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# Assessment Report on Issues of Concern

***Published September 2020***

# ENDOCRINE DISRUPTING CHEMICALS (EDCs)

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## 1. Sources

An endocrine-disrupting chemical (EDC) is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.

## 2. Why is it relevant?

Known EDCs include, among others, polychlorinated biphenyl (PCBs), dichlorodiphenyltrichloroethane (DDTs) , polybrominated diphenyl ethers (PBDEs) and some phthalates, however no commonly accepted criteria for the identification of EDCs are yet available.

While uncertainties remain, a number of laboratory and epidemiological studies have suggested associations between exposure to certain EDCs and adverse effects in humans, including reproductive dysfunctions, cancers, neurodevelopmental disorders, diabetes and metabolic disorders, among others.

Some studies suggest that certain chemicals have endocrine disrupting effects on wildlife, including feminization of some species.

EDCs were identified as an issue of concern under the Strategic Approach to International Chemicals Management (SAICM) at the third meeting of the International Conference on Chemicals Management (ICCM3) in 2012.

Stakeholders decided "*to implement cooperative actions on endocrine-disrupting chemicals with the overall objective of increasing awareness and understanding among policymakers and other stakeholders*".

## 3. Existing instruments and actions

To address EDCs at the regional and national level, most efforts by governments have been focused on the development of infrastructure for identifying and regulating EDCs.

For example, some countries and regions have developed overarching strategies to guide different lines of work and other countries and regions have developed or updated their laws with explicit references to EDCs, providing a clear framework on how EDCs are to be addressed.

For more detailed information on EDCs, please see Chapter 3.2 of the ***Assessment Report on Issues of Concern*** and Part A, Chapter 2 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.


# 3. Existing instruments and actions (cont.)

Additional actions have focused on screening, assessment and identification of EDCs, particularly development of standardized criteria, guidance and tools for testing and assessment, and screening programmes under respective legal frameworks.

These actions are complemented by other stakeholders mostly focusing on synthesizing and sharing existing scientific information, developing guidance and tools for testing and assessment, and awareness raising.

On the international level, actions are coordinated by the work plan developed by intergovernmental institutions adopted at ICCM4.

Some civil society organisations have also been active in screening and assessment of EDCs, and their work indicates that many more potential EDCs exist than are currently being screened and assessed by regulators.

See Annexes for more

# 4. Challenges and opportunities

The current states of actions and knowledge of the state-of the-art science in different countries on the issue of EDCs vary considerably. Awareness has been built within and among developed countries however more in required in developing regions.

Countries have taken different approaches to assessing and managing EDCs. As a result, some chemicals may be identified as EDCs and regulated by some countries but not by others. Inconsistencies across countries could hamper sound management of EDCs internationally.

Increased awareness raising and information sharing on the issue remains necessary in countries in the African, Asian and Pacific, Central and Eastern European, and Latin American and Caribbean regions, possibly in local languages. This may enable those countries and regions' work on EDCs, including integrating EDCs into their national and regional regulatory and policy frameworks.

Within the policy arena, strengthened dialogues and concerted actions at the national, regional and international levels could enable an effective and efficient way forward.

For more detailed information on EDCs, please see Chapter 3.2 of the ***Assessment Report on Issues of Concern*** and Part A, Chapter 2 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.

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# PHTHALATES

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## 1. Sources

Phthalates are a large family of semi-volatile organic compounds. They are a group of plasticizers with softening and elastic effects, and they are produced in high volumes to be used in products such as vinyl flooring, adhesives, detergents, lubricating oils, automotive plastics, plastic clothing and personal care products. Phthalates accounted for 65 per cent of global consumption of plasticizers in 2017.

## 2. Why is it relevant?

The widespread use of phthalates has resulted in extensive human and environmental exposures.

Several ortho-substituted phthalates have been found to adversely affect mammalian male reproductive tract development with endocrine-disrupting modes of action which has resulted in their restriction by some countries since the 1990s.

The restrictions have also resulted in increased use of replacements.

Di(2-ethylhexyl) phthalate (DEHP) was classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B) with sufficient evidence in experimental animals for its carcinogenicity, but no human data available.

The European Union has identified 17 phthalates or phthalate mixtures as substances of very high concern due to one or a combination of the following: toxicity for reproduction, endocrine-disrupting properties to human health and endocrine-disrupting properties to the environment.

Some long-range transport is possible for short-chain phthalates, but degradation prevents their accumulation and limits their persistence in the environment.

Most phthalates are human-made. They are released to the environment from indoor (e.g. candles) and outdoor uses (e.g. agricultural applications), and discharges from industrial sources, wastewater treatment plants and landfills.

Wildlife and humans are exposed to phthalates through contaminated environmental media (air, water, soil) and foodstuffs (including breastmilk).

Phthalates can also be absorbed through the skin (e.g. from personal care products) and direct mouthing (toys).

When phthalate-containing materials such as paper and plastic are recycled, this can result in a so-called secondary use of phthalates and may lead to unintended exposures.

Due to the widespread application, exposure to phthalates occurs globally. Phthalates have been detected in air, water, drinking water, sediment, sludge, wastewater, soil, dust and biota.

Phthalates are generally present at higher concentrations in urban than in rural areas. Nevertheless, phthalates are also detected in remote Arctic air.

For more detailed information on phthalates, please see Chapter 4.9 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 9 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.


# 3. Existing instruments and actions

Many countries have either banned, restricted or set a maximum allowable concentration for the use of specific phthalates in specific products, however the scope of these restrictions and bans varies among countries and regions.

Overall, most of them have focused on toys and childcare products. Additional restrictions exist for electrical and electronic products, medical devices, food contact materials and cosmetics.

Some other instruments have also been introduced to limit the use of and exposure to phthalates.

Legally binding instruments to limit the use of phthalates are complemented by voluntary actions including voluntary industry phase-out by retailers and producers, as well as third-party standards and certification schemes.

See Annexes for more

# 4. Challenges and opportunities

Human biomonitoring studies continue to show almost 100% detection frequencies of restricted phthalates, with higher levels among people living in poverty as well as in children and adolescents.

Data needs to be found on current and temporal trends for global production. Such data are needed to judge whether levels are decreasing in some populations at the expense of increases in other populations.

A growing challenge is the "regrettable substitution" of phthalates with other plasticizers that could be hazardous. For example, DEHP, which has been classified as a possible human carcinogen by IARC, has been substituted with di-isononyl phthalate (DiNP) as a plasticizer of Polyvinyl chloride (PVC) in numerous applications.

Other challenges stem from protecting subpopulations at higher risk. Low-income populations have higher exposures to phthalates than high-income populations.

More comprehensive sets of instruments and actions in most countries are needed to address exposure for all vulnerable populations.

The most vulnerable life stage for adverse effects is the foetus, which means that exposures need to be limited for women of childbearing years, who are not the target population for restrictions on children's products.

Future development of regulatory and voluntary instruments and actions need to be mindful of implications for substitution.

For more detailed information on phthalates, please see Chapter 4.9 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 9 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.


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# BISPHENOL A (BPA)

## 1. Sources

Bisphenols are a group of dozens of organic compounds that have been used as building blocks in the production of polycarbonate plastics, epoxy resins and other products since the 1960s. The variety of products include water bottles, sports equipment, medical devices, household electronics, thermal paper receipts, and food and beverage cans.

Among the bisphenols, bisphenol A (BPA) has attracted the most attention. The consumption of BPA and related products is widespread and estimated to continue to grow in the foreseeable future, driven mainly by increasing demand for polycarbonates and other plastics.

## 2. Why is it relevant?

The Global Chemicals Outlook II has identified BPA in products as an issue with emerging evidence indicating risks to human health and the environment. Available governmental assessments show that;

BPA may cause multiple adverse effects on human health, particularly on infants and young children, including effects on their reproductive system (for females), spatial memory and learning functions, and developing mammary glands.

In the European Union, BPA has been recognized as a substance of very high concern under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) due to its reproductive toxicity and endocrine-disrupting properties in the environment and for humans.

BPA is not persistent in the environment and biota, and thus has limited long-range transport potential and low bioaccumulation potential in wildlife and humans.

However, it may be transported hundreds of kilometres in rivers due to its degradation half-life of about 4.5 days in water and soil.

BPA is highly toxic to aquatic organisms, with adverse effects related to development identified at very low levels.

Polymers containing bisphenols are commonly used in many everyday products across the globe. The degradation of these polymers is a major mechanism responsible for bisphenol releases from products.

The primary source of exposure to BPA for most people is through food and beverages, by migration from containers.

Studies have also shown that small amounts of BPA may remain in polycarbonates, epoxy resins and other plastics as impurities that can be released during their use and disposal (including recycling), causing environmental and human exposures.

Furthermore, marine plastic debris, including polycarbonate, may be another source and transport mechanism for nearshore BPA.

For more detailed information on BPA, please see Chapter 4.2 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 2 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.


# 3. Existing instruments and actions

Significant progress has been made in addressing child-exposure to BPA around the globe, in particular by removing BPA from baby bottles through bans in some countries and voluntarily action by manufacturers and retailers in others.

Some countries have addressed additional sources such as food packaging, containers and utensils, and toys, through legal bans, voluntary industry phase-out and legally binding migration limits.

A number of countries and regions have legally banned the use of BPA in cosmetics. To a lesser extent, legal bans have been introduced for the use of BPA in thermal paper and all food packaging, containers and utensils, complemented by voluntary industry standards.

While these actions address "upstream" BPA uses, guideline values have also been developed for "downstream" levels of BPA in different environmental media.


# 4. Challenges and opportunities

While progress is being made, substantial gaps remain in addressing BPA exposure, as indicated by an estimated increase of BPA intake by adults around the world.

Low-dose effects and different subgroups' susceptibility or vulnerability also needs to be considered.

The use of BPA analogues such as BPS and BPF has increased as replacements for BPA where it is being phased out, while recent studies have also pointed out that these chemicals may cause similar adverse effects as BPA does, though with different potencies.

Action needs to be scaled up to address all relevant exposure sources, taking into account possible challenges and uncertainties related to disposal and recycling of thermal paper and plastics.

The health risks of low-dose exposure that consider sensitive and vulnerable populations (e.g. patients, pregnant women and children) need to be determined and inform existing and future instruments and actions.

Further studies need to be conducted and actions taken to determine and manage the health risks of BPA analogues in light of existing scientific evidence of potential adverse effects. Such studies should be complemented by regular biomonitoring, so as to avoid regrettable substitutions to BPA.

For more detailed information on BPA, please see Chapter 4.2 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 2 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.

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# INTENTIONALLY ADDED MICROPLASTICS in PRODUCTS

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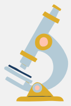
## 1. Sources

Microplastics are solid particles made of synthetic polymers, typically defined as smaller than 5 mm. Microplastics have been intentionally added to a wide range of products and application areas for diverse technical functions.

For example, they are added in cosmetics and personal care products, detergents and maintenance products, agriculture and horticulture, medical devices and in vitro diagnostic medical devices, medicinal products for human and veterinary use, food supplements, paints, coatings and inks, oil and gas drilling and production, plastics, technical ceramics, media for abrasive blasting, adhesives, 3D printing materials and printing inks.

## 2. Why is it relevant?

The Global Chemicals Outlook-II has identified microplastics in personal care products and cosmetics as an issue with emerging evidence of risks to the environment.

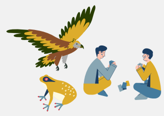


Some adverse short- and long-term effects of microplastics have been observed in laboratory studies.

However, current levels of environmental occurrence or human exposure (e.g. via drinking water, seafood) to microplastics are generally still low.

The continuous release of microplastics will result in environmental accumulation, due to their high persistence in the environment and biota, and thus may result in certain adverse effects on the environment and/or human health in the long term.

There are uncertainties on certain aspects of the risks of microplastics, particularly toxicological and epidemiological, especially as pertains to nano-sized plastic particles.



Microplastic ingestion may still be relevant for elevated exposure to intentional additives, such as plasticizers and flame retardants.

Due to their small size, microplastic particles are readily available for ingestion and potentially liable to transfer within food chains from prey to predator.

Releases can occur through various pathways, depending on the uses, principally via wastewater and/or municipal solid waste.

Their small size makes microplastics practically impossible to remove from the environment after release and many microplastics may transport to far distances in water or by air currents.

Wastewater treatment processes in the Global North can nearly completely (84–99.9%) remove microplastics in wastewater.

Microplastics are resistant to environmental degradation and when they do (bio)degrade in the environment, they progressively fragment theoretically becoming "nanoplastics" before further breaking down.

Current exposure to intentionally added microplastics is complex and information in the public domain is limited. Furthermore, data on releases are mostly focusing on specific cosmetics and personal care products.

For more detailed information on microplastics, please see Chapter 4.6 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 6 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.


# 3. Existing instruments and actions

To date, different instruments and actions have been taken and are being developed by many countries and stakeholders to address intentionally added microplastics.

Most of them have focused on rinse-off products. In particular, legally binding bans have been adopted by a number of countries.

Voluntary phase out has taken place (e.g., by multinational companies or industry associations) and voluntary actions through third-party standards and verification schemes have been taken.


# 4. Challenges and opportunities

Microplastics are ubiquitous in the environment and come from many different sources. Continuous use and releases of microplastics will result in increasing accumulation of microplastics in the environment and thus increasing exposure and risks.

The current level of action is not yet adequate for addressing sound management of intentionally added microplastics.

The current actions to ban microplastics in rinse-off products need to be expanded to cover those countries and regions that have taken no action, and other intentional uses of microplastics.

In particular, future actions addressing intentionally added microplastics need to start from the product design phase, to avoid the need for monitoring and clean-up in later life-cycle stages if possible at all.

It may be worthwhile to first have an international discussion on a common definition of “microplastics”.

Other sources such as microplastics formed unintentionally during the production and processing of larger plastics and secondary microplastics that are a result of progressive plastic degradation need to be properly addressed, possibly in the larger context of addressing plastics overall.

