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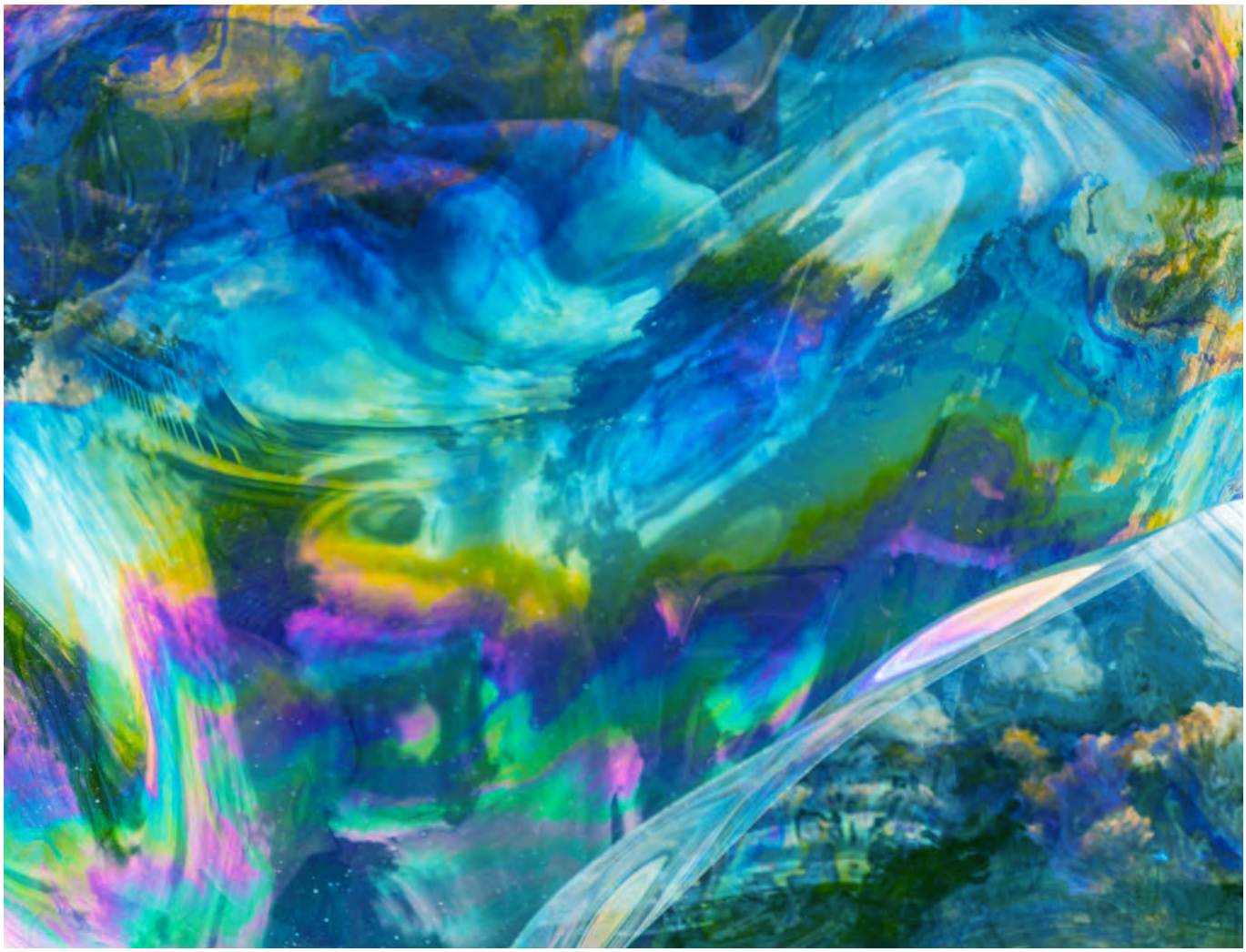
An Assessment Report on Issues of Concern: Chemicals and Waste Issues Posing Risks to Human Health and the Environment

September 2020



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Further technical contributions were kindly made by Abhishek Kumar Awasthi (Tsinghua University); Kastalie Bougas, Leonie Constantine, Ellen Cunningham, Ian Keyte and David Tyrer (Wood Environment & Infrastructure Solutions UK); Changer Chen, Punniyakotti Elumalai, Mingzhi Huang, Sisi Liu, Xiaohui Yi, Guangguo Ying, Qianqian Zhang, Jianliang Zhao (South China Normal University); Yuan Chen, Sifan Liu, Hongbin Shi (Basel Convention Regional Centre for Asia and the Pacific); Miriam Diamond (University of Toronto); Melanie Kah (University of Auckland); Adelene Lai Shen Lyn (University of Luxembourg); Antonia Praetorius (University of Amsterdam); Thomas Roiss (Independent Consultant); Akshat Sudheshwar (ETH Zürich); and Noriyuki Suzuki, Hiroshi Yamamoto (National Institute for Environmental Studies, Japan).

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Feedback and contact

The United Nations Environment Programme encourages interested readers of this report to engage and share their views about the report.

Email: science.chemicals@un.org

Website: https://www.unenvironment.org/explore-topics/chemicals-waste

An Assessment Report on Issues of Concern:

Chemicals and Waste Issues Posing Risks to Human Health and the Environment

September 2020

Executive Summary

Many countries and regions have set up regulatory and policy frameworks to achieve sound chemicals and waste management. In addition to national and regional efforts, the international community has taken concerted joint actions to address specific issues of concern, including chemicals that can be transported over long distances by wind and water, are transported through global trade in resources, products and waste, or are used or are present in many countries.

Substantial progress has been made by the international community, including establishment of several multilateral environmental agreements (MEAs) and international initiatives. However, as assessed by the Global Chemicals Outlook II (GCO-II), the global goal of sound chemicals and waste management in ways that lead to minimised adverse effects on human health and the environment has not been achieved by 2020. Ambitious international action is urgently required to ensure reaching these goals in the foreseeable future.

This report responds to Resolution 4/8 by the United Nations Environment Assembly (UNEA) and aims to inform the international community about the current situation of specific issues of concern, based on a review of evidence published within the past decade. It is meant to inform and support decision making at UNEA and other international forums working towards sound chemicals and waste management.

After introduction and methods chapters, Chapter 3 assesses the eight emerging policy issues and issues of concern (for simplicity, hereafter both are referred to as "issues of concern") identified by the International Conference on Chemicals Management (ICCM) under

the Strategic Approach to International Chemicals Management (SAICM). It reviews how current regulatory and policy frameworks address them by specific instruments and actions, building on GCO-II findings and highlighting challenges and opportunities.

Chapter 4 addresses the 11 issues with emerging evidence of risks identified by GCO-II. It assesses current exposure as well as instruments and actions under current regulatory and policy frameworks, highlighting challenges and opportunities. It also provides background information on environmental or human health effects of the issues based on existing assessments by national governments and intergovernmental institutions, to raise awareness among governments and stakeholders.

Chapter 5 presents a "thought starter" on identification of issues of concern, including a review of existing approaches, a map of other current relevant initiatives, and considerations of potential areas in which future issues of concern might be identified and possible identification processes.

Chapter 6 provides an overarching outlook for future international work on issues of concern.

Progress has been made under SAICM, but not enough

To date, eight issues of concern have been identified under SAICM: chemicals in products (CiP), endocrine disrupting chemicals (EDCs), environmentally persistent pharmaceutical pollutants (EPPPs), hazardous substances in the life cycle of electrical and electronic products (HSLEEP), highly hazardous pesticides (HHPs), lead in paint, nanotechnology and manufactured nanomaterials (Nanomaterials), and per- and polyfluoroalkyl substances (PFASs). Overall, most of these issues have received recognition from policymakers and stakeholders, with many instruments developed and actions taken. However, these instruments and actions are as yet inadequate to solve these issues at a global scale.

For long-standing issues (e.g. lead in paint, HHPs), progress has been uneven across countries and regions. The issues may have been addressed in many developed countries and therefore have less urgency as issues of concern there. Developing and transition countries might use some of the many instruments and actions established and taken by governments and stakeholders in developed countries; however, actions in developing and transition countries are limited due to their specific circumstances and conditions, such as lack of awareness, capacity and financial resources, among other factors.

For more recently recognized issues, limited actions have been taken locally, regionally and globally, resulting in success in addressing some aspects of the issues in some parts of the world. This success is only partial, largely due to gaps in the scopes of existing instruments and actions. For example, for EPPPs, HSLEEP and PFASs, partial coverage of life-cycle stages, relevant chemicals and uses are addressed. Also, existing instruments and actions have

limitations in terms of what they can address: while efforts have been considerable, for example, in developing guidance and tools for testing, assessment, and identification of EDCs, a limited number of chemicals have been tested, identified, and regulated as EDCs in this arena.

An overarching challenge (as well as an opportunity) is how to communicate and scale up existing instruments and lessons learned in one region or sector to others, particularly for developing and transition countries. Detailed challenges and opportunities for individual issues are summarized below.

CiP	**(1)** Foster communication of chemicals present in products throughout the supply chain, versus the current common practice of communicating what should not be present. **(2)** Extend CiP communication to actors outside supply chains, e.g., by exploring instruments such as fiscal policies, extended producer responsibility, corporate sustainability reporting, and new public-private partnerships. **(3)** Ensure CiP information is relevant, accurate, current and accessible through strong regulatory and voluntary actions on effective monitoring and enforcement.
EDCs	**(1)** Regularly synthesize and disseminate relevant scientific evidence in a policy-ready format to bring governments and stakeholders worldwide to the same level of awareness and knowledge. **(2)** Strengthen dialogues and concerted actions at all levels to enable an effective and efficient way forward, including advancement and implementation of, for example, standard data requirements and testing methods, mutual acceptance of data and existing assessments, joint assessments and joint strategies for addressing EDCs.
EPPPs	**(1)** Expand the current scope under SAICM to encompass all pharmaceutical pollutants, including those that may not be long-lasting but may still accumulate in the environment due to continuous use and releases, and those that may lead to outcomes that are not readily reversible, such as antimicrobial resistance. **(2)** Step up global efforts to prevent pharmaceutical pollutants from entering waste streams, including strengthened engagement with pharmaceutical manufacturers, and filling in knowledge gaps of existing pharmaceuticals.
HSLEEP	**(1)** Address the early life-cycle stages of EEP, e.g., by taking proactive approaches such as adopting applicable fiscal policies and design guidelines to foster development of EEP made with minimal use of hazardous substances and by green manufacturing processes. **(2)** Properly address the situation of informal workers who handle EEP waste through improved understanding of their role and impacts on their health, best practices, and other conditions.
HHPs	**(1)** Address the current ambiguity of the criteria for identifying HHPs. **(2)** Strengthen international support for developing and transition countries, possibly through legally binding instruments and partnerships, including building up resources and capacities to establish and enforce national pesticide legislation, combatting illegal trafficking of illicit pesticides, and treatment of existing stockpiles.
Lead in paint	Continue global efforts in phasing out lead paints, including upscaling technical assistance in establishing legal limits, evaluation and improvement of the effectiveness of control measures, addressing lead pigments trade, fostering effective monitoring and enforcement, and exploring novel approaches to voluntary actions, while taking into account the specific circumstances and conditions in developing and transition countries.
Nanomaterials	**(1)** Establish regulatory data requirements on nanomaterials around the world, taking into account their properties and life cycles, to inform future hazard and risk assessments of them. **(2)** Strengthen dialogues and concerted actions at the international level to work towards common definitions and grouping strategies for nanomaterials.
PFASs	**(1)** Accelerate the global phase-out of those PFASs listed under the Stockholm Convention on Persistent Organic Pollutants. **(2)** Explore novel approaches to managing PFASs (e.g. grouping by similarities, the "essential use" concept in the Montreal Protocol). **(3)** Foster regular information exchange and joint efforts to accelerate actions on PFASs that are not listed under the Stockholm Convention, including transition to safer alternatives.

The issues identified by GCO-II warrant urgent international concerted actions

GCO-II identified 11 chemicals or groups of chemicals where emerging evidence indicates a risk. Environmental and human health effects are not a part of the assessment in this report; however, as noted in the report, a compilation of existing assessments by national governments and intergovernmental institutions confirms their possible significant adverse effects on the environment and humans. In addition, the assessment of current exposure to these substances, as well as existing instruments and actions, suggests pressing needs for international concerted action for all of them.

	Persistence in the environment?	Long-range transport potential?	Global prevalence of current exposure (and trends)?	Major sources being addressed globally?
Arsenic	✓	✓ (emissions from high-temperature processes)	✓	✗
Bisphenol A	✗	✗	✓ (↗ in adults)	✗
Cadmium	✓	✓ (emissions from high-temperature processes)	✓ (↘ in some regions, ↗ in others)	✗
Glyphosate	✓ (up to months to years in soil & sea water)	✓ (land-to-sea transport)	✓	✗
Lead	✓	✓ (emissions from high-temperature processes)	✓ (↗ as shown by global burden of disease data)	✗
Microplastics	✓	✓	✓	✗
Neonicotinoids	✓ (up to months to years in soil & sediment)	✗	✓	✗
Organotins	✓	✓ (some organotins)	✓	✗
Phthalates	✗	✗	✓	✗
PAHs	✓	✓	✓	✗
Triclosan	✗	✗	✓	✗

Overall, limited attention has been paid or actions taken for these issues, with uneven progress across countries and regions, although as with the issues of concern under SAICM, many of the issues identified by GCO-II have long been recognised (for over a century for lead, for example). Also, when instruments are established and actions taken, their scopes often are not comprehensive; for example, major sources of a substance may not

be covered in their entirety by existing instruments and actions. In the case of microplastics, actions have been taken to limit their use in cosmetics and personal care products, but instruments and actions addressing other major uses, which may result in additional and even more significant environmental releases, are limited.

Furthermore, substitution has often not been properly tackled when addressing these issues, with known toxic materials used as substitutes for those that are of concern. For example, lead used as a PVC stabiliser was first replaced by cadmium, which was then largely replaced by organotins — despite extensive knowledge about the high toxicity of both cadmium and organotins. Opportunities for addressing individual issues are identified and may be considered for future concerted actions (see below).

A thought starter on identification of issues of concern

In the future, it may be appropriate to address a wider range of issues of concern that have previously received insufficient attention, rather than specific hazardous chemicals or groups of chemicals. This includes issues where sound management of chemicals and waste is necessary to achieve greater sustainability and to achieve wider environmental or development objectives, particularly for climate change or biodiversity and for various Sustainable Development Goals (SDGs).

In addition to the various mechanisms used to identify issues of concern, such as tracking national regulatory actions, other methods could be introduced, such as seeking nominations by countries and other stakeholders. A case may also be made for horizon scanning and early warning mechanisms; discussions on strengthening the science-policy interface will be relevant to how this could be achieved.

When selecting issues, it will be important to focus on a manageable number at any one time where coordinated international action can have the greatest impact. One relevant international forum for addressing issues of concern will be the future instrument for the sound management of chemicals and waste beyond 2020, now being discussed by governments and stakeholders, and in particular how issues of concern should be identified within that process. It is also important to note here the linkages to discussions on the science-policy interface that UNEA-5 might have.

Outlook for future development

No one-size-fits-all solution can tackle all the challenges and opportunities of addressing the issues documented in this report and elsewhere. Nevertheless, an overarching enabling environment established by concerted international action could help countries and

stakeholders address both the issues addressed in this report and future issues of concern. Elements could include (1) strengthened leadership with clear roles and responsibilities to coordinate concerted actions, (2) regular monitoring and evaluation of progress, (3) new mechanisms, including legally binding ones, by the international community to raise its efforts on addressing issues where progress has been limited, (4) active knowledge management, including knowledge capture, synthesis and sharing, and (5) strengthened involvement of the scientific community.

This report highlights a continued need to address the eight issues under SAICM by the international community; properly addressing them can also contribute to solutions of many issues identified by GCO-II. This report also highlights that several issues identified by GCO-II warrant further consideration by the international community: for example, PAHs (polycyclic aromatic hydrocarbons) could be taken up by the Stockholm Convention, as they are already regarded as POPs under the Convention on Long-Range Transboundary Air Pollution. For arsenic, cadmium and lead, many sources of these elements are the same or similar to those of mercury. Hence, the Minamata Convention on Mercury provides a good model, and linkages and synergies might be investigated to inform best ways to address these related elements internationally.

Considering that resources for the international community and many countries are limited, addressing individual issues of concern may not be sensible. New ways for addressing many of them in an integrated and holistic manner may be explored, including using a sector-specific value chain approach, grouping substances by similar intrinsic properties, or taking into account all life-cyle stages of specific chemicals and products. Also, efforts on sound chemicals and waste management should be integrated with other environmental and societal priorities (e.g. climate, biodiversity, human rights, labour standards).

Chemicals have brought many benefits to modern life, but often at high costs to the environment and human well-being. It is time for the international community to draw on lessons learned from past successes and failures, and together drive a transformative change of our global society for a sustainable future.

List of Acronyms

ADI:	Acceptable Daily Intake
AMPA:	Aminomethylphosphonic Acid
ANSES:	Agency for Food, Environmental and Occupational Health & Safety (France)
ASEAN:	Association of Southeast Asian Nations
BaP:	Benzo[a]pyrene
BBP:	Benzylbutyl phthalate (also referred to be Butylbenzyl phthalate or BBzP, BzBP)
BDP:	Bisphenol A bis(diphenyl phosphate)
BPA:	Bisphenol A
CiP:	Chemicals in Products
CLP:	Regulation on Classification, Labelling and Packaging
CLRTAP:	Convention on Long-Range Transboundary Air Pollution
CMS:	Convention on Migratory Species
COP:	Conference of the Parties
DALYs:	Disability-Adjusted Life Years
DBP:	Dibutyl Phthalate
DcHP:	Dicyclohexyl Phthalate
DEP:	Diethyl Phthalate
DEHP:	Bis(2-ethylhexyl) Phthalate
DHP:	Dihexyl Phthalate
DiBP:	Di-isobutyl Phthalate
DiDP:	Di-isodecyl Phthalate
DiPP:	Di-isopentyl Phthalate
DiNCH:	Di-isononyl hexahydro phthalate
DiNP:	Di-isononyl Phthalate
DiHpP:	Di-isoheptyl phthalate
DiHxP:	Diisohexyl Phthalate, also referred to as Bis(4-methylpentyl) Phthalate
DMP:	Dimethyl Phthalate
DMEP:	Bis(2-methoxyethyl) Phthalate
DnBP:	Di-n-butyl Phthalate also referred to as dibutyl phthalates or DBP
DnOP:	Di-n-octyl Phthalate
DOP:	Dioctyl phthalate
DPP:	Dipentyl Phthalate
ECCC:	Environment and Climate Change Canada
ECHA:	European Chemicals Agency
EDC:	Endocrine Disrupting Chemical
EEA:	European Environment Agency
EEE:	Electronic and Electrical Equipment
EEP:	Electrical and Electronic Products

EFSA:	European Food Safety Authority
EMA:	European Medicines Agency
EPI:	Emerging Policy Issue
EPPP:	Environmentally Persistent Pharmaceutical Pollutant
ERA:	Environmental Risk Assessment
EU:	European Union
FAO:	Food and Agricultural Organization
GAELP:	Global Alliance to Eliminate Lead Paint
GBD:	Global Burden of Disease, Injuries, and Risk Factors
GCO and GCO-II:	Global Chemicals Outlook (first edition) and Global Chemicals Outlook II
GEF:	Global Environment Facility
GESAMP:	Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals
GOs:	Global Outlooks
GWMO:	Global Waste Management Outlook
HCFC:	Hydrochlorofluorocarbon
HELCOM:	Baltic Marine Environment Protection Commission, also as Helsinki Commission
HFC:	Hydrofluorocarbon
HHP:	Highly Hazardous Pesticide
HMW:	High-molecular weight
HSLEEP:	Hazardous Substances within the Life Cycle of Electrical and Electronic Products
IARC:	International Agency for Research on Cancer
ICCM:	International Conference on Chemicals Management
IHR 2005:	International Health Regulations
ILO:	International Labour Organization
IOMC:	Inter-Organization Programme for the Sound Management of Chemicals
IPBES:	Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services
IPCC:	Intergovernmental Panel on Climate Change
IPCS:	International Programme on Chemical Safety
ITU:	International Telecommunications Union
JMPM:	Joint FAO/WHO Meeting on Pesticide Management
LMW:	Low-molecular weight
MEA:	Multilateral environmental agreement
MRL:	Maximum Residue Level
NICNAS:	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NOAEL/NOAEC:	No Observed Adverse Effect Level/Concentration
nPiPP:	n-pentyl-isopentylphthalate
OECD:	Organisation for Economic Co-operation and Development
OEHHA:	Office of Environmental Health Hazard Assessment (California)
OPS:	Overarching Policy Strategy
PAH:	Polycyclic aromatic hydrocarbon

PAN:	Pesticide Action Network
PBT:	Persistent, Bioaccumulative and Toxic
PFAS:	Per- and Polyfluoroalkyl Substance
PFCA:	Perfluoroalkylcarboxylic Acid
PFC:	Per- and Polyfluorinated Chemical or Perfluorinated Chemical
PFHxS:	Perfluorohexanesulfonate Anion
PFOA:	Perfluorooctanoic Acid
PFOS:	Perfluorooctanesulfonic Acid
PNEC:	Predicted No Effect Concentration
POPRC:	POPs Review Committee
POP:	Persistent Organic Pollutant
PRTR:	Pollutant Release and Transfer Register
PIC:	Prior Informed Consent
PVC:	Polyvinyl Chloride
REACH:	Registration, Evaluation, Authorisation and restriction of Chemicals
RIVM:	Rijksinstituut voor Volksgezondheid en Milieu (Ministerie van Volksgezondheid, Welzijn en Sport, Nederlands)
SAICM:	Strategic Approach to International Chemicals Management
SAPEA:	Science Advice for Policy by European Academies
SDG:	Sustainable Development Goal
SME:	Small and Medium Enterprises
StEP:	Solving the E-waste Problem
SVHC:	Substance of Very High Concern, or Substances of Very High Concern
TBBPA:	Tetrabromobisphenol A
TBT:	Tributyltin
TCBPA:	Tetrachlorobisphenol A
TDI:	Tolerable Daily Intake
TSCA:	Toxic Substance Control Act (US)
tTDI:	Temporary Tolerable Daily Intake
WEEE:	Waste Electrical and Electronic Equipment
WHO:	World Health Organization
WWTP:	Wastewater Treatment Plant
UBA:	German Environment Agency
UN:	United Nations
UNEA:	United Nations Environment Assembly
UNEP:	United Nations Environment Programme
UNHCR:	United Nations Human Rights Council
UNICRI:	United Nations Interregional Crime and Justice Research Institute
US ATSDR:	US Agency for Toxic Substances and Disease Registry
US EPA:	US Environmental Protection Agency
US FDA:	US Food and Drug Administration
USGS:	US Geological Survey

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1.

Introduction

Chemicals are essential for modern societies, improving quality of life and more. Today's chemical industry is one of the largest manufacturing sectors in the world, and is projected to grow further in coming years due to increasing global population and urbanisation (United Nations Environment Programme [UNEP] 2019a). Unsound management of chemicals and products during manufacture, use and disposal results in chemical pollution that may cause adverse effects on human health and the environment at local, national, regional and global levels.

Chemical pollution includes many well-known cases reported around the world. Chemical pollution was proposed as one of the "planetary boundaries", or the planetary environmental limits within which humanity can safely operate, with impacts on other planetary boundaries such as climate change, stratospheric ozone depletion and biosphere integrity (Rockström *et al.* 2009, Persson *et al.* 2013, Steffen *et al*. 2015).

Governments and other stakeholders, including those from the private sector, academia and civil society, are striving to assess and soundly manage chemicals throughout their life cycles, in part driven by health and environmental safety concerns. As cornerstones to achieving this goal, many countries have established their own national and regional regulatory and policy frameworks for chemicals and waste. While these may be well-established in many countries, these regulatory and policy frameworks have limitations in addressing issues beyond national jurisdictions. For example, once released, some chemicals may be transported via wind or water currents long distances, far from the sources where they were originally released. In addition, chemicals may be transported through global trade of products and waste, with

limited surveillance and control. Also, as the same chemicals are often used in many countries, it is often not cost-effective for individual countries to assess the chemicals, particularly for developing countries and countries with economies in transition (hereafter referred to as "developing and transition countries"), which have limited resources and capacities to do so, in comparison to their developed counterparts.

Hence, the international community has taken concerted joint actions to address specific issues related to sound chemicals and waste management that warrant international action, including establishment of many multilateral legally binding treaties. Substantial progress has been made towards the sound management of chemicals and waste.

However, the global goal to have all chemicals used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment will not be achieved by 2020; more ambitious international action by all stakeholders is urgently required. A large portion of chemicals on the market remain to be assessed and managed in a sound manner, while recent scientific developments suggest that many of these chemicals may give rise to issues of concern and warrant joint international action (UNEP 2017; UNEP 2019a). In addition, growing volumes and complexity of waste being generated around the world put increasing pressure on the local, national, regional and global waste management systems, resulting in new and emerging issues of concern, such as waste electrical and electronic products and marine plastic litter.

This report aims to inform the international community about the current state of and possible advances for issues of concern in the chemicals and waste area, in order to support further discussion at the fifth session of the United Nations Environment Assembly (UNEA5) in February 2021 and other international forums working towards sound management of chemicals and waste as part of the 2030 Sustainable Development Goals (SDGs), such as the International Conference on Chemicals Management (ICCM). It is a direct response to the request by UNEA at its fourth session (UNEA4) in March 2019, as set out in Resolution 4/8 (UNEP 2019b). The UNEA4 requested the work of UNEP as follows:

- to "follow trends in the design, production, use and release of chemicals and the generation of waste in order to identify issues of concern for future editions of the Global Chemicals Outlook and the Global Waste Management Outlook and catalyse sound management actions" (paragraph 14, subparagraph e) and
- to prepare "a report on matters in which emerging evidence indicates a risk to human health and the environment, identified by the Strategic Approach to International Chemicals Management, the Global Chemicals Outlook and under subparagraph (e) above, including an analysis of existing regulatory and policy frameworks and their ability to address those matters in the achievement of the 2020 goal, in particular for lead and cadmium" (paragraph 14, subparagraph f).

1.1 The 2020 Goal

At the World Summit on Sustainable Development in Johannesburg in 2002, United Nations (UN) Member States pledged to "renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment". In paragraph 23 of the Johannesburg Plan of Implementation adopted at the Summit, a goal set by UN Member States further aimed to "achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment" (UN 2002).

This goal was further adopted as the overall objective of the Strategic Approach to International Chemicals Management (SAICM) by the International Conference on Chemicals Management at its first session (ICCM1) in 2006 (SAICM 2015). The political commitment to achieve the SAICM 2020 goal was renewed in 2015, when all UN Member States adopted the 2030 Agenda for Sustainable Development and included sound chemicals management as SDG 12.4 (UN General Assembly Resolution A/RES/70/1; UN 2015).

1.2 SAICM, the Intersessional Process and Issues of Concern

Adopted by the ICCM in 2006, SAICM is a voluntary, multistakeholder and multisectoral policy framework to promote chemical safety around the world. It is comprised of the Dubai Declaration on International Chemicals Management, which expressed high-level political commitment to SAICM, and an Overarching Policy Strategy that sets out its scope, needs, objectives, financial considerations, principles and approaches, and implementation and review arrangements. The Dubai Declaration and Overarching Policy Strategy are accompanied by a Global Plan of Action that serves as a working tool and guidance document to support implementation of SAICM and other relevant international instruments and initiatives (SAICM 2015). Activities in the Global Plan are to be implemented as appropriate by stakeholders according to their applicability.

The Overarching Policy Strategy (paragraph 24) sets the functions of ICCM, the governing body of SAICM, including a specific provision (j) calling "for appropriate action on emerging policy issues as they arise and to forge consensus on priorities of cooperative action" (SAICM 2015). At ICCM2 in 2009, governments agreed on modalities for considering such issues of concern; these include requests for information on how issues meet the following criteria:

(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;

(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;

(iii) existing knowledge and perceived gaps in understanding about the issue;

(iv) extent to which the issue is of a cross-cutting nature; [and]

(v) information on the anticipated deliverables from action on the issue.

To date, six Emerging Policy Issues (EPIs) and two other Issues of Concern have been identified under SAICM. The six EPIs are Chemicals in Products (CiP), Endocrine Disrupting Chemicals (EDCs), Environmentally Persistent Pharmaceutical pollutants (EPPPs), Hazardous Substances within the Life Cycle of Electrical and Electronic Products (HSLEEP), Lead in Paint, and Nanotechnology and Manufactured Nanomaterials, and the two other Issues of Concern are Highly Hazardous Pesticides (HHPs) and Per- and Polyfluoroalkyl Substances (PFASs). Hereafter, all eight are referred to together as "issues of concern". In addition, governments and other stakeholders have adopted a number of resolutions with specific international cooperative action sets for these eight issues of concern (for details, see the analysis in Chapter 3 and Annex A).

ICCM4 initiated an intersessional process to prepare recommendations regarding SAICM and the sound management of chemicals and waste beyond 2020. The recommendations will be discussed and decided at ICCM5 in July 2021. The intersessional process is currently ongoing, with issues of concern as a core discussion theme, focusing on the definition, criteria and modalities for adoption, and considerations on implementation (ICCM Resolution IV/4).

1.3 Global Chemicals Outlook and Issues of Concern

The first edition of the *Global Chemicals Outlook: Towards Sound Management of Chemicals* (GCO) was published in February 2013 and assembled scientific, technical and socioeconomic information on the sound management of chemicals (UNEP 2013). Decision 27/12 adopted by the Governing Council of UNEP in 2013, recognized the significance of the findings of this first edition of the GCO (UNEP 2016). In 2016, UNEA adopted a resolution (2/7) at its second session and requested UNEP to submit an update of GCO and "ensure that the updated Global Chemicals Outlook addresses the issues which have been identified as emerging policy issues by the ICCM, as well as other issues where emerging evidence indicates a risk to human health and the environment". In response to the request, UNEP released *Global Chemicals Outlook II: From Legacies to Innovative Solutions* (GCO-II) in April 2019 (UNEP 2019a).

GCO-II included a brief assessment of the state of science and policy for the individual issues of concern identified under SAICM. The report concluded that the nomination of different issues has successfully raised awareness, focused the attention of stakeholders and catalysed initiatives; however, challenges remain. A set of potential measures to further address these issues was recommended, which provides a basis for this current report.

Furthermore, GCO-II presented other issues where emerging evidence indicates a risk to human health and the environment. It used the selection criteria (i.e. entry points and necessary conditions for inclusion) that at least two countries or regional economic integration organisations have undertaken the following two types of actions since 2010, including at least one regulatory risk management action: (1) There has been a regulatory risk management action on a chemical or group of chemicals, based on emerging evidence indicating a risk to human health and the environment. (2) A full risk assessment or reassessment action for the same chemical or group of chemicals has been completed or initiated.

In total, GCO-II identified 11 issues where emerging evidence indicates a risk: arsenic, bisphenol A (BPA) in products, glyphosate in agriculture and residential use, cadmium, lead, microbeads in personal care products and cosmetics, neonicotinoids in outdoor agriculture, organotins as biocides, polycyclic aromatic hydrocarbons (PAHs) in products, phthalates in consumer products, and triclosan in hygiene products. A brief introduction was provided in GCO-II for these issues, including some possible adverse effects and existing regulatory actions.

1.4 Report Scope and Structure

In response to the UNEA Resolution 4/8 and building on GCO-II and discussion under SAICM, this assessment report consists of three major parts.

Chapter 3 is an assessment of the ability of existing regulatory and policy frameworks through specific instruments and actions to address the individual issues of concern identified by SAICM. Building on potential measures proposed in GCO-II, this part also highlights challenges and opportunities to address these issues.

Chapter 4 provides a comprehensive assessment of the current exposure and the ability of existing regulatory and policy frameworks through specific instruments and actions to address the 11 individual issues with emerging evidence of risks identified by GCO-II, including challenges and opportunities. It also provides background on the environmental and/or human health effects of respective issues based on existing assessments by national governments and intergovernmental institutions, to raise overall awareness among governments and stakeholders.

Chapter 5 presents a “thought starter” on identification of issues of concern. It addresses how future editions of the Global Chemical and Waste Management Outlooks might identify issues of concern, and it may also help inform the work by UNEA, UNEP, ICCM and other UN agencies related to issues of concern with regard to chemicals and waste and wider sustainability goals.

Building on lessons learned from Chapter 3, 4 and 5, this assessment also provides an overarching outlook for future international work on issues of concern in Chapter 6, with a summary of the previous assessments.

Given the complexity, breadth and rapid ongoing development of scientific research and action with regard to the individual issues that are the subject of this assessment, it is neither feasible nor possible to include in-depth detail and discussions related to all the potentially relevant aspects, nor to predict future developments. Instead this assessment report provides a snapshot of the overall situation at the time the report was prepared and references to further detailed and relevant information.

2.

Preparation of the Assessment Report

This assessment report was prepared between November 2019 and April 2020. The sections below outline the methodology and process for the preparation.

2.1 Methodology of the Assessment Report

This report aims to be comprehensive but not exhaustive. Reviews of individual issues are based on a literature review of peer-reviewed scientific articles; technical reports published by national governments, intergovernmental institutions, private sector and civil society organisations; and information published on SAICM and stakeholders' websites [for example, see the following SAICM-related reports: *Activities of the Inter-Organizational Programme for the Sound Management of Chemicals (IOMC) to Support Strategic Approach to International Chemicals Management (SAICM) Implementation* (IOMC 2019); *Independent Evaluation of the Strategic Approach from 2006–2015* (Nurick 2019)].

The information presented here is focused on evidence published within the past decade, since 2010 where possible, to reflect the current state of knowledge for each aspect considered. In many parts of the world, such evidence may not be available currently or may be available only from before 2010. In some cases, evidence from before 2010 was also included as an indication of the possible current state, and limitations were documented where necessary and possible.

For all the issues, the review of existing regulatory and policy frameworks focused on providing a comprehensive overview of different types of specific instruments and actions taken to address the issues, and they were grouped based on their legal status into three

groups: legally binding instruments, soft law instruments and voluntary initiatives. Legally binding instruments refer to those based on legal obligations that are binding for the parties involved, e.g. multilateral agreements, legislation, regulations and directives. Soft law instruments refer to instruments such as agreements, principles, declarations, resolutions, codes of conduct, guidelines, strategies, action plans and fiscal policies that are not legally binding, but which set certain norms.

Actions such as meetings, workshops and training courses were generally not included in the review of existing regulatory and policy frameworks. For individual types of instruments and actions, examples considered in this report were not exhaustive. In addition, the assessments looked into the geographical scale, scope and content of existing instruments and actions, but did not specifically look into their effectiveness. In some cases, the effectiveness of some instruments and actions has been assessed by others, and such information was included in the assessment if relevant.

Similarly, for the issues with emerging evidence of risks identified by GCO-II, the assessments of current exposures focused on providing a comprehensive overview of evidence on key aspects, including the major sources of the specific chemicals and their prevalence, their levels and the trends of current exposure to them across the globe. In addition, the assessments looked into some key characteristics of current exposure, including persistence, bioaccumulation potential, long-range transport potential via wind and water currents, and global trade of associated products and waste.

For the issues with emerging evidence of risks identified by GCO-II, additional information on the environmental and human health effects of respective issues was provided as background for readers. These respective sections in Chapter 4 are a compilation of existing hazard or risk assessments by national governments, intergovernmental institutions and their associated bodies. Additional hazard and risk assessments of individual chemicals may exist in the scientific literature or as parts of regulatory processes; however, they are scattered across thousands of scientific journals and databases. In this context, it is important to note that the objective of this report is to assess the ability of existing regulatory and policy frameworks through specific instruments and actions to address current environmental and human exposures to individual chemicals and groups of chemicals, not on conducting new hazard and risk assessments of these chemicals.

The main body of the report, described above, is supported with an annex that contains additional information for interested readers. Depending on specific issues, additional information may include more details on the existing hazard or risk assessments by national governments and intergovernmental institutions; on the instruments and actions taken to address the specific issues; and data on production and use, exposure pathways, costs of inaction, occurrence in the environment and humans, and other pertinent characteristics of the issues.

2.2 Preparation Process

To prepare this report, experts across the globe were engaged to draft reviews on individual issues. In addition, experts from the African, Latin American and the Caribbean, Central and Eastern European, and Asian and the Pacific regions were engaged to gather specific inputs from their regions or countries. The input from all experts was then integrated and harmonised to produce a complete draft.

The complete draft report was reviewed by UNEP, and was circulated for comments to the other members of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC) and the secretariats of the Basel, Rotterdam, Stockholm and Minamata conventions, as well as of SAICM.

3.

Assessment of the Issues of Concern under SAICM

This chapter presents the assessments of the eight issues of concern under SAICM, officially referred to as “emerging policy issues and other issues of concern”, in alphabetical order. The assessments are meant to be a comprehensive but not exhaustive overview of the different types of instruments and actions that currently exist to address these issues, and thus highlight major gaps and challenges as well as opportunities for future sound management actions.

3.1 Chemicals in Products

Chemicals may be released at any stage of a product's life cycle (including production, use, recycling or reuse, end-of-life disposal), resulting in potential exposures for humans and the environment. Information exchange in the value chain is fundamental for manufacturers, brands, retailers, end consumers, waste managers and regulators in identifying and soundly managing any chemicals of technical, environmental or human health concerns in products. It is closely linked to the right to know, one of the basic human rights defined by the UN.

The Overarching Policy Strategy of SAICM includes the objective of "ensuring that information on chemicals throughout their life cycle, including, where appropriate, chemicals in products, is available, accessible, user-friendly, adequate and appropriate to the needs of all stakeholders" (SAICM 2015a). CiP was identified as an issue of concern under SAICM at ICCM2 in 2009, "with a view of taking appropriate cooperative actions, to consider the need to improve the availability of and access to information on chemicals in products in the supply chain and throughout their life cycle" (SAICM 2009). SAICM stakeholders also identified four priority sectors: textiles, toys, building products and electronics (SAICM 2009).

