

Exposure of pregnant consumers to suspected endocrine disruptors

Survey of chemical substances in consumer products no. 117

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Introduction

The project on exposure of pregnant consumers to suspected endocrine disruptors was carried out during the period July 2011 to March 2012.

This report describes the results of the project, including selection of substances, review of existing knowledge in this area (incl. previous surveys from the Danish EPA), a survey of new products selected for chemical analyses, exposure scenarios, and risk assessment of the overall exposure to suspected endocrine disruptors of pregnant women and women who want to become pregnant.

The results of the report will be followed up by an information campaign mainly targeting pregnant women in Denmark and women who want to become pregnant. The information campaign is launched in March 2012.

The project was carried out in cooperation between DHI, Food DTU, FORCE Technology, Institute for Environment and Health, and Operate.

Project management was managed generally by DHI, by head of projects, MSc. Dorthe Nørgaard Andersen.

The survey was carried out by Pia Brunn Poulsen and Maria Strandesen, FORCE, and Lise Møller, Tina Haugaard Stephansen and Dorthe Nørgaard Andersen, DHI. Daniela Bach, FORCE, has been responsible for the analyses The risk assessments were carried out by Julie Boberg, Marta Axelstad Petersen, Sofie Christiansen, Ulla Hass, Food DTU, Pia Brunn Poulsen and Maria Strandesen, FORCE, and Lise Møller, Helle Buchardt Boyd and Dorthe Nørgaard Andersen, DHI

Communication consultant Torben Clausen, Operate, has the overall responsibility for the information campaign.

The project was overseen by a focus group consisting of Shima Dobel, the Danish Environmental Protection Agency Louise Fredsbo Karlsson, the Danish Environmental Protection Agency Marie Louise Holmer; the Danish Environmental Protection Agency Christel Søgaard Kirkeby; the Danish Environmental Protection Agency Dorthe Nørgaard Andersen, DHI

The project is funded by the Danish Environmental Protection Agency.

Summary and Conclusions

In daily life, all humans are exposed to chemical substances from various sources such as food, medical products, indoor environment, cosmetics and other consumer products surrounding us at home, in connection with hobbies, and at work. Among the thousands of chemical substances one could possibly be exposed to in daily life, some have been shown to act as endocrine disruptors in laboratory animals. These substances are also suspected of being endocrine disruptors to humans and to contribute to e.g. cryptorchidism (undescended testicles to scrotum) or hypospadias (birth defect of the penis) in baby boys, premature puberty in girls and low semen quality, increased occurrence of testicular cancer and reduced levels of the male sex hormones in men.

In this project the exposure of women in the child-bearing age to a number of selected suspected endocrine disruptors was investigated. Some of the most sensitive periods of human life are the fetal stage and childhood, because the human being and its organs during these stages undergo a significant development which requires balance in the hormonal systems that are involved in regulating the various stages of the development. The pregnant woman was in focus in this project, because her exposure to suspected endocrine disruptors can give an impression of what her fetus may be exposed to in sensitive stages of its development. Women who wish to become pregnant are included in the target group for the subsequent information campaign, because they are typically pregnant two weeks before they know it, and because some suspected endocrine disruptors accumulate in the body and are only released very slowly. Exposure even a long time before pregnancy may therefore have an impact on the exposure of the fetus.

The project forms the basis for an information campaign which includes the conclusions of the report and gives advice to pregnant women and women who want to become pregnant.

A number of chemical substances suspected of being endocrine disruptors were selected. The endocrine disrupting effects included are antiandrogenic (reduce production of or block effect of male sex hormones), estrogenic (affects the balance of female sex hormone) and/or thyroid disrupting (disrupts the balance or effects of the thyroid gland's hormones).

The criteria for including a substance in the project were as follows:

- substances from group 1 and group 2a according to the criteria for identification of endocrine disruptors made by the Danish Centre for Endocrine Disruptors (CEHOS) for The Danish EPA (Danish EPA 2011),
- substances, where the endocrine disrupting effect is related to an antiandrogenic, estrogenic or thyroid hormone disrupting mode of action,
- substances, for which there is sufficient knowledge in animal studies to calculate the doses of the substance, which may be assumed to be safe for humans (with regard to the specific endocrine effect),
- substances expected to be present in products commonly used by the pregnant women,
- substances expected to contribute with a significant exposure,

• finally, it was considered that the selected substances should cover several different product groups and several different materials within the selected exposure situations/activities

The focus is thus on substances with antiandrogenic, estrogenic and thyroid disrupting mode of action. It should be noted that some substances have multiple modes of action and that it is not always possible to categorise, whether, for example, changes in the reproductive system are due to an antiandrogenic or estrogenic mode of action.

The Selected substances are:

Substance name (CAS No.)	Antiandro- genic	Estrogenic	thyroid disrupting
Phthalates			
DEHP (di-ethyl-hexyl-phthalate) (117-81-7)	Х		Х
DiNP (di-iso-nonyl-phthalate) (28553-12-0)	Х		
DBP (di-butyl-phthalate) (84-74-2)	Х		
DiBP (di-iso-butyl-phthalate) (84-69-5)	Х		
BBP (butyl-benzyl-phthalate) (85-68-7)	Х		
DPP (dipentyl phthalate) (131-18-0)	Х		
DnHP (di-n-hexyl phthalate) (84-75-3)	Х		Х
DnOP (Di-n-octyl phthalate) (117-84-0)	Х		Х
Other environmentally hazardous chemical substance			
Dioxin and dioxin-like PCBs	Х		Х
Bisphenol A (80-05-7)		Х	
Nonylphenol (25154-52-3)		Х	
TBBPA (Tetrabromobisphenol A) (79-94-7)		Х	Х
Perfluorooctanoate (PFOA) (335-67-1)	Х		Х
Perfluorooctane sulfonate (PFOS) (1763-23-1)	Х		Х
Octamethylcyclotetrasiloxane (D4) (556-67-2)		Х	
Substances in cosmetic products			
Propylparaben (94-13-3)		Х	
Butylparaben (94-26-8)		Х	
Isobutylparaben (4247-02-3)		Х	
Octyl methoxycinnamate, 2-ethylhexyl-4-		Х	Х
methoxycinnamate (OMC) (5466-77-3)			
3-Benzylidene camphor (3-BC) (15087-24-8)		Х	
4-Methylbenzylidene camphor (4-MBC) (36861-47-9)		Х	
Benzophenone 3 (BC-3) (131-57-7)		Х	
Triclosan (3380-34-5)		Х	Х
Resorcinol (108-46-3)			Х
Pesticides			
Chlorpyrifos (2921-88-2)	Х		Х
Dithiocarbamates:	Х		Х
- Mancozeb (8018-01-7)			
- Maneb (12427-38-2)			
- Propineb (12071-83-9)			
Imazalil (35554-44-0)	Х		
Iprodione (36734-19-7)	X		
Pirimiphos-methyl (29232-93-7)	X		
Procymidon(32809-16-8)	X		
Propamocarb (24579-73-5)		Х	
Tebuconazole (107534-96-3)	Х		
Thiabendazole (148-79-8)	X		Х
	~		

The selection of the 35 substances reflects the knowledge available today. There are many other substances under suspicion of being endocrine disruptors. There are for instance almost 200 substances in category 1 on the EU list of potential 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 substances 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.

Based upon knowledge from previously completed surveys of consumer products from the Danish EPA, as well as a behaviour analysis focussing on the target group's use of consumer products, which might contain substances from the above table, new product groups were chosen for survey and analysis. A total of 8 product groups were included in this survey: cell phone covers, sleeping mats, work gloves, hand bags made of synthetic leather, sneakers, antibacterially treated clothes, moisturisers for full body/pregnant belly creams and sunscreens. The survey gave insight into the number of products within the 8 product groups, types of material used in the product groups and for cosmetics the content of the selected substances. Within these 8 groups, products were selected for quantitative analyses of a number of the selected substances depending on the type of material of the product. For certain products in de different groups also migration analyses were performed.

The quantitative analyses gave the following results:

Phthalates were identified by a content analysis in the following product groups (the number between brackets indicates the number of products with detected content of the substance in question):

- 20 cell phone covers tested (DEHP in 5 products, DiNP in 1 product)
- 11 work gloves tested (DEHP in 1 product, DiNP in 2 products)
- 10 sleeping mats tested (DEHP in 1 product)
- 9 sneakers tested (DEHP in 1 product)
- 10 handbags tested (DEHP in 2 products, DBP in 1 product)

Content analyses identified traces of bisphenol A (i.e. concentrations under quantification limit) in 6 cell phone covers made of polycarbonate plastic, also known as PC.

The content of triclosan and nonylphenol were analysed in antibacterial clothes and sneakers. No triclosan or nonylphenol were identified in the analyses (including nonylphenolethoxylates with up to approx. 4 ethoxylate units in the chain).

The content of octamethylcyclotetrasiloxane (D4) was analysed in cell phone covers, work gloves, sneakers, antibacterial clothes and cosmetic products. The substance was only identified in cosmetic products. In 10 out of 15 cosmetic products a content of D4 above the detection limit was identified.

