National Research Program "Endocrine Disruptors"

Consensus Platform "Endocrine Disruptors in Waste Water and in the Aquatic Environment" Final Document

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Content

Editor's Note:
This is an English translation of the original German version. The German version is binding.

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Executive Summary

Introduction

Chemicals with endocrine activity, also termed "endocrine disruptors", can exert a variety of detrimental effects on humans, animals or entire ecosystems. In animals, numerous studies attest negative effects on the reproductive system for broad range of species from fish and birds to marine and terrestrial mammals.

In the year 2000 the Swiss Federal Council mandated the Swiss National Science Foundation (SNSF) to implement the National Research Program 50 "Endocrine Disruptors". This program aims to develop scientific strategies to assess the risks and hazards that arise when endocrine disruptors are processed through ecosystems to cause human and animal exposure. In consensus platforms representatives of the NRP, of the authorities and of the producing and applying industries make recommendations on how to avoid the negative impact of endocrine disruptors.

The methodology of the consensus platform was developed exclusively for the National Research Program "Endocrine Disruptors" on the basis of the objectives defined by the Steering Committee. The consensus platform is a structured, constructive dialogue between industry, the authorities and scientists; it aims to achieve general agreement on the impact of endocrine disruptors on humans, animals and ecosystems and on action to minimize any detrimental effects (see pages 7f.).

The work of the consensus platform "Endocrine Disruptors in Waste Water an in the Aquatic Environment" lasted from January to December 2007. It involved a total of 15 representatives of the producing and applying industries, the authorities and scientists, in addition to two moderators (see page 9).

With their joint effort to prepare impact and action-related statements, all partners participating in the platform – industry, regulatory authorities and scientists of the National Research Program "Endocrine Disruptors" – expressed their intention to participate in a constructive dialogue, thereby making a valuable contribution towards preventing negative impacts of endocrine disruptors.

Results

The members of the consensus platform accepted and approved 32 impact related statements and 20 action related statements/recommendations (see pages 10ff).

Endocrine disruptors in the aquatic environment present a local and regional problem in Switzerland, especially where dilution of the treated waste water in the receiving water is not sufficient (1:10 or more), either at certain times of year or all year round. This can be the case in densely populated regions and with waste water treatment plants that feed into small streams. In treated domestic waste water, it is natural and synthetic steroid hormones that are responsible for the majority of the estrogen activity. According to our current knowledge, the appropriate bioindicator is the identification of increased vitellogenin levels in male fish. In a minority of the Swiss water bodies studied to date, slight to moderate increases in vitellogenin values were measured in male fish in the impact zone of waste water treatment plants, which

suggests local or regional contamination of the aquatic environment with estrogen substances. Apart from this, there are few indications of any impact of endocrine disruptors in Swiss surface waters.

So far there are no indications that the high prevalence of gonadal abnormality in whitefish in Lake Thun is attributable to endocrine disruptors.

In general, it can be assumed that the endocrine disruptors ingested via drinking water in Switzerland are not critical for human health. Isolated cases of higher contamination of groundwater and drinking water must be assessed on a case-by-case basis.

The environmental behavior of micropollutants, which include endocrine disruptors, needs more detailed study. In Switzerland, chemical flows of endocrine disruptors need to be systematically analyzed and modeled in order to identify relevant exposure situations. It will then be possible to derive impact-related actions based on scientifically grounded risk assessments. Fish and other aquatic organisms should be studied to establish the biological impact of the environmental stress calculated by means of chemical analyses or forecast using models.

Since estrogen steroid hormones are to be viewed as the main cause of any estrogen effects in aquatic organisms, the introduction of a quality objective for estrogen activity in the aquatic environment is very important. This is particularly true of sensitive rivers and streams affected by waste water treatment plants in which the treated waste water is insufficiently diluted.

The construction of waste water treatment plants should permit optimum elimination of the substances contained in the waste water. It is necessary to ensure that the plants function as well as possible. Problems can arise as a result of micropollutants, particularly where the treated waste water in the water body is insufficiently diluted. In such cases, the following measures should be examined:

- State-of-the-art construction
- Further technical measures (activated carbon, ozonation, increasing sludge age, etc.)
- Alternative courses of action, e.g. creation of integrated waste water networks so that more efficient waste water treatment plants can be established

The regulation and implementation of urban drainage measures should be preceded by an integrated strategy and planning. The key causes of the pollution of the aquatic environment at catchment area level should be taken into account and prioritized, and actions should be identified that maximize the benefit for the aquatic environment at an economically affordable cost (including agricultural actions, renaturation, etc.). Measures for optimizing rainwater and sewer system management (discharges, leakage losses) should also be assessed. Waste water treatment plants in Switzerland should be reviewed in terms of their elimination performance and their technical optimization potential.