For more detailed information on microplastics, please see Chapter 4.6 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 6 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.

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# POLYCYCLIC AROMATIC HYDROCARDBONS (PAHs)

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## 1. Sources

Polycyclic aromatic hydrocarbons (PAHs) are a class of more than 100 organic compounds. They occur naturally in coal and crude oil, but are also formed as a by-product during the incomplete combustion from both natural (e.g. volcanic eruptions, burning of coal, oil and gas) or anthropogenic (e.g. vehicle emissions, industrial processes, food preparation).

PAHs may also be present in consumer products (e.g. plastic components, footwear); however they are never intentionally added during manufacturing. Plant-based foods may contain PAHs as a result of pollutant deposition before harvest.

## 2. Why is it relevant?

Multiple assessments have concluded that PAHs have no safe threshold below which no health risks exist. PAHs in products are identified by Global Chemical Outlook II as an issue with emerging evidence of risks to human health.

A number of PAHs have been classified as carcinogenic, mutagenic and/or toxic for reproduction substances.

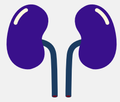
Benzo[a]pyrene (BaP) is a key PAH compound which is classified as Group 1 (carcinogenic to humans).

Fourteen PAHs have been classified as Group 2A (probably carcinogenic) or Group 2B (possibly carcinogenic.

Many PAHs are genotoxic carcinogens, which cause gene mutations.

PAHs have been documented to activate mechanisms that further accelerate PAH metabolism.

Repeated exposure to PAHs boosts their carcinogenic and mutagenic properties.



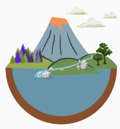
Some PAHs are persistent, bioaccumulative and toxic to humans and other organisms.

Other documented risks include exposures that irritate the eyes, throat and lungs and may damage to the liver and kidneys.

PAHs are ubiquitous in the environment and exposures are always to a mixture of PAHs simultaneously.

Many PAHs pose significant risks to the environment and human health due to their high persistence, bioaccumulation potential, toxicity and long-range transport potential.

Human exposure may occur via multiple routes, including dermal and oral uptake, and such exposures may occur through both environmental media and consumer products.



Because PAHs are not intentionally added in products the levels of PAHs in products may depend on many different factors.

PAHs can migrate and diffuse from consumer products through skin and migration and diffusion from packaging material into foodstuff may also occur.

Molecules with lower weights diffuse faster and migrate farther into both skin and foodstuff. Other factors responsible for the migration of PAHs into foodstuff are the exposure area of the packaging used and the fat content in the food.

For more detailed information on PAHs, please see Chapter 4.10 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 10 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.


# 3. Existing instruments and actions

At the international level, the Basel Convention addresses PAHs at the end of products' life cycles, but does not directly address consumer products that contain PAHs during their production and use.

The United Nations Economic Commission for Europle's Aarhus Protocol on Persistent Organic Pollutants obliges Parties to reduce their emissions of polycyclic aromatic hydrocarbons (PAHs) below their levels in 1990.

Current national and regional instruments and actions typically prioritise and group several PAHs according to environmental relevance, which may vary between countries and product categories.

Several major legally binding instruments restrict the levels of PAHs in consumer products, e.g. for cosmetics and foodstuffs or in extender oils and consumer products containing rubber or plastics. Similarly, legally binding maximum permissible levels of selected PAHs have been set for cosmetics, foodstuffs, consumer products, packaging and waste asphalt that can be recycled.

These legally binding instruments are complemented by recommended guidelines developed by intergovernmental institutions and by various voluntary actions initiated by the private sector, including voluntary standards. Some organisations have also developed different consumer education o public documents to raise awareness of PAH exposures.

See Annexes for more

# 4. Challenges and opportunities

Voluntary standards alone are unlikely to be able to address PAHs in consumer products due to their current limited scope in terms of geographic coverage or product categories.

BaP is used as a reference compound for the presence of PAHs in general. however, due to the large variety of PAH mixtures, some products may contain different PAHs but not BaP. In such cases, testing for the presence of PAHs using a single reference chemical will lead to false negatives.

It may be necessary to raise global awareness towards establishment and implementation of legally binding instruments for addressing PAHs in consumer products across different jurisdictions.

Although food items generally meet guideline values issued in legislation from multiple countries, food processing standards may be fostered to minimize PAH contamination.

The use of reference PAHs needs to be carefully considered, and expanded beyond the sole use of BaP.

For more detailed information on PAHs, please see Chapter 4.10 of the ***Assessment Report on Issues of Concern*** and Part B, Chapter 10 of the ***Annexes to the Assessment Report on Issues of Concern***. Available on the UNEP website.