

MINISTERO DELL'AMBIENTE e della tutela del territorio e del mare

> Italian Ministry for the Environment, Land and Sea

CONOSCI, RIDUCI, PREVIENI GLI INTERFERENTI ENDOCRINI

Knowing, reducing, preventing Endocrine Disruptors



A DECALOGUE FOR CITIZENS

National Istitute of Health





The "Decalogue for citizens" aims to inform the public about risks arising from the exposure to certain chemicals found in commonly used objects. The knowledge of both the sources of exposure to these substances and the possible alternatives would help citizens taking appropriate decisions and consequently reducing risks.

Edited by the Italian Ministry for the Environment, Land and Sea and the National Institute of Health.

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In 2008 the Italian Ministry for the Environment, Land and Sea promoted and financed the "PREVIENI" Project "Studio in aree Pilota sui Riflessi ambiEntali e sanitari di alcuni contaminanti chimici emergenti (interferenti endocrini): ambiente di VIta, Esiti riproduttivi e ripercussioNI nell'età evolutiva" – Study in model areas on the environmental and health impact of some emerging chemical contaminants (endocrine disruptors): living environment, reproductive outcomes and repercussions in childhood.

EDs are substances capable of altering the hormonal balance, thus, EDs may cause diseases of various kinds; in recent years their role has been increasingly brought to the attention of both the scientific and the policy-making communities.

Anticipating one recommendation of the 2010 WHO "Parma Declaration on Environment and Health" urging governments to adopt specific initiatives to protect children's health from the risks related to the presence of EDs in the environment, the PREVIENI project has provided guidance for the development of methodologies to monitor and to prevent risk factors related to EDs exposure.

The project provided a multidisciplinary research effort coordinated by the National Institute of Health (*Istituto Superiore di Sanità*-ISS) and carried out in cooperation by three scientific bodies: Department of Gynecology, Perinatology and Childcare of the University of Rome "La Sapienza", Department of Environmental Sciences of the University of Siena and Department of Veterinary Public Health and Food Safety of the ISS. PREVIENI aimed to build up an assessment "tool" to estimate the risks related to EDs exposure in some "pilot areas".

The study findings showed how people living in major urban areas were most exposed to EDs and people suffering from infertility or specific reproductive pathologies (e.g. endometriosis) had higher levels of these chemicals in their biological fluids.



The outcomes of the "PREVIENI" project can provide a significant contribution in order to fulfil the objectives set out in Regulation (EC) No. 1907/2006 ("REACH Regulation") promoting specific prevention initiatives and progressive replacement of the potential EDs in commonly used products. Empowering citizens through information initiatives, such as the "Decalogue", has the ultimate goal of favouring the adoption of behaviours aimed at protecting health and the environment.



Conosci, riduci PREVIENI gli IE: A DECALOGUE FOR CITIZENS

Endocrine disruptors are chemicals that can alter the hormonal balance of living organisms, including human beings. EDs can "turn on/off" or otherwise modify the normal hormone signals: their effects cause concern, because of their insidiousness. But which substances can be considered EDs? Although not definitive, the list of EDs is becoming increasingly large and includes:

- substances that persist in the environment for a long time and tend to accumulate in living organisms, thus also in food. Some substances (e.g. PCBs widely used as lubricants in the past) have been banned for several years, some, such as dioxins, are released in combustion processes and others are present in commonly used products (PFOS/PFOA and PBDE); - some pesticides, despite the fact that substances used in agriculture are carefully assessed and controlled throughout Europe; - some not persistent but widespread substances, such as some phthalates (e.g. DEHP) and bisphenol A. These substances are "less toxic" "than the wellknown pesticides and dioxins, but it has to be considered that they are less investigated and controlled.

Why do we worry about EDs? Hormonal balance is essential for the development and growth of foetuses and children: let's think of the role of estrogens and testosterone in sexual development and puberty or the role of thyroid in brain development. The same ED can induce different effects in males and females, therefore the evaluation of EDs should take into account the vulnerability related to both age and sex.

Adverse effects produced by EDs exposure are pointed out by scientific studies that show how highly exposed people undergo an increased risk of reproductive disorders (infertility, miscarriages, endometriosis, etc.), behavioural disorders in childhood and possibly also of diabetes and some types of cancer (testicular, breast, etc.).

Finally, even exposure to very low doses, in the environment and/or in food, of several different EDs with the same action or the same target, might sum up to induce a combined ("cocktail") adverse effect.

