Global Consultation on Chemicals and Waste Issues of Concern
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Challenges and Opportunities in Sound Management of Chemicals and Waste Issues of Concern

This document contains a full extraction of the challenges and opportunities in the sound management of issues of concern taken from the Assessment Report on Issues of Concern. It has been prepared to support the discussions of the Global Consultation on Chemicals and Waste Issues of Concern taking place 11-12 July 2023. The document is intended for ease of reference to the points raised in the Assessment Report on Issues of Concern.

The 19 issues of concern covered below are ordered by the groupings in reflection of the structure of the Global Consultation.

Metals and Metalloids: (Arsenic, Cadmium, Lead, Lead in Paint, and Organotins)

Chemicals in Products 1 (Endocrine disrupting chemicals (EDCs); Phthalates; Bisphenol A (BPA); Microplastics; Polycyclic Aromatic Hydrocarbons (PAHs))

Chemicals in Products 2 (Chemicals in Products; Hazardous Substances in the Lifecycle of Electrical and Electronic Products (HSLEEP); Nanotechnology and Manufactured Nanomaterials and Per- and Polyfluoroalkyl Substances (PFASs) and the transition to safer alternatives).

Bioactive Substances (Highly Hazardous Pesticides; Glyphosate; Neonicotinoids, Triclosan and Environmentally Persistent Pharmaceutical Products)

Arsenic

Challenges and Opportunities in Sound Management of Arsenic

Addressing global exposure to arsenic and arsenic compounds is critical, due to ubiquitous exposures around the world and the resulting significant human health impacts and thus associated societal costs.

At the same time, addressing global exposure to arsenic and arsenic compounds is complex. First, it involves different strategies for a wide range of sources, from natural sources that are not controllable and may contribute to significant exposure (particularly through drinking water in many places), to unintentional releases during mining and fossil combustion, to multiple intentional uses. Second, while many sources may have only local influence, others may also influence places far away from the original sources through long-range transport via air (e.g. atmospheric emissions from fossil combustion) and global trade of goods including foodstuffs. Third, substantial releases have been made and accumulated over centuries.

Current instruments and actions, while important for addressing several particular issues in some specific countries and regions, are far from comprehensive in addressing current widespread exposure to arsenic and arsenic compounds at the global level.

The continuous releases of arsenic and arsenic compounds in large volumes, both from unintentional anthropogenic sources and from intentional production, use and disposal at current levels, will further exacerbate the global pollution and burden of disease related to arsenic exposure. ***Therefore, further international concerted actions that cover all major sources are urgently needed to address arsenic in an integrated and holistic manner, possibly through legally binding instruments.***

Notably, while arsenic and arsenic compounds differ from mercury with regard to some properties (for example, mercury has higher atmospheric transport potential in general), the challenges associated with addressing global exposure to arsenic and mercury are generally similar (as described above). As naturally occurring elements that are intentionally used by people, these challenges are also shared by other metals such as cadmium (see Section 4.3) and lead (see Section 4.5). In particular, arsenic, cadmium, lead and mercury share several major unintentional anthropogenic sources, including fossil fuel and coal combustion, as well as mining and smelting of metals. Hence, similarities between arsenic, mercury, cadmium and lead need to be taken into consideration for future actions, particularly at the international level, in order to capitalize on any possible synergies.

Cadmium

Challenges and Opportunities in Sound Management of Cadmium.

Sound management of cadmium is critical given the toxic metal's capacity to cause significant adverse effects on human health and the environment at very low levels. Substantial progress has been made in managing cadmium, as shown in the decrease of cadmium emissions and levels in air in some parts of the world. However, ***these existing efforts are likely still inadequate to eliminate or minimise cadmium exposures from anthropogenic sources globally as a whole*** (see Section 4.3.2). Emissions from growing coal combustion, metal smelting and other sources are quickly increasing in some parts of the world. Along-side these increases come higher occupational exposures as well, and recent GBD studies estimated steady (and possibly increasing) numbers of deaths and DALYs each year associated with occupational exposure to cadmium.

Addressing cadmium can be complex, not only due to the diversity and prevalence of sources around the world, but also due to many other factors. For example, cadmium is not mined on its own, but rather produced as a by-product of zinc; this means that ***simply reducing cadmium demand by restricting or banning its use may not effectively limit its global production***. A sound management of cadmium during and after mining and processing of zinc is also crucial, in order to minimise releases into air, water and soil and to reduce occupational exposures.

An increased demand for cadmium in some uses may help reduce its emissions in others. For example, as the demand for renewable energy sources increases in light of the current global climate crisis, so will the use of photovoltaics and batteries that contain cadmium. The expected advantages will be less fossil fuel combustion for energy and transport, which will in turn reduce far-reaching atmospheric emissions of cadmium and other contaminants. However, these same products could become a source of cadmium-containing wastes at the end of their lifetimes, which may present longer-term local and regional challenges, particularly for developing and transition countries. Thus, ***future international concerted actions need to take such trade-offs into consideration***.

While sound management of cadmium is complex, much can be learned from the global sound management of arsenic (see Section 4.1), lead (see Section 4.5), and mercury.

These elements have many similarities: each is naturally occurring, is emitted in coal combustion and other similar human activities, appears in foodstuffs and products in everyday life, and can be successfully addressed with international actions.

Lead

Challenges and Opportunities in Sound Management of Lead

The dangers of lead and lead compounds have been known for over a century.

The ILO adopted its first formal recommendation concerning the protection of women and children against lead poisoning in 1919. More recently, scientific evidence continues to show no safe levels of lead exposure for children and that very low levels of lead can cause severe adverse health effects, including cancer risks in people of all ages (see Section 4.5.1).

This knowledge led to, for example, considerable international and national efforts to virtually eliminate leaded petrol worldwide.

The overall global benefits of the phase-out of leaded petrol have been estimated to be about USD$2.45 trillion per year, and in the US, the benefit-to-cost ratio was at least 10:1.

However, ***efforts to date are likely to be inadequate to eliminate or minimise lead exposures from other anthropogenic sources***. As reviewed in Section 4.5.2, new emissions from growing coal combustion and other sources have likely offset the reduction by the phase-out of leaded petrol, particularly in developing countries. This is also clearly shown in the estimated steady (and possibly increasing) numbers of deaths and DALYs each year from the GBD studies.

