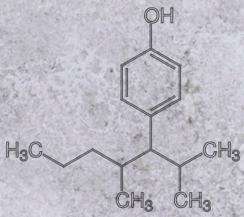
Toxics Link
for a toxics-free world

UNWRAPPING THE TRUTH

Review of Endocrine disruptors in Food Packaging Material



About Toxics Link

Toxics Link is an Indian environmental research and advocacy organization set up in 1996, engaged in disseminating information to help strengthen the campaign against toxics pollution, and to provide cleaner alternatives. We work with other groups around the country as well as internationally in an understanding that this will help bring the experience of the ground to the fore, and lead to a more meaningful articulation of issues. Toxics Link engages in the emerging issues of highly hazardous pesticides (HHPs), Persistent Organic Pollutants (POPs), hazardous heavy metal contamination, pharmaceutical pollutants etc. from the environment and public health point of view. We also work on ground in areas of municipal, hazardous and medical waste management and food safety among others. We have successfully implemented various best practices and have brought in policy changes in the aforementioned areas apart from creating awareness among several stakeholder groups.

Our work on Endocrine Disrupting Chemicals (EDCs) management has spanned over a decade, entailing significant diverse body of work such as country specific research data, policy engagement, involvement in setting standards, and capacity building of all stakeholders.

Acknowledgment

We take this opportunity to thank all those who were instrumental in compiling and shaping this report.

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Abbreviations

ADHD	Attention-deficit/hyperactivity disorder
ADI	Average Daily Intake
APs	Alkyl phenols
APEs	Alkyl phenol ethoxylates
BBP	Benzy butyl phthalates
BIS	Bureau of Indian Standards
BP	Benzophenone
BPA	Bisphenol-A
Bw	Body weight
CAGR	Compound annual growth rate
CDCs	Centers for Disease Control and Prevention
CPSC	Consumer Product Safety Commission
DEHP	Di(2-ethylhexyl) adipate
DiNP	Diisononyl phthalate
DiBP	Diisobutylphthalate
ECHA	European Chemicals Agency
EDCs	Endocrine disrupting chemicals
EFSA	European Food Safety Authority
ER	Epoxy resins
EU	European Union
FCM	Food contact materials
FDA	Food and Drug Administration
FERA	Food and Environment Research Agency
FPM	Food packaging materials
FSSAI	Food Safety and Standards Authority of India
FTOH	Fluorotelomer alcohols
FTSH	Fluorotelomer thiols
IARC	International Agency for Research on Cancer
IPCS	International Programme for Chemical Safety
KFDA	Korea Food and Drug Administration
µg	Microgram
NIAS	Non-intentionally added substances
NP	Nonylphenol
NPE	Nonylphenol ethoxylates

OP	Octylphenol
OML	Overall migration limit
OPEs	Octylphenol ethoxylates
PC	Polycarbonates
PE	Polyethylene
PET	Polyethylene terephthalate
PFAS	Per-and polyfluoroalkyl substances
PFHxA	Perfluorohexanoic acid
PFOS	Perfluorooctaine sulfate
POPs	Persistent organic pollutants
PP	Polypropylenes
PVC	Poly vinyl chloride
PVA	Polyvinyl acetate
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	Reference dose
SAICM	Strategic Approach to International Chemical Management
SMLs	Specific migration limits
SVHC	Substances of Very High Concern
TDI	Tolerable daily intake
TNPP	Tris (nonylphenol) phosphite
UNEP	United Nations Environment Programme
USD	US Dollar
UV	Ultraviolet
WHO	World Health Organization


Sweet
Paprika
turmeric
Nutmeg

Overview

Food packaging is essential for storage, preservation, and transportation of food and beverages. The most common materials use for food packaging are paper and board, metal, glass, different types of plastic polymers, and various multilayer materials. Packaging also provides information to the consumer such as nutrition facts label, product identification, ingredient declaration, net weight, manufacturer details and other information about food being offered for sale. Apart from the base food packaging materials, there are other chemical ingredients being used in these packaging materials. These chemicals have multiple purposes including prevention of corrosion of the container, spoiling of the foods etc. However, many of these chemicals are known EDCs and their health impacts are well documented. Further, the food packaging materials are not disposed in an environmentally sound manner as a result the chemicals are leaching out and contaminating the ecosystem.

The report has been prepared based on the most published research studies and data from India and across the globe. Moreover, the study has also pointed out the gaps and challenges on the management of EDCs in packaging material and the critical need to manage these chemicals at the upstream and downstream level considering the recycling potential of the food packaging materials and the growing thrust on the circular economy. The study has identified all the EDCs linked with the packaging materials and the alternative available those can replace these EDCs.


2,29
0,99

1. FOOD PACKAGING MATERIALS (FPMs)

1.1. Introduction

Food packaging materials applies to the material in which foods are packaged and stored. These are designed and used to delay product deterioration, prolong shelf-life, and preserve the quality & safety of food. The layer that is in direct contact with the food or beverages is called “food contact material”, it applies to all the materials that come into contact, either during storage, processing and filling, or consumption like cooking utensils.

In recent decades, packaging and containers have become an important component in food industry not just for transportation and storage but also to provides information to the consumer such as product identification, ingredient declaration, nutritional facts label, net weight, manufacturer details and other information about food being offered for sale. It also acts as a modern marketing medium for manufacturers and sellers to attract consumers worldwide. Based on technical requirements throughout the supply chain and marketing needs, food packaging materials comes in many different forms. The applications of food packaging include bakery, confectionery, dairy products, convenience foods, sauces, dressings, condiments, fruits & vegetables, meat, fish & poultry, and others.

Items used for food packaging

Aluminum

Plastic

Cardboard

Glass containers and jars

The purposes of packaging are:

- To contain foods (to hold the contents and keep them clean and secure without leakage or breakage until they are used).
- To protect foods against a range of hazards during distribution and storage (to provide a barrier to dirt, micro-organisms and other contaminants, and protection against damage caused by insects, birds and rodents, heat, oxidation, and moisture pickup or loss).
- To give convenient handling throughout the production, storage and distribution system, including easy opening, dispensing and re-sealing, and being suitable for easy disposal, recycling or re-use.
- To enable the consumer to identify the food, and give instructions so that the food is stored and used correctly.

Food Contact Articles: the actual articles that contain or wrap food, e.g., burger wrap, yogurt cup, juice bottles etc.

Food Packaging Materials: the materials used in the articles e.g., plastics, paper, cardboard, tin etc.

Food Contact Chemicals: the chemicals used to make food contact articles and leaches to the food e.g., monomers such as BPA, additives such as Phthalates, PFAS etc.

1.2. Market Overview

The food packaging market is driven by the growing need to prevent food counterfeiting. According to the market report the global food packaging market size is expected to reach USD 456.6 billion by 2027, expanding at a CAGR of 5.2% over the forecast period. The report also mentioned that the fastest growing sector would be paper and paper-based packaging and will exhibit a CAGR of 6.1% from 2020 to 2027, due to its low cost and sustainability parameters.

The Packaging Industry Association of India (PIAI) had valued the India Packaging Market at $50.5 billion in 2019, and expected it to reach $204.81 billion by 2025, registering a CAGR of 26.7% from 2020 to 2025. According to the Directorate General of Commercial Intelligence and Statistics & Department of Commerce (India), the value of paper and paperboard packaging products (comprising folding cartons, corrugated boxes, paper bags, and liquid paperboard) exported from India valued USD 1,998.26 million in 2021.

India is a growing hub for manufacturer and there are about 700 packaging manufacturers in India and 95% of them are classified as being a small-to medium-sized operation.

This rapid growth in the industry majorly exhibits the increasing urban population and their attraction toward ready-to-eat meals. Since COVID demand for single-serve and portable food packs has increased significantly. The increased sales in e-commerce platforms also expected to spur the demand for food packaging. However, with increasing demand of packaging materials risk of exposure to harmful chemicals that leached out of these packaging materials is also increasing.

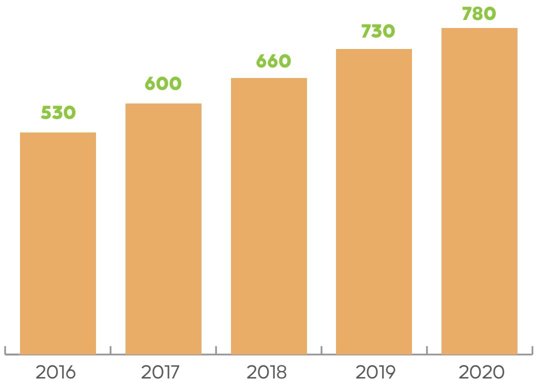


Figure 1 Market size of organized packaged food, in INR million, India, 2016-2020

Source: The Associated Chambers of Commerce & Industry of India

1.3. Types Of FPM

Based on the materials, there are different types of segment in the food packaging industry which include paper & board, rigid & flexible plastic, glass, metal. Many traditional polymers, such as poly vinyl chloride (PVC), polyvinyl acetate (PVA), polyethylene (PE), polypropylenes (PP) and polycarbonates (PC), are the main components of plastics based FCM.

However, it is often difficult to know about all the components of complex packaging materials since several entities are involved in its manufacturing including the polymer producer, additives producer, manufacturer and converter. Also there is no guidelines to enforce mentioning of polymers/additives on the packaging materials.

In India the FPM sector is majorly driven by growth in the paper & board packaging, which is forecast to register the fastest volume CAGR of 7.8% during 2019-2024. The category is followed by rigid metal, which is expected to record a CAGR of 7.1% during the next five years.

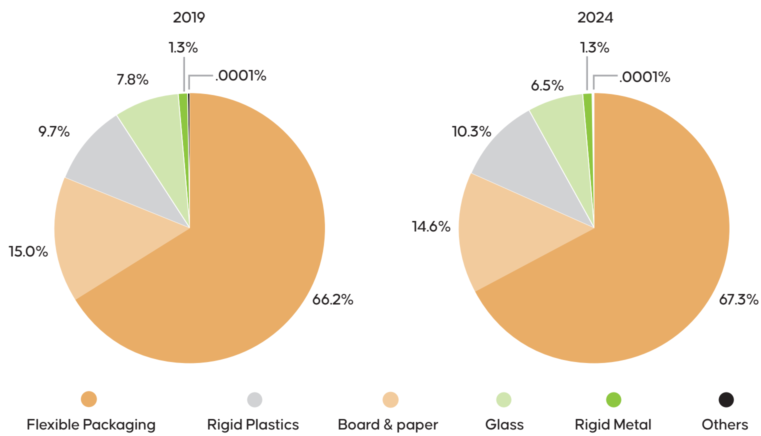


Figure 2 Volume share (million units) of key pack materials in Indian packaging industry.

Source https://www.manufacturingtodayindia.com/sectors/9250-indias-packaging-market-to-reach-4223-billion-units-at-65-cagr-in-2024-says-globaldata

1.3.1. Wood, cardboard and papers

The wood based products are commonly used in the packaging of food especially in the form of paper and cardboard. Paper bags are used to package loose foods, carton board is commonly used for liquid and dry foods, frozen foods and fast food while corrugated board finds broad application in direct contact with food (e.g. pizza boxes) and as secondary packaging.

The common additives or processing aids used to improve the quality of paper and cardboards are defoamers, biocides, antioxidants, felt cleaners, and deposit control agents. These additives are mostly non-volatile compounds with low molecular weight that can easily migrate from (and through) the packaging into the food hence can contaminate it. These contaminants are mineral oils, photo-initiators, phthalates, and per- and polyfluorinated substances etc.

