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Exposure of pregnant consumers to suspected endocrine disruptors - conclusion

In this project, the exposure of pregnant consumers to a number of selected substances suspected of being endocrine disruptors is examined. Some of the most sensitive periods in human life are the fetal stage and the childhood, as the human being and its organs undergo an important development during these stages. This development requires a balance in the hormonal systems involved in the various developmental stages. The pregnant woman is in focus in this project, as her exposure to suspected endocrine disruptors can give an impression of what her fetus may be exposed to in sensitive stages of its development.

A number of industrial chemicals, ingredients in cosmetic products and pesticides have been selected for inclusion in this project. The exposure of pregnant women to these substances is estimated by including mainly exposure from food, indoor environment and consumer products (including cosmetics). Medical products and phytoestrogens in food are not included in the calculations, but possible exposures from these sources have been included in the discussion.
Combined exposures were assessed using a basis scenario, where food, indoor environment and consumer products are included. Furthermore, exposures were estimated for a holiday scenario, a transport scenario and a work scenario, because specific groups are expected to be exposed to the selected substances in other more specific ways, e.g. via work or in shorter periods of life for example on holiday and by use of sunscreen. Where relevant, several of the scenarios have also been combined and the combined exposure assessed.

The selection of the 35 substances reflects the knowledge available today as well as the framework of this project. There are many other substances suspected to be endocrine disruptors. There are for instance almost 200 substances in category 1 on the EU list of suspected endocrine disruptors, but many have not been included in this project. The reason may be that the exposure of pregnant women is expected to be very small or not occuring, that data available for risk assessment are inadequate or that the substance is part of a group of substances, represented by some of the selected substances. Furthermore, only a small part of the approximately 50.000 chemical substances, which surround us in daily life, are tested for endocrine disrupting effects. Consequently it cannot be ruled out, that several other substances, which pregnant women are exposed to in daily life, may contribute to the risk of endocrine disrupting effects.

The risk assessments of each of the selected substances showed that dioxins and dioxin-like PCBs (foodstuff, dust), propyl- and butylparabens (cream /sunscreen), OMC (sunscreen), triclosan (deodorant, toothpaste), nonylphenol (clothes) and phthalates (various consumer products and dust) are the substances/substance groups with the highest risk characterisation ratios (RCR).

Propyl- and butylparaben contribute considerably to the total RCR when use of body lotions and sunscreens with parabens are included.
The calculated RCR values are based on conservative estimates for no effect levels of propyl- and butylparabens, but even use of less conservative no effect levels lead to high RCR values in the realistic worst case holiday scenario.
The group of pesticides contributes only minimally to the RCR at the estimated exposure levels. It cannot be determined in this project if exposure to bisphenol A via foodstuffs or consumer products may lead to endocrine disrupting effects in humans.

Normally, a risk assessment is based upon exposure from a single substance at a time and often just for one situation at a time. However, we are exposed to many different products on a daily basis, of which several contain the same chemical substances, having the same toxicological effects. In this project, this has been taken into account by performing cumulative risk assessments and thereby including combination effects of the substances. An overall result is that many single substances contribute with an RCR, which in itself does not lead to an immediate concern, but that the cumulative risk assessment leads to RCR values which indicate a possible risk in case of a combined exposure to these single substances.

For all three endocrine disrupting modes of action (antiandrogenic, estrogenic and thyroid disrupting) the combined RCR values were between 0.5 and 0.8 for medium exposure in the basis scenario. For maximum exposure in the basis scenario, combined RCR values were between 1.4 and 3.1. In the holiday scenario, the use of sunscreen containing propyl- and butylparabens contribute considerably to the combined RCR for estrogenic effects, so that an RCR above 1 will appear under realistic average conditions of use (medium exposure). Since it is realistic to also be exposed to food and other sources from the basis scenario in the holiday scenario, the combined values for holiday+basis scenarios are also calculated with the result of an RCR above 1 for both antiandrogenic and estrogenic effects at medium exposure. For the combined values for basis+work+transport scenarios RCR values below 1 were observed at medium exposure.

