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

## Annexes

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# Supporting Information on Existing Instruments and Actions to Address the Issues of Concern under SAICM

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# 1. Chemicals in Products (CiP)

**Table A–1.** A comprehensive but not exhaustive overview of existing instruments and actions addressing chemicals in products (CiP) information exchange. For more examples of existing CiP systems and related initiatives, see Annex 1 of the Guidance for Stakeholders on Exchanging Chemicals in Products Information (UNEP 2015).

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments**<br>[e.g. bilateral and multilateral treaties; national/regional legislation and regulations] | | | | |
| **Information exchange requirements** | **Regional and national** | **Cosmetics and personal care products, food additives; all substances** | Proper labelling is a mandatory aspect of marketing cosmetic and personal care products, cleaning products, foodstuffs (in terms of ingredients including additives), pharmaceuticals and pesticides in many if not all parts of the world, e.g. the US, Australia (ACCC n.d.), the EU, Japan and Canada. Labelling is used to help inform consumers of a product's intended use and any related warnings, its ingredients and net quantity of contents, and its place of manufacture or distribution. Labelling requirements may differ from country to country. | In force |
| | **EU** | **All sectors; Substance of Very High Concern (SVHC)** | Under REACH, suppliers of an article containing a substance that is a SVHC in a concentration above 0.1% weight by weight (w/w)<br>• shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the substance (Article 33). This applies when the article is supplied to recipients who are to use or handle it as part of their work. Equivalent information should be supplied to consumers if it is requested.<br>• has the duty to provide this information within 45 days of receipt of this request.<br>• shall notify ECHA, including the company's details, the chemical identity, its classification and labelling, and a brief description of the use of it in the article and the uses of the article, when the total amount of the substance in the articles exceeds one tonne per producer or importer per year and the substance has not been registered for that specific use. There may be no obligation to notify if the producer or importer can exclude exposure to humans or the environment during normal or foreseeable conditions of use and disposal [Article 7(3)].<br>• ECHA has developed a guidance document (ECHA 2017) and is currently establishing a database, which will be ready in early 2021. The database will contain the submitted information on Substances of Concern in articles as such or in products for waste operators and consumers. | In force |
| | **California, US** | **All sectors; toxic chemicals** | Proposition 65, officially the Safe Drinking Water and Toxic Enforcement Act of 1986, is a law that requires warnings be provided to California consumers when they might be exposed to chemicals identified by the State of California as causing cancer, birth defects or other reproductive harm. The California Office of Environmental Health Hazard Assessment (OEHHA) administers the Proposition 65 program and publishes the listed chemicals, which include more than 850 chemicals. | In force |
| | **EU, Japan, China, etc.** | **Electrical and electronic products** | A number of countries have established laws to restrict specific chemicals in electrical and electronic products. Often such laws include provisions on labelling requirements with regard to compliance. For more details, see Table A.4 for Hazardous Substances in the Life Cycle of Electrical and Electronic Products (HSLEEP) below. | In force |
| | **Costa Rica** | **Toys** | Technical Regulation RTCR 421:2008 establishes the labelling requirements for toys to ensure that the necessary information is available to consumers and that their purchase decisions are not adversely affected as well as to guarantee user safety. It states that paints used in toys shall not contain lead, mercury or other chemicals that are banned by the Ministry of Health. This Regulation applies to all domestically manufactured and imported toys marketed in Costa Rica. | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Resolutions** | **International** | **All sectors; all chemicals** | The ICCM4 adopted a resolution on CiP in which, inter alia,<br>• welcomed the CiP Programme document as a voluntary framework for all Strategic Approach stakeholders;<br>• took note with appreciation of the guidance on chemicals in products as a practical means of implementing the CiP Programme;<br>• encouraged the private sector, governments, intergovernmental organisations and nongovernmental organisations, including worker organisations, to participate actively and report on the implementation of the CiP programme and<br>• invited all stakeholders to provide adequate human, financial and in-kind resources for further work. | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Sector-specific chemical lists for suppliers** | **International** | **Declarable or restricted substances** | All: chemSHERPA (chemical information sharing and exchange under reporting partnership in supply chain) by Joint Article Management Promotion-consortium (https://chemsherpa.net/english) is an information transfer scheme, aiming to transfer chemical information through companies on supply chain smoothly and effectively. It has been developed by the initiative of Ministry of Economy, Trade and Industry (METI) in Japan.<br>Automotive: The Global Automotive Stakeholders Group maintains the Global Automotive Declarable Substance List (GADSL, https://www.gadsl.org/). The GADSL is intended "to facilitate communication and exchange of information regarding the use of certain substances in automotive products throughout the supply chain. The GADSL only covers substances that are expected to be present in a material or part that remains in a vehicle at point of sale." The substances on the list are those that are regulated, projected to be regulated, or demonstrated to be associated with a significant hazard to human health and/or the environment and its presence in a material or part in a vehicle may create a significant risk to human health and/or the environment (American Chemistry Council 2020).<br>Textile: The ZDHC Foundation is an association of brands, associates and value chain affiliates, and it maintains a Manufacturing Restricted Substances List (MRSL, http://mrsl.roadmaptozero.com) of chemical substances that would be voluntarily removed from intentional use in facilities processing textile materials, leather, rubber, foam, adhesives and trim parts in textiles, apparel and footwear by the brands that pledge to follow the MRSL. | Ongoing |
| **Company-specific chemical lists for suppliers** | **International** | **Declarable or restricted and permitted substances in manufacturing, products and packaging** | **Automotive:** Volvo maintains several standards for its suppliers, including "Environmentally adapted chemical products" (STD 100-0001), "Chemical substances which must not be used within the Volvo Group: Volvo's black list" (STD 100-0002), "Chemical substances whose use within the Volvo Group shall be limited: Volvo's grey list" (STD 100-0003) "Substitutes for hazardous chemical substances: Volvo's white list" (STD 100-0004), "Chemical substances which shall be declared and substances that must not be present in Volvo Group products placed on the market: Volvo's red list" (STD 100-0005).<br>**Electronics:**<br>• Major companies have chemical lists for manufacturers and others in their supply chains, including customers. For example, Apple maintains a Regulated Substances Specification that describes the company's global restrictions on the use of certain chemical substances and materials in Apple's products, accessories, manufacturing processes and packaging used for shipping products to Apple's end-customers. Suppliers must certify compliance with this specification and provide required documentation, including required test data, full material disclosure (FMD), and disclosure of reportable substances, and Apple says it "hold[s] our suppliers accountable by conducting factory audits and testing materials and components at certified laboratories for substances of high concern" or verify compliance with in-house testing (Apple 2018).<br>• Another example is the "Nokia Substance List" that specifies the substances Nokia has restricted, targeted for reduction, or required to be reported to the company. The scope of the restrictions is generally defined as materials and substances present in the final product, including components, materials, parts, assemblies, accessories and packaging materials, unless a substance is identified as specifically restricted for processing. | Ongoing |
| **Third party standard or certification scheme** | **International** | **Restricted substances (and positive list)** | **All sectors:** Ecolabels identify products or services proven environmentally preferable within a specific product or service category by meeting specific criteria. There are many different ecolabels across product categories and across countries/regions.<br>**Textile:**<br>• One example is the bluesign® system, based on input stream management and chemicals management to assure that harmful substances are minimised or eliminated from the manufacturing process. A network of companies from chemical suppliers to manufacturers and brands participates. Among its tools, it includes a "bluesign® system substances list", which specifies limits and bans for chemical substances following the bluesign® criteria for chemical assessment, and a "bluesign® finder", a list of preferred chemicals.<br>• The OEKO-TEXT certification includes ECO PASSPORT, an independent certification for chemicals, colourants and accessories used in the production of textiles and leather articles, and DETOX TO ZERO, a verification system for the textile and leather industry that aims to implement the criteria of the Greenpeace DETOX Campaign within production facilities. | Ongoing |
| **Voluntary programme** | **International** | **Textiles, toys, electronics and building materials** | UNEP developed the CiP Programme on the policy and practical aspects of access to information on the chemicals contained in everyday products. The activities focus on increasing the availability and access to the information that actors need, throughout the life cycle of products, so that they can properly manage those products and the chemicals in the products. The programme has the following objectives: within supply chains, to know and exchange information on CiP, 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 CiP; and, to ensure that, through due diligence, information is accurate, current and accessible. In addition, a guidance document for stakeholders on exchanging information on CiP has also been provided and aims at helping interested stakeholders to apply the CiP Programme. | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Full material disclosure | International | All chemicals | Kimberly-Clark: The company requires that upon request, a supplier will provide 100% of the chemical composition of all materials, ingredients, products and packaging. Full material disclosure includes the trade name, supplier name and concentration of each component. A supplier will provide additional documentation and data such as, but not limited to, certifications, letters of compliance and test data as requested to demonstrate or verify compliance. | |
| Tools and guidance for communic-ation | International | All chemicals | **All sectors:** In 2017, UNEP published the *Guidelines for Providing Product Sustainability Information*. The Guidelines offer value chain and public sector professionals clear guidance on making effective, trustworthy claims to consumers, on product-related sustainability information. They are applicable to all regions and companies of all sizes.<br>**All sectors:** Full material disclosure, which usually requires suppliers to disclose on the concentrations or masses of all substances in a product to the brands.<br>**Textile:** The ZDHC Foundation published the *Chemical Management System Guidance Manual*, the objective of which is to develop a management framework that assists brands, retailers, Tier 1 and 2 suppliers, and chemical suppliers in understanding their roles, by developing clear guidelines that allow all committed supply chain stakeholders to participate and take responsibility for their part of the value chain, including communication. It also developed a template Chemical Inventory List that is meant to help facilities keep an inventory of chemicals being used in each work area. Furthermore, it maintains the ZDHC Gateway – Chemical Module, an online platform that helps with registering and finding chemicals that conform to the ZDHC MRSL; it provides useful tools and facilitates the exchange of information between brands, suppliers and chemical formulators (brands can engage their supply chain and communicate their requirements for safer chemistry; suppliers see their customers' requirements; chemical companies register themselves and their products).<br>**Automotive:** The International Material Data System (IMDS) is a global data repository that contains information on materials used by the automotive industry. Leading auto manufacturers use the IMDS to maintain data for various reporting requirements.<br>**Electronics:** The Association Connecting Electronics Industries (founded as the Institute of Printed Circuits and known as IPC) is a trade association of designers, board manufacturers, assembly companies, suppliers and original equipment manufacturers in the electronic interconnection industry. IPC developed a set of standards (IPC-175x) for a standardized reporting format for data exchange between supply chain participants, including "Generic Requirements for Declaration Process Management" (IPC-1751A WAM 1), "Laboratory Declaration Standard" (IPC-1753 WAM 1).<br>**Toy:** Chemical Management Database (CMD) is a software solution for toy chemical safety compliance management to be used by the toy industry (DynaSys Solutions 2016). | |
| Consumer assistance and education | International | Cosmetics and personal care products; all chemicals | A number of online databases and smartphone apps have been developed to help consumers better understand ingredient lists on cosmetics and personal care products. For example, non-profit organisations built and maintain ToxFox (BUND, Friends of the Earth Germany, Federation for the Environment and Nature Conservation Germany) and Skin Deep (Environmental Working Group, supporting the app EWG Healthy Living), and the CodeCheck app for helping consumers track and understand ingredients in food and cosmetics is built by a Swiss company of the same name. | |
| | International | Building sector; substances of concern | BASTA is an online database of building and construction products that fulfill requirements on hazardous properties, based on REACH and CLP, "for anyone who wants to make conscious product selections with the aim of phasing out substances of concern – for example building owners, contractors, architects, structural engineers or individuals" (www.bastaonline.se). Suppliers and manufacturers of building and construction products voluntarily register products that meet the BASTA or BETA criteria requirement concerning substances with hazardous properties. The Swedish non-profit organisation BASTA undertakes regular third-party audits of the suppliers in the system. | |
| Public-private partnership and actions | International | | Currently, UNEP and its partners are implementing the Global Environment Facility [GEF] project "Global Best Practices on Emerging Chemical Policy Issues of Concern under the Strategic Approach to International Chemicals Management" (2018–2022), in which one component focuses on "lifecycle management of chemicals present in products". The project outputs include a platform to identify and quantify chemicals of concern present in supply chains, based on existing and expanded CiP initiatives, and green economy tools and guidance refer to CiP data to improve product design, purchasing and use practices (GEF 2020a).<br>UNEP also implemented the GEF project "Defining and Demonstrating Best Practices for Exchange of Information on Chemicals in Textile Products" (2014–2019), including establishment of a set of best practices for CiP information exchange for the textiles sector based on an assessment of existing activities, the roles and responsibilities of stakeholders in exchanging CiP information, and what chemicals information should be exchanged between stakeholders in the sectors (GEF 2020b). | |

# 2. Endocrine Disrupting Chemicals (EDCs)

**Table A–2.** A comprehensive but not exhaustive overview of existing instruments and actions in sound management of EDCs.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislation and regulations] | | | | |
| **Regulations with explicit references to EDCs** | **EU** | **Pesticides** | Regulation (EC) No 1107/2009 concerning the placing of plant protection products (sometimes referred to as PPP) on the market requires that a substance shall only be approved if it meets certain approval criteria: e.g., "an active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005."<br>Commission Regulation (EU) 2018/605 of 19 April 2018 amended Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. These entered into force on 10 November 2018. | In force |
| | | **Biocides** | Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products ensures that all biocides are risk assessed for toxicity to humans and the environment before they are permitted to be placed on the market and that they are sufficiently active against the harmful organisms they are designed to target. Article 5 lists exclusion criteria from approval including one such criterion being substances considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified as having endocrine disrupting properties.<br>On 4 September 2017, the Commission adopted a Delegated Regulation on scientific criteria to identify endocrine disruptors for biocidal products which came into force on 7 December 2017 (EU 2017). | In force |
| | | **Industrial chemicals** | Under the REACH Article 57(f), "substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis" may be included in the Candidate List of SVHC for Authorisation. The listing will also trigger obligatory reporting and notification by manufacturers/importers of the chemicals.<br>In December 2016 the European Commission released a review on the level of concern for EDCs within the authorisation process compared to other substances listed as SVHC under REACH (European Commission 2016a). The review recommended not to extend the scope of the existing REACH text Article 60(3), accepted that it may be difficult to determine a safe threshold with reasonable certainty for EDCs, and noted that it remains the responsibility of applicants for authorisation to demonstrate that a threshold exists and to determine that threshold in accordance with Annex I to REACH (European Commission 2018).<br>As of November 2018, two EDCs have been placed on the list requiring a specific authorisation to be placed on the market. Another 13 substances have been identified as EDCs and are included in the Candidate List for possible inclusion in the authorisation list in the future (European Commission 2018). EDCs are also subject to restrictions: as of December 2019, four phthalates have been added to Annex XVII to REACH with concentration limits (0.1% by weight) of the plasticised material, in toys and children's articles (ECHA 2019). As of 27 January 2020, over 60 substances/mixtures are subject to substance evaluation on the grounds of potentially causing endocrine disruption (ECHA 2020). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Regulations with explicit references to EDCs | EU | Cosmetics | Article (15)(4) of the Regulation (EC) 1223/2009 on cosmetic products instructs the European Commission to review the cosmetic products regulation on substances with endocrine-disrupting properties. In November 2018 the Commission published its review report and committed to establishing a risk-assessment priority list of potential endocrine disruptors not already covered by the bans in the cosmetics regulation by the end of March 2019. A final list of 28 substances was later consolidated and separated into two groups of 14 substances each. Group A chemicals are to be treated with higher priority for assessment as they are undergoing substance evaluation under REACH for endocrine-disrupting concerns or if such concerns already have been confirmed, and Group B where either no substance evaluation has been initiated or the outcome of the substance evaluation is of a concern for endocrine disruption in the environment and not for human health.<br>In May 2019 the Scientific Committee on Consumer Safety announced a call for data on the 14 ingredients in Group A in the framework of Regulation (EC) 1223/2009 on cosmetic products. The call was made for relevant scientific information including data regarding all physicochemical properties, toxicokinetics and toxicological endpoints, assessment of exposure through consumer products and/or an indication of the suggested safe concentration limits for the substances. The deadline for submissions was on 15 October 2019 (European Commission 2018b, 2019). | Ongoing |
| | US | Pesticides | In August 1996, the US Congress passed the Food Quality Protection Act, which amended the Federal Food, Drug and Cosmetic Act (FFDCA), requiring the US Environmental Protection Agency (US EPA) to find that a pesticide poses a “reasonable certainty of no harm” before it can be registered for use on food or feed. In addition, it set out several factors that must be addressed before a tolerance can be established. These factors include, among others, that the US EPA needs to review “whether the pesticide produces an effect in humans similar to an effect produced by a naturally occurring estrogen or produces other endocrine-disrupting effects” (US EPA 1996; US EPA 2016). Neither Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) nor the FFDCA state any statutory criteria for EDCs. Pesticides with endocrine-disrupting potential are to be identified under the US EPA Endocrine Disruptor Screening Programme (EDSP), according to 42 U.S. Code § 300j–17. | In force |
| | | Drinking water contaminants | The Food Quality Protection Act also amended the Safe Drinking Water Act, explicitly mandating the US EPA to test a drinking-water contaminant for possible endocrine disrupting effects when it determines that a substantial population is exposed to such a contaminant. The testing and identification of possible endocrine disrupting effects of a drinking-water contaminant is conducted within the EDSP. | In force |
| | | Drugs | As a part of the safety evaluation of drugs for human use, if endocrine effects are identified, other factors — such as the indication; target population; and route, duration and level of exposure relative to the expected clinical exposure — will determine how to proceed (e.g. whether further non-clinical testing or clinical monitoring is appropriate or not warranted). The evaluation of extensive non-clinical and clinical test data demonstrating a drug’s safety and effectiveness for its proposed use, and that its benefits outweigh the risks, is the basis for the FDA to approve a new drug before it can be placed on the market (US FDA 2015). | In force |
| | Canada | Research | The Canadian Environmental Protection Act of 1999 (CEPA), in subsection 44(4), places mandatory obligations by the Canadian Government to conduct research related to EDCs including preventive, control and abatement measures to deal with those substances to protect the environment and human health. This research informs the identification of new priorities for risk assessment or if there is a need to take additional action (Health Canada 2018a).<br>In 2017, the House of Commons Standing Committee on Environment and Sustainable Development released a report with recommendations on strengthening the Canadian Environmental Protection Act (CEPA) 1999. It made recommendations on EDCs, including that risk assessments under CEPA should consider endocrine disruption, to revise the term “toxic” to also address endocrine disruptors, and to implement measures, thresholds, techniques and reporting requirements specifically addressing endocrine disruptors (House of Commons Canada 2017).<br>In a follow-up report from the Minister of Environment and Climate Change and the Minister of Health, the Government supported and agreed with the intents of the recommendations on EDCs. The government pledged to continue to improve its ability to consider endocrine-disrupting effects in its risk assessments and to further consider the Committee’s recommendations in informing how CEPA is reformed. | In force |
| | | Pesticides | The potential for endocrine disruption is considered in the current risk assessment of pesticides under the Pest Control Products Act: “Endocrine-disruptor potential (such as interference with the production of sex hormones) is evaluated in the course of examining the information from reproduction, developmental toxicity, and short- and long-term toxicity studies. If the results of these studies indicate the need for further information regarding interference with normal endocrine function, additional testing may be required” (Health Canada 2018b). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Regulations with explicit references to EDCs | Republic of Korea | Industrial chemicals | EDCs are explicitly addressed in the Act on the Registration and Evaluation of Chemicals (K-REACH), which entered into force in January 2015. Article 25(1) states that substances that cause or are likely to cause endocrine disrupting effects may be designated as substances subject to authorisation. A substance subject to authorisation requires permission by the Ministry of Environment before its manufacture, import or use. Furthermore, any substance that is found to pose a risk but is not designated as a substance subject to authorisation can also be regulated by restriction or be subject to prohibition. The regulation does not include specific criteria for the identification of EDCs (UNEP 2017b).<br>In March 2018, the Korea's Ministry of Environment (MoE) adopted amendments to K-REACH and Strengthened designation of priority-controlled substances containing highly hazardous chemicals including CMR substances and substances having endocrine-disrupting properties. The amendment came into force in January 2019. In December 2018, the MoE announced 2 lists of priority control substances, substances having endocrine-disrupting properties is one of the 4 qualifiers for inclusion in a Priority control substances list. List 1 contains 204 substances and it came into force in July 2019. List 2 contains 468 substances and comes into force on 1 July 2021. K-REACH requires that producers and importers of products containing a priority control substance report to the Minister of Environment before manufacture or importation. | In force |
| Ban or restriction of specific EDCs | National / regional | | A number of EDCs have been identified and restricted by specific countries/groups of countries, including four phthalates, BPA, nonylphenols. This list will grow overtime, for a non-exhaustive overview as of July 2017 (UNEP 2017b). | In force, and ongoing |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| ICCM Resolutions | International | | In 2012, the third session of the ICCM3 recognized EDCs as one of the EPIs under SAICM in resolution III/2 F (SAICM 2012). In 2015 the ICCM4 affirmed to support further research and develop cooperative actions regarding EDCs in Resolution IV/2 E (SAICM 2015). | |
| Action plan | China | | EDCs are explicitly addressed in the 13th Five-Year Plan of National Environmental Protection released by the State Council of the People's Republic of China in November 2016. The plan states that the pollution by endocrine disrupting chemicals will be strictly controlled, including implementation measures such as phase-out, restriction and replacement of EDCs by 2017. | Published in 2016 |
| | EU | | The European Commission published in 2018 a communication "Towards a comprehensive European Union framework on endocrine disruptors", which is an update of its Community Strategy from 1999 (European Commission 2018a). The strategy includes the following: the Commission will launch a Fitness Check to assess whether relevant EU legislation on EDCs delivers its overall objective to protect human health and the environment by minimizing exposure to these substances; in its future framework programme for research and innovation, Horizon Europe, the Commission will continue to ensure the necessary support to research on protecting citizens and the environment from exposure to harmful chemicals, including EDCs; the Commission will organise a Forum on EDCs on an annual basis; the Commission will step up its support to the work of relevant international organisations and encourages Members States to do the same; the Commission will also explore possibilities for the inclusion of EDCs in the existing international system for classification of chemicals; the Commission will launch a one-stop shop web portal on EDCs; the Commission will encourage Member States which deem it necessary to develop specific information and educational campaigns. | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| Guidance and tools for testing, assessment and identification of EDCs | International | Testing and assessment | OECD has developed a set of guidance documents for testing and assessment of EDCs, including the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters (OECD 2019). In 2018 OECD adopted new and updated test guidelines for chemicals safety testing, including endocrine-related endpoints in two test guidelines. The guidelines are an internationally accepted tool for assessing the potential effects of chemicals on human health and the environment. In the same year, OECD also released a revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption to interpret the results from the test guidelines that were developed (OECD 2018). | Ongoing |
| | Europe | Assessment | In June 2018, EFSA and ECHA,with the support of the European Commission Joint Research Centre (JRC), published a guidance on how to identify substances with endocrine-disrupting properties in pesticides and biocides. The document aims to assist users in complying with their obligations under the Biocidal Products Regulation (EU) No 528/2012 or the Plant Protection Products Regulation (EC) No 1107/2009 (EFSA et al. 2018). | Published in June 2018 |
| | US | Industrial chemicals, pesticides, drinking water contaminants | US EPA developed a series of test Guidelines that are generally intended to meet testing requirements under TSCA, FIFRA and FFDCA to determine if a chemical substance may pose a risk to human health or the environment due to the disruption of the endocrine system. These include 11 EDSP Tier 1 Test Guidelines and 3 EDSP Tier 2 Test Guidelines (US EPA 2016b). | |
| | | Drugs; testing | US FDA (2015) published *Nonclinical Evaluation of Endocrine-Related Drug Toxicity: Guidance for Industry*, which provides recommendations to sponsors of investigational new drug applications, new drug applications, and biologics license applications regulated by the Center for Drug Evaluation and Research, regarding nonclinical studies intended to identify the potential for a drug to cause endocrine-related toxicity. | |
| | International | Testing | Tiered Protocol for Endocrine Disruption (TiPED) was developed in 2012 by a team of experts in biology, chemistry and toxicology to help industrial scientists detect endocrine-disrupting potential early in the chemical development process and guide the synthesis of inherently safer materials. The authors include what they believe to be the best assays for detecting effects on the endocrine system, in five testing tiers: Tier 1 offers computer-based approaches, Tier 2 consists of targeted-cell assays, Tier 3 consists of "process and function"-based assays, Tier 4 consists of fish and amphibian whole-animal tests and Tier 5 is for mammalian tests (TiPED 2014). | Developed in 2012 |
| | China | Pesticides; testing | In December 2015, the Chinese Ministry of Agriculture announced the publication of industry standard NY/T2873-2015 "Evaluation Methods of the Endocrine Disruption Effects of Pesticides". This standard entered into force on 1 April 2016. It comprises a two-tiered approach with seven in-vitro or in-vivo testing guidelines for the evaluation of endocrine-disruption effects of pesticides (UNEP 2017b). | In force since 2016 |
| Information synthesis and sharing | International | Various | Numerous efforts have been made to synthesize and share information on EDCs. A few examples follow:<br>• In 2013 the WHO and the UNEP released a comprehensive report on EDCs that pointed out existing gaps in knowledge and called for more research to fully understand the risks to human and animal life and the environment (WHO/UNEP 2013).<br>• In 2018, UNEP published three overview reports, focusing on a review of existing initiatives to identify EDCs and on existing scientific knowledge of the life cycles, environmental exposure, effects, legislation, and measures and gaps regarding EDCs and potential EDCs (including information from developing and transition countries; UNEP 2017a,b,c).<br>• The Endocrine Society is an international medical organisation that released its first scientific statement in 2009 to alert the scientific community on how environmental EDCs affect health and disease. They presented evidence that endocrine disruptors have effects on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology. In 2015 the Endocrine Society released its second scientific statement on EDCs focusing on a subset of topics for which the translational evidence is strongest: 1) obesity and diabetes; 2) female reproduction; 3) male reproduction; 4) hormone-sensitive cancers in females; 5) prostate; 6) thyroid; and 7) neurodevelopment and neuroendocrine systems (Diamanti-Kandarakis et al. 2009, Gore et al. 2015).<br>• The Institute of Mathematical Sciences (Chennai) released a Database of Endocrine Disrupting Chemicals and Their Toxicity profiles (DeDuCt), compiling potential EDCs based on the observed adverse effects of endocrine-mediated endpoints in published experiments on humans or rodents to support basic research.<br>• The Endocrine Disruption Exchange (TEDX) maintained a List of Potential Endocrine Disruptors, which identifies chemicals with at least one study demonstrating ED activities, as a master list to serve a broad array of needs by stakeholders. | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Scientific assessments for identification of EDCs | EU | Pesticides, biocides, industrial chemicals, cosmetics, water contaminants | The European Commission carried out a comprehensive impact assessment to analyse different options for defining the criteria for the identification of endocrine disruptors. A roadmap of the impact assessment was published in June 2014. The "Impact Assessment. Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation" was later published in June 2016. To determine which substances would be tentatively identified as EDCs under different options, the impact assessment report also included a screening of approximately 600 substances selected from the total lists of substances subject to the regulations on plant protection products, biocidal products, chemicals (REACH), cosmetic products and priority substances under the Water Framework Directive. The screening used a methodology developed by the Joint Research Centre of the European Commission (JRC). | Published in 2016 |
| | International | Industrial chemicals | The International Chemical Secretariat (ChemSec, an international non-profit organisation based in Sweden) has established its Substitute It Now! (SIN) List of substances that may qualify as SVHC of equivalent concern under REACH. In 2011, ChemSec first added 22 chemicals they identified as EDCs to the SIN List based on a level-of-evidence approach requiring at least three high-quality studies. The Danish Centre on Endocrine Disruptors reviewed these same chemicals in 2012 and confirmed them as EDCs or potential EDCs based on the WHO/IPCS 2002 definitions. In 2014, an additional 10 chemicals were added to the SIN List using the WHO/IPCS definitions, and as of February 2020, the SIN List includes 127 chemicals marked as endocrine disruptors (International Chemical Secretariat 2020, UNEP 2017a). | Ongoing |
| | International | Pesticides | The civil society organisation Pesticide Action Network (PAN) International updated its list of HHPs in March 2019. The list was first published in 2009, building on the Joint FAO/WHO Panel of Experts on Pesticide Management (JMPM) criteria for HHPs and including other criteria including among others, endocrine-disrupting potential (PAN International 2019). | Ongoing, last published in March 2019 |
| Programmes of screening for EDCs | US | Endocrine Disruptor Screening Program (EDSP) | Launched in 1996, EDSP uses a two-tiered approach to screen pesticides, chemicals and environmental contaminants for their potential effect on estrogen, androgen and thyroid hormone systems. The Food Quality Protection Act requires that US EPA screen pesticide chemicals for their potential to produce effects similar to those produced by estrogen in humans and gives US EPA the authority to screen certain other chemicals and to include other endocrine effects. This act also amended the FFDCA and the Safe Drinking Water Act. In 2009, US EPA sent out the first orders to industry requiring testing of 67 chemicals using the Tier 1 test battery (US EPA 2009), as well as the final second list of chemicals for Tier 1 screening, including 109 chemicals and substances that have been listed as priorities within US EPA's drinking water and pesticides programs (US EPA 2013). As of September 2015, the results from the Tier 1 screening of 52 chemicals were available online. Of the 52, 16 chemicals have been recommended for additional Tier 2 testing (US EPA 2015). Results of Tier 2 testing will be fed into a risk assessment to inform risk mitigation measures as needed and regulatory decisions concerning chemicals. | Launched in 1996, testing began in 2009 - ongoing |
| | Japan | | The Ministry of Environment first began to address EDCs in 1998, with follow-up programmes in 2005, 2010 and 2016, i.e. EXTEND 2005, 2010 and 2016 (Ministry of the Environment, Japan 2016). Ecological effects remain the highest priority on the assessment of priority chemicals, aimed at risk management, and the MOE will also collect information on human health risk caused by chemical substances in the environment, in collaboration with other national programs such as the Japan Environment and Children's Study (JECS), and internationally, participating in test method establishment in the OECD, among other activities. The Japan Chemical Substances Control Law on the Evaluation of Chemical Substances and Regulation of Their Manufacture was first enacted in 1973 and last amended in 2009. It controls the importation and manufacture of both new and existing substances. | Ongoing |
| Awareness raising | International | | Numerous efforts have been made on raising awareness on EDCs, including the following:<br>• UNEP developed a set of awareness raising material on EDCs, including four infographics themed "things we buy", "things we grow", "places we work and live" and "things we make" and a brochure on EDCs.<br>• In December 2014, the Endocrine Society and IPEN published a guide to present a comprehensive picture of global EDC exposures and health risks. The publication is targeted for "public interest organizations and policy-makers" (Gore et al. 2014). | Ongoing |
| Coalition/ network | Europe | | EDC-Free Europe is a coalition of public interest groups representing more than 70 environmental, health, women's and consumer groups across Europe who share a concern about hormone disrupting chemicals (EDCs) and their impact on human health and wildlife. The aim of the organisation is to raise awareness and urge faster governmental action on EDCs at the European level. The organisation maintains a website and publishes reports and position papers. | Ongoing |
| Voluntary action | International | | Currently, UNEP, FAO and WHO are developing a medium-sized project proposal on the theme "Global best practices on emerging chemical policy issues of concern under the Strategic Approach to International Chemicals Management", with a focus on EDCs, EPPPs and HHPs and with the objective of accelerating and measuring the adoption of national activities to control emerging policy issues to achieve the implementation by 2020 of the Strategic Approach goal and to support early planning for chemicals management in the 2030 Agenda for Sustainable Development. | In preparation |

# 3. Environmentally Persistent Pharmaceutical Pollutants (EPPPs)

**Table A–3.** A comprehensive but not exhaustive overview of existing instruments and actions in sound management of EPPPs

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislation and regulations] | | | | |
| ERA-based marketing authorisation | **EU** | **All pharmaceuticals** | The environmental risk assessment (ERA) of medicinal products is a legal obligation for all new applications for marketing authorisation and is to be performed by companies during the development of new medicines (European Medicines Agency 2015, 2017, Lee and Choi 2019). The results are submitted to the European Medicines Agency (EMA) for evaluation. The ERA starts with an initial screening phase, aimed at identifying the environmental exposure of pharmaceuticals based on their potential for bioaccumulation and persistence in the environment. If significant environmental exposure is anticipated, or if specific risks are identified due to compound-specific characteristics, more detailed studies should be performed on the environmental fate and effects for refinement and extended risk assessment. Details are included in the publicly available European public assessment reports (EPAR) on medicines approved for both veterinary and human use.<br>For human pharmaceuticals, the results of the assessment should not constitute a criterion for the refusal of marketing authorisation, whereas for veterinary pharmaceuticals, an unacceptable risk to the environment can lead to refusal of authorisation. In any case, the outcome of an ERA will serve as the basis for minimizing the amount released into the environment by appropriate measures; identification of specific risk-minimization activities to be taken by the user of the medicine; and appropriate labelling, to facilitate the correct disposal by patients and healthcare professionals (e.g. ensure that the pharmaceutical is disposed of in special containers or returned to a pharmacy). | In force |
| | **US** | **All pharmaceuticals** | In the US, under the National Environmental Policy Act of 1969 (NEPA), environmental assessments must be submitted as part of "certain" new drug applications, abbreviated applications, applications for marketing approval of a biological product, supplements to such applications, investigational new drug applications and for various other actions (see 21 CFR 25.20), unless the action qualifies for categorical exclusion (US FDA 1998, 2020). Failure to submit an adequate environmental assessment or provide a claim of categorical exclusion may constitute a reason to refuse to file or approve the application. | In force |
| | **Canada** | **Pharmaceutical ingredients** | According to the Canadian Environmental Protection Act (CEPA), drugs are subject to the New Substances Notification Regulations (Lee and Choi 2019). When a particular pharmaceutical ingredient is not included in Canada's Domestic Substances List (DSL), its environmental toxicity information should be submitted and evaluated by the government according to the NSNRs. If a given substance is determined not to pose a risk to the environment or human health, this substance is added to the DSL. | In force |
| Collection system for unused or expired pharmaceuticals | **EU** | **Human pharmaceuticals** | According to the EU Directive 2001/83 on the Community Code Relating to Medicinal Products for Human Use, Article 127b, EU "Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired" (EU 2001). In the UK, for example, the disposal of unwanted medicines has constituted essential service no 3 of the National Health Service community pharmacy contract. | In force |
| | **US** | | In 2014, the US Drug Enforcement Administration (US DEA) released a final rule that implements the Secure and Responsible Drug Disposal Act of 2010 (US Drug Enforcement Administration 2014). The Act authorised the US DEA to develop and implement regulations that outline methods to transfer unused or unwanted pharmaceutical controlled substances to authorised collectors for the purpose of disposal. The Act also permits long-term care facilities to do the same on behalf of residents or former residents of their facilities. The 2014 Rules provided additional options for end users to dispose of controlled substances and created a voluntary role for industry registrants, i.e. "collectors", which are entities to which end users can transfer controlled substances for disposal. | |
| Upgrade of wastewater treatment facilities | **Switzerland** | **Pharmaceutical pollutants** | In Switzerland, about 100 wastewater treatment plants will be upgraded between 2016 and 2040 to increase removal efficiencies of micropollutants including pharmaceutical pollutants, among others. Total investment was estimated to be ca. 1.2 billion CHF (Joss et al. 2015). | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Political declaration** | **International** | **Antimicrobial pharmaceuticals** | The UN General Assembly (2016) adopted the "Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance" (A/RES/71/3), including, inter alia, commitment to work at national, regional and global levels,<br>• to develop multisectoral national action plans, programmes and policy initiatives with a view to implementing national measures for strengthening appropriate antibiotic use in humans and animals,<br>• to take steps to ensure that national action plans include the development and strengthening, as appropriate, of effective surveillance, monitoring and regulatory frameworks on the preservation, use and sale of antimicrobial medicines for humans and animals that are enforced according to national contexts and consistent with international commitments,<br>• to initiate, increase and sustain awareness and knowledge-raising activities on antimicrobial resistance in order to engage and encourage behavioural change in different audiences and promote evidence-based prevention, infection control and sanitation programmes; the optimal use of antimicrobial medicines in humans and animals and appropriate prescriptions by health professionals,<br>• calling upon the WHO, together with FAO and the World Organisation for Animal Health, to finalize a global development and stewardship framework to support the development, control, distribution and appropriate use of new antimicrobial medicines, diagnostic tools, vaccines and other interventions, while preserving existing antimicrobial medicines, and to promote affordable access to existing and new antimicrobial medicines and diagnostic tools, taking into account the needs of all countries and in line with the global action plan on antimicrobial resistance. | |
| **Communication** | **EU** | **All pharmaceuticals** | The European Commission (2019) published the "European Union Strategic Approach to Pharmaceuticals in the Environment", which identifies six action areas concerning all stages of the pharmaceutical life cycle (from design and production to disposal and waste management) where improvements can be made. The six areas identified include 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. | |
| **Policy note** | **Netherlands** | **All pharmaceuticals** | In 2019, the Dutch Government released *Reducing pharmaceutical residues in water: a chain approach*. Implementation programme 2018-2022, including actions to be taken at different stages development and authorisation, prescription and use, and waste and sewage treatment (Government of the Netherlands 2019). | |
| **Informed prescription and other use of pharmaceuticals** | **International** | **Antimicrobial pharmaceuticals** | In 2015, the World Health Assembly endorsed a "global action plan to tackle antimicrobial resistance", including antibiotic resistance, with strategic objectives, inter alia, to improve awareness and understanding of antimicrobial resistance through effective communication, education and training; to optimize the use of antimicrobial pharmaceuticals in human and animal health; to develop the economic case for sustainable investment that takes account of the needs of all countries; and increase investment in new medicines, diagnostic tools, vaccines and other interventions (WHO 2015). | |
| | **International** | **Veterinary antimicrobial pharmaceuticals** | WHO (2017) launched new guidelines on the use of medically important antimicrobials in food-producing animals, recommending that farmers and the food industry stop using antibiotics routinely to promote growth and prevent disease in healthy animals. These guidelines aim to help preserve the effectiveness of antibiotics that are important for human medicine by reducing their use in animals. | |
| | **Stockholm County, Sweden** | **Human pharmaceuticals** | Essential drug recommendations (EDR) were issued and launched as a "Wise List" by the regional Drug and Therapeutics Committee in Stockholm in 2000/2001 (Stockholm County Council n.d.a,b). The County published additional classifications of the environmental hazards (persistence, bioaccumulation, toxicity) and risks of the pharmaceuticals on the Wise List, as determined by the Swedish Association of the Pharmaceutical Industry (Läkemedelsindustriföreningen). Based on this type of risk assessment, a table of environmentally hazardous drugs has been developed within the framework of Stockholm County Council's environmental programme 2017–2021. | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Guidance and tools** | **EU, US** | **All pharmaceuticals** | The EMA has developed a set of guidelines on ERA to help pharmaceutical developers prepare marketing authorisation applications (European Medicines Agency 2016, 2018, 2020), as has the US Food and Drug Administration (US FDA 1998). | |
| **Knowledge sharing and awareness raising** | **International** | **All pharmaceuticals** | The OECD (2019) published the technical report *Pharmaceutical Residues in Freshwater. Hazards and Policy Responses*, which included chapters on “defining the challenge of managing pharmaceuticals in water”, “opportunities to build a policy-relevant knowledge base”, and “emerging policy instruments for the control of pharmaceuticals in water”. The report also provides cross-cutting, source-directed, use-oriented and end-of-pipe policy recommendations on addressing pharmaceutical residues in freshwater. | |
| | **International** | **All pharmaceuticals** | Health Care Without Harm Europe (2016) launched a public website (http://saferpharma.org) for raising awareness of healthcare professionals and citizens on pharmaceuticals in the environment, including a database for current initiatives related to the issues. They have also developed infographics, a set of documents include *The Environmental Impact of Pharmaceutical Manufacturing, How doctors can help reduce pharmaceutical pollution* | |
| | **International** | **Pharmaceutical pollutants in the environment** | The German Environment Agency (Umweltbundesamt n.d.) developed a public database of existing measurements of pharmaceutical pollutants in the environment published in peer-reviewed journals up to and including 2016, including 178,708 data entries of measurements in 75 countries of all five UN regions from 1,519 publications. | |
| | **International** | **all pharmaceuticals** | The Swedish Environmental Protection Agency (Naturvårdsverket 2016) published the study “Procurement of pharmaceuticals in an environmental context and its inclusion into the CSR Compass” within the UN 10YFP SPP Programme on Promoting Supply Chain Sustainability, to understand the current knowledge of procurement of pharmaceuticals in the literature, review the use of public procurement in Sweden, understand the implications of public procurement applied to case studies, and to suggest amendments to the Corporate Social Responsibility (CSR) Compass by taking into account the environmental dimension. | Completed |
| | **EU** | **All pharmaceuticals** | The EMA (2012) developed a “reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products”, providing a critical review of the adequacy and appropriateness of risk mitigation measures included in current marketing authorisations of veterinary medicinal products in the EU. | |
| **Awareness raising** | **International** | **Antimicrobial pharmaceuticals** | World Antibiotic Awareness Week, held annually in November (WHO 2019), is a campaign coordinated by WHO with the aim to increase global awareness of antibiotic resistance and encourage best practices among the general public, health workers and policymakers in order to avoid the further emergence and spread of antibiotic resistance. | |
| **Voluntary actions** | **International** | **Pharmaceutical pollutants in the environment** | A Global Environment Facility (GEF) medium-sized project under SAICM has been finalized and is being reviewed by GEF (SAICM 2019). As planned, the project will be implemented in 11 countries over a four-year period, and it will include outputs such as a global toolkit on pharmaceutical pollutants in the environment managed by WHO and undertaken in conjunction with efforts by UNEP and national monitoring bodies to confirm related emissions pathways from manufacturing and wastewater. | Work in progress |
| | **International** | | The European pharmaceutical industry developed and is implementing an Eco-Pharmaco-Stewardship (EPS) initiative (EFPIA 2015, iPie 2017). It considers the entire life-cycle of the medicine and addresses the roles and responsibilities of all parties involved including public services, the pharmaceuticals industry, environmental experts, doctors, pharmacists, and patients. The initiative entails the following activities: 1) IMI iPIE project: the identification of the potential environmental risks of existing and new active pharmaceutical ingredients (API) through intelligent and targeted assessment strategies; 2) Manufacturing effluents management: the compilation of best industry practices enabling manufacturers to minimize risks to the environment; 3) Extended ERA: the refinement of the existing environmental risk assessment (ERA) process for medicinal products to ensure that they remain up-to-date and relevant | |
| | **Australia, Canada** | **Unused or expired pharmaceuticals** | In Australia, the Return Unwanted Medicines (RUM) project is funded by the Commonwealth Government (Return Unwanted Medicines 2020). Anyone can return their household medicines to any community pharmacy at any time, for safe collection and disposal by high-temperature incineration, which is in accordance with regulatory and Australia Environment Protection Agency requirements.<br>In Canada, the Health Products Stewardship Association, a non-profit organisation representing producers of consumer health products in Canada, operates return programmes for the effective and safe collection and disposal of unused and expired consumer health products. | |

# 4. Hazardous Substances in the Life Cycle of Electrical and Electronic Products (HSLEEP)

**Table A–4.** A comprehensive but not exhaustive overview of existing instruments and actions related to HSLEEP. Please note that the following table focuses on those that specifically address EEP throughout their life cycles; those that do not focus specifically on EEP, even though they also address specific chemicals of concern in EEP, are not included here (e.g. REACH, TSCA, Stockholm Convention).