As well as reducing endocrine disruptors, the intended actions for waste water treatment plants also reduce contamination by other substances relevant for the aquatic environment. Actions at source, such as alternative systems for urban drainage or hospital waste water treatment, need to be evaluated and, if need be, promoted.

Industry endeavors to replace substances that have a significant toxicological or ecotoxicological risk with lower-risk substances. For this to work, the substitute products need to be subjected to a risk assessment as thorough as that applied to the substances they are designed to replace.

Efforts should be made to manage agricultural areas in ways appropriate for the site, since this limits contamination by endocrine disruptors and other substances via surface rain-wash and drainage.

The rapid development of internationally (OECD) recognized methods for detecting endocrine disruptor characteristics of chemicals and mixtures must be promoted. The same applies to test procedures for prioritizing micropollutants and for monitoring water body quality. For practical application, efforts should be made to establish scientifically grounded quality criteria for hormone activity in the aquatic environment: a chronic quality criterion (CQC) for long-term contamination and an acute quality criterion (AQC) for short-term contamination peaks. It is recommended that these quality criteria be added to the Swiss water protection ordinance (Gewässerschutzverordnung).

National Research Program 50 "Endocrine Disruptors" (NRP 50)

Chemicals with endocrine activity, also termed "endocrine disruptors", can exert a variety of detrimental effects on humans, animals or entire ecosystems. In animals, numerous studies attest to reproductive disturbances across a broad species spectrum ranging from fish and birds to marine and terrestrial mammals. Various solvents, insecticides, pesticides, combustion products, certain drugs, cosmetics and even plant products are suspected of interfering with the endocrine system of humans and animals.

In 2000, the Swiss Federal Council mandated the Swiss National Science Foundation (SNSF) to implement the National Research Program 50 "Endocrine Disruptors". The scientific program, with total funding of CHF 15 million, started in 2002 and will end in 2007. The international Steering Committee approved a total of 30 research projects in three program phases.

The National Research Program "Endocrine Disruptors" aims to develop scientific strategies to assess the risks and hazards that arise when endocrine disruptors are processed through ecosystems to cause human and animal exposure. In consensus platforms representatives of the NRP, of the authorities and of the producing and applying industries make recommendations on how to avoid the negative impact of endocrine disruptors.

Methodology of the Consensus Platforms

The methodology of the consensus platform was developed by the Implementation Officer of the National Research Program "Endocrine Disruptors", Dr. Marcel Trachsel, in cooperation with the consultancy int/ext Communications AG, Basel. It was based on the objectives defined by the Steering Committee.

The consensus platform is a structured, constructive dialogue between industry, the authorities and scientists; it aims to achieve general agreement on the impact of endocrine disruptors on humans, animals and ecosystems and on action to minimize any detrimental effects. The methodology is based on a series of meetings and individual preparatory reflection.

A successful consensus platform requires certain conditions to be met:

- The issue to be treated must be defined as narrowly as possible.
- The members are willing to cooperate within the limits of the process, to accept divergent interests and viewpoints and work together to achieve agreement.
- The meetings are moderated professionally.
- All developments and interim results are treated as confidential until the consensus platform is completed. On termination of the work, only approved results are communicated.

Step 1: On the basis of their knowledge the members define their individual position, or that of the organization they represent, on the impact and action of endocrine disruptors.

Step 2: At the first joint meeting the members of the consensus platform put across their position on the impact and action and respond to questions on their position from other members of the consensus platform (hearing). On the basis of this meeting *a list of impact related statements and one of action related statements/recommendations are compiled*. These lists are then made available to the members of the consensus platform.

Step 3: In this step each member decides on *acceptance, conditional acceptance or non-acceptance of each impact related statement*. In the event of conditional acceptance, conditions must be defined. The results are collected and categorized centrally as follows:

- Category i1: generally accepted >>> immediate inclusion in the final list of accepted statements
- Category i2: accepted or conditionally accepted, no more than one non-acceptance >>> to be discussed at the joint meeting
- Category i3: more than one non-acceptance>>> is not further pursued

Step 4: At the joint meeting, the Category i2 impact related statements are subjected to further discussion in order to find a formulation that is acceptable to all members of the consensus platform. The outcome of this meeting, together with the Category i1 statements, yields *the final list of accepted impact related statements*. These are set out in a logical sequence and approved by the consensus platform.

