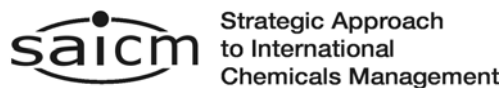




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**Open-ended Working Group of the International Conference
on Chemicals Management
First meeting
Belgrade, 15–18 November 2011
Item 5 (c) of the provisional agenda *
Implementation of the Strategic Approach: New and emerging policy issues**

Final versions of submissions for nominated new emerging policy issues

Note by the secretariat

The secretariat has the honour to circulate, for the information of participants, the final versions of the submissions of the two nominated new emerging policy issues. Submission on international cooperation to build awareness and understanding and promote actions on endocrine disrupting chemicals, and environmentally persistent pharmaceutical pollutants, are included in Annex 1 and 2, respectively. Submissions have been reproduced as received and have not been formally edited.

* SAICM/OEWG.1/1/Rev.1

Annex 1

Questionnaire for Governments and organizations to nominate possible emerging policy issues for consideration by the International Conference on Chemicals Management at its third session



Strategic Approach
to International
Chemicals Management

SAICM – ICCM3 emerging Issues – UNEP Nomination
EDP – November 2010, Rev Aug 2011

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Issue

International cooperation to build awareness and understanding and promote actions on endocrine disrupting chemicals

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(Submission developed in cooperation with the World
Health Organization)

State the problem

Chemical interferences with hormonal systems started to be more intensely discussed 15 years ago. At that time, however, there were several examples of how endocrine effects impacted wildlife and humans, but still the effects were rarely presented as hormonal effects. During the latter part of the 1990's numerous national reports and assessments were presented regarding endocrine effects and endocrine disrupting chemicals. A global assessment of the state-of-the-science was published in 2002 by IPCS. At that point it was clear that endocrine effects occurred in wildlife while effects in humans at low-level (population) exposure levels were much more uncertain and the mechanisms not well understood.

Endocrine effects are caused by a variety of chemicals with very different chemical structures and lead to a variety of effects and endocrine endpoints. These effects may be manifested at relatively low doses. The situation is further complicated by multi-chemical exposures with synergistic potential. The time of exposure may be critical, especially in developing foetuses - whether wildlife or humans.

Problems are accentuated by the fact that production and use of chemicals are increasing in developing countries where the risk management capacity is often limited. Furthermore, many products containing these chemicals can constitute a significant source of exposure and may also pose serious risks during recycling and disposal operations, in particular in countries that lack adequate risk management capacity. Only a small portion of all the anthropogenic chemicals and their metabolites currently in use have been adequately studied for their endocrine disruption potential.

The Global Plan of Action of SAICM also proposes to stakeholders some work areas and activities to address EDC related issues, including the development of action plans to address priority concerns in relation to groups with specific vulnerabilities; prioritization of assessment and related studies of groups of chemicals that pose an unreasonable risk for human health and the environment which might include chemicals adversely affecting the endocrine system; filling gaps in scientific knowledge such as gaps in understanding of endocrine disruptors and; harmonizing principles and methods for risk assessment (e.g. for vulnerable groups) and specific toxicological endpoints (such as endocrine disruption and ecotoxicology) and for new tools.

Hence, there is a need to continue to improve how EDC characteristics are addressed in risk assessments and to support management decision making and prioritization with better scientific understanding. For this, the different EDC endpoints are being defined and improved risk assessment methodologies developed. The problem is global although the issues can be different in different regions of the world. In developed countries the EDC issue is not well understood for all endpoints and although legislation has been or is being developed, more work is being done on risk assessment methodologies in order to support such legislative mechanisms. In developing countries and countries with economies in transition the EDC problems are much less studied and rarely addressed. An initiative at international level is therefore needed to help address these different issues regarding EDCs ensuring involvement and support to developing countries and countries with economies in transition.

