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Contents

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Position paper of the preparatory group on Endocrine Disrupting Compounds (EDCs)

1 Introduction

The group met in Brussels on the 19th of September 2003. Membership is listed in appendix 1. Its goal was to identify current and future problems and make statements and recommendations on how EDCs should be addressed in the European Directive on the quality of water intended for human consumption (DWD).

Currently EDCs are not regulated in the DWD. No limits for individual EDCs or the total (potential) effects have been set in the DWD. For pesticides, polycyclic aromatic hydrocarbons (PAHs), chlorinated hydrocarbons and metals, of which some are (suspected) EDCs, limit values are part of the DWD. However, these limit values have not been set based on endocrine effects.

The group identified the next main topics for discussion:

- Exposure of humans to EDCs
- Environmental concern of EDCs
- Occurrence of EDCs in drinking water sources
- Occurrence of EDCs in drinking water
- Human health risk, priority EDCs
- Development of analytical methods and bioassays
- Removal of EDCs in water treatment

- Release of EDCs from materials in contact with drinking water

To assist in improving the discussion the group considered a number of recent documents. These are listed in appendix 2.
The group has intentionally kept this report concise. Some statements may be considered controversial, but the group hopes that this paper will stimulate discussions on this topic.

2 Exposure of humans to EDCs

In literature many groups of substances are described for their (potential) endocrine disrupting properties. There are strong differences in origin (natural, industrial), emission sources (manure, effluents of sewage treatment plants, diffuse pollution of pesticides), chemical structure and behavior of EDCs.
Exposure routes are not the same for the different classes of EDCs. Humans are exposed mainly to phytoestrogens, like isoflavones, via food. Also for bioaccumulating compounds like PCBs, food is the main exposure route. Synthetic hormones, like 17α-ethinylestradiol are an exception, as drinking water is theoretically the main route for unintended exposure to these compounds. However, we don't expect these to be present in drinking water in significant levels. Since 17α-ethinylestradiol is one of the most potent synthetic estrogenic compounds unintended exposure must be avoided in any case.

Statement:
Drinking water is not the main exposure route for most EDCs. Many EDCs, especially bio-accumulating compounds, are taken up by food (dairy products, meat, fish, ...) in higher amounts on a daily basis.

3 Environmental concern of EDCs

According to our present knowledge, the effects of EDCs in the water cycle are mainly of environmental concern. The data that initiated this concern relate to effects on wildlife like fish, amphibians and reptiles. However, good raw water for the production of drinking water is needed as well. Ideally, production of drinking water should be achievable with only conventional treatment methods (for example aeration and filtration for groundwater). This need was taken into account in the Water Framework Directive (2000/60/CE), adopted by the European Parliament and the Council in September 2000, which aims at improving the quality of water and ecosystems in Europe. In accordance with article 16 of the Directive, a list of 32 priority substances, selected among those which present a significant risk to or via the environment, was established. These substances will be subject to the "cessation or phasing out of discharges, emissions and losses" by the year 2020. EDCs such as nonylphenols, octylphenols, tributyltin compounds and several pesticides, are included in this list.

FOOD Main exposure route for natural hormones & EDCs

→ Natural hormones in milk.
→ Bioaccumulating compounds in Fish
→ 17β-EE → drinking H_2O

Statement:
With regard to EDCs control in drinking water the Water Framework Directive will help as an "upstream" action. However, the effects of the WFD need to be monitored with respect to the consequences for drinking water quality.

4 Occurrence of EDCs in drinking water sources

- Effluents of sewage treatment plant
- Effluents of industrial waste H_2O treatment plant
- Manure.
- Diffuse pollut from Agricult

Both natural and synthetic estrogenic substances commonly enter freshwater systems through sewage treatment works effluents. Evidence for the estrogenic activity of such effluents comes from various European countries including the UK.
The compounds found to be responsible for the majority of the in vitro estrogenic activity of domestic wastewater treatment works effluents have been the natural estrogens, 17β-estradiol (E2) and estrone (E1) and the synthetic E2 derivative17α-ethinylestradiol (EE2). The concentrations of these steroid estrogens that are present in wastewater treatment works effluents depend on the efficiency of their removal in the various wastewater treatment processes. Generally removal rates are high, usually above 75% and often up to 95%. However, even at low concentrations these compounds can be extremely potent. For example less than 1 ng/l EE2 can induce vitellogenin production in male rainbow trout (vitellogenin is an egg yolk protein usually only found in adult females). Total concentrations of E1, E2 and EE2 reported to be present in UK sewage effluents are generally in the range 1-10 ng/l, with E1 and E2 predominating. Concentrations reported in river waters are generally in the range 1-5 ng/l – again E1 and E2 are present at higher concentrations than EE2.