It is not estimated to which extent use of products for professionals in the work environment may contribute to an endocrine disrupting effect. However, contributions from use of consumer products in the work environment have been estimated. Assuming that in certain professions there is a frequent use of hand cream and plastic sandals it was estimated, that these sources can contribute to the RCR values. No particular contribution has been found from indoor environment in cars.

All in all this indicates that an increased risk of endocrine disrupting effects may exist for women, who because of their consumption pattern are exposed to many suspected endocrine disruptors at the same time. It appears to be of major importance that a cumulative risk assessment is performed instead of a risk assessment for each single substance. It is clearly the combined contribution from the various substance groups from many different sources that lead to combined RCR values above 1 in the realistic worst case basis scenario, as the RCR for the individual substances is below 1.
The only exception from this is the exposure to dioxins and dioxin-like PCBs which alone lead to an RCR above 1 at maximum exposure in the basis scenario. It

is, however, also interesting here that further contributions from phthalates causes a significant increase of this RCR.

The assessment of the exposure levels from consumer products, food and indoor environment are compared with actual measured concentrations of the substances, as observed in a biomonitoring study, measuring some of the substances in urine samples from Danish pregnant women. Neither the estimated nor the measured exposure levels constitute a complete picture of the exposures levels the individuals experience. For the estimated exposures this is due to the fact that not all exposure sources are estimated and known. For the biomonitoring study there are both big individual differences in exposure levels and big differences in exposure between different days for the same individual. Therefore also the levels observed in the biomonitoring study differ remarkably between individuals. Since only a limited number of women are included in the biomonitoring study, it cannot be excluded that the other levels may be observed in other pregnant women who did not participate in the study.

The estimated exposures and the biomonitoring study, however, give a picture of the combined exposure that at least some individuals experience. For several of the specific substances included in this project, there is coherence between the exposure levels found in the realistic worst case scenarios (maximum exposure) and the highest levels measured in the urine samples. The single substances (DEHP, DBP, propylparaben and triclosan), which in the project are found to contribute the most to the combined RCR values for antiandrogenic, estrogenic and thyroid disrupting effect are also the substances which in the boimonitoring study correspond best to the estimated realistic worst case exposure levels..

In this project combined RCR values for substances with the same modes of action are estimated, and RCR values above 1 are interpreted as an indication that a risk of endocrine disrupting effect may be present at the estimated exposure levels, i.e. that the risk is not controlled, and that there is a need for a detailed assessment of whether the risk applies to a considerable part of the target group, and whether the exposure to the relevant substances can be limited.

Overall it can be concluded that for some pregnant women there is a need to reduce the exposure to suspected endocrine disruptors. Substances with antiandrogenic, estrogenic and thyroid disrupting effect may increase the risk of endocrine disrupting effects for the group of pregnant women, who are exposed to high levels of the substances from food, indoor environment and consumer products. Based on the estimated exposures to suspected endocrine disruptors included in this project it seems the majority of the pregnant women are not exposed to endocrine disruptors at such high levels that there is a cause for immediate concern. Many sources of suspected endocrine disruptors are however not included in the risk assessment of this project, such as e.g. phytoestrogens in food, medical products and food supplements. Furthermore, there is still a high level of uncertainty as to which substances are endocrine disruptors and how we are exposed to them. Consequently, it cannot be ruled out, that several other substances, to which pregnant women are exposed in daily life, may contribute further to the risk of endocrine disrupting effects.

It is not possible to avoid all exposure to endocrine disruptors (e.g. exposure to dioxins and dioxin-like PCBs in food), but for certain substance groups it is possible to limit the exposure for example by avoiding propyl- and butylparabens

in cream and sunscreens, OMC in sunscreens, triclosan in deodorant and toothpaste, nonylphenol by washing new clothes and phthalates in various consumer products as well as in dust.