeutic groups.

2. Most chemicals of pharmaceutical origin have been detected in surface water and sewage effluent, but also in other environmental matrices, including groundwater, tap water/drinking water, manure and soil. According to the database, 16 different chemicals of pharmaceutical origin are found in surface water, groundwater, and/or drinking or tap water in each of the five United Nations regional groups. In many countries, certain chemicals of pharmaceutical origin prevail at concentrations above established predicted no-effect concentrations, and mainly in surface waters, suggesting adverse eco-toxicological effects on organisms and microorganisms at these locations. Urban wastewater discharge is the dominant emission pathway, while discharge from manufacturing, animal husbandry and aquaculture are important regionally.

3. Chemicals of pharmaceutical origin have adverse effects on the environment and biodiversity. Therapeutic levels of the hormone levonorgestrel have been found in rainbow trout downstream from a sewage plant. In a whole lake experiment, male fish exposed to synthetic oestrogen at concentrations found in polluted environments became feminized and within seven years were almost extinct, with downstream effects on the entire ecosystem. The antidepressant oxazepam alters the behaviour and feeding rate of the wild fish species Perca fluviatilis at environmentally relevant concentrations, so that antidepressants in surface water may alter animal behaviours that are known to have ecological and evolutionary consequences. Livestock excrement containing residues of antiparasitic macrocyclic lactones has been shown to affect dung fauna, resulting in reduced degradation rates. Antibiotics reduce the growth of plants and are toxic to photoautotrophic aquatic organisms. The anti-inflammatory drug diclofenac has been shown to cause kidney failure and death of Indian vultures feeding on livestock treated with the drug, leading to a significant decline in the Indian vulture population.

4. The impact on human health of chemicals of pharmaceutical origin in the environment cannot be clearly demonstrated yet. Based on the current level of scientific information, adverse impacts on human health of environmental exposure to chemicals of pharmaceutical origin present in the environment are unlikely, as concentrations of these chemicals present in drinking water are generally below minimum therapeutic doses, although locally high concentrations of these chemicals occur in well water used as drinking water. Uncertainties prevail regarding the risks of low-level chronic exposure in humans, exposure from conception, during childhood and reproductive age and in other vulnerable populations (third age as well as in people with health conditions), due to the presence of chemicals of pharmaceutical origin in drinking water.

5. There is a gap in the knowledge regarding multiple exposures (additive, synergistic or antagonistic effects) to chemicals of pharmaceutical origin and multiple exposures to other pollutants concurrently present in surface and drinking water. There is a scarcity of systematic monitoring schemes. The increasing prevalence of antimicrobial resistance shows how the emission of antibiotics into the environment may have direct negative health consequences for human and veterinary health.

6. The presence in the environment of chemicals of pharmaceutical origin poses an increasing problem. As the world population is ageing, the production, use and disposal of pharmaceutical products are growing along with the demand for pharmaceuticals in food production and veterinarian uses. The degree of environmental pollution from chemicals of pharmaceutical origin can thus be expected to increase unless adequate global preventive measures are introduced.

(b) Extent to which the issue is being addressed by other bodies, particularly at the international level, and how it is related to, complements, or does not duplicate such work

7. The issue of chemicals of pharmaceutical origin present in the environment is currently insufficiently addressed at the international level. However, due to the global and interdisciplinary scope of the problem, international coordination is needed.

8. Initiatives at the international level include activities conducted by the World Health Organization (WHO), the joint United Nations project on sustainable procurement of pharmaceuticals, and the Strategic Approach. WHO has conducted activities that address the issue of chemicals of pharmaceutical origin present in the environment to a certain extent, including the Pre-qualification of Medicines Programme, the Member State Mechanism on Substandard/spurious/falsely-labelled/falsified/counterfeit medical products and the Global Strategy for Containment of Antimicrobial Resistance. Moreover, chemicals of pharmaceutical origin present in the environment have been addressed to varying degrees in WHO reports and guidelines on health care waste management, and in the assessment of health risks of pharmaceuticals in drinking water.

9. In Europe, the joint United Nations project (United Nations Development Programme, United Nations Environment Programme, United Nations Population Fund, United Nations Office for Project Services and WHO) aims to improve the sustainability of the procurement procedures of United Nations entities and criteria for health products and services, and thereby to diminish possible future negative environmental effects of pharmaceuticals. Two different approaches to reach the target are being undertaken: (a) to develop and implement WHO evidence-based technical guidelines on sustainable procurement of health care products including pharmaceuticals, thereby creating an incentive for manufacturers to strive towards the production of more "green" products, and (b) to integrate environmental criteria into good manufacturing practice (GMP) utilized by WHO to pre-qualify medications for procurement.

