National Research Program "Endocrine Disruptors"

Consensus Platform "UV Filters in Sun Screens" 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

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 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 formulate 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 page 5 f.).

The work of the consensus platform "UV Filters in Sun Screens" lasted from June 2005 to September 2006. It involved a total of 16 representatives of the producing and applying industries, the authorities and scientists, in addition to two moderators (see page 7).

Out of a total of 51 impact related statements, 19 were accepted and approved in their present form by all members of the consensus platform (see page 8 f).

Out of a total of 18 action related statements/recommendations, all 18 were accepted and approved in their present form by all members of the consensus platform (see page 10 f).

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 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 formulate 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 "UV Filters in Sun Screens"

The following persons have kindly accepted the invitation of the National Research Program "Endocrine Disruptors" to play an active role in the consensus platform "UV Filters in Sun Screens". The persons in charge of the National Research Program wish to thank the members of the consensus platform for their valued participation.

Producing Industry

Uli Osterwalder, Dr. Helmut Elbert, Ciba Specialty Chemicals, Basel

Dr. Gabriele Allard, Dr. Jochen Bausch, Michael Weller, DSM Nutritional Products, Basel

Applying Industry

Dr. Bernhard Irrgang, Mibelle, Buchs (AG)

Dr. Hans-Jürg Furrer, Louis Widmer, Schlieren

Dr. Marcel Langenauer, Spirig, Egerkingen

Authorities

Prof. Georg Karlaganis, Dr. Christoph Studer, Federal Office for the Environment, Bern

Dr. Michel Donat, Dr. Judith Amberg-Müller, Federal Office of Public Health, Bern

Dermatology

Prof. Lasse Braathen, University of Bern

National Research Program 50 "Endocrine Disruptors"

Dr. Margret Schlumpf PD, Prof. Walter Lichtensteiger, GreenTox, University of Zurich

Dr. Karl Fent PD, University of Applied Sciences Northwestern Switzerland, Basel

Moderation and Editing

Prof. 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 "UV Filters in Sun Screens" lasted from June 2005 to September 2006.

Results of the Consensus Platform "UV Filters in Sun Screens": Impact Related Statements

From a total of 51 impact related statements the following 19 have been accepted and approved in their present form by the consensus platform:

General statements on the endocrine effect of chemicals

There are chemicals that can influence the endocrine systems of organisms, including those of humans.

There is a confirmed causal relationship between the occurrence of endocrine disruptors in ecosystems and certain detrimental effects in wild animals. It is postulated that biodiversity is impaired by endocrine disruptors. Endocrine disruptors such as tributyltin have led to the eradication of water snails from contaminated sites.

Endocrine-like effects have been observed worldwide in fish exposed to effluent from biomechanical wastewater treatment plants. Endocrine disruptors have been clearly demonstrated in such water.

Humans are exposed to endocrine disruptors in different ways; for many chemicals, little is known about their endocrine potential.

Human beings are exposed to very low concentrations of endocrine disruptors. These chemicals may have a concerted effect. Many of them can be demonstrated in human tissue and in the maternal milk, so that human beings already come into contact with them in early stages of their life. Further scientific research is required in this area.

Experimental *in vitro* and *in vivo* studies show that mixtures of different endocrine disruptors exert an endocrine effect even if an effect cannot be demonstrated for the individual components in the given concentration.

Steroid and thyroid hormones play an important part in biological effects and developmental processes. Contamination of the environment can have an effect on these systems. In the case of polychlorinated biphenyls (PCBs) this has been demonstrated in humans. A great deal of progress has been made in identifying new endocrine substances. The new substances include chemicals such as certain UV filters and certain antioxidants in cosmetics and preservatives in food. Further scientific research is required.

The mechanisms of early sexual development are similar in a large number of mammals. Observations in animals can therefore yield pointers to effects on humans.

The problems raised by endocrine disruptors necessitate long-term monitoring and research measures.

There is a lack of validated study protocols.

Scientific uncertainty must not be used as an argument for postponing preventive action aimed at risk reduction. A risk-benefit analysis must be performed.

If a number of valid studies of the same species yield different results, the precautionary principle is applied.

Statements on the endocrine effect of certain UV filters

Laboratory studies have shown that certain UV filters exert endocrine effects in mammals and fish. UV filters have been demonstrated as residues in ecosystems, fish and the maternal milk.