Therefore, ***considering the successful story of the global phase-out of leaded petrol, the international community as a whole can step up action to address lead exposure in a much more comprehensive manner. This message has been reiterated many times at different international forums since the World Summit of Sustainable Development in 2002*** (for examples, see Table B5–2 in the Annex and UNEP n.d.). Action needs to be taken not only to address sources that may result in exposure far away from the original sources through long-range transport via air (e.g., from fossil combustion, smelting of metals), but also with regard to sources for which exposure may occur only locally or regionally. Local or regional effects may travel far (e.g., in the case of migratory species); many of them are common across countries and regions; and some are closely associated with global supply chains.

While the sources of lead exposure are complex due to the metal's diversity and prevalence, much can be learned from the global sound management of arsenic, cadmium (see Sections 4.1 and 4.3) and mercury. These elements have many similarities: each is naturally occurring, is emitted in coal combustion and other similar human activities, appears in foodstuffs and products in everyday life, and can be successfully addressed with international actions.

Lead in Paint

Current Challenges and Opportunities in Sound Management of Lead Paint

Stepping up global efforts in phasing out lead paints.

To date, the majority of countries have yet to remove all lead paints from their markets. Not only does this lack of action influence lead exposure in these countries, it may also impact other countries.

In an effort to encourage national level actions on issues of concern under SAICM, including lead in paint, a GEF project, "Global Best Practices on Emerging Chemical Policy Issues of Concern under the Strategic Approach to International Chemicals Management (SAICM)", is being implemented. One component is to assist the governments of 40 countries in developing and implementing legislation to restrict the use of lead paint; another is to work with at least 50 small and medium enterprises (SME) that manufacture paint in eight countries to phase out lead from their production processes by 2020.

While this GEF project will contribute to an important milestone in the global phase-out of lead paints, the 2020 targets of the GAELP will not be achieved. Thus, stepping up global efforts is needed to ensure a complete phase-out by non-participatory countries of the GEF project, including scaling up awareness-raising activities and technical assistance in establishing legal limits. Global efforts also could include a consideration of establishing legally binding instruments together with the other uses of lead (see Chapter 4.5).

In addition, the scope of control measures may vary considerably among countries with legally binding or voluntary instruments (e.g. restrictions for all paints vs. only house paints, limits on soluble lead vs. total lead). Not all these instruments are as protective as they are intended to be, and thus, efforts are needed to evaluate their effectiveness and improve them if necessary (e.g. addressing industrial paints in addition to consumer paints). Furthermore, parallel efforts addressing the trade of lead pigments may also be useful in accelerating the phase-out in countries still using lead paints. These two additional aspects also need to be taken into consideration for stepping up global efforts.

At national scales, innovative initiatives to foster voluntary actions should also be considered and encouraged. Such measures could include establishing independent third-party verification schemes and the use of economic tools and incentives that target both supply and demand, including possible levies to increase the cost of lead paint or subsidies for lead-free paint.

Effective monitoring and enforcement.

While lead paint regulations have been adopted and implemented in many countries, monitoring and enforcement is still an issue in some of these countries. Continued manufacture and sale of lead paints has been observed in some of these countries, as well as continued formal and informal trade of paints, goods and articles containing high lead content in some cases (e.g. the US Consumer Products Safety Commission continues to issue violation notices for products that exceed US regulatory levels on lead in paint in children's products). Efforts should also be made to foster effective monitoring and enforcement in all countries, including ensuring the presence of necessary laboratory infrastructure and scientific and other capacities in developing and transition countries.

Small and medium-sized companies and informal economy.

Although alternatives to lead paint are available, a number of SME and informal economy participants face obstacles in reformulating their paints, e.g. a lack of awareness and knowledge of where they may obtain lead-free raw materials. Their specific needs should be taken into consideration when designing and implementing suitable instruments to address the sound management of lead in paint, e.g. by including components that provide technical and financial assistance to SME.

Organotins

Challenges and Opportunities in Sound Management of Organotins

The high toxicity that organotins have on human health and the environment, as briefly summarised in Section 4.2.1, makes it clear that sound management of these compounds is imperative. ***Efforts have been made to address environmental and human exposure to organotins, particularly with regard to their use in anti-fouling paints on ships. Success in some regions has brought many benefits to society***: For example, the regulation of tributyltin in the EU has been estimated to benefit commercial fishing about €22–€158 million per year because of protected marine fisheries; in contrast, no regulation would have led to €21–€237 million in remediation costs in the EU.

However, ***current efforts are rather fragmented and likely not enough, as shown by continued contamination and exposure*** (reported in Section 4.2.2). Tributyltin levels in many places have not yet declined due to ongoing uses. In addition, ongoing uses of many organotins, including as biocides and pesticides, in many parts of the world remain significant and are of concern.

While further investigation may be needed to understand the magnitude of current exposure from these ongoing uses (including from PVC recycling), ***immediate actions can be taken by more governments and stakeholders to minimise environmental and human exposure to the large family of organotins***. Given the widespread use and contamination of organotins (and long-range transport potential of some organotins), ***international concerted action may also be warranted***. Existing instruments and actions may be used as models to inform future actions at national, regional and international levels, as described above.

EDCs

Current Challenges and Opportunities in Sound Management of EDCs

Research on EDCs has been a fast-growing scientific field and has expanded over the past several decades. While some knowledge gaps are yet to be addressed by the scientific community, the current level of knowledge and concern over potential significant impacts of EDCs on the environment and human health warrant swift actions. Sound management of EDCs faces a number of challenges, which in turn present great opportunities for global actions.

Bringing countries to the same level of awareness and knowledge.

The current states of actions and knowledge of the state-of-the-art science in different countries on the issue of EDCs vary considerably. Awareness has been built within and among developed countries, which has resulted in concrete actions addressing EDCs. In contrast, increased awareness raising and information sharing on the issues remains necessary in countries in the African, Asian and Pacific, Central and Eastern European, and Latin American and Caribbean regions, possibly in local languages. This may enable those countries and regions' work on EDCs, including integrating EDCs into their national and regional regulatory and policy frameworks.