Further, the use of recycled paper for food packaging materials is also a possible source of food contaminants as the residues of printing inks, adhesives and other substances, present in the previous use of the paper could migrate into food content and can pose health concerns for the consumers.

Many countries are now regulating and/or banning the use of recycled paper and cardboard materials for packaging. India also has recently notified such regulation. Regulations are also in place for the additives, colorants, printing inks etc. in some countries including India.

1.3.2.Plastics

Plastics are organic polymeric materials that can be molded into the desired shape making it the most preferred choice of packaging material for various products- from grains, beverages, dairy, confectionary, fruits and vegetables to ready-to-eat foods as plastic FPM are easy to handle, hygienic and offer an effective surface for printing labels or brands. The lightness and flexibility as well as low cost of plastics have given them important place in the processing and packaging of food.

Table 1 Polymers most commonly applied in plastic packaging

Plastic materials	Packaging applications
Polyethylene terephthalates (PET)	Drinking bottles, Microwavable packaging, soft drink bottles, food jar for butter, jelly, plastic films
Polypropylene (PP)	Drinking bottles, Bottles for milk & juice
Poly vinyl acetate (PVA)	Common food packaging
Epoxy resins (ER-BPA)	Lining of cans, stretch films
Poly vinyl chloride (PVC)	Plastic bags, stretch films, container lid
Polystyrene (PS)	Food container, bottle caps, coffee cups, plates, straws etc.
Low density polyethylene	Disposal cups, cutleries
High density polyethylene	Custom packaging

Besides basic polymer, there are major families of plastics additives which are used in FPMs as fillers, plasticizers, flame retardants, colorants, stabilizers, lubricants, foaming agents, and antistatic agents. There are various stabilizers with more specific functions like antioxidants, antiozonants, heat stabilizers, UV stabilizers, and bio-stabilizers (biocides) are also used in plastics. Groh et al (2019) had reviewed and compiled list of chemicals associated with plastic packaging along with their possible environmental and health hazards. Out of several thousand chemicals, they have zeroed down on 148 most hazardous chemicals out of that thirty five chemicals are having potential to disrupt endocrine system.

In India BIS standards have been formulated for regulating use of plastics for food packaging such as Plastic woven sacks for food-grain (IS 14887:2000) and sugar (IS: 14968: 2001) Packaging. FSSAI has set the migration limit of 60mg/kg for plastic FCM.

1.3.3. Metals

Metals, such as aluminium, tin plate, tin free steel and stainless steel etc. in both rigid and semi-rigid forms, are most commonly used for food packaging applications as it provides an excellent barrier to light, gas and moisture. Metal have properties like the ability to withstand high heating temperatures, rigid structure, recyclability, easy conversion into various shapes etc. that make it useful as FPM.

The different types of metal packaging include:

- Beer and soft drink cans
- Food cans
- Open trays
- Drums and pails
- Foil wraps
- Aerosol containers
- Tubes
- Retort pouches
- Caps and closures (e.g. lids on glass jars and bottle tops)
- Lids (e.g. for yoghurt and butter containers)

The main use of these metals is the preservation of canned foods and beverages. Besides, metals are used for dairy, fruits, vegetables, beverages, and confectionaries also.

However, metals may impart negative impact on the stored food materials depending upon its chemistry. Interaction of metal and food results in corrosion, pitting, perforation, loss of coating and product deterioration & discolouration. For example acidic soft drinks may corrode uncoated metal; similarly some fish, meats and soups may cause sulphur staining. Some common catalysts for enhancing these reactions are nitrates, phosphates, plant pigments, synthetic colours, copper and sulphur compounds present in the food products.

To avoid these reactions, certain substances are used to cut the contact between metal cans and food materials. These are known as coatings, lacquers or enamels such as epoxy lacquers, vinyl lacquers, phenolic lacquers and oleoresins. As an alternative to applying coatings on metal, these days thermoplastic films are laminated or extruded onto the metal and then used to form cans or can components. These thermoplastics may consist of polypropylene, polyethylene terephthalate, polyamide (nylon) or a polypropylene/nylon co-extruded combination. However, certain toxic chemicals migrate from these coatings to food products. These migrants include bisphenol A (BPA), lead, chromium etc.

1.3.4. Glass

Glass has been widely used as a packaging material for thousands of years as it is virtually inert and impermeable. Glass packaging is easy to reuse and recycle as well. It preserves food and beverages for a long time and avoids contamination. It is commonly used in many foods ranging from heat treated or pressure-packed solid and powdered products to liquid products.

Glass packaging usually involves a glass container and a closure (made of glass, metal, cork, or plastic based on the type of foodstuff). For example, foods that require sterilization after filling by heat and pressure application will be closed with a gasket-type seal, i.e. a rubbery, heat resistant rim that is airtight. Such gaskets are typically made with PVC, rubber or alternative materials.

Although glass is considered as the safest inert packaging material, scientific studies shows that lead can migrate from glass containers to foods. Lead is naturally present at very low levels in the silica sand that is the raw material of glass. During recycling of glass containers lead content get increased

ADDITIVES

In addition to the basic polymers such as cellulose, PVC, PC, PE, PP etc. there are certain other chemicals which are used as additives to obtain the desired properties and/or simplify the manufacturing process. These additives are used in small quantity as fillers, heat and light stabilizers, antimicrobials, antioxidants, colorants, UV absorbers, light screening pigments and dehydrating agents, etc.

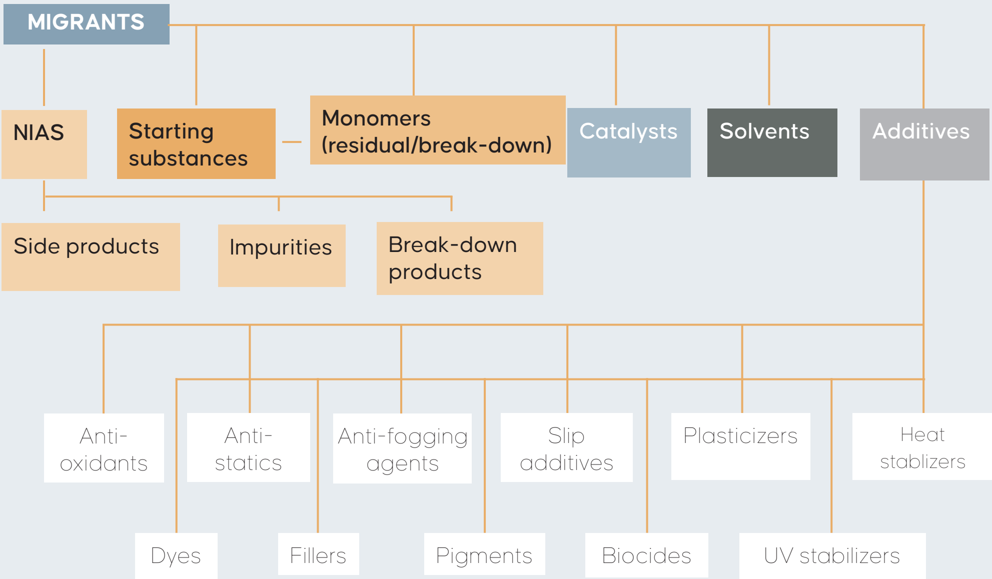


Figure 3 **Classification of possible migrants from food packaging.**

Source: Bolgar et al 2008; Ash and Ash 2008 when mixed with non-food packaging materials such as crystal glass or other glass which have a higher lead content.

1.4. Concerns on Food Packaging Materials

In recent times, specific attention has been focused on chemicals which are used in food packaging and contact materials. Though most of them are used at low concentrations, they are capable of migrating from packaging into food. This is one of the most important risk factors in food supplying chain. These migration depends on various factors. Research studies have reported that the migrating chemicals can cause several health hazards especially in children including obesity, asthma, preterm birth, and neuro-behavioural disturbances.

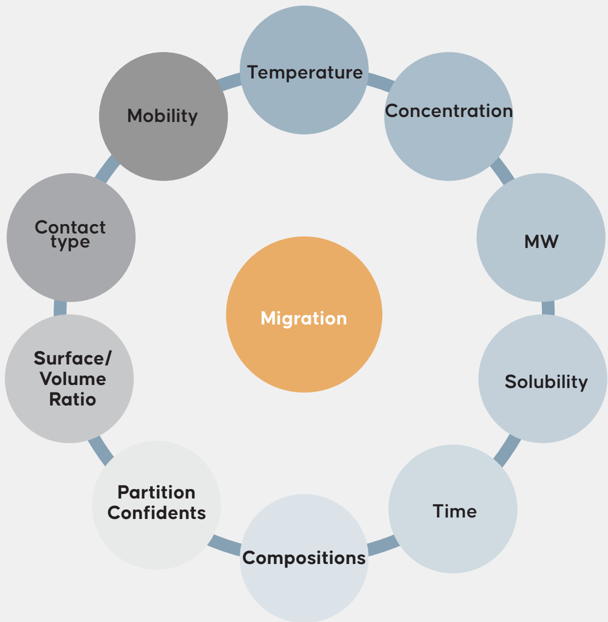


Figure 4 Factors responsible for migration

Further, FPM represent a large faction of municipal solid waste. According to the US Environmental Protection Agency (EPA), food and food packaging materials make up almost half of all municipal solid waste. Most packaging is designed as single-use, and is typically thrown away rather than reused or recycled. These packaging materials, especially when made from plastics, do not degrade quickly or, in some cases, at all. Chemicals from the packaging materials, including inks and dyes from labeling, can leach into various environmental matrices hence pose threat to animal, birds as well as marine life. Chemicals from food packaging materials may enter into the food chain and get bioaccumulated and ultimately harm human health. Most of these health hazards originates from plastic, glass, and aluminum based food packaging materials.

To control the hazardous impacts of chemicals used in FPM, countries are coming up with various migration limits. Based on the toxicology data and risk assessment, European Regulation EU No 10/2011 specifies the allowed substances in plastic food package along with the specific migration limits (SML). The equivalent law to EU No 10/2011 in China is GB9685 and in India this is regulated by FSSAI.

