

Chemical cocktails – a serious matter of concern



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In 2009, the Nordic Council of Ministers supported a workshop with the aim to investigate possible solutions for regulation of combination effects of endocrine disrupting chemicals. The results and conclusions from this workshop are summarized in this folder. The entire workshop report, Endocrine Disruptors – Combination effects, can be found on the Internet:

<http://www.norden.org/en/publications/publikationer/2011-537>

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Nordic co-operation

Nordic co-operation is one of the world's most extensive forms of regional collaboration, involving Denmark, Finland, Iceland, Norway, Sweden, Faroe Islands, Greenland, and Åland.

Nordic co-operation has firm traditions in politics, the economy, and culture. It plays an important role in European and international collaboration, and aims at creating a strong Nordic community in a strong Europe.

Nordic co-operation seeks to safeguard Nordic and regional interests and principles in the global community. Common Nordic values help the region solidify its position.



Chemical cocktails affect our health

Why do girls go into puberty at an earlier age today, than they did 15 years ago? Why is an increasing amount of baby boys born with genital malformations? Why do an increasing number of young men develop testicular cancer?

Chemical cocktail effects are suggested to be one explanation for these findings. Every day, we are exposed to a large number of chemicals coming from many different sources; toys, cosmetics, electronic equipment, indoor air, dust, food, and pharmaceuticals. An increasing amount of well documented studies suggests that these chemicals, in combination, can have severe effects on animals, nature and on humans too.

Currently, risk assessment and current EU-regulation of chemicals is generally carried out by a “substance-by-substance approach”. However, we seriously underestimate the risk of chemicals, if we do not address the effects caused by simultaneous exposure to multiple chemicals from multiple sources.

To be able to deal reasonably with combination effects of chemicals in the future, it is necessary to develop new regulatory approaches, in which combination effects are addressed consistently under various relevant EU legislation.

On the following pages, we explain what chemical cocktails do to us – and what we can do about it. The results and conclusions in this folder are based on a workshop with the aim to investigate possible solutions for regulation of combination effects of chemicals supported by the Nordic Council of Ministers in 2009.



What is the problem?

It is becoming increasingly evident that in combination some chemicals can cause harmful effects in wildlife species, in laboratory animals, and in humans, even in concentrations considered safe for the individual chemical.

During recent years findings of serious effects induced by mixtures of endocrine disruptors have further increased the concern.

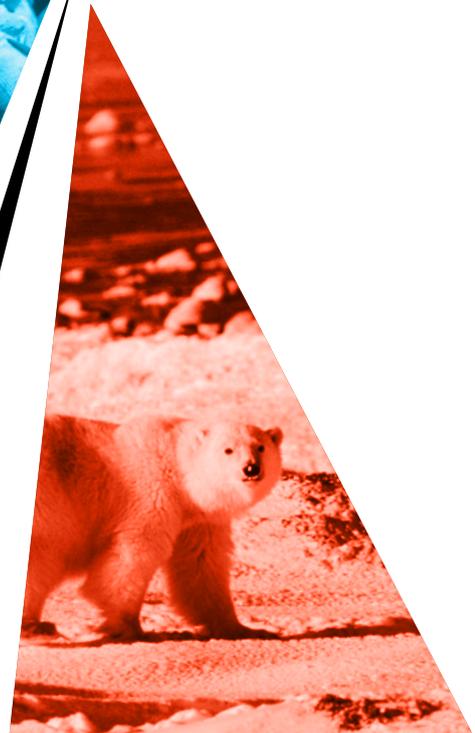
In wildlife species like fish, snails, and polar bears, exposure to endocrine disrupting substances is linked to a higher incidence of genital malformations and effects on reproduction. In humans, serious reproduction effects have been reported linking decreasing semen

quality, increasing testicular cancer, genital malformations in baby boys, and early onset of puberty in girls to combined effects of endocrine disruptors.

The same types of effects that are observed in humans and wildlife can be induced in laboratory animals exposed to a mixture of endocrine disrupting chemicals.