Migration tests with sweat simulators were performed. None of the phthalates DEHP or DiNP, or bisphenol A migrated out of the products under the used conditions – not even in trace amounts. Migration analyses were not performed for triclosan and nonylphenol/nonylphenolethoxylates, as the quantitative analyses did not find any content of these substances. Migration analyses were not performed

for D4, as no products apart from cosmetic products contained D4. For the cosmetic products a migration analysis is irrelevant, as the products are applied directly onto the skin. A dermal absorption factor is used instead in the subsequent exposure assessement, to estimate the amount of D4 expected to be absorbed through the skin.

A **hazard assessment** of the selected chemical substances was performed in order to determine the no or lowest adverse effect levels (NOAELs or LOAELs) of the substances based on their endocrine disrupting effect in laboratory animals. These were used both to assess the risk from exposure to each substance, and to calculate the combined risk from exposure to a group of substances with the same mode of action.

The **exposure** of pregnant women to the selected substances was assessed using a basis scenario, and with different other inputs to exposure such as a holiday scenario and a work scenario. The scenarios were divided into a medium and a maximum exposure respectively, with the approach that the exposure is evened out over a week's exposure, as the project assesses exposure for pregnant women. In the pregnancy period it is important to focus on a very short exposure period because of the several short critical windows of exposure, where the fetus is very vulnerable to endocrine disrupting effects, as shown in animal studies. Medium exposure describes a situation, which many in the target group is expected to experience, i.e. a **realistic scenario**, whereas the maximum exposure describes a situation expected to be experienced by fewer in the target group, i.e. a **realistic worst case scenario**.

The starting point has been the available information and an estimate of which products a pregnant woman is expected to use during a week. A lot of women may use the products in other ways than described here, but the assumptions are made to be able to calculate an estimated exposure. Even though some of the assumptions in the scenarios may not cover all the women in the target group, it should be kept in mind that other women in the target group may also use other products not included here, but which may contain the selected substances and thereby add to the total exposure.

The **basis scenario** includes exposure to food, indoor environment and the activities normally practiced in daily life, and includes contributions from toothbrushing, footwear/clothing, use of cream (including pregnant belly cream and body lotions), sex toys, bath soaps, bath mats etc. as well as sport, leisure and shopping. The exposure assessments are based on available data, i.e. for the consumer products, contributions from products with available migration data are included (e.g. oilcloth, pilates ball, rucksack, bath soap packaging and plastic sandal). Consequently, the exposures do not cover the contribution from all consumer products, which the target group is expected to be in contact with in daily life.

Apart from the basis scenario, an exposure in connection to a **holiday scenario** is estimated, where mainly the contribution from sunscreens is included in the assessment, a **work scenario**, where a risk of exposure from a few consumer products, such as hand cream and plastic sandals used by health staff and cashiers in work scenarios, is estimated. Also a risk from indoor environment in cars is estimated in a **transport scenario**.

Risk assessments of each of the selected substances showed, that dioxins and dioxin-like PCBs (from food and dust), propyl- and butylparabens (from cream/sunscreen), OMC (from sunscreen), triclosan (from deodorant and

toothpaste), nonylphenol (clothes) and phthalates (from various consumer products and dust) are the substances/substance groups with the highest contributions to exposure and the highest risk characterisation ratios (RCR). RCR describes the ratio between exposure and "safe dose levels" with regard to endocrine disrupting effect of a substance. The higher the RCR, the higher the risk is assumed to be. In this project the total RCR values for substances with the same mode of action are calculated, and RCR values above 1 are interpreted as an indication that a risk of endocrine disrupting effects may occur 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 for a considerable part of the target group, and whether the exposure to the relevant substances can be limited.

Propyl- and butylparaben contribute considerably to the total RCR for estrogenic effects due to the use of sunscreens with parabens. Other products which are also used on a large surface area, such as for example body lotions, contribute considerably as well. The calculated RCR values are based on conservative estimates for no effect levels of propyl- and butylparabens, but even use of less conservative estimates for no effect levels lead to high RCR values at the estimated exposures to propyl- and butylparaben in the realistic worst case holiday scenario. The group of pesticides only contributes minimally to the RCR at the estimated exposure levels. It cannot be determined in this project if exposure to bisphenol A in food or products may cause endocrine disrupting effects in humans.

Normally a risk assessment is based upon an estimate of exposure from a single substance from a single product. However, we are exposed to many different products on a daily basis, of which several contain the same chemical substances, and thereby the same toxicological effect. This has been taken into account in this project by performing cumulative risk assessments and thereby including **combination effects** of the substances.

In this project, for all three effect types (antiandrogenic, estrogenic and thyroid disrupting effect), combined RCR values are between 0.5 and 0.8 for medium exposure in the basis scenario. For maximum exposure in the basis scenario, combined RCR values are between 1.4 and 3.1. In the holiday scenario the use of sunscreen containing propyl- and butylparabens contributes considerably to the combined RCR value for estrogenic effects. The combined RCR for propyl- and butylparabens alone is above 1 (1.1) at medium exposure in this scenario. Risk assessment of use of consumer products in work scenarios showed that e.g. use of extra hand cream containing propyl- and butylparabens during a work day will contribute to the RCR for estrogenic effects. Only an insignificant contribution was determined from indoor environment in cars.

Since it is realistic to also be exposed to food and other sources from the basis scenario during a holiday, the combined values for holiday+basis scenarios were also calculated. This resulted in an RCR above 1 for both antiandrogenic and estrogenic effects at medium exposure. For the combined values for basis+work+transport, RCR values below 1 were observed at medium exposure.

			Medium	Exposure		Maximum Esposure						
Effect	RCR _{BASI}	RCR _{HOLI}	RCR _{wor}	RCR TRANSPORT	RCR _{BASI} s+holiday	RCR _{BASI} S+ WORK+TRA NS	RCR _{BASI}	RCR _{HOLI}	RCR _{WOR}	RCR TRANSPORT	RCR _{BASI} s+holiday	RCR _{BASI} s+ work+tra ns
Anti- androg en	0.72	0.56	0.08	<0.00	1.28	0.80	2.23	1.12	0.15	<0.00	3.35	2.39
Estroge n	0.76	1.41	0.21	0	2.17	0.97	3.10	9.96	0.81	0	13.04	3.88
Thyroid	0.47	0.36	<0.0	<0.00	0.84	0.48	1.43	1.33	<0.00	<0.00	2.76	1.43

All in all this indicates that an increased risk of endocrine disrupting effects may exist for women, who because of their consumption pattern are in contact with many suspected endocrine disruptors at the same time. It appears to be of major importance that a cumulative risk assessment is made instead of a risk assessment for each single substance. It is clearly the combined contribution from the various substance groups that leads to RCR values above 1 at maximum exposure in the basis scenario, since the RCR for each individual substance is below 1. The only exception from this is that the RCR for dioxin and dioxin-like PCBs, at maximum exposure in the basis scenario is 1.1.

The estimated exposure levels from the 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 which exposures levels the individuals experience. For the estimated exposures this is due to the fact that not all exposure sources are known and included. 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 that are observed in the biomonitoring study differ remarkably between individuals. Since only a certain number of women are included in the biomonitoring study, it cannot be ruled out that 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 combined picture of the 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 worst case estimations (maximum exposure) and the highest levels measured in the urine samples. The substances, (DEHP, DBP, propylparaben and triclosan), which in the project contribute the most to the combined RCR, are also the substances, which in the biomonitoring study correspond best to the estimated realistic worst case exposure levels.

All in all, it can be concluded, that for some pregnant women there is a need to reduce the exposure for suspected endocrine disruptors. Substances with antiandrogenic, estrogenic and thyroid disrupting effects 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 that the majority of pregnant women are not exposed to endocrine disrupting chemicals in levels that lead to immediate concerns. However, several sources of suspected endocrine disruptors are 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 are we 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 exposures 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, nonvlphenol by washing new clothes and phthalates in various consumer product as well as in dust.

1 Introduction

1.1 Project background

All humans are exposed to chemicals in everyday life, from food, indoor environment, cosmetics and other products that surround us at home and at work. Also the use of food supplements, medicines and herbal medicines cause a chemical effect of the body, which can have both desired and unintended effects. Among the thousands of chemicals, you might be exposed to in daily life, some have been shown to act as endocrine disruptors in laboratory animals. These substances are also suspected of being endocrine disruptors to humans and to contribute to e.g. cryptorchidism (undescended testicles to scrotum) and hypospadias (malformation of the genitals) in baby boys, earlier onset of puberty in girls and low semen quality, increased incidence of testicular cancer and reduced levels of the male sex hormone in men.

Some of the most sensitive periods in the human life are fetal life and childhood, as humans and human bodies during these periods are undergoing a significant development, which requires a balance of the endocrine systems involved in the various stages of development.