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislation and regulations] | | | | |
| **Restriction / Ban (and labelling) of specific chemicals in EEE + ESM** | **EU** | **Batteries and accumulators** | Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators, commonly known as the Battery Directive, regulates the manufacture and disposal of batteries in the EU with the aim of “improving the environmental performance of batteries and accumulators” (European Commission 2006). With some exceptions, it applies to all batteries and accumulators, no matter their chemical nature, size or design.<br>The Directive prohibits the marketing of batteries containing some hazardous substances, defines measures to establish schemes with high levels of collection and recycling, and fixes targets for collection and recycling activities. The Directive also sets out provisions on labelling of batteries and their removability from equipment. Producers of batteries and accumulators and producers of other products incorporating a battery or accumulator are given responsibility for the waste management of batteries and accumulators that they place on the market. | In force |
| | **Republic of Korea** | **Products and e-waste** | Act for Resource Cycling of Electrical and Electronic Equipment and Vehicles (Korea RoHS) restricts levels of cadmium, mercury, lead, hexavalent chromium, PBBs and PBDEs in EEE (Eco-Frontier 2007; Korea Law Translation Center 2019). It applies to TVs, refrigerators, mobile devices, washers (household use only), personal computers, audio equipment, air-conditioners, printers, copiers and fax machines. Certain products such as batteries, medical devices and packing materials are out the scope. Producers and importers of EEE shall make self-declarations of their compliance with the concentration limits of hazardous substances. The declaration method is to report product information to an electrical and electronic assurance system (www.ecoas.or.kr) or publish declarations on company webpages. There is no mandatory certification requirement under Korea RoHS. However, producers or importers who do not comply with the regulation are subject to punishment of confinement or fine payment. Manufacturers, importers of EEE or their contractors for the recycling of waste shall carry out recycling of their waste in accordance with the Recycling Methods and Standards by Product Categories as prescribed by a Ministry of the Environment Ordinance. Producers and importers of EEE may collect and recycle their waste individually (including recycling of waste by employing a waste recycler) or join a Recycling Mutual Aid Association. | In force |
| | **Turkey** | **Products + e-waste** | Atık Elektrikli ve Elektronik Eşyaların (AEEE) Kontrolü Yönetmeliği (Turkey RoHS) restricts the same six substances (cadmium, mercury, lead, hexavalent chromium, PBBs and PBDEs) at the same concentration limits as EU RoHS 2 with the same or similar exemptions (Ministry of Environment and Urbanization 2012). It also sets collection targets for WEEE. Recycling facilities have differing recovery and recycling percentage targets set for them. Also, it sets similar labelling requirements as the EU. | In force |
| | **India** | **Products + e-waste** | E-waste (Management and Handling) Rules 2011 restricts the same six substances (cadmium, mercury, lead, hexavalent chromium, PBBs and PBDEs) at the same maximum concentrations as in the EU but the scope of products is different (Ministry of Environment and Forests 2011). The rules define responsibilities of the various entities, including producers, consumers (including bulk consumers), collection centres, dismantlers and recyclers, together with the procedures for obtaining registration and authorisation from pollution control entities, including sample forms. | In force |
| **Tax** | **National** | **Specific EEP** | Sweden imposed an excise duty levied on producers and importers of certain EEP, such as kitchen appliances, that contain bromine, chlorine or phosphorus (Skatteverket 2015). Tax reduction is applied if a producer or importer can prove that EEPs do not contain additive compounds of bromine, chlorine or phosphorus. | In force |
| **Ecolabels** | **EU** | **Televisions** | Commission Decision 2009/300/EC established the revised ecological criteria for the award of the Community Eco-label to televisions, including requirements on the levels of heavy metals and flame retardants in products (European Commission 2009). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| ESM | Global | E-waste | Under the Basel Convention (Secretariat of the Basel Convention 2018), A1180 in Annex VIII [characterized as hazardous under Article 1, paragraph 1(a) of the Convention, and their designation on this Annex does not preclude the use of Annex III to demonstrate that a waste is not hazardous]:<br>Waste electrical and electronic assemblies or scrap containing components such as accumulators and other batteries included on list A, mercury-switches, glass from cathode-ray tubes and other activated glass and PCB-capacitors, or contaminated with Annex I constituents (e.g. cadmium, mercury, lead, polychlorinated biphenyl) to an extent that possess any of the characteristics contained in Annex III (note the related entry on list B B1110).<br>Also under the Convention, B1040 and B1110 in Annex IX [wastes contained in the Annex will not be wastes covered by Article 1, paragraph 1(a), of this Convention unless they contain Annex I material to an extent causing them to exhibit an Annex III characteristic]:<br>B1040 - scrap assemblies from electrical power generation not contaminated with lubricating oil, PCB or PCT to an extent to render them hazardous;<br>B1110 - electrical and electronic assemblies, i.e. electronic assemblies consisting only of metals or alloys; waste electrical and electronic assemblies or scrap (including printed circuit boards) not containing components such as accumulators and other batteries included on list A, mercury-switches, glass from cathode-ray tubes and other activated glass and PCB-capacitors, or not contaminated with Annex I constituents (e.g., cadmium, mercury, lead, polychlorinated biphenyl) or from which these have been removed, to an extent that they do not possess any of the characteristics contained in Annex III (note the related entry on list A A1180); and, electrical and electronic assemblies (including printed circuit boards, electronic components and wires) destined for direct reuse, and not for recycling or final disposal.<br>The Ban Amendment entered into force on 5 December 2019 and prohibits the export of hazardous waste from developed countries (OECD, EU member states, Liechtenstein) to developing countries.<br>In addition, the Basel Convention started to address e-waste issues in 2002, including, among others, environmentally sound management; prevention of illegal traffic to developing countries; and building capacity around the globe to better manage e-waste (see below). | In force |
| | EU | E-waste | Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) lays down requirements for the disposal of WEEE with the underlying principle of producer responsibility (i.e. the producers are responsible for the management throughout their product's entire life cycle; EU 2018). Member States must ensure that producers of EEE ensure of the treatment and recovery of collected and returned WEEE; producers guarantee the financing of the environmentally sound disposal when they place new equipment on the market; distributors take back WEEE from private households under certain conditions; the recovery targets for collecting, recycling and recovering stipulated in the Directive are met. Pursuant to the Directive, WEEE must be collected separately from general waste; consumers must be able to return WEEE free of charge; corresponding collection systems must be established in line with population density; Member States must meet a binding target for collection; and, producers have to observe special marking obligations. The Directive also lays down minimum technical requirements for storage and treatment of WEEE.<br>Commission Implementing Regulation (EU) 2017/699 established a common methodology for the calculation of the weight of WEEE placed on the market of each Member State and of the quantity of WEEE generated by weight in each Member State (EU 2017);<br>Commission Implementing Regulation (EU) 2019/290 established the format for registration and reporting of producers of EEE to the register (EU 2019). | In force |
| | US | E-waste | Wastes, including electronic waste, are considered under the Resource Conservation and Recovery Act (US EPA 2019). Some electronic wastes, such as cathode ray tube (CRT) TVs and monitors, are classified as hazardous waste. However, some e-waste (CRTs, whole used circuit boards, shredded circuit boards) that are sent for recycling can be exempted from US EPA's rules governing hazardous waste. | In force |
| | national | E-waste | A number of Latin American countries have established national legislation on e-waste, including 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) and Chile. | In force |
| | Sub-national | US; e-waste | Some states have implemented laws governing Extended Producer Responsibility (EPR) or rules on e-waste collection and recycling, such as California and Minnesota (CalRecycle 2020, Minnesota Pollution Control Agency n.d.), which have electronic waste recycling acts. | In force |
| | | Canada; e-waste | Provinces have implemented laws governing EPR with national oversight from the Canadian Council of Ministers of the Environment (CCME 2007). Implementation for e-waste is the responsibility of the Electronic Products Recycling Association (EPRA 2014), an industry-led non-profit organisation. | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Restriction / Ban (and labelling) of specific chemicals in EEE | Global | Batteries, switches, relays, lamps | Parties to the Minamata Convention on Mercury shall not allow manufacture, import or export of batteries containing mercury except for button zinc silver oxide or button zinc air batteries with a mercury content < 2%; switches and relays containing mercury with certain exceptions; compact fluorescent lamps for general lighting purposes with a mercury content exceeding certain limit values; high pressure mercury vapour lamps for general lighting purposes; and cold cathode fluorescent lamps and external electrode fluorescent lamps for electronic displays with a mercury content exceeding certain limit values. Phase out date is 2020, unless parties have registered exemptions up to five years. | In force |
| | EU | Products | Directive 2002/95/EC (Restriction of Hazardous Substances 1 or RoHS1), 2011/65/EU (RoHS2) and 2015/863 (RoHS3) have been adopted and entered in force in the EU on restrictions of certain hazardous substances in EEE with certain exemptions (European Commission 2020). The directives set limits for lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), bis (2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBD), dibutyl phthalate (DBO) and diisobutyl phthalate (DiBP) for 11 product categories. In order to comply with the legislation, all of these substances must be removed or reduced within maximum permitted concentrations in any products containing electrical or electronic components to be sold within the EU. The directive 2011/65/EU also sets out that equipment within its scope must carry a CE marking if offered for sale or placed on the market in the EU. | In force |
| | Japan | Products | The Japanese Industrial Standard (JIS) C 0950 is referred to as J-MOSS, a combination of the initials of “Japan” and the title, “Marking for presence Of Specific chemical Substances for electrical and electronic equipment” (Japan Electronics and Information Technology Industries Association 2008). The JIS C 0950 specifies rules about “marking for presence” of six specific chemical substances for seven specific electrical and electronic products (personal computers, unit-type air conditioners, television sets, refrigerators, washing machines, clothes dryers and microwaves). The JIS is quoted in the ministry ordinance of the Japanese Recycling Law (the Law for Promotion of Effective Utilization of Resources) as a method of marking, and then its requirement is mandatory for the designated seven products. J-MOSS restricts the same six substances (cadmium, mercury, lead, hexavalent chromium, PBBs and PBDEs) at the same concentration limits as EU RoHS 2.<br>All products in the above listed categories are marked with either an orange “R” mark or a green “G” mark, depending on whether any of the six restricted substances exceed concentration limits or not. If the content of a substance in a product exceeds its concentration limit, it must be disclosed on the product website in Japanese in accordance with the JIS C 0950 standard. | In force |
| | China | Products | Administrative Measures on the Restriction of Hazardous Substances in Electrical and Electronic Products (China RoHS) restricts levels of cadmium, mercury, lead, hexavalent chromium, PBBs and PBDEs in EEE, and it does not allow any technology exemptions, unlike the EU RoHS2 Directive. All items shipped to China have to be marked as to whether the items contained in the box are compliant or non-compliant. The Electronic Information Products (EIP) logo or other label is used to mark parts and assemblies that do not contain unacceptable amounts of substances identified by the regulations, and that are environmentally safe. Units that do contain hazardous substances are marked with the EIP logo including an Environment Friendly Use Period (EFUP) value in years, which is the period of time before any of the restricted substances are likely to leak out. | In force |
| **Soft law instruments [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies]** | | | | |
| Resolution | International | E-waste | The Plenipotentiary Conference, the governing body of the International Telecommunication Union (ITU), adopted a number of resolutions relating to e-waste (ITU 2018a; ITU 2018b). In particular, it established targets in ITU’s Strategic Plan for 2020-2023: By 2023 increase the global e-waste recycling rate to 30% and by 2023 raise the percentage of countries with e-waste legislation to 50%. In addition, ITU’s Development Bureau has been given a mandate to “assist developing countries in undertaking proper assessment of the size of e-waste and in initiating pilot projects to achieve environmentally sound management of e-waste through e-waste collection, dismantling, refurbishing and recycling.” | |
| Declaration | International | E-waste | Parties to the Basel Convention adopted the Nairobi Declaration on the Environmentally Sound Management of Electrical and Electronic Waste, at the eighth COP meeting in 2006, 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” (Secretariat of the Basel Convention 2006). | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Recomendations | Interntional | E-waste | The ITU developed a series of recommendations to help deal with e-waste from different aspects, including extended producer responsibility, e-waste management framework, life-cycle management of ICT goods, and green public internet and communications technology (ICT) procurement (International Telecommunication Union 2019). | |
| Action Plan | International | HSLEEP | At ICCM4, a work plan for the period 2016-2020 based on the Global Plan of Action was presented and adopted by the Stakeholders, including steps to compile and communicate lists of chemicals of concern in e-products, promote public and private partnerships, analyse, assess and fill gaps in existing policies and legal institutional frameworks addressing design of e-products, green design of e-products, policy instruments taking into account the need to ensure that they address the hazard and actions that support hazardous chemical reduction, elimination and substitution in e-products, sustainable consumption and production, pollution prevention, etc. (SAICM 2015). | |
| Strategy | US | Whole life cycle | The National Strategy for Electronics Stewardship provides a roadmap of how the US federal government can use its authorities and leverage resources for laying the groundwork for improving the design of electronic products and enhancing management of used or discarded electronics (US EPA n.d.). It provides overarching goals in the following four areas, with action items under each goal, and the projects that will implement each action item: build incentives for design of environmentally preferable electronics and enhance science, research and technology development in the US; ensure that the federal government leads by example; increase safe and effective management and handling of used electronics in the US; and reduce harm from US exports of e-waste and improve handling of used electronics in developing countries. | |
| | Canada | E-waste | In 2010, Canada launched a federal e-waste strategy to ensure that e-waste resulting from government operations is disposed of properly (Government of Canada 2019). The strategy emphasizes reuse first, followed by environmentally sound and secure recycling. | |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| Third party verification and labelling scheme | International | Electronic Product Environmental Assessment Tool (EPEAT) | EPEAT is a label for IT devices awarded according to meeting required and optional criteria. Available in 43 countries. Administered by the Green Electronics Council (GEC) which is a US mission-driven 501c(4) non-profit organization. | |
| | Regional | Certain electronic products | Nordic Swan Ecolabel is the official ecolabel, a voluntary certification scheme, in Denmark, Finland, Norway, Sweden and Iceland. It defines criteria for different product groups, e.g. no harmful flame retardants and mercury for computers. | |
| Partnership / Network | International | Electronics production | The Clean Electronics Production Network (CEPN) is a multi-stakeholder Innovation Network, formally launched in June 2016 by the Center for Sustainability Solutions to address complex workplace health and safety challenges in the electronics supply chain. It serves as a platform for collaborative innovation where diverse stakeholders – including technology suppliers, brands, labor and environmental advocates, governments and other leading experts – work together to understand, address, and eliminate worker exposures to toxic chemicals in electronics production.<br>Network members share their detailed knowledge of the health and safety hazards posed by chemicals used in electronics production and assembly facilities, and collaborate to develop solutions across five focus areas: Worker Empowerment and Engagement, Tracking and Monitoring Exposures, Qualitative Exposure Assessment, Targeted Safer Substitutions, and Standardized Process Chemicals Data Collection. | Ongoing |
| | International | Product design; recycling | The Electronics TakeBack Coalition (ETBC) promotes green design and responsible recycling in the electronics industry. Its goal is to protect the health and well being of electronics users, workers, and the communities where electronics are produced and discarded by requiring consumer electronics manufacturers and brand owners to take full responsibility for the life cycle of their products, through effective public policy requirements or enforceable agreements. It aims to accomplish this goal in part by establishing extended producer responsibility (EPR) as the policy tool to promote sustainable production and consumption of consumer electronics (all products with a circuit board). | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| Guidance and tools | International | **E-waste; transboundary movement** | In 2019, Parties to the Basel Convention adopted on an interim basis the revised "Technical guidelines on transboundary movements of electrical and electronic waste and use electrical and electronic equipment", in particular regarding the distinction between waste and non-waste under the Basel Convention (Secretariat of the Basel Convention 2019). | |
| | International | **Computing equipment** | By decision BC-13/12, the Parties adopted, on an interim basis, the guidance document on environmentally sound management of used and end-of-life computing equipment (UNEP 2017). It emphasizes reuse and recycling, with the aim of avoiding the final disposal of such used and end-of life products in final-disposal facilities such as landfills or incinerators. | |
| | International | **Used and end-of-life mobile phones** | Under the Mobile Phone Partnership Initiative (MPPI, 2002-2009), the *Guidance document on the environmentally sound management of used and end-of-life mobile phones* was adopted by the tenth COP meeting of the Basel Convention in 2011. It provides general guidance pertaining to the environmentally sound management of used and end-of-life mobile phones that includes such considerations as awareness-raising on design considerations, collection, processing, refurbishment, material recovery and recycling. It also provides guidance on reducing or eliminating releases to the environment from waste disposal and treatment processes. It should be noted that each of these operations should employ best available techniques (BAT) and be in line with best environmental practise (BEP) so that releases of hazardous constituents are prevented or minimized. | |
| | International | **Best practices** | In 2014, the SAICM Secretariat made available the *Compilation of best practices on hazardous substances within the life cycle of electrical and electronic products* based on a survey results with regard to the following areas: tools that lead to progress in the development of designs that reduce and eliminate the use of hazardous chemicals in the production of EEE; business standards and practices for tracking and disclosing the presence of hazardous chemicals in the manufacturing, use and end-of-life stages of EEE; tools and information on potential safer substitutes for chemicals of concern in EEE; green purchasing strategies of business and governments; extended producer responsibility policies of business and governments; and, provisional strategies and actions in design and manufacturing that should be implemented until elimination is possible or safer substitutes are available (SAICM 2014). | |
| | International | **E-waste ("informality" or informal economy)** | In 2014, the International Labour Organization (ILO) published the working paper *Tackling Informality in E-Waste Management* (ILO 2014). It provides further insight on the e-waste sector, focusing on labour challenges and opportunities to leverage working conditions through the promotion of cooperatives and other social and solidarity economy organisations. | |
| | International | **E-waste** | The International Environmental Technology Centre (IETC), UNEP has developed a number of guidance and tools to assist national and local governments and stakeholders to develop strategies and policies toward the sound management of wastes including e-waste (UNEP International Environmental Technology Centre 2019). These include *Future E-waste Scenarios* (2019), *Global Mercury Waste Assessment* (2019), *Compendium of Technologies for the Recovery of Materials from WEEE/E-waste* (2016), *E-Waste volume IIII: WEEE/E-waste "Tack Back System"* (2012). In addition, the IETC maintains a "kNOwWaste" platform for sharing knowledge. | |
| | International | **E-waste** | The ITU has developed a series of studies, guidelines and specific recommendations to help governments establish effective environmental frameworks in the areas of telecommunications/ICT generated e-waste, including *Handbook for the Development of a Policy Framework on ICT/E-Waste, E-Waste Management Policy and Regulatory Framework for Saint Lucia* and *Successful Electronic Waste Management Initiatives* (International Telecommunication Union 2015, 2018c, 2020a). The ITU also maintains the Global Portal on e-Waste, featuring external resources on e-waste, including municipal waste, directed towards empowering institutional and governmental capabilities (International Telecommunication Union 2020b). | |
| | Latin America region | **E-waste** | ITU, ECLAC, UNIDO, UNESCO, WHO, Basel Convention Regional Center for Latin America and WIPO – with support from UNU representatives – developed and launched in May 2015 a joint report which provides an overview of e-waste management in Latin America and provides guidance to countries on how to handle e-waste, including 10 key steps for a sustainable e-waste management (International Telecommunication Union 2015). | |
| | Peru | **E-waste** | A guide for the general public about the collection and management of e-waste (2015). | |
| | Rio de Janeiro, Brazil | **E-waste** | A guide for the general public about the collection and management of e-waste (2017). | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Partnership / Network** | **International** | **E-waste** | Ten organisations from the UN system have formed an E-waste Coalition for coordination and collaboration on UN system-wide support for E-waste management. The E-waste Coalition is currently being shaped in line with the Letter's aims of committing to increased collaboration, building partnerships and supporting Member States to address the global e-waste challenge. Three core functions of the Coalition are envisaged: advocacy including awareness raising and campaigns; knowledge and best practice sharing including through the website globalewaste.org; and the development of a joint intervention model for the implementation of e-waste work at the country level.<br>In 2019, the E-waste Coalition, together with the World Economic Forum and the World Business Council for Sustainable Development, released the report *A New Circular Vision for Electronics - Time for a Global Reboot*. The report compiles data and research from throughout the UN system to make the case for a new vision and describes and analyses challenges and opportunities, laying the groundwork for the process of systemic change. Collaboration continues to further develop this new vision with the purpose to align all the relevant United Nations entities, key governments and some of the largest electronics multinationals around a common plan for the future of the electronics sector based on the principles of the circular economy. | Ongoing |
| | **International** | **E-waste; statistics** | The International Telecommunication Union (ITU), in cooperation with the United Nations University (UNU) acting through its Vice Rectorate in Europe hosted Sustainable Cycles (SCYCLE) Programme and the Solid Waste Association (ISWA), have joined forces to form the Global e-waste Statistics Partnership. Its main objectives are to improve and collect worldwide e-waste statistics. The Partnership will also raise visibility on the importance of tracking e-waste, and deliver capacity building workshops. In December 2017, the Partnership published the Global E-waste Monitor 2017. | Ongoing |
| | **International** | **E-waste; capacity building** | Since 2009, the UNU has guided the organisation of E-waste Academies. So far, there exist two different editions: one for policy makers and representatives of small- and medium-sized companies (EWAM) and one for young scientists (EWAS). | Ongoing |
| | **International** | **E-waste** | Under the Basel Convention, the Partnership for Action on Computing Equipment (PACE) was developed in 2006 as a multi-stakeholder public-private partnership that provides a forum for representatives of personal computer manufacturers, recyclers, international organisations, associations, academia, environmental groups and governments to tackle environmentally sound refurbishment, repair, material recovery, recycling and disposal of used and end-of-life computing equipment. Under PACE, a number of guidelines, manual and reports were published. In 2017, the PACE Working Group submitted the final documents developed under the partnership to the thirteenth meeting of the Conference of the Parties to the Basel Convention. By decision BC-13/12, the Parties adopted, on an interim basis, the guidance document on environmentally sound management of used and end-of-life computing equipment. The Parties further decided that the Working Group had successfully completed its mandate and was disbanded. | 2006-2017 |
| | **International** | **E-waste** | The UN Environment Management Group (EMG), a UN coordination body, established an Issue Management Group on e-waste through full life-cycle considerations. The EMG's Issue Management Group on Tackling E-waste published the report United Nations System-wide Response to Tackling E-waste (2017), highlighted the need for strengthened collaboration among United Nations organisations, with over 20 organisations active in tackling e-waste and over 150 e-waste initiatives having been undertaken since 2004. The report offers recommendations on maximizing system-wide coherence towards a life-cycle approach to tackling e-waste. | |
| | **International** | **E-waste using a life-cycle approach** | The Solving the E-waste Problem (StEP) initiative emerged in 2004 as an independent, multi-stakeholder platform for designing strategies that address all dimensions of electronics in an increasingly digitized world. StEP applies an integrated, science-based approach to create salient solutions to global e-waste challenges throughout the entire electronics life cycle. StEP focuses its projects and activities on five life cycle areas – design, production, usage, reuse and recycling, final disposal – which are carried out by its diverse members network. Project results support three broad domains: reduce adverse environmental and human impacts resulting from improper e-waste management; implement the waste hierarchy by reducing the generation of e-waste, promoting repair and reuse and supporting material recovery; and, re-consider the design of products to support repair, re-use and recycling ideally out-designing hazardous elements. Completed projects include quantification activities and an e-waste world map, support of a sustainable e-waste management system in Ethiopia, implementing best management practices for used electronics in West Africa, transboundary e-waste controversy map, business plan calculation tool. | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| Voluntary action | **Interna-tional** | **E-waste; children** | WHO recently launched the E-Waste and Child Health Initiative with the goal of protecting children and their families from health consequences from e-waste. | |
| | **International** | **E-waste** | Sustainable Cycles (SCYCLE) is a programme hosted by the United Nations University. Its activities are focused on the development of sustainable production, consumption/usage, and disposal of ubiquitous goods with a special focus on electrical and electronic equipment. SCYCLE leads the global e-waste discussion and advances sustainable e-waste management strategies based on life-cycle thinking. It conducts research on eco-structuring towards sustainable societies; develops interdisciplinary and multi-stakeholder public-private partnerships; assists governments in developing e-waste legislation and standards, meeting a growing need for such support; undertakes education, training and capacity development; and facilitates and disseminates practical, science-based recommendations to the United Nations and its agencies, governments, scholars, industry and the public. | |
| | **Sri Lanka** | **E-waste** | IETC has initiated an activity to develop an action-oriented policy for e-waste management in Sri Lanka.The policy will cover issues including institutional aspects, sustainable financing mechanisms, infrastructure, health and environment, gender, and stakeholders. Particular focus will be given on extended producer responsibility which involves the producers, distributors, and consumers of electrical and electronic equipment towards responsible and environmentally sound e-waste management. In conjunction with the new e-waste strategy, an “E-Waste Academy” will be held in Sri Lanka to provide knowledge and facilitate discussion regarding e-waste management, and the new strategy specifically. | |
| | **National** | **E-waste** | UNIDO and UNDP have implemented, and are implementing, a number of projects with regard to environmentally sound management of e-waste that were co-funded by GEF in countries including Jordan (GEF ID 9189), Philippines (GEF ID 9078) and Colombia (GEF ID 6928). | |
| | **National** | **E-waste** | ILO has ongoing country projects in Argentina and Peru to analyse the employment situation in the e-waste sector and improve working conditions in the e-waste value chain. | |
| Challenges | **US** | **E-waste** | In 2012, EPA launched the Sustainable Materials Management (SMM) Electronics Challenge. The Challenge encourages electronics manufacturers, brand owners and retailers to strive to send 100 percent of the used electronics they collect from the public, businesses and within their own organizations to third-party certified electronics refurbishers and recyclers. The Challenge’s goals are to ensure responsible recycling through the use of third-party certified recyclers; increase transparency and accountability through public posting of electronics collection and recycling data; and encourage outstanding performance through awards and recognition. | |
| Scientific statements | **International** | **E-waste** | In June 2013, WHO convened a workshop of international scientists, policy experts and UN representatives to discuss the challenges of exposure of children and vulnerable populations to the toxic substances resulting from improper management of e-waste. The resulting 2013 Geneva Declaration on E-Waste and Children’s Health aimed to raise awareness of human health risks by exposures to e-waste (Alabaster *et al*. 2013), especially children’s health, through poor management and calls upon global stakeholders to act on this issue. | |

# 5. Highly Hazardous Pesticides (HHPs)

**Table A–5.** A comprehensive but not exhaustive overview of existing instruments and actions in sound management of HHPs.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislation and regulations] | | | | |
| **Restriction / Ban** | **Global** | **Production, use** | A pesticide active ingredient listing in annex A or B of the Stockholm Convention is one of the JMPM criteria for designation as being an HHP. To date, the Convention lists 16 pesticides (aldrin, chlordane, chlordecone, dicofol, dieldrin, endrin, heptachlor, hexachlorobenzene, alpha hexachlorocyclohexane, beta hexachlorocyclohexane, lindane, mirex, pentachlorobenzene, pentachlorophenol and its salts and esters, technical endosulfan and its related isomers, and toxaphene) are under Annex A (for elimination) and two pesticide (DDT, Sulfluramid) under Annex B (for restriction). Specific Exemptions and Acceptable Purposes exist for a couple of them, with more details provided in the Convention Annexes. Of the 18 Pesticides listed in these annexes, 6 were listed after 2009. | In force and ongoing |
| | **Global** | **Trade** | The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade regulates the exchange of information in international trade on certain hazardous pesticides (active ingredients and formulations). The Convention obliges its Parties to notify on final regulatory actions that have been taken to prohibit or severely restrict pesticides as a result of their adverse impacts. A pesticide active ingredient listing in Annex III of the Rotterdam Convention is one of the JMPM criteria for designation as being an HHP. Annex III of the Convention currently (as of October 2019) lists 36 pesticides, of which 3 are Severely Hazardous Pesticide Formulations (SHPFs). | In force and ongoing |
| | **Global** | **Production, use** | The Montreal Protocol on Substances that Deplete the Ozone Layer is an international treaty designed to protect the ozone layer by phasing out the production of a number of substances believed to be responsible for damaging or destroy the stratospheric ozone layer. A pesticide listed under the Montreal Protocol is one of the JMPM criteria for designation as being an HHP; one pesticide, methyl bromide, is currently listed under the Montreal Protocol. By 1 January 2015, its global phase-out for uses as a fumigant for controlling a wide range of pests and pathogens present in soil as well as in post-harvest storage of commodities, in buildings or structures was completed.<br>The Protocol has a provision for "Critical Uses," which applies to specific cases where a sector or region does not have technically or economically viable alternatives to methyl bromide are not available. Exemptions are granted annually by the Parties under this provision on a case-by-case country basis. In addition, methyl bromide continues to be used as phytosanitary treatment to control pests and pathogens of quarantine importance on various traded goods. These treatments are known as "Quarantine and Pre-shipment" (QPS) uses of methyl bromide, which are usually done before a country exports the traded goods or upon their arrival in the importing country. QPS uses of methyl bromide are not controlled under the Montreal Protocol; however there are annual data reporting requirements. | In force |
| | **Global** | **Transboundary movement of waste** | The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal aims to protect human health and the environment against the adverse effects of hazardous wastes, including waste from pesticides. Parties are obliged to ensure that such wastes are managed and disposed of in an environmentally sound manner. Wastes from the production, formulation and use of pesticides, including waste pesticides and which are off-specification, outdated or unfit for their originally intended use, as well as wastes from the manufacture, formulation and use of wood preserving chemicals, are explicitly defined as hazardous wastes under the Convention. | In force |
| **Framework for sustainable use of pesticides** | **EU Wide** | **Pesticide use and monitoring** | The EU adopted a Directive 2009/128/EC that aims to achieve a sustainable use of pesticides in the EU by reducing the risks and impacts of pesticides use on human health and the environment and promoting the use of Integrated Pest Management (IPM) and of alternative approaches or techniques, such as non-chemical alternatives to pesticides. EU Member States have drawn up National Action Plans to implement the range of actions set out in the Directive. The main actions 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 (e.g. public parks, playgrounds, sports fields or near healthcare facilities), and information and awareness raising about pesticide risks. EU Member States must also promote IPM, for which, general principles are laid down in Annex III to the Directive. | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Marketing authorisation** | **National / regional** | **All pesticides** | Many countries/regions have established their own pesticide legislation, including pesticide registration. For example, in the EU, Regulation 1107/2009/EC concerning the placing of plant protection products (PPPs) on the market stipulates that pesticide substances (active substance) proven to be carcinogenic, mutagenic, toxic for reproduction and endocrine disruptors shall not be authorized in the EU. Before any PPP can be placed on the market or used, it must be authorized in the EU country concerned and Regulation (EU) 1107/2009 sets out the requirements, procedure and timeframes for authorization of Plant Protection Products (PPPs). In addition, in the West-African Sahel region, nine countries jointly evaluate and authorize pesticides through the Sahelian Pesticides Committee CSP). To date, the review reports for many pesticides by countries such as Australia and Canada are publicly accessible.<br>In a recent survey by WHO and FAO, it shows that 53 out of 56 countries have pesticide legislation. However, 65% of countries lack special provisions for HHP, for example, to prohibit or restrict their use. One-third of countries lack guidelines on the registration process and on data requirements for pesticide registration, which was particularly noted in the African region. Guidance on HHP is used by few countries for their registration decisions.<br>As of March 2019, one or more of 150 countries have banned a total of 366 pesticide active ingredients or groups of actives regarded as still "currently in use" in the global market, including many HHPs. | In force and ongoing |
| | **Mozambique** | **All uses** | Following an FAO pilot programme in Mozambique from 2012 to 2014 to reduce risks posed by HHPs, the Government of Mozambique cancelled the registration of 61 pesticides that were determined to be highly hazardous under the conditions in Mozambique. | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Resolution** | **Global** | **All intentional uses** | The ICCM4 adopted a resolution in 2015 recognizing HHPs as an issue of international concern and calling for concerted action to address HHPs. | Resolution passed in 2015 |
| **Code of Conduct** | **International** | **All intentional uses** | The fourth version of the International Code of Conduct on Pesticide Management was approved by the FAO Conference in June 2013 as the successor to the International Code of Conduct on the Distribution and Use of Pesticides (adopted in 1985 and revised in 2002). The WHO adopted the Code in 2014 as its reference framework for international guidance on pesticide management.<br>It is the pesticide management framework for all public and private entities engaged in (or associated with) the production, regulation and management of pesticides. The Code serves as a point of reference in relation to sound pesticide life cycle management practices, in particular for government authorities and the pesticide industry. The voluntary standards it sets out are especially relevant where there is inadequate or no national legislation concerned with pesticide regulation. The Code is supported by additional technical guidelines. Specific reference is made to HHPs in the new Code and a technical guideline on HHPs. For example, Article 7.5 of the Code states that "prohibition of the importation, distribution, sale and purchase of highly hazardous pesticides may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment." | Last revised in 2013 |
| **Strategy** | **International** | | FAO, UNEP and WHO, in consultation with Strategic Approach stakeholders, developed *Strategy to address highly hazardous pesticides in the context of the Strategic Approach to International Chemicals Management*. | |
| **Safeguard / fiscal policy** | **International** | | In 1998, the World Bank issued a safeguard policy on pest management that is binding for all projects it finances. It stipulates that assistance related to crop protection should follow integrated pest management approaches. It does not permit the financing of formulations of products that fall in the WHO hazard classes Ia or Ib if i) the country lacks restrictions on their distribution and use or ii) they are likely to be used by, or be accessible to, lay personnel, farmers or others without training, equipment, and facilities to handle, store, and apply these products properly. Compliance with this policy is actively monitored. | Ongoing (issued in 1998, revised in 2004) |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Guidelines / Recommendations | International | | Several Technical Guidelines for the implementation of the International Code of Conduct on Pesticide management have been developed by the FAO/WHO Joint Meeting on Pesticide Management (JMPM; for more details on JMPM, see below). Outdated guidelines are revised by the JMPM. The guidelines apply to all pesticides, including agricultural, public health, household, amenity and industrial pesticides. Several technical guidelines have explicit recommendations on HHPs. For example, in 2016, the JMPM developed the FAO/WHO Guidelines on Highly Hazardous Pesticides, which listed a set of eight criteria of which HHPs are defined as meeting one or more of these criteria. The JMPM in its second session in October 2008 recommended that WHO, FAO and UNEP develop workable criteria on how to determine whether pesticide active ingredients and their formulations have shown a high incidence of severe or irreversible adverse effects on human health or the environment; currently, the assessment is at the discretion of national regulatory authorities. In addition, in 2019, under the Guidelines on household pesticides, the JMPM recommends that HHPs should not be registered for household pest control use by non-professional pesticide users. Highly hazardous rodenticides should only be registered for use by professional pest control operators. | Ongoing - |
| | International | | WHO Recommended Classification of Pesticides by Hazard was last revised in 2009 replacing the 2004 edition. It sets out a classification system to distinguish between the more and the less hazardous forms of selected pesticides based on acute risk to human health (that is the risk of single or multiple exposures over a relatively short period of time). It takes into consideration the toxicity of the technical active substance and also describes methods for the classification of formulations. The document lists common technical grade pesticides and recommended classifications together with a list of active ingredients believed to be obsolete or discontinued for use as pesticides, pesticides subject to the prior informed consent procedure (Rotterdam Convention), limitations to trade because of the Stockholm Convention, and gaseous or volatile fumigants not classified under these recommendations. The document contains approximately 870 pesticides. The active ingredients for pesticides are listed in eight different classes, and those classified as Ia or Ib are regarded as HHPs, based on the criteria set by the JMPM. | Last revised in 2009 |
| | International | | Standard procedures for assessment of pesticide data have been developed by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS; for more details on JMPS, see below). Since 1999, 95 specifications and evaluations have been developed under the new procedure first described in the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products” and later in the 1st edition of “Manual for Development and Use of FAO and WHO Specifications for Pesticides” (2002). More recently, a third revision of the 1st edition was published in 2016 titled the “Manual on Development and Use of FAO and WHO Specifications for Pesticides”. | Ongoing |
| | International | **Public procurement** | WHO developed and maintains “Guidelines for procuring public health pesticides” | Last revised in 2012 |
| | International | **Waste management including transboundary movement** | A series of technical guidelines and manuals have been developed under the Basel Convention with the aim of assisting countries in the environmentally sound management of pesticides waste in May 2017 at the 13th Conference of the Parties to the Convention; including one on the environmentally sound management of wastes consisting of, containing or contaminated with pesticides listed under the Stockholm Convention. | 2017 |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Expert groups** | **International** | | The FAO/WHO Joint Meeting on Pesticide Management (JMPM) combines the FAO panel of experts on pesticide management and the WHO panel of experts on vector biology and control. It provides advice on matters pertaining to pesticide regulation, management and use, and alerts to new developments, problems or issues that otherwise merit attention. In particular, it advises FAO and WHO on the implementation of the International Code of Conduct on Pesticide Management, including setting up criteria for defining HHPs.<br>The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) is an international expert administered jointly by FAO and WHO. JMPR meets regularly since 1963 to review residues and analytical aspects of the pesticides, estimate the maximum residue levels, review toxicological data and estimate acceptable daily intakes (ADIs) for humans of the pesticides under consideration.<br>The FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) is an ad hoc expert group administered jointly by FAO and WHO. It makes recommendations to FAO and/or WHO on the adoption, extension, modification or withdrawal of specifications for pesticides. It elaborates an evaluation report and a hazard summary for each pesticide having a specification.<br>The OECD Working Group on Pesticides (WGP) and the OECD Task Force on Biocides (TFB) composed of government officials from the 30 OECD member countries. The WGP/TFB also includes representatives of the European Commission and other international organisations, of the pesticide/biocide industry, and of the environmental and public interest community. It directs the OECD Pesticide/Biocides Programme. | Ongoing |
| **Partnership** | **International** | | In 2016, nine members of the International Social and Environmental Accreditation and Labelling Alliance (ISEAL) came together to form the Integrated Pest Management (IPM) Coalition, including Better Cotton Initiative, Bonsucro, Fairtrade, Forest Stewardship Council, GEO Foundation, Global Coffee Platform, Rainforest Alliance, Roundtable on Sustainable Biomaterials, and the Sustainable Agriculture Network (SAN). It aims to reduce and eventually eliminate the use of HHPs, and to promote more sustainable alternatives. It also aims to harmonize approaches to pesticides between ISEAL member standards. | |
| **Guidance and tools** | **International** | | The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) maintains a toolbox for decision-making in chemicals management. In 2015, a new version of the toolbox was launched including a module on pesticide management schemes with the FAO Toolkit for Pesticides Registration Decision Making which supports the evaluation of pesticides for registration purposes | |
| | **International** | | CropLife International, a global federation representing the plant science industry, published in 2017 “Obsolete and unwanted pesticide stocks. Practical guidance on safeguarding, disposal and prevention”. In addition, they have developed a number of guidelines, training manuals, posters and leaflets for use in stewardship programs, in addition to guidelines around the GHS. Furthermore, it developed an e-learning tool to help the industry understand the International Code of Conduct on Pesticide Management. | |
| **Voluntary joint action programmes** | **International** | | The WHO pesticide evaluation scheme (WHOPES) promotes and coordinates the testing and evaluation of pesticides for public health through the participation of Governments, research institutions, and manufacturers of pesticides and pesticide application equipment. The WHOPES recommendations guide the procurement of public health pesticides (including insecticide-treated mosquito nets) by Governments and aid agencies for vector control.<br>The OECD Pesticides Programme was created in 1992 to increase the efficiency and effectiveness of pesticide regulation by OECD governments. The Pesticide Programme has three main objectives: to help OECD governments share the work of pesticide registration and re-registration - the licensing of new products and re-licensing of old ones (this involves finding ways for governments to work together in assessing pesticide risks to man and the environment); to harmonise the data and methods used to test and assess pesticide risks; and, to help OECD governments reduce the risks associated with pesticide use (focusing on the variety of things that governments can do to supplement pesticide registration and further reduce the risks that may result even when registered pesticides are used properly). Today, the Programme is implementing more than a dozen projects. These projects focus on different aspects of pesticide regulation for both chemical pesticides (insecticides, herbicides, fungicides, and so forth) and biological pesticides (such as bacteria, viruses, and predatory insects) used in agriculture.<br>The OECD Biocide Programme was created in 1996 as a spin-off from the OECD Agricultural Pesticides Programme. It has two objectives: to increase the efficiency in the registration of Biocides for both governments & industry; and, to help countries to reduce risks associated with biocides use. | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Voluntary joint action projects | Mali, Senegal | | With the funding received from the Quick Start Programme Trust Fund under SAICM, the Pesticide Action Network (PAN) Africa implemented a number of activities with communities in Mali and Senegal to raise awareness and build capacity of civil society organizations and local communities to reduce risks related to pesticides use in agricultural and health sector, and to monitor and gather data on pesticide use and incidents of exposure to chemicals. | completed |
| | Multiple countries | | Multiple GEF projects have been implemented by FAO to promote the sound management of pesticides, including “Disposal of Obsolete Pesticides including POPs, Promotion of Alternatives and Strengthening Pesticides Management in the Caribbean” (GEF ID 5407), “Pesticide Risk Reduction in Bangladesh” (GEF ID 9076). | |
| Information exchange | International | | FAO maintains an “Agroecology Knowledge Hub” to highlight and share relevant knowledge on agroecology, including information on phasing out highly hazardous pesticides and possible alternatives. | |
| | International | | Pesticide Action Network (PAN) develops and maintains a “Consolidated List of Banned Pesticides” to identify which pesticides have been banned by particular countries. It also shows whether these pesticides are regarded as HHP according to the criteria established by the JMPM and/or according to the criteria agreed by PAN. It does not include those banned pesticides regarded as being obsolete according to the 2009 WHO Recommended Classification of Pesticides by Hazard. It also does not include severe restrictions; entries are for complete bans only. | Ongoing |
| | International | | The IPM Coalition developed and maintains an open-access online database of pesticides. The database contains information on 688 pesticides, detailing their potential hazards and their status under different ISEAL standard systems (whether they are restricted or banned). The database also contains information on alternative pest control or IPM techniques for different crops and forestry species.<br>Building on the database, the IPM Coalition have developed a mobile App to share transparent information on pesticides and less harmful alternatives with users on the ground. The Pesticides & Alternatives App is available online and offline, giving farmers, foresters and golf course managers the information they need. | |
| Scientific assessments | Global | | The International Agency for Research on Cancer (IARC) forms part of the WHO and it evaluates evidence of carcinogenicity and to publish them in monographs. This began in 1972 and the IARC has listed some chemicals as ‘carcinogenic to humans’ or ‘probably carcinogenic to humans’. The IARC also evaluates pesticide active ingredients. In 2015, the IARC convened a working group of 17 experts from 11 countries to assess the carcinogenicity of five organophosphate pesticides: glyphosate, malathion, diazinon, tetrachlorvinphos, and parathion. These are classified as either “probably carcinogenic to humans” (2A) or “possibly carcinogenic to humans” (2B). | Ongoing |
| | US | | The US EPA Office of Pesticide Programs maintains a List of Chemicals evaluated for potential carcinogenicity. This list is a product of the general risk assessment included in the process of pesticide registration. This classification includes the potential exposure of humans, its carcinogenic potency and if they cause cancer in laboratory animals. The list is updated annually in the Annual Cancer Report. | Updated annually |
| | Global | | The NGO Pesticide Action Network (PAN) International in March 2019 updated its PAN International list of highly hazardous pesticides. The list was first published in 2009 building on the JMPM criteria for HHPs, including other criteria such as the evaluation of its carcinogenicity according to the International Agency for Research on Cancer (IARC) and the US EPA, its endocrine-disrupting potential, inhalation toxicity, and a pesticide’s toxicity to bees. | Ongoing, last published in March 2019, the database is updated about every year. |

# 6. Lead in Paint

**Table A–6.** A comprehensive but not exhaustive overview of existing instruments and actions in sound management of lead paints.

| Types of instruments | Scale | Content | Status |
|---|---|---|---|
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling;; partnerships] | | | |
| Partnership | International | The Global Alliance to Eliminate Lead Paint was established in 2012 by the International Conference on Chemicals Management at its third session (ICCM3) to prevent children's exposure to paint containing lead and to minimize occupational exposure to lead paint. A strategic goal of the Alliance is for all countries to have lead paint laws in place by 2020. Currently with over 90 Partners from governments, IGOs, civil society organizations, private sector institutions, and academic institutions across the world, the Alliance is active in, inter alia, enhancing communication and outreach, as well as assisting countries in drafting legislations on lead paints. It has organised a number of awareness-raising workshops and campaigns in different regions and published several guidance and tools in all UN languages (see below). | Ongoing |
| Guidance and tools | International | Partners of the Global Alliance to Eliminate Lead Paint developed an online "Toolkit for Establishing Laws to Control the Use of Lead in Paint", to provide information to government officials who are interested in establishing legal limits for lead in paints in their countries. Modules include "understanding the problem", "identify the market" and "take action".<br>In 2017, UNEP developed in partnership with WHO and US EPA the "Model Law and Guidance for Regulating Lead Paint" to assist countries to enact new laws (or to modify their existing laws) to establish a single regulatory limit on the total lead content in paints. It describes the key elements of effective and enforceable legal requirements and provides a model law that incorporates the key elements and reflects the best approaches currently found in lead paint laws around the world. | Completed |
| GEF Project | International | As a part of the SAICM GEF project "Global best practices on emerging chemical policy issues of concern under the Strategic Approach to International Chemicals Management" in 2019-2021, it aims for 40 countries to legislate and implement legislation to restrict the use of lead paint, and for 50 small and medium enterprises (SME) paint manufacturers in eight countries to phase out lead from their production processes. | Work in progress |
| Voluntary phase out | International | Several companies have voluntarily stopped using lead in their paints and coatings or have begun phasing it out. For example, AkzoNobel, the world's largest paint manufacturer, had completely removed lead pigments and drying agents from its products by 2011. In addition, PPG has phased out lead in their consumer paints and committed to remove lead from remaining non-consumer coatings formulations by 2020. | Ongoing |
| Awareness raising | International | The International Lead Poisoning Prevention Week of Action is being organized annually, with a particular focus on eliminating lead paint. Among others, UNEP and WHO developed relevant campaign resource packages, including multilingual posters, flyers, infographics and videos. In 2019, over 89 events took place in 57 countries. | Ongoing |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislation and regulations] | | | |
| National laws with legal limits of lead in paints | National / Regional | Two legal approaches have been taken by different countries: 35 countries have established a single regulatory limit on the total or soluble lead concentration in paint, ranging from 90 ppm to 1,000 ppm or higher. 38 countries have established a set of chemical-specific regulatory limits based on the risks of individual compounds that are used as additives in paint (e.g. in the EU Reach regulation). In addition to different ways of setting legal limits, lead paint laws in different countries often have different scopes in terms of the life cycle stage they regulate (manufacture, import, export, sale, etc.) and types of paint (all paint, some paint, etc.). For details, see the Update on the Global Status of Legal Limits on Lead in Paint published by UNEP (UNEP 2019c). | As of January 2020, 75 countries have established laws |
| Levies | California | In 1993, California (US) adopted an annual fee on manufacturers and other entities involved with the production or sale of lead and lead-based products collected from business in the petroleum and architectural coatings industries and from facilities reporting releases of lead into the air (Health Impact Project 2017). The department employs a "historical market share attributions" concept to estimate each payer's long-term contribution to environmental lead contamination and allocate fees. It then deploys collected funds to support health care referrals, assessments of homes for hazards, and educational activities. The fee generated $20.6 million in fiscal 2015. | In force |

| Types of instruments | Scale | Content | Status |
|---|---|---|---|
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | |
| **UNEA Resolutions** | **International** | UNEA 3/9, *inter alia*,<br>1. Encourages Governments that have not yet done so and in the light of national circumstances to develop, adopt and implement legislation or regulations and to support the development of private sector strategies to eliminate lead paint, and to undertake actions throughout the value chain, including disposal, in order to remove the risks such paints pose, especially to vulnerable groups including pregnant women, infants and children;<br>2. Invites Governments and other relevant stakeholders to become a partner of the Global Alliance to Eliminate Lead Paint. | Ongoing |
| **ICCM Resolutions** | **International** | ICCM IV/2, IIA, *inter alia*,<br>1. Welcomes the efforts of the Global Alliance to Eliminate Lead PAint to achieve its goal to phase out lead in paint by 2020; 2. Encourages Governments, civil society organizations and the private sector to participate in the work of the Global Alliance to Eliminate Lead Paint and assist in achieving the above goal;<br>2. Encourages Strategic Approach stakeholders to promote and/or initiate national and/or regional discussions to address the possible establishment of effective measures, including regulation, to phase out the use of lead in paint. | Ongoing |
| **Roadmap** | **International** | At the 70th meeting of the World Health Assembly, a roadmap was approved, including a component on WHO to finalize guidelines on the prevention and management of lead poisoning, and WHO Member States to implement forthcoming guidelines, and phase out paints containing lead by 2020 as per the objectives of the Global Alliance to Eliminate Lead Paint. | |
| **Declaration / Goal** | **African, LAC region** | In September 2018, the 7th annual African Ministerial Conference on the Environment made a declaration on lead paint laws.<br>In October 2018, a goal to establish lead paint laws was approved at the XXI Forum of Ministers of Environment of LAC countries. | |
| **Standards** | **National (e.g. China, Indonesia); regional (e.g. East African Community)** | In 2004, a voluntary component of the ECO Mark scheme under the Bureau of Indian Standards (BIS) cited a limit of 1,000 ppm of lead in paints (BIS IS 15489:2004) which was reduced to 300 ppm in 2013 (BIS IS 15489:2013). Note that in 2016, India issued a new standard that is mandatory, limiting the lead content of household and decorative paints to 90 ppm (Gazette of India 33004/99, 2 Nov 2016).<br>The National Standards of the People's Republic of China on the limit of certain harmful substances in coatings for consumer products that contact the human body (GB/T 23994) specify that the content of soluble lead in consumer product coating should not exceed 90 ppm.<br>In 2015 Indonesia passed a voluntary standard for solvent-based decorative paints with a maximum concentration of 600 mg/kg (SNI 8011 2014: Organic Solvent-based Decorative Paints).<br>In January 2019, the East African Community (EAC) Technical Committee on Paints, Varnishes and Other Products amended EAC standards to establish a 90 ppm limit for lead in paints. Note that once the Member States of the EAC adopts this standard, this standard becomes legally binding in respective countries (e.g. in Kenya). | In force |

# 7. Nanotechnology and Manufactured Nanomaterials

**Table A–7.** A comprehensive but not exhaustive overview of existing instruments and actions on nanotechnology and manufactured nanomaterials

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Capacity building** | **International** | | UNITAR e-learning course for the "sound management of manufactured nanomaterials" under SAICM for policy makers, industry, academia and interested members of the public. | |
| **Voluntary action** | **National** | | In late 2013, UNITAR embarked on a second phase of pilot projects at the national level, in Armenia, Jordan and Viet Nam, all of which have completed their activities since the fourth session of the Conference. The project in Viet Nam developed a proposal for activities for the period 2016–2020 and a national vision up to 2025, provided a review of activities and ongoing research in the country related to nanotechnology, and assessed national nanosafety priorities. Armenia formulated a new nanosafety policy and added a nanosafety chapter to the national profile on chemicals management. Jordan increased awareness of the issue at the national level, shared information on activities in-country and developed workplace safety guidelines. | |
| **Guidances and tools** | **International** | **OECD test guidelines** | OECD series of reports includes "guiding principles" for measurements, risk assessments, test evaluations and test guidelines, as well as the analysis of a survey of consumer and environmental exposures.<br>Existing OECD test guidelines are often not (directly) applicable to nanomaterials. Special considerations or modifications are required for nanomaterials as outlined in several updated guidance documents (see EUON 2019). A first nanomaterial-specific OECD test guideline was published in 2017: " Test No. 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media" (OECD 2017). Additionally, Test No. 412 and 413 for inhalation toxicity (subacute and subchronic, respectively) were updated to be applicable to nanomaterials. Further test guidelines are currently under development, for example for dissolution.<br>See also the "Malta Initiative" below: https://www.nanosafetycluster.eu/international-cooperation/the-malta-initiative/ | |
| | **National to international** | **Directories of products containing nanomaterials** | Environmental Working Group's Skin Deep database tracks cosmetics, sunscreens and other products that purport to contain or use nanomaterials. | |
| | **International** | **Nanomaterial database and behaviour modelling** | S2Nano is a consortium of universities, corporate services labs and other nongovernmental entities that maintains a database of nanomaterials and their chemical properties, collected from peer-reviewed literature and reports. Also available are a "curated database" for dataset assessment for metallic nanomaterials and modelling for potential properties and classification or determination of nanomaterial relationships. | |
| **Voluntary partnership** | **International** | | The Malta Initiative is "a self-organised group without any legally binding status" that consists of EU countries, ECHA, the European Commission and industry partners that are working to develop OECD test guidelines and documents specific to nanomaterials. | |
| **Classification** | **International** | **SIN List** | Carbon nanotubes (CNTs) are the first nanomaterial to have been added to the SIN ("Substitute It Now") List of ChemSec, the International Chemical Secretariat, an international nonprofit organisation based in Sweden, in November 2019 for being "carcinogenic, persistent and probably toxic to reproduction". The organisation maintains the SIN List as a tool for corporations to use for removing hazardous chemicals from products and manufacturing processes. | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislations and regulations] | | | | |
| **Marketing registration or notification (some may include additional label requirements)** | **EU** | **Industrial chemicals** | Included under the REACH Regulation, special provisions in force since 1 January 2020 for nanomaterials have been introduced to REACH Annexes I, III and VI-XII, for both new and already registered substances (European Commission 2019). Each nanoform of a substance, defined according to the European Commission's recommendation for the definition of nanomaterials of 18 October 2011, requires specific data for characterization and hazard assessment (European Commission 2011). | In force |
| | | **Cosmetic products** | Regulation (EC) No 1223/20209 (Art. 13) on cosmetic products: manufacturers have to notify the European Commission of nanomaterials in a product before it goes on the market and provide information on identification and reasonably foreseeable exposure conditions for these nanomaterials. Additional notification (Art. 16) is necessary for certain nanomaterials for protection of human health six months prior to placement on the market and requires additional information (e.g. specification of particle size, estimate of the quantity of nanomaterial contained in the product and to be placed on the market, the toxicological and safety profile of the nanomaterial). According to Art. 19, nanomaterials present in cosmetic products have to be clearly labeled in the lists of ingredients with the word "nano" in brackets after the ingredient name. | In force |
| | | **Novel foods; food information to consumers; food contact materials** | Food containing nanomaterials is considered "novel food" according to Regulation (EU) No 2015/2283 and therefore requires authorisation by the European Commision prior to being placed on the market. Verification with the most up-to-date test methods is required for their safety assessment. The same labelling requirements apply to nanomaterials in food as for those in cosmetics.<br>Food Contact Material (FCM) Regulation No 10/2011 (Art. 9) requires explicit authorisation for use of substances in the nanoform (specified in Annex I). Nanomaterials are not covered by authorisation of the same substance of larger size but have to be assessed on a case-by-case basis regarding their risk. | In force |
| | | **Biocides** | Regulation (EU) No 528/2012 on biocidal products requires a dedicated risk assessment for the nanoform of an active substance used in a biocidal product. A biocidal product containing nanomaterials must be labelled with "nano" and is excluded from a simplified authorisation procedure. | In force |
| | | **Medical devices** | Regulation (EU) 2017/745 on Medical Devices requires assessment for devices incorporating or consisting of nanoparticles particularly for high or medium potential for internal exposure in humans. | In force |
| | **National** | **Nanomaterials registers** | France, Belgium, Denmark, Norway and Sweden require manufacturers, importers and sometimes distributors to register and provide specific information on nanomaterials used/produced/imported above a certain amount. | Ongoing |
| | **US** | **Nanoscale substances reporting** | The US Toxic Substance Control Act (TSCA) includes reporting and recordkeeping obligations for "nanoscale materials" (definition: 1-100 nm; exhibiting unique and novel properties). Companies manufacturing or importing nanoscale substances must notify the EPA regarding specific chemical identity, production volume, manufacturing methods, processing, use, exposure and release information, as well as available health and safety data. | In force |
| | **Republic of Korea** | **All nanomaterials, particularly those in biocides and household products** | Nanomaterials are required to register according to the Act on the Registration and Evaluation of Chemical Substances (Korea's REACH) and the Safety Control Act on Household Chemical Products and Biocidal Products, also known as K-BPR or Chemical Products Safety Control Act, in March of 2018. Approval is required by the K-BPR if nanomaterials are used in biocidal products (personal communication, TK). (See also Park & Yeo 2016.) | In force |
| **Mapping** | **International** | **Waste materials containing nanoscale substances** | The Basel Convention (BC-13/17) requested a report at its 11th meeting for consideration by the Open-ended Working Group "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." The report was filed in draft form in August 2018 and open to comments through January 2019. The COP14 of the Basel Convention made a further call for information and case studies to be submitted by the end of December 2019, to be published in early 2020. | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| Guidelines | International | Occupational exposure | WHO published “guidelines on protecting workers from potential risks of manufactured nanomaterials” in 2017, with recommendations on best practices, assessing health hazards and exposures, and controlling exposures (WHO 2017). | |
| Strategic planning | US | R&D | US National Nanotechnology Initiative (nano.gov) supports that “responsible development includes understanding potential environmental, health, and safety (EHS) implications of nanomaterials as well as the ethical, legal, and societal implications (ELSI) of nanotechnology”. It published *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. | Ongoing |
| | Republic of Korea | Research programmes | Under various ministries including Environment, Trade, Industry and Energy, and Food and Drug Safety, the Korean government has established goals for and implementation of research programmes for nanomaterials under the second National Nano-safety Master Plan (2017-2021). | Ongoing |

# 8. Per- and Polyfluoralkyl Substances (PFASs)

**Table A–8.** A comprehensive but not exhaustive overview of existing instruments and actions in sound management of PFASs.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national/regional legislations and regulations] | | | | |
| Restriction / Ban | International | PFOS, its salt and POSF | Listed under Annex B (for restriction) of the Stockholm Convention on Persistent Organic Pollutants (POPs), with Acceptable Purpose on the production and use in insect baits with sulfluramid (CAS No. 4151-50-2) as an active ingredient for control of leaf-cutting ants from *Atta* spp. and *Acrymyrmex* spp. for agricultural use only, and Specific Exemptions on (i) metal plating (hard-metal plating) only in closed-loop systems and (ii) fire-fight foam for liquid fuel vapour suppression and liquid fuel fires (Class B fires) in installed. | In force (included by 86 out of 183 Parties in their National Implementation Plan, as of 19 November 2019) |
| | | PFOA and PFOA precursors | Listed under Annex A (for elimination) of the Stockholm Convention in 2019, with Specific Exemptions on the use in (i) photolithography or etch processes in semiconductor manufacturing; (ii) photographic coatings applied to films; (iii) Textiles for oil and water repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety; (iv) invasive and implantable medical devices; (v) fire-fighting foam for liquid fuel vapour suppression and liquid fuel fires (Class B fires) in installed systems, including both mobile and fixed systems, in accordance with specific requirements set by the Convention Annex; (vi) use of perfluorooctyl iodide for the production of perfluorooctyl bromide for the purpose of producing pharmaceutical products, in accordance with specific requirements set by the Convention Annex; (vii) manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of: high-performance, corrosion-resistant gas filter membranes, water filter membranes and membranes for medical textiles, industrial waste heat exchanger equipment, and industrial sealants capable of preventing leakage of volatile organic compounds and PM2.5 particulates; (viii) manufacture of polyfluoroethylene propylene (FEP) for the production of high-voltage electrical wire and cables for power transmission; and (ix) manufacture of fluoroelastomers for the production of O-rings, v-belts and plastic accessories for car interiors, as well as the production for these uses except for fire-fighting foam. | Entered into force: 01.2020 |
| | | PFHxS and its precursors | Recommended by the POPRC for listing under Annex A of the Stockholm Convention with no exemptions, with an earliest possible decision to be made at the 10th meeting of the Conference of the Parties (COP 10) in 2021. | Evaluation in progress |
| | EU | PFOA and PFOA-related compounds | Adopted a restriction that they shall not be manufactured, used or placed on the European market as substances, as constituents of other substances, in a mixture, or in an article, with a number of specific, time-limited exemptions. | Enter into force: 04.07.2020 |
| | | 6:2 FT-silanetriol and TDFAs; in spray products | Shall not be placed on the market for supply to the general public after 2 January 2021 individually or in any combination, in a concentration equal to or greater than 2 ppb by weight of the mixtures containing organic solvents, in spray products (i.e. aerosol dispensers, pump sprays, trigger sprays, marketed for proofing or impregnation spray applications; additional requirements on labelling and safety data sheets for professional use | In force |
| | | C6, C9–C14 PFCAs, PFHxS, and related substances | Nominated for the following restriction under REACH: these substances shall not be manufactured, used or placed on the European market as substances, as constituents of other substances, or in a mixture. Articles or any parts thereof containing one of the substances shall not be placed on the European market. | Evaluation in progress |
| | Denmark | All PFASs; in paper and cardboard as food contact materials | The Ministry of Environment and Food of Denmark announced that the Danish Government will ban the use of PFASs in paper and cardboard used in food contact materials by July 2020. It will continue to be possible to use recycled paper and cardboard for food, but if there is a PFAS content in the material, then it must be separated from the food with a barrier that ensures that PFASs do not migrate into the food. | Undergoing external consultation, with expected enter in force: 01.07.2020 |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| | **South Australia** | **Firefighting foams** | Amendments to the *Environment Protection (Water Quality) Policy 2015* (a disallowable instrument under South Australia's *Environment Protection Act 1993*) prohibit the use of fluorinated firefighting foams in South Australia, subject to transition arrangements to assist industry meet the requirements of the ban. | In force |
| | **Queensland** | **Firefighting foams** | Operational Policy: Environmental Management of Firefighting Foam – outlines requirements and expectations for the handling, transport, storage, use, release, waste treatment, disposal and environmental protection relevant to the use of fighting foam in accordance with Queensland's *Environmental Protection Act 1994*. Provisions include:<br>• withdrawing from use and disposal of foams containing PFOS, PFOA, precursors and higher homologues<br>• requirements for use of foams containing short-chain fluorotelomers where such use is the only viable option | In force |
| **PIC procedure for trade** | **International** | **PFOS, its salt and POSF; trade** | Listed under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. | In force |
| **Identification as chemicals of concern** | **EU** | **PFHxS, PFBS, HFPO-DA** | Identified as a Substance of Very High Concern (SVHC) under REACH, with the legal obligations by companies, including notification to ECHA about, and provision of sufficient information to their customers to allow safe use of, the articles containing the substances in a concentration above 0.1% w/w.<br>PFHxS due to vPvB.<br>• PFBS due to a combination of the following factors: potential for irreversible and increasing presence in the environment, potential for irreversible and increasing contamination of surface water, marine water and groundwater, continuous presence in water results in continuous bioavailability, worldwide occurrence, PFBS enters the biosphere via several routes, intergenerational effects, observed mother-to-offspring transfer, potential for delay of effects, potential for causing serious effects although those would not be observed in standard tests, derivation of future exposure levels and safe concentration limits will be highly uncertain, and high societal concern for the presence of PFBS in drinking water sources.<br>• HFPO-DA due to their properties which cause probable serious effects to human health and the environment, giving rise to an equivalent level of concern to carcinogenic, mutagenic and reprotoxic (CMR), persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances). | In force |
| **Substance evaluation** | **EU** | **Several PFASs** | A number of PFASs including a PFBS precursor and three 6:2 FTs are being evaluated by the EU Member States under REACH. The evaluation may in the end conclude that the risks are sufficiently under control with the measures already in place. Otherwise, it may lead to the proposal of EU-wide risk management measures such as restrictions, identification of SVHC, harmonised classification or other actions outside the scope of REACH. | Evaluation in progress |
| | **Australia** | | Under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), there are additional data requirements specifically for new PFAS so that the risks of these chemicals can be properly assessed, particularly in relation to the bioaccumulation and toxicity of their breakdown products. NICNAS has also made recommendations on the use and disposal of PFAS including restriction of PFOS, PFOA and related chemicals to essential uses where alternatives are not available; phasing out of the use of PFAS of concern; use of PFAS-based firefighting foams only in essential applications (not including firefighting training). | In force |
| **Enforceable standards** | **EU** | **Drinking water** | The new Drinking Water Directive introduces for the first time a limit value for the 20 most important of the PFASs. Over the next three years, the European Commission is to develop a method for measuring all PFAS. A new limit value for all PFASs will then be set by the European Parliament and the Council on the basis of this method. In addition, the EU Commission must develop a method over the next three years to measure all PFAS. The member states can then decide to use the existing limit value for the 20 substances or to use a new higher limit value for all PFASs - or to apply both limit values simultaneously. After five years, the Commission must present a new proposal on the PFAS limit value in order to harmonise the two parallel limit values as far as possible. | In legislative process |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| Voluntary phase-out | International | Long-chain PFASs | A global phase-out of its production and use by 3M, the then-dominant manufacturer | Completed in 2002 |
| | International | Long-chain PFCAs and precursors | Under the US EPA PFOA 2010/15 Stewardship program, eight leading manufacturers of fluoropolymers and fluorotelomers in Europe, Japan and the US committed: 1) to achieving a 95 percent reduction in both facility emissions and product content levels by 2010 measured from a year 2000 baseline, and 2) to working toward their elimination in emissions and products by 2015 globally (four of these companies also participated in a similar, Canadian-focused Environmental Performance Agreement program [171]). | Completed in 2015 |
| | Denmark | All PFASs; in cosmetics and personal care products | Coop Denmark, a retail group, informed all its suppliers in the week of 9 March 2019 that all purchases of cosmetic products containing PFASs will be discontinued with immediate effect. | Completed by 9 September 2019 |
| | Australia | PFAS-containing firefighting foams | Since 2004, Airservices Australia (the Australian Government body that provides aviation rescue and firefighting services at major airports) has been phasing out the use of PFAS-containing firefighting foams, and since 2010 uses only protein-based foam at civilian airports.<br>The Australian Department of Defence has phased-out use of 3M Lightwater at all Defence bases, and now uses a product that contains only short-chain PFAS as active ingredients (but is likely to contain trace amounts of PFOS and PFHxS as impurities). | 2010 and ongoing |
| Partnership & clearing house mechanisms | International | All PFASs | The OECD/UNEP Global PFC Group was established to facilitate the exchange of information on PFASs and to support a global transition towards safer alternatives, in response to the ICCM2 Resolution II/5. Detailed activities include, inter alia, technical reports and webinars. It also maintains the webportal on PFASs hosted by the OECD (https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/), serving as a clearing house to share information on risk reduction approaches, alternatives to PFASs, and production and emissions of PFASs. | Ongoing |
| | International | All PFASs | The Green Science Policy Institute and the Social Science Environmental Health Research Institute at Northeastern University together maintains the PFAS Central website (https://pfascentral.org/about/), providing current and curated information about PFAS, including press, peer-reviewed scientific articles, meetings, job listings, and consumer information. | |
| | Australia | All PFASs | Australian Government website www.pfas.gov.au has information (aimed at the general public, regulators and industry) about PFAS contamination, use and health and environmental impacts and links to information provided by Australian, State and Territory government agencies. | |
| | US | All PFASs | The Interstate Technology and Regulatory Council (ITRC) developed a series of fact sheets to summarize the latest science and emerging technologies for per- and polyfluoroalkyl substances (PFAS). The fact sheets are tailored to the needs of state regulatory program personnel who are tasked with making informed and timely decisions regarding PFAS-impacted sites. The content is also useful to consultants and parties responsible for the release of these contaminants, as well as public and tribal stakeholders. Each synthesizes key information for one of the following core subjects: (1) Naming Conventions and Physical and Chemical Properties, (2) Regulations, Guidance, and Advisories, (3) History and Use, (4) Environmental Fate and Transport, (5) Site Characterization Considerations, Sampling Precautions, and Laboratory Analytical Methods, (6) Remediation Technologies and Methods, and (7) Aqueous Film-Forming Foam (AFFF). | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Consumer education** | **National** | **All PFASs** | *Per- and Poly-Fluoroalkyl Substances (PFAS): Health Effects and Exposure Pathways* – Fact Sheet issued by the Australian Department of Health to provide information to the public.<br>*Per- and poly-fluoroalkyl substances (PFAS) and the general food supply* – Fact Sheet issued by the Australian Food Regulation Standing Committee<br>The German Environment Agency (UBA) developed a smartphone app "PFC Planet" to inform consumers about what PFASs are, where they are used and how consumers can do about them. | |
| **Scientific statements** | **International** | **All PFASs** | The Helsingør, Madrid and Zurich Statements to raise awareness of and call for action on PFASs. | |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Action Plan** | **US** | **All PFAS** | US EPA's PFAS Action Plan outlines concrete steps the agency is taking to address PFAS and to protect public health. It provides a multi-media, multi-program, national research, and risk communication plan to address this emerging environmental challenge. | |
| **Guide** | **Australia** | **PFAS contamination** | PFAS National Environmental Management Plan (NEMP) – It provides the Australian governments at different levels with a consistent, practical, risk-based framework for the environmental regulation of PFAS-contaminated materials and sites. | Came into effect in January 2018 |
| **Standards** | **China** | **PFOA; in textile products** | In 2016, Chinese government published a new technical requirement for textile products, setting the limits of PFOS and PFOA levels to be 0.05 mg/kg in coated infants textile products and 0.1 mg/kg in all other coated textile products, respectively. | In force |
| **Guidance, and advisory values** | **China** | **PFOA, fluoropolymers** | In 2011, PFOA-relevant technology and products were added to the Catalogue for the Guidance of Industrial Structure Adjustment: new installation of PFOA production facilities should be restricted, PFOA-containing paints and fluorpolymers that use PFOA in the polymerisation should be eliminated, and development of alternatives to PFOA should be encouraged.<br>In 2013, fluoropolymer coatings for non-stick pans, kitchenware and food processing equipment that use PFOA in the polymerisation were recognized as products with high pollution and high environmental risk ("dual-high" products) in the Comprehensive Catalog for Environmental Protection. | |
| | **Australia, Canada, Western European countries, and the US** | **PFOA, PFOS and a limited number of other PFASs; in environmental media** | A large number of 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, e.g. the US EPA has established drinking water health advisories for PFOA and PFOS at 70 parts per trillion. As individual values may be updated/expanded and new values may be added, readers are encouraged to check out the latest updates, e.g., via the US Interstate Technology & Regulatory Council (ITRC)'s website: https://pfas-1.itrcweb.org/fact-sheets/. | |