In addition, the rapid developments in the science of EDCs warrants regular assessment and synthesis of scientific knowledge in a format that is ready to be used by policymakers around the world, e.g. modelled on the state-of-the-science reports on EDCs in 2002 and 2012.

Bridging different approaches to assessing and managing EDCs.

Countries have taken different approaches to assessing and managing EDCs. As a result, some chemicals may be identified as EDCs and regulated by some countries but not by others. Any resulting policy inconsistencies across countries could hamper sound management of EDCs internationally.

In addition, over 1,400 chemicals have been documented to have possible endocrine-disrupting properties, supported by evidence from at least one peer-reviewed study. A tremendous amount of human and financial resources will be needed to test and assess all of these compounds and identify EDCs, not to mention the many more as-yet-untested chemicals that may require testing and assessment.

Therefore, within the policy arena, strengthened dialogues and concerted actions at the national, regional and international levels could enable an effective and efficient way forward. Initial steps for informed decision-making and action globally include further development and implementation of, for example, standard data requirements and testing methods, mutual acceptance of data and existing assessments, joint assessments and joint strategies.

An important milestone could be the exploration of the possible inclusion of EDCs in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); this action could be supported by other countries and stakeholders. Under the auspices of the Organisation for Economic Co-operation and Development (OECD), efforts have been made and are ongoing to further develop

standardized testing guidelines and data interpretation tools; such work could be further strengthened and adopted by non-OECD countries.

Phthalates

Challenges and Opportunities in Sound Management of Phthalates

Concentrations of many phthalates, particularly of those considered to have the greatest risks to human health, have been declining over time. Presumably these declines have occurred in response to legal restrictions. However, ***human biomonitoring studies continue to show almost 100% detection frequencies of these restricted phthalates, with higher levels among people living in poverty as well as in children and adolescents***. Phthalates and other plasticizers remain among the most abundant of all semi-volatile organic compounds measured in indoor environments, especially in low-income housing. It remains to be seen whether male reproductive abnormalities associated with exposure to phthalates with chain lengths of 4 to 6 will decline as exposures decline. At the same time, as exposures to many phthalates are decreasing, production of and exposures to alternative plasticizers are increasing. Therefore, several challenges remain for phthalates.

The first challenge comes in finding data on current and temporal trends for global production.

Such data are needed to judge whether levels are decreasing in some populations at the expense of increases in other populations. Data clearly show decreasing exposure to and production of phthalates in the US, but also increased production in China, which could translate to higher exposures there.

Other challenges stem from protecting subpopulations at higher risk. ***Low-income populations have higher exposures to phthalates than high-income populations.*** Reasons for higher exposures among low-income populations are not clear. It could be related to more widespread use of vinyl building materials such as vinyl flooring in low-income housing. If that is the case, then such populations could experience prolonged exposure due to the long lifespans of these materials. Another possible reason for high exposure is the consumption of highly processed foods in plasticizer-treated packaging, rather than fresh foods with minimal packaging that may be less affordable. It is noteworthy that phthalates have been restricted but not eliminated from use in food contact materials, for example, in the EU.

Regional and national restrictions on the use of certain phthalates (in the EU, US and Canada, for example) pertain to uses in children's toys and products. However, the most vulnerable life stage for adverse effects is the foetus, which means that exposures need to be limited for women of childbearing years, who are not the target population for restrictions on children's products. ***Therefore, more comprehensive sets of instruments and actions in most countries are needed to address exposure for all vulnerable populations***.

A growing challenge is the "regrettable substitution" of phthalates with other plasticizers that could be hazardous. For example, DEHP, which has been classified as a possible human carcin-ogen by IARC, has been substituted with DiNP as a plasticizer of PVC in numerous applications. Evidence from animal testing indicates that DiNP could be carcinogenic and could also cause endocrine disruption. Other substitutes include terephthalates (para-substituted phthalic acid), meta-substituted phthalate di-esters (e.g., DINCH), phosphate esters, citrates and sebacates. Thus, ***future development of regulatory and voluntary instruments and actions need to be mindful of implications for substitution***.

BPA

Challenges and Opportunities in Sound Management of BPA

While progress is being made, substantial gaps remain in addressing BPA exposure, as indicated by the estimated increase of BPA intake by adults around the world.

Foremost, action needs to be scaled up to address all relevant exposure sources, taking into account possible challenges and uncertainties related to disposal and recycling of thermal paper and plastics. In addition, the increasing agricultural use of reclaimed water and sewage sludge may also lead to adverse effects by BPA on soil organisms, and further investigation is necessary in these areas.

Low-dose effects and different subgroups' susceptibility or vulnerability also needs to be considered.

Several experimental studies have shown that BPA exposure during the perinatal period or childhood to adulthood affects innate and adaptive immune responses at levels relevant to human exposure, or equivalent to or lower than current EFSA tTDI. Furthermore, the CLARITY-BPA program studies identified consistent low-dose effects that demonstrated adverse effects of BPA at relevant doses to human exposure. Therefore, the health risks of low-dose exposure that consider sensitive and vulnerable populations (e.g. patients, pregnant women and children) need to be determined and inform existing and future instruments and actions.

Furthermore, the use of BPA analogues such as BPS and BPF has increased as replacements for BPA where it is being phased out, while recent studies have also pointed out that these chemicals may cause similar adverse effects as BPA does, though with different potencies. For example, measured levels of BPA and BPA analogues in thermal papers from 14 countries and detected BPA at the highest frequency, followed by BPS. Annual production volumes of BPA analogues are increasing, even as BPA production decreases, with the reported production volumes above 1,000 tonnes per year in some cases. Recent reports of BPA and its analogues BPS and BPF in children and adults found nanogram/millilitre levels in the US, Canada, China and elsewhere. However, overall the measured data for BPA analogues were quite limited and current scientific knowledge is lacking. ***Hence, in light of existing scientific evidence of potential adverse effects, further studies need to be conducted and actions taken to determine and manage the health risks of these BPA analogues, complemented by regular biomonitoring, so as to avoid regrettable substitutions to BPA.***

Microplastics

Challenges and Opportunities in Sound Management of Intentionally Added Microplastics

Microplastics are ubiquitous in the environment and come from many different sources. While ***contributions from individual sources to the overall burden are not yet fully understood, it is certain that continuous use and releases of microplastics will result in increasing accumulation of microplastics in the environment and thus increasing exposure and risks***. It is encouraging that many countries and stakeholders have taken actions to address microplastics in rinse-off products. However, the current level of action is not yet adequate for addressing sound management of intentionally added microplastics.