Figure 5 **Chemicals present in food packaging materials**

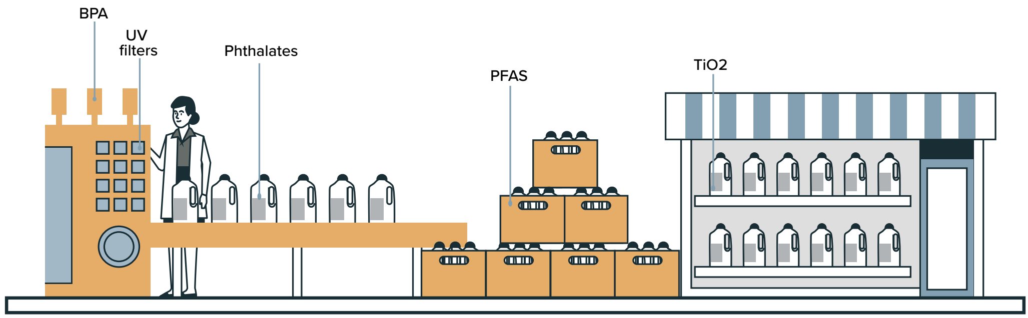


Table 2: Commonly used toxic chemicals in FPM and their Harmful effect

Chemicals group/name	Packaging use and migration	Health effects
Bisphenol A & alternatives	Used as epoxy resin liners in cans and additives in polycarbonate plastic. BPA migrates from polycarbonate bottles/cans into the water & food, migration increases with rise in temperatures.	Endocrine disruption, liver damage, cardiac toxicity, obesity and pulmonary effects such as asthma etc. California Health Department has enlisted BPA as human carcinogen under Prop65. Alternatives may be endocrine disrupters as well.
Phthalates such as Di(2-ethylhexyl) adipate (DEHP), Diisononyl phthalate (DiNP), Disobutylphthalate (DiBP) etc.	Used as plasticizers —these are often added to plastic resins to create flexibility.	Endocrine disruption, cancer (Prop 65). DEHP is well known for its Cardiac toxicity.
4-Nonylphenol	A breakdown product of tris (nonylphenol) phosphite (TNPP). It is found to be present in rubber products and food wraps made of polyvinylchloride (PCV). Found in high levels in polystyrene and PVC food packaging	Endocrine disruption
Fluorinated compounds such as Perfluorooctane sulfate (PFOS) , Perfluorooctanoic Acid (PFOA), Perfluoroalkyl acids (PFAAs)	Used in greaseproof paper wrappings and coating for the fiber-based food containers. May migrate from paper packaging to food.	Cardiac disease and toxicity, Endocrine disruption, potent carcinogens, liver damage, low birth weight.


jovial
TATE'S
LEMON SNAKAROONS
CHOCOLATE SNAKAROONS
SALTED CARAMEL SNAKAROONS
MATCHA SNAKAROONS
SMALL BATCH
BISCOTTI
emmy's
COCONUT COOKIES
Go Raw
New Product
$2.39
$3.99
Ginger Cookies
SimpleBites
ALMONDINA
CAVEMAN COOKIES
$5.39
$3.29
Annie's
Bunny Grahams
Cocoa & Vanilla
Cinnamon Grahams
Honey Grahams
MI-DEL
Ginger Snaps
Organic Sugar Cones
Organic Ice Cream Cones

2. ENDOCRINE DISRUPTING CHEMICALS IN FOOD PACKAGING MATERIALS

The appropriate use of food packaging materials is important for food safety and personal health. However, migration of food packaging-associated chemicals with endocrine disruptive properties has been reported in foods as well as humans since long. As EDCs are toxic at low concentration, it is important to have data on the types and quantity of chemicals leaching into food, and their long-term impact on health.

Many chemical contaminants have been reported in food packaging materials that are considered as **non-intentionally added substances (NIAS)**. These are present as impurities or by-products of manufacturing processes.

Scientists from the University of Gothenburg and the Vrije University in Amsterdam had identified over 4000 chemicals that are potentially present in plastic packaging. Out of these 68 chemicals were identified as being most hazardous for the environment and 64 were identified as being most hazardous for human health. Similarly, Geueke et al (2022) have analytically compiled the database on migrating and extractable food contact chemicals in a total of six FCM groups: plastics, paper & board, metal, multi-materials, glass & ceramic, and other FCMs.

Chemicals such as BPA, NP, phthalates, PFAS etc. are used as important raw materials for epoxy resin, phenolic resin, and plastic production, etc., Studies have reported the presence of these in plastic food packaging bags, disposable paper cup (PE), disposable PET plastic bottles, and many other disposable products as well as in the stored food products.

The external factors such as the prolongation of the storage time of food, usage time, and microwave heating time and the increase in temperature, acidity or ethanol concentration, and some internal factors, such as oil/fat content have great impact on the migration of EDCs from the packaging material into the food. Smaller convenience packaging are having larger surface/volume ratio that also contributes to increased food contamination.

EDCs are naturally occurring or man-made substances that may mimic or interfere with the function of hormones, particularly the estrogens, androgens and thyroid hormones in the body. EDCs may turn on, shut off, or modify signals that hormones carry and thus affect the normal functions of tissues and organs.

According to the definition given by the World Health Organization (WHO)/International Programme for Chemical Safety (IPCS) in 2002, an endocrine disrupter 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. People are exposed to EDCs in their everyday lives because these chemicals are used in thousands of products and present in food as contaminants.

EDCs may be associated with various human health effects such as effects on reproduction, endometriosis, precocious puberty, neural function (particularly prenatal exposure), immune function, and different types of cancer (i.e. breast, endometrial, testicular, prostate and thyroid). However, further studies are needed to confirm the causal links.

EDCs are linked to economic burden

Studies find a plethora of adverse effects from exposure to EDCs, including prostate and breast cancer, infertility, male and female reproductive dysfunction, birth defects, obesity, diabetes, cardiopulmonary disease, and neurobehavioral and learning dysfunctions such as autism. These diseases and lost wages (caused due to diseases) contributes to substantial disease burden. Scientists have estimated this economic burden to be US$340 billion in the USA and $217 billion in Europe. Similarly, Dutch government has released a report mentioning the total estimate of socio-economic burden of EDC-associated health effects for the EU28 ranges between 46 and 288 billion € per year. Unfortunately, there is no such data available from Asian region or India.

ENDOCRINE DISRUPTING CHEMICALS – in food packaging materials

2.1 BISPHENOL-A

BPA is a high-production-volume industrial chemical which is used as monomer in the production of polycarbonate (PC) plastics and epoxy resins. To avoid direct contact between food and beverages with metals, epoxy resins are used as interior/protective coatings for food packaging bags and beverage cans. The surface lining of the food containers accounted for about 50% of all ER consumption.

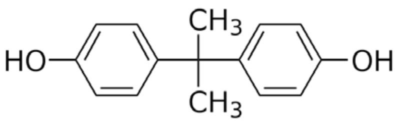


Figure 6 Chemical Structure of BPA

2.1.1 USES OF BPA IN FPM

The products manufactured from BPA monomers are mainly designed for contact with food. Polycarbonate is widely used in food contact materials such as infant feeding bottles, tableware, microwave ovenware, food containers, water bottles, milk and beverage bottles, processing equipment and water pipes.

Epoxy resins are used as protective linings for a variety of canned foods and beverages and as a coating on metal lids for glass jars and bottles, including containers used for infant formula. BPA has been used in food packaging since the 1960s. These uses result in consumer exposure to BPA via the diet.

BPA has also been reported in PVC stretch films used to store vegetables and fruits. BPA epoxy resins are used as an antioxidant or inhibitor in the manufacture and processing of PVC stretch films.

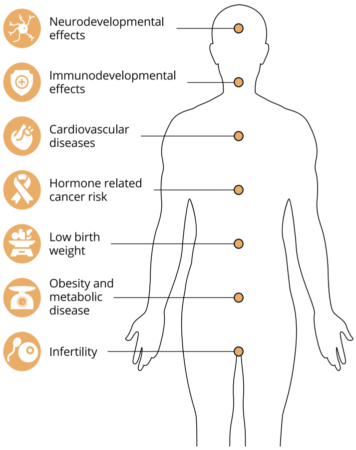
BPA molecules are interlinked by ester bonds to form PC and epoxy resins, however, these bonds breaks due to hydrolysis hence releasing free BPA. This hydrolysis increases with heat, acidic foods such as tomato sauce, alkaline beverages, rough washing etc. PC get also degrade due to UV light, humidity, microwave and temperature variations. PC food storage and beverage containers are re-usable, and repeated use leads to an increase in leaching of BPA which is a big health concern.

2.1.2 HEALTH IMPACTS OF BPA

BPA can easily migrate from food packaging, such as plastic containers, baby feeding bottles and coated food cans, into the food.

BPA acts as a weak estrogen. But due to low-dose effects on reproductive system & neuro-behavior, and continuous exposure for years, BPA is a big concern especially for fetus & neonate.

A study estimated that BPA in FCM and thermal paper was likely responsible for obesity in 42,400 children of 4 year-olds in EU (with health costs of 1.54 billion euros per year). Based on recent scientific studies the European Food Safety Authority (EFSA) has revised the tolerable daily intake (TDI) to 0.04 ng/kg bw for BPA in Dec 2021.



HEALTH IMPACT

- Altered brain development & behavior
- Endocrine disruption
- Reproductive effects
- Immune response
- Cardiovascular diseases
- Altered mammary gland development
- Increased adiposity
- Diabetes
- DNA alterations related to estrogen
- Neurological disorders
- Neoplasias & preneoplastic lesions
- Polycystic ovary syndrome (PCOS)

2.1.3 RESEARCH STUDIES ON BPA IN FPM

Several scientific studies are there representing the migration of BPA from FCM to food. This migration is amplified by heating, contact with alkaline or acidic substances, overuse, and exposure to microwaves, and leads to BPA intake through food. Canned food is significantly exposed to BPA, which is released from lacquer coatings for tins.

Cao et al (2011) had reported BPA in paper used to pack foodstuffs, PVC plastic packaging film, or equipment and containers used during the production process with epoxy resin or plastic coating. Simultaneously also reported migration of BPA from these packaging materials to baker's yeast, cheese, bread, cereals, and fast food.

Rudel et al (2011) had studied exposure of BPA from food packaging materials by doing urine analysis in 4 members of 5 families. They have concluded that by reducing the packaged food from diet concentration of BPA in urine has reduced drastically. The study also suggested that removing BPA from food packaging will significantly decrease exposure in human.

Wang et al (2016) had reported BPA alongwith BPAF and BPAP in plastic food packaging bags, water bottles and disposable paper cups. In plastic food packaging bags maximum BPA were reported in the range of 88.16 to 237.8 ng/ml. While Cao et al (2017) had detected BPA with levels ranging from 0.022 to 0.030 ng/g for products in PET bottles, and 0.085 to 0.32 ng/g for products in cans.

Liu et al (2018) had investigated the quantity of BPA migrated from plastic packaging materials in the liquid food simulants. Wang et al had reported migration of bisphenol A from 0.079 to 0.403 mg kg−1 from PVC plastics to food in China. Similarly, studies have reported BPA in fresh, frozen, and canned foods.

2.1.4 REGULATIONS

Considering the health impact, BPA has been banned from use in all food packaging in France. BPA has been banned in the packaging of foods intended for children under 3 years old in Sweden, Denmark and Belgium. Germany is currently reviewing the need for legislation on inks in food packaging materials.

In 2011 the European Commission has banned the use of BPA in baby bottles and drinking cups. While under Regulation (EU) 2018/213 amending Regulation (EC) 10/2011 the allowed migration level for BPA in food contact plastics and food coated products has been set to $\leq$0.05 mg/kg.

FDA has banned BPA based polycarbonate resins in baby bottles and sippy cups in 2012 and in 2013 it has banned the use of BPA-based epoxy resins as coatings in packaging for infant formula. But the agency still allows the chemical to be used in other food-contact materials.

Since 2015 BPA is banned in India under "IS 14625:2015 for Plastic Feeding Bottles" in baby feeding bottles and sippy cups. Under Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020, BPA is banned in the packaging material used for infant nutrition products.