# B.

# Supporting Information on Assessment of Issues Where Emerging Evidence Indicates Risks Identified by GCO-II

# 1. Arsenic

**Table B–1.1.** Supporting information on the life cycle of and exposure to arsenic, as well as examples of cost-of-inaction and benefits-of-action information.

| Chemical name, CAS number, and molecular formula | Arsenic; 7440-38-2; As. For chemical names, CAS numbers and molecular formula of other arsenic compounds, see (International Agency for Research on Cancer [IARC] 2012). |
|---|---|
| **Production information** | |
| **Production overview** | Arsenic occurs naturally as an element and can be obtained as a byproduct from the smelting of copper, gold, lead and cobalt ores and from roasting arsenopyrite (United States Geological Survey [USGS] 2019). Arsenic may also be recovered from the minerals orpiment and realgar, recovered from copper-gold ores and from the copper mineral enargite (USGS 2019). Operations in different countries use different production techniques (George 2018; USGS 2019;). There is limited demand for elemental arsenic (Agency for Toxic Substances and Disease Registry [ATSDR] 2007). Arsenic trioxide is the most common commercial arsenic compound (United States National Toxicology Program [US NTP] 2016). |
| **Key producers** | • China is reported to be the leading global producer of arsenic trioxide (Brown *et al.* 2019; USGS 2019).<br>• USGS (2019) estimated the global production of arsenic trioxide in 2018 at around 35,000 tonnes (approximate values quoted), without considering production in Chile, Mexico and Peru, although it is believed that these countries are also significant producers of commercial-grade arsenic trioxide. The majority of production is in China (24,000 tonnes), Morocco (6,000 tonnes), Namibia (1,900 tonnes), Russia (1,500 tonnes), Belgium (1,000 tonnes), Iran (110 tonnes), Japan (45 tonnes) and Bolivia (40 tonnes).<br>• Brown *et al.* (2019) reported the global production of arsenic trioxide in 2017 as follows: China (25,000 tonnes), Peru (22,319 tonnes), Morocco (7,600 tonnes), Russia (1,500 tonnes), Belgium (1,000 tonnes), Namibia (700 tonnes), Japan (45 tonnes) and Bolivia (40 tonnes).<br>• China was also the global leading producer of arsenic metal, supplying the US with 90% of its 2018 arsenic metal imports (USGS 2019). |
| **Global trends of production** | Figures produced by USGS (2017) indicate arsenic production has generally declined since 2006 when global production of arsenic content reached 46,100 tonnes, in comparison to its 2018 data (USGS 2019). It is expected that arsenic use in chromated copper arsenate (CCA) for treating wood will continue in industrial applications. The use of gallium arsenide (GaAs) components in cellular handsets and GaAs-based light-emitting diodes in lighting applications are also expected to increase arsenic metal consumption (George 2018), although it is uncertain whether this relates to an increase in use in the US or globally. |
| **Global trade** | Arsenic is traded both as a metal and as compounds (George 2018). There is limited information on the global trade flow of arsenic. Data is available for the US. In 2016, the US exported 1,760 tonnes of arsenic, although no arsenic metal was produced in the US, and so exports are therefore assumed to represent arsenic-containing compounds and waste alongside nonferrous alloys with low quantities of arsenic (George 2018). This figure may have included arsenic-containing electronic waste (George 2018). Arsenic is also traded in products (see below). |
| **Use information** | |
| **Key uses/applications** | Arsenic is a metalloid and occurs within three major groups of compounds: inorganic arsenic compounds, organic arsenic compounds and arsine gas (IARC 2012). The most common inorganic arsenic compounds include arsenic trioxide, sodium arsenite, arsenic trichloride, arsenic pentoxide, arsenic acid and arsenates (IARC 2012). Organic arsenic compounds include arsanilic acid, methylarsonic acid, dimethylarsinic acid and arsenobetaine (World Health Organization [WHO] 2000 in IARC 2012).<br>• Inorganic arsenic compounds are mainly used as wood preservatives (ATSDR 2007), where inorganic arsenic (more specifically, arsenic trioxide) is an active component of CCA. This is a pesticide and preservative used to treat wood (IARC 2012; USGS 2019; George 2018).<br>• Organic arsenic compounds are used as pesticides on cotton fields and orchards (ATSDR 2007). Some organic arsenicals have been used as feed additives in poultry and swine husbandry (United States Environmental Protection Agency [US EPA] 2000; Al-Alebd and Jegadeesan 2006; IARC 2012).<br>• Other uses of arsenic compounds include the manufacturing of silicon-based computer chips and the manufacturing of glass (Gilbert and Hepp 2016). For example, boron arsenide has been shown to be effective in spreading heat for cooling down electronics (Li *et al.* 2018)<br>• Elemental arsenic is used in alloy manufacturing, often with lead and copper (IARC 2012).<br>• Gallium arsenide (GaAs) and arsine are widely used in electronics and semiconductors (IARC 2012; Gilbert and Hepp 2016; Human Biomonitoring for Europe 2019).<br>• Arsenic trioxide (known as Trisenox and ATO) is also approved by the United States Food and Drug Administration (US FDA) to treat acute promyelocytic leukaemia (APL), when other chemotherapy treatments have failed to do so (US NTP 2016). Trisenox is also authorised for use in the European Union (EU) (European Medicines Agency n.d.). Realgar-Indigo naturalis formula (RIF), a commercially available oral arsenic drug used as a treatment for patients with acute promyelotic leukaemia, was approved for use in China in 2009 (Zhu et al. 2019). |

| | |
|---|---|
| **Key markets** | There is limited information on the global consumption of arsenic, although historically, the US was the largest consumer (IARC 2012).<br>• In 1998, the US consumed 30,100 tonnes of arsenic, estimated to be the same as net imports (USGS 2002), which by 2003 had declined to 21,600 tonnes. Before 2004, around 90% of US arsenic consumption was for arsenic trioxide in wood preservative manufacture (IARC 2012), but by 2004 there was a substantial drop in apparent consumption to 6,800 tonnes, estimated to be the same as net imports (USGS 2007). In 2018, estimated US apparent consumption of arsenic was 5,500 tonnes (USGS 2019), estimated to be the same as imports.<br>• Gallium-arsenide (GaAs) semiconductors are widely used in applications such as biomedical devices, communications devices, computers, electronics and photovoltaics (George 2018). Global GaAs device revenues in 2016 were reported at $8.2 billion (George 2018). |
| **End-of-life information** | |
| **End-of-life issues** | • Waste flows containing arsenic vary between locations. Data have been identified for some specific countries, most notably the US.<br>• In the US, the US EPA (Al-Alebd and Jegadeesan 2006) identifies arsenic-bearing solid residuals (ABSRs) from drinking water treatment facilities, wood treated with CCA and debris from construction and demolition, wallboards made from FGD materials and industrial solid waste, as common wastes containing arsenic.<br>• Disposal methods can vary by country and the type of waste. For example, the US disposes of CCA-treated wood through landfills, although in other countries, CCA-treated wood may be disposed of in waste-to-energy facilities (Jambeck *et al.* 2007).<br>• Where landfills are used for disposal, potential problems include groundwater contamination, impact on leachate quality and long-term operational issues. Tests used to estimate contaminant release may not accurately predict leaching (Al-Alebd and Jegadeesan 2006). The release of arsenic from different sources will also vary depending on the disposal scenario (i.e. the type of site and landfill disposal – municipal, construction and demolition, industrial, hazardous, mining, etc.; Al-Alebd and Jegadeesan 2006). The classification of waste (e.g. hazardous, non-hazardous, mixed waste etc.) is country dependent.<br>• Electrical and electronic equipment containing arsenic requires special end-of-life handling (Mudgal *et al*. 2013). Where waste electrical and electronic equipment is improperly treated hazardous compounds may be released into the environment (Mudgal *et al*. 2013). |
| **Exposure information** | |
| **Main exposure sources and pathways** | • Arsenic may be released to the environment from natural events, including volcanic activity, the desorption or dissolution of minerals or exudates from dust and vegetation (WHO 2019). Human activities including metal smelting, fossil fuel combustion and wood treatment, as well as agricultural pesticide use and production (historically), may also release arsenic to the environment. Other potential sources of exposure include drinking water from tube wells drilled in geological deposits containing arsenic and the remobilisation of sources such as mine drainage water (WHO 2019).<br>• Most people are exposed to low but constant levels of arsenic (Gilbert and Hepp 2016); however, elevated levels of inorganic arsenic are caused by drinking or using contaminated water in food preparation or irrigating food crops (such as rice), industrial processes, consuming contaminated food, or smoking tobacco (Baker *et al.* 2018; WHO 2018).<br>• The greatest threat to public health from arsenic is considered to be the drinking of contaminated water and its use in food preparation and the irrigation of food crops (WHO 2018; WHO 2019). In countries such as Argentina, Bangladesh, Chile, China, India, Mexico and the US, groundwater contains naturally high levels of inorganic arsenic (WHO 2018). It is estimated that at least 140 million people across 50 countries have consumed arsenic-contaminated water at levels higher than the WHO provisional guideline value in recent decades (Bagchi 2007; WHO 2018).<br>• The primary route of occupational exposure is considered to be the inhalation of arsenic-containing particulates. Dermal exposure and ingestion may also occur in certain situations (IARC 2012). |
| **Examples of costs-of-inaction and benefits-of-action information** | |
| **Costs of inaction** | A 2012 study estimated the annual total deaths of around 43,000 in Bangladesh were attributable to chronic arsenic exposure (Flanagan *et al.* 2012; WHO 2019). In another estimate in 2004, diseases from arsenic exposure in contaminated water in Bangladesh resulted in more than 9,100 deaths per year and the loss of over 174,000 disability-adjusted life years (DALYs; undiscounted) per year (Lokuge *et al.* 2004). |
| **Benefits of action** | Limited information is available on the quantifiable benefits of action on arsenic. Arsenic emissions in the UK decreased 68% (by 63 tonnes) from 1990 to 2012. Data on “suspected” occupational diseases in Germany linked to arsenic exposure also decreased from 1995 to 2014 (Amec Foster Wheeler *et al.* 2017). |

**Table B–1.2.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of arsenic.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral or /multilateral treaties; national or regional legislation and regulations] | | | | |
| **Ban / restriction** | **European Union (EU)** | **Anti-fouling, treatment of industrial waters, preservation of wood** | Arsenic compounds (represented by 144 CAS numbers) are restricted under REACH (European Chemicals Agency [ECHA] 2020), including<br>• shall not be placed on the market, or used, as substances or in mixtures where the substance of mixture is intended for use to prevent the fouling by microorganisms, plants or animals of the hulls of boats, cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, any totally or partly submerged appliances or equipment.<br>• shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use.<br>• shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market, with certain exceptions. | In force |
| | | **Fertilisers** | Regulation (EU) 2019/1009 contains rules on making EU fertilising products available on the market, limiting values, for example, of inorganic arsenic, which in an organic fertiliser must not exceed 40 mg/kg dry matter (EU 2019). | Stepwise entry into force from 15 July 2019 to 16 July 2022 |
| | | **Food items** | Regulation (EU)2015/1006 establishes maximum levels for inorganic arsenic in rice and rice products (European Commission 2015a). | In force |
| | **Canada** | **Food; use in certain infants' products** | List of Contaminants of Other Adulterating Substances in Food sets out the maximum levels for arsenic in food.<br>An act on Cribs, Cradles, Bassinets and Toys limits the amount of arsenic in these sources (Government of Canada 2016). | In force |
| | **China** | **Animal feed** | A ban of the use of phenylarsonic feed additives in chicken and pig feed, estimated to prevent USD$85 million in health costs and over 1,100 deaths (Hu et al. 2019). | In force |
| | | **Imported copper concentrates** | Under the current rules introduced in April 2006, shipments of metal concentrate into China must undergo inspection by the China Inspection and Quarantine Services (CIQ) and may not contain levels of more than 0.5% arsenic, 6% lead, 0.1% fluorine, 0.05% cadmium and 0.01% mercury. These limit values are being revised now (Luk 2019). | In force |
| | **Eurasian Economic Union (EEU)** | **Toys, packaging material, perfumery and cosmetic products, food products, certain infants' products** | The Union has adopted a series of technical regulations, which establish requirements to technical regulation objects, in particular safety requirements, mandatory for application and execution in the territory of the Union:<br>• TR CU 008/2011 on toy safety sets the release (migration) of arsenic contained in 1 kg of any toy materials into the model medium (hydrochloric acid) not to exceed 25 mg.<br>• TR CU 005/2011 on safety of packaging sets the allowable quantity of migration of 0.05 mg/L from food contact packaging made from paper, cardboard, parchment, colorless and semi-white glass, and titanium enamels.<br>• TR CU 009/2011 on the safety of perfumery and cosmetic products forbids the use of arsenic in perfumes and cosmetics.<br>• TR CU 021/2011 on safety of food products sets the acceptable levels of arsenic in different food products: 0.1 mg/kg in meat and meat products, poultry and poultry products, canned meat, poultry; 0.05 mg/kg in raw milk, raw skim milk, raw cream, drinking milk and drinking cream, milk drinks, fermented milk products, sour cream, ice cream of all types from milk and on a milk base; 0.2 mg/kg in food grains; 1.0 mg/kg in sugar; 0.2 mg/kg in vegetables, potatoes, melons, juice products and vegetables; 0.1 mg/kg in all types of vegetable oils.<br>• An application of sanitary measures within the Customs Union (EEU 2010):<br>• Prohibits arsenic in milk dummies and pacifiers from silicone polymers and latex<br>• Limits arsenic in diapers and baby swaddling bands. | In force |
| **Notification** | **EU** | **Export** | Arsenic is subject to an export notification procedure (ECHA n.d.). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Environmentally sound management of Waste** | **International** | **Waste** | The Basel Conventional lists arsenic-containing waste streams as "hazardous wastes", including waste materials that contain arsenic or arsenic compounds as constituents (classification Y24 in Annex 1; classification A1030 in Annex VIII) and metal wastes and waste consisting of alloys of arsenic (classification A1010 in Annex VIII). Therefore, Parties to the Convention are to manage this waste stream in accordance with the provisions set out in the Convention, including by reducing to a minimum their generation; restricting the transboundary movements of such wastes, except where it is perceived to be in accordance with the principles of environmentally sound management; and taking appropriate measures to ensure their environmentally sound management. Each Party has the obligation to transmit to the Secretariat a national report on an annual basis that contains information about the amount of wastes generated, among other data. | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Guidelines** | **International** | **Drinking water; air; food intake** | The WHO provisional guideline value of arsenic in drinking water is 10 ug/L, in light of practical difficulties in removing arsenic in drinking water (WHO 2019). Every effort should therefore be made to keep concentrations as low as reasonably possible and below the guideline when resources are available.<br>A safe level of arsenic in air cannot be established.<br>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) determined the lower limit on the benchmark dose for a 0.5% increased incidence of lung cancer (BMDL0.5) from epidemiological data to be 3.0 ug/kg body weight per day (2-7 ug/kg body weight per day based on the range of estimated total dietary exposure. The Committee withdrew the previous provisional tolerable weekly intake. No new tolerable intake level could be established. In areas where levels in water are below the WHO drinking-water guideline value, human health effects are unlikely (WHO 2019). | In force |
| | **National or regional** | **Environmental media, occupational exposure** | A number of guideline values for different exposure media, including occupational exposure, have been developed in different United States Centers for Disease Control and Prevention 2018), for example in the US (US FDA 2019;, United States National Library of Medicine 2019) and Canada (Health Canada 2006). | In force |
| | **EU** | **Food monitoring** | Commission Recommendation (EU) 2015/1381 on the monitoring of arsenic in food by EU Member States (EC 2015b). | |
| **Prioritisation** | **China** | **Manufacturing and use** | In 2017, the Government of China published the Prioritized List of Substances to be Subject to Control (1st Batch), including arsenic and arsenic compounds (Ministry of Ecology and Environment of the People's Republic of China 2017). To control the manufacturing and use of these chemicals, the Government will adopt one or several of the following risk management measures: Enterprises should obtain the sewage discharge permission before they discharge these chemicals; the State will restrict the use of these substances in some products and encourages enterprises to use substitutes; and a clean production audit will be implemented. | Ongoing |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Voluntary phase-out** | **US** | **Residential uses of chromated copper arsenate (CCA)** | In 2003, the US EPA and the largest industrial user of arsenic concluded a bilateral voluntary agreement for a voluntary phase-out of CCA in residential uses by the pressure-treated wood industry. As such, aggregate arsenic use has been lowered to pre-1920 levels (Hsueh 2013). | completed |
| | **US, Canada** | **Animal feeds** | Alpharma, a subsidiary of Pfizer, Inc., decided to voluntarily suspend sale of 3-Nitro® (i.e. Roxarsone) in 2011; ownership of the veterinary drug subsequently changed to Zoetis, Inc., which continued the suspension of sales of 3- Nitro®. In 2014, Zoetis voluntarily withdrew the new animal drug application for 3- Nitro®, as did Huvepharma AD. At the same time that the two companies voluntarily withdrew all new animal drug approvals and supplements for 3- Nitro®, they also withdrew arsanilic acid and carbarsone (two other arsenical new animal drugs) for use in animal feed (including all combinations with other approved new animal drugs). In 2015, Zoetis announced that it would discontinue marketing Histostat (nitarsone), the only remaining arsenic-based animal drug on the market and would request withdrawal of the approval for the drug by the end of that year. Histostat (nitarsone) ceased to be available in the 2016 growing season (United States Food and Drug Administration 2019). | completed |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **third-party standards and certification schemes** | **International** | | Arsenic is included in the bluesign® Restricted Substances List for a usage ban with the limit of trace of 0.2 mg/kg (Bluesign 2020). Similarly, arsenic is included in the Zero Discharge of Hazardous Chemicals (ZDHC) Manufacturing Restricted Substances List (ZDHC 2019).<br>Nordic Swan Ecolabel (a.k.a. Nordic Swan) criteria include the requirement that arsenic in the dye products used must not exceed the limit of 50 ppm (Nordic Ecolabelling 2019). | |
| **Monitoring** | **Australia** | **Foods** | Food Standards Australia New Zealand (FSANZ) regularly monitors levels of contaminants in a range of foods through the Australian Total Diet Study and targeted surveys (FSANZ 2020). | Ongoing |
| **Guidance and tools** | **International** | **drinking water** | In 2018, the United Nations Children's Fund (UNICEF), together with WHO, published a Guidance on the Investigation & Mitigation of Arsenic Contamination, including a module on understanding the problem, reducing exposure to arsenic in drinking water, and multi-sectoral responses to arsenic contamination (UNICEF and WHO 2018).<br>US EPA (2003) published a guidance document, *Arsenic Treatment Technology Evaluation Handbook for Small Systems*, aiming to help small drinking water systems make treatment decisions to comply with the revised arsenic rule in the US. | Ongoing |

# 2. Bisphenol A (BPA)

**Table B–2.1.** A comprehensive but not exhaustive overview of existing assessments of environmental and human effects of BPA by national governments and intergovernmental institutions since 2010.

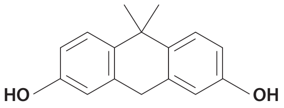
| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| EFSA (2015a) | Re-evaluation of the safety of BPA, based on the most recent experimental evidence | **Risks to public health related to BPA, particularly in foodstuffs** | (i) Literature review; (ii) exposure assessment (in three different ways: external, internal and aggregated); (iii) toxicological assessment and risk characterisation | • The estimated BPA dietary intake was highest in infants and toddlers, and the highest aggregated exposure from diet, dust, cosmetics and thermal paper was estimated for adolescents.<br>• A benchmark dose (BMDL10) of 8,960 µg/kg bw per day was calculated for changes in the mean relative kidney weight in a two-generation toxicity study in mice, and no BMDL10 could be calculated for mammary gland effects.<br>• A temporary Tolerable Daily Intake (t-TDI) of 4 µg/kg bw per day was established.<br>• By comparing the t-TDI with the exposure estimates for the European general public, there is no health concern for any age group from dietary exposure and low health concern from aggregated exposure.<br>• EFSA is currently working on a new assessment of the potential hazards of BPA in food and review of the t-TDI safe level. This new assessment should be ready by 2020. (See EFSA 2010 and the report from the Danish National Food Institute 2015, noted below in this table.) | Considerable uncertainty in the exposure estimate for non-dietary sources. |
| ECHA (2015b), EFSA (2015) | EU-wide restriction of BPA in thermal paper | **Risks for human health of fetuses exposed *in utero* in pregnant workers and pregnant consumers who handle thermal paper or other surfaces with BPA** | (i) Literature review;<br>(ii) hazard and exposure assessment | • Pregnant women's exposure to BPA might cause multiple effects on the health of fetuses, affecting their reproductive systems (for females), cholesterol (metabolism) and body weight, spatial memory and learning functions, as well as developing mammary glands. These different health outcomes may be expressed through very different forms, for example as an inconvenience due to more frequent menstruation, to more serious effects such as endometriosis, obesity or breast cancer, affecting individuals over their entire lifetimes.<br>• BPA in thermal paper migrates from the paper, especially from non-topcoated and non-protected "ecopaper", to cashiers' and consumers' fingers during handling. The BPA from thermal tickets or receipts also has been found on other objects with which they come into contact, such as banknotes or wallets. Reported measured exposures for cashiers and consumers could be from 1 to 11 µg in one handling event.<br>• Internal derived no-effect level (DNEL) by application of an assessment factor of 300 on the internal no observed adverse effect level (NOAEL): 1) 0.005 µg/kg/d for brain and behaviour, 2) 0.01µg/kg/d for female reproductive system, 3) 0.009 µg/kg/d for metabolism and obesity, 4) 0.0025 µg/kg/d for mammary gland. According to the results of the exposure calculations, the handling of thermal receipts leads to risk situations for the four types of effects considered, both for fetuses of pregnant women working as cashiers and tellers as well as for fetuses of pregnant consumers handling thermal receipts. | Health risks only assessed for a single target population: pregnant women and fetuses lack of good quality studies describing the effects of BPA on animals exposed exclusively as adults, young or prepubescent young |
| FSC (2010) | Food Sanitation Law (Japan) for packaging safety | **Tracking other countries' reviews of BPA** | | • There is no direct evidence that exposure to BPA affects human reproduction or development, but many findings have been reported suggesting that low-dose exposure to BPA affects reproduction, development, neurodevelopment, and immune systems in laboratory animals. The range of these effects might fall under the category of adaptation of organisms to effects that should be regarded as toxic; however, insufficient evidence has been reported for direct relationships between doses and responses, and some test results have not been easily replicated.<br>• Taking current findings into account, a possibility needs to be kept in mind that doses lower than the NOAEL of 5 mg/kg bw/day used by foreign government agencies can cause a mild effect in an animal study. | |

| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| US FDA (2014) | Update safety assessment of BPA | Safety of BPA at current levels of exposure in the US from food contact uses | Review of newly available toxicological and scientific studies | • Available pharmacokinetic data and comparisons between ages and species further support use of previously identified NOAEL of 5 mg/kg bw/day for systemic toxicity from subchronic/multigenerational studies as very conservative in extrapolating to humans.<br>• Exposure for infants and toddlers less than 2 years old is expected to decrease based on recent amendments to the food additive regulations. These no longer authorise the use of polycarbonate resins in infant feeding bottles and spill-proof cups designed to help train babies and toddlers to drink from cups (77 FR 41899, July 17, 2012), and BPA-based epoxy resins can no longer be used as coatings in packaging for infant formula (78 FR 41840, July 12, 2013). An increase in effective notifications for “BPA-free” materials including can coatings could also lead to lower exposures.<br>• Compared to the 90th percentile exposures cited above for populations of <2 years old and >2 years old, the margins of safety exceed the uncertainty factor of 1,000. The conclusion of this report is that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses in the US. | |
| EFSA (2010) | Assess the impact of literature in 2007–2010 on the TDI as set by EFSA in 2006; provide advice on the Danish risk assessment underlying the Danish ban of BPA in food contact materials for children aged 0-3 years | Human health risk assessment of BPA | Literature review of toxicological data published between 2007 and July 2010, mainly focusing on toxicokinetic, human and animal toxicity | • No new study could be identified, that would call for a revision of the current TDI, that is based on the NOAEL of 5 mg/kg bw per day from a multi-generation reproductive toxicity study in rats and the application of an uncertainty factor of 100.<br>• Some studies conducted on developing animals have suggested other BPA-related effects of possible toxicological relevance, in particular biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours. These studies had several shortcomings. At present the relevance of these findings for human health cannot be assessed. | |
| FAO/WHO (2011) | To assess the safety of BPA | Human health effects of BPA, with a focus on dietary exposure to low doses of BPA | Experts were selected from an open call according to expertise needed and taking regional and gender aspects in account. Drafters of the background papers in advance of the meeting were identified from the qualified experts. A stakeholder meeting was organised prior to the Expert Meeting. | • Studies on developmental and reproductive toxicity in which conventional end-points were evaluated have shown effects only at high doses, if at all, and at doses that are much higher than human exposure. Hence, there is no health concern for these end-points.<br>• However, some emerging new end-points (sex-specific neurodevelopment, anxiety, preneoplastic changes in mammary glands and prostate in rats, impaired sperm parameters) in a few studies show associations at lower levels.<br>- The points of departure for these low-dose effects are close to the estimated human exposure, so there would be potential for concern if their toxicological significance were to be confirmed.<br>- Interpreting these findings is difficult, taking into account all available kinetic data and current understanding of classical estrogenic activity. However, new studies indicate that BPA may also act through other mechanisms<br>- While it would be premature to conclude that these evaluations provide a realistic estimate of the human health risk, given the uncertainties, these findings should drive the direction of future research with the objective of reducing this uncertainty. | |
| Danish National Food Institute, DTU (2015) | Propose an alternative TDI | Endocrine-disrupting effects of BPA | | • The EFSA uncertainty evaluation is considered insufficient by the DTU. Based on that uncertainty, EFSA chose the extra factor of 6, leading to the use of 100 µg/kg bw/day as the basis for deriving the new EFSA t-TDI of 4 µg/kg bw/day.<br>• DTU has determined that 4 µg/kg bw/day is not sufficiently protective with regards to endocrine-disrupting effects of BPA. Instead, DTU has determined that a TDI for BPA must be 0.7 µg/kg bw/day or lower to be sufficiently protective with regards to endocrine disrupting effects of BPA. | |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| Australia (NICNAS 2019) | As part of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework | **Environmental impacts of BPA** | IMAP framework | • The main sources of emission to the environment are likely to be due to the use of BPA in PVC articles, and releases due to recycling of BPA-containing thermal paper.<br>• Monitoring of Australian surface waters and sewage treatment plant effluent indicates that BPA is present at levels that are generally below 200 ng/L.<br>• BPA is toxic, with adverse effects related to development identified at very low concentrations. Intergenerational exposure appears to cause an increased sensitivity to BPA-induced adverse effects in aquatic organisms (GHS classification: acute aquatic, H401; chronic aquatic, H410). In addition, BPA is an endocrine-active chemical, which may cause effects mediated through an endocrine-related mode of action.<br>• BPA is assessed as posing a marginal risk to the Australian riverine and marine environment at current exposure levels.<br>• It is recommended that BPA be added to the list of organic contaminants that are routinely monitored in sewage treatment effluent and surface waters in Australia.<br>• Further assessment may be required if reliable studies become available demonstrating adverse intergenerational effects of BPA on aquatic life at current exposure concentrations in the Australian environment. |  |
| ANSES (2011) | Summarise the effects on human health, identify practices leading to human exposure, characterise exposure, and assess the feasibility and relevance of conducting a health risk assessment | **Effects on the male/female reproductive system; brain and behaviour; metabolism and the cardiovascular system; thyroid, immune system, intestine, prostate and breasts** | Documents published by national and international expert assessment authorities | • The ANSES expert panel first considered the effects found to be "recognised" in animals (since no recognised effects have been identified in humans to date) and "suspected" in humans when undertaking the health risk assessment, as well as "controversial" where relevant, when undertaking the health risk assessment.<br>• The following recognised effects in animals were considered for the risk assessment: increased occurrence of ovarian cysts, hyperplastic modifications of the endometrium, early onset of puberty, altered sperm production, histological changes in neurogenesis, effects on lipogenesis, effects on the mammary gland (acceleration of the mammary gland's structural maturation in adulthood and development of intraductal hyperplastic lesions).<br>• The following suspected effects in humans were considered for the risk assessment: effects on oocyte maturation in females in infertile couples undergoing assisted reproductive technology, effects on cardiovascular diseases (coronary diseases) and diabetes. |  |
| Australia (NICNAS 2016) | As part of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework | **Human health risks of BPA** | IMAP framework | • The chemical is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) identified by Safe Work Australia: risk of serious damage to eyes (Xi; R37/41); may cause sensitisation by skin contact (Xi; R43); possible risk of impaired fertility (Xn; R62).<br>• The critical health effects for risk characterisation include systemic long-term effects of reproductive toxicity and general toxicity (liver and kidney effects), and local effects of skin sensitisation and eye and respiratory irritation.<br>• Food Standards Australia New Zealand (FSANZ 2010) concluded that Australians of all ages are exposed to extremely low levels (in the range of nanograms to micrograms per kilogram of food) of BPA via packaged foodstuffs.<br>• Given the critical systemic long-term and local health effects, the chemical could pose an unreasonable risk to workers without implementation of adequate control measures to minimise oral, dermal and ocular exposure. The chemical should be appropriately classified and labelled to ensure that a "person conducting a business or undertaking" (a worker) at a workplace (such as an employer) has adequate information to determine the appropriate controls. |  |

| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| ECHA (2016, 2017a,b) | Support document for identification as a substance of very high concern (SVHC) | **Environment and human health hazard assessment** | Literature review and expert meeting (Member States Committee of ECHA) | • ECHA noted that BPA should be considered an endocrine disruptor, according to OECD guidance and study results as of 2012, the WHO/IPCS definition, and recommendations by the European Commission's Endocrine Disruptor Expert Advisory Group in 2013 for a substance to be identified as an endocrine disruptor. Overall, BPA clearly disrupts steroid- (oestrogen) and thyroid-mediated processes in fish and amphibians respectively, leading to adverse effects on the organisms that can affect population stability and recruitment. Endocrine-mediated effects occur at lower concentrations than acute, systemic or narcotic toxicity.<br>• On the basis of evidence available in relation to alteration of reproductive function, mammary gland development, cognitive function and metabolism, BPA can be considered an endocrine disruptor for human health. It may also alter other physiological functions, e.g. immune function, through a similar endocrine-disrupting mechanism of action, but the level of evidence was considered insufficient at the time for this effect to be presented. All these endocrine-disrupting-related effects are characteristically (but not only) observed after developmental exposure to BPA, with consequences that are observed later in life, and often with serious health outcomes. In particular breast cancers, neurobehavioural disorders and diabetes are observed with high prevalence and increasing trends during the last decades in Europe and raise indisputable societal concern, also in relation to their potential economic burden on local health systems. Finally, for each of the four effects, the database shows important uncertainties in establishing a quantitative dose-response as well as safe levels, with some studies identifying effects at doses below the point of departure used by the ECHA Committee for Risk Assessment for DNEL derivation and ongoing discussions on the shape of the dose-response relationship and the parameters impacting the dose response (period of exposure and concomitant presence of estrogen in particular).<br>• BPA has a harmonised classification for the hazard class Reproductive Toxicity Category 1B (H360F, may damage fertility) based on effects on reproductive function. | |

**Table B-2.2.** Supporting information on the life cycle of and exposure to BPA, as well as examples of cost-of-inaction and benefits-of-action information.

| **Chemical name(s)** | **Bisphenol A** |
|---|---|
| **IUPAC name** | 4,4'-(propane-2,2-diyl)diphenol |
| **Other name(s)** | BPA, p,p'-Isopropylidenebisphenol, 2,2-Bis(4-hydroxyphenyl)propane |
| **CAS number(s)** | 80-05-7 |
| **Chemical formula** | $C_{15}H_{16}O_2$ |
| **Chemical structure** |  |
| **Production information** | |
| **Production** | BPA is produced synthetically via a reaction of phenol with acetone in the presence of a strongly acidic ion exchange resin which acts as a catalyst. It is usually also produced with a promoter such as methyl mercaptan. BPA is then washed with water and neutralised with calcium hydroxide before being distilled under a vacuum. Newer production processes purify the BPA by carrying out distillation and extractive crystallisation under pressure. There are two grades of BPA – one which is suitable for the manufacturing of epoxy resins, the other higher purity grade BPA can be used in polycarbonate production (ICIS 2007, Fischer *et al.* 2014, Mikołajewska *et al.* 2015). |
| **Key producers** | Based on a non-verified market report, global BPA production is highly consolidated, with up to five companies dominating. These include DuPont, Mitsui Chemical Inc, SABIC Innovative Plastics, LG Chem Ltd and Covestro AG (Mordor Intelligence 2020). Based on the 2013 data from another non-verified market report, the top five BPA producing countries are the US, South Korea, Taiwan, China and Japan (Merchant Research and Consulting LTD. 2013). |
| **Geographic distribution** | Available non-verified market data for 2013 indicates Asia Pacific accounted for over half of global supply, followed by Europe for a quarter and North America, about one fifth (Merchant Research and Consulting LTD. 2013). |
| **Production volumes and global trends** | • Around 1 million tonnes of BPA were produced each year in the US in the early 2000s – with an approximate value of $2 billion (Allard 2014). In Europe, BPA is produced in Germany, the Netherlands, Belgium and Spain. Based on an estimate of the registration dossiers submitted to ECHA, the total amount of BPA manufactured in the EU in 2011 is between 1 and 10 million tonnes per year (Fischer *et al.* 2014). Currently, BPA is registered under REACH with an annual volume of 0.1-1 million tonnes in the EU (ECHAb 2019). China's production is estimated to have drastically increased after 2009, from 48,000 tonnes in 2009 to 745,000 tonnes in 2014 (Jiang *et al.* 2018; see the supporting material).<br>• Current annual production volumes of BPA analogues are projected to increase, in comparison to BPA. For example, for current estimates for BPS, production is 500–5,000 tonnes in the US (United States Environmental Protection Agency [US EPA] 2012), 10,000–100,000 tonnes in Europe (ECHA 2019b) and about 2,000 tonnes in Japan (CMC 2016), and BPF, about 160 tonnes in the US (US EPA 2012) and about 4,000 tonnes in Japan (CMC 2017). |
| **End-of-life information** | |
| **End-of-life** | • Pivnenko *et al.* (2015) measured waste paper and board from households in a municipality in Southern Denmark. BPA was measured in all analysed waste paper samples. As BPA is only used for a limited range of paper products (i.e. thermal paper), this suggests potential spreading of BPA through recycling of secondary waste paper. In a follow up study, Pivnenko *et al.* (2018) modelled the flows of BPA use in thermal paper in the EU and estimated that more than 90 tonnes of BPA would be in paper even after 60 years.<br>• Chi *et al.* (2017) reported that the repeated melting of polycarbonate during recycling fractures the molecular chains, leading to increased degradation of polycarbonate macromolecules and increased release of free BPA.<br>• Arp *et al.* (2017) conducted a material flow analysis for several waste categories in Norway in 2011. Combined, 92 tonnes per year of BPA are disposed of via glass, vehicle, electronic, plastic and combustible waste in Norway, with 98.5% associated with plastic and electronic waste. During the model year 2011, the researchers showed that BPA in these waste categories was destroyed through incineration (60%), exported for recycling into new products (35%), stored in landfills (4%) or released into the environment (1%). Landfilling led to the greatest environmental emissions (up to 13% of landfilled BPA), and incinerating the smallest (0.001% of incinerated BPA).<br>• In China, optical media (DVD/VCD/CDs) are the largest contributor to China's current end-of-life BPA flow, totaling 0.9 million tonnes per year. However, the end-of-life BPA flow due to e-waste is projected to increase quickly and will soon become the largest end-of-life BPA flow in China. The changing quantities and sources of such flows may require a shift in the larger-scale BPA management strategies (Jiang *et al.* 2018).<br>• Dreolin *et al.* (2019) reported on the analysis of BPA in virgin and recycled polyethylene terephthalate (PET). The results of the study showed significantly higher levels of BPA in recycled PET, which is likely linked to the recycling process, indicating that BPA levels should be monitored in recycled plastics. |

| Use information | |
|---|---|
| **Key uses/applications** | BPA is a monomer used in the production of polycarbonates, epoxy resins and other polymers (Fischer *et al.* 2014, Mikołajewska *et al.* 2015). Globally and in China, over 90% of the BPA monomers are used to synthesize polycarbonates and epoxy resins (PlasticsEurope 2020, Jiang *et al.* 2018).<br>• Polycarbonates: Due to its high strength over a wide range of temperatures, its resistance to acids and high optical clarity, polycarbonates are used extensively in applications for bottles (including baby bottles) and food packaging materials, in building and construction and automotive applications and household appliances. They are also used in the production of polymers for medical devices (e.g. in surgical instruments drug delivery systems, and hemodialysis membranes), domestic electronics (e.g. in circuit breakers, electrical housing, lighting applications, domestic switches, plugs and sockets, and battery packaging material; Carlisle *et al.* 2009, Liao and Kannan 2011, Mendum *et al.* 2011). Polycarbonates produced from BPA are also used as substituents for glass in applications where weight is a key factor (e.g. energy efficiency of cars; Fischer *et al.* 2014). They accounted for nearly 64% of global BPA demand in 2018 (IHS Markit 2018).<br>• Epoxy resins: Epoxy resins are the second largest use for BPA in the EU and it is estimated that 90% of world epoxy production is produced from BPA (Fischer *et al.* 2014). Desired properties include chemical resistance, heat resistance, adhesion and thermal stability. They are widely used as coatings including food and drink cans, protective coatings for cars and marine uses, laminates, adhesives as well as water infrastructure (pipes, tubes and associated fittings; Fischer *et al.* 2014, Mikołajewska *et al.* 2015). They accounted for nearly 30% of total BPA use (PlasticsEurope 2020).<br>• Other polymers: BPA is also used in the production of a range of other polymers and resins such as phenoplast resins, phenolic resins, unsaturated polyesters and formaldehyde resins. Formaldehyde resins are used for paper impregnation and wood fibre coatings to make high pressure laminated materials used for parts in electrical applications (e.g. electronics, aviation and antifriction parts in construction/insulation) (Fischer *et al.* 2014).<br>• Other uses include as a reagent for the manufacture of flame retardants (ECHA 2015, IHS Markit 2018), including tetrabromobisphenol A (TBBPA), tetrachlorobisphenol A (TCBPA) and BPA bis(diphenyl phosphate) (BDP); ink developers on thermal paper receipts to trigger colour formation in the paper when exposed to heat; antioxidant in the manufacture of tyres, brake fluids and hydraulic fluids for processing PVC; and others.<br>• The use of thermal paper in the EU in 2018 amounted 491,000 tonnes (332,000 tonnes from members of the European Thermal Paper Association, whereas the rest from China, India, Japan, Korea and the US); the share of BPA-based thermal paper was 48% and the share of BPS-based paper was 21%. 3,304 tonnes BPA and 1,476 tonnes BPS were estimated to be used in thermal paper on the EU market in 2018 (ECHA 2019a). |
| **Key markets** | • Northeast Asia accounts for half of global BPA consumption and more than half of global production capacity as of 2018. Within Northeast Asia, China accounts for almost 50% of regional BPA consumption in 2018. China is also projected to be one of the fastest-growing regions for consumption of BPA over the next five years through 2023 (IHS Markit 2018). In China, the BPA consumption has increased 10-fold since 2000, to ca. 3 million tonnes/year. With increasing consumption, China's in-use BPA stock has increased 500-fold to 14 million tonnes (i.e., 10.2 kg BPA/capita). Electronic products are the biggest contributor, responsible for roughly one-third of China's in-use BPA stock (Jiang *et al.* 2018).<br>• The Indian subcontinent is forecast to see the largest increase in BPA demand, with an average annual growth rate of almost 30% during the same period; this is mostly due to hypothetical polycarbonate capacity starting up in 2023 (IHS Markit 2018).<br>• Western Europe and the US are the other significant BPA markets; however, both are expected to see declining demand during the forecast period. Over the past five years, total BPA consumption grew at an average annual rate of 2.5%. Global BPA consumption is projected to increase at an average annual rate of 3.6% per year through the forecast period to 2023 (IHS Markit 2018). |
| **Exposure information** | |
| **Main exposure sources and pathways** | • Exposure is primarily via diet and by contact with food (Mikołajewska *et al.* 2015, US EPA 2017, ECHA 2017a). BPA has been widely used in common products such as baby bottles, household electronics, medical devices and coatings on food containers and cans. It has been found to leach from these materials, leaving users exposed to its effects (ECHA 2017a). For example, Hartle *et al.* (2016) illustrated that the consumption of even small amounts of canned foods is associated with higher urinary BPA concentrations.<br>• BPA exposure may also be caused by environmental pollution (dust, air, drinking water, leachate from landfills) via ingestion, inhalation or dermal contact (Mikołajewska *et al.* 2015). Children playing on the floor and frequently putting their hands into their mouths are at heightened risk (Christensen *et al.* 2012).<br>• Quantitative exposure data are lacking in low- and middle-income countries and limited action has been taken in Africa, Southeast Asia, India and South and Central America (Baluka and Rumbeiha 2016).<br>• US research indicates socioeconomic differences in exposure. As part of the ACE (America's Children & Environment) Biomonitoring Programme for the US EPA, from 2009–2012, median concentrations of BPA in the urine of black non-Hispanic women was higher than other race/ethnicity groups. Women living below the poverty line also had higher concentrations of BPA in their urine (US EPA 2017).<br>• Incubation experiments confirmed that TBBPA could be transformed into BPA. Once released, BPA could accumulate in waterlogged paddy soils, explaining why BPA levels were higher than the levels of the parent compound (TBBPA) in the Longtang area of China (Huang *et al.* 2014). |

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|---|---|
| **Foreseeable global trends** | The risks in developing and developed nations to BPA exposure are judged to be similar due to increasing adoption of dietary habits reliant on canned foods and packaged meals and the increased use of packaged baby formulas. However, data on the exposure to compounds such as BPA remains poorly studied in "developing countries" (emerging and transition economies), despite the risks associated with BPA exposure. Biomonitoring data is required to evaluate exposure and changes over time (Baluka and Rumbeiha 2016). Furthermore, no legislation currently restricts the use of BPA in food packaging in Africa, India and Southeast Asia. As such, further growth of markets for packaged baby formulas and other foodstuffs in developing nations may increase human exposure to BPA (Baluka and Rumbeiha 2016, Parkur and Rakesh 2017). |
| **Examples of costs-of-inaction and benefits-of-action information** | |
| **Costs of inaction** | • In the US, according to Trasande (2014), BPA exposure was linked to an estimated 124,040 cases of childhood obesity and 33,863 cases of coronary heart disease per year in 2008, with costs of around $2.98 billion. Trasande (2014) estimated that elimination of BPA from food uses could prevent 6,236 cases of childhood obesity and 22,350 new cases of coronary heart disease with potential annual economic benefits of $1.74 billion in the US. |
| **Benefits of action** | • There is limited economic evidence on the benefits of action for BPA. Biomarker evidence suggests that BPA levels in people have decreased concurrent with regulatory action. In Germany, this has been demonstrated for urinary BPA, for example. While not necessarily representative of Europe as a whole, data show sustained and significant decreases for BPA over time of around 36% from 1995–2004 (European Commission 2017).<br>• In 2015, ECHA conducted a socioeconomic assessment study weighing the costs and benefits of restricting BPA in thermal paper. The study concluded the "benefits were unlikely to be higher than the costs of restriction". However, it was noted that a relatively small, low-income population were at risk (cashiers dealing with thermal paper receipts), while the costs of the restriction would be spread across all EU citizens and as such, would be affordable – amounting to only €0.20–€0.60 per person per year (ECHA 2015). |

**Table B–2.3.** Examples of measurements of BPA in the environment, biota and humans across the globe.

| Medium | Asia & Pacific | Africa | CEE | North America | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|---|
| **Air** | Japan (Ministry of the Environment (MOE) 2013), Hong Kong (Deng *et al.* 2018), New Zealand (Fu and Kawamura 2010) | | | US (Graziani *et al.*2019, Xue *et al.* 2016, Ferrey *et al.* 2018) | Argentina (Graziani, Carreras, and Wannaz 2019) | Norway (Morin, Arp, and Hale 2015) | |
| **Rain** | | Nigeria (Ignatius *et al.* 2010; E. Inam *et al.* 2015) | | USA (M. L. Ferrey *et al.* 2018) | | France (Gasperi *et al.* 2014) | |
| **Snow** | | | Germany (Prieto, Schrader, and Moeder 2010) | USA (M. L. Ferrey *et al.* 2018) | | | |
| **Fresh water** | Japan (Yamazaki *et al.* 2015; Ministry of the Environment (MOE) 2016), Korea (Yamazaki *et al.* 2015), China (Yamazaki *et al.* 2015; Yang *et al.* 2014), India (Yamazaki *et al.* 2015) | South Africa (Wanda *et al.* 2017), Nigeria (Ignatius *et al.* 2010; E. Inam *et al.* 2015; E. J. Inam *et al.* 2019) | Bulgaria, Croatia, Czech Republic, Hungary, Romania, Serbia, Slovakia (NORMAN Association, n.d.), Czech Republic (Matějíček, Grycová, and Vlček 2013; Matějíček 2012; Zounkova *et al.* 2014), Germany to Romania and Ukraine (Loos, Locoro, and Contini 2010), Hungary (Faludi *et al.* 2015) | Canada (Jeffries *et al.* 2008; 2010; 'Survey of the Occurrence of Pharmaceuticals and Other Emerging Contaminants in Untreated Source and Finished Drinking Water in Ontario \| ODW GovDocs' n.d.; Kleywegt *et al.* 2011), USA (Barber *et al.* 2011; 2013; 2015; Karalius *et al.* 2014; Kassotis *et al.* 2015; Guo *et al.* 2007; K. E. Lee *et al.* 2011; Martinovic-Weigelt *et al.* 2013; Minarik *et al.* 2014; Renz *et al.* 2013; Schultz *et al.* 2013; Shala and Foster 2010; Sidhu, Wilson, and O'Connor 2015; Singh *et al.* 2010; Subedi *et al.* 2015; Vajda *et al.* 2011; G. Wang *et al.* 2012; Writer *et al.* 2010) | Jamaica (Karalius *et al.* 2014), Mexico (Félix-Cañedo, Durán-Álvarez, and Jiménez-Cisneros 2013; Díaz-Torres *et al.* 2013) | Austria, France, Germany, Italy, Netherlands, Sweden (NORMAN Association, n.d.), Denmark (Matamoros *et al.* 2012), France (Mathieu Cladière *et al.* 2013; M. Cladière *et al.* 2010; Colin *et al.* 2014; Dupuis *et al.* 2012; Gust *et al.* 2014; Tran *et al.* 2015), Germany (Dsikowitzky *et al.* 2015; Andreas Musolff *et al.* 2009; A. Musolff *et al.* 2010; Bundesanstalt für Gewässerkunde International Commision for the Protection of the Rhine (ICPR), n.d.), Greece (Arditsoglou and Voutsa 2010; 2008; Stasinakis *et al.* 2012), Portugal (Carvalho *et al.* 2015; Jonkers *et al.* 2010; M. J. Rocha *et al.* 2012; 2013; M. J. Rocha, Cruzeiro, and Rocha 2013; M. J. Rocha, Cruzeiro, Reis, *et al.* 2014; Salgueiro-González *et al.* 2015), Spain ((Azzouz and Ballesteros 2014; Calderón-Preciado *et al.* 2011; Carmona, Andreu, and Picó 2014; Esteban *et al.* 2014; Gorga, Petrovic, and Barceló 2013; Gorga *et al.* 2015; Banjac *et al.* 2015; Herrero-Hernández *et al.* 2013; Huerta *et al.* 2015; 2016; Ruhí *et al.* 2016; Martínez *et al.* 2013; Rivetti *et al.* 2015; Salgueiro-González *et al.* 2015; Sánchez-Avila *et al.* 2011) | |
| **Freshwater biota** | Japan (Ministry of the Environment (MOE) 2016), China (Yang *et al.* 2014) | | | | | France (Miège *et al.* 2012) | |
| **Soil** | China (D.-Y. Huang *et al.* 2014) | | | | | | |
| **Vegetation** | | | | | | France (Bemrah *et al.* 2014) | |

| Medium | Asia & Pacific | Africa | CEE | North America | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|---|
| **Fresh water sediment** | Japan (Ministry of the Environment (MOE) 2016), China (Yang *et al.* 2014), Korea (Liao, Liu, Moon, *et al.* 2012) | Nigeria (E. J. Inam *et al.* 2019) | Czech Republic (Matějíček, Grycová, and Vlček 2013), Hungary, Romania, Serbia, Slovakia (NORMAN Association, n.d.) | Canada (Lu *et al.* 2015; Chu, Haffner, and Letcher 2005), USA (Dong *et al.* 2015; M. Ferrey *et al.* 2010; Writer *et al.* 2010; Nilsen *et al.* 2015; Liao, Liu, Moon, *et al.* 2012; Lu *et al.* 2015; Chu, Haffner, and Letcher 2005) | | Austria, France, Spain, Sweden (NORMAN Association, n.d.), France (Kinani *et al.* 2008; 2010; Vulliet *et al.* 2014), Germany (Grund *et al.* 2011), Norway (Thomas *et al.* 2014), Portugal/Spain (Salgueiro-González *et al.* 2015), Spain (Gorga *et al.* 2015; 2014; Guerra, Eljarrat, and Barceló 2010; López-Jiménez, Rosales-Marcano, and Rubio 2013) | |
| **Marine water (incl. sea ice)** | Japan (Yamazaki *et al.* 2015; Ministry of the Environment (MOE) 2016) | | | Canada (Keil *et al.* 2011), USA (Keil *et al.* 2011; Singh *et al.* 2010; Vidal-Dorsch *et al.* 2012; G. Wang *et al.* 2012) | | Poland (Staniszewska *et al.* 2014), Greece (Arditsoglou and Voutsa 2012), Portugal (Jonkers *et al.* 2010; M. J. Rocha *et al.* 2011; 2012; M. J. Rocha, Cruzeiro, and Rocha 2013; M. J. Rocha *et al.* 2013; S. Rocha *et al.* 2013; M. J. Rocha, Cruzeiro, Reis, *et al.* 2014; M. J. Rocha, Cruzeiro, Peixoto, *et al.* 2014; M. J. Rocha *et al.* 2015; Salgueiro-González *et al.* 2015; Jonkers *et al.* 2010), Spain (Martínez *et al.* 2013; S. Rocha *et al.* 2013; Salgueiro-González, Turnes-Carou, *et al.* 2012; Salgueiro-González *et al.* 2015; Sánchez-Avila *et al.* 2011; Sánchez-Avila, Tauler, and Lacorte 2012; Sánchez-Avila *et al.* 2013; de los Ríos *et al.* 2012) | Erebus Bay, Antarctica (Emnet *et al.* 2015) |
| **Marine sediment** | Japan (Liao, Liu, Moon, *et al.* 2012; Ministry of the Environment (MOE) 2016) | | | USA (G. Wang *et al.* 2012) | | France (Vulliet *et al.* 2014), Greece (Arditsoglou and Voutsa 2012), Italy (Casatta *et al.* 2015), Norway (Ruus *et al.* 2014; Thomas *et al.* 2014), Spain (de los Ríos *et al.* 2012; Puy-Azurmendi *et al.* 2013; Salgueiro-González *et al.* 2014) | ☒ |
| **Sea ice** | | | | | | | Erebus Bay, Antarctica (Emnet *et al.* 2015) |
| **Drinking water** | | South Africa (Van Zijl *et al.* 2017), Nigeria (Ignatius *et al.* 2010) | | | | | |
| **Marine biota** | Japan (Ministry of the Environment (MOE) 2016) | Morroco (Azzouz *et al.* 2019) | | | | Spain (Álvarez-Muñoz *et al.* 2019; Salgueiro-González, Concha-Graña, *et al.* 2012), Greece (Gatidou, Vassalou, and Thomaidis 2010) | |
| **Sludge/ biosolids** | Korea (S. Lee *et al.* 2015), China (Song *et al.* 2014; Pang *et al.* 2019), Australia (Langdon *et al.* 2012) | South Africa (Olujimi *et al.* 2013) | | USA (Xue and Kannan 2019; Yu *et al.* 2015) | Mexico (Gibson *et al.* 2010) | UK (Petrie *et al.* 2019) | |

| Medium | Asia & Pacific | Africa | CEE | North America | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|---|
| **WWTP influents/ effluents** | Korea (S. Lee *et al.* 2015), China (L. Y. Wang, Zhang, and Tam 2010) | South Africa (Wanda *et al.* 2017), Nigeria (Olujimi *et al.* 2017) | Slovenia (Česen *et al.* 2018), Poland (Wilk *et al.* 2019) | USA (Xue and Kannan 2019) | Brazil (Queiroz *et al.* 2012) | Austria (Clara *et al.* 2012), UK (Petrie *et al.* 2019) | Erebus Bay, Antarctica (Emnet *et al.* 2015) |
| **Dust** | China, Japan, Korea (Liao, Liu, Guo, *et al.* 2012; W. Wang *et al.* 2015), India, Kuwait, Pakistan, Saudi Arabia, Vietnam (W. Wang *et al.* 2015) | | Romania (W. Wang *et al.* 2015) | USA (W. Wang *et al.* 2015; Liao, Liu, Guo, *et al.* 2012) | Colombia (W. Wang *et al.* 2015) | Greece (W. Wang *et al.* 2015) | |
| **General population** | Australia (Callan *et al.* 2013; Heffernan *et al.* 2013; 2014; 2016), China (M. Chen *et al.* 2012; X. Chen *et al.* 2013; M. Chen *et al.* 2013; Engel *et al.* 2014; Huo *et al.* 2015; T. Zhang *et al.* 2016; Perera *et al.* 2012), Korea (K. Kim *et al.* 2011; Hong *et al.* 2013; Choi *et al.* 2014; M. Chen *et al.* 2012; Ha *et al.* 2014) | South Africa (Gounden *et al.* 2019), Cameroon (Manfo *et al.* 2019) | Israel (Berman *et al.* 2014), Germany (Kasper-Sonnenberg *et al.* 2012; 2014; Koch *et al.* 2012), Slovenia (Covaci *et al.* 2015) | Canada (Arbuckle *et al.* 2014; 2015; Kubwabo *et al.* 2014; Health Canada 2015), USA (Braun *et al.* 2012; *Fourth National Report on Human Exposure to Environmental Chemicals* 2014; Harley *et al.* 2013; Hoepner *et al.* 2013; Buck Louis *et al.* 2014; Evans *et al.* 2014; D. E. Cantonwine *et al.* 2015; Cox *et al.* 2016; Braun *et al.* 2011) | Jamaica (Karalius *et al.* 2014), Mexico (D. Cantonwine *et al.* 2010; Ferguson *et al.* 2014; 2014) | Spain (Martín *et al.* 2019), Belgium (Geens *et al.* 2014; 2015), Cyprus (Kalyvas *et al.* 2014; Andra and Makris 2015), Denmark (Frederiksen *et al.* 2013; 2014), France (Harthé *et al.* 2012), Italy (Galloway *et al.* 2010), Norway (Guidry *et al.* 2015), Portugal (Cunha and Fernandes 2010), Spain (L. Casas *et al.* 2011; M. Casas *et al.* 2013; Cunha and Fernandes 2010; Cutanda *et al.* 2015), Sweden (Larsson *et al.* 2014) | |
| **Thermal Paper** | Japan, Korea, Vietnam (Liao and Kannan 2011; Liao, Liu, and Kannan 2012), South Korea, Thailand ((Vervliet *et al.* 2019) | | Germany, Slovenia, Romania (Vervliet *et al.* 2019) | USA (Liao and Kannan 2011; Liao, Liu, and Kannan 2012; Vervliet *et al.* 2019), Canada (Vervliet *et al.* 2019) | | Sweden (Björnsdotter *et al.* 2017), Switzerland (Goldinger *et al.* 2015; Vervliet *et al.* 2019), Austria, France, Luxemburg, Netherlands, Norway, Spain, UK (Vervliet *et al.* 2019; Björnsdotter *et al.* 2017), Belgium (Vervliet *et al.* 2019; Geens, Goeyens, *et al.* 2012) | |
| **Vulnerable population** | China (Ning *et al.* 2011; Z. Zhang *et al.* 2011; G. Wang *et al.* 2012; X. Li *et al.* 2013; D.-K. Li *et al.* 2013; Ning *et al.* 2011; L. Shen *et al.* 2013; Tang *et al.* 2013; T. Zhang, Sun, and Kannan 2013; L. Liu *et al.* 2014; Yueping Shen *et al.* 2015; M. Zhang *et al.* 2015; C. Liu *et al.* 2016; Yang Shen *et al.* 2016; I.-J. Wang, Chen, and Bornehag 2016; T. Zhang *et al.* 2016), Korea (H. A. Lee *et al.* 2013; B.-E. Lee *et al.* 2014; K. Kim *et al.* 2011; J.-H. Park *et al.* 2016), India (Z. Zhang *et al.* 2011; Xue *et al.* 2015), Japan, Kuwait, Malaysia, Vietnam (Z. Zhang *et al.* 2011) | South Africa (Gounden *et al.* 2019), Egypt (Nahar *et al.* 2012; Youssef *et al.* 2018), Ghana (Karalius *et al.* 2014), Tunisia (Jiménez-Díaz *et al.* 2016) | Germany (Völkel, Kiranoglu, and Fromme 2011; Moos *et al.* 2014) | Canada (Health Canada 2015), USA (Meeker, Calafat, and Hauser 2010; Mendiola *et al.* 2010; Wolff *et al.* 2010; Morgan *et al.* 2011; Martina, Weiss, and Swan 2012; Perera *et al.* 2012; Nachman *et al.* 2013; Philippat *et al.* 2013; Quirós-Alcalá *et al.* 2013; Robledo *et al.* 2013; Mendonca *et al.* 2014; Mortensen *et al.* 2014; Upson *et al.* 2014; Vagi *et al.* 2014; Nachman *et al.* 2015; Ye *et al.* 2015; Nomura, Harnack, and Robien 2016; Teeguarden *et al.* 2016; Waldman *et al.* 2016; X. Zhou *et al.* 2014) | Mexico (Lewis *et al.* 2013; Watkins *et al.* 2014), Brazil (B. A. Rocha *et al.* 2016), Puerto Rico (Meeker *et al.* 2013) | Belgium (Pirard *et al.* 2012), Denmark (Tefre de Renzy-Martin *et al.* 2014), France (Vandentorren *et al.* 2011; Philippat *et al.* 2012; 2014; Ndaw *et al.* 2016), Italy (Melzer *et al.* 2011; Nicolucci *et al.* 2013), Spain (Perez-Lobato *et al.* 2016), Sweden (Lind and Lind 2011; Larsson *et al.* 2014), Finland (Porras, Heinälä, and Santonen 2014), Greece (Myridakis, Fthenou, *et al.* 2015; Myridakis, Balaska, *et al.* 2015; Myridakis *et al.* 2016), Netherlands (Snijder *et al.* 2013), UK (Melzer, Osborne, *et al.* 2012; Melzer, Gates, *et al.* 2012) | |