Industrial compounds, such as the nonylphenols and nonylphenol ethoxylates can also enter surface waters via wastewater treatment works effluent. Although these compounds are much less potent estrogens than the steroids (by a factor of about 10^5), their concentrations in such effluents can be significantly higher, so their presence cannot be ignored. [The use of nonylphenol ethoxylates is due to be phased out in the next few years, so the contribution of these particular compounds to the estrogenicity of effluents should be considerably reduced].

Other weakly estrogenic compounds, such as some pesticides, can enter groundwaters due to agricultural usage. For example, atrazine and simazine (both of which are herbicides) have been detected in some groundwaters at concentrations in the low µg/l range and occasionally at lower concentrations in the derived drinking waters. Because, in comparison to 17β-estradiol, their estrogenic potency is very low (at least 10^6 lower) these findings are not considered to present a risk to drinking water consumers.

Statement:

Most of the European surface waters and some groundwaters are contaminated with low levels of EDCs. With the presently applied sewage treatment technologies EDCs cannot be fully avoided in surface waters receiving sewage effluent. Without adequate drinking water treatment steps low levels of EDCs have to be expected in drinking water.

5 Occurrence of EDCs in drinking water

So far, measurements have not indicated that significant levels of EDCs have been found in drinking water. Low concentrations in the ng/l range have been reported for some pesticides (atrazine, simazine, and metabolites), bisphenol A, several phthalates and alkylphenolethoxylates. Most of the drinking water samples are negative. Most studies did not detect natural or synthetic hormones. However, relatively few data are available for only a few countries and much more representative monitoring in all European countries is needed. The Commission will, in close cooperation with the Member States, establish monitoring programmes in water to estimate exposure to and effects of the substances on the priority list of endocrine disruptors in order to gather evidence that could be used in future revisions of different legislative instruments, such as the DWD and the WFD.

Statement:
For an European wide assessment of the occurrence of EDC s in drinking water, more reliable data are required.

6 Human health risk, priority EDCs

There is not enough knowledge available to evaluate the potential health risks from exposure to low levels of EDCs via drinking water. For many EDCs little data of the occurrence in the water cycle are available. Research on low dose effects and combined effects is still going on.

As hormones are the most potent EDCs, they are at present the most relevant ones for drinking water. But since we don't know all the relevant EDCs, there is still a need for screening of the total (potential) effect using bioassays. At present, most bioassays are aimed at estrogenicity; more bioassays for other endocrine effects (such as androgenicity) are needed.

Bioassays give an indication of the total potential endocrine effect of a sample, whereas chemical analysis gives information about individual compounds. Both techniques are complementary and are needed to study the relevance of EDCs in the water cycle.

Statement:
More toxicological data as well as more reliable drinking water concentrations are essential to evaluate the relevance of EDCs in drinking water. The contribution of drinking water to the exposure of humans seems to be very low.

7 Development of analytical methods and bioassays

In order to be able to provide exposure data it is essential to have access to robust and validated analytical methods. In particular, the determination of hormones as the most potent species in terms of endocrine disrupting effects require detection limits of less than 1 or even 0.1 ng/L. Although sophisticated technologies (high resolution or tandem mass spectrometry) and advanced techniques (isotope dilution) are available to measure pollutants in traces, only few laboratories have the instrumental resources and the necessary experience to produce valid and comparable data that are needed.
Moreover, sample preparation procedures are mostly time consuming and for many compounds still no standard reference materials are available. Since many of the EDCs are part of our daily life they can be found ubiquitously. Hence, special procedures to avoid cross-contamination have to be taken into account both for analytical and for sampling purposes.
Chemical analysis determines concentrations of individual pollutants but cannot describe endocrine effects that may be provoked by the total content of pollutants. Certain in-vitro tests are already available to measure the estrogenic potency of a sample but so far most of them are not sensitive enough to determine effects of low concentrations that are expected in drinking water.
Analytical measurements in the nanogram per litre range cannot be regarded as "routine work" and because of the lack of standardised methods special emphasis must be placed on additional quality assurance, e.g. proficiency tests for laboratories to prove the comparability of results.

Statements:
Methods for monitoring individual EDCs and total (potential) effects are available on a limited scale. Implementation on a larger scale is needed to carry out monitoring programmes. Special precautions for sampling methods, materials in contact with samples and pretreatment of samples must be followed. Different laboratories can use different methods, as long as the performance is shown to be satisfactory. However, implementation and validation of these methods in the (new) MS is probably a problem. Instrumentation is expensive, and technicians need to develop experience with these methods before reliable results can be achieved.

8 Removal of EDCs in water treatment

→ Ozonation
→ Granular activated carbon filtration
→ Nanofiltration.
→ Reversed osmosis.

The processes used in drinking water treatment differ much according to the water quality of the source, the endorsement of standards for drinking water quality (WHO guidelines, European and national standards), the policy of the individual water works on improved performance, and the willingness and ability of the consumers to pay. Advanced treatment processes are often installed for disinfection of surface water intakes or for groundwater contaminated with agrochemicals or industrial chemicals. Much research has recently been conducted to study the additional positive effects of conventional and advanced drinking water treatment regarding the removal of EDCs. Ozonation, GAC, nanofiltration and reversed osmosis have proved to be very effective; coagulation, filtration and chlorination are less effective.

Statement:
Advanced drinking water treatment is capable of removing EDCs at high rates.

9 Release of EDCs from materials in contact with drinking water

Organotic comps
Phtalates
BIS-A.
Alkylphenols.

There is evidence to show that EDCs of low potency, such as organotin compounds, phthalates, alkylphenols and bisphenol A can migrate from certain organic materials used in contact with water intended for human consumption. This is of potential concern as no action can be taken by drinking water supply companies to remove them prior to consumption of the affected waters. Bottled waters can also become contaminated by EDCs which migrate from the bottles or containers in which they are stored.

As there is a separate expert working group on substances and materials used in the preparation and distribution of drinking water (Topic 5), there is obviously some overlap between this group and the EDCs group. The EDCs group consider that the potential for the introduction of EDCs into drinking waters from materials should be addressed by the European Acceptance Scheme (EAS). Therefore, brief details of the EAS are presented here.

In the near future, the EAS will be applied throughout the EU. This scheme will include the use of positive lists for substances used in the preparation of materials to be used in contact with drinking water. The toxicology of substances on these lists will have been assessed to ensure the substances are safe to use and the body that carries out these assessments will need to consider potential endocrine disrupting effects.

Statement:
Evidence of release of EDCs from materials to drinking water / bottled water is available. The release of EDCs from materials in contact with drinking water, such as for example organotin compounds, phthalates, bisphenol A and alkylphenols needs to be addressed in the EAS.

10 Recommendations

Currently EDCs are not regulated in the DWD. It is not recommended to set limit values for individual EDCs in the DWD at this point, because:

- several hundreds of substances have been identified as potential EDCs; prioritization is still ongoing;
- the knowledge to evaluate the potential human health risk is insufficient;
- sufficient occurrence data for both raw and drinking water are not available yet;
- validated bioassays for screening the total potential effects of EDCs are required.

More toxicological data and monitoring data are needed to evaluate the risk of human consumption of drinking water, especially at places with high risk factors for pollution.

It is recommended that European laboratories participate in the setup of a proficiency testing scheme for EDCs.

Risk assessment and risk management approach as recommended by the third edition of the WHO-guidelines is probably the best tool for controlling EDCs in drinking water. This approach was developed in the 1960s for the food industry, and since then has extensively and successfully been implemented in this sector, in the form of HACCP (Hazard Analysis and Critical Control Points), as recommended by the Codex Alimentarius, and the Directive 93/43/CEE on the hygiene of foodstuffs. Its application to drinking water production in Australia and several European countries is recent. As regards to EDCs in drinking water, risk factors (such as sewage and industrial effluents) are known. Drinking water treatment performances for EDC-removal have been assessed. This allows for risk ranking of the drinking water treatment plants, and can allow for identification of those production plants that need to be adapted to improve removal of EDCs.

Appendix 1: Members of the preparatory group on EDC's

Philipp Hohenblum, chairman
Leo Puijker, rapporteur
Andrea Wenzel
Jean-François Loret
Huw James
Corina de Hoogh, assistent rapporteur

Appendix 2: Documents considered by the group

A framework for assuring the quality of drinking water in the 21st century - Bonn workshop, October 2001.

Community Programme of Research on Environmental Hormones and Endocrine Disruptors (COMPREHEND). Final report by A.D. Pickering. January 2002.

Study on Endocrine disruptors in drinking water. Final Report ENV.D.1/ETU/2000/0083, by Andrea Wenzel, Josef Müller and Thomas Ternes. Schmallenberg and Wiesbaden, Germany, February 2003.

Summary of presentations and discussions on EDC's in drinking water at the IWA Leading Edge Technology Conference, 26-28 May 2003, Noordwijk, The Netherlands.

Endocrine disruptors in Austria's waters - a risk? by Renate Paumann and Stefan Vetter; Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna, Austria, July 2003.