Foremost, the current actions to ban microplastics in rinse-off products need to be expanded to cover those countries and regions that have taken no action, and to cover other intentional uses of microplastics.

In particular, future actions addressing intentionally added microplastics need ***to start from the product design phase***, to avoid the need for monitoring and clean-up in later life cycle stages if possible, at all. To do so, it may be worthwhile to first have an international discussion on a common definition of "microplastics", as they are often defined differently under different instruments and actions in different jurisdictions.

Furthermore, in addition to intentionally added microplastics, ***other sources such as unintentionally formed microplastics during the production and processing of larger plastics and secondary microplastics that are a result of progressive degradation of larger plastics during their life cycles, including in the environment, need to be properly addressed***, possibly in the larger context of addressing plastics overall.

PAHs

Challenges and Opportunities in Sound Management of PAHs in Consumer Products

There is a dearth of relevant legislation to control PAH exposure from consumer items. Voluntary standards alone are unlikely to be able to address PAHs in consumer products due to their current limited scope in terms of geographic coverage or product categories. Therefore, it may be necessary to raise global awareness towards establishment and implementation of legally binding instruments for addressing PAHs in consumer products across different jurisdictions. In particular, occupational and consumer exposures associated with recycled waste tyres should be taken into consideration. Also, exposure from foodstuffs and packaging needs to be carefully addressed, as these are the most widespread and immediately relevant human health exposures.

With regard to foodstuffs, although food items generally meet guideline values issued in legislation from multiple countries, food processing standards may be fostered to minimise PAH contamination.

For example, studies have shown that proper washing procedures can reduce the levels of higher-molecular-weight PAHs in food items; this is because these heavier PAHs, deposited on plants from the atmosphere, do not diffuse into plants and instead stay adhered to the dust deposited on plant surfaces. Similarly, various refining procedures can remove PAHs dissolved in edible oils. And different processing techniques can minimise many of the PAHs in foods that originate from thermal processes during which food items come in contact with combustion gases.

Finally, ***the use of reference PAHs needs to be carefully considered, and expanded beyond the sole use of BaP***. The motivation behind using BaP as a reference compound for the presence of PAHs in general was the numerous toxicological studies available for the substance. However, due to the large variety of PAH mixtures, some products may contain different PAHs but not BaP. In such cases, testing for the presence of PAHs using a single reference chemical will lead to false negatives. Therefore, it may be better to take into account the total levels of multiple PAHs in products, building on existing grouping methods (see Table B10–3 in the Annex).

CiP

Current Challenges and Opportunities in Addressing CiP Information Exchange

By comparing the information objectives set in the CiP Programme and existing instruments, the following challenges and opportunities can be identified. Overarching challenges and opportunities include how to communicate, expand and scale up existing instruments and lessons learned in one specific region or sector to other regions or sectors, particularly for developing and transition countries.

From restricted substances to full disclosure.

While chemical information is often available in the upstream side of a supply chain, downstream companies have reported difficulties in identifying chemicals in materials and products because relevant information was not communicated to them in usable forms in their supply chains, was lost along the supply chain, or was protected as confidential business information. Today, a passive approach is commonly used by many companies by communicating throughout their supply chain which chemicals should not be present in their products. This approach has a relatively low initial cost and needs no extra investment for inventorying chemical ingredients, requires no consideration of product reformulation, and shifts the responsibility for product verification and testing to the upstream supplier. However, this approach has its limitations, as the science around chemicals evolves fast, new chemicals of concern may be identified before companies can update their lists, and companies may have a hard time keeping up with changes, including identifying the suspect chemicals in their supply chain and then reacting.

Therefore, the more active approach should be promoted and fostered, in line with the first information objective identified in the CiP Programme, by building on existing regulatory and voluntary initiatives, including existing legal labelling requirements for cosmetics, personal care products and food additives. Benefits of this approach include the ability to quickly address rapid changes in market and regulatory requirements with much lower costs for crisis management, increased sales and improved brand reputation, increased supply chain reliability and quality, and better and more innovative products. As the number of chemicals regulated in the future is likely to increase, knowing which chemicals are in products (i.e. by applying the active approach) could ease the otherwise challenging task of ensuring that chemicals of concern are not present in a product in the future.

Getting the information to designers, consumers, regulators and waste managers.

In many sectors, the existing instruments and actions have focused on information exchange within supply chains, but not further transfer of the information to designers, consumers, regulators, waste managers and workers (both formal and informal). As a result, for example, a lack of data on the chemical content in products hampers assessing and managing chemical exposure through products by these stakeholders, including those who may be considered vulnerable populations (e.g. pregnant women, children and elderly people).

With the increasing global interest in creating so-called circular economies, in which materials do not become “waste” but are always repurposed, information must be available at all stages of a

product's life. Communication of CiP information must reach the designers, consumers and end-of-life sector in an easy-to-understand format. Those working in the recycling and waste handling industry need to know if they face exposure to harmful chemicals when handling and recycling certain products and if the recycling of those products could possibly (re)introduce contaminants into the supply chain, as seen by recent studies that found high levels of heavy metals, brominated flame retardants and other chemicals of concern in recycled materials.

Therefore, for these sectors, CiP information exchange remains to be extended to actors outside supply chains, in line with the second information objective identified in the CiP Programme (see Section 3.1.1 above). This can be challenging, given the complexity of today's supply chains; for example, the production, use and recycling phases of a product's life may occur in different parts of the world. Studies are thus warranted on the feasibility of existing instruments such as taxes and fiscal policies, extended producer responsibility policies and corporate sustainability reporting, and new public-private partnerships for strengthening CiP information exchange within and outside supply chains. Additional challenges may be related to protection of intellectual property and possible concerns that consumers, regulators and waste managers may be overwhelmed by CiP information. However, exploring possible solutions may be worthwhile with current technologies, such as smartphone apps and "big data" to address these challenges.

Effective monitoring and enforcement.