Timeline of BPA

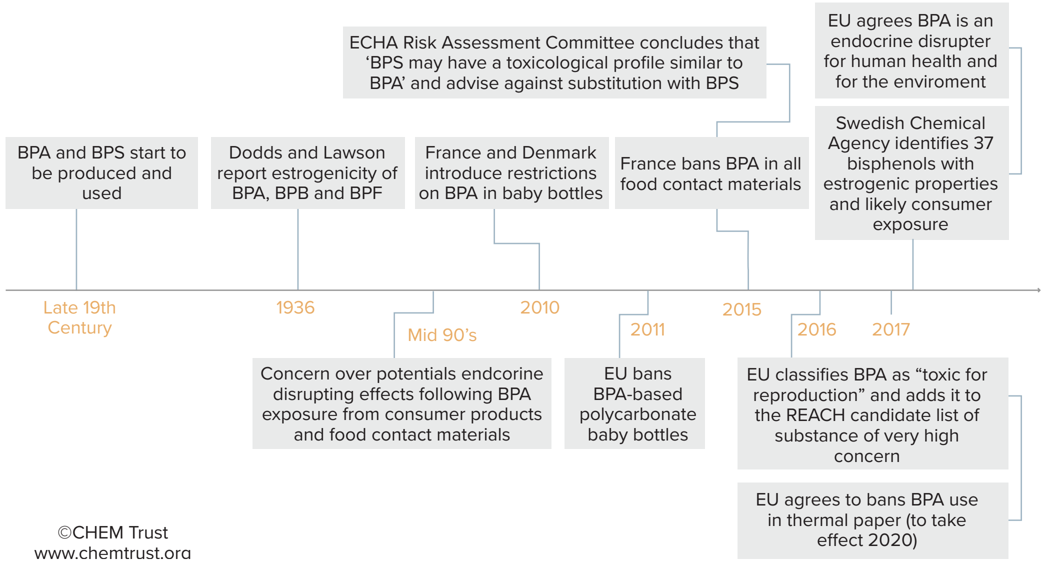
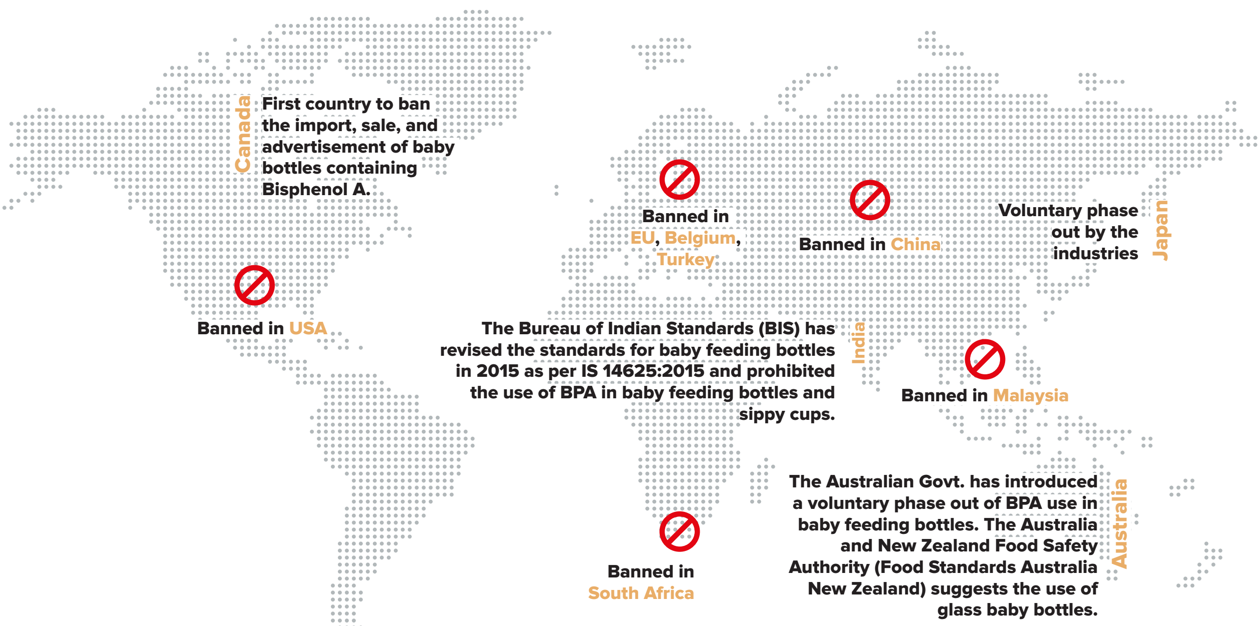


Figure 7 Global Regulation of BPA in Baby Feeding Bottles



2.2 NONYLPHENOL

Nonylphenol (NP) is a phenolic substance and is the most extensively used member of Alkylphenol ethoxylates. NP is a complex mixture predominantly containing 4-nonylphenol (>90%) with varied alkyl chain branching. Nonylphenol is primarily used as a raw material in the production of Nonylphenol ethoxylates (NPEs) which is widely used as a nonionic surfactant, emulsifiers as well as in other household and industrial applications. In food packaging industry it is used as raw ingredient for tris(nonylphenyl) phosphate (TNPP) which is a common antioxidant. These NPEs, TNPP and other chemicals breakdown into NP which contaminates the environment and food.

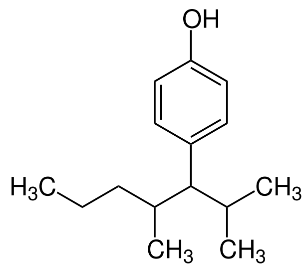


Figure 8. Chemical structure of nonylphenol

2.2.1 USES OF NONYLPHENOL IN FPM

According to European Union Risk Assessment Report on Nonylphenol the overall exposure to nonylphenol from food packaging materials is 140 µg/day (equivalent to 2 µg/kg/day).

NP is used for its different properties in food packaging materials.

1. As **dispersing or stabilizing agents** in
   a. Polycarbonate tableware and baby bottles,
   b. Polystyrene disposable cups and food cases,
   c. PVC stretch films,
   d. Cellulose and cellulose esters,
   e. Thermoset phenolic polymers,
   f. Paper, and rubber products.

2. To manufacture an **antioxidant TNPP** which is used as
   a. Heat stabilizer in styrenes, vinyl polymers, rubber polyolefins, etc.
   b. Phosphite stabilizer to maintain the colour stability, processing stability and performance integrity of the polymers in which it is incorporated. However, because of prolong storage, storage conditions, food types, water and acidic medium etc TNPP get hydrolyzed into NP which than leaches into packaged food. TNPP may contain up to 3% free Nonylphenol. It is also likely that any free Nonylphenol formed would be preferentially adsorbed by the food.

3. As an **accelerator or curing agent** in epoxy resins in the hardening component (alkanolamine).

4. As an **antifogging agents** to prevent fogging through the condensation of water vapour. Antifogging agents can either be added during manufacture or externally applied to the polymer surface such as PVC, pigmented coated paper and polyolefins. It has been reported that approximately 80% of PVC used in food-packaging contains NPE-4 upto 2.7%. NP is present as a residual impurity at a typical level of 0.1% in NPE.
5. NP is also present in food packaging materials as a non-intentionally added substance (NIAS) typically in adhesives, printing inks, etc.

2.2.2 HEALTH IMPACTS OF NONYLPHENOL

Nonylphenol have estrogenic effects in the body. It is also known as xenoestrogens. NP upon entering the human body gets rapidly and extensively absorbed in the gastrointestinal tract from where it is widely distributed throughout the body but with the highest concentration in fat. Impact of NP in body includes:

- Hormone (endocrine) disruptor
- Persistent and bioaccumulative
- Skin and eye irritation
- Diarrhea and nausea
- Reproductive harm
- Birth defects
- Obesity and diabetes
- Breast cancer

2.2.3 RESEARCH STUDIES ON NONYLPHENOL IN FPM

FDA in Taiwan had tested 35 samples which belong to 9 different types of food packaging materials. In their test 15 samples were found to contain nonylphenol at the levels of 0.6 ~ 2,002 ppm.

Votavova et al (2009) had reported NP in seven samples of stretch PVC films and two PVC dishes for food packaging. Four of the PVC films contained NP at the concentrations of 0.44 mg/g, 1.03 mg/g, 1.28 mg/g, and 1.72 mg/g, respectively. Several other studies also represented migration of NP from FPM to food products.

Danish Consumer Council THINK Chemicals in 2015 had conducted random check on pizza boxes and had reported Nonylphenol in boxes besides other EDCs.

Kawamura et al (2017) had reported that PVC stretch film contain 1–2.6 mg/g of NP as a degradation product of TNPP while the migration levels of NP from PVC stretch films into foods were 8–93 µg/dm^2 at 5°C for 24 hr. They concluded that NP migrated much more easily into lipid-soluble stimulants and fatty foods owing to its phenolic function.

2.2.4 REGULATIONS

According to **The Food and Environment Research Agency (FERA), UK,** NP itself is not authorised for use in food contact plastics it may be present as an impurity or a breakdown product of APE or TNPP. The EU has set the Tolerable Daily Intake (TDI) of 5 µg/kg body weight for NP; however, there is no specific migration limit has been assigned.

In Japan, NP has become a social concern as a suspected endocrine-disrupting chemical, and Japanese consumers have refused products containing NP since the end of 1990s. Therefore, the Japan Vinyl Goods Manufacturers Association changed the composition of PVC stretch films in 2002; since then, NP has not been detected in Japanese stretch films.

In 2019, ECHA has proposed TNPP with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP), to be identified as substances of very high concern due to their endocrine disrupting properties in the environment.

On 22nd May 2019, the Chinese National Health and Wellness Commission Office opened a public consultation on national food safety standards drafts including "National Food Safety Standards Food Contact Materials and Products Determination of Nonylphenol Migration". China also have set the specific migration limit of NP to 0.01 mg/kg in adhesives that are in direct contact to FPM.

Table 4 Global food contact regulations specific to TNPP

Country	Regulation
USA	Food and Drug Administration (FDA) – 21 CFR Part 178.2010
Japan	Self-restrictive Requirements on Food-Contact Articles Japan, Hygienic Olefin and Styrene Plastics Association (JHOSPA) (March 1996), Section A4-2, maximum 1.2%
European Union	Plastics Directive 2002/72/EC, pm/ref. No. 74400, specific migration limit 30 mg/kg
Germany	BfR Recommendation VI, maximum 2.0% total of all stabilisers BGA: maximum 6% in plastics
Netherlands	Food Packaging and Utensils Decree of 01.10.1979 as amended Chapter 1
France	Brochure 1227 (Avril 1990) maximum 1.0%
Belgium	Royal Decree of 11.05.1992, specific migration limit 30 mg/kg
Spain	Royal Decree 125/1982 of 30.04.1982 Resolution of 4.11.1982
Italy	Min. Decree of 21.03.1973 maximum 0.3% Min. Decree of 0.04.1985
United Kingdom	BIBRA/BBF Code of Practice (1991) Rec. No. C.159, maximum 1.0%
India	No regulation

2.3 OCTYLPHENOLS

Octylphenols (OP) belongs to the wider family of alkylphenols, and is used as an intermediate in the production of phenolic resins and in the manufacture of octylphenol ethoxylates (OPEs). Like other alkylphenols, OP are also moderately persistent, lipophilic and can bio-concentrate in aquatic biota.

2.3.1 USES OF OCTYLPHENOL IN FPM

OP is widely used in the production of nonionic surfactants and a plasticizer that are used as additives in the production of food packaging materials. It provides a protective barrier between food and metal in cans, and also gives shape and durability (impact resistance) to plastics. OP can also be used to produce solubilized phenolic resins, rubber auxiliaries, printing inks, and adhesives which are directly or indirectly used in food packaging. Foods packaged in PVC have been shown to contain OPs.

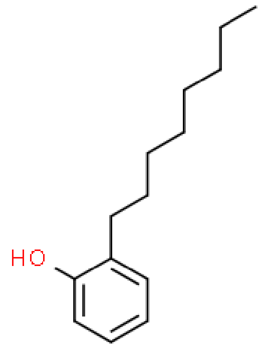


Figure 9. Structure of Octylphenol

2.3.2 HEALTH IMPACTS OF OCTYLPHENOL

OPs appear to have a number of endocrine-disrupting properties on the developing human reproductive system. Recent epidemiological studies have demonstrated significant associations between maternal exposure to some OPs and adverse developmental impacts on the male fetus. OPs have been associated with:

- obesity,
- insulin resistance,
- asthma and allergies,
- uterine fibroids,
- breast cancer
- neurobehavioral outcomes in children such as increased aggression, attention deficits, depression, and impaired executive functioning and emotion control

2.3.3 RESEARCH STUDIES ON OCTYLPHENOL IN FPM

Cacho et al (2012) analysed OP in vegetables and migration studies from their packages. Shuangqiao et al (2015) had determined octylphenol alongwith BPA and BPAF in milk plastic packets and bottles using HPLC. Similarly, David et al (2022) reported Octylphenols in bottled water.

2.3.4 REGULATIONS

Considering the potential adverse impacts, the U.S. Environmental Protection Agency has designated OPs (currently authorized for use in food packaging by the FDA) as high priority chemicals under the Toxic Substances Control Act (U.S. EPA 2019). In EU the use of OPs is banned in certain children's products (Consumer Product Safety Commission 2017) (European Commission 2018). However, its use in food packaging is still allowed. In India there is no guidelines on the use of Octylphenols.

2.4 PFAS

Per- and polyfluoroalkyl substances (PFAS) are a family of man-made high-volume chemicals that are found in an extensive range of products used by consumers and industry. According to OECD/UNEP Global PFC1 Group, PFAS contain one or more C atoms on which all the H substituents have been replaced by fluorine (F) atoms, in such a manner that they contain the perfluoroalkyl moiety (C_nF_{2n+1})."

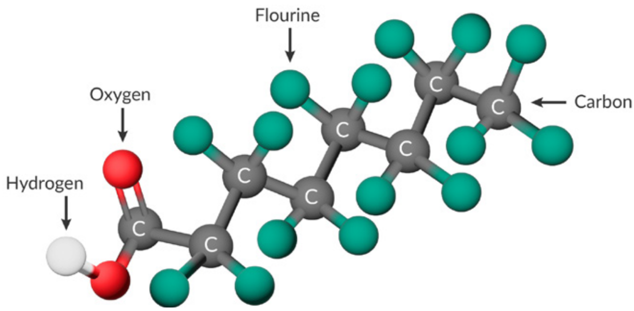


Figure 10: Chemical structure of PFOA.

There are nearly 5,000 types of PFAS having different lengths and/or differ in their properties at one end, which can change the toxicity of the chemicals. PFOA and PFOS have been the most extensively produced and studied of these chemicals. Being extremely persistent in the environment and in our bodies, these are also known as "forever chemicals". This can risk human health and wildlife in the long term.

2.4.1 USES OF PFAS IN FPM

PFAS are resistant to grease, oil, water and heat. They have high chemical and thermal stability. For this reason PFAS have been used in a variety of consumer products and industrial applications including in cookware, food packaging and processing. PFAS are extensively used in disposable food packaging and tableware used by popular fast-food chains and restaurants.

Take out boxes and clam shells		
Baking paper and muffin cups		
Take out cups and ice cream tubs		
French fries and popcorn packaging		
Biscuits and sweets packaging		
Bread/pastry packaging		

Figure 11 Common examples of FPM where PFAS are used

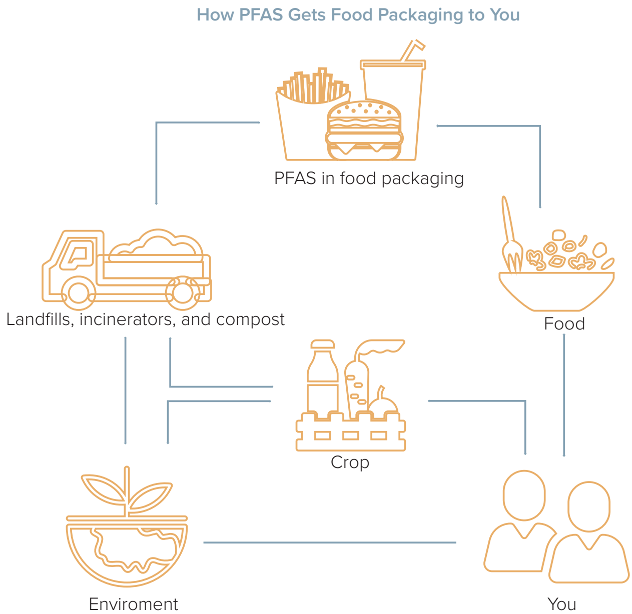


Figure 12 Exposure route of PFAS from food packaging

Since 1950's PFAS congeners have been used in paper and board food packaging. Common examples include paper wrappers like those for burgers and sandwiches, paperboards like pizza boxes or french-fry holders, microwave popcorn bags, paper cups, molded-fiber plates and bakery bags and more. Food intake was found to be the most important route of exposure to PFOS and PFOA, with percentages of 97 % and 98 % of the total intake, respectively.

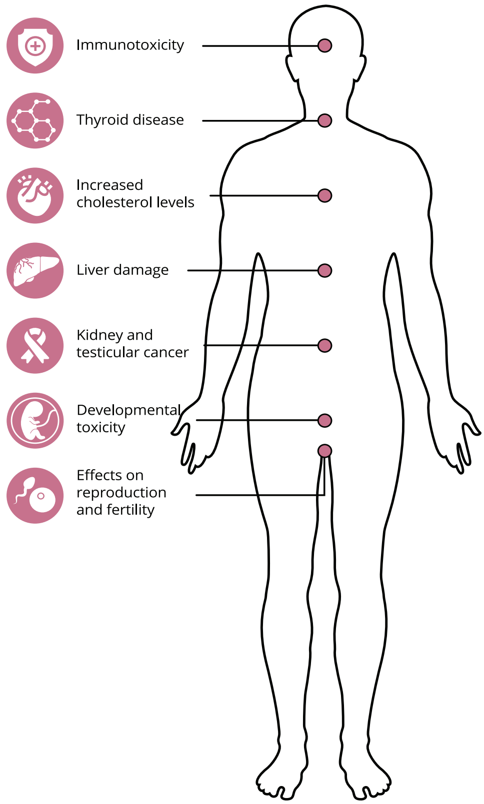
PFAS coatings are made of fluoropolymers such as PTFE (Teflon™) or they are built by not fluorinated polymers (acrylates, polyesters, etc.) with side groups basing on perfluorinated sulfonamide derivatives, fluorotelomer alcohols (FTOH) or fluorotelomer thiols (FTSH). In addition non polymeric fluorinated surfactants are also applied in FCM, which is based on phosphate esters of fluorotelomer alcohols, thiols and derivatives. A prominent examples of these fluorinated surfactants are PAPs (polyfluoroalkyl phosphate esters), that have been identified in popcorn bags, fast food wraps etc. These FTOHs are known to degrade to the well-known persistent PFAS such as PFHxA.

The use of PFAS in FPM is a potential hazard not just for people who eat food served with treated paper but also to the environment since the chemicals can migrate from FPM, and contaminate landfills and compost after disposal.

2.4.2 HEALTH IMPACTS OF PFAS

The elimination half-life of PFOA in humans has been estimated to be 3.5 years and for PFOS, approximately 4.8 years. As PFAS can remain in the human body for years, it is a risk factor for several lethal diseases and disorders.

- pregnancy-induced hypertension/pre-eclampsia
- liver damage
- increases in serum lipids, particularly total cholesterol and LDL cholesterol
- increased risk of thyroid disease
- decreased antibody response to vaccines
- increased risk of asthma
- immune suppression
- low birth weight
- decreased fertility
- Possible carcinogen such as testicular and kidney cancer



Prenatal PFAS exposure could be associated with reproductive disorders in children, including abnormal menstruation/length as well as decreases in semen quality and sperm count. Children are especially at risk for health effects because their developing bodies are more vulnerable to toxic chemicals.

2.4.3 RESEARCH STUDIES ON PFAS IN FPM

Several scientific research data are available on PFAS and its impact on environment & human health. Scientists and Governments are now focusing on food products and packaging products as they are direct source of exposure to humans.

Yuan et al (2016) had investigated 69 samples from China and 25 samples from USA. They have reported FTOH and polyfluoro carboxylic acids in paper tableware and microwave popcorn bags. They have also studied the emigration rate of FTOHs from paper bowls.

Laurel et al in 2017 tested for PFAS in more than 400 samples from 27 fast food chains throughout the US. The samples were paper wrappers, paperboard, and drink containers. The study found that almost half of paper wrappers (e.g., burger wrappers and pastry bags) and 20 percent of paperboard samples (e.g., boxes for fries and pizza) contained fluorine. The study also concluded that some packaging was deliberately treated with fluorinated compounds, whereas in other cases, the chemicals may have come from recycled materials or other sources.

The Danish Food and Drug Administration had examined a number of food packaging materials in 2015 and later in 2018. These materials were made of cardboard and paper. The fluorinated compounds were found in almost 50 per cent of the samples. These were burger paper, muffin tins, and microwave popcorn bags that typically have the highest content. Based on the report Government has decided to ban the fluorinated chemicals in food packaging.

The Scottish non-governmental organization Fidra in 2019 has tested PFAS in 92 samples from 41 UK take away restraints and 51 supermarkets. 20 of the collected samples tested positive with range of 19.3 µg/dm2 dw to 3,480 µg/dm2 dw. The highest PFAS content was consistently found in molded fiber takeaway boxes.

List of various coating alternatives to PFAS
Starch
Carboxymethyl cellulose (CMC)
PVOH
Wax dispersions
Hydroxyethylcellulose (HEC)
Copolymer (styrene-butadiene)
Chitosan
Alkyl Ketene Dimer (AKD)
Alkenyl Succinic Anhydride (ASA)

2.4.4 REGULATIONS

Seeing the hazardous impact of PFAS on health, developed countries are now bringing or discussing to bring regulation to check PFAS and its salts into food packaging materials. Because of their widespread occurrence, toxicity, bioaccumulation potential and extreme persistency, PFAS and their precursors are increasingly being regulated by international regulations, such as the Stockholm Convention on persistent organic pollutants (POPs), the European chemicals legislation REACH (REACH 2006), SAICM and are also included on the SIN list of the International Chemical Secretariat (Chem Sec).

- In December 2016, the EU decided to restrict all use and import of PFOA (25 µg/kg) and its precursors (1000 µg/kg) in products and articles. The restriction entered into force on 4 July 2020.
- On December 11, 2019, the German Environment Agency (UBA) published a final report to support the preparation of restriction proposals under REACH for PFAS, PFOAs, their salts and precursors as well.
- US FDA had recently developed studies to quantify PFAS in food, however they said concentration are in range and are not harmful. However, Washington State has announced to ban the sale, manufacture, and distribution of food packaging containing intentionally added PFAS. It is effective from 1st Jan 2020; meanwhile orders have been given to find out the alternatives.
- Denmark has announced that cardboard and paper food contact materials (FCMs) in the country will not be allowed to contain PFAS after July 1, 2020; exceptions will be made for FCMs with a functional barrier that prevents migration into food.
- In June 2022, the Netherlands had announced to ban the use of four PFAS substances in all paper and board food contact materials as of July 1st, 2022.
- The legislature of Maine has passed an Act to prohibit the sale of food package containing PFAS from July 2022.

However, there is no such discussion going on in India.