The international community is dealing with the ED problem and the European Union, through the REACH Regulation, promoted a project of a regulatory framework for the evaluation, authorisation and restriction of chemicals on the market, also in order to replace those of major concern, such as EDs. Some EDs have already been banned in certain products (for example, bisphenol A in baby bottles); as it concerns other EDs, their levels in food and consumer products are regulated by law in order to prevent health risks. However, regulations are evolving, following the development of scientific knowledge.

Citizens can never replace the regulatory actions by the European and national authorities but they can adopt responsible and smart behaviours in everyday life in order to protect their health, the health of their children and their environment.



Conosci, riduci PREVIENI gli IE: A DECALOGUE FOR CITIZENS

Endocrine disruptors and the environment

The impact of EDs on the environment can be significant if we consider their ubiquitous presence, in some cases their persistence and their potential effects on living organisms.

The main sources of environmental risks caused by EDs are represented by behaviours not in line with the current legislation, by industrial processes and wastes and by improper disposal of products that contain plastics, glues, paints, etc. The more persistent EDs tend to accumulate in organisms: contaminants become more concentrated in organisms' tissues or organs as they move up the food chain. (Biomagnification - see illustration below).

Pollutants that can interfere with the sexual hormones' function are particularly relevant because of their adverse effects on the conservation of species and the safeguard of biodiversity. The presence of EDs in the environment is assessed through the monitoring of water, soil and sediments and the use of sentinel animals (indicator organisms).

By comparing the obtained data, it is possible to determine the environmental quality and the effects of EDs on different organisms.

Adverse effects have been observed in organisms in their natural habitats (aquatic and terrestrial) and confirmed by laboratory studies, including alterations in thyroidal and reproductive functions with decreased survival rate and developmental alterations in the progeny.

Human beings are exposed both through the environment and the food chain, therefore the protection of environment and wildlife plays a key role in the protection of human health.



 \Rightarrow toxic substance

- \Rightarrow water
- \Rightarrow sediments
- \Rightarrow aquatic vegetation
- \Rightarrow small fishes
- \Rightarrow big fishes
- \Rightarrow human beings

The "Decalogue"

People are exposed to many different chemicals through consumer products, the environment where they live and food. Control measures are in place to ensure that hazardous substances levels are below the limits established by regulations. The main impact of exposure to EDs is on reproductive and developmental health, therefore mainly on young adults and children. Which measures could be implemented to reduce exposure to these chemicals? One objective of scientific research and, therefore, of current legislative effort is the identification of substances that pose a lower risk for humans and for the The adoption of a mindful behaviour and lifestyle can also environment. contribute to minimize exposure and vulnerability of the organism, protecting it from a contaminants overload. Such behaviours include careful observance of instructions contained in products labels and their correct use. Moreover the knowledge of possible EDs generated by natural processes, e.g. polycyclic aromatic hydrocarbons (PAHs) deriving from "burnt" food or not adequately controlled combustion, is essential.

The outcomes of the "PREVIENI" project highlighted the need to communicate to the general public the possible risks arising from the substances investigated and to provide useful information.

Fact sheets

For each ED examined in the "PREVIENI" study a fact sheet provides detailed information on its use, its effects, where it can be found and useful tips to minimize exposure to EDs.



Decalogue

To be limited or avoided	To be preferred and/or replaced
1. Do not reuse worn out plastic containers for food and beverages	Use only plastic containers in pristine conditions, following the manufacturer's instructions
2. Restrain from using non-stick cooking utensils, if the coating is worn	Use cookware suitable for food contact and undamaged
3. Use grease-proof paper or film for food packaging only following the manufacturer's instructions. Read the label!	
4. When cooking ensure a proper ventilation in the room and use an appropriate kitchen range hood	
5. Limit incense burning , candle smoke and avoid smoking cigarettes in the environment where you live	Ensure a frequent change of air when living indoor
6. Replace torn and /or worn out wrappings of objects containing foam padding (i.e. car seats, mattresses, etc.)	
7. Avoid clothing products with optional waterproof or anti-stain treatments	Prefer clothing products showing an easily identifiable origin and composition
8. Avoid the consumption of partially charred / burned foods and limit smoked foods. Remove burned parts from food (i.e. meat or pizza)	
9. When choosing home materials limit the use of soft PVC containing DEHP	
10. Avoid the accumulation of dust indoor	Ensure an adequate and frequent cleaning of rooms and make sure that your vacuum cleaner is kept in a proper state of maintenance (clean filters and dust container regularly and replace the dust bag as appropriate)