In line with the information objectives of the CiP Programme, CiP information needs to be relevant, accurate, current and accessible, which is still often not the case. In a recent Forum Pilot Project on enforcement in 15 participating European Union (EU) countries, inspectors found that 12% of inspected products contained Substances of Very High Concern (SVHC), and the majority (88%) of suppliers of these products failed to communicate sufficient information to their customers about SVHC in products they supply.

A key component to ensure the proper functioning and trust of the whole system of communicating CiP information is effective monitoring and enforcement. For this, both regulatory and voluntary approaches may be considered (e.g. brands internally check whether their suppliers follow company policies on CiP information exchange; regulators, civil society organisations and others conduct sampling campaigns of products on the market to check accuracy of product labels and whether legal requirements have been satisfied). Voluntary approaches may learn from (and build on) existing initiatives such as the "Mind the Store" (https://saferchemicals.org/mind-the-store) and the "Chemical Foot-print" Project (https://www.chemicalfootprint.org/), created by the US-based non-profit organisations Safer Chemicals, Healthy Families and Clean Production Action, respectively.

HSLEEP

Challenges and Opportunities for Sound Management of HSLEEP

Stepping up global action to address the early life-cycle stages of EEP.

Many instruments and actions have focused on e-waste, i.e. the end-of-life stage of EEP. Although an increasing number of countries have set up their own laws to restrict certain chemicals in EEP, complemented by voluntary restrictions by some manufacturers, the current level of such efforts is likely still not adequate. In particular, the coverage of such instruments has often been limited to a handful of chemicals. Therefore, a more proactive approach in all countries to addressing the early life-cycle stages of EEP needs to be considered, including levies.

Such a shift may arise from fostering a better understanding and assessments of chemicals in EEP, e.g. in conjunction with actions to address CiP. Such knowledge can be used to inform and foster a new generation of "green" (environmentally friendly or following the principles of "green chemistry") EEP made with minimal use of hazardous substances and by green manufacturing processes.

The use of some hazardous substances in EEP may be unavoidable because those substances confer unique functionalities, such as tantalum. Product design and associated regulations need to take such cases into account to minimise exposure throughout every step of the EEP life cycle. For example, some flame retardants such as those surrounding the batteries of consumer devices appear to confer safety, but flammability standards pertaining to outer casings of EEP merit reassessment. Also, design decisions could be made to reduce the need for flame retardants that can migrate from plastic casings.

Regular compilation and sharing of best practices may be considered.

Furthermore, with projected increases in digitalisation, global population growth and other factors, the use of EEP will likely grow and thus exacerbate current challenges in handling hazardous substances in EEP and e-waste. Therefore, novel action may also be taken to increase the longevity of products, for example, by mapping drivers and barriers for product longevity, developing best practices guidelines on product design, and encouraging the growth of repair and recycling sectors; fuelling shifts in consumer behaviour through increased awareness of sustainable consumption; and scaling up voluntary initiatives and sustainable business models such as product leasing, where producers lease the functionality of EEP and remain responsible for all stages of the EEP life cycle.

Addressing the needs of informal sectors.

In developing and transition countries, a substantial fraction of e-waste is handled by informal sectors, often with limited awareness of hazardous substances in EEP and minimal protection. Therefore, efforts are needed to improve understanding of the role and impact of the informal sectors in these countries and thus explore concrete steps to reduce the exposure of informal workers, including through promotion of best practices and extended producer responsibility. This can be used as an opportunity to foster local jobs and economic development while ensuring occupational safety and environmental sustainability.

Nanotechnology and Manufactured Nanomaterials

Current Challenges and Opportunities in Sound Management of Nanotechnology and Manufactured Nanomaterials

Fostering wider integration of nanomaterials in regulatory data requirements.

Despite the existence of some databases and registries, perhaps the largest gaps in knowledge necessary for regulation and sustainable management of nanomaterials are production, use and end-of-life of nanomaterials. For example, car tires with silica (SiO2) nanoparticles embedded in them are now transported all over the world for use and may be shedding nanomaterials during use and then transported to other sites for recycling and end-of-life management. While these nanoparticles have benefits such as reducing tyre friction to lower fuel consumption and vehicle emissions, where they end up in the environment is ultimately unknown. Academic and commercial interests remain high in developed countries, which have great capacity to develop and use nanomaterials in everything from medicine to agriculture to consumer products, but policymakers have yet to follow up on these rapid developments and the fast-growing introduction of these materials markets and waste streams. There exists a need to adapt regulatory data requirements around the world to take into account the properties and life cycles of nanomaterials, and thus inform hazard and risk assessments.

Working towards a common definition and grouping strategies.

While the wide-ranging types and applications of nanomaterials may justify a product-specific regulatory approach, this could lead to regulatory gaps. A particular challenge of nanotechnology regulations is that in contrast to “conventional” chemical substances, nanomaterials cannot be identified and assessed based on their chemical identity alone (i.e. they cannot be regulated based on CAS numbers). Their physical characteristics (e.g. size/size distribution, shape, density, surface characteristics) strongly affect nanomaterials’ behaviour and hence potential risks. As a result, no uniform definition exists and currently, different regulatory instruments apply different definitions.

The classification and grouping of similar nanomaterials, or nanoforms as defined under REACH, presents challenges. The wide range of possible properties and unavoidable heterogeneity of nanomaterial-containing samples makes it difficult to define criteria and thresholds for grouping.

Fostering scientific development to reduce uncertainties in sound management of nanomaterials. Challenges in the analysis of nanomaterials and especially related to their detection, identification, characterization and quantification in product samples makes it unlikely that regulations could truly be enforced at present. More work is needed to develop new analytical tools or further develop existing ones until robust and routine high-throughput methods are available.

In many ways, hypotheses from the first development of nanomaterials more than two decades ago regarding the environmental and human health impacts of these materials remain current today. Environmental impacts have been documented, for example, for nanosilver, but whether these effects are from nanosilver or from the behaviour of ionic silver from the bulk form remains unclear. Metal, metal-oxideand carbon nanomaterials have been shown to be toxic to cells in laboratory tests, but are difficult to track in the environment (e.g., carbon nanotubes behave similarly to asbestos but are harder to detect in soils). These issues could make specific regulatory actions difficult. Despite the unknowns, safety outlooks for nanomaterials have been published, for example, by the Republic of Korea (Ministry of Environment) and Finnish Institute of Occupational

Health at the request of the European Commission, with strategic priorities for protecting human and environmental health.

