

## SUBMISSION FROM WHO (PART B)

Name of country (for Members of the committee)	N/A
Name of organization (for observers to the committee)	World Health Organization, including the Secretariat of the WHO Framework Convention on Tobacco Control, an entity hosted by WHO
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### **Input on the potential areas of intersessional work to inform the work of INC-3 (following the lists compiled by the co-facilitators of the two contact groups)**

#### **Potential areas for intersessional work**

The list of potential areas for possible intersessional work compiled by the co-facilitators of the two contact groups at INC-2 is set out below. Members and observers may wish to provide input on one or more of these areas.

#### **Contact group 1:**

1. Information on definitions of, e.g. plastics, microplastics, circularity
2. Information on criteria, also considering different applications and sectoral requirements, including:
  - a. Chemical substances of concern in plastics,
  - b. Problematic and avoidable plastic polymers and products and related applications
  - c. Design e.g. for circularity, reuse
  - d. Substitutes and alternatives to plastic polymers and products
3. Potential substances of concern in plastics, problematic and avoidable plastic polymers and products
4. Potential sources of release of microplastics (applications and sectors).

*(Please note: A longer list is included in the co-facilitators report on discussions in contact group 1<sup>1</sup>. Submissions may also include input on any of the items in that longer list, such as, amongst others, the development of criteria to prioritise problematic and avoidable plastics; the development of targets for the reduction, reuse and repair of problematic and avoidable plastic products; or the guidelines on EPR)*

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<sup>1</sup> The report can be accessed here: <https://wedocs.unep.org/bitstream/handle/20.500.11822/42621/CG1.pdf>.

**Contact Group 2:**

1. To consider the potential role, responsibilities and composition of a science and technical body [to support negotiation and/or implementation of the agreement]
2. To consider potential scope of and guidance for National Action Plans [including optional and/or suggested elements]
3. To identify current provisions within existing MEAs [and other instruments] on cooperation and coordination that could be considered
4. To consider how other MEAs provide for monitoring, and suggest best practice
5. To consider options to define 'technology transfer on mutually agreed terms
6. To further consider how a potential financing mechanism could work [including a new standalone mechanism, a hybrid mechanism, or an existing mechanism]
7. To identify options to mobilise and align private and innovative finance (including in relation to matters at 24(e) and the proposed Global Plastic Pollution Fee (GPPF))
8. To map current funding and finance available [to address plastic pollution] and determine the need for financial support for each Member
9. To identify capacity building and training needs for each Member.

Inputs relating to potential areas for intersessional work.

**General comments**

WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

The WHO Constitution provides that the objective of the World Health Organization shall be the attainment by all peoples of the highest possible level of health and provides a broad mandate and functions for the Organization to achieve this objective, including the following functions which are highly relevant to the development and implementation of an international legally binding instrument on plastic pollution:

- to act as the directing and coordinating authority on international health work;
- to establish and maintain effective collaboration with the United Nations, specialized agencies, governmental health administrations, professional groups and such other organizations as may be deemed appropriate;
- to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments;
- to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective;
- to promote and conduct research in the field of health;
- to provide information, counsel and assistance in the field of health; and

- to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products; and generally, to take all necessary action to attain the objective of the Organization.

WHO is a leader on matters critical to health and can mobilize a network of partners where joint action is needed as a Member State Organization WHO works with Ministries of Health across the globe. WHO shapes the health research agenda and stimulates the generation, translation and dissemination of valuable knowledge related to health. WHO sets norms and standards and promotes and monitors their implementation and articulates ethical and evidence-based policy options. WHO provides technical support to its Member States, monitors the health situation and assesses health trends. WHO Chemicals Risk Assessment Network of 92 institutions around the world and its network of government ministries engaged in chemicals safety may be well placed to contribute to treaty negotiations and implementation.

Over the past 25 years WHO has had a role in providing international leadership of a comprehensive health response to climate change, which enhances population resilience to climate risks, and supports health-promoting climate change mitigation policies, through advocacy, developing partnerships, assessing evidence and strengthening the capacity of health and related systems in Member States. At the Seventy-sixth World Health Assembly in May 2023, a resolution (WHA76.17 – Attached as an annex to this Submission)<sup>2</sup> on the impact of chemicals, waste and pollution on human health was adopted with wide support. The Resolution amongst other things:

- recognized that the health sector has a critical role and unique expertise to contribute to the sound management of chemicals and waste and protecting from their harmful impacts on health and well-being;
- recognized the linkages between the health impacts of chemicals, waste and pollution and other priority global health issues including inequity and vulnerability, maternal and child health, antimicrobial resistance and the meaningful achievement of Universal Health Coverage, and that inaction on these linkages limits our collective capacity to strengthen our health systems, including in the context of health emergencies;
- recalled the WHO Global strategy on health, environment and climate change: the transformation needed to improve lives and well-being sustainably through healthy environments, that builds on: scaling up primary prevention; acting on determinants of health in all policies and sectors; strengthening health sector leadership, governance and coordination; building mechanisms for governance, and political and social support; generating the evidence base on risks and solutions; and monitoring progress; and
- welcomed the acknowledgement of the interlinkages between climate change, biodiversity and health.

Specifically in relation to the work of the Intergovernmental Negotiating Committee (INC) to develop an international legally binding instrument on plastic pollution, WHA76.17 among other things:

- welcomed the resolution 5/14 entitled “End plastic pollution – Towards an international legally binding instrument”, adopted by the fifth session of the United Nations Environment Assembly;
- expressed concern that the production, consumption and disposal of plastic products, including microplastics and related chemicals, which can be released to the environment, may potentially impact human, plant and animal health as well as the environment, directly or indirectly;
- invited the governing bodies of relevant multilateral agreements, other international instruments, and intergovernmental bodies to consider the present resolution, as appropriate;

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<sup>2</sup> [https://apps.who.int/gb/ebwha/pdf\\_files/WHA76/A76\\_R17-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R17-en.pdf)

- called upon Member States (and, where applicable, regional economic integration organizations), taking into account national contexts and legislation:
  - to support WHO in scaling up work on plastics and health to enable better information of the potential human health impacts associated with plastic, including plastic pollution, with the aim of strengthening the public health aspects, including under the work of the INC to develop an international legally binding instrument on plastic pollution; and
  - requested the WHO Director-General to actively contribute, in accordance with WHO's mandate, to the work of the Intergovernmental Negotiating Committee, that is in charge of developing a legally binding instrument on plastic pollution; ... and to explore the full range of options for the future involvement of WHO for the consideration by the Seventy-seventh World Health Assembly through the Executive Board at its 154th session, considering its collaboration with the United Nations Environment Programme and other organizations, ...

WHO has participated in the first two negotiating sessions of the plastics treaty and is committed to contributing to the development and implementation of an international legally binding instrument to end plastic pollution. To this end, WHO would be pleased to share information and provide technical input regarding its:

- Relevant WHO norms and standards;
- Relevant decisions and resolutions of WHO governing bodies and reports; and
- Technical documents: Materials, Guidelines, and Reports developed under relevant WHO programmes including:
  - Chemical safety;
  - Water, sanitation, and hygiene;
  - Food safety;
  - Microplastic exposure from the environment, via food, water and air;
  - Management of healthcare waste;
  - Essential medicines, medical devices and products; and
  - Climate change, biodiversity, and environmental sustainability.

WHO also notes the importance of transparency and management of potential conflicts of interest with public health or environmental objectives in the development and implementation of the treaty and has procedures for achieving this which may provide a useful model for the development of the treaty.

WHO offers the following submissions in relation to areas of intersessional work proposed by Members in the contact groups at INC2.

#### **Areas of intersessional work proposed by Contact group 1:**

##### **1. Information on definitions**

WHO has published a set of harmonized risk assessment terminology which might provide a useful reference <https://www.who.int/publications/i/item/9241562676>

- ***Chemicals of concern***

There is not, and nor there should be, a universally accepted definition of chemicals of concern and therefore an explicit process to identify chemicals of concern in the context of plastics will be required. WHO supports having a process which is authoritative (an appropriate, independent, trusted body using suitable methods), is free from conflicts of interest and which considers all the stages in the life cycle of plastic materials where there is potential exposure (from manufacture through use to waste). Many Member States also have their own risk assessment processes for

chemicals which should be considered. WHO is committed to supporting Member States to strengthen their processes, to making information on hazardous chemicals available and to harmonizing tools and processes for risk assessment and risk management, both in its own programmes and works in this context in cooperation and collaboration with other IOMC organizations. The experience of WHO and other IOMC organizations in carrying out chemical assessments which are accepted globally should inform this process.

- **Essential use**

WHO does not offer a definition of ‘essential use’ but notes that in some cases plastics currently have essential uses in health care which will need careful consideration. Whether or not a health care use is essential could be considered by reference to the right to health. Article 12 of the International Covenant on Economic, Social and Cultural Rights (1) recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and (2) provides that the steps to be taken by the States Parties to achieve the full realization of this right shall (relevantly) include those necessary for: (a) The provision for ... for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; and (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness. [https://treaties.un.org/doc/treaties/1976/01/19760103%2009-57%20pm/ch\\_iv\\_03.pdf](https://treaties.un.org/doc/treaties/1976/01/19760103%2009-57%20pm/ch_iv_03.pdf) General Comment 14 of the Committee on Economic, Social and Cultural Rights further provides that the right to health under Article 12 contains the interrelated and essential elements of:

- Availability of functioning public health and health-care facilities, goods and services, and programmes in sufficient quantity;
- Accessibility: Health facilities, goods and services have to be accessible to everyone without discrimination;
- Acceptability: All health facilities, goods and services must be respectful of medical ethics and culturally appropriate; and
- Quality: health facilities, goods and services must also be scientifically and medically appropriate and of good quality.

WHO recommends that these interrelated and essential elements are given full consideration for the respect, fulfilment and protection of the fundamental right of everyone to the enjoyment of the highest attainable standard of physical and mental health. [Human rights \(who.int\)](https://www.who.int/humanrights) In this sense there will need to inevitably be a balance of risk and benefit when applying any definition, or criteria for determination, of essential use as it relates to plastics used in health care. Beyond these principles WHO recognizes there are opportunities for reducing the use of plastics in health care and stands ready to assist in this area.

- **Full life cycle approach and Life cycle assessment**

In any assessment or evaluation of plastic products, polymers or chemicals, in particular to consider whether they may be banned, phased out or reduced, potential health impacts across all stages of the life cycle should be considered. Document UNEP/PP/INC.1/6 adopts the ISO definition of *life cycle* as the ‘consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal.’ Accordingly, life cycle approaches and assessments should cover all stages in the life cycle of a product and should be considered in the contexts they appear in the instrument and Annexes. With the addition of legacy

plastics as the context requires, the definition included in the Background Information of Appendix II of UNEP/PP/INC.2/4 (Options Paper) may be most appropriate:

*5. A life cycle approach to plastic considers the impact of all the activities and outcomes associated with the production and consumption of plastic materials, products and related services – from raw material extraction and processing (refining, processing, cracking, polymerization) to design, manufacturing, packaging, distribution, use (and reuse), maintenance and end of life management, including segregation, collection, sorting, recycling and disposal. Transportation and trade of plastic products also occur at each stage of the life cycle, its direct or indirect impact linked to climate change from production and disposal of plastics.*

- **Health**

WHO strongly supports including the protection of human health and the environment from potential adverse effects of plastic pollution as a core objective of this treaty. We suggest including a definition of health and propose the following definition from the WHO Constitution: ‘*Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*’ <https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1>

- **Microplastics**

Microplastics represent a diverse range of material types, shapes, colours and sizes (Thompson, 2015). To account for these complexities, researchers have proposed definitions for plastic debris (Hartmann et al., 2019) and microplastics (Verschoor, 2015), for example, by describing them according to specific criteria. Most definitions in the literature focus on composition and size. A widely used definition describes microplastics as plastic particles smaller than 5 mm in length. However, this is a rather arbitrary definition and is of limited value in the context of drinking water since particles at the upper end of the size range are unlikely to be found in treated drinking-water. Some groups define a lower bound at about 1 µm. The lower bound is often simply a function of the sampling and analytical technique used in the study. A subset of microplastics smaller than 1 µm in length are often referred to as nano plastics, but again with an inconsistent upper bound.

As for the composition of microplastics, there is again no standard definition. Many studies focus on particles made from synthetic polymers rather than using the International Organization for Standardization (ISO) definition, which excludes elastomeric materials (ISO, 2013). The German Federal Ministry of Education and Research defines plastics as a subgroup of polymers including elastomers and modified natural polymers (Braun et al., 2018). The European Chemicals Agency (ECHA, 2019) uses solid polymer-containing particles but excludes natural polymers that have not been modified.

Microplastics are sometimes categorized as two types, primary and secondary. Primary microplastics are specifically manufactured in the microplastic size range, for example industrial abrasives used in sandblasting and microbeads used in cosmetics. Secondary microplastics are formed by the fragmentation and weathering of larger plastic items (e.g. bags, bottles, clothing, tyres, etc.) either from wear or from their release into the environment. [Microplastics in drinking-water \(who.int\)](#)

- **Plastic pollution**

WHO supports applying a broad definition of ‘plastic pollution’ covering plastic products, micro- and nano-plastics, chemicals and additives, and releases and emissions at each stage of the plastics lifecycle, would provide the most effective protection against health risks and harms which

arise in plastic production, use, recycling, disposal and from plastic pollution in the air, water and soil.

- **Toxicity**

As with 'hazard', toxicity is an inherent property of a material and risk of health impacts occurring will also depend on exposure at different points in the life-cycle.

**2. Information on criteria, also considering different applications and sectoral requirements, including:**

**a. Chemical substances of concern in plastics**

- In Resolution WHA76.17 on the impact of chemicals, waste and pollution on human health, the WHA recognized the work on the promotion of the sound management of chemicals and waste and the prevention of pollution by multilateral agreements and intergovernmental bodies, including the Inter Organization Programme for the Sound Management of Chemicals (IOMC) and the International Conference on Chemicals Management (ICCM), and welcomed the continuation of their work to contribute further to the sound management of chemicals and waste and to prevent pollution.
- WHO has a long history of conducting risk assessments on chemicals of concern such as:
  - Through its series of monographs on Environmental Health Criteria <https://www.inchem.org/pages/ehc.html>
  - Concise International Chemical Assessment Documents <https://www.inchem.org/pages/cicads.html>
  - International Chemical Safety Cards <https://www.who.int/publications/m/item/international-chemical-safety-cards-leaflet> and <https://www.ilo.org/dyn/icsc/showcard.home>
  - As part of the Joint FAO/WHO work on food additives [https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)) and on pesticides residues [https://www.who.int/groups/joint-fao-who-meeting-on-pesticide-residues-\(jmpr\)/about](https://www.who.int/groups/joint-fao-who-meeting-on-pesticide-residues-(jmpr)/about); and
  - through working in collaboration with other UN Agencies.
- WHO also has an active programme on the harmonization of risk assessment methodology which supports risk assessments conducted by national authorities, for example on methods for assessing dermal absorption and to detect immunotoxins (WHO Human Health Risk Assessment Toolkit: Chemical Hazards (2<sup>nd</sup> Ed) <https://www.who.int/publications/i/item/9789240035720> ).
- WHO is committed to strengthening Member State risk assessment processes and making available information and harmonization tools and processes for risk assessment and management, both under WHO programmes and with other IOMC members. Existing WHO, IOMC and national processes provide a valuable base on which to build and harmonize criteria and processes for management of chemicals under the treaty.
- Accordingly, in developing criteria to determine chemicals, or groups of chemicals of concern WHO strongly recommends that:
  - to build on existing evidence, WHO and multilateral work undertaken by other IOMC organizations, relevant normative instruments and materials detailed above (including WHO risk assessments, methodologies and technical products) should be taken into account;

- WHO and relevant IOMC participating organizations should have a role in identifying or nominating independent health experts to be active members of any panel or mechanism developing, applying, reviewing and amending such criteria in a process which is free of conflicts of interest; and
  - potential impacts on human health should be a primary factor to be considered in the development, application and review of criteria with treaty provisions to ensure that health impacts cannot be circumvented or ignored.
- The procedure for amendment of Annexes (if adopted) or other decision-making processes developed for chemicals (and polymers) of concern should be in line with scientific developments and adaptable to change.
    - An example of an approach allowing flexibility in the application of measures to listed substances is found in Article 4 of the Minamata Convention.
    - Another example of a flexible mechanism is found on the Cartagena Protocol on Biosafety, which covers transboundary movement, handling, transport, use, transfer and release of living modified organisms. Decisions of States Party within the scope of the treaty are obliged to follow a process set out in Article 11, which includes a provision allowing for decisions to be made even without full scientific certainty:

*(8). Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.*

Article 12 of the Cartagena Protocol also specifically allows Parties to review such decisions in line with scientific developments:

*(1). A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement....*

## **b. Problematic and avoidable plastic polymers and products and related applications**

### General Comment

- Separate criteria and assessment methodologies to assess plastic polymers vs plastic products may simplify the assessment process and provide greater clarity, given the range and variation in their common uses and exposures at each stage in the plastics life cycle. Such differences may impact whether, in what circumstances, and to what extent a plastic polymer or plastic product may be assessed as ‘problematic’ or ‘avoidable’ in the context of the hazard or risk it presents to human health (or to animal or plant health or biodiversity).
- An assessment of whether a plastic polymer or a plastic product is ‘problematic’ should include:
  - an assessment of potential health risks at different points in its life cycle, taking into consideration the best available scientific evidence on potential health impacts in the development of criteria;



- consideration of common uses and exposures; and
- allow flexibility for scientific developments, including in relation to potential health risks and harms.
- Whether a plastic polymer or product, having met the criteria to be considered ‘problematic’, is ‘avoidable’ should include consideration of its uses, whether the product or use is essential and whether viable alternatives are available, allowing flexibility for developments over time.