Decalogue for children

To be limited or avoided	To be preferred and/or replaced	
 Avoid the stagnation of air and dust in the rooms where babies spend their time crawling or playing on the floor 	Ensure a frequent change of the air and the regular cleaning of rooms. Make sure that your vacuum cleaner is kept in a proper state of maintenance (clean filters and dust container regularly and replace the dust bag as appropriate)	
 If you have a PVC floor containing DEHP where children play, use a carpet made of untreated fibers 		
3. Avoid clothing products for children with optional waterproof or anti-stain treatments	Prefer clothing products showing an easily identifiable origin and composition	
4. Avoid mattresses with tarpaulin cover not in accordance with current legislative standards and avoid mattresses covers in soft PVC containing DEHP		
5. Use linings made of untreated fibers if you have baby changing table and / or strollers coated with soft PVC containing DEHP; in general prevent children from coming into mouth contact with PVC objects		
6. When heating milk beverages and baby food, use only plastic containers in pristine conditions following the manufacturer's instructions		
7. Let hot liquids cool as appropriate before pouring them into plastic containers not specifically suitable for use at high temperatures		
8. Thoroughly wash baby bottles and other containers after sterilization, do not use polycarbonate baby bottles		
9. Give children fresh and seasonal food; rinse fruits and canned vegetables properly before consumption		
10. Avoid the consumption of foods with charred / burned parts	When cooking food for children, do prefer methods that preserve the content of water-soluble vitamins (e.g. steam cooking)	

PERFLUORINATED COMPOUNDS (PFCs): PFOS AND PFOA

What they are

PFOS and PFOA are chemical compounds widespread in the environment because of their persistence. According to the EFSA Panel on Contaminants in the Food Chain some foods (especially seafood) are an important source of exposure to PFCs. However, mainly as regards PFOA, also other non-food related sources can contribute to the total exposure: indoor dust and air polluted by PFCs released from consumer products.

PFCs are able to accumulate and persist for years in the human body.

Where they can be found

EU regulations state several limitations for these compounds (see below). PFCs are used in industrial processes and consumer goods such as water and stain repellent treated carpets and upholstery fabric, anti-grease coated food containers, food contact wax paper, flame retardants used in some foam-padded mattresses, couches and car seats, and some floor paints.

What they do

Exposure to high levels of PFCs can be harmful: impaired thyroid function, liver toxicity and increased risk of infertility.

PFOA has been used in the past in the production of non-stick coatings. Currently, Italian manufacturers of cookware coatings do not use products with PFOA anymore. Therefore, consumers have to turn their attention to products coming from non-European countries, especially those without the CE mark.

PERFLUORINATED COMPOUNDS (PFCs): PFOS AND PFOA

How to reduce exposure

- Reduce the use of clothes with water/stain repellent treatments, and prefer those of readily identified origin and composition
- Phase out the use of worn non-stick cookware
- Use food contact wax paper only in accordance with the manufacturer's instructions
- Reduce the use of PFC-containing popcorn bags for microwave cooking
- When purchasing furniture or carpets, prefer those without stain and/or water-repellent treatments

EU Regulations

- **Regulation (EU) No 757/2010** PFOS and its derivatives are included in the persistent organic pollutants (POPs) list. The production, placing on the market and use of PFOS, whether on its own, in preparations or as constituent of articles, are prohibited. The Regulation includes limited exemptions, subject to periodical reviewing, and standards for PFOS-containing waste management.

- PFOA is included in **2010/161/EU European Commission Recommendation** on the monitoring on perfluoralkilated substances in food.

- Decisions 2009/543/EC and 2009/544/EC of 13 August 2008 lay down the ecological criteria of Community eco-label to indoor and outdoor paints and varnishes: "Perfluorinated alkyl sulfonates (PFAS), perfluorinated carboxylic acids (PFCA), including PFOA and related substances and chemicals that may degrade to PFCA are not permitted in the products".

- **Regulation (EC) No 1935/2004** lays down general principles and requirements for materials and articles intended to come into contact with food. Such materials must be produced according to good manufacturing practices; specific limits are set on the migration of certain constituents or groups of constituents into or on to food at normal conditions of use, taking due account of other possible sources of exposure to those constituents.



DI(2-ETHYLHEXYL)PHTHALATE (DEHP)

What it is

DEHP is a phthalate plasticizer used in the production of PVC and vinyl chloride resins: DEHP is added to increase plastic flexiblity/softness. Being a cost-effective, general purpose plasticizer, DEHP is still commonly used, thus, it is still a widespread environmental pollutant.