At the international level, enabling a systematic assessment of the risks of manufactured nanomaterials may be considered. In addition to further developing standardized tests, it would be useful to validate and possibly harmonise existing testing methods to facilitate comparison and reliability of data.

PFASs

Challenges and Opportunities in Sound Management of PFASs

Accelerating the global implementation of phasing out long-chain PFASs.

The current and forthcoming listings of long-chain PFASs under the Stockholm Convention will be a key force to address these contaminants at the global scale. However, some limitations will remain.

In particular, a number of exemptions exist under the Convention, including those for which the Persistent Organic Pollutants Review Committee recommended no need for exemptions during its evaluation and some that may cause substantial direct environmental exposures to humans and ecosystems. Such exemptions would need to be closed as soon as possible to ensure sound management of PFASs.

Also, concerted actions are needed on an ongoing basis to accelerate and expand the current global implementation of phasing out long-chain PFASs under the Convention. For example, as of November 2019, only 86 out of the 183 Parties to the Stockholm Convention incorporated PFOS in their National Implementation Plan, a decade after its initial listing.

Non-regulatory actions may take less time to set up. However, in such cases, measures are needed to avoid geographical shifts in production, major uses and releases into countries with less strict regulations. The progress of phasing out long-chain PFASs needs to be periodically assessed, e.g. under the Global Monitoring Plan under the Stockholm Convention.

Novel approaches to managing PFASs as a group or groups.

Most existing instruments take a chemical-by-chemical approach, which requires enormous amounts of time, societal resources and human resources to assess and manage the thousands of existing PFASs. In some cases, approaches to addressing both the parent compound and precursors as a group have been used (e.g. under the Stockholm Convention). However, this grouping strategy cannot work effectively for the current practices of replacing existing PFASs with novel PFASs with similar structures and properties. Hence, novel regulatory and voluntary approaches need to be developed to assess and manage the many PFASs on the market and their potential fluorinated alternatives as a group or groups.

Notably, the concept of “essential use”, which is modelled from the Montreal Protocol, is emerging as an option for PFASs. It suggests a stepwise approach, namely immediately phasing out all PFAS uses that are not critical for health and safety and the functioning of society, substituting the uses where technically adequate and safe (or safer) alternatives are available, and fostering and scaling up the development and transition of safe alternatives to PFASs, including non-chemical alternatives, for the uses where PFASs are currently essential for health and safety and the functioning of society and where no alternatives are currently available.

Enhancing information exchange between stakeholders and fostering joint actions.

In the case of long-chain PFASs, duplicate efforts often overlap and opportunities for efficiency and information sharing are missed. For example, governments invested substantial resources via publicly funded research to generate information, including the chemical identity, production and uses of many PFASs, often when manufacturers already had this information. Other instances of duplicated efforts include, for example, knowledge generation, chemical assessment and setting

guidance values among governments and stakeholders at the local, national, regional and global scale.

In order to accelerate action on PFASs that are not long-chain compounds and transition to safer alternatives, information exchange needs to be strengthened and joint actions need to be fostered across all stakeholders. For example, information can be exchanged through the OECD/UNEP Global Per-fluorinated Chemicals Group or other international forums, and engagement of downstream industrial users, retailers and insurance companies could be strengthened. Specific working areas may include filling in knowledge and data gaps, ensuring that basic and consistent information on all PFASs and alternatives is available, accessible and visible to all, and fostering transitions to safer alternatives (including making safer alternatives available and accessible to all, particularly those in developing and transition countries).

HHPs

Current Challenges and Opportunities in Sound Management of HHPs

Substantial progress has been made in sound management of pesticides, with a large number of instruments and norms established at the international, regional and national levels. However, current instruments do not comprehensively address the sound management of HHPs at a global scale. Challenges and opportunities for stepping up global efforts are described below. Note that UNEP is currently preparing a report on the environmental and health impacts of pesticides and fertilisers and ways to minimise these impacts, in response to UNEA3 Resolution 3/4. Readers are encouraged to consult that report for more details on some of the items below.

Reducing ambiguity of the criterion for identifying HHPs.

While most criteria recommended by the Joint FAO/WHO Meeting on Pesticide Management (JMPM) are explicit and clear, one criterion remains ambiguous, for "pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment". Currently, whether a pesticide meets this criterion is at the discretion of national regulatory authorities. While this criterion provides important flexibility to countries to identifiy a pesticide as a HHP if it was found to cause severe environmental or health effects in local settings, this ambiguity may also result in inconsistent understanding and implementation across countries. Hence, this criterion needs to be further properly addressed to reduce ambiguity while still allowing sufficient flexibility by countries, for example, under the leadership of FAO, WHO and UNEP, as recommended by the JMPM in its second session. Detailed activities may include, inter alia, developing practical guidance on how to identify severe adverse effects on human health and the environment, and fostering and coordinating international cooperation in supporting developing and transition countries to implement the criterion.

Strengthened support for developing and transition countries.

While most countries have set up their own pesticide legislation, as shown in the latest WHO and FAO global survey, many developing and transition countries still face many challenges for sound management of HHPs, resulting in substantial ongoing use of and exposure to HHPs. For example, paraquat, a pesticide that has been recommended by the Chemical Review Committee for listing under the Rotterdam Convention, is still being used in large quantities in many parts of the world.

This disconnect between international recognition and national action is due to a number of factors. First, as noted in the WHO and FAO global survey, legislation in many countries lacks special provisions for HHPs, for example, to prohibit or restrict their use.

Second, many developing and transition countries lack the necessary resources and capacities to enforce national pesticide legislation. For example, increased efforts for risk assessment are needed in many countries in Asia to justify regulatory decisions, particularly with regard to HHPs. However, only a few have the resources and capacity to carry out a full risk assessment that includes the assessment of local exposure data. An FAO survey in 2011 found that out of 109 developing countries, 97% had fewer than six people working in pesticide registration and regulation and that, of these, 77% had no more than two technical staff dealing with pesticide registration. Also, the equipment in laboratories for quality and residue control is often out-of-date or non-existent in many developing and transition countries, limiting the ability of enforcement.