In a previous project, the Environmental Protection Agency has investigated the suspected endocrine disruptors, to which 2-year-old children may be exposed (Danish EPA 2009a). In this project the exposure of women in the child-bearing age to a number of selected suspected endocrine disruptors was investigated. It focuses on the pregnant woman, as her exposure to suspected endocrine disruptors may give a impression of what her fetus may be exposed to during the sensitive periods of its development. It is not completely clarified which period or periods of the pregnancy that are the most sensitive to changes in the hormonal balance that could potentially affect fetal development. However, the first three months of pregnancy are mentioned as a period where there is a specific basic development of the fetus, and where the disruption of the hormonal balance due to chemical exposure may cause developmental disorders of the fetus. Therefore, pregnant women (and women who wish to become pregnant) are advised to be particularly careful with the use of e.g. alcohol and medication during this period. However, there is a significant development of the fetus throughout pregnancy, and it is essential that the whole pregnancy period is considered a period during which the fetus is protected against adverse chemical impacts to the greatest extent possible. Women, who wish to become pregnant, are included in the target group for the subsequent information campaign, because a woman is typically pregnant for 2 weeks before she knows it, and because some suspected endocrine disruptors accumulate in the body and are excreted only very slowly. An exposure even long before pregnancy may therefore have an impact on the exposure of the fetus.

1.1.1 Knowledge of endocrine disrupting effects

Endocrine disruptors have for years been suspected to be a contributory cause of reproductive adverse effects, especially in boys and men (Toppari et al., 2010; Universitetsafdelingen for Vækst og Reproduktion 2011). Studies in recent years have shown:

- that one in five Danish men between the age of 18 and 20 have a semen quality below the normal limit, which is established by the WHO,
- that Denmark has experienced a large increase in testicular cancer over the past 60 years, and is the country in Europe that has the highest incidence. Nearly 1% of Danish men get testicular cancer during their lifetimes,
- that 9% of Danish boys are born with cryptorchidism (undescended testicles to scrotum). It is significantly more than in the 1960s. Cryptorchidism is associated with an increased risk of low semen quality and testicular cancer,
- that testosterone levels in the blood of Danish men have decreased. Men born after the 1930s-40s have lower testosterone levels than their fathers and grandfathers had in the same age. A 30-40 year-old man today has a level corresponding to that of a 70-year-old then.

An important background for the fact that endocrine disruptors are suspected to be among the reasons for the increasing incidence of the above reproductive problems is, that similar effects are also seen in laboratory animals, which have been exposed to endocrine disruptors with antiandrogenic or estrogenic effect during embryonic development.

Endocrine disruptors with estrogenic effect are also suspected to be a contributing factor to adverse health effects in girls and women, such as earlier puberty and the increased incidence of breast cancer (Diamanti-Kandarakis et al., 2010; Mouritsen et al., 2010).

Endocrine disruptors that affect the thyroid hormones thyroxine (T4) and triiodothyronine (T3) play an important role in brain development during fetal life. It has long been known that a strongly reduced level of the thyroid hormone during embryonic development inhibits children's brain development, and at worst can lead to mental retardation. In recent years, it has further been found that moderate and transient decrease in maternal T4-levels during pregnancy also may have a negative impact on children's behavior and intelligence. Several endocrine disruptors can reduce T4-levels and cause behavioral effects in laboratory animals, and are on this background suspected to be a contributing cause of the effects on children's behavior and intelligence (Axelstad 2011).

In recent years, hypotheses have been put forward that endocrine disruptors may contribute to the development of e.g. breast and prostate cancer, metabolic syndrome, obesity, diabetes and cardiovascular diseases (Diamanti-Kandarakis E 2009). These other effects are not included in this report as there is still considerable doubt about the connections.

1.1.2 Combination effects

For risk assessment of chemicals, human exposure to a single substance is usually compared with the so-called no-observed-effect-level. The no-observed-effectlevel is the highest dose of the substance, which has not caused any harmful effects in animal studies. The risk assessment is normally made for one substance at a time, and it is very rare that there is a risk of exposure to one substance seen alone. Humans, however, are daily exposed to many different chemicals from many different sources. Combination effects, also reffered to as cocktail effects, represent the fact that small amounts of several substances together may cause an undesirable effect, which is not seen when exposed to the individual substances separately in the same doses. Combination effects due to exposure to low doses of many chemicals with endocrine disrupting effects are suspected to have contributed to e.g. cryptorchidism and hypospadias in male offspring, earlier onset of puberty in girls, and low semen quality, increased incidence of testicular cancer and reduced levels of the male sex hormone in men.

A number of methods have been developed to predict what happens when a laboratory animal is exposed to several substances simultaneously. One of these is dose-addition. The principle of dose-addition can be used, if it is well known for a group of substances that they have identical mechanisms of action, e.g. interact with the same receptor, or have the same mode of action, e.g. affect the same organ system. Dose-addition is based on the fact that as increasing doses of a single substance can cause increasing effect, the co-presence of several substances (acting in the same way) can give an effect similar to an increased dose of a single substance. The same model can be used for risk assessment of chemical substances' significance to human health.

In this context, the mode of action should be broadly understood as a series of cellular or biochemical events, which may be different for different substances, but cause the same type of effects in an animal or a human. This is contrary to the concept of the mechanism of action, which covers a specific molecular event (e.g. activation of a receptor), causing a specific effect.

In January 2009, the Environmental Protection Agency held an international expert workshop on the possibilities to legislate in order to handle the problems of combination effects. Here, the total existing knowledge on the combination effects of chemical substances, incl. active ingredients, in pesticides were assessed with particular focus on endocrine disruptors.

The conclusions of the workshop were, among others, that the use of dose-addition was recommended generally until any other better alternatives might emerge, and that the grouping criteria should focus on the same type of effects and/or modes of action and the likelihood of combination exposure (Kortenkamp et al., 2009). A number of research projects contributing to better knowledge of combination effects are described below:

• in a larger EU-funded international research project, comprehensive experimental rat studies were conducted with exposure to several antiandrogens simultaneously. The results showed that there were clear combination effects at doses of the individual antiandrogens around or below NOAEL (Hass et al., 2007; Metzdorff et al., 2007; Christiansen et al., 2008; Christiansen et al., 2009). The effects included severe malformations of the male offspring genitals and could generally be predicted from the effects of the single substances using dose-addition. The examined combinations of antiandrogens included mixtures of substances

- studies *in vitro* and short-term studies in animals have found combination effects of endocrine disruptors with estrogenic effect (Rajapakse et al., 2002; Silva et al., 2002; Tinwell et al., 2004).
- in a project under the Danish Pesticide Research program, combination effects of 5 used endocrine disrupting pesticides with different mechanism of action have been examined, incl. antiandrogenic effect and effect on progesterone. The research results generally show that combinations of endocrine disruptors with the same type of effects have more serious effects than the individual substances alone (Hass *et al.*, in preparation, Jacobsen *et al.*, in preparation). Specifically, severe combination effects on the pregnant female rats' ability to give birth and effects on the development of the genitals of male offspring, incl. malformations, were found (Jacobsen et al., 2010).
- studies in the U.S. of combinations of chemical substances affecting thyroid hormones have shown combination effects that could be predicted by using dose-addition (Crofton et al., 2005).

Overall there is good scientific evidence and consensus among experts that endocrine disruptors with the same types of effects, including antiandrogenic, estrogenic and thyroid disrupting effects, may cause combination effects predictable by dose-addition. At this time, there is no knowledge of any combination effects of exposure to e.g. antiandrogens and estrogens at the same time. There is reason to believe that there may be a combination effect of simultaneous exposure to antiandrogens and estrogens, because the change in the hormonal balance caused by both antiandrogens and estrogens may cause harmful reproductive effects on the same organ systems.

Dose-addition is mentioned above as a calculation model, which is shown to be able to predict the effects of several substances co-administered in animal studies. The dose-addition model is also used for risk assessment of chemical substances in human health. Data from animal studies with the individual chemical substances is used to determine safe doses for humans. When these doses are compared with the doses, to which humans are actually exposed, it can be assessed whether there are grounds for concern about exposure to the individual chemical. For several chemical substances with the same mechanism of action, an overall assessment of whether there is cause for concern for the total exposure for this group of chemicals can be made by dose-addition. These calculations of the overall risk will be undertaken in this project.

1.2 The aim of the project

The project focuses on pregnant women's exposure to substances suspected of having endocrine disrupting effects (antiandrogenic, estrogenic and/or thyroid disruptors).

The overall strategic objective of this project is that:

existing and new knowledge about endocrine disruptors and combination effects should be collected and processed so that they can form the basis for the preparation of information for pregnant women in Denmark and women in Denmark who wish to become pregnant. This overall objective is pursued by

1. Generating knowledge about:

- which suspected endocrine disruptors the target group comes into contact with
- which amounts of suspected endocrine disruptors the target group is exposed to

and to:

- generate knowledge about the combined effects of exposure to several suspected endocrine disruptors simultaneously
- assess whether the detected substances and quantities of these substances are potentially harmful to the women and their fetuses
- 2. Prepare an information campaign with active advice, including for example whether
 - there are products/product groups you should try to avoid, and why
 - there are products/product groups to which you should pay special attention regarding the use, and why
 - how you as a consumer relate to a possible identified risk,
 - there are specific substance groups you should be aware of
 - there are good stories of unproblematic products and product groups

Based on the academic report, the information campaign will be launched with the overall goal to prepare and spread simple, clear and guiding information.

