



Endocrine-disrupting chemicals (EDCs) in food and drinking water in India

State-of-affairs and recommendations
for policy makers

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Credits

The project EDIFY is a joint research effort of: NIVA (Norwegian Institute for Water Research), Mu Gamma Consultants Pvt Ltd, SRM Institute of Science & Technology, RECETOX (Research centre for toxic compounds in the environment), NIBIO (Norwegian Institute for Bioeconomy), Toxics Link, TERI (The Energy and Resources Institute) and Bharat Learn.



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MESSAGE

It gives me immense pleasure to write a message for this highly valuable study carried out by scientists from India, Norway and the Czech Republic. This research project titled: "Endocrine Disruptors in Indian Food: Minimizing children exposure and fostering a safer space for agriculture and food market" has assessed the exposure of the Indian population to Endocrine Disrupting Chemicals (EDCs) and have enhanced our collective knowledge about it.

EDCs have increasingly captured the interest of researchers as well as policymakers in recent years. In addition to evidence of the health effects of these chemicals, the knowledge of global policy action and international regulation is vital for initiating policy discourse at the national and regional levels. It is also vital that the policy community at all times has access to the best available scientific knowledge for developing robust regulations and effective management.

In this regard, this Policy Brief titled- "Endocrine-disrupting chemicals (EDCs) in food and drinking water in India: State-of-affairs and recommendations for policy makers" is very timely, which provides a summary of the research outcomes and aims to raise awareness for initiating policy action related to safe food production. This is a significant step towards directing regulatory measures for necessary action to protect human health.

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Foreword to policy note for the EDIFY project

Norway is committed to supporting the Sustainable Development Goals (SDGs) and playing a leading role in international development policy. A key fundament is building and consolidating critical knowledge on today's global challenges and how to tackle them. Through the NORGLOBAL-2 research programme administrated by the Norwegian Research Council, Norway stimulates innovative, high-quality and relevant research in support of global efforts towards the SDGs. Such an effort is framed around the ambition of enhancing Norway's contribution to the global research production about development issues and to make Norway a global partner.

Human exposure to endocrine disrupting chemicals (EDCs) through the environment and especially through the diet is recognized as a serious challenge for societal development. The scientific community has built a solid body of knowledge documenting the negative health outcomes from exposure to this broad group of hazardous chemical contaminants, and the unacceptable pressure they pose to present and future generations. We also know that the environmental, social and economic cost of non-action in reducing exposure to EDCs is very high. Policy makers in several countries have recently raised the urgency of integrating EDCs in the health protection agenda. Dealing with such a problem in globalized markets and food systems requires an effort to harmonize policies and actions across borders.

Through supporting the research project Endocrine Disruptors in Indian Food: minimizing children exposure and fostering a safer space for agriculture and food market (EDIFY), Norway aims at strengthening communication and dialogue between researchers, policy makers, industry and other relevant actors internationally. Building such a synergy with India is a unique opportunity to contribute to better health protection and chemical management. India is an emerging industrial hub, with a rapidly developing chemical industry. It is also a key international supplier of food and feedstocks. Improving EDC management in India will generate far-reaching global benefits.

We are proud to introduce this report summarizing the results from the project EDIFY by the team of European and Indian researchers and experts. The document presents a set of important recommendations for policy makers, based on new knowledge identified by the project, in order to improve chemical management and food safety in India and internationally.

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March 4, 2022

MESSAGE

Recent years have seen an increase in research and discourse surrounding "endocrine-disrupting chemicals" (EDCs) and their human exposure. Chemical contaminants in food have health and environmental impacts. Around 800 chemicals are categorized as EDCs, or chemical compounds that adversely affect endocrine, neurological, and reproductive systems when humans and other living organisms are exposed to them through inhalation, food, water or dermal contact. These impacts have huge economic costs that tend to be underestimated in a developing country like India. Besides, it is of serious concern that children are negatively affected by these substances to a significantly greater extent.

The Norwegian Institute for Water Research (NIVA), The Energy and Resources Institute (TERI), Mu Gamma Consultants Pvt Ltd (MGC), SRM Institute of Science & Technology (SRMIST), Toxics Link, Research Centre for Toxic Compounds in the Environment (RECETOX) and The Norwegian Institute of Bioeconomy Research (NIBIO) conducted a study titled 'Endocrine Disruptors in Indian Food: minimizing children exposure and fostering a safer space for agriculture and food market (EDIFY)'. Supported by the Research Council of Norway, the EDIFY project conducted a comprehensive assessment of the exposure of the Indian population to selected EDCs, identified risk reduction and management options to reduce exposure to EDCs, and strengthened the knowledge base for policy development.

To raise awareness through research-based evidence this policy brief summarizes the results of the EDIFY project effectively advocating lower levels of EDCs in food. It primarily targets policymakers in India and societal actors with a stake in chemical pollution and management, food production, and distribution.

The policy brief will hopefully lead to the Indian legislative system specifically addressing the tolerance limits and regulations for EDCs in food, water, and other consumer products and help strengthen the Chemical Safety and Management Rule (CMSR), that India has currently drafted. We further hope that the study will encourage new research into the occurrence and effects of these chemicals, initiate programs to increase awareness of EDCs, recognize emerging issues related to EDCs, and develop a framework for their effective and sound management. Best wishes

S K Sarkar



Foreword

Research on environmental contamination shows that India might be a hotspot for endocrine-disrupting chemicals (EDCs). EDC is a class of chemical contaminants that can produce adverse health effects following chronic exposure at very low concentrations. This is especially of concern when exposure occurs during the foetal stage and in the early stages of development. Several EDCs can be transmitted from mother to child during pregnancy and lactation.

This issue has been centralised in scientific, societal and policy debates. Still, the impacts of EDCs on public health are not sufficiently understood. This is due to the difficulties of establishing clear causal relationships between exposure and health in a context of multiple stressors. Internationally, these uncertainties cause delays in taking concrete regulatory actions. The scientific community and many environmental and health organisations, including international, governmental and non-governmental organisations, have advocated for a precautionary approach when dealing with authorisation and use of certain chemicals.

Diet is a main determinant of people's health and a very important pathway for exposure to EDCs. In order to enable a better control over the pressure of EDCs on the Indian population, a pivotal step is to develop a better understanding of the occurrence and levels of a broad number of EDCs in food items representing the main element of the Indian diet.

We conceived the project EDIFY (Endocrine Disruptors in Indian Food: Minimising children exposure and fostering a safer space for agriculture and food market) with two identified gaps in mind:

- The need in India for more holistic chemical management and pollution control.
- The scarcity of data on dietary exposure to several priority contaminants and suspected EDCs.

With these identified gaps as backdrop, the objectives of the EDIFY project are

1. to develop the first assessment of endocrine disruptors in the diet of Indian people focusing on how socioeconomic determinants can affect exposure;

2. to develop knowledge-based recommendations to define policies tailored to protect Indian children and fertile women;
3. to compare regulatory approaches and policies on endocrine disruptors in the European Union (EU) and India, to identify potential transmission value; and
4. to promote discussion of a quality labelling scheme for food with low levels of endo-crine disruptors.

This document summarises the results of this research effort. It primarily targets policymakers in India and societal actors with a stake in chemical management, food production and distribution. The aim is to provide evidence and through this to raise awareness and inspire the development of policy and innovation in food production, effectively advocating science-based for a diet with lower levels of EDCs.

The first section of the report, Background, introduces the issue. The following section, New insights on EDCs in the Indian diet, provides highlights from the research findings through infographics. In section three, Way forward for India, we discuss some scientific and policy aspects of concern to India. In the final section, Policy recommendations, we offer our overarching recommendations to policymakers, food producers and distributors, recommendations that rather readily could inform a possible national policy.

The EDIFY project was kindly supported by the Research Council of Norway through an international cooperation scheme. The research was jointly conducted by teams of the Norwegian Institute for Water Research (NIVA) – Norway, The Environmental Resource Institute (TERI) – India, the SRM Institute of Science and Technology – India, Mu Gamma Consultants Pvt Ltd – India, Toxic Links – India, and RECETOX Research Centre for Toxic Compounds in the Environment (RECETOX) – Czech Republic. Research and communication activities were also supported by Bharat Learn and the Norwegian Institute for Bioeconomy (NIBIO).

In creating and developing this work, we acknowledge the immense historical, environmental, and cultural capital nested in the Indian food culture: A heritage of great significance for India and for the whole of humanity. Working towards the protection of such capital was an important driver motivating our international team.



Luca Nizzetto (PhD)
Project Coordinator

is a leading scientist at the Norwegian Institute for Water Research with a background in environmental contamination, ecosystem research and food safety. He has been coordinating several large-scale international projects in the context of global fate and distribution of chemical and plastic pollution and the analysis of agricultural practices sustainability in the context of ecosystem pollution and food contamination.



Girija K Bharat (PhD)
Project Coordinator

is the Founder Director of Mu Gamma Consultants Pvt Ltd, India. She is an international expert with 30 years of experience in water quality management and conducts research and capacity-building activities in India on water resource management, water supply and sanitation, chemical pollution control (persistent organic chemicals [POPs]) and environmental management. She has drafted the National Policy Framework of India on Safe Reuse of Treated Water.

Background

Endocrine-disrupting compounds (EDCs) are substances capable of impairing the functionality of the hormone system in exposed individuals. Substances with EDC properties are present as contaminants in air, soil, vegetation, water, and biota, or as additives in some consumer products such as personal care products or food packaging, among others. Human exposure occurs through diet, inhalation and dermal contact. However, diet is the main path, especially for those EDCs with bio-accumulative properties that can accumulate in the food chain. The past few years have witnessed a rise in documented endocrine-related disorders in the human population worldwide, including in relation to fertility. This has generated scientific and societal concern. Internationally, several research programmes have focused on investigating sources, routes of exposure, bioaccumulation, and the effects of EDCs.