10. The Strategic Approach initiative on endocrine-disrupting chemicals partially overlaps with the issue of chemicals of pharmaceutical origin in the environment, as some pharmaceuticals (e.g., hormones and contraceptives) have endocrine-disrupting properties.

11. In a recent workshop held in Geneva in April 2014 and organized by the German Federal Environment Agency, international experts gathered to discuss the current state of knowledge on the issue of chemicals of pharmaceutical origin in the environment as well as the results of a research project on the global occurrence of chemicals of pharmaceutical origin in the environment.

12. At the national level, several countries (e.g., Canada, China and the United States of America) and the European Union have funded extensive research on chemicals of pharmaceutical origin in the environment. An environmental risk assessment of these pharmaceutical chemicals is required in, for example, the United States and the European Union. This is partially harmonized via the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products. At the national and local levels, initiatives to manage chemicals of pharmaceutical origin in the environment have started, such as the classification system of the Stockholm County Council and the Swiss programme to upgrade large sewage treatment plants.

(c) Existing knowledge and perceived gaps in understanding about the issue

13. Existing knowledge gaps in understanding of the issue of chemicals of pharmaceutical origin in the environment relate to the risks of early (since conception) and low-level chronic exposure in humans when present in drinking water or bio-concentrate in food. Moreover, uncertainties prevail regarding the combined (additive, synergistic or antagonistic) effects of multiple environmental chemical exposures (synergistic effect).

14. Understanding of the behaviour, fate and effects of chemicals of pharmaceutical origin in the environment should be further developed, especially of those that are widespread, are highly toxic, have been on the market for several years or decades and/or are diffuse pollutants.

15. Furthermore, the scarcity of systematic environmental monitoring programmes, lack of a standardized, harmonized and comparable sampling system according to established analysis protocols, as well as regional capacity to support multi-centric studies, should be addressed.

16. There are currently no test methods to assess whether negative effects may occur after long-term environmental diffuse exposure in humans since conception and during the vulnerable period of development, on aquatic microorganisms, or how it may affect other animals. Consideration must be given to bioaccumulation in fish and other aquatic food used by humans. Therefore, the precautionary principle must be guiding.

(d) Extent to which the issue is of a cross-cutting nature

17. The global problem posed by the pollution of surface water (as well as groundwater, drinking water, tap water and to some extent farmland and soil) with chemicals of pharmaceutical origin and their residues is well known to scientists in the field.

18. Pharmaceuticals are synthetic chemicals belonging to a wide group of different chemical families and may also react differently in the environment as they are not conceived or designed to enter the environment. As there are thousands of different synthesized chemicals present in the environment at the same time, different interactions may occur and the result of these multiple exposures in humans and in nature are not sufficiently studied or understood.

19. Documented evidence shows that some pharmaceuticals enter and persist in the environment.

20. Little is known about the possible negative effects and impacts of environmentally persistent pharmaceutical pollutants in humans and the environment by diffuse and systematic exposure for long periods of time, especially during the vulnerable periods of development.

21. The issue of chemicals of pharmaceutical origin in the environment is of a cross-cutting nature as it encompasses the issue of antibiotic resistance, among others, and endocrine disruptors.

22. Chemicals of pharmaceutical origin in the environment (such as antibiotics, which are designed to kill bacteria, and those designed to kill viruses) can increase the risk of antimicrobial resistance. The presence of antimicrobials in the gut of humans and animals leads to the development of resistant bacteria and resistance genes that can be excreted in faeces and spread to wastewater, sludge, manure and soil. Resistance genes can also spread through the food chain, for example via human consumption of animals treated with antibiotics. Resistance genes can also develop in the environment if chemicals with antibiotic activity are present in the environment. The resistance genes from the increasing environmental reservoir can then be transferred to pathogenic bacteria. There is also evidence of an exchange of resistance genes between environmental bacteria and clinical isolates. The issue of antibiotic resistance is addressed for example by WHO.

23. Moreover, some chemicals of pharmaceutical origin in the environment have hormone activity (synthetic hormones) with endocrine-disrupting potential (see para. 3 above). The issue of endocrine disruptors is addressed by the Strategic Approach. These may affect microorganisms and wildlife in severe and unexpected ways.

(e) Information on the anticipated deliverables from action on the issue

24. Anticipated deliverables include greater visibility and policy engagement, greater coordination, consistency and synergies between different initiatives around the globe, engaging actors from different sectors and improved capacity for assessing and managing risks from environmentally persistent pharmaceutical pollutants, in particular in developing countries. Particular outputs would include expert guidance for risk identification and assessment; priority-setting for research and for risk management and control actions of environmental effects; and information exchange and networking from which scientists and policymakers in developing countries and countries with economies in transition could especially benefit, resulting in greater understanding of the environmentally persistent pharmaceutical pollutant issues and of the need for priority action.