2 Selection of substances and product groups for analysis

There is a total of about 143,000 different chemical substances (the number of substances pre-registered with ECHA in connection with REACH). For many of these chemical substances, knowledge of their effects is lacking today, but the EU has drawn up a list of 432 substances, which are suspected of being endocrine disruptors. These substances must be further investigated for their endocrine disrupting effects, as they are suspected of having endocrine disrupting effects based on studies in test tubes or in animals.

In this project it is not possible to embrace all substances that are endocrine disruptors, or suspected endocrine disruptors. Therefore, a number of substances from the EU list of suspected endocrine disruptors and substances, which are used to an extent that may give rise to significant exposure of women in the target group, have been chosen in this project.

This section presents the criteria underlying the selection of the relevant substances and the product groups that have been analysed in detail in this project. At first, the relevant substances chosen to focus on in this project are presented, and finally the product groups that have been selected for further study are presented. Lastly, this chapter presents a comprehensive list of the relevant substances, and an overview of the expected occurrence of these substances (food, indoor environment, occupational health and consumer products). It should be emphasized that the selection of both substances and product groups are closely related and that the existing knowledge from the Environmental Protection Agency on 100 survey projects has played a major role in the selection of both substances and product groups.

2.1 Selection of substances

In order to select appropriate substances, suspected of being endocrine disruptors in humans, it is essential to have clear criteria for when a substance is an endocrine disruptor or suspected of being an endocrine disruptor. Work is underway in the EU on common criteria for definition of endocrine disruptors, and as input to this, the National Food Institute and the Danish Center for Endocrine Disruptors (CEHOS) have prepared a report to the Environmental Protection Agency on criteria for endocrine disruptors (Danish EPA 2011). These criteria are operating with 3 groups, which can be described as follows:

- group 1, Endocrine disruptor: the substance has caused serious effects in animal studies or in humans, where an endocrine mechanism is very plausible. The group also covers substances, which in animal studies or in humans have an endocrine mode of action, which clearly can be related to serious effects.
- group 2a, Suspected endocrine disruptor: there are data similar to group 1, but it is assessed to be inadequate for this group. This group covers substances which 1) in animal studies pose serious effects suspected to be caused by hormonal disturbances, and/or 2) in animal studies cause

• group 2b, Indication of endocrine disrupting effect: a substance is placed in this group if there is *in vitro* or *in silico* data (QSAR) indicating potential for endocrine disrupting effects.

The selection of substances, which are the focus in this project, has been made on the basis of the following conditions:

- substances from groups 1 and 2a are selected
- substances, where the endocrine disrupting effect is related to an antiandrogenic, estrogenic or thyroid disrupting mode of action, are selected
- substances, for which there is sufficient knowledge in animal studies to calculate the doses of the substance, which may be assumed to be safe for humans (with regard to the specific endocrine effect), are selected
- substances expected to be present in products commonly used by pregnant women or women who wish to become pregnant.
- substances expected to contribute with a significant exposure are selected
- finally, it was considered that the selected substances should cover several different product groups and several different materials within the selected exposure situations/activities

The focus is thus on substances with antiandrogenic, estrogenic and thyroid disrupting mode of action. It should be noted that some substances have multiple modes of action, and that it is not always possible to categorise, for example, whether changes in the reproductive system are due to an antiandrogenic or estrogenic mode of action. Detailed information on the mode of action of the selected substances can be found in Section 6, risk assessment.

The suspected endocrine disruptors selected in this project are:

Substance name (CAS no.)	Antiandro	Estrogenic	Thyroid
	-genic		disrupting
Phthalates			
DEHP (di-ethyl-hexyl-phthalate) (117-81-7)	Х		Х
DiNP (di-iso-nonyl-phthalate) (28553-12-0)	Х		
DBP (di-butyl-phthalate) (84-74-2)	Х		
DiBP (di-iso-butyl-phthalate) (84-69-5)	Х		
BBP (butyl-benzyl-phthalate) (85-68-7)	Х		
DPP (dipentyl phthalate) (131-18-0)	Х		
DnHP (di-n-hexyl phthalate) (84-75-3)	Х		Х
DnOP (Di-n-octyl phthalate) (117-84-0)	Х		Х
Other environmentally hazardous chemical sub	ostances		•
Dioxins and dioxin-like PCBs	Х		Х
Bisphenol A (80-05-7)		Х	
Nonylphenol (25154-52-3)		Х	
TBBPA (Tetrabromobisphenol A) (79-94-7)		Х	Х
Perfluorooctanoate (PFOA) (335-67-1)	Х		Х
Perfluorooctane sulfonate (PFOS) (1763-23-1)	Х		Х
Octamethylcyclotetrasiloxane (D4) (556-67-2)		Х	
Substances in cosmetic products		<u> </u>	
Propylparaben (94-13-3)		Х	
Butylparaben (94-26-8)		Х	
Isobutylparaben (4247-02-3)		Х	
Octyl methoxycinnamate, 2-ethylhexyl-4-		Х	Х
methoxycinnamate (OMC) (5466-77-3)			
3-Benzylidene camphor (3-BC) (15087-24-8)		Х	
4-Methylbenzylidene camphor (4-MBC)		Х	
(36861-47-9)			
Benzophenone 3 (BC-3) (131-57-7)		Х	
Triclosan (3380-34-5)		Х	Х
Resorcinol (108-46-3)			Х
Pesticides			
Chlorpyrifos (2921-88-2)	Х		Х
Dithiocarbamates:	Х		Х
- Mancozeb (8018-01-7)			
- Maneb (12427-38-2)			
- Propineb (12071-83-9)			
Imazalil (35554-44-0)	Х		
Iprodion (36734-19-7)	Х		
Pirimiphos-methyl (29232-93-7)	Х		
Procymidon(32809-16-8)	Х		
Propamocarb (24579-73-5)		Х	
Tebuconazole (107534-96-3)	Х		
Thiabendazole (148-79-8)	Х		Х

Table 2-1 Suspected endocrine disruptors selected in this project

The selection of the 35 substances reflects the knowledge we have in this area today. There are many other substances suspected to be endocrine disruptors. There are for instance nearly 200 substances in category 1 on the EU list of potential endocrine disruptors, but many are not included in this project. This may be due to the fact that exposure to these substances of pregnant women is expected to be very small or not occuring, that data available for risk assessment are inadequate, or that the substance belongs to a group of substances, represented by some of the selected substances. Additionally, only a small proportion of the approximately 50,000 chemical substances that surround us in everyday life are tested for endocrine disrupting effects. It is therefore conceivable that several other substances, to

which pregnant women are exposed in daily life, may contribute to the risk of endocrine disrupting effects. In this project, it has not been possible to make calculations for all the substances expected to be relevant for pregnant women. Among others, the number of parabens is limited to some of those, for which there is the strongest evidence for their endocrine disrupting effects, while other parabens (methyl, ethyl, isopropyl, benzylbutyl and other parabens) may also have endocrine disrupting effects, but with less clear data basis for risk assessment. Among the pesticides, only pesticides, which in recent years have been on the Food Administration lists of those pesticides, which give rise to the highest intake in humans, are selected. Among phthalates, flame retardants, UV-filters and siloxanes are several other substances that may be suspected of having endocrine disrupting effects, but they are not included in this project. This is partly due to lack of data avaible for risk assessment, and to the fact that the selected substances belong to a group of substances, which some of the selected substances have been chosen to represent.

2.2 Materials in which the selected substances are expected to occur

Table 2-2 gives an overview of the selected suspected endocrine disruptors, and information on where the substances are expected to occur, i.e. the types of consumer products or materials. In relation to the selection of consumer products for this survey, it is relevant to go in depth with an examination of, which of the selected substances is likely to be found in which materials.

The following table indicates the types of materials, in which these substance groups are expected to be present. The table is resulting partly from the project team experience, partly from searches on the Internet.

Selected substances	Udvalgte stoffer	Substance group	Material in which the substances can be found
DEHP DiNP DBP DiBP BBP DPP DnHP DnOP	DEHP DiNP DBP DiBP BBP DPP DnHP DnOP	Phthalates	Phthalates are present in softened plastic material, mainly of PVC, but are also found in rubber. Phthalates may also occur in plastic prints on clothes, inks, books, magazines, glue, and in various synthetic leather materials. Phthalates can be found in the following types of materials: Vinyl film, PVC, PES (polyethersulfone), TPE (common name for thermoplastic elastomers) and other soft plastics.
Bisphenol A	Bisphenol A		Bisphenol A is an ingredient in polycarbonate plastic, and can be found e.g. in cash receipts of thermal paper, cell phone covers and pacifiers.
Nonylphenol	Nonylphenol		Nonylphenol may be present in textiles and in plastic. Nonylphenol ethoxylates are surfactants (cleaning substances) that may be part of the detergents used when textiles are produced. Nonylphenol ethoxylates are degraded to nonylphenol.
TBBPA	ТВВРА		TBBPA is a flame retardant. Flame retardants are used in electronic products and in some furnishing textiles.