The International Programme on Chemical Safety (IPCS) – a joint programme of the World Health Organisation (WHO), United Nations’ Environmental Programme (UNEP) and International Labour Organisation (ILO) – defines an endocrine disruptor as “an exogenous substance or mixture that can alter the functions of the endocrine system and consequently causes adverse health effects in an intact organism or its progeny or population”. Approximately 800 substances are known or are suspected to interfere with the hormone system¹. Yet only a fraction of these have been tested for endocrine effects or have undergone regulatory screening for safe use.

RECOGNIZED MAJOR SOURCES OF EDCs FOR THE GENERAL POPULATION



Figure 1. Main sources of EDCs for the human population

EDIFY - Endocrine disruptors in Indian food: minimizing children exposure and fostering a safer space for agriculture and food market

There is a scientific consensus that EDCs represent a pressure for humans and the environment. Such a concern has only partly been translated into policy and regulation for health protection; see, for example, the Strategic Approach to International Chemical Management (SAICM), the Stockholm Convention on persistent organic pollutants (POPs), the Minamata Convention on mercury, and OECD test guidelines for EDCs. Some substances identified as EDCs are handled, often indirectly, in a range of different regulatory contexts (e.g. as inherent to chemical management, crop protection, waste management). Not a single cohesive regulatory approach directly addressing EDCs exists, nationally or internationally. Beyond such a fragmentation, there is clearly a disconnect between the rapidly rising scientific understanding of EDC identities and impacts, and the definition of health-preserving policies.

Health impacts of EDCs

EDCs enter the human body through different routes of exposure, such as air, food, water, and through dermal contacts. Even at trace levels, EDCs can lead to various adverse human health outcomes under prolonged exposure. A global estimate shows that about 24% of human diseases and disorders, including cancer, respiratory and cardio-vascular diseases, are attributable to environmental factors². Consequently, EDCs may be important determinants of health. **EDCs accumulate in the body from food and the environment during one's lifetime. They can be transferred to foetuses causing transgenerational effects. Particular attention should be paid to reducing exposure in women of child-bearing age and children.** Research points to EDCs as the possible cause of health impairments such as obesity, diabetes, female and male reproductive dysfunctions, hormone-sensitive cancer insurgence in females, prostate cancers, thyroid dysfunction, and neurodevelopment and neuroendocrine system impairments^{3,4,5}.

The Endocrine Society (clustering the international scientific and medical community working on EDC research and clinical studies) has stated that **causal links between exposure to EDCs and manifestation of these diseases are substantiated by experimental animal models and are consistent with correlative epidemiological data in humans**⁶. The endocrine system acts naturally by releasing hormones that trigger actions in specific target cells which regulate the correct functioning of the organism. Receptors on target cell membranes bind to one type of hormone. EDCs can mimic or block the metabolism of naturally circulating hormones by binding to hormone receptors or affecting the rate of hormone synthesis and degradation in the body. The second scientific statement of the Endocrine Society⁵ provides a complete overview of the state of knowledge on the health conditions linked to EDC exposure. A list of common EDCs, their uses, and related health impacts are summarised in **Annexure 1**.

EDCs in diet

EDCs are found at trace levels in food and drinking water around the world. Acknowledging the concern for bioaccumulation in the human body and the subtle chronic effects, some countries have introduced monitoring programmes for EDCs in food. For instance, the European Food Safety Authority (EFSA) conducts yearly monitoring of thousands of food samples to determine the concentration of several currently used pesticides, heavy metals, and POPs which, incidentally, are also recognised as proven or potential EDCs. Research case studies are also available reporting the occurrence of several EDCs in food and drinking water in Europe, Asia and North America. The most frequently monitored substances include Bisphenol A, DDT and other organochlorine pesticides, polychlorinated biphenyls (PCBs), Perchlorinated alkyl substances (PFAS), mercury, other heavy metals, and some currently used pesticides. Most regulated POPs are EDCs and their dietary exposure has been a major international concern over decades^{7,8,9}.

Mercury and other endocrine-disrupting metals have also been measured routinely in vegetables and animal products in different parts of the world, often detected at levels higher than the maximum allowed residue level (a regulatory proxy for a safety threshold)^{10,11,12,13}.

Rice from different locations in South and Southeast Asia has been found to be a potential global dietary source of methyl mercury for humans ¹⁴. PFAS, a group of chemicals used in industrial processes and in coatings, is a common water contaminant and has been routinely found to contaminate ground and drinking water resources around the world ¹⁵. Previous research from our group has identified a diffuse contamination of several PFAS in drinking water resources of the Gangetic plan ¹⁶. Global food trade has further exacerbated risk of exposure to EDCs in regions where environmental EDC levels are low. Marine fish exported from Europe to sub-Saharan African countries has been found to be a significant contributor to the consumer exposure of PCB ¹⁵³ ¹⁷.

In India, EDCs such as hexachlorocyclohexane (HCH), dichloro-diphenyl trichloroethane (DDT), endosulfan, cypermethrin, cyhalothrin, permethrin, chlorpyrifos, ethion and profenophos pesticides have been detected in concentrations higher than respective maximum residue limits for pesticide in peri-urban bovine milk ¹⁸. Bisphenol A has been detected in canned food and plastic bags in contact with food ¹⁹. A review on maximum residual levels set for substances classified as EDCs by different national or international authorities/ regulations are presented in **Annexure 2**.

Policies on EDCs in India and internationally

Unlike most countries, India does not have a consolidated regulation dealing with EDCs in general. However, fragments of different regulations also covering some compounds recognised as EDCs come under the jurisdiction of different sectors, as for example the General Chemical Safety Regulation, Food Protection, and specific regulations for children's articles. The lack of a policy strategy determines a “reactive approach” in managing EDCs – which stands in contraposition to a more desirable preventive approach. For instance, under the current system, only after the availability of a large body of evidence on subtle endocrinological effects, is a substance considered for limitation or bans in the market. Unfortunately, given the historical lack of consolidated methods and criteria for early or pre-market identification of EDCs, such a retrospective approach is the norm, internationally.

The time lag between a new substance entering the market and its identification as a harmful EDC can be decades, leading to persistent, multi- generational exposure in the human population. Obviously, this is not only an Indian problem, but a general shortfall in most international chemical regulation, including those such as the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation that are based on risk evaluation and management, but that do not yet fully and systematically assimilate endocrine-disrupting-specific criteria for the evaluation of risks.

The upcoming new chemical regulation in India – the Chemical Management and Safety Rules (CMSR), expected to enter into force in 2022 – represents an ambitious and potentially very important step forward. Drawn on the principle of risk management, similarly to REACH, it will require any chemical being manufactured, imported or placed in the Indian market (in quantities above one ton per annum) to undergo registration and authorisation following a detailed evaluation of risk posed to human health and the environment throughout its entire life cycle. Promisingly, in the CMSR draft, endocrine-disrupting properties are set as a hazard category for defining priority substances ²⁰, which provides some encouraging insights that this regulation will tackle EDCs in a more systematic way.

In the Annexure to this policy brief, we have included information on the international development on policies and public advocacies regarding EDCs. We also included information on different regulatory documents adopted in India covering individual or groups of substances identified as EDCs.



New insights on EDCs in the Indian diet

Results from the EDIFY project.

The EDIFY project (**Endocrine Disruptors in Indian Food: minimising children exposure and fostering a safer space for agriculture and food market**) has recently provided a seminal contribution in advancing the understanding of EDC dietary exposure in India. EDIFY was financed by the Research Council of Norway through a grant supporting international cooperation. From Norway, the project involved the Norwegian Institute of Water Research (NIVA) and the Norwegian Institute for Bioeconomy (NIBIO). From the Indian side, participants in the project were Mu Gamma Consultants Pvt Ltd, The Energy and Resources Institute (TERI), the SRM Institute of Science and Technology and Toxics Link.

EDIFY was the first study to systematically provide comprehensive data on levels of several important groups of EDCs in the Indian food basket, assessing dietary intakes of several groups of EDCs such as POPs, current-use pesticides, heavy metals and plasticisers. A total of 112 substances were analysed in 24 food items (cereals, vegetables, fruits, dairy products, fish, meat samples) and two types of drinking water (tap water and package water) from different zones of Delhi (taken as a reference urban context) and in Dehradun, Uttarakhand (taken as a reference peri-urban/rural context). In the following pages, results from our research are presented divided in four groups of EDCs: POPs, heavy metals, currently used pesticides, and plasticisers.

POPs in the Indian diet

Several POPs act as EDCs and pose a pressure to human health mainly through dietary exposure. **A broad range of organochlorine pesticides (OCPs), polychlorinated biphenyls (PCBs), polybrominated diphenyl ethers (PBDEs), dioxins and furans were systematically measured, for the first time, in several items of the Indian food basket.** All of the over 50 targeted contaminants were found in most food items, especially in dairy and meat products. OCPs and PBDEs were the substances with the highest concentrations in these products. Children were assessed to be the most exposed group (compared to adults and seniors). Cereals (wheat and rice) being the main items of the Indian diet, represented the largest contributor of POPs in all age groups.

Food supplied to urban markets had higher residuals of most POPs compared to that supplied in a reference rural area, possibly as a result of different food production and preservation practices between traditional and industrially processed food. Because of these differences in food contamination and different food consumption habits, the rural population was estimated to have a considerably lower exposure (average factor of 5–10, depending on compound) compared to the urban population. This behaviour was also observed for other groups of EDCs, in particular plasticisers. Despite a lower level of control and restrictions, and the lack of a national monitoring plan for POPs in food in India, we have not collected any clear evidence that the Indian population has a significantly higher exposure than the European population.

POPs are ubiquitous in the Indian diet. Although some of these compounds such as HCH and DDT have been banned or strongly restricted for over a decade, they still appear to be the main contributors to POP content in the Indian diet. HCHs were found in drinking water at levels comparable to the US Environmental Protection Agency (EPA) safety threshold. However, by comparing results with previous studies in India, we collected evidence that level of OCPs in food items could have dropped during the last three decades. Animal-derived food products (chicken, chicken egg, goat meat, and fish) had the highest concentration of POPs, especially DDTs and PBDEs. The highest intake of POPs was, however, associated with HCHs and DDTs in wheat and rice (because cereals represent a major component of the Indian diet).



DIETARY EXPOSURE TO PERSISTENT ORGANIC POLLUTANTS

URBAN POPULATION



RURAL POPULATION



Proportions reflect the mean variability of daily intakes across different groups of EDCs: DDT, HCH, HCBs, PCBs, Dioxins, PBDEs. The figure is redrawn from Sharma BM, Bharat GK, Chakraborty P, Martiník J, Audy O, Kukučka P, Přibylková P, Kukreti PK, Sharma A, Kalina J. A comprehensive assessment of endocrine-disrupting chemicals in an Indian food basket: levels, dietary intakes, and comparison with European data. Environmental Pollution, 2021, 288, 117750, <https://doi.org/10.1016/j.envpol.2021.117750>.

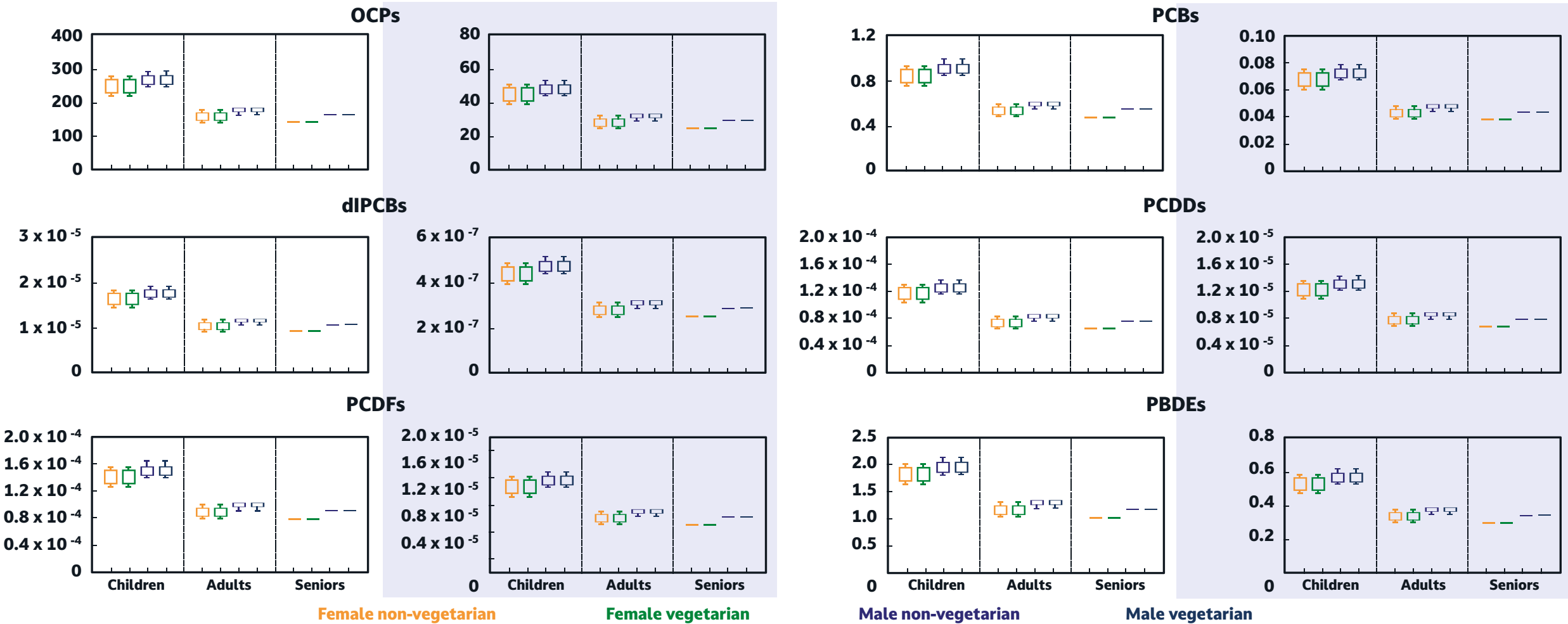


Fig. 2.²¹ Daily dietary intakes of contaminants (by group) based on a comprehensive food basket analysis. The x-axis displays the age groups (children (3 – 12 years), adults (18 – 60 years), seniors (>61 – 75 years)) and the y-axis displays EDIs through food consumption (including drinking water) (in ng/kg-bw/day; for dl-PCBs, PCDDs, and PCDFs in ng-TEQ WHO05/kg-bw/day). The boxes represent 25th and 75th percentiles and the whiskers mark non-outlier range (1st–99th percentile). The plots on white background show dietary intakes for the urban population while the plots on gray background show intakes for the rural population.

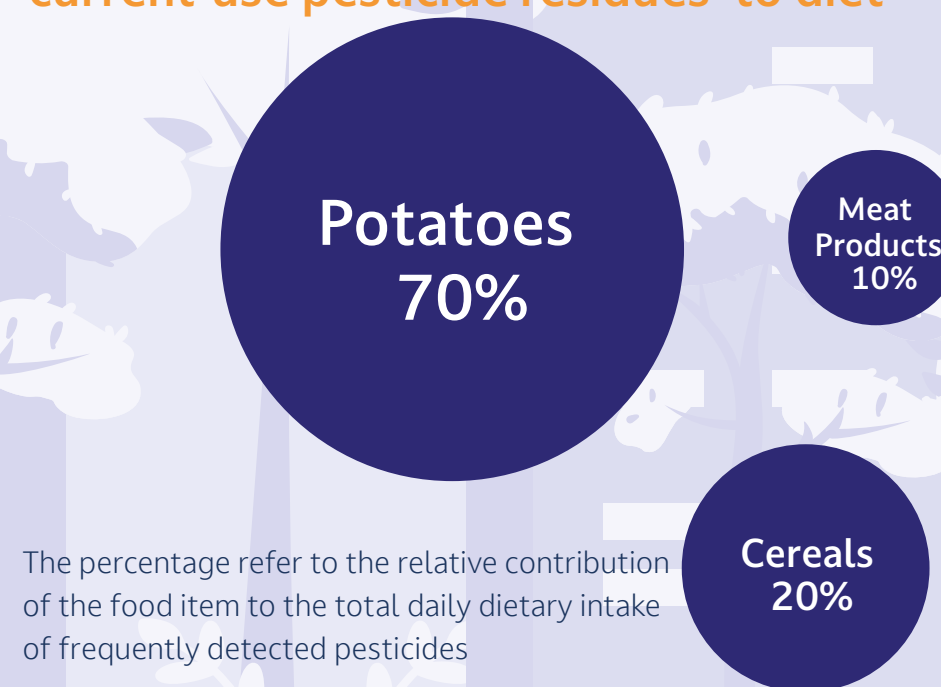
Current-use pesticides in the Indian diet

Current-use pesticides (CUPs) were introduced to increase crop yield and preserve agricultural produce after harvest. CUPs were also a replacement to earlier harmful substances such as DDT and HCH. CUPs were meant to have less environmental impact (with no or low persistence/bioaccumulation) than earlier pesticides. However, owing to their extensive use, residuals of CUPs are commonly detected in soil, surface and groundwater, in the air and in food items. Regulatory bodies in several countries (including India) have acknowledged the health concern from dietary exposure and introduced safety thresholds and monitoring programmes for certain substances.

In the EDIFY project, food items were analysed for a list of more than 40 CUPs.

Two pesticides (chlorpropham and chlorpyrifos) were frequently detected in several products except for eggs, cabbage, mango, watermelon and orange. Irrespective of dietary preferences, the consumption of potato represented a main vector of chlorpropham to the human body (representing about 70% of the total dietary daily intake of this pesticide). Cereals (~22%), were the next major contributors to dietary exposure to CUPs. Rice contained the highest levels of chlorpyrifos. Animal food products contained only chlorpyrifos traces which contributed negligibly to the total daily intake. Similar to what was observed for POPs, food originating from the rural areas was clearly less contaminated than food originating from urban markets. In fact, in Dehradun, most CUPs were below detection limits in the majority of food groups. **Food production and preservation practices linked to the large distribution (compared to traditional food systems) seem to determine higher pesticide residues in food in India.**

Food items observed to act as main suppliers of current-use pesticide residues to diet



The percentage refer to the relative contribution of the food item to the total daily dietary intake of frequently detected pesticides

Figure 3. main contributors of measured current-use pesticides to dietary exposure

Toxic heavy metals in the Indian diet

The EDIFY project provided a comprehensive overview of essential and toxic heavy metal contamination in the Indian diet. **All food analysed in this study contained residues of toxic heavy metals, and in some cases, at levels above the safety standards set by FAO/WHO.** In this case, no substantial differences were observed in metal concentrations in food collected in the urban market in comparison to the food from the rural region. Toxic metals such as cadmium and lead (and to a lower extent nickel), were dominant across all food matrices. The highest concentrations of the target heavy metals were found in vegetables, with cadmium, lead, and nickel being found beyond permissible limits in okra, spinach, and cauliflower. The maximum loading in distribution of individual toxic heavy metals for estimated daily intake (EDI) was observed in vegetables having contributed as much as 92% cadmium. Dairy products had the highest loading for zinc, nickel and selenium. Heavy metals were also found at trace levels in packaged and municipal supplied waters.

These results call for the need of a higher level of control on metal presence in milk and spinach. Authorities should consider emanating dietary recommendations dedicated to children and pregnant women to reduce exposure to heavy metals.

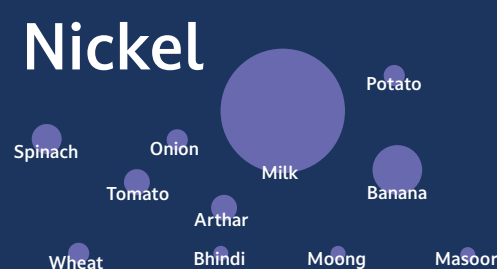
Arsenic



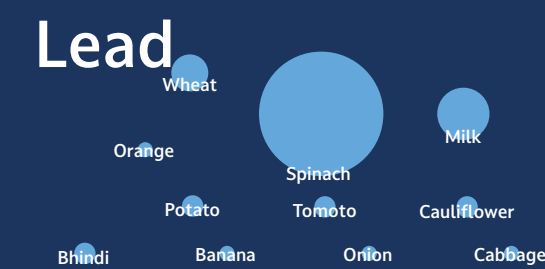
Chromium



Nickel



Lead



Cadmium



Mercury

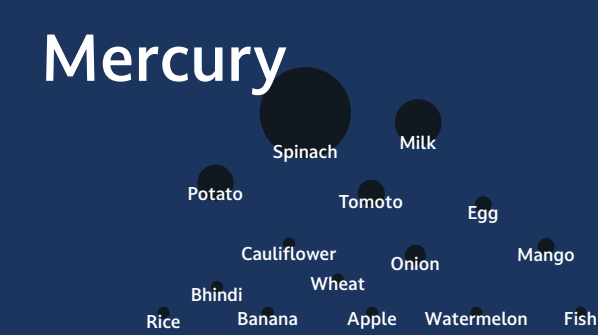


Figure 4. main contributors of measured metals to dietary exposure

Plasticisers in the Indian diet

Plastic has become an important asset in food production, preservation, and distribution. Plastics are frequently used in food packaging, including in India. Plastic containers for crops and food are added with plasticisers such as several phthalates and bisphenols that are recognised as EDCs. Some plasticisers are also environmental contaminants and can accumulate in the trophic webs. Diet is the key exposure pathway for endocrine-disrupting plasticisers into the human body. The EDIFY project studied, for the first time in India, the occurrence of 12 common phthalic acid esters (PAEs) and Bisphenol A (BPA) in Indian food and drinking water.

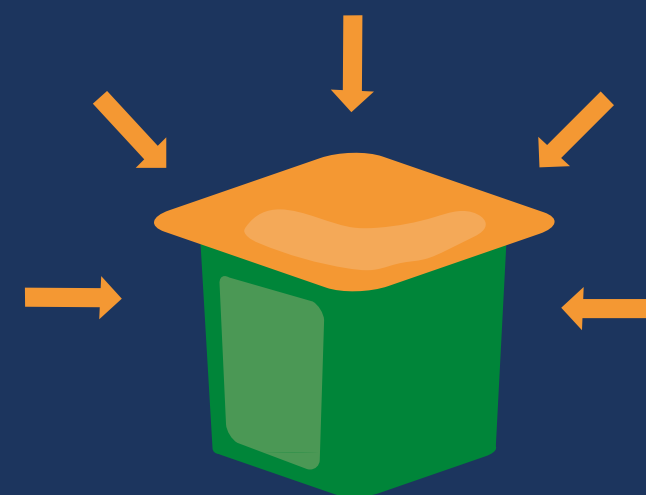
Maximum levels of PAEs were found in industrially packaged cottage cheese, and fish. BPA was found at higher levels in potatoes and fish compared to other food types. Municipal supply water from the west zone of Delhi was also found to contain BPA and PAEs.

Other items with considerable concentrations of these EDCs were wheat, poultry, and dairy products. Dairy products were the major pathways for priority PAEs exposure in adults, leading to 54% and 52% of PAEs for vegetarians and non-vegetarians respectively, in Delhi. Cereals were the next highest PAE-contaminated food group contribution ~25% of PAE exposure in adults. In children, PAEs were consumed mainly from dairy products which contributed to over 80% of their daily p-PAE intake, irrespective of dietary preference.

Suspected carcinogenic PAEs were found in the highest levels in dairy products in Delhi, especially in cottage cheese, leading to increased risk of exposure to children.

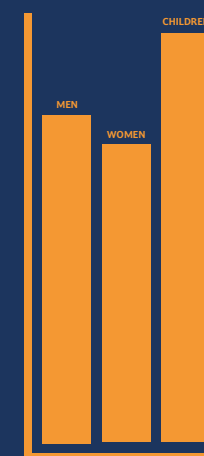
In general, adults in Delhi faced more than seven to eight folds higher exposure to PAEs compared to adults from the rural reference site. In Delhi, consuming "supply water" led to a higher exposure to PAE compared to consuming "bottled water" from local and international brands. Water in the rural reference site was considerably less contaminated. **Packaging material was clearly identified as a source of the plasticiser DnBP in packaged food.** In Delhi, BPA was mainly found in potatoes, contributing to over 80% of BPA intake. In children, dairy products were the second highest suppliers of BPA, contributing almost 20% of the total EDI, compared to the 70% from potato consumption. Similar to PAEs, EDI of BPA was highest when consuming supply water (compared to bottled water).

FOOD PACKAGING MATERIAL AS SOURCE OF PLASTICISERS TO FOOD



COMPARISON OF DAILY INTAKE OF PLASTICISERS BY URBAN AND RURAL POPULATION

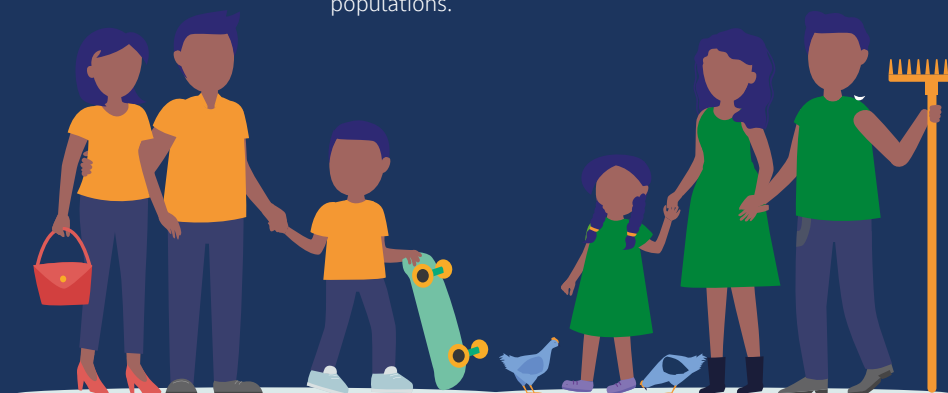
URBAN POPULATION



RURAL POPULATION



Figure 5. Comparison of exposure to plasticizers in urban and rural populations.



Way forward for India

Awareness and science-based decision-making

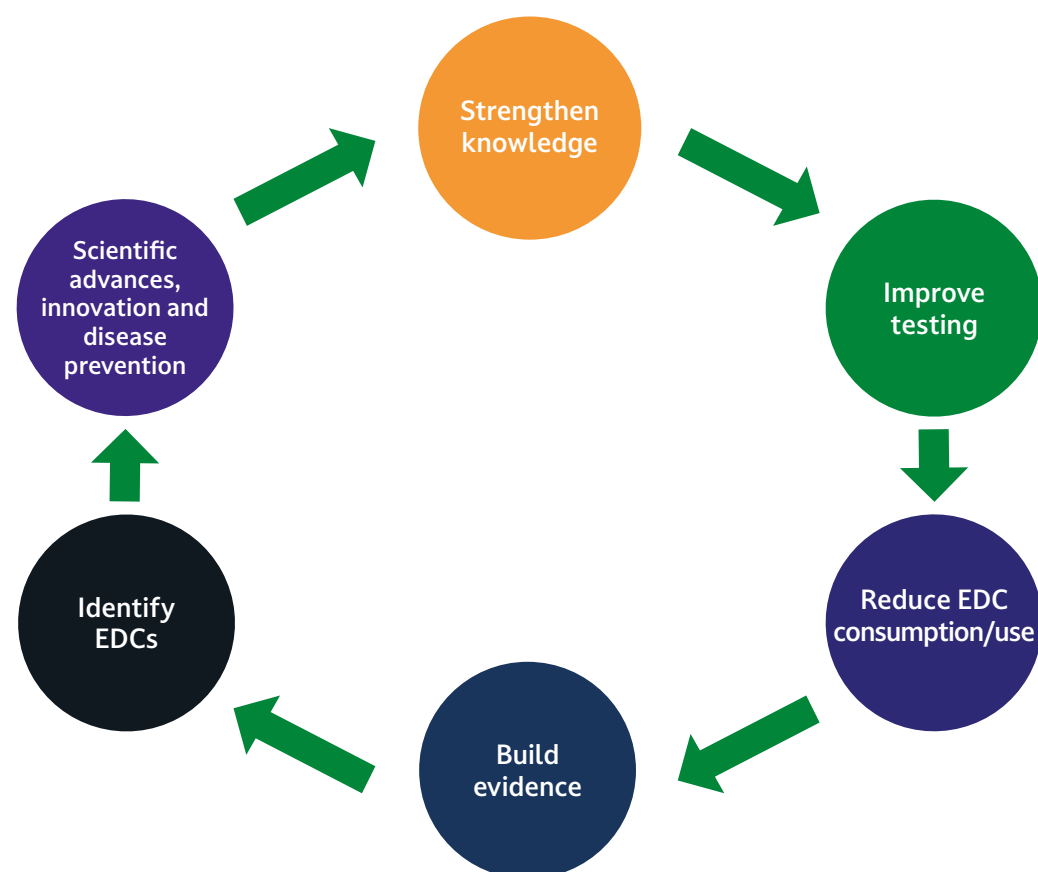


Figure 5: Actions required for management of EDCs: Need for a paradigm shift to evaluate risks and prioritise actions to reduce risks

EDCs affect human health and environment in a subtle manner. While there is scientific consensus on the significance of EDCs as determinants of human health in contemporary society, such an awareness is not sufficiently assimilated by policy. It is the responsibility of the scientific community to enhance awareness of this hazard, especially within governance. **The number of EDCs in the market, the environment and in food, is much larger than the number of EDCs regulated under the different existing Acts.** The scientific community stresses the urgent need of adopting practical but science-based screening tools for enabling a rapid assimilation of environmental and food quality criteria in regulatory health-protection Acts. Recent scientific advances have provided new tools for early identification and classification of EDCs. These can solve the current gap between science and policy and can be instrumental for the definition of regulatory Acts.

Solving the disconnect between science and policy

Because of the difficulties in specifying fundamental measurable criteria for a generalist definition of EDCs and identifying safety thresholds (owing to subtle and difficult-to-measure modes of chronic and transgenerational toxic action), policymakers face a challenge in translating scientific recommendations into regulation. EDCs include compounds with diverse characteristics and modes of toxicological action. As such, the policy approach has typically focused on individual substances or groups of homogeneous substances, after robust evidence of their potential endocrinological effects emerged from scientific reports. Unfortunately, **a retrospective risk reduction approach does not guarantee a timely protection of health, as it may take time for this evidence to be collected and disseminated.**

The Endocrine Society is an international scientific organisation representing the global research community acting in fundamental and clinical studies around EDCs. According to their recent position statement, a large body of literature has solidified the understanding of plausible mechanisms underlying EDC actions and how exposure in animals and humans – especially during development – may lay the foundations for disease later in life. Knowledge is now consolidated regarding the way in which EDCs alter gene-environment interactions via physiological, cellular, molecular, and epigenetic changes, thereby producing effects in exposed individuals as well as their descendants. Causal links between exposure and manifestation of disease are substantiated by experimental animal models and are consistent with correlative epidemiological data in humans.

It is firmly supported that a precautionary principle in chemical management and food safety regulation for EDCs is possible and represents a better and more sustainable option than risk acceptance.

Scientific knowledge on EDCs has, in fact, developed considerably in recent years, and the following pillars must be considered for policy and regulation on EDCs:

Research and clinical experts around the world, the World Health Organisation, the Endocrine Society, and others have sufficient evidence that currently recognised EDCs pose a risk to the health of humans.

There exists a comprehensive list of substances for which there is a developing or already consolidated scientific consensus on their EDC properties.

Traditional methods of evaluating chemical toxicity may be inadequate for addressing EDCs. However, new approaches now exist to include toxicity assessments and endpoints that are more relevant to endocrine diseases.

The recently described “key characteristics (KC)” approach represents a framework that can be used to evaluate the evidence that an environmental chemical affects any of the 10 common features of EDCs.

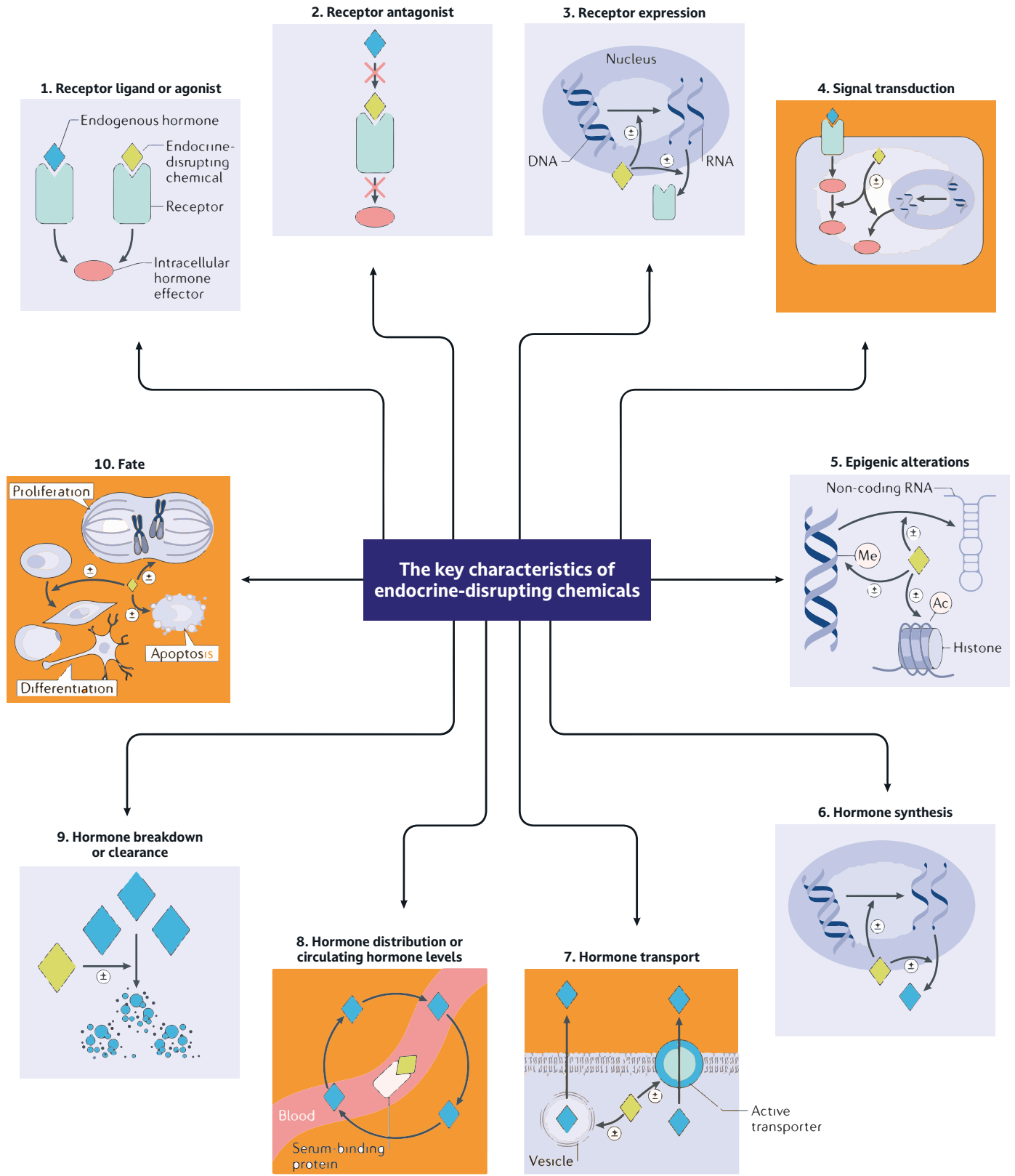
To resolve the gap between science-based evidence and regulation, the KC can represent a powerful set of empirical criteria to enable early identification and prioritisation of substances (Table 1). A consensus on the validity of these 10 criteria has been presented in a recent publication²². For the reader’s reference, KCs are listed in Table 1 and graphically depicted in Figure 5 (reprinted from²²).

Table 1. Ten “key characteristics (KC)” for early identification of EDC. Redrawn from²²

Key characteristics		Examples of relevant streams of mechanistic evidence
KC1	Interacts with or activates hormone receptors	Binding or agonism of hormone receptors
KC2	Antagonises hormone receptors	Antagonism of nuclear or cell surface hormone receptors
KC3	Alters hormone receptor expression	Abundance, distribution and degradation of hormone receptors
KC4	Alters signal transduction in hormone-responsive cells	Abundance of post-translational modifications, cofactors, transcription factors and transcripts, and activity of associated enzymes
KC5	Induces epigenetic modifications in hormone-producing or hormone-responsive cells	Chromatin modifications, DNA methylation and non-coding RNA expression
KC6	Alters hormone synthesis	Expression or activity of enzymes or substrates in hormone synthesis
KC7	Alters hormone transport across cell membranes	Intracellular transport, vesicle dynamics or cellular secretion
KC8	Alters hormone distribution or circulating hormone levels	Blood protein expression and binding capacity, blood levels of pro-hormones and hormones
KC9	Alters hormone metabolism or clearance	Inactivation, breakdown, recycling, clearance, excretion or elimination of hormones
KC10	Alters fate of hormone-producing or hormone-responsive cells	Atrophy, hyperplasia, hypertrophy, differentiation, migration, proliferation or apoptosis

OECD, Organisation for Economic Co-operation and Development; TG, test guideline; US EPA, US Environmental Protection Agency. Only assays that serve as the basis of regulatory decisions of the OECD and US EPA are provided.

Figure 7. Depiction of 10 key characteristics of EDC that can be used for early or even pre-authorisation screening of EDC substances for regulatory purposes. Reproduced from²².



Present and future human health protection from EDC: challenges for India

India is an industrialised developing country, hosting important chemical industries. It is also a global hub for food production, where traditional farming practices and food choices are being rapidly substituted by contemporary food systems where chemicals play a key role in both food production and preservation. **The upcoming Indian chemical management regulations (i.e. the Chemical Management and Safety Rules (CMSR)) have the potential to represent a guiding document for chemical management of emerging developing countries and beyond.**

Environmental protection, and therefore food protection, from chemical pollution in India presents several challenges. As an emerging economy, India is a recipient of national and international investment focused on industrial relocation (including for the chemical industry). Expanding domestic markets, increased consumption and demand for export, together with less restrictive environmental controls can favour rapid industrialisation and a concrete risk of a double standard in environmental and human protection regulation, where manufactures and products considered obsolete in the developed work are transferred and traded here. Such a phenomenon has been observed, for example, in chemical markets where pesticides ruled out in Europe are traded and used in the developing world.

Climate change represents another concern for Indian food security, with India being one of the most exposed and sensitive countries to its consequences. **Indian food systems will increasingly face direct and indirect climate-related stress, demanding measures for protection of crops and produce.** The chemical industry can play a key role in such adaptation, for example, by providing assets for plasticulture to fight droughts and for seed and produce preservation, and pesticides for crop protection and food preservation. Considering these peculiarities, the CMSR will necessarily strive to keep India an attractive manufacturing region and market for national and international investors. It will also be designed to enable a broad margin for innovation and operational space in the chemical and food sector. At the same time, it will have to guarantee that such an operational space will unfold while safeguarding the environment and the health of present and future generations. India can use the opportunity of the new CMSR to frame a regulation that, before others, considers the most recently developed knowledge and scientific consensus on the role of EDCs as a persistent and serious pressure on public health, assimilating the notion and criteria of the KC.

There are various legislations for chemical management in India, but very few regulate chemicals based on their specific properties, such as EDCs. The regulations and policies that indirectly regulate EDCs are either non-binding with no legal obligations of compliance, fragmented, or very issue-specific. **[The new CMSR can and will make a major statement on EDCs adopting new science-based criteria for their early identification as priority substances for restriction or ban].** The integration of EDC criteria in the EU REACH regulation is an example which India may want to follow, to take knowledge-based policy decisions for effective management of EDCs, whereby such knowledge is now available from the recent consensus on the use of KCs.

Specific tolerance limits and standards for many important EDCs in food, water, and consumer products are absent in the Indian legislative system. Moreover, the available limits that exist for a few EDCs are based on the application in selected consumer products and are mostly based on the standards established in developed countries. These safety thresholds can be readily transferable to India (although tuning is required to match local conditions, food basket composition etc., as demonstrated by the results of the EDIFY project). In defining food quality standards for chemical residues, regulation in India should also take into consideration that health implications are typically greater in vulnerable populations with limited access to medical care and those who are already facing poor living conditions. Therefore, the prescribed tolerance limits may be lower than those perceived, or those set to protect people in Europe or North America. This highlights the relevance of supplementing international scientific data with specific Indian data to be able to develop robust policies.



Policy recommendations

A substantial part of endocrine-disrupting potential in the diet derives from food and animal feeds internationally traded between developed and developing countries. **With increasingly globalised food systems, internationally harmonised policies on EDCs in food can lead to better protection of health in both these contexts. Protecting human health from EDCs links directly to food safety management, and in turn, is tightly connected with the preservation of safe and productive agricultural landscapes. The following policy recommendations elaborated during the development of the EDIFY project are proposed, keeping in mind such a holistic perspective.**

1 Acknowledge the general scientific consensus on EDCs as a threat to health and the environment

EDCs have been identified as a global health threat by the World Health Organisation¹. Experts around the world have arrived at a consensus that it is imperative to manage EDCs by enhancing knowledge, increasing public awareness, improving testing facilities, controlling sources, and reducing exposures to the extent possible. This will help both to reduce the vulnerability to related diseases and create an enabling environment for improving research, innovation, and scientific enhancements. In alignment with the global advancements on understanding EDCs, the Indian Government should make concerted efforts to enhance domestic scientific knowledge of the life cycles, environmental exposure, and effects of EDCs, identify measures and gaps on existing and potential EDCs, and hence create a specific policy framework to manage these chemicals for better public health, especially in the context of food safety and life cycle components of the food systems.

2 Draw on existing initiatives and learned lessons

To tackle the problem of EDCs, India may benefit significantly by drawing on and expanding the existing initiatives. The upcoming CMSR and its categorisation of EDCs as a hazard may be further expanded to include a broader range of well-known EDCs, such as those indicated by the Endocrine Society, or by generating new comprehensive lists of EDCs through the adoption of EDC-identification criteria, such as those elaborated by EFSA, those inherent to the KC approach (described above), along with the systematic adoption of regulatory testing based on the OECD guidelines. Another accessible option which may mean a leap forward to EDC management would be to advance ratification and implementation of the Stockholm and the Minamata Conventions, both covering a wide range of EDC chemicals.

3 Reduce the disconnect between policy and scientific advancements

Through reaching a consensus and proposing the concept of EDC KCs, the scientific community has posed a major milestone to enable a pragmatic, yet holistic, regulatory frame to be elaborated for EDCs. Another example of guidelines for the evaluation of EDCs are those under elaboration by EFSA in the EU²³. Adopting KCs as criteria for classification of chemicals as EDC before they enter the market is the way to enable a reasonable and science-informed precautionary approach. India could be the first country to systematically introduce such criteria and directly regulate chemicals for their inherent properties as EDCs. This adoption would turn India's chemical management into an exemplary beacon for chemical management in the global context.

4 Establish capacity for monitoring of chemical contaminants in food

India will develop capacity and adopt a routine national monitoring plan to track occurrence and temporal trends of EDCs in food. Monitoring food is a proxy for evaluating the general quality of the environment. In an initial stage, the monitoring programme could focus on one or several reference case studies (such as the EDIFY project implemented in Delhi and Dehradun). However, the ambition should be to have a full-scale regional level resolution to enforce effective health protection and a warning system for hotspot contamination cases. Beyond the obvious benefit of better public health, such high-level quality control will substantially increase the credibility and competitiveness of India in the international food and feed trade market, with direct benefits for economic development.

5 Strengthen institutional capacity

State governments in India play a key role in setting and implementing food safety regulations through the involvement of science, technology, logistics and management aspects to make the "safe food supply system" work at all levels. It is crucial to set up or enable research and laboratory facilities like the well-equipped state laboratories to detect the EDCs in food. Also, it is very important to enhance and further develop the knowledge and capacity of the concerned officials in the state agencies on the emerging issues, and thereby facilitate the prevention of EDC contamination in the food supply chain. Such capacity-building initiatives could involve the vital and dynamic small- and medium-size enterprise sector in India, as a resilient, adaptable, and dynamic system, capable of rapid assimilation and innovation.

6 Strengthen risk assessment and management systems

The Food Safety Standards Act (FSSA), 2006 of India lays down science-based food quality standards to regulate the manufacture, storage, distribution, sale, and import of food, and to ensure availability of safe and wholesome food for better public health. The Food Safety and Standards (contaminant, toxins, and residue) Regulations 2011 of the FSSA Act have prescribed limits to various chemicals in food. A first and urgent step in food regulation in India is to introduce quality standards for a set of substances already recognised as hazardous EDCs and prioritise regulatory assimilation of standards for suspected and newly identified EDCs. For instance, dioxins and furans in the diet clearly represent a concern for health, but the Indian regulations have not yet prescribed or updated the standards for these chemicals. The Food Safety and Standards (contaminants, toxins and residue) Regulations 2011 therefore need to be updated based on the global benchmarks. This regulatory framework should stand on a solid and truly independent national risk assessment system, empowering, for example FSSAI, in defining nationally tailored guidelines and to provide independent expert judgement to public and private stakeholders.

7 Consider promotion of quality labelling systems for EDCs in food

Data from routine monitoring can help ranking food items within the main cluster of food typology (e.g. fruit, cereals, meat, diary) for the level of EDC they typically contain. This information could be used to define dietary recommendations and a quality labelling system for EDCs in food. Such a labelling system would, in particular, be a novelty in the international landscape of policy instruments for food safety, and a potentially effective system to gently guide consumers or groups of citizens towards health-preserving consumption choices. Different options are available in principal to enable this:

- i) An EDC food quality label targeted specifically on the protection of health of children and women of childbearing age.** Implementing a routine monitoring of recognised and suspect EDCs in food in India will provide sufficient information to confidently identify food items with typically higher residues of EDCs. A first-tiered labelling system for EDCs in food could be based on creating a quality label and/or a systematic information campaign that can help vulnerable groups to adopt precautionary safer choices in their diet, during the stages of life that make them more vulnerable to EDC-related adverse health outcomes.
- ii) A general quality label for ranking food products by EDC content.** A more ambitious approach to labelling “low-EDC-content” food could be the introduction of a ranking system for food items based on their relative ranking (among other products) as carrier of EDCs in the average Indian diet. Neither the list of EDCs is fully consolidated, nor is the knowledge of their chronic or transgenerational effects adequate. Hence, such a ranking and label would inherently be adaptive and evolving as knowledge of new EDCs, their level in food, and knowledge of their toxicity, develops over time. The label could carry information for EDCs divided into group of substances (e.g. POPs, Plasticisers, CUP, heavy metals). Such an adaptive approach (similar to that used for defining the energetic efficiency) would enable the market to promote better food quality “from farm to fork”, as consumers and producers will tend to privilege safer food and better food production practices.

It is important to realise that maintaining a trustable food labelling system such as the one described in point (ii), requires a robust control system and an active participation from the food industry and food traders.



Figure 6. An example of a possible food safety labelling system for EDCs. Individual food typologies are ranked among items belonging to the same group (fruit, vegetables, diaries, cereals, meat, fish) based on their EDC content. A high number of stars signals food with lower content of a given group of compounds.

8 Adopt a holistic risk reduction approach

EDCs cause contamination of the food chain and the environment. A successful reduction of residues of EDCs in food does not only depend on improved food production systems. Reducing sources and protecting the environment from EDC contamination is a key step towards safer food. EDCs need to be managed at source with suitable preventive measures. Therefore, a general chemical management regulation that inherently prioritises controls and measures on identified and potential EDCs in different economic sectors and applications will also improve food safety. Regulatory actions taken in India on BPA, Endosulfan, DDT, mercury and Triclosan represent notable examples of pilots for management of EDCs. However, gaps in implementation and jurisdiction of these regulations can hinder the efficacy of well-intended policies. The regulation of BPA and mercury has been dealt with by considering individual uses of these chemicals, rather than through a holistic life cycle approach. For example, mercury containing lamps is not being adequately dealt in the regulations, and BPA is still being used in thermal paper and other items on a large scale, limiting the impact of its ban in other applications.

9 Creating a research agenda to protect public health

Various research studies on the different aspects of EDCs have been conducted globally as well as in India. When compared to the global scale of research on EDCs (including Asian countries like China), the number of research studies in India is comparatively scarce. Also, very few studies have been conducted on the presence and interlinkages of EDCs in food in India. It is imperative for Indian research institutions to carry out advanced research on EDCs in order to generate robust datasets for strengthening the policy framework and regulatory mechanisms in the country. This effort needs to be supported by a consistent expansion of institutional and private sector capacity in conducting analysis and research on chemical contamination.

10 Considering SDGs

The occurrence, risks and management of EDCs provide insights into the key aspects of environmental sustainability (pollution control, best practices), economic prosperity, and public health protection (disease control, regulated exposure), which are inevitably interlinked with the achievement of many of the United Nations Sustainable Development Goals (SDGs). The interlinked SDGs include Goal 1 (No Poverty), Goal 2 (Zero Hunger), Goal 3 (Good Health and Well-being), Goal 6 (Clean Water and Sanitation), Goal 7 (Affordable and Clean Energy), Goal 8 (Decent Work and Economic Growth), Goal 11 (Sustainable Cities and Communities), Goal 12 (Sustainable Consumption and Production), Goal 14 (Life Below Water), Goal 15 (Life on Land), and Goal 17 (Partnerships for the Goals). Voluntary public-private partnerships (PPPs) play a significant role in different sectors, contributing towards attaining the SDGs globally. Efficient PPP models – including spontaneous bans or substitution of chemicals by industries, or the voluntary development of food quality labels for EDCs by industries – can be used to ensure improved infrastructure in the food processing sector in India, and minimise trade barriers to meet the increasing need for healthy and safe food products.



Publications

Peer reviewed scientific articles emerging from EDIFY

1. Chakraborty, P., Bharat, G.K., Gaonkar, O., Mukhopadhyay, M., Chandra, S., Steindal, E.H., Nizzetto, L., 2022, Endocrine-disrupting chemicals used as common plastic additives: Levels, profiles, and human dietary exposure from the Indian food basket. *Sci Total Environ.*, 810, 152200. <https://doi.org/10.1016/j.scitotenv.2021.152200>
2. Chakraborty, P., Sampath, S., Mukhopadhyay, M., Selvaraj, S., Bharat, G.K., Nizzetto, L., 2019, Baseline investigation on plasticizers, bisphenol A, polycyclic aromatic hydrocarbons and heavy metals in the surface soil of the informal electronic waste recycling workshops and nearby open dumpsites in Indian metropolitan cities, *Environ. Pollut.*, 248, 1036–1045. <https://doi.org/10.1016/j.envpol.2018.11.010>
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5. Sharma, B.M., Bharat, G.K., Chakraborty, P., Martiník, J., Audy, O., Kukučka, P., Příbylová, P., Kukreti, P.K., Sharma, A., Kalina, J., Steindal, E.H., Nizzetto, L., 2021, A comprehensive assessment of endocrine-disrupting chemicals in an Indian food basket: Levels, dietary intakes, and comparison with European data, *Environ. Pollut.*, 288, 117750. <https://doi.org/10.1016/j.envpol.2021.117750>
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7. Steindal, E.H., Furst, K., Noklebye, E., Drives and Obstacles for Regulating Endocrine Disrupting Chemicals in India: The cases of BPA in baby feeding bottles and phthalates in toys and childcare products, In preparation.

Other non peer reviewed publication emerging from EDIFY

1. Mohapatra, P., Rajankar, P., Dubey, A., 2021, EDCs and Food, Policy and research review on endocrine disrupting chemicals in food, *Toxics* Link, Delhi.

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Annexures

Annexure 1

Common EDCs, their uses and health impacts

SNo	Common EDCs List	Uses	Known Health Impacts
1	Bisphenol-A	Monomer for polycarbonate plastics, epoxy resins, flame retardants, DVDs, electronic equipment; Lining of drinking water pipes, thermal and carbonless paper coatings ²⁴	Heart diseases Liver toxicity Anxiety Miscarriage of foetus Metabolic syndrome (diabetes obesity) Disruptive effects in androgen- or oestrogen-responsive tissues within the immune system, thyroid, and the developing nervous system
2	Triclosan	Paints, Personal care products, Preservative for rubber, textile and paper products ²⁵	Disrupts steroidogenic enzymes involved in the production of testosterone and oestrogen Could lead to reduced reproductive success in both males and females ¹
3	Phthalates	Plasticisers, Vinyl flooring, Lubricating oils, Personal care products ²⁶	Endocrine and reproductive dysregulation Endometriosis Infertility Altered foetal development Breast and skin cancer Obesity, type II diabetes Attention-deficit hyperactivity disorder Autism spectrum disorders Cardiotoxicity Hepatotoxicity Nephrotoxicity Asthma and allergy ²⁷
4	Mercury	Healthcare instruments, Dental amalgam, CFL and other lighting equipment, Paints, Cosmetics ²⁸	Mercury vapour is harmful for nervous, digestive and immune systems Inorganic salts of mercury are corrosive to skin, eyes, and gastrointestinal tract Kidney toxicity ²⁹
5	Polychlorinated Biphenyls (PCBs)	Electrical, heat and hydraulic equipment, Plasticiser, Pigments, dyes, carbonless copy paper ³⁰	Fibroids Endometriosis Immune dysfunction Increased risk of diabetes Reduced cognitive function in children ¹

SNo	Common EDCs List	Uses	Known Health Impacts
6	Deca BDE	Textiles, Flexible polyurethane foams, Electronic equipment, Plastics used in casing of televisions, Personal computers ³¹	Neurological impact(headaches) Development of allergy
7	Penta BDE	Carpet padding, imitation wood, sound insulation panels, small electronic parts, fabric coating, epoxy resins, conveyor belts	Reproductivity Neurodevelopment
8	Octa BDE	Casing for fax machines, computers, automobile trim, telephone handsets, remote control products	Increased liver weights Immunotoxicity Neurotoxicity
9	Lindane	Organochlorine pesticide, Certain prescription-only shampoos, Topical lotions used to treat pediculosis and scabies ³²	Irritation of nose, throat Effects on blood, skin Effects on nervous system (convulsions) Vomiting and nausea Effects on cardiovascular and musculoskeletal systems Effects on liver, kidney, immune and nervous systems ³³
10	Methoxychlor	Methoxychlor is used as an insecticide against biting flies, houseflies, mosquito larvae, cockroaches, and chiggers ²⁴	Detrimental to reproductive health Negative impacts on central nervous system and digestive tract Affects kidneys, lungs, eyes, and skin
11	Chlorpyrifos	Organophosphorus insecticide ³⁴	Runny nose, increased saliva/drooling, tears Headaches, nausea, dizziness Vomiting, abdominal cramps Muscle twitching, tremors, weakness Loss of coordination ³⁴
12	Dichlorodiphenyltrichloroethane (DDT)	Insecticide	Endometriosis Disruption of ovarian cyclicity Increased risk of breast cancer, leukaemia, lymphoma Obesity risk with perinatal exposure ¹
13	Endosulfan	Insecticide Wood preservative ³⁵	Impaired memory Anatomical deformities
14	Dioxins	It is a contaminant formed during the production of some chlorinated organic compounds ³⁰	Reproductive and developmental problems Damage to immune system Interferes with hormones and also causes cancer ³⁶
15	Furans	Created when products like herbicides are made	<ul style="list-style-type: none">• Cancer• Changes in hormone levels• Skin diseases like chloracne

Annexure 2

Partial chronology of international policy developments and public advocacy on EDCs

<p>2009. For the first time ever, the Endocrine Society released a public statement on the state of EDC science titled “Scientific Statement on EDCs”. The Society released the Statement of Principles on EDCs and Public Health Protection (2012), letters to the European Commission (March 2013), and to the Secretariat of the Strategic Approach to International Chemicals Management (SAICM, June 2013) promoting “science-based action on EDCs” for better management.</p>
<p>In November 2009, the American Medical Association (AMA) decided to work with the US federal government to decrease the public’s exposure to EDCs for improved regulatory oversight of EDCs based on “comprehensive data covering both low-level and high-level exposures”.</p>
<p>In November 2009, the American Public Health Association called for “a precautionary approach to reducing American exposure to endocrine-disrupting chemicals.</p>
<p>2012-2015. The American Chemical Society issued a policy statement on testing for endocrine disruption, and focusing on better education and research, improved testing protocols, and the development of safer alternatives to EDCs.</p>
<p>In February 2013, the World Health Organisation and the United Nations Environment Programme launched a report on the state of the science of EDCs (2012) that recommended improved testing and reduced exposures to EDCs.</p>
<p>In 2013, the Collegium Ramazzini (international academy) released a statement on EDCs in the EU calling for the expansion of the scope of the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) legislation and inclusive assessment of scientific evidence in regulatory decision-making.</p>
<p>In 2013, the Berlaymont Declaration was issued expressing concern over EDCs and calling on the European Commission for improved management of EDCs.</p>
<p>In October 2013, the American College of Obstetrics and Gynaecology and the American Society of Reproductive Medicine issued a statement calling for “timely action to identify and reduce exposure to toxic environmental agents”</p>
<p>In 2013, the British Royal College of Obstetrics and Gynaecology issued a Scientific Impact Paper on chemical exposures during pregnancy.</p>
<p>In 2013, the International Conference on Children’s Health and Environment issued a Jerusalem Statement on its “commitment to protect children’s health from environmental hazards.”</p>
<p>In December 2013, many countries as signatories of the UNEP Stockholm Convention on POPs (SC) - including India - expressed their intention to use DDT (for actual or proposed production). The SC banned or drastically restricted global use of DDT in 2004 including for disease vector control.</p>
<p>In December 2013 the SC banned the Polybrominated diphenyl ethers (PBDEs) with specific exemptions that allow for their presence in products made of recycled materials.</p>
<p>In 2021, the US EPA developed the Endocrine Disruptor Screening Program Test Guidelines (in vitro and in vivo) intended to meet testing requirements of Federal Food Drug and Cosmetic Act (FFDCA) to determine if a chemical substance may pose a risk to human health or the environment due to the disruption of the endocrine system.</p>