**Table B–2.4.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of BPA.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Legally binding instruments** | | | | |
| Ban / restrictions | EU-wide | **Polycarbonate bottles** | • A ban on the use of BPA in polycarbonate infant feeding bottles, and in polycarbonate drinking bottles or cups for infants and young children (European Commission 2011b).<br>• The specific migration limit for BPA from varnishes or coatings applied to materials and articles is 0.05 mg/kg of food (European Commission 2018). | In force |
| | | **Thermal paper** | A **restriction** on the placing on the market of BPA in thermal paper in a concentration equal to or greater than 0.02 % by weight (European Commission 2011a). | In force |
| | | **Toy materials** | The **migration limit** for BPA from toy materials is 0.04 mg/L (European Commission 2016). | In force |
| | | **Cosmetics** | BPA is listed on Annex II of the EU Cosmetics Directive, prohibiting its use in cosmetics in the EU (2019). | In force |
| | France, Denmark, Belgium, Sweden | **Food packaging, containers and utensils** | A **ban** on the use of BPA in all food packaging, containers and utensils. The bans in Denmark, Belgium and Sweden specifically refer to those materials intended to come into contact with food for 0-3 year olds (Danish EPA 2014). | In force |
| | Canada | **Cosmetic ingredients** | A **ban** on the use of BPA in cosmetic products as ingredients (Health Canada 2019). | In force |
| | | **Polycarbonate baby bottles** | A **ban** on manufacturing, advertisement, sale or import of polycarbonate baby bottles that contain BPA (Government of Canada 2018). | In force |
| | National (e.g. China, South Africa, Malaysia, Argentina, Brazil) | **Polycarbonate baby bottles** | • A ban on the production, import and sale of infant nursing bottles containing BPA (Ministry of Health Malaysia 2011TK, ANMATM 2012, ANVISA 2011).<br>• The provisions in South Africa also prohibit the export of infant bottles containing BPA (South Africa Government 2011).<br>• http://www.chinadaily.com.cn/china/2011-06/01/content_12616422.htm | In force |
| | ASEAN | **Cosmetics** | BPA is on the ASEAN Cosmetic Directive Annex II Part 1. BPA may not form part of cosmetic products in ASEAN countries (ASEAN 2019). | In force |
| | Colombia | **Use in products in contact with food and drinks** | Bans use of BPA in products in contact with food and drinks (MSPS 2012). | In force |
| | Eurasian Economic Union | **Cosmetics** | Adopted technical regulation TR CU 009/2011 “on safety of perfumery and cosmetic products”, which forbids the use of BPA in perfumes and cosmetics | In force |
| Marketing authorisation | EU | **Non-polymer applications** | ECHA (2019) has made a recommendation that BPA be added to Annex XIV (the Authorisation list), which would require industry to seek authorisation for use of BPA in non-polymer applications. | In process |
| Notification | EU | **All uses under reach** | BPA is identified as a SVHC due to its endocrine-disrupting properties for human health and the environment, and for its reproductive toxicity (ECHA 2017c). Manufacturers and importers thus have legal obligations to provide sufficient information to allow safe use of the article containing BPA. | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Mandatory standards** | **India** | **Baby bottles** | Section 11(2) of The Infant Milk Substitutes, Feeding Bottle and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992, states that 'No person shall sell or otherwise distribute any feeding bottle unless it conforms to the Standard Mark specified by the Bureau of Indian Standards referred to in sub-section (1) for feeding bottles and such mark is affixed on its container'. The Act has been subsequently amended as The Infant Milk Substitute, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 2003. Section 2(c) of this Act defines the feeding bottles (see 3.3.1.1). In this (first) revision, use of polycarbonate as a material for manufacturing infant feeding bottles have been deleted in view of reports on BPA and olefin-based polymers as material for manufacture of feeding bottles have been included (Bureau of Indian Standards 2015). The materials used should be of no health hazards to babies and shall not contain BPA. | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Guidelines** | **Canada** | **Environmental levels** | Canadian federal environmental quality guidelines for BPA were released in 2018. These included a water concentration of 3.5 µg/L, sediment concentration of 25 µg/kg dry weight, and dietary concentrations of 660 µg/kg wet weight of food for mammalian wildlife and 110 µg/kg wet weight for food for avian wildlife (Environment and Climate Change Canada 2018). | |
| | **Australia** | **Drinking water** | BPA concentrations in recycled water for drinking water augmentation are recommended to not exceed 200 µg/L (Environment Protection and Heritage Council *et al.* 2008). This guideline was derived from a tolerable daily intake value of 0.05 mg/kg body-weight per day. | |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Voluntary industry phase-out** | **Canada** | **Packaging for liquid infant formula** | The Food Directorate's Bureau of Chemical Safety confirmed that industry has abandoned or phased out the use of BPA-containing packaging for liquid infant formula (Health Canada 2014). | |
| | **US** | **Baby bottles; packaging for liquid infant formula** | In July 2012, the US FDA amended the food additive regulations to no longer provide for the use of polycarbonate resins in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups) because these uses have been abandoned (US FDA 2012).<br>In July 2013, the US FDA amended the food additive regulations to no longer provide for the use of BPA-based epoxy resins as coatings in packaging for infant formula because these uses have been abandoned (US FDA 2013). | |
| | **Australia** | **Baby bottles, food packaging** | In June 2010, the Australian Government announced the voluntary phase-out by major Australian retailers of polycarbonate plastic baby bottles containing BPA. A 2016 monitoring campaign found little or no BPA in food samples in plastic packaging (FSANZ 2019). | Completed |
| **Voluntary standards** | **Japan** | **Metal cans for food and drinks** | The Can Manufacturers Institute of Japan has drawn up guidelines that specify the elution limits of 0.005 µg/mL and 0.01µg/mL for beverage cans and general food cans manufactured in Japan, respectively (Kawamura 2013). | |

# 3. Cadmium

**Table B–3.1.** Supporting information on the life cycle of and exposure to cadmium, as well as examples of cost-of-inaction and benefits-of-action information

| Chemical name, CAS number, and molecular formula | Cadmium (Cd), 7440-43-9. For chemical names, CAS numbers and molecular formulas of other cadmium compounds (IARC 2012). |
|---|---|
| **Production information** | |
| **Production overview** | Primary cadmium is produced as a byproduct from mining, smelting and refining of sulphide ores of zinc. It can also be found in zinc-bearing lead ores, as well as complex copper-lead-zinc ores (Nordic Council of Ministers 2003; Achternbosch *et al.* 2009). Secondary cadmium can be recovered from products such as recycled NiCd batteries (Plachy 2003). |
| **Key producers** | A total of 19 countries outside the US contained the 32 major primary cadmium production facilities in 2017 (United States Geological Survey [USGS] 2019a). Of 32 major primary cadmium production facilities outside the US in 2017, 6 are in China (USGS 2019a), 4 in Japan (USGS 2019a) and 2 each in Canada, India, Republic of Korea, Mexico and Russia (USGS 2019a). |
| **Geographic distribution** | The global refinery production of cadmium in 2017 (excluding the US because proprietary data are not available) was around 25,400 tonnes, with China as the world's largest producer (estimated 8,200 tonnes) followed by the Republic of Korea (estimated 5,600 tonnes), Japan (2,142 tonnes) and Canada (1,800 tonnes; USGS 2019b). US production of cadmium was reported to be 550 tonnes in 2017 (Brown *et al.* 2019). |
| **Production volumes and global trends** | World production of cadmium has been fairly constant with a slight increase over the last 10-20 years. The British Geological Society reported that 19,600 tonnes were produced globally in 2000 (British Geological Survey [BGS] 2002), 21,100 tonnes in 2006 (BGS 2008) and 22,100 tonnes in 2012 (Brown *et al.* 2018). Production in 2018 was estimated to increase to 26,000 tonnes (excluding the US), with growth expected in the Netherlands, Mexico, Peru and "other countries", while Japan would experience a slight decline (USGS 2019b). In 2018, Asia produced most of the world's primary cadmium metal, namely in China, the Republic of Korea, and Japan (USGS 2019b). |
| **Use information** | |
| **Key uses/applications** | • Nickel-cadmium batteries: used in railway and aeronautical applications (Tolcin 2020; International Cadmium Association [ICdA] n.d.) and in consumer electronics (Tolcin 2020). Nickel-cadmium batteries (NiCd) are also used in cellular phones, cameras, hand-held cordless power tools, portable computers, emergency lights and emergency power supplies in hospital rooms (Minerals Education Coalition n.d.).<br>• Pigments: inorganic cadmium pigments are colouring agents used in plastics, glasses, ceramics and paints (ICdA n.d.; Tolcin 2020).<br>• Coatings/Platings: cadmium coatings provide resistance to corrosion and are often applied to iron, steel, brass and aluminium. They are used in electronics, aerospace, automotive, mining and defence applications, where they are applied to components including bolts and connectors (ICdA n.d.).<br>• Cadmium is also used in nuclear reactor control rods to keep control of the fission reactions (Minerals Education Coalition n.d.), solar cells, plastic stabilisers and alloys (USGS 2019a; ICdA n.d.). |
| **Key markets** | China was the largest consumer of cadmium followed by India, Belgium, Sweden and Japan in 2017, based on production and trade data. Most of the global cadmium consumption is thought to be for NiCd batteries; other remaining uses include solar cells, alloys and pigments, among others (Tolcin 2020). |

<table>
<tr><th colspan="2">Exposure</th></tr>
<tr><td>**Main exposure sources and pathways**</td><td>• Cadmium can be released into the environment by a number of sources, including natural activities (e.g. volcanic activity and weathering and erosion), human activities such as mining and the incineration of cadmium-containing waste, and the “remobilisation” of historic sources (World Health Organization [WHO] 2010). It can accumulate in soils, leach into ground and surface water and damage human health via the consumption of crops and animals that have consumed contaminated soil and water (Ulrich 2019).<br>• Emissions from cadmium during the production process occur from mining and smelting, waste incineration, use of sewage sludge on soil, use of phosphate fertilisers as well as the use of cadmium-containing manure in agriculture (WHO 2010).<br>• Cadmium can be present in air, water, food and drinking water. In air, cadmium levels are generally higher in the vicinity of metallurgical plants (WHO 2011). Evidence also indicates cigarette smoking increases indoor concentrations (WHO 2011). WHO reported human exposure pathways predominantly occur via the consumption of contaminated food, inhalation of tobacco smoke as well as industrial activities leading to worker inhalation (WHO 2010). For the non-smoking population, foodstuffs are the main source of cadmium exposure (European Commission n.d.). For the non-occupationally exposed, food is the main source of cadmium intake (WHO 2011).<br>• Exposure via drinking water can occur from impurities present in pipes, fittings, water heaters, coolers and taps, but is considered “relatively unimportant compared with exposure from diet” (WHO 2010).<br>• Cadmium is present in soil, with several studies indicating the presence of cadmium in farmland, transported by air deposition, synthetic fertilizers and livestock manure application (United Nations Environment Programme [UNEP] 2019). Long-range atmospheric transport is also a risk (WHO 2010). Increased concentrations of cadmium may occur in crops or meat from animals that have grazed on pastures with contamination in the soil or water used for irrigation (WHO 2011).<br>• Urban sewage can also often contain heavy metals such as cadmium and the use of treated sewage in agriculture can distribute cadmium to the soil, as discussed above. Other key sources of exposure include household dust (UNEP 2019).<br>• WHO (n.d.) also considers that the disposal and recycling of electronics and electrical waste as well as plastics, toys and jewellery containing cadmium is potentially a source of exposure of particular concern for children (WHO n.d.).<br>• Occupational exposure of workers to cadmium in the non-ferrous smelting industry is significant (WHO 2010). For example, US worker exposure to cadmium mostly occurs in manufacturing and construction sectors, such as during the smelting and refining of metals, manufacturing of products including batteries, plastics, coatings and solar panels (US Department of Labor [DOL] n.d.). Recycling NiCd batteries is also a concern (US DOL n.d.).</td></tr>
<tr><td>**Foreseeable global trends**</td><td>• European cadmium emissions have declined by approximately 65% from 1990 to 2017 in the EEA-33. In 2017, Germany, Italy and Poland were the largest EEA-33 emitters of cadmium (EEA 2019). Industrial processes and product use (33.2%), energy use in industry (24.2%) and commercial, institutional and households (21.3%) remain the largest emitters (EEA 2019).<br>• NiCd batteries are gradually being replaced by other products including lithium-ion batteries. This trend is expected to continue as manufacturing costs decrease and lithium-ion battery efficiency increases. European and national policies are expected to accelerate Li-ion battery uptake (Recharge 2018), due to, e.g. the Electrical Vehicle Initiative for 2020, the Paris Declaration on Electro-Mobility, and Climate Change and Call to Action for 2030.<br>• The use of cadmium in solar cells is an important driver in cadmium production and this is likely to increase over time (UNEP 2019).<br>• Cadmium content has been widely present in mineral fertilisers. Twenty-one European Union (EU) countries currently have provisions to limit cadmium in national mineral phosphate fertilisers (Ulrich 2019).</td></tr>
<tr><th colspan="2">Examples of costs-of-inaction and benefits-of-action information</th></tr>
<tr><td>**Costs of inaction**</td><td>Cadmium has been identified as one of the eight occupational carcinogens that were responsible for 111,000 deaths and 1,011,000 Disability Adjusted Life Years (DALYs) from lung cancer in 2004 (Prüss-Ustün *et al.* 2011).</td></tr>
<tr><td>**Benefits of action**</td><td>• With regards to the restriction of placing on the market and use of cadmium and its compounds in artists’ paints and pigments, the accumulated benefits after 50 years are estimated to be €18 million and €113 million after 150 years, with the majority of accumulated benefits relating to prevention of breast cancer (Swedish Chemicals Agency 2013).<br>• Regarding cadmium in brazing alloys, for consumers, the benefits from preventing deaths (monetised) from increased urinary cadmium levels are estimated at €1.3-25 million over 20 years and for professional users, between €98-473 million over 20 years from the prevention of lung cancers and emphysemas (Risk and Policy Analysts 2010).</td></tr>
</table>

**Table B–3.2.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of cadmium.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national and regional legislation and regulations] | | | | |
| Ban / restriction | EU | Plastic materials, paints, cadmium plating metallic articles, brazing fillers, jewellery | • The EU restriction of cadmium and cadmium compounds (including 216 CAS numbers) includes the following (European Chemicals Agency [ECHA] 2020)<br>• Shall not be used in mixtures and articles produced from the following synthetic organic polymers: polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]; polyurethane (PUR) [3909 50]; low-density polyethylene (LDPE), with the exception of LDPE used for the production of coloured masterbatch [3901 10]; cellulose acetate (CA) [3912 11]; cellulose acetate butyrate (CAB) [3912 11]; epoxy resins [3907 30]; melamine-formaldehyde (MF) resins [3909 20]; urea-formaldehyde (UF) resins [3909 10]; unsaturated polyesters (UP) [3907 91]; polyethylene terephthalate (PET) [3907 60]; polybutylene terephthalate (PBT); transparent/general-purpose polystyrene [3903 11]; acrylonitrile methylmethacrylate (AMMA); cross-linked polyethylene (VPE); high-impact polystyrene; polypropylene (PP) [3902 10].<br>- Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01% by weight of the plastic material, with the exception of articles placed on the market before 10 December 2011; articles coloured with mixtures containing cadmium for safety reasons; mixtures produced from PVC waste/recovered PVC; and, mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0.1% by weight of the plastic material in the following rigid PVC applications: (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC". Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: "Contains recovered PVC" or with requested pictogram.<br>• Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0.01% by weight, with the exception of articles coloured with mixtures containing cadmium for safety reasons. For paints with codes [3208] [3209] with a zinc content exceeding 10% by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0.1% by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.1% by weight of the paint on the painted article.<br>• Shall not be used for cadmium plating metallic articles or components of the articles used in equipment and machinery for food production, agriculture, cooling and freezing, and printing and book-binding; and equipment and machinery for the production of household goods, furniture, sanitary ware, and central heating and air conditioning plants.<br>• Shall not be used in brazing fillers in concentration equal to or greater than 0.01% by weight, with the exception of brazing fillers used in defence and aerospace applications and for safety reasons. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.01% by weight.<br>• Shall not be used or placed on the market if the concentration is equal to or greater than 0.01% by weight of the metal in metal beads and other metal components for jewellery making; and, metal parts of jewellery and imitation jewellery articles and hair accessories, with exception of articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011. | In force |
| | | Electrical and electronic equipment | The Restriction of Hazardous Substances Directive specifies maximum levels by weight for cadmium (0.01%) in electrical and electronic equipment (EC 2020). | In force |
| | | Battery | Under the Directive 2006/66/EC, portable batteries or accumulators, including those incorporated into appliances, that contain more than 0.002% of cadmium by weight shall be prohibited from being placed on the market, with certain exemptions (EU 2006).<br>Under the Directive 2013/56/EU, the EU Battery Directive (2006/66/EC) was amended to prohibit the inclusion of Ni-Cd batteries in cordless power tools beginning 31 December 2016, after which Ni-Cd batteries could only be used in emergency systems and medical equipment in the EU (European Parliament 2012). | In force |
| | | Food items | Regulation (EU) 488/2014 establishes maximum levels for cadmium in a range of foodstuffs, including chocolate and cocoa powder, vegetables and fruits, meat and fungi (EC 2014). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Ban / restriction** | **EU** | **Fertilizers** | Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products, and sets limit values of cadmium in different fertilisers. For example, cadmium in an organic fertiliser must not exceed 1.5 mg/kg dry matter (European Union 2019). | Stepwise enter into force from 15 July 2019 to 16 July 2022 |
| | **China** | **Imported copper concentrates** | Under the current rules introduced in April 2006, shipments of metal concentrate into China must undergo inspection by the China Inspection and Quarantine Services (CIQ) and may not contain levels of more than 0.5% arsenic, 6% lead, 0.1% fluorine, 0.05% cadmium and 0.01% mercury. These limit values are being revised now (Luk 2019). | In force |
| | **Taiwan, China** | **Cosmetics** | Cosmetic products with cadmium contained in the final products shall not exceed over 5 ppm (Taiwan Food and Drug Administration 2018). | In force |
| | **Eurasian Economic Union** | **Toys, packaging material, perfumery and cosmetic products, food products, certain infants' products** | The Eurasian Economic Union has adopted a series of technical regulations, which establish requirements, in particular with regard to safety, mandatory for application and execution in the territory of the Union:<br>• TR CU 008/2011 on toy safety sets the release (migration) of cadmium contained in 1 kg of any toy materials into the model medium (hydrochloric acid) not to exceed 75 mg; migration of cadmium from lead-silver alloys into aqueous media no more than 0.001 mg/dm3; and, migration of cadmium contained in 1 kg of forming masses and paints applied by fingers into the model medium (hydrochloric acid) no more than 50 mg.<br>• TR CU 005/2011 on safety of packaging sets the allowable quantity of migration of 0.001 mg/L from food contact packaging made from paper with additives simulating the properties of parchment of vegetable, as well as 0.5 mg/L from food contact packaging made from glass, porcelain, fayence, ceramic products (Eurasian Economic Union 2011a).<br>• TR CU 021/2011 on safety of food products sets the acceptable levels of cadmium in different food products: 0.05 mg/kg in meat and meat products, poultry and poultry products, canned meat, poultry; 0.03 mg/kg in raw milk, raw skim milk, raw cream, drinking milk and drinking cream, milk drinks, fermented milk products, sour cream, ice cream of all types from milk and on a milk base; 0.1 mg/kg in food grains; 0.05 mg/kg in sugar; 0.03 mg/kg in vegetables, potatoes, melons, juice products and vegetables; 0.05 mg/kg in all types of vegetable oils (Eurasian Economic Union 2011b). | In force |
| | **National** | **Electrical and electronic products** | A number of countries and regions have adopted laws to restrict the levels of cadmium in electrical and electronic products. For more information, see Section 3.4. | In force |
| **Mandatory national standards** | **China** | **Infant and children textile products** | In 2015, the Government of China published the mandatory standard related to infants and children textile production (GB 31701-2015; Standardization Administration of China 2015). It covers technical requirements for fabric, filling materials and attached components for infants' and children's textile products, including the limit value of 100 mg/kg for cadmium. Products imported into the Chinese market that do not comply with the requirements of this standard are prohibited from sale. The instructions for use shall indicate the code of the standard and the safety category. | In force |
| **Guidelines** | **US** | **Drinking water** | The Maximum Contaminant Level of cadmium in drinking water is 0.005 mg/L (United States Environmental Protection Agency 2020). | In force |
| **Notification** | **Australia** | **Emissions** | In Australia, cadmium and cadmium compounds are subject to reporting under the Australian National Pollutant Inventory (NPI). Under the NPI, emissions of cadmium and cadmium compounds are required to be reported annually by facilities that use or emit more than 10 tonnes of cadmium or cadmium compounds, burn more than 2000 tonnes of fuel, consume more than 60,000 megawatt hours of electricity (excluding lighting and motive purposes), or have an electricity rating of 20 megawatts during a reporting year (Government of Australia n.d.). | In force |
| | **EU** | **Articles; export** | Cadmium and cadmium compounds, totalling 9 CAS numbers (cadmium and cadmium chloride/fluoride/oxide/sulphate/sulphide/carbonate/hydroxide/nitrate), are listed as SVHCs under REACH, owing to their reproductive toxicity, mutagenicity, specific target organ toxicity after repeated exposure, and/or carcinogenicity, depending on chemical. Manufacturers and importers thus have legal obligations to provide sufficient information to allow safe use of the article containing cadmium above 0.1 wt% (ECHA n.d. a).<br>Cadmium and cadmium compounds are subject to the export notification procedure (ECHA n.d. b). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Mandatory recycling rate** | **Republic of Korea** | **Ni-Cd battery** | The mandatory recycling rate for manufacturers is set as 33% by the Ministry of Environment in 2010 (personal communication). | In force |
| **ESM of Waste** | **International** | **Waste lead-acid batteries; waste containing lead** | Wastes including those having cadmium or cadmium compounds as constituents (classification Y26 in Annex 1), metal wastes and waste consisting of alloys of cadmium (classification A1010 in Annex VIII), waste having cadmium as constituents or contaminants, excluding metal waste in massive form (classification A1020 in Annex VIII), waste zinc residues not included on list B, containing lead and cadmium in concentrations sufficient to exhibit Annex III characteristics (classification A1080 in Annex VIII), and Waste electrical and electronic assemblies or scrap containing components or contaminated with Annex I constituents (classification A1180 in Annex VIII) are listed as "hazardous wastes" under the Basel Convention. Therefore, Parties to the Convention are to manage this waste stream in accordance with the provisions set out in the Convention, including by reducing to a minimum their generation; restricting the transboundary movements of such wastes, except where it is perceived to be in accordance with the principles of environmentally sound management; taking appropriate measures to ensure their environmentally sound management. Each Party has the obligation to transmit to the Secretariat a national report on an annual basis that contains information, among other things, on the amount of wastes generated, etc. | In force |
| **Emission reduction** | **International** | **Emissions** | The 1998 Aarhus Protocol on Heavy Metals of the Convention on Long-Range Transboundary Air Pollution includes provisions that Parties must reduce their emissions for cadmium below 1990 levels (or an alternative year between 1985 and 1995). It aims to cut emissions from industrial sources (iron and steel industry, non-ferrous metal industry), combustion processes (power generation, road transport) and waste incineration. It lays down stringent limit values for emissions from stationary sources and suggests best available techniques (BAT) for these sources. It also introduces measures to lower heavy metal emissions from other products.<br>In 2012, Parties to the Protocol on Heavy Metals adopted decision 2012/5 to amend the Protocol to include more stringent controls of heavy metals emissions and to introduce flexibilities to facilitate accession of new Parties, notably countries in Eastern Europe, the Caucasus and Central Asia. As of March 2020, these amendments have not yet entered into force. | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Resolution** | **International** | | UNEA Resolution 2/7 includes "recognizing the significant risks to human health and the environment arising from releases of lead and cadmium into the environment" and requested UNEP to cooperate with governments, with the private sector, including industry, and with other non-governmental organisations to continue work on lead and cadmium (UNEP 2016). | |
| **Guidelines** | **International** | **Drinking water; air; food intake** | The WHO (2019) guidelines for cadmium are 3 ug/L in drinking water and 5 ng/m3 (annual average) in air. The Joint FAO/WHO Expert Committee on Food Additives established a provisional tolerable monthly intake for cadmium in 2010 of 25 µg/kg body weight, based on meta-analysis of epidemiological studies on the relationship between urinary cadmium and beta-2-microglobulin (a marker of renal tubular effects). In light of the long half-life of cadmium in humans, the Committee decided to express the tolerable intake as a monthly value. | In force |
| | **National (or regional)** | **Environmental media, occupational exposure** | A number of guidelines for cadmium in different exposure media including occupational exposure have been developed in different countries, e.g. in Australia (Government of Australia 2019), the US (United States Agency for Toxic Substances and Disease Registry 2011), the Netherlands (Health Council of the Netherlands 2019) and Canada (CARcinogen Exposure Canada n.d.). | In force |
| **Strategy** | **New Zealand** | **Agriculture** | The Government of New Zealand established a National Cadmium Management Strategy for agriculture, with the objective to ensure that cadmium in rural production poses minimal risks to health, trade, land-use flexibility and the environment over the next 100 years. Detailed work programmes include governance, food monitoring, soil and fertiliser monitoring and fertiliser management, management and education, and environmental monitoring and research (New Zealand Ministry of Agriculture and Forestry 2011). | Ongoing |
| **Prioritisation** | **China** | | In 2017, the Government of China published the Prioritized List of Substances to be Subject to Control (1st Batch), including cadmium and cadmium compounds. To control the manufacturing and use of these chemicals, the Government will adopt one or several of the following risk management measures: Enterprises should obtain sewage discharge permission before they discharge these chemicals; the State will restrict the use of these substances in some products and encourages enterprises to use substitutes; and clean production audit will be implemented (Ministry of Ecology and Environment of the People's Republic of China 2017). | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Industry limit** | **New Zealand** | **Fertiliser** | In response to concerns in the late 1990s about cadmium levels in fertilisers, the fertiliser industry in New Zealand voluntarily adopted a limit for cadmium in fertilisers of 280 ppm (New Zealand Ministry for Primary Industries 2020). | Ongoing |
| **Voluntary industry phase-out** | **International** | | Apple includes cadmium in its Regulated Substances Specification (Apple 2018). | |
| **Third-party standards and certification schemes** | **International** | | Cadmium is included in the bluesign® Restricted Substances List for a usage ban with the limit of trace of 0.2 mg/kg (Bluesign 2020). Similarly, cadmium is included in the Zero Discharge of Hazardous Chemicals (ZDHC) Manufacturing Restricted Substances List (MRSL; ZDHC 2019).<br>Nordic Swan Ecolabel (a.k.a. Nordic Swan) criteria include the requirement for cadmium (Nordic Ecolabelling 2020). | |

# 4. Glyphosate

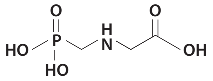
**Table B–4.1.** SA brief overview of existing assessments of environmental and human effects of glyphosate by national governments and intergovernmental institutions.

| Institution | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| (IARC 2017) | Hazard identification | (i) literature review of peer-reviewed studies and publicly available government documents (including exposure agricultural studies published since 2001 and laboratory studies in mice).<br>(ii) Unpublished data and reports that have not undergone independent peer review or are not publicly available are not taken into account. | • Limited evidence in humans for the carcinogenicity of glyphosate. A positive association has been observed for non-Hodgkin lymphoma.<br>• Sufficient evidence in experimental animals for the carcinogenicity of glyphosate.<br>• Strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic based on studies in humans in vitro and studies in experimental animals.<br>• Strong evidence that glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid can act to induce oxidative stress based on studies in experimental animals, and in studies in humans in vitro.<br>• Glyphosate is probably carcinogenic to humans (Group 2A). | The IARC Working Group considered that the data were too few for an evaluation of several key characteristics of human carcinogens.<br>No data on cancer-related susceptibility after exposure to glyphosate were available to the Working Group.<br>For cancers other than non-Hodgkin lymphoma, multiple myeloma, Hodgkin lymphoma, glioma and prostate, results from only one study were available for evaluation. |
| (FAO and WHO 2016) | Re-evaluation of glyphosate | (i) literature review;<br>(ii) focus on dietary exposure | • Case–control studies and overall meta-analysis presented some evidence of a positive association between glyphosate exposure and risk of non-Hodgkin lymphoma. However, the only large cohort study of high quality found no evidence of an association at any exposure level.<br>• The overall weight of evidence indicates that administration of glyphosate and its formulation products, at doses as high as 2,000 mg/kg body weight by the oral route, was not associated with genotoxic effects in an overwhelming majority of studies conducted in mammals. Therefore, glyphosate is unlikely to be genotoxic at anticipated dietary exposures.<br>• Glyphosate is not carcinogenic in rats but the assessment could not exclude the possibility that it is carcinogenic in mice at very high doses.<br>• Glyphosate is unlikely to pose a carcinogenic risk to humans through dietary exposure.<br>• The group acceptable daily intake (ADI) for the sum of glyphosate and its metabolites of 0-1 mg/kg body weight on the basis of effects on the salivary gland is reaffirmed. | The only large cohort study of high quality found no evidence of an association with non-Hodgkin lymphoma at any exposure level. |
| (EFSA 2015a; 2015b) | Carcinogenicity assessment of glyphosate, in parallel to pesticide review | 10 cohort studies, nine case-control studies.<br>Weight of evidence approach | • Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for reproduction category 2.<br>• Considering a weight of evidence approach, taking into account the quality and reliability of all available data, the EFSA peer review concluded that glyphosate is unlikely to be genotoxic in vivo and does not require hazard classification regarding mutagenicity according to the CLP Regulation. It is noted that unpublished studies that were the core basis of the peer review evaluation were not available to the IARC experts as reported in the IARC monograph 112 on glyphosate.<br>• The toxicity of formulations and in particular their genotoxic potential should be further considered and addressed.<br>• Based on the representative uses, limited to conventional crops only, chronic or acute risks related to residues for consumers have not been identified.<br>• The risk to non-target terrestrial plants was considered low, but only when mitigation measures are implemented.<br>• The risk for aquatic organisms, bees, non-target arthropods, soil macro- and microorganisms, and microorganisms used as biological methods for sewage treatment was considered low. | Data gaps were identified, including further information on analytical methods of residues, toxicological data for glyphosate degradates, and more. |

| Institution | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| **EFSA (2019)** | **Review of the existing maximum residue levels for glyphosate in crops, only for consumer exposures** | (i) evaluation of peer-reviewed scientific literature, including toxicological studies;<br>(ii) peer-reviewed report | • Recommendations for maximum residue levels in various crops, for humans and livestock exposures.<br>• "The highest chronic exposure was calculated for British toddlers, representing 19.1% of the ADI; the highest acute exposure was calculated for sugar beetroots, representing 91% of the ARfD" [acute reference dose].<br>• No validated or significant relationship between exposure to glyphosate and an increased risk of non-Hodgkin lymphoma or other types of cancer. | Only for food consumption for animals and humans. |
| **EFSA (2017)** | **Review of potential endocrine activity** | (i) call for information;<br>(ii) initial assessment;<br>(iii) peer-review and expert consultation | • Glyphosate does not have oestrogen-, androgen-, thyroid- and steroidogenesis-mediated endocrine-disrupting properties based on the lack of identification of endocrine-mediated adverse effects in apical (bee) studies.<br>• No evidence was found in the available ecotoxicology studies which would contradict the conclusion of mammalian toxicology studies, where there is no evidence of endocrine mode of action of glyphosate. | |
| **EFSA (2018)** | **Assess the health risk for farm animals, in relation to the presence of glyphosate and residues in feed, including GM feed** | (i) registrant data;<br>(ii) published scientific studies;<br>(iii) consultation with Member States;<br>(iv) external review | • For cattle and sheep (bovine and ovine species), equine, porcine and selected avian (poultry) species, glyphosate and its metabolite AMPA are not expected to have an impact on the health of these animals on the basis of the available data (resulting in margins of exposure between 4 and 44).<br>• Even at the maximum dietary burden, glyphosate is not expected to have effects on the microbial communities in the rumen, impacting on the health of bovine and ovine species. | |
| **(ECHA 2019)** | **Hazard classification** | Review of published studies on glyphosate, original reports of studies conducted by industry, and assessment of "scientifically relevant information received during the public consultation in summer 2016". | • The available scientific evidence did not meet the criteria in the CLP Regulation to classify glyphosate for specific target organ toxicity; as a carcinogen; as a mutagen; or for reproductive toxicity.<br>• The scientific evidence available at the moment warrants the following classifications for glyphosate according to the CLP Regulation: Eye Damage 1 (causes serious eye damage); Aquatic Chronic 2 (toxic to aquatic life with long lasting effects). | |
| **Australian Pesticides and Veterinary Medicines Authority (APVMA 2016)** | **Consideration of the evidence for a formal reconsideration of glyphosate** | Scientific weight-of-evidence evaluation of information in the IARC monograph, risks assessments undertaken independently by regulatory agencies in other countries and expert international bodies, in addition to Adverse Experience Reports (AERs) submitted to the APVMA. | • Exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans.<br>• There is no scientific basis for revising the APVMA's satisfaction that glyphosate or products containing glyphosate: would not be an undue hazard to the safety of people exposed to it during its handling or of people using anything containing its residues; would not be likely to have an effect that is harmful to human beings; would not be likely to have an unintended effect that is harmful to animals, plants or to the environment; would be effective according to criteria determined by the APVMA by legislative instrument; and would not unduly prejudice trade or commerce between Australia and places outside Australia.<br>• There are no scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration. | |
| **New Zealand Environmental Protection Agency (2016)** | **Chemical reassessment program, post-IARC review** | Published literature, IARC, United States Environmental Protection Agency (US EPA) and other bodies' assessments | Based on a weight of evidence approach, taking into account the quality and reliability of the available data, glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification under HSNO as a carcinogen or mutagen. | Additional data may be necessary to fully evaluate risks to bees |
| **California, US (California Office of Environmental Health Hazard [OEHHA] 2017)** | **Review for consideration under Proposition 65** | Review of the available data from the rodent carcinogenicity studies discussed by IARC | The most sensitive study of sufficient quality was the two-year study conducted in male CD-1 mice fed glyphosate (purity, 98.6%) in the diet, and OEHHA determined that it met the criterion in Section 25703 for quantitative risk assessment in health and safety. | |

| Institution | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| United States Agency for Toxic Substances and Disease Registry (ATSDR) 2019) | ATSDR toxicological profile | (i) identify and review the key literature that describes a substance's toxicological properties;<br>(ii) peer-review | • Gastrointestinal disturbance and effects on the salivary gland appear to be the most sensitive non-cancer effects in animal studies that employed oral exposure to glyphosate. Ocular, hepatic, renal and body-weight effects have been reported as well. Developmental effects were observed at dose levels resulting in maternal toxicity. Effects observed in animals are considered relevant to human health in the absence of experimental data to indicate otherwise.<br>• The carcinogenic potential of glyphosate has been evaluated in three meta-analyses and a number of case-control and cohort epidemiology studies. The meta- analyses reported positive associations between glyphosate use and selected lymphohematopoietic cancers. Most of the case-control and cohort studies used self-reported ever/never glyphosate use as the biomarker of exposure, and subjects were likely exposed to other pesticides as well. Numerous studies reported risk ratios greater than 1 for associations between glyphosate exposure and risk of non- Hodgkin lymphoma or multiple myeloma; however, the reported associations were statistically significant only in a few studies.<br>• Collectively, animal studies in which glyphosate-containing herbicide formulations were tested by the oral exposure route have identified the following targets of toxicity:<br>- body-weight effects (depressed body-weight gain in mice),<br>- hematological effects (decreases in red blood cells, hematocrit and hemoglobin and increases in mean corpuscular volume and neutrophils in mice),<br>- hepatic effects (increased serum liver enzyme activity and histopathologic liver lesions in male rats),<br>- renal effects (histopathologic kidney lesions in male rats) and<br>- reproductive effects (increased percentage of morphologically abnormal sperm in rats). | Draft for public comment; public comment period closed on July 8, 2019 |
| Government of Canada (2017) | Re-evaluation decision for pesticide use approval | (i) registrant data;<br>(ii) published scientific reports;<br>(iii) regulatory agencies' information;<br>(iv) "and any other relevant information". | • Glyphosate is not genotoxic and is unlikely to pose a human cancer risk.<br>• Dietary (food and drinking water) exposure associated with the use of glyphosate is not expected to pose a risk of concern to human health.<br>• Occupational and residential risks associated with the use of glyphosate are not of concern, provided that updated label instructions are followed.<br>• Spray buffer zones are necessary to mitigate potential risks to non-target species (for example, vegetation near treated areas, aquatic invertebrates and fish) from spray drift.<br>• When used according to revised label directions, glyphosate products are not expected to pose risks of concern to the environment.<br>• All registered glyphosate uses have value for weed control in agriculture and non-agricultural land management. | |
| US EPA (2018; 2020) | Human health and ecological risk assessment, for registration review | Based on case studies, peer-reviewed literature, public comment | • No dietary risks of concern of any segment of the population, and no residential, non-occupational bystander, aggregate or occupational risks of concern from the current registered uses of glyphosate.<br>• Glyphosate is not likely to be carcinogenic to humans.<br>• Insufficient evidence to conclude that glyphosate plays a role in any human diseases.<br>• Did not identify potential risks of concern for fish, aquatic invertebrates or aquatic-phase amphibians. Low or limited potential risks of concern were identified for mammals and birds.<br>• Potential risks to non-target terrestrial and aquatic plants were primarily from spray drift, and the resulting distances from the edge of the field to below-toxicity threshold were heavily dependent on the application rate used.<br>• The likelihood of acute adverse effects to adult bees is considered low at application rates up to 6.4 kg acid equivalent per hectare (kg a.e./ha); however, it is uncertain if effects would occur at higher application rates (i.e., up to 9 kg a.e./ha).<br>• The agency conducted a review of ecological incidents and determined the majority of the glyphosate incidents are for terrestrial plants. Most plant incidents involved spray drift onto adjacent agricultural crops and grass. | |

**Table B–4.2.** Supporting information on the life cycle of and exposure to glyphosate, as well as examples of cost-of-inaction and benefits-of-action information

| Chemical name(s) | Glyphosate |
|---|---|
| **IUPAC name(s)** | 2-[(phosphonomethyl)amino]acetic acid |
| **Other name(s)** | Glycine, N-(phosphonomethyl)- |
| **CAS number(s)** | 1071-83-6 |
| **Chemical formula** | $C_3H_8NO_5P$ |
| **Chemical structure** |  |
| **Production information** | |
| **Production overview** | The three main processes for glyphosate production are the hydrogen cyanide process, the diethanolamine process and the glycine process. Data are unavailable on global production processes; in China, the HCN and DEA processes both constitute 20% of production, with the remaining 60% of production via the glycine process (Royal Society of Chemistry 2012). |
| **Key producers** | Glyphosate was first incorporated into a pesticide product by Monsanto in the 1970s but its patent expired in the year 2000. Subsequently production in China has increased. A variety of glyphosate herbicide formulations are sold around the world. Bayer CropScience AG holds the patent for "Roundup Ready" crops in soy, corn and cotton. |
| **Production volumes and global trends** | According to Székács and Darvas (2018), in 2012, the overall global glyphosate production capacity was 1.1 million tonnes/year, far exceeding the worldwide demand in the same year. Of the overall production, China represents a substantial portion and has increased its production capacity in recent years. For example, Chinese production capacity was 323,000 tonnes/year in 2007 but increased by 2.6-fold to 826,000 tonnes/year in 2010. This corresponds to an annual increase rate of 37%. Székács and Davos (2018) stated that China alone is capable of meeting full global glyphosate demand to date. |
| **Use information** | |
| **Key uses / applications** | • Glyphosate is a broad-spectrum systemic herbicide used to control weeds in agricultural, forestry, horticultural and domestic applications (WHO 2015). Commonly sold under trade names including "Roundup" or "Ranger PRO", the use of glyphosate-based herbicides increased after the introduction of glyphosate-resistant "Roundup Ready" crops in 1996 (Zhang *et al.* 2019). It is applied in a variety of forms including isopropylamine salt, ammonium salt, diammonium salt, dimethylammonium salt and potassium salt. Typically applied prior to conventional crops being sown as a means of controlling weeds, it facilitates crop growth via removal of competing plants (Benbrook 2016; European Commission [EC] n.d.). It can also be applied after sowing as a pre-harvest treatment to regulate plant growth and the ripening process (EC n.d.).<br>• In areas where genetically modified plants with a resistance to glyphosate are grown (e.g. US), it can be applied after sowing to kill weeds growing amongst the crops. The EU has banned growing genetically modified plants, while under consideration for risks and hazards, and so glyphosate-resistant crops are not grown within its borders (ECHA n.d.). |
| **Key markets** | • Glyphosate is used in over 750 products (formulations), predominantly in agricultural and horticulture. Benbrook (2016) highlighted that the glyphosate market had grown exponentially since 1994 and the adoption of resistant crops. The study concluded, worldwide, glyphosate is expected to remain the most widely applied pesticide in the future driven by continued adoption of genetically modified crops. The current total global use of glyphosate is estimated at 8.6 million tonnes, with Asia Pacific, the US and Europe as the largest markets.<br>• The Asia Pacific market accounts for around 38% of the global market. Its use has been driven by a growing population, adoption of genetically modified crops and changing agricultural patterns in developing economies (particularly China and India; Huang, Wang and Xiao 2017).<br>• The United States constitutes around 19% of the global market. In 2014 alone, US farmers used enough glyphosate to apply 1 kg per hectare on every hectare of national cultivated cropland (Benbrook 2016). The US is a key market for glyphosate and no other pesticide has "come close to such intensive and widespread use" (Fernandez-Cornejo *et al.* 2014; Benbrook 2016).<br>• Less quantitative data was available for the European market. However, glyphosate remains widely used for agricultural purposes across Europe. It is likely that due to policy restrictions for its use and lack of GM modified crops, growth has been slower in Europe than in the US and China. The overall consumption of glyphosate in Germany was boosted 5.7-fold between 1992 and 2012 (Benbrook 2016; Huang, Wang and Xiao 2017; Berger *et al.* 2018; Székács and Darvas 2018). |

| | |
|---|---|
| **End-of-life issues** | Leaching of pesticides is an end-of-life issue. For example, there is a large body of evidence which illustrates glyphosate transport after high rainfall events shortly after applications to soil occur (Vereecken 2005). However, it has also been emphasized that the fate of glyphosate depends on soil structure and amount of rainfall (Borgaard and Ginsing 2008). In addition to glyphosate leaching, concerns have also been raised regarding ecotoxicological concerns as the use of glyphosate adds phosphorus (P) to agricultural land, which thus influences accumulation of P in soil and surface waters. For example, Hebert *et al.* (2018) highlighted that glyphosate derived P is a largely overlooked source of anthropogenic P, arguing for greater recognition of the influence of glyphosate on P flow in watershed management. |
| **Exposure information** | |
| **Main exposure sources and pathways** | The main source of glyphosate exposure is via application to crops and soils in the agricultural and horticultural sectors, which can result in exposure among herbicide applicators via inhalation and dermal exposure (Connolly *et al.* 2019). Human exposure can also occur via the diet (Office of Chemical Safety and Pollution Prevention 2017). |
| **Foreseeable global trends** | While regulatory action may slow growth rates of glyphosate use, its application is expected to continue to grow worldwide well into the future, particularly in the US (Benbrook 2016). The reliance on glyphosate herbicides in the US has triggered the spread of glyphosate resistant weeds. As a result, farmers have increased application rates. This increased use has heightened risk concerns for environmental and human exposures (Benbrook 2016). |
| **Examples of costs-of-inaction and benefits-of-action information** | |
| **Costs of inaction** | • Very little literature was available on the specific costs of inaction attributable to glyphosate; this may reflect ongoing debate regarding exposure and risks. Recent analysis has been published on the economic costs of regulatory action glyphosate, however (e.g. Gianessi *et al.* 2008).<br>• Costs of inaction could include the provision of occupational health care, or litigation and reputational damage. A first court case in California found glyphosate-based weedkillers responsible for a man's terminal cancer. The judgement was expected to precipitate more liability cases (US District Court 2020). |
| **Benefits of action** | There were no specific studies valuing the benefits of action for glyphosate. |

**Table B–4.3.** Examples of measurements of glyphosate in the environment, biota and humans across the globe. Max. = maximum concentration detected; n = number of samples analysed

| SURFACE WATER | Glyphosate frequency of detection | Glyphosate concentration range (µg/L) | AMPA frequency of detection | AMPA concentration range (µg/L) | Reference |
|---|---|---|---|---|---|
| Australia<br>(surface water) | 79% (n=9 urban)<br>4% (n=10 rural) | 1.8 max. | - | - | (Okada *et al.* 2020) |
| Sri Lanka 2015<br>(surface water) | 100% (n=9) | 28-45 | 0 (n=9 samples) | n/a | (Gunarathna *et al.* 2018) |
| USA 2002<br>(surface water) | 36% (n=154) | 8.7 max.<br><0.1 median | 69% (n=154) | 3.6 max.<br><0.1 median | (United States Geological Survey 2019) |
| USA 2013<br>(surface water) | 44% (n=100) | 27.8 max.<br>1.68 median | - | - | (Mahler *et al.* 2017) |
| USA 2001-2010<br>(stream) | 53 % (n=1508) | 73 max.<br>0.03 median | 72 % (n=1508) | 28 max.<br>0.2 median | (Battaglin *et al.* 2014) |
| USA 2001-2010<br>(large rivers) | 53 % (n=318) | 3.08 max.<br>0.03 median | 89 % (n=318) | 4.43 max.<br>0.22 median | (Battaglin *et al.* 2014) |
| USA 2001-2010<br>(lakes, ponds, wetland) | 34 % (n=104) | 301 max.<br><0.02 median | 30 % (n=104) | 41 max.<br><0.02 median | (Battaglin *et al.* 2014) |
| France 2007<br>(surface water) | 22% (n=1714) | 2.4 max. | 43% (n=4714) | 8.7 max. | (French Agency for Food, Environmental and Occupational Health & Safety [ANSES] 2019) |
| France 2017<br>(surface water) | 50% (n=21253) | 10.9 max. | 74% (n=21205) | 46.4 max. | (ANSES 2019) |
| **GROUNDWATER** | **Glyphosate frequency of detection** | **Glyphosate concentration range (µg/L)** | **AMPA frequency of detection** | **AMPA concentration range** | **Reference** |
| France 2007 | 1% (n=3242) | 0.294 (annual average) | 2% (n=2912) | 0.133<br>(annual average) | (ANSES 2019) |
| France 2017 | 3% (n=3523) | 0.065 (annual average) | 3 % (n=3523) | 0.391<br>(annual average) | (ANSES 2019) |
| Sri Lanka 2015 | 100% (n=9) | 1–4 | 36% (n=9) | 2–11 | (Gunarathna *et al.* 2018) |
| USA 2001-2010 | 6 % (n=1171) | 2.03 max.<br><0.02 median | 14 % (n=1171) | 4.88 max.<br><0.02 median | (Battaglin *et al.* 2014) |
| **SOIL** | **Glyphosate frequency of detection** | **Glyphosate concentration range (µg/kg)** | **AMPA frequency of detection** | **AMPA concentration range (µg/kg)** | **Reference** |
| Argentina 2012-2014<br>(top soil) | 41% (n=58) | 102–323 | 22% (n=58) | 223–732 | (Alonso *et al.* 2018) |
| Argentina 2004-2010<br>(top soil) | 100% (n=3) | 2-132 | 100% (n=3) | 6-703 | (Aparicio *et al.* 2018) |

| | | | | | |
|---|---|---|---|---|---|
| Sri Lanka 2015<br>(surface soil) | 100% (n=9) | 270–690 | 100% (n=9) | 2–8 | (Gunarathna *et al.* 2018) |
| Sri Lanka 2015<br>(sediment) | 100% (n=9) | 85–1000 | 77% (n=9) | 1–15 | (Gunarathna *et al.* 2018) |
| Europe 2015<br>(top soil) | 21% (n=317) | 2050 max.<br>140 median | 42 % (n=317) | 1920 max.<br>150 median | (Silva *et al.* 2018) |
| USA 2001-2010<br>(soil and sediments) | 91 % (n=45) | 476 max.<br>9.6 median | 93 % (n=45) | 341 max.<br>18 median | (Battaglin *et al.* 2014) |

| AIR particles/ rain | Glyphosate frequency of detection | Glyphosate concentration range | AMPA frequency of detection | AMPA concentration range | Reference |
|---|---|---|---|---|---|
| Argentina 2012-2014 (rain water) | 81% (n=112) | 1.24–67.3 µg/L | 34% | 0.75–7.91 µg/L | (Alonso *et al.* 2018) |
| USA Mississippi (air, 2007) | 86% (n=21 over one growing season) | 9.12 ng/m3 max.<br>0.567 ng/m3 median (all particles, no detection in gas phase) | 86% (n=21 over one growing season) | 0.487 ng/m3 max.<br>0.074 ng/m3 median (all particles, no detection in gas phase) | (Majewski *et al.* 2014) |
| USA 2007 (rain) | 77% (n=15 samples over growing season) | 1.90 max.<br>median 0.245 µg/L | 77% (n=15 samples over growing season) | 0.270 µg/L max.<br>0.065 µg/L median | (Majewski *et al.* 2014) |
| Argentina 2004-2010<br>(windblown material) | 100% (n=18) | 247 µg/kg max. | 100% (n=18) | 218 µg/kg max. | (Aparicio *et al.* 2018) |
| USA 2001-2010<br>(rain) | 71 % (n=85) | 2.50 µg/L max.<br>0.11 µg/L median | 72 % (n=45) | 0.48 µg/L max.<br>0.04 µg/L median | (Battaglin *et al.* 2014) |