Where it can be found

DEHP is present in many general purpose products of our everyday life: food contact materials (film, blister packaging, screw caps, bottles, trays and transport packaging), building materials (flooring, cables, wall cladding and roofs), soft plastic-made accessories for vehicles, office supplies and stationery.

However, DEHP use in Europe has dramatically dropped; for some usages, such as flooring and food contact film, European manufacturers almost completely substituted and phased-out DEHP. For other applications, as well as for imported goods, its use is regulated as indicated below.

What it does

DEHP can impair the production of sex hormones (estrogens and testosterone), resulting in an increased risk of infertility, as well as the liver lipid metabolism, with possible predisposition to metabolic syndrome (tipe-2 diabetes and obesity).





DI(2-ETHYLHEXYL)PHTHALATE (DEHP)

How to reduce exposure

- For stationery and office supplies reduce the use of items made of soft PVC containing DEHP
- Consider building and furniture materials carefully when you're making purchases: reduce the use of soft PVC containing DEHP
- The household PVC plastic wrap (also known as cling film) has a label statement for safe use: use only in accordance with manufacturer's instructions Read product's label!
- Prevent babies and small children from coming into contact with materials made of soft PVC containing DEHP

EU Regulations

- **Directive 2005/84/EC** of the European Parliament and of the Council Restriction for placing on the market and use of phthalates as plasticizers in toys and childcare articles. This Directive has been subsequently repealed and replaced by Annex XVII of the REACH Regulation.

- **Commission Regulation (EC) No 552/2009** amending Regulation (EC) No 1907/2006: toys and childcare articles containing DEHP, in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market. Whereas "childcare article" shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.

- **Commission Regulation (EU) No 143/2011** DEHP is included in the list of substances of concern subject to authorization.

- **Regulation (EC) No 1935/2004** lays down general principles and requirement, in compliance with the food legislation, for materials and articles intended to come into contact with food.

- **Regulation (EU) No 10/2011** on plastic materials and articles intended to come into contact with food: DEHP shall only be used in repeated use materials and articles contacting non-fatty foods.

POLICYCLIC AROMATIC HYDROCARBONS (PAHs)

What they are

Polycyclic aromatic hydrocarbons are a group of compounds that are formed from combustion processes, both industrial and household, in particular from incomplete combustion of fossil fuels such as coal. In the environment PAHs can be found as complex mixtures, tens of compounds, of which 15 (especially benzofluoroanthenes and benzopyrenes) are considered critical from the standpoint of toxicological risks.

Where they can be found

PAHs exposure can occur both from airborne pollution and from other sources such as cigarette smoke, cooking fumes, incense burning and candle smoke. In order to prevent exposure, lifestyle and nutrition play a key role: PAHs form at high temperatures within burnt/overheathed parts of foods, especially with some cooking methods, such as grilling or charring, smoking, barbecuing.

What they do

Exposure to PAHs produces genotoxic and carcinogenic effects: it increases the risk of t<u>umours</u>, especially those associated to hormonal imbalances, such as postmenopausal breast cancer and prostate cancer, and the occurrence of lung cancer among non-smokers. Prenatal exposure to PAHs is associated with low birth weight



POLICYCLIC AROMATIC HYDROCARBONS (PAHs)

How to reduce exposure

- During cooking make sure that there is adequate ventilation and use exhaust hoods
- Reduce the consumption of smoked foods
- Remove the fatty portion of meat before cooking: reduce barbecuing or grilling, especially those over charcoal, prefer other cooking methods
- Remove any burnt/charred portion of foods before eating
- Use undamaged nonstick cookware to ensure cooking without charring/carbonization



EU Regulations

- **Commission Regulation (EC) No 552/2009** amending Regulation (*EC*) No 1907/2006 and concerning the restriction of some PAHs.

- **Commission Regulation (EU) No 835/2011** amending Regulation (EC) No 1881/2006 as regards maximum levels for PAHs in foodstuffs.

- **Commission Regulation (EU) No 231/2012** laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 on the additive E153 vegetable carbon: benzo(a)pyrene less than 50 μ g/ kg in the extract obtained by extraction of 1 g of the product with 10 g pure cyclohexane in a continuous extraction.

POLYBROMINATED DIPHENYL ETHERS (PBDEs)

What they are

PBDEs are industrial chemicals used for various commercial purposes, mainly as flame retardants. PBDEs accumulate in the fatty tissues of organisms, thus some PBDEs are included in the list of persistent organic pollutants (POPs).

Where they can be found

PBDEs can be used as additives in the manufacture of furniture, curtains, carpets and upholstery and in some polyurethane foams paddings. Even the indoor dust may be contaminated by these substances. According to Directive 2002/95/EC, electric and electronic equipment put on the market in Europe from 2006 cannot contain PBDE.

Furthermore, their chemical stability resulting in bioaccumulation in the food chain can lead to high concentrations of PBDEs in some fat-containing foods

What they do

PBDEs may disrupt the endocrine balance, especially thyroid function, thus altering neurological and neurobehavioural development.

EU Regulations

- **Directive 2003/11/EC** amending for the 24th time Council Directive 76/769/ EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations including pentabromodiphenyl ether, octabromodiphenyl ether. This Directive was subsequently repealed and replaced by Annex XVII of the REACH Regulation.

- **Commission Regulation (EC) No 552/2009,** amending Regulation (EC) No 1907/2006, laying down octabromodiphenyl ether restriction.

- **Commission Regulation (EU) No 757/2010** adding *tetrabromodiphenyl ether, hexabromodiphenyl ether, heptabromodiphenyl ether* and *pentabromodiphenyl ether* to persistent organic pollutants list (POPs).

Since 2006, in accordance with **Directive 2002/95/EC**, electrical and electronic equipment placed on the market should be PBDEs free.

- **Directive 2011/65/EU** of the European Parliament and of the Council states that PBDE in electrical and electronic equipment cannot exceed 0.1% by weight in homogeneous materials.

POLYBROMINATED DIPHENYL ETHERS (PBDEs)

How to reduce exposure

- Check items padded with foam (car seats, mattresses, sofas, etc.): if the casing is damaged and the foam is not completely enclosed by a protective fabric, replace the item
- To reduce indoor dust, ensure the household hair exchange and a proper maintenance of the vacuum cleaner (filter and collection chamber cleaning / bags replacement if any)
- Pay attention when removing old fitted carpet because the underlying layer may contain PBDEs: keep the work area isolated from the rest of the house
- When purchasing new products ask information about what type of flame retardants was used.
- Remember: natural or latex foam and natural cotton are flammable and may require a fire retardant. When purchasing ask what flame retardant they contain.
- Take care of not purchasing electric or electronic equipment containing PBDE



BISPHENOL A

What it is

Bisphenol A is a chemical «building block» for the manufacture of polycarbonate plastic, a kind of plastic widespread for its properties of transparency, mechanical and heat resistance used in food contact materials and epoxyne resins (lining protective of most cans and food recipients)

Where it can be found

BPA is a compound the use of which is, in some cases, regulated (see below). Its uses range from polycarbonate plastics used in the manufacture of bottles and food containers, thermal paper receipts and dental equipment.

Therefore, the overall exposure of the population derives from multiple sources.

What it does

BPA has estrogenic effects, can alter thyroid function and the development of reproductive, nervous and immune systems. In the adult, BPA toxicity appears to be modest; however, foetuses and newborns may be much more vulnerable due to their smaller size and reduced ability to metabolise.



BISPHENOL A

How to reduce exposure

- Use undamaged containers to heat food and beverages and only for the uses specified by the manufacturer
- Let cool hot food and beverages before pouring in plastic containers not suitable for high temperature
- Do not use worn plastic containers
- Use dishwasher only for plastic containers suitable for high temperatures
- Rinse canned fruits and vegetables before consumption; prefer fresh seasonal fruits and vegetables



EU Regulations

- **Regulation (EC) No 1223/2009** on cosmetic products: Bisphenol A included among substances banned in cosmetics.

- **Regulation (EU) No 321/2011** amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles - banning of Bisphenol A in polycarbonate-made infant feeding bottles

- **Regulation (EC) No 1935/2004** lays down general principles and requirement, in compliance with the food legislation, for materials and articles intended to come into contact with food.

The website of the Ministry for the Environment, Land and Sea http://www.minambiente.it/pagina/gli-interferenti-endocrini

The National Institute of Health (ISS) website area dedicated to the PREVIENI project www.iss.it/prvn/

The ISS website area dedicated to EDs www.iss.it/inte/

The website of the Ministry of Health www.salute.gov.it

The website of the European Commission on EDs http://ec.europa.eu/environment/chemicals/endocrine/index_en.htm



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