OTHER TYPES OF COMBINATION EFFECTS

Synergistic and antagonistic effects are observed quite rarely. In these cases, the combination effect is respectively larger and smaller than would be expected if the doses were added. There are no good methods to predict either of synergism and antagonism yet – but thorough research is currently going on in this area.



Something from nothing

Research indicates that combined exposure to multiple chemicals can add up the effects of these substances, thus having a much larger effect than the chemicals would have individually.

Well documented studies on effects of endocrine disruptors show that multiple endocrine disruptors in doses that are considered safe individually can have serious effects when mixed. In experiments with laboratory rats, the effects include severe malformations of reproductive organs, increased distance between anus and genitals and increased retention of nipples in male rat pups. Such effects are sensitive markers for endocrine disruption.

Scientists expect these substances to have a similar impact on human baby boys.

0 + 0 + 0 = 3? DOSE ADDITION

For chemicals with similar types of effects, dose addition is the most widely used method for calculation of combination effects. This means that even if the individual substances are present in doses that do not cause effects on their own, the added doses may reach a level, which causes effects. As an example animal experiments have shown that exposure to small quantities of endocrine disrupting substances that individually are considered safe cause severe malformations of reproductive organs in rats. In this case the dose of each of these chemicals is put on top of each other. This is often referred to as “something from nothing”.



Female



Male

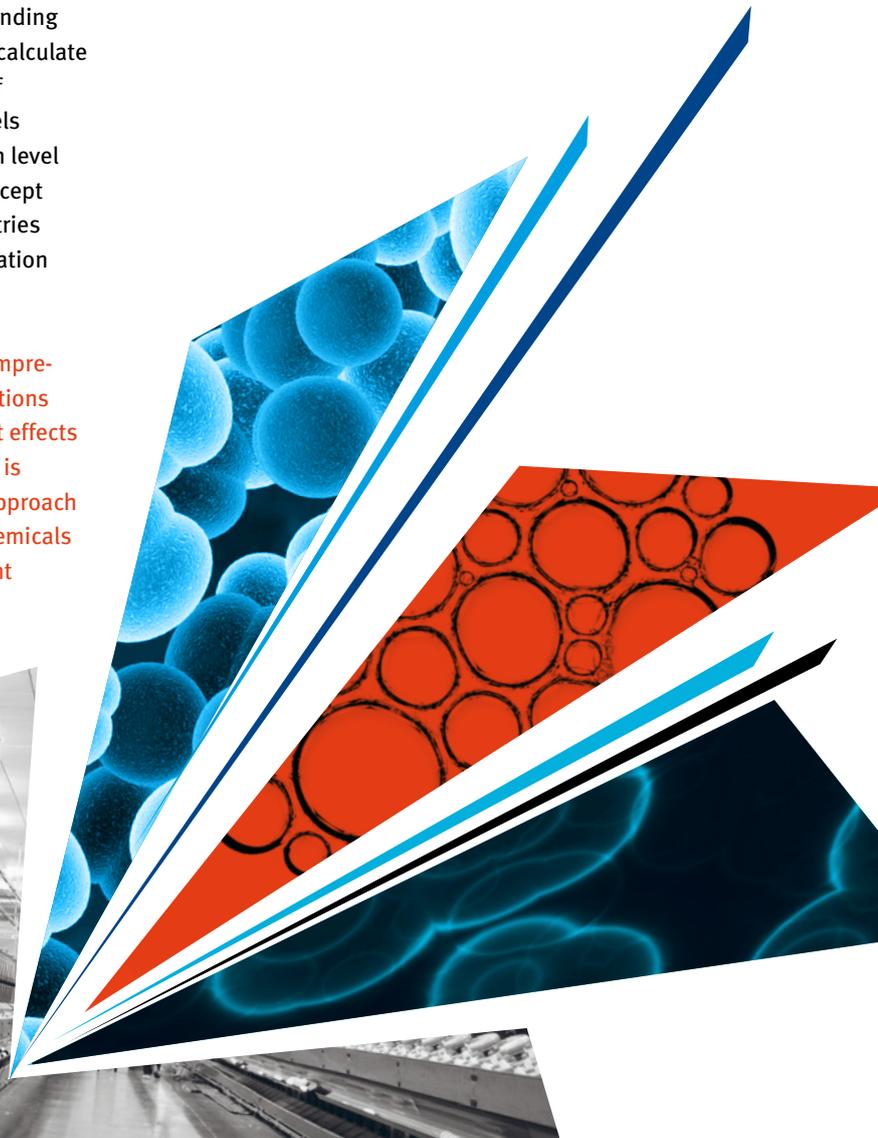
TESTS ON RATS SHOW US THAT when rats are exposed to a mixture of endocrine disruptors each in safe doses, the male rat pups retain nipples like their female counterparts.