#### Application to the health sector

- Considering the requirements of the health sector, plastics are used widely in healthcare from packaging to components of medical devices.
- Obligations under the plastics treaty aimed at reducing production and use of plastics will need to be balanced with ensuring access to more sustainable, safe, effective, quality assured health products.
- Whilst recognizing there are significant opportunities to reduce the use of plastics in the healthcare sector, health products including medicines and medical devices should be afforded special consideration where plastic packaging or components meet criteria to be determined as ‘problematic’ or ‘avoidable plastic products’. Such considerations will require specific specialist input, including from WHO.
- Where banning or phasing out plastics would undermine affordable access to health care or clinical standards, it is essential that additional control measures should be available as alternatives to banning or phasing out. For example, in the absence of alternatives, health products including medicines and medical devices might be allowed additional time for transition, including to allow proper scientific testing of proposed alternatives for efficacy, feasibility and safety.
- As an example, Article 4 of the Minamata Convention provides a model mechanism for phase-out of products listed through annexes which allows flexibility to vary the implementation of measures including exemptions from bans and phase-outs, which can be registered under article 6.

#### Potential WHO contribution to treaty development and implementation

- WHO has extensive experience in the assessment of risks and benefits to human health.
- WHO and other independent scientific experts should be consulted on the development of criteria and assessment /evaluation methodologies for determining and prioritizing what plastic products are considered ‘problematic’ and ‘avoidable’.
- Utilizing its normative and technical functions, WHO can contribute to research and innovation on alternatives to problematic and avoidable plastics.
- WHO provides leadership and sets the health research agenda. It develops norms and standards and provides technical guidance on health products, including medicines and medical devices, by developing target product profiles for research and development, setting norms and standards for production and regulation and defining technical specifications to guide procurement. This experience could be drawn on for development of criteria, methodologies and processes under the plastics treaty.
- WHO uses rigorous processes to make evidence-based recommendations for health products including medicines and medical devices, involving expert committees and advisory groups. Relevant advisory mechanisms that could have a role in developing or supporting implementation of treaty provisions include:
  - Expert Committee on Specifications of Pharmaceutical Preparations  
<https://www.who.int/teams/health-product-policy-and-standards/standards-and->

[specifications/norms-and-standards-for-pharmaceuticals/expert-committee-on-specifications-for-pharmaceutical-preparations](https://www.who.int/groups/expert-committee-on-specifications-for-pharmaceutical-preparations) Expert Committee on Selection and Use of Essential Medicines, <https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines>)

- Strategic and Technical Advisory Group on Medical Devices [https://www.who.int/groups/strategic-and-technical-advisory-group-of-experts-on-medical-devices-\(stag-medev\)](https://www.who.int/groups/strategic-and-technical-advisory-group-of-experts-on-medical-devices-(stag-medev))
- Strategic Advisory Group on in Vitro Diagnostics <https://www.who.int/groups/who-strategic-advisory-group-of-experts-on-in-vitro-diagnostic>

**c. Design e.g. for circularity, reuse**

- Different health products have different requirements for maintenance, collection, sorting, reuse, repair and repurposing, as well as disposal.
- WHO has extensive relevant experience in developing target product profiles for research and development, setting norms and standards for production and regulation, defining technical specifications to guide procurement, and developing guidance on waste management for health products including medicines and medical devices. These could inform circularity and design criteria specific to health products, packaging and best practices regarding reprocessing, reuse and recycling of medical products, ensuring that safety, efficacy, performance and quality standards are met and affordable access to essential medicines and medical products remains a primary priority.
- WHO has existing processes for setting standards for health products including medicines and medical devices as listed above. Setting standards on procurement of medical devices and pharmaceuticals that include the concept of circularity, including waste minimization and criteria for sustainable procurement such as reducing carbon emissions from the supply chain.
- Examples of relevant WHO guidance include:
  - The WHO Compendium on Innovative Technologies compiles and showcases emerging innovative health technologies for low-resource settings. WHO performs rapid evidence-based assessments focused on the life cycle of health technology in low-resource settings <https://www.who.int/publications/i/item/9789240049505>
  - WHO publication (2018) on Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers in Tropical Climates, including performance requirements for reusable PPE to withstand repeated disinfection and recommending that as part of the full product life cycle, waste decontamination and disposal should avoid leaving toxic waste and negatively impacting the environment. <https://www.who.int/publications/i/item/9789241514156>
  - Course available on Open WHO (since 2020) on decontamination of instruments and medical devices <https://openwho.org/courses/IPC-DECON-EN>
- Accordingly, in developing criteria and requirements for circularity of health products including medicines and medical devices:
  - WHO standards and guidance to ensure safety, efficacy, performance and quality should be used in the development of criteria for design for circularity and reuse of health products; and
  - plan to reduce single use medical devices and supplies and plastic waste and reduce greenhouse gas emissions linked to the production, transportation, use and disposal of such plastics.

#### **d. Substitutes and alternatives to plastic polymers and products**

- WHO has an important role to play in defining the research agenda, developing norms and standards and technical specifications for substitutes and alternative to plastics in health products, including medicines and medical devices.
- We refer to submissions in 2(b) and (c) above regarding the need for WHO normative standards and technical specifications to be met, and for adherence to WHO norms and standards to ensure that substitutes and alternatives to plastics proposed for health products, including medicines and medical products, meet established safety, efficacy, performance and quality criteria in addition to other assessments of feasibility.
- The FAO / WHO Codex Alimentarius is a collection of internationally adopted food standards, guidelines and codes of practice intended to contribute to the safety, quality and fairness of international food trade to protect consumer health guide and ensure fair practices.
  - Codex standards and related texts need to be translated into national legislation or regulations to be enforceable but are intended to assist in harmonization of requirements in relation to food and in doing so to facilitate international trade.
  - Codex guidance is provided in relation to food packaging and labelling, to trade in specific food products and food hygiene (e.g. <https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/jp/> ).
  - Codex Standards provide normative guidance which is widely internationally accepted and should be considered in relation to substitutes and alternatives where relevant. Codex guidance could be cross-referenced in the treaty to ensure that these existing norms are recognized and not duplicated.
  - The Codex Commission could potentially also provide a mechanism for developing guidance and standard-setting or inform methodologies under the plastics treaty.

#### **3. Potential substances of concern in plastics, problematic and avoidable plastic polymers and products**

- WHO and the Secretariat of the WHO FCTC aim to highlight the pervasive use of plastics in nicotine and tobacco products:
  - Cigarette butts, which are the most-littered items in the world (estimated 4.5 trillion butts littered each year), do not have any proven health benefits and harm the environment.<sup>3 4</sup> Cigarette butts are made of cellulose acetate, a plastic that is slow to break down and littered cigarette butts leach nicotine, heavy metals, and other toxic chemicals into soil and water supplies.<sup>5</sup>
  - The use of plastics in filters and packaging material of tobacco products is an environmental issue. An estimated 6 trillion cigarettes are manufactured every year, and these are marketed in about 300 billion packages composed of paper, ink, cellophane, foil and glue.<sup>6</sup>

<sup>3</sup> Laila Hamzai, Thomas E. Novotny, Liz Hendrix, and Rebecca Williams, The Cigarette Filter: A Review of Utility, Environmental Impacts, and Policy Solutions, *San Diego State University* ([https://merg.sdsu.edu/wp-content/uploads/2022/05/Appendix-B1-The-Cigarette-Filter -A-Review-of-Utility-Environmental-Impacts-and-Policy-Solutions.pdf](https://merg.sdsu.edu/wp-content/uploads/2022/05/Appendix-B1-The-Cigarette-Filter-A-Review-of-Utility-Environmental-Impacts-and-Policy-Solutions.pdf))

<sup>4</sup> M-A. Song, N.L. Benowitz, M. Berman, et al. [Cigarette filter ventilation and its relationship to increasing rates of lung adenocarcinoma](#), *Journal of the National Cancer Institute*, 2017, 109(12), doi:10.1093/jnci/djx075

<sup>5</sup> <https://www.who.int/publications/i/item/9789240051287>

<sup>6</sup> *ibid*

- Plastic and electronic waste (e-waste) from heated tobacco products and devices, electronic nicotine (and non-nicotine) delivery systems (including single use e-cigarettes).
- The Federal Minister of Climate, Environment, Sustainable Development of Belgium requested an opinion from the Superior Health Council on the scientific basis to ban cigarette filters.<sup>7</sup> The Council concluded that from a public health perspective that cigarette filters have no proven benefits in preventing adverse health effects of smoking. Altogether, both the health and environmental aspects provide sufficient arguments in favour of a general ban on cigarette filters.<sup>8</sup>
- WHO supports the immediate ban of plastics in nicotine and tobacco products and where immediate ban is not feasible, a gradual phase out or stringent control of plastics present in tobacco products, electronic delivery systems, and packaging, recognizing them as problematic and avoidable plastics under the treaty.
- This example also illustrates that there may be other considerations in eliminating plastic use and doing so would help to achieve significant health improvements.

#### 4. Addressing the full lifecycle

- As submitted above, potential health risks and harms arise, and must be addressed under the plastics treaty, at each stage of plastics lifecycle.
- WHO has engaged in research and technical work concerning the linkages between pollution and health risks, which also highlight gaps in current knowledge.
- In 2019 WHO released a report on microplastics in drinking water <https://www.who.int/publications/i/item/9789241516198>. This report critically examines the evidence related to the occurrence of microplastics in the water cycle (including both tap and bottled drinking-water and its sources), the potential health impacts from microplastic exposure and the removal of microplastics during wastewater and drinking-water treatment. Further, recommendations are made with respect to monitoring and management of microplastics and plastics in the environment, and to better assess human health risks and inform appropriate management actions, a number of key knowledge gaps are identified. A series of FAQs are available to provide additional information. [21 Aug 19022 Q&A.pdf \(who.int\)](#)
- WHO has undertaken extensive work on urban health and air pollution, regarding the health impacts of inhalation of plastics and constituents in air pollution, particularly from unsound waste management practices including the open burning of plastic and during the stripping and recycling of e-waste. For example:
  - WHO Air Quality Guidelines: <https://www.who.int/teams/environment-climate-change-and-health/air-quality-and-health/planning-and-evaluation-tools>
  - Tracking urban health policies: a conceptual framework with special focus on air pollution in African cities <https://www.who.int/publications/i/item/9789240060883>
  - <https://www.who.int/tools/integrating-health-in-urban-and-territorial-planning--the-directory>
  - <https://www.who.int/about/accountability/results/who-results-report-2020-mtr/country-story/2021/ghana>
- In support of the need for further research on the potential human health impacts associated with plastic, in Resolution WHA76.17 on the impact of chemicals, waste and pollution on human health, the WHA, among other things:

<sup>7</sup> See

[https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth\\_theme\\_file/20230612\\_shc\\_9726\\_cigarette\\_filters\\_vweb\\_1.pdf](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/20230612_shc_9726_cigarette_filters_vweb_1.pdf)

<sup>8</sup> *Ibid*

- called upon Member States (and, where applicable, regional economic integration organizations), taking into account national contexts and legislation:
- to support WHO in scaling up work on plastics and health to enable better information of the potential human health impacts associated with plastic, including plastic pollution, with the aim of strengthening the public health aspects, including under the work of the Intergovernmental Negotiating Committee (INC) to develop an international legally binding instrument on plastic pollution;
- to further explore, recognize and act on the linkages between chemicals, waste and pollution and other health priorities at the domestic and international levels, such as maternal and child health, antimicrobial resistance, and the importance of identifying, preventing and addressing environmentally related disease in Universal Health Coverage;
- requested the WHO Director-General to publish a report, incorporating science and risk based-assessments and conclusions on the human health implications of chemicals, waste and pollution as well as reporting on existing data gaps, including from a One Health approach, ensuring data disaggregation by sex, age, disability and any other relevant factor, that takes into account persistent and bio accumulative and persistent and mobile substances, as well as substances that are carcinogenic, mutagenic or reprotoxic, neurotoxic, immunotoxin or harmful to cardiovascular, respiratory and other organ systems, or endocrine disruptors. This report will be made available to assist the INC process.