Information that can be used to assess the nominated issue

(i) 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: The issue is clearly global, there are already numerous chemicals identified as potential EDCs. These include chemicals widely used in consumer products such as flame-retardants, plasticizers, human care products, pesticides, pharmaceutical (human and veterinary) etcetera. Studies on EDC related effects are mainly available from OECD countries but some studies from developing regions have observed EDC effects in both humans and wildlife. Exposure to EDCs is hence of global concern, but some vulnerable sub-populations are at higher risks such as Northern Inuits due to their consumption of food with high fat content; others are those subjected to pesticide spraying and use while those in rapidly growing economies with increased production and use of pesticides, pharmaceuticals and of industrial chemicals are at risk as well. However, the most vulnerable group is children, and in particular the developing foetus that can be exposed via their mothers. Close to 300 body-foreign chemicals (i.e. substances that are not natural to the human body) have been demonstrated in the umbilical blood of new-borns in developed countries. Children are also more exposed than adults via food, food containers, toys and other products that they can put into their mouths.

(ii) 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: WHO and UNEP are presently developing an update of the 2002 IPCS state of the science document with internationally recognized experts. The ongoing chemical assessment programmes of WHO include assessment of endocrine-active chemicals as well as development of risk assessment methodologies relevant to such chemicals. Activities are on-going in OECD countries and in particular the EU is analysing assessment and other needs for EDCs in relation to regulatory requirements. The US EPA is also undertaking a screening program on EDCs. The OECD test guidelines programme has and is developing test protocols for specific EDC endpoints and is also developing a guidance document on hazard identification. As approaches for addressing the EDC issue are still under development by different organizations and countries, an international initiative should help in raising the awareness about them and thereby facilitate understanding and harmonization between these and any new initiatives.

(iii) Existing knowledge and perceived gaps in understanding about the issue: Even though many endocrine active chemicals have been assessed, the majority of these compounds still need to be studied to understand their actions and confirm the need for control actions. A large number of chemicals are not yet at all tested or assessed for their endocrine disruptive activity.

(iv) Extent to which the issue is of a cross-cutting nature: This is a truly cross-cutting issue with the great variety of chemicals with potential ED action means that all sectors of chemical use are potentially affected. Furthermore, ED active chemicals may be included and present in all types of products from food packaging, cosmetics, and textiles to computers and construction materials. The issue of EDC is interdisciplinary requiring expertise from a variety of scientific disciplines including, but not limited to, environmental epidemiology, chemistry, medicine, biochemistry, eco-toxicology and statistics.

(v) Information on the anticipated deliverables from action on the issue.:

Greater visibility and policy engagement, in particular in non-OECD countries.

Greater coordination, consistency and synergies between different initiatives around the globe engaging actors from different sectors.

Improved capacity for assessing and managing risks from EDCs, in particular in developing countries.

Particular outputs would include: Expert guidance for risk identification and assessment; priority setting for research and for risk management / control actions; information exchange and networking from which scientists and policy makers in developing countries and countries with economies in transition could especially benefit, resulting in greater understanding of the EDC issues and of needs for priority actions.

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Describe the proposed cooperative action

With the objective of improving understanding among policy makers and other stakeholders of risks posed by EDCs to human health and the environment and promoting actions to reduce these risks, it is proposed that an international project on EDC be established to undertake the following by building on existing activities, in particular of OECD, UNEP and WHO including the update of the 2002 IPCS Global Assessment of the State-of-the-Science of EDCs:

- i) provide up-to-date information and scientific expert advice to policy decision makers and others responsible for chemicals risk management, for the purpose of identifying or recommending potential measures that can contribute to reductions in exposures and / or effects from EDCs, *inter alia* through timely updates to the new IPCS document with the involvement of relevant expertise.
- ii) raise awareness and facilitate information exchange and networking, *inter alia* through regional and sub-regional workshops / discussion forums and a dedicated website that links to relevant information sources.
- iii) provide international support activities to build capacities in countries, in particular developing countries and countries with economies in transition, for assessing EDC issues in order to support decision making including prioritization of actions, e.g. through guidance and training tools / activities involving relevant expertise. .
- iv) create an international network of scientists, risk managers and others that are particularly concerned with EDC issues to facilitate information exchange, discussion forums and mutual support in research and advice on translation of research results into control action.

<p>Questionnaire for Governments and organizations to nominate possible emerging policy issues for consideration by the International Conference on Chemicals Management at its third session</p>	 <p>Strategic Approach to International Chemicals Management</p> <p>SAICM – ICCM3 emerging Issues – ISDE Nomination EPPP - November 2010, Rev Aug 2011</p> <p>SAICM secretariat 11–13 chemin des Anémones CH-1219 Châtelaine, Geneva Switzerland Tel: 41 22 917 86 31 Fax: 41 22 797 34 60 E-mail: saicm@unep.org</p>
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<p>State the problem</p> <p>Pharmaceuticals comprise one of the few groups of chemicals specifically designed to act on living cells, which presents a special risk when they enter, persist and disseminate in the environment. Pharmaceutical chemicals are designed to be non-degradable to resist the acid environment in the stomach and to be long-lasting. They are also designed to be administered according to a specific, defined time schedule. In this paper, we suggest the term Environmentally Persistent Pharmaceutical Pollutants, EPPP. EPPP are insufficiently addressed, as they are not covered by other international or regional agreements or arrangements.</p> <p>Pharmaceutical chemicals, widely used globally by humans and for food production for an intended purpose, may enter and persist in the environment during their lifecycle creating a new and emerging problem. They may pose a threat of important magnitude with significant adverse effects on the environment and on human health with special impact on vulnerable populations.</p> <p>As the world's population is growing and ageing, more people can afford medical treatment and as new treatments are developed the amounts of pharmaceuticals can be expected to increase rapidly. Pharmaceutical chemicals entering the environment persist there and residues are presently found in drinking water. They are found in fish where they may accumulate. The presence of different pharmaceutical chemicals contributes to the increasing multiple chemical cocktail that today's population is exposed to. Vulnerable populations are exposed, for example foetuses during the phases of development, with possible important consequences for life.</p> <p>With the exception of downstream sewage plants, the concentration of pharmaceuticals in water is probably extremely low. However, the combined effect of chronic exposure to pharmaceutical chemicals in the environmental with the effects of other chemicals in the cocktail is not yet studied. The different chemicals might be creating a synergistic effect (1+1=3). An extremely sensitive group in this respect are foetuses.</p>	
<p>EPPP are already found in water all over the world. That diffuse exposure might contribute to</p> <ul style="list-style-type: none"> - extinction of species and imbalance of sensible ecosystems, as many such chemicals affect the reproductive 	

systems of, for example, frogs, fish and mussels;

- genetic, developmental, immune and hormonal health effects to humans and other species, in the same way as, for example, oestrogen-like chemicals;
- development of microbes resistant to antibiotics, as is found in India (1).

Pharmaceuticals reach the environment mainly in three ways:

- They are excreted from humans and animals, intact or metabolized, mainly into the urine, passing in to the environment directly or via sewage plants.
- Unused, they reach the environment either via household water or via urban solid garbage handling.
- Manufacturing plants producing the active substances might unintentionally release pharmaceuticals into the environment.

Some pharmaceuticals are degraded to various extents in sewage treatment plants, but others leave the plant in active forms. Active residues of pharmaceuticals have been detected in surface water, and they may persist in the environment for long periods of time. Large amounts of antibiotics and other pharmaceuticals have been found downstream from sewage plants for pharmaceutical industries. EPPPs from sewage sludge used as fertilizer are absorbed by soya, and antibiotics have been found in the leaves.

Which EPPPs are found in drinking water depends on what resources and detection methods are available. Atenolol (beta blocker), citalopram (antidepressant drug), diclofenak (analgesic), ibuprofen (analgesic), metoprolol (beta blocker), naproxen (anti-inflammatory) and trimetoprim (antibiotic) have been found in the drinking water of Stockholm. Fish caught downstream from the sewage plants of Stockholm contain EPPPs like citalopram and propoxyphene (narcotic/anaesthetic). Several broad-spectrum antibiotics in very high concentrations, as well as bacteria resistant to all known antibiotics, were found downstream from a sewage plant in India. In Indian drinking water cetirizin (antihistamine), ciprofloxacin (antibiotic), enoxacin (antibiotic), terbinafin (antimycotic), and citalopram were found. Up to 14 different pharmaceuticals have been found in the drinking water of big cities around the world. There also exist publications reporting the presence of cancer drugs in surface water in some countries.

Some of these environmental pharmaceuticals chemicals are well known to have serious genotoxic effects in humans. Many are not very well studied for their toxic effects on humans during their period of development. Their half-life in nature varies depending on the environment (air, water, soil, sludge), but is more than one year for several compounds (2, 3). Clofibric acid, a metabolite of the lipid-lowering agent clofibrate, can still be found in surface as well as well-water, although clofibrate has been withdrawn long ago. Concentrations of EPPPs can vary from 1 ng to 1 mg per litre (2). Serious effects of EPPPs on water-living organisms, especially on the reproductive systems, as well as on microbial communities have been already shown (4, 5, 6, 7).

Concentrations in surface waters, groundwater and partially treated water are typically less than 0.1 µg/l (or 100 ng/l), and concentrations in treated water are generally below 0.05 µg/l (or 50 ng/l) (8 WHO). However, all water on the earth is part of the same stable pool and as larger amounts of pharmaceuticals are consumed, there is a risk that the concentration of pharmaceuticals in drinking water will increase. The tendency of bio-accumulation in fish is alarming, as fish is an important source of nourishment.

The impact of pharmaceutical chemicals, due to diffuse exposure by their presence in the water environment, might contribute to the wide chemical exposure of all species and to their possible extinction, as well as to the imbalance in sensitive eco-systems. Consequences for human health and the equilibrium of the biological environmental system may be irreversible.

Multiple human exposures to EPPP may start at conception and may be combined with a cocktail of other chemicals present in the environment. The effects of exposure to these mixtures are difficult to understand due to the complexity of the situation during a period of special vulnerability and sensitivity, but cannot be denied. Another very serious threat is the development and spread of bacteria, viruses and other microbes resistant to the antibiotics present in the environment, with possible unpredictable and important consequences.

Information that can be used to assess the nominated issue

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

i) *Pharmaceuticals are special kinds of chemicals.* They are manufactured to be biologically active in living organisms, to be persistent to biodegradation and to have long half-lives. This makes them more risky in nature. Release is ongoing always and everywhere, diffuse and impossible to control. They cannot be forbidden.

ii) The levels of *pharmaceuticals in surface or drinking water* are generally below 1 mg per litre, often measured in ng per litre (2, 8). This low concentration might appear to guarantee that they hardly pose any problem to public health. Assuming a concentration of 100 ng/l of a pharmaceutical that in humans has a DDD (defined daily dose) of 10 mg implies that a volume of 100,000 litres would be required to make up one single DDD. Such calculation, however, is an over-simplification that does not take into account several important dynamic aspects of the *low chronic exposure to concentrations of pharmaceuticals* in the water or the *vulnerable population exposure for example during the period of development.*

iii) *Aquatic organisms may bio-concentrate and bio-accumulate lipid soluble chemicals, including pharmaceuticals.* It is well known that certain fish species, like herring, may contain very high concentrations of the persistent and lipophilic chemicals DDT (dichlorodiphenyl-trichloroethane, an insecticide) and PCB (polychlorinated biphenyls, a group of industrial chemicals earlier used in, for example, building materials). The same mechanism may also be applied for chemicals synthesized for pharmaceutical uses. Bioaccumulation of citalopram (SSRI, antidepressant) and propoxyfen (painkiller) has been found in perch in the Baltic Sea. Therapeutic levels of levonorgestrel (a sex hormone) have been found in Rainbow trout downstream from a sewage plant (9).

iv) *Pharmaceutical chemicals are not conceived or designed to enter in the environment and persist there but rather are developed for a clear pharmaceutical purpose.* Pharmaceuticals are synthetic chemicals. They belong to a wide group of different chemical families and may also react differently in the environment. When a new medicine is developed, its pharmacological and toxicological effects are tested in acute trials before being accepted for marketing. However, clinical test procedures are not entirely sufficient to completely guarantee that a new pharmaceutical is devoid of unacceptable side effects when used in large cohorts of patients for a long time. Furthermore, *there are currently no test methods to assess whether such effects may occur after long-term use in humans during periods of development, on aquatic microorganisms or how they may affect other animals.* Based on this, the persistent and diffuse exposure to low doses of pharmaceutical synthetic chemicals, for long periods of time, is not currently well known or studied.

v) *The diffuse dissemination of the EPPP in the environment may indiscriminately expose vulnerable populations: embryos/foetuses, children and adolescents, men and women of reproductive age, and elderly or weak persons.* Some of the pharmaceuticals found in surface water are prescribed to patients under special controlled conditions for short periods of time due to the risk of side effects. Others are prohibited from prescription to pregnant women or children. These chemicals were not synthesized to expose the general population in a diffuse manner. This presents a new and emerging issue under chemical safety and global pollution.

vi) *It can be assumed that a large proportion of excreted or disposed medicines reach the public sewage treatment plants.* Today, sewage plants do not have the capacity to ensure the treated water does not contain pharmaceutical chemicals. This is sometimes also the case for the industries' own sewage plants. In many parts of the world, sewage plant water is reused as drinking water, not always after cleaning treatment. To add a step for cleaning sewage water from pharmaceuticals means more energy, more chemicals and higher costs. - Alternatively, the sewage is dumped directly into various surface waters such as rivers, lakes, streams or the open sea. Detection and monitoring on a global scale of EPPPs in drinking and surface water, as well as in animals and plants, is necessary to understand the magnitude of the problem. The first step is to recognize EPPP as an emerging issue to be able to invest the necessary human and financial resources and develop effective environmental detection methods.

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.

EPPP are insufficiently addressed or not covered by other international or regional agreements or arrangements. Pharmaceuticals differ from other anthropogenic chemicals with respect to legal requirements. They are regularly excluded in laws and regulations that control manufacture, marketing, use, and disposal of other consumer products of a chemical character (solvents, paints, glues etc). *As a consequence the possible negative environmental impact of pharmaceuticals is much less documented in comparison to other consumer chemicals.*

In the European Union, the new directive for human pharmaceuticals explicitly requires that all member states should

establish collection systems for unused or expired medicines. Such systems were already in use in several member countries at the time the new legislation went into action in 2004. Nevertheless, the extent to which such systems have been established and made publicly known, varies between regions. Furthermore, the directive does not regulate how the collected pharmaceuticals should be handled. Disposal into the sewage system is still a legally accepted route of elimination. However, incineration at high temperature (1200 degrees centigrade) is a preferred alternative to avoid environmental pollution.

For pharmaceuticals approved for marketing in the European Union before 1995, there are no requirements for documentation of environmental effects. Hence, pharmaceuticals that have been on the market for decades may have serious environmental effects that have not been detected. **c) Existing knowledge and perceived gaps in understanding about the issue**

Examples showing the presence of pharmaceuticals in water and in animals:

Below are some examples that illustrate the state of the science of this important emerging problem.

Estradiol (oestrogen, synthetic hormone)

Concentrations in surface water alone are not sufficient to assess the risk of negative environmental effects in the aquatic environment. Synthetic hormones are endocrine disruptors. Thus, estrogenic compounds like ethinyl-estradiol (oestrogen hormone) at concentrations < 1 ng per litre may cause both vitellogenin production (a frequently used index for feminization of male fish) and structural change in their sex organs. It has also been demonstrated that fish exposed to sewage treatment plant effluent can take up and concentrate estrogenic compounds, including ethinyl-estradiol, to very high internal levels. These observations on feminization of fish by estrogenic compounds in sewage treatment plant effluents have been observed in many countries, and have also been observed in other species, such as frogs, alligators and molluscs.