Step 5: In this step each member of the consensus platform decides on *the acceptance, conditional acceptance or non-acceptance of each action related statement/recommendation*. In the event of conditional acceptance, condition must be defined. The results are collected and categorized centrally as follows:

- Category a1: generally accepted >>> immediate inclusion in the final list of accepted statements
- Category a2: accepted or conditionally accepted, no more than one non-acceptance >>> to be discussed at the joint meeting
- Category a3: more than one non-acceptance>>> is not further pursued

Step 6: At the joint meeting, the Category a2 action related statements are subjected to further discussion in order to find a formulation that is acceptable to all members of the consensus platform. The outcome of this meeting, together with the Category a1 statements, yields *the final list of accepted action related statements*. These are set out in a logical sequence and approved by the consensus platform.

Step 7: The approved lists of impact and action related statements are set out *in a final document* and made available for communication to other stakeholders.

Members of the Consensus Platform "Endocrine Disruptors in Waste Water and in the Aquatic Environment"

The following persons have kindly accepted the invitation of the National Research Program "Endocrine Disruptors" to play an active role in the consensus platform "Endocrine Disruptors in Waste Water and in the Aquatic Environment". The persons in charge of the National Research Program wish to thank the members of the consensus platform for their valued participation.

Industry

Dr. Peter Dollenmeier, Ciba AG, Basel

Dr. Urs Friederich, Dow (Europe) GmbH, Horgen

Dr. Paul Vesel, Swiss Society of Chemical Industries, Zurich

Authorities

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Dr. Beat Brueschweiler, Federal Office of Public Health, Zurich

Dr. Ueli Ochsenbein, Cantonal Office for Water Protection, Bern

Association

Martin Würsten, Swiss Water Pollution Control Association, Zurich

National Research Program "Endocrine Disruptors"

Prof. Dr. Walter Giger, Dr. Hans-Peter Kohler, Dr. Marc J.-F. Suter, Swiss Federal Institute of Aquatic Sciences and Technology, Duebendorf

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Prof. Dr. Felix R. Althaus, President of the Steering Committee NRP „Endocrine Disruptors", University of Zurich

Dr. Marcel Trachsel, Implementation Officer NRP "Endocrine Disruptors", int/ext Communications AG, Basel

The work of the consensus platform "Endocrine Disruptors in Waste Water and in the Aquatic Environment" lasted from January to December 2007.

Results of the Consensus Platform "Endocrine Disruptors in Waste Water and in the Aquatic Environment": Impact Related Positions

(Potential) endocrine disruptors in the aquatic environment

- Chemicals and chemical groups (primary substances and metabolites) that can have an endocrine effect have been detected in Swiss rivers and streams.

- Endocrine disruptors are carried into aquatic systems both from point sources (e.g. waste water treatment plants) and from diffuse sources (e.g. surface rain-wash or dry deposition).

- Even compounds that break down easily, such as the steroid hormone estradiol, can be permanently present in low concentrations in water bodies downstream of waste water treatment plants ("pseudo-persistence").

- Field studies conducted all over the world show that the occurrence of endocrine disruptors in the aquatic environment leads to local impacts as well.

- The impact of pollution peaks (e.g. from pulse pollution events as a result of sewer system discharges) is not clear.

- In Switzerland, endocrine disruptors in the aquatic environment represent a problem at hot spots and at regional level, especially where dilution of the treated waste water in the receiving water is not sufficient (1:10 or more), either at certain times of year or all year round. This can be the case in densely populated regions and with waste water treatment plants that feed into small streams.

- Research in Switzerland has shown that fungal metabolites with endocrine activity (e.g. the highly potent zearalenone) can enter surface waters from cereal crops, but are usually quickly diluted to below the effect concentration.

(Potential) endocrine disruptors in waste water

- Waste water treatment plants play a key role in the emission of steroid hormones and lead to their constant release into the aquatic environment. The construction standard of waste water treatment plants has a decisive influence on emissions.

- It is not really known what part discharges of untreated waste water from sewage systems (pulse pollution events) play in hormone activity in the aquatic environment and what the resultant effects are on aquatic life.

- In treated domestic waste water, it is natural and synthetic steroid hormones that are responsible for the majority of the estrogen activity. Overall, estrogen contamination of the aquatic environment is primarily from this source.