**Table B–4.4.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of glyphosate.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral or multilateral treaty; national/regional legislation and regulations] | | | | |
| **Ban / restrictions** | **Austria** | **All uses** | Measure to ban use of glyphosate passed in July 2019 and took effect January 2020. | In force |
| | **France** | **Scheduled ban with limits** | Ban scheduled with limitations for 2021; planned phase-out by half of 2019 levels by 2025 (French Ministry of Agriculture and Food n.d.). | |
| | **Germany** | **All uses, scheduled ban** | Ban scheduled for 2023, with increasing restrictions on use ongoing until that time (German Ministry for Environment, Nature Conservation and Nuclear Safety 2019). | |
| | **India, State of Punjab** | **Sales ban** | Punjab banned the sale of glyphosate (Government of Punjab 2018). | |
| | **Mexico** | **Import ban** | Mexico blocked imports of glyphosate (Roundup) in November 2019 (Secretariat of Environment and Natural Resources, Mexico 2019). | In force |
| | **Saudi Arabia** | **Import ban, banned use** | Glyphosate (as well as Roundup and other products) is banned for use and import by the Ministry of Environment, Water and Agriculture, Kingdom of Saudi Arabia (2018). | In force |
| | **United Arab Emirated (UAE)** | **Banned use** | Glyphosate is banned as an ingredient in pesticides in the UAE, as of 2014 (Government of the UAE 2014). | In force |
| **Guideline values** | **National** | **Drinking water, food and feed, soil** | A number of countries and intergovernmental institutions including the US, EU, Japan, Canada and others have established the allowed levels of glyphosate in drinking water, food and feed, residential surface soil and others. For more details, see Li and Jennings (2017), Xu *et al.* (2019) and New Zealand Food Safety (2020). | In force |
| **Labelling / Notification** | **National** | **All uses** | After the re-evaluation of the registration of glyphosate, countries such as Canada and the US have revised their labelling requirements as risk-reduction measures to protect human health and the environment (Government of Canada 2017; US EPA 2020). | |
| | **California, US** | **Consumer warning** | Issued in 2017, glyphosate is included on a list of chemicals that cause cancer (Proposition 65). This requires businesses to inform Californians about exposures to such chemicals. | |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| **Consumer education or action** | **EU Citizens' Initiative** | **"Ban Glyphosate"** | Initiated 25 January 2019 (EC n.d.), and collecting signatures for a ban of glyphosate (Stop Glyphosate n.d.). | |
| **Voluntary industry phase-out** | **Luxembourg, Germany and elsewhere** | **Grocery store and DIY gardening chains** | Companies such as Cactus (supermarket chain in Luxembourg) and REWE (toom Baumarkt chain of hardware and gardening stores across the EU) removed all products from their shelves that contained glyphosate in 2016, after the IARC report that glyphosate is a possible carcinogen. | completed |
| **Third-party standards and certification schemes** | **International** | | Glyphosate has been included by different third-party standards and certification schemes including Fairtrade, Sustainable Agriculture Network (SAN) and UTZ certified products. For example, glyphosate is included in the Orange List (restricted materials) of the Fairtrade's Hazardous Materials List. More details can be found searched on the pesticide and Integrated Pest Management (IPM) online database by the ISEAL IPM Coalition (n.d.). | |

# 5. Lead

**Table B–5.1.** Supporting information on the life cycle of and exposure to lead, as well as examples of cost-of-inaction and benefits-of-action information

| Chemical name, CAS number, and molecular formula | Lead (Pb), 7439-92-1. For chemical names, CAS numbers and molecular formulas of other lead compounds, see Table 1 in International Agency for Research on Cancer [IARC] (2006). |
|---|---|
| **Production information** | |
| **Production overview** | • Most lead is derived from ore, from which other materials are separated, yielding lead concentrate (usually lead sulphide). Primary lead production then uses the lead sulphide (or mixed lead and zinc sulphide concentrates), which is treated via sintering/smelting in a blast furnace or by direct smelting. This converts into lead oxide which is then refined to remove copper, arsenic, tin and other impurities.<br>• Secondary lead production involves processing scrap into refined lead, lead alloys or lead oxide for re-use. This can be done via smelting. The majority of secondary lead is used in processing of scrap lead-acid batteries (Thornton, Rautiu and Brush 2001; Kuenen *et al.* 2013;). |
| **Key producers, production volumes and global trends** | • Historically, the highest production rates have taken place in North America and Western Europe. Worldwide production of refined lead metal (i.e. primary production) amounted to around 6.5 million tonnes in 2000. Of this, some 1.7 million tonnes were from North America, 1.6 million tonnes from Western Europe, and over 1 million tonnes each from China and the rest of Asia (Thornton, Rautiu and Brush 2001).<br>• In terms of secondary production, rates have been higher in high income countries, in North America this accounted for about 70% of outputs; in Western Europe, about 60% and in Africa and Latin America around 50%. In Asia primary lead production has been the main source, with less than 30% produced from secondary sources in the year 2000 (Thornton, Rautiu and Brush 2001).<br>• In the past two decades, primary production has decreased and eventually leveled off at about 4.5 million tonnes globally (Guberman 2017; Klochko 2019; United States Geological Survey [USGS] 2019;). In the past few years, the US, Australia and China, the main primary mining sources of lead, remained steady in their production, annually producing about 300,000 tonnes, 430,000 tonnes and more than 2 million tonnes, respectively (Klochko 2019; USGS 2019). Meanwhile secondary lead production grew slowly to 5.8 million tonnes in 2015 (Guberman 2017). The International Lead and Zinc Study Group (ILZSG) reported that global refined lead production in 2019 decreased by 0.3% to 11.76 million tonnes, and metal consumption decreased by 0.5% to 11.81 million tons; a decline in automobile production and increased uses of lithium-ion batteries could account for the decrease in lead (from production to consumption; ILZSG 2019).<br>• A total of 118 registrants/suppliers are registered as “active” in Europe under REACH (European Chemicals Agency [ECHA] 2011). |
| **Global trade** | • Lead ore is globally traded, both as a part of impure and refined metals as well as in final products. According to the International Lead Association (ILA) (Thornton, Rautiu and Brush 2001), the largest importers of lead (the form is not stated) are the US, South East Asia and Western Europe. Refined metal is also exported by these countries (quantitative data is not available).<br>• In terms of trade in final products, the largest use of lead is in batteries, as noted above. While many jurisdictions have taken regulatory action to control use, the EC estimated import and export values of lead–acid batteries was €1.3 billion and just under €1.5 billion in 2016. Moreover, these values were judged to be understated, as batteries incorporated into exported and imported final products were not included. Cars, of which the EU28 is a net exporter, and consumer electronics, a net importer, were highlighted as important in overall trade flows.<br>• Data gaps on end-of-life disposal methods of batteries, along with discrepancies between production and collection volumes, were noted as a concern (European Commission 2019). |
| **Use information** | |
| **Key markets** | Just under 10.5 million tonnes of lead were used globally in 2012. Of this:<br>• 44.2% was in China (4.6 million tonnes)<br>• 14.3 in the United States (1.5 million tonnes)<br>• 5% was in India (521,000 tonnes)<br>• 4.1% in the Korean Republic (428,000 tonnes).<br>• 26.6% were used in “other” locations (some 1.8 million tonnes), including Germany, Japan, Brazil, Spain, Mexico and the United Kingdom (ILA 2012).<br>Overall lead usage remained largely constant between the late 1970s and early 1990s at around 5.5 million tonnes. From the mid 1990s to 2012 usage increased, particularly from the early 2000s. It stood at over 10 million tonnes in 2012 (ILA 2012). ILZSG reports nearly 11.9 million tonnes of lead used globally in 2018 (ILZSG TK). |
| **Geographic distribution** | There have been marked differences in lead usage, driven by elimination of lead in petrol, as well as in paints, solders and water systems. Demand for lead in batteries has continued to grow (USGS 2019), even as the use of lithium batteries grows as well. |

| **Use information (continuation)** | |
|---|---|
| **Key uses/applications** | In 2012, the largest use of lead worldwide was in batteries, with more than 9 million tonnes per year or 85% of global use, according to the ILA (2019), followed by pigments and other compounds (580,000 tonnes, 5.5%), rolled and extruded products (380,000 tonnes, 3.6%), shot and ammunition (150,000 tonnes, 1.4%), alloys (140,000 tonnes, 1.3%) and cable sheathing (100,000 tonnes, 0.9%).<br>In 2018, the largest use was still batteries, at around 80%, according to the ILZSG (2020). Other unquantified uses include weights for lifting and diving, lead crystal glass, radiation protection, storage of corrosive liquids, and some solders (Royal Society of Chemistry 2019). |
| **End-of-life information** | |
| **End-of-life issues** | • The ILA (2015) notes that global secondary lead production has been increasing and was c. 54% of total global production in 2013 – accounting for all lead produced in the US and 74% of lead produced in Europe. Recycling rates for lead batteries were 99% in the US and Europe.<br>• Despite this, concern from leaching of lead (and other heavy metals) in waste and the contamination of recycled products, for example from lead stabilisers in recycled PVC, has been noted (Janssen and van Broekhuizen 2016; European Chemicals Agency [ECHA] 2017). The leaching of heavy metal, including lead, to the environment from waste disposed in landfill sites is also an issue (EC 2002). Batteries and waste electrical and electronic equipment (WEEE) have been found to be the main sources of heavy metals in municipal waste (Ishchenko 2019). |
| **Exposure information** | |
| **Main exposure sources and pathways** | Fewtrell, Kaufmann and Prüss-Üstün (2003) distinguished between several exposure causes, all of which are reflected in the "body burden", measured by blood lead levels, for example. Humans can ingest lead in water, air, dust and food. Lead exposures occur from drinking water transported via leaded pipes, contact with leaded paint, atmospheric deposition from leaded gasoline, industrial activity, lead in cans or glazed ceramics and in cosmetics.<br>Wani, Ara and Usmani (2015) explores pathways in detail, noting risk from old paints (often inhaled during stripping and sanding), traditional medicines, fruit and vegetables contaminated via soil, and residual emissions from leaded gasoline and industrial activities stored in soils. Occupational exposure is a major source of both adult lead poisoning and lower level exposures, more generally. Children living and playing near such sites are at particular risk. |
| **Foreseeable global trends** | • The policy framework set out via SAICM along with the World Health Organization (WHO) Chemicals Road Map sets out a series of actions to reduce the harmful effects of chemicals (WHO 2017). This includes priority actions to eliminate use of lead in paints by 2020 (WHO 2017; WHO 2019).<br>• The above information suggests a key determinant of longer-term lead production and usage will be the extent of secondary lead production, as well as the feasibility and uptake of alternatives to lead batteries, in particular. |
| **Examples of costs-of-inaction and benefits-of-action information** | |
| **Costs of inaction** | • A relatively large body of quantitative and monetary analysis of the effects of lead exist (Sørensen *et al.* 2016). There are well-established dose-response associations and blood lead levels over time - particularly in cohorts of children in Europe and the United States. These show extensive and sustained decreases. In the US, the removal of lead from petrol between 1976 and 1995 resulted in a 90% reduction in mean blood lead levels, for example (Landrigan 2002; see also Amec Foster Wheeler *et al.* 2017 for the European context). The economic effects of lead exposure include loss of productivity – often quantified in lowered IQ reflected in lifetime economic productivity and earnings (Nedellec and Rabl 2016).<br>• Bartlett and Trasande (2013) suggested the ongoing health burden from lead remains significant, imposing costs in the order of €57 billion per year to the EU. Low-level exposure to lead in the US has been associated with over 400,000 deaths per year from cardiovascular and ischemic heart disease (Lanphear *et al.* 2018).<br>• While still limited, recent research has focused on low- and middle-income countries (LMICs). These reports suggest that despite action on lead in petrol, the largest burdens may now be borne in these countries, from sources including batteries, paint, water pipes and waste. The economic costs are estimated at up to USD$1 trillion (some 1% of global GDP) in lost lifetime economic productivity (LEP) in 2011. These comprise USD$135 billion in Africa (4% of GDP), $700 billion in Asia (~2% of GDP) and USD$140 billion in Latin America and the Caribbean (2% of GDP; Attina and Trasande 2013). |
| **Benefits of action** | As noted above, the available evidence indicates significant reductions in lead emissions – at least in some parts of the world – along with decreases of lead levels in blood (Amec Foster Wheeler *et al*. 2017).<br>The global phase-out of leaded petrol has been judged "the single most important strategy" in reducing overall lead exposures and lead-induced illnesses, with economic benefits exceeding costs by more than 10 times (Lovei 1998; Tsai and Hadfield 2011).<br>More recent evaluations of the cost effectiveness of lead-in-paint hazard control concluded each dollar invested yielded a return of between USD$17 and USD$221 (Gould 2009). |

**Table B–5.2.** A comprehensive but not exhaustive overview of existing actions in relation to sound management of lead (apart from lead paint; for lead paint, see Table A—6 above)

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties, national and regional legislation and regulations] | | | | |
| Ban / restrictions | EU | Jewellery and specific articles used by the general public | • A ban of jewellery articles with any individual parts containing lead (expressed as metal) that is equal to or greater than 0.05% by weight, with the exception of jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before December 1961.<br>• A ban of articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05% by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. (ECHA 2012) | In force |
| | | Electrical and electronic equipment | The Restriction of Hazardous Substances (RoHS) Directive specifies maximum levels by weight for lead (0.1%) in electrical and electronic equipment. These maximum levels are exempted when lead is used as an alloying element in steel, aluminum, copper; in specific solders; and in specific glass and ceramic applications, through 2024. For more information, see RoHS Annex III Lead Exemptions; latest consolidated version of the directive (European Union [EU] 2011). | In force |
| | | Vehicles | The Directive 2000/53/EC on end-of-life vehicles restricts the use of certain hazardous substances in materials and components of vehicles put on the market after 1 July 2003. Currently, vehicles and parts for vehicles placed on the EU market shall not contain lead, mercury, cadmium and hexavalent chromium, with specific exemptions listed in Annex II of the Directive (EU 2000; EU 2020). | In force |
| | | Fertilisers | In Regulation (EU) 2019/1009, which lays down rules on marketing of EU fertilising products, limit values of lead in different fertilizers are set. For example, lead in an organic fertiliser must not exceed 120 mg/kg dry matter (EU 2019). | Stepwise enter into force from 15 July 2019 to 16 July 2022 |
| | | PVC, shot, ammunition and fishing tackle | • A restriction proposal on the use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds is being processed under REACH.<br>• A restriction proposal on the use of lead shot over wetlands is being processed under REACH, to harmonise national legislation already enacted by some Member States (or regions in some Member States) at the EU level. This action is further to international action through the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of UNEP to which the EU is a Party. As of 2016, a decision is still pending from the European Commission (European Chemicals Agency [ECHA] 2018a).<br>• In addition, the European Commission requested ECHA to restrict placing on the market and use of lead in ammunition (gunshots and bullets) and fishing tackle. The assessment will cover the use of lead in gunshot in terrains other than wetlands, bullets used both in wetlands and in terrains other than wetlands as well as lead in fishing tackle. Currently, a restriction dossier is being prepared by ECHA and the expected date of submission is October 2020 (ECHA 2019). | In process |
| | Philippines | Lead and lead compounds in seven uses | In 2013, the Philippines Government adopted the Chemical Control Order (CCO) for Lead and Lead Compounds. The use of lead and lead compounds shall be strictly prohibited in production and manufacturing of the following: packaging for food and drink; fuel additives; water pipes; toys; school supplies; cosmetics; paints (as a pigment, a drying agent or for some intentional use) with more than 90 ppm threshold limit beyond three years (2013-2016) for architectural, decorative and household applications and six years (2013-2019) for industrial applications. In addition, the order sets a number of general requirements and procedures including registration and permitting, a lead and lead compounds management plan, labelling requirements, manufacturing and training requirements, storage requirements, transport, treatment and disposal requirements, and substitution and phase-out plans (Philippines Department of Environment and Natural Resources 2013). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Ban / restrictions** | **Canada** | **Cosmetics, consumer products including children's jewellery** | • The use of lead compounds in cosmetic products is prohibited in Canada (Government of Canada 2019). Furthermore, various regulations under the Canada Consumer Product Safety Act (CCPSA) set out a 90 mg/kg total lead limit for applied surface coatings on toys, children's articles, carriages and strollers, and cribs, cradles and bassinets, as well as Group 1 products under the LRRS, which include all toys for children under 3 years of age, and including children's jewellery (Government of Canada 2018a; Government of Canada 2018b).<br>• Each accessible part of a consumer product containing lead must not contain more than 90 mg/kg of lead when tested in accordance with good laboratory practices. Exceptions can be made for lead that is necessary to produce an essential characteristic of the part; when no alternative part containing less lead is available; and the part, when tested in accordance with good laboratory practices, does not release more than 90 mg/kg of lead. A consumer product refers to an object that is brought into contact with the user's mouth during normal use, except for a kitchen utensil, or a product that is subject to the Glazed Ceramics and Glassware Regulations; any clothing or clothing accessory that is intended for use by a child under 14 years of age; a product that is intended for use in learning or play by a child under 14 years of age; a book or similar printed product that is intended for a child under 14 years of age, except if it is printed on paper or cardboard, and printed and bound in a conventional manner using conventional materials; a product whose primary purpose is to facilitate the relaxation, sleep, hygiene, carrying or transportation of a child under four years of age (Government of Canada 2018a). | In force |
| | **Australia** | **Industrial surface coatings or inks; import goods** | • Use of lead bis(2-ethylhexanoate and lead dioctanoate in industrial surface coatings or inks at concentrations greater than 0.1% of the non-volatile content is prohibited (Government of Australia 2014).<br>• The import of cosmetic products containing more than 250 mg/kg of lead as lead or lead compounds is prohibited under the *Customs (Prohibited Imports) Regulations 1956* (Cwlth) unless the permission in writing of the Minister or an authorised person has been granted, along with toys coated with a material the non-volatile content of which contains more than 90 mg/kg of lead; money boxes coated with a material that contains more than 90 mg/kg of lead; pencils or paint brushes coated with a material the non-volatile content of which contains more than 90 mg/kg of lead; erasers, resembling food in scent or appearance, that contain more than 90 mg/kg of lead. However, lead acetate compounds for use in hair products are exempt from this prohibition. The regulations also prohibit without permission under regulation 4U candles with wicks that contain greater than 600 mg/kg by weight and candle wicks containing greater than 600 mg/kg lead. The regulations further include a list of articles of glazed ceramic ware, methods of testing and permissible levels of lead release (Government of Australia 2016). | In force |
| | **US** | **Hair dyes** | Lead acetate compounds are approved for use in hair dyes intended for scalp hair only in the US at concentrations of less than or equal to 0.6% by weight (United States Food and Drug Administration 2017). | In force |
| | **Eurasian Economic Union** | **Toys, packaging material, perfumery and cosmetic products, food products, certain infants' products** | The Eurasian Economic Union has adopted a series of technical regulations, which establish requirements to technical regulation objects, in particular safety requirements, mandatory for application and execution in the territory of the Union:<br>• TR CU 008/2011 on toy safety sets the release (migration) of lead contained in 1 kg of any toy materials into the model medium (hydrochloric acid) not to exceed 90 mg; migration of lead from tin bronzes and lead-silver alloys into aqueous media no more than 0.03 mg/dm3.<br>• TR CU 005/2011 on safety of packaging sets the allowable quantity of migration of 0.03 mg/L from food contact packaging made from paper, cardboard, parchment, titanium enamels, epoxyphenol varnishes, as well as 2 mg/L from food contact packaging made from glass, porcelain, fayence and ceramic products.<br>• TR CU 009/2011 on the safety of perfumery and cosmetic products forbids the use of lead in perfumes and cosmetics.<br>• TR CU 021/2011 on safety of food products sets the acceptable levels of arsenic in different food products: 0.5 mg/kg in meat and meat products, poultry and poultry products, canned meat, poultry; 0.1 mg/kg in raw milk, raw skim milk, raw cream, drinking milk and drinking cream, milk drinks, fermented milk products, sour cream, ice cream of all types from milk and on a milk base; 0.5 mg/kg in food grains; 0.5 mg/kg in sugar; 0.5 mg/kg in vegetables, potatoes, melons, juice products and vegetables; 0.1 mg/kg in all types of vegetable oils. | In force |
| | **National** | **Lead in electrical and electronic products** | A number of countries and regions have adopted RoHS-like laws to restrict the levels of lead in electrical and electronic products. For more information, see Section 3.4. | In force |
| | **National and local** | **Ammunition** | • Lead shot is banned for shooting over wetlands in Peru (UNEP 2014a).<br>• Lead shot use has been legally restricted in 23 European countries. Of these, Denmark and the Netherlands have a total ban of lead gunshot use in all types of habitats, 16 countries have a total ban in wetlands and/or for waterbird hunting, and 5 have a partial ban implemented only in some wetlands. The legal regulation of lead bullets is limited to some German regions (Mateo and Kanstrup 2019).<br>• Effective 1 July 2019, nonlead ammunition is required when taking any wildlife with a firearm anywhere in California, US (California Department of Fish and Wildlife n.d.). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Ban / restrictions** | **China** | **Imported copper concentrates** | Under the current rules introduced in April 2006, shipments of metal concentrate into China must undergo inspection by the China Inspection and Quarantine Services (CIQ) and may not contain levels of more than 0.5% arsenic, 6% lead, 0.1% fluorine, 0.05% cadmium and 0.01% mercury. These limit values are being revised now. (See Metal Bulletin, Luk 2019) | In force |
| **PIC procedure** | **International** | **Tetraethyl lead; tetramethyl lead** | Tetraethyl lead and tetramethyl lead (CAS No. 78-00-2; 75-74-1) are listed in Annex III of the Rotterdam Convention (i.e. they have been banned or severely restricted for health or environmental reasons by two or more Parties) and subject to the PIC procedure. | In force |
| **Environmentally Sound Management (ESM) of Waste** | **International** | **Waste lead–acid batteries; waste containing lead** | • Under the Basel Convention, the following wastes related to lead are listed as "hazardous wastes": those wastes having lead or lead compounds as constituents (classification Y31 in Annex 1); metal wastes and waste consisting of alloys of lead (classification A1010 in Annex VIII)' waste having lead as constituents or contaminants, excluding metal waste in massive form (classification a1020 in Annex VIII); waste zinc residues not included on list B, containing lead and cadmium in concentrations sufficient to exhibit Annex III characteristics (classification A1080 in Annex VIII); waste lead-acid batteries (classification A1160 in Annex VIII) and waste electrical and electronic assemblies or scrap containing components or contaminated with Annex I constituents (classification A1180 in Annex VIII).<br>• Parties to the Convention are to manage this waste stream in accordance with the provisions set out in the Convention, including by reducing to a minimum their generation; restricting the transboundary movements of such wastes, except where it is perceived to be in accordance with the principles of environmentally sound management; taking appropriate measures to ensure their environmentally sound management. Each Party has the obligation to transmit to the Secretariat a national report on an annual basis that contains information, among other things, on the amount of wastes generated. | In force |
| **Emissions reductions** | **Regional** | **Emissions** | The 1998 Aarhus Protocol on Heavy Metals of the Convention on Long-Range Transboundary Air Pollution includes provisions that Parties must reduce their emissions for lead below 1990 levels (or an alternative year between 1985 and 1995; United Nations Economic Commission for Europe n.d.). It aims to cut emissions from industrial sources (iron and steel industry, non-ferrous metal industry), combustion processes (power generation, road transport) and waste incineration. It lays down stringent limit values for emissions from stationary sources and suggests best available techniques for these sources. In addition, the Protocol requires Parties to phase out leaded petrol. It also introduces measures to lower heavy metal emissions from other products.<br>In 2012, Parties to the Protocol on Heavy Metals adopted decision 2012/5 to amend the Protocol to include more stringent controls of heavy metals emissions and to introduce flexibilities to facilitate accession of new Parties, notably countries in Eastern Europe, the Caucasus and Central Asia. As of March 2020, these amendments have not yet entered into force. | In force |
| **Marketing authorisation** | **EU** | **Three lead compounds** | Under REACH, lead chromate, lead chromate molybdate sulfate red and lead sulfochromate yellow are listed in the Authorisation List with a sunset date of 21 May 2015. They are thus banned in the European Union (EU) unless an Authorisation is granted for a definite period of time (ECHA n.d. b). | In force |
| **Mandatory National standards** | **China** | **Toys, water pipes** | In 2014, China adopted a revised National Safety Technical Code for Toys (GB 6675-2014, China National Institute of Standardization 2014) that specified and limited the plastics additives that could be used in plastic toys, including maximum limited quantities of lead (90 mg/kg in any toy material except finger paint, and 25 mg/kg in finger paint). Products that fail to meet the mandatory GB standards may not be placed on the China market. | In force |
| | | **Infant and children textile products** | In 2015, the Government of China published the mandatory standard related to infants and children textile production (GB 31701-2015; Standardization Administration of China 2015). It covers technical requirements for fabric, filling materials and attached components for infants and children's textile products, including the limit value of 90 mg/kg for lead. Products imported into the Chinese market which do not comply with the requirements of this standard are prohibited from sale. The instructions for use shall indicate the code of the standard and the safety category. | In force |
| | **US** | **Drinking water** | The action level for lead in drinking water is set to 0.015 mg/L. If more than 10% of tap water samples exceed the action level, water systems must take additional steps to treat the water or water delivery systems, which can release lead through corrosion (United States Environmental Protection Agency 1991). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Notification | EU | | Lead and lead compounds, in total 32 CAS numbers, are listed as SVHCs under REACH, owing to reproductive toxicity, and carcinogenicity for some compounds. Manufacturers and importers thus have legal obligations to provide sufficient information to allow safe use of the article containing lead above 0.1 wt% (ECHA 2018b; ECHA, n.d. b). | In force |
| | Australia | Emissions | In Australia, lead and lead compounds are subject to reporting under the Australian National Pollutant Inventory (NPI). Under the NPI, emissions of lead and lead compounds are required to be reported annually by facilities that use or emit more than 10 tonnes of lead or lead compounds, burn more than 2000 tonnes of fuel, consume more than 60,000 megawatt hours of electricity (excluding lighting and motive purposes), or have an electricity rating of 20 megawatts during a reporting year (Government of Australia n.d.). | In force |
| Guideline values | National (or regional) | Occupational, water, air, waste, soil, food | A number of lead guideline values for different exposure media including occupational exposure have been developed in different countries. Pohl, Ingber and Abadin (2017) provides an overview of existing guidelines in Australia, the US, the EU, Singapore and Uruguay. Note that not all guideline values are legally binding, but are only recommended (thus, some of them would rather be considered as soft-law instruments). Additional information may also be found in Silbergeld (1995) with caution that some values may have been updated. | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| Resolution | International | Waste, paint and other | In 2018, UNEA 3 adopted a Resolution "Eliminating exposure to lead paint and promoting environmentally sound management of waste lead-acid batteries", including 1. reiterates its strong determination to continue to reduce exposure to lead, including through promoting the environmentally sound management of waste lead-acid batteries and eliminating lead paints; 3. encourages Member States to continue their efforts for the environmentally sound management of waste lead-acid batteries, including by: (a) developing national strategies in order to manage the collection of waste lead-acid batteries and addressing the issue of remediation of contaminated sites; (b) adequately addressing releases, emissions and exposures from waste lead-acid batteries, including recycling, and utilizing appropriate standards and criteria; (c) cooperating in collecting waste lead-acid batteries for environmentally sound processing at regional or national recycling facilities, consistent with the relevant provisions of the Basel Convention and relevant regional conventions, such as the Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa, as applicable (UNEP n.d. b).<br>In addition, UNEA adopted a resolution 2/7 at its second session, and a resolution 1/5 at its first session (UNEP n.d. b). | |
| | International | Ammunition | The World Conservation Congress (2016) of the IUCN adopted a resolution WCC-2016-Res-082 on "A path forward to address concerns over the use of lead ammunition in hunting", including reference to Resolution 11.15 by the Convention on Migratory Species. | |
| Resolution + Guidelines + Task force | International | Ammunition | In 2014, the COP of the Convention on Migratory Species adopted a resolution 11.15 on preventing poisoning of migratory birds, which was revised and adopted in 2017 at the subsequent meeting of the COP (UNEP 2017a). Its provisions include "highlighting the need to provide practical guidance on preventing, reducing or controlling poisoning from, ... use of lead for hunting and fishing", and "acknowledging the positive actions undertaken by some Parties to the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) to phase out the use of lead shot for hunting in wetlands.<br>In addition, through the Resolution, the COP adopted the "Guidelines to Prevent the Risk of Poisoning to Migratory Birds" (UNEP 2014b), including recommendations on phase-out the use of lead ammunition across all habitats (wetland and terrestrial) with non-toxic alternatives within the next three years with Parties reporting to Conference of the Parties (COP12) in 2017, working with stakeholders on implementation; promotion of leadership from ammunition-users on safe alternatives, and remediation of lead-polluted sites where appropriate.<br>Furthermore, there is a Lead Task Group established under the Preventing Poisoning Working Group under the Convention. The role of the Lead Task Group is to facilitate concerted efforts, knowledge and information sharing, including communication, education and public awareness raising to minimizing poisoning of migratory birds from anthropogenic environmental sources of lead prioritizing ammunition and fishing weights and also those identified in the Guidelines: leaded paint, discarded lead and that from industrial mining and smelting processes. | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| Strategy | Canada | | Health Canada has developed a Risk Management Strategy for Lead that outlines the existing and planned control actions for lead that comprise the Canadian federal risk management strategy for this substance (Health Canada 2013). | Ongoing |
| Prioritization | China | | In 2017, the Government of China published the Prioritized List of Substances to be Subject to Control (1st Batch), including lead compounds (Ministry of Ecology and Environment of the People's Republic of China 2017). To control the manufacturing and use of these chemicals, the Government will adopt one or several of the following risk management measures: Enterprises should obtain sewage discharge permission before they discharge these chemicals; the State will restrict the use of these substances in some products and encourages enterprises to use substitutes; and clean production audits will be implemented. | Ongoing |
| Recommended Standard | China | **PVC pipes for water supply** | In 2006, the national standard GB/T 10002.1-2006 - Unplasticized Poly(vinyl chloride) (PVC-U) Pipes for Water Supply - came into force (Standardization Administration of China 2006). The standards prohibit the use of lead as a heat stabiliser in plastic pipes for drinking water. | In force |
| | International | **Drinking water; air; tolerable intake level** | WHO set a guideline value of 0.01 mg/L for lead in drinking water (WHO 2017b) and a guideline value of 0.5 ug/m3 (annual average) for lead in air (WHO 2000).In a review of the latest scientific evidence, conducted in 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) estimated that the previously established provisional tolerable weekly intake (PTWI) of 25 ug/kg body weight per week could no longer be considered health protective and withdrew it (WHO 2011). As the dose-response analyses did not provide any indication of a threshold for the key adverse effects of lead, the Committee concluded that it was not possible to establish a new PTWI that would be health protective. The dose-response analyses conducted by the Committee should be used as guidance to identify the magnitude of effect associated with identified levels of dietary lead exposure in different populations. | In force |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| Partnership | International | **Leaded gasoline** | Establishment and operation of the public-private Partnership for Clean Fuels and Vehicles (PCFV) by UNEP in 2002 to assist the 82 countries that were still using leaded petrol at that time in phasing out leaded gasoline (UNEP n.d. c). | |
| Guidance and tools | International | **Lead-acid batteries** | • Under the framework of the Basel Convention, a number of guidance documents have been developed, including<br>- *Technical Guidelines for the Environmentally Sound Management of Waste Lead-acid Batteries* (Secretariat of the Basel Convention 2003), which provides a comprehensive approach to the management of waste lead-acid batteries including when implementing recycling programmes.<br>- A Fact Sheet that is intended for use by collectors, transporters and operators of facilities that store, recycle or otherwise dispose of waste lead-acid batteries (UNEP 2017b).<br>- A draft practical guidance for the development of inventories of used lead-acid batteries and other waste streams, aiming to provide practical instructions to assist Parties and others in developing an inventory of waste lead-acid batteries (UNEP 2017c). It is meant to be used in conjunction with the methodological guide for the development of inventories of hazardous wastes under the Basel Convention, which provides complementary guidance on the methods of developing national inventories for the preparation of national reports.<br>• WHO (2017c) developed the document Recycling used lead-acid batteries: health considerations, which "aims to help the health sector recognize recycling used lead-acid batteries as an important source of lead exposure so that they can advocate for this practice to be better controlled and regulated. It also aims to inform policymakers of the health and economic burdens of lead exposure as a stimulus to introducing and enforcing control measures."<br>• UNEP in collaboration with the ILA provides ongoing training on the Benchmarking Assessment Tool of Lead, which enables regulators to make a proper assessment on used lead-acid battery activities in all affected regions (Wilson 2018). | Ongoing |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Voluntary phase-out | EU | PVC | VinylPlus is the 10-year Voluntary Commitment of the European PVC Industry (VinylPlus 2011). It included a target for lead replacement in the EU-27 by the end of 2015 (extended to the EU-28 in 2014), which was achieved (VinylPlus 2020). | completed |
| | International | | Apple includes lead in its Regulated Substances Specification (Apple 2018). | |
| Third-party standards and certification schemes | International | | Lead is included in the bluesign® Restricted Substances List for a usage ban with the limit of trace of 0.2 mg/kg (Bluesign 2020). Similarly, lead is included in the Zero Discharge of Hazardous Chemicals (ZDHC) Manufacturing Restricted Substances List (MRSL; ZDHC 2019).<br>Nordic Swan Ecolabel (a.k.a. Nordic Swan) criteria include the requirement for cadmium (Nordic Ecolabelling 2020). | |
| Voluntary action | International | | The ILA Lead Action 21 (LA21) programme provides a focus for members to share information, best practices, and expertise to provide practical help and guidance to countries, in the developing world and those in transition, that need it (ILA 2020). | Ongoing |
| | International | Lead-acid batteries | Intergovernmental institutions have implemented country projects that are co-financed by the Global Environment Facility ([GEF] 2014), e.g. GEF ID 5701: Reducing Environmental and Health Risks to Vulnerable Communities from Lead Contamination from Lead Paint and Recycling of Used Lead Acid Batteries in Indonesia and the Philippines. | |

# 6. Microplastics

**Table B–6.1.** A brief overview of existing assessments of environmental and human effects of microplastics by national governments and intergovernmental institutions since 2010.

| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| European Chemicals agency (ECHA 2019) | Proposal for an EU-wide restriction | Uses in<br>(i) agriculture and horticulture;<br>(ii) cosmetic and personal care products;<br>(iii) detergents and maintenance products;<br>(iv) paints, coatings and inks;<br>(v) chemicals used in the oil and gas sector;<br>(vi) construction;<br>(vii) medicinal products;<br>(viii) medical devices; and<br>(ix) food supplements and medical food | (i) Literature review;<br>(ii) risk assessment using the threshold, non-threshold and "case-by-case" approaches as outlined in Annex 1 of REACH, considering down-the-drain, municipal solid waste, and direct releases;<br>(iii) open stakeholder consultation | • Information is lacking to derive robust predicted no-effect concentrations (PNECs), particularly for terrestrial ecosystems.<br>• Conventional threshold-based risk assessment cannot currently be carried out for microplastics with sufficient reliability, even with PNEC values derived using large assessment factors, e.g., 1,000 to 10,000. In this respect, microplastics should be treated as non-threshold substances for the purposes of risk assessment, with any release to the environment assumed to result in a risk, similarly to persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBT/vPvB) substances.<br>• Their "extreme", arguably permanent, persistence in the environment results in a situation where any releases contribute to a progressively increasing environmental stock, which would eventually result in exposures exceeding safe thresholds in the future, assuming that sufficient information becomes available to reliably derive values for different ecosystems. In this respect, the relevant risk characterization could be considered in terms of when safe thresholds will be exceeded, rather than if safe thresholds will be exceeded. | |
| World Health Organization (WHO 2019) | State-of-the-knowledge assessment | Human health risks of microplastics in drinking water | (i) Review of scientific studies;<br>(ii) a very conservative exposure scenario and margin of exposure assessment | • The potential hazards associated with microplastics come in three forms: physical particles, chemicals in the particles or sorbed/absorbed to them, and microbial pathogens as part of biofilms. Based on the limited evidence available, chemicals and biofilms associated with microplastics in drinking water pose a low concern for human health. However, microplastics may enable pathogens to travel longer distances in freshwater environments, and related biofilms may contribute to antimicrobial resistance.<br>• Although there is insufficient information to draw firm conclusions on toxicity related to the physical hazard of plastic particles, particularly for nano-sized particles, no reliable information suggests it is a concern for human health. | Very limited reliable toxicological or epidemiological studies available to inform human health risk assessment for microplastic ingestion via drinking water |
| Science Advice for Policy by European Academies (2019) | Scientific perspective on the state of knowledge about the implications in nature and society | Health and environmental impacts of nano- and microplastic pollution | (i) Literature review of over 450 scientific studies;<br>(ii) workshop with external experts for additional input;<br>(iii) peer review by independent scientists | • Currently at least some locations may have predicted or measured environmental concentrations (P/M-EC) that exceed the PNEC, i.e. P/M-EC:PNEC > 1.<br>• Given the current generally large differences between known MEC and PNEC, it is more likely than not that ecological risks of microplastics are rare (no widespread occurrences of locations where PEC:PNEC > 1); if microplastics emissions to the environment remain the same over the next century, the ecological risks of microplastics eventually may be widespread.<br>• Even though "high quality" risk assessment is not yet feasible, actions to reduce, prevent and mitigate pollution is suggested to be needed. | Uncertainties in the assessment due to data gaps on, e.g., evidence that the negative effects recorded in the laboratory happen in the real-world environment and in humans |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP 2016) | **Provide an improved evidence base, to support policy and management decisions on measures that might be adopted to reduce the input of microplastics to the oceans** | **Focus on the effects in the marine environment; research priorities** | (i) **Literature review;**<br>(ii) **assessment framework based on the Driver-Pressure-State-Impact-Response (DPSIR) model** | GESAMP is an advisory body of specialized expert nominated by the Sponsoring Agencies (International Maritime Organization, FAO, Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific and Cultural Organization, United Nations Industrial Development Organization, World Meteorological Organization, International Atomic Energy Agency, United Nations, UNEP and United Nations Development Programme) to provide scientific advice concerning the prevention, reduction and control of the degradation of the marine environment to the Sponsoring Agencies.<br>• "Microplastics have been documented in a diversity of habitats and in over 100 species of biota. Microplastics can impact an organism at many levels of biological organization. Still, the majority of the evidence is for sub-organismal effects (e.g. changes in gene expression, inflammation, tumour promotion) or effects on individual organisms (i.e. death). Microplastics can present a physical hazard, but can also be a source of hazardous chemicals to organisms. The importance of microplastics as a source of chemicals relative to others (e.g. water, sediment, diet) remains under investigation. Microplastics can also act as a vector for invasive species, including harmful algal blooms and pathogens. Nano-sized plastics are probably as common as micro-sized plastics, yet the hazards are less understood and may be more complex.<br>• "The impacts of the consumption of microplastics by food fish are unknown; however, studies on non-commercial species suggest microplastics have the potential to negatively affect organism health, and hence food security although at current observed concentrations this appears to be unlikely. It is possible that microplastics may increase the chemical contamination of seafood, but there is little evidence to suggest that this represents a significant increase in risk to human health at the current observed microplastic concentrations."<br>• "In many cases, environmental levels of microplastics may be difficult to interpret due to the lack of consistency in the assays used and technical challenges. As sampling, extraction, detection methods and techniques are developed worldwide, a harmonization and standardization of techniques and protocols is urgently needed to better assess risk in a reproducible manner, and assist in data comparisons."<br>Based on the DPSIR model, an example of potential responses to reduce the impact of marine litter on turtles would be as follows: driver (coastal tourism) → pressure (littering on beach) → state (plastics in sea) → impact (loss of ecosystem service) → responses to address driver (create nature reserve), pressure (install litter bins, education programme), state (coastal clean-up), and impact (rescue centre for injured turtles). |  |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| **Food and Agriculture Organization of the United Nations (FAO. 2017)** | **Review of the available scientific evidence, provide a risk assessment framework related to commercial fish stocks and consumers** | **Fisheries and aquaculture perspective** | (i) **Existing scientific literature published in international journals and expert knowledge;**<br>(ii) **review by an expert workshop** | • Experimental studies show some negative impacts on marine animals (at very high exposures), but there are currently no reliable data on wild populations.<br>• From a food safety point of view, the exposure to contaminants from the ingestion of microplastics through seafood consumption is negligible compared to contaminant exposure from other sources.<br>• Future research efforts as well as risk analysis and management need to focus on the smaller particles (e.g. microfibres and nanoparticles) that have the capacity to enter cell membranes.<br>• Fisheries and aquaculture products are important in many diets as a source of essential nutrients. On the basis of current evidence, the risk of not including fish in our diets is far greater than the risks posed by exposure to plastic-related contaminants in fish products. | Uncertainties in the assessment due to data gaps on, e.g., the occurrence of microplastics (including nanoplastics) in seafood and their toxicological impacts |
| **Environment Climate Change Canada (ECCC 2015)** | **Science summary for justification of recommendation for regulation** | **Focus on environmental impacts of intentionally produced microplastics only** | (i) **Review of more than 130 scientific studies of microbead pollution;**<br>(ii) **open stakeholder consultation** | In laboratory studies, microbeads have shown adverse short- and long-term effects in aquatic organisms. Microbeads may reside in the environment for a long time and continuous release of these substances to the environment may result in long-term effects on biological diversity and ecosystems. It is recommended that microbeads be considered toxic under subsection 64(a) of the Canadian Environmental Protection Act, 1999 (Government of Canada 2019). | Human health risks and nano-sized microplastics not included in the assessment due to data gaps |

**Table B–6.2.** Supporting information on the life cycle of and exposure to microplastics, as well as examples of cost-of-inaction and benefits-of-action information.

| | |
|---|---|
| **Chemical identity** | Microbeads are defined in UNEP (2019) as pieces of plastic typically less than 5mm in length, but ECHA (2019) and Scudo *et al.* (2017) note differences in definitions used. Essel *et al.* (2015) identifed both primary microplastics (tiny plastic particles directly manufactured and intentionally added to articles as such – also called microbeads); and secondary microplastics (plastic fragments from larger plastic articles in the environment, including from textiles via washing and use of tyres). |
| **Production information** | |
| **Production overview** | Microplastics derive from a wide range of conventional plastics. Scudo *et al.* (2017) identified 14 synthetic polymers for intentionally added microplastics, of which the most common are polyethylene (PE) and polyurethane (PU). The former is manufactured via the polymerisation of ethylene (Zhong 2017); the latter via reaction between polyol and isocyanate (Gama 2018). Polypropylene (PP), polyvinyl chloride (PVC) Polystyrene (PS) and polyethylene terephthalate (PET) are also noted in GESAMP (2015), with PE, PP, PS the three most common polymer types found in debris sampled at sea, based on a review of 42 studies. |
| **Use information** | |
| **Key uses/applications** | Based on the recent review by ECHA (2019), uses of primary microplastics (including microbeads) include:<br>• Cosmetics and personal care products (rinse off and leave on). They provide a range of exfoliating and cleansing functions, illuminating effects on skin and opacity control. They can be used in lipstick, loose or pressed powders and liquid or thick emulsions with powdery feel. Microplastics may also be used as a carrier for other ingredients. For more information, see UNEP (2015).<br>• Detergents and maintenance products, including surface cleaning products, fabric softeners, dishwashing liquids, waxes and polishes. They are used as abrasives, fragrance encapsulation, opacifying and anti-foam agents.<br>• Agriculture and horticulture: controlled-release formulations (CRF) for fertilisers and plant protection products (typically as microencapsulation), as fertiliser additives (e.g. anti-caking agents) and as soil conditioners. Similar to microencapsulation, seed coating involves the deposition of polymeric material on seeds such that coated seeds may be considered microplastic particles as they fall below the upper size limit of 5 mm.<br>• Medical devices and in vitro diagnostic (IVD) medical devices – components in ultrasound devices, reagents in in-vitro diagnostic medical devices. Microplastics are also frequently used in the manufacturing of IVD reagents and devices (e.g. chromatography columns used to purify antibodies).<br>• Medicinal products for human and veterinary use - main component of controlled-release medicines. In medicinal products, microplastics are often classified as excipients, but they can also be authorised as an active pharmaceutical ingredient (API).<br>• Food complement and medical food - used in the formulation of food complements (e.g. vitamins) as 'controlled-release' agent, and to hide unpleasant taste.<br>• Paints, coatings and inks (professional and consumer use). Used to provide a film forming function in water-based paints and coatings; used as speciality additives in architectural and industrial coatings (wood, plastic, metal); microplastic additives enhance properties like matting, abrasion resistance, scratch resistance, mark resistance and side sheen control; used to add texture and structure to surfaces; used in combination with metallic pigments to achieve a sparkle effect by controlling pigment orientation.<br>• Oil and gas – additives in drilling and production chemicals (lubricants, friction reducing agents, antifoam agents, demulsifiers).<br>• Plastics – speciality additives in thermoplastic masterbatches and engineered materials as light diffusion agents, anti 'blocking' agents and to introduce surface structure.<br>• Technical ceramics – used as a pore forming additive to achieve the correct size and amount of pores in porous ceramics, and combusted as part of the production process.<br>• Media for abrasive blasting – used to remove difficult contaminants, e.g., paint, plastics, rubber and adhesive, from plastic tools and dies, etc. The material of the granules varies depending on the wanted features; they may consist of poly methyl metacrylic polymer, melamine, urea formaldehyde, urea amino polymers or poly amino nylon type. The granulate size ranges from 0.15-2.5 mm and the relative density is >1000 kg/m3.<br>• Adhesives – used as a spacer in adhesives; metallic plated microplastic particles can be used in conductive adhesives in electronics.<br>• 3D printing – used in Fused Deposition Modelling (FDM) printers for consumers.<br>• Printing inks – The toner in laser printing is mostly made of granulated plastic to make the powder electrostatic. |
| **Examples of costs-of-inaction and benefits-of-action information** | |
| **Benefits of action** | ECHA (2019) estimated that the proposed restriction may result in a cumulative emission reduction of approximately 400 thousand tonnes of microplastics over the 20 year period following its entry into force (a reduction of 85-95% of the quantified emissions of intentionally added microplastics that would otherwise have occurred in the absence of the restriction taking effect) at a cost of approximately €9.4 billion (NPV). The average cost effectiveness of avoided emissions, for sectors where those have been quantified, is estimated to be €23/kg per year ranging from €1/kg to €820/kg per year. The costs of the labelling requirements could not be quantified, but are considered to be negligible. |

**Key markets**

- Application-specific data on intentionally added microplastics (microbeads) is limited, but ECHA (2019) note the following for the EU28 (more detailed disaggregation is available in the source document, pp. 74 and 75:

| **Sector/application** | **Use / disposal/ loss of (t/yr),** including releases down the drain (via wastewater); via municipal solid waste and or direct application/deposition to soil | **Eventual releases to the environment (t/yr)** |
|---|---|---|
| Cosmetics | 9,300 (18%) | 3,800 (11%) |
| Detergents and maintenance | 9,700 (19%) | 4,400 (12%) |
| Agriculture and horticulture | 23,500 (46%) | 23,500 (65%) |
| Oil and gas | 1,200 (2%) | 270 (1%) |
| Paints and coatings | 5,200 (10%) | 2,700 8%) |
| Construction products | No data available | |
| Medicinal products | 2,300 (4%) | 1,100 (3%) |
| Total | 51,500 (100%) | 36,000 (100%). |

- Other reported examples and estimated releases in parentheses, if available
  - facial scrubs in China (306.9 t/yr to freshwaters; Cheung and Fok 2017)
  - toothpaste and facial cleaner/scrub in Malaysia (199 billion particles/yr; Praveena *et al.* 2018)
  - toothpaste in Turkey (Ustabasi and Baysal 2019)
  - facial scrubs purchased in Canada in 2016 (Hernandez *et al.* 2017); total annual use of microbeads in rinse-off personal care products in Canada 30,000-68,000 kg/year in 2015 (ECCC 2015) and more (Guerranti *et al.* 2019)

## Exposure information

**Main exposure sources and pathways**

- The environmental compartments affected are land and marine, with most empirical evidence focussing on oceans. Aquatic organisms are exposed via direct ingestion, indirect ingestion via food as well as dermal exposure (Beaman *et al.* 2016). In marine animals, feeding appendages and/or gastrointestinal tracts can become blocked, with plastic constituents/impurities leaching into flesh (ECHA 2019). Human exposure arises via contaminated food (shellfish in particular; Smith *et al.* 2018) and drinking water (WHO 2019).
- Most evidence focuses on the exposure pathways of microplastics more generally, rather the intentionally added microplastics. But ECHA (2019), identify the pathways of concern along with estimates of the percentage of releases to each pathway, by applications:
  - Down the drain disposal (accounts for the majority of releases from rinse off cosmetics, detergents, paints and coatings and medical devices and around half of leave on cosmetics and from medical devices). Wastewater effluents are a significant point source.
  - Municipal solid waste disposal (around half of leave on cosmetics and half from medical devices, with small amounts c.5% from rinse of cosmetics)
  - Direct release to the environment (account for all releases from agriculture, horticulture and oil and gas and around a third of those from waxes and polishes).
- The proportion of total microplastic waste comprised by intentionally added microplastics is not quantified, but Boucher and Friot (2017), describe those in detergents and personal care products as generating a “smaller but significant share”. ECHA (2019) note one study (Siegfried *et al.* 2017) which model releases – estimating microbeads from personal care products accounting for 10% of the total. Although modern wastewater treatment may capture up to 99% of microplastics, significant amounts may nevertheless enter waterways, depending on the existence and efficacy of wastewater treatment facilities, application of sewage sludges to soils and other pathways. European releases were more prevalent in the Mediterranean and Black seas, reflecting less effective waste water treatment plants (WWTP) (ECHA 2019).

**Foreseeable global trends**

- Microplastic pollution was “acknowledged as a globally pervasive pollutant” with concentrations expected to progressively increase, given increases in plastics production volumes and the inability of removal.
- A recent review suggests that “the replaceability of microplastic by more natural materials, the public interest in microplastic pollution, the improvement of WWTPs and bans on the use of microplastic in several countries make it unlikely that the development, marketing, disposal and consumption of products containing microplastic will increase” (Besseling *et al.* 2019).
- ECHA (2019) assumed that no net change in annual (European) demand for intentionally added microplastics to 2041.

**Table B–6.3.** A comprehensive but not exhaustive overview of existing actions in relation to sound management of microplastics.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national and regional legislation and regulations] | | | | |
| **Restriction / Ban** | **France** | **Use in (certain) personal care products and cosmetics** | A **ban** on the use in rinse-off exfoliating and cleaning cosmetic, with exemptions for particles of natural origins (i) not persisting in the environment, (ii) not releasing active or biologic substances, (iii) not affecting animal food chain. | In force |
| | **Italy** | | A **ban** on the production and marketing of all exfoliating rinse-off cosmetic products or detergents containing microplastics. | 01.07.2020 |
| | **Canada** | | A **ban** on the sale, import and production of personal care products containing microbeads as exfoliants or cleansers. | In force |
| | **US** | | A **ban** on the manufacturing, packaging, and distribution of rinse-off cosmetics containing plastics microbeads. It also applies to products that are both cosmetics and non-prescription drugs, such as toothpastes. (See https://www.fda.gov/cosmetics/cosmetics-laws-regulations/microbead-free-waters-act-faqs.) | In force |
| | **Mexico** | | Senate proposal to amend Health Law in Mexico to prohibit manufacturing, selling and distributing microplastics-containing cosmetics. (Ávila 2019) | Proposed in 2017. Proposal is being evaluated. |
| | **Argentina** | | Bill for the phase-down and phase-out of single-use plastics, including an Article on immediate ban of manufacture, import, export, sale and distribution of cosmetics and oral hygiene products containing microbeads. (Government of Argentina 2019)` | Presented in 2019. |
| | **Costa Rica** | | Bill for the phase-out of single-use plastics, including an Article on immediate ban of manufacture, import, export, sale and distribution of cosmetics and oral hygiene products containing microbeads. (Government of Costa Rica n.d.) | Presented in 2019 |
| | **Brazil** | **Bans of all uses intentional addition of microplastics to consumer cosmetics products** | The law would specifically prohibit the handling, manufacture, importation and marketing, throughout the national territory, of toiletries, cosmetics and perfumery containing the intentional addition of plastic microspheres. The law defines microbeads as any solid plastic or solid plastic particle less than 5 mm, used to clean, lighten, exfoliate the body or any of its parts (Heringer 2016). | Introduced |
| | **Belgium** | | The Federal Minister for Energy, the Environment and Sustainable Development and representatives of the Belgian and Luxembourg association for producers and distributors of cosmetics, cleaning and maintenance products, adhesives, sealants, biocides and aerosols (DETIC) prepared a Draft Sector Agreement that is legally binding but also a voluntary agreement to support the replacement of microplastics in consumer cosmetic rinse-off products and oral care products in the Belgian market by 31 December 2019 (UNEP 2018). | |
| | **India** | **Cosmetics and consumer products** | The Ministry of Health, along with different departments of the Bureau of Indian Standards, placed microbeads in a category not allowed as ingredients of various cosmetic and other such products including household laundry detergent bars, synthetic detergents for washing woolen and silk fabrics, synthetic detergents for industrial purposes, and household laundry detergent powders. However, final notification, including any modifications, will be published after inviting comments from the public (UNEP 2018). | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Restriction / Ban** | **EU-wide** | **All intentional uses** | A proposal for a restriction under REACH has been developed by ECHA, including<br>(i) a **restriction** on the placing on the market of microplastics on their own or in mixtures where their use will inevitably result in releases to the environment, irrespective of the conditions of use (including a transitional period for some of these uses);<br>(iii) a **labelling requirement** to minimize releases to the environment for uses of microplastics where they are not inevitably released to the environment but where residual releases could occur if they are not used or disposed of appropriately to enable information exchange along the supply chain; and<br>(iv) a **reporting requirement** to improve the quality of information available to assess the potential for risks in the future | Proposal being evaluated |
| | **Republic of Korea** | **Subset of personal care products documented to contain microbeads** | Regulations on safety standards for cosmetics, Annex 1 (No. 2017-114, Notice, Article 3, Dec. 29, 2017; UNEP 2018). | In force |
| | **Sweden** | | Regulation amending Regulation (1998: 944) prohibiting etc. in certain cases in connection with handling, import and export of chemical products (UNEP 2018). | In force |
| | **UK and Northern Ireland** | | The Environmental Protection (Microbeads) (England) Regulations 2017 The Environmental Protection (Microbeads) (Scotland) Regulations 2018 The Environmental Protection (Microbeads) (Wales) Regulations 2018 The Environmental Protection (Microbeads) (Northern Ireland) Regulations 2018 (UNEP 2018). | In force |
| | **New Zealand** | **Personal care wash-off products; abrasive household, car and industrial cleaning products** | Waste Minimisation (Microbeads) Regulations 2017, under section 23(1)(b) of the Waste Minimisation Act 2008 (UNEP 2018). | In force |
| **Soft law instruments** [e.g. resolutions and recommendations; codes of conduct; guidelines; communications; fiscal policies] | | | | |
| **Resolution** | **Global** | **All intentional uses** | The UNEP United Nations Environment Assembly [UNEA] Resolution 4/6, inter alia,<br>(i) calls upon Members States and stakeholders to address the problem of microplastics;<br>(ii) decides to strengthen coordination and cooperation by establishing a multi-stakeholder platform within UNEP to take immediate action towards the long-term elimination, through a life-cycle approach, of discharges of litter and microplastics into the oceans;<br>(iii) invites Member States, in close collaboration with the private sector to reduce the discharge of microplastics into the marine environment, including, where possible, through the phasing out of products that contain microplastics;<br>(iv) requests UNEP to develop guidelines for the use and production of plastics in order to inform consumers, including about standards and labels; to incentivize businesses and retailers to commit themselves to using sustainable practices and products. (UNEA 2019) | Adopted in 03.2019 |
| | **EU-wide** | **All intentional uses** | The European Parliament's resolution on European Strategy for plastics in a circular economy (2018/2035(INI)), inter alia,<br>(i) calls on the European Commission to introduce a ban on microplastics in cosmetics, personal care products, detergents and cleaning products by 2020; and<br>(ii) calls on ECHA to assess and prepare, if appropriate, a ban on microplastics which are intentionally added to other products, taking into account whether viable alternatives are available. | Adopted on 13.09.2018 |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Voluntary initiatives** [e.g. voluntary phase-out; awareness raising; capacity building; industry standards; labelling; partnerships] | | | | |
| Voluntary industry phase-out | Australia | Use in "rinse-off" personal care, cosmetics and cleaning products | • led by Accord - the peak industry association for cosmetics, hygiene, and specialty products, supported and overseen by the governmental authorities to phase out microbeads in "rinse-off" personal care, cosmetics and some cleaning products by July 2018.<br>• includes a "BeadRecede" campaign: (i) raising industry awareness and encourage companies to comply with the phase-out; (ii) offering government agencies a one-stop-shop for broad industry outreach and for consolidation of six-monthly progress reports.<br>(Government of Australia n.d.) | Ongoing monitoring and assurance |
| | International | | Adidas ended the use of microbeads in its body care products by 01.01.2016. (Denninger 2015) | |
| | ASEAN | | The ASEAN Cosmetic Association recommends that the use of plastic microbeads be discontinued in rinse off personal care products. (ASEAN Cosmetics Association 2020) | |
| | Belgium, France, Germany, UK | | Cosmetics industry agreements with governments to phase out uses in rinse-off products include the UK Cosmetic, Toiletry and Perfumery Association, French Federation of Beauty Companies (FEBEA or Fédération des Entreprises de la Beauté) and Belgian DETIC, for example (UNEP 2018). | |
| Voluntary standards | International | Use in "rinse-off" cosmetics | The EU Ecolabel requirements for the "rinse-off cosmetics" product group, comprising toilet soaps, shower gels, shampoo, conditioners, and shaving products explicitly restricted the use of microplastics (European Commission 2019). | Ongoing |
| | Nordic Swan Ecolabelling | Cosmetics labelling | Denmark, Finland, Iceland, Norway and Sweden participate in the Nordic Swan Ecolabel, "a voluntary official ecolabel introduced by the Nordic Council of Ministers in 1989. The cosmetics ecolabel criteria include limits on the use of microbeads including the prohibition of microplastics in the product or raw materials" (UNEP 2018). | |
| Consumer education | International | Use in personal care products and cosmetics | A "Beat the Microbead" campaign led by the Plastic Soup Foundation since 2012 and supported by 100 NGOs from over 42 countries around the world, informing consumers to stop using products containing microbeads, including (i) a website serving as clearing house, (ii) a "Beat the Microbead" App for consumers to check whether a product contains microplastics, and (iii) a "Zero Plastic Inside" logo labelling system to reward cosmetic brands that 100% free of microplastics in their products | Ongoing |

# 7. Neonicotinoids

**Table B–7.1.** A brief overview of existing assessments of environmental and human effects of neonicotinoids by national governments and intergovernmental institutions.

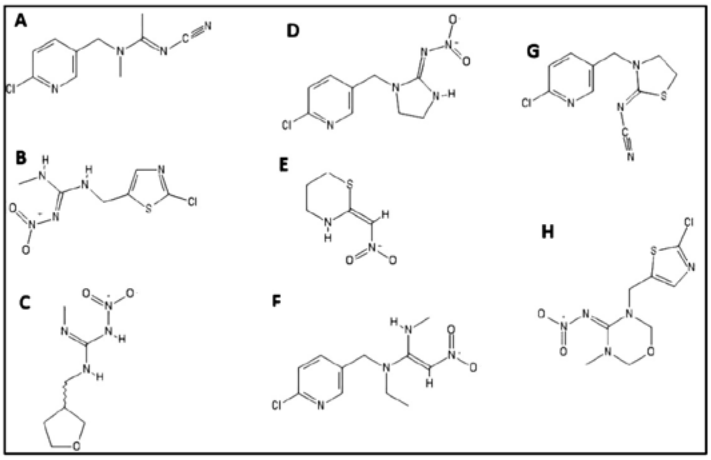
| | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| **European Food Safety Authority (EFSA 2016a; EFSA 2016b; EFSA 2016c; EFSA 2016d; EFSA 2018a; EFSA 2018b; EFSA 2018c; EFSA *et al.* 2019)** | **Assessments of clothianidin, imidacloprid, thiamethoxam, acetamiprid, thiacloprid** | (i) peer review,<br>(ii) risk assessment for environmental and human exposures | **Clothianidin** (EFSA 2018a)<br>For exposure via residues in pollen and nectar a low risk was concluded for some bee groups/use/scenario combinations, while a high risk was concluded in other cases. In the majority of cases where a Tier 3 risk assessment could be performed, the available data did not allow a low risk to be demonstrated, despite not indicating a clear high risk.<br>For the exposure via residues from dust drift during the sowing/application of the treated seeds, a low risk to honeybees for the use to sugar and fodder beet was concluded, whereas for bumblebees and solitary bees a low risk was not demonstrated with a screening assessment. For all other outdoor uses, a high risk to honeybees and bumblebees was concluded. Again, for solitary bees a low risk was not demonstrated with a screening assessment.<br>For exposure via water consumption, a low risk to honeybees was concluded for all uses via residues in puddles. A low risk to honeybees was concluded for residues in guttation fluid for the uses to winter cereals, sugar beet and potatoes. A high risk was concluded for all other uses.<br>A low risk to honeybees, bumblebees and solitary bees was concluded for the use to maize and sweet maize, which will be sown and maintained in permanent greenhouses. A risk assessment for the granular use to forestry nursery could not be performed with the available information.<br>**Imidacloprid** (EFSA 2018b)<br>For exposure via residues in pollen and nectar (where a Tier 3 risk assessment could be performed) and exposure via residues from dust drift, a low risk was concluded for some crops for honeybees. However, when all the bee groups (honeybees, bumblebees and solitary bees) are considered, a high risk was concluded or it was concluded that a low risk was not demonstrated for all the uses assessed.<br>For exposure via water consumption, a low risk to honeybees was concluded for all uses via residues in puddles or via surface water and for residues in guttation fluid, for the uses to winter cereals, sugar beet and potatoes. A high risk was concluded for all other uses.<br>**Thiamethoxam** (EFSA 2018c)<br>For exposure via residues in pollen and nectar, a low risk was concluded for some bee groups/use/ scenario combinations, while a high risk was concluded in other cases. In the majority of cases where a Tier 3 risk assessment could be performed, the available data did not allow a low risk to be demonstrated, despite not indicating a clear high risk.<br>For the exposure via residues from dust drift, a low risk was concluded for those uses that foresee planting in permanent greenhouses. For all other uses, either a high risk was concluded or the assessment could not be finalised.<br>For exposure via water consumption, a low risk to honeybees was concluded for all uses via residues in puddles. A low risk to honeybees was concluded for residues in guttation fluid for the uses for sugar beet. A high risk was concluded for all other uses.<br>**Acetamiprid** (EFSA 2016c)<br>It is extensively metabolised by animals and not detected in any animal matrices, except in milk. EFSA proposed to limit the enforcement residue definition to the N-desmethyl metabolite (IM-2-1).<br>A maximum residue limit was proposed for potato crops only. A risk for consumers was not identified considering the supported use on potatoes only.<br>Considering the acute reference dose (ARfD) value of 0.025 mg/kg body weight (bw) and the highest residue levels related to the uses evaluated under the review, an exceedance of the ARfD is identified for several food commodities. Therefore, the maximum residue limits listed in the EU legislation for these food commodities need to be reconsidered.<br>A low risk to honeybees (acute, chronic and larvae) and to bumble bees (acute) was concluded for all scenarios for the representative uses on pome fruit (post-flowering application) and potatoes.<br>The risk was concluded as low for terrestrial non-target plants, soil microorganisms and organisms used for biological sewage treatment.<br>It is unlikely that acetamiprid is an endocrine disruptor in mammals; however, no firm conclusion can be drawn for birds and fish.<br>**Thiacloprid** (EFSA *et al.* 2019)<br>It has a harmonised classification and labelling as carcinogen category 2 and toxic for reproduction category 1B.<br>It was identified as an endocrine disruptor for mammals based on scientific information. | Missing data led to some assessments being “could not be finalised” and some findings being “indicative only” and “require further consideration”. |

|  | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| United States Environmental Protection Agency (US EPA 2020a; US EPA 2020b; US EPA 2020c; US EPA 2020d; US EPA 2020e) | Review for authorisation renewal; imidacloprid, acetamiprid, clothianidin, thiamethoxam, dinotefuran | **Peer-reviewed literature, epidemiological assessments, public comments, economic impacts** | **Imidacloprid** (US EPA 2020a)<br>• Humans may be exposed to imidacloprid in food and drinking water from crop uses, residential applications, in occupational settings, and from exposures to spray drift. The primary target system for mammals via the oral route is the nervous system; observed effects include tremors/trembling, decreased motor activity, etc., in multiple neurotoxicity studies in dogs and rats. No signs of toxicity were observed through the dermal and inhalation routes in the available studies.<br>• Classified as a Group E chemical ("Evidence of non-carcinogenicity for humans"), oral Toxicity Category II (high oral lethality), and dermal Toxicity Category IV (low lethality by the dermal and inhalation routes).<br>• No acute and chronic dietary risks of concern were identified.<br>• Residential risks of concern: for children 1 to <2 years old, combined dermal and incidental oral exposure, dermal high-contact play on treated turf scenarios, and hand-to-mouth scenarios; for adults, high-contact play on treated turf scenario.<br>• Non-occupational spray drift exposure was determined to not be of concern.<br>• Most occupational handler risk estimates were not of concern, with exceptions for certain agricultural work activities.<br>• Overall, acute risks to avian and mammalian species from foliar and soil treatments of imidacloprid appear to be low. It is classified as moderately toxic to mammals on an acute oral exposure basis. Risk of concern is more likely from chronic (long-term) consumption of treated seed.<br>• Imidacloprid is characterized as highly toxic to birds on an acute oral exposure basis and slightly toxic on a subacute dietary exposure basis.<br>• Bees: Foliar or soil applications of imidacloprid to honeybee-attractive crops that are not harvested prior to bloom result in the potential for colony-level risks of concern. Risks associated with pre-bloom applications are generally greater than those associated with post-bloom applications. Based on the evaluated data, imidacloprid is classified as very highly toxic to adult honeybees with acute oral and acute contact LD50 values of 0.0039 and 0.043 µg of active ingredient per bee, respectively. The highest acute exceedances were from uses on citrus, pome fruit, ornamentals and turf. Like with the acute risk exceedances, the highest chronic risk exceedances noted were from uses on citrus, pome fruit, ornamentals and turf.<br><br>**Acetamiprid** (US EPA 2020b)<br>• No risks of concern were identified for dietary, residential, aggregate, bystander, or occupational post-application exposures.<br>• Nearly all the exposure scenarios for those working with acetamiprid yield risk estimates that are not of concern. Exceptions are mixing, loading and applying liquid and wettable powder formulations to the basal bark of landscaping, trees/shrubs/bushes using backpacks (reduced risks may be found with double layer clothing and chemical resistant gloves) and manually-pressurized handwands.<br>• Acetamiprid is highly toxic to mammals on an acute oral exposure basis. There are both acute and chronic risks of concern from consumption of acetamiprid-treated seeds, though not from foliar applications of acetamiprid.<br>• Acetamiprid is very highly toxic to passerine species and moderately toxic to larger birds on an acute oral exposure basis. There are both acute and chronic risks of concerns to birds from both foliar applications and seed treatments with acetamiprid.<br>• Honey bees may be exposed to acetamiprid through ingestion of residues in nectar and pollen foraged from treated plants, contact with pesticide residues on plants treated with foliar applications, and direct contact via spray drift. Acetamiprid is classified as moderately toxic to adult bees and highly toxic to larvae on an acute exposure basis. There are acute and chronic risks of concern to adults and larvae from registered uses of acetamiprid. Though there are risks of concern to individual honey bees, which serve as a surrogate for non-Apis bees, colony-level studies show that these risks are not likely to translate into long-term adverse effects on the colony.<br>• No acute risks of concern for freshwater or estuarine/marine fish, and no chronic risks of concern for freshwater fish.<br>• Aquatic invertebrates may become exposed to acetamiprid through residues in runoff, flooding of treatment sites, and spray drift. Acetamiprid is very highly toxic to both freshwater and estuarine/marine invertebrates on an acute exposure basis. There are both acute and chronic risks of concern to both freshwater and estuarine/marine invertebrates from registered uses of acetamiprid.<br><br>**Dinotefuran** (US EPA 2020e)<br>• No risks of concern were identified for dietary, residential handling, residential post-application, aggregate, or occupational handling or post-application exposures.<br>• No acute risks to avian and mammalian species from foliar and soil treatments are expected.<br>• Bees: highly toxic to adult bees on an acute contact and oral basis, and classified as non-toxic to honey bee larvae on an acute (single dose dietary) exposure basis; acute risk exceedances for on-field foliar uses; on a colony-level, potential risks were identified for several scenarios; and spray drift from foliar treatments resulted in risks at greater than 1,000 feet from the field for honey bees. | In process: updated pollinator risk assessment and a proposed interim decision issued for public comment in early 2020. |

|  | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| United States Environmental Protection Agency (US EPA 2020a; US EPA 2020b; US EPA 2020c; US EPA 2020d; US EPA 2020e) | Review for authorisation renewal; imidacloprid, acetamiprid, clothianidin, thiamethoxam, dinotefuran | **Peer-reviewed literature, epidemiological assessments, public comments, economic impacts** | **Clothianidin** (US EPA 2020c; US EPA 2020d)<br>• Classified as "not likely to be carcinogenic to humans".<br>• It is a registered pesticide active ingredient but is also a major degradate of thiamethoxam (in plants).<br>• Applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching, seed treatments, basal bark treatments and spot treatments. Except for seed treatment use on corn, no agricultural-use occupational handler scenarios result in risk estimates of concern. Two non-agricultural scenarios result in risk estimates of concern: for mixers/loaders/applicators of liquid formulations via mechanically pressurized handguns livestock housing other than poultry, and for an applicator treating commercial buildings using liquid cans.<br>• No acute or chronic dietary (food and drinking water combined) exposure estimates of concern, no residential risk estimates of concern for handlers.<br>• Low acute risks to avian and mammalian species from foliar and soil treatments.<br>• Chronic risks of concern to small-medium mammals from soil applications at certain application rate and exposure to residues from poultry litter soil amendment applications on agricultural fields; chronic risks of concern for all size classes of mammals consuming any of the assessment treated seed, particularly lettuce seeds.<br>• Moderately toxic to birds on an acute oral exposure basis and practically non-toxic on a subacute dietary exposure basis.<br>• Bees: classified as toxic to adult honeybees; acute contact risks to adult bees exposed to foliar applications and acute dose-based oral exposure risks from foliar use, from soil treatment and from seed treatment use.<br>• Clothianidin is practically non-toxic to water fleas (Daphnia magna) but is very highly toxic to other taxa, including shrimp and aquatic insects.<br><br>**Thiamethoxam** (US EPA 2020c; US EPA 2020d)<br>• Classified as "not likely to be carcinogenic to humans".<br>• Applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching, and seed treatments.<br>• No acute or chronic dietary risk estimates of concern; no residential risk estimates of concern for handlers.<br>• Risks of concern for a number of occupational exposure scenarios, including mixing/loading/applying DF formulations of thiamethoxam using a backpack sprayer in poultry house use scenario.<br>• Low acute risks to avian and mammalian species from foliar and soil treatments.<br>• No acute or chronic risks of concern identified for mammals from any foliar or soil applications.<br>• Potential acute risks of concern have been identified for mammals from certain thiamethoxam seed treatment uses, and chronic risks of concern for corn, cotton and sugar beet, though not for soybean.<br>• Slightly toxic to birds on an acute oral exposure basis and practically non-toxic on a subacute dietary exposure basis.<br>• Bees: classified as toxic to adult honeybees; acute contact risks to adult bees exposed to foliar applications and acute dose-based oral exposure risks from foliar use, from soil treatment and from seed treatment use. | In process: updated pollinator risk assessment and a proposed interim decision issued for public comment in early 2020. |
| Government of Canada (2020) | Re-evaluation for registration review; clothianidin, imidacloprid, thiamethoxam | (i) peer review;<br>(ii) scientific literature;<br>(iii) public and stakeholder comments | • Varying degrees of impact on bees, depending on the uses of clothianidin, imidacloprid and thiamethoxam.<br>• Some current uses are not expected to affect bees. For some uses, mitigation measures are required to minimize exposure to bees, including changes to the use pattern and label improvements. When clothianidin is used in accordance with these new measures, the reduced environmental exposure is considered adequate and risks are acceptable. For other uses, risks to pollinators were not found to be acceptable; therefore, these uses are cancelled.<br>• Health Canada continues to evaluate the risks to aquatic insects from the use of neonicotinoids. Current research shows that these pesticides are detected frequently in waterbodies at levels that could be harmful to certain aquatic organisms. | Continued evaluation of risks for aquatic insects, with report expected at the end of 2019. |

|  | Purpose | Methods | Findings | Limitations |
|---|---|---|---|---|
| **Network of African Science Academies (2019)** | **Review and recommendations to policymakers specific to African agriculture** | (i) an initial scoping study to synthesise the main themes of the extensive literature reviewed by EASAC, IPBES and WIA;<br>(ii) usage review,<br>(iii) literature review;<br>(iv) expert workshops and external peer review | • All African countries appear to be using neonicotinoids (mostly imidacloprid, acetamiprid, thiamethoxam and thiacloprid).<br>• There is already evidence of widespread environmental contamination in Africa. Residues are found in honey from several countries, with some levels similar to or higher than levels found in Europe before the restrictions imposed by the EU. A limited number of studies have also confirmed contamination in soils, again with examples where levels are very high compared with the highest levels found in European studies. Neonicotinoids have also been found in water, snails and sediment near agricutlural areas.<br>• Honey bee populations are in decline, as shown in decreases in wild population, few migratory swarms, disappearance and loss of hives, some mass bee mortality and reduced honey production. Declines observed in other species include edible insects such as crickets, as well as insectivorous birds. Pollination of cocoa flowers by the natural pollinator (a midge) also has been affected and expensive manual alternatives had to be introduced.<br>• Evidence of negative effects of neonicotinoids includes loss of honey bee colonies and contamination of agricultural products, soils and freshwater systems with neonicotinoid residues.<br>• Regarding use in cocoa crops, the control of mirid bugs using neonicotinoids led to the proliferation of some pests considered as secondary owing to the destruction of their natural enemies. | • Peer-reviewed, published research about the prevalence of use, efficacy, toxicity testing, etc. of neonicotinoids is lacking for more than half of individual African countries.<br>• Unintentional omission of some information, due to limited accessibility to such information from several government and institutions |
| **California (California Department of Pesticide Regulation 2018, with addendum 2019)** | **Risk determination report for neonicotinoid product re-evaluation; imidacloprid, clothianidin, thiamethoxam and dinotefuran** | (i) ecological risk assessment;<br>(ii) ipeer-reviewed publications;<br>(iii) "registrant-submitted studies" | • The California State Department of Pesticide Risk based its risk determination on colony-level effects on bees from four neonicotinoids, imidacloprid, thiamethoxam, clothianidin and dinotefuran, and their residue levels in pollen and nectar that produced no observed effects on the colonies (No Observed Effect Concentrations, or NOECs).<br>• Neonicotinoids applied to different crops have varying impacts on bee colonies and the final report categorised risks according to different crop groups and worst-case scenarios of pesticide application.<br>• High-risk crops for at least one neonicotinoid included "fruiting vegetables (e.g., cucumbers, tomatoes), berries, citrus, and tree nuts". Low-risk crop groups included "root and tuber vegetables (e.g., potatoes, turnips), bulb vegetables (e.g., onions, garlic), leafy vegetables and legumes". | • Risk determinations were made for plant and soil applications, not for seed treatments. • Limited data available for some crops. • Colony-level impacts, Tier II, only. • Only worst-case application scenarios, as allowed by currently registered labels in California, were included for analysis. Studies involving less frequent application intervals or lower application rates were excluded from consideration in this document. |
| **Food Safety Commission of Japan (FSCJ)** | **Nitenpyram** | (i) risk assessment based on results from various studies | • The reduction of body weight gain is an observed and major adverse effect of nitenpyram.<br>• Nitenpyram has no carcinogenicity, teratogenicity and genotoxicity.<br>• Decreases in number of implantations and of offspring were observed in a reproduction study in rats.<br>• FSCJ specified an acceptable daily intake of 0.53 mg/kg bw/day and an acute reference dose of 0.6 mg/kg bw. |  |
| **Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (Potts *et al.* 2016)** | **Assessment of pollinators, pollination and food production for decision-makers; thiamethoxam, imidacloprid; clothianidin** | (i) scientific literature;<br>(ii) indigenous and local knowledge;<br>(iii) socioeconomic and technical sources | • **Well established:** Most studies of sublethal impacts of insecticides on pollinators have tested a limited range of pesticides, recently focusing on neonicotinoids, and have been carried out using honeybees and bumblebees, with fewer studies on other insect pollinator taxa. Thus, significant gaps in knowledge remain with potential implications for comprehensive risk assessment. Recent research focusing on neonicotinoid insecticides shows evidence of lethal and sublethal effects on bees under controlled conditions.<br>• **Established but incomplete:** some evidence of impacts on the pollination they provide; evidence from a recent study that shows impacts of neonicotinoids on wild pollinator survival and reproduction at actual field exposure.<br>• **Unresolved:** Evidence of effects reported in various studies of managed honeybee colonies is conflicting. What constitutes a field realistic exposure, as well as the potential synergistic and long-term effects of pesticides (and their mixtures), remains unresolved. | Studies of mixtures of pesticides and their impacts on pollinators are lacking. |

**Table B–7.2.** Supporting information on the life cycle of and exposure to neonicotinoids, as well as examples of cost-of-inaction and benefits-of-action information

| Chemical name(s) | Neonicotinoids |
|---|---|
| IUPAC name (s), CAS number(s), chemical formula | **Thiamethoxam** - *N*-[3-[(2-chloro-1,3-thiazol-5-yl)methyl]-5-methyl-1,3,5-oxadiazinan-4-ylidene]nitramide; 153719-23-4; $C_8H_{10}ClN_5O_3S$<br>**Clothianidin** - 1-[(2-chloro-1,3-thiazol-5-yl)methyl]-3-methyl-2-nitroguanidine; 210880-92-5; $C_6H_8ClN_5O_2S$<br>**Imidacloprid** - *N*-[1-[(6-chloropyridin-3-yl)methyl]-4,5-dihydroimidazol-2-yl]nitramide; 138261-41-3; $C_9H_{10}ClN_5O_2$<br>**Acetamiprid** - *N*-[(6-chloropyridin-3-yl)methyl]-*N'*-cyano-*N*-methylethanimidamide; 135410-20-7; $C_{10}H_{11}ClN_4$<br>**Thiacloprid** - [3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene]cyanamide; 111988-49-9; $C_{10}H_9ClN_4S$<br>**Dinotefuran** - 2-methyl-1-nitro-3-[(tetrahydro-3-furanyl) methyl] guanidine; 165252-70-0; $C_7H_{14}N_4O_3$<br>**Nithiazine** - 2-(nitromethylidene)-1,3-thiazinane; 58842-20-9; $C_5H_8N_2O_2S$<br>**Nitenpyram** - (E)-1-N'-[(6-chloropyridin-3-yl)methyl]-1-N'-ethyl-1-N-methyl-2-nitroethene-1,1-diamine; 120738-89-8, 150824-47-8; $C_{11}H_{15}ClN_4O_2$ |
| Chemical structure |  <br>A) Acetamiprid; B) Clothianidin; C) Dinotefuran; D) Imidacloprid; E) Nithiazine; F) Nitenpyram; G) Thiacloprid; H) Thiamethoxam. |
| **Use information** | |
| End-of-life issues | • Some pesticides are considered as hazardous waste, with high temperature incineration often being the most widely used method of disposal (FAO n.d.). Issues associated with high temperature incineration include emissions to the environment and energy usage.<br>• There is concern that in most "developing" countries the technology is not available to achieve the safe disposal of hazardous chemical waste (FAO n.d.). |
| Geographic distribution | The most recent available data indicates that Latin America represents 30% of the global use of neonicotinoids in agriculture, followed by Asia (23%), North America (22%), Europe (11%) and the Middle East (1%), with 13% reported as "unallocated" (Bass *et al.* 2015). |
| Key uses/applications | • The main use of neonicotinoids is in insecticides (Craddock *et al.* 2019). Neonicotinoids are the most widely used and important class of insecticides worldwide (Bass *et al*. 2015; Craddock *et al*. 2019). Prophylactic seed-coatings are used on 90% of maize crops in the US, and maize accounts for 60% of neonicotinoid use in the US (United States Geological Survey 2018). They target a wide selection of pests and have versatile application methods (Jeschke *et al.* 2011). Neonicotinoids become incorporated into plant tissues and are therefore systemic (Sparling 2016).<br>• In China, neonicotinoids have been registered for use against rice plant hopper, aphids, leafhopper, whitefly, thrips and other pests in rice, wheat, cotton, fruit (including oranges), vegetables and flowers. Rice is the largest application of imidacloprid (Shao *et al.* 2013).<br>• Neonicotinoids may also be used as tree soil drenches or tree trunk injections in urban or forested areas, against invasive insects such as the Emerald Ash borer (Benton *et al*. 2016; Hladik *et al*. 2018). In China, thiacloprid is used to prevent longicorn beetle in forests (Shao *et al.* 2013).<br>• Neonicotinoids can also be used to kill insects in homes and control fleas on pets (Government of 2017) and are used in tick control and flea collars (European Commission [EC] n.d.). In China, imidacloprid is used against lice and other pests on pets (Shao *et al.* 2013). |
| Key markets | • In 2011, neonicotinoid pesticides were used in over 120 countries (Jeschke *et al.* 2011) and in 2012, thiamethoxam, imidacloprid and clothianidin accounted for around 85% of neonicotinoid sales for crop protection (Bass *et al.* 2015; Craddock *et al.* 2019). In 2014, neonicotinoids represented more than 25% of the total global market share of insecticide sales (Bass *et al.* 2015). Around 60% of neonicotinoids were used as seed and soil treatments to combat "soil-dwelling arthropods and early-season leaf-feeding and sucking insect pests" (Jeschke *et al.* 2011).<br>• Of this global market share, in 2015, thiamethoxam held 37.6% followed by imidacloprid (33.5%), clothianidin (14.7%), acetamiprid (7.2%), thiacloprid (3.8%), dinotefuran (2.9%) and nitenpyram (0.3%; Bass *et al.* 2015). The total market share of neonicotinoids in 2012 was reported at US$3.2 billion (Bass *et al.* 2015). Regulation introduced in several countries since (discussed below) may have had an impact on neonicotinoid market share. No information on tonnages could be identified. |

| Production data | |
|---|---|
| **Production volumes and global trends** | • By 2008, after nearly two decades of launching on the market, neonicotinoids had gained a 24% share of a total market of €6.330 billion, mainly at the expense of organophosphates (13.6%) and carbamates (10.8%). "In 1990, before the launch of the first neonicotinoid insecticide, imidacloprid, the agrochemical market (total volume of €7.942 billion) was dominated by organophosphates (OPs) (43%), pyrethroids (18%), and carbamates (16%)" (Jeschke *et al.* 2011).<br>• In 2010, the global production of imidacloprid was estimated to be around 20,000 tonnes of active substance (Simon-Delso *et al.* 2015).<br>• In 2011, seven neonicotinoids were on the global market: imidacloprid and thiacloprid (Bayer CropScience), thiamethoxam (Syngenta), nitenpyram (Sumitomo Chemical Takeda Agro Co.), acetamiprid (Nippon Soda), clothianidin (Sumitomo Chemical Takeda Agro Co./Bayer CropScience) and dinotefuran (Mitsui Chemicals; Jeschke *et al.* 2011).<br>• Production for domestic use and exports from China dominated in the early part of the past decade. In 2010, six types of neonicotinoids were reportedly registered for production on the domestic market in China. Whereas imidacloprid, acetamiprid, nitenpyram, and thiacloprid were developed by companies outside China, paichongding and imidaclothiz were developed domestically with independent intellectual property rights. In 2013, China had 36 domestic manufacturers of imidacloprid (52 active ingredient manufacturers) and was the largest producing and exporting country of imidacloprid, with annual output and export at 14,000 and 8,000 tonnes, respectively. The second largest neonicotinoid in terms of output was acetamiprid with 34 registered manufacturers and an annual output of 8,000 tonnes. There were eight registered manufacturers for nitenpyram, with an output of 100 tonnes, and four registered manufacturers for thiacloprid, with an output of less than 1,000 tonnes (Shao *et al.* 2013). In 2016, the production of imidacloprid in China was 23,000 tonnes (Chen *et al.* 2019). |
| **Products** | • Neonicotinoids are traded in insecticide products. Trade names for products containing the five neonicotinoid compounds below are reported to include (Mokbel *et al*. 2017; Buszewski *et al*. 2019; Fishel 2019): Thiamethoxam (Cruiser, Platinum, Actara, Cruiser); Clothianidin (Acceleron, Arena, Belay, Celero, Clutch, NipsIT Inside, Poncho, Dantotsu, Fullswing, Apacz); Imidacloprid (Admire, Advantage, Gaucho, Merit, Premise, Touchstone, Agroprim, Gauncho, Confidor, Admire 2 Flowable, Merit, Provado, Marathon); Acetamiprid (Acetamiprid, Assail, Tristar, Mospilan, Cezar, Hekplan, Mospildate, Shark, Tenaz, Vapcomore, Mortal, Profil, Intruder); Thiacloprid: Calypso (Bariard, Atlanto).<br>• Different characteristics of the active substances have led to different formulations. For example, in China, the common formulations are emulsifiable concentrates, wettable powders, micro-emulsions, emulsions, oil in water, water-soluble powders and water-dispersible granules (Shao *et al.* 2013). |

| Exposure | |
|---|---|
| **Main exposure sources and pathways** | • The primary application method for agricultural pest control with neonicotinoids is the planting of insecticide-treated seeds (Bonmatin *et al*. 2015; Hladik *et al* 2018).<br>• Key routes to the environment include the air, where contaminated dust is generated from the sowing of seeds treated with neonicotinoids and exacerbated using seed lubricants during seed planting, where the lubricant powder has direct contact with treated seeds. (Bonmatin *et al.* 2015).<br>• Other key routes include direct application, release from seed coatings and/or the breakdown of plant material into the soil (Bonmatin *et al.* 2015).<br>• Surface water and sediments may also become contaminated through a range of routes including spray and dust drift, surface runoff, leaching followed by transport through drainage channels, improper operations leading to draining to sewerage, septic tanks or surface waters, pesticide applications on roadsides, lawns and pesticide use in building materials (Bonmatin *et al.* 2015).<br>• Bees may be exposed via pollen and nectar, dust and guttation (EFSA 2013). Neonicotinoids can then be consumed or transported back to bee colonies (Muth and Leonard 2019).<br>• Neonicotinoids are systemic insecticides, which means that the insecticide is transported through the whole plant (Buszewski 2019). Neonicotinoids are present in the leaves, flowers, roots and stems, and pollen and nectar (EC n.d.).<br>• There are occupational risks from exposure to pesticides. For example, rural and greenhouse workers are at heightened risk, along with those manufacturing pesticides, mixing, involved in application and bystanders (Gangemi *et al.* 2016). There is also concern over poor occupational risk awareness and a lack of training and equipment to ensure safe use, particularly in developing countries (Gangemi *et al.* 2016).<br>• Exposure may also occur through the consumption of contaminated food and water, or through use of pesticides in the home, or from living in close proximity to fields that are sprayed (Gangemi *et al.* 2016). |

| Examples of costs of inaction and benefits of action information | |
|---|---|
| **Costs of inaction** | Some neonicotinoids threaten pollinators such as foraging bees and solitary bees (EFSA 2013; US EPA 2017a). Pollination is estimated to contribute $20 to $30 billion annually to the US economy in crop production (Stevens and Jenkins 2014). Valuations of native insect pollination have been estimated at $3.07 billion in 2006, again for US crops (Stevens and Jenkins 2014). The risk of neonicotinoids contributing to the reduction in production of bee products, such as honey, is noted, yet attribution is considered complex (Stevens and Jenkins 2014).<br>Neonicotinoids are only one possible trigger for honey bee declines, as bees have been negatively impacted by many stressors (Stevens and Jenkins 2014).<br>Industry-sponsored surveys indicate that farmers perceive restrictions on neonicotinoids as costly and time consuming, and that alternatives are less effective and lead to lower crop yields (Kathage *et al*. 2017; Noleppa 2017). |
| **Benefits of action** | A literature review conducted by the Centre for Food Safety (Stevens and Jenkins 2014) on the use of neonicotinoids as seed treatments found that in many cases, neonicotinoids were not providing yield or economic benefits to farmers. It suggests there is "often no economic justification for using them as a prophylactic control measure" (Stevens and Jenkins 2014).<br>Neonicotinoids have been tied to colony collapse disorder (CCD), though the understanding of the causes of CCD remains incomplete. An estimated 10 million beehives have been lost since 2006, with replacement costs valued at some $2 billion for beekeepers in the US (Steinhauer *et al*. 2014; Stevens and Jenkins 2014). |

**Table B–7.3.** Examples of measurements of neonicotinoids in the environment, biota and humans across the globe. IMI = imidacloprid, THM = thiamethoxam, THA = Thiacloprid, CLO = clothianidin, DNT = dinotefuran, ACE = acetamiprid; NTN = Nitenpyram

| Medium | Contamination level of Neonicotinoids | Country | Reference |
|---|---|---|---|
| **Streams** | IMI and THM were detected with about 37% and 21%, respectively | US | Hladik and Kolpin 2015 |
| **River water** | IMI and THA concentration of about 4.56 and 1.37 μg/L, respectively | Australia | Sanchez-Bayo and Hyne 2014 |
| **Surface water** | CLO and THM concentration of about 2,280 and 1,120 ng/L respectively | Canada | Struger *et al.* 2017 |
| **Surface water** | DNT was the most detected in surface water | Japan | Yamamoto *et al.* 2012 |
| **Yangtze River water** | IMI had a highest concentration of 4.37 ng/L, followed by ACE (2.50 ng/L), THM (1.10 ng/L), NTN (0.34 ng/L), CLO (0.10 ng/L), and THD (0.02 ng/L). | China | Mahai *et al.* 2019 |
| **Pearl River water and sediment** | (∑5neonicotinoids) in surface water and sediment ranged from 24.0 to 322 ng/L, and from 0.11 to 11.6 ng/g dw respectively. | China | Zhang *et al.* 2019 |
| **Sixteen rivers (east coast of China)** | Neonicotinoids were predominantly present. In the dry season and wet season were 343 ± 210 ng/L and 74 ± 162 ng/L, respectively. | China | Chen *et al.* 2019 |
| **Human urine samples** | The 57 known metabolites of three neonicotinoids were detected in three patients. | Japan | Taira *et al.* 2013 |
| **Children's urine samples** | 58% of DNT was detected from 223 three-year-old children. | Japan | Osaka *et al.* 2016 |
| **Human urine samples** | The detection rate of neonicotinoids in rural residents had higher IMI (65.6%) than urban residents | Greece | Kavvalakis *et al.* 2013 |
| **Henan Province Rural farmers urine samples** | IMI and its major metabolite 6-chloronicotinic acid (6-CNA) limits of quantitation at 0.029–0.038 ng/mL | China | Tao *et al.* 2019 |
| **Human urine samples** | The order of detection of neonicotinoids was as follows: ACE (35%), IMI (19.7%), CLO (7.7%), and IMI (4.3%) | US | Ospina *et al.* 2019 |

**Table B–7.4.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of neonicotinoids.

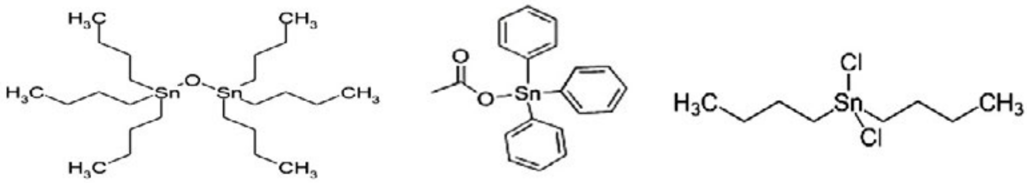
| Example(s) | | | |
|---|---|---|---|
| **Scale** | **Scope** | **Content** | **Status** |
| **Actions by governmental institutions** | | | |
| **US** | **Thiacloprid, thiamethoxam, clothianidin, dinotefuran, acetamiprid; restrictions/bans, + labelling requirements + voluntary stewardship** | • In 2012, the US EPA cancelled the use of **imidacloprid** on almonds (US EPA 2012).<br>• In 2013, the US EPA communicated to the pesticide registrants on registered pesticide products containing **imidacloprid**, **dinotefuran**, **clothianidin** or **thiamethoxam** with regard to labelling changes so they better protect bees by being clearer and more precise in their directions for pesticide application. The revised labels include specific limits such as “Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen ….” (US EPA 2017b).<br>• In 2014, **thiacloprid** (EPA-HQ-OPP-2012-0218) was voluntarily cancelled by the registrant and US EPA issued a Final Cancellation Order on August 6. The registrant is prohibited from selling or distributing this product except for export in accordance with FIFRA section 17 or for proper disposal. Persons other than the registrant may sell, distribute, or use existing stocks of products until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labelling on, or that accompanied, the cancelled product.<br>• In May 2019, the US EPA cancelled the registration of 12 pesticide products based on **thiamethoxam** or **clothianidin**. Sales and distribution of existing stocks can continue until May 2020. After this, registrants will be prohibited from selling and distribution of these particular products (US EPA 2019).<br>• US EPA reviewed imidacloprid, clothianidin, thiamethoxam, dinotefuran and acetamiprid, and the proposed interim decisions were issued in January 2020 for a 60-day public commenting period, including the following regulatory and voluntary actions:<br>- **Dinotefuran** (US EPA 2020e): cancel use on bulb vegetables; reduce maximum application rates or restricting applications during pre-bloom and/or bloom, targeting certain uses with potentially higher pollinator risks and lower benefits; preserve the current restrictions for application at-bloom; require advisory language for residential ornamental uses; apply targeted application rate reductions for higher risk uses; require additional spray drift and runoff reduction label language; and, promote voluntary stewardship efforts to encourage employment of best management practices, education and outreach to applicators and beekeepers.<br>- **Clothianidin, thiamethoxam** (US EPA 2020c): cancel certain clothianidin uses; restrict certain thiamethoxam uses; require additional personnel protection equipment; reduce maximum application rates or restrict applications during pre-bloom and/or bloom, target certain uses with potentially higher pollinator risks and lower benefits; preserve the current restrictions for application at-bloom; require additional label language reducing use by homeowners; apply targeted rate reductions for higher risk uses; require additional spray drift and runoff reduction label language; and, promote voluntary stewardship efforts to encourage the use of best management practices, education, and outreach to applicators and beekeepers<br>- **Acetamiprid** (US EPA 2020b): add personnel protection equipment for basal bark treatments in landscape uses; update the glove statement; add best management practices language for handling and adding water-soluble packets to spray tanks; add advisory statements for acetamiprid seed treatment uses; add environmental hazard statement for pollinators; label changes to reduce off-target spray drift; add buffers from water bodies of 25 feet for ground application and 150 feet for aerial applications to limit the amount of spray drift that enters water bodies; and add pesticide resistance management labelling.<br>- **Imidacloprid** (US EPA 2020a): cancel residential spray applications to turf, on-farm seed treatment (of canola, millet, and wheat), and use on bulb vegetables; require additional personnel protection equipment; reduce maximum application rates or restricting applications during pre-bloom and/or bloom, targeting certain uses with potentially higher pollinator risks and lower benefits; preserve the current restrictions for application at-bloom; require advisory language for residential ornamental uses; apply targeted application rate reductions for higher risk uses; require additional spray drift and runoff reduction label language; and promote voluntary stewardship efforts to encourage employment of best management practices, education and outreach to applicators and beekeepers. | In force or in process |
| **France** | **Clothianidin, imidacloprid, thiamethoxam, acetamiprid, thiacloprid; ban** | In 2016, the French government banned the use of **clothianidin**, **imidacloprid**, **thiamethoxam**, **acetamiprid** and **thiacloprid** (Jactel *et al.* 2019). The ban came into force in September 2018. | In force |
| **UK** | | In October 2018, the UK government rejected applications for emergency authorisation to use two products containing neonicotinoids to treat sugar beet seed for the following year (Government of the UK 2018). | In force |

| Example(s) | | | |
|---|---|---|---|
| **Scale** | **Scope** | **Content** | **Status** |
| **Fiji** | **Imidacloprid; ban** | Banned the use, import and sale of **imidacloprid**, as of January 2020 (Fijian Government 2019). | In force |
| **Canada** | **Clothianidin, imidacloprid, thiamethoxam; restrictions/ bans + additional labelling requirements** | After re-evaluations, Health Canada reached the following decisions.<br>**Clothianidin** (Health Canada 2019a):<br>• cancelled the uses in foliar application to orchard trees and strawberries and to municipal, industrial and residential turf sites;<br>• reduced maximum number of foliar applications to cucurbit vegetables to one per season;<br>• additional label requirements are required for seed treatment of cereal crops.<br>• **Imidacloprid** (Health Canada 2019b):<br>• cancelled the uses in foliar application to pome fruit, stone fruit, certain tree nuts with high pollinator attractiveness, lavender and rosemary and soil application on legume, fruiting, and cucurbit vegetables when grown outdoors; herbs harvested after bloom; small fruit and berries (caneberry; bushberry; low-growing berry; berry and small fruit vine excluding grapes); and ornamentals that are attractive to pollinators and planted outside;<br>• proposed that the following crops cannot be sprayed before or during bloom: foliar application to fruiting vegetables, herbs that are harvested after bloom, legume vegetables (broad beans/fava beans/Vicia faba only), berry crops (with renovation after harvest for woody berries), tree nuts excluding those with high pollinator attractiveness;<br>• proposed that the following crops cannot be sprayed during bloom: foliar application to potato, grapes, legume vegetables (excluding broad beans/fava beans/vicia faba), peanut and tobacco;<br>• additional label statement for seed treatment of cereal and legume crops.<br>**Thiamethoxam** (Health Canada 2019c):<br>• cancelled the uses in foliar and soil application to ornamental crops that will result in pollinator exposure (in other words, are planted outdoors and are attractive to pollinators), soil application to berry crops, cucurbit crops and fruiting vegetables, and foliar application to orchard trees;<br>• foliar application to legume and outdoor fruiting vegetables and berry crops (with renovation required for woody berries) cannot be sprayed before or during bloom;<br>• foliar application to sweet potato and potato cannot be sprayed during bloom<br>• additional label statements required seed treatment of cereal and legume crops. | In force and to be stepwise implemented over a 24-month period since April 2019 |
| **EU** | **Clothianidin; imidacloprid; thiamethoxam; thiacloprid; acetamiprid; restrictions/ban** | • In 2013, the European Commission severely restricted the use of plant protection products and treated seeds containing **clothianidin**, **imidacloprid** and **thiamethoxam** to protect honeybees; see Regulation (EU) No 485/2013. In 2018, the EU banned all outdoor uses of these three neonicotinoids, which are now only available for use in permanent greenhouses [Regulations (EU) 2018/783; 2018/784; 2018/785] (European Commission 2018a-c).<br>• Applicants for the renewal of approval of **clothianidin** and **thiamethoxam** withdrew their applications and their approval expired on 31 January 2019 and 30 April 2019, respectively.<br>• The expiration date of approval for **imidacloprid** is set for 31 July 2022, and the deadline for submission of the renewal dossier was due 31 January 2020.<br>- **Thiacloprid:** Included on the list of Candidates of Substitution due to its endocrine-disrupting properties; EU countries are required to evaluate if replacement (substitution) by other adequate solutions (chemical and non-chemical). The approval for thiacloprid expires on 30 April 2020. On 13 January 2020, Commission Implementing Regulation (EU) 2020/23 was adopted that its approval is not renewed (European Commission 2020a-b).<br>- **Acetamiprid:** The approval is renewed until 28 Feb 2033 with specific provisions, e.g. conditions of use shall include risk mitigation measures, where appropriate (European Commission 2018d). | In force |
| **Australia** | **acetamiprid, clothianidin, dinotefuran, imidacloprid, thiacloprid, thiamethoxam; review** | In November 2019, the Australian Pesticides and Veterinary Medicines Authority (n.d.) decided to commence a chemical reconsideration of neonicotinoid insecticides (**acetamiprid, clothianidin, dinotefuran, imidacloprid, thiacloprid, thiamethoxam**) to reconsider approved active constituents, registrations of selected products containing neonicotinoids, and all associated label approvals on the basis of risks to the environment. | Ongoing |
| **Columbia, Chile, Uruguay and Mexico** | **Neonicotinoids; seed treatment; restrictions** | In several countries in Latin America, bills including articles on neonicotinoids have been proposed, and are currently in progress. For example, in Mexico, in 2018, the Senate exhorted the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food to take measures to protect bees from toxic pesticides; the Federal Commission for Protection of Sanitary Risks to regulate or ban the use of neonicotinoids and any other pesticide that is toxic for pollinators; and the Ministry of Environment to indicate the instruments to be used to protect pollinators. | In progress |

| Example(s) | | | |
|---|---|---|---|
| **Scale** | **Scope** | **Content** | **Status** |
| **Actions by non-state actors** | | | |
| **US** | **Thiacloprid; voluntary phase-out** | In 2013, the sole registrant of **thiacloprid** pesticide products, Bayer CropScience, informed the US EPA that they were requesting to voluntarily cancel their thiacloprid technical and end-use product registrations, which led to the final cancellation by the US EPA in April (US EPA 2014). | |
| **EU** | **Clothianidin; thiamethoxam; voluntary phase-out** | The applicants for the renewal of approval of **clothianidin** and **thiamethoxam** withdrew their applications. Consequently, the approval of these substances expired on 31 January 2019 and 30 April 2019, respectively (EC 2020a). | |
| **EU** | **Neonicotinoids** | The Save the Bees Coalition (n.d.) is a platform of European NGOs working to achieve a ban on neonicotinoids in the European Union. The Coalition also aims at implementing a better protection of pollinators against pesticides in general. The goal of the coalition is to bring together civil society organisations from all European Union (EU) countries so as to join efforts at local, regional, national and European levels in order to obtain a full ban on neonicotinoids, and a European pesticide policy that ends the use of bee-harming pesticides in Europe. | |
| **International** | **Neonicotinoids; third-party standards and certification schemes** | Neonicotinoids, including **clothianidin**, **thiacloprid**, **thiamethoxam**, **imidacloprid**, **acetamiprid**, **dinotefuran** and **nitenpyram**, have been included by different third-party standards and certification schemes, including Fairtrade, Forest Stewardship Council (FSC), Sustainable Agriculture Network (SAN) and UTZ-certified products. For example, **imidacloprid** is included in the Orange List (restricted materials) of the Fairtrade's Hazardous Materials List. More details can be found on the pesticide and Integrated Past Management (IPM) online database by the ISEAL IPM Coalition (n.d.). | |

# 8. Organotins

**Table B–8.1.** Supporting information on the life cycle of and exposure to organotins, as well as examples of cost-of-inaction and benefits-of-action information

<table>
<tr><th>Chemical name(s)</th><th>Organotin compounds (or organostannic compounds)</th></tr>
<tr><td><b>Examples</b></td><td>• Tributyltin (TBT) compounds (e.g. tributyltin oxide; tributyltin chloride);<br>• Triphenyltin (TPT) compounds (e.g. triphenyltin hydroxide; triphenyltin acetate);<br>• Dibutyltin (DBT) compounds (e.g. dibutyltindichloride)</td></tr>
<tr><td><b>CAS number(s) of example organotins</b></td><td>• Tributyltin oxide: 56-35-9<br>• Tributyltin benzoate: 4342-36-3<br>• Tributyltin chloride: 1461-22-9<br>• Tributyltin fluoride: 1983-10-4<br>• Tributyltin linoleate: 24124-25-2<br>• Tributyltin methacrylate: 2155-70-6<br>• Tributyltin naphthenate: 85409-17-2</td></tr>
<tr><td><b>Chemical structure of three examples</b></td><td></td></tr>
<tr><th colspan="2">Production information</th></tr>
<tr><td><b>Production overview</b></td><td>At the industrial scale, organotin compounds are commonly prepared by alkylation of tin chloride (SnCl4) with organo-magnesium or organo-aluminium compounds. These Grignard reagents, RMgX, are prepared from the metal and an alkyl or aryl halide and subsequently reacted with SnCl4 to form the organotin compound. The reaction is usually taken to completion, and the resulting tetraalkylstannane R4Sn is later heated again with SnCl4 to give the desired alkyltin chlorides RnSnCl4-n in a redistribution reaction. (Ghazi <i>et al.</i> 2018).</td></tr>
<tr><td><b>Geographic distribution</b></td><td>While Western Europe and the US have previously been major producers and users of organotins, current data suggests their production and use are declining in these regions, with production now growing in and being dominated by China and Southeast Asia (see below). Production capacity for some organotin compounds is increasing, especially in China (Pearce and Wallace 2015).</td></tr>
<tr><td><b>Production volumes and global trends</b></td><td>The estimated global annual production of organotins was about 60,000 tonnes (Sousa <i>et al.</i> 2014). The International Maritime Organization (IMO) banned the use of TBT compounds for use as an anti-fouling agent since 2008 under the International Convention on the Control of Harmful Anti-fouling Systems in Ships (AFS Convention; IMO 2020; IMO n.d.). To date, 81 states have ratified this convention (representing about 94% of the total tonnage of global merchant shipping), significantly reducing the use of organotins for this use. In the EU, gradually more restrictive regulations have prevented production and use of organotins, e.g. under REACH, biocides and cosmetics regulations (van Herwijnen 2012; Sousa <i>et al.</i> 2014).</td></tr>
<tr><th colspan="2">Use information</th></tr>
<tr><td><b>Key markets</b></td><td>Global use data for organotins are limited across all sectors and different geographical areas. The only detailed quantitative information available for organotins relates to the EU, from 2002 (Risk and Policy Analysts Limited 2005), which estimated quantities sold for different uses as follows:
<table>
<tr><th>Organotin (tonnes/year)</th><th>Applications % of total</th><th colspan="2">Quantity</th></tr>
<tr><td><b>Tetra-</b></td><td>Intermediate in synthesis</td><td>N/A</td><td>0%</td></tr>
<tr><td rowspan="3"><b>Tri-</b></td><td>Biocide</td><td><100</td><td><1%</td></tr>
<tr><td>Pesticide</td><td>100</td><td>1%</td></tr>
<tr><td>Synthesis</td><td><150</td><td><1%</td></tr>
<tr><td rowspan="3"><b>Mono- and di-</b></td><td>PVC stabilizers</td><td>15 610</td><td>85%</td></tr>
<tr><td>Catalysts</td><td>1300–1650</td><td>9%</td></tr>
<tr><td>Glass coating</td><td>760–800</td><td>4%</td></tr>
<tr><td><b>Total</b></td><td colspan="3"><b>18 410</b></td></tr>
</table>
</td></tr>
</table>

| **Use information (continued)** | |
|---|---|
| **Key uses/applications** | Different organotin classes/groups have specific uses. Typically, the most common uses are as follows (Dobson, Howe and Floyd 2006; Sousa *et al.* 2014; Apparel and Footwear International RSL Management Group 2018; UNEP 2019):<br>• mono- and disubstituted organotins:<br>- heat stabilizer in polyvinyl chloride (PVC) – typically the loading of the stabilizer is 0.5–2% by weight of the polymer (Ghazi *et al.* 2018);<br>- coatings to form electrically conductive thin films on the surface of glass (e.g. in windshield screens, security glass, or display systems);<br>- catalysts for the production of polymeric materials, for example, polyurethane foams and silicones.<br>• tri-substituted organotins:<br>- biocides in anti-fouling paints for boats<br>- biocides or preservatives in textiles, leathers and synthetic fabrics<br>- use as pesticides<br>- intermediates in the production of other chemicals |
| **Geographic distribution** | Based on data for the whole organometallics industry (IHS Markit 2016), in 2015 about 80% of the total market was covered by the US, China and Western Europe. In 2015, Chinese consumption of organotins accounted for more than 40% of estimated global demand, of which approximately 93% was used as heat stabilizers in PVC manufacture (IHS Markit 2016). China is the largest consumer of organotins for PVC applications, while both China and the US use nearly the same volume of organotins for biocides. |
| **Exposure** | |
| **Main exposure sources and pathways** | • Generally, ingestion of contaminated food is considered to be the main source of human exposure to organotins (EFSA 2004; Sousa *et al.* 2014).<br>- Consumer exposure – Among food items, shellfish and fish products tend to present the highest levels of organotins for consumer exposure (Müller, Nielsen and Ladefoged 2013). Drinking water transported by PVC piping and the use of PVC and silicone food packing materials can also contribute to exposure, although to lesser degrees (Sousa *et al.* 2014).<br>- Environmental – The main pathways of organotins to the marine environment are direct releases from anti-fouling on ships, discharges to water from industry, wastewater treatment plants and agricultural spraying (Goud 2011).<br>- Occupational – Main routes for worker exposure are manufacturing factories for organotin compounds and facilities where they are used directly (e.g. as biocides).<br>• Historically, a primary use for organotin compounds has been in marine anti-fouling paints, resulting in direct release to the marine environment. With this use being rapidly phased out worldwide, other sources of release have become more prevalent (e.g. runoff from agricultural areas, release from wastewater treatment plants and sewage sludge applications; Sousa *et al.* 2014).<br>• PVC is now the primary use for organotin compounds (see above). At the end of their life cycles, PVC products will enter the solid waste stream. Historically, the main disposal method has been in landfills, which can result in organotins leaching into the environment. Since many countries are now restricting the volumes and types of waste that can be landfilled, attention has focussed on PVC recycling options (Plinke *et al.* 2000). This raises the question of the potential incorporation of organotins in recycled consumer products. No specific data on organotin concentrations in recycled PVC materials are currently available. |
| **Foreseeable global trends** | The continued phase-out of lead stabilisers may increase demand for organotins, especially for potable water pipes. There are potential new markets suggested for organotins, for example in energy and electronics materials, including lithium-ion batteries, solar cells, thermoelectric materials and photocatalysts, as well as in stabilising halogenated polymers used in thermoplastics (Pearce and Wallace 2015). If organotins are used for these purposes, the new demand could increase production, use and potential exposure. |
| **Costs of inaction and benefits of action** | |
| **Costs of inaction** | • Quantitative estimates of the costs associated with organotin pollution in the aquatic environment (for Europe only) have been provided by Amec Foster Wheeler *et al.* (2017). Imposex, or the imposition of male genitalia on female organisms, has been widely documented by OSPAR in the northwest Atlantic and was found to affect the Common Whelk, with evidence suggesting that TBT caused local extinction in the Dutch Wadden Sea (1970s). The loss of whelk production in the Bassin d'Arcachon (Atlantic French coast) between 1979 and 1983 was estimated to be 28,000 tonnes, with a loss in market value of €130 million (Amec Foster Wheeler *et al.* 2017).<br>• Residual costs also arise, for example, due to exemptions to the current regulation and also transboundary effects from an unknown number of ships outside of ratified areas and the continued illegal use of TBT. In order to ensure compliance with the environmental quality standards for surface water bodies, ongoing remediation and restoration of TBT-contaminated water bodies (largely harbours and waterways) are needed. Without regulation of TBT, the estimated cost of remediation at EU level would be much higher than the currently estimated €21-€237 million (Amec Foster Wheeler *et al.* 2017). |
| **Benefits of action** | Quantitative estimates of the benefits associated with regulation preventing or reducing organotin pollution in the aquatic environment (for Europe only) have been provided by Amec Foster Wheeler *et al.* (2017). For example, regulation of organotins has been linked to a recovery of affected shellfish populations, increasing the number and variety of fish in European waters. The benefits to revenues for commercial fishing and to nutrient cycling from TBT regulation in Europe were estimated to be about €22-€158 million per year (2015 prices) and about €158 million-€126 billion (2015 prices) respectively, according to an extrapolation to the EU. |