3.1.1 A Comprehensive Overview of Existing Instruments and Actions

In 2015, at ICCM4, governments and stakeholders welcomed the CiP Programme, which sets out three information objectives, as well as roles and responsibilities of actors within and outside supply chains, for CiP information exchange. The three information objectives are related to broader knowledge exchange, disclosure to stakeholders outside the supply chain for better management, and information that is accurate and accessible. In practice, depending on the sectors, different instruments have been developed for addressing CiP information exchange along product value chains (see Figure 3–1; for details, see Table A–1 in the Annex and references therein).

In several sectors, such as for cosmetics, personal care products and food additives, communication of chemicals used in products has become mandatory through labelling of the full ingredient list in many if not all parts of the world. However, in other sectors, legal requirements of CiP information exchange have been limited. They often have much narrower scopes in terms of geographical coverage (e.g. limited to the EU or California, US), chemicals coverage (i.e. limited to defined chemicals of concern) and sector coverage (e.g. limited to electrical and electronic products).

CiP information exchange relies instead primarily on voluntary initiatives by the sector or individual companies within the sector, mostly within the supply chains. Two types of approaches have been applied by companies and sectors to implement their voluntary initiatives. One is a passive approach, which focuses on providing suppliers with a declarable or restricted substance list in products or manufacturing processes; in some cases a positive list of chemicals approved for use may be developed by the sectors, companies or third-party standard and certification schemes. The other approach is an active one, in which companies may actively invest in knowing which chemicals are used by their suppliers and set up or join an existing system to collect and manage CiP information, e.g. through tools such as full material disclosure (often referred to as FMD) in their supply chain management. Companies may choose to take either of the approaches, or both.

To support and facilitate CiP information exchange, specific guidance and tools have also been developed. Many of these focus on supply chains, whereas multiple initiatives specifically target actors outside supply chains (e.g. online databases and apps for consumers to understand chemicals on the ingredient lists of cosmetics, personal care products and food additives). In addition, an ongoing project co-funded by the Global Environment Facility (GEF) is building capacity, expanding guidance and tools, and promoting best practices across countries.

FIGURE 3-1. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING CIP INFORMATION EXCHANGE.

INFORMATION OBJECTIVES IDENTIFIED IN THE UNEP CHEMICALS IN PRODUCTS (CIP) PROGRAMME

INSIDE	OUTSIDE	OVERALL
Within supply chains, to know and exchange information on chemicals in products, associated hazards and sound management practices;	to disclose information of relevance to stakeholders outside the supply chain to enable informed decision-making and actions about chemicals in products;	to ensure that, through due diligence, information is accurate, current and accessible

GUIDE

INSTRUMENTS RELATED TO CIP INFORMATION EXCHANGE PRACTICES

PARTIAL DISCLOSURE

LEGALLY BINDING

EXAMPLES OF LEGALLY BINDING REQUIREMENTS

EU: according to REACH, suppliers of articles containing Substances of Very High Concern (**SVHCs**) at a level >0.1 wt% shall provide sufficient information to downstream users and consumers.

- ECHA has developed a guidance document and is establishing an online database by early 2021.

California, US: according to Proposition 65, warnings shall be provided to consumers when they might be exposed to **chemicals that may cause cancer, birth defects or other reproductive harm**, as identified by the State of California (about 850 chemicals).

EU, Japan, China, and others: labelling requirements for **electrical and electronic products** that comply with respective laws

Costa Rica: labelling requirements for **toys**, according two RTCR 421:2008

Worldwide: proper labelling with full ingredients is required for **cosmetic and personal care products, cleaning products, foodstuff, pharmaceuticals** and **pesticides** in many if not all parts of the world. Labelling requirements may differ from country to country.

VOLUNTARY

EXAMPLES OF LISTS OF DECLARABLE/RESTRICTED SUBSTANCES FOR SUPPLIERS

SUPPORT

SECTOR-SPECIFIC EXAMPLES

Automotive: Global Automotive Declarable Substance List (GADSL) by the Global Automotive Stakeholders Group

Textile: Manufacturing Restricted Substances List (MRSL) by the ZDHC Foundation

COMPANY-SPECIFIC EXAMPLES

Electronics: Regulated Substances Specification by Apple; Nokia Substance List by Nokia

Automotive: Chemical substances which must not be used (black list), whose use shall be limited (grey list), and which shall be declared and must not be present in products placed on the market (red list), and substitutes for hazardous chemical substances (white list) by Volvo

THIRD PARTY STANDARD OR CERTIFICATION, E.G.

Multiple sectors: various ecolabels

Textile: bluesign® SYSTEM, including a "bluesign® system substances list" that specifies limits and bans of chemicals and a "bluesign® finder" containing bluesign® approved chemicals

ECO PASSPORT certification by OEKO-TEX® for chemicals, colourants & accessories used in the manufacturing of textiles and leather articles

EXAMPLE OF FULL MATERIAL DISCLOSURE POLICY

SUPPORT

Kimberly-Clark: Upon request, supplier will provide 100% of the chemical composition of all materials, ingredients, products and packaging.

FULL DISCLOSURE

EXAMPLES OF GUIDANCE AND TOOLS

International: *Chemicals in Products Programme, Guidance for Stakeholders on Exchanging Chemicals in Products information & Guidelines for Providing Product Sustainability Information* by UNEP

WITHIN SUPPLY CHAINS

All sectors: full material disclosure as means for suppliers to disclose all chemicals used in products/parts; chemSHERPA, an information transfer scheme

Textile: Chemical Management System Guidance Manual, ZDHC MRSL Conformance Guidance, a template Chemical Inventory List, online platform "ZDHC Gateway - Chemical Module" by the ZDHC Foundation

Automotive: International Material Data System (IMDS) as the global data repository by manufacturers

Electronics: standardised reporting format via a set of standards (IPC-175x) by the Institute of Printed Circulates

Toys: Chemical Management Database

OUTSIDE SUPPLY CHAINS

EU: Under the AskREACH project, smartphone apps for consumers to check SVHCs in products have been made available in seven EU countries.

Cosmetics and personal care products: Online databases and apps, such as Skin Deep, ToxFox and CodeCheck, help consumers to understand chemicals on ingredient lists, including those that may present risks or hazards.

Building and construction products: online databases, e.g., BASTA, for designers and users to make conscious product selections

EXPAND

AN EXAMPLE OF MAJOR INTERNATIONAL ACTION

Ongoing GEF Project "Global Best Practices on Emerging Chemical Policy Issues of Concern under the Strategic Approach to International Chemicals Management" in 2018–2022 (ID 9771)

- A platform to identify and quantify chemicals of concern in supply chains;
- green economy tools and guidance refer to CiP data to improve product design, purchasing and use practices

3.1.2 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 (UNEP 2011), 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 (Rossi 2014). 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 (Rossi 2014). 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 (UNEP 2011).

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 (Leslie *et al.* 2016; Pivnenko, Laner and Astrup 2016; Pivnenko *et al*. 2016).

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 (UNEP 2017), 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 (European Chemicals Agency [ECHA] 2019a).

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 Footprint" Project (https://www.chemicalfootprint.org/), created by the US-based non-profit organisations Safer Chemicals, Healthy Families and Clean Production Action, respectively.

3.2 Endocrine Disrupting Chemicals (EDCs)

An EDC is "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations" (World Health Organization [WHO] 2002). EDCs have garnered heightened international attention, particularly after the publication of *Our Stolen Future* (Colborn, Dumanoski and Myers 1996), which was a scientist-written book for the general public in the same vein as Rachel Carson's *Silent Spring*, and *Global Assessment of the State-of-the-Science of Endocrine Disruptors* (WHO 2002), by the International Programme on Chemical Safety (IPCS), which is a joint venture of UNEP, the International Labour Organization (ILO) and WHO. Substantial efforts have been made over the past two decades to develop a better scientific understanding of EDCs and their characteristics, to test and identify EDCs, and to develop scientific approaches in order to support risk management measures.

In 2012, at ICCM3, EDCs were identified as an issue of concern under SAICM, and SAICM stakeholders decided "to implement cooperative actions on endocrine-disrupting chemicals with the overall objective of increasing awareness and understanding among policymakers and other stakeholders" and invited IOMC organisations to lead and facilitate a series of cooperative actions on EDCs, which was renewed in a Resolution at ICCM4 (SAICM 2012; SAICM 2015b).

3.2.1 A Comprehensive Overview of Existing Instruments and Actions

To address EDCs at the regional and national level, most efforts by governments have been focused on the development of infrastructure for identifying and regulating EDCs within their respective jurisdictions (see Figure 3–2; for details, see Table A–2 in the Annex and references therein). Notably, some countries and regions such as the EU, Japan and China have developed overarching strategies, some of which are comprehensive, to guide different lines of work. In addition, some countries and regions have developed or updated their laws with explicit references to EDCs, providing a clear framework on how EDCs are to be addressed. Additional actions have focused on screening, assessment and identification of EDCs, particularly development of standardized criteria, guidance and tools for testing and assessment, and screening programmes under respective legal frameworks. To date, more than 10 chemicals have been identified and thus regulated as EDCs in the EU under its chemicals regulation, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), and more than 100 other chemicals are being screened by regulators in the EU, United States (US), Japan and elsewhere as suspected EDCs.

The above actions are complemented by other stakeholders, which mostly focus on synthesizing and sharing existing scientific information, developing guidance and tools for

testing and assessment, and awareness raising. On the international level, actions are co-ordinated by the work plan developed by intergovernmental institutions adopted at ICCM4. Some civil society organisations have also been active in screening and assessment of EDCs, and their work indicates that many more potential EDCs exist than are currently being screened and assessed by regulators.

FIGURE 3–2. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING EDCS.

ACTIONS BY STATE ACTORS

EXAMPLES OF LAWS WITH EXPLICIT REFERENCES TO EDCS

pesticides	(EC) No 1107/2009	FQPA	PCPA	
biocides	(EU) No 528/2012			
industrial chemicals	(EC) No 1907/2006			K-REACH
cosmetics	(EC) No 1223/2009			
drinking water		FQPA		
research			CEPA	

FQPA = Food Quality Protection Act; **PCPA** = Pest Control Products Act; **CEPA** = Canadian Environmental Protection Act; **K-REACH** = Act on Registration and Evaluation of Chemicals of Korea

IMPLEMENT

EXAMPLES OF SCREENING AND IDENTIFICATION OF EDCS

10+ chemicals identified and regulated as EDCs in the EU and some other countries

100+ chemicals being screened in the EU (CoRAP), US (EDSP) and Japan (SPEED98, EXTEND2005, 2010 and 2016)

100+ chemicals identified as EDCs by civil society organisations, e.g. in the Substitute It Now! (SIN) List by ChemSec and in the International List of Highly Hazardous Pesticides by PAN

1400+ chemicals with evidence of possible endocrine-disrupting properties reported in at least one study, as compiled in the List of Potential Endocrine Disruptors by TEDX as of December, 2019.

GUIDE

EXAMPLES OF ACTION PLANS AND STRATEGIC PROGRAMMES

EU: Towards a comprehensive European Union framework on endocrine disruptors, including actions on EU legislations, research and innovation, and information exchange.

China: 13th Five-Year Plan of National Environment Protection, stating strict control of the pollution by EDC.

Japan: Strategic Programs on Environment Endocrine Disruptors: SPEED'98 and its follow-ups (EXTEND2005, 2010 and 2016), including aspects such as field investigations, assessment and management

GUIDE

SUPPORT

EXAMPLES OF GUIDANCE AND TOOLS FOR TESTING, ASSESSMENT AND IDENTIFICATION

US: eleven EDSP Tier 1 Test Guidelines, three EDSP Tier 2 Test Guidelines and the Nonclinical Evaluation of Endocrine-Related Drug Toxicity — Guidance for Industry

China: industry standard NY/T2873-2015 Evaluation Methods of the Endocrine Disruption Effects of Pesticides

EU: Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (i.e. biocides and pesticides)

OECD: *Conceptual Framework for Testing and Assessment of Endocrine disrupters, Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption,* and various Test Guidelines

An interdisciplinary expert team developed a Tiered Protocol for Endocrine Disruption (TiPED) to help detect possible ED properties early in the chemical development process.

INFORM AND SUPPORT

INFORM AND SUPPORT

EXAMPLES OF SCIENTIFIC INFORMATION SYNTHESIS

State of the Science of Endocrine Disrupting Chemicals by UNEP and WHO in 2012

Overview reports on EDCs by UNEP in 2018

EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals

Online database of Endocrine Disrupting Chemicals and Their Toxicity Profiles (DeDuCt) by the Institute of Mathematical Sciences, India

EXAMPLES OF AWARENESS-RAISING MATERIALS

Brochure and infographics themed "things we buy", "things we grow", "places we work and live" and "things we make" by UNEP

Introduction to Endocrine Disrupting Chemicals (EDCs). A guide for public interest organisations and policy-makers by IPEN and Endocrine Society

Websites by EDC Free Europe

International: Joint workplan by UNEP, WHO and OECD adopted at ICCM4 coordinating their work on guidance and tools, scientific information synthesis and awareness raising

ACTIONS BY NON-STATE ACTORS

3.2.2 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 (WHO 2002; WHO and UNEP 2013).

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 (TEDX 2019). 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.

3.3 Environmentally Persistent Pharmaceutical Pollutants (EPPPs)

Pharmaceuticals are important for human and animal health, and therefore they have positive impacts on food production and economic welfare. At the same time, pharmaceuticals, including antibiotics, and their metabolites can enter the environment through a variety of pathways, including wastewater and solid waste from pharmaceutical manufacturing, consumption and excretion, improper disposal of unused or expired products, animal husbandry and aquafarming. Their presence in the environment may result in different adverse effects on wildlife and ecosystems; some well-known cases include endangerment of some vulture species, reproductive failures in fish, and the development of antimicrobial resistance (Kümmerer 2008).

Internationally, EPPPs were recognized as an issue of concern under SAICM at ICCM4 in 2015. The same resolution "considers that information dissemination and awareness-raising on EPPP are particularly relevant and that improving the availability of and access to information on such chemicals is a priority", "recognizes the current knowledge gaps on exposure to and the effects of EPPP", "decides to implement cooperative actions on EPPP with the overall objective of increasing awareness and understanding among policymakers and other stakeholders", and "requests all interested stakeholders and organizations to provide support, including expertise, financial and in-kind resources, on a voluntary basis, for such cooperative action, including by participating in developing and making available relevant information and guidance" (SAICM 2015b).

3.3.1 A Comprehensive Overview of Existing Instruments and Actions

Sound management of EPPPs is a complex issue: while the focus is on pharmaceutical pollutants in the environment, action needs to be taken at every stage of pharmaceutical products' life cycles, starting from drug development stages (see the EU Strategic Approach to Pharmaceuticals in the Environment, European Commission 2019a; the report *Pharmaceutical Residues in Freshwater: Hazards and Policy Responses*, OECD 2019). In response to EPPPs and pharmaceutical pollutants in the environment in general, instruments and actions have been and are being developed and taken (see Figure 3–3; for details, see Table A–3 in the Annex and references therein).

In this emerging field, many efforts by governments and other stakeholders have focused so far on gathering knowledge and raising awareness; examples include the database of

existing environmental measurements across the globe gathered from peer-reviewed literature by the German Environment Agency (Dusi, Rybicki and Jungmann 2019) and World Antibiotic Awareness Week coordinated by WHO. In addition, declarations and policy strategies have been developed to guide action to address specific pharmaceuticals (i.e. antimicrobial pharmaceuticals) or in specific regions (e.g. EU, the Netherlands), in a demonstration of the political commitment to solving potential EPPP issues. Some policy strategies have taken the whole life cycle of pharmaceuticals into consideration (European Commission 2019a; Government of the Netherlands 2019).

Development of actions or instruments for sound management of individual stages of pharmaceutical life cycles has been uneven. Many different instruments and actions have been developed for areas such as marketing authorisation and take-back of unused and expired pharmaceuticals. Substantial information on the hazards and in some cases risks of many pharmaceuticals has been generated and made publicly available during different marketing authorisation processes, e.g., in the EU and US, and such information can be shared with and made visible more widely to other countries and regions. In contrast, actions remain lacking in other areas, such as treatment of waste from manufacturing and domestic sources containing pharmaceuticals, as well as from prescriptions and use. However, some examples in these areas are notable, such as the Wise List maintained by the Stockholm County Council in Sweden, used to inform doctors about environmental risks of different pharmaceuticals (Stockholm County Council 2020).

FIGURE 3–3. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING EPPPS.

DRUG DEVELOPMENT → PRODUCTION → PRESCRIPTION & USE → DISPOSAL

EXAMPLES OF DECLARATION / POLICY STRATEGIES

International: The UN General Assembly adopted the *Political Declaration of the High-Level Meeting of the General Assembly on* Antimicrobial Resistance (A/RES/71/3)

EU: *European Union Strategic Approach to Pharmaceuticals in the Environment*, including actions to raise awareness and promote prudent use, improve training and risk assessment, gather monitoring data, incentivise green design, reduce emissions from manufacturing, reduce waste and improve wastewater treatment.

Netherlands: *Reducing pharmaceutical residues in water: a chain approach*, an implementation programme for 2018–2022 to take action on development and authorisation, prescription and use, and waste and sewage treatment.

EXAMPLES OF ERA-BASED MARKETING AUTHORISATION

DRUG DEVELOPMENT (STATE ACTORS)

EU: Environmental Risk Assessment (ERA) is mandatory for new applications.
- human pharmaceuticals, the results should not constitute a criterion for the refusal of marketing authorisation;
- veterinary pharmaceuticals, an unacceptable environmental risks can lead to refusal of authorisation;
- reports are publicly available.

US: Under the National Environmental Policy Act, ERA must be submitted as part of applications, unless qualified for categorical exclusion.

Canada: ingredients subject to the New Substances Notification Regulations of the Canadian Environmental Protection Act.

SUPPORT

EXAMPLES OF GUIDANCE AND TOOLS

DRUG DEVELOPMENT (STATE ACTORS)

EU, US: guidelines on the preparation of ERA for marketing authorisation applications

EXAMPLES OF VOLUNTARY ACTIONS

DRUG DEVELOPMENT (NON-STATE ACTORS)

PRODUCTION (NON-STATE ACTORS)

EU: the "Eco-Pharmaco-Stewardship" (EPS) initiative by the pharmaceutical industry, including (1) research and development: intelligence-led assessment of pharmaceuticals in the environment (iPiE), (2) extended environmental risk assessment (eERA) and (3) manufacturing: effluent management.

EXAMPLE OF ACTION PLAN

PRESCRIPTION & USE (STATE ACTORS)

International: *Global Action Plan to Tackle Antimicrobial Resistance* endorsed by the World Health Assembly, including strategic objectives to optimise the use of antimicrobial pharmaceuticals in human and animal health

EXAMPLES OF GUIDELINES

PRESCRIPTION & USE (STATE ACTORS)

WHO: *WHO Guidelines on the Use of Medically Important* Antimicrobials *in Food-Producing Animals*

Stockholm, Sweden: publishes the Wise list, a list of recommended pharmaceuticals for common diseases in Stockholm County, taking into account of environmental risks

EXAMPLES OF COLLECTION SYSTEMS FOR UNUSED/EXPIRED ONES

DISPOSAL (STATE ACTORS)

EU: Directive 2001/83/EC, Art. 127b — Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.
- UK: essential service n°3 of the National Health Service community pharmacy contract

US: regulated by the Secure and Responsible Drug Disposal Act

DISPOSAL (NON-STATE ACTORS)

Canada: through the Health Products Stewardship Association, a non-profit organisation representing domestic producers of consumer health products

EXAMPLE OF UPGRADE OF WASTE TREATMENT

DISPOSAL (STATE ACTORS)

Switzerland: ca. 100 facilities to be upgraded in 2016–2040

EXAMPLES OF KNOWLEDGE SHARING AND AWARENESS RAISING

Pharmaceutical Residues in Freshwater. Hazards and Policy Responses by OECD, providing cross-cutting, source-directed, use-oriented and end-of-pipe policy recommendations on addressing pharmaceutical residues in freshwater.

Procurement of Pharmaceuticals in an Environmental Context and Its Inclusion into the CSR Compass by the Swedish Environment Protection Agency

Reflection Paper on Risk Mitigation Measures Related to the Environmental Risk Assessment of Veterinary Medicinal Products by EMA

World Antibiotic Awareness Week coordinated by WHO, raising global awareness of antibiotic resistance and encouraging best practices among the general public, health workers and policymakers in order to avoid the further emergence and spread of antibiotic resistance

Database - Pharmaceuticals in the Environment by the German Environment Agency, compiling existing environmental measurements from peer-reviewed articles

Safer Pharma website by Health Care Without Harm Europe, raising awareness of healthcare professionals and citizens on pharmaceuticals in the environment, including a database for current initiatives related to the issues.

3.3.2 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" (SAICM 2015c). 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 (Segura *et al*. 2015; Madikizela, Tavengwa and Chimuka 2017). 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 (Mackey and Liang 2011). 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; Kümmerer and Hempel 2010), 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 (Taylor and Senac 2014); 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 (BIO Intelligence Service 2013). Analysing the risks and hazards of all the products that contain >4,000 medicinal ingredients currently in use is a practical challenge (Boxall et al. 2012). Prioritisation schemes might assist, and they have been extensively discussed in peer-reviewed scientific literature (Letsinger and Kay 2019). In brief, the criteria that may be used include sales data, ecotoxicity, excretion factor, bioconcentration factor, wastewater treatment removal efficiency, and environmental levels (Mansour et al. 2016). 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 (Lee and Choi 2019).

3.4 Hazardous Substances in the Life Cycle of Electrical and Electronic Products (HSLEEP)

Electrical and electronic products (EEP), also referred to as electronic and electrical equipment (EEE), include any device with a circuit, battery or plug. They can contain many chemical additives for certain properties such as flame retardancy. Some chemical additives may be hazardous, including heavy metals and persistent organic pollutants (POPs), and may be released during production, use, transport, and end-of-life treatment (disposal or recycling), leading to environmental and human exposures and possible adverse effects. Sound management of hazardous substances in EEP, particularly during end-of-life treatment, is challenging. In particular, informal and rudimentary recycling methods, as well as uncontrolled disposal, are responsible for large releases of hazardous chemicals in many developing and transition countries, impacting human health and the environment locally. Women and children, as well as those living in the vicinity of recycling sites, remain among the most vulnerable groups (UNEP 2019a). Current rates of global e-waste generation are highly uncertain but have been estimated at 44.7 million tonnes or 6.1 kg per capita in 2016 and are projected to further increase (Baldé *et al.* 2017).

It would be far more effective to act on the earlier life stages of EEP. Changing design features and other preventative actions would facilitate minimising the use of certain hazardous substances, which would not only help minimise upstream environmental impacts from mining and other primary resource extraction activities that supply raw materials for EEP, but also contribute to the environmentally sound management of waste EEP (hereafter referred to as e-waste). Such a life-cycle approach to addressing hazardous substances in EEP was recognized by the international community, when adopting HSLEEP as an issue of concern under SAICM in 2009.

3.4.1 A Comprehensive Overview of Existing Instruments and Actions

Many instruments and actions have been developed to address HSLEEP at different life-cycle stages and at different levels (see Figure 3–4; for details, see Table A–4 in the Annex and references therein). In particular, multiple resolutions, declarations and strategic plans have been adopted at the international level, showing high political commitment on the matter. For example, the Plenipotentiary Conference, the governing body of the International Telecommunications Union (ITU), adopted targets to increase the global e-waste recycling rate to 30% and raise the percentage of countries with e-waste legislation to 50% by 2023.

At the national level, many countries have set up their own laws to restrict certain hazardous substances in EEP or to define roles and responsibilities and targets in managing e-waste, or both. For example, the EU Waste Electrical and Electronic Equipment Directive (WEEE Directive) introduced extended producer responsibilities, to encourage better design and collection of

products. As of 2017, laws adopted by 67 countries have led to national regulations governing e-waste management for 66% of the world's population (Baldé *et al.* 2017). In addition, levies have been used as an instrument to address chemicals in EEP; e.g. Sweden has set up a tax for certain products containing chlorine, bromine and phosphorus.

These instruments are complemented by voluntary instruments and actions. On the product side, some producers have voluntarily phased out or restricted certain hazardous substances in their products, and third-party verification and labelling schemes (e.g. ecolabels) have been set up to address certain hazardous substances in defined product categories. On the e-waste side, many intergovernmental organisations have played an important role in setting up recommendations, guidance and tools, as well as implementing country-level projects, to support countries in sound management of e-waste. Furthermore, different partnerships and programmes have been initiated to address either specific issues (e.g. worker exposure by the Clean Electronics Production Network; Global E-waste Statistics Partnerships) or with the aim of addressing the whole life cycle (e.g. the Solving the E-waste Problem, StEP initiative; Sustainable Cycles, SCYCLE programme).

3.4.2 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.

FIGURE 3–4. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING HSLEEP.

PRODUCTS ⟷ **END-OF-LIFE**

EXAMPLES OF RESOLUTIONS / DECLARATION / ACTION PLAN / STRATEGY

Basel Convention: *Nairobi Declaration on the Environmentally Sound Management of Electrical and Electronic Waste*, including the "phas[ing]-out of hazardous substances used in production and included in components" and the promotion of "integrated waste management in order to reduce the harm caused by the hazardous components contained in e-waste"

SAICM: 2016-2020 Workplan based on the Global Plan of Action adopted at ICCM4

US: *National Strategy for Electronics Stewardship*, a roadmap of how the federal government can use its authorities and leverage resources for lay the groundwork for improving the design of electronic products and enhancing management of used or discarded electronics

International: *ITU's Strategic Plan for 2020-2023*, by 2023
➔ increase the global e-waste recycling rate to 30% and raise the percentage of countries with an e-waste legislation to 50%.

Canada: Federal Electronic Strategy to ensure the E-waste resulting from government operations is properly disposed of.

LEGALLY BINDING INSTRUMENTS

EXAMPLES OF LAWS ON RESTRICTION OF HAZARDOUS SUBSTANCES (ROHS)

EU: Directive 2011/65/EU (RoHS2) and 2015/863 (RoHS3)
➔ Pb, Hg, Cd, Cr(VI), PBBs, PBDEs + 4 phthalates in 11 tproduct categories, with certain exemptions; product labelling (CE mark)

Japan: J-MOSS
➔ Pb, Hg, Cd, Cr(VI), PBBs, PBDEs in 7 product categories, with certain exemptions; product labelling ("G" or "R" mark)

China: Administrative Measures
➔ Pb, Hg, Cd, Cr(VI), PBBs, PBDEs in all applicable products, without exemptions; product labelling (Electronic Information Products (EIP) logo)

EXAMPLES OF LAWS ON E-WASTE

International: Under the Basel Convention, A1180 in Annex VIII refers to certain E-waste as hazardous waste.

EU: Directive 2012/19/EU
➔ requirements for the disposal of E-waste with the underlying principle of producer responsibility

US: Resource Conservation and Recovery Act (RCRA)

South America: Colombia (Law Nº 1672 adopted in 2013), **Costa Rica** (Regulation Nº 35933-S), **Ecuador** (Ministerial Agreement Nº 190 adopted in 2013), **Peru** (Decree Nº 001-2012), **Brazil** (Law Nº 12.305 adopted in 2010)

EXAMPLES OF LAWS ON ROHS AND E-WASTE

EU: Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators; **Republic of Korea:** Act of Resource Cycling of Electrical and Electronic Equipment and Vehicles; **India:** E-waste (Management and Handling) Rules 2011

EXAMPLES OF TAX

Sweden: duty levied on producers and importers of certain products, e.g. kitchen appliances, that contain bromine, chlorine or phosphorus

VOLUNTARY INSTRUMENTS AND ACTIONS

EXAMPLES OF LISTS OF RESTRICTED SUBSTANCES FOR SUPPLIERS

Regulated Substances Specification by Apple; Nokia Substance List by Nokia

EXAMPLES OF CHALLENGES

US: the Sustainable Materials Management (SMM) Electronics Challenge launched by US EPA targeting E-waste collection and recycling

EXAMPLES OF THIRD PARTY VERIFICATION AND LABELLING SCHEMES

International: Electronic Product Environment Assessment Tool (EPEAT), a label for IT devices meeting required and optional criteria

EU: Commission Decision 2009/300/EC — EU Ecolabel requirements on the levels of heavy metals and flame retardants in televisions

Nordic countries: Nordic Swan Ecolabel, e.g. no harmful flame retardants and mercury for computers

EXAMPLES OF RECOMMENDATIONS, GUIDANCE AND TOOLS

Basel Convention: e.g. *Technical Guidelines on Transboundary Movements of Electrical and Electronic Waste and Use Electrical and Electronic Equipment,* guidance documents on environmentally sound management of used and end-of-life computing equipment and mobile phones

SAICM: *Compilation of Best Practices on Hazardous Substances within the Life Cycle of Electrical and Electronic Products*

ITU: e.g. recommendations on extended producer responsibility, E-waste management framework, life-cycle management of ICT goods, green public ICT procurement, etc.; *Handbook for the Development of a Policy Framework on ICT/E-Waste*

ILO: e.g. *Tackling Informality in E-Waste Management*

IETC: e.g. *Future E-waste Scenarios, Compendium of Technologies for the Recovery of Materials from WEEE/E-waste, E-Waste Volume III: WEEE/E-waste "Tack Back System", "kNOwWaste"* platform

LAC region: *Gestión Sostenible de Residuos de Aparatos Eléctricos y Electrónicos en América Latina*

EXAMPLES OF PARTNERSHIPS AND PROGRAMMES

Electronics TakeBack Coalition (ETBC) promotes green design and responsible recycling in the electronic industry

Sustainable Cycles (SCYCLE), a programme hosted by UNU on the development of sustainable production, consumption/usage, and disposal of ubiquitous goods with a specific focus on electrical and electronic products

Solving the E-waste Problem (StEP) initiative, a multi-stakeholder platform for designing strategies that address the entire lifecycle of electronics

Clean Electronics Production Network (CEPN), a multi-stakeholder network to understand, address and eliminate worker exposure to toxic chemicals in electronics production

Clean Electronics Production Network (CEPN), a multi-stakeholder network to understand, address and eliminate worker exposure to toxic chemicals in electronics production

E-waste Coalition by ten organisations from the UN system
➔ core areas: advocacy, knowledge and best practice sharing, and development of a joint intervention model for country-level work
➔ *A New Circular Vision for Electronics - Time for a Global Reboot*

Global E-waste Statistics Partnership; E-waste Academies

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; fueling 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.

3.5 Highly Hazardous Pesticides (HHPs)

Pesticides have been a focus of sound management of chemicals and waste for decades, as they are widely used, biologically active compounds designed to kill target organisms. A number of pesticides have also been shown to cause adverse effects on non-target organisms. Among them, HHPs[1] have attracted particular attention at international scales, due to their high potential to cause adverse impacts on human health, the environment and the sustainability of agricultural production.

In 2006, the Food and Agriculture Organization of the United Nations (FAO) Council suggested "that the activities of FAO could include risk reduction, including the progressive ban on highly hazardous pesticides, promoting good agricultural practices, ensuring environmentally-sound disposal of stock-piles of obsolete pesticides and capacity-building in establishing national and regional laboratories" (FAO 2006). At ICCM4 in 2015, HHPs were further identified as an issue of concern. In addition, among other actions, governments and other stakeholders supported "concerted action to address HHPs in the context of SAICM" and encouraged "relevant stakeholders to undertake concerted efforts to implement the strategy at the local, national, regional and international levels, with emphasis on promoting agroecologically-based alternatives and strengthening national regulatory capacity to conduct risk assessment and risk management, including the availability of necessary information, mindful of the responsibility of national and multinational enterprises", and welcomed "the offer of the FAO, UNEP and WHO to develop modalities for international coordination in the context of the IOMC" (SAICM 2015b).

1 The FAO/WHO International Code of Conduct on Pesticide Management defines HHPs as "pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as the World Health Organization (WHO) or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous."

The FAO/WHO Joint Meeting on Pesticide Management (FAO and WHO 2008) recommended that HHPs should be defined as having one or more of the following characteristics: pesticide formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard, pesticide active ingredients and their formulations that meet the criteria of carcinogenicity/mutagenicity/reproductive toxicity Categories 1A and 1B of the GHS, pesticide active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention, pesticide active ingredients and formulations listed by the Rotterdam Convention in its Annex III, pesticides listed under the Montreal Protocol, or pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

3.5.1 A Comprehensive Overview of Existing Instruments and Action

Figure 3–5 shows an overview of the current global landscape of sound management of HHPs; for details, see Table A–5 in the Annex and references therein. At the international level, no overarching legally binding instruments exist for all HHPs. Some HHPs may be identified and partially regulated under the Stockholm and Rotterdam conventions and the Montreal Protocol. In general, the management of HHPs primarily takes place through national and regional pesticide legislation and implementation of these laws. Meanwhile, international organisations have developed and used different instruments to support countries in managing HHPs; these include setting norms, particularly in the form of codes of conduct and guidelines for identification and sound management of HHPs under the joint leadership of FAO and WHO (FAO and WHO 2019); the development of guidance and tools; and joint activities assisting countries in raising awareness, building capacity and managing HHPs.

3.5.2 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 (FAO and WHO 2016; FAO not dated [n.d.]). 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 (FAO and WHO 2008). 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.

EXAMPLES OF ACTIONS BY INTERGOVERNMENTAL ORGANISATIONS AND UNDER MULTILATERAL ENVIRONMENTAL AGREEMENTS

EXAMPLES OF ACTIONS BY NONGOVERNMENTAL ORGANISATIONS

THROUGH INDIVIDUAL OR JOINT PROGRAMMES

EXAMPLES OF CODE OF CONDUCT, GUIDELINES, GUIDANCE AND TOOLS

International Code of Conduct on Pesticide Management. Guidelines on Highly Hazardous Pesticides by FAO & WHO	*Consolidated List of Banned Pesticides by Pesticide Action Network (PAN)*
WHO Recommended Classification of Pesticides by Hazard	PAN International list of Highly Hazardous Pesticides by PAN
Manual on Development and Use of FAO and WHO Specifications for Pesticides	Online Pesticides Databases and smartphone app Pesticides & Alternatives by the IPM Coalition
Guidelines for Procuring Public Health Pesticides by WHO	
Technical Guidelines on the environmentally sound management of wastes consisting of, containing or contaminated with pesticides under the Stockholm Convention published by the Basel Convention	*Obsolete and Unwanted Pesticide Stocks. Practical Guidance on Safeguarding, Disposal and Prevention* by the CropLife International
Toolkit for Pesticides Registration Decision Making by FAO	

SUPPORT

EXAMPLES OF VOLUNTARY COUNTRY-SUPPORTING PROJECTS

Multiple GEF-funded projects implemented by FAO to promote sound management of pesticides, including in the Caribbean (GEF ID 5407) and Bangladesh (GEF ID 9076)	Funded by SAICM QSP, PAN Africa conducted projects in Mali and Senegal to raise awareness and build capacity

NATIONAL AND REGIONAL PESTICIDE LEGISLATION

A 2018 WHO-FAO survey shows that 53 out of the 56 countries responded have pesticide legislation.

- 65% of the countries lack special provisions for HHPs, e.g., to prohibit or restrict their use.
- 33% of the countries lack guidelines on the registration process and data requirements.
- Guidance on HHPs is used by few countries for their registration decisions.

+ FRAMEWORK FOR SUSTAINABLE USE OF PESTICIDES

EU: adopted a Directive 2009/128/EC aiming to achieve a sustainable use of pesticides in the EU, including action related to training of users, advisors and distributors of pesticides, inspection of pesticide application equipment, the prohibition of aerial spraying, limitation of pesticide use in sensitive areas, and information and awareness raising about pesticide risks. EU Member State must also promote integrated pest management.

CRITERIA FOR IDENTIFYING HHPS

Criterion 1: pesticide formulations that meet the criteria of Ia or Ib of the *WHO Recommended Classification of Pesticides by Hazard*, or

Criteria 2-4: pesticide active ingredients and their formulations that meet the criteria of carcinogenicity, mutagenicity, or reproductive toxicity Categories 1A or 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS), or

Criterion 5: Stockholm Convention on persistent organic pollutants (POPs)

Criterion 6: Rotterdam Convention Share Responsibility

Criterion 7: MONTREAL PROTOCOL

Criterion 8: pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment

SELF-INTERPRET

AS OF MARCH 2019, A TOTAL OF 366 INDIVIDUAL OR GROUPS OF PESTICIDE ACTIVE INGREDIENTS REGARDED AS "CURRENTLY IN USE" IN THE GLOBAL MARKET HAVE BEEN BANNED IN ONE OR MORE OF 150 COUNTRIES, INCLUDING POSSIBLE HHPS.

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 (WHO and FAO 2019), 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 (Rotterdam Convention 2013), is still being used in large quantities in many parts of the world (ECHA n.d.a; Hakim 2016).

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 (WHO and FAO 2019).

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 (FAO 2015). 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 (WHO and FAO 2019). 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 (WHO and FAO 2014; SAICM n.d.).

Third, many developing and transition countries also face high levels of illegal trafficking of illicit pesticides, including HHPs (Vázquez 2013; WHO and FAO 2014; United Nations Interregional Crime and Justice Research Institute [UNICRI] 2016; United Nations Human Rights Council [UNHCR] 2017).

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 (WHO and FAO 2014; Khan, Mahmood and Damalas 2015; Damalas and Abdollahzadeh 2016; FAO and WHO 2016; Dugger-Webster and LePrevost 2018; Rother 2018). Also, the applicability of some PPE may be significantly reduced by thermic and mechanical discomfort (Garrigou *et al.* 2020).

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 (Okoffo, Mensah and Fosu-Mensah 2016).

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; see FAO 2015); 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 (FAO 2015; UNHCR 2017; FAO 2018); and revisiting national, regional and international legal frameworks for sound pesticide management, including trade, liability, sustainable use of pesticides, and integrated pest management (Porto *et al*. 2010; FAO 2015; Tirado 2015; Watts and Williamson 2015; UNEP 2016; UNHCR 2017; WHO and FAO 2019). 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 inivitatives whose common objective is to eliminate the harm caued by HHPs, consolidate the commitments and efforts of diverse organisations, and challenge stakeholders to commit to working together to achieve significant and measureable change over a specific timeframe.

