Endocrine Disruptors

Risk Management Options

Emerging Risk Initiative – Position Paper

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Some pesticides widely used in agriculture are potential endocrine disruptors

1 Executive Summary

Human and animal life is widely exposed to many artificial substances that interfere with the sensitively constructed hormonal system. Substances that interfere with hormones are called Endocrine Disrupting compounds/chemicals (EDC). Harmful effects on fish and amphibian have been proven. Evidence is mounting that specific substances are connected to human bodily injuries. Liability insurers may therefore be exposed from affected industries as policies do not exclude these risks.

Many processes in the human and animal body are controlled by hormones. Among such processes are metabolism, sexual development, reproductive functions, immunity, sleep-wake-cycle, growth, stress-response and mood regulation. Some of these hormones have slow but long-lasting effects.

EDC can be natural products such as genistein from soy or zearalenone from fungus. Of concern are man-made chemicals, which are produced and dispersed in large quantities. Some of these reach the human body via direct food contact; others are stable enough to enter it through the food-chain.

Environmental research and lab- data suggest a high susceptibility of fish and amphibians to the amounts of EDC stemming from agricultural use, combustion, sewage and smokestacks.

Singular events have spilt large quantities of EDC accidently into the environment (e.g. Dioxin in the Seveso accident or Corexit after the Deepwater Horizon oil-spill). Dramatic effects of EDC may be observed in humans after such high level exposure. A direct link between human health problems and chronic low-dose EDC intake has not yet been established. But concerns regarding the effect on sexual differentiation in fish or amphibians as well as impaired survival of affected offspring led to precautionary measures. Use of some substances has been limited if not totally phased out.

Regulation differs among the diverse legal environments. Some specific agreements that require phase-out of the most problematic substances have been signed across borders.

Liability exposures arise from environmental pollution and have led to successful claims for clean-up costs. The highest risk for the insurance industry emerges from the probable link between low-level EDC exposure and bodily injury. Taking into account the environmental stability, the long term exposure and the late disease onset, bodily injury claims could result.

Beside this casualty catastrophy scenario for all liability insurers, there already exist large settlements for clean-up costs or upgrades of water-treatment facilities to remove EDC from drinking water. For the risk management of liability insurers it is crucial to monitor this emerging risk. A greater clarity regarding the associated costs has to be achieved.

This paper gives a brief introduction to the risk and aims at increasing awareness. A dialogue should be started taking into account risk-mitigation strategies and the involvement of all stakeholders. We recommend to minimise the use and release of EDC and we encourage the removal of EDC/micropollutants from waste water and drinking water taking into account individual circumstances.

Corexit spraying aircraft at the Deepwater Horizon site

2 Introduction

Manufacturing operations, product use and waste disposal derived from industrial activities lead to many exposures to potentially hazardous materials. Identifying and quantifying risks related to such exposures is of crucial importance to the insurance industry. If causal links between exposure to certain products and adverse health or environmental effects are clearly established, manufacturers and consequently insurance companies can be heavily impacted. This is of special concern in the case where products are on the market for a long time, various exposure routes to these products exist and there is a lag between exposure and manifestation of potential adverse effects.

2.1 Background, History

First evidence suggesting that some chemicals could impact processes regulated by hormones was gathered from observations of adverse health effects following exposures of individuals to high concentrations of certain substances (see boxes).

The DES case
From the 1940s to the 1970s, pregnant women were treated with the synthetic hormone diethyl stilbestrol (DES) against miscarriage. As a consequence of in utero exposure to this active pharmaceutical ingredient, offspring were shown to have an increased risk to develop certain forms of tumors or prostatic diseases later on in life. This was attributed to the impact of DES on fetal development, a highly sensitive phase in life in which hormonal activity plays a key role. DES was then banned in the 1970s.

The Seveso catastrophe
In 1976, a chemical plant explosion in Seveso, Italy released high amounts of dioxins to the environment. As a consequence of the exposure to these environmental pollutants, several health disorders in individuals were observed. Amongst others, impacts to semen quality as well as to hormonal levels were later on related to potential endocrine disrupting properties of dioxins.

In the following years, increased efforts were made to investigate the potential endocrine disrupting properties of chemicals. Research work focused on understanding the mechanisms of endocrine disruption and on establishing causal links between exposure to certain chemicals and the increased incidence of several serious human health disorders as well as adverse effects observed in the environment. (Reference 1; Reference 2)

2.2 Hormones and Endocrine System

Hormones (derived from ancient Greek “horman” = to set into motion) are specialised chemical substances produced naturally in organisms. They are biologically highly active, even in very low concentrations and are essential for the regulation of many important physiological processes and bodily functions.

Examples for processes and bodily functions regulated by hormonal activity:

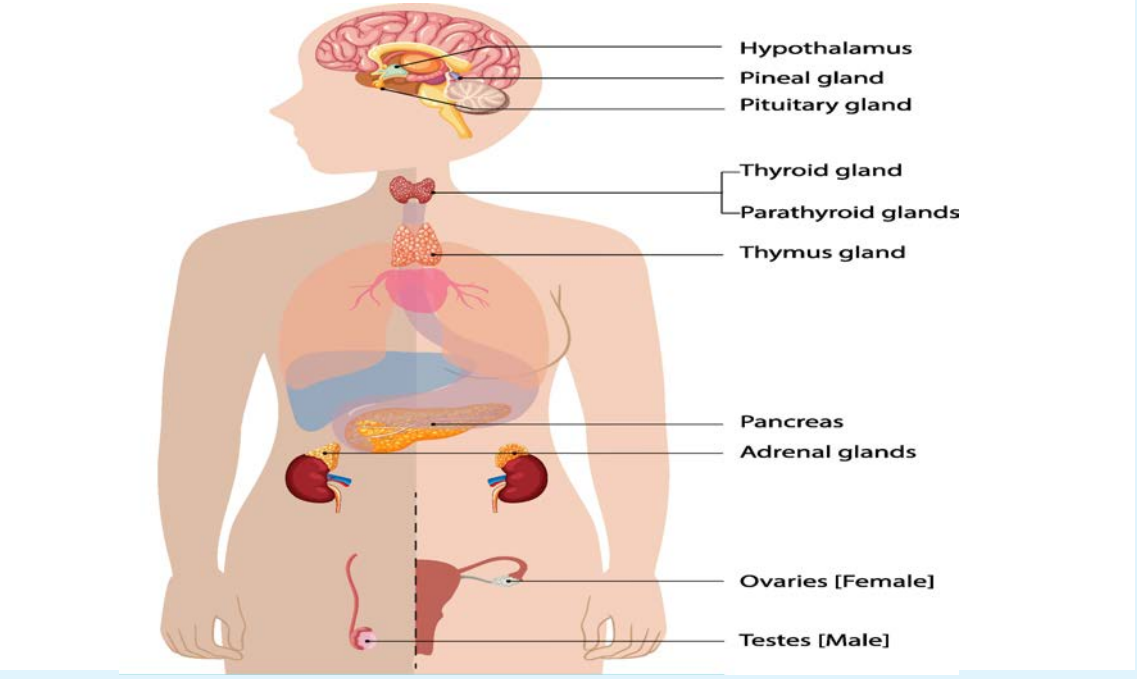
- Metabolism
- Sexual development and reproductive functions
- Menstruation
- Mood regulation
- Immunity
- Sleep-wake cycle
- Growth
- Response to stress

Hormones are produced in specialised cells and tissues of the body. Under control of the nervous system, they are secreted into the blood or other body fluids before being transported to their final targets, where they trigger physiological reactions by binding to specific receptors. Following this action, they can be deactivated by various biochemical modifications or secretion.

A well-known example, adrenalin, is a stress hormone produced in the adrenal gland. In stressful situations, it is secreted to the blood stream and reaches blood vessels and the heart amongst others as targets, where it binds to adreno-receptors triggering increased heart rate, elevated blood pressure and release of energy reserves as physiological reactions preparing the body for a “fight-or-flight” response.

The system of specialsed glands, cells, tissues and receptors regulating complex bodily functions by the use of hormones is called the Endocrine System.

The Endocrine System

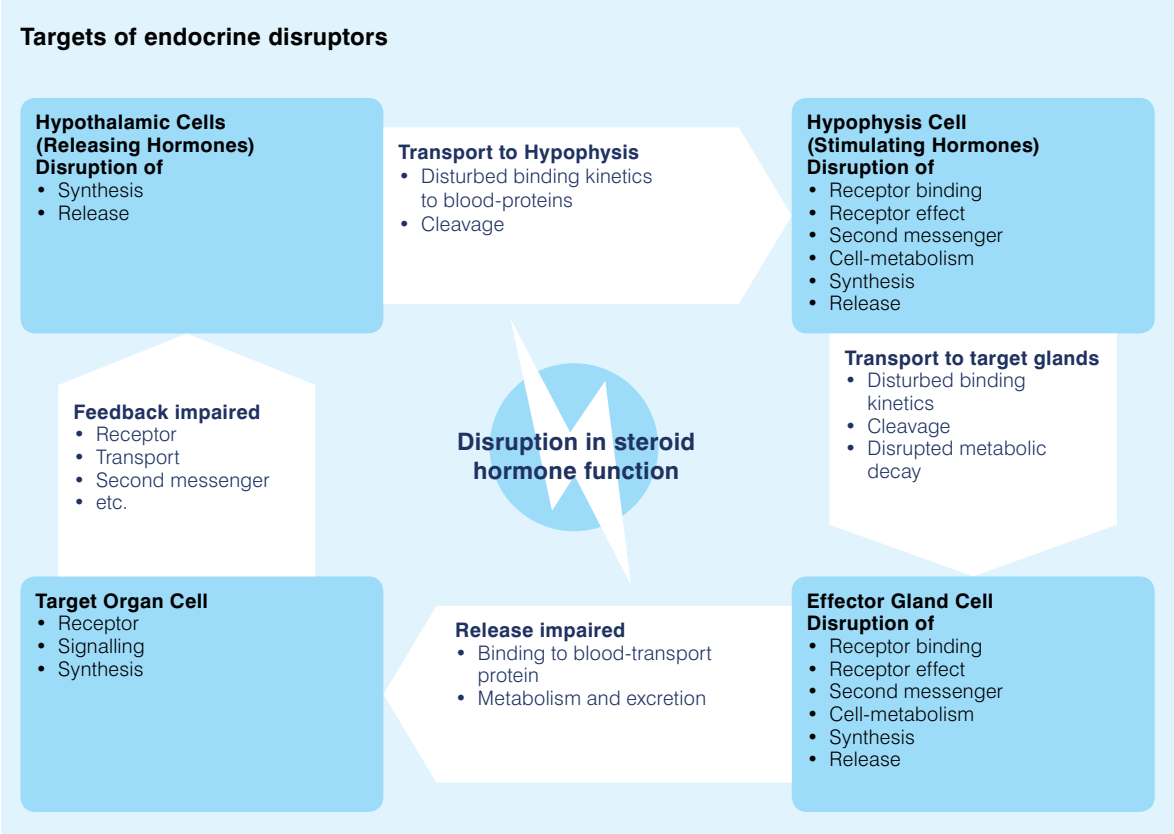


Hormone releasing glands in the human body

2.3 Types of EDC

EDC are exogenous substances which upon exposure can disturb the hormonal activities of the organism leading to adverse health effects. In general, EDC can act by:

- Mimicking natural hormones by binding to their receptors triggering physiological reactions at abnormal times or amplifying the activity of natural hormones (agonistic effect),
- Blocking hormone receptors preventing the binding of natural hormones consequently leading to a reduction in their activities (antagonistic effect),
- Indirectly affecting biosynthesis, transport or deactivation of natural hormones (agonistic or antagonistic effects).



All these modes of actions disturbing the hormonal system can lead to abnormalities and health disorders. In this regard, exposure during highly sensitive phases of the life cycle (e.g. fetal development and childhood) is of the highest concern.

Currently, several hundred chemicals are known to show hormonal activity. They are of very heterogeneous types and origin.

Besides man-made sources, several natural products such as soy beans and linseed contain substances showing hormonal activities. In general, they are less potent than man made disruptors. However, evaluation of their potential for endocrine disruption has to take into consideration the consequences from their exposure due to their extensive use in foodstuffs. (Reference 3)

EDC exposure during fetal development is of high concern

2.4 Sources of EDC

Special focus has been put on other man made chemicals, with unintentional hormone-like activity. These chemicals have been used for decades and were spread widely. Some of them are still in use:

- **Pesticides** such as DDT, vinclozolin, endosulfan, toxaphene, dieldrin, atrazine
- **Industrial chemicals and by-products**, such as polychlorinated biphenyls (PCBs), dioxins, bisphenol A and other phenols. Some of these phenols are breakdown products of surfactants, found in soaps and detergents.
- Also implicated are heavy metals, plastics, cosmetics, textiles, paints, lubricants. Sewage treatment effluent may contain a variety of natural and man made endocrine disruptors, including natural hormones from animal and human waste.
- Most of these substances have oestrogenic activity and environmental studies usually focus on the observation of effects of such activity. Nevertheless there are substances with similarities to the thyroid hormones which interfere with the thyroid metabolism and that can severely affect the thyroid control-loop. Some of them are widely used even in consumer products. Examples are:
  - Perchlorate (ClO_4^- – formerly used to treat hyperthyroidism, now used as an oxidiser in rocket fuel and explosives.) It can be found in airbags and fireworks and is increasingly contaminating the global surface.
  - Nutritive components from plants, such as C-and O-glycosidic glucosinolates (cruciferacea), cyanates, isocyanates and thiocyanates (e. g. cassava), which (irreversibly) inhibit thyroperoxidase (TPO), leading to goitre formation in susceptible individuals.
  - Several flavonoids and isoflavonoids, widely used as “green” “natural plant steroids” in postmenopausal hormone replacement therapy such as genistein
  - UV screens (e. g. benzophenone 2) regularly applied as sun protectants to prevent erythema, sun burns and skin cancer are potent TPO inhibitors and lead to goitre formation if the iodine supply is inadequate as is the case in many parts of the world.
  - Most natural compounds capable of modulating hormonal function are biodegradable and do not accumulate. Known artificial endocrine disruptors, their use, diffusion, stability and geographical extension make them prone to being accused of causing many different effects.

2.4.1 PHARMA

Besides exposure to pharmaceutical doses of EDC (e. g. contraception) there are vaccine-additives, dental sealants or haemodialysis materials with alleged EDC-properties.

In terms of quantity, (contraceptive-) hormone pills present the highest environmental exposure. Active hormones are found in large quantities in human urine. For sewage treatment contraceptives appear to be problematic. So far it is unresolved whether contraceptives are still active after sewage treatment.

Contraceptives appear as active EDC in sewage

2.4.2 CONSUMER GOODS

In recent years the Bisphenol-A (BPA) level in blood and urine samples and its potential EDC-effects has caught attention. BPA is used in many polymer products and can be found in baby-bottles, pacifiers, food-can linings and other food containers, thermo-printer paper (e. g. cashier receipt) and cigarette smoke. Consumer awareness has led to a phase-out of baby-bottles made from polycarbonate- (BPA-containing) materials.

Polyfluorinated chemicals (PFC) have unique properties as repellents of dirt, water and oils. They are increasingly used as surfactants in various industry- and consumer products. PFC are very active in the environment, some are global pollutants of air, water, soil and wildlife, and found even in remote polar areas. Bioaccumulation occurs in humans, traces are found in blood, internal organs and testes. Some of these PFC, such as PFOS and PFOA, are potential developmental toxicants and are suspected endocrine disruptors with effects on sex hormone levels resulting in lower testosterone levels and higher oestradiol levels.

The industrial production of PFOS and its derivatives stopped in 2000, and the European Union has banned most uses from the summer of 2008. However, hundreds of related chemicals (e. g. homologues with shorter or longer alkyl chains) are not being regulated (Reference 4; Reference 5).

Beverage and food may contain EDC leaking from polymer bottles or linings

2.4.3 FOOD & BEVERAGE

Natural compounds in plants represent the highest amounts of EDC from food-sources (phyto-oestrogens). Genistein for example is present in soy products in quantities that prompted regulatory bodies to impose warnings on soy-milk products. However, a high intake of phyto-oestrogens is linked with a higher life-expectancy and a lower risk of cardiovascular diseases and prostate pathology.

Besides the natural sources of EDC in food, many man-made substances can be found in food and water at least in traces. Alleged sources are pesticides from agriculture, cleaning-chemicals (e. g. soaps) from food production, chemicals from food containers and micro-contaminants from general pollution including dioxin-accumulation via the food chain in animal products.

There are still some pesticides found in food, which are heavily used in parts of the world and heavily restricted or forbidden in other parts.

The question, whether or why high amounts of phyto-oestrogens do not harm and why or whether the traces of artificial EDC do harm still remains unanswered.

2.4.4 AGRICULTURE

Some widely used pesticides are potential EDC. Well known to the public is DDT, a very stable substance that develops in the environment, particularly in cold areas. Substantial parts of EDC found in food enter the food-chain from general pollution. Dioxins are mainly unintentional by-products from combustion, found in dairy, eggs and meat. Other substances have been phased out as a result of several supranational agreements such as the Stockholm Agreement on persistent organic pollutants (POPs). However, due to their chemical stability they are still present in soil, water and air.

Animal fat contains significant amounts of EDC

3 Potential Impacts of EDC

The widespread manufacturing and use of substances with potential endocrine disrupting properties lead to many exposure routes, in some cases supported by the special properties of these substances: some EDC are very stable and are not degraded in the environment. Therefore, if released from any sources to soil, air or water, they lead to long term exposures and furthermore spread unchanged into environments with air and water streams that are remote from any human activity.

In addition, several EDC can accumulate in adipose tissues of humans and animals. As a consequence they enter the food chain and finally accumulate in humans where they cause persistent low level exposures.

Consequently, EDC can today be detected virtually in all human individuals as well as everywhere in the environment.

Dioxins climb the food-chain through fat-deposits

3.1 Environment

Evidence for potential endocrine disrupting properties of certain substances was mainly obtained from observations of reproductive disorders in animals.

Feminization of alligators

During heavy rainfalls in 1980, a waste water pond of a pesticide manufacturer in Lake County/FL/USA overflowed and waste water contaminated with a mixture of pesticides and other chemicals discharged into the nearby Lake Apopka. Exposure of alligators in the lake to these chemicals was later on related to a population decrease of about 90%. It was suggested that the hormonal (oestrogenic) effect of the contaminants caused feminization of male alligators leading to infertility.

Furthermore, malformations, an increased mortality of offspring, retarded growth and changes to immune system have been observed and associated with EDC.

Some of these disorders followed sudden exposures of species to high concentration levels of contaminants, whereas others were linked to a longer exposure to lower levels.

Today the causal link between EDC, dysfunction of the hormone system and subsequent health impacts has been established for animals (Reference 6).

3.2 Human Health

The evaluation of the potential impacts of EDC on human health is more complicated. Health disorders suggested to be related to EDC amongst human are:

- Breast and ovary cancer,
- Testes and prostate cancer,
- Genital malformations,
- Retarded sexual development,
- Declining sperm count,
- Obesity,
- Neurological disorders such as retarded development of memory and intelligence.

Establishing a clear relationship between EDC and human health disorders has been so far very difficult. Insights into the effects of EDC have been gained mainly from in vitro and in vivo models and epidemiological studies. However, the validity of these approaches is limited. In addition, research work is complicated due to the highly complex biochemical mechanisms of endocrine disruption and often due to a considerable latency of their action: there can be a lag of years between time of exposure (e. g. during fetal development) and manifestation of adverse health effects (e. g. retarded sexual development during puberty) making the evaluation of type and extent of exposure almost impossible. The lag can even increase to decades for the cases, where EDC are suspected to affect subsequent generations of exposed individuals.

Due to the ubiquity of EDC and the diversity of environmental contaminants, people are typically exposed for a long period to varying mixtures of EDC and other chemicals. Even if individual EDC activities are considered too low to disturb the hormonal system, long term exposures to mixtures of several contaminants could be critical due to additive or synergistic effects. Generally, the possible consequences of such multiple long term exposures have not yet been sufficiently understood.

Beside single cases of health impacts following sudden exposure to high concentrations of EDC (e. g. dioxins), no clear relationship has been established yet between EDC and human health disorders. However, in view of their potential effects on human health, their widespread use and ubiquity as environmental contaminants, EDC are still considered to have a significant hazard potential.

It has to be expected that research efforts will increase to get more insight into the adverse effects of EDC on human health (Reference 7).

Breast cancer is considered to be one of the possible consequences on EDC impact

4 Removal of EDC from the hydrological cycle

Measures at various levels are necessary to prevent EDC and other organic micropollutants (OMP) from entering the hydrological cycle and/or to remove them again. This includes measures at the source as well as measures to remove EDC during waste water treatment and drinking water purification.

To ensure water-purity is challenging when it comes to EDC and micropollutants

4.1 Measures at the source

Measures at the source seek to prevent micropollutants from entering the hydrological cycle in the first place by reducing their sale, use and disposal. This includes

- **Regulatory measures**, e. g. strict approval and/or registration processes for potentially polluting substances as well as prohibition or restriction measures for certain substances;
- **Incentive systems**, e. g. encouraging farmers not to use plant protection agents in the immediate vicinity of surface waters;
- **Intelligent product design**, e. g. washing machines using less washing detergent;
- **Measures to influence consumer behaviour**, e. g. targeted information campaigns, deposit systems for certain products or adjusted disposal pathways;
- **Technical measures**, e. g. separation and direct disposal of highly contaminated water and/or specific pre-cleanings to reduce the pollutant freight produced by individual large emitters.

4.2 Removal of EDC during waste water treatment

Since the majority of EDC enter the aquatic environment through a waste water treatment plant (WWTP), it is appropriate to reduce them at this level. Today's municipal WWTP generally feature three stages to remove solids, degradable organic substances and nutrients. As many micropollutants are not biodegradable and are not absorbed easily into sewage sludge, an additional fourth cleaning stage needs to be established to remove them during the waste water treatment process.

There are several advanced treatment technologies available for removing EDC from waste water, but not all of them are economically feasible. The two most promising processes are ozonation and powdered activated carbon absorption. These processes are already used in drinking water treatment (see below) and industrial waste water treatment and have the potential for a broader application in municipal waste water treatment (see Switzerland case study).

Powdered activated carbon (PAC) is a very finely ground activated carbon. It is mixed with the waste water so that the effluent ingredients can be deposited on the surface of the carbon particles. When loaded with micropollutants, the PAC has to be separated from the purified waste water and needs to be disposed of. This can be achieved by means of sedimentation followed by cloth filtration, sand filtration, or membrane-based ultrafiltration and subsequent incineration along with the sludge.

In the **ozonation** process, gaseous ozone is added to treated waste water. The dissolved ozone reacts with the micropollutants and transforms them. It is generally easy to integrate and operate an ozonation stage at an existing WWTP. Due to the process-related formation of reactive transformation products, it is recommended to install a stage with biological activity (e. g. sand filter) after ozonation of the wastewater so that these products can fully biodegrade in the WWTP.

Case study: "Project MicroPoll" – Upgrading sewage treatment plants in Switzerland

In the "MicroPoll" strategy project (2006-2011), the Swiss Federal Office for the Environment (FOEN) has tested ozonation and powdered activated carbon (PAC) treatment in pilot trials at two Swiss waste water treatment plants. The results show that it is both technically and economically feasible to remove EDC and other organic trace substances from municipal wastewater.

The average elimination of organic trace substances was above 80% for both processes. Additional energy consumption for micropollutant removal was estimated to be 5-30%, and additional total costs were estimated to be 5-30% (depending on the size of the treatment plant). These costs are considered acceptable given the additional purification effect of the tested measures. Both ozonation and PAC facilities can be installed relatively easily in existing plants.

Switzerland now plans to upgrade around 100 of its more than 700 municipal waste water treatment plants (WWTP) with either of the tested measures. Which measure will be most suitable for upgrading a specific sewage treatment plants depends on local circumstances and must be determined on a case-by-case basis.

To maximise the effect of the upgrade measures while keeping costs low, a risk-based approach is used for selecting the WWTP to be upgraded. Priority is given to

- Large WWTP,
- WWTP on watercourses with a high wastewater percentage, and
- WWTP in the catchment area of lakes.

By upgrading the selected plants, around 50% of Swiss waste water will undergo additional treatment. It is estimated that the measures will result in additional annual waste water treatment costs of around CHF 130 million (CHF 17 per capita).

To remove EDC and micropollutants WWTP might need upgrades at additional costs

4.3 Removal of EDC from drinking water

As drinking water is possibly the most important source of human body exposure to EDC, there is already a good awareness of the need for removal of EDC in drinking water. In addition, the removal at the source and in sewage plants will never be perfect, which means that further cleaning of drinking water will remain necessary. Last but not least, the levels of EDC or pollutants accepted in drinking water will always be lower than those accepted in cleaned water discharged into rivers or other water streams.

The removal processes for EDC are not selective, which means these processes are not removing simply EDC, but equally other micropollutants and even other chemicals or substances. The advantage is that they have been used already for quite some time to remove other substances, but have the problem that they do not remove all pollutants.

The process currently used for the removal of EDC and other OMP is activated-carbon filtering (ACF). This process has already been utilised for a very long time, mainly in areas where the water sources being the raw material for the production of drinking water were polluted (for example in Germany along the Rhine river). The removal of the pollutants is based on an adsorption process. The problem is that not all EDC are removed through this process. For some EDC the removal rates are close to 100%, but some OMP are hardly removed at all. These are mostly very polar substances, but there are equally chemicals, where it is unclear, why they cannot be removed by ACF. A further problem is that the concentration of pollutants in the water is very low and large quantities of water need to be treated. Both are difficult factors for adsorption processes. Nevertheless there are ongoing efforts to improve these processes mainly by modification of the characteristics of the used activated-carbon to be able to remove substances that are currently difficult to retain. The cost of this process is relatively low. It is clear that these costs may vary depending on the nature and extent of the pollution, but in general the costs are roughly 5 to 10 Cents/m^3 water treated. This means for example for Germany, where the mean cost of drinking water is €1.90/m^3 water the increased costs for further treatment of polluted water would be roughly 5%. As explained before this additional treatment is nowadays already necessary in various cases to remove substances other than EDC.

Other processes used for the removal of EDC and other OMP are nanofiltration (NF), microfiltration (MF), ultrafiltration (UF) and reverse osmosis (RO). The problem with these processes is that they remove – depending on the way they are used – far more substances from the water than ACF, changing therefore the chemistry of the water, which is not desired. In addition these processes are more expensive than ACF. There is a lot of research going on in this area, but most of the installations are still in a research stage regarding the removal of EDC and other OMP, but are standard for other applications (for example desalination). The solution of the problem of removing EDC might equally be a combination of ACF and filtration processes possibly including other water treatment processes as well.

As a conclusion it can be said that there are processes available to remove EDC from water to get potable water. At the moment these processes do not operate perfectly and not all EDC can be removed. Nevertheless research is going on to improve removal rates and performance by improving single processes or by combining several techniques. The costs involved are currently acceptable, but depending on the purity of water that needs to be achieved in the future, these costs may well rise.

5 Regulation

As there is still a lot of uncertainty in regard to the existence and extent of adverse health effects caused by endocrine disruptors, the focus of regulation has usually been on testing, screening and monitoring chemicals containing these substances. Another major objective of regulation is preventing or limiting the use of such chemicals, especially with regard to products mainly used by children, such as baby-bottles or infant plastic toys.

5.1 EU

The EU has been exploring the necessity for improvement in the legislative framework in regard to endocrine disruptors since 1998. A Community Strategy for Endocrine Disruptors (COM 1999, 706) was agreed in 1999 and four reports on the implementation of this strategy have since been published (the last one in 2011, SEC 2011, 1001). Since 2007 Regulation (EC) No. 1907/2006 (REACH) has been regulating the registration, evaluation and authorization of chemicals within the EU. The regulation introduced a complex authorisation process for substances of very high concern, including endocrine disruptors in general. However at the end of 2012 Octylphenol was the only endocrine disruptor, which was on the candidate list of substances of very high concern. As a result of the authorisation process the use of the substance can be restricted or even phased out. With regard to liability for the use of substances containing endocrine disruptors, national tort law and strict liability regulation remain the basis for action.

Regulation (EC) No. 1907/2006 (18 December 2006)
Art. 138 Review

7. By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals.

5.2 US

Due to the broad range of products containing (putative) endocrine disruptors, an equally broad range of regulation is covering these issues. Based on the Food Quality Protection Act and the Safe Drinking Water Act of 1996 the US Environmental Protection Agency (EPA) has initiated the Endocrine Disruptor Screening Program (EDSP), aimed at screening and testing chemicals for their impact on human health, fish and wildlife, in 1998. The US Food and Drug Administration (FDA) is also monitoring (putative) endocrine disruptors and providing information on their effects, e.g. through the Endocrine Disruptor Knowledge Base (EDKB). In 2010 the FDA voiced “some concern” about the potential effects of bisphenol-A (BPA) and has since supported stricter regulation of products containing BPA.

Among other federal laws that might be relevant for the use of and liability for endocrine disruptors are the Toxic Substances Control Act, the Clean Water Act, the Clean Air Act, the Federal Hazardous Substances Act and the Food, Drug and Cosmetic Act. State legislators have also been very active in regard to regulating endocrine disruptors recently. Typical examples for such activities are the BPA-Free Kids Act (New York), the Ban Poisonous Additives Act (Massachusetts) and the Children´s Chemical Risk Reduction Act (Oregon). Similar laws have been proposed in other US states, most primarily trying to ban BPA from being used in infant-related products.

Bisphenol A-Free Children and Babies Act of New York (2010)
§ 37-0505. Child care products.

1. *Beginning December first, two thousand ten, no person, firm, partnership, association, limited liability company or corporation shall sell or offer for sale any child care product intended for use by a child three years of age or younger containing bisphenol A.*

2. *The provisions of this section shall not apply to the sale or distribution of child care products resold or offered for resale, or distributed by consumers for consumer use.*

Bisphenole A in child care products prompted legislation in various states

5.3 Rest of the world (ROW)

Movements to ban the use of BPA in regard to baby-bottles and similar infant products are also active in other parts of the world. Most notably so in Canada, where the government has declared BPA a toxic substance in 2010.

Japan has developed Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98). Through these programs scientific studies will be carried out to assess the risks and adopt effective counter measures to tackle the issue. Environmental risk assessment and risk management are carried out, and research, screening and testing methods have been developed.

6 EDC and Insurance

6.1 Current situation

Today there is no EDC exclusion in product liability policies. If a causal link between personal bodily injury and the intake of EDC from consumer products would be proven without doubt some day, a defending producer would refer to his/her ordinary product liability insurance.

6.2 Claims and litigation

BPA
Especially in the US, claims for a variety of adverse health effects, ranging from cancer to reproductive or developmental abnormalities and from mental illness to obesity, have been based on the exposure to products containing endocrine disruptors. Most of this litigation is focused either on polychlorinated biphenyls (PCB) or, more recently, on bisphenol-A (BPA). While some of the PCB-lawsuits led to high settlements, all, like the aforementioned BPA-claims, involve numerous legal controversies. Among them are causation aspects (in regard to medical, general and specific causation) and the evidence standards applicable for scientific experts in court. As far as plaintiffs did not suffer any personal injury, as in most consumer fraud lawsuits, establishing legal standing was difficult.

Atrazine
Atrazine is seen as an EDC. Since 2004 it is a subject of litigation on both the federal and state levels of US courts. The plaintiffs claim that exposure to atrazine at any level is harmful to human health. The lawsuits seek class-action remedies, financial penalties and payment for water filtration based on their water being harmful to human health. A recent settlement awarded 105 million USD for the upgrade of water-treatment facilities (Reference 8).

Corexit
In 2010, Corexit was used in large quantities in the Deepwater Horizon oil spill. The first analysis of the 57 chemicals found in Corexit formulas 9500 and 9527 showed that the dispersant could contain cancer-causing agents, hazardous toxins and endocrine disrupting chemicals. Part of the massive multidistrict litigation for the oil spill involves claims by those who have allegedly suffered injuries from exposure to Corexit. The defendants are BP, Transocean, Halliburton, Cameron International, Nalco – the manufacturer of the dispersant Corexit – and numerous others (Reference 9).

6.3 Insurance Loss Scenarios

6.3.1 PRODUCT LIABILITY / PRODUCT RECALL

One scenario could be an established link between plastic by-products in food containers and breast-cancer. Such proof would allow virtually anybody with breast cancer to claim compensation from food-packers. Should a scientific proof indicating causality between EDC contamination and bodily injury be established, many actual product liability-policies of food-packers could be triggered.

6.3.2 ENVIRONMENTAL LIABILITY

EDC originating from production processes as well as from agricultural use have been found worldwide in soil, surface- and groundwater. A proven link between EDC pollution and bodily injury would increase the pressure on water supply works to refine the treatment for the removal of EDC. The costs of refined treatment can be claimed from the main and/or identifiable polluters such as the agricultural industry.

Sophisticated analytic chemical methods may lead to more liability

6.3.3 WORKMEN'S COMPENSATION / EMPLOYERS LIABILITY

Exposure of workers to EDC happens in the production process (chemical industry and manufacturing) as well as in all sorts of business processes using chemicals (e. g. agriculture, food-storage and -processing).

6.3.4 DIRECTORS & OFFICERS

If management fails to take preventive measures in order to avoid damages caused by exposure to EDC, the employees, public authorities or shareholders might start litigation against directors or officers.

Some developments in pharmaceutical liability led to shareholder action against the boards of pharmaceutical companies in the US. It could well be that shareholders take class action against board-members for insufficient control of endocrine disruptor claims, false statements and delayed phase-out of dangerous products (Reference 10).

6.3.5 LIFE & HEALTH INSURANCE

Further unlimited exposure of consumers in many countries poses a substantial risk of shortening life expectancies due to a rise in endocrine tumors and other EDC related health problems. Moreover EDC have epigenetic effects that cause health impairments in first and/or second generation offspring of exposed subjects. Effects of distorted sex ratios on life-expectancy and health-problems are as yet difficult to estimate. A negative effect is most probable for cancer incidence. A rising cancer incidence would interfere with health insurance calculations and affect life insurer's balance-sheet.

7 Conclusion

EDC are a truely emerging risk. There is strong evidence for negative effects on animal organisms and mounting evidence for effects on human health. A direct proof of human health problems and EDC-pollution has not yet been established. However results from animal experiments can – to a certain degree – be extrapolated. The widespread use and the severe negative and long-term harm to life should keep awareness high. Regulation and e. g. liability for clean-water serve as an example for the precautions that could help to minimise the risk. Meanwhile the production and release of new EDC is increasing, therefore environmental and human exposure is not declining.

Environmental liability will lead to an increase in legal actions. Claimants are from a very broad array of potentially jeopardised groups such as waterworks, farmers, house-owners, tourism/natural reservation agencies, fisheries etc. Under US-jurisdiction these claims have increased defence costs. When a causal relationship between human hazard and the discharge of EDC has been established, virtually all lines of liability insurance could be affected, with amplified impacts on product liability.

Insurers could start to mitigate such exposures by instituting a dialogue with EDC producing industries. Regulators and suppliers should be supported in their efforts to limit exposure.

We recommend to minimise the use and release of EDC and we encourage the removal of EDC/micropollutants from waste water and drinking water taking into account individual circumstances.

Ubiquitous EDC in modern life require careful consideration of exposure-limiting measures

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9 Abbrevations

ACF	Activated Carbon-Filtering
BPA	Bisphenole A (chemical by-product and solvent)
COM	Community Strategy for Endocrine Disruptors (EU)
DDT	Very persistent organic Pesticide
DES	Diethyl Stilbestrol (estrogen-like pharmaceutical)
EDC	Endocrine Disrupting Compounds/Chemicals
EDKB	Endocrine Disruptor Knowledge Base
EDSP	Endocrine Disruptor Screening Program
EPA	US Environmental Protection Agency
FDA	US Food and Drug Administration
FOEN	Swiss Federal Office for the Environment
MF	Micro-filtration
NF	Nano-filtration
OMP	Organic Micro Pollutants
PAC	Powdered Activated Carbon
PCB	Polychlorinated Biphenyl (chemical solvent)
PFC	Polyfluorinated Chemicals (chemicals used as surfactants)
PFOA	Perfluoroctanoic Acid (e. g. industrial solvent for PTFE (Teflon, Gore-tex etc.) synthesis)
PFOS	Polyfluorinated Organic Substance
POP	Persistant Organic Pollutants (artificial substances regulated in specific treaties)
ROW	Rest of the world
SPEED '98	Strategic Programs on Environmental Endocrine Disruptors '98; Japanese Program to gather scientific evidence on EDC
TPO	Thyro-Peroxidase (Enzyme in thyroid gland)
UF	Ultra-filtration
WWTP	Wastewater Treatment Plant

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The CRO Forum's Emerging Risks Initiative

The Emerging Risks Initiative (ERI) was launched in 2005 to raise awareness of major emerging risks relevant to society and the (re)insurance industry. In 2012 the initiative is chaired by Dr. Andreas Tacke (Hannover Re) and consists of nine members representing AIG, Allianz, AXA, Hannover Re, Lloyds, Munich Re, RSA, Swiss Re and Zurich Insurance Group. This initiative pursues the following goals:

– Raising awareness and promoting stakeholder dialogue.

– Developing best practice solutions.

– Standardizing disclosure and sharing knowledge of key emerging risks.

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