UV filters with an endocrine effect are only part of the overall problem of endocrine disruptors.

The health risk associated with 4-MBC is unclear and will be reassessed.

A close watch must be kept on the risk-benefit ratio in light of current scientific findings: the benefits of protecting skin against sun-induced damage (sunburn, skin cancer, etc.), as compared with the adverse endocrine effects of certain UV filters.

Statements on exposure to and protection against solar radiation

Regular, unprotected exposure to solar radiation is considered a health risk that triggers a number of different skin diseases.

The most important measures for preventing sun-related skin diseases are to seek shade, wear appropriate clothing and use sun screens.

By skillfully combining different UV filters, the cosmetic industry is able to produce sun screens with high sun-protection factors while using relatively low filter quantities.

Results of the Consensus Platform "UV Filters in Sun Screens": Action Related Statements/Recommendations

From a total of 18 action related statements, all 18 statements/recommendations have been accepted and approved in their present form by the consensus platform:

Statements/recommendations on general action against endocrine disruptors

The development of validated test methods for determining endocrine endpoints is to be promoted/supported.

The endocrine effects of individual chemicals and of mixtures are to be taken into account in assessing the risk to humans and ecosystems.

If a number of valid studies of the same species yield different results, the precautionary principle is applied.

Statements/recommendations on data-based action on UV filters

Assessment of the risk to humans requires data

- on the frequency and quantity of sun screen use in the Swiss population, particularly by risk groups (women of childbearing age, children);
- on the concentrations in ecosystems, on the "internal impact" (monitoring studies, e.g. non-invasive analysis of extraneous substances in human milk) and on the reproductive and developmental toxicity of UV filters in mammals and aquatic organisms.

These data, as well as data on absorption of UV filters by the skin and the quantities found in the blood (kinetics), have still to be obtained for individual UV filters.

Data on the location and fate of UV filters in aquatic and terrestrial ecosystems are to be obtained. These data, together with data on bioaccumulation and ecotoxicological effects, provide the basis for assessing ecological risk.

Data on the accumulation of UV filters in the food chain, particularly on bioaccumulation in fish, are to be obtained.

Comprehensive ecological risk analyses of UV filters and UV filter mixtures are needed. They require data on the reproductive effects of long-term exposure in fish and other key aquatic and terrestrial organisms.

Statements/recommendations on action on UV filters by the authorities

The Federal Office for the Environment examines the possibility of banning UV filters on the basis of scientifically substantiated risk assessments and, if required, drafts a corresponding bill. The replaceability of the UV filters proposed for such a ban is taken into account, as are the EU's risk assessments and regulations.

The Federal Office of Public Health examines the possibility of banning UV filters that are hazardous to health on the basis of a scientifically substantiated risk assessment and, if necessary, adapts the Cosmetics Ordinance, taking account of the EU's risk assessments and regulations.

The risk to the consumer's health from 4-MBC in sun screens is to be definitively assessed.

The Federal Office for the Environment and the Federal Office of Public Health examine the revised results of industrial self-monitoring in relation to the ecotoxicology and human toxicology of UV filters.

Statements/recommendations on action on UV filters by industry

As part of the legally stipulated self-monitoring process, industry must ensure that UV filters do not exert detrimental effects on humans or ecosystems.

Manufacturers of UV filters revise the self-monitoring process of their UV filters in light of new findings from the NRP "Endocrine Disruptors" and international research programs (EU) and of findings from relevant peer reviewed scientific publications and submit it to the authorities.

Manufacturers of UV filters and sun screens exercise their personal responsibility by taking the latest generally accepted scientific findings on the endocrine effects of UV-filters into account in safety assessments of their products.

Technological opportunities for reducing concentrations of chemical UV filters in sun screens without loss of protective effect are to be further developed or optimally utilized by industry.

Industry supports the further development of new UV filters, e.g. colloidal UV filters, organic pigments, etc., and of other filters with low toxicological risk potential.

The formulating industry examines whether it can voluntarily dispense with the use of 4-MBC in sun screens.

Statements/recommendations on action affording protection against the effects of the sun

Consumers are informed on the proper way to behave in sunlight and protect themselves from its effects.