Table 2-2 Indication of types of materials, in which the selected substances are likely to be found

PFOS PFOA	PFOS PFOA	Fluorinated substances	Fluorinated substances are used as preservatives in various products such as textiles (especially outdoor clothing, footwear, carpets, etc.), greaseproof paper (for food) and impregnating agents. PFOS and PFOA can be found as impurities in the fluorinated impregnating agents, and some fluorinated substances degrade to PFOA in the environment.
D4	D4	Siloxanes	Siloxanes are used for softening, smoothing, and wetting. Siloxanes may therefore occur in many different cosmetic products (including creams). In cosmetic products cyclomethicone is used, which is a mixture of low molecular weight cyclic siloxanes. Primarily these are octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in various concentrations. If cyclomethicone is used in cosmetics, it is not certain that D4 has been added. Siloxanes can also occur in textiles, paints, antiperspirants, lubricants, plastics, silicone materials, pharmaceutical products etc. Siloxanes may occur in materials such as PU, TPU (polyurethane), silicon and plastics generally.
Propylparaben Butylparaben Isobutylparaben	Propylparaben Butylparaben Isobutylparaben	Parabens	Parabens are preservatives, which may occur in aqueous products to secure a certain shelf life, preferably for cosmetic products.
OMC 4-MBC 3-BC BC-3	OMC 4-MBC 3-BC BC-3	UV-filters	UV-filters can be found in products designed to protect against the sun's rays. That is mostly in sunscreens and facial creams.
Triclosan	Triclosan		Antibacterial agents such as triclosan, are used in various products, to inhibit bacterial growth. Antibacterial agents may occur in different types of products such as cosmetics (toothpaste, deodorants), and textiles.
Resorcinol	Resorcinol		Resorcinol is found in hair dye products and can be emitted from coloured hair. Resorcinol is also found in some eye drops and creams against acne, etc.

2.3 Criteria for selection of products for further examination

Selection of products for mapping and analysis is based on the following considerations to ensure relevance, timeliness and familiarity in the information campaign:

- products which the target group is expected to come into contact with during their daily life
- products where the contact is significant in either duration or frequency of contact (i.e. at least weekly exposure of the target group via consumption, application to the skin, inhalation or contact)
- products are expected to contain some of the selected suspected endocrine disruptors (i.e. from Groups 1 or 2a)
- product group has not been specifically studied in the past (or data assessed to be obsolete)

In the section below it is outlined which of the selected substances that are expected to occur in the selected products.

2.4 Selection of product groups

Based on the above criteria/points to consider, 8 product groups for mapping and further analyses have been selected in cooperation with the Danish EPA. These are:

- cell phone covers
- sleeping mats
- work gloves/household gloves
- sneakers
- antibacterial treated clothes
- handbags made of synthetic leather
- pregnant belly creams/pregnancy oils/moisturisers
- sunscreens

Table 2-3 provides an overview of the suspected endocrine disruptors, which have been chosen in this project. The list further indicates the kind of knowledge of exposure expected for each substance, and where to find data for use in the risk assessment. The list has been prepared in consultation with the Danish EPA and with input from the Working Environment Authority, the Food & Drug Administration and the Health Administration.

The table shows the endocrine mode(s) of action listed for each substance, together with relevant sources of exposure and knowledge about exposure from previous surveys by the Danish EPA.

For some of the newer existing surveys, only quantitative analyses have been made, and no migration analyses. Therefore, the results cannot be used in the calculations in risk assessment. In the list, it is noted if migration analyses are lacking for a given product group. The new product groups to be mapped and analysed in this project are marked in bold in Table 2-3 to indicate that in this project there is analysed for the indicated substances. The analytical results stated later in this report (Section 5) show whether these substances have actually been identified in the products.

As shown in Table 2-3, relevant substances have been identified in a wide range of consumer products in previous studies. Many of the products are aimed at children, with whom the target group may only have very limited contact unless they already have children or work in e.g. a daycare centre. Some children's products (bath soap packaging, rucksacks) are included in the final exposure calculations, but only those products that have also been assessed to be relevant for the target group. The product groups, expected to be included in the exposure assessment, are marked in grey in the table.

Table 2-3 List of suspected endocrine disruptors, which are part of this project, expected sources of the selected substances, and a list of existing/new knowledge used in the risk assessment. The consumer products involved in exposure and risk assessment are marked in grey

Substance	CAS-no.					Previously mapped products New product groups, mapped in this
		Consumer products	Food	Indoor environme nt	Work environm.	project, are marked in bold
Phthalates DEHP (di-ethyl-hexyl- phthalate)	117-81-7	x	x	x	X	Sex toys (vibrator and gag) Eraser Pencil case for children Toy bag for children (rucksack) Lamination materials Lunchbox Mitten for children (in label on mitten) Bath soap packaging Bathmat Indoor air in cars Oilcloth Pilates ball Plastic sandals Role play materials – no migration analysis Pants – no migration analysis Pool for children - no migration analysis Shower curtains – no migration analysis Swim gear (children) – no migration analysis Bags (children) – no migration analysis Air mattress – no migration analysis Game console – no migration analysis Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers
DiNP (di-iso-nonyl- phthalate)	28553-12-0	x	x	x		Emission from modeling wax Toy (Bratz doll) Game console – no migration analysis Prints on T-shirts – no migration analysis Eraser – no migration analysis Christmas decoration (keychain) – no migration analysis Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers

Substance	CAS-no.		ecte	d sourc	ces	Previously mapped products New product groups, mapped in this
		Consumer products	Food	Indoor environme nt	Work environm.	project, are marked in bold
DBP (di-butyl-phthalate)	84-74-2	x	x	x		Emission from modeling wax Surface-treated wooden toys Plastic sandals Indoor air in cars Prints on T-shirts – no migration analysis Shower curtains - no migration analysis Lamp – no migration analysis Plastinc sandals – no migration analysis Flooring – no migration analysis Bar stool – no migration analysis Dining chair – no migration analysis Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers
DiBP (di-iso-butyl-phthalate)	84-69-5	x	x	x		Surface-treated wooden toys Toy bag (children) Eraser Pencil case (children) School bag (children) Jacket (children) – outer fabric Plastic sandals Flooring – no migration analysis Shower curtains – no migration analysis Lamp – no migration analysis Bar stool – no migration analysis Oilcloth – no migration analysis Pilates ball – no migration analysis Dining chair – no migration analysis Swim gear (children) – no migration analysis Bags (children) – no migration analysis Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers
BBP (butyl-benzyl-phthalate)	85-68-7	x	x	x		Emission from modeling wax Toothbrushes Surface-treated wooden toys Indoor air in cars Plastic sandals Flooring - no migration analysis Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers
DPP (dipentyl phthalate)	131-18-0	x	-	х		Emission from modeling wax Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers

Substance	CAS-no.	Expected sources of exposure			ces	Previously mapped products New product groups, mapped in this
		Consumer products	Food	Indoor environme nt	Work environm.	project, are marked in bold
DnHP (di-n-hexyl phthalate)	84-75-3		-	х		Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers
DnOP (Di-n-octyl phthalate)	117-84-0	x	-	х		Emission from modeling wax Sex toys (vibrator) Plastic sandals Sex toys (dildo) – no migration analysis Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather Sneakers
Other xenobiotic chemical su	bstances	1				L eu
Dioxins and dioxin-like PCBs Bisphenol A	80-05-7	x	x	x	x	Fillers Sex toys (vibrator) Feeding bottles for children Pacifiers Cash receipts Cell phone covers Work gloves/household gloves Sleeping mats Handbags made of synthetic leather
Nonylphenol	25154-52-3	x			x	SneakersEmission fra modellervoksTowels – no migration analysisFiller – no migration analysisRecreational clothes (print) – nomigration analysisClothesAntibacterial clothesSneakers
TBBPA (Tetrabromobisphenol A)	79-94-7	х		х		Computer – no migration analysis
Perfluorooctanoate (PFOA)	335-67-1	x	х	х		Impregnation products (from 2004) Raincoats for children – no migration analysis
Perfluorooctane sulfonate (PFOS)	1763-23-1		х	х		Raincoats for children – no migration analysis
Octamethylcyclotetrasiloxa ne (D4)	556-67-2	x			х	Sunscreen/body lotion Pregnant belly creams/pregnancy oils Antibacterial clothes Sneakers
Substances in cosmetics	04.40.0					
Propylparaben	94-13-3	x		x	x	Animal care products Hand soap Children's make-up kit Sunscreen Body lotion
Butylparaben	94-26-8	x		х	x	Theatre and carnival make-up Hand soap Children's make-up kit Sunscreen for children Body lotion for children Sex cream