#### **5. Impact of plastic pollution on ecosystems, climate change and biodiversity**

- In Resolution WHA76.17 on the impact of chemicals, waste and pollution on human health, the World Health Assembly:
  - recognized the importance of the One Health approach, including the work of the One Health High-Level Expert Panel, as well as the importance of WHO's role in this integrated, unifying approach in collaborating with the other Quadripartite Organizations (Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Organisation for Animal Health (WOAH, founded as OIE) and their 2022–2026 One Health Joint Plan of Action;
  - welcomed the acknowledgement of the interlinkages between biodiversity and health and the three objectives of the Convention for Biological Diversity in the Kunming-Montreal Global Biodiversity Framework, agreeing that that framework is to be implemented by States Parties, with consideration of the One Health approach, among other holistic approaches that are based on science, mobilize multiple sectors, disciplines and communities to work together and aim to sustainably optimize the health of people, animals and plants and the equilibrium of ecosystems based on scientific evidence and on risk assessments developed by relevant international organizations, and recalling decision 14/4 of the Conference of the Parties of the Convention on Biological Diversity which requested the Executive Secretary and the World Health Organization, as well as other partners, to continue the development of a draft global action plan to mainstream biodiversity and health linkages into national policies, strategies, programmes and accounts;
  - expressed concern that the production, consumption and disposal of plastic products, including microplastics and related chemicals, which can be released to the environment, may potentially impact human, plant and animal health as well as the environment, directly or indirectly

- Called on the WHO Director-General, in consultation with other One Health Quadripartite members, to further develop research on the linkages among human and animal health and the environment, such as in the case of chemicals, waste and pollution.

## 6. One Health framework

- One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent. [https://www.who.int/health-topics/one-health#tab=tab\\_1](https://www.who.int/health-topics/one-health#tab=tab_1)
- In Resolution WHA76.17 on the impact of chemicals, waste and pollution on human health, the World Health Assembly:
  - recognized the importance of the One Health approach, including the work of the One Health High-Level Expert Panel, as well as the importance of WHO's role in this integrated, unifying approach in collaborating with the other Quadripartite Organizations (Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Organisation for Animal Health (WOAH, founded as OIE) and their 2022–2026 One Health Joint Plan of Action; and
  - requested the WHO Director-General, in consultation with other One Health Quadripartite members, to further develop research on the linkages among human and animal health and the environment, such as in the case of chemicals, waste and pollution.

## 7. Linkages with health, environment and biodiversity

- Climate change is one of the greatest health challenges of the 21st century. As climatic conditions change, we are witnessing more frequent and intensifying weather and climate events, such as storms, extreme heat, floods, droughts and wildfires. The Sixth Assessment Report of the Intergovernmental Panel on Climate Change estimates that up to 3.6 billion people around the globe live in contexts that are highly vulnerable to the impacts of climate change.<sup>9</sup>
- For a useful reference please see: World health statistics 2023: monitoring health for the SDGs, sustainable development goals – See section 1.4 on climate change and health.
- In 2014, WHO together with leading researchers conducted a quantitative risk assessment of the effects of climate change on selected causes of death. Under a medium high emissions scenario, it was estimated that by 2030 climate change would cause around 250 000 additional deaths per year ([link](#))
- Health benefits from climate change mitigation save lives, provide cost-savings for health systems and improved productivity from a healthier workforce. These economic gains have been shown to be of the same magnitude as mitigation costs and in some cases even double the costs of mitigation ([link](#)), providing a strong motivation for climate action.
- The [UNFCCC Paris Agreement](#) and the [2030 Agenda for Sustainable Development](#) lay out coherent and complementary goals to reduce global emissions, achieve health for all people and preserve our natural systems. Under the Paris Agreement, countries set out their mitigation commitments and adaptation priorities through their Nationally Determined Contributions (NDCs) and National Adaptation Plans (NAPs). The 2023 WHO Review of Health in the NDC report found that over 90% of countries reflect health priorities in their NDCs but only 30% identify the health co-benefits of mitigation action and even fewer (10%) quantify them

<sup>9</sup> [World health statistics 2023: monitoring health for the SDGs, sustainable development goals \(who.int\)](#)

- The health sector is responsible for approximately 4–5% of global greenhouse gas emissions ([link](#)). WHO guidance for climate-resilient and environmentally sustainable health care facilities, highlights that Health systems can decarbonize through measures such as sustainable procurement practices, more efficient or renewable energy sources, waste reduction, and optimization of the use of resources, which will contribute to a higher quality of care, greater accessibility, more reliable services, reduced occupational hazards from air pollution and waste, and reduced costs ([link](#)).
- The WHO-led Alliance for Transformative Action on Climate Change and Health (ATACH) was formed in 2022 to support countries in implementing their UNFCCC 26th Conference of Parties (COP26) health programme commitments to build climate-resilient and sustainable health systems. Over 60 countries have committed to this initiative with more countries expected to join ([link ATACH.](#))

#### **8. Reduction of hazardous plastic waste**

- Healthcare generates a substantial amount of waste, including plastics, plastic components and chemicals.
- WHO has published specific guidance on management of healthcare waste, which can assist member states in determining appropriate practices, making decisions on waste collection, sorting, recycling and disposal practices, including potential health risks associated with different practices, including:
  - WHO has published a handbook on Safe management of wastes from health-care activities (2014, 2nd ed). The handbook provides comprehensive guidance on safe, efficient, and environmentally sound methods for the handling and disposal of healthcare wastes in normal situations and emergencies. The Handbook pays particular attention to basic processes and technologies that are not only safe, but also affordable, sustainable, and culturally appropriate in low resource settings and includes discussion on future issues such as climate change and the changing patterns of diseases and their impacts on health-care waste management. <https://www.who.int/publications/i/item/9789241548564>
  - WHO publication (2022) on Global analysis of health care waste in the context of COVID-19 which describes current healthcare waste management systems and their deficiencies, and summarizes emerging best practices and solutions to reduce the impact of waste on human and environmental health [Global analysis of health care waste in the context of COVID-19 \(who.int\)](#)
  - WHO publication (2019) on decommissioning medical devices <https://www.who.int/publications/i/item/9789241517041>
- It has been WHO's experience that Member States face challenges in financing waste management for health products, so it should be anticipated that financing support for strengthening waste management will be required.

#### **9. Reduction of production**

- The Sustainable Markets Initiative's mandate, better known as the Terra Carta, has a mission to build a coordinated global effort to enable the private sector to accelerate the achievement of global climate, biodiversity and Sustainable Development Goal targets. <https://www.sustainable-markets.org/> WHO is part of the group with key industry leaders to reduce the carbon footprint of the supply chain, this includes practices such as reduce use of plastics and more reusable products. <https://www.sustainable-markets.org/taskforces/health-systems-taskforce/>

## Areas of intersessional work proposed by Contact Group 2:

### 1. To consider the potential role, responsibilities and composition of a science and technical body [to support negotiation and/or implementation of the agreement]

- In strong support of the importance of support from a science/policy interface or technical body to address the impact of chemicals, waste and pollution on human health, in Resolution WHA76.17 the WHA recognized the importance of science and risk-based assessments to inform the development of policies and strategies concerning public health issues and expressed conviction that the availability of policy-relevant scientific evidence and findable, accessible, interoperable and reusable (FAIR) data on the impacts of and interactions between chemicals, waste and pollution could help countries design effective public health policies.
- WHO supports the need for science/ technical work by a specific body or mechanism established to provide scientific and technical cooperation and coordination to support the treaty development and implementation.
- Subsidiary bodies developed for scientific cooperation should include as members international organizations with a mandate in areas relevant to this instrument. WHO has a broad existing mandate, under its Constitution and subsequent decisions of its governing bodies, to undertake, direct and coordinate scientific and technical work for protection of health, including in the areas intended to be governed by this treaty.
- WHO would appreciate an invitation to participate in any scientific and/or technical mechanism consistent with WHO's mandate and to play an active role, including in coordination, cooperation, decision-making and identification of science and policy experts.
- A clear and sufficient mandate and resources are critical to ensure that the science/technical mechanism has capacity to undertake its intended tasks.
- The principle of transparency and reliance on best available science will be critical to the function of any body, panel or group of experts tasked with providing policy-relevant scientific, technical and socioeconomic information, assessment and advice to support the development or implementation of the treaty. This principle should be a key consideration in the establishment, structure, processes and membership of such a body. To avoid potential bias or misinformation and ensure the quality of scientific and technical analysis and advice, subsidiary bodies should function independently of the governing body, parties and stakeholders and should have robust processes in place requiring disclosure of interests, transparency of data and methodologies and opportunities for independent review of advice, recommendations and analysis.
- The WHO handbook for guideline development, 2<sup>nd</sup> ed ([WHO handbook for guideline development](#)) provides guidance that may be useful to Member States in the development and functions of the science/policy mechanism. For example, it is a WHO requirement that all data used for formulating norms and standards such as guidelines is available in the public domain.
- A good example of a mechanism for convening scientific, technical and economic panels of experts to provide guidance on NAPs, produce reports and assessments of progress, provide recommendations on any revisions that might be needed to increase ambition and make recommendations is found in the [Montreal Protocol on Substances that Deplete the Ozone Layer](#) (Montreal Protocol).



## **2. To consider potential scope of and guidance for National Action Plans [including optional and/or suggested elements]**

- WHO's review of the initial assessment reports submitted by national governments for the Minamata Convention highlighted a need to improve engagement with health ministries in implementing the health-related articles of the Convention.<sup>10</sup> The report also recommended Parties to the Convention to enhance intersectoral collaboration, particularly with the health sector, through their national focal points.<sup>11</sup> A broader, whole of government approach is needed in this context, including health agencies in the process.
- WHO also has experience in the development, evaluation and support of National Action Plans to meet a wide range of public health objectives and to implement global policy guidance, WHO technical packages and treaty obligations, including for example the National Action Plan for Health Security (NAPHS) process under the International Health Regulations <https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/national-action-plan-for-health-security>

## **3. To identify current provisions within existing MEAs [and other instruments] on cooperation and coordination that could be considered**

- Under its mandate and numerous existing arrangements, WHO cooperates and coordinates with other international organizations, Member States and WHO networks of collaborating centres, risk assessment institutions and expert bodies, which is expected to continue and expand in relation to health impacts of plastic pollution.
- WHO supports binding requirements under the treaty for:
  - Member States to exchange information concerning human and animal exposure to plastic pollution and the associated risks and reduction options with other Member States as well as among policymakers, stakeholders and the public.
  - Producers and suppliers of products should be required to report to authorities on any health impacts associated with exposures.
  - Information regarding health impacts related to plastics pollution to be shared with WHO as needed to perform its functions.
- Other treaty processes provide lessons and guidance on how this treaty could address cooperation and coordination.
- The Minamata Convention provides a set of provisions that could be considered a minimum level for establishing cooperation and coordination, including:
  - Article 5(8) encourages Parties to exchange information on relevant new technological developments, economically and technically feasible mercury-free alternatives, and possible measures and techniques to reduce and where feasible to eliminate the use of mercury and mercury compounds in, and emissions and releases of mercury and mercury compounds from, manufacturing processes.
  - Under Article 11(5) Parties are encouraged to cooperate with each other and with relevant intergovernmental organizations and other entities, as appropriate, to develop and maintain

<sup>10</sup> See: [Review of Minamata convention initial assessment reports: key findings for health \(who.int\)](#).

<sup>11</sup> *ibid*

global, regional and national capacity for the management of mercury wastes in an environmentally sound manner.