Third, many developing and transition countries also face high levels of illegal trafficking of illicit pesticides, including HHPs.

Fourth, adequate pesticide management measures including comprehensive labelling, correct use and storage of pesticides, and proper use of personal protective equipment (PPE) are important in managing risks from HHPs; however, farmers in developing and transition countries often lack adequate knowledge and financial resources to implement these measures, as is also true for some of their developed counterparts. Also, the applicability of some PPE may be significantly reduced by thermic and mechanical discomfort.

Furthermore, other issues around sound management of HHPs, including treatment of existing stockpiles and containers as well as availability and accessibility of alternatives to HHPs, may pose additional challenges. For example, in developing countries, empty pesticide containers are frequently discarded in the field, burned, or reused to store food or water, causing significant human and environmental exposure.

In order to address these challenges, concerted international actions are urgently needed in all possible forms to support developing and transition countries in managing HHPs and pesticides in general, including through possible legally binding instruments and partnerships among governments, intergovernmental organisations, civil society organisations, pesticide manufacturers and farmers. Apart from capacity building, these concerted actions may cover areas including the following: increased synthesis and exchange of available and often scattered information on pesticide use, toxicity and exposure and making such information available, accessible and visible to the public and to regulators across the globe (e.g. development of a consolidated list of HHPs by FAO, WHO and/or UNEP); increased research and development of safer alternatives, particularly non-chemical alternatives such as agroecology techniques that minimise chemical uses and methods such as integrated pest management, and making them available, accessible and visible to farmers across the globe; and revisiting national, regional and international legal frameworks for sound pesticide management, including trade, liability, sustainable use of pesticides, and integrated pest management. To do so, strong coordination and leadership at the international level are necessary.

Currently, in collaboration with WHO and UNEP and together with relevant partners, FAO is developing a Global Action Plan on HHPs that aims to bring together key stakeholders and initiatives whose common objective is to eliminate the harm caused by HHPs, consolidate the commitments and efforts of diverse organisations, and challenge stakeholders to commit to working together to achieve significant and measurable change over a specific timeframe.

Glyphosate

Challenges and Opportunities in Sound Management of Glyphosate

Sound management of glyphosate is critical for achieving the SDGs in several ways. ***While its carcinogenicity may still be under discussion and risks of consumer exposure through diet are low, significant risks for non-target terrestrial and aquatic plants may exist, particularly when officially designated risk mitigation measures on product labels are not properly implemented***. Such incidents have been reported in the US (US EPA 2020) and are likely to be prevalent in developing countries due to local farmers' lack of awareness, knowledge or financial resources to implement protective measures developed in other parts of the world (see Section 3.5.2 on highly hazardous pesticides) and the sale of fraudulent products in those markets (see above). In addition, the reliance on glyphosate in many parts of the world has triggered the spread of weeds that have developed resistance to glyphosate; as a result, farmers have increased application rates and this increased use has heightened environmental risks and human exposure.

Furthermore, wide use of glyphosate promotes the adoption of genetically modified glyphosate-tolerant crops, which may significantly influence biodiversity.

The adoption of such crops leads to reduced crop rotation, and weed management that is solely based on the use of herbicides. As a result, while integrated weed management approaches (such as crop rotations, mechanical weeding and inter-mulching) have been promoted for over a decade, herbicides continue to be used as the sole method to control weeds, particularly glyphosate-based herbicide formulations. Agricultural management based on broad-spectrum herbicides such as glyphosate further decreases diversity and abundance of wild plants, and thus has indirect impacts on arthropod fauna and other farmland animals.

While effects such as biodiversity and weed resistance may seem to be local or regional in scale, the widespread nature of the use of glyphosate and glyphosate-tolerant crops and of glyphosate contamination in many parts of the world makes this an international issue.

In particular, international action is warranted for assisting developing countries without the necessary capacity and means to address glyphosate contamination and related problems.

Efforts to address glyphosate need to look beyond chemical substitutions. For example, glyphosate and crops genetically modified to be tolerant to the herbicide are now being replaced by another broad-spectrum herbicide, dicamba, and dicamba-tolerant crops. However, this alternative combination has essentially the same impact on biodiversity as glyphosate and glyphosate-tolerant crops. In addition, recent evidence shows that even the new generation of dicamba formulations cannot prevent high volatilisation of dicamba, as well as accompanying human injury; in combination with its high toxicity, dicamba may cause more environmental risks on off-field non-target plants. Therefore, future efforts to manage glyphosate risks need to incorporate lessons learned from glyphosate and glyphosate-tolerant crops. A transition towards alternatives that minimise chemical use such as agroecological techniques and integrated pest management and other solutions could improve the sustainability of urban and agronomic systems while preserving human and environmental health.

Neonicotinoids

Challenges and Opportunities in Sound Management of Neonicotinoids

Neonicotinoids as a class were meant to be a safer alternative to many older generations of pesticides, including in malaria vector control. They rapidly became some of the most widely used insecticides in the world. They have been used in large quantities in most of the world, which has resulted in ubiquitous, extensive exposure. Recent assessments clearly demonstrate that a wide range of neonicotinoid uses may result in significant risks of concern to bees, other wildlife and humans. In addition, scientific evidence shows that ***the various compounds have complex exchanges among environmental compartments, persist in water and soil environments, and may be transported off-field, and that bees, other wildlife and humans may be exposed to them through many different routes***.

Due to public concern about neonicotinoids, a number of countries and stakeholders have taken steps to limit uses and exposure to them through legal bans, restrictions, requirements of personnel protection equipment and labelling, voluntary phase-out, and third-par-ty standards and certification schemes. However, **these efforts are likely not enough to address neonicotinoids as a whole**, due to the many challenges that have been elaborated in Section 3.5 on Highly Hazardous Pesticides.

In particular, while current measures contribute to solving issues in many developed countries, ***developing countries lack adequate measures to address neonicotinoid exposure***. Third-party standards and certifications may contribute to reducing some exposure in developing countries; however, they focus primarily on agriculture products for export and neonicotinoids may still be permitted to be used in agriculture production for domestic consumption.