In February 2014. the European Chemical Agency (ECHA) established the Endocrine Disruptor Assessment Process and the Endocrine Disruptors Expert Group with the support of the competent authorities for REACH and CLP (CARACAL) and the competent authorities for biocides. The expert group provides informal and non-binding scientific advice on matters related to the identification of endocrine-disrupting properties of chemicals, in particular:

- Matters related to screening methods or activities to identify potential endocrine disruptors
- Matters related to the development of integrated approaches to testing and assessment of endocrine-disrupting properties
- Feedback and recommendations on complex (specific/generic) scientific issues related to information and (tiered) testing needs for potential endocrine disruptors (e.g. under dossier or substance evaluation, or under biocidal active substance evaluation)
- Specific questions on the interpretation of test data or other relevant information in relation to the identification of endocrine-disrupting properties.

In December 2017, EU national representatives voted in favour of a new draft regulation, setting criteria for the identification of endocrine disruptors in the context of the pesticides legislation. The criteria for biocidal products were published and entered into force on 7 December 2017. They applied from 7 June 2018 to all new and ongoing applications for biocides. Guidance and criteria are available at: <https://www.efsa.europa.eu/en/efsajournal/pub/5311>

Since the 1990s, the OECD has developed a comprehensive programme of test guidelines and tools to support countries’ needs related to testing and assessment of chemicals for endocrine disruptor properties ³⁷. The programme includes more than 150 standardised test guidelines, provides a system to avoid costly duplicative testing, and is available to members and key partners. India is a key partner to the programme that adheres to the Mutual Acceptance of Data (MAD) and may take full advantage of all data, guidance, and support ³⁷.

List of different regional/national regulatory frameworks dealing directly or indirectly with some EDC substances

Region/Country	Framework on EDCs
Europe (EU)	REACH Plant Protection Product Regulation The Biocidal Products Regulation The Water Framework Directive
United States of America	Regulatory framework on pesticides Regulatory framework on drinking water contaminants Regulatory framework on new drug approval
Canada	Canadian Environmental Protection Act (CEPA) Regulatory framework for pesticides under the PCPA (Pest Control Products Act) Food and Drugs Act (F&DA)
Brazil	Regulatory framework on pesticides Initiative to establish a national legislation on industrial chemicals
China	13 th Five-Year Plan of National Environmental Protection Industry standard on evaluation methods of endocrine disruption effects of pesticides
Korea	Korean Regulation on the Registration and Evaluation of Chemicals (K-REACH)
Australia	National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Current EDCs regulations by substance or group of substances in India and comparison with international food safety regulatory context

Substances	Regulations
Bisphenol-A (BPA)	The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (IMS Act), amended in 2003, mandates that all the baby feeding bottles to be sold in India should meet the standard IS-14625 of the Bureau of Indian Standards (BIS). The BIS revised the standard for baby feeding bottles in 2015, stating that BPA will not be used in these applications. Only virgin Polycarbonate is allowed for baby feeding bottles. Olefin based polymers have been included as material for manufacture of feeding bottles. BPA is also suggested to be phased from cup, spout, and straws in India. India has no specific regulation for BPA nor any prescribed TDI limits for food items.
Triclosan	BIS standards for cosmetics raw materials & adjuncts, in India maximum authorised concentration (MAC) of Triclosan as preservatives in cosmetics is 0.3%
Phthalates	The BIS mandates that Phthalates in toys and childcare articles should align with the Phthalate limit in other countries including the United States, Canada and the EU which stipulates not more than 0.1% of each banned Phthalate (U.S. Consumer Product Safety Commission guidelines). Earlier, the level of Phthalates in toys was limited to 0.1% for a total of three Phthalates (DEHP, DDP and DBP or DINP, DIDP, and DNOP) and not for each individual. The BIS has proposed to restrict the use of Phthalates (as well as toluene, titanium, acetylacetone) in the printing of packaging materials used for food products. These chemicals are to be included in the existing exclusion list of IS 15495.
Mercury and other toxic metals	In 2011, the Indian Food Safety and Standards Authority of India (FSSAI) has introduced the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 determining the safety standards for a range of contaminants including total mercury and methyl mercury for a range of food items ³⁸ .
Polychlorinated biphenyls (PCBs)	The Stockholm Convention (ratified by India) banned the production and use of PCBs. However, it states that the existing equipment contaminated with PCBs may continue to be used until 2025. In India, the manufacture, import and export of PCBs and PCB containing equipment or trade of PCB contaminated equipment is regulated as per the provisions of the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008. The use of PCB in any form will be completely prohibited by December 31, 2025. FSSAI has introduced safety standards for PCBs setting maximum residual limits in different types of fish products.
PBDE	As party in the Stockholm Convention, India is phasing out PBDE There is currently no regulation in India on Deca-BDE related in food products.
Methoxychlor	The use of Methoxychlor as a currently used pesticide (CUPs) was banned in the European Union in 2002 and in the United States in 2003. India does not have specific standards or regulation for Methoxychlor and it has not been registered as a pesticide.
Chlorpyrifos	The currently used pesticide, Chlorpyrifos, in food in India is regulated through Food Safety and Standards (contaminants, toxins and residues) Regulations, 2011.

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Substances	Regulations
Dioxins and furans	In India, there are standards for industries and incinerators on release of dioxins and furans into the environment, but there is no regulation on dioxins/ furans standards in food.
Parabens	Parabens are esters of para-hydroxybenzoic acid. BIS IS4707 (Part 2) 2009 has regulations on Parabens, which are used as raw materials and adjuncts in cosmetics. The maximum authorised concentration (MAC) for parabens in cosmetic products is 0.4% for a single paraben and 0.8% for a mixture of parabens.
Triclocarban	Triclocarban is used as an antimicrobial agent and a raw material in cosmetics. BIS of IS 4707(Part 2): 2009 has regulations on Triclocarban, which is allowed only in rinse-off products. The MAC in the finished product is 1.5% of the product while as a preservative, the MAC is 0.2%.
Di-Ethanolamine	Diethanolamine is banned in raw material of cosmetics under the BIS of IS 4707(Part 2): 2009
Pesticidal POPs	FSSAI has introduced safety standards for PCBs, DDTs, Lindane, setting maximum residual limits in different types of food products. In 1989, the Government of India withdrew the use of DDT in agriculture. But the use of DDT is restricted for disease vector control related to certain human diseases (malaria, leishmaniasis, dengue). DDT is covered under the Insecticides Act, 1968 and 1971 of the Ministry of Agriculture, Government of India. In 2010, the use of Endosulfan was banned in the State of Kerala. The Supreme Court of India has put an interim order to ban the manufacture, sale, use, and export of Endosulfan throughout the country from May 13, 2011, but later allowed export of the chemical produced before the ban was in place. However, reports indicate that the implementation of the Supreme Court order has not been totally met.



EDIFY - Endocrine disruptors in Indian food: minimizing children exposure and fostering a safer space for agriculture and food market

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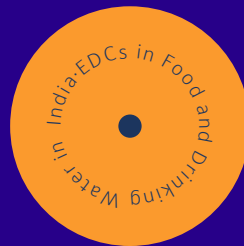
Summary
Research on environmental contamination shows that India might be a hotspot for endocrine-disrupting chemicals (EDCs), a class of chemical contaminants that can produce adverse health effects following chronic exposure at very low concentrations, especially when exposure occurs during the foetal stage and in the early stages of human development. Several EDCs can be transmitted from mother to child during pregnancy and lactation. While this issue has been centralised in scientific, societal and policy debates, the impacts of EDCs on public health are not sufficiently understood, owing to the difficulties of establishing clear causal relationships between exposure and health in a context of multiple stressor. Internationally, these uncertainties cause delays in taking concrete regulatory actions. Diet is a main determinant of people’s health and a very important pathway for exposure to EDCs. The research project EDIFY (Endocrine Disruptors in Indian Food: minimising children exposure and fostering a safer space for agriculture and food market) was conceived to provide a first holistic overview on the levels of EDCs in the Indian diet and a comparative analysis of current health protection policies. This document summarises the results of this research effort and primarily targets policymakers in India and societal actors with a stake in chemical management, food production and distribution. The objective is to raise awareness and inspire the development of policy and innovation in food production, aiming for a diet with lower levels of EDCs.

Four keywords	Fire emneord
1. Endocrine Disrupting Compounds	1. Hormonforstyrrende forbindelser
2. Food safety	2. Matsikkerhet
3. Chemical Management	3. Kjemisk håndtering
4. POPs	4. POP

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