- Cooperation is also required under Article 14, which provides that Parties shall cooperate to provide, within their respective capabilities, timely and appropriate capacity-building and technical assistance to developing country Parties, in particular Parties that are least developed countries or small island developing States, and Parties with economies in transition, to assist them in implementing their obligations under the Convention.
- Article 15 establishes an Implementation and Compliance Committee as a subsidiary body of the Conference of the Parties (COP) to promote implementation and review compliance with all provisions of the Convention. This Committee consists of 15 members, nominated by Parties and elected by the COP.
- Article 16(2) provides that the COP, in considering health-related issues or activities, should itself consult and collaborate with, and promote cooperation and exchange of information with, the World Health Organization, the International Labour Organization and other relevant intergovernmental organizations, as appropriate. The inclusion of a specific article (article 16) setting out the health aspects of the Minamata Convention has also been useful in the engagement of ministries of health in its implementation.
- Article 17 of the Convention requires Parties to facilitate the exchange of scientific, technical, economic and legal information concerning mercury and mercury compounds, including toxicological, ecotoxicological and safety information; information on the reduction or elimination of the production, use, trade, emissions and releases of mercury and mercury compounds; and information on technically and economically viable alternatives, including information on the health and environmental risks and economic and social costs and benefits. Parties are also required to facilitate exchange of information on health impacts associated with exposure and epidemiological information in close cooperation with WHO and other relevant organizations, which would assist in building global evidence bases, development of guidance and criteria and other activities. The Secretariat is also required to facilitate cooperation in the exchange of information referred to in this Article, as well as with relevant organizations, including the secretariats of multilateral environmental agreements and other international initiatives, including information from Parties, from intergovernmental and nongovernmental organizations with expertise in the area of mercury, and from national and international institutions with such expertise.
- Article 17 also importantly provides that *information on health and safety of humans and the environment shall not be regarded as confidential*, to prevent withholding of health and safety information to protect commercial or other interests. This provision also appears in the Stockholm Convention (Article 9).
- Article 19 requires Parties to endeavour to cooperate to develop and improve, taking into account their respective circumstances and capabilities: inventories of use, consumption, and anthropogenic emissions; monitoring; assessments; harmonized methodologies for monitoring and assessment; and information on environmental cycles, commerce, trade and research.
- Additionally, a provision for consideration in relation to cooperation and information sharing on threats to human health and the environment, the Convention on access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention) requires (Article 5) each Party to ensure that:
  - ‘(c) *In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the*

*public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated immediately and without delay to members of the public who may be affected.'*

- Further guidance on cooperation and coordination is available in tobacco control treaties, in which protection of human health is a primary objective:
  - The WHO Framework Convention on Tobacco Control (WHO FCTC) (an international health treaty with 183 Parties) calls for a multisectoral approach to implementation, which in practice means cooperation with a variety of United Nations and other international organizations. Articles 23 and 25 of the WHO FCTC highlight the importance of such cooperation with competent international and regional intergovernmental organizations, including financial and development institutions. Article 24.3(e) of the Convention mandates the WHO FCTC Secretariat to ensure, under the guidance of the Conference of the Parties (COP), that the necessary coordination takes place.
  - The Protocol to Eliminate Illicit Trade in Tobacco Products (a Protocol to the WHO FCTC) contains obligations in relation to information sharing (Articles 20-22) and international cooperation on issues such as jurisdiction, administration and enforcement (Articles 23-31) <https://fctc.who.int/protocol/overview>.

#### **4. To consider how other MEAs provide for monitoring, and suggest best practice**

- As above, Article 17 of the Minamata Convention provides at least minimum requirements for monitoring and importantly also integrates human biomonitoring data with other emissions and modelled data in its effectiveness evaluation. The treaty Secretariat are very open for collaboration which has facilitated this 'state of the science' modelling and evaluation, which could be further improved by specifying in the treaty language the roles of health ministries and WHO in collection, reporting and analysis of biomonitoring data.
- As an example from outside MEAs, Article 21 of the WHO FCTC requires all Parties to submit regular reports on their implementation of the Convention. These reports from the Parties are analyzed by the Secretariat of the WHO FCTC, WHO and other experts and biennial Global Progress Reports published by WHO on the Parties' achievements and challenges. The WHO FCTC [needs assessment](#) exercise also provides another mechanism through which Parties' implementation of the Convention is evaluated jointly by the Secretariat, its partners and the Party concerned.

#### **5. To identify capacity building and training needs for each Member.**

- In Resolution WHA76.17 on the impact of chemicals, waste and pollution on human health, the World Health Assembly called on the WHO Director-General:
  - to continue to provide technical support to countries, in particular developing countries, upon request, to build capacity to conduct science-based assessments and research, including on the association of pollution from plastics, including microplastics, as well as cadmium, arsenic, lead, agrochemical pesticides, among others, with known health effects, in order to inform the development of public health policies and support the strengthening of health systems in this area; and
  - to support countries upon request, especially developing countries, to develop national, or regional, human biomonitoring programmes for chemicals of concern, through capacity-building and technology transfer on voluntary and mutually agreed terms and in line with

international obligations, aiming at helping to identify potential risks in the territories regarding population groups; to collect data to support the development of public policies; as well as to support the improvement of national health systems;

- WHO has experience, in addition to the areas identified in the Resolution, to building capacity of Member States in areas such as:
  - implementation of measures under core obligations discussed above relating to protection of health;
  - scientific research on potential health risks;
  - data management and analysis of health-related data;
  - technical specifications and standards for medical products and devices; and
  - management of healthcare waste.

**In closing**, WHO submits that there are clear mutual benefits to overall reduction in plastic pollution at all stages of the plastics life cycle, reduction of waste and addressing pressing climate issues. In respect of the protection of health under the plastics treaty that:

- There is a need for specific consideration of health risks (health impacts and potential harms) and benefits (particularly affordable access to health products including medicines and medical devices) and for collaboration and exchange of information with WHO (and other health experts) in each obligation.
- This could most clearly be incorporated by including the health considerations, support for research and requirement for collaboration within each core obligation. An example of this approach is in the [Cartagena Protocol](#), where the provision that Parties must ‘take also into account risks to human health’ is included in specific legally binding obligations under the Protocol.
- Alternatively, or in addition, measures for protection of human health could also be implemented through a specific clause (or clauses). In this case, the general health clause(s) could state that:
- the obligation to protect human health must be a primary consideration in all decisions and actions under the treaty;
- potential health risks and benefits must be a key factor for consideration in all decision-making processes by the treaty governing body and by states parties under this treaty where there is any potential for adverse impacts on human health, or where a decision may benefit human health;
- that facilitation of research includes research on potential health impacts; and
- treaty obligations must take account of relevant WHO norms and standards and relevant decisions and resolutions of WHO governing bodies to ensure that treaty functions are coherent with and not duplicative of WHO work.