

Topic Sheet

Criteria for Chemicals



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Criteria for prioritisation of control measures on chemicals in plastics

Over 13,000 chemicals are associated to plastics (UNEP 2023), of which many are of concern. They cover additives, monomers, processing aids and non-intentionally added substances. Different approaches may be followed to identify those chemicals and prioritise them as they could be subject to control measures. This topic sheet, which draws from UNEP’s ‘[Chemicals in Plastics: A Technical Report](#)’ (UNEP 2023), provides an overview of potential criteria which may be useful to consider and highlight a selection of prioritisation methods.

What could criteria on chemicals in plastics look like?

Existing chemicals governance frameworks

- Chemicals of global concern regulated under international instruments such as persistent organic pollutants (POPs) and mercury;
- Chemicals of global concern identified under international voluntary frameworks, for instance emerging policy issues and other issues of concern in the context of the Strategic Approach to International Chemicals Management (SAICM), including perfluorinated chemicals (PFCs);
- Chemicals of concern identified in existing national or regional regulation systems.

Credible sources to support further prioritization

- Chemicals of potential concern, including issues with emerging evidence of risks identified by the 2019 Global Chemicals Outlook II (GCO-II) (UNEP 2019);
- Scholarly research papers (Aurisano *et al.* 2021; Wiesinger *et al.* 2021).

Possible criteria for elimination or reduction can focus on:

Chemicals components

Criteria may apply to chemicals or groups of chemicals, and may be based on:

- Hazard: based on intrinsically unacceptable hazardous properties of chemicals, including persistent, bioaccumulative and toxic substances (PBTs); very persistent and very bioaccumulative substances (vPvB); chemicals that are carcinogens or mutagens or that adversely affect, inter alia, the reproductive, endocrine, immune or nervous systems;
- Exposure: Chemicals produced or used in high volumes; or subject to wide dispersive uses; or chemicals in products with high consumer contact/exposure (unless confirmed to present no hazard).

Polymer components¹

Criteria may apply to chemicals or groups of polymers, and may be based on:

- Hazard: based on intrinsically unacceptable hazardous properties of polymers (see examples of hazard types above);

¹ OECD has developed criteria to identify polymers of concern that are used selectively by many jurisdictions to identify polymers of low concern (PLCs). These criteria focus on chemical identities (e.g. molecular weight and reactive functional groups), physico-chemical properties (e.g. water absorption) and/or indication of hazard. Typical exposure-based criteria (e.g. production volume and intended uses) are not used, although they are recommended by OECD (Groh *et al.* 2023). Scholars have also proposed using the DPSIR framework for characterizing the risk of polymers (Senathirajah *et al.* 2023).

- Exposure: based on physio-chemical properties (e.g. stability/degradability, unreacted monomers and oligomer content).

Material and product components

Specific criteria may be adopted for material and product components based on:

- Chemical composition (and circularity) to prioritize the reduction or elimination of problematic, unnecessary and avoidable plastics. Consideration of material and product that the chemicals are used in, including whether the product/material is (part of) unnecessary plastics items, whether the chemicals is considered essential or may be substituted with a safe and sustainable alternative;
- Socio-economic aspects, such as efficacy and efficiency of possible control measures, alternative products and approaches, and possible societal impacts of control measures, particularly with respect to protection of human health and the environment; waste and disposal implications.

Approaches such as avoiding regrettable substitution, and addressing issues from a holistic approach, as well as the precautionary approach, may be used to prioritise action on groups of chemicals. In that respect, the recent report 'Chemicals in plastics: a technical report' (UNEP 2023), based on the latest studies, identifies more than 13,000 chemical substances as being associated with plastics. These are either known to be used in plastic production or have been detected in plastic materials (Aurisano *et al.* 2021; Wiesinger *et al.* 2021), with 10 groups of chemicals associated with plastics identified as being of major concern due to their known toxicity and potential to migrate from plastics. These include specific flame retardants, ultraviolet light stabilizers, per- and polyfluoroalkyl substances (PFASs), phthalates, bisphenols, alkylphenols and alkylphenol ethoxylates, biocides, toxic metals and metalloids, polycyclic aromatic hydrocarbons (PAHs) and other non-intentionally added substances, amongst which unintentional POPs such as dioxins and furans.

Criteria may also be used for establishing negative or positive lists of chemicals, as highlighted in the study on 'Global governance of plastics and associated chemicals' commissioned by the Secretariat of the Basel, Rotterdam and Stockholm conventions (BRS 2023).

Approach 1: Global negative list based on selection criteria

- This approach would resemble the model provided by the Stockholm Convention. An assessment of the chemicals that fulfil the criteria will have to be undertaken, which could be duplicative efforts if mechanisms already exist. While data on hazard traits is becoming increasingly available, data gaps remain

especially data on exposures. Although prioritisation of chemicals of concern under a binding instrument would assumably not apply to uses in materials other than plastics, their restriction would provide a strong signal for producers, manufacturers and retailers to also phase out their use in other materials.

Approach 2: Global negative list based on existing regulatory lists of chemicals of concern

- This approach would have the advantage that it would make use of assessments and decisions already taken by authorities. However, there are no guarantees that the ad hoc nature of submissions can comprehensively address groups of chemicals of concern. A mapping of chemicals of potential concern used in plastics that are restricted in at least two regions organized under a groups of chemicals approach, could help to facilitate listing in an organised manner.

Approach 3: Global positive list based on chemicals deemed safe

- This approach is to adopt a positive list of chemicals that can be used safely in the production of plastic materials and articles. At the global level, an example can be found in the London Protocol, which includes a whitelist in Annex 1 that lists those wastes or other matter that may be considered for dumping. However, considering the large number of chemicals used in plastics, the workload could be enormous. There is a risk that a positive list leads to regrettable substitution as it is commonly not based on groups of chemicals. Furthermore, the full scope of adverse human health impacts associated with plastic chemicals are unknown. A process for re-evaluating and updating the list would be required, including removing chemicals from the positive list.

Approach 4: Hybrid of any approaches 1-3

- The lack of information identifying chemicals used to produce plastics and found in plastics as well as their hazardous properties is often cited as a barrier to addressing chemicals of concern. Ensuring transparency and raising awareness of chemicals used in plastics, as well as of specific chemicals or chemical families that may be of concern, is thus crucial. The report 'Chemicals in plastics: a technical report' (UNEP 2023) aims at closing some of these gaps, providing amongst others an overview of chemicals used and found in plastics, identifying groups of chemicals of concern as well as priority sectors.

Existing approaches using prioritisation criteria for chemicals of concern

Hazardous chemicals in the European Union (EU)

The European Union sets out criteria for hazardous chemicals, in its Chemicals Strategy for Sustainability Towards a Toxic-Free Environment², launched in 2020, which highlights the objective to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system (CMR) or are persistent and bioaccumulative.

It builds upon article 57 of the REACH regulation, where a substance may be proposed as a substance of very high concern (SVHC) if it meets one or more of the following criteria: carcinogenic; mutagenic; toxic for reproduction; persistent, bioaccumulative and toxic (PBT substances); very persistent and very bioaccumulative (vPvB); with “scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern”.

In order to prioritise, the following categories are considered:

- PBT substances and vPvB substances
- substances which are widely dispersed during use
- substances which are used in large quantities

The chemicals strategy further outlines ongoing plans to introduce a new hazard class in the classification, labelling and packaging (CLP) regulation (on the classification, labelling and packaging of substances and mixtures), so that ‘endocrine disruptors’, ‘persistent, mobile and toxic’ and ‘very persistent and very mobile’ are categories of substances of very high concern.

Finally, it defines criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health.

Prioritizing existing chemicals for risk evaluation – approach by the US Environmental Protection Agency³

The US Environmental Protection Agency designated 20 chemical substances as a high priority for risk evaluation, based, amongst other, on the following characteristics:

- Persistence and bioaccumulation scores
- Known human carcinogens
- High acute or chronic toxicity

Then available information was gathered with respect to:

- The hazard and exposure potential of the chemical substance
- Persistence and bioaccumulation
- Potentially exposed or susceptible subpopulations
- Storage near significant sources of drinking water
- The conditions of use or significant changes in the conditions of use of the chemical substance
- The volume or significant changes in the volume of the chemical substance manufactured or processed

Under this risk-based approach, both hazard and exposure criteria are used in determining whether a chemical gets considered for priority.

International approaches using criteria to consider chemicals

Chapter 5 of the UNEP Assessment Report on Issues of Concern: Chemicals and Waste Issues Posing Risks to Human Health and the Environment (UNEP 2020) offers a thought starter on the identification of issues of concern, and a review of existing mechanisms. Approaches range

from broader management issues and identifying actions initiated by public bodies to regulate a chemical (or group of chemicals), to conduct a full risk assessment or reassessment based on emerging evidence indicating a risk. A short summary is provided below.

² <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>.

³ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation#approach>.

SAICM and the sound management of chemicals and waste beyond 2020

Under the current Strategic Approach to International Chemicals Management (SAICM) framework, the following criteria were defined to prioritise emerging policy issues:

- Magnitude of the problem and its impact on human health or the environment, taking into account vulnerable subpopulations and any toxicological and exposure data gaps;
- Extent to which the issue is being addressed by other bodies, particularly at the international level, and how it is related to, complements or does not duplicate such work;
- Existing knowledge and perceived gaps in understanding about the issue;
- Extent to which the issue is of a cross-cutting nature;
- Information on the anticipated deliverables from action on the issue.

There are ongoing discussions on the identification of 'issues of concern' under SAICM and the sound management of chemicals and waste beyond 2020, for consideration and adoption by the fifth International Conference on Chemicals management, scheduled to be held in Bonn in September 2023. Acknowledging that issues of concern may cover a larger scope than chemicals in plastics, the final adopted text may be considered in its relevance and application to chemicals in plastics.

Multilateral Environmental Agreements (MEAs) on chemicals and waste

The Basel, Rotterdam, Stockholm and Minamata conventions and the Montreal Protocol amongst others all contain provisions to consider additional chemicals, products or wastes within their scope, so these lists can evolve over time. Expert subsidiary bodies may analyse and make recommendations for inclusion in the annexes, for consideration by the governing body of the Convention, Conference of the Parties (COP).

For the Stockholm Convention on POPs, which controls production, use, import/export, unintentional releases and stockpiles and waste of chemicals classified as 'persistent organic pollutants', a Party submits a proposal for listing a chemical under the Convention based on the screening criteria set out in Annex D to the Convention. These criteria relate, among other things, to persistence, bioaccumulation, potential for long-range environmental transport, and adverse effects on human health and the environment.

Information is evaluated by the scientific subsidiary body, the POPs Review Committee (POPRC)⁴. If POPRC is satisfied that the screening criteria have been met, it undertakes a further review and prepares a risk profile considering the information specified in Annex E submitted by Parties and observers. If POPRC decides that "the chemical is likely as a result of its long-range environmental transport to lead to significant adverse human health and/or environmental effects such that global action is warranted, the proposal shall proceed" (Article 8 of the Stockholm Convention).

POPRC then prepares a risk management evaluation based on the information provided by Parties and observers on socio-economic considerations – for example, concerning the efficacy and efficiency of possible control measures, alternative products and processes, and positive and/or negative impacts on society of implementing such control measures (as specified in Annex F to the Convention). The COP, taking due account of the recommendations of the POPRC, including any scientific uncertainty, decides, in a precautionary manner, whether to list the chemical, and specify its related control measures, in Annexes A, B and/or C to the Convention.

For the Rotterdam Convention, which makes certain hazardous chemicals and pesticides in international trade subject to the prior informed consent procedure, the Chemical Review Committee⁵, an expert subsidiary body, considers the case for listing a chemical in Annex III, when Parties from at least two different prior informed consent regions have notified that they have taken final regulatory action on the basis of a risk evaluation, or in response to a proposal by a developing or transition country experiencing problems caused by a severely hazardous pesticide formulation.

The Montreal Protocol controls human-made chemicals that deplete the ozone layer, and hydrofluorocarbons (HFCs) that are not ozone-depleting but are powerful greenhouse gases used as substitutes for ozone-depleting substances in many applications. Under the Protocol, new controlled substances may be included under its purview through the adoption of amendments by the Meeting of the Parties to the Protocol, which require Parties' ratification. A recent example is the inclusion of measures to control the production and consumption of HFCs through the Kigali Amendment to the Protocol, adopted in October 2016 and entered into force on 1 January 2019. Changes to control measures such as acceleration of the production and consumption phaseout schedules are made through adjustments to the Protocol, which do not require ratification and have immediate effect upon adoption (UNEP 2020).

⁴ <http://chm.pops.int/tabid/2806>.

⁵ <http://www.pic.int/tabid/1059>.

Other key linkages

There are established processes, such as the POPRC's review under the Stockholm convention that have been addressing POPs in plastics such as brominated flame retardants and certain PFAS. There are other chemicals in plastics that are posing risks to human health or the environment, and they could deserve dedicated attention in the plastics legally binding instrument.

The Minderoo-Monaco Commission highlights the need to regulate polymers of concern, suggesting they could be listed under the Stockholm Convention because they meet some of the criteria for listing POPs.

These include persistence (P), adverse effects (T) and long-range environmental transport potential (LRTP) (Landrigan *et al.* 2023).

The Beyond 2020 on chemicals and waste and the Science Policy Panel to contribute further to the sound management of chemicals and waste and to prevent pollution under negotiations should be considered as potential support or models for prioritising issues.

Finally, consideration of mechanisms to identify unnecessary and problematic plastics will also support a more limited and manageable number of chemicals of concern in plastics and their potential control measures, including elimination.

Additional resources

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