Cardiovascular medicines

Other examples of environmental impact in the aquatic environment of human medication concern both cardiovascular and neuro-psychiatric medicines. The non-selective beta-blocking agent propranolol was found to cause a significant decrease in egg production in medaka fish at a concentration close to that demonstrated in the sewage treatment plants effluents. Gemfibrozil (cholesterol and triglycerides lowering drug) often appears in the effluent from sewage treatment plants. At concentrations close to those reported in sewage treatment plant effluent, gemfibrozil lowers the blood levels of testosterone in fish.

Citalopram / Fluoxetine (serotonin re-uptake inhibitor anti-depressants, SSRI's)

Some serotonin re-uptake inhibitor anti-depressants have been shown to accumulate in exposed fish. Citalopram has been detected in liver from wild perch in low µg per kg levels and fluoxetine affects the serotonin system in the same way that it does in humans. Fluoxetine has also been shown to affect swimming activity in shellfish; whether this is linked to a disturbance of serotonin function in the brain is still unknown.

Antibiotics

High levels of antibiotics in the water are a cause for alarm as there is an increased risk of selecting resistant bacteria, an issue of global concern. This can lead to some highly effective antibiotics becoming ineffective. There are several examples: In India, bacteria resistant to ciprofloxacin have been found downstream from pharmaceutical plants, genes for multi resistance were found in drinking water and multi resistant Salmonella were found in water sprayed on vegetables. From Europe there is the case of an epidemic with multi resistant enterohemorrhagic Escherichia coli (EHEC) in the summer of 2011 originating from water sprayed vegetables.

The term "eco-shadow" has been introduced to describe the ecological impact of antibiotics. Antibiotics with a wide spectrum that are also stable will have a greater impact on the bacterial flora (a long eco-shadow) than those with a narrow antibacterial spectrum, which disintegrates more rapidly (a short eco-shadow).

The ecological effects of tetracyclines and quinolones have been observed. They are not metabolized in the human body and are therefore excreted unmodified. When entered into the environment they are poorly degraded. They can be toxic to other animals, affecting particularly microorganisms and fish. In the effluent from a sewage plant in India, several broad spectrum antibiotics were found in concentrations toxic to bacteria and plants. In the sewage plant itself, there were enterococcae resistant to all known antibiotics.

The development of resistant bacteria in sewage plants is stimulated by high concentrations of antibiotics (e.g. in plant sewage), large amounts of bacteria (e.g. from human sewage water that is added to plant sewage) and selection of bacteria via active slime technology (bacteria are chosen that can resist the antibiotics).

Oseltamivir (antivirus use to treat H1N1 influenza) does not break down in sewage plants. The active substance has been found in water where birds with influenza virus were living thus raising the possibility that resistance might occur.

Pharmaceuticals reach the environment also from cattle breeding. A number of antibiotic compounds, as well as an insect repellent, DEET, used in herd health programmes on dairy farms have been shown foot printing into extensive aquatic environments.

Personal-care products

Synergetic effects on algae by a mixture of pharmaceuticals and personal-care products have been observed.

Environmental classification of pharmaceuticals

In Sweden, the pharmaceutical industry, together with universities and the health care sector, has developed a method for environmental risk assessment and environmental classification of drugs (10, 11). Environmental risk refers to the risk of toxicity to the aquatic environment. It is based on the ratio between predicted environmental concentration of the substance (PEC) and the highest concentration of the substance that does not have a harmful effect in the environment (PNEC). Environmental hazard expresses the inherent environmentally damaging characteristics of the substance in terms of persistence, bioaccumulation and toxicity. The toxicity tests used are acute toxicity of fish, acute toxicity of Daphnia species and growth inhibition test of algae. Most medication on the Swedish market are now classified. This gives the health care sector the possibility to make better choices when prescribing medicines.

Good manufacturing practice

“Good manufacturing practice” or “GMP” are practices and the systems required to be adapted in pharmaceutical manufacturing, quality control, quality system covering the manufacture and testing of pharmaceuticals or drugs including active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. The World Health Organization (WHO) version of good manufacturing practice is used by pharmaceutical regulators and the pharmaceutical industry in over one hundred countries worldwide, primarily in the developing world. So far emissions into the environment are not included.

Gaps

Effective environmental detection methods have to be developed and a global detection strategy applied to map the current global situation.

There are currently no test methods to assess whether negative effects may occur after long term environmental diffuse exposure in humans, during the vulnerable period of development, on aquatic microorganisms, or how they may affect other animals. Therefore the precautionary principle must be guiding.

Concentrations in surface water alone are not sufficient to assess the risk of negative environmental effects of these synthetic chemicals. Consideration must be given to bioaccumulation in fish and other aquatic food used by humans, as well as to additive and synergetic effects between pharmaceutical and other chemicals in the contaminated water.

In a small study several pharmaceuticals were found in the milk of goats, cows and humans (12). More research is needed to find out how common this is, the actual concentrations and the sources of the contamination.

The industry must be invited to actively work on reducing pharmaceuticals in the environment. Emission of pharmaceuticals should be included in good manufacturing practice.

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

EPPP are not conceived or designed to enter and persist in the environment. Pharmaceuticals are synthetic chemicals belonging to a wide group of different chemical families and may also react differently in the environment.

There exists very well documented evidence that some pharmaceuticals enter and persist in the environment, some are endocrine disruptors (synthetic hormones) and some are designed to kill bacteria and viruses (antibiotics). These may affect microorganism and wild life in severe and unexpected ways.

Little is known on the possible negative effects and impacts of EPPP in humans and the environment by diffuse and systematic exposure, for long periods of time, especially during the vulnerable periods of development.

As there are thousands of different synthesized chemicals present at the same time in the environment, different interactions may occur and the result of these multiple exposures in humans and to nature are not sufficiently studied or understood.

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Further reading

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[Emerging contaminants in the Environment](#). USGS Toxic Substances Hydrology Program

These and other references are found on the webpage of Swedish Doctors for the Environment
http://www.lakareformiljon.org/index.php?option=com_content&view=article&id=151&Itemid=78

Describe the proposed cooperative action

a) Dissemination of information through the secretariat's clearing house function or other mechanism

- Involve different sectors to create awareness on this important emerging issue.
- Help to improve the public recognition of pharmaceuticals as chemical environmental pollutants, with possible important negative effects on the environment, biodiversity and human health.
- Help to include all important sectors involved in this emerging issue.
- Help to disseminate the existing information and to identify new emerging information and partners already working in the issue.

b) Recommendations for the Conference which could include requests for actions addressed to the governing bodies of international organizations, governments, scientific bodies, civil societies stakeholders and private sector

- Inclusion of EPPP as one of the emerging issues for the third session of the Conference
- Inclusion of EPPP in the SAICM Global Plan of Action.
- Recommend the main actors to get involved and become leaders in this new and emerging issue, inviting, for example, WHO to lead the actions.
- Invite scientific and health sector bodies and other main private sector and civil society actors to engage and recognize this important issue.

c) Initiation of follow up work under the auspices of the Conference, including through intersessional work at regional meetings, workshops, training sessions, internet-based consultations, teleconferences, work by subsidiary bodies, the secretariat or other mechanisms

At the third session of the Conference:

- Convene a one-day workshop on EPPP at the third session of the Conference.
- Identify and invite expert scientists and researchers to present the current state-of-science on EPPP.
- Identify and invite experts on chemical safety policies to present the current state-of-the-art of policies at the global, regional and national level.
- Prepare a document or statement to highlight the importance of EPPP and call for action.
- Promote the organization of a multi-sectoral working group to continue working intersessionally and presenting the results of progress to the following session of the Conference.