Substance	CAS-no.		ecte xpos	d sourc sure	ces	Previously mapped products New product groups, mapped in this
		Consumer products	Food	Indoor environme nt	Work environm.	project, are marked in bold
lsobutylparaben	4247-02-3	х			x	Theatre and carnival make-up Hand soap Sunscreen for children Body lotion for children
OMC, octyl methoxycinnamate, 2- ethylhexyl-4- methoxycinnamate	5466-77-3	x				Foundation Facial cream Sunscreen
4-MBC, 4- methylbenzylidene camphor	36861-47-9	x				Sunscreen
3-BC, 3-benzylidene camphor	15087-24-8	х				Sunscreen
BC-3, Benzophenone 3	131-57-7	х				Facial cream Sunscreen
Triclosan	3380-34-5	x				Toothpaste Deodorants Ski socks – no migration analysis Underpants – no migration analysis Bike pants – no migration analysis Sandals – no migration analysis Hand soap – no migration analysis Work gloves – no migration analysis Antibacterial clothes
Resorcinol	108-46-3	Х			Х	Hair dyes – no content analysis
Pesticides		r —		1		
Dithiocarbamates: - Mancozeb - Maneb - Propineb	8018-01-7 12427-38-2 12071-83-9		х			
Chlorpyrifos Imazalil Iprodion Pirimiphos-methyl Procymidon Propamocarb Thiabendazole	2921-88-2 35554-44- 36734-19-7 29232-93-7 32809-16-8 24579-73-5 148-79-8		x			
Tebuconazole	107534-96- 3		х		х	

¹AA: antiandrogenic effect, ²Ø: estrogen like effect, ³T: interferes with the thyroid hormone system

3 Survey

Based on the information collected on previously studied substances and products, 8 product groups were selected for survey.

The aim of this survey was to

- supplement the existing knowledge from i.a. the Environmental Protection Agency's previous surveys on products, used in the daily lives of pregnant women or women who wish to become pregnant
- identify the products within each product group, which are mostly used by pregnant women or women who wish to become pregnant
- examine which materials each product group consists of
- attempt to obtain information about the materials including components to the extent information is available
- select products for chemical analyses

The survey included the following activities:

- contact to trade associations and retailers trade associations and retailers were contacted for information on i.e. brands/trade names, brands/trade names with the largest sales, and materials/components
- contact to retailers
- internet search a number of retailers on the web have been contacted to obtain information about products within each product group with large sales

A complete survey of all products within each product group was not made, but an effort was made to include the products/brands with the highest sales. This attempt was made, partly through

- contact to trade associations to get information about the shops with the highest sales within each product group, and
- contact to the staff in each shop (retail and internet shops) to get information about products/models with the highest sales

3.1 Cell phone covers

3.1.1 Definition of the product group

In this project, cell phone covers mean all kinds of protection for a cell phone. That is, various covers/holsters, and "skins" (a film to protect the front and back of the phone) and "screen protectors" (a film to protect the screen). All cell phone covers are designed to protect the cell phone from bumps and scratches. However, it is clear that not all cell phone covers are interesting in relation to examining the contents of the selected substances. For example, cell phone covers of leather are irrelevant in this context.

Cell phone covers examined in this project therefore cover all types of soft phone covers for all types of cell phones, and cell phone covers of polycarbonate. The survey focused exclusively on soft cell phone covers and cell phone covers of polycarbonate, as it was expected that soft phone covers might contain phthalates and cell phone covers of polycarbonate might contain Bisphenol A.

There is a kind of "bag" for e.g. attaching to a belt or the like for keeping a cell phone. Furthermore, there is a kind of bag or purse, which the cell phone can be placed in to protect it when not in use. These are not included in this survey. This survey has focused on the cell phone covers, remaining on the cell phone to protect it - even when in use - because of the expected prolonged contact time.

The product group is also further defined by not identifying cell phone covers made entirely of metal or leather, as these are not interesting in this project, because they are not expected to contain the selected substances. These types of cell phone covers are therefore not described in detail in this survey.

3.1.2 How is knowledge obtained

A search for cell phone covers on the Danish market has been made using the following tools:

- Internet search (webshops)
- contact to the branch (The branch ConsumerElectronics)
- investigation of the range in retail (shops as Expert, Telenor, Føtex, Kvickly, Telia, Fona, Bog&Ide)

Cell phone covers belong only peripherally to the branch ConsumerElectronics, so they could not provide much relevant information.

3.1.3 Categories

The survey has shown that typically the following categories of cell phone covers are found on the market - see Table 3-1.

Category	Description	Typical material
Back cover	Typically consists of hard material. A back cover for the cell phone. Perhaps with a hole for the camera.	Metal (aluminium) or hard plastic
Back and frame cover	A cover covering the frame and back of the cell phone. Perhaps with a hole for the camera. The front (screen) may be protected by enclosed protective film (screen cover) - i.e. here are two products in one package.	Metal (aluminium), leather, soft plastic (TPU), acryl, silicone or polycarbonate plastic
Frame cover	A frame to place on the frame of the cell phone. Covers only the frame, not the front or back. Is typically seen for iPhones.	Plastic/silicone or just silicone
Skin	A protective film that is "pasted" on the back and front (not on the screen). On the front the film is put around the screen. Skins protect against scratches, but are mostly used for the sake of the design (pattern and color). It is not the same as a cover.	Plastic film (foil with glue), vinyl or leather
Screen cover	A transparent protective film covering the screen to protect from scratches - also for smartphones.	Plastic film (foil with glue)

Source: http://www.mytrendyphone.dk/shop, and various manufacturer websites.

Regardless of what the various cell phone covers are called, they have the same function - to constantly cover the cell phone - also when used - and protect the phone against scratches and shock.

3.1.4 What brands/products are found on the market?

A wide range of cell phone covers are on the Danish market for virtually all brands and models of cell phones. There are more than 40 different brands of cell phones. Within each cell phone brand there are many different models of cell phones - and for each of these different models there may be cell phone covers. Several manufacturers can produce cell phone covers for each cell phone model. Furthermore, cell phone covers are often made in many different colours, patterns and designs.

The survey identified more than 35 different manufacturers of cell phone covers. There are both manufacturers producing covers for specific cell phone models or covers that are compatible with several cell phones, and original producers, i.e. the cell phone companies, that produce (or have produced) their own cell phone covers for their own cell phone models. Some brands manufacturers only produce covers for e.g. the iPhone.

In the following, cell phone covers of the individual brands/manufacturers have been further examined for information regarding the material, etc. The overview is exclusively focused on the cell phone covers and screen protectors, made of soft materials or polycarbonate. The stated information is exclusively from the manufacturers/brands, where it has been possible to obtain information, e.g. via their websites.

The different types of cell phone covers from each manufacturer/brand are primarily identified via the manufacturer's own website. That is, there may be

specific types of cell phone covers not on the Danish market. However, all the listed manufacturers were identified on the Danish market either through Danish webshops or by seeing the products in the Danish retail trade. The focus has been to describe the materials used by the manufacturers for making covers.

Manufacturer/brand	Description	Material
Griffin	Covers for different cell phone brands	Polycarbonate Polycarbonate/synthetic leather
		Polycarbonate/polyurethane Vinyl textile Soft TPU
		Polycarbonate/TPU Silicone/ synthetic rubber
		Vinyl Silicone/ polycarbonate Silicone
	Screen protectors for smartphones	Unknown
Puro	Covers for different cell phone brands	Silicone Material not available TPU
	Screen protectors	Unknown (soft material)
Collection	Covers for different cell phone brands	Silicone TPU
	Screen protectors	Unknown (soft material)
Gear 4	Covers for different cell phone brands	Unknown (soft material)
Xqisit	Covers	Silikone Unknown (soft material, metal or hard plastic) TPU
	Screen protectors	Unknown (soft material)
Belkin	Exclusively covers for iPhone	TPU Silicone Unknown (silicone) Polycarbonate Mixed materials. Which ones?
	"Screen Guard Anti-Glare Overlay" til skærmen	Unknown (soft material)
cm (case-mate)	Covers for different cell phone brands	Plastic (flexible) Silicone Silicone and polycarbonate Flexible thermo plastic material Plastic and rubber
Contor	Screen protectors	Self adhesive polymer
Copter Zagg	Screen protectors Skins – designs their own skin (film for the front and back of the cell phone)	Urethane film Unknown
	Covers	Polycarbonate and silicone Polycarbonate Silicone Polycarbonate and synthetic leather Polyurethane
	Screen protectors (Invisible Shield)	Unknown
Scandinavian Unit	Covers	TPU PVC and rubber

Table 3-2 Overview of different cell phone covers from various manufacturers, and information about cover materials