No time to waste

In recent years, huge efforts have been put into the analysis of combination effects and development of methods to predict if, when and how they may occur.

This has led to a common international understanding that in general dose addition should be used to calculate combination effects. This requires a high level of knowledge about both effects and exposure levels of all the involved chemicals. Whenever this high level of knowledge is available, the dose addition concept is the approach to be used by authorities, industries and NGO's to properly assess the risk of combination effects.

However, it is important to understand that a comprehensive risk assessment of all possible combinations of chemicals requires a level of knowledge about effects and exposure of the individual chemicals, which is normally not available. Therefore, a pragmatic approach for risk assessment of combination effects of chemicals is needed. Current EU legislation and assessment practices need to be updated in this respect.



The logical way forward

The threats of combination effects of chemicals to human health and the environment are too immense to be ignored.

During the last ten years, the REACH legislation has been established in the European Community with focus on industry's responsibility for safe use of single chemicals.

However, the existing regulatory frameworks are neither designed, nor sufficient, to address combination effects of chemicals properly.

The Nordic Proposals

In 2009, the Nordic Council of Ministers supported a workshop with the aim to investigate possible solutions for regulation of combination effects of endocrine disrupting chemicals. The following solutions were agreed upon:

In the short term, EU member states should explore the limitations of existing regulations by providing well-documented examples of mixture toxicity, e.g. risk assessments, restrictions and quality criteria.

In the long run, the protection of humans and wildlife species against the hazards of chemical combination effects must be approached horizontally in the EU, thus addressing combination effects in the numerous pieces of relevant legislation.

In order to deal with substances that are regulated under different regulatory regimes (e.g. cosmetics, industrial

RELEVANT LEGISLATION THAT SHOULD CONSIDER COMBINATION EFFECTS

REACH Regulation
Pesticides Authorisation Directive
Pesticides Residues Regulation
CLP Regulation
Biocides Directive
Cosmetics Directive
Human Medicines Directive
Food Additives Authorisation Directive
Food Contact Materials Regulation
Water Framework Directive

chemicals, pesticides etc.), it is as a starting point proposed to allow only a part (e.g. 10 %) of the "safe dose" within each area of regulation. This would be an easy and cost-effective way to decrease the risk of effects due to cumulative exposure of simultaneous exposure to chemicals with similar effects from different routes, e.g. food, water, and the environment.

AT THE NORDIC WORKSHOP IT WAS PROPOSED THAT

- EU member states should explore the limitations of existing regulations by providing well-documented examples of mixture toxicity
- The dangers of chemical combination effects should be approached horizontally in the EU
- Only a part (e.g. 10 %) of the "safe dose" should be allowed within each area of regulation

REACH is the European Community Regulation on industrial chemicals and their safe use, which entered into force on 1 June 2007. However, exposure to combination endocrine disruptors also comes from food, pesticides etc. Thus, the REACH legislation is not sufficient to address combination effects properly.



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Finland: Finnish Safety and Chemicals Agency, www.tukes.fi

Iceland: Umhverfisstofnun, www.umhverfisstofnun.is

Nordic Chemical Group, www.norden.org/nkg

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