3.6 Lead in Paint

Lead is a multi-system toxicant for which no safe level of exposure has been identified. Exposure to lead can cause chronic and debilitating health impacts in all age groups, and children are particularly vulnerable to its neurotoxic effects (WHO 2010). The widespread use of lead has caused extensive environmental and human exposure across the globe. One major source of exposure, particularly for children, is through "lead paint", or paint to which lead compounds have been added as pigments, drying agents or anti-corrosives. While many countries have taken actions to ban or restrict the use of lead in paints, it is still being widely used in developing and transition countries (UNEP 2019b); in 2012, such use accounted for up to 5.6% of the total use of lead worldwide (International Lead Association 2012).

Nearly two decades ago, in 2002, in the Plan of Implementation of the World Summit on Sustainable Development, governments agreed to "phase out lead in lead-based paints and in other sources of human exposure, work to prevent, in particular, children's exposure to lead and strengthen monitoring and surveillance efforts and the treatment of lead poisoning" (UN 2002). This motion is reinforced by the resolutions from the UNEA and the ICCM sessions. Among others, "Lead in Paint" was recognized as an issue of concern at ICCM2 (SAICM 2009). The ICCM2 also endorsed an international partnership to assist in phasing out lead paint worldwide, eventually giving rise to the Global Alliance to Eliminate Lead Paint (GAELP). The GAELP aims to have all countries adopt "legally binding laws, regulations, standards and/or procedures to control the production, import, sale and use of lead paints with special attention to the elimination of lead decorative paints and lead paints for other applications most likely to contribute to childhood lead exposure" and to have all paint manufacturers eliminate "the use of added lead compounds in priority areas" by 2020 (UNEP and WHO 2012).

3.6.1 A Comprehensive Overview of Existing Instruments and Actions

Lead paint can remain a source of exposure for many years after its first application, and safely removing lead paint once it has been applied is costly (e.g. estimated to be USD$1,200–$10,800 per housing unit in the US; Gould 2009) and can lead to environmental contamination when done improperly (WHO 2020). It has been more cost-effective, as well as more protective to public health, to stop the manufacture and sale of lead paint than to remediate homes and other buildings and deal with the health consequences of lead exposure after the fact, particularly as safer alternatives to lead compounds in paints have become available at similar cost. Thus, the assessment here focuses on actions with regard to phasing out the manufacture, sale and use of lead paint, while

acknowledging the need for many other actions, such as remediation of lead paint from homes and other buildings, which have high returns despite higher costs (Gould 2009; Jacobs *et al*. 2016; Billings and Schnepel 2017).

To date, a number of instruments are in place or are being developed to address the phase-out of lead paint from the market (see Figure 3–6; for more details, see Table A–6 in the Annex and references therein). Among others, as of 30 January 2020, 75 countries have legally binding controls to limit the production, import and sale of lead paints, which is 39% of all countries. Such legally binding instruments are complemented by other non-legally binding instruments, including voluntary standards (e.g. Indonesia) and voluntary phase-out by major multinational paint manufacturers (e.g. AkzoNobel, PPG Industries). In addition, intergovernmental organisations and the GAELP continue to play an important role in phasing out lead paints, including organising awareness raising events, developing guidance and tools for policymakers who are interested in setting up legally binding laws on restricting lead paints, and assisting countries in developing legal limits.

3.6.2 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 (International Pollutants Elimination Network [IPEN] 2017).

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 (GEF 2017). 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 (O'Connor *et al.* 2018), and thus, efforts are needed to evaluate their effectiveness and improve them if necessary (e.g. addressing industrial paints in addition to consumer paints; O'Connor *et al*. 2018; Shen *et al*. 2018). 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 (Gottesfeld 2015) 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 (Health Impact Project 2017).

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 (Kessler 2014; IPEN 2017; O'Connor *et al*. 2018), as well as continued formal and informal trade of paints, goods and articles containing high lead content in some

FIGURE 3–6. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING LEAD IN PAINTS.

INTERNATIONAL OR REGIONAL ACTIONS, INCLUDING RESOLUTIONS, ROAD MAPS, DECLARATIONS AND GOALS

UN environment assembly

saicm

AMCEN African Ministerial Conference on the Environment

XXI Forum of Ministers of Environment of Latin America and the Caribbean 2018

ENCOURAGES

ESTABLISHED

Global Alliance to Eliminate Lead Paint

SUPPORT

CAPACITY BUILDING & TECHNICAL ASSISTANCE
- guidance & tools (e.g. model law)
- GEF SAICM project in 40 countries

+ EXAMPLES OF OTHER INTERNATIONAL ACTIONS

BAN LEAD PAINT

International Lead Poisoning Prevention Week of Action

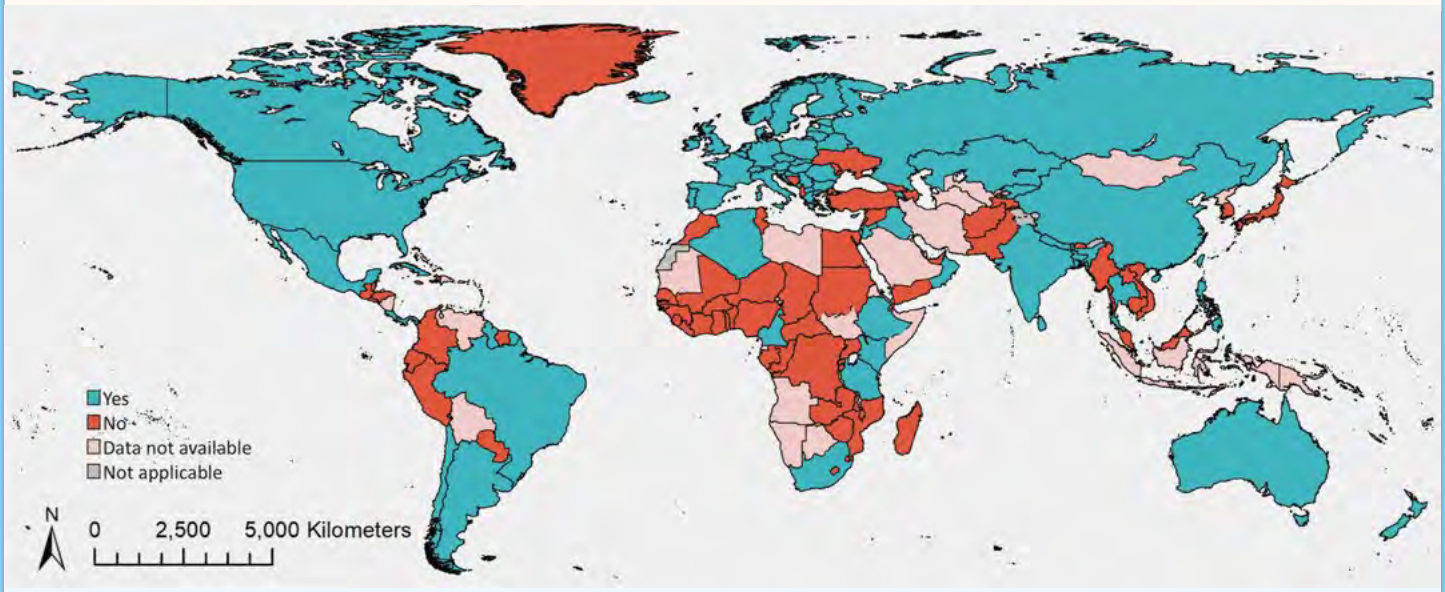
AWARENESS RAISING

East African Community (EAC): amended EAC **standards** to establish a 90 ppm limit for lead in paints in 2019.

Completed and ongoing **voluntary phase-out** by multinational companies, e.g., AkzoNobel, PPG.

COMPLEMENT

NATIONAL LAWS WITH LEGAL LIMITS OF LEAD IN PAINTS



As of September 2019, 73 countries (in green) have established laws with varied legal limits (UNEP 2019b).
As of January 2020, 2 additional countries established laws on lead paints, not shown here.

+ EXAMPLE OF LEVY

California, US: an annual fee on those involved with the production or sale of lead paints and from facilities reporting releases of lead into the air. The fees (e.g. $20.6 million in fiscal 2015) are then deployed to support health care referrals, assessments of homes for hazards, and educational activities.

+ EXAMPLE OF VOLUNTARY NATIONAL STANDARDS

Indonesia: a voluntary standard for solvent-based decorative paints with a maximum concentration of 600 mg/kg (SNI 8011 2014: Organic Solvent-based Decorative Paints).

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 (Mohanty *et al.* 2013; Kessler 2014). 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.

3.7 Nanotechnology and Manufactured Nanomaterials

While no definition has been internationally agreed upon, nanomaterials are commonly defined as materials having at least one external or internal dimension between 1 and 100 nm (for more discussion on definitions of nanomaterials, see below and Miernicki *et al.* 2019). Nanotechnology, i.e. the manipulation of matter at the nanometre scale, has rapidly developed in the past few decades and led to the widespread presence of nanomaterials in consumer products and industrial applications.

Despite being often composed of known chemicals (e.g. metals, metal oxides or carbon structures), the small size of manufactured nanomaterials and nanoparticles can lead to behaviour different from the "bulk phase", mostly related to nanomaterials' very high surface-to-volume ratios, quantum effects (Roduner 2006) and potential to cross biological borders due to their small size. While enabling a multitude of nanotechnology applications, this "nano-behaviour" has also given rise to concerns about potential adverse effects of nanomaterials. The low level of knowledge of these effects on human and environmental health coupled with a rapidly growing market led to the identification of "nanotechnology and manufactured nanomaterials" as an issue of concern under SAICM at ICCM2 in 2009 (Karlaganis and Willis 2009; SAICM 2009).

3.7.1 A Comprehensive Overview of Existing Instruments and Actions

The variety and variability of nanomaterials and their behaviours make it difficult to determine a "one-size-fits-all" approach to nanomaterials as a whole. At the moment, no global-scale regulation is in place (see Figure 3–7; for more details, see Table A–7 in the Annex and references therein).

Intergovernmental institutions have worked on developing guidelines (e.g. on occupational settings; WHO 2017a), developing guidance for testing and assessments (e.g. by OECD), capacity building (e.g. e-learning course by United Nations Institute for Training and Research [UNITAR]), and technical assistance (e.g. projects by UNITAR in Armenia, Jordan and Viet Nam). A report is being prepared under the Basel Convention "compiling information on existing activities that address waste containing nanomaterials and identifying issues related to waste containing nanomaterials that may be relevant to work under the Convention and on options for further work" (UNEP 2018). These are complemented by tools and actions by other stakeholders. For example, several clearinghouse mechanisms have been set up for information sharing (e.g. the Deep Skin Database, databases by S2Nano, and the EU Observatory for Nanomaterials). In addition, ChemSec has listed

carbon nanotubes in its Substitute It Now (SIN) List, a tool to inform businesses about chemicals likely to be banned or restricted in the near future, for being "carcinogenic, persistent and probably toxic to reproduction".

At the regional and national scales, different regulatory instruments containing specific provisions for nanomaterials have been and are being developed, building on existing regulations that apply to the substances of which a nanomaterial is composed. For example, in the EU, recent revision of the REACH Regulation introduced special provisions for nanomaterials to REACH Annexes I, III and VI–XII. These amendments entered into force on 1 January 2020 and apply to substances that are both new and already registered (European Commission 2019b). With these new amendments, registrants are required to identify and characterize so-called "nanoforms" of the substance to be registered. Nanoforms are defined according to the European Commission's recommendation for the definition of nanomaterials of 18 October 2011 (European Commission 2011). Nanoforms of a substance can differ based on parameters related to size distribution, shape and surface characteristics (e.g. surface chemistry, functionalization; ECHA 2019b; ECHA n.d.b). For each nanoform, specific data for characterization and hazard assessment needs to be compiled (European Commission 2019b).

In addition, in the EU, several product-specific regulations contain provisions for nanomaterials and specify notification and/or labelling requirements for nanomaterial-containing products (Table A–7 in the Annex): the Cosmetic Products (EC No 1223/2009); Novel Foods (EU 2015/2283), Food Information to Consumers (EU No 1169/2011) and Food Contact Materials (EU No 10/2011); Biocides (EU No 528/2012); and Medical Devices (EU No 2017/745) regulations. Each of these EU regulations defines nanomaterials differently, meaning that the regulations do not necessarily apply to the same types of nanomaterials within the EU (Miernicki *et al.* 2019).

Furthermore, the US Environmental Protection Agency (US EPA) established specific reporting and recordkeeping obligations in 2017 under the Toxic Substance Control Act (TSCA) for "nanoscale materials". Nanoscale materials are defined in Section 3 of TSCA as falling into the size range of 1–100 nm and exhibiting unique and novel properties. Under TSCA, companies manufacturing or importing nanoscale substances are to notify the US EPA of certain information, including specific chemical identity, production volume, manufacturing methods, processing, use, exposure and release information, as well as available health and safety data (US EPA 2017a; US EPA 2017b).

Additionally, several European countries require manufacturers, importers and sometimes distributors to register nanomaterials falling above a certain usage threshold. Registrations started for the French registry R-Nano in 2013 and subsequently other reporting schemes have been established in Belgium, Denmark, Norway and Sweden (EU Observatory for Nanomaterials n.d.). The different registries or reporting schemes vary in terms of their scope and with respect to the specific information that registrants need to provide (for details, see the EU Observatory for Nanomaterials, https://euon.echa.europa.eu).

From a non-regulatory perspective, voluntary partnerships between regulators, industry and other stakeholders also have led to various actions. For example, within the Malta Initiative, EU countries and companies have cooperated to support OECD guidance and testing development for nanomaterials (OECD 2017).

FIGURE 3–7. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING NANOMATERIALS.

INSTRUMENTS AND ACTIONS ON THE INTERNATIONAL LEVEL

EXAMPLES OF GUIDELINES

Guidelines on Protecting Workers from Potential Risks of Manufactured Nanomaterials by WHO, with recommendations on best practices, assessing health hazards and exposures, and controlling exposures

EXAMPLES OF GUIDANCE AND TOOLS

OECD published series of reports including "guiding principles" for measurements, risk assessments, test evaluations, test guidelines, as well as the analysis of a survey of consumer and environmental exposures

Skin Deep by Environmental Working Group tracks cosmetics and personal care products that contain or use nanomaterials; databases by S2Nano, compiling nanosafety datasets from literature, in addition to experimental datasets of nanomaterials; EU Observatory for Nanomaterials aims to increase the transparency and availability of information on nanomaterials to the general public. It collects existing information from databases, registries and studies and generates new data through additional studies and surveys on nanomaterials on the EU market

listing of carbon nanotubes in the SIN (Substitute It Now) List of ChemSec for being "carcinogenic, persistent and probably toxic to reproduction";

AN EXAMPLE OF CAPACITY BUILDING

e-learning course "Sound Management of Manufactured Nanomaterials" by UNITAR

AN EXAMPLE OF TECHNICAL ASSISTANCE

In 2013, UNITAR embarked on pilot projects in Armenia, Jordan and Viet Nam. Under the projects, Armenia formulated a new nano safety policy and added a nano safety chapter to the national profile on chemicals management, Jordan increased awareness and developed workplace safety guidelines, and Viet Name developed a national vision up to 2025 and assessed national nano safety priorities.

INSTRUMENTS AND ACTIONS ON THE NATIONAL LEVEL

EXAMPLES OF STRATEGIES

US: *National Nanotechnology Initiative (NNI) Environmental, Health, and Safety (EHS) Research Strategy*, providing guidance to the Federal agencies that produce the scientific information for risk management, regulatory decision making, product use, research planning, and public outreach. It describes NNI's EHS vision and mission, the state of the science, and the research needed to achieve the vision.

Republic of Korea: second National Nano-safety Master Plan (2017-2021), setting goals for and implementation of research programmes

EXAMPLES OF LEGAL REQUIREMENTS FOR MANUFACTURERS, IMPORTERS AND SOMETIMES DISTRIBUTORS

EU: Specific provisions with regard to nanomaterials exist in different regulations, including data requirements under **REACH** (according to Annexes I, III and VI-XII); notification, data and labelling requirements for relevant **cosmetics** under Regulation (EC) No 1223/20209; authorisation and labelling requirements for relevant **food** under Regulation (EU) No 2015/2283; authorisation requirements for relevant **food contact materials** under Regulation No 10/2011; risk assessment and labelling requirements for relevant **biocides** under Regulation (EU) No 528/2012; assessment requirements for relevant **medical devices** under Regulation (EU) 2017/745

France, Belgium, Denmark, Norway and Sweden: registration and specific data requirements for nanomaterials used/produced/imported above a certain amount.

US: under **TSCA**, notification and data requirements for manufactured or imported nanomaterials

Republic of Korea: registration requirements under **K-REACH** and **K-BPR**

AN EXAMPLE OF PARTNERSHIP

EU: the Malta Initiative, a self-organised group of EU member states, ECHA, the European Commission and industry that are working to develop OECD test guidelines and documents specific to nanomaterials

3.7.2 Current Challenges and Opportunities

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 (Zimmermann, Jepsen and Reihlen 2018). 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 (Miernicki *et al.* 2019). 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-oxide and 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; see Kane, Hurt and Gao 2018). 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 (Savolainen *et al.* 2013), 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.

3.8 Per- and Polyfluoroalkyl Substances (PFASs)

The PFAS[2] family is composed of thousands of synthetic organic chemicals that contain at least one perfluorocarbon moiety (e.g. $-CF_2-$) in their molecular structures. These substances have been widely used in numerous commercial and consumer applications since the late 1940s (see Banks, Smart and Tatlow 1994; Kissa 2001). Since the late 1990s and early 2000s, studies have been conducted to assess some "long-chain" PFASs[3]. Their findings resulted in the listing of perfluorooctanesulfonic acid (PFOS) and its precursors under the Stockholm Convention in 2009. That same year, at ICCM2, SAICM stakeholders identified "managing PFASs and the transition to safer alternatives" as an issue of concern. A resolution by ICCM2 further invited intergovernmental organisations, governments and other stakeholders "to consider the development, facilitation and promotion in an open, transparent and inclusive manner of national and international stewardship programmes and regulatory approaches to reduce emissions and the content of relevant perfluorinated chemicals of concern in products and to work toward global elimination, where appropriate and technically feasible" (SAICM 2015a).

3.8.1 A Comprehensive Overview of Existing Instruments and Actions

A diverse set of instruments and actions have been taken to address PFASs on different levels (see Figure 3–8; for details, see Table A–8 in the Annex and references therein). Because the science and policy around PFASs is evolving at a fast pace, readers are advised to regularly check online sources such as the OECD PFAS Portal (https://oe.cd/2M9; OECD 2018) and PFAS Central (https://pfascentral.org/policy) for updates on national, regional or international regulatory frameworks and voluntary initiatives addressing PFASs.

To date, the majority of efforts have focused on phasing out the long-chain PFASs. The Stockholm Convention has been a key platform for doing so at the international level (though multiple uses are exempted under the Convention), complemented by other regulatory and voluntary actions. Available evidence suggests that levels of PFOS and perfluorooctanoic

2 In the past, PFASs were often referred to as PFCs (per- and polyfluorinated chemicals or perfluorinated chemicals), but the term PFCs can also be understood as perfluorocarbons (e.g. under the Kyoto Protocol), which are only a subset of PFASs and contain only carbon and fluorine. In this assessment, the focus is on a much broader range of substances, beyond perfluorocarbons. To avoid confusion, we use the current commonly accepted term PFASs instead of PFCs.

3 Based on the OECD definition, long-chain PFASs refer to perfluoroalkylcarboxylic acids (PFCAs) with ≥7 perfluorinated carbons, perfluoroalkanesulfonic acids (PFSAs) with ≥6 perfluorinated carbons, and their precursors.

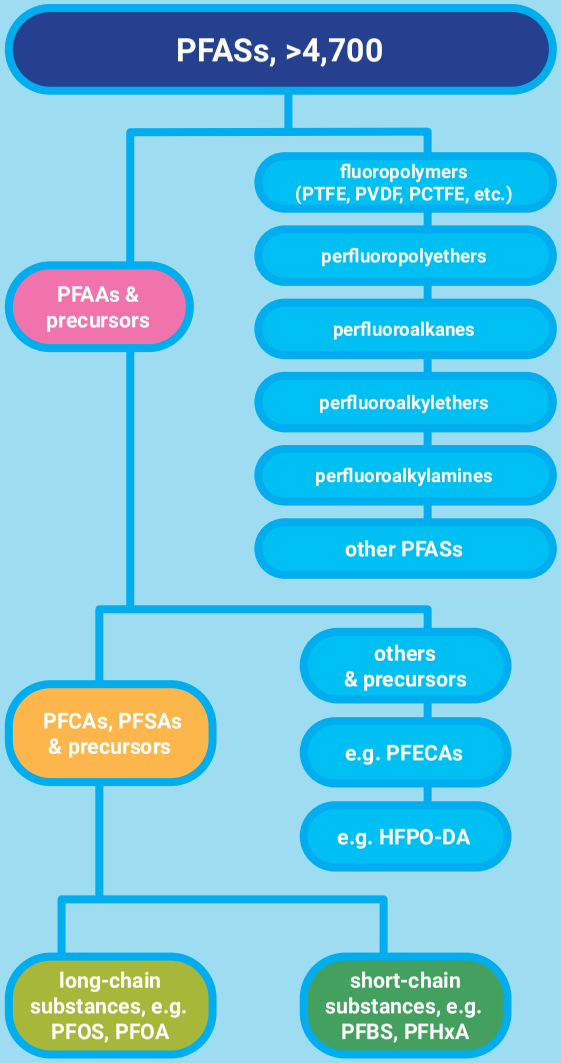
acid (PFOA) in humans generally are declining in Europe and the US, likely due to significant activities to phase out these two substances there (Land *et al.* 2018). In 2019, PFOA and its precursors were listed under the Stockholm Convention, and perfluorohexanesulfonate anion (PFHxS) and its precursors are being evaluated for listing, to be decided in 2021; therefore, substantial reductions may be expected for the global production and use of long-chain PFASs overall in the near future.

Significant efforts are also under way to address other PFASs. For example, some regulatory actions have been initiated to better understand PFASs that are not long-chain, including how to manage them. These include, for example, data reporting requirements for companies when they aim to introduce new PFASs on the Australian market and substance evaluation of some PFASs under REACH in the EU. More regulatory actions have also been taken to manage some non-long-chain PFASs, including using instruments such as identification as SVHC in the EU. Some governments, downstream industrial users and retailers have taken a more proactive approach in certain sectors, either restricting all PFASs to only essential uses or entirely phasing out all PFASs in relevant products, for example, for food contact materials, cosmetics and firefighting foams.

In addition to actions to assess and manage PFASs with a focus on their upstream production and use, substantial progress has been made in other areas. In particular, many regulatory, advisory and guidance values for PFAS levels in different environmental compartments have been developed for managing contamination at the local, national and regional scales, mostly for PFOS, PFOA and a limited number of other PFASs. Values set for the same substances vary across different jurisdictions, up to three orders of magnitude.

The WHO is working to include PFOS and PFOA in its Guidelines for Drinking-water Quality, which may be a milestone for helping to set harmonised guidance values for PFOS and PFOA in drinking water, particularly in developing and transition countries (WHO 2017b). Notably, the EU initiated work to explore a limit value for all PFASs in drinking water over the next three years. Some other action areas include facilitation of information exchange (e.g. by the OECD/UNEP Global Perfluorinated Chemicals Group on the international level) and consumer education.

FIGURE 3–8. A COMPREHENSIVE OVERVIEW OF EXISTING INSTRUMENTS AND ACTIONS ADDRESSING DIFFERENT PFASS.



HFPO-DA: tetrafluoro-2-(heptafluoropropoxy) propanoic acid
PFAA: perfluoroalkyl acid
PFBS: perfluorobutanesulfonic acid
PFCA: perfluoroalkylcarboxylic acid
PFECA: perfluoroalkylether carboxylic acid
PFHxA: perfluorohexanoic acid
PFSA: perfluoroalkanesulfonic acid
PFOA: perfluorooctanoic acid
PFOS: perfluorooctanesulfonic acid

legally binding

EXAMPLES OF LEGALLY BINDING BANS OR RESTRICTIONS

All PFASs

Denmark: ban of PFASs in paper and cardboard used in food contact materials (in force as of July 2020)

Australia: ban on the use of fluorinated firefighting foams in South Australia, subject to transition arrangements; Operational Policy: Environmental Management of Firefighting Foam in Queensland, includes requirements for use of foams containing short-chain fluorotelomers where such use is the only viable option

long-chain substances, e.g. PFOS, PFOA

International: PFOS, PFOA and their precursors listed under the Stockholm Convention, with some exemptions; PFHxS and its precursors being evaluated for listing

EU: Restriction of PFOA and related substances to be in force from July 2020 with some exemptions; restriction proposal of C9-C14 PFCAs, PFHxS, and their related substances under evaluation

short-chain substances, e.g. PFBS, PFHxA

EU: Restriction of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (TDFAs); in spray products in force; restriction proposal of PFHxA and its related substances under evaluation

EXAMPLE OF PIC PROCEDURE FOR TRADE

long-chain substances, e.g. PFOS, PFOA

International: PFOS and its precursors listed under the Rotterdam Convention, subject to PIC procedure

EXAMPLE OF IDENTIFICATION AS CHEMICALS OF CONCERN

short-chain substances, e.g. PFBS, PFHxA

PFASs other than PFCAs, PFSAs and precursors

EU: PFBS and HFPO-DA identified as Substances of Very High Concern (SVHCs)

EXAMPLES OF SUBSTANCE EVALUATION

short-chain substances, e.g. PFBS, PFHxA

PFASs other than PFCAs, PFSAs and precursors

EU: A number of PFASs including a PFBS precursor and three PFHxA precursors being evaluated under REACH

Australia: Under NICNAS, additional data requirements set specifically for new PFAS

legally binding or voluntary

EXAMPLES OF HEALTH-BASED GUIDANCE VALUES

All PFASs

Regional/national/local: Many health-based guidance and advisory values have been set for PFOA, PFOS, and a limited number of other PFASs in different environmental compartments including drinking water, see https://pfas-1.itrcweb.org/fact-sheets/.

EU: The new Drinking Water Directive adopted in 2019 introduces a limit value for the 20 most important PFASs. Over the next three years, the EU is to develop a method for measuring all PFASs and possibly set a new limit value for all PFASs.

voluntary

EXAMPLES OF PARTNERSHIPS AND CLEARING HOUSES

All PFASs

International: The OECD/UNEP Global PFC Group — a multi-stakeholder partnership — to facilitate the information exchange and to support a global transition towards safer alternatives (https://oe.cd/2M9); PFAS Central website (https://pfascentral.org/about/) by the Green Science Policy Institute and Northeastern University, providing current information including press, peer-reviewed scientific articles, meetings, and consumer information.

US: fact sheets developed and maintained by the Interstate Technology and Regulatory Council (ITRC) summarise latest science and emerging technologies

Australia: Australian Government maintains a website (www.pfas.gov.au), providing information on PFAS contamination, use and health and environmental impacts and links to information provided by governmental agencies to the general public, regulators and industry.

EXAMPLES OF VOLUNTARY NATIONAL STANDARDS

long-chain substances, e.g. PFOS, PFOA

China: HJ2546-2016, setting the limits of PFOS and PFOA in textile products

EXAMPLE OF CONSUMER EDUCATION

All PFASs

Germany: smartphone app "PFC Planet" to inform consumers about what PFASs are, where they are used and what consumers can do.

EXAMPLES OF VOLUNTARY PHASEOUTS

All PFASs

Denmark: COOP Denmark discontinued the sales of all cosmetics products containing PFASs in March-September 2019.

Australia: Airservices Australia has phased out PFAS-containing firefighting foams in civilian airports since 2010.

long-chain substances, e.g. PFOS, PFOA

International: A global phase-out of its global production and use of long-chain PFASs by 3M in 2000-2002; under the US EPA PFOA Stewardship programme, eight major producers phased out their global production and use of PFOA, its longer homologues and precursors by 2015.

3.8.2 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 (Wang *et al.* 2014). 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 (Wang *et al.* 2013; Wang *et al.* 2015). 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 (Cousins *et al.* 2019). 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 Perfluorinated 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).

4.

Assessment of Issues Where Emerging Evidence Indicates Risks

GCO-II identified 11 chemicals or groups of chemicals where emerging evidence indicates a risk (see Section 1.3). This chapter presents assessments of current exposure to the substances, as well as the ability of existing regulatory and policy frameworks through different instruments and actions in addressing these substances.

The 11 issues identified by GCO-II are discussed in alphabetical order. This report does not conduct any hazard or risk assessments. Instead, background information on the scientific evidence for the environmental and human health effects of the 11 issues is provided in the form of a compilation of existing assessments by national governments, intergovernmental institutions, or both. For each of the 11 issues, this chapter first presents this background information, then focuses on key characteristics of current exposure, existing instruments and actions for sound management, and a brief discussion of challenges and opportunities.

4.1 Arsenic

Arsenic (As) is ubiquitous in a variety of geologic deposits around the world, present in many different inorganic and organic forms (US National Research Council 1977, International Agency for Research on Cancer [IARC] 2018). Arsenic and many arsenic compounds are highly toxic to human health and many wildlife species (e.g. carcinogenic). Exposure to arsenic and arsenic compounds may originate from both natural sources, such as volcanic activity, and anthropogenic sources, through a wide variety of uses of arsenic and related compounds in products; mining and smelting of non-ferrous metals; and burning of fossil fuels. Elevated contamination levels of arsenic and arsenic compounds have been measured in environmental media, wildlife and humans, resulting in major concern. Thus, arsenic and arsenic compounds are of high concern, as identified as one of WHO's 10 chemicals of major public health concern and by GCO-II.

4.1.1 Background on Environmental and Human Health Effects Based on Assessments by Intergovernmental Institutions

Arsenic and arsenic compounds have been extensively assessed by national governments and intergovernmental institutions over the past decades, providing a wealth of

information. A compilation of all existing assessments is not made here; instead, this section highlights major conclusions from several authoritative assessments by inter-governmental institutions.

In particular, the monograph prepared by the IPCS reviewed the adverse effects both on human health and on other organisms in the environment (WHO 2001). With regard to human health, it concluded the following:

- "Soluble inorganic arsenic is acutely toxic".
- "Long-term exposure to arsenic in drinking-water is causally related to increased risks of cancer in the skin, lungs, bladder and kidney, as well as other skin changes such as hyperkeratosis and pigmentation changes", and "exposure-response relationships and high risks have been observed for each of these end-points".
- "Occupational exposure to arsenic, primarily by inhalation, is causally associated with lung cancer."
- "Conclusions on the causality of the relationship between arsenic exposure and other health effects are less clear-cut. The evidence is strongest for hypertension and cardiovascular disease, suggestive for diabetes and reproductive effects and weak for cerebrovascular disease, long-term neurological effects, and cancer at sites other than lung, bladder, kidney and skin."

With regard to environmental effects, the IPCS monograph concluded that

- "Aquatic and terrestrial biota show a wide range of sensitivities to different arsenic species" and in general, inorganic arsenic compounds are more toxic than organic arsenic compounds, and among inorganic arsenic compounds, arsenite is more toxic than arsenate.
- "Arsenic compounds cause acute and chronic effects in individuals, populations and communities at concentrations ranging from a few micrograms to milligrams per litre, depending on species, time of exposure and end-points measured", "these effects include lethality, inhibition of growth, photosynthesis and reproduction, and behavioural effects", and "arsenic-contaminated environments are characterized by limited species abundance and diversity".

Furthermore, IARC (2012) classified arsenic and inorganic arsenic compounds as carcinogenic to humans (Group 1) and dimethylarsinic acid and monomethylarsonic acid, two organic arsenic compounds, as possibly carcinogenic to humans (Group 2B), while acknowledging that arsenobetaine and other organic arsenic compounds that humans do not metabolise are not classifiable as to their carcinogenicity to humans (Group 3).

Based on latest scientific evidence, WHO has set a provisional guideline value of 10 µg/L arsenic in drinking water (WHO 2017).

4.1.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics of arsenic and arsenic compounds. Arsenic and arsenic compounds may exhibit different environmental fate and transport characteristics depending on their form, which also impacts their levels of bioavailability and toxicity. Among the different forms of arsenic, inorganic and some organic arsenic compounds have been well studied, while many other organic arsenic compounds, such as arsenobetaine, arsenoproteins, arsenolipids and arsenosugars, are less so (Carlin *et al.* 2016). In the environment, physical and biological processes can readily transform arsenic and arsenic compounds, which complicates the overall picture of environmental fate and transport of arsenic and arsenic compounds.

Some major lessons learned include the following. Inorganic arsenic compounds in the environment are primarily arsenite, As(III), compounds such as As2O3 and arsenate, As(V), compounds such as PbHAsO4 (Mandal and Suzuki 2002; Melamed 2005). Arsenic is released into the atmosphere primarily as As2O3 where it is mainly adsorbed on particulate matter, and these particles are transported away from sources by the wind and undergo wet or dry deposition to the ground, with atmospheric lifetimes of about 4 to 5 days (Wai *et al*. 2016). Through long-range atmospheric transport, emissions from Asia are estimated to contribute 39% and 38% of the total arsenic deposition over the Arctic and North America, respectively, and another 14% of the arsenic deposition to the Arctic region is attributed to European emissions (Wai *et al*. 2016).

Dissolved forms of arsenic in water include arsenate, arsenite, methylarsonate and dimethylarsinate, with arsenite much more soluble and more mobile than arsenate (WHO 2001). Arsenate compounds are immobilised on geologically available surfaces, often on iron oxides, and leaching usually results in transportation only over short distances. In well-oxygenated water and sediments, nearly all inorganic arsenic compounds are present as arsenate compounds, which are thermodynamically more stable than arsenite compounds. In humans and many other biota, elemental arsenic [As(0)] and inorganic arsenic compounds generally share the same metabolic pathway: arsenate [As(V)] → arsenite [As(III)] → methylarsonate → dimethylarsinate, with several other intermediates possibly formed during the metabolism; both transformation end products (e.g. methylarsonate) and intermediates may be excreted from biota (IARC 2012; Rahman *et al*. 2012). Organic arsenic compounds may undergo photolysis or biodegradation (e.g. by microbes in soil) back to inorganic arsenic compounds (Huang *et al.* 2011). Therefore, once arsenic and arsenic compounds are released, they undergo complex biogeochemical cycles in the environment; after being released to the environment, arsenic persists and accumulates even as it is transformed into different forms, from inorganic or organic to the other and back again.

Major Sources of Current Exposure. Releases of arsenic and arsenic compounds to the environment may occur both naturally and through anthropogenic activities. The former

includes volcanic activity and, to a lesser extent, low-temperature volatilisation, exudates from vegetation, and windblown dusts. Anthropogenic releases include fossil fuel and coal combustion, mining and smelting of metals, and the intentional use of arsenic in wood preservatives, pesticides, animal feed additives and pharmaceuticals, as well as in glass production, alloy manufacturing, and electronics and semiconductor manufacturing. The global production and use of arsenic varied between 33,000 and 37,000 tonnes per year in the past five years (US Geological Survey [USGS] 2020; for more details on the intentional production and uses of arsenic, see Table B1–1 in the Annex and references therein).

Estimates of emissions have varied between studies, and most are from the 1980s and early 2000s (e.g. Chilvers and Peterson 1987; Nriagu and Pacyna 1988; Matschullat 2000; WHO 2000; WHO 2001: Wai *et al*. 2016). Due to a general lack of methodological details, it is not possible to reconcile the reported numbers. However, these studies do point out that anthropogenic sources play a major role in the global exposure to arsenic. For example, anthropogenic atmospheric emissions were estimated to contribute about 12,000–28,000 tonnes per year, up to 66% to nearly 90% of the total atmospheric emissions (Chilvers and Peterson 1987; Nriagu and Pacyna 1988; Matschullat 2000; WHO 2000; WHO 2001; Wai *et al*. 2016). In addition, global annual anthropogenic soil and water emissions were estimated to be about 24,000–132,000 tonnes and 12,000–70,000 tonnes per year, respectively (Nriagu and Pacyna 1988; Matschullat 2000).

As of 2000, the cumulative global releases from fossil fuel and coal combustion was estimated to be about 1.24 million tonnes. In comparison, the cumulative global volumes associated with mining and smelting of metals was estimated to be about 3.3 million tonnes (Han *et al.* 2003); some of that was directly released to the environment during mining and smelting, and the rest made into different products and (partially) released later on during use and disposal. Another study estimated that copper smelting and coal combustion accounted for about 60% of anthropogenic atmospheric emissions, and the rest came from the intentional production and use of arsenic (Matschullat 2000).

At the same time, previous studies may have also overlooked some other unintentional anthropogenic sources. For example, a recent study assessed 22 glyphosate- and non-glyphosate–based pesticide formulations on the French market and detected heavy contamination by arsenic from unknown sources in all tested formulations (Defarge *et al.* 2018).

Humans are exposed to arsenic through multiple pathways. For the general population, the primary route is via ingestion of contaminated food or water, generally in the range of 20–300 µg per day (IARC 2012). Inhalation of arsenic from ambient air is minor for the general population, with estimated daily intake of about 20–200 ng in rural areas, 400–600 ng in cities without substantial industrial arsenic emissions; non-smokers inhale about 1 µg per day and more in polluted areas, and smokers up to approximately 10 µg per day due to tobacco plants treated with lead arsenate insecticide (WHO 2000; WHO 2001). In addition, exposure may occur from arsenic-related industry activities (Mandal and Suzuki 2002) and

arsenic-containing products (e.g. child exposure due to contact with timber treated with chromated copper arsenate, or CCA; Hemond and Solo-Gabriele 2004; Kwon *et al*. 2004), with large variabilities depending on exposure conditions. Children playing in contaminated regions around the world might directly eat arsenic-bearing soil or inhale particles (US Agency for Toxic Substances and Disease Registry [US ATSDR] 2007).

In contrast, in an occupational setting, inhalation of arsenic-containing particles is a primary route, with possible significant ingestion and dermal exposure in particular situations (e.g. during preparation of timber treated with CCA; IARC 2012).