Intersessional work:

- Maintain the links with the EPPP ad hoc Working Group
- Present the discussion on and dissemination of already existing information on EPPP and promote the identification of experts at the regional level to complete the global picture
- Promote capacity building by including all sectors involved to initiate discussions
- Open discussion forums by using internet based interactive mechanisms (for example Twitter, Facebook, Fss) to promote the participation, dissemination and identification of the state of the situation
- Prepare a document to report on the state of the science and technology, global pollution situation, possible effects on health and the environment and recommendations for actions to be presented at the fourth session

of the Conference.

Other tasks of the Working Group on EPPP:

- *Include representatives of all sectors involved with special emphasis on science/technology/health/private/policy and community interest sectors*
- *Science and technology:*
 - Review of the already existing information on:
 - Presence of pharmaceutical chemicals in the environment
 - Monitoring of the presence of pharmaceutical chemicals in surface and underground water
 - Monitoring of the presence of pharmaceutical chemicals in wildlife
 - Persistence of pharmaceutical chemicals in the environment
 - Human health and environmental effects of the persistent, diffuse, long-term exposure to EPPP
 - Identification of vulnerable populations and populations at risk among humans but also in the environment
 - Identify the existing gaps in science and technology and promote research to fulfil them
- *Regulatory framework:*
 - Identification of existing regulations or mechanisms to control EPPP emissions to the environment (conduct a survey including also national experiences)
 - Explore possible coordination mechanisms with other relevant regulations
 - Promote the discussion to define and implement regulations at the global level
 - Explore existing regulations on information on the persistence of pharmaceutical synthetic chemicals on the environment
 - Identification of existing limits for pharmaceutical chemicals in drinking and surface water and the reason those limits were adopted in relation to the protection of human health and the environment.

d) Specific commitments by Governments, civil society, intergovernmental organizations and the private sector, such as international work or partnerships

- *Possible main partners may be:*
 - World Health Organization under Public Health and the Environment
 - UNEP Chemicals
 - Government of Sweden, Government of the United Kingdom, Environmental Protection Agency of the United States of America
 - International Society of Doctors for the Environment, Collegium Ramazzini
 - ICCA and other associations of pharmaceutical producers

e) Relevance, as appropriate, to the Global Plan of Action and the Strategic Approach Overarching Policy Strategy or other mechanism for providing capacity building to proponents.

- This proposal is under the framework of the **Dubai Declaration**
- Relevance to the **Overarching Policy Strategy**

EPPP is a relevant global issue under the scope of the SAICM Overarching Policy Strategy as it affects environmental and health aspects of chemical safety. Pharmaceutical chemicals become undesirable pollutants when present in the environment. EPPP represents a new and emerging issue that pose a problem of important magnitude for human health and the environment. EPPP are not regulated by domestic food or pharmaceutical authorities or arrangements.

- Relevance to the **Global Plan of Action**

To recognize EPPP as a new and emerging issue and being able to include them in the SAICM Global Plan of Action will target a new topic not currently addressed in existing agreements and work areas.

EPPP clearly may be classified as Persistent Bio-accumulative and Toxic Substances (PBTs), some of them with endocrine disrupting and genotoxic characteristics that may affect reproductive, endocrine, immune and nervous systems, affecting human health and the environment.

The proposed actions can be summarized as follows:

The co-facilitators have drawn attention to the increasing but still low concentrations of pharmaceuticals in the environment and the evolving state of knowledge on potential environmental and health and safety risks. A range of cooperative actions is proposed, including raising awareness, sharing existing information and undertaking cooperative work. The attention of the Conference is drawn to the possible need to undertake intersessional work to explore issues relevant to developing countries and countries with economies in transition, and to a possible amendment to the Global Plan of Action of the Strategic Approach so as to include new work areas for pharmaceuticals.