2.5 PHTHALATES

Phthalates belong to a group of high volume chemicals called phthalic acid diesters. They are used as plasticizers i.e., added to increase the flexibility, transparency, durability, pliability and elasticity of polymer products. Phthalates are found in many household items and in food packaging as well. Foods packaged in PVC materials have been shown to contain Phthalates, According to CDC, people are exposed to phthalates by eating and drinking foods that have been in contact with containers and products containing phthalates. The higher molecular phthalates such as DEHP have been reported in fat-rich foods such as poultry, dairy products, yogurts and oils. As per US EPA (2015) the most common exposure to DEHP comes through food with an average consumption of 0.25 milligrams per day. The American Academy of Pediatrics' 2018 policy statement on food additives and child health designates phthalates as one of five chemicals of emerging concern with respect to children's health. However, the use of some Phthalates in food packaging is still allowed.

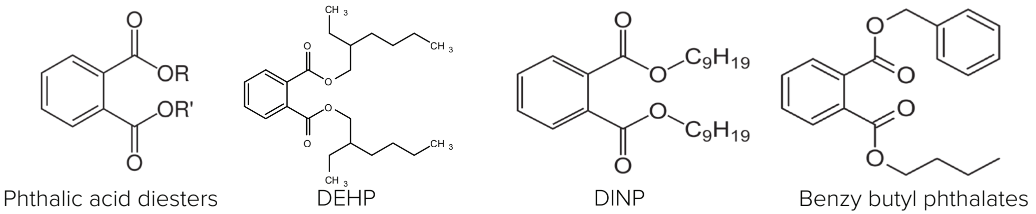


Figure 13 **Chemical structures of few commonly used phthalate congeners**

Table 5. **Some commonly used Phthalate congeners**

Low Molecular weight phthalates	High molecular weight phthalates
di-methyl phthalate (DMP)	di-2-ethylhexyl phthalate (DEHP)
di-ethyl phthalate (DEP)	di-n-octyl phthalate (DnOP)
di-butyl phthalates (DBP)	di-iso nonyl phthalate (DiNP)
di-isobutyl phthalate (DIBP)	di-iso decyl phthalate (DiDP)
benzyl butyl phthalate (BBP)	Benzyl butyl phthalate (BBzP)

2.5.1 USES OF PHTHALATES IN FPM

Phthalates are used as plasticizers in PVC and in a wide range of industries such as in packaging materials for foods and can also be found in components of certain food processing equipment such as conveyor belts and tubing.

Found in:

- Plastic food containers & packaging.
- Mason jars with PVC gaskets.
- Beverage cartons.
- Insecticides (farming).
- Food preparation material such as PVC gloves

The thin packaging film, also known as the cling film, made from regenerated cellulose film (RCF) are coated with phthalates to provide flexibility and heat sealability. The commonly used phthalate congeners for such films are DBP, dicyclohexyl phthalate (DCHP), BBzP etc.

Cardboard boxes, used for baked food packages, are coated with 16-18% phthalates such as DEP. The principal sources of phthalates in paper and board-packaging materials are the printing inks and adhesives used in the materials. The adhesive used for the bottom and side joint of a boxboard contain DiBP and DBP. For paper and board packaging made from recycled materials, phthalates could also be carried over from the inks and adhesives on previous materials due to an incomplete removal during the recycling process. Phthalates are also used in lacquers.

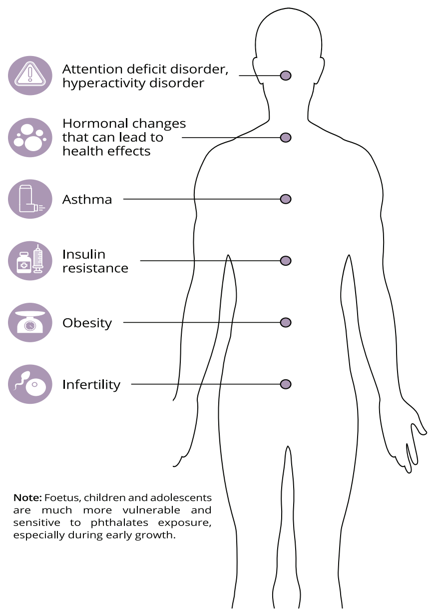
Since Phthalates are not chemically bound to the raw materials of these products they can easily leach out from the products into food, air, and other environmental matrices. Phthalates can also leach out to food during food processing by contact with plastics, resins, lacquers, surfactants, and paints from pipes, gaskets, and containers.

2.5.2 HEALTH IMPACTS OF PHTHALATES

Phthalates have relatively short half-life in humans, for e.g., 67% of the DEHP is eliminated via urine as the monoester with an elimination half-life of about 24 hr in human while DiBP in 5hr. However, due to frequent exposure even the low concentration of phthalates are imposing severe health issues. There are enough evidences on the impact of Phthalates in human health. Toxicological and epidemiological studies have found that some phthalates have estrogenic and/or antiandrogenic properties that can lead to the reproductive effects. Therefore, Phthalates have been considered as endocrine disrupting chemicals (EDCs).

Health impacts of Phthalates in humans:

- Endocrine disruptor
- Liver/kidney/lung damage
- Cancer
- Increased allergic symptoms
- Metabolic disorders
- Autistic behaviors
- Altered reproductive development & male fertility issues
- Type II diabetes & obesity
- attention-deficit/hyperactivity disorder (ADHD)
- Lower cognitive and motor development
- Neurodevelopmental issues



Secondary research analysis on health impact of DEHP and other higher phthalates shows that children under the age of three are more prone to adverse effect of these phthalates in comparison to adults. They have ever present exposure to phthalates containing products (like toys, personal care products, flooring etc.) and habit of hand-to-mouth hence making them vulnerable. In adults certain enzymes are present in liver, intestines and other organs which metabolites DEHP into MEHP which after further metabolism excrete out of the body via urine. However, liver of infant is not fully mature hence lacks those enzymes and few metabolic pathways such as glucuronidation because of which DEHP remain intact hence increasing the vulnerability.

2.5.3 RESEARCH STUDIES ON PHTHALATES IN FPM

Phthalates are not chemically bound to products and most of the phthalates used in FPM are of low molecular weight because of which they can leach out from packaging material to food during storage, heating and processing. Beside the chemical nature of the food and the plastic in contact with the food, the overall storage conditions, such as temperature and time, longer contact time, and higher dynamic frequency also affect the migration from FCMs into food.

The migration of phthalates from plastic materials to the food in contact has been widely reported in the case of polyethylene film bags, packaging and bottling material, envelopes, and printed tints etc. Guo et al (2010) had reported migration of phthalates into foodstuffs from plastic food containers. They had analyzed six phthalates in orange juice packaged in PVC bottles. The highest were DEP and DEHP 0.385 µg/mL and 0.662 µg/mL, respectively. Cacho et al. (2012) had investigated the migration of six phthalates (DMP, DEP, DBP, DOP BBP, DEHP) in plastic packed salads and canned greens. DEP, DBP, and DEHP were found to migrate from the bags to the simulant and were detected in vegetables at concentrations in the 8–51 ng/g range.

Hua et al (2017) had studied on routine plastic products that were used to package or store food, including plastic tableware (e.g., bowl, dish, spoon), plastic cups, plastic bottles, plastic bags and boxes, and wrapping films. On their investigation in 2140 participants they had reported that plastic containers contributed to phthalate exposure via the diet.

Carlos et al (2018) had investigated 56 products including plastic food wrap to identify and quantify primary plasticizers. They have reported three phthalates DEHP, DINP, and DIDP at concentrations ranging from 6-53%. However, they concluded that uses of phthalates are gradually decreasing and other alternative chemicals are used in food packaging which are needed to investigate.

Alp et al (2019) had reported DEHP, DBP, BBP, DINP, DIDP, and DNOP in food packaging material made from PP, PVC, tin can, and glass containers and also the migration of these phthalates in seafood stored in food packaging materials. The highest DEHP value 830.30 ng/kg was recorded in PP. They concluded that migration of phthalates from FPM to food increases with prolonged contact time with packaging material.

Similarly, Baranenko et al (2022) have reported translocation of Phthalates from food packaging materials into minced beef as high as 34.5 to 378.5 $\mu g \cdot kg^{-1}$. They concluded that the larger contact area and the presence of distributed fat on the surface of the minced meat resulted in significantly higher phthalate translocation than beef slices.

However, studies had demonstrated that by avoiding packaged food items it’s possible to avoid exposure to phthalates and eventually can reduce the phthalates burden of the body.

2.5.4 REGULATIONS

Food, and food packaging have been shown to increase human exposure to phthalates. To address this issue, few countries, such as European Union (EU), United States, China, etc., have taken action.

Since July 2008, the European Commission has limited the use of certain phthalates in food contact materials made of plastic. In Sep 2019 the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) had established the aggregated dietary exposure (group-TDI) of 50 micrograms per kilogram of body weight (µg/kg bw) per day based on their effects on the reproductive system whereas separate TDI of 150 µg/kg bw per day has been set for DIDP based on its effects on the liver.

In Korea, DEHP has been banned from use in food packaging materials since 1989. In China, 16 phthalates are restricted in food and food containers, including DNP, DnOP, DEHP, DiNP, DiBP, BBP, etc.

Beginning July 1, 2022, the legislature of Maine has approved a bill to eliminate the use of phthalates in food packaging that includes inks, dyes, pigments, adhesives, stabilizers, coatings, plasticizers or any other additives to which phthalates have been intentionally introduced.

In India, Food Safety and Standards (Packaging) Regulations, 2018, and the Bureau of Indian Standards (BIS) has excluded the use of DINP and DBP from use in printing ink for food packaging materials. While, Food Safety and Standards (Packaging) Amendment Regulations, 2020 has set the specific migration limits of DEHP from plastic materials intended to be in contact with food articles as 1.5mg/kg.

Government of India has listed almost 15 phthalates such as DEHP, DiDP, DiBP, BBP, DiOP, DiNP etc under Draft Chemicals (Management and Safety) Rules 20XX, Schedule-II list of priority substances.

2.6 UV Filters

UV filters are chemical additives that are used in consumables to block or absorb ultraviolet (UV) light. They are used in plastics, rubber, coatings, adhesive, polymer, and different resins that are ultimately used in packaging materials, cosmetics, automobile parts, printing ink, textile, leather, etc.

UV light describes the part of the light spectrum between 10 and 400nm. Generally, products are exposed to light be it direct sunlight or light from the lamp. UV light has a relatively high energy level

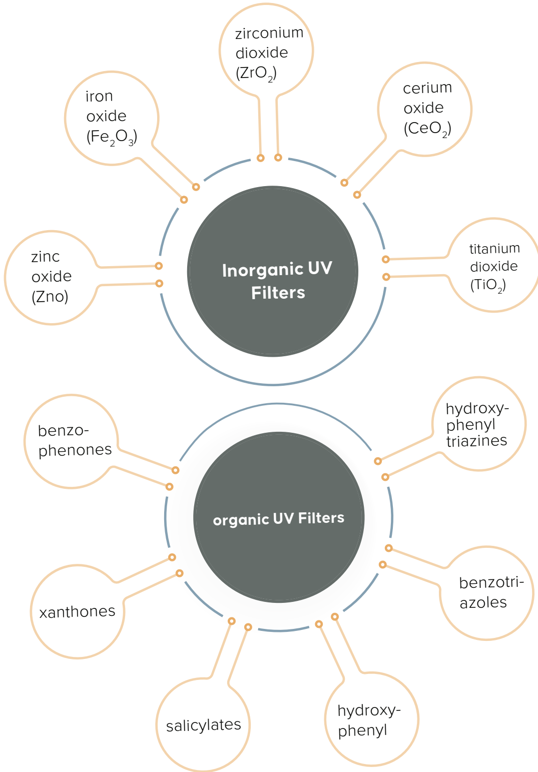


Figure 14: Types of UV filters

- **UV absorbers:** This form of UV stabilizer absorbs the UV radiation to prevent the initiation of photo oxidation reactions. Once absorbed the heat from the UV rays is dissipated through the polymer chain. Benzotriazoles and hydroxy-phenyltriazines are also examples of UV absorbers.

- **Quenchers:** Quenchers work by quenching the energy that is generated during the photo oxidation reactions, thus, returning excited molecules to a ground state where they are less likely to propagate photo oxidation reactions that produce free radicals. Nickel quenchers are an example of this form of UV stabilizer.

- Hindered Amine Light Stabilizers, or **HALS** are a form of UV stabilizer that function by targeting and trapping the free radicals produced during photo oxidation, preventing them from reacting with the polymer structure. HALS vary in their structure but generally have the 2,2,6,6-tetramethylpiperidine ring structure.

Source: https://amcorplastics.com/blog/additives-for-uv-stabilization/

and can cause cracking, yellowing and delamination of the products. To prevent such degradation or damage and significantly extend the life span of the final product, UV filters are used as additives and printing ink.

According to their chemical nature, UV filters can be classified into two group inorganic UV filters, and the organic UV filters. **Inorganic UV filters,** also called physical UV filters, principally work by reflecting and scattering the UV radiation. They are opaque, non-soluble in water and provide higher protection to both food as well as the packaging material than the chemical ones. **Organic UV filters,** also called chemical UV filters, absorbs the light. They act as ultraviolet degradation inhibitors. Organic filters have wider application., Each type of filter has a limited spectral band of absorption; therefore, they are mostly used in combination.

Whereas depending upon the ways of using, it can be categorized as UV absorbers, quenchers, or HALS and in some cases more than one additive can be used to provide the desired level of UV stabilization in the products.

Considering their extensive usage in various products, organic UV filters have been reported in different aquatic matrices, including rivers, lakes, seawater, wastewater and sludge.

2.6.1 Uses of UV filters in FPM

Food and beverage gets exposed to natural and artificial light during manufacturing, packaging, distribution, storage, and display. This may results in the photo-oxidation or photo-degradation of proteins, fat and oil, pigment, vitamin etc. that generates several oxygen radicals (i.e., superoxide anion, hydroxyl, peroxy, alkoxy and hydroperoxy radical) and non-radical derivatives (i.e., hydrogen peroxide, ozone, and singlet oxygen) causing various undesirable chemical changes in food constituents such as the formation of unpleasant off-flavors, losses of nutritional value, and the discoloration of pigments etc.

To prevent such rapid degradation of the food stuff and food packaging material (especially plastic/ polymer based materials) UV filters are used.

UV filters are also added to printing inks. Here they act as photo initiators, which start the reaction that eventually dries the ink rapidly and prevents leaching of other substances contained in ink into the food. Since these photo-initiators are not chemically bound, they can migrate from packaging materials to food and may pose a potential threat to consumers.

2.6.2 Health Impacts of UV filters

Leaching of UV-screens both from printing inks as well as packaging material polymers has been observed. UV filters are highly lipophilic, and therefore tend to accumulate in fatty tissues of living organisms. This leads to bio-magnification as well. Some photo-initiators are suspected to cause cancer and/or have been linked to endocrine disrupting properties. These UV filters can interact with androgens, estrogens, and thyroid hormone receptors, indicating their endocrine-disrupting capacity.

Studies indicate that the chronic toxicity of benzophenone could cause severe diseases, such as kidney cancers, liver tumors, and histiocytic sarcomas. Ghazipura et al (2017) reported that in human high levels of BP-3 exposure could be linked to an increase in male birth weight but a decline in female birth weight and male gestational age.

- IARC has classified benzophenone as "possibly carcinogenic to humans". European Food Safety Authority had identified non-cancer effects on the kidney and maternal effects as critical effects for characterizing the risk to human health.

2.6.3 Research Studies on UV filters in FPM

The extensive usage in various products has resulted in their ubiquitous presence in different aquatic matrices, including rivers, lakes, seawater, wastewater and sludge. It has been reported in various human biological samples, such as urine, blood, breast milk, human placenta, and amniotic fluid. In 2011, Germany announced a recall of frozen vermicelli in which benzophenone (BP) was detected. There have been few reports about the migration behaviors of photoinitiators into a wide variety of dry foods.

Zhang et. al. (2016) had studied migration of 13 UV filters from a polyethylene (PE) packaging to food simulants with concentration of PIs to range from 0.02 to 2.16 mg/L and reported migration of almost all type of filters.

Cai et. al. (2017) reported the migration behavior of four UV filters (BP, EHA, MBP, and Irgacure 907) used as printing ink onto four different food packaging materials (Kraft paper, white cardboard, PE coated paper, and composite paper) and tracking movement into the food. Similarly, Hu et al (2019) had reported six BP-type UV filters in eight different brands of plastic films obtained from supermarkets were analyzed in range of 35ng/g to 535.4ng/g.

A 2019 study has tested 76 different highly printed paper and board food contact materials, such as coffee and soda cups (board), paper plates and straws, napkins, muffin forms, paper bags. It has reported photoinititators in all tested samples. Similar other studies are also there highlighting migration of UV filters to FPM.

2.6.4 Regulations

Several organic and inorganic chemicals are used as UV filters in food packaging materials. There is no general regulation for all but different countries have different guidelines on certain UV filters. Several BP-type UV filters, such as 2,4-dihydroxybenzophenone (BP1), 2,2 -Dihydroxy4-methoxybenzophenone (BP8) and 4,4 -Dihydroxybenzophenone (4DHB), are currently authorized in the EU with the total specific migration limit (SML(T)) of 6 mg/kg from packaging into food, but are not authorized for use as additive or monomer in food contacting materials by the US FDA. However, 2,2,4,4 -tetrahydroxybenzophenone (BP2) is strictly forbidden in both the US and the EU.

FDA also removed benzophenone (listed as synthetic flavoring substance and plastic additive) from approved food additives lists in 2018. While California has listed benzophenone as a carcinogen under Proposition 65.

ECHA has listed four benzotriazole UV stabilizers (UV-320, UV-327, UV-328, and UV-35) as Substances of Very High Concern (SVHC) due to persistent, bioaccumulative and toxic (PBT) properties (ECHA, 2018a).

Annex 10 of the Swiss FCM Ordinance establishes limits for UV filters used in the printing of FCM: Part A sets out specific migration limits (SMLs) for toxicologically evaluated substances, such as benzophenone (0.6 mg/kg). Part B establishes an analytical limit of 10 ppb (10 µg/kg) for non-evaluated substances.

There is no guideline in India.

3. Circular Economy and EDCs in food packaging materials

A **circular economy** is based on business models that replace the end-of-life concept with minimizing waste, reducing raw material and energy inputs, alternatively reusing, and recycling materials. It is often promoted as a solution to the current production, use, and disposal of food packaging. Circular economy in food packaging industry include redesigning of packaging formats and delivery models, promoting reusable packaging, and improvinwg the quality of recycled materials. The **reusing and recycling** potentially reduce raw material use and environmental impacts.

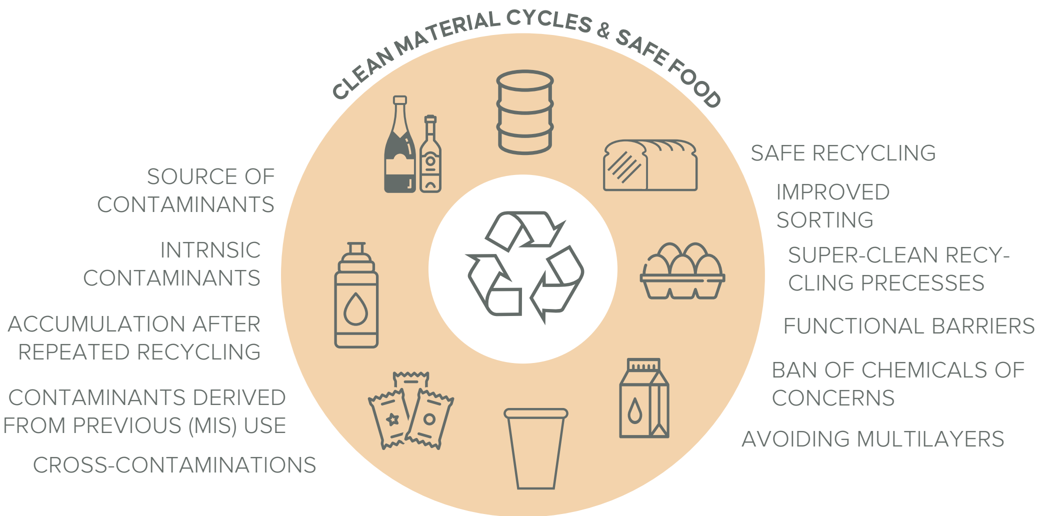


Figure 15: Sustainability of reusable packaging

3.1. Reuse

Reuse is encouraged under circular economy or circular packaging solutions and improving the economics of food packaging materials. Infact, circular economy describes the reuse of packaging materials, rather than recycling or throwing it away, a feasible option as instead of sending the package straight to the recycling bin, the container can be reused as a storage container extending the life of the packaging materials, and resulting in less waste to landfill.

Though its economically feasible but not all containers are safe to reuse. The scientific research has already established the fact of migration of EDCs and other harmful chemicals while reusing the container especially of plastic origin. During storage, heating, processing these chemicals are more prone to leaching from containers and continuous consumption of these may result in exceeding the minimal risk limit hence negatively impacting health. Migration is affected by temperature, storage time, the chemistry of both the food contact article and food, the thickness of the food contact layer, and the packaging size (proportionally higher migration from smaller packaging sizes due to the increasing surface-area-to-volume ratio). When the polycarbonate plastics and can lined with epoxy resins are exposed to hot liquids, BPA leaches out 55 times faster than it does under normal conditions.

In addition to intentionally added chemicals some NIAS have also been reported in FPM which breakdown due to heating, washing, etc. and leached to stored food materials. Considering the chronic diseases associated with exposures of such chemicals, reuse of food packaging materials should be addressed with more attention.

3.2. Food Packaging and Recycling

Recycling is currently seen as an important measure to manage environmental impact of packaging waste especially plastic packaging materials. Some materials can be recycled almost infinitely into new food packaging such as glasses. For others, the number of cycles is limited, and special measures are needed to guarantee the safety of the recycled material before it is used in contact with food again. Some materials cannot be recycled into new food packaging and are either down-cycled or not recycled at all. (Table 7)

Further, with the circular economy and recycling of the materials have gained wide attention, the recycling of packaging materials have been taken up by the industries and also by the policy makers. In this context, the presence of endocrine disrupting chemicals can be hindrance to the circularity of the packaging materials. . During recycling properties such as stability, color, and smell of the packaging materials get change. Additionally, the chemical safety can also be compromised when the material allows carryover of hazardous chemicals in recycled food packaging.

The use of recycled food packaging may increase the number and range of contaminating substances and potentially hazardous chemicals that can migrate from the packaging into food. The materials intended for recycling may contain intrinsic chemicals such as dyes, additives and their degradation products that may degrade during use and/or recycling. Such chemicals may accumulate when materials are recycled several times. Even non-food grade materials may enter the recycling stream. Therefore, It is essential to monitor recycled materials of the packaging for the presence of non-

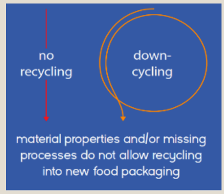
intentionally added substances (NIAS), including (often unknown) impurities, reaction and break-down products.
Exposure to such migrating chemicals has been associated with chronic diseases like endocrine disruption, it is of high importance to assess the safety of recycled packaging.

Figure 16: Images of some recycled food packaging materials
https://www.glbc.com/blog/food-packaging-trends-in-2022/

Regulation on recycled Food Contact Materials (FCM)

- In Europe, the use of recycled plastics in FCMs is specifically regulated under the Plastics Recycling Regulation (EC 282/2008). However, no harmonized regulation exists for food contact materials based on recycled paper and board.
- EU regulation set an overall migration limit (OML) of 60 mg of the total migrated substances (total sum of IAS and NIAS)/kg food or 10 mg of total substances/dm2 food contact surface, as well as specific migration limits (SMLs) for each migrated IAS from food packaging material into food ((EC) No 282/2008; (EU) No 10/2011).
- Switzerland has banned the use of recycled paper and board in direct contact with food (FDHA, 2016).
- In the US, the use of recycled paper and board is regulated under 21 CFR 176.260 in this it mentioned that waste paper shall not contain any poisonous or deleterious substance that is retained in the recovered pulp and migrates into food, except those specifically regulated under 21 USC 346 and 21 USC 348. The US FDA considers recycling processes for plastic FCMs on a case-by-case basis and invites recyclers of plastic to submit information on their process for evaluation and comment (US FDA, 2006; 21 CFR 176.260).
- In January 2022, the Food Safety and Standards Authority of India (FSSAI) amended the Food Safety and Standards (Packaging) Regulation, 2018, to allow the use of recycled plastics as food contact material based on the plastic Plastic Waste Management (Amendment) Rules, 2021 ; however, specific recycling processes has been listed out to safeguard the health.
- In February 2022, the Ministry of Environment Forest and Climate Change (the MoEF&CC) has published guidelines for Extended Producer Responsibility (EPR) for plastics packaging, which set quantitative targets for the use of recycled content in packaging.

Table 6. Specific migration limits for substances from recycling plastic materials.

S.No.	Packaging materials	Composition	Pics	End of life	Issues	Recycling status
1	Multi-material	75% paperboard 20% Plastic (polyethylene) 5% Aluminium foil		Commonly incinerated or sent to landfills in many countries. For fiber-based multi-material packaging such as beverage cartons, separated collections and optimized sorting procWesses are currently being implemented in many places. Plastics and aluminum that are used in multi-material packaging cannot be recycled efficiently at present.	Chemicals from the outer layer of packaging, the adhesive, and the printing ink can migrate to the inner layer & into the food. Material properties &/w missing processes do not allow recycling into new food packaging.	
2	Plastic	Plastics consist of polymers forming the structure of the material, besides various additives and non-intentionally added substances also present.		End-of-life options for plastic packaging include landfill, incineration, and recycling. However, incorrect disposal and leaching of plastic packaging into the environment leads to severe pollution.	Chemicals like additives and non-intentionally added substances can easily leach out of the packaging into food. microplastic particles can leach out during production, use, and at the end-of-life only selected types of plastic are currently recycled into new food packaging, but most plastic food packaging is either not at all recycled or it is down-cycled recycled plastic food packaging can also contain contaminants originating from food components or non-food chemicals absorbed during previous use, degradation products in aged plastics, and process chemicals	

S.No.	Packaging materials	Composition	Pics	End of life	Issues	Recycling status
3	Paper and card board	Cellulose fibers. Also contains additives such as water & oil resistant		In many countries, paper and board are separately collected and recycled, but are often not recyclable due to coatings, chemical treatments, or contamination with food residues. It also include disposal at incineration and landfill. Although paper and board packaging is compostable, but persistent chemicals (like PFAS, phthalates, UV 328 etc) may be dispersed in the environment through this practice.	Currently, only the paperboard fraction of beverage cartons can be separated in established recycling processes, but the recovered material is not used in contact with food again. Bisphenols that were used in thermal paper receipts entered the recycling stream. Similarly, Photo initiators such as UV filters, and Phthalates can cross contaminate and add-up the concentration during recycling.	
4	Metals	consists of alloys of >90% aluminum with other metals, such as copper, zinc, and manganese		If the packaging mainly consists of metal (e.g., cans, lids), it can be separated and recycled repeatedly	metal packaging is often coated with an organic polymer such as epoxy resins preventing unwanted interactions between metal and food. However, many chemicals present in these coatings were found to migrate into food, for example, bisphenol A	
5	Glass	Silicon dioxide and metal oxides.		When treated carefully, glass is very durable and stable. It can be recycled without loss of quality.	The constituents of glass are strongly retained in the material.	


SALT
COCONUT
STAR ANISE
HONEY
GOJI BERRIES
MIXED NUTS
PASTA
CHIA SEEDS
CINNAMON
SALT
PAPRIKA

4. The Food Packaging Regulatory Landscape: Indian scenario

The changing socio- economic paradigm has shifted the way foods are being delivered from one part of the world to the other part of the world. This led to the huge demand of the food packaging materials (FPM) during these years not only globally but also in India. The India Packaging Market was valued at $50.5 billion in 2019, and expected it to reach $204.81 billion by 2025, registering a CAGR of 26.7% from 2020 to 2025. Recently, online food ordering companies, have introduced 100% tamper-proof packaging. The companies are coming up with innovative, consumer friendly packaging materials. However, these packaging materials contains additives such as photoinhibitors, anti-greasing agent, heat and light stabilizers, antimicrobials, antioxidants, colorants, dehydrating agents etc. and some NIAS as well. And the research studies have proved that many of these chemicals or additives have potential to disrupt hormone system and hence the well-being of human.

S.No.	Substance	Maximum Migration limit (mg/kg)
1.	Barium	1.0
2.	Cobalt	0.05
3.	Copper	5.0
4.	Iron	48.0
5.	Lithium	0.6
6.	Manganese	0.6
7.	Zinc	25.0
8.	Antimony	0.04
9.	Phthalic acid, bis (2-ethylhexl) ester (DEHP)	1.5

Table 6. Specific migration limits for substances leacing from recycling plastic materials

In India, considering the safety of food and human health the Food Safety and Standards Authority of India (FSSAI). FSSAI has issued a new packaging regulations Food Safety and Standards (Packaging) Regulations, 2018 to replace the 2011 regulation with the stringent standards in place for heavy metals and Phthalates. As per the regulation migration limits for specific contaminates in plastic packaging materials has been specified.

However, the regulation has not specified any standards about other additives or chemicals that are present in FPM and has tendency to migrate easily. The research studies and data have confirmed that many of the EDCs are migrating from the food packaging materials and cause serious health hazards.

Recommendations

In this context, few recommendations have been drawn out, which could restrict EDCs in food packaging in India, in order to minimize the adverse impact on human health and the environment:

- **Recognizing EDCs as a threat:** Considering global developments focused on EDCs, the Government of India needs to recognize the emerging problems associated with EDCs and create a specific policy framework to manage these chemicals considering the larger public health consideration. The Draft Chemicals (Management and Safety) Rules, 20xx government has enlisted certain commonly used chemicals in packaging material such as Bisphenol- A, phthalate congeners, Nonylphenol etc. in restricted or banned list but this is applicable for manufacturing, importing, storage etc. of chemicals not specific to food packaging materials and the draft is still not notified by the ministry.
- **Preventive measures:** There are several chemicals with EDCs properties which are used as dye, additives, photo initiators, printing ink etc. in food packaging materials. These chemicals have been dealt in an isolated manner in India and many of the products still contain these chemicals, for ex BPA is banned in baby feeding bottles and infant food packaging but there are no guidelines on other packaging of food supplements & products. Thus, intensive efforts are required for suitable preventive measures to address the issue of EDCs in India.
- **Stringent Guidelines for FPM:** As intrinsic chemicals may get accumulate when materials are recycled several times, Regulatory agencies should come up with stringent guidelines to monitor recycled materials for the presence of non-intentionally added substances (NIAS), including (often unknown) impurities, reaction and break-down products. Migration limit should be set for these chemicals. For example Food Safety and Standards (Packaging) Amendment Regulations, 2020 has set the specific migration limits of DEHP from plastic materials intended to be in contact with articles of food as 1.5mg/kg, but no such guidelines exist for other congeners of phthalates or other EDCs.

  Similarly, considering the recent research data and global development there is a need to amend existing regulations on different food packaging materials. For ex., in Corrugated Fibre Board Boxes- Specification (Part 1) – IS 2771, migration limit should be set for PFOS and PFOA which are already restricted in many countries.
- **Stringent guidelines for recycling:** In January 2022 the FSSAI has amended the Food Safety and Standards (Packaging) Regulation, 2018, to allow the use of recycled plastics as food contact material and specific recycling processes has been listed out to safeguard the health. However, the recycling may accumulate the number and range of contaminants and chemicals such as dyes, additives and their degradation products that can migrate from the packaging materials to the food. Even non-food grade materials may enter the recycling stream. Considering the long term exposure and health impacts, it is important to put the stringent regulation in place from the perspective of chemical migration to check the carryover of such chemicals specially EDCs into recycled materials.

- **Periodic Monitoring:** There are limited studies in India on the migration of EDCs from the food packaging material. Further with the thrust on the circular economy in India and allowing the use of the recycled plastic for food contact materials, there is a growing need to conduct periodic monitoring of the food stuffs meant to use for the food packing materials.
- **Role of Industries:** The industries should be sure that the food packaging materials they are using should be clean products and free from any form toxics chemicals like EDCs. So the industries should invest and come up with an innovative suitable food packaging materials which are reusable, recyclable, resalable, and convenient to use and free from toxic ingredient. The industries should understand that choosing a healthier and safer materials will help them to create a positive brand image.
- **Labelling and consumer awareness:** The labelling is very important to build the consumer confidence. Furthermore, it is a way through which health of consumer get protected in terms of nutrition and food safety. Therefore the packaging food should be labeled with all the ingredients it contains, so that the consumers will take an informed decision.

5. ANNEX

Annex-I Types and properties of resins used in internal can coatings

	Nature	Flexibility	Pack resistance	Main end-uses
Epoxy-phenolic	High molecular weight epoxy resins cross-linked with phenolic resole resins	Good	Very good	Universal gold lacquer for three-piece cans shallow drawn cans
Organosol	PVC dispresed in an appropriate varnish and conventionally stabilised with a low molecular weight epoxy resin or novolac epoxy resin. epoxidised oils can also be used	Very good	Very good	Drawn cans easy-open end often used over epoxy-phenolic basecoat
Epoxy-anhydride	High molecular weight epoxy resins cross-linked with anyhydride hardeners	Good	Very good	Internal white for three-piece cans
Epoxy-amino	High molecular weight epoxy resins cros-linked with amino resins. Also epoxy acrylic water-based spray internals for B&B DWI	Good	Limited	Universal lacquer for beer and beverage cans (water reducible) side seam stripes Some food system
Polyester	Polyester resins cross-linked with amino or phenolic resins. May contain lower molecular weight epoxy resins	Very good	Pack-dependent	May not be suitable for very acidic and aggressive foods
Phenolic	Phenolic resins (s) which self-crosslink (cure)	Very poor, but film quality is weight-dependent	Excellent particularly for aggressive foodstuffs	Drums and pails where flexibility is not a critical factor
Oleoresinous	Naturally occuring oils with synthetic modification	Variable	Pack-dependent	Very limited uses

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