Prevalence, levels and trends of current exposure. High levels of arsenic contamination in water and foodstuffs are a global phenomenon. At least 140 million people in 50 countries are estimated to have access to drinking water containing arsenic at levels above the WHO's provisional guideline value of 10 µg/L, while drinking water in many parts of the world remains untested (Ravenscroft *et al.* 2009). Most high-arsenic groundwater provinces, and thus contaminated drinking water, are a result of the natural occurrence of arsenic, while the contamination in some other areas is affected by geothermal, mining and industrial activities (Mandal and Suzuki 2002).

Studies have also looked into the global burden of disease related to inorganic arsenic in food and estimated a high number of additional cases of cancers and disability-adjusted life years (DALYs). Oberoi *et al.* (2014) estimate that worldwide, more than 9,000–119,000 additional cases of bladder cancer, nearly 12,000–121,000 of lung cancer, and nearly 11,000–110,000 of skin cancer result from these arsenic exposures. Other studies estimated that about 1.4 million DALYs for the related cancers occur worldwide each year (Gibb *et al*. 2019; Oberoi *et al*. 2019). In addition, the Global Burden of Disease, Injuries, and Risk Factors (GBD) studies looked into the global burden associated with occupational exposure to arsenic and estimated about the deaths and DALYs in the years 2010, 2015, 2016 and 2017, respectively, see Table 4–1 below (Lim *et al*. 2012; GBD 2015 Risk Factors Collaborators 2016; GBD 2016 Risk Factors Collaborators 2017; GBD 2017 Risk Factors Collaborators 2018).

Table 4–1. Global burden associated with *occupational* exposure to arsenic. DALYs = disability-adjusted life years.

Year	Deaths	DALYs
2010	2600	63,000
2015	9000	194,000
2017	8000	219,000
2018	9000	245,000

Sources: Lim *et al*. 2012; GBD 2015 Risk Factors Collaborators 2016; GBD 2016 Risk Factors Collaborators 2017; GBD 2017 Risk Factors Collaborators 2018.

The magnitude of the global arsenic exposure from other anthropogenic sources remains unclear. However, it is noted that the global extraction of arsenic for intentional use has remained at about 35,000–58,000 tonnes per year since the 2000s (Brown *et al*. 2019; USGS

2020), while the extraction and use in some countries and regions have decreased in recent years due to actions taken by governments and stakeholders (see below).

4.1.3 An Assessment of Existing Instruments and Actions

Different instruments and actions have been developed and taken to address arsenic and arsenic compounds (for details, see Table B1–2 in the Annex). Internationally, under the Basel Convention, wastes that have arsenic or arsenic compounds (waste category code Y24) as well as metal wastes and waste consisting of alloys of arsenic (waste category code A1010) are listed as hazardous wastes and thus subject to the Convention provisions. In addition, some countries and regions have adopted legally binding instruments to restrict the use or presence of arsenic in one or more product categories, including anti-fouling systems, treatment of industrial waters, wood preservatives, fertilisers, animal feeds, toys, packaging material, perfume and cosmetics, and foodstuffs. In the EU, export of arsenic is additionally subject to the prior informed consent notification procedure.

These legally binding instruments are further complemented by guideline values related to exposure. In particular, WHO has established a provisional guideline value for arsenic in drinking water (10 µg/L) but could not establish such values for arsenic in air and through dietary exposure. Further guideline values for arsenic levels in different exposure media, including those found in occupational settings, have also been established in a number of countries.

Furthermore, voluntary actions have also been taken, including industrywide phase-out of CCA in timber treatment for residential uses in the US, phase-out of arsenic-containing animal feeds by some major manufacturers in the US and Canada, and regular monitoring of arsenic contaminants in a range of foodstuffs in Australia. Similarly, multiple third-party standards and certification schemes have included arsenic in their listings (e.g. bluesign®). Further, multiple guidance documents have been developed to address technical issues around investigation and mitigation of arsenic contamination. Some more actions are likely to be taken by some countries in the foreseeable future, as suggested by the addition of arsenic and arsenic compounds by China in its first Batch of Prioritized List of Substances to be Subject to Control in 2017 for forthcoming control measures on the production and use of these chemicals.

4.1.4 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; UNEP 2019). 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.

4.2 Bisphenol A

Bisphenols are a group of dozens of organic compounds that have been used as building blocks in the production of polycarbonate plastics, epoxy resins and other products since the 1960s (Pelch *et al.* 2017). Among them, bisphenol A (BPA) has attracted the most attention; the GCO-II identified BPA as an issue with emerging evidence indicating risks to human health and the environment with high reproductive toxicity and (potential) endocrine disruption. This assessment focuses on BPA; issues with its bisphenol-group analogues, many of which are currently used as replacements for BPA, are briefly touched upon in Section 4.2.4 below.

4.2.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

BPA has repeatedly been assessed by different national governments and intergovernmental institutions over the past two decades, though often with different scopes and mostly focusing on human health; assessments made between 2010 and 2019 are summarised in Table B2–1 in the Annex. The scientific and regulatory debate is still ongoing with regard to which modes or mechanisms of action should be considered in risk assessments. Nevertheless, available governmental assessments conclude that BPA may cause multiple

adverse effects on human health, particularly on infants and young children, including effects on their reproductive system (for females), cholesterol (metabolism) and body weight, spatial memory and learning functions, and developing mammary glands. In the EU, BPA has been recognized as a SVHC under REACH due to its reproductive toxicity and endocrine-disrupting properties in the environment and for humans (ECHA 2017a).

Based on the latest scientific findings, some governmental assessments have substantially lowered estimated safety limits from their previous assessments. For example, the temporary tolerable daily intake (t-TDI) set by the European Food Safety Authority (EFSA) was reduced from 50 µg/kg body weight per day in its 2006 assessment to 4 µg/kg body weight per day in its 2015 assessment (EFSA 2019a). In 2015, the Danish National Food Institute (2015) argued that the limits would need to be further reduced by an order of magnitude, due to consideration of potential endocrine-disrupting activities, which may warrant further research and assessment. In 2018, EFSA formed a working group of scientific experts to reassess the potential hazards of BPA in food and review the temporary safe level set in its 2015 assessment; the new assessment is to be ready in 2020. Furthermore, the latest assessment from the Australian Government also shows that BPA is highly toxic to aquatic organisms, with adverse effects related to development identified at very low levels; intergenerational exposure appears to cause an increased sensitivity to BPA-induced adverse effects in aquatic organisms (National Industrial Chemicals Notification and Assessment Scheme (Australia) [NICNAS] 2019).

4.2.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics. In general, BPA is not persistent in the environment and biota, and thus has limited long-range transport potential (Cousins *et al.* 2002) and low bioaccumulation potential in wildlife (Flint *et al.* 2012) and humans (Stahlhut *et al.* 2009). It may be transported hundreds of kilometres in rivers due to its degradation half-life of about 4.5 days in water and soil, but long-range transport in air is negligible due to its degradation half-life of less than 1 day in air (Cousins *et al.* 2002).

Despite these fast breakdown times, BPA has been detected in the atmosphere, water and animals in remote regions, at levels much lower than, or close to the lower end of, measurements in the areas close to sources (Fu and Kawamura 2010; Ademollo *et al*. 2018; Ozhan and Kocaman 2019). Because BPA does not occur naturally, BPA in remote regions is expected to have been transported over long distances from the original sources. Atmospheric transport is a possible pathway, although atmospheric deposition of BPA to the world's ocean remains to be fully clarified (Huang *et al*. 2012; Corrales *et al*. 2015). Marine plastic debris, including polycarbonate, may be another source and transport mechanism for nearshore BPA (Ademollo *et al*. 2018; Ozhan and Kocaman 2019). The mechanisms that lead to the presence of BPA in remote regions warrant further investigation.

Major sources of current exposure. BPA is a high-production-volume chemical, with production volumes of about 1 million tonnes per year in the US reported in the early 2000s (Allard

2014), about 745,000 tonnes in 2014 in China (Jiang *et al.* 2018), and between 0.1 and 1 million tonnes per year in the EU at present (ECHA 2019a). Over 90% of BPA is estimated to have been used as a monomer in the production of different polymers. Recent estimates show that nearly 64% of the global BPA demand in 2018 was for polycarbonates, nearly 30% for epoxy resins, and the rest for other polymers such as phenoplast resins, phenolic resins, unsaturated polyesters and formaldehyde resins (Fischer *et al.* 2014; IHS Markit 2018). These polymers are commonly used in many everyday products across the globe. For example, polycarbonates are used in drinking bottles, food packaging materials, building and construction, optical media, electronics and more, and epoxy resins are applied in marine and protective coatings, powder coatings, electronics, can and coil coatings, automotive materials and other uses (ECHA 2017b).

To a much lesser extent, BPA has also been used as an ink developer on thermal paper; it is estimated that 3,304 tonnes of BPA were used in thermal paper on the EU market in 2018 (ECHA 2019b). Some other relatively minor uses include as a reagent for the manufacture of flame retardants, including tetrabromobisphenol A (TBBPA), tetrachlorobisphenol A (TCBPA) and bisphenol A bis(diphenyl phosphate) (BDP; ECHA 2015; IHS Markit 2018).

The consumption of BPA and related products is widespread and estimated to continue to grow in the foreseeable future, driven mainly by increasing demand for polycarbonates and other plastics. For additional information on production and use, readers are advised to consult Table B2–2 in the Annex and references therein.

Depending on the use, exposure to BPA may occur in different paths along the life cycle of a product. For example, thermal paper containing BPA may result in direct human dermal exposure and has been identified as a cause of concern for pregnant cashiers, tellers and consumers handling thermal receipts (ECHA 2015). BPA may also be spread through recycling of thermal paper; analyses showed that all the waste paper samples from households in a Danish town contained BPA (Pivnenko *et al*. 2015).

Studies have also shown that small amounts of BPA may remain in polycarbonates, epoxy resins and other plastics as impurities that can be released during their use and disposal (including recycling), causing environmental and human exposures. Some well-known examples are polycarbonate baby bottles (Hoekstra and Simoneau 2013), canned food (Hartle *et al*. 2016), stockings and tights (Murata and Nakata 2015; Li and Kannan 2018), and infant socks (Xue, Liu and Kannan 2017). Similarly to thermal paper, recycling these plastics may result in significant amounts of BPA passed on to new products (Arp *et al*. 2017; Dreolin *et al*. 2019). Some studies suggest that these BPA-derived polycarbonates may break down over time during use and recycling and release free BPA, acting as a source of exposure (Watanabe 2004; Chi *et al*. 2017), which warrant further investigation.

Among other chemicals derived from BPA, laboratory experiments confirmed that TBBPA may be transformed back into BPA, which may be partially responsible for elevated

concentrations of BPA in soils close to an e-waste recycling facility in China (Huang *et al*. 2014). Recent evidence also suggests that BPA is present in personal care products in Europe (Spain), Asia (China) and the US, with unclear origins (Cacho *et al*. 2013; Liao and Kannan 2014).

Furthermore, the general population may also be exposed to BPA due to environmental pollution (dust, air, drinking water, landfill leachate) via ingestion, inhalation or dermal contact (Mikołajewska, Stragierowicz and Gromadzinska 2015). Children are at heightened risk because they play on the floor and frequently put their hands into their mouths (Christensen *et al*. 2012).

The prevalence, levels and trends of current exposure across the globe. BPA has been detected in different indoor and outdoor environmental media, in wildlife and in humans around the world (see Table B2–3 in the Annex). Most studies have targeted the concentration of BPA in water, sewage sludge, sediment, wildlife and humans, with limited data reported from soil and air. Measurements of BPA have largely been reported in Asia, Europe and North America; the number of reports from other regions is small but gradually increasing (Chen *et al*. 2016). Staples *et al*. (2018) reviewed BPA measurements in surface waters and sediments in Europe and North America between 1996 and 2014 and concluded that BPA freshwater concentrations in both regions appear to have remained relatively unchanged over the 19-year period. Another review of over 500 peer-reviewed studies estimated that more than half of the wastewater treatment plant effluents in Asia, Europe and North America, and 80% of surface waters from Asia, contained BPA at levels exceeding a predicted no-effect concentration of 750 ng/L for aquatic life (Corrales *et al*. 2015).

With regard to human exposure, available evidence shows that dietary exposure, especially via canned food coated with epoxy resin, is generally a primary exposure source for most studied subgroups within general populations across the globe (Nakanishi, Miyamoto and Kawasaki 2007; Geens *et al*. 2012; von Goetz *et al*. 2017). For some subgroups of the general population, other sources may also play an important role (e.g. dermal exposure from thermal papers by pregnant cashiers, tellers and consumers handling thermal receipts; ECHA 2015).

Recently, Huang *et al*. (2017) assessed the levels of human BPA intake in 30 countries worldwide based on available urinary concentrations between 2000 and 2016, and they identified the top 10 countries for adult intake: Italy, Sweden, Denmark, France, Cyprus, Australia, Israel, Ghana, Jamaica and Belgium. The researchers noted that although the national and global estimated BPA daily intakes were generally below the tTDI recommended by EFSA, some normal individuals' daily intakes exceeded the tTDI. A follow-up study by Huang *et al*. (2018) calculated BPA intakes across six continents based on urinary levels and ranked the average BPA intake from high to low as follows: Oceania, Asia, Europe and North America for children and Oceania, Europe, Asia and North America for adults (for African and South American regions, limited data were available). The same study also assessed time trends for BPA intake and found similar trends for adult and child populations: a decrease from 2000 to 2008 and then a slight increase from 2008 to 2011. After 2011, adults' intake

continued to increase, while children's decreased. The authors suggested this decrease in children likely can be attributed to the widespread phase-out of the use of BPA in children's food-related products since 2009.

4.2.3 An Assessment of Existing Instruments and Actions

Different instruments and actions have been developed and taken to address BPA in different uses and in environmental media (see Table B2–4 in the Annex). Significant progress has been made in addressing children's exposure to BPA around the globe, in particular by removing BPA from baby bottles through bans in some countries and voluntarily by manufacturers and retailers in others. In addition, some countries have addressed additional sources such as food packaging, containers and utensils (e.g. legal bans in Denmark, Belgium and Sweden; voluntary industry phase-out of BPA-containing packaging for liquid infant formula in the US and Canada) and toys (e.g. legally binding migration limit of 0.04 mg/L for BPA from toy materials in the EU). These actions have likely resulted in significant reduction of children's exposure to BPA, as mentioned above (Huang *et al.* 2018).

In addition, a number of countries and regions, e.g., EU, Canada, Association of Southeast Asian Nations (ASEAN), Eurasian Economic Union have legally banned the use of BPA in cosmetics. To a lesser extent, legal bans have been introduced for the use of BPA in thermal paper (e.g. EU) and all food packaging, containers and utensils (e.g. EU, France, Colombia), complemented by voluntary industry standards (e.g. on elution limits for food-related metal cans manufactured in Japan). The European Commission plans to look into the risk of BPA in clothing and the potential need for legislative amendments and thus requested the Scientific Committee on Consumer Safety to provide a scientific opinion on "the safety of the presence of BPA in clothing articles" (European Commission 2019).

Some action has also been initiated to address BPA in a more comprehensive manner. For example, BPA has been listed as a SVHC under REACH, which requires manufacturers and importers to provide adequate information to allow safe use of all products containing more than 0.1 wt% of BPA. In addition, a process has been initiated in the EU to add BPA on the authorisation list, which would require manufacturers to seek authorisation for use of BPA in any non-polymer applications.

While these actions address "upstream" BPA uses, guideline values have also been developed for "downstream" levels of BPA in different environmental media, for example, in Canada and in recycled water for drinking water augmentation in Australia.

4.2.4 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 (Huang *et al.* 2018). 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 (Kwak *et al.* 2017), 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 (Ménard *et al*. 2014a; Ménard *et al*. 2014b; Luo *et al*. 2016) or childhood to adulthood (Koike *et al*. 2018; Özaydın *et al*. 2018; Yanagisawa *et al*. 2019) 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 (Prins *et al.* 2019). 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 (Chen *et al.* 2016), while recent studies have also pointed out that these chemicals may cause similar adverse effects as BPA does, though with different potencies (Pelch *et al*. 2019; Rochester and Bolden 2015; Zhang *et al*. 2018; Chen *et al*. 2016). For example, Vervliet *et al.* (2019) 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 (US EPA 2012; CMC 2016; CMC 2017; ECHA 2019a). 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 (Lehmler *et al*. 2018; Liu *et al*. 2018; Zhang *et al*. 2011; Liao *et al*. 2012a; Liao *et al*. 2012b; Liao *et al*. 2012c; Liao *et al*. 2012d). However, overall the measured data for BPA analogues were quite limited and current scientific knowledge is lacking (Chen *et al.* 2016). **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.**

4.3 Cadmium

Cadmium (Cd) generally occurs at low levels in the natural environment, but the heavy metal has been produced, used and released in large quantities and thus intentional human uses have caused widespread contamination and exposure. Cadmium and cadmium compounds are highly toxic to humans and the environment at very low exposure levels, including being carcinogenic to humans. To date, cadmium has been identified as one of WHO's 10 chemicals of major public health concern and as an issue with emerging evidence of risks to human health and the environment by GCO-II.

4.3.1 Background on Environmental and Human Health Effects Based on Assessments by Intergovernmental Institutions

Cadmium and cadmium compounds have been extensively assessed by national governments and intergovernmental institutions over the past decade, providing a wealth of information. A compilation of all existing assessments is not made here; instead, major lessons learned from several authoritative assessments by intergovernmental institutions are highlighted here.

Cadmium and cadmium compounds exert high toxicity at very low exposure levels. In particular, a recent IARC monograph concludes that cadmium and cadmium compounds

are Group 1 carcinogens (carcinogenic to humans) with sufficient evidence in humans for causing lung cancers and positive associations observed between exposure and cancer of the kidney and of the prostate (IARC 2012).

In addition to carcinogenicity, cadmium may also cause a range of other adverse health effects, mainly to the kidneys. For example, cadmium accumulates primarily in the kidneys with a biological half-life of 10–35 years in humans, causing proximal tubular cell damage that leads to increased excretion of proteins, glucose and amino acids in urine (Nordic Council of Ministers 2003; UNEP 2010). This dysfunction of the kidneys is considered the most critical health effect associated with cadmium for both the general population and workers. Secondary effects, likely caused by kidney dysfunction, include skeletal damage (osteoporosis) and disturbances in calcium metabolism (Nordic Council of Ministers 2003; WHO 2011).

Long-term, high-level occupational exposure to cadmium and cadmium compounds is associated with lung changes, primarily characterised by chronic obstructive pulmonary disease (IPCS 1992). Certain population groups are particularly vulnerable regarding cadmium exposure, particularly those who already suffer from renal insufficiency (e.g. diabetes patients) and multiparous women with inadequate nutrition (UNEP 2010). Given the long half-life of cadmium in the body, the FAO/WHO Expert Committee on Food Additives has replaced the previous tolerable weekly intake value of 7 µg/kg body weight with a tolerable monthly intake value of 25 µg/kg body weight (WHO 2011). In addition, WHO has set guidelines values of 3 µg/L and 5 ng/m3 in drinking water and air, respectively (WHO 2019).

Similarly to humans, animals exposed to cadmium in the environment also suffer from cadmium-induced kidney damage. Cadmium is especially dangerous to animals because of its high bioavailability and bioaccumulation potential, meaning animals readily ingest it and keep it in their tissues so that cadmium concentrations increase over time. High levels of cadmium have been reported in marine mammals and seabirds, particularly in the Arctic. Furthermore, cadmium is toxic to various plants and microorganisms (UNEP 2010).

4.3.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics. Cadmium is a metal element and it persists in the environment once released. It presents primarily in its inorganic forms. UNEP (2010) and Cullen and Maldonado (2012) reviewed their key environmental fate and transport characteristics as follows.

In air, cadmium is mainly emitted as particles; in some cases, high-temperature processes such as combustion may emit elemental cadmium as a vapour, which quickly binds to particles once cooled down. The particles containing cadmium may be transported away from original sources and then deposited on the ground, with atmospheric lifetimes of days to weeks, depending on particle sizes. Small particles may travel up to thousands of kilometres, in line with measurements of aerosol and precipitation samples in remote areas such as Greenland, the Arctic Ocean and Antarctic (Cullen and Maldonado 2013).

In water, some cadmium compounds are quite soluble, such as cadmium sulfate and cadmium chloride. These water-soluble compounds form free Cd2+ ions that are readily bioavailable. Some others are almost insoluble, such as elemental cadmium, cadmium oxide and cadmium sulfide. In fresh water, cadmium may bind with natural organic matter and can also adsorb to particles; this reduces the free ions available and lowers exposure for organisms. Cadmium in surface water can flow to the ocean, and annual global riverine fluxes to the ocean were estimated to be 3,000 and 23,000 tonnes per year for dissolved and particulate cadmium, respectively. Increasing salinity from fresh to sea waters can reduce the amount of cadmium on particles and thus increase the amount of dissolved cadmium in sea water that is more bioavailable (Cullen and Maldonado 2013).

In soil, the fate and transport depends on factors such as pH. Under acidic conditions, with pH <6, cadmium solubility increases with reduced adsorption by soil; in contrast, when soil pH is greater than 6, cadmium will adsorb on the soil solid phase or will precipitate, consequently reducing the cadmium's mobility.

In biota, cadmium tends to readily bioaccumulate (UNEP 2010), including in plants (Khan *et al.* 2015) and crayfish (Kouba, Buřič and Kozák 2010). As mentioned above, cadmium accumulates mostly in the kidneys of animals, where its concentration increases with time.

Major sources of current exposure. Environmental and human exposure to cadmium and cadmium compounds may occur both from natural and anthropogenic sources (see UNEP 2010, Cullen and Maldonado 2013 and references therein). Natural sources of cadmium and cadmium compounds are largely the same as arsenic, lead (see Sections 4.1.2 and 4.5.2), mercury (see UNEP 2019) and many other heavy metals, including volcanic activity and weathering of rocks. Anthropogenic sources include both cadmium-specific ones (including cadmium as impurities in phosphate rock and thus phosphate fertiliser, and those related to production, use, disposal and recycling of cadmium and related products) and more general sources for many metals (including arsenic, lead and mercury, related to smelting, fossil-fuel combustion for power generation, and other processes).

In the past decade, the USGS (2017; 2020) estimated that global primary production of cadmium, excluding the US due to undisclosed company proprietary data, was around 20,000–25,000 tonnes per year, generally as a byproduct from mining and smelting of zinc ores (US annual production was estimated at around 500 tonnes for 2013–2017; Brown *et al.* 2019). Secondary production of cadmium from recycling also occurs in many parts of the world, with no recent numbers identified in the public domain. Today, cadmium and cadmium compounds are mainly used in nickel-cadmium batteries, followed by alloys, coatings and plating, pigments in plastics, glasses, ceramics and paints, solar cells, PVC stabilisers and others (USGS 2017). For more details on production, use, disposal and related exposure pathways, see Table B3–1 in the Annex.

Among the different sources of cadmium, anthropogenic ones have likely contributed substantially to current exposures, as calculated by emission estimates. For example, total emissions from natural sources to air were estimated to be at 150 to 2,600 tonnes per year (over

60% comes from volcanic activities and 15% from windblown dust; Nriagu 1989). In contrast, total anthropogenic emissions to air were estimated to be about 7,600, 2,400 and 3,000 tonnes in 1983, 1991 and the mid-1990s, respectively; most of these emissions were from fossil fuel combustion, as well as mining and smelting of metals (Nriagu and Pacyna 1988; Jackson and Macgillivray 1995; Pacyna and Pacyna 2001). This dominance of anthropogenic versus natural emissions to air is also suggested by various measurements of field samples from remote regions, e.g. snowpack and glaciers of the high Himalaya, the Arctic and Antarctic, as reviewed by UNEP (2010) and Cullen and Maldonado (2013). Emissions from effluents and solids have been estimated to be about 1,200–13,400 and 9,900–45,000 tonnes in 1983, respectively, and 1,100 and 23,810 tonnes in 1991, respectively, from global anthropogenic sources; most of these emissions were from production, use, disposal and recycling of cadmium and related products and, to a lesser extent, from fossil fuel combustion and mining and smelting of metals (Nriagu and Pacyna 1988; Jackson and Macgillivray 1995).

Once released, cadmium reaches wildlife and humans through contaminated air, water, soil and foodstuffs. Humans may additionally be exposed to cadmium through house dust (Hogervorst *et al.* 2007), tobacco smoking (Tellez-Plaza *et al.* 2012) and cadmium-related consumer products (Turner 2019). For the general, non-smoking population, the main exposure lies in the ingestion of food (about 90%), and to a lesser extent, via inhalation of ambient air and the ingestion of contaminated drinking water, soil or dust (UNEP 2010; IARC 2012). In occupational settings, the main exposure route is via the respiratory tract; incidental ingestion of dust from contaminated hands and food may occur as well (IARC 2012).

Prevalence, levels and trends of current exposure.. Humans around the world are continually exposed to cadmium. Among the different exposure routes, foodborne cadmium was estimated to account for about 12,000 new severe and end-stage chronic kidney disease cases, 2,000 deaths and 70,513 DALYs worldwide in 2015 (Gibb *et al.* 2019; Zang *et al.* 2019). In addition, the estimates by the GBD studies suggest that occupational exposure to cadmium has resulted in significant global illness and deaths, and that the exposure rate has been relatively steady in the past decade, see Table 4–2 below (Lim *et al.* 2012; GBD 2015 Risk Factors Collaborators 2016; GBD 2016 Risk Factors Collaborators 2017; GBD 2017 Risk Factors Collaborators 2018).

Table 4–2. Global burden associated with *occupational* exposure to cadmium. DALYs = disability-adjusted life years.

Year	Deaths	DALYs
2010	555	13,000
2015	2,000	47,000
2017	460	16,830
2018	1000	18,000

Sources: Lim *et al*. 2012; GBD 2015 Risk Factors Collaborators 2016; GBD 2016 Risk Factors Collaborators 2017; GBD 2017 Risk Factors Collaborators 2018.

A geographical shift of releases and exposures has taken place in the past half-century. Cadmium emissions in Europe have decreased since the 1970s (Van de Velde *et al.* 2000; Pacyna, Pacyna, and Aas 2009); as of 2017, cadmium emissions in Europe had dropped by about 65% from the baseline level in 1990, although the emissions have remained rather constant since 2009 (European Environment Agency [EEA] 2019). Meanwhile, due to rapid increases in fossil fuel use and the mining and smelting of metals, cadmium releases in China quickly increased over the past several decades, from about 2,700 tonnes in 1990 to about 34,000 tonnes in 2015, mostly in the form of solid wastes (87% in 1990 and 96% in 2015), followed by emissions to air (11% in 1993 and 3% in 2015) and to surface waters (7% in 1990 and 0.05% in 2015; Shi *et al.* 2019).

4.3.3 An Assessment of Existing Instruments and Actions

Different instruments and actions have been taken at the international, national and regional levels to address cadmium (for more details, see Table B3–2 in the Annex). At the international level, governments have recognized "the significant risks to human health and the environment arising from releases of lead and cadmium into the environment" and requested cooperative actions on cadmium (e.g. UNEA Resolution 1/5 and 2/7). Other detailed actions include the recognition of cadmium-related wastes as hazardous wastes under the Basel Convention, which establishes legally binding obligations for Parties to address such wastes according to the Convention provisions, and the development of international guidelines for cadmium levels, for example, in drinking water, air and food.

On the national and regional levels, instruments and actions have been more diverse both in terms of type and scope. A number of countries and regions have taken actions to legally restrict, ban or set mandatory national standards for cadmium in specific uses, which are not being addressed internationally. For example, the EU has comprehensive legal restrictions or bans for many major uses of cadmium, such as in polymers, jewellery, paints and food-related items, and it also goes beyond intentional production and use by setting legal limits for the unintentional presence of cadmium in different fertilisers. Some other countries outside the EU have in place legal restrictions or bans with narrower scopes, such as restrictions on cadmium in specific electrical and electronic products (for specifics, again, see Table B3–2 in the Annex).

Various other legally binding instruments have also been used. For example, cadmium and cadmium compounds are listed as SVHC in the EU, and thus manufacturers and importers have legal obligations to provide sufficient information to downstream industry users and consumers to allow safe use of products containing these substances above 0.1 wt%. In the EU, cadmium and cadmium compounds are also subject to export notification through a prior informed consent procedure. In the Republic of Korea, the mandatory recycling rate of nickel-cadmium batteries for manufacturers is set at 33%. For some uses, voluntary actions have included adoption of limits of cadmium in fertilisers by the fertiliser industry in New Zealand, voluntary industry phase-out (e.g. Apple), and inclusion of cadmium in

multiple third-party standards and certification schemes (e.g. the Manufacturing Restricted Substance List by ZDHC Foundation, Nordic Swan Ecolabel).

In addition to instruments and actions to address cadmium in specific uses, a large number of countries have looked at emissions and exposure media. For example, in Australia, mandatory emission reporting requirements have been set for certain industrial facilities. In addition, legally binding obligations have been set for cadmium emissions under the Convention on Long-Range Transboundary Air Pollution (CLRTAP), including provisions that Parties have to reduce their emissions for cadmium below their levels in 1990 (or an alternative year between 1985 and 1995). These provisions under CLRTAP also take into account unintentional anthropogenic sources, such as from the iron and steel industry, non-ferrous metal industry, combustion (power generation, road transport) and waste incineration. Many countries and regions have also set up guideline values for different exposure media, including for occupational exposures, that are either legally binding (e.g. drinking water in the US) or that are recommended or guidance values. Multiple countries have also developed a national strategy or declared cadmium a national priority, which may guide them to address cadmium and cadmium compounds in a comprehensive manner.

4.3.4 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. Alongside 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 (Raugei and Fthenakis 2010). 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 (Ramos-Ruiz *et al.* 2017). 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.

4.4 Glyphosate

Glyphosate is an organophosphorus herbicide for agricultural, forestry and residential weed control that kills or suppresses all plant types, with the exception of those genetically modified to be tolerant to the active ingredient. Since its introduction in 1974, glyphosate has become the most widely used herbicide worldwide. Recently, a number of countries have initiated or taken actions to address glyphosate due to growing public concern about human health risks, as identified by GCO-II (UNEP 2019).

4.4.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

As a herbicide, glyphosate has been subject to regulatory assessments by different national governments since the 1970s. These previous assessments concluded that glyphosate has a relatively low hazard potential to mammals and led to the wide approval of glyphosate. In 2015, the IARC reclassified glyphosate as "probably carcinogenic" (Group 2A; Guyton *et al*. 2015; IARC 2017). This category is used when there is limited evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity in experimental animals. After the IARC's conclusion, other governmental institutions also

conducted their own reassessments or assessed glyphosate for the first time (see Table B4–1 in the Annex and references therein).

The different assessments reached seemingly different conclusions. Many concluded that glyphosate is not carcinogenic (e.g. US EPA 2015; EFSA 2015; Australian Pesticides and Veterinary Medicines Authority [APVMA] 2016; New Zealand Environmental Protection Authority 2016; ECHA 2017; Health Canada 2017; US EPA 2017), whereas some others agreed with the conclusion of the IARC (e.g. California Office of Environmental Health Hazard Assessment [OEHHA] 2017; US ATSDR 2019).

These differing conclusions on the carcinogenicity of glyphosate originate in part from the exclusion or consideration of different studies or data sets, due to differences in the authoring agencies' quality assessments of some of the published case studies or to the consideration of unpublished data. Several peer-reviewed articles presented and discussed these discrepancies and their consequences on the assessment results in detail (e.g. Portier *et al*. 2016; Portier and Clausing 2017; Tarazona *et al*. 2017; Douwes *et al*. 2018; Benbrook 2019). In addition, some assessments are based solely on the hazardous properties of glyphosate (e.g. Guyton *et al.* 2015; IARC 2017), whereas others also consider the likelihood of exposure (for instance, the assessment of the FAO/WHO Joint Meeting on Pesticide Residues concluded that glyphosate is unlikely to pose a carcinogenic risk from dietary exposures; FAO and WHO 2016).

In comparison, assessments of the environmental impacts of glyphosate are in agreement. ECHA (2017) concluded that glyphosate is toxic to aquatic life with long-lasting effects (i.e. harmonised classification Aquatic Chronic 2). The assessments by EFSA, Health Canada and US EPA identified potential risks from glyphosate to non-target terrestrial and aquatic plants (e.g. from off-field spray drift) and concluded that the risks to non-target plants would be low, provided risk mitigation measures are implemented (EFSA 2015; Health Canada 2017; US EPA 2020).

4.4.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics. Glyphosate is non-volatile and has high water solubility (>1 g/L) and strong adsorption to soil minerals. In general, apart from limited photodegradation in specific environments, glyphosate is primarily degraded by microorganisms. Aminomethylphosphonic acid (AMPA) and sarcosine are the major degradation products; AMPA is resistant to further degradation, whereas sarcosine can be readily degraded further (Vereecken 2005; Borggaard and Gimsing 2007; Zhan *et al*. 2018).

Glyphosate may be present as airborne particles due to drift during spraying operations (Ravier *et al.* 2019) or windblown particles, on which the co-presence of AMPA can be observed (Chang, Simcik and Capel 2011; for more examples, see Table B4–2 in the Annex). Glyphosate-containing airborne particles can be transported away from the original source by wind, with transport distances depending on particle size and weather conditions (Aparicio

et al. 2018). In general, field measurements have found that rainfall removes glyphosate particles from air, with weekly rainfall ≥30 mm estimated to remove an average of 97% of airborne glyphosate (Chang, Simcik and Capel 2011).

Once released to water, through spray drift or deposition from air, for example, the majority of glyphosate binds to particles; a small fraction of glyphosate may remain dissolved in water and transported via currents (Aparicio *et al.* 2013; Mercurio *et al.* 2014). In fresh water, glyphosate has an average degradation half-life of >60 days. Depending on particle sizes and hydrological conditions, glyphosate-containing particles may either undergo sedimentation and remain locally deposited, or be transported away from sources via currents. In some cases (e.g. the Baltic Sea area), land-to-sea transport has been observed (Skeff *et al*. 2015). In salt water, glyphosate may persist for months to years (Mercurio *et al.* 2014), which raises concerns for seagrass and other plants that are a foundation for marine ecosystem food webs, as well as for corals.

Once released to soil, glyphosate may undergo complex fate and transport processes, depending on physical, chemical and microbiological characteristics of the soil. In general, glyphosate is strongly adsorbed by soil, with the exception of some phosphate-rich soils, in which the phosphate may compete with the glyphosate for soil adsorption sites (Borggaard and Gimsing 2007). The degradation half-life of glyphosate in soil may vary from a few days up to several months and even years (Vereecken 2005). Glyphosate and its metabolite AMPA in soil may be transported to surface waters in both dissolved and particle-bonded forms (Borggaard and Gimsing 2007). In some cases, through drainage water or agricultural runoff, glyphosate and AMPA may also be transported to groundwater (for examples, see Table B4–2 in the Annex). Furthermore, genetically modified glyphosate-tolerant crops can take up and accumulate glyphosate and pass it on to livestock or humans (see Cuhra 2015, Bai and Ogbourne 2016, and references therein). When animals and humans eat plants that have absorbed glyphosate, the herbicide is poorly metabolised, widely distributed in the body, and rapidly excreted in urine and faeces, showing no potential for bioaccumulation (EFSA 2015).

Major sources of current exposure. Glyphosate is currently the most used herbicide in the world (for more details on the production, use and exposure pathways of glyphosate, see Table B4–3 in the Annex and references therein). In brief, its global consumption increased from about 67,000 tonnes per year in 1995 to over 825,000 tonnes per year in 2014 (Benbrook 2016). The largest use of glyphosate has been in agriculture, with an increase from about 76% of the total annual use in 1995 to about 90% in 2014. Between 2010 and 2012, over 50% of the agricultural use was for genetically modified crops (Benbrook 2016). Other agricultural uses include weed control, pre-harvest treatment of crops to regulate plant growth and the ripening process (European Commission 2019a), and post-harvest treatment of fields to kill weeds or residues of intermediate crops before the next crop is sown (Hanke *et al.* 2010). In non-agricultural settings, glyphosate is used for weed control in households, on ditch banks and roadsides and under power

lines, and to control invasive species in aquatic or wetland systems (IARC 2017). The use of glyphosate in urban settings can also be a significant source of contamination, as previous studies in Australia, Switzerland and the US have shown (Hanke *et al*. 2010; Mahler *et al*. 2017; Okada *et al*. 2020).

As described in the past section, once released in the environment, glyphosate may undergo complex distribution and transport processes among different environmental media. Wildlife and humans may be exposed to glyphosate and its metabolite AMPA via contaminated environmental media such as air, water and soil. Wildlife and humans may also be exposed to glyphosate by consuming contaminated crops, and humans may additionally be exposed through drinking water and during the application and disposal of glyphosate-based herbicide formulations (see WHO 2011; also, Gillezeau *et al.* 2019 and references therein). Note that one study detected elevated levels of different heavy metals such as arsenic and lead in glyphosate-based herbicide formulations on the French market, and thus, the use and disposal of such formulations may also result in exposure to these heavy metals (Defarge *et al.* 2018).

The prevalence, levels and trends of current exposure across the globe. Globally, glyphosate is ubiquitous in surface waters (Székács and Darvas 2018) and croplands (Maggi *et al.* 2020) due to its widespread use. However, studies on human exposure are limited. In particular, a recent review highlights the paucity of data on glyphosate levels among individuals exposed occupationally, para-occupationally or environmentally; the authors concluded that as such, it is challenging to fully understand the extent of exposure overall and in vulnerable populations such as children (Gillezeau *et al.* 2019). This scarcity of data is also partially due to limitations in current detection methods that make it hard to measure glyphosate in various media samples (Székács and Darvas 2018).

Existing human exposure studies have focused on developed countries. Glyphosate is often detected in human urine, from occupational or residential exposures, from dietary intake, or from a combination of these pathways. Dietary pathways tend to be low (US Food and Drug Administration [US FDA] 2017; EFSA 2018; French Agency for Food, Environmental and Occupational Health & Safety [ANSES] 2019). However, workers tend to have higher glyphosate levels in their urine after applying plant protection products than consumers have from dietary intake (Niemann *et al.* 2015; Connolly *et al.* 2018). Monitoring of urine concentrations also suggests higher exposure of populations in the US than in Europe (Niemann *et al.* 2015) and a considerable increase of exposure at least in some regions over time (e.g. Niemann *et al*. 2015; Conrad *et al*. 2017; Mills *et al*. 2017). One study shows that local reductions in glyphosate applications could be correlated to decreases in levels in young people in the general population (Conrad *et al.* 2017).

Less information is available on the occurrence and exposure to glyphosate in developing countries, despite the wide use of glyphosate there. Occupational exposure is likely to be higher in developing countries, where a significant percentage of farmers may not use personal protective equipment, may use glyphosate above the recommended dose, or may

be using fraudulent products that are diluted compared to registered products and can accelerate weed resistance because of "widespread underdosing" (FAO 2012; Gunarathna *et al.* 2018; Haggblade *et al*. 2019; Wumbei *et al*. 2019).

Some evidence suggests that glyphosate levels in the environment and some foodstuffs in some regions may be worrisome. For example, glyphosate was detected in many rainwater samples close to agricultural fields in Argentina at levels above safety levels set for drinking water in the EU, suggesting risks for human consumption via rainwater harvesting in the region (Lupi *et al.* 2019). High levels of glyphosate in soybean also were detected in Argentina, exceeding the maximum residual levels set in the EU and US (Cuhra 2015).

4.4.3 An Assessment of Existing Instruments and Action

As a herbicide, glyphosate is subject to pesticide regulations for placement on the market, use and related activities that lead to human exposure in many parts of the world. Guideline values for different exposure media have been one important regulatory instrument used for managing glyphosate. For example, a number of national governments and intergovernmental institutions have set up maximum residual levels that are allowed for glyphosate in or on food and feed (e.g. the EU, US, Canada, Japan, FAO/WHO Codex Alimentarius) and maximum contaminant levels in drinking water (e.g. the US, Australia; Xu *et al.* 2019). Overall, these guideline values may vary considerably among countries, which have set different levels for different media. For example, the regulatory guidance values for glyphosate in residential surface soil span 6.5 orders of magnitude (0.011 to 36,000 mg/kg) and the maximum contaminant levels for glyphosate in drinking water span 5.45 orders of magnitude (0.0001 to 28 mg/L; Li and Jennings 2017). In some cases, such guideline values have changed over time: for example, the EU raised maximum residual levels in soybean from 0.1 mg/kg to 20 mg/kg in 1999, and the US raised its levels from 20 mg/kg to 40 mg/kg in 2014 (Cuhra 2015).

Many countries have taken steps to legally ban or restrict glyphosate, including Argentina, Bermuda, Brazil, Columbia, India, Oman (together with five other countries in the Persian Gulf), Sri Lanka and Thailand (Xu *et al.* 2019; see Table B4–4 in the Annex). In the EU, while one of the co-formulants (POEA) has been banned from glyphosate-containing products since 2016, the European Commission renewed the approval of glyphosate as an active ingredient for five years (until December 2022) instead of the usual 15 years (European Commission 2019b). Meanwhile, several EU Member States (including Austria, Belgium, Czech Republic, France, Germany, Italy and Luxembourg) have taken actions to ban or restrict the use of glyphosate or have announced plans to do so. Similar to the situation in the EU, Canada and the US have authorised glyphosate at the country level, while many of these two countries' states or provinces and cities have put in place strong restrictions, e.g. banning private sales, spraying in public spaces or use on crops post-emergence (Baum Hedlund Aristei & Goldman, PC, 2020; see Table B4–4 in the Annex, for more details and references).

In some cases, while no legal bans or restrictions have been imposed, other instruments have been adopted or actions taken. For example, in 2017, California (US) added glyphosate to its "Proposition 65 list" under the Safe Drinking Water and Toxic Enforcement Act of 1986, as a substance known to the state to cause cancer, and thus the state requires businesses to provide warnings to consumers about significant exposure to glyphosate (OEHHA 2017). Countries such as Canada and the US have also revised product labelling requirements as risk reduction measures to protect human health and the environment (Health Canada 2017; US EPA 2020).

In addition to legal bans or restrictions of glyphosate, voluntary phase-out has also taken place by some retailers (e.g. supermarket chains in Luxembourg, Germany and Switzerland) and third-party standards and certification schemes (e.g. Fairtrade, Sustainable Agriculture Network or SAN, and UTZ certification). Such voluntary phase-out and certification can reduce the demand for agricultural products using glyphosate. For more details on all the instruments and actions described above, see Table B4–4 in the Annex.

4.4.4 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 (Heap and Duke 2018); as a result, farmers have increased application rates and this increased use has heightened environmental risks and human exposure (Benbrook 2016).

Furthermore, wide use of glyphosate promotes the adoption of genetically modified glyphosate-tolerant crops, which may significantly influence biodiversity (Environment Agency Austria *et al*. 2015; FAO and Intergovernmental Panel on Climate Change [IPCC] 2017; Schütte *et al*. 2017). 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 intermulching) 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 (FAO 2012). 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 broadspectrum 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 (Bish *et al.* 2019); in combination with its high toxicity, dicamba may cause more environmental risks on off-field non-target plants (Schütte *et al.* 2017). 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.

4.5 Lead

Lead is a multi-system toxicant for which no safe level of exposure has been identified. Exposure to lead can cause chronic and debilitating health impacts in all age groups, and children are particularly vulnerable to its neurotoxic effects (WHO 2010). The widespread use and sources of lead and lead compounds has caused extensive environmental and human exposure across the globe. To date, lead has been identified as one of 10 chemicals of major public health concern by WHO and as an issue with emerging evidence of risks to human health by GCO-II. Among the uses of lead and lead compounds, lead in paint has been recognized as an EPI under SAICM and is analysed in Section 3.6 above. The assessment here focuses on the uses of lead other than in paints.

4.5.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

Lead and lead compounds have been extensively assessed by national governments and intergovernmental institutions, providing a wealth of information. A compilation of all existing assessments is not made here; we highlight major conclusions from several authoritative assessments.

Lead can be harmful to the health of people of all ages; infants and children are particularly susceptible to the effects of lead exposure. In particular, lead exposure in infants and children presents high risks to cognitive function (e.g. a reduction of intelligence quotient and deficits in attention-related behaviours), with no evidence of a threshold below which there are no adverse effects on cognition (Health Canada 2013; US EPA 2013). Lead exposure can harm the cardiovascular system and may also affect a broad array of others, including the haematological, gastrointestinal, renal and reproductive systems (US EPA 2013). Adults may also suffer from cognitive function decreases, depression and anxiety, and immune effects from lead exposure (US EPA 2013). Health effects have been associated with blood lead levels as low as 1–2 µg/dL (Health Canada 2013).

Inorganic lead compounds have been classified by IARC (2006) as "probably carcinogenic" to humans (Group 2A); in other words, while there is limited evidence for carcinogenicity in humans, there is sufficient evidence of carcinogenicity in experimental animals. The IARC Working Group noted that organic lead compounds are metabolised, at least in part, to ionic lead both in humans and animals, to the extent that the metabolic products are expected to exert the same toxicities associated with inorganic lead; however, IARC acknowledged that organic lead compounds are not classifiable as to their carcinogenicity to humans (Group 3; IARC 2006).

Considering the scientific evidence available, the FAO/WHO Expert Committee on Food Additives concluded that it was not possible to establish a provisional tolerable weekly intake that would be health protective. For drinking water and air, WHO set the guideline values of 10 µg/L in water and an annual average of 0.5 µg/m3 in air (WHO 2019).

Adverse effects of lead on the ecosystem have also been observed and well documented. For example, millions or more waterbirds that ingest lead-containing shot or sinkers are contaminated or poisoned by the lead and in turn, contaminate their predators, including humans (secondary poisoning; UNEP 2010).

4.5.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics. Lead is a metal element and it persists in the environment in different forms once released. It may exist in both inorganic and organic forms. Depending on their forms, lead and lead compounds may exhibit different environmental fate and transport characteristics.

Inorganic lead may exist in three oxidation states: Pb(0), Pb(II) or Pb(IV). The elemental lead Pb(0) rarely occurs in nature; oxidation of the metal takes place rapidly in moist air and yields Pb(II), which is the most abundant among the three forms of lead in the environment (UNEP 2010, Cullen and McAlister 2017). Inorganic lead compounds may undergo complex environmental transport that will vary depending on their specific chemical compositions and environmental conditions; however, previous reviews by UNEP (2010) and Cullen and McAlister (2017) have reached the following general findings (with some additional references included).

Once emitted to air, inorganic lead compounds exist mainly in the particulate form and can be transported by wind and subsequently delivered to terrestrial and aquatic environments by wet and dry deposition (for example, by rain or snow and by wind, respectively). Depending on environmental conditions and the size of particles, their atmospheric residence times range from hours to weeks; in particular, tiny particles such as those formed by high-temperature combustion processes may travel up to thousands of kilometres away from sources. This is in line with elevated lead levels from anthropogenic sources observed in remote snowpack and in ice core records recovered from glaciers, as reviewed in Cullen and McAlister (2017).

In aquatic environments, inorganic lead compounds may exist in dissolved ionic form (which is highly mobile and bioavailable), attached to colloidal particles such as iron oxide (with reduced mobility), as organic complexes formed with dissolved humus materials (with reduced mobility), or attached to solid particles of clay or dead remains of organisms (very limited mobility and availability). Annual riverine fluxes to the ocean of dissolved and particulate lead were estimated to be 3,000 and 916,000 tonnes per year, respectively (Viers *et al.* 2009), with a residence time of about 2 years in surface waters of the ocean (Bacon, Spencer and Brewer 1976).

In soils and sediments, a small portion of lead present is in solution and thus bioavailable, whereas the majority of lead is strongly adsorbed (or bound to the surface) on matrices such as organic matter and iron oxide. Thus, the movement of inorganic lead compounds from soil to groundwater by leaching is very slow under most natural conditions; however, these compounds may enter surface waters (rivers and lakes) through erosion of soil particles. Inorganic lead compounds are known to bioaccumulate in most organisms and can undergo trophic transfer up the food web, often without magnification in higher trophic level organisms (Naikoo *et al.* 2019).

Overall, there are more than 200 known organic lead compounds; of these, only tetramethyl-lead (TML) and tetraethyl-lead (TEL) have found large-scale commercial applications, used as petrol additives (UNEP 2010). Petrol combustion mostly decomposes TML and TEL into inorganic lead compounds, which are then released in exhaust, although a small proportion may escape to the atmosphere unchanged (Harrison and Laxen 1978). These TML and TEL particles have atmospheric residence times ranging from hours to days before deposition or transformation to other compounds such as ionic trialkyl-lead, dialkyl-lead and inorganic lead compounds (UNEP 2010). In water and soil, TML and TEL undergo similar stepwise transformation and form inorganic lead compounds within days to weeks (Rhue *et al.* 1992).

Major sources of current exposure. Environmental and human exposure to lead and lead compounds may occur from natural and anthropogenic sources (see Cullen and McAlister 2017 and references therein). Natural sources of lead and lead compounds are largely the same as other heavy metals such as arsenic, cadmium and mercury, including volcanic activity, exudates from vegetation and windblown dust (see Sections 4.1.2 and 4.3.2, and

UNEP 2019). Anthropogenic sources include both lead-specific sources (i.e. releases from production, use, disposal and recycling of lead and related products) and more general sources for many metals, including arsenic, cadmium and mercury (e.g. fossil fuel combustion, mining and smelting of metals).

Historically, the lead compounds TML and TEL were widely used additives in petrol, from the introduction of TEL in 1923 (Rhue *et al.* 1992) until the 1970s, when countries started to phase them out; today, only one country, Algeria, may still be using them (UNEP 2018). As of 2018, the current global uses of lead are batteries (80%), rolled and extruded products (e.g. sheets of lead; 6%), pigments and other product additives (e.g. for paints, cathode ray tubes, enamels and ceramics, PVC stabilisers; 5%), ammunition (3%), alloys (2%), cable sheathing (1%) and other uses (3%; UNEP 2010, Natural Resources Canada 2019). Lead in these uses is from primary mine production and secondary recycling of used lead–acid batteries, lead-sheathed cables, lead sheet and a variety of industrial and metallurgical wastes (Roberts 2020), with total global volumes of about 4.5 million tonnes produced from mines and 7.3–10 million tonnes recovered through recycling in 2018 (Roberts 2020; USGS 2020). For more details on production, use and related exposure routes of lead and lead compounds, see Table B5–1 in the Annex and UNEP (2010). Depending on life-cycle stages and uses, releases may occur to different environmental media (UNEP 2010), with most releases to soil and to a much lesser extent to air and water (Rauch and Pacyna 2009, UNEP 2010).

Anthropogenic sources of lead substantially surpassed natural sources long ago. For example, estimates suggested that lead releases from anthropogenic sources to the atmosphere in the mid-1990s were approximately 120,000 tonnes per year compared to median natural fluxes totalling 12,000 tonnes per year (Cullen and McAlister 2017). Similarly, annual riverine fluxes of lead from natural sources to the ocean were estimated to be roughly 295,000 tonnes per year (Cullen and McAlister 2017), which is only about a third of the estimated total annual lead fluxes of about 950,000 tonnes per year to the ocean (Viers *et al.* 2009).

These estimates are in line with reported lead contamination records from lakes, peat mires and ice fields that are remote from anthropogenic sources around the world. A review of these records estimated that current global average lead enrichment rates are between 6 and 35 times natural background levels, with high spatial variability, for example >100 times natural background levels in Europe and North America and 5–15 times background levels in Antarctica (Marx *et al.* 2016). They are also in line with the measured dominance of lead from anthropogenic sources in an ice core that contains a record of the past 2000 years from an alpine glacier in Switzerland (More *et al*. 2017; More *et al*. 2018) and in surface waters of the global ocean (Bridgestock *et al*. 2016; Pinedo-Gonzalez *et al*. 2018; Rusiecka *et al*. 2018; Gamo 2020). Only in Antarctica do natural background levels dominate, with 40% of deposition from anthropogenic sources (Ndungu *et al.* 2016).

Among anthropogenic lead sources, the top three sources for air emissions were leaded petrol, fossil fuel combustion for power and heat production, and metal smelting; leaded petrol

amounted to four times as much as the other two sources in 1995, according to calculations by Pacyna and Pacyna (2001). The global phase-out of leaded petrol has led to drastic reductions of lead levels in air, ocean surface waters and humans in many parts of the world (Thomas *et al*. 1999; Boyle *et al*. 2014; Hatje *et al*. 2018; Pinedo-Gonzalez *et al*. 2018; Gamo 2020). Meanwhile, other anthropogenic sources continue to emit lead to the environment. In particular, growing coal consumption and metal smelting in some parts of the world might have offset the emission reductions from phasing out leaded petrol. For example, while current data are lacking, the most recent estimates suggested global releases of 85,000 tonnes from fossil fuel combustion to air (Rauch and Pacyna 2009), nearly as much as air emissions from leaded petrol in 1995 (Pacyna and Pacyna 2001). In 2000, 61,000 tonnes of lead were deposited to soil (Rauch and Pacyna 2009). Recent emission estimates and soil measurements in China show similar trends at a regional scale (Li *et al*. 2012; Shi *et al*. 2019). This recent development may have different impacts on different parts of the world, as shown in different trends in ocean surface waters around the world (Boyle *et al*. 2014; Hatje *et al*. 2018; Pinedo-Gonzalez *et al*. 2018; Gamo 2020). Further investigation is warranted.

When considering direct emissions to all environmental media, the estimated total global releases from production, use, disposal and recycling of lead and related products were up to about 4 million tonnes per year between 1970 and 2010. After the 1980s, the emissions from production and use declined, due to phase-out of petrol additives and reduced non-battery uses such as solder and pipes, whereas the emissions from waste management and recycling increased (Liang and Mao 2015). In 2010, the estimated total global emissions were about 3.6 million tonnes (about 22% from production, 13% from use, and 65% from waste management and recycling); these amounts are equal to more than 25% of the total amount of lead produced from mining in the same year (Liang and Mao 2015). About half of these emissions likely occurred in China, which is a major producer and user of lead globally (Liang and Mao 2014; Liu *et al*. 2018).

Wildlife and humans may be exposed to lead once it is released, via contaminated air, water, soil and foodstuffs (including herbal products and medicine). Lead can enter the food chain through crops growing on contaminated land, from direct deposition onto crops, through food animals foraging in contaminated areas and consuming lead particles, and from fish and shellfish living in lead-contaminated water (UNEP 2010). Humans may additionally be exposed to lead through ingestion of lead-contaminated dust (e.g. from contaminated soils or during the removal or flaking of lead paints) and through lead-related products (e.g. drinking water contamination from lead pipes; food contamination from lead-glazed or lead-soldered containers). Workers may further be exposed through, e.g., inhalation of lead particles generated by burning materials containing lead, for example, during smelting and recycling, or while stripping lead paint (UNEP 2010).

The prevalence, levels and trends of current exposure across the globe. Due to its ubiquitous presence in the environment, humans around the world are continually being exposed to lead. As of 2004, WHO reported that blood lead levels had been steadily declining in

industrialized countries following the phase-out of leaded petrol, with only certain populations still exposed to high lead levels, mainly from housing with lead paint. Overall, lead exposure resulted in about 117,000 deaths (0.2% of the global total) and 9.25 million DALYs (0.6% of the global total) in 2004; of the adults and children affected, nearly all (98% of adults and 99% of children) lived in low- and middle-income countries (WHO 2009).

Following a similar methodology based on reported blood and bone lead levels, the Global Burden of Disease (GBD) studies further estimated the global burden of disease of lead exposure in the past decade, showing rather constant and even increasing trends, see Table 4–3 below (Lim *et al*. 2012; GBD 2015 Risk Factors Collaborators 2016; GBD 2016 Risk Factors Collaborators 2017; GBD 2017 Risk Factors Collaborators 2018). For comparison, in 2017, second-hand smoke caused about 1.22 million deaths and 36.3 million DALYs worldwide (GBD 2017 Risk Factors Collaborators 2018). Based on 2015 data, lead exposure was estimated to account for 12.4% of the global burden of idiopathic intellectual disability, 2.5% of the global burden of ischaemic heart disease and 2.4% of the global burden of stroke (Institute for Health Metrics and Evaluation 2016).

Table 4–3. Global burden associated with exposure to lead. DALY = disability-adjusted life years

Year	Deaths	DALYs
2010	674,000	13,900,000
2015	495,000	9,300,000
2017	540,000	13,800,000
2018	1,050,000	24,400,000

Sources: Lim *et al*. 2012; GBD 2015 Risk Factors Collaborators 2016; GBD 2016 Risk Factors Collaborators 2017; GBD 2017 Risk Factors Collaborators 2018

Among the different lead exposure pathways, foodborne lead may contribute substantially to human health problems; while not directly responsible for any deaths in 2015, it could have contributed to 5.23 million DALYs that year (Gibb *et al.* 2019). In addition, among the sources to lead exposure, informal processing sites of used lead-acid batteries in developing countries have likely contributed substantially. A recent study reviewed the situation in 90 low- and middle-income countries and thus estimated that they had a total of about 10,600 to 29,200 such informal sites, with 6 to 16.8 million people being exposed at these sites, resulting in about 127,000 to 1.6 million DALYs in 2013 (Ericson *et al.* 2016).

Similarly, worldwide, lead exposures to wildlife most likely occur everywhere and continually, but limited data are available to inform the current situation. However, reviews by UNEP (2010), Haig *et al.* (2014) and ECHA (2018) point out that a wide range of bird species worldwide are exposed to lead (mainly through its application in ammunition and sinkers), including many endangered species, and these exposures have caused substantial population losses.

4.5.3 An Assessment of Existing Instruments and Actions

To date, many instruments and actions have been developed at the international, regional and national levels to address lead; here we provide a brief summary, and more details can be found in Table B5–2 in the Annex (note that given the virtual global phase-out, information on leaded petrol is not included in Table B5–2).

At the international level, in addition to the focus on lead paint (see Section 3.6), actions have focused on lead and lead compounds in petrol, batteries, ammunition and wastes, while some resolutions also referred to the wider sources of lead exposure (e.g. Johannesburg Plan of Implementation; UNEA Resolution 3/9). Among these areas, the phase-out of leaded petrol is the most successful one, with only one possibly still using them (UNEP 2018). Several international instruments and actions have contributed to this success, including early political commitment through the call by the UN Commission on Sustainable Development to governments to eliminate leaded petrol. Other examples include early work by the World Bank, UNECE, OECD, US, Canada and others to support developing countries in baseline assessment, developing phase-out strategies, technical assistance and financing (OECD 1996; Lovei 1999; The LEAD Group 2011), as well as the establishment and operation of the public-private Partnership for Clean Fuels and Vehicles (PCFV) by UNEP (Todd and Todd 2010) and the listing of the main ingredients (TEL and TML) in the Annex III of the Rotterdam Convention in 2004 (Rotterdam Convention 2005).

For lead in batteries, ammunition and wastes, international efforts are ongoing. Most importantly, lead wastes including waste lead–acid batteries have been included as hazardous wastes under the Basel Convention, which establishes legally binding obligations for Parties to address them according to the provisions set out in the Conventions. In addition, resolutions and recommendations have been adopted at other international forums with regard to environmentally sound management of waste lead–acid batteries (e.g. UNEA Resolution 2/7 and 3/9) and phase-out of lead ammunition for hunting and fishing (e.g. Resolution 11.15 of the Convention on Migratory Species; Resolution WCC-2016-Res-082 of the World Conservation Congress of the IUCN).

Additional efforts have also been taken to assist countries in taking actions. In the case of waste lead–acid batteries, these include development of guidance documents and tools as well as implementation of country projects co-financed by, e.g., GEF. In the case of lead ammunition, the Lead Task Group under the Convention on Migratory Species has been established to facilitate concerted efforts, knowledge and information sharing, education, and public awareness raising.

On the national and regional levels, instruments and actions have been more diverse both in terms of types and their respective scopes. Many countries and regions have taken actions to legally restrict or ban lead in a wide variety of specific uses that may go beyond those that are being addressed internationally at a global scale. The EU has comprehensive restrictions set in place or in process for the many uses of lead, whereas many others have

legal restrictions or bans with narrower scopes. Several other legally binding instruments have also been used, including marketing authorisation (e.g. on the import of copper concentrates in China and on three lead compounds in the EU), mandatory national standards (e.g. on toys, water pipes and infants' and children's textile products in China) and notification obligations (e.g. in the EU for certain lead compounds). These legally binding instruments and actions are also complemented by others, including nationally recommended standards (e.g. on lead in PVC pipes for water supply in China) and voluntary industry phase-out (e.g. on the use of lead in PVC in Europe).

In addition to instruments and actions to address specific uses of lead, a large number of countries have looked at releases from anthropogenic sources and exposure media that are not lead-specific. For example, legally binding obligations have been set for lead emissions under CLRTAP, including provisions that Parties have to reduce their emissions for lead below their levels in 1990. These provisions under CLRTAP take into account non-specific sources of lead such as the iron and steel industry, non-ferrous metal industry, combustion (power generation, road transport) and waste incineration. Many countries and regions have also set up guideline values for different exposure media, including for occupational exposures, that are either legally binding (e.g. on drinking water in the US and Uruguay; lead emissions in Australia) or as recommended or guidance values. In the EU, legal limits have also been set for lead levels in different fertilisers. Multiple countries have developed a national strategy or declared lead a national priority, actions which may guide them to address lead and lead compounds in a comprehensive manner (see Table B5–2 in the Annex for more examples and details).

4.5.4 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 (ILO 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 (Tsai and Hatfield 2011), and in the US, the benefit-to-cost ratio was at least 10:1 (Lovei 1998).

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.

4.6 Intentionally Added Microplastics in Products

Microplastics are solid particles made of synthetic polymers, typically defined as smaller than 5 mm (Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection [GESAMP] 2016), though many definitions currently co-exist. The assessment here focuses on intentionally added microplastics in products, following the identification of microplastics in personal care products and cosmetics as an issue with emerging evidence of risks to the environment in GCO-II.

Other categories of microplastics are not included in this assessment, as follows: intentional production and use of micro-sized plastic resin pellets for later production of larger plastics, unintentionally formed microplastics during the production and processing of larger plastics, and secondary microplastics that are a result of progressive degradation by physical or biological processes of larger plastics during their life cycles, including in the environment. For these categories of microplastics, sound management measures are distinct from those associated with the intentionally added microplastics in products, and are briefly touched upon in Section 4.6.4 below.

4.6.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

Six assessments by national governments and intergovernmental institutions have been identified (see Table B6–1 in the Annex). In general, these assessments have different scopes (Environment and Climate Change Canada [ECCC] 2015; GESAMP 2016; Lusher *et al*. 2017; ECHA 2019; Science Advice for Policy by European Academies [SAPEA] 2019; WHO 2019). For example, the two assessments from ECHA and SAPEA have a comprehensive scope, whereas the other four assessments from WHO, FAO, ECCC and GESAMP have specific and rather narrow scopes, focusing on certain sectors, exposure media or protection goals (i.e. environment vs. human health). In addition, two assessments focus on intentionally added microplastics, whereas others looked into the effects of microplastics in general.

Nearly all the assessments have reached similar conclusions, despite each having a different focus. In brief, some adverse short- and long-term effects have been observed in laboratory studies, and in comparison, current levels of environmental occurrence or human exposure (e.g. via drinking water, seafood) to microplastics are generally still low. The current scientific evidence suggests that ingestion of microplastics does not significantly enhance exposure/bioaccumulation of organic pollutants (including POPs) relevant to other types of particles present in the environment, or other exposure pathways (e.g. water, diet) in general. However, the continuous release of microplastics will result in environmental accumulation, due to their high persistence in the environment and biota, and thus may result in certain adverse effects on the environment and/or human health in the long term. In addition, the assessments acknowledge considerable uncertainties due to as-yet limited evidence on certain aspects of the risks of microplastics, particularly toxicological and epidemiological, especially as pertains to nano-sized plastic particles.

4.6.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics of microplastics. A wide range of microplastics with different base polymers, e.g. polyethylene (PE) and polypropylene (PP), are used in products. Depending on the base polymer and factors such as size, shape and surface structure, microplastics may exhibit different behaviour and thus undergo complex transport processes in the environment and biota (for details, see e.g. Horton and Dixon 2018 and references therein).

In general, microplastics are resistant to environmental degradation due to high molecular weights and rare occurrence of microbial species that can metabolise polymers (Andrady 2011), which means they will be present in the environment for a long time after their initial releases. When they (bio)degrade in the environment, they progressively fragment into smaller and smaller particles, theoretically becoming “nanoplastics” before further breaking down.

Many microplastics may transport to far distances. For example, a special characteristic of many microplastics is their low density (e.g. PE and PP), which may lead to accumulation at or near the water surface where they can be transported with water currents, e.g. from freshwater to the ocean. Because they are lightweight, microplastic particles might be carried by air currents to remote areas (Dris *et al.* 2016). Furthermore, their small size makes microplastic particles readily available for ingestion and potentially liable to transfer within food chains from prey to predator (Carbery *et al.* 2018).

Recent studies have also looked into the possibility that microplastics might carry other chemicals that could lead to environmental and human exposures, both to intentional additives and chemicals unintentionally adsorbed later to the particles. Current scientific evidence shows that in the marine environment, microplastic ingestion is not likely to increase the exposure to hydrophobic organic chemicals from adsorption because overall, the flux of these chemicals from natural prey overwhelms the flux from ingested microplastics for organisms in most habitats (Bakir *et al*. 2016; Koelmans *et al*. 2016). Meanwhile, microplastic ingestion may still be relevant for elevated exposure to intentional additives, such as plasticizers and flame retardants (Koelmans 2015; Tanaka *et al*. 2015; Jang *et al*. 2016; Schrank *et al*. 2019).

Their small size makes microplastics practically impossible to remove from the environment after release. In contrast, typical wastewater treatment processes can nearly completely (84–99.9%) remove microplastics in wastewater before discharging it to the environment (HELCOM [The Baltic Marine Environment Protection Commission] 2014; Dris *et al*. 2016; Conley *et al*. 2019; Lusher, Hurley and Vogelsang 2019). Most of the microplastic particles captured during the wastewater treatment processes end up in sludge (or waste solids). High-temperature incineration is needed to fully destroy the microplastic particles in sludge, but this is less common than other practices such as landfilling and land treatment of such sewage waste, which result in the releases of these particles to the environment, representing a potentially significant release pathway (Lusher *et al.* 2019).

Major sources of current exposure. Current exposure to intentionally added microplastics is complex and information in the public domain is limited (for more information on production, use and exposure, see Table B6–2 in the Annex and references therein). In brief, microplastics have been added to a wide range of products and application areas for diverse technical functions. They are in cosmetics and personal care products, detergents and maintenance products, agriculture and horticulture, medical devices and in vitro diagnostic medical devices, medicinal products for human and veterinary use, food supplements, paints, coatings and inks, oil and gas drilling and production, plastics, technical ceramics, media for abrasive blasting, adhesives, 3D printing materials and printing inks (ECHA 2019).

While many uses likely occur on the global scale, publicly available quantitative information is limited. A recent estimate suggests that more than 51,000 tonnes (with an uncertainty range of 11,000–63,000 tonnes) were used in all the uses listed above except construction products in the EU, Norway and Switzerland in 2017 (ECHA 2019). Of that mass, cosmetics and personal care products accounted for an estimated 3,800 tonnes (with an uncertainty

range of 1,700–5,900 tonnes; ECHA 2019). In general, the most information available in the public domain is for cosmetics and personal care products. In Canada in 2015, 30–68 tonnes of microplastics are estimated to have been used in "rinse-off" products alone (Gouin *et al.* 2015; ECCC 2015).

Releases of these intentionally added microplastics to the environment can occur through various pathways, depending on the uses, principally via wastewater and/or municipal solid waste, including landfilling of and land treatment using microplastic-containing sludge (Lusher *et al.* 2019). In addition, certain microplastics are inevitably released directly to the environment, such as those used in agriculture and horticulture. In Europe, an estimated 36,000 tonnes of intentionally added microplastics (with an uncertainty range of ca. 10,000–60,000 tonnes per year) were eventually released from all the uses listed above except construction products into the environment in 2017 (ECHA 2019). Limited additional data are available for other parts of the world, mostly focusing on specific cosmetics and personal care products (see Table B6–2 in the Annex). For example, estimates from mainland China and Malaysia suggest 300 tonnes per year (Cheung and Fok 2017) and 199 billion particles per year (Praveena *et al.* 2018) are emitted from facial scrubs to freshwaters, respectively.

The prevalence, levels and trends of current exposure across the globe. Microplastics have been measured at almost every location on the globe, for example in air (Liu *et al.* 2019; Zhang *et al.* 2020), freshwater and drinking water (Li, Liu and Chen 2018, Koelmans *et al.* 2019), marine waters (Cole *et al.* 2011), sediments (Van Cauwenberghe *et al.* 2015), soils (Xu *et al.* 2019), biota (Rezania *et al.* 2018), and even in remote areas such as deep-sea sediment deposits (Woodall *et al.* 2014) and Arctic sea ice (Obbard *et al.* 2014). These monitoring data do not distinguish intentionally added microplastics from other sources such as unintentionally formed microplastics during the production and processing of larger plastics (e.g. textile fibers) and secondary microplastics from progressive degradation of larger plastics. Therefore, assessing the contribution of intentionally added microplastics to the total amount of microplastics around the world is challenging. However, it is fair to say that it is considerable based on the release estimates from the EU, and continuous use of intentionally added microplastics will exacerbate current exposures across the globe.

4.6.3 An Assessment of Existing Instruments and Actions Addressing Intentionally Added Microplastics

To date, different instruments and actions have been taken and are being developed by many countries and stakeholders to address intentionally added microplastics (for more details, see Table B6–3 in the Annex). Most of them have focused on rinse-off products. In particular, legally binding bans have been adopted by a number of countries (e.g. in France, Italy, Canada, US, Republic of Korea, New Zealand) or are on their way to being adopted (e.g. Mexico, Argentina, Brazil, Costa Rica). In addition, voluntary phase-out has taken place, for example, led by industry associations in Australia and ASEAN countries or by multinational companies such as Adidas. Also, voluntary actions have

been taken through third-party standards and verification schemes such as the EU Ecolabel and "zero plastic inside" label, as well as the "Beat the Microbead" campaign and its associated smartphone app, meant to inform, educate and assist consumers in selecting products without intentionally added microplastics.

Recently, in line with the European Parliament's resolution on European Strategy for plastics in a circular economy [2018/2035(INI)] and UNEA Resolution 4/6, a restriction of all intentional uses of microplastics has been proposed in the EU, including labelling requirements, and is currently under evaluation. The proposed restriction could result in a cumulative emission reduction of an estimated 400,000 tonnes of microplastics over the 20-year period following its entry into force (ECHA 2019). The average cost of avoided emissions, for sectors where those have been quantified, is estimated to be about 23 euro per kilogram per year (€/kg/yr), ranging from 1 to 820 €/kg/year, and that the costs of the proposed labelling are considered to be negligible (ECHA 2019).

4.6.4 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 cleanup 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 (Verschoor 2015; Frias and Nash 2019).

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 (Raubenheimer and Urho 2020).

4.7 Neonicotinoids

Neonicotinoids are a class of insecticides that have chemical structures similar to nicotine. They target the central nervous system of insects and are highly effective with low rates of developed resistance in pest insects. Since the first neonicotinoid (imidacloprid) was commercialized in the 1990s, seven main compounds (acetamiprid, clothianidin, dinotefuran, imidacloprid, nitenpyram, thiamethoxam and thiacloprid) are now available on the global market. Today, they are used in protecting plants, livestock and pets from pest insects, as well as for malaria vector control, i.e., mosquitos, to protect humans, in more than 100 countries. Products containing neonicotinoids accounted for more than 25% of the global insecticide market in 2014. Recent evidence suggests that the widespread use of neonicotinoids may be a threat to bees and other pollinators, resulting in broad public concern, and identification by GCO-II as an issue with emerging evidence of risks to the environment.

4.7.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

As insecticides, neonicotinoids have been extensively assessed by many countries through their national pesticide registration schemes before marketing, with a wealth of information available. Concerns about possible impacts on non-target organisms, particularly bees, have led some national governments and intergovernmental institutions to reassess these compounds in the past few years, a process that is still underway in some countries, such as Australia. Here we provide a brief summary of the major findings from these additional focused reassessments and new assessments undertaken; additional details of the individual assessments can be found in Table B7–1 in the Annex.

Multiple assessments reported here have considered imidacloprid, clothianidin and thiamethoxam. Clear evidence shows that they are highly to very highly toxic and can result in lethal and sublethal effects on adult honeybees (e.g. Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services [IPBES] 2016; US EPA 2020a; US EPA 2020b; US EPA 2020c). The IPBES assessment in 2016 concluded that for these three neonicotinoids, the evidence is established but incomplete for their impacts on wild pollinator survival and reproduction at actual field exposure (IPBES 2016). This gap was addressed by more recent in-depth risk assessments for these compounds in Canada, the EU and US, conducted for bees under different scenarios. Despite differences in methodologies and scenarios, they all concluded that these three compounds may result in high risks for bees in specific realistic scenarios, including risks at the colony level (EFSA 2018a; EFSA 2018b: EFSA 2018c; Health Canada 2019a; Health Canada 2019b; Health Canada 2019c; Health Canada 2020; US EPA 2020a; US EPA 2020b; US EPA 2020c). Also, current levels of exposure to the three compounds, measured or estimated under specific realistic scenarios, may result in significant impacts on other wildlife, including birds, mammals and aquatic organisms (Health Canada 2019a; Health Canada 2019b; Health Canada 2019c; US EPA 2020a; US EPA 2020b; US EPA 2020c).

Similarly, the US EPA assessment concluded that dinotefuran has high acute toxicity to adult bees and larvae, and specific uses may result in acute risk exceedances (i.e. exposure levels higher than predicted no effect concentrations) and potential risks for bee colonies under several scenarios.

For two other neonicotinoids, acetamiprid and thiacloprid, the assessments concluded that risks to bees, particularly at the colony level, might be low, but risks to other wildlife are of concern. For acetamiprid, the EFSA assessment considered only the representative uses on pome fruit (post-flowering application) and potatoes, and concluded a low risk to bees and other terrestrial wildlife for all scenarios, including bee colonies (EFSA 2016). In contrast, the US EPA assessment concluded that registered uses of acetamiprid pose acute

and chronic risks of concern to adult bees and larvae, including uses on potatoes, but also suggested that these risks are not likely to translate into long-term adverse effects on bee colonies. Additionally, the US EPA assessment concluded that registered uses of acetamiprid present acute and chronic risks of concern to birds, as well as to freshwater, estuarine and marine invertebrates. For thiacloprid, conclusive risk assessments for bees and other wildlife could not be made; however, the EFSA assessment concluded there is a high in-field and off-field risk to non-target arthropods for the representative use of thiacloprid on oilseed rape (EFSA 2019).

While other reassessments focused solely on the environmental impacts of the neonicotinoids, those by US EPA also examined consumer and occupational risks (US EPA 2020a; US EPA 2020b; US EPA 2020c; US EPA 2020d; US EPA 2020e). They concluded that while acetamiprid, clothianidin, dinotefuran, imidacloprid and thiamethoxam are unlikely to cause dietary risks of concern for consumers, the uses of these compounds may cause risks of concern to consumers and professionals in a number of realistic scenarios during applications and other activities (e.g. children playing on imidacloprid-treated turf). Some of these risks may be mitigatable through personnel protection equipment, whereas some others are not. In addition, WHO concluded that when used strictly as instructed (including the use of personal protection equipment), two clothianidin-based formulations and an imidacloprid-based formulation do not pose undue hazards to the spray operators or residents of treated dwellings. This conclusion and other factors such as efficacy constitute the basis for WHO's recommendations of these formulations as prequalified vector control products (WHO 2017; WHO 2018; WHO 2019). For thiacloprid, the EU has classified it as carcinogen category 2 and toxic for reproduction category 1B and identified it as an endocrine disruptor (EFSA 2019), indicating high human toxicity.

For nitenpyram, no assessment on its environmental impact is identified. Based on a review of existing studies of consumer and occupational risks, the Food Safety Commission of Japan identified that decreases in number of implantations and offspring were observed in a reproduction study in rats and specified an acceptable daily intake (ADI) of 0.53 mg/kg body weight per day and an acute reference dose (ARfD) of 0.6 mg/kg body weight (Food Safety Commission of Japan 2016).

4.7.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics. In general, neonicotinoids have low vapour pressure and high water solubility, and they can bind to soil and sediment particles (Bonmatin *et al.* 2015; Hladik, Main and Goulson 2018). Due to their low vapour pressure, neonicotinoids do not tend to stay in air, but because they may be present on particles (e.g. exhaust from seed planting machines; dust from contaminated soil), they can be transported certain distances in air before settling, depending on particle size and environmental conditions (Bonmatin *et al*. 2015; Raina-Fulton 2015). In one study, neonicotinoid-bearing particles coming from planting could travel as far as 690 m (Forero *et al.* 2017).

In water and soil environments, neonicotinoids can undergo many different environmental processes depending on specific compound and environmental conditions, as reviewed by Bonmatin *et al.* (2015) and Hladik *et al.* (2018). In general, in water, while a large portion of neonicotinoids released may be removed from aqueous environments by adsorption on soil and sediments or by rapid photodegradation in surface water layers, some remains in aqueous phase and may persist for weeks and may be transported far, including to adjacent seas. In soil, neonicotinoids may remain adsorbed on soil particles, or they may undergo abiotic and biotic degradation, plant uptake, and transport to receiving surface and ground waters (note that commercial formulations often contain surfactants, which may significantly reduce soil adsorption and increase movement of neonicotinoids). Overall, in some soil conditions (e.g. cool, dry and high organic matter), neonicotinoids can persist and possibly accumulate for months to years. Similarly, in sediment, they may persist for up to months or longer.

Plants take up neonicotinoids via their roots or leaves; depending on compounds and crop types, uptake efficiencies vary considerably (e.g. imidacloprid uptake via the roots has been reported at 1.6% and 20% for aubergine and corn, respectively; Bonmatin *et al.* 2015). Once taken up, these compounds and their metabolites circulate throughout the whole plant.

In urban areas, neonicotinoids may also end up in wastewater treatment facilities with varied removal efficiencies. Conventional wastewater treatment processes, for example, result in insignificant removal of imidacloprid, limited removal of acetamiprid and clothianidin (about 20–30%), and almost complete removal of thiamethoxam, thiacloprid and dinotefuran (Sadaria *et al.* 2016). Similarly, conventional drinking water treatment cannot remove clothianidin and imidacloprid, and can moderately remove thiamethoxam (about 50%); in contrast, granular activated carbon filtration can rapidly and nearly completely remove all three (Klarich *et al.* 2017). Note that chlorination in drinking water treatment may also result in understudied chlorinated byproducts from degradation of neonicotinoids, which are structurally similar to the parent compounds (Klarich Wong *et al.* 2019).

Major sources of current exposure. Since imidacloprid was commercialized in the early 1990s, the class and use of neonicotinoids have expanded greatly. Today, they have been registered as pesticides in over 120 countries (Jeschke *et al.* 2011) and are used in a wide range of consumer, agricultural, industrial, and public health applications, including on hundreds of crops (Simon-Delso *et al.* 2015). For more details on production and uses, including trade names, see Table B7–2 in the Annex, Jeschke *et al*. (2011), Network of African Science Academies (2019) and US EPA (2020a; 2020b; 2020c; 2020d).

Quantitative information on current production and use is scarce in the public domain. Available information shows that in 2014, the sum of the seven neonicotinoids accounted for more than 25% of the total global market share of insecticides; as of 2012, thiamethoxam accounted for 37.6% of the total neonicotinoids market share, imidacloprid for 33.5%, clothianidin for 14.7%, acetamiprid for 7.2%, thiacloprid for 3.8%, dinotefuran for 2.9% and nitenpyram for 0.3% (Bass *et al.* 2015). For agricultural use, in 2012, Latin America had the

highest usage of neonicotinoids (30% of the global total application of neonicotinoids), followed by Asia (23%), North America (22%), Europe (11%), Middle East (1%) and others (as of 2012; Bass *et al.* 2015).

To date, China has become a major producer and exporter of neonicotinoids. For example, the production of imidacloprid in China was reported to be about 12,000–14,000 tonnes in the early 2010s, about two-thirds of the then total global production, and increased to 23,000 tonnes in 2016 (Shao *et al*. 2013; Chen *et al*. 2019). In addition, China produced 8,000 tonnes of acetamiprid in 2010 and unknown amounts of thiacloprid, nitenpyram and clothianidin (Shao *et al.* 2013).

Neonicotinoids are applied through leaf (foliar), soil or seed treatments; in 2011, approximately 60% of all applications were soil or seed treatments (Jeschke *et al.* 2011). Regardless of application methods, environmental and human exposure may occur. Key routes to the environment include direct releases, leaf run-off, leaching, (subsurface) drains, spillage, greenhouse wastewater, and spray or dust drift during applications (including during seed planting) to air, water and soil, both in the immediate vicinity and off-field; for more details, see Table 2, Bonmatin *et al.* (2015) and US EPA (2020a; 2020b; 2020c; 2020d). Thus, wildlife and humans may be exposed to neonicotinoids through contaminated environmental media. Wildlife may be additionally exposed by eating treated seeds, crops, and their pollen and nectar (US EPA 2020a; US EPA 2020b; US EPA 2020c; US EPA 2020d), and humans may be additionally exposed through contaminated pollen, foodstuffs and drinking water (Zhang *et al.* 2018). Different levels of occupational exposure may also occur, depending on the activities, application methods, and personnel protection equipment used (US EPA 2020a; US EPA 2020b; US EPA 2020c; US EPA 2020d).

The prevalence, levels and trends of current exposure across the globe. Due to their widespread use, neonicotinoids are now detected around the world in a wide range of media. These include air, surface water, groundwater, drinking water, soil, raw and treated sewage, crops and foodstuffs, house dust and human urine samples (for examples, see Table B7–3 in the Annex, Blacquière *et al*. 2012, Sanchez-Bayo and Goka 2014, Bonmatin *et al*. 2015; Anderson, Dubetz and Palace 2015; Morrissey *et al*. 2015; Wood and Goulson 2017; Zhang *et al*. 2018; Network of African Science Academies 2019).

Measurements in surface water and groundwater around the world show that waterborne neonicotinoids were frequent, occurred over the long term (i.e., also outside of the growing season), and often at microgram-per-litre levels or higher, exceeding existing water-quality guideline values for aquatic organisms. Also, often more than one neonicotinoid was detected in the same sample (Anderson, Dubetz and Palace 2015; Bonmatin *et al*. 2015; Morrissey *et al*. 2015). For example, one study along the east coast of China found that under current agricultural practices, 27% and 84% of the river water samples exceeded estimated thresholds for acute and chronic ecological risks, respectively, and over 1,200 tonnes of neonicotinoids were transported in run-off into nearby marine waters (Chen *et al.* 2019).

Another study analysed five neonicotinoids in 198 honey samples from six continents, and at least one of the five were detected in 75% of all samples and 45% of the samples contained two or more of these compounds (Mitchell *et al.* 2017). Although the levels in honey were relatively low (at the level of nanograms per gram of honey) and are below the maximum residual level authorised for human consumption, this study confirms worldwide exposure of bees to neonicotinoids, as previously reviewed by Blacquière *et al.* (2012) and Sanchez-Bayo and Goka (2014).

In some parts of the world, measurements have also shown likely increases in use and exposure of some neonicotinoids. For example, detection frequencies of acetamiprid, clothianidin and thiamethoxam increased in food and water samples in the US between 1999 and 2015 (Craddock *et al.* 2019), and detection frequencies and levels of total urinary neonicotinoids increased in Japanese women between 1994 and 2011 (Ueyama *et al.* 2015).

4.7.3 An Assessment of Existing Instruments and Actions

As neonicotinoids are insecticides, they must conform to standard regulatory requirements for pesticides that exist in many countries, particularly in the form of limit values for levels in different environmental media and maximum residual levels in agricultural products. These requirements are not reviewed here. The focus is on efforts, both regulatory and voluntary, that have gone beyond standard regulatory requirements in different countries to address neonicotinoids. A brief summary is provided below; for more details by individual actors, see Table B7–4 in the Annex.

On the regulatory side, instruments and actions include total bans and restrictions on specific uses, strengthened personnel protection equipment requirements, and additional labelling requirements and scheduled re-review of the compounds. For example, to date, clothianidin, imidacloprid, thiamethoxam, acetamiprid and thiacloprid have been banned in France, 12 pesticide formulations containing thiamethoxam or clothianidin in the US, thiacloprid in the EU, and imidacloprid in Fiji. In addition, Canada and the EU have issued a number of restrictions in order to protect pollinators such as bees from neonicotinoids. The restrictions on clothianidin, imidacloprid and thiamethoxam in the EU only allow uses in permanent greenhouses. In contrast, the restrictions in Canada are more detailed and complex, including restrictions on application methods, frequencies, and timing for different crops, depending on specific neonicotinoids, and often accompanied with additional labelling requirements by manufacturers for directions on application (see Table B7–4 in the Annex).

Apart from these existing actions, a number of countries are also in the process of taking more actions on neonicotinoids. For example, US EPA has concluded the risk assessments and released proposed interim decisions for imidacloprid, clothianidin, thiamethoxam, dinotefuran and acetamiprid, pending comments (US EPA 2020a). The proposed regulatory actions in these proposed interim decisions include detailed restrictions on application methods, frequencies and timing for different crops, depending on specific

neonicotinoids, and often accompanied with additional labelling requirements by manufacturers for directions on application and use of personal protection equipment to protect relevant workers. Bills have been introduced in a number of countries in the Latin America region for various limitations, restrictions and bans, and the Australian government is in the process of re-reviewing six neonicotinoids (see Table B7–4 in the Annex).

The regulatory instruments and actions are complemented by voluntary actions. Registrants in the US for thiacloprid voluntarily cancelled its registration, and the same occurred for clothianidin and thiamethoxam in the EU. These voluntary actions have led to the virtual ban of the respective neonicotinoids as pesticides in these jurisdictions. In addition, several international third-party standards and certification schemes such as Fairtrade, FCS and UTZ have included neonicotinoids in their frameworks. For example, imidacloprid is included in the Orange List (restricted materials) of Fairtrade's Hazardous Materials List. In the EU, civil society organisations have also formed the Save the Bees Coalition to inform policymakers and the general public on risks of neonicotinoid uses.

4.7.4 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-party 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; Siviter, Brown and Leadbeater 2018; Tosi and Nieh 2019), **and towards alternative techniques that minimise chemical uses**, such as agroecological techniques and integrated pest management**.**

4.8 Organotins (Organic tin compounds)

Tin (Sn) is a naturally occurring element used in both inorganic and organic forms for a variety of industrial and consumer applications. Inorganic tin compounds generally exhibit low toxicities in humans and wildlife, largely due to their low solubility, poor absorption, relatively low accumulation in tissues and rapid excretion (WHO 2005). In contrast, organic tin compounds, or organotins, have become well known for their high toxicity to aquatic organisms and humans. Among this family of hundreds of mostly human-made compounds, tributyltin (often referred to as TBT) compounds have been banned in anti-fouling systems on ships since 2008 due to their high toxicity to marine organisms. More recently, organotins as biocides have been identified by GCO-II as an issue with emerging evidence of risks to human health and the environment. This chapter looks into the large family of hundreds of compounds and all their uses, including those other than biocides.

4.8.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

The human and environmental health risks of organotins have been extensively assessed by many national governments and intergovernmental institutions. Harmonised classification

has also been made in the EU for many organotins (ECHA 2020). A compilation of all existing assessments is not made here; major lessons learned from several authoritative assessments by WHO (2004; 2006), US ATSDR (2005) and Environment Canada (2009), among others, are highlighted.

Organotins are a family of hundreds of compounds that have tin binding to one to four organic functional groups or "moieties" (i.e. mono-, di-, tri- and tetra-organotins). Depending on the number and type of organic moieties in the molecule, organotins may exhibit different patterns of toxicity, even at very low levels. Organotins are skin and eye irritants (US ATSDR 2005; WHO 2006). Among the family of organotins, methyltins and ethyltins are highly neurotoxic (e.g. causing neuronal damage; US ATSDR 2005, WHO 2006), with a related no-observed-adverse-effect-level (NOAEL) estimated to be about 0.6 mg/kg body weight for dimethyltin (WHO 2006). Dibutyltin, tributyltin, monooctyltin and dioctyltin are immunotoxic (e.g. causing reduced resistance to infection; US ATSDR 2005; WHO 2006), with related NOAELs estimated to be 0.87, 0.23 and 0.025 mg/kg body weight per day (bw/day) for monooctyltin, dioctyltin and tributyltin, respectively (WHO 1999; WHO 2006). Hepatic and hematological effects as well as reproductive and developmental effects have also been reported in animals treated with some organotins (US ATSDR 2005; WHO 2006). Studies have also shown that toxicity of organotins may increase with the number of organic moieties (mono- < di- < tri-organotins; US ATSDR 2005; WHO 2006). Furthermore, endocrine-disrupting potential has been observed for many organotins. In aquatic environments, tributyltin compounds have been reported to lead to male sexual characteristics in female marine snails and have the potential to induce sex reversal in marine fish (WHO 1999; Environment Canada 2009).

To date, the EU has identified several dibutyltin, dioctyltin and tributyltin compounds as SVHC under REACH, based on the reproductive toxicity of dibutyltin and dioctyltin compounds, and the persistence, bioaccumulation potential and toxicity of tributyltin.

Based on toxicity measured in lab animals, national governments and intergovernmental institutions have developed different guideline values. For example, US ATSDR derived minimal risk levels at 5 µg/kg bw/day for dibutyltin and at 0.3 µg/kg bw/day for tributyltin for intermediate-duration oral exposure (15–364 days; US ATSDR 2005). WHO estimated medium-term exposure TDI of 1.2 µg/kg bw/day for monomethyltin and dimethyltin based on neurotoxicity, 3 µg/kg bw/day for dibutyltin based on immunotoxicity, and 2 µg/kg bw/day for dioctyltin based on immunotoxicity (WHO 2006). Similarly, EFSA set a group TDI of 0.25 µg/kg bw/day for tributyltin, dibutyltin, triphenyltin and dioctyltin compounds; based on tributyltin oxide molecular mass, this group TDI is 0.1 µg/kg bw/day when expressed as tin content, or 0.27 µg/kg bw/day when expressed as tributyltin chloride (EFSA 2004). The Dutch Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) set Serious Risk Concentrations (SRC) for three organotins in the environment at which harmful effects for wildlife are expected for dibutyltin, tributyltin and triphenyltin, respectively: 28, 0.052 and 0.24 mg/kg dry weight soil and 50, 0.046 and 0.4 mg/L groundwater (van Herwijnen 2012).

4.8.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics of organotin compounds. Organotins exhibit different environmental fate and transport characteristics depending on how many organic functional groups (or moieties) are attached to the tin atom. Below are some general behaviours.

Organotins may undergo several transformation processes in the environment and biota. Photolysis (i.e. UV light exposure) is one of the most significant modes of degradation in the environment (de Carvalho Oliveira and Santelli 2010). Degradation processes sequentially remove organic functional groups (i.e. tetra-organotins to tri-organotins to di-organotins to mono-organotins) until finally only inorganic tin atoms remain. Organotins with a larger number of moieties degrade faster in the environment (mono- ≥ di- > tri-organotins). Degradation half-lives are on the order of months to years, and even decades, in soil and sediment; days to months in water; and days in activated sludge (WHO 2006). However, other processes in the environment, particularly microbial methylation in sediments and landfill, can turn inorganic tin into organotins or add methyl moieties to organotins, for example, turning tributyltin (tri-organotin) into tributylmonomethyltin (tetra-organotin; Amouroux *et al*. 2000; Kurihara *et al*. 2009; Krupp *et al*. 2011).

In general, most organotins have low vapour pressure and moderate to high water solubility. Depending on the number and type of organic moieties, some organotins have high affinity to particles, with sorption potential decreasing as the number of moieties increases (in the order of mono- ≥ di- > tri-organotins and butyltins > methyltins; Huang and Matzner 2004). For some organotins, accumulation in biota may occur, resulting in high tissue concentrations in some organisms (US ATSDR 2005; Environment Canada 2009); for example, tributyltin and triphenyltin are identified as bioaccumulative according to criteria specified under the Canadian Environmental Protection Act (CEPA) 1999 (Environment Canada 2009).

Releases of most organotins to air from various surfaces are insignificant due to their low vapour pressures and rapid photolysis on surfaces. In water, a large fraction of most organotins stick to particles and may thus remain in sediment for a long time. A smaller fraction may be absorbed by aqueous organisms such as algae, invertebrates and fish, or remain dissolved in water. In seawater, aerosol bubbling may additionally result in sea-to-air fluxes and subsequent atmospheric transport of some organotins (Saint-Louis and Pelletier 2004).

Methylated organotins may be an exception; they are volatile and some of them have atmospheric half-lives of days to weeks (Krupp *et al.* 2011). As described above, such methylated organotins can be generated by the methylation of inorganic and organic tin compounds in sediments and landfill. Thus, they may be released from sediments and landfills to air and transported via wind, as measured in air at landfill sites and coastal areas (e.g. Amouroux *et al.* 2000; Krupp *et al.* 2011). The extent of such transformation and subsequent atmospheric transport occurring in sediments and landfill on the global scale remains unclear and warrants further investigation.

Major sources of current exposure. Organotins, with the exception of some methylated compounds made by bacteria, have solely anthropogenic origins (Sousa *et al.* 2014). They may be released to the environment at any point throughout their life cycles. The large industrial scale of production and use of organotins started in the 1940s. Below a summary is provided on their production, use, disposal and related sources of exposure; for more details, see Table B8–1 in the Annex and references therein.

To date, a wide range of organotins has been produced and used in a variety of applications (Sousa *et al.* 2014). Mono- and di-organotins with methyl, butyl and octyl moieties are mainly used as heat stabilisers in PVC in a wide range of applications, including window frames and house siding, PVC pipe, food contact blister packs and water bottles. These organotins are also used for depositing tin oxide coatings on reusable glass bottles and other glass products, as catalysts in production of polyurethane foams and silicones, as dewormers in poultry farming, and other applications. Tri-organotins are used mainly as biocides (e.g. in wood preservatives, in anti-fouling paints for boats, in textiles, leathers and synthetic fabrics) and as pesticides. Tri-organotins also occur as significant contaminants in other commercial organotin products. Tetra-organotins have been used as intermediates in the preparation of other organotins and as oil stabilisers.

Limited information is available with regard to the volumes of organotins produced and used on the global market, particularly for the past decade. Some early estimates suggested that global production of organotins could be about 60,000 tonnes per year in the early 2000s (Nath 2008) and that the majority of organotins (76%) went to the PVC industry with another less than 20% used as biocides and pesticides (Sousa *et al.* 2014). In 2015, about 40% of estimated global consumption of organotins occurred in China, about 93% of which was used as heat stabilizers in PVC manufacture (>60,000 tonnes; IHSMarkit 2016). Currently, in the EU, at least 10 organotins are used in the range of 100–1000 tonnes per year, and another 6 in the range of 1000–10,000 tonnes per year (ECHA 2020).

Organotins may be released during production, use (e.g. direct releases from pesticidal uses, leaching from ship hulls and PVC piping) and disposal (e.g. from landfills, through the removal of old organotin paint from ships during maintenance, and through leaching from PVC microplastics; Sousa *et al.* 2014). Wildlife and humans are exposed to organotins through contaminated environmental media and foodstuffs. In addition, humans may be exposed to organotins through the use of organotin-containing products (e.g. through leaching from silicone baking containers). Organotins may also enter the foetus via the placenta (Danish Environmental Protection Agency [Danish EPA] 2013). Occupational exposure may occur during the production and processing of organotins and associated products.

The prevalence, levels and trends of current exposure. Due to their widespread use (e.g. in anti-fouling paints on boats and in PVC), releases and exposure to organotins are likely ubiquitous. To date, most of the studies have focused on exposure related to anti-fouling paints in marine environments.

Studies in Europe have shown a decrease of the levels of organotins in marine waters and a corresponding decline in imposex, where female sea snails and other organisms develop male sex organs, in comparison to historic values, following the ban of tributyltin in anti-fouling paints there (Commission of the Convention for the Protection of the Marine Environment of the North-East Atlantic [OSPAR Commission] 2011; Arp *et al.* 2014; Anastasiou *et al.* 2016; Sousa and Pastorinho 2017). Similarly, overall levels of butyltins and associated incidence of imposex in Arctic fauna have also likely declined, although further monitoring studies are needed (Kucklick and Ellisor 2019).

These studies also underscore the significance of highly polluted areas such as docks and shipyards where, despite the banning of organotin-based anti-fouling paints, imposex is still observed at high rates, due to the persistence of historic pollution and secondary pollution from sediments (Wang *et al.* 2019). Other studies have not yet observed declines, e.g., in Hong Kong (Ho *et al.* 2016) and Chile (Mattos *et al.* 2017). In Peru, tributyltin pollution decreased for international ports, where legislation may be better enforced, in contrast to smaller ports and marinas, which are still important sources of tributyltin likely due to lack of legal controls and enforcement effectiveness (Castro *et al.* 2018), which may also be the case in some parts of Brazil (Maciel *et al.* 2018). The extent of current exposure to organotins, particularly from sources other than anti-fouling paints, warrants further investigation.

4.8.3 An Assessment of Existing Instruments and Actions

To date, a wide variety of instruments and actions have been developed and taken on different levels to address specific organotins (for details, see Table B8–2 in the Annex and references therein).

At the international level, the focus has been on tri-organotins and their uses in anti-fouling paints on ships, with the listing of tributyltin compounds under the Rotterdam Convention (UNEP and FAO 2014; UNEP and FAO 2015) and the inclusion of organotins (i.e. tributyltins) in the International Convention on the Control of Harmful Anti-fouling Systems on Ships (the AFS Convention; signed in 2001 and entered into force in 2008). In 2011, the AFS Convention covered about 75% of the world's shipping fleet (OSPAR Commission 2011); as of March 2020, the Convention has 89 Contracting States. Additionally, under Annex II to the Pollutant Release and Transfer Register (PRTR) Protocol, ratifying parties are required to report releases in their respective PRTRs of tributyltins, triphenyltins and total organotins. Also, WHO is in the process of developing a group guideline value for several organotin compounds (tributyltin, triphenyltin, dibutyltin and dioctyltin) in drinking water.

At the national and regional levels, many countries have taken action to address tributyltin in anti-fouling paints on ships before or in response to the AFS Convention. Some countries and regions (e.g. Canada, EU, Japan, Republic of Korea) have gone further and

set legal restrictions on more organotins in a wider range of uses. For example, in the EU, multiple uses of dibutyltins, dioctyltins and tri-organotins have been banned or restricted, including as anti-fouling biocides, in the treatment of industrial waters, and in many different consumer products. The EU has also listed three organotin compounds as SVHC and is currently evaluating a fourth one for addition to the SVHC list; such listing sets legal obligations for manufacturers and suppliers to provide sufficient information for industrial users and consumers, to allow for safe use of products containing these compounds. Governments have also used soft law instruments by setting norms such as guideline values in different exposure media including air, soil and groundwater and during occupational exposures. Also, Canada has developed a Code of Practice for tetrabutyltin with the purpose to minimise releases to the aquatic environment by identifying best management procedures and practices.

These actions through the conventions, by intergovernmental institutions and by national governments have been complemented by voluntary industry phase-out through tools such as restricted substances lists (e.g. by H&M, American Apparel & Footwear Association, Apple) and third-party standards and certification schemes (e.g. by bluesign®).

4.8.4 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 (Amec Foster Wheeler and EC 2017).

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.

4.9 Phthalates

Phthalates are a large family of semi-volatile organic compounds; among them, ortho-substituted phthalates have been identified by GCO-II as an issue with emerging evidence of risks to human health. They have been or are now produced in high volumes to be used as plasticizers, lubricants and solvents for a wide range of applications, such as in building, medical and fragranced consumer products, as well as vehicles, among other applications. The breadth of their use has resulted in extensive human and environmental exposures.

Several ortho-substituted phthalates have been found to adversely affect mammalian male reproductive tract development with endocrine-disrupting modes of action (US National Academies of Sciences, Engineering, and Medicine 2017; Radke *et al*. 2018), which has resulted in their restriction by some countries since the 1990s. The restrictions have also resulted in increased use of replacements. Some replacements are longer-chain homologues to their predecessors, whereas others include different types of phthalates and related compounds (Bui *et al*. 2016).

Here we limit the focus to ortho-substituted phthalates, referred to hereafter as phthalates, because of their widespread use and concerns or actions taken with respect to environmental abundance, human exposure, toxicity and health effects. As such, we do not discuss replacement phthalates that are not ortho-substituted (such as terephthalates), which may also be high-production-volume chemicals.

4.9.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

Most assessments focus on carbon chain lengths of 4 to 10, though some consider shorter carbon chains of 1 to 3 (WHO 2003a; US Consumer Product Safety Commission 2011; NICNAS 2013; NICNAS 2014). For more details, see Table B9–1 in the Annex.

There is broad consensus that phthalates with carbon chain lengths of 4 to 8 cause adverse effects on the male reproductive system. For example, some cause androgen insufficiency and decreased testosterone levels during the development of the male reproductive tract (US National Research Council 2008; US NAS 2017). Among these phthalates, the US NAS (2017) concluded that di(2-ethylhexyl) phthalate (DEHP) "is presumed to be a reproductive hazard to humans". They based this conclusion on human and animal studies evaluated for quality and reproducibility. Adverse effects, more specifically decreased anogenital distance in infants, are seen in a dose-response fashion as a function of maternal DEHP metabolite levels, with the most sensitive window of susceptibility occurring during foetal development. Recently, DEHP has also been classified by IARC as possibly carcinogenic to humans (Group 2B) with sufficient evidence in experimental animals for its carcinogenicity, with no human data available (IARC 2011).

More recent assessments have concluded that exposure to other high-molecular weight (HMW) phthalates, such as di-isononyl phthalate (DiNP) and di-isodecyl phthalate (DiDP) with carbon chain lengths of 9 and 10, can also cause adverse male reproductive effects due to foetal exposure, but the most sensitive effects are changes to the liver (EFSA 2019a).

To date, the EU has identified 17 phthalates or phthalate mixtures as SVHC due to one or a combination of the following: toxicity for reproduction, endocrine-disrupting properties to human health and endocrine-disrupting properties to the environment. These substances include benzyl butyl phthalate (BBP), di(2-methoxyethyl)phthalate (DMEP), dibutyl phthalates (DBP, including di-*n*-butyl phthalate, DnBP, and di-isobutyl phthalate, DiBP), dipentyl phthalate (DPP), di-isopentyl phthalate (DiPP), n-pentyl-isopentyl phthalates (n-PiPP), dihexyl phthalate (DHP), di-isohexyl phthalate (DiHxP), dicyclohexyl phthalate (DcHP), di-isoheptyl phthalate (DiHpP) and DEHP.

Another key finding of the US NAS study was that current toxicity test methods can identify the hazard of DEHP, for example, but the testing "may not be able to accurately predict exposures at which humans are affected" (US NAS 2017). This point is critical because it calls into question the reference doses and other "safe" limits established by regulatory agencies based on animal testing, which may not in fact be safe.

Much less work has been done with regard to impacts caused by phthalate exposure to ecosystem health, e.g. through nearby discharges to water bodies from industries using

phthalates or from wastewater treatment plants. Some long-range transport is possible for short-chain phthalates, but degradation prevents their accumulation in the environment. Evidence shows some endocrine-disruption effects of exposed aquatic organisms, but baseline narcosis also has been used to assess ecological risks. ECCC and Health Canada (2017) assessed 13 phthalates and concluded that DEHP and B79P (a mixture of phthalates with carbon chain lengths of 7 to 9) meet the criteria under paragraph 64(a) of CEPA 1999, that they are entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

4.9.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics. An overview of physical and chemical properties of several phthalates can be found in a recent review by Net *et al.* (2015, Table 1 therein). The water solubility of phthalates is generally low and decreases with increasing carbon chain length, whereas *K*OA and *K*OW (octanol-air and octanol-water partition coefficients) increase with increasing carbon chain length (i.e. increasing affinity to organic matter).

Depending on the carbon chains connected through the ester bond, phthalates are often categorised as high- (HMW) or low-molecular weight (LMW). Once released indoors, LMW phthalates tend to remain in air, whereas HMW phthalates deposit on dust and films on indoor surfaces. Those indoor surfaces include uncovered skin and clothing (Saini *et al.* 2016; Xu, Hubal and Little 2010), which has implications for human exposure (Morrison, Weschler and Beko 2017).

Outdoor transport processes are also predictably governed by the physical and chemical properties of each compound. In air, LMW phthalates are subject to wet and dry deposition, whereas HMW compounds readily adsorb to air particles, soil, vegetation surfaces and films on outdoor impervious surfaces. Phthalates readily degrade outdoors by microbial transformation, photo-oxidation and photolysis (Net *et al.* 2015). Photo-oxidation of phthalates decreases with increasing side chain length.

Multimedia mass balance modelling of phthalates emitted to an “evaluative” environment indicates that soil would be the greatest sink, but that overall persistence in the environment is governed by loss due to degradation (Cousins and Mackay 2003). Cousins and Mackay (2003) estimated overall persistence or residence time of DBP and DEHP of 15 and 38 days, respectively, in an area equivalent to that of approximately England, Greece or Portugal. The consistent finding of high-production-volume phthalates in the environment is attributable to their continual release as opposed to accumulation due to persistence (ECCC and Health Canada 2017). An exception is the ability of phthalates, notably HMW ones, to accumulate in sediments where sorption to particles reduces degradation rates and where low-oxygen conditions slow degradation.

In the environment, phthalates are bioavailable, but uptake is subject to their limited solubility. Phthalates do not tend to bioaccumulate because of rapid metabolism. Thus, phthalates do not biomagnify through food webs (Net *et al.* 2015).

Major sources of current exposure. While most phthalates are human-made, natural production of some phthalates has been observed. For example, DBP and DEHP can be synthesised by red algae, but this production is negligible compared to intentional industrial production (Chen 2004). Different phthalates with carbon chain lengths of 1 to 13 have been used in many different applications (for more details, see Table B9–2 in the Annex and Godwin 2010).

Phthalates with carbon chain lengths of 1 to 4 have been used as solvents and "keepers" to solubilise fragrances and other ingredients in cosmetics, medical devices, and household and personal care products. They also aid in spreading or the application of some products (see e.g. Godwin 2010; Katsikantami *et al*. 2016).

Phthalates with carbon chain lengths of 4 to 13 are commonly added as plasticizers, comprising 10–60% by weight of the final plastic, to confer flexibility to rigid polymers; these include DEHP, dioctyl phthalate (DOP), DiNP, DiDP and di(2-propylheptyl) phthalate in particular (IHS Markit 2018). Because of high volatility, phthalates with carbon chain lengths of 4 to 6 are no longer used as PVC plasticizers in most countries (Godwin 2010; IHS Markit 2018). In total, phthalates accounted for ~70% of the global consumption of plasticizers in 2017 (ca. 6 million tonnes in 2015; Malveda 2015; IHS Markit 2018), which is a decrease from 88% in 2005. Projections suggest that the share of phthalates in total plasticizer use would further decrease due to replacement by terephthalates, cyclohexanoates and other alternatives (European Plasticisers 2018); the absolute amount might still grow due to the growth of the overall use of plasticizers (IHS Markit 2018).

Phthalates used as plasticizers and solvents are not chemically bound to the matrix to which they are added. As such, they inevitably migrate over time from the matrix to the surrounding media, both indoor and outdoor, with migration rates depending on the phthalates and matrix. Overall, phthalates are released to the environment from indoor (e.g. personal care products, candles) and outdoor uses (e.g. vehicles, agricultural applications), and discharges from industrial sources, wastewater treatment plants and landfills. Wildlife and humans are exposed to phthalates through contaminated environmental media (air, water, soil) and foodstuffs (Mayer, Stalling and Johnson 1972; Meng *et al*. 2014; Gao and Wen 2016; Lü *et al*. 2018). In addition, phthalates can be absorbed through the skin (e.g. from personal care products and clothing; Koniecki *et al*. 2011; Gong *et al*. 2016). For infants, exposure also can occur via breast milk (Fromme *et al.* 2011).

Phthalate plasticizers can transfer directly to dust lying on top of phthalate-bearing plastic products. Thus, for HMW phthalates, humans can be exposed via dust (Kashyap and Agarwal 2018). In addition, human exposure can occur from phthalate plasticizers that have migrated from food packaging to food or bottled water (Luo *et al*. 2018; Buckley *et al*. 2019;

Luo *et al*. 2020). An important exposure route for children is mouthing of toys and other phthalate-containing products, including in textiles, furniture and clothing (ECHA 2018; Babich *et al*. 2004; Bouma and Schakel 2002; Korfali *et al*. 2013).

When phthalate-containing materials such as paper, paperboard and plastic are recycled, the resulting materials are often used differently than in their previous life cycle(s). This so-called secondary use of phthalates may thus result in unintended exposures, not expected from the original primary use (Bononi and Tateo 2009; Ionas *et al*. 2014; Lee *et al*. 2014).

The prevalence, levels and trends of current exposure across the globe. Due to their widespread application, exposure to phthalates occurs globally and phthalates have been detected in various environmental compartments and other matrices, such as air, water, drinking water, sediment, sludge, wastewater, soil, dust and biota (Net et al. 2015; Gao and Wen 2016). For a detailed list of reported phthalate concentrations in different matrices worldwide, see the Supporting Information of Net *et al.* (2015).

As reviewed by Net *et al.* (2015), in surface waters, both marine and fresh, the most frequently detected phthalates are dimethyl phthalate (DMP), diethyl phthalate (DEP), di-*n*-octyl phthalate (DnOP), BBP, DBP, DEHP and DMEP. DEHP is the predominant phthalate found in fresh water (and freshwater sediments) and marine waters, with concentrations frequently exceeding the annual average environmental quality standard of 1.3 µg/L (European Council 2008). In drinking water, phthalate concentrations of several µg/L have been found around the world, with no clearly recognizable predominant phthalate; DEHP was generally found at levels below existing drinking water standards. Phthalates in sludge sometimes exceed limit values for land application (set for example by the EU), which can result in sludge, if used as a land treatment, contributing significantly to phthalates in soil. In soils, DEHP and DnBP are the most abundant phthalates, followed by DnOP and DiBP. Particularly high concentrations of phthalates have been found in some Chinese soils.

Phthalates are detected in both indoor and outdoor air, with indoor levels usually higher than outdoors, due to major phthalate sources present indoors and faster degradation outdoors. They are generally present at higher concentrations in urban than in rural areas. Nevertheless, phthalates are also detected in remote Arctic air (Net *et al.* 2015; Gao and Wen 2016). Phthalates have also been detected in dust, with indoor dust containing levels of phthalates several orders of magnitude above that of outdoor dust (Gao and Wen 2016).

Various human biomonitoring studies in the EU, US and Asia indicate the use of phthalates has resulted in continuous and widespread exposure of the general public (Katsikantami *et al*. 2016; Wang *et al*. 2019). Human biomonitoring studies are noticeably absent from Africa and Latin and South America, except for Brazil (Wang *et al.* 2019). A recent study found that DEP, DBP and DEHP were among 13 chemicals most commonly detected in the silicone wristbands worn by volunteers in 14 communities from Senegal, South Africa, the US and Peru, indicating human exposure there (Dixon *et al.* 2019).

A comparison of reported concentrations of phthalates and their metabolites in urine, serum and less conventional biological matrices (hair, saliva, semen, sweat, meconium) among different countries found similar exposure levels between Europeans and North Americans, but lower levels in Asian populations. For many phthalates, children were found to be more highly exposed than adults (Katsikantami *et al*. 2016; Wang, Zhu and Kannan 2019).

Temporal trends in phthalate exposures vary among countries. In the US, DBP, BBP and DEHP exposure has declined since 2005, whereas DiNP exposure has increased (US EPA 2018; Health Canada 2019; Wang *et al*. 2019). Similarly, exposures to DEP, DBP, BBP and DEHP in first-time mothers in Uppsala, Sweden, declined significantly between 2009 and 2014, with reports of increased exposure to a replacement substance, di-isononyl hexahydro phthalate (DINCH; Gyllenhammar *et al.* 2016). In China, DEHP exposure has increased since 2000 (Wang *et al.* 2019). Data from the US National Health and Nutrition Examination Survey 2015–2016 showed that phthalate concentrations in this statistically representative sample of the US population were highest among those living below the poverty line (US Centers for Disease Control and Prevention 2018; US EPA 2018). A trend of higher phthalate exposure among children of low socio-economic income was also found in Canada (Navaranjan *et al.* 2019). Of particular importance is occupational exposure for workers in the plastics industry (Hines *et al.* 2012).

4.9.3 An Assessment of Existing Instruments and Actions

To date, many countries have officially either banned, restricted or set a maximum allowable concentration for the use of specific phthalates in specific products; for more details, see Table B9–3 in the Annex. The scope of these restrictions and bans varies among countries and regions.

Overall, most of them have focused on toys and childcare products (e.g. in Canada, China, the EU, the Eurasian Economic Union, the US), with one or more of the following phthalates included: BBP, DBP, DPP, DHP, DCHP, DEHP, DOP, DiNP and DiDP. Additional restrictions exist for electrical and electronic products (e.g. for BBP, DBP and DEHP in the EU), medical devices (e.g. for BBP, DBP and DEHP in the Republic of Korea; for DEHP in Canada), food contact materials (e.g. for DMP, DiBP, DOP and DiDP in China; for DBP and DOP in the Eurasian Economic Union), and cosmetics (e.g. for DBP, DEHP and DMEP in the Eurasian Economic Union; for DEHP in Canada).

Some other instruments have also been introduced to limit the use of and exposure to phthalates. For example, Denmark previously introduced a tax on products containing PVC and phthalates; the tax was then repealed in 2019, in part due to reductions in the use of phthalates overall (UNEP 2019). In addition to those restricted phthalates, many more have been identified as SVHC in the EU, and thus, manufacturers and suppliers of products containing more than 0.1% of such phthalates are obliged to provide downstream industrial users and consumers sufficient information to allow for safe use.

These legally binding instruments to limit the use of phthalates are complemented by voluntary actions including voluntary industry phase-out by retailers (e.g. CVS, the largest pharmacy chain in the US) and producers (e.g. Apple), as well as third-party standards and certification schemes (e.g. by bluesign®, ZDHC, EU Ecolabel and Nordic "Swan" Ecolabel).

There have also been actions to address the releases and environmental exposure to phthalates. For example, guideline values, both legally binding or recommended, have been established for DEHP in surface waters (e.g. in the EU) and in drinking water (e.g. in the US and by WHO). In addition, DBP and DEHP are listed on the US Toxics Release Inventory (TRI) with mandatory reporting of industrial releases. Canada proposed that DEHP and B79P (1,2-benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters, CAS RN 68515-40-2) be considered as harmful to the environment and as such, subject to risk management measures, though the follow-up regulatory action is still in process (Health Canada 2017).

4.9.4 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 (Bi *et al.* 2018; US EPA 2018; Wan, Diamond and Siegel 2020). 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 (Bi *et al*. 2018; Wan *et al*. 2018). 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 (EFSA 2019b).

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 carcinogen 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 (Tomar, Budroe and Cendak 2013). 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.**

4.10 Polycyclic Aromatic Hydrocarbons (PAHs)

Polycyclic aromatic hydrocarbons (PAHs) are a class of more than 100 organic compounds that consist of at least two fused aromatic rings. Many PAHs pose significant risks to the environment and human health due to their high persistence, bioaccumulation potential, toxicity and long-range transport potential. PAHs are byproducts of incomplete combustion or pyrolysis from both natural (e.g. volcanic eruptions, forest fires) or anthropogenic (e.g. vehicle emissions, industrial processes) sources, and they are ubiquitous in the environment. PAHs may also be present in consumer products due to contaminated raw materials and contamination during processing. The assessment here focuses on human exposure to PAHs that are present in consumer products, including packaged foodstuffs other than smoked items, as identified in GCO-II. Environmental releases of PAHs and associated exposure through environmental media are also very important to address, but these pathways require a distinct set of instruments and actions and therefore are not included here. For these topics, information can be found in peer-reviewed literature such as Ramesh *et al.* (2013), Shen *et al.* (2013) and Dat and Chang (2017), among other sources.

4.10.1 Background on Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

A number of assessments of PAHs by national governments and intergovernmental institutions are currently available, primarily focusing on human health risks (see Table B10–1 in the Annex). Of the more than 100 existing PAHs, a number have been classified as carcinogenic, mutagenic or toxic to reproduction based on available scientific evidence (German Institute for Risk Assessment [BfR] 2009; IARC 2010). A key PAH compound is benzo[*a*]pyrene (BaP), which is a Group 1 carcinogen (IARC 2010). In addition, 14 other PAHs have been classified by IARC as Group 2A (probably carcinogenic) or Group 2B (possibly carcinogenic; IARC 2010).

Many PAHs are genotoxic carcinogens, meaning that they cause gene mutations, and multiple assessments have concluded that PAHs have no safe threshold below which no health risks exist. Additionally, PAHs have been documented to activate mechanisms that further accelerate PAH metabolism, so that repeated exposure to PAHs boosts their carcinogenic and mutagenic properties (IARC 2010; European Medicines Agency [EMA] 2016; German Environment Agency [UBA] 2016).

Other documented risks include exposures that can irritate the eyes, nose, throat and lungs; skin contact that can cause irritation or a skin allergy; and very high levels of exposure that may cause headaches, nausea, damage to the red blood cells, liver and kidneys, and even death (Australian Department of the Environment and Energy 2019). Due to the ubiquity of PAHs, human exposure may occur via multiple routes, including dermal uptake from consumer products containing PAHs. One assessment estimated that the dermal uptake of children through skin contact with PAH-containing toys may be higher than the amount that an adult takes in daily through food or by smoking 40 cigarettes a day, assuming a concentration of 100 mg/kg in toys and one hour of skin contact-play time by children (BfR 2009).

4.10.2 An Assessment of Current Exposure across the Globe

Key fate characteristics of PAHs in consumer products. This assessment focuses on human exposure to PAHs from consumer products. In brief, lab studies show that migration and diffusion of PAHs from consumer products through skin occurs and is relevant for dermal exposure (Bianchi *et al.* 2018); for example, rubber matrices containing distillate aromatic extracts as extender oils have shown the release and migration of PAHs through the skin. These studies also show that lower molecular weight PAHs such as chrysene migrate faster and deeper into the skin. The nature of the matrix material and additives therein is also crucial for the release of PAHs. For example, although rubber matrices exhibit release of PAHs from the extender oils, studies show that dermal exposure to plastic matrices is not as concerning because they do not detectably release PAHs. Polymeric coatings on rubber granules may significantly reduce releases of PAHs. Additionally, PAHs contained in the extender oils are observed to be more mobile than those adhered to carbon black in rubber.

Migration of PAHs from packaging material such as recycled polyethylene into foodstuff may occur (EMA 2016). The diffusion and migration of PAHs from packaging material to food is similar to that of skin, where PAH molecules with lower weights diffuse faster and migrate farther into the foodstuffs. Other factors responsible for the migration of PAHs are the fat content in food and the exposure area: foods with high fat content dissolve more lipophilic PAHs, and larger surface areas with higher exposures (such as for porous packaging materials for example extruded polystyrene foam) allow easier diffusion of PAHs (Schweighuber *et al.* 2019).

Major sources of current exposure. PAHs are never intentionally added during manufacturing, and the presence of PAHs in consumer products may be a result of contaminated raw materials, often filler materials and extender oils, or due to contamination linked to improper processing methods, or both. Exposures are always to a mixture of PAHs simultaneously (FAO 2009; Danish EPA 2012; for examples, see Table B10–2 in the Annex and references therein). With regard to non-food consumer products, for example, carbon black — a typical black pigment and reinforcing filler material in rubber and plastics, printing inks and coatings — is produced by incomplete combustion or thermal composition of a hydrocarbon source such as wood, oil, coal and gas, and thus often contains PAHs as byproducts (Geiss *et al.* 2018; Alawi, Abdullah and Tarawneh 2018). In addition, different mineral oil products are used extensively as softeners for polymers, to impart elasticity to rubber, as common ingredients in cosmetics, and as extender ink formulations; because these are obtained from processing coal and petroleum naturally rich in PAHs, these may often contain PAHs as impurities (UBA 2016).

Incorporation of such contaminated raw materials in consumer products raises health concerns regarding oral and dermal exposures from household items such as clothing, tools, footwear, toys and tools containing rubber or plastic components (Geiss *et al.* 2018, BfR 2009). There is also growing concern around exposure to PAHs from recycled products, particularly synthetic turfs and playground or athletic surface tiles manufactured from contaminated end-of-life tyres. These particular products can release PAHs that may contaminate surrounding soils and groundwater; the rate of contamination may be expedited by the larger exposure area of shredded material that allows higher release of pollutants. For cases where tyres have been recycled for playgrounds and sports surfaces, dermal exposure to PAHs and their migration through sweat is relevant for children and athletes of any age. Additionally, due to higher abrasion activity on such turfs, formation of dust particles may also create pathways for exposure through inhalation or ingestion (Diekmann, Giese and Schaumann 2019). By considering such details, synthetic turfs and tiles from recycled tyres have been identified as posing unacceptable health risks to athletes and children in the EU (RIVM 2018; Geiss *et al.* 2018).

With regard to foodstuffs, plant-based foods may contain PAHs as a result of pollutant deposition on the original plants or crops before harvest. Due to the hydrophobicity of PAHs, washing processes are sometimes ineffective and therefore the pollutants

travel through manufacturing systems and end up in the final product (Duedahl-Olesen *et al.* 2015; EMA 2016). PAHs may also originate in food, particularly animal products, from the thermal treatments applied to improve shelf-life, taste, colour and appearance. Apart from smoking, processes such as frying, roasting, drying and baking have been found to be responsible for either introducing or increasing the PAH content in foods: the amount of PAHs generated from thermal treatment of food varies with treatment temperature, treatment time, fuel source or type, oxygen availability, and fat content in the food (Ciecierska and Obiedziński 2010; Ciecierska and Obiedziński 2013a; Ciecierska and Obiedziński 2013b).

Fat content affects PAH contamination because PAHs are lipophilic and dissolve in fat; therefore, the higher the fat content in foods such as yogurt and milk, the higher the scope for PAH dissolution and contamination from thermal treatment (Santonicola *et al.* 2017). Also relevant to lipophilicity of PAHs is contamination of edible oils; drying and roasting processes applied to oil seeds may result in contact with combustion gases that are rich in PAHs that readily dissolve in the oil (Dost and İdeli 2012; Ciecierska and Obiedziński 2013a; Kang, Lee and Shin 2014). Additionally, for all packaged food items, contamination is possible from PAHs that leach out of plastic packaging (Bianchi *et al.* 2018; Schweighuber *et al.* 2019).

The prevalence, levels and trends of current exposure to PAHs through consumer products across the globe. Human exposure to PAHs may occur through both environmental media and consumer products; assessing which fractions of PAH exposures in human biomonitoring data are attributable to which sources is challenging. In addition, because PAHs are not intentionally added in products and the levels of PAHs in products may depend on many different factors, including the origins of raw materials, assessing current human exposure to PAHs through consumer products using a "bottom-up" approach is challenging. However, human exposure to PAHs through consumer products is very likely ubiquitous across the globe due to factors such as the widespread use of (potentially) contaminated raw materials such as extender oils and carbon black.

4.10.3 An Assessment of Existing Instruments and Actions Addressing PAHs in Consumer Products

To date, a number of instruments and actions have been taken to address PAHs present in consumer products, including foodstuffs (see Table B10–2 in the Annex and references therein). Other numerous efforts focusing on exposure sources other than consumer products, which establish limits on PAH emissions and their levels in drinking water and soil, are beyond the scope of this assessment and thus not reviewed here.

Current instruments and actions typically prioritise and group several PAHs according to environmental relevance, which may vary between countries and product categories. Nevertheless, BaP has been accepted almost universally as a reference compound to test for the presence of PAHs in general (BfR 2009; UBA 2016).

Several major legally binding instruments restrict the levels of PAHs in consumer products. For example, under REACH, eight PAHs have been prioritised and restricted in extender oils and consumer products containing rubber or plastics; the exact PAH concentration thresholds for different products varies according to the frequency and duration of use and exposure potential (ECHA 2018; Geiss *et al*. 2018). Similarly, legally binding maximum permissible levels of selected PAHs have been set for cosmetics and foodstuffs in the EU, toys and packaging in the Eurasian Economic Union, packaging and consumer products in the Netherlands, and sealants in the District of Columbia, US (see Table B10–2 in the Annex). Germany has set additional legally binding maximum permissible levels to guide which waste asphalt can be recycled and which cannot be. The Basel Convention addressed PAHs at the end of products' life cycles, for example in ship breaking, and could cover the movement of used tyres, but it does not directly address consumer products that contain PAHs during their production and use.

These legally binding instruments are complemented by recommended guidelines developed by intergovernmental institutions [e.g. the FAO *Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes*; FAO 2009]. In addition, the private sector has initiated various voluntary actions. For example, H&M (2014) restricts the use of a number of PAHs, listed on its Manufacturing Restricted Substance List, and limits the total amount of PAHs in different substances used in its products. Voluntary standards for PAH levels in different product categories have been set by third-party standard and certification schemes, for example, bluesign® (2019) for textiles and GS Certification for electrical and electronic products, toys, food packaging materials, plastic products, rubber products and machinery (following criteria set by the German Committee for Technical Equipment and Consumer Products). Furthermore, a number of organisations have developed different consumer education or public documents to raise awareness of PAH exposures.

4.10.4 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 (EMA 2016). Similarly, various refining procedures can remove PAHs dissolved in edible oils (Kiralan, Toptancı and Tekin 2019). 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 (Martena et al. 2011).

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; Alexander et al. 2008; EU 2009; European Commission 2011; ECHA 2018).

4.11 Triclosan

Triclosan is a synthetic, broad-spectrum antibacterial chemical used as an additive in thousands of consumer and medical antibacterial products — such as soaps, cosmetics and therapeutics — and plastics (Yueh *et al*. 2014; Quan *et al*. 2019). Intensive use and continuous release of triclosan to the environment have raised public concerns, as scientific evidence of adverse environmental and human health impacts emerged, as identified in GCO-II.

4.11.1 Background on Environmental and Human Health Effects Based on Assessments by National Governments and Intergovernmental Institutions

To date, several assessments of the environmental and human health risks of triclosan have been made, including by ECHA (2015), ECCC and Health Canada (2016), US FDA (2016) and US EPA (2019), and the Australian Department of Human Health (NICNAS 2009; see Table B11–1 in the Annex and references therein). While the assessments have different scopes, the following common conclusions have been drawn.

With regard to human health, these assessments acknowledged that current levels of general population exposure to triclosan in their jurisdictions through relevant products and

breast milk, as well as associated health risks, may still be low according to the evidence available, but potential adverse effects such as endocrine disruption cannot be ruled out. In addition, in the two assessments that considered occupational exposure, by US EPA and by the Australian Department of Human Health, exposure in an open working environment without controls is identified as a risk of concern.

With regard to the environment, triclosan is highly toxic to aquatic organisms such as fish, amphibians, invertebrates and algae, as well as some soil organisms. Evidence of effects on the endocrine system at environmentally relevant concentrations has also been noted. Multiple assessments conclude that measured or estimated concentrations of triclosan in surface water in their jurisdiction may cause harmful effects in aquatic ecosystems. Triclosan in the environment might also promote antimicrobial resistance, but more evidence is required.

Furthermore, three assessments, conducted by ECHA (2015), US FDA (2016) and the Canadian Agency for Drugs and Technologies in Health (Brett and Argáez 2019), also looked into the effectiveness of triclosan in different products. These three assessments concluded that limited evidence exists to demonstrate the efficacy of triclosan in certain products such as soaps and hand washes in the given concentrations.

4.11.2 An Assessment of Current Exposure across the Globe

Key environmental fate and transport characteristics of triclosan. Triclosan is moderately soluble in water (10 mg/L at 20°C), and with log *K*OW value of 4.78. Previous assessments suggest that triclosan is not likely to persist in the environment and undergo long-range transport as indicated by its rather short half-lives in the various environmental compartments (ECHA 2015; ECCC and Health Canada 2016). It may be readily degraded under aerobic conditions, but resistant to degradation under anaerobic conditions (Ying *et al.* 2007); for example, it was detected in 30-year-old sediment samples from the Greifensee Lake in Switzerland (Singer *et al.* 2002).

When triclosan is washed down the drain and discharged into typical wastewater treatment plants in developed countries, it can be removed from the influents with reported efficiencies of 57% to 99% (Samaras *et al.* 2013), through degradation and transformation, and partition into sludge or biosolid waste (up to 50%; Heidler and Halden 2007). Note that in wastewater treatment plants, triclosan may be methylated to methyl-triclosan (Lozano *et al.* 2013), which is suspected to be persistent and bioaccumulative (ECHA 2015). In addition, triclosan may largely remain in sludge even after anaerobic digestion of the sludge (Heidler and Halden 2007).

Major sources of current exposure. Triclosan has been used commercially across the globe since the 1970s; for more details on the production, use and exposure pathways of triclosan, see Table B11–2 in the Annex and references therein. In brief, a global survey by the Danish EPA in 2016 estimated the total global production of 4,770 tonnes in 2015,

down from the 6,581 tonnes in 2011, with 42% in China, 26% in India, 18% in Europe and 14% in other locations including the US (Halden 2014; Danish EPA 2016). In 2018, the only producer in the EU reportedly ceased its production of triclosan (BZ Editors 2018). Triclosan has been used in a wide range of products, with major global use in cosmetics and personal care products (68%, particularly deodorants) and lower amounts in paints (8%), disinfection and medical use (16%) and in plastic materials, toys and appliances (8%; Kasprak 2009; Fang *et al*. 2010; Danish EPA 2016; Macri 2017; Weatherly and Gosse 2017). Typical concentrations of triclosan in these applications range from 0.03% to 0.3% (WHO 2006; Dhillon *et al.* 2014). It is estimated that major uses in 2015 occurred in Asia (34% in China and 19% in India), with lower amounts in Europe (18%) and the rest of the world (29%; Danish EPA 2016).

The primary route of human exposure to triclosan, but not the only one, is topical contact of consumer products including soaps, sanitizers and toothpaste that contain the compound (Allmyr *et al.* 2008). For example, elevated levels of triclosan in saliva and urine were detected in populations using triclosan-containing toothpastes (Silva and Nogueira 2008; Dix-Cooper and Kosatsky 2019). Also, additional (minor) exposure by the general population may rise from ingestion of dust (particularly for toddlers; e.g. Geens *et al.* 2009; Chen *et al.* 2018), drinking water (e.g. Li *et al*. 2010) and contaminated food (e.g. Macherius *et al.* 2012). To a low extent, infants may be exposed to triclosan through breast milk (Allmyr *et al.* 2006). Workers may have additional significant exposure through inhalation and dermal contact where triclosan is produced or largely used (e.g. in healthcare settings; NICNAS 2009; US EPA 2019).

The primary route of environmental release is through wastewater from the production and use (Loos *et al.* 2012), which is either directly discharged into the environment or go through a wastewater treatment plant. As stated above, even after influent passes through a wastewater treatment plant with good removal efficiencies, triclosan may still enter the environment through effluent (to a much reduced, but possibly still significant extent) or through the application of triclosan-containing sludge on agricultural land.

The prevalence, levels and trends of current exposure across the globe. Based on monitoring data, triclosan has been detected everywhere around the world, including the Antarctic (Emnet *et al*. 2015; Zhang *et al*. 2015; Guo and Iwata 2017; Montes-Grajales, Fennix-Agudelo and Miranda-Castro 2017). The compound can be detected in various compartments, including air, water, sediment, soils, vegetation, wildlife, freshwater and marine biota, and even human urine, blood and milk (see Table B11–3 in the Annex and references therein). Monitoring efforts using urine samples from general populations in Norway have detected triclosan in adults and infants (up to 2 years old; Husøy *et al.* 2019). With regard to both surface waters and drinking water, monitoring has been conducted in multiple locations around the world. The reported triclosan concentrations varied greatly across countries and spanned five orders of magnitude (10-2–105 ng/L) across all individual samples and water types, excluding wastewater; the concentrations in groundwater were also reported with similar concentrations (about 10-2–102 ng/L; Sorensen *et al.* 2015; Sharma *et al.* 2019).

4.11.3 An Assessment of Existing Instruments and Action Addressing Triclosan

A wide range of instruments and actions have been developed and taken across the globe to address some specific uses of triclosan (see Table B11–4 in the Annex).

In particular, some countries and regions have established legally binding obligations to ban the use of triclosan in different products, e.g. in over-the-counter consumer antiseptic products in the US, biocidal products in the EU and liquid soap in Japan. It is estimated that annual benefits for banning the use of triclosan in over-the-counter consumer antiseptic products in the US would result in a reduction in exposure of about 360 tonnes of triclosan per year, with the total costs estimated to be between USD$10.4 and USD$14.4 million for reformulation and re-label (US FDA 2016). In addition, for many other countries and regions, the usage of triclosan is restricted in cosmetics products, non-prescription drugs and natural health products, including in Canada, China, the Association of Southeast Asian Nations and the Eurasian Economic Union, with the maximum allowed concentration of triclosan typically set at 0.3%.

These efforts are complemented by other instruments such as legally binding requirements of pollution prevention plans by those who use and import triclosan-containing cosmetics, natural health products or drugs in Canada (Health Canada 2019) and voluntary phase-out by some major multinational companies including P&G (Procter & Gamble Company) and Unilever.

Building on the registration review for the use of triclosan in different materials and articles as an antimicrobial agent, US EPA has released a proposed interim registration review decision, which includes requirements of label changes and mitigation measures for occupational exposure to triclosan through specific personal protective equipment and engineering controls (US EPA 2019).

Recently, over 200 scientists, medical doctors and public health professionals signed the Florence Statement on Triclosan and Triclocarban. The statement calls for avoidance of triclosan, triclocarban and other antimicrobial chemicals except where they provide an evidence-based health benefit and there is adequate evidence demonstrating they are safe, among other recommendations (Halden *et al.* 2017).

4.11.4 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-chlorophenoxy)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).

5.

A Thought Starter: Identifying Issues of Concern

5.1 Introduction

UNEA resolution 4/8 requested UNEP "to follow trends in the design, production, use and release of chemicals and the generation of waste in order to identify issues of concern for future editions of the Global Chemicals Outlook and the Global Waste Management Outlook and catalyse sound management actions" (paragraph 14, subparagraph e). This chapter responds to that remit.

There is a long history of global action taken to identify and address issues of concern when evidence of harm has emerged, and GCO-II gave examples where actions have been taken. For example, the production and use of some hazardous chemicals has been phased out or significantly reduced under the Stockholm Convention on Persistent Organic Pollutants, and under the Montreal Protocol on Substances that Deplete the Ozone Layer, 99% of the production and consumption of ozone-depleting substances have been phased out. More recently, UNEA and ICCM have sought to identify and address specific issues of concern more systematically and proactively.

The earlier chapters of this report have described progress in addressing the issues of concern that have been identified under SAICM and in GCO-II. Other UN agencies and multilateral environmental agreements (MEAs) concerned with the sound management of chemicals and waste have also done a great deal on emerging issues of concern within their mandates.

Despite this, however, the goal adopted by governments at the World Summit on Sustainable Development in 2002 that "by 2020 chemicals will be produced and used in ways that minimize significant adverse impacts on the environment and human health" has not been achieved and more needs to be done.

This chapter therefore addresses how future editions of the Global Outlooks (GOs), GCO and the Global Waste Management Outlook (GWMO), might identify issues of concern, and brings up the question of any roles of science-policy interface approaches in triggering identification of issues of concern. It may also help inform the work by UNEA, UNEP, ICCM, and other international agencies concerned with chemicals and waste also seeking to identify and address issues of concern. It summarises the approaches that have been used previously, before considering which approaches might be used in the future. It is a thought starter — it therefore aims to stimulate debate rather than make recommendations.

It should be noted that while the UNEA mandate refers specifically to future editions of the GOs, other discussions in the context of ICCM and UNEA could have implications for whether, when and in what form the next GOs are commissioned and how issues of concern are dealt with within them, particularly on the future strategic approach and on strengthening the science-policy interface. But no matter what international governance structures and processes are in place to deliver the sound management of chemicals and waste in future, it will be necessary to identify issues of concern that merit international attention.

5.2 The Challenge

GCO-II identified a number of trends that provide the context against which the sound management of chemicals and waste will need to be delivered over the coming years. The size of the global chemicals industry, which exceeded USD$5 trillion in 2017, is expected to double by 2030. Consumption and production are rapidly increasing in emerging economies. Global supply chains, and the trade of chemicals and products, are becoming increasingly complex. Similarly, the problem of dealing with a growing volume of waste will become more challenging.

Global economic growth and global population dynamics will affect market demand for chemicals, creating both risks and opportunities. The consumption of chemicals per capita is increasing steadily — highlighting the need to achieve sustainable consumption and production, as called for by SDG 12 of the 2030 Agenda for Sustainable Development. These trends highlight the pressing need to shift towards sustainable consumption and production, including through decoupling material use from economic growth, enhancing resource efficiency and ecosystems protection, and advancing sustainable materials management; and following the waste management hierarchy (prevent, minimize, reuse, recycle, recover and dispose).

Our understanding of the links between the sound management of chemicals and waste and other environmental and societal priorities is increasing, particularly the links with climate change and biodiversity and with many of the related SDGs adopted as part of the 2030

Agenda for Sustainable Development. A failure to achieve sound management of chemicals and waste will prevent targets being achieved in these areas.

While a great deal remains to be done to manage the direct risks to human health and the environment arising from chemicals and waste, the links between chemicals and waste and wider issues of sustainability should be more explicitly addressed. In areas such as sustainable production as well as green and sustainable chemistry, or in promoting energy efficiency, there may even be significant "issues of opportunity" (as opposed to issues of concern) for the sound use of chemicals to contribute to solutions. These opportunities warrant attention in the GOs.

The mandate set out in UNEA resolution 4/8 is not restricted to issues directly related to risks to human health and the environment. In the light of the connections between sound management of chemicals and waste and these broader agendas, this thought starter takes a wider approach. The GOs might not only highlight issues of concern about the hazard or risk profiles of substances, but also the links with sustainable consumption and production and with other environmental and societal priorities such as climate change, biodiversity and protection of the ozone layer. The GOs will need to continue to highlight the conditions necessary to enable the sound management of chemicals and waste, as well as any specific issues concerned with how sound management can be delivered on the ground.

It is also worth emphasising the close connection between the manufacturing and use of chemicals and waste management. This argues for ensuring that future editions of GCO and GWMO are closely coordinated — or even that they might be integrated.

As described in earlier chapters, an "issue of concern" is a specific issue that has been newly identified or which has previously received insufficient attention, where evidence suggests that action may be needed. This chapter suggests that in future, in addition to addressing traditional areas where action is needed to address significant adverse effects on human health and the environment, "issues of concern" might also include issues that are critical to achieving greater sustainability or wider environmental or development objectives or to enable the practical sound management of chemicals and waste.

The remaining parts of this chapter review first how issues of concern have been identified under existing processes; the areas that the GOs might consider in future; and the approaches that might be used to identify and prioritise issues of concern.

5.3 Existing Approaches

This section reviews briefly how issues of concern have been identified under SAICM, by GCO-II and GWMO II, under the chemicals and waste conventions, and by WHO. This section also describes the work of the OECD chemicals and biosafety committee.

5.3.1 SAICM

SAICM was adopted in 2006 to support the achievement of by 2020 of the World Summit on Sustainable Development goal of sound chemical management mentioned above. One of the functions of the ICCM, set out in the SAICM Overarching Policy Strategy (OPS), is "to focus attention and call for appropriate action on emerging policy issues as they arise and to forge consensus on priorities for cooperative action". An EPI is defined as "an issue involving any phase in the life cycle of chemicals and which has not yet been generally recognized, is insufficiently addressed or arises from the current level of scientific information, and which may have significant adverse effects on human health and/or the environment".

ICCM2 adopted a procedure for nominating, screening and evaluating proposals for new EPIs:

- *Call for nominations:* Any SAICM stakeholder is free to nominate EPIs.
- *Submission of initial information:* Proponents are required to provide information on why the issue is considered an EPI and how it meets the selection criteria (see below), and a description of the proposed cooperative action.
- *Initial review and publication of submissions:* The SAICM secretariat sets out the results of a screening of the nominated EPI against the agreed criteria and compiles a list of nominations.
- *Prioritisation through consultation and advice from stakeholders and experts:* After publication of the nomination list, the regions may prioritise submissions by engaging formally with the full range of their stakeholders.
- *Inclusion of EPIs on the provisional agenda of the Conference:* The SAICM Open-ended Working Group will consider the regional inputs and other information to assess the proposals, taking into account the criteria below, and proposes a limited number of priority EPIs to the Conference for its consideration.

To provide a basis for considering the priority of each nominated EPI, the following criteria were developed:

- 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;
- 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;
- Existing knowledge and perceived gaps in understanding about the issue;
- Extent to which the issue is of a cross-cutting nature;
- Information on the anticipated deliverables from action on the issue.

5.3.2 GCO-II

When UNEA commissioned GCO-II in 2016, it requested UNEP to "ensure that [it] addresses the issues which have been identified as emerging policy issues by the ICCM, as well as other issues where emerging evidence indicates a risk to human health and the environment."

A Steering Committee provided oversight, strategic direction and guidance for GCO-II, as well as making technical inputs and undertaking reviews. It comprised 38 representatives from governments, non-governmental organisations (including civil society, industry or the private sector, and academia) and intergovernmental organisations, from all five UN regions and a wide range of stakeholders. Overall, substantive contributions were received from more than 400 experts.

Several approaches to identifying and categorising issues where emerging evidence indicates a risk to human health and the environment were explored. They included considering broader management issues and identifying actions initiated by public bodies to regulate a chemical (or group of chemicals) or to conduct a full risk assessment or reassessment based on emerging evidence indicating a risk.

As a large and potentially unmanageable number of issues would have emerged from these approaches, the following approach was identified for the selection criteria (i.e. entry points and necessary conditions for inclusion): At least two countries or regional economic integration organisations have recently (since 2010) undertaken two types of action, including at least one regulatory risk management action:

- There has been a regulatory risk management action on a chemical or group of chemicals, based on emerging evidence indicating a risk to human health and the environment.
- A full risk assessment or reassessment action for the same chemical or group of chemicals has been completed or initiated.

Chemicals or groups of chemicals comprehensively covered by existing MEAs and issues covered by the SAICM were not included. A number of governments had taken risk assessment or regulatory risk management action prior to 2010, both on chemicals/groups of chemicals identified in GCO-II as well as many other chemicals/groups of chemicals.

The GCO-II report makes this important point:

> It is important to note that the approach taken does not aim to conduct and deliver an international science-based assessment of specific chemicals or groups of chemicals. Rather, it is meant to facilitate international sharing of knowledge on specific actions recently taken based on emerging evidence indicating a risk. By undertaking a meta-review and drawing attention to existing risk assessment and regulatory risk management action, the objective is to facilitate understanding of issues of potential interest to governments and other stakeholders, which could facilitate future action in other countries or internationally.

5.3.3 GWMO II

GWMO II is in development and is planned to be launched in February 2021 at the fifth meeting of UNEA. It will address several global trends that have become more relevant in the five years since the first GWMO was published in 2015, and how they affect waste generation and how waste management (or lack thereof) affects them. Examples of these trends include global warming, the transition towards circular economy, and most recently the Covid-19 pandemic and the challenges in dealing with medical and contaminated waste. In addition to the SDGs, two cross-cutting themes will be addressed throughout the outlook: impact on health and gender aspects of waste management.

The outline and content of GWMO II have been developed jointly by the UNEP International Environmental Technology Centre (IETC) and the International Solid Waste Association and has been reviewed by the IETC International Advisory Board. It will not be merely an update of the first edition, but instead will complement it with a review of the global progress made through policies and actions to improve sound waste management at the national and local levels. It will focus on the future trends in waste production and management and explore ways to integrate circular economy and resource optimization strategies such as prevention, reduction, reuse, recycling and recovery into the narrative, with the ultimate aim to reduce final disposal of waste. It will not identify specific issues of concern as the GCO-II did, though it will highlight trends, key findings and challenges associated with waste management on the basis of which issues of concern could be identified.

5.3.4 The Chemical and Waste Conventions

The Basel, Rotterdam, Stockholm and Minamata conventions and the Montreal Protocol all contain provisions that allow them to bring additional chemicals or wastes within their scope, according to the specific provisions and requirements of each instrument. In that sense, they are dynamic.

For example, in May 2019, at its 14th meeting, the Conference of the Parties (COP) to the Basel Convention on the Transboundary Movements of Hazardous Wastes and their Disposal amended Annexes II, VIII and IX to the Convention with the objectives of enhancing the control of the transboundary movements of plastic waste and clarifying the scope of the Convention as it applies to such waste. Hazardous plastic waste and plastic waste requiring special consideration are now subject to the prior informed consent (PIC) procedure under the Convention. UNEA had previously identified marine pollution by plastic and microplastics as an issue requiring urgent, global action. The COP to the Basel Convention also decided to update the technical guidelines on the environmentally sound management of plastic waste that had been adopted in 2002.

Also in 2019, the COP to the Minamata Convention established a process to review Annexes A and B of the Convention, which list mercury added to products and manufacturing

processes in which mercury or mercury compounds are used — providing an opportunity to address any issues not included when the Convention was adopted in 2013.

The Rotterdam and Stockholm conventions both have formal standing processes for addressing new substances. In recent years, the COP to each Convention has considered recommendations by its expert subsidiary bodies for new substances to be added to the relevant annexes of each Convention.

For the Rotterdam Convention, which introduces a prior informed consent procedure for hazardous chemicals and pesticides in international trade, the Chemical Review Committee, an expert subsidiary body, considers the case for listing a chemical in Annex III if Parties from at least two different prior informed consent regions have taken final regulatory action on the basis of a risk evaluation, or in response to a proposal by a developing or transition country experiencing problems caused by a severely hazardous pesticide formulation. The COP decides on the listing based on the recommendations of the Chemical Review Committee.

For the Stockholm Convention, which is concerned with the control of POPs, Parties may nominate substances on the basis of the screening criteria set out in Annex D to the Convention. These criteria relate among other things to the persistence, bioaccumulation, potential for long-range transport, and adverse effects to human health and the environment. Information is evaluated by the POPs Review Committee (POPRC), an expert subsidiary body. If POPRC is satisfied that the screening criteria have been met, it undertakes a further review and prepares a risk profile taking into account the information specified in Annex E submitted by Parties and observers. If POPRC is satisfied that "the chemical concerned is likely, as a result of its long-range environmental transport to lead to significant adverse human health or environmental effects such that global action is warranted, the proposal shall proceed".

POPRC then prepares a risk management evaluation based on the information provided by Parties and observers on socio-economic considerations — for example, concerning the efficacy and efficiency of possible control measures, alternative products and approaches, and possible impacts on society of implementing possible control measures (as specified by Annex F of the Convention). The COP makes the decision to list the chemical in the appropriate Annex to the Convention based on the recommendations of POPRC.

The Rotterdam and Stockholm conventions therefore have formal processes for identifying new chemicals to be subject to procedures or controls. The final decision on which chemicals to list rests, however, with the COP.

The Montreal Protocol controls human-made chemicals that deplete the ozone layer, and hydrofluorocarbons (HFCs) that are not ozone-depleting but are powerful greenhouse gases used as substitutes for ozone-depleting substances in many applications. Under the Protocol, new controlled substances may be included under its purview through the adoption of amendments by the Meeting of the Parties to the Protocol, which require Parties' ratification. A recent example is the inclusion of measures to

control the production and consumption of HFCs through the Kigali Amendment to the Protocol, adopted in October 2016 and entered into force on 1 January 2019. Changes to control measures such as acceleration of the production and consumption phase-out schedules are made through adjustments to the Protocol, which do not require ratification and have immediate effect upon adoption. The most recent example is the acceleration of the phase-out control measures of hydrochlorofluorocarbons (HCFCs), adopted in September 2007.

5.3.5 WHO

WHO is the directing and coordinating authority on international health work and has a number of instruments, networks and activities that establish methodologies for and identify issues of international concern including those of a chemical nature. Instruments include the FAO/WHO Codex Alimentarius Commission and its expert committees covering pesticides, food additives, naturally occurring toxicants and other chemicals relevant for food safety; and the International Health Regulations, or IHR 2005, which provide a public health framework in the form of obligations and recommendations that enable countries to better prevent, prepare for and respond to public health events and emergencies of potential international concern, including chemical events. Chemical events notified by Parties under the IHR 2005 are assessed against criteria for international public health significance set out in the Regulations.

The WHO Chemical Risk Assessment Network of approximately 90 risk assessment institutions worldwide includes in its functions to assist WHO in the identification of emerging risks to human health from chemicals; a WHO report including recommendations for future work is in preparation following an expert workshop in 2019. WHO also has a global network of poison centres. Relevant WHO publications include estimates of the burden of disease attributable to specific chemicals and WHO's series on chemicals of major public health concern, as well as issue-specific reports.

WHO is a specialized organisation with a technical secretariat headed by the Director General who has the authority to set up expert committees and panels and to issue guidelines, norms and standards based on health evidence (it does not require nomination by a stakeholder).

5.3.6 OECD Chemicals Committee: Chemicals Safety and Biosafety

The OECD assists countries in developing and implementing policies and instruments that make their systems for managing chemicals as efficient and robust as possible, while protecting human health and the environment. It has worked with member countries and other stakeholders to cooperatively assess the hazards of industrial chemicals to generate OECD-agreed assessments that are available to the public and that can be used for priority setting, risk assessment and other activities within national or regional programmes.

It publishes agreed standard test guidelines and has established "good laboratory practice", as well as a number of tools to support countries in undertaking risk assessments and devising risk management strategies. The OECD's work therefore underpins much of the work done by national regulatory authorities and, indirectly, the work done by international organisations.

5.3.7 Summary

International forums have different procedures for responding to new and emerging issues according to the circumstances. The chemicals and waste conventions and the IHR 2005, which set out legally binding control measures, have the most formal procedures. In most cases, the initiative lies with Parties or stakeholders; they either nominate chemicals or management-related issues for consideration, or, in the case of GCO-II, the national action was a prerequisite for consideration. And a process of prioritisation was necessary for ICCM and GCO-II to focus on a manageable number of issues at a given time.

5.4 Other Current Relevant Initiatives

Any decision to commission further GOs and to address how issues of concern should be identified must take account of two other significant initiatives that will set the future international framework.

5.4.1 SAICM and the Sound Management of Chemicals and Waste beyond 2020

SAICM covered the period 2006 to 2020. The fifth meeting of ICCM, due to be held in July 2021, will consider a future instrument for the sound management of chemicals and waste beyond 2020. This is likely to set out a vision and objectives for the coming period, as well as considering how issues of concern should be identified in future. Any mandate that UNEA gives to UNEP will need to take into account complementary, existing processes and relate to both the new instrument and to existing processes, with close coordination with other UN agencies, the MEAs and ICCM — recognising their different mandates, status and modes of working.

5.4.2 A Strengthened Science-Policy Interface for the Chemicals and Waste Cluster

Interest is growing in the science-policy interface for the chemicals and waste cluster. UNEA Resolution 4/8 stressed the urgent need to strengthen this interface and requested UNEP to produce a report on options. UNEA will consider that report at its fifth meeting, in February

2021. The issue has been under discussion in the intersessional process and will be discussed by the fifth meeting of ICCM.