As elaborated in Section 3.5, factors that need to be taken into account include financial and human capacities in developing countries, accessibility to suitable personnel protection equipment and their alternatives, and education of farmers and other users. ***These needs require international action, for example, under an international framework of sound management of Highly Hazardous Pesticides. Efforts to reduce exposure to neonicotinoids need to look beyond substitutions with other chemicals having similar mechanisms and effects*** (e.g. sulfoxaflor, flupyradifurone), ***and towards alternative techniques that minimise chemical uses***, such as agroecological techniques and integrated pest management.

Triclosan

Challenges and Opportunities in Sound Management of Triclosan

Due to such characteristics as low persistence in most environmental media and low long-range transport potential, the impact of triclosan remains largely local. However, ***its ubiquitous use may be a major cause of concern and a focus for international actions***.

Considerable progress has been made, through the development and implementation of different instruments, to reduce environmental and human exposures to triclosan in the foreseeable future. However, ***the current instruments and actions on triclosan have limitations, in terms of geographical coverage and their respective scopes***. In particular, most of them focus only on cosmetics and personal care products. While these are major uses of triclosan, other smaller but still significant uses (e.g. uses in paints; disinfection and medical uses; in plastics, toys and appliances) exist without limited oversight and control. Also, in many countries, as the permissible concentration limit in cosmetics and personal care products is set to 0.3%, continuous use and release can be expected. This may be particularly an issue for countries without proper wastewater treatment facilities.

Therefore, considering the limited efficacies of triclosan in certain products, as shown by existing evidence, ***future action may focus on reduction and elimination of triclosan in all uses where no evidence-based health benefits are shown***. While such action would be mostly taken on the national level, the ***international community may share assessment results and lessons learned*** so as to avoid repeated efforts to assess triclosan, particularly for developing and transition countries. In addition, ***the international community may also look into other antimicrobial chemicals for the same or similar uses as triclosan***. They include chemicals that are structurally similar to triclosan [e.g. 5-chloro-2-(4-chloro-phenoxy)phenol, a congener of triclosan that has one less chlorine atom; triclocarban]. Replacements that have very different molecular structures from triclosan, but which still have similar hazardous properties, such as high toxicity to aquatic organisms, have been introduced but could prove to be regrettable substitutions (e.g. benzalkonium chloride; see Table B11–2 in the Annex).

EPPPs

Current Challenges and Opportunities in Sound Management of EPPPs

Expanding the scope from EPPPs to pharmaceuticals in the environment.

Under SAICM, the current designation of EPPPs is limited to pharmaceutical pollutants that "are designed to be slowly degradable or even non-degradable" and "resist chemical degradation during passage through the human or animal body", as "they present a special risk when they or their active metabolites or degradants enter, persist, and disseminate in the environment". This specific scope needs to be expanded to a more general scope of "pharmaceuticals in the environment" in order to include those pharmaceutical pollutants that are not environmentally persistent. These include those that are "pseudo"-persistent, which may not be long-lasting (persistent) in the environment but may still accumulate in the environment due to continuous use and releases, and those that may cause effects that are difficult to reverse, such as antimicrobial resistance. A broader scope would also avoid the need for developing criteria for which pharmaceutical pollutants can be regarded as EPPPs, criteria which are currently lacking under SAICM.

Step up global efforts to prevent pharmaceutical pollutants from entering waste streams.

Preventing pharmaceuticals from entering waste streams in the first place is an effective solution to sound management, due to the financial and technical challenges associated with the treatment of pharmaceutical pollutants once they become waste. While encouraging efforts have been initiated to tackle different life-cycle stages of pharmaceuticals — including marketing authorisation, use and prescription, and collection of unused pharmaceuticals — these efforts are still limited in their success, particularly in terms of their geographical coverage, participating stakeholders, or coverage for the type of pharmaceuticals addressed. Hence, global efforts to prevent pharmaceutical pollutants from entering waste streams need to be stepped up in areas including, inter alia, the following:

Strengthened support of developing and transition countries.

Developing and transition countries often face different challenges than their developed counterparts. For example, different drugs are more common in the environment in Africa, such as antimalarial and antiretroviral drugs, as well as low-cost pharmaceuticals, as opposed to more expensive alternatives on the market. In addition, developing and transition countries also face the rapid spread of counterfeit medicines, which they do not have sufficient infrastructure and technical expertise to regulate. Therefore, strengthened international concerted actions are needed to assist these countries in developing adequate regulatory and voluntary frameworks and actions tailored for their markets, in areas such as assessment and marketing authorisation, public procurement, proper prescription and use, and take-back and sound disposal of unused or expired pharmaceuticals.

Strengthened engagement of pharmaceutical manufacturers, particularly multinational corporations.

Areas of interest may include developing new drugs using the concept of "green and sustainable pharmacy" (e.g. development of more easily degradable drugs, among other goals), awareness raising of environmental risks and risk mitigation measures for existing pharmaceuticals, innovative

manufacturing processes for minimising waste, and designing and implementing take-back programmes of unused or expired pharmaceuticals (e.g. using take-back programmes in Canada as an example). The European initiative Eco-Pharmaco-Stewardship may be a good starting point for considering such engagement. Further studies of possible drivers and barriers for pharmaceutical manufacturers taking actions in these areas may be warranted.

Filling in gaps associated with existing pharmaceutical products.

Existing pharmaceuticals licensed before the introduction of the Environmental Risk Assessment (ERA) systems in the EU and the US have continued to be used without any risk assessment. For example, in the EU market, approximately 3,000 pharmaceutical products are estimated to be distributed without ERA; in Germany, 10 human medicinal ingredients that were detected at levels between 0.35 and 1.81 ug/L in surface water have been marketed without ERA. Analysing the risks and hazards of all the products that contain >4,000 medicinal ingredients currently in use is a practical challenge. Prioritisation schemes might assist, and they have been extensively discussed in peer-reviewed scientific literature. In brief, the criteria that may be used include sales data, ecotoxicity, excretion factor, bioconcentration factor, wastewater treatment removal efficiency, and environmental levels. Furthermore, because an ERA is performed only for individual products, environmental loads of the same pharmaceutical ingredient included in other medicinal products cannot be evaluated. Therefore, a new system that follows up and manages the total pollution load, which includes existing medicinal products within the framework of ERA, may be warranted.