**Table B–8.2.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of organotins.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| **Legally binding Instruments** | | | | |
| Restriction / Ban | EU | Tri-organotins, dibutyltin compounds, dioctyltin compounds | Under Annex XVII to REACH (European Chemicals Agency 2009),<br>• These compounds shall not be placed on the market, or used as substances or in mixtures where the substance or mixture<br>- Is acting as biocide in free association paint.<br>- Acts as biocide to prevent the fouling by microorganisms, plants or animals of: (a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes; (b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming; (c) any totally or partly submerged appliance or equipment.<br>- Is intended for use in the treatment of industrial waters.<br>• Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used after 1 July 2010 in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0.1% by weight of Sn. Articles that were already in use in the Community before that date can remain on the market.<br>• Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0.1% by weight of tin. Articles that were already in use in the Community before that date can remain in the market.<br>- Some items for supply to the general public had exceptions until 1 January 2015: one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives, paints and coatings containing DBT compounds as catalysts when applied on articles, soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC, fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications, outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades.<br>- Materials and articles regulated under Regulation (EC) No 1935/2004 do not apply to these limitations.<br>• Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0.1% by weight of tin: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies, two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits). Articles that were already in use in the Community before that date can remain on the market. | In force |
| | South Korea (Korean Agency for Technology and Standards [KATS] 2012; KATS 2016) | Textile and leather products for infants and children; others | • Under the Special Act on Safety Management of Children's Products:<br>- Products include outerwear and innerwear, bedding, shoes, socks, gloves, hats, bags, and newborn baby products<br>- For infants' textile products, DBT ≤ 1 mg/kg of product and TBT ≤ 0.5 mg/kg of product<br>- For children's textile products, TBT ≤ 1 mg/kg of product<br>- For infants' leather products, DBT ≤ 1 mg/kg of product and TBT ≤ 0.5 mg/kg of product<br>- For children's leather products, TBT ≤ 1 mg/kg of product (SGS 2015)<br>• The Toxic Chemicals Control Act<br>- restricts manufacture, import, sale, keeping, storage, transportation or use of tributyltin compounds and mixtures containing any of them at the level of 0.1% or more in anti-fouling paint for Korean ships (excluding warships and police ships) defined under Article 2 of the Shipping Law and for fishing boats defined under Article 2 of the Fishing Boat Law; anti-fouling paint for structures or facilities, fishing nets, or fishing tackle of which the whole or part contact seawater at marine facilities under the Marine Pollution Preservation Law, and harbor facilities under the Harbor Law, and in wood preservatives defined under the Forestry Law<br>• Under the Law Concerning Quality Promotion and Safety Management of Consumer Products<br>- triphenyltin and tributyltin compounds must not be detected in general-use adhesives for consumers (Park and Marrapese 2009). | Active |
| | International | Organotins; anti-fouling systems on ships | Under the International Convention on the Control of Harmful Anti-fouling Systems on Ships, Annex I states that all ships shall not apply or re-apply organotins compounds, which act as biocides in anti-fouling systems. This applies to all ships (including fixed and floating platforms, floating storage units, and floating production storage and offtake units). The Convention entered into force in 2008, and as of March 2020, it has 89 Contracting States (IMO 2020; IMO n.d.). | In force |

|  |  |  |  |  |
|---|---|---|---|---|
| **Restriction / Ban** | **Canada** | **Tributyltin** | The Prohibition of Certain Substances Regulation 2012 classifies tributyltin and triphenyltins as toxic substances and prohibits their manufacture, use, sale, offer for sale or import, and products containing them (Environment and Climate Change Canada 2017). | In force |
|  | **Japan (Ministry of Health, Labour and Welfare of the Japanese Government 2015)** | **Textile and other household products** | TBT and TPhT should be below the detection limits when GC-MS (Gas Chromatography-Mass Spectrometry) are applied to measure and confirm the presence of organotins in the products addressed by the Act on Control of Household Products Containing Harmful Substances:<br>• Textile products, diapers, diaper covers, bibs, underwear, sanitary bands, sanitary panties, gloves and socks<br>• Household adhesive, household paints, household waxes, shoe polish and shoe cream. | Active |
| **PIC procedure** | **International** | **Tributyltin compounds** | Tributyltin compounds (CAS Nos. 1461-22-9, 1983-10-4, 2155-70-6, 24124-25-2, 4342-36-3, 56-35-9, 85409-17-2) are included in Annex II of the Rotterdam Convention and subject to the PIC procedure along with the associated Decision Guidance Documents, as well as any additional information (Secretariat of the Rotterdam Convention n.d.). | In force |
| **Notification** | **EU** |  | • Under REACH, dibutyltin dichloride, bis(tributyltin) oxide, and one dioctyl tin compound have already been identified as SVHC.<br>• Dibutylbis(pentane-2,4-dionato-O,O')tin is being evaluated multas a candidate SVHC as it is classified as toxic for reproduction category 1B. | In force; in evaluation |
| **Pollutant Release and Transfer Register (PRTR) Protocol** | **International (United Nations Economic Commission for Europe 2003)** | **TBT, TPhT and total organotins** | • Ratifying parties need to ensure that the prescribed thresholds are not exceeded by company operators through the employment of appropriate waste and emission treatment.<br>• Thresholds for release of both TBT and TPhT to land and water from facilities is set to 1 kg/year.<br>• Off-site transfer thresholds for both TBT and TPhT from facilities is set to 5 kg/year.<br>• Manufacture, process, or use threshold for both TBT and TPhT is 10,000 kg/year.<br>• Thresholds for "release to land and water", "off-site transfers", and "manufacture, process or use" for total organotins are 50 kg/year, 50 kg/year, and 10,000 kg/year (as total tin), respectively.<br>• Each party needs to ensure public access to information contained in its pollutant release and transfer register. | Active |
|  | **Australia** | **National emission of all organotins** | Releases of organotins are required to be reported if a facility exceeds substance reporting thresholds of 10 tonnes per year (Government of Australia 2019). | In force |
| **Soft Law Instruments** |  |  |  |  |
| **Code of practice** | **Canada** | **Tetrabutyltin** | In 2011, ECCC adopted a Code of Practice with the purpose to minimize releases of tetrabutyltin to the aquatic environment by identifying best management procedures and practices for activities involving the import, distribution, manufacture and use of tetrabutyltin. The Code provides best management practices for the following activities: Packaging, storage and secondary containment; handling and dispensing; uncontrolled, unplanned or accidental releases; empty packaging; waste disposal; record keeping and reporting; and training and management systems (ECCC 2011). |  |
| **Guideline values** | **International (Hirose 2016)** | **Organotins in drinking water** | • Health-based value of 1.5 µg/L in drinking water has been set, expressed as a sum of TBT, TPhT, DBT, and dioctyltin (DOT) concentrations.<br>• Intake of total TBT, TPhT, DBT and DOT from drinking water would at maximum be one order of magnitude lower than levels of health concern; establishing a guideline value is not considered necessary.<br>• For other organotins, current knowledge is inadequate for setting a health-based guideline value. | Under public review (only draft available) |
|  | **EU** | **TDI from foodstuffs** | EFSA set a group tolerable daily intake (TDI) of 0.25 ug/kg bw for tributyltin, dibutyltin, triphenyltin and dioctyltin compounds (based on tributyltin oxide molecular mass, this group TDI is 0.1 µg/kg bw when expressed as tin content, or 0.27 µg/kg bw when expressed as tributyltin chloride; EFSA 2004). |  |
|  | **National** | **Air, soil, sediment, occupational exposure limits** | Different countries have set up guideline values for different exposure media including occupational exposure, including the Netherlands, Denmark, Germany and others (van Herwijnen 2012; Müller, Nielsen and Ladefoged 2013). |  |

| Voluntary Initiatives | | | | |
|---|---|---|---|---|
| Stewardship programme | Canada | **Organotins; stabilizers in PVC** | An Environmental Performance Agreement Respecting the Use of Tin Stabilizers in the Vinyl Industry has been in place since March 10, 2008, to manage the release of tin stabilizers (mono- and dibutyltins) into the environment, including any TBTs that may be present in the stabilizers (Government of Canada 2019). The agreement was in effect from March 17, 2015 to March 16, 2020. The participating companies agreed to:<br>• undergo site visit verifications to determine whether the guideline continues to be fully implemented as specified in the agreement, at three randomly selected participating facilities that were previously verified under the former agreement but that do not meet the definition of new facilities;<br>• new facilities will be verified within 24 months after the facilities start to use tin stabilizers;<br>• prepare corrective action plans for any deficiencies that are identified when the final site visit report is issued.<br>Participating facilities that have undergone significant changes, as defined in the 2015 agreement, will submit all required documentation to the VIC and ECCC within three months following the signing of the agreement or following the submission of their annual compliance report identifying those changes. The verifiers will conduct a verification by examining the submitted documentation and by performing a site visit, if required. | |
| Voluntary industry phase-out | International | **Textiles; electronic products** | • Organotin compounds are not allowed to be used in the production of H&M products (Global Sustainability Department 2016).<br>• All tri-organotins (including tributyltin, triphenyl), dibutyltin and dioctyltin are listed in the Restricted Substances List of the American Apparel & Footwear Association (2014).<br>• Organotin compounds are listed in the Restricted Chemicals for Wearables and Regulated Substances Specification by Apple (Apple 2015; Apple 2018). | Ongoing |
| | Japan (Japan Paint Manufacturers Association [JPMA] 2019) | **Paints manufactured and distributed by Japan Paints Manufacturers Association (JPMA)** | • JPMA List of Registered Organotin-free Anti-fouling Systems: self-regulatory management of Japan Paint Manufacturers Association to comply with the International Convention on the Control of Harmful Anti-fouling Systems on Ships.<br>• Sharing relevant compliance information with ship owners, ship operators, government authorities in charge, and other related bodies. | Ongoing |
| Third-party standards and certification scheme | International (bluesign® 2019) | **Articles and accessories made of textile and leather** | Usage ban on organotin compounds in articles and accessories. | Ongoing |

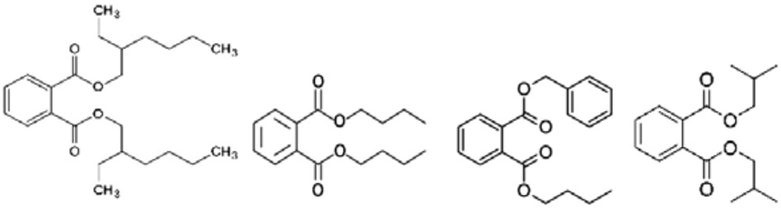
# 9. Phthalates

**Table B–9.1.** A brief overview of existing assessments of environmental and human effects of phthalates by national governments and intergovernmental institutions.

| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| **United States National Research Council ([US NRC] 2008)** | **Review health effects of phthalates, determine use of cumulative risk assessment** | **Committee primarily tasked with determining if cumulative risk assessment should be conducted on phthalates and secondarily an assessment of low dose effects** | **Considered most sensitive health outcomes on male reproductive system** | • Phthalates with carbon chain lengths of 4 to 6 are most potent in causing adverse effects on the development of the male reproductive system, where age of exposure is critical for determining the severity of effects (foetal exposure is most sensitive).<br>• Phthalate syndrome (infertility, decreased sperm count, cryptorchidism, hypospadias and other reproductive tract malformations) has many similarities to "hypothesized" testicular dysgenesis syndrome in human but no human data directly link testicular dysgenesis with phthalate exposure. | Not intended to be comprehensive toxicologic profile or risk assessment |
| **US National Academy of Sciences (2017)** | **Evaluation of low dose effects from endocrine active chemicals** | **DEHP** | **Demonstration of systematic review method of extensive vetting and review of data** | • Foetal exposure to DEHP is associated with decreases in anogenital distance (AGD) as an indicator of reduced foetal androgen production. Concluded that DEHP is a "presumed" reproductive hazard to humans based on a high level of evidence from animal studies and on a moderate level of evidence from human studies.<br>• Animal studies may not accurately indicate exposures which could predict adverse effects in humans. | Determination of hazard and not risk<br>Used AGD as 1 indicator of endocrine disruptive effects |
| **European Union (EU; European Chemicals Bureau 2008)** | **Risk assessment of DEHP** | **Human and aquatic ecosystem outcomes throughout DEHP life cycle from manufacturing through to disposal of phthalate-containing products and materials** | **Literature searched up to 2005** | • No need for further testing or risk assessment, as current restrictions are sufficient to limit human exposure and exposure of aquatic ecosystems.<br>• Need for further information and/or testing because of concern for benthic organisms near sites processing DEHP or products containing DEHP (e.g., producing lacquers, paints, printing inks).<br>• Need to limit risks to soil organisms and mammals consuming earthworms exposed to DEHP near sites processing polymers using DEHP or products that could contain DEHP.<br>• Need to limit risks, by applying current risk reduction measures, for occupational exposure, children exposed through toys, and children and adults exposed through medical uses (e.g., tubing, blood bags), humans exposed near phthalate "hot spots" exposed through locally grown food nearby industrial facilities using phthalates, paper recycling or wastewater treatment plants. | |
| **European Chemicals Agency (2013)** | | **Re-evaluation of evidence used to conclude restriction to DiNP and DiDP used in toys and childcare articles that can be mouthed by children** | **Literature search** | • Concluded maintaining restrictions on use of DINP and DIDP used in toys and childcare articles that can be mouthed by children.<br>• No further risk management measures are warranted to reduced exposure of children to DiNP and DiDP from exposure via food or the indoor environment.<br>• Concluded unlikely risk to adults from using sex toys while acknowledging substantial uncertainties regarding exposure duration and migration rates from sex toys.<br>• Concluded unlikely risks from dermal exposure from, for example, PVC clothing, food or the indoor environment. | |
| **International Agency for Research on Cancer (2011)** | **Carcinogenicity** | **DEHP** | **literature review** | • There is sufficient evidence in experimental animals for the carcinogenicity of DEHP.<br>• DEHP is possibly carcinogenic to humans (Group 2B). | |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| **United States Environmental Protection Agency ([US EPA] 2012)** |  | **Phthalate Action Plan** | **Review of uses, exposures and health effects from the literature, summarizes regulatory and non-regulatory actions** | • Conclusions drawn from other organisations, e.g., National Toxicology Program, Environment Canada.<br>• Concluded that US EPA's concerns for potential human health hazards, and reproductive effects in particular, from evidence taken from human and animal studies.<br>• Concluded that the greatest evidence for toxicity to terrestrial organisms, fish and aquatic invertebrates comes for BBP, DEHP, DBP at environmentally relevant exposures in the low ng/L to ug/L range with adverse effects related to reproduction and impaired development. |  |
| **ECCC and Health Canada (1993; 1994a; 1994b; 2000; 2015a; 2015b; 2015c; 2015d; 2015e)** | **Draft risk assessments** | **DBP, BBP, DEHP, DNOP** |  | • DBP and BBP determined not to present risk to environment or human health; DNOP determined not to present risk to environment, insufficient information on DNOP regarding human health however, 2003 assessment concluded that DNOP did not pose a risk to human health.<br>• DEHP determined to present risk to human health but insufficient data to make a determination for risk to the environment. |  |
| **Canada (ECCC and Health Canada 2017)** | **Draft Screening Assessment, Phthalate Substance Grouping** | **14 short- to long-chained phthalates plus 14 previously assessed short- to long-chained phthalates in a final cumulative risk assessment** | **Extensive review of existing evidence subject to scrutiny for data quality, weight-of-evidence approach and use of precaution, use of read-across and QSARs in absence of data** | • For aquatic environments, concluded that cumulative risk, based on the Sum of Internal Toxic Units, was not a concern based on lethality and a narcotic mode of action (endocrine disruption was noted but was considered improbable at ambient exposures), except for B79P and DEHP that were found to pose a risk to the environment [meeting the criteria under paragraph 64(a) of CEPA as 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].<br>• For human health, concluded no concern for the general Canadian population and more sensitive subgroups pregnant women, infants, children) from cumulative risk of medium-chain phthalates. | Disqualified some epidemiological evidence as not meeting data quality criteria |

**Table B–9.2.** Supporting information on the life cycle of and exposure to phthalates, as well as examples of cost-of-inaction and benefits-of-action information

<table>
<tr><td><b>Chemical name(s)</b></td><td>Ortho-phthalates (di-esters of ortho-phthalic acid), generally referred to as ‘phthalates’, are a wide group of chemical compounds. They differ in the hydrocarbon chains of the two ester groups. Some of the common ones include: bis (2-ethylhexyl) phthalate (DEHP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP); diisobutyl phthalate (DIBP); their chemical identifiers and structures are presented below.<br>Phthalates can be broken down into high molecular weight (HMW) phthalates and low molecular weight (LMW) phthalates, based on the number of carbon atoms in the backbone of the ester groups. Definitions of HMW <i>vs.</i> LMW vary among users. Typically, HMW phthalates include diisononyl phthalate (DiNP), diisodecyl phthalate (DiDP) and dipropylheptyl phthalate (DPHP), and LMW phthalates include dimethyl phthalate (DMP) and diethyl phthalate (DEP).</td></tr>
<tr><td><b>IUPAC name(s) of example phthalates</b></td><td>1,2-Benzenedicarboxylic acid bis (2-ethylhexyl) ester (DEHP); 1,2-Benzenedicarboxylic acid, dibutyl ester (DBP); 1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester (BBP): Bis(2-methylpropyl) benzene-1,2-dicarboxylate (DIBP)</td></tr>
<tr><td><b>Other name(s) of example phthalates</b></td><td>1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl)ester (DEHP); 1,2-dibutyl benzene-1,2-dicarboxylate (DBP); 1-benzyl 2-butyl benzene-1,2-dicarboxylate (BBP); bis(2-methylpropyl) benzene-1,2-dicarboxylate (DIBP)</td></tr>
<tr><td><b>CAS number(s) of example phthalates</b></td><td>(DEHP); 84-74-2 (DBP); 85-68-7 (BBP); 84-69-5 (DIBP)</td></tr>
<tr><td><b>Chemical formula of example phthalates</b></td><td>$C_6H_4(CO_2C_8H_{17})_2$ (DEHP); $C_6H_4(CO_2C_4H_9)_2$ (DBP); $C_{19}H_{20}O_4$ (BBP); $C_6H_4(COOCH_2CH(CH_3)_2)_2$ (DIBP)</td></tr>
<tr><td><b>Chemical structure of example phthalates</b></td><td> </td></tr>
<tr><td colspan="2"><b>Production information</b></td></tr>
<tr><td><b>Production overview</b></td><td>Phthalates cover a wide family of industrial compounds. They are the esters of 1,2-benzene dicarboxylic acid produced by the addition of an excess of linear-chain or branched alcohols to phthalic anhydride in the presence of a catalyst (Peijnenburg 2008).</td></tr>
<tr><td><b>Production volumes and global trends</b></td><td><ul><li>Phthalates, more specifically ortho-phthalates, are the most common plasticisers and 8.4 million tonnes per year are consumed globally (Lange et al. 2017). More than 2 million tonnes of DEHP are produced annually worldwide (Rowdhwal and Chen 2018). Production figures for other phthalates were not readily available.</li><li>In Europe, 1 million tonnes per year of phthalates are produced, which represents 80% of the EU plasticiser market. The European market has evolved substantially. For example, production of DEHP in Western Europe decreased from ca. 595,000 tonnes in the early 1990s to 187,000 tonnes in 2007 (COWI 2009). Similarly, production of DBP decreased from 26,000 tonnes per year in the EU15 in 1998 to less than 10,000 tonnes in the EU25 in 2007 (ECHA 2010). Data for other regions was not available.</li><li>According to the US EPA, in 2014 the US imported 13,000 tonnes of DEHP while producing only 816 tonnes, consuming 3,900 tonnes and exporting 41 tonnes. In comparison, the US imported 11,200 tonnes of DINP in 2014 with domestic manufacturing of only 33 tonnes. China’s production of raw plastics reached 50 million tons in 2011. This production value translates to the use and/or production in China of phthalates used as plasticizers of China of <1 million ton annually.</li></ul></td></tr>
<tr><td><b>Global trade</b></td><td>Phthalates are traded as substances on their own, as preparations or within articles. No information was available on global imports and exports. The table below presents the EU27 external import and exports of all phthalates in 2012 (Mikkelsen et al. 2014).<br><b>Table 22</b> EU 27 External import of all Phthalates (Eurostat, 2012A)
<table>
<tr><th rowspan="2">CN code</th><th rowspan="2">Text</th><th colspan="2">Import, t/y</th><th colspan="2">Export, t/y</th></tr>
<tr><th>Average 2006-2010*</th><th>2011</th><th>Average 2006-2010*</th><th>2011</th></tr>
<tr><td>2917.3100</td><td>Dibutyl <i>orthophthalates</i></td><td>298</td><td>:</td><td>4,864</td><td>:</td></tr>
<tr><td>2917.3200</td><td>Dioctyl <i>orthophthalates</i></td><td>5,218</td><td>4,716</td><td>53,002</td><td>31,872</td></tr>
<tr><td>2917.3300</td><td>Dinonyl or dodecyl <i>orthophthalates</i></td><td>17,471</td><td>19,838</td><td>151,188</td><td>260,506</td></tr>
<tr><td>2917.3400</td><td>Esters of <i>orthophthalic</i> acid (excl. cibutyl, doctyl, dinonyl or dodecyl <i>orthophthalates</i>)</td><td>3,129*</td><td>-</td><td>71,181*</td><td>-</td></tr>
<tr><td>2917.4100</td><td>Diisooctyl, diisononyl and <i>diisodecyl orthophthalates</i></td><td>739</td><td>1,201</td><td>7,301</td><td>864</td></tr>
</table>
*Average for those years where data are reported.</td></tr>
</table>

| Use information | |
|---|---|
| **Key uses/applications** | Phthalates are a group of chemicals typically used as plasticisers. These make plastics more flexible, easier to work with and less brittle. Some, especially LMW phthalates, are also used as solvents (i.e. dissolving agents), for other materials (US Centers for Disease Control and Prevention [US CDC] 2017).<br>Examples of phthalate applications:<br>• Phthalates – particularly DEHP – are mainly used as plasticisers in plastic and rubber manufacturing such as polyvinyl chloride plastics (PVC). In turn, PVC is used in various products like children's toys, blood-storage containers or medical tubing. Products that contain the largest quantities of phthalates are flooring, wallpapers, roofing membranes, cables (in particular DIDP in plastic jackets of wiring and cables), foil and plastic-coated fabrics. They can also be found in various paints and adhesives, as plasticisers for binders, inside and outside of vehicles and in final articles, such as footwear, artificial leather coverings of furniture, plastic tubes, garden hoses and some fabrics/clothing (Swedish Chemicals Agency 2015). Phthalates are also found in food contact materials and sometimes as illicit additives ("clouding agents") in foods and beverages.<br>• They are also used as dissolving agents (or to improve formulation) for other materials, such as paints, coatings and inks and in some personal care products (soaps, shampoos, skin care, body lotions, hair sprays, fragrances, mouth wash, insect repellents and nail polishes) (US CDC 2017).<br>• Some medicinal products and dental materials use phthalates, e.g. in the enteric coating of certain medications or dietary supplements. |
| **Use volumes** | • Phthalates are the most widely consumed plasticisers. In 2017, 65% of plasticisers were phthalates, down from approximately 88% in 2005. By 2022 the figure is expected to be 60%. The observed decrease in market share is due to the rapid consumption growth for non-phthalate plasticisers (e.g. terephtalates, epoxy, aliphatics and benzoates, replacing DEHP, DINP and BBP). Despite the decrease in share, the overall global consumption of phthalate plasticisers is expected to grow at an average annual rate of 1.3% between 2017 and 2022. Consumption of lower-molecular-weight phthalates is forecast to decrease as they are replaced by non-phthalates. (IHS Markit 2018).<br>• China represents the single largest plasticiser market in the world (42% of world consumption in 2017) and is the region with highest expected growth (2017-2022). Western Europe and the United States are second and third largest markets, respectively (IHS Markit 2018). |
| **End-of-life issues** | A key disposal route for plastic products that contain phthalates is municipal solid waste landfill sites. If those landfills do not have sufficient environmental protection systems installed, such as leachate collection systems, phthalates can represent a threat to the environment and human health. Leachate is generally generated by the penetration of precipitated water into the landfill; phthalates can be easily released from waste and be found in high concentration in landfill leachate (Wowkonowicz and Kijeńska 2017). Some phthalates have been identified in samples of waste plastics and recycled and virgin plastics (Pivnenko *et al.* 2016). In particular, DBP, DiBP and DEHP had the highest frequency of detection in analysed samples. Research also showed that phthalates were possibly added in the later stages of plastic product manufacturing, such as labelling, gluing, etc, and are not removed following recycling of household waste plastics (Pivnenko *et al.* 2016). In addition, a recent study led in the residential and agricultural soils from Guiyu, Shantu (China) the largest e-waste processing and recycling areas in the world, indicated that electronic waste (e-waste) recycling was a substantial source of phthalate contamination in the environment (Zhang *et al.* 2019). Finally, due to their use as plastic softeners, phthalates may also be found in cosmetics as leaked materials from the contact with plastic materials in the production process and also during storage (Fromme 2019). |
| **Exposure information** | |
| **Main exposure sources and pathways** | Various human-biomonitoring studies in the EU, US and Asia indicate the widespread use of phthalates resulted in a continuous exposure of the general public. (Lange *et al*. 2017). Phthalates are not strongly bound in products and therefore, can leach out. The main route of exposure is food ingestion for most phthalates, with some found at higher levels in fatty foods, e.g. dairy products, fish, seafood and oils. Infant exposure can take place via breast milk and an important exposure route for children is mouthing of toys, as well as other products (e.g. textiles/clothing). Other routes of exposure are inhalation, dust ingestion, drinking contaminated water, absorption through the skin (from personal care products or textiles), dermal and hand-to-mouth contacts via paints/coatings (US EPA 2019). Despite these findings occurring at higher levels of exposure than the general population, the US NRC concluded that similar effects could occur in humans (US EPA 2019). |
| **Foreseeable global trends** | Over the past decade, the use of some phthalates in certain applications has been restricted in different regions of the world. There is some evidence of declining metabolites in urine amongst US women and children - but evidence is available only from 1999–2014 and decreases were observed only from 2009–2010, with some increases observed in 2013-2014. (US EPA 2019). Phthalates are a large class of chemicals, only some of which have been studied to date, for which some have adverse effects on human health (Shu *et al.* 2018). By replacing one phthalate of concern by another, there is a risk of regrettable substitution, as was the case for DEHP which was increasingly substituted by DiNP, which in turn was assessed to have reprotoxic properties (Shu *et al.* 2018). |

| Examples of costs of inaction and benefits of action information | |
|---|---|
| **Costs of inaction** | There is no quantitative data on the extent of physical damage or the costs of this for phthalates as a whole. However, Trasande *et al.* (2016) assessed the annual disease burden and costs of exposure to phthalates and multiple EDCs in the EU, amounting to circa EUR 30 billion in 2010. Some of these costs were attributed to specific phthalates:<br>• DEHP: €15 billion (from Adult obesity) and a further €0.6 billion (from adult diabetes)<br>• Benzyl and butyl phthalates: €8 billion (from male infertility requiring assistance for reproduction)<br>• Phthalates: €8 billion (from low testosterone leading to early mortality) and a further €1.3 billion (from endometriosis). |
| **Benefits of action** | A study on benefits from chemicals legislation (Amec Foster Wheeler *et al.* 2017) reports benefits associated with historic reductions in EU level DEHP and DBP exposure, between 1996 and 2008, as follows:<br>• Female reproductive health: the incident cases of endometriosis attributable to DEHP exposure decreased by c.700,000. Benefits in terms of avoided medical costs, lost economic productivity and other indirect costs, were estimated at €7.0 billion.<br>• Male infertility and assisted reproduction: male infertility cases associated with DBP exposure decreased, leading to a reduction of assisted reproduction technology treatments, with benefits valued at €6.7 billion.<br>• Male mortality attributable to decrease in serum testosterone: cumulative benefits were estimated between €100 billion and up to €910 billion (depending on assumptions and method). |

**Table B–9.3.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of phthalates.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** [e.g. bilateral and multilateral treaties; national and regional legislation and regulations] | | | | |
| **Restriction / Ban** | **Republic of Korea** | **DBP, BBP and DEHP; medical devices** | The Ministry of Food and Drug Safety (2016) adopted regulations on medical device approval, notification and examination for three phthalates: DBP, BBP and DEHP, and prohibited the production, import sale or use of intravascular administration medical devices containing phthalates. | 2016 |
| | **EU-wide** | **DEHP, BBP, DnBP, DiBP; toys, childcare articles, and plasticised materials in the article** | REGULATION (EU) 2018/2005 amended Entry 51 of Annex XVII to Regulation (EC) No 1907/2006 (REACH) with respect to DEHP, BBP, DnBP and DiBP to specify limits of concentrations (0.1% by weight) of different combinations of these four phthalates in articles such as toys, childcare articles and plasticized material in the article (European Commission 2018). | additional restrictions of (EU) 2018/2005 come into force in July 2020 |
| | **EU-wide** | **DEDEHP, BBP, DnBP, DiBP; electrical and electronic equipment** | Directive (EU) 2015/863 amended Annex II to Directive 2011/65/EU (four phthalates: DEHP, BBP, DnBP, DiBP) to restrict use in all electrical and electronic equipment (European Commission 2015). Use of these in medical devices and monitoring and control equipment is given an extension for substitution of 22 Jul 2021. | 2015 |
| | **China** | **DEHP, DBP, BBP, DiNP, DOP, DiDP; infants' and children's textile products** | The GB 31701-2015: Safety technical code for infants and children's textile products restricts the use of six phthalates (DEHP, DBP, BBP, DiNP, DiDP and DNOP) in infants' and children's textile products (Standardization Administration of China 2015). | 2015 |
| | **China** | **DMP, DiBP, DiOP, DiDP; food contact materials** | National Food Safety Standard GB 9685-2016 prohibits use of four phthalates (DMP, DiBP, DIOP, DiDP) as additives in food contact materials (National Health and Family Planning Commission, China 2016). | 2016 |
| | **Canada** | **DEHP; cosmetics, medical devices, toys and childcare articles** | An assessment led to restrictions banning use of DEHP in cosmetics, medical devices, vinyl in children's toys and childcare articles (Government of Canada 2017; Health Canada 2019). | 1994 |
| | **Canada** | **DEHP, DBP, BBP, DiNP, DiDP, DOP; toys and childcare articles** | Canada's Consumer Product Safety Act was amended in 2016 to include Phthalates Regulations for six phthalates: DEHP, DBP, BBP, DiNP, DiDP, DNOP. It restricts concentrations of DEHP, DBP and BBP to 1,000 mg/kg in vinyl included in a toy or childcare article, and concentrations of DiNP, DiDP, and DNOP to 1,000 mg/ kg in vinyl in any part of a toy or childcare article that can be reasonably be mouthed by a child under four years of age (Government of Canada 2016). | 2016 |
| | **US** | **DEHP, DBP, BBP; childcare** | The US Consumer Product Safety Improvement Act limits use of DEHP, BBP and DBP to no more than 0.1% in a childcare article designed or intended by the manufacturer to be used to facilitate sleep or feeding of children 3 years old or younger, or for a product intended to be used for sucking or teething (US Consumer Product Safety Commission 2008). | 2008 |
| | **US** | **DiBP, DPP, DHP, DCHP, DiNP** | In 2017, the US Consumer Product Safety Commission adopted the Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates under section 108 of the Consumer Product Safety Improvement Act of 2008. Children's toys and childcare articles are prohibited from containing more than 0.1% of five phthalate chemicals: DiBP, DPP, DHP, DCHP and DiNP (US Consumer Product Safety Commission 2019). | April 25, 2018 |
| | **US** | **DPP** | US EPA announced a significant new use rule for di-n-pentyl phthalate (DnPP), among other substances, with a designation of any use other than as a chemical standard for analytical experiments as a significant new use based on concerns of potential human adverse effects, both developmental and reproductive (US EPA 2014). | February 27, 2015 |
| | **Argentina** | **Security requirements for manufacture, import, export and sale of toys; imports** | Ministerial resolutions 583/08 and 373/2009 (Ministry of Health of Argentina 2009) restrict phthalate content in products of flexible material that can be introduced in babies' mouths, with guidance on compliance. A subsequent ministerial resolution establishes a certification system for products and toys regulated under Ministerial Resolution 583/08. Importers shall make tests for phthalates and request a certification (Ministry of Health of Argentina 2011). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Restriction / Ban** | **Colombia** | **Technical regulation for manufacture, import, and sale of toys and their accessories** | The Ministry of Health and Social Protection adopted Ministerial Resolution 686-2018 (Ministry of Health and Social Protection 2018) restricts content of certain phthalates (BBP, DBP, DOP, DEHP, DiNP and DiDP) in flexible plastic toys for children under 3 years of age. | In force |
| | **Peru** | **Manufacture, import, export, sale of toys** | Law 28376 and subsequent regulation Decree 008-2007-SA restrict the content of phthalates (BBP, DBP, DOP, DEHP, DINP and DIDP) in toys (Ministerio de Salud 2004; Government of Peru 2007). | In force |
| | **Uruguay** | **Technical regulation for manufacture, import, and sale of toys** | Decree 388/05, 2005, and its amendments establish requirements and certification system for toys, including for phthalate content (National Customs Directorate, Uruguay 2005). | In force |
| | **MERCOSUR Group** | **Technical regulation on accepted additives for plastic materials to be used in packaging and others in contact with food** | The treaty group MERCOSUR set limits for plasticizers by percent according to thickness of material and use, for example, for DiNP, at 24% for 125-micron thickness in refrigeration and 35% for 50-micron thickness next to fatty substances in other storage conditions (MERCOSUR 2007). To be adopted by all MERCOSUR member countries by 2008. | In force |
| | **Eurasian Economic Union** | | The Eurasian Economic Union has adopted a series of technical regulations, which establish requirements to technical regulation objects, in particular safety requirements, mandatory for application and execution in the territory of the Union:<br>• TR CU 008/2011 on toy safety sets permissible levels of migration of four phthalates in PVC and rubber-latex compositions to aqueous and air media: DBP - not allowed; DMP - 0.3 mg/dm3 (to aqueous media), 0.007 mg/m3 (to air); DOP - 2.0 mg/dm3 (to aqueous media), 0.02 mg/m3 (to air); DEP - 3.0 mg/dm3 (to aqueous media), 0.01 mg/m3 (to air).<br>• TR CU 005/2011 on safety of packaging sets the allowable quantity of migration of 2 mg/L and maximum allowable concentration in atmospheric air for DOP in rubber and rubber-plastic materials (gaskets, can seals, sealing rings of caps for canning, etc.) and PVC plastics, and DBP is not allowed in packaging<br>• TR CU 009/2011 on the safety of perfumery and cosmetic products forbids the use of DBP, DEHP, DMEP in perfumes and cosmetics.<br>• The draft TR CU on safety of paint and varnish materials is currently under discussion, which sets the allowable level of migration of 0.1 mg/m3 for DBP in paint and varnish based on copolymer vinyl chloride, perchlorovinyl, polyvinyl chloride, vinyl acetate, styrene butadiene, rubber, chlorinated rubber | In force; under discussion |
| **Tax** | **Denmark** | | A tax on products containing PVC and phthalates was adopted in 1999. The rate was levied at approximately €0.3/kg of PVC and €0.9/kg of phthalate, with some variation depending on the product (UNEP 2019). | In force 2000; repealed 2019 |
| **Notification** | **EU-wide** | **BBP, DBP, DCHP, DEHP, DHP, DiBP, DiPP, DiHP, DMEP, DPP, nPiPP, DiHxP** | Under REACH, some phthalates and phthalate-containing mixtures have been added to the Candidate List of substances of very high concern (SVHC) for authorization due to toxicity for reproduction and endocrine-disrupting properties in humans (ECHA n.d.). | |
| | **US** | **DBP, DEHP, PRTR** | Reportable under the Toxic Release Inventory (TRI) under section 313 of Emergency Planning and Community Right-to-know Act (EPCRA; US EPA 2012). | |
| | **China** | **DMP, DEP and DOP** | Listed as priority pollutants by China National Environmental Monitoring (Liu, Chen and Shen 2013). | |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Guideline values** | **national or regional: EU** | **DEHP** | DEHP is a priority substance under the EU Water Framework Directive with an Environmental Quality Standard of 1.3 μg/L (annual average) in inland and other surface waters (European Union 2008). | |
| | **national: US** | **DEHP** | In the US, DEHP is regulated under the Safe Drinking Water Act, with maximum contaminant levels (MCL) of 0.006 mg/L<br>DEHP and DBP are listed as hazardous air pollutants under the Clean Air Act.<br>Phthalates are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) if discarded as a commercial chemical product (US EPA 2012). | |
| **Soft law instruments** | | | | |
| **Recom-mend-ation** | **WHO** | **DEHP** | Guideline value of 8 μg/L in drinking water (WHO 2003) | 1996 |
| **Voluntary initiatives** | | | | |
| **Voluntary industry phase-out** | **US** | | The company CVS, a large pharmacy chain in the US, added phthalates to a list of chemicals restricted for use in baby, beauty and personal care and food products sold under its store brand labels (CVS Health 2017). | |
| | | | Several “home improvement” companies that operate large chains of stores in the US, such as Home Depot said they would stop selling vinyl flooring containing phthalates in 2015 (Home Depot 2017) | ongoing |
| | **International** | | Apple has included 21 phthalates on its Regulated Substances Specification with the threshold of 1000 ppm total content (Apple 2018). | |
| **Third-party standards and certification schemes** | **International** | | More than 20 phthalates, including BBP, DBP, DCHP, DEHP and DiBP, are included in the bluesign® Restricted Substances List (Bluesign 2020). Similarly, a number of phthalates have been included in the Zero Discharge of Hazardous Chemicals (ZDHC) Manufacturing Restricted Substances List (MRSL, ZDHC 2019).<br>EU Ecolabel criteria include that DOP, DINP and DIDP should not intentionally be added to the product (EU Ecolabel n.d.).<br>Nordic Ecolabel (a.k.a. Nordic Swan) criteria include the requirement that phthalates shall not be present in the dyes and adhesives used, nor in indoor paints and varnishes (Nordic Ecolabelling 2018; Nordic Ecolabelling 2019). | |

# 10. Polycyclic Aromatic Hydrocarbons (PAHs)

**Table B–10.1.** A brief overview of existing assessments of environmental and human effects of PAHs by national governments and intergovernmental institutions.

| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| IARC (2010) | Evaluation of carcinogenic risk to humans | **60 individual PAHs; human health** | Review of experimental data | Reviewed 60 PAHs grouped according to evidence related to cancer risk:<br>• Benzo[*a*]pyrene (BaP), classified in Group 1, is carcinogenic to humans.<br>• Four PAHs classified in Group 2A are probably carcinogenic to humans, namely cyclopenta[*cd*]pyrene, dibenz[*a,h*]anthracene, dibenzo[*a,l*]pyrene, and creosotes.<br>• The 10 PAHs classified in Group 2B are possibly carcinogenic to humans, namely benz[j]aceanthrylene, benz[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*j*]fluoranthene, benzo[*k*]fluoranthene, benzo[c]phenanthrene, chrysene, dibenzo[*a,h*]pyrene, dibenzo[*a,i*]-pyrene, indeno[*1,2,3-cd*]pyrene and 5-methylchrysene.<br>The remaining 45 PAHs allocated to Group 3 are not classifiable on the basis of carcinogenicity. | PAH classification is limited by inadequate experimental evidence. |
| BfR (2009) | For special safety of children against carcinogenic, mutagenic or toxic to reproduction (CMR) substances | **Children's health risk through toys** | (1) Hazard potential based on the previous BfR opinion;<br>(2) exposure potential based on PAH measurements in 104 toy samples provided by a commercial enterprise | • Focused on 16 PAHs listed by the US EPA in 1984, based on aspects of environmental analysis and relevance;<br>• Because of genotoxic mechanisms, no safe lowest-effect threshold can be deduced for a number of PAHs. Furthermore, some PAHs have a mutagenic effect on humans and impair reproduction. PAHs can activate genes and change transcription of genetic information, leading to mutations.<br>• The 16 individual PAHs have a generally comparable carcinogenic potential. However, they do exhibit different carcinogenic potencies.<br>• PAH-containing plasticizer oils or carbon black are used in production of rubber or plastics that can be a part of consumer goods and lead to direct contact with PAHs for consumers.<br>• Children can be exposed at high levels through skin contact with PAH-containing toys. Assuming the maximum allowable content of BaP in toys according to the EU Toy Safety Directive and guidelines, children's dermal uptake can be noticeably higher than the amount that adults take in daily through food or heavy smoking.<br>BfR recommends the PAH threshold for toys to be identical to those of plastic materials coming in contact with foodstuffs (i.e. be undetectable and below <0.01 mg/kg). | **• Exposure assessment is uncertain due to lack of data pertinent to migration of PAHs and human skin penetration.<br>• The considerably more potent carcinogenic PAHs, the dibenzopyrene isomers, are not included in the analysis, resulting in possible underestimation of the carcinogenic risk of PAH exposure through toys.** |
| ECHA (RIVM 2018, ECHA 2019) | To propose restriction on the maximum tolerable PAH content in the infill material used in synthetic turf pitches and playgrounds | **Total content of eight PAHs listed in REACH for granules or mulches made from end-of-life tyres** | Compilation of previous analysis and risk assessment by ECHA and RIVM | • Covered 8 PAHs: BaP, benzo[e]pyrene, benzo[*a*]anthracene, dibenzo[*a,h*]anthracene (DBahA), benzo[*b*]fluoranthene, benzo[*j*]fluoranthene, benzo[*k*]fluoranthene, chrysene.<br>• They all are genotoxic carcinogens, with no threshold value below which no health risks exist.<br>• PAHs are present in recycled rubber granules and mulches due to the processes applied for manufacturing tyres; all individuals in the EU may come in contact with such granules and mulches; workers for installation and maintenance, professional athletes, amateur athletes and children playing at playgrounds are most likely to come in contact with surfaces made from recycled tyres.<br>• Current REACH legislation for such granules and mulches limits the PAHs at individual concentrations equal to or above 0.01% by weight (100 mg/kg) for BaP and DBahA or 0.1% by weight (1000 mg/kg) for the other six PAHs.<br>• These current limits on PAH concentration are associated with unacceptable health risks to professional athletes and children.<br>"The proposal restricts the placing on the market and use of granules or mulches containing >17 mg/kg (0.0017 % by weight) of eight carcinogenic polycyclic aromatic hydrocarbons (REACH-8 PAHs) as infill material in synthetic turf pitches or in loose form on playgrounds and in sport applications." | **• Uncertainties related to benefits from the proposed restriction persist.<br>• Estimated costs and benefits may be affected by uncertainties.** |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| Agency for Toxic Substances and Disease Registry (ATSDR 1995, 2020) | Complete toxicological profile of PAHs for the US government | **Toxicological focus on PAHs; all health effects due to exposure explored in detail** | Extensive compilation of toxicological studies | • Cancer is the endpoint of PAH toxicity; non-carcinogenic effects involve the pulmonary, gastrointestinal, renal and dermatologic systems; metabolites and derivatives of PAHs can be potent mutagens.<br>• Incidences of skin, lung, bladder, liver and stomach cancers are reported from exposure to PAHs in lab animals; immune and hematopoietic systems also affected, causing reproductive, neurological and developmental defects.<br>• Occupational PAH exposure associated with incidences of lung, skin, bladder and gastrointestinal cancers.<br>Ascribing health effects after epidemiological studies to specific PAHs is difficult, as most exposure happens from a mix of PAHs. | Uncertainty with regards to mutagenic and carcinogenic effects from chronic exposure to PAHs. |
| EFSA (Alexander et al. 2008) | Scientific opinion on contamination of food with PAHs on request of European Commission | **16 PAHs in foods** | Nearly 10,000 results for PAH levels in different food commodities | • Lack of data from oral carcinogenicity studies on individual PAHs invalidate the risk characterization through a toxic equivalency factor (TEF) approach.<br>• BaP is not a suitable indicator for the occurrence of PAHs in food, as genotoxic and carcinogenic PAHs were detected in samples despite negative testing for BaP. Larger groups of PAHs work better as indicators of the presence of PAHs than looking only for BaP or for BaP and chrysene together.<br>• PAH2 represents the total concentration of BaP and chrysene<br>• Similarly, PAH4 represents the total concentration of BaP. Chrysene, benzo[*a*]anthracene and benzo[*b*]fluoranthene<br>• PAH8 grouping consists of BaP. Chrysene, benzo[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*k*]fluoranthene, benzo[*ghi*]perylene, dibenzo[*a,h*]anthracene and indenol[*1,2,3-cd*]pyrene<br>• PAHs are of low concern for consumer health at the average estimated dietary exposures.<br>"PAH4 and PAH8 are the most suitable indicators of PAHs in food, with PAH8 not providing much added value compared to PAH4" |  |

**Table B–10.2.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of PAHs in products.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** | | | | |
| Restriction / Ban | EU (ECHA 2018) | **Extender oils used to manufacture tires; products with rubber and plastic components; toys** | Under Annex XVII to REACH:<br>• Eight BaP, BeP, BaA, CHR, BbFA, BjFA, BkFA, and DBahA have been listed as PAHs, including chrysene and benzo[a]pyrene (BaP), have been listed of concern, with restrictions on manufacturing, marketing and using these substances.<br>• Extender oils shall not be placed on the market or used in tyre production if they contain more than 1 mg/kg of BaP or more than 10 mg/kg of the sum of all listed PAHs.<br>• Articles containing rubber or plastic that come in contact with the human skin or the oral cavity repeatedly over short-term or prolonged periods should not contain more than 1 mg/kg of any listed PAHs. Articles covered include sport equipment (bicycles, golf clubs, racquets), household items (utensils, trolleys, walking frames), tools, clothing (including footwear, gloves and sportswear) and other apparel (watch straps, wristbands, masks, headbands).<br>• Articles containing rubber or plastic that come in contact with human skin or the oral cavity repeatedly over short-term or prolonged periods should not contain more than 0.5 mg/kg of any listed PAHs. | In force |
| | EU (European Commission 2011, 2006) | **Foodstuffs** | • Initial legislation listed limits on BaP content in food items such as oils, smoked products, fish, crustaceans, molluscs, processed cereals, baby food, infant formula and dietary foods, among others.<br>• Amended PAH legislation considers maximum permissible levels of BaP and PAH4 (BaP, chrysene, benz[*a*]anthracene, benzo[*b*]fluoranthene) in all the aforementioned food categories in addition to cocoa derivatives, canned foods and coconut oil. | In force |
| | EU (2009) | **Cosmetics** | • Use of eight PAHs (including BaP, chrysene and DBahA) is prohibited in cosmetics.<br>• Additionally, for distillates, oils, extract residues, paraffin waxes, coal residues, coal liquids and pyrolysis derivatives used in cosmetics, BaP concentration should be below 0.005% by weight of material. | In force |
| | District of Columbia, US (The Council of the District of Columbia 2019) | **Sealants** | It is prohibited to use sealant material such as coal tar applied to impermeable surfaces and has a PAH concentration more than 0.1% by weight of product. | In force |
| | Netherlands (Dutch Ministry of Health, Welfare and Sport 2016) | **Packaging and consumer articles** | • Detailed list of products within the scope of this legislation: plastics, paper and cardboard, rubber products, metals, glass and glass ceramics, ceramic materials and enamels, textile products, foil made of regenerated cellulose, wood and cork, coatings, colourants and pigments, and epoxy polymers.<br>• For condensation products, resins and polymerization products with further application in the above listed product categories, the specific migration limit (SML) limit for PAH (through BaP measurements) is set to 0.01 mg/kg. | In force |
| | Eurasian Economic Union | **Toys, packaging** | The Customs Union TR CU 008/2011 on toy safety and TR CU 005/2011 on the safety of packaging set the permissible level of migration of BaP so that it must not exceed the values corresponding to the lower limit of detection, according to the measurement methods approved in monitoring by the Customs Union. | In force |
| | Germany (Senatsverwaltung für Umwelt, Verkehr und Klimaschutz 2018) | **Recycled tar/pitch components and asphalt used for road construction** | Waste asphalt shall be classified as hazardous (disposed of as special waste) and not recycled for construction if the following apply:<br>• PAH content greater than 100 mg/kg of dry weight<br>• BaP content greater than 50 mg/kg of dry weight | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Soft law instruments** | | | | |
| **Resolutions** | **EU** | **Tattoo inks, permanent make-up** | Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up includes recommendations of maximum levels of PAHs in tattoo inks and permanent inks. | |
| **Voluntary initiatives** | | | | |
| **Voluntary industry phase-out** | **International (Global Quality Department 2014)** | **Apparel, accessories, footwear, cosmetics, toys, chemical and medical items sold by H&M** | Usage ban on PAH compounds; PAHs classified as substances not allowed to be used in H&M production globally. | Active |
| **Voluntary standards** | **International (bluesign® 2019)** | **Articles and accessories made of textile and leather** | • Usage ban on PAH compounds in articles and accessories<br>• Limit value on occurrence set to 0.2 mg/kg for BaP<br>• Limit values set 0.5 – 1.0 mg/kg for benzo[*e*]pyrene, benzo[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*j*]fluoranthene, benzo[*k*]fluoranthene, chrysene and DBahA, as listed in accordance to REACH | Active |
| | **Primarily Germany, but applied internationally (LCIE 2012)** | **Technical equipment** | For awarding the GS certification mark to any product, the following constraints must be considered:<br>• Concentration of individual PAH < 0.2 mg/kg of materials intended to be put in the mouth or materials of toys with intended long-term skin contact<br>• Concentration of individual PAH between 0.2–0.5 mg/kg of materials with repeated short-term or long-term skin contact<br>• Concentration of individual PAH between 0.5–1 mg/kg of materials with short-term skin contact | Active |
| **Consumer education / public awareness** | **International** | **All sources of PAHs** | The German Environment Agency (UBA 2016) developed a background paper (*Polycyclic Aromatic Hydrocarbons. Harmful to the Environment! Toxic! Inevitable?*) describing aspects of PAHs for the general public and other interested readers, including origins, reasons for concern, the path of PAHs into the environment and to the consumer, which products may contain PAHs, what legislation is in place with respect to PAHs, and what individuals can do to protect themselves, get more information or change company policies through consumer behaviour. | |
| | **International** | **PAHs in herbal substances, herbal preparations and herbal medicines** | The EMA (2016) developed a reflection paper to promote discussion about the presence of PAHs in herbal substances, herbal preparations and herbal medicines. The EMA invited all interested parties, including suppliers and manufacturers of herbal substances and preparations, pharmaceutical industry associations, health-care professional groups, consumers and patients' associations, governmental institutions, and EU and EEA-EFTA Member States, to submit any scientific data or documented information (new, published or unpublished) and comments relevant to the evaluation of the problem. | |
| **Guidance and tools** | **International (Basel Convention)** | **Transport of hazardous chemicals across borders at products' end-of-life stages** | PAHs in ships, consumer electronics and other goods may be transported illegally for recycling, and the Convention aims to limit this movement of hazardous waste and promote their environmentally sound management. Included in this convention are technical guidelines for the environmentally sound management of used and waste tyres, unintentionally produced persistent organic pollutants (including PAHs), plastics and other relevant consumer products that might contain PAHs (http://www.basel.int/Implementation/TechnicalMatters/DevelopmentofTechnicalGuidelines/TechnicalGuidelines). | Active |

# 11. Triclosan

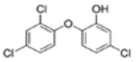
**Table B–11.1.** A brief overview of existing assessments of environmental and human effects of triclosan by national governments and intergovernmental institutions.

| | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| ECCC and Health Canada (2016) | To determine if triclosan “poses a risk to Canadians and their environment” | Material preservative and antimicrobial agent in a wide range of products, except pest control products (as the Canadian registrants discontinued the sale of pest control products containing triclosan, as of 31 December 2014) | Biomonitoring data from national studies;<br>toxicological database examination;<br>peer-reviewed literature | • The principal toxicity in rodents and dogs following ingestion of triclosan is mainly in the liver, with the mouse being the most sensitive species. Triclosan exposure also results in modest decreases in serum thyroid hormone thyroxine (T4) levels. However, the overall database does not support the effects of triclosan on thyroid function as a critical effect for risk characterisation in humans.<br>• Considering the current available information on the adverse effects of triclosan, an overall database no-observed-adverse-effect level (NOAEL) of 25 mg/kg bodyweight per day (bw/day) was identified from a 90-day oral toxicity study in mice.<br>• Triclosan-resistant bacteria could exist in laboratory and clinical settings; such bacterial resistance to triclosan has not been documented outside of clinical use. Based on available information, induction of antimicrobial resistance from current levels of triclosan has not been identified as a concern for human health.<br>• Triclosan is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.<br>• Triclosan is highly toxic to a variety of aquatic organisms, such as algae, macrophytes, invertebrates, amphibians and fish. Adverse effects that have been observed include reduction in growth, reproduction and survival, and there is evidence of effects on the endocrine system at environmentally relevant concentrations. Triclosan can also accumulate in fish, and there is evidence of bioaccumulation in algae and aquatic invertebrates. Triclosan is also highly toxic to certain soil organisms.<br>• A Predicted No-Effect Concentration (PNEC) of 376 ng/L was derived for the water environments and includes consideration of endocrine disruptive effects in fish and amphibians.<br>• Measured concentrations of triclosan in surface waters across Canada indicate that triclosan may cause harmful effects in aquatic ecosystems.<br>• Triclosan does not meet the persistence or bioaccumulation criteria in CEPA. Continuous releases from products and wastewater treatment plants (effluents and biosolids) “result in the ubiquitous presence of this chemical in the environment”. | |
| Canadian Agency for Drugs and Technologies in Health (Brett, K., Argáez 2019) | To inform decision making on single-use medical devices and other items that use triclosan in medical settings | Clinical effectiveness and safety for hospitalized patients | (i) “Synthesize and critically appraise the available evidence on the clinical effectiveness and safety of using triclosan on single use medical devices or consumables for infection prevention in hospitalized patients” using a limited literature search;<br>(ii) review evidence-based guidelines for infection prevention. | “Limited evidence of variable quality” suggested that triclosan-coated sutures “had outcomes that were better or not different than patients treated with uncoated sutures”. These included lower use of antimicrobials after operations, fewer outpatient visits and lower readmission rate, but no differences in quality of life, post-operative mortality, *Clostridium difficile* infections, and other outcomes when compared to untreated sutures. | Limited studies, trials and other reports of evidence are available, sometimes “of variable quality”. For human health in hospitals only. |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| US FDA (2016) | To ensure that drugs are both safe and effective | **Certain consumer antiseptic products containing triclosan** | **Literature review; open for public comments** | • Laboratory studies demonstrate triclosan's ability to alter microbes' susceptibility to antibiotics;<br>• data define triclosan's mechanisms of action and demonstrate that these mechanisms are dose-dependent;<br>• data demonstrate that exposure to triclosan changes efflux pump activity, a common nonspecific bacterial resistance mechanism;<br>• data show that low levels of triclosan may persist in the environment;<br>• insufficient evidence exists for health benefits from use of antibacterial soap over non-antibacterial soap and water in reducing the incidence of disease in consumer settings. | Only applies to household daily use, not medical settings. |
| Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS 2009) | To ensure human and environmental health | **Public health, occupational health and safety, and environmental effects of industrial uses of triclosan** | **Inventory Multi-tiered Assessment and Prioritisation framework:**<br>**(i) literature review**<br>**(ii) Weight of evidence** | • **Public health:** NICNAS found no concern for the public in general; however, a subgroup of the population that uses several triclosan-containing products simultaneously may be at risk, and NICNAS recommended regulatory controls for maximum concentrations in cosmetics and personal care products.<br>• The low levels of triclosan detected in breast milk samples from Australian mothers (<1 ppb in most samples) do not present potential harm to breastfed babies, and NICNAS underscored that breastfeeding is recommended in accordance with Australian Dietary Guidelines. The NICNAS assessment "did not find convincing evidence that triclosan poses a risk to humans by inducing or transmitting antibacterial resistance."<br>• **Occupational health:** Workers who breathe in large quantities of dust generated during occupational use of triclosan powder can have health effects in addition to skin and eye irritation.<br>• **Environment:** "Measured levels of triclosan in Australia are at the lower end of the international observed values for sewage effluent, biosolids and surface water. If these limited screening study values are representative of Australian levels, then the risk does not warrant regulatory action at this stage. However, there is uncertainty that these values are characteristic of the full range of Australian situations. NICNAS recommends sampling studies be conducted to validate environmental assumptions."<br>• The hazard classification of triclosan in SafeWork Australia's HSIS was revised and now includes the following risk phrases: "Toxic by inhalation (R23)"; "Irritating to eyes, respiratory system and skin (R36/37/38)"; "Very toxic to aquatic organisms (R50)"; and "May cause long-term adverse effects in the aquatic environment (R53)". |  |
| US EPA (2019) | To inform the pesticide registration review | **Human health and ecological risks** | **(i) Literature review;**<br>**(ii) public comments** | • **Occupational health:** occupational dermal risks of concern were identified for liquid pouring for the materials preservative use of triclosan, and occupational inhalation and dermal risks of concern were identified for the powder use if used as an open pour without the proper personal protection equipment or engineering controls.<br>• **Residential use:** no EPA-registered products containing triclosan can be applied directly by homeowners, thus there are no risks of concern. Triclosan is also regulated by the US FDA for personal care products, including soaps, sanitizers and toothpaste.<br>• **Residential post-application risks:** the assessment of exposures and risks to all triclosan-treated products does not exceed the level of concern.<br>• **Ecological risks:** triclosan is very highly toxic to aquatic organisms and slightly to moderately toxic to birds. However, triclosan is expected to sorb strongly to sediment and sludge and no significant release of triclosan into the aquatic or terrestrial environments is expected based on the registered uses (triclosan as a materials preservative is registered for use only in the manufacturing of textiles and plastics. After production, only negligible amounts will remain in the finished products. Little, if any, of the remaining triclosan will leach out of these products during use). Therefore, exposures and risks to nontarget organisms are presumed to be minimal. It should be noted that most of the triclosan released into the environment is from non-pesticidal uses (health care products). | Pesticides only. |

|  | Purposes | Scope | Methods | Major Findings | Limitations |
|---|---|---|---|---|---|
| ECHA (2015) | To support the opinion of the Biocidal Products Committee and a decision on the approval of triclosan for product-type 1 (human hygiene) in the EU | **Human health and environmental risks via human hygiene products** | **(i) Dossier from the applicant;**<br>**(ii) literature review;**<br>**(iii) peer-review** | • The harmonised classification for triclosan according to the CLP Regulation is Eye Irrit. 2, Skin Irrit. 2, Aquatic acute 1 and Aquatic chronic 1.<br>• Tests were submitted with a triclosan concentration of 0.1%. Efficacy was demonstrated only for Gram-positive bacteria and not against Gram-negative bacteria, which was considered insufficient for active substances used in disinfectants.<br>• Triclosan is not acutely toxic to animals via oral, dermal or inhalation routes. Pure triclosan is irritating to skin and eyes, whereas the low concentrations used in personal hygiene products do not pose an irritant hazard.<br>• The critical effects of triclosan in rats were determined in a two-year carcinogenicity study. The NOAEL was determined to be 40 mg/kg bw/day based on reduced white blood cell counts in female rats and increased clotting time/decreased monocyte count in male rats.<br>• A growing number of studies show potential problems concerning endocrine disruption.<br>• Potential indirect exposure via breast milk, albeit mostly from non-biocidal sources of triclosan, has been shown to be of acceptable levels.<br>• Based on the consumption-based approach, a risk is identified for both surface water and for the non-compartment-specific effects relevant to the food chain (secondary poisoning). Based on the specific evaluated use, no possibilities for any risk mitigation measures seem to be realistic.<br>• Triclosan does not meet persistence, bioaccumulation and long-range transport criteria. |  |

**Table B–11.2.** Supporting information on the life cycle of and exposure to triclosan, as well as examples of cost-of-inaction and alternative information

| Chemical name(s) | Triclosan (TCS) |
|---|---|
| **IUPAC name(s)** | 5-chloro-2-(2,4-dichlorophenoxy)phenol |
| **Other name(s)** | 2,4,4'-trichloro-2'-hydroxydiphenyl ether; 2-Hydroxy-2',4,4'-trichlorodiphenyl Ether |
| **CAS number** | 3380-34-5 |
| **Chemical formula** | $C_{12}H_7Cl_3O_2$ |
| **Chemical structure** |  |
| **Production information** | |
| **Production overview** | Triclosan is typically produced by treatment of 2,4,4'-trichloro-2'-methoxydiphenyl ether with aluminium chloride in benzene under reflux (Fiege *et al.* 2000). |
| **Key producers** | Data from a global survey by the Danish EPA (2016) indicate that the majority of the production and use of triclosan occurs in Asia (China and India), with lower production volumes in Europe, the US and other countries. |
| **Geographic distribution** | The Danish EPA (2016) study indicates that of the total global production volume of triclosan in 2015, 42% was in China (eight companies), 26% in India (five companies), 18% in Europe (one company) and 14% in other locations. ECHA (2019) lists one supplier of triclosan in Europe (in Germany) that is now listed as "inactive", suggesting no production in Europe, although export from Europe to other parts of the world is still reported (ECHA 2019). Production and use in the US has been reported with a market value of USD$1.4 billion in 2014 (Halden 2014); more recent estimates of the volume of triclosan produced and used in the US are not available. No manufacture of triclosan occurs in Australia (Australian Government 2009). |
| **Production volumes and global trends** | • Data from the Danish EPA study (2016) indicate that the total global production has declined from 6,581 tonnes in 2011 to 4,770 tonnes in 2015 (a 28% decline) with broadly similar declines noted for China (29%), India (25%), Europe (25%) and "other" (32%). In the US, annual production of triclosan rose to as high as 4,500 tonnes in 1998 (Fang *et al.* 2010), but the Danish EPA (2016) data suggest that figure declined substantially during the 2000s. ECHA (2019) data indicate that production in Europe declined during the 2000s and may now have ceased.<br>• Locally and globally, these declines were driven by increased legislative action and scrutiny by regulatory agencies in the US (e.g. the US EPA and FDA), Canada, and the EU (e.g. ECHA), as indicated by data from the past 10-15 years (Halden 2014, UNEP 2019). For example, the US banned triclosan in consumer soap products in 2016 (Weatherly and Gosse 2017), and in the EU, regulation reduced the production and use of TCS, for example by promoting the phase out of triclosan in biocidal products, disinfectants and algicides, film preservatives, fibre, leather, rubber and polymerised materials preservatives (Amec Foster Wheeler 2017).<br>• A steady decline in the number of triclosan-containing products on the market in the last few years has come with companies eliminating or planning to eliminate it in the near future (e.g. Johnson & Johnson, Proctor and Gamble, Avon and Unilever; Weiss *et al.* 2015, Unilever 2019). There do not appear to be new or developing markets for triclosan, so further declines can be expected in the US and European markets.<br>• There is no information available on previous or likely future trends on production or use in other key areas, particularly Asia. |
| **Global trade** | • While it is known that the key products in which triclosan can be found (e.g. toothpastes, antibacterial soap and cosmetics) are traded globally, no data were found on key exporters or importers of triclosan globally, or on the volumes traded. No information was identified to indicate if or how regulatory action on triclosan in specific countries (e.g. the US) has impacted imports or exports of triclosan.<br>• The global exports (by value) of toothpaste, soap and cosmetics are dominated by Europe followed by Asia and North America, as a possible indication (Workman 2019). The reported relative contributions from these global regions is as follows:<br>- toothpastes – Europe (56.5%); Asia (24.3%); North America (15%);<br>- cosmetics – Europe (46.5%); Asia (38.1%); North America (12.6%);<br>- soaps – Europe (44.8%); Asia (34.4%); North America (12.9%). |
| **Use information** | |
| **Key markets** | Data from the global survey of triclosan production and use by the Danish EPA (2016) indicate the main global use of triclosan is in cosmetics and personal care products (68%), with lower amounts in paints (8%), disinfection and medical use (16%) and in plastic materials, toys and appliances (8%). The product category with the highest share of triclosan-containing products is personal hygiene products, particularly deodorants (Lee *et al.* 2019). |
| **Geographic distribution** | Data from the global survey of triclosan production and used by the Danish EPA (2016) suggest the global pattern of use in 2015 mirrored production, with the dominant use in Asia (China, 34%, and India, 19%) with lower amounts in Europe (18%). The proportion attributed to "other" areas was 29% (about 1,400 tonnes). Imports of triclosan into Australia were reported to be about 27 tonnes in 2005 (Australian Government 2009). Sweden consumes 2 tonnes per year (Weatherly and Gosse 2017). |

| **Use information (cont.)** | |
|---|---|
| **Key uses/applications** | Triclosan has been used commercially since the 1970s, most commonly as an antibacterial and antifungal agent (Fang *et al.* 2010). It has been used in a wide variety of consumer products (including soaps, facial wash, dishwashing liquids, laundry detergents, toothpaste, mouthwash, cosmetics, deodorants, shaving cream, feminine hygiene products, skin cream and antiseptic first aid products) and as a material preservative (for example, in toys, mattresses, toilet fixtures, clothing, furniture fabric, kitchen utensils and paints) and in hand washes to prevent the spread of bacteria (e.g. methicillin-resistant *Staphylococcus aureus*, MRSA) in hospitals (Macri 2017, Kasprak 2009, Weatherly and Gosse 2017, USFDA 2008). Typical concentrations of triclosan in these applications range from 0.03% to 0.3% (WHO 2006, Dhillon *et al.* 2014). |
| **End-of-life data** | |
| **End-of-life issues** | The disposal/release of triclosan-containing consumer products (soaps, detergents, cosmetics) is predominantly through rinsing down drains, resulting in delivery to wastewater treatment plants if available. Incomplete removal of triclosan from wastewater effluent and the applications of triclosan-containing sewage sludge to agricultural soils can therefore lead to triclosan being distributed in aquatic and terrestrial environment (Dhillon *et al.* 2015). |
| **Exposure** | |
| **Main exposure sources and pathways** | The primary exposure risk for triclosan is to consumers through direct use in consumer applications and products (Weatherly and Gosse 2017); other exposures can occur in work settings and through the environment:<br>• Consumer exposure – Data from Australian Government (2009) suggest that the two main routes of exposure (total internal dose) for triclosan are through dermal contact with cosmetic or personal care products, and inhalation from use of household cleaning products/sprays. Exposure may occur through ingestion of toothpaste, mouthwash, or dentifrices containing triclosan (USFDA 2008).<br>• As a preservative, triclosan may be incorporated into plastics and resins, rubbers, fabrics, adhesives, inks and more, and so may be in countertops, toys, household goods such as bedding and cutting boards, and other products. Industrial products that contain triclosan include items such as agricultural film and paper mulch, paints, and HVAC exchange coils paper and paperboard coatings. Dermal contact, inhalation of dust, biosolids, domestic wastewater and solid waste are also routes of consumer exposure and occupational exposure for workers who make or handle these products and wastes.<br>- High concentrations of triclosan (1,570 ng/mL) were found in saliva immediately after brushing teeth using a commercial toothpaste with 0.27% triclosan (Silva and Nogueira 2008).<br>- In Asian immigrant women living in Vancouver, Canada, Colgate Total® toothpaste users had higher urinary triclosan concentrations (median = 34.0 µg/L) than non-users (median = 2.5 µg/L, $\rho < 0.001$; Dix-Cooper and Kosatsky 2019).<br>• Occupational Exposure – Workers can be exposed through inhalation and dermal contact where it is produced or used (PubChem 2019; USFDA 2008). Industrial wastewater may also be a source of exposure or pathway to the environment. Healthcare settings use medical products with triclosan as chemical disinfectant for surgical gloves, detergents to clean bedpans and other surfaces, and implantable devices or sutures. These also result in solid wastes, wastewater and other materials that can result in dermal, inhalation and other exposures, not only for workers but for patients (and eventually the environment).<br>• Environmental Exposure – The primary emissions route to the environment for triclosan is through wastewater (EU 2012). For example, after several washes, nearly all triclosan in fabrics was released into washing water in Sweden (Swedish Chemicals Agency 2011). Up to 96% of triclosan is washed into wastewater treatment plants (Reiss 2002). In wastewater treatment plants, the removal rate is reported to be about 90%, so some triclosan is released in effluent (EU 2012). Triclosan has been detected at levels of microgram per litre or per kilogram in sewage treatment plants (influents, effluents and sludges), natural waters (rivers, lakes and estuarine waters) and sediments, as well as in drinking water (Bedoux *et al.* 2012). |
| **Examples of costs of inaction information** | |
| **Costs of inaction** | Prichystalova *et al.* (2017) conducted a risk assessment, based on toxicological data, for the calculation of health costs associated with endocrine-disrupting effects of triclosan in Europe. **If triclosan is confirmed to be a factor in obesity, then** the economic costs associated with increased body-mass-index or BMI due to triclosan exposure could be up to €5.8 billion per year, depending on the model used to estimate such risks. |
| **Examples of alternatives** | |
| **Alternative to triclosan in antibacterial hand soap** | • Benzalkonium chloride (BAC); CAS: 8001-54-5 (Rundle *et al.* 2019)<br>- Halden *et al.* (2017) note that alternative antimicrobial substances may be used in place of triclosan in personal care, consumer, and building products, but these replacement substances may have little to no publicly available safety information.<br>- In the EU - Notified classifications and labelling according to CLP criteria, including: very toxic to aquatic life (H400*); very toxic to aquatic life with chronic effects (H410*); causes severe skin burns and eye damage (H314) (*denotes where the same risk exists for triclosan)<br>- BAC could promote antimicrobial resistance, potentially presenting a similar hazard as triclosan (Kim *et al.* 2018)<br>• Other possible alternative: Chloroxylenol (Rundle *et al.* 2019) |

**Table B–11.3.** Examples of measurements of triclosan in the environment, biota and humans across the globe.

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| **Air** | Indoor dust, in Shanghai, China (Ao *et al.* 2017) | | | | France (Mandin *et al.* , 2016);<br>a house, an apartment, an office and a day nursery, Paris, France (Laborie *et al.* , 2016);<br>Indoor dust, in Oregon,USA (Chen *et al.* , 2018) | |
| **Rain** | Singapore (Tran *et al.* 2019); Huizhou and Dongguan, China (Liu *et al.* 2018b) | | | | | |
| **Snow** | Jinan, China (Zhao *et al.* 2011) | | | | | |
| **Vegetation** | Broussonetia papyrifera from Chongqing, China (Geng *et al.* 2019); Sugarcane leaves, Parthenium, rice straw and wheat straw, Rohtak district of Haryana, India (Singh *et al.* 2019) | | Uptake of Galaxolide, Tonalide, and Triclosan by Carrot, Barley, and Meadow Fescue Plants, Germany (Macherius *et al.* 2012) | Lettuce, México (Cabrera-Peralta and Pena-Alvarez al.2018) | Leafy and root vegetables, Spain (Aparicio *et al.* 2018); Carrots , tomatoes, lettuce and onions, Madrid Spain (Albero *et al.* 2017) ; Carrot, celery, lettuce, spinach, and cabbage, cucumber, bell pepper, and tomato, California, USA (Wu *et al.* 2014); | |
| **Wildlife** | The earthworm (E. fetida) species was selected as a test organ-ism, Tianjin, China (Lin *et al.* 2010); Chicken samples were purchased from supermarkets in Beijing (China) (Yao *et al.* 2019a); | Xenopus laevis larvae and Bufo woodhousii (Palenske *et al.* 2010); fish and seafood from European and North African (Azzouz *et al.* 2019) | fish and seafood from European and North African (Azzouz *et al.* 2019) | | Zebrafish larvae and fish roe samoles, Madrid, Spain (Gonzalo-Lumbreras *et al.* 2012); shellfish, Catalonia, Spain (Alvarez-Munoz *et al.* 2019) ; Xenopus I (Dexter, MI), USA (Fort *et al.* 2010); Adult specimens of Eisenia foetida, Carolina Biological Supply Company, USA (Higgins *et al.* 2011); Premetamorphic Rana catesbeiana tadpoles,Canada (Hinther *et al.* 2011); Male and female adult channel catfish used in this study were purchased from a local aquaculture supplier in Florida, USA (James *et al.* 2012); Dead or moribund bats,United States Fish and Wildlife Service (USFWS), New York, Pennsylvania, Vermont, Massachusetts, and New Hampshire, USA (Secord *et al.* 2015); Birds,Japan (Tanoue *et al.* 2014); The native population of earthworms, Ottawa, Canada (Macherius *et al.* 2014); 100 pet urine samples (from 50 dogs and 50 cats), Albany area of New York State, USA (Karthikraj *et al.* 2019) | |
| **Marine water (incl. sea ice)** | Singapore (Bayen *et al.* 2013) | | | | Baltic Sea (Bollmann *et al.* 2019); Northbound Baltic current, Sweden (Gustaysson *et al.* 2017) San Francisco Bay, USA(Kerrigan *et al.* 2015); | Sea water across Erebus Bay, Antarctic (Emnet *et al.* 2015); Oslo, Tromsø, Longyearbyen, Norway (Kallenborn *et al.* 2018) |

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| Freshwater | Pearl River, China (Zhao *et al.* 2010);<br>Daming Lake, Jinan, China (Zhao *et al.* 2011);<br>Yellow River, Jinan, China (Zhao *et al.* 2011);<br>Yangtze River, China (Liu *et al.* 2015);<br>Jiaosu River, Dian-Bao River, China (Yang *et al.* 2015a);<br>groundwater and reservoirs, Guangzhou, China (Peng *et al.* 2014);<br>drinking water source, Dongjiang River, China (Chen *et al.* 2014, Liu *et al.* 2018a);<br>Danjiangkou Reservoir, China (Bu *et al.* 2014);<br>Wuluo River in southern Taiwan, China (Liu *et al.* 2018);<br>Yangshupugang River, northeast Shanghai City, China (Zhou *et al.* 2018);<br>Beigang, Jishuei, Tsengwen, Yanshuei, Erren, and Agondian rivers, Taiwan, China (Chen *et al.* 2016);<br>Qinhuai River, China, and Ganges River, India (Sharma *et al.* 2019); Lui, Selangor, and Gombak rivers, Federal Territory of Kuala Lumpur, Malaysia (Praveena *et al.* 2018);<br>Lorong Halus wetland, northwest Singapore (Wang *et al.* 2017);<br>Sri Lanka (Guruge *et al.* 2019); Wolpyeong-dong, Daejeon, Korea (Kim *et al.* 2013); Singapore (You *et al.* 2015); Tokushima, Kyoto and Saitama, Japan (Kimura *et al.* 2014) | Lake Balaton, Hungary (Faludi *et al.* 2015); Algeria, Ghana, Kenya, Mozambique, Nigeria, South Africa (Fekadu *et al.* 2019); Liphiring River, the National University of Lesotho (NUL) Roma campus in Maseru, Lesotho (Letseka *et al.* 2018) | Czech Republic, Germany, Hungary, Poland, Romania (Fekadu *et al.* 2019)<br>The Sokołówka River, Lodz, Central Poland (Urbaniak *et al.* 2016) ; Tagus River estuary,Sapal de Coina,Turkey (Couto *et al.* 2018); Çamlıdere and Kesikköprü Reservoirs☒Ankara, Turkey (Yavuz *et al.* 2015); | Tula Valley, Mexico (Duran-Alvarez *et al.* 2015); Colima City, Mexico (Salvatierra-Stamp *et al.* 2015, 2015a); the Monjolinho River, Brazil (Campanha *et al.* 2015); Rio Preto River, Tanque Grande Reservoir, Atibaia River, Capivari River, Sorocaba River, Cotia River, São Paulo, Brazil (Montagner *et al.* 2014); Ground water and surface water, the metropolitan zone of Mexico City, Mexico (Felix-Cariedo *et al.* 2013); the Xochimilco Wetland, Mexico City (Diaz-Torres *et al.* 2013); São Paulo State, Brazil (Montagner *et al.* 2019); Iguassu River,Parana´ State, Brazil (Mizukawa *et al.* 2018); Belém River, Curitiba, Brazil, Colima, Mexico(Salvatierra-Stamp *et al.* 2018); Piraí Creek and the Jundiaí River, Jundiaí River Basin-São Paulo State, Brazil (de Sousa *et al.* 2018); Upper Iguassu Watershed, Metropolitan Region of Curitiba, Brazil (Santos *et al.* 2016) | Kalamas River and Lake Pamvotis, Greece (Nannou *et al.* 2015); Ebro, Llobregat, Júcar and Guadalquivir rivers, Spain (Gorga *et al.* 2015); Alcala de Henares, Spain (Nallanthigal *et al.* 2014); the estuary of the Guadalete River, Spain (Pintado-Herrera *et al.* 2014); River Acheloos, located in Western Greece (Stamatis *et al.* 2013); Llobregat River, Spain (Boleda *et al.* 2013); Guadalquivir river, Spain (Fernandez-Gomez *et al.* 2013); Croatia, Denmark, Finland, France, Greece, Italy, Luxembourg, Netherlands, Portugal, Serbia, Spain, Sweden, UK (Fekadu *et al.* 2019); Sperchios river, Central-Eastern Greece (Noutsopoulos *et al.* 2019); Lambro, Seveso and Olona Rivers in the Lambro River basin,Milan, Italy (Riva *et al.* 2019); Meurthe river, France (Ayoub *et al.* 2018); Po River, Italy (Gredelj *et al.* 2018); Lambro River, Milan, Italy (Palmiotto *et al.* 2018);<br>Fountain Creek and the Arkansas River, Colorado, USA (Gautam *et al.* 2014); Rio Grande, Texas, USA (Wilson *et al.* 2015); Mississippi River and Cuyahoga River; Chicago Area Waterways, USA (Barber *et al.* 2015); San Luis Valley of south-central Colorado, USA (Zenobio *et al.* 2015); The East Fork Little Miami Watershed, Southwestern Ohio, USA (Schenck *et al.* 2015); Minnesota lakes and rivers, USA (Lyndall *et al.* 2017); Narragansett Bay, north of Rhode Island Sound within Rhode Island and parts of Massachusetts, USA (Walsh *et al.* 2017); 24 States and Puerto Rico, USA (Bradley *et al.* 2017); Lake Mead Marina,The Las Vegas Wash,USA (Bai *et al.* 2017); Kaveri, Vellar, and Tamiraparani rivers (Ramaswamy *et al.* 2011); the Grand River,Canada (Arlos *et al.* 2015); Southern Ontario,-Canada (Ferrer *et al.* 2017); Santa Clara River, Los Angeles, CA, USA (Maruya *et al.* 2016); Puget Sound, Washington, USA (Meador *et al.* 2016); Kawartha Lakes, Canada (Larsen *et al.* 2019); Napan River,Mill Creek,St. John River, Grand River, Thames River, Red River, and Wascana Creek,Canada (Lalonde *et al.* 2019);<br>Enoggera Reservoir catchment of Brisbane, Australia (Turner *et al.* 2019); | Norway (Fekadu *et al.* 2019) |

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| Freshwater sediment | Yangtze River, China (Liu *et al.* 2015);<br>Jiaosu River, Dian-Bao River, China, Taiwan Province of China (Yang *et al.* 2015a);<br>Dianbao River in Southern Taiwan, China (Yang *et al.* 2015b);<br>Tamiya and Tsumeta creeks, Japan (Tamura *et al.* 2013);<br>Hooghly River, Bangladesh (Chakraborty *et al.* 2019);<br>tropical mangrove ecosystems in Singapo (Bayen *et al.* 2019); Yangshupugang River, Shanghai, China (Zhou *et al.* 2018); drinking water source, Dongjiang River, China (Liu *et al.* 2018);<br>Pearl and Yangtze rivers, China (Yao *et al.* 2018b); Singapore (Wang *et al.* 2017b) | Lake Greifensee located in northeastern Switzerland (Chiaia-Hernandez *et al.* 2013) | River sediment, Leipzig, Germany (Ferreira *et al.* 2011) ; Tagus River estuary, Sapal de Coina, Turkey (Couto *et al.* 2018); | The Piraí creek, the Jundiaí River, São Paulo State, Brazil (de Sousa *et al.* 2015); Piraí Creek and the Jundiaí River, Jundiaí River Basin-São Paulo State, Brazil (de Sousa *et al.* 2018); "Las Fuentes Brotantes National Park", located in Mexico City (Diaz *et al.* 2017): | Ebro, Llobregat, Júcar and Guadalquivir rivers, Spain (Gorga *et al.* 2015); France (Souchier *et al.* 2015); the estuary of the Guadalete River, Spain (Pintado-Herrera *et al.* 2014); Mississippi River, USA (Buth *et al.* 2010); Boston Harbor, Narragansett Bay, the Lower Hudson River, and Chesapeake Bay, USA (Cantwell *et al.* 2010); The Sha River,China (Zhang *et al.* 2015a); The Rio Grande,Texas, USA (Wilson *et al.* 2015); Fountain Creek and the Arkansas River, Colorado, USA (Gautam *et al.* 2014); Lacustrine Sediment Cores, Minnesota lakes,USA (Anger *et al.* 2013); Minnesota lakes and rivers,USA (Lyndall *et al.* 2017); Santa Clara River, Los Angeles, CA, USA (Maruya *et al.* 2016); Lake Apopka, USA (Dang *et al.* 2016) | |
| Sludge/biosolids | Activated sludge, Thiruvananthapuram, Kerala, India (Krishnakumar, *et al.* 2011); Shanghai, China (Zhou *et al.* 2015a); South Korea (Subedi *et al.* 2014); The Kansai region, Japan (Narumiya *et al.* 2013); Hong Kong, China (Zhou *et al.* 2019); Sewage sludge samples covering 21 provinces and municipalities across China (Chen *et al.* 2019b); Israel and the Palestinian West Bank (Dotan *et al.* 2016) | | | Santiago, Chile (Jachero *et al.* 2015); Rio Grande, Rio Grande do Sul state, Brazil (Cerqueira *et al.* 2014); Rio Grande city, Rio Grande do Sul state, Brazil (Cerqueira *et al.* 2018) | Denmark (Chen *et al.* 2011); Four different Danish WWTPs-Aalborg West, Aalborg East, Aabybro, Hirtshals, Denmark (Chen *et al.* 2015)<br>WWTPs of Athens and Mytilene, Greece (Samaras *et al.* 2013); Spain (Abril *et al.* 2018); Ireland (Healy *et al.* 2017); Crete, Greece(Vakondios *et al.* 2016); Athens, Greece(Thomaidi *et al.* 2016) ; land application of biosolids, Australia (Langdon *et al.* 2012); effluent and pond sediment in Georgia, USA (Kumar *et al.* 2010); Biosolids in the Mid-Atlantic region of the US (Lozano *et al.* 2010); Biosolid in WWTP located in Chicago, USA (Ogunyoku *et al.* 2014); Municipal wastewater from Ayr, Burlington, Calgary, Edmonton, Guelph, Paris, St. George, Toronto (four plants), and Vancouver, Canada (Lee *et al.* 2014); WWTP in the Mid-Atlantic region of the USA (Lozano *et al.* 2013); Windsor, Ontario, Canada (McPhedran *et al.* 2013); Mid-Atlantic region of USA (Armstrong *et al.* 2018); Guelph, Canada (Baalbaki *et al.* 2016); | |

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| **Freshwater biota** | Japanese medaka (*O. latipes*), Japan (Nassef *et al.* 2010);<br>fish, Japan (Tanoue *et al.* 2014); fish, Missouri, USA (Foltz *et al.* 2014);<br>fish from the Kaveri River, India (Shanmugam *et al.* 2014);<br>fish in the Yangtze River, China (Yao *et al.* 2019b);<br>fish in the Pearl River, China (Fan *et al.* 2019);<br>green mussels and lokan clams from Singapo (Bayen *et al.* 2019);<br>algae, a filter-feeding cladoceran, a filter-feeding detritivorous snail, an insect midge larvae at fourth instar stage, and a sediment-dwelling worm, Guangzhou, China (Peng *et al.* 2018);<br>fish bile, Yangtze River, China (Yao *et al.* 2018);<br>common carp, Lake Mead, USA (Jenkins *et al.* 2018); Fish, Pearl River and Yangtze River, China (Yao *et al.* 2018a); Ambazari lake, Gorewada lake, Futala lake, Sakkardara lake, Sonegaon lake and Gandhi sagar lake, India (Archana *et al.* 2017); | | *H. portulacoides* and *S. maritima*, Tagus River estuary,Sapal de Coina, Turkey (Couto *et al.* 2018); | fish, Rio Grande and Florianópolis, Brazil (Escarrone *et al.* 2014) | Specimens of R. philippinarum, southern basin of the Lagoon of Venice, Italy (Matozzo, Devoti *et al.* 2012); D. polymorpha specimens, L. Lugano, Northern Italy (Riva *et al.* 2012); fish and seafood from European and North African (Azzouz *et al.* 2019); Fish of four representative Spanish River Basins- Llobregat, Ebro, Júcar and Guadalquivir (Pico *et al.* 2019); Phytoplankton;Zooplankton;Macroinvertebrates; Fish,Po River,Italy (Gredelj *et al.* 2018); mackerel, tuna, cod, perch, pangasius, sole, seabream, plaice, salmon, mussels, shrimp and brown crab from 11 European countries (Alvarez-Munoz *et al.* 2018) ; newly hatched and mature fathead minnows, USA (Schultz *et al.* 2012); Fish, Mississippi River, Cuyahoga River, Detroit River, Fox River, Indiana Harbor Canal, North Branch of the Chicago River, North Shore Channel, Des Plaines River, Lake Huron, and Lake Michigan, USA (Barber *et al.* 2015); Fish,the San Luis Valley of south-central Colorado, USA (Zenobio *et al.* 2015); St. Joseph River for smallmouth bass from Bristol, Elkhart and South Bend, northern Indiana, USA (Abdel-moneim *et al.* 2017); Fish,Puget Sound, Washington, USA (Meador *et al.* 2016); Fish, Missouri, USA (Foltz *et al.* 2014) | |
| **Soil** | Zhe Jiang province, He Bei province and Jiang Xi province of China (Chen *et al.* 2019); Northern VA,USA (Lozano *et al.* 2018); Lincoln University dairy farm, Christchurch, New Zealand (Zaayman *et al.* 2017) | | garden soil (Norway), sandy soil (Leipzig, Germany) (Ferreira *et al.* 2011) | Cropland, Mexico (Duran-Alvarez *et al.* 2012); Tula Valley, Central Mexico (Duran-Alvarez *et al.* 2015) | Agri-cultural soils at Silsoe Farm in Bedfordshire, United Kingdom (Butler *et al.* 2012); The soil at a former manufactured gas plant site at Hjørring, Denmark (Ozaki *et al.* 2011); (Ozaki, Bester *et al.* 2011) (Ozaki, Bester *et al.* 2011) the Seine catchment in the Bourgogne region, France (Nasri *et al.* 2019); Spain (Abril *et al.* 2018); Mount Com-pass in South Australia ( Langdon *et al.* 2011) ; Grand Rapids area, Michigan, USA (Cha and Cupples 2010); Terry County located in West Texas, USA, Harlan County in South Central Nebraska, USA (Karnjanapiboonwong *et al.* 2010); An agricultural field near Guelph, Ontario, Canada (Prosser *et al.* 2014); Colorado, Nevada, and North Dakota,USA (Roberts *et al.* 2014); An agricultural field in Ottawa, Canada (Macherius *et al.* 2014); | |

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| **Marine biota** | Marine Catfish, Grunter, Mandai Mangrove, Singapore (Zhang *et al.* 2015b); Shellfish, Shenzheng, China (Lu *et al.* 2019); Fish (Paralichthys olivaceus), shrimp (Fenneropenaeus chinensis), shellfish (Chlamys nobilis) and squid (Loligo chinensis), Laizhou Bay ,Weifang, China (Gao *et al.* 2018); Fish, Singapore Strait (Zhang *et al.* 2018b); | | | | Fish and seafood from European and North African (Azzouz *et al.* 2019); Gdansk Basin in the Baltic Sea (Kobusinska *et al.* 2018) ; Atlantic croaker from a live bait facility in Corpus Christi, Texas, USA (Hedrick-Hopper *et al.* 2015); Brown bullhead,Lakes Ontario and Erie, Canada (Gilroy *et al.* 2017); Horse mussels,Greater Victoria,Vancouver Island, Canada(Krogh *et al.* 2017); Barred sandbass, cabezon, kelp bass, rockfish, and white croaker, southern California estuaries, USA (Maruya *et al.* 2016) | |
| **Drinking water** | Bottled and tap water in Guangzhou, China (Li *et al.* 2010); Langat River, Kajang, Malaysia (Nasir *et al.* 2019); Putrajaya, Malaysia (Praveena *et al.* 2019); Patiala, Punjab, India (Kaur *et al.* 2019); Wenzhou, China (Gao *et al.* 2017); | | The Švihov Reservoir, Czech Republic (Vymazal *et al.* 2017); Dobczyce drinking water reservoir, southern Poland (Styszko *et al.* 2016) Kesikköprü Reservoir, Ankara,Turkey (Ogutverici *et al.* 2016) | A reservoir that is used to provide water to a purification plant in Colombia (Martinez *et al.* 2013); San Antonio, Chile (Arismendi *et al.* 2019); São Paulo State, Brazil (Montagner *et al.* 2019); Brazil (Machado *et al.* 2016) | drinking water treatment plant, Spain (Boleda *et al.* 2013); Madrid, Spain (Ana Perez *et al.* 2016) drinking water supplier in the southeast USA (Padhye *et al.* 2014); | |
| **General population** | 50 women and 50 men, Shanghai, China (Engel *et al.* 2014); 249 individuals (ages 20-74) from five different regions in Israel (Berman *et al.* 2014); the Korean adult population, Korea (Kim *et al.* 2014); Women of reproductive age (20–48 years old) from Seoul, Gyeonggi, Incheon, and Jeju of South Korea (Lee *et al.* 2019a); University students in South China (Zhang *et al.* 2018); 'infant' (up to 2 years old), 'toddler' (between 3 and 6 years of age), 'child' (between 7 and 12 years of age), 'adolescent' (between 13 and 18 years of age), and 'adult' (≥19 years of age), Seoul, Korea (Kim *et al.* 2018); several Asian countries, Greece and the USA (Iyer *et al.* 2018); 209 healthy volunteers, aged 19–82 years, who lived in Beijing or Sichuan Province, China (Yin *et al.* 2016) | | Clinical study in six healthy Caucasians（Germany (Queckenberg *et al.* 2010);<br>Female, Leipzig, Germany(Martín *et al.* 2015); German（Moos *et al.* 2014） | | Belgium (Geens *et al.* 2015); Athens, Greece (Asimakopoulos *et al.* 2014); young Danish men, Denmark (Lassen *et al.* 2013); Flemish adolescents (14-15 years) and adults (20-40 years), Flanders (Den Hond *et al.* 2013); Men with a mean age of 20 years (range 18–30 years), Denmark (Frederiksen *et al.* 2020); Adults and children (2–12 years old), island Crete, Greece (Karzi *et al.* 2018); Greece (Iyer *et al.* 2018); Healthy volunteers, lactating women, Jaén, Spain (Azzouz *et al.* 2016) ; Human milk, Australia (Toms *et al.* 2011);<br>Human urine in USA (Clayton *et al.* 2011) ; Peripheral blood from healthy adult (male and female) volunteer donors, USA (Udoji *et al.* 2010); Queensland, Australia (Heffernan *et al.* 2015); lactating women, Westat (Chapel Hill, NC), USA (Hines *et al.* 2015); New York, USA (Wang *et al.* 2015a); Husband–wife couples, Flanders, USA (Koch *et al.* 2014); 46 volunteers living in Quebec City, Canada (Provencher *et al.* 2014); eligible participants, Canada (Juric *et al.* 2019); | Patients, Norway (Seim *et al.* 2012) |

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| **WWTP influents/effluents** | two sewage treatment plants in Kanagawa Prefecture, Japan (Nakada *et al.* 2010); Stonecutters Island WWTP, Cheung Chau Island WWTP, Sha Tin WWTP, Hongkong,China (Tohidi *et al.* 2015); Shanghai, China (Gao *et al.* 2015); Hospital wastewater treatment plant (HWWTP) in southern Taiwan, China (Yang *et al.* 2015a); Hangzhou,China (Zhu *et al.* 2014); Wolpyeong-dong, Daejeon, Korea (Kim *et al.* 2013); Five WWTPs serving varied communities in Riverside County of California, USA (Yu *et al.* 2013); Windsor, Ontario, Canada (McPhedran *et al.* 2013); Bangkok city and Chao Phraya River, Thailand (Juksu *et al.* 2019); Patna, India (Roy, S. *et al.* 2019); Canada (Guerra *et al.* 2019); Chandigarh, India (Jayalatha *et al.* 2019); Singapore (Tran *et al.* 2019); Patiala, Punjab, India (Kaur *et al.* 2019); Hong Kong, China (Zhou *et al.* 2019); Seri Iskandar, Perak, Malaysia (Alshishani *et al.* 2019); Saitama Prefecture, Japan (Sankoda *et al.* 2019); Chennai, Tamil Nadu, India (Mohan *et al.* 2019); Xiamen,China (Ashfaq *et al.* 2018; Wang *et al.* 2018); Saitama, Kyoto, Tokushima, Japan (Tamura *et al.* 2017); Israel and the Palestinian West Bank (Dotan *et al.* 2016); | influent and effluent samples from wastewater treatment plant, Krakow, Poland (Nosek *et al.* 2014);<br>WWTPs in nine cities in Poland (Kotowska *et al.* 2014) Denizli, Turkey (Atar *et al.* 2015); | Influent and effluent samples, Krakow, Poland (Nosek *et al.* 2014); WWTPs in nine cities in Poland (Kotowska *et al.* 2014) | Tula Valley, Central Mexico (Duran-Alvarez *et al.* 2015); Metropolitan Area of the Valley of Mexico (Peña-Álvarez *et al.* 2015); Santiago, Chile (Arismendi *et al.* 2019); São Paulo State, Brazil (Montagner *et al.* 2019); Rio Grande city, Rio Grande do Sul state, Brazil (Cerqueira *et al.* 2018) | Santiago de Compostela, Galicia, Spain (Villaverde-de-Saa *et al.* 2010); Paris, France (Gasperi *et al.* 2014); Eight WWTPs of various cities in Greece (Kosma *et al.* 2014); Agrinio city, Greece (Stamatis *et al.* 2013a); WWTPs of Athens and Mytilene, Greece (Samaras *et al.* 2013); Alzet and other rivers, Luxembourg (Galle *et al.* 2019); Sperchios river, Central-Eastern Greece (Noutsopoulos *et al.* 2019); Lambro River, Milan, Italy (Palmiotto *et al.* 2018); Enerife Island, Canary Islands, Spain (Rocio-Bautista *et al.* 2018); Águas de Lisboa e Vale do Tejo Group located in Quinta do Conde, Sesimbra, Portugal (Ferreira *et al.* 2017); Sicily Italy (Sgroi *et al.* 2017) ; Influents, Georgia (Kumar *et al.* 2010); Surface flow constructed wetland located at the Pecan Creek WWTP in Denton, Texas, USA (Zarate *et al.* 2012) ; Manitoba, Canada (Anderson *et al.* 2015); Canada (Guerra *et al.* 2015); St. Paul, Duluth, Chicago North Side, and Chicago Calumet WWTPs, USA (Barber *et al.* 2015); A Canadian full-scale WWTP equipped with an MBR, Canada (Kim *et al.* 2014b); Municipal wastewater from Ayr, Burlington, Calgary, Edmonton, Guelph, Paris, St. George, Toronto, Canada (Lee *et al.* 2014); Lake Michigan and the sampling locations in Lake Michigan near Milwaukee, Wisconsin, USA (Blair *et al.* 2013); WWTP in the Mid-Atlantic region of the USA (Lozano *et al.* 2013); Streams in Morris County, NJ that receive WWTP effluent: Loantaka Brook and the Whippany River, USA (Middleton *et al.* 2013); Narragansett Bay, north of Rhode Island Sound within Rhode Island and parts of Massachusetts, USA (Walsh *et al.* 2017); Greater Victoria,Vancouver Island,Canada (Krogh *et al.* 2017); Guelph, ON, Canada (Baalbaki *et al.* 2016); Puget Sound, Washington, USA (Meador *et al.* 2016); Ontario, Canada (Kleywegt *et al.* 2016); Molonglo River, Canberra, Australia (Roberts *et al.* 2016) | McMurdo and Scott Base, two Antarctic research stations (Emnet *et al.* 2015); Oslo, Tromsø, Longyearbyen, Norway (Kallenborn *et al.* 2018) |

| Medium | Asia & Pacific | Africa | CEE | LAC | WEOG | Remote regions |
|---|---|---|---|---|---|---|
| Marine sediment | Mandai Mangrove (near-shore site); East Coast (off-shore site), Singapore (Zhang *et al.* 2015b); Hong Kong, China (Zhou *et al.* 2019); Laizhou Bay, Weifang, China (Gao *et al.* 2018); Boli river estuary and Sihchong river estuary, Taiwan, China (Kung *et al.* 2018); Singapore Strait (Zhang *et al.* 2018b); Yantai, China (Gao *et al.* 2017); | | | The Santos and São Vicente estuarine, São Paulo, Southeastern Brazil (Pusceddu *et al.* 2018) | Gdansk Basin in the Baltic Sea (Kobusinska *et al.* 2018); Cadiz Bay, Spain (G.Pintado-Herrera *et al.* 2016) ; San Francisco Bay, USA (Kerrigan *et al.* 2015); California coast, USA (Maruya *et al.* 2015); Greater Victoria, Vancouver Island, Canada (Krogh *et al.* 2017) | |
| Vulnerable population | 49 obese and 27 non-obese children, India (Xue *et al.* 2015); 287 children and students aged from 3 to 24 years old in Guangzhou, China (Li *et al.* 2013); 52 elementary school children of 11–13 years old and 71 college students of 19–21 years old in southern Taiwan, China (Chang *et al.* 2017); healthy pregnant woman aged from 20 to 38 years, India (Shekhar *et al.* 2017); One hundred children (59 boys and 37 girls, aged 3–6 years, averaging 89–132 cm height and 11.5–40.0 kg weight), Guangzhou, China (lv *et al.* 2016) | | | Pregnant women, Northern Puerto Rico (Watkins *et al.* 2015); pregnant women, Puerto Rico (Meeker *et al.* 2013)<br>Pregnant women, Northern Puerto Rico (Aker *et al.* 2019); urban resident Brazilian school children aged 6 to 14 years, Brazil (Rocha *et al.* 2018) | male patients, Belgium (Den Hond *et al.* 2015); the French EDEN mother–child cohort, France (Philippat *et al.* 2014); pregnant women, Denmark (de Renzy-Martin *et al.* 2014); mother–child pairs, Uppsala and Västerbotten, Sweden (Larsson *et al.* 2014); healthy Danish children and adolescents (6-21 years), Denmark (Frederiksen *et al.* 2013a); 6 to 11 years Danish children and their mothers, Denmark (Frederiksen *et al.* 2013b); Patients undergoing non-cancer-related surgery at two public hospitals in Southern Spain (Artacho-Cordon *et al.* 2018) ; Children aged 6-18 years, USA (Savage, Matsui *et al.* 2012); child patient, New Jersey, USA (Ihde *et al.* 2015); Girls, New York City; the greater Cincinnati metropolitan area;the San Francisco Bay Area,USA (Wolff *et al.* 2015); Pregnant women,Ottawa, Canada (Weiss *et al.* 2015); pregnant women, Canada (Arbuckle *et al.* 2015a) (Arbuckle *et al.* 2015b); 1600 pregnant women, Boston, USA (Aung *et al.* 2019); male and female children (ages 6–11 years) and adolescents (ages 12–19 years) in USA (Scinicariello *et al.* 2016); Pregnant women, Brooklyn, New York, USA (Pycke *et al.* 2014); pregnant women, USA (Mortensen *et al.* 2014); 97 pregnant women, USA (Philippat *et al.* 2013); | Pregnant women, Norway (Bertelsen *et al.* 2014); children, Norway (Bertelsen *et al.* 2013; Oslo and Akershus in Norway (Husoy *et al.* 2019); 48 mother-child pairs, Norway (Sakhi *et al.* 2018) |

**Table B–11.4.** A comprehensive but not exhaustive overview of existing instruments and actions on sound management of triclosan.

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | **Scale** | **Scope** | **Content** | **Status** |
| **Legally binding instruments** | | | | |
| **Ban / Restriction** | **US** | **Topical anti-microbial drug products for over-the-counter human use** | • The US FDA (2016) issued a final rule establishing that certain active ingredients used in over-the-counter consumer antiseptic products intended for use with water -- in other words, consumer antiseptic washes -- are not generally recognized as safe and effective and are misbranded.<br>• A restriction on the use of triclosan in over-the-counter health-care antiseptic products went into effect in September 2017, e.g. companies will not be able to use triclosan or 23 other active ingredients in such products without premarket review due to insufficient data regarding their safety and effectiveness. | In force |
| | **EU** | **Banned in pesticides, human biocidal products; also PIC procedure required for export** | • "Triclosan has not been approved for use in biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, with the effect that this substance is banned for use as a pesticide and thus should be added to the lists of chemicals contained in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012." Such listing in Annex I part 2 "implies that explicit consent must be obtained for the export to proceed."<br>• "Triclosan (EC No 222-182-2, CAS No 3380-34-5) is not approved as an active substance for use in biocidal products for product-type 1," which are "human hygiene biocidal products" that include products meant to be applied to human skin or scalp (ECHA 2012, European Commission 2016). | In force |
| | | **Toys** | The standard for finger paints (DS/EN 71-7:2014) states that a maximum concentration of 0.3% triclosan may be used. Following standards for toys is not required; however, if the standards are not followed, a type approval of the toy indicating the toy is safe must be present (EU 2009). | In force |
| | **Japan** | **Liquid soaps** | Manufacturers were given one year to substitute other chemicals for use medicinal or medicated soap products in Japan, following the US FDA rule in September 2016 (MHLW 2016). | In force |
| | **Canada** | **Cosmetics, non-prescription (or over-the-counter) drugs and natural health products** | Canada regulates cosmetics, non-prescription drugs and natural health products (Health Canada 2019). The maximum amount of triclosan allowed is:<br>• 0.03% in mouthwashes<br>• 1.0% in non-prescription drugs<br>• 0.3% in cosmetics and natural health products | In force |
| | **China** | **Cosmetics products** | China regulates cosmetics, including soap, bathing soap, bath liquid, deodorant (non-spray), cosmetic deodorant (non-spray), cosmetic deodorant (non-spray), cosmetic deodorant (non-spray), makeup powder and concealer, nail polish, blemish concealer, and masks (use frequency of nail cleaner shall not be higher than once every 2 weeks).<br>The maximum amount of triclosan allowed is 0.3% in cosmetics products (National Health Commission 2019). | In force |
| | **Eurasian Economic Union** | **Cosmetics products** | Triclosan is allowed to be used as a preservative in the perfume and cosmetic products with the maximum permissible concentration of 0.3% in the ready-to-use product (Eurasian Economic Commission 2011). | In force |
| | **ASEAN** | **Cosmetics products** | • Toothpastes; hand soaps; body soaps/shower gels; deodorants (non-spray); face powders and blemish concealers; nail products for cleaning the fingernails and toenails before the application of artificial nail systems; shampoos; hair conditioners; facial cleansers: maximum authorised concentration in the ready-for-use preparation is 0.3%.<br>• Mouthwashes: Maximum authorised concentration in the ready-for-use preparation is 0.2%.<br>• Singapore only: Pending inclusion in Annex III until completion of a review of triclosan for non-preservative use. | In force |
| | **MERCOSUR countries** | **Manufacture and import of cosmetics** | Technical regulation of MERCOSUR restricts concentrations of triclosan in cosmetics to 0.3%. All MERCOSUR member countries shall adopt it (MERCOSUR 2011). | In force |
| | **Andean Community countries** | **Manufacture and import of cosmetics** | Resolutions of the Andean Community that restrict various ingredients in antibacterial soaps, including triclosan. All member countries shall adopt it. Resolutions 1953 (Communidad Andina 2017) and 2025 (Communidad Andina 2018). | In force |

| Types of instruments | Example(s) | | | |
|---|---|---|---|---|
| | Scale | Scope | Content | Status |
| Pollution prevention plan | Canada | Risk management under CEPA to prevent emissions to the environment | Pollution prevention plans to prevent releases of triclosan to the environment will be necessary to reduce the quantity in the environment to levels below the PNEC of 376 ng/L in water bodies, as aquatic ecosystems are most susceptible (Environment and Climate Change Canada and Health Canada 2016, Government of Canada 2018).<br>The guidance will address manufacturing practices; wastewater treatment plant releases and biosolids; possible replacements for preservative, antiseptic and other functions of triclosan in products; and other concerns while taking into account socioeconomic and technical considerations. | Proposed notice of requirement in 2018 |
| Registration review | US | All intentional uses | Triclosan is currently undergoing registration review, a programme that re-evaluates all pesticides on a 15-year cycle. During registration review, US EPA will:<br>• conduct an updated human health risk assessment and consider all available data on triclosan, including data on endocrine effects, developmental and reproductive toxicity, chronic toxicity and carcinogenicity;<br>• conduct an aggregate assessment to account for exposure to triclosan from dietary and residential exposures;<br>• assess ecological risks and gather data to evaluate the potential direct and indirect effects of triclosan on organisms in the environment. The environmental assessment will consider modelling and monitoring data of releases from pesticidal uses. | |
| **Voluntary initiatives** | | | | |
| Voluntary phase-out | International | Multiple companies | • Proctor and Gamble: phase-out of triclosan in all products as of 2014. (https://anz.pg.com/ingredients/);<br>• Avon: No triclosan in new products, replacing triclosan in existing products (https://www.avonworldwide.com/about-us/our-values/policies-positions/triclosan, visited 12/23/19)<br>• Unilever: Stopped manufacturing skin care and cleansing products with triclosan in 2015; phase-out of triclosan and triclocarban by the end of 2018. https://www.unilever.com/brands/Our-products-and-ingredients/Your-ingredient-questions-answered/Triclosan-and-triclocarban.html<br>• Colgate-Palmolive gained permission from the US FDA to use triclosan in its toothpaste, but recently reformulated its product without triclosan, released in 2019. | |
| Statements | International | The Florence Statement on Triclosan and Triclocarban (2016) | Recommendations:<br>• Avoid the use of triclosan, triclocarban, and other antimicrobial chemicals except where they provide an evidence-based health benefit (e.g., physician-prescribed toothpaste for treating gum disease) and there is adequate evidence demonstrating they are safe.<br>• Where antimicrobials are necessary, use safer alternatives that are not persistent and pose no risk to humans or ecosystems.<br>• Label all products containing triclosan, triclocarban, and other antimicrobials, even in cases where no health claims are made.<br>• Evaluate the safety of antimicrobials and their transformation products throughout the entire product life cycle, including manufacture, long-term use, disposal, and environmental release. | |

# C.

# Annex References

# A.1. CiP

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## B.3. **Cadmium**

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## B.11. **Triclosan**

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