The key functions of any platform or arrangement designed to strengthen the science-policy interface are likely to include undertaking scientific assessments, which among other things will identify and prioritise candidate issues of concern (possibly via horizon scanning), monitoring trends, and understanding the environmental and human health issues associated with chemicals and waste in the environment. It would then be for the relevant policy body to consider the science-based advice it receives. A number of options are possible for the form a strengthened interface might take, including the possibilities of establishing a freestanding platform similar to the Intergovernmental Panel on Climate Change (IPCC) or the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES); building on the approaches used for GCO-II and GWMO II; or establishing a science subsidiary body under UNEA or ICCM or following the example of the three expert Assessment Panels established under the Montreal Protocol. Any decisions on strengthening the science-policy interface will therefore have implications for whether, when, and with what mandate future editions of the GOs are commissioned, and what range mechanism might be available to identify issues of concern.

5.5 Issues of Concern in Future

In line with the approach suggested in the introduction, this section considers potential areas in which future issues of concern might be identified. It addresses first issues where substances, or groups of substances, may pose a risk to human health and the environment; second, issues concerning sustainability, life-cycle approaches, and links with other environmental and societal priorities — particularly biodiversity and climate change; and finally issues concerning the enabling conditions for the sound management of chemicals and waste, applied on the ground.

5.5.1 Substances Which May Pose a Risk to Human Health and the Environment

The issues identified by ICCM and GCO-II focused primarily on substances, or groups of substances, that pose a risk to human health and the environment as a result of their inherent physical, chemical and biological properties. Many of the issues of concern that will merit policy action by the international community in the future are likely to follow the same considerations: they will continue to be related to specific substances, or groups of substances, identified on the basis of their intrinsic hazardous properties coupled with factors such as the degree of human exposure, how they are transported and how long they endure in the environment.

5.5.2 Existing Screening criteria

Given the very large number of chemicals on the market and in use, regulators have adopted screening procedure–based standard tests that capture the main characteristics of hazards. For example, the SAICM Global Plan of Action specified the following list as a basis for prioritising groups of chemicals for assessment:

> Groups of chemicals that might be prioritized for assessment and related studies include: persistent, bioaccumulative and toxic substances (PBTs); very persistent and very bioaccumulative substances; chemicals that are carcinogens or mutagens or that adversely affect, inter alia, the reproductive, endocrine, immune, or nervous systems; persistent organic pollutants (POPs), mercury and other chemicals of global concern; chemicals produced or used in high volumes; those subject to wide dispersive uses; and other chemicals of concern at the national level.

Many national and regional regulatory systems similarly use some or all of these characteristics as a basis for identifying substances (and waste containing them) as hazardous and therefore candidates for restrictions on their manufacture or use, or requiring special treatment. The OECD test guidelines provide internationally recognised assessment methods for endpoints associated with many of the characteristics. However, data are lacking for many of the vast number of chemicals currently on the market. Regulatory regimes such as the EU REACH regulation and similar registration schemes in some other jurisdictions now require those who manufacture or import substances to provide dossiers of information (with details depending on the volume of chemicals produced or imported), so the data gaps are being addressed to some extent. Industry and the private sector have spent significant amounts of time and money generating data. However, according to one recent estimate, over 350,000 chemicals and mixtures of chemicals have been registered for production and use, up to three times as many as previously estimated, so the task is significant though some of these chemicals may be produced only in very small quantities.

The approach used by GCO-II based on tracking national and regional regulatory decisions will benefit from these national and regional efforts. It is therefore implicit that GCO-II, and any future GCO building on the same approach, is relying to a large extent on the definitions and associated criteria of hazard and risk which have been adopted nationally or regionally, as well as their implementation.

5.5.3 Other Routes of Entry and Wider Risks Concerning Human Health and the Environment

An approach based on existing regulatory screening criteria will not capture all cases where substances, or groups of substances, may pose a risk to human health and the environment. Many national and regional regulatory regimes recognise that substances are likely to exist that pose risks but which will not be identified by standard testing regimes. They therefore

include the scope to address "chemicals of equivalent concern" — indeed the SAICM definition quoted above refers to "other chemicals of global concern".

In many cases in the past, risks have been identified by observing impacts on health or on ecosystems, and tracing back to find the cause. Indeed, many of the substances now well recognised as hazardous were first identified in this way: diminished birdsong in spring was one of the observations that led to the safety of DDT being questioned, and observations of the thinning of the stratospheric ozone layer led to the finding that chlorofluorocarbons (CFCs) were harmful.

Some well-recognised issues also exist where conventional criteria-based approaches may not be adequate. For example, regulators have increasingly acknowledged that they may be missing the effects of mixtures or chemicals acting in combination, or the long-term implications of even low levels of exposure. Regulators also need to be alert to the risk of "regrettable substitutions" — that is, cases where a ban on one substance results in an alternative substance being used which may give rise to equal or even greater concern. One example is the substitutions of ozone depleting substances by HFCs (potent greenhouse gases) with HCFCs, which would avoid depletion of the ozone layer but would harm the climate. This highlights the need for holistic approaches — possibly by considering chemicals in groups with similar chemical structures or similar technical functions.

Therefore "routes of entry" need to be considered to capture issues of concern where the standard, predefined tests do not raise an alarm, as well as for broader approaches. A case can also be made for keeping global developments under review to allow emerging suspicions based on scientific evidence to be identified, brought forward, and assessed.

5.5.4 Sustainability, Life-Cycle Approaches, and Links with Other Environmental and Societal Priorities

As mentioned earlier, sound management of chemicals and waste contributes to, and is a prerequisite for, achieving many of the SDGs. It is relevant particularly to those concerning food safety, biodiversity loss, clean water and sanitation, facilitating access to clean energy, climate action, ensuring quality education, and gender equality, for example. Conversely, the implementation of several other SDGs is essential for achieving the sound management of chemicals and waste — for example, those concerned with education, financing and partnerships. There is a growing recognition of the need to improve resource efficiency and to encourage a circular economy. Since chemicals are central to many aspects of life, their sound management is a central part of achieving this agenda.

There is also a growing awareness of the links between the chemicals and waste cluster and other environmental and societal priorities such as health, biodiversity, the world of work, climate change, protection of the ozone layer, agriculture and food, sustainable consumption and production, and human rights. The box (Figure 5-1) on the following two pages, reproduced from document SAICM/IP.4/INF/3, lists some of the main connections.

Figure 5–1 The following provides a summary of key options on how and on what topics opportunities exist to coordinate and cooperate between the chemicals and waste cluster and the other clusters (SAICM/IP.4/INF/3).

HEALTH

- Further link the World Health Organization's (WHO) Chemicals Road map with SAICM beyond 2020 framework
- Enhance cooperation in the implementation of the International Health Regulations (IHR)
- Consider collaboration and joint research on topics including:
  - (i) antimicrobial resistance (AMR)
  - (ii) pesticides and fertilizers
  - (iii) environmental and health risk assessment of plastics an microplastics
  - (iv) leadpaint,cadmium,etc.

BIODIVERSITY

- Aligning and strengthening relevant targets and indicators of the Post-2020 Global Biodiversity Framework and SAICM beyond 2020 by jointly identifying priority chemicals of concern, and parameters and methodologies for monitoring
- Mobilizing the chemicals and waste conventions in achieving biodiversity goals
- Consider collaboration and joint research on topics including:
  - (i) Plastic pollution, including harmonized monitoring, reporting and assessment methodologies
  - (ii) Artisanal mining driven land degradation
  - (iii) Waterbirdsandleadpoisoning
  - (iv) Pesticides use and loss of pollinators
  - (v) Nutrient management, etc.

WORLD OF WORK

- Knowledge sharing and linking the chemical databases
- Share technical guidance and expertise on occupational safety and health (OSH)
- Continue and enhance the ongoing cooperation between multilateral environmental agreements and International Labour Organization (ILO)
- Consider collaboration and joint research on topics including:
  - (i) Chemical accident prevention, preparedness and response
  - (ii) Child labour
  - (iii) Promotion and creation of decent and safe work opportunities
  - (iv) E-waste
  - (v) Greening industries and jobs
  - (vi) Elimination of work-related diseases, etc.

CLIMATE CHANGE

- Collaboration on achieving the objectives of the Paris Agreement
- Joint efforts on long-term monitoring data to evaluate the impact of climate change on chemical releases
- Consider collaboration and joint research on topics including:
  - (i) Climate change triggered chemical releases
  - (ii) Climate change impacts on contaminants in the ocean
  - (iii) Clean technologies
  - (iv) Waste and resource management as a contributor to climate change mitigation measures, etc.
  - (v) Climate change triggered channelling of fossil fuel use for plastic production, etc.

Figure 5–1 Cont.

AGRICULTURE AND FOOD

- Collaboration on implementation of the International Code of Conduct on Pesticide Management and implementation of the Fertilizer Code
- Applying lessons learned from the transboundary movement of pesticides and the Food and Agriculture Organization of the United Nations (FAO) training programme
- Consider collaboration and joint research on topics including:
  - (i) climate change triggered chemical release
  - (ii) use of harmful pesticides and herbicides;
  - (iii) exposure of farmers due to unsound use of pesticides;
  - (iv) contaminationofgroundwater
  - (v) use of chemical fertilizers
  - (vi) use of food conservation, colouring agents, food safety (pesticides residues)
  - (vii) addressing food waste, etc.

HUMAN RIGHTS

- Enhance engagement with the Office of the United Nations High Commissioner
- Consider collaboration and joint research on topics including:
  - (i) Right to know, Right of Access to Information, e.g. by strengthening the efforts to promote global participation in Pollutant Release and Transfer Register (PRTR) and compliance with Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
  - (ii) Access to Justice and effective remedy, e.g. by engaging with UNEP's Environmental Rights Initiative
  - (iii) Awareness raising and information sharing, e.g. by drawing lessons learned from the Minamata National Action Plans (NAPs) that inter alia aims to address child labour.

SUSTAINABLE CONSUMPTION AND PRODUCTION

- Collaboration to increase resource management and efficiency, for example through:
  - (i) Phase out of hazardous chemicals throughout life cycle of products
  - (ii) Applying green chemistry to reduce materials use and increase material efficiency
  - (iii) Exploring ways to turn waste into resources
- Strengthening linkages with the 10-Year Framework of Programmes on Sustainable Consumption and Production Patterns (10YFP)
- Enhancing participation in Eco-innovation programme and private sector engagement
- Promoting life cycle approach for environmentally sound management (ESM) of wastes
- Applying lessons learned from the Life Cycle Initiative
- Informing consumers about chemicals of concern in products.

CROSS CUTTING THEMES

- Strengthening the science-policy interface, e.g. by applying lessons learned from previous initiatives and Science Policy platforms from other clusters (IPCC, IPBES, etc.)
- Enhancing national coordination e.g. by engaging multisectoral cooperation in the context of meeting obligations of the multilateral environmental agreements (MEAs)
- Promoting stakeholder involvement, e.g. by:
  - (i) Mapping relevant events and parallel processes across clusters,
  - (ii) Increasing participation in each other's governing body meetings
  - (iii) Exploring possibilities of resource mobilization for cross thematic initiates
  - (iv) Increasing collaboration between scientific/ technical bodies across clusters

Two well-known issues starkly demonstrate the need for more sustainable consumption and production patterns: the rapidly growing volume of plastics that have been produced, and the resulting problem of waste and the lack of adequate treatment, and the growing volume of e-waste being transported internationally. Neither waste stream is being managed in environmentally sound ways. In many cases, it is developing countries, which have the least capacity to respond, that bear the brunt of the problem. Both issues have been identified by UNEA and others as requiring urgent international action and indeed steps are being taken (for example, through the Basel Convention Plastic Waste and BAN Amendments as well as further actions to address plastic waste under the Convention). In both cases however, the recognition of the need for action has come after much damage has been done; sound management of chemicals and waste requires greater foresight.

These are just two examples where inappropriate production, consumption or disposal practices or management approaches create problems. Issues of concern can arise at any stage of the life cycle(s) of products, from initial design, material extraction, production, through use, end-of-life and disposal, recycling and reuse. Often a problem may have been designed into the product at the very outset — for example, many articles contain multiple types of plastic and other chemicals that cannot be easily separated, making recycling much more difficult or even impossible, and creating avoidable waste.

As GCO-II noted, while the growth in chemical-intensive industry sectors such as construction, agriculture, and electrical and electronic engineering creates risks, it also offers opportunities to advance sustainable consumption, production and product innovation. In particular, widespread implementation of sustainable supply chain management, full material disclosure, transparency and sustainable product design are needed. Consumer demand, as well as green and sustainable chemistry education and innovation (e.g. start-ups), are among the important drivers of change. They can be scaled up through enabling policies, reaping the potential benefits of chemistry innovations for sustainable development.

Therefore, potential opportunities exist to both seek to avoid future problems, ideally through prevention by early identification, and contribute to solutions. GCO-II noted a number of significant trends. For example, the market for lead–acid batteries is projected to grow significantly in some regions — the move to renewable sources to meet energy demand is welcome, but it requires batteries for storage. While some regions have the capacity to recycle virtually all used batteries, most regions, especially those low- and middle-income ones, do not. Globally 1.9 million people are at risk from severe damage to their health from exposure due to unsound lead-acid battery recycling. It also represents a failure to achieve resource efficiency. As an alternative to lead–acid batteries, lithium-ion batteries are also expected to pose a quickly growing environmental and human health challenge in coming decades. Innovation needs to be encouraged not only in order to develop cheaper batteries with higher capacities, but also to design them to be more sustainable throughout their life cycles, including their end-of-life treatment and to increase recyclability.

Similarly, GCO-II noted that the global construction sector is expected to grow by 3.5% annually, with the associated chemicals market projected to grow by 6.2% annually between 2018 and 2023 — primarily driven by the rapidly urbanizing Asian and African regions. There are opportunities to promote sustainability in the design of building components and insulation materials, and to anticipate the issues that will arise once the buildings reach the end of their lives and components need to be recycled or managed as waste.

One possible issue of concern is the supply of cobalt, a metal used in permanent magnets for batteries, wind turbines and electric vehicles, all of which are growing markets. Primary production is often unregulated, leading to conflict and the use of child labour, and environmentally damaging; supplies are limited. These characteristics contribute to a strong case for ensuring recycling. Facilities are however limited, and the current rules and practices on the management and transport of hazardous waste can make it more difficult for cobalt-containing wastes to reach them. Finding better technologies and approaches to enable valuable metal to be used in more sustainable ways would have many benefits.

5.5.5 Enabling Conditions for the Sound Management of Chemicals and Waste

Finally, issues of concern may be related to enabling conditions. These are the approaches, tools and mechanisms that need to be in place if the policy objective of sound management is to be delivered on the ground, as well as national capacity, awareness and commitment to address the challenges.

The SAICM Overarching Policy Strategy identified five key themes: risk reduction, knowledge and information sharing, governance, capacity building and technical cooperation, and illegal international traffic. These are likely to remain central areas of concern under the SAICM Beyond 2020 instrument. GCO-II concluded that addressing legislation and capacity gaps in developing and transition countries remains a priority, and also noted that resources have not matched needs. Risk reduction and a wider responsibility to contribute to sustainable development are covered above. The remaining issues to support an enabling environment are about building the capacity and creating the conditions nationally, regionally and globally to deliver sound management of chemicals and waste, to fulfil these objectives.

UNEA and ICCM have regularly drawn attention to the need for action, and the new instrument to be adopted by ICCM5 will carry forward this work. Similarly, MEAs contain provisions about capacity building, technical assistance, and (in some cases) financial mechanisms. The integrated approach to the sustainable financing of sound management of chemicals and waste addresses these issues in its support to developing and transition countries. The needs are well recognised, even if much still needs to be done.

A great deal of work is being undertaken by UNEP and other UN agencies, under the current SAICM framework, by the MEAs, by supporting agencies such as UNIDO and UNITAR, by funding agencies such as GEF and the Special Programme on Institutional Strengthening,

and by other stakeholders to develop the capacity for and to implement the sound management of chemicals and waste. It would serve no further useful purpose to identify them specifically as "issues of concern" in the GOs. But there may be specific areas where coordinated international action through a specific and time-limited project or work programme could make a significant impact.

A good existing example is the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), an internationally agreed standard set up to replace the assortment of hazardous material classification and labelling schemes previously used around the world. This has contributed significantly to sound management, helping both regulatory authorities and chemical suppliers and users.

There may be other issues where UNEA or another forum could initiate action in future which would similarly facilitate good management. They could include, for example, further work to promote harmonised standards or to provide better information for consumers for particular products and what they contain: many countries have taken or are taking national action on these fronts, but some degree of voluntary harmonisation might help both manufacturers, national enforcement authorities and consumers have greater clarity and make national schemes more effective. Similarly, practical projects may be developed to facilitate enforcement — particularly for international trade, which could produce benefits.

5.6 Processes for Identifying Issues of Concern

If UNEA were to decide that there should be a broad approach to addressing issues in the next GOs, new ways will be needed to identify and prioritise them.

There appear to be three broad approaches that might be used to identify candidate issues:

- continuing to monitor national and regional regulatory actions (as was done for GCO-II), to identify issues arising in several jurisdictions as candidates for international consideration, against a set of agreed sifting criteria;
- seeking nominations of issues from countries or a wider range of stakeholders, against a broad set of indicative criteria, followed by process of assessment and decision making;
- commissioning experts, via a science policy platform, to undertake horizon scanning to identify issues and send early warnings. It may also be appropriate to monitor issues identified in other international forums, where there are links to the chemicals and waste agenda.

These are not mutually exclusive — it is possible, and may be desirable, to have several avenues for identifying new issues. They have different strengths, and different approaches will be more suitable for different types of issues.

5.6.1 Tracking National and Regional Regulatory Actions

With regard to identifying substances, or groups of substances, that pose a risk to human health and the environment, an option is to monitor national and regional regulatory actions, as was done for GCO-II. This approach draws on the extensive (and resource intensive) work of national and regional authorities to gather consistent data about chemicals and their toxicological and ecotoxicological properties. Moreover, because national and regional authorities have regulatory powers, they can require manufacturers or users of chemicals to generate and provide data about safety and also about production volumes and uses (including commercially sensitive data). Many national and regional authorities have established systematic programmes to assess substances (or groups of substances) to identify those which are "substances of concern" and should be regulated. This approach is therefore likely to continue to provide a sound starting point for identifying substances, or groups of substances, that may be candidate issues of concern.

However, potential disadvantages come with relying on action by national and regional authorities alone. As the GCO-II process noted, the approach is essentially reactive, and global action (if it is necessary) would follow only after action in several countries, potentially in more than one region. Moreover, it is not always easy to track national and regional actions, in the absence of any centralised clearing house mechanism. There is also the risk that the process will be biased towards the concerns of countries and regions with the resources to run extensive regulatory processes — as a generalisation, potential concerns specific to the least developed or small countries could be overlooked. And some concerns that may not be adequately addressed by "standard" criteria of risk may be missed (even though national and regional authorities may be well aware of the limitations of their regulatory approaches). In addition, many regimes have examined and regulated chemicals one by one. It may be more efficient and effective to adopt broader approaches, addressing broader groups of chemicals with similar properties or which serve similar technical functions — indeed, UNEP already seeks to follow a more integrated approach rather than considering individual chemicals in an isolated manner.

In summary, an approach relying on national and regional regulatory initiatives therefore appears to offer a practical and proven way of identifying many issues of concern; indeed, seeking to screen a large number of chemicals directly at the international level (even if it would be possible to agree an international set of hazard- and/or risk-based criteria) would be wholly impractical. But this approach will not necessarily identify all issues associated with risks to human health and the environment, and does not address wider issues concerned with sustainability or enabling sound management more generally.

5.6.2 Nomination by Countries or Other Stakeholders

This approach, used within the SAICM process, allowed nominations by stakeholders, with criteria (described above) guiding the process and ICCM making final decisions on which

issues should be adopted as issues of concern. The independent evaluation found that the identification of emerging policy issues is generally regarded as a major success of SAICM, while its implementation proved to be more difficult.

The SAICM and chemical and waste intersessional process is discussing how issues could be identified and nominated for the beyond 2020 instrument. There has also always been a way forward where UNEA (or previously the Governing Council) addresses an issue and calls for action through a UNEA resolution — many previous resolutions have dealt with issues such as heavy metals, endocrine disruptors, or marine plastic litter. And, as described earlier, the MEAs also rely on Parties to nominate new substances to be added.

The process for GCO-II did not include any formal process to seek nominations for topics to be designated "issues of concern" outside of the screening process described above (not least because the mandate of GCO-II was about issues that pose a risk to human health and the environment). However, there was wide consultation with countries and stakeholders during the preparation of the Outlook with opportunities to review and suggest content more generally, and GCO-II did adopt a broad and comprehensive approach.

The opportunity for countries and other stakeholders to nominate issues is likely to be important for those concerning sustainability, and particularly important for those about creating the enabling frameworks for sound management (where practical, on-the-ground experience of the challenges is likely to be very relevant).

5.6.3 Horizon Scanning and Early Warning

The case can be made for a more systematic approach to horizon scanning and assessment, and the discussion on strengthening the science-policy interface will be addressing this, as mentioned earlier. Also relevant is the work of the WHO Chemical Risk Assessment Network on the identification of emerging risks to human health from chemicals. If UNEA decides to take forward an initiative, then the links with the GOs and the processes for identifying issues of concern will need to be addressed.

More formalised arrangements for horizon scanning would provide the opportunity to seek to identify risks and opportunities at an earlier stage, to enable policy-making bodies to consider them and take timely action. A horizon-scanning approach may well provide better opportunities to identify linkages between chemicals and waste and other environmental and societal priorities — issues which may not be picked up by tracking national regulatory actions to control hazards and risks, for example. It also provides the potential to build more direct links with the scientific and other expert communities not normally involved in international work on chemicals and waste.

There is also the possibility of monitoring development in other international forums, to identify any issues that need to be taken forward in the context of the sound management of chemicals and waste. Such monitoring requires close coordination with other agencies and particularly with WHO.

5.6.4 The Need for Prioritisation

Given the number of chemicals on the market, the range of potential issues associated with promoting sustainability and life-cycle approaches, and the extent of the challenge of enabling sound management, the GOs will need to prioritise. They will need to draw attention to and set out an analysis of a manageable number of issues of concern at any one time. Based on this analysis, the governing bodies of UNEP and other UN agencies and MEAs, as well as other stakeholders, can decide what actions should be commissioned, focusing on the issues likely to be the most significant and where international coordinated action is most appropriate.

Issues are likely to merit international attention, rather than local or national attention, if they have at least one of the following features — this list of suggestions is put forward to stimulate discussion:

- Only coordinated international action can address the problem. This is the case, for example, where there is long-range transboundary transport of a pollutant and only coordinated action will be effective. Countries may be more ready to take steps to control emissions within their own territories if there is confidence that other countries will similarly take action to prevent transboundary effects.
- A failure to act will have global implications, even if the concern arises in only a small number of countries or even just one. For example, the spread of antimicrobial resistance genes or some adverse impacts on biodiversity may have wide impacts beyond the boundaries of a single country.
- Coordinated action will be more effective or efficient in dealing with a problem. The volume of chemicals in products and waste crossing national boundaries is growing. Common standards or understandings on, for example, hazard classifications, information flows and labelling can help promote sound management. Systems of "prior informed consent", as in the Basel and Rotterdam conventions, provide importing countries the opportunities to control what is entering their territories, so that they can for example forbid the import of chemicals and waste if they lack the necessary infrastructure to ensure that they can be managed safely.
- The problem is faced by many countries, and it is more efficient to share approaches, resources, and possible solutions — for example through guidance or partnerships approaches.

Beyond this, it is hard to set out predetermined criteria that are likely to serve in all circumstances, given the wide range of issues that the GOs may potentially consider. Factors such as the impact on human health and the environment, whether the impact is reversible or irreversible, the number of countries or regions concerned, or the expected level of effectiveness of coordinated global action may be taken into consideration. There are also issues of

timeliness and urgency: certain issues may require urgent action in weeks or months (particularly health crises for example), not the longer period needed for a typical GO process. There must be scope to respond to these urgent issues.

It will also be important for governing bodies to keep under review issues that have already been identified as issues of concern, to ensure that progress is being made, to step up action where necessary, and also to ensure that once adequate action has been completed work programmes are closed down, to free capacity to move on to other new and emerging issues.

5.7 Conclusion

Achieving the goal of sound management of chemicals and waste will require comprehensive and urgent action by all stakeholders. The process for designing the new instrument beyond 2020 is seeking to define objectives and targets to deliver these outcomes. One important component will be to identify and prioritise specific issues of concern that merit international attention and to implement focused and timebound work programmes to address them. Suggested here is a broad approach, looking not only at risk to human health and the environment, but also at the links between chemicals and waste and other environmental and societal priorities. There are various paths the international community might take to identify and prioritise issues — seeking a broader approach to defining issues is likely to require a variety of avenues for issues to come forward.

6.

Summary

The following conclusions are based on the assessment above, about the current state of and possible paths forward for the 8 EPIs and other issues of concern under SAICM (Chapter 3) and the 11 issues with emerging evidence of risks to human health and the environment identified by GCO-II (Chapter 4). This final synthesis also refers to the thought starter on identification of new issues of concern in future global chemicals and waste management outlooks and beyond (Chapter 5), taking into account major lessons learned from the 19 issues reviewed in this report that may be useful for the future in this context.

One main takeaway is that while progress has been made, the global goal to achieve sound management of chemicals and waste by 2020 has not been reached. What has been accomplished so far, while significant in many cases, is not enough to protect the health of humans and the environment at a global scale.

This remains the case despite all the knowledge available that more actions must be taken. Concerted international action by all stakeholders (governments, intergovernmental organisations, private sector actors, civil society organisations, academic institutions) at all levels is urgently required (Section 6.1). The following sections outline possible next steps towards sound management of these current and future issues of concern, including creating an enabling environment for international concerted action (Section 6.2), options for moving forward on the issues identified by GCO-II (Section 6.3), and driving a transformative change of sound chemicals and waste management (Section 6.4).

6.1 Progress Made, But Not Enough

Overall, most of the issues of concern under SAICM and identified by GCO-II have long been recognized, in some cases for several decades or longer. The chemicals or groups of chemicals that have been identified as issues of concern can have severe adverse impacts on human health, the environment or both. Other issues such as CiP and HSLEEP are critical components of the effectiveness of sound chemicals and waste management systems. Indeed, substantial progress has been made to address the 19 issues reviewed in this report, with many types of instruments developed and actions taken. However, the present analysis also shows that current regulatory and policy frameworks through these existing instruments and actions are inadequate to fully address these issues at a global scale. Thus, business-as-usual practices will not solve the 19 issues, a conclusion that echoes the major findings of GCO-II.

For many long-standing issues, progress has been uneven across countries and regions. For example, lead paint, HHPs and tributyltin in anti-fouling systems have been well addressed in developed countries and may have less urgency as issues of concern there. Many instruments and actions established and taken by governments and stakeholders in developed countries are available as possible models for developing countries; however, adaptation and implementation have been limited due to specific circumstances and conditions in developing countries, such as lack of awareness, capacity and financial resources, among other factors.

For many other issues assessed in this report, limited attention has been paid or actions taken, resulting in limited effectiveness in addressing the issues. These include both long-standing issues such as arsenic, lead and cadmium, as well as those more recently identified issues such as EPPPs, EDCs and microplastics. This ineffectiveness is largely due to gaps in terms of scope (e.g. limited coverage of life-cycle stages and relevant uses) and limitations of existing instruments and actions. For example, while considerable efforts have been invested in developing guidance and tools for testing, assessment, and identification of EDCs, a limited number of chemicals have been tested, identified, and regulated as EDCs. Another example is microplastics: many actions have been taken to address their presence in cosmetics and personal care products, particularly those in rinse-off products, but instruments and actions to look into other uses are limited.

Furthermore, substitution has often not been properly tackled when addressing these issues. Known toxic materials have been used as substitutes for chemicals or groups of chemicals that are of concern. For example, lead used as a PVC stabiliser was first replaced by cadmium, which was then largely replaced by organotins, despite extensive knowledge about the high toxicity of both cadmium and organotins.

6.2 Creating an Enabling Environment for International Concerted Actions Towards the 2020 Goal and Beyond

No one-size-fits-all solution can address all the gaps documented in this report and elsewhere. This section highlights the need for an overarching enabling environment as a part of concerted international action for addressing the above issues and future ones, or assisting countries and stakeholders to address them.

Successful stories, such as the global efforts in phasing out leaded petrol, provide important lessons. Strengthened leadership and partnerships with clear roles and responsibilities are much needed, to coordinate limited international resources to move forward and solve the 19 issues reviewed in this report and future ones in a cost-effective manner and with no one left behind. Progress needs to be regularly monitored and assessed in order to inform further planning and action in addressing the issues. Where progress on an issue is limited, new mechanisms need to be considered and selected by the international community to elevate its efforts on addressing the issue.

The preparation of this report also highlights that information available on existing instruments and actions is fragmented, in different languages and often poorly accessible, particularly for those in many developing and transition countries. To overcome this barrier, experts from different countries and regions have been engaged in the preparation of this report. However, this information barrier makes it generally challenging to readily track and capture the big picture of actions taken over time before assessing how they may contribute or have contributed to sound management of the respective issues of concern at national, regional and global scales. This barrier also prevents other countries and stakeholders from learning of existing instruments and actions without long delays if at all.

Similar information barriers also exist with regard to the life cycle(s) of many chemicals and associated products (e.g. how, where and how much a chemical is produced and used). While such information is critical as a baseline for determining the action and resources needed, it is often not publicly available and accessible.

Therefore, adequate active knowledge management, including knowledge capture, synthesis and sharing, at the international level with regard to these current issues of concern and future ones, and sound management of chemicals and waste in general, is desirable. One starting point may be the ongoing SAICM GEF project, “Global Best Practices on Emerging Chemical Policy Issues of Concern under SAICM”, which has a specific component on knowledge management. At the same time, parallel efforts are needed to continue exploring opportunities to strengthen the engagement of the scientific community, and the science-policy interface.

In addition, monitoring and enforcement, including measurements of the presence or absence of hazardous chemicals in target media, are key components of any effective measures. However, many countries and regions, particularly those that are developing or with economies in transition, currently lack necessary capacities and resources to do so in an adequate manner (for examples, see Sections 3.1, 3.5 and 3.6). Addressing this need belongs to the wider discussion at many international forums of increasing national capacities, including the ongoing discussion of the Beyond 2020 framework, and thus is not discussed in detail here. Strengthened engagement and involvement of the scientific community, including universities and research institutions in developing and transition countries, may be additional ways to be considered in enhancing monitoring capacities, among other measures. Also, the scientific community may be encouraged to develop cheaper and easier analytical methods that would meet specific circumstances and conditions in developing and transition countries.

Furthermore, many of the issues of concern have strong linkages to other environmental and societal priorities and to the SDGs to be attained by 2030. For example, CiP is closely tied to the Right to Know, a basic human right, about individuals' chemical exposures; HHPs to biodiversity integrity; and EPPPs to health for all. Such linkages need to be comprehensively assessed and explored as new means to bring the issues into the mainstream political agenda and gain wider support and commitment in addressing them in an integrated and holistic manner. This also means that strong engagement of a wider array of stakeholders is very much needed, including those communities that have not been strongly associated with sound chemicals and waste management, such as law scholars, social scientists, and civil society organisations focused on environmental and societal priorities other than chemicals management. This also means that strong engagement of a wider array of stakeholders is very much needed, including those communities that have not been strongly associated with sound chemicals and waste management, such as law scholars, social scientists, and civil society organisations focused on environmental and societal priorities other than chemicals management.

More details can be found in the report prepared by UNEP on linkages and opportunities between sound management of chemicals and waste and other environmental and societal priorities (SAICM 2020). In addition, in Chapter 5, linkages between future editions of the global chemicals and waste outlooks might further assist in identifying issues connected with sustainability, climate change or biodiversity, and creating conditions that enable sound management of chemicals and waste in addition to issues of direct risk to human health and the environment.

6.3 Moving Forward on the Issues Identified by GCO-II

Discussion is currently ongoing regarding SAICM and the new international framework for sound management of chemicals and waste beyond 2020, including over how the 8 existing

issues of concern will be further addressed. In contrast, it is not clear how the 11 issues identified by GCO-II will be further taken up and addressed by the international community. This section aims to inform this discussion.

Some of the issues identified by GCO-II have linkages with the issues under SAICM (see Figure 6–1). In addition, addressing some of the existing issues of concern under SAICM can also contribute to sound management of some of the issues identified by GCO-II.

Some of these chemicals identified by GCO-II fall squarely within specific issues of concern under SAICM. For example, BPA, tributyltin and multiple phthalates are EDCs, which is well supported by solid scientific evidence and official identification by competent authorities such as the EU; scientific evidence for identifying triclosan as an EDC has been established, but no official assessment and identification has been made. Similarly, the severe adverse impacts of glyphosate and neonicotinoids on human health and the environment may qualify them as HHPs. By addressing the respective related existing issues under SAICM, the international community can also address these six chemicals or groups of chemicals.

Several others identified by GCO-II could be considered to be partially covered by existing issues under SAICM. For example, addressing CiP, HSLEEP and Lead in Paint can help to address some of the ongoing uses of cadmium, lead and phthalates.

Beyond SAICM, microplastics have recently been discussed and taken up by several meetings of the UNEA, including the establishment and extension of the Ad Hoc Open-Ended Expert Group to advise UNEA on marine litter and microplastics. Thus, the issue with regard to microplastics may be expected to be further elaborated and worked on under UNEA.

However, arsenic, cadmium, lead and PAHs are issues that are inadequately addressed by the international community. Among them, PAHs may be taken up by the Stockholm Convention, as they have already been regarded as POPs under the CLRTAP, which has criteria for POPs that are very similar to those of the Stockholm Convention (for details, see UNEP/POPS/POPRC.5/INF/21).

Arsenic, cadmium and lead have often been compared to mercury (see Table 6–1). In contrast to mercury, these metals are not intrinsically volatile and arguably have only limited potential for long-range transport. However, as reviewed in Chapter 4 (Sections 4.1, 4.3 and 4.5), when they are released from high-temperature processes such as fossil fuel combustion and metal smelting, they are released in the form of small to fine particles and can undergo long-range transport via wind to remote areas up to thousands of kilometres away from sources. In addition, extensive trade and widespread uses of these toxic chemicals have resulted in significant human and environmental exposures around the world. Despite decades of efforts by members of the international community, current progress is not enough. Therefore, elevated global concerted actions on arsenic, cadmium and lead are warranted, possibly including legally binding instruments. Considering that they have many sources that are essentially the same or similar to those of mercury (Table 6–1), the Minamata Convention on Mercury provides a good model. These linkages and synergies between mercury and these three elements may be further investigated to inform the international community for determining the best ways to address arsenic, cadmium and lead.

Figure 6–1. An overview of interlinkages between the issues under SAICM and identified by GCO-II

IoCs under SAICM		IoCs identified by GCO-II
Endocrine Disrupting Chemicals (EDCs; Section 3.2)	←	Bisphenol A (BPA; Section 4.2)
	←	Organotins (Section 4.8)
	←	Phthalates (Section 4.9)
	←	Triclosan (Section 4.11)
Highly Hazardous Pesticides (HHPs; Section 3.5)	←	Arsenic (Section 4.1)
	←	Glyphosate (Section 4.4)
	←	Neonicotinoids (Section 4.7)
Chemicals in Products (CiP; Section 3.1)	→	All issues
Hazardous Substances within the Life Cycle of Electrical and Electronic Products (HSLEEP; Section 3.4)	→	Arsenic (Section 4.1)
		Cadmium (Section 4.3)
		Lead (Section 4.5)
		Phthalates (Section 4.9)
Lead in Paint (Section 3.6)	→	Lead (Section 4.5)

→ established link of the chemical to the target issue;

→ established link of a subset of chemicals or uses to the target issue;

→ possible link for all uses of the chemical(s) to the target issue based on established scientific evidence, but no official identification yet

Table 6–1. A comparison of long-range transport potential, exposure around the world, and sources of mercury compared to arsenic, cadmium and lead.

	Mercury	Arsenic	Cadmium	Lead
Long-range transport potential				
via natural currents	very volatile →high potential	non-volatile, but high potential via small to fine particles on which they are adsorbed		
via trade	extensive	extensive		
Exposure around the world	prevalent	prevalent		
Natural sources, e.g. volcanic activity; vegetation exudates; windblown dusts; biomass burning	yes	yes		
anthropogenic sources				
unintentional, e.g. fossil fuel combustion, metal smelting	yes (major sources to air)	yes (major sources to air)		
intentional production, use, disposal and recycling, including	chlor-alkali production, artisanal and small-scale gold mining, lamps, batteries, dental fillings	wood preservatives, pesticides, alloys, animal feed additives and pharmaceuticals, electronics and semiconductor industry	nickel-cadmium batteries, alloys, coatings and plating, pigments, solar cells, PVC stabilisers	lead-acid batteries, lead sheets, pigments, enamels and ceramics, PVC stabilisers, ammunition, alloys, cable sheathing

6.4 Striving for a Transformative Change of Sound Chemicals and Waste Management

As reviewed in Chapter 5, a broader set of issues of concern may need to be considered and identified by the international community in the future (e.g. through future editions of the global chemicals and waste management outlooks; by UNEA and other international forums). These include not only individual chemicals or groups of chemicals, but also issues related to creating enabling conditions for sound chemicals and waste management, as well as linkages to other environmental and societal priorities and to sustainable development in general.

As resources for both the international community and many countries are limited, individually addressing issues of concern may be unreasonable; instead, looking into new ways for addressing many of them in an integrated and holistic manner may be more sensible (e.g. using a sector-specific value chain approach, grouping by similarities in intrinsic properties, or taking all life cycle stages into account). Also, efforts to address sound chemicals and waste management should be addressed in an integrated manner with other environmental and societal priorities, such as climate change, biodiversity, human rights, labour standards and so forth. In order to do so, strengthening the engagement of all relevant stakeholders, including those in other environmental and societal priority areas, may be a first step to assess and identify common needs, interlinkages, and possible synergies and cooperation.

Chemicals have brought many benefits to modern life, but often at the cost of the environment and human well-being. It is time for the international community to draw on lessons learned from past successes and failures, and together drive a transformative change of how our global society functions, shifting towards a sustainable future.

7.

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Chapter 4

4.1 Arsenic

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Chapter 5

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Chapter 6

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