Manufacturer/brand	Description	Material		
Ozaki	Exclusively covers for iPhone	Silicone		
		Unknown (anti-slip material)		
Skinmania	At skinmania.com you can upload your own image and in this way make your own skin (film) for the front and back of your cell phone.	Vinyl		
Ed Hardy	Exclusively covers (skins) for iPhone. Specially designed (drawn) covers that are "pasted" on the back and front (around the screen).	Soft anti-slip surface of unknown material		
Incipio	Primarily covers for iPhone (and BlackBerry).	Silicone Polycarbonate Semi-rigid polymer TPU Polycarbonate/silicone Silicone/acryl		
Krusell	Covers	Polycarbonate/leather Unknown silicone material		
Otterbox	Covers	Silicone/polycarbonate Polycarbonate with TPE rubber Silicone		
Turtle Brand	Covers for different cell phone brands	Soft TPU TPU/polycarbonate		
	Screen protectors	Unknown (film)		
Body Glove	Various types of covers for different cell phones (iPhone, HTC etc.)	Plastic (polyurethane) possibly with rubber on the side		
Dolce Vita Roma	Covers especially for iPhone	Unknown		
ICU	Covers especially for iPhone	Unknown		
iLuv	Covers especially for iPhone and BlackBerry	Silicone TPU Polycarbonate		
Katinkas	Covers for different cell phone brands	Soft TPU Hard polymer		
Konkis	Covers especially for iPhone	Unknown		
NazTech	Covers especially for iPhone	ABS plastic Silicone/polycarbonate		
Deltaco	Exclusively screen protectors for iPhone	Unknown		
Adapt	Screen protectors	Unknown		
Wrapsol	Exclusively screen protectors for various phones	Polyurethane		

Sources:

Griffin: Puro: Collection: Gear 4:	http://store.griffintechnology.com/iphone www.puroitalianstyle.it/en/home.jsp www.teled.net www.gear4.com
Xqisit:	www.xqisit.com
Belkin:	http://www.belkin.com/IWCatSectionView.process?Section_Id=208807
Cm:	www.case-mate.com
Golla:	www.golla.com/#/en/products
Copter:	http://www.copter.cc/
Zagg:	www.zagg.com
Unit:	http://www.pc-electro.com/ (Scandinavian Unit)
Ozaki:	http://ozaki.weebly.com/iphone-4-cases.html
Incipio:	www.myincipio.com
Krusell:	http://www.krusellcases.com/uk/p_krusell_listing.aspx?f=1562
Otterbox:	www.otterbox.com
Turtle Brand:	www.turtlebrand.com
Body Glove:	www.bodyglovemobile.com
iLuv:	www.i-luv.com

Katinkas:www.katinkas.de/enNazTech:www.naztech.comDeltaco:http://www.deltaco.dk/menu/354/355/products/categories.aspxWrapsol:www.wrapsol.com

It is thus seen that the cell phone covers are typically made of the following materials:

- silicone
- polycarbonate
- polyurethane (TPU) is typically soft/flexible
- vinyl/PVC
- ABS plastic (only one manufacturer indicates this as a starting material for some covers)

For some covers, it was not possible to obtain information about the material. Of the above materials, it is quite clear that silicone, polycarbonate, and TPU are the typical materials used. Vinyl is only seen at a few producers and only for a few models of cell phone covers. ABS plastic is only seen at one manufacturer and only for a few cell phone covers. Furthermore, there are, of course, the cell phone covers made of leather or metal, which are not surveyed in detail here.

Furthermore, there are many cell phone covers made of a combination of different materials. The combinations seen in the survey are:

- combination of polycarbonate and TPU
- combination of silicone and polycarbonate
- combination of silicone and synthetic rubber
- combination of silicone and acryl
- combination of polycarbonate and TPE rubber

3.1.5 Price

Through a search in various web shops, it has been found that the various cell phone covers are typically within the following price ranges:

- cell phone covers: 20 338 DKK (and the vast majority between 89 and 199 DKK)
- skins: 18 159 DKK
- screen protectors: 8 261 DKK

Information on prices is used in connection with selection of products for analysis, as there is a wish for analysis of both cheap and expensive products.

3.1.6 Where is it sold?

A lot of different shops sell cell phone covers. Of physical shops, cell phone covers are available in major supermarkets (e.g. Bilka, Føtex), in bookshops, Teleshops (e.g. Telia, Telenor, TDC), and electronics shops like Fona, Expert etc.

Furthermore, cell phone covers are available in a number of web shops, such as:

- <u>www.mytrendyphone.dk</u>
- <u>www.cdon.com</u>
- <u>www.callme-mobiltilbehoer.dk</u>
- <u>www.lux-case.dk</u>
- www.e-tasker.dk

- <u>www.elpefa.dk</u>
- <u>www.ioffer.com</u>
- <u>www.my-phoneshop.dk</u>
- <u>www.goblue.dk</u>
- <u>www.proshop.dk</u>
- <u>www.imania.dk</u>
- <u>www.happii.dk</u>
- <u>www.nemoware.dk</u>
- <u>www.modify.dk</u>
- <u>www.cdon.com</u>
- <u>www.stratek.dk</u>
- <u>www.shopitonline.dk</u>

3.1.7 Market shares

It has been difficult to find market share information when it comes to cell phone covers. There is a wide range of shops and online shops selling the same kinds of cell phone covers. There are cell phone covers for virtually every model within every cell phone brand, i.e. vast numbers of cell phone covers.

When visiting shops selling cell phone covers, we asked whether some covers are more popular than others, but there was no clear answer anywhere. In addition, a single shop was asked which brands of cell phone covers are sold the most, but it did not result in any useful information. Instead we focused on the most popular brands of cell phones, in order to able in this way to select cell phone covers for analyses.

Comparing information on the 10 most popular cell phones in 2010 (Mobilsiden.dk 2011) with information on the currently most popular cell phones (28 September 2011) (telepristjek.dk 2011), leads to the following overview of the most popular cell phones in 2010/2011:

- Apple iPhone 4 (32 GB)
- Apple iPhone 4 (16 GB)
- Apple iPhone 3GS (8 GB)
- HTC Wildfire
- HTC Desire
- HTC Desire S
- HTC Desire HD
- HTC Legend
- HTC Sensation
- HTC Wildfire S
- Nokia N8
- Nokia C5-03
- Nokia C2-01
- Nokia 6700 classic
- Samsung Galaxy S 2
- Sony Ericsson XPERIA X10 mini
- Sony Ericsson XPERIA X10 mini pro
- Sony Ericsson LT15i Xperia Arc

Please note that the above list is in alphabetical order.

It would therefore be relevant to concentrate the purchase of cell phone covers on these most popular cell phones for 2010/2011, also covering a range of smart phones, which must be considered popular among the target group of this project.

3.1.8 How much is sold?

To understand the significance of the survey of this product group, the quantities of cell phone covers sold on the Danish market have been examined.

It is not possible via Statistics Denmark (Statistics Bank) to see the number of cell phone covers sold each year. The statistics are not detailed enough for this product group. There are specific product groups for plastics and rubber products, but cell phone covers cannot be found as a specific group.

It is possible, however, via the Statistics bank to find out how many cell phones are sold annually through the KN code:

85171200 Telephones for cellular networks "mobile telephones" or for other wireless networks.

The sales are indicated by Statistics Denmark via "Foreign Trade", which indicates exports and imports, and "Industry sales of own goods", i.e. production in Denmark. Foreign trade is, beyond the indication in kilos and DKK, also indicated in numbers. However, industry sales of own products are not indicated. Industry sales of own products constitute only approx. one thousandth of foreign trade, and is thus irrelevant. Therefore, industry sales of own products are not included in Table 3-3.

Table 3-3 Foreign trade with cell phones – numbers of sold cell phones in Denmark in 2010

Product code	Import in 2010	Export in 2010	Sold in DK in 2010
85.171.200 Telephones for cellular networks "mobile telephones" or for other wireless networks	3.508.854	628.942	2.879.912

Assuming that many who buy cell phones will also buy some form of cell phone cover for their cell phones, it can be assumed that a relatively large number of cell phone covers are sold in Denmark on an annual basis. Probably up to about 500,000 - 1,000,000 cell phone covers annually, assuming that up to one in three, who buys a cell phone, buys a cover for this cell phone. There is, however, no information on how large a percentage of those, who have a cell phone, also have a cell phone cover. A third is thus pure guesswork.

3.1.9 Selection of products for analyses

20 different cell phone covers have been analysed for contents of phthalates, bisphenol A and D4, as it is assumed that these substances may occur in the materials used for the manufacture of cell phone covers.

The market for cell phone covers is very large. The following criteria were used for selection of cell phone covers for analyses:

- cell phone covers have been selected from different manufacturers of cell phone covers
- cell phone covers have been selected in various categories, primarily back and frame covers, skins and screen protectors. Back covers are often seen in metal, so these are less relevant, and frame covers are typically seen

- cell phone covers of different materials have been selected, i.e. a fairly even distribution has been made among the following materials, which are considered the most important in relation to content of phthalates, bisphenol A, and D4:
 - silicone
 - polycarbonate hard plastic
 - TPU is often soft/flexible
 - vinyl/PVC
 - film of unknown material (possibly urethane film), which screen protectors are made of
- cell phone covers have only been selected for the most popular cell phones, i.e. the listed models from 2010 and 2011. Several of the manufacturers of cell phone covers produce cell phone covers for smartphones or exclusively for the iPhone. Therefore, a majority of covers for smartphones in general have been naturally selected. It is, however, not considered a major problem, as the target group (young women) is considered to belong to the generation where the use of smart phones is most prevalent.
- cell phone covers have been selected from both the cheap and the expensive price range (however, this parameter is not assessed to be the most important one, as all cell phone covers are within roughly the same price range)

3.2 Sleeping mats

3.2.1 Definition of the product group

The product group "sleeping mats" is in this project defined as:

- yoga mats and other exercise mats
- sleeping mats for use in tents, etc.

Sleeping mats in the form of air mattresses are not included, as these were examined in a previous project. Likewise, sleeping mats of textile (i.e. cotton, wool, etc.) have been disregarded.

Primarily, the focus is on sleeping mats of plastic materials. Products such as wooden bead seats in cars and lying pillows, etc. are not included. Sleeping mats covered with aluminum foil (often used in regular sleeping mats for additional insulation) are also disregarded.

3.2.2 How is the knowledge obtained?

Information for this survey has been found through the following sources:

- internet searches
- telephone contact to selected sports and leisure shops

In the following section, all information - except where otherwise indicated - results from internet search.

3.2.3 Categories

The survey has shown that the following categories of yoga/exercise mats and sleeping mats are typically found:

- yoga mats/exercise mats often foam pads
- self-inflatable sleeping mats
- manually inflatable sleeping mats
- children's sleeping mats
- women's sleeping mats
- Oeko-Tex labelled sleeping mats/yoga mats
- extra long sleeping mats
- lightweight sleeping mats
- luxury sleeping mats

However, they can all be divided into two relevant main categories:

Table 3-4 Categories of sleeping mats

Category	Example	Typical material*
Yoga mats/ foam pads		Natural rubber, jute, TPE, jute combined with synthetic material, polyethene**, PVC, PES, (polyethersulfone), EVA
Sleeping mats (both inflatable and non- inflatable)	11	Polyester, nylon, TPU coated, polyethylene, polyethene foam, PU, PVC, polyethylene- terephthalate (PET),

* according to the websites from which the products are sold.

** The product is described as a sleeping mat, but looks like a foam mat.

The noted "typical materials" are examples of product materials; it is not an exhaustive list of all the materials used in the manufacture of sleeping mats and yoga mats.

3.2.4 Brands/products

Manufacturers/brands of yoga mats identified during the survey of yoga/ exercise mats:

- Sun Salutation
- Microcell
- Jade Professional
- JadeYoga (only manufactures PVC free mats)
- Manduka
- Adidas
- Casall

Manufacturers/brands of sleeping mats identified during the survey:

- High Peak
- Outwell
- Pacific Outdoor
- Asivik ("Spejdersport's" own brand)
- Mammut
- Evazote
- Nordpol
- Thermarest
- Robens
- Nordisk
- AB-Camping
- Mountain Eagle
- VAUDE
- Easycamp
- DownMat
- Exped
- Helsport
- HD Camp
- Wanderlust
- Hajk

- Haglöfs
- Mat Minto
- Wolf Camper
- Active Leasure
- Grand Canyon
- Bramming Plast-Industri A/S

The materials used in the manufacture of sleeping mats and yoga mats, revealed by the survey, are listed below:

Yoga mats: Natural rubber, jute, TPE, wool, synthetic material, polyethene, PVC, PES (polyethersulfone), EVA.

Sleeping mats: Polyester, nylon, TPU coated, polyethylene, polyethene foam, PU, PVC, polyethylene-terephthalate (PET).

Of the above identified mat materials, the following materials are relevant in relation to potential content of phthalates, refer to Section 2:

- PVC
- PES
- TPE (common name for thermoplastic elastomers PVC may be one)

3.2.5 Price

A search for "yoga mats", "exercise mats" and "sleeping mats" on pricerunner.dk (site that compares prices from different online shops) showed prices from 118 DKK to 1835 DKK (including freight) - the typical price was around 3-400 DKK.

According to a purchaser from "Spejdersport", the typical price for foam mats is approx. 100 DKK, while the price for inflatable sleeping mats is approx. 500 DKK. A contact at "Fjeld og Fritid" informed that the typical price for foam mats was between 20 and 100 DKK.

Therefore, the average price for a sleeping mat/yoga/exercise mat can be assumed to be approx. 300 DKK.

Information on the prices is used in the selection of products for analyses, as analyses of both cheap and expensive products are required.

3.2.6 Where are they sold?

Sleeping mats and yoga/exercise mats can be purchased from the following types of shops:

- large supermarket chains
 - Kvickly
 - SuperBrugsen
 - Føtex
 - Bilka
 - other large super markets
- sports and leisure shops
 - Stadium
 - Fjeld og Fritid
 - Intersport
 - Sportmaster
 - Spejdersport

- Friluftsland
- Eventyrsport
- Lasse Hjortnæs Ski & Outdoors
- DIY centres etc.
 - Silvan
 - Jysk Sengetøjslager
- internet shops, e.g.:
 - www.yogamudra.dk
 - <u>www.alun.dk</u>
 - <u>www.yogaudstyr.dk</u>
 - <u>www.bodystore.dk</u>
 - www.hvidovresport.dk
 - www.rejsequip.dk/vligunlg.htm
 - <u>www.outnet.dk</u>
 - <u>www.ellos.dk</u>

3.2.7 Market shares

Various distributors of sleeping mats were contacted, and the project team has obtained information on the best selling/most popular types. This information is confidential, but has been used in connection with the selection of products for analyses. The best selling/most popular brands have been selected for analyses.

3.2.8 How much is sold?

To understand the significance of the survey of this product group, the quantities of sleeping mats sold on the Danish market have been examined.

Data from Statistics Denmark in the category resembling sleeping mats the most ("Mattresses of cellular rubber, ie. foam rubber and the like, coated or uncoated") indicates a sale of 46 billion DKK in 2010. This does not seem correct, as it would mean that every Dane purchased sleeping mats for approx. 8500 DKK in 2010. The category most likely contains considerably more products than sleeping mats

Thus, it is not possible to obtain reliable data on the sale of sleeping mats and yoga mats in Denmark. A contact to one of the larger sports and leisure shops in Denmark confirmed this; not even they can obtain valid numbers via Statistics Denmark for sleeping mats/yoga mats sold in Denmark.

3.2.9 Selection of products for analysis

The sleeping mats (incl. the yoga mats) should be analysed for phthalates, as this product group is expected to contain phthalates. The following materials are relevant in relation to potential content of phthalates:

- PVC
- PES
- TPE (common name for thermoplastic elastomers PVC may be one)

The criteria for the selection of sleeping mats/yoga mats for analyses were as follows:

- 4 sleeping mats and 6 yoga mats (as it is expected that pregnant women will use yoga mats rather than sleeping mats, which are most commonly used for camping, and is typically used with a sleeping bag or the like, which means that there is less skin contact with these products)
- where possible, balance between price ranges
- where possible, all relevant materials were covered
- the most famous brands were represented
- some were purchased in shops to represent the "physical market" as well. Here, sleeping mats/yoga mats were purchased that seemed "sticky" on the surface, which is a typical sign of release of phthalates
- products were partly purchased in the most popular yoga/fitness centres, but products were also purchased from supermarkets or other cheap shops (e.g. "Søstrene Grene")

It has not been possible through the survey to identify more than 3 yoga mats, which are described as containing PVC, PES or TPE on the internet. This may partly be because it seems to have become popular to advertise yoga mats as "PVC free" – i.e. other manufacturers (who may sell yoga mats with PVC) choose not to disclose what is in the product.

3.3 Work gloves/household gloves

3.3.1 Definition of the product group

The definition of the survey of work gloves/household gloves has been based on selection of materials and products considered to appeal to women. Below is focused more on the tight-fitting, thinner glove types than on the more traditional and thick, loose-fitting "male work gloves" with leather.

The survey has included the following glove types:

- work gloves
- allround gloves
- gardening gloves
- knitted gloves
- rubber gloves (also for cleaning use)
- disposable gloves

Gloves used in sports, such as riding gloves, kayaking gloves, bicycle gloves, are not covered by the survey.

3.3.2 How is knowledge obtained?

Knowledge of the use of gloves has been obtained partly by searching the Internet and partly by visiting a number of retail stores (DIY centres, supermarkets, garden centres) in Copenhagen/North Zealand. The following websites and shops have been visited for their range of work gloves/household gloves:

- websites:
 - www.Silvan.dk
 - www.Bauhaus.dk
 - www.billigkoste.dk
 - www.saekko-industri.dk
- DIY centres:
 - Silvan
 - Bauhaus
 - Fog byggemarked
 - Harald Nyborg
 - Jem&Fix
 - XL Byg
 - Stark
 - Bygma
- garden centre:
 - Bo Grønt
 - supermarkets:
 - Føtex
 - Super Brugsen
 - Netto
 - Fakta
 - Aldi

On Google search, we used various keywords and combinations of keywords in order to obtain general information on work gloves/household gloves on the market and to identify a number of webshops selling these product groups. A number of specific sites were also searched.

3.3.3 Categories

The survey has clarified that the following glove types are available on the Danish market either through purchase in retail stores (DIY centres, supermarkets, garden centres) or on the Internet:

- work gloves: