1.1 Guidance
Understanding chemicals of concern

This document is part of the *International Chemicals Management Toolkit for the Toy Supply Chain* developed by the United Nations Environment Programme (UNEP) in collaboration with the Baltic Environmental Forum (BEF) within the framework of the Global Environment Facility (GEF) project ID: 9771 on Global Best Practices on Emerging Chemical Policy Issues of Concern under the Strategic Approach to International Chemicals Management (SAICM).

This guidance helps you understand which chemicals are considered as **chemicals of concern** (CoC) and **how to recognise** if your chemical is a CoC. In this toolkit

Chemicals of Concern (CoCs) are: Chemical compounds or substances, which have hazardous properties and cause concern to human health or the environment. Among CoCs, three categories can be distinguished:

1) Chemicals for which risk reduction action has been agreed on at an international level (e.g., a chemical being listed under the Stockholm Convention on Persistent Organic Pollutants)

2) Chemicals for which scientific evidence exists to advance risk reduction action. These include chemicals that have been regulated at national or at regional level (e.g. chemicals that have been restricted for certain uses in China or the EU).

3) Chemicals for which evidence for risk to human health or the environment is currently emerging from scientific research, but which are not yet regulated.

CoC of categories 1 and 2 are subject to mandatory regulations (e.g. bans or limit values). Addressing the third category of CoCs can be part of a high-ambition and proactive approach to chemicals management and can go beyond regulatory compliance.

How can chemicals harm people?

Chemicals that have the potential to harm human health are for example:

a) **acutely toxic** (cause poisoning)
b) **carcinogenic** (cause cancer/tumours)
c) **mutagenic** (cause changes in genes, which are inherited to the children and may cause diseases)
d) **toxic to reproduction** (disturbs the normal development of children or reduces the fertility of humans)
e) **neurotoxic** (damage the nervous system)
f) **cause harm to inner organs**, such as the kidneys or the liver
g) **sensitisers** (cause or accelerate allergies if inhaled or via skin contact)
h) **corrosive** (cause irreversible damage to the skin)
i) **seriously damaging eyes** (cause tissue damage in the eye, or serious physical decay of vision, which is not fully reversible)

j) **endocrine disrupting** (acting similar to a hormone, which may disturb several body systems, including the immune system, reproduction or the metabolism)

CoC may be harmful to human health if:	**Some examples of adverse impacts on human health**:
a) inhaled, b) swallowed c) absorbed through the skin	a) cancer b) chronic respiratory diseases c) reduced intelligence in offspring d) allergies

How can chemicals harm the environment?

Chemicals that have the potential to harm the environment can have one or several of the following properties:

1) **persistent, bioaccumulative and toxic** or **very persistent and very bioaccumulative** (PBT/vPvB): such substances are not degraded in the environment and therefore, their concentrations build up in soil, water or organisms over time
2) **hazardous to the aquatic environment:** such substances have acute or chronic toxicity for aquatic organisms or have a certain potential for bioaccumulation
3) **endocrine disrupting chemicals**: acting similar to a hormone, which may disturb several body systems of wildlife, including the immune system, reproduction or the metabolism.

Some examples of common CoCs, which may be found in toys:

a) Certain Phthalates, which are used as softeners in plastic materials
b) Bisphenol A, which may be included in any epoxy resins used for / in toys
c) Cadmium, which may be part of pigments used to colour plastic toys
d) Certain Perfluoroalkyl chemicals (PFOS, PFOA, PFHxS)

Assessing impacts of CoC: exposure and risk

The concept of chemical risks

Chemicals of concern have the potential to cause harm to human health or the environment because they have hazardous properties (c.f. above). However, adverse impacts on health or the environment will only occur if humans or the environment are exposed to a relevant amount of the chemical of concern. The 'relevant amount' above which a substance causes harm is called 'threshold of concern'. The 'threshold of concern' is determined based on test results from toxicity studies and different methods are applied across the globe.

There is a risk that a CoC in a toy causes harm to (a child's) health if the child is exposed to a dose that exceeds the threshold of concern.

$$\text{Risk of damage} = \frac{\text{Dose (exposure)}}{\text{Threshold of concern (hazard)}} > 1$$

In this equation the term "risk of damage" indicates that there is not 100% certainty of the damage to occur. This is due to several reasons, including the use of 'safety factors' in the derivation of the threshold of concern (methodological) and differences in how organisms react to chemical exposure (biology).

For example, the plasticiser DEHP (CAS 117-81-7) is used to soften PVC, i.e. make it flexible. According to European legislation, its hazardous properties include reproductive toxicity and endocrine disruption (European Chemicals Agency [ECHA]). The threshold of concern is determined as 36µg per kg body weight and per day. Hence, if a child of 10 kg ingests more than 0,36 mg of the phthalate per day, its reproductive system could be damaged.

It should be noted that there are many sources of exposure (not only one toy) and several exposure pathways (not only ingestion).

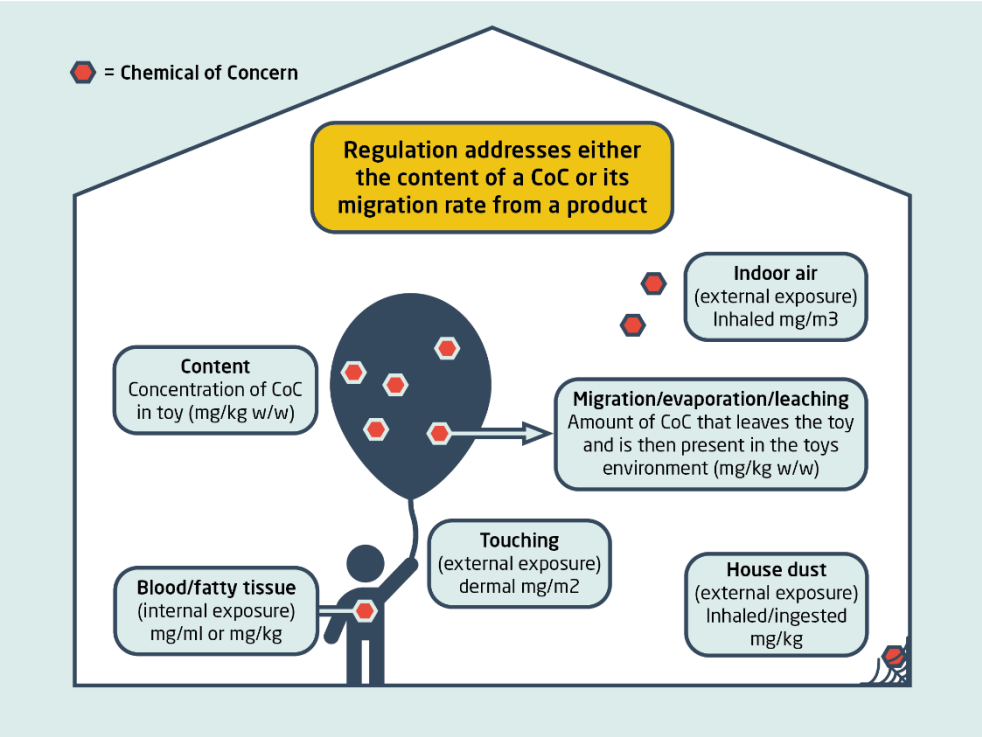
Exposure

Humans may be exposed to chemicals in three ways: they may inhale chemicals, they may be in contact via the skin, e.g. when touching a surface coated with a lacquer or when using chemicals directly (e.g. toy cosmetics or slimy toys), or they may be exposed to a chemical by ingestion. The latter is particularly relevant for (young) children because

a) they explore their surroundings by putting everything (including toys) into their mouth and sucking on it
b) they are close to the floor most of the day and therefore take up house dusts (inhalation and ingestion), which accumulate chemicals inside the house

The exposure level, i.e. the dose is determined by a) the amount or concentration to which a person is exposed and the duration of the exposure. The higher the amount or concentration and the longer or the more often the exposure occurs the higher is the risk of damage to occur.

Exposure can be expressed as the dose that exists in the surrounding of a person (external exposure) or the dose that has been taken up (internal exposure). In the regulatory context, the external exposure is addressed either by limiting the allowed concentration or limiting the allowed migration. The internal exposure or the 'body burden' is used to identify if a particular CoC is of particularly high concern (i.e. if many people have high body burdens), which is an indicator of a need for stronger or more comprehensive regulation.



In addition to the exposure of humans, chemicals used in products can be released and reach the different environmental compartments (water, air, soil and biota (all organisms i.e. plants, animals, microorganisms)). Chemicals can be emitted from the production processes but a large share of emissions stems from the products themselves. The exposure level of the environment is the concentration the chemical has, for example in a lake or ocean. The exposure duration depends on how quickly the chemical degrades (e.g. destroyed by sunlight, chemical reactions like oxidation or reduction or by microorganisms).

Non-threshold chemicals

For the hazards of some chemicals no threshold of concern can be determined, i.e. theoretically contact with just one molecule could cause health damage/disease. One example of such a substance is lead, for which no safe level can be determined (World Health Organisation [WHO] 2021). Lead-containing paints were used for many applications, including toys. Children could mouth lead-painted toys or take up lead accumulating in house-dust from paint chips and thereby ingest the lead in these lacquers. Lead has been phased out in many uses and respective efforts are still ongoing at global level.

In summary: when judging if the content of a chemical of concern is critical and whether and what action should be taken, it is not only important to assess the regulatory status and the hazard of a chemical but also to assess the concentration in a toy and/or the potential exposures to the chemical.

How to identify chemicals of concern

The next sections explain approaches to identify CoCs. The assessment steps are provided in further detail in the ‘Checklist for identification of CoCs’.

Three categories of CoCs are distinguished (United Nations Environment Programme [UNEP] 2017a) and you can identify them according to these categories. To know if you use a CoC or if one is contained in your input materials or wastes, you have to compare the chemicals in your input material or production processes to the criteria below.

1. Chemicals for which international risk reduction action has been agreed on via Multilateral Environmental Agreements (international conventions)

The mandatory international agreements banning or restricting certain chemicals of concern are:

- ✓ Stockholm Convention, Listing of POPs in the Stockholm Convention
  Note that only the chemicals with an orange triangle are relevant for toys production
- ✓ Montreal Protocol, The Montreal Protocol on Substances that Deplete the Ozone Layer
  Note that these substances are gases and generally not expected in toys (maybe only as blowing agent in foamed plastics)
- ✓ Minamata Convention on Mercury, Homepage | Minamata Convention on Mercury (mercuryconvention.org)
  Note that mercury is unlikely to be contained in toys
- ✓ Rotterdam Convention, Annex III Chemicals (pic.int)
  Note that only the chemicals indicated as 'industrial' may be contained in toys

Examples of chemicals that are banned or restricted by these agreements are:

- Polychlorinated biphenyls (PCBs)
- Polybrominated diphenyl ethers (PBDEs)
- Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
- Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOS-F)
  Short-chained chlorinated paraffins (SCCPs)
- 1,1,1-trichloroethane
- Carbon tetrachloride
- Mercury
- Tributyltin compounds

Generally, the use of chemicals listed in these international conventions is either banned or largely restricted. Hence, it is crucial not to have them in toys. This is further explained in the Section on Legislation.

2. Chemicals for which scientific evidence exists to advance risk reduction action - this includes chemicals that are regulated at national or at regional level

Regulatory requirements for chemicals in toys are different across the world. Toys must comply with the legislation applicable in the country, where it is placed on the market. This could be the country where a company producing toys is located in or the country to which the toy or toy part is exported. Guidance on how to identify obligations in the countries where toys are placed on the market is provided in the Section on Legislation.

To ensure that chemicals for which other countries may have identified concern are not contained in toys, it may be useful to check legislation also in countries that are not target markets. Countries or regions with advanced regulatory frameworks on chemicals and product safety, such as the EU or the United States, can serve as helpful reference.

3. Chemicals for which the evidence for risk to human health or the environment is currently emerging from scientific research, but which are not yet regulated

In principle, any property of a chemical that may damage humans or the environment could be an indicator for a chemical being of concern. The main hazards of chemicals are explained in the 'Guidance: GHS and chemical hazards for beginners', which includes information sources on hazards of chemicals.

One example of emerging evidence is the hazardous property **endocrine disruption.** There is a growing concern about the extent of the risk posed by endocrine disrupting chemicals and calls for action to reduce such risks.

Endocrine disruptors are chemicals that can change the function of the hormone system, such as, for example, the reproductive system or the immune system and cause harmful effects on human health or the environment. Such chemicals may be effective at very low doses and may cause long-term damage to humans or animals. The UN has published a list of chemicals that have been identified as endocrine disrupting chemicals (EDCs) or potential EDCs (UNEP 2017b, p. 25-28). Examples of substances included in the list of EDCs are:

- Bisphenols F and S
- Selected phthalates
- 4-nonylphenols
- 4-tert-octylphenols

!	• Taking action on category 1 and 2 chemicals of concern generally is compulsory for regulatory compliance • Taking action on the emerging risks (category 3 chemicals of concern) is recommended as part of a higher-ambition and proactive approach to chemicals management

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