- Waste water discharges must not result in effects in rivers or streams due to estrogen substances from the waste water (protection objective). According to our

current knowledge, the appropriate bioindicator for this is the identification of increased vitellogenin levels in male fish.

(Potential) endocrine disruptors in drinking water

- The steroid hormone concentrations in drinking water measured in scientific studies in Germany are not critical from a health point of view. Contamination via drinking water is several orders of magnitude smaller than the body's own hormone production.

- It can be assumed that in general the endocrine disruptors ingested via drinking water are not critical for human health in Switzerland either. Isolated cases of higher contamination of groundwater and drinking water must be assessed on a case-by-case basis.

- Certain substances (bisphenol A, phthalates) that mimic estrogen can come not only from environmental pollution of groundwater and drinking water, but also from materials that are in contact with drinking water. Their activity is, however, much lower than that of estradiol.

Impact of endocrine disruptors on aquatic life

- There are chemicals that trigger adverse effects by disrupting the human and animal hormone system.

- Different organisms exhibit different sensibilities to endocrine disruptors.

- Even invertebrates are sensitive to endocrine disruptors (e.g. imposex in water snails).

- The consequences of the impact of endocrine disruptors for ecosystems and biodiversity are not yet foreseeable.

- Similarly, the consequences of combinations of stressors, such as parasite stress, poor habitat and physical parameters, on the hormonal impact are largely unknown. There is a clear need for research at this level.

- As shown by *in vitro* tests, the estrogen potency of natural and synthetic steroid hormones is several orders of magnitude greater than that of previously investigated industrial chemicals.

- In the case of some chemicals (e.g. nonylphenolpolyethoxylates) it is only the degradation products that exhibit endocrine activity.

- Experimental studies show that mixtures of various endocrine disruptors have an endocrine impact, even where no impact can be demonstrated for the individual components in the concentrations present (cumulative effect).

- Laboratory experiments on aquatic invertebrates, fish and amphibians show clearly that environmental substances disrupt the hormone balance of such organisms. Chronic exposure to endocrine disruptors at environmentally relevant concentrations can lead to adverse changes in development, growth and reproduction.

- All over the world, hormone-like impacts have been observed in fish that are exposed to treated waste water from mechanical-biological waste water treatment plants.

- Organisms (fish) show effects especially when continually exposed to even very low concentrations of endocrine disruptors (e.g. increased vitellogenin levels).

- Effects on organisms (both the type of effect and effect thresholds) are dependent on the lifecycle of the organism. For instance, the gonadal differentiation phase in fish is very sensitive to exposure to endocrine disruptors.

- In a minority of the Swiss water bodies studied to date, slight to moderate increases in vitellogenin values were measured in male fish in the impact zone of waste water treatment plants, which suggests exposure to estrogen. Apart from this, there are few indications of any impact of endocrine disruptors in Swiss surface waters.

- So far, apart from a very few exceptions, only incomplete impact data are available in Switzerland indicating that exposure to endocrine disruptors under environmental conditions leads to undesirable biological changes.

- So far there are no indications that the high prevalence of gonadal abnormality in whitefish in Lake Thun is attributable to endocrine disruptors.

Test systems, quality

- Vertebrates all react in a similar way to steroid hormones and xenoestrogens. It appears unlikely, though, that all invertebrates also react in the same way to estrogens. It is therefore impossible in practice with current test procedures to establish quality criteria that protect all organisms in the environment against adverse effects.

- Acute toxicity tests are usually not suitable for predicting chronic effects.

- The total contamination of water bodies with endocrine disruptors could be measured using biotests in specialized laboratories. Estrogens and androgenic contamination are already measured in this way. For total assessments they are therefore to be preferred to an analysis of individual substances.

Results of the Consensus Platform "Endocrine Disruptors in Waste Water and in the Aquatic Environment": Action Related Statements/Recommendations

General actions

- The risks posed by endocrine disruptors call for long-term monitoring and research projects.

- Scientific research in the area of endocrine disruptors should be promoted generally. Further fundamental research is necessary, particularly into the potential effects of endocrine disruptors on the human and animal organism so that a comprehensive risk assessment can be conducted.

- There is a clear need for research into the following questions:
  - How do endocrine disruptors affect biological functions outside of the reproductive system?
  - Can experimental results relating to specific modes of action be transferred from one species to the others?
  - What heritable impacts on gene regulation and gene expression do endocrine disruptors have (epigenetic consequences)?
  - What impact do endocrine disruptors have on sensitive development stages? Could this impact be behind later diseases such as cancer or immune deficiency?
  - What impact does the combination of stressors have on aquatic life?

- The environmental behavior of micropollutants needs to be investigated in greater detail. In Switzerland, chemical flows of endocrine disruptors need to be systematically analyzed and modeled in order to identify relevant exposure situations. It will then be possible to derive impact-related actions based on scientifically grounded risk assessments.

- Fish and other aquatic organisms should be studied to establish the biological impact of the environmental stress calculated by means of chemical analyses or forecast using models.

- When carrying out risk assessments for technical mixtures, the interaction of the components and degradation products should be studied where possible, as well as their individual environmental behavior. Their complex composition and the different toxicity levels of the key individual components should also be considered.

Actions concerning (potential) endocrine disruptors in waste water and in the aquatic environment

- It is highly probable that estrogenic steroid hormones are the primary contributors to this kind of hormone activity in the aquatic environment. This means that they are to be viewed as being primarily responsible for any estrogen effects in fish. In practice, therefore, the introduction of a quality objective for estrogen activity in

the aquatic environment is very important. This applies particularly to sensitive rivers and streams affected by waste water treatment plants in which the treated waste water is insufficiently diluted.

- Whenever possible, treated waste water from waste water treatment plants should be fed into a receiving body of water that ensures a sufficiently high dilution ratio.

- The construction of waste water treatment plants should permit optimum elimination of the substances contained in the waste water. It must be ensured that the plants function as well as possible. Problems can arise as a result of micropollutants, particularly where the treated waste water in the water body is insufficiently diluted. In such cases, the following measures should be examined:
  - State-of-the-art construction
  - Further technical measures (activated carbon, ozonation, increasing sludge age, etc.)
  - Alternative courses of action, e.g. creation of integrated waste water networks so that more efficient waste water treatment plants can be established

Official actions concerning (potential) endocrine substances in waste water and in the aquatic environment

- The regulation and implementation of actions in urban drainage should be based on integrated strategy and planning. The key causes of the pollution of the aquatic environment at catchment area level should be taken into account and prioritized, and actions should be identified that represent optimum benefit for the aquatic environment at an economically affordable cost (including agricultural actions, renaturation, etc.). Measures for optimizing rainwater and sewer system management (discharges, leakage losses) should also be assessed. As well as reducing endocrine disruptors, the intended actions for waste water treatment plants also reduce contamination by other substances relevant for the aquatic environment.

- Waste water treatment plants in Switzerland are to be reviewed in terms of their elimination performance and their technical optimization potential.

- Actions at source, such as alternative systems for urban drainage, hospital waste water treatment or the NoMix toilet from EAWAG, need to be evaluated and, if appropriate, promoted.

Industrial actions concerning (potential) endocrine disruptors in waste water and in the aquatic environment

- If a risk is identified for a particular substance or particular groups of substances in an officially recognized risk assessment, industry takes the relevant precautions to reduce or eliminate this risk.

- Industry endeavors to replace substances that have a significant toxicological or ecotoxicological risk with lower-risk substances. For this to work, the substitute

products need to be subjected to a risk assessment as thorough as that applied to the substances they are designed to replace.

Agricultural actions concerning (potential) endocrine disruptors in waste water and in the aquatic environment

- Site-appropriate management of agricultural areas limits contamination by endocrine disruptors and other substances via surface rain-wash and drainage.

- The selection of suitable cereal varieties and optimized working of harvest residues to promote rotting can minimize environmental contamination by the fungal endocrine disruptor zearalenone and its metabolites.

Actions for developing test systems and quality criteria

- Test methods are to be established for prioritizing micropollutants and for monitoring/assessing the quality of water bodies.

- Strategies for recording pollution of the aquatic environment can be based on models and/or biological screening. Pollution hotspots are to be verified using chemical analysis investigations of water bodies.

- The rapid development of internationally (OECD) recognized methods for detecting endocrine disruptor characteristics of chemicals and mixtures must be promoted.

- For practical application, efforts should be made to establish scientifically grounded quality criteria for hormone activity in the aquatic environment: a chronic quality criterion (CQC) for long-term contamination and an acute quality criterion (AQC) for short-term contamination peaks. It is recommended that these quality criteria be added to the Swiss water protection ordinance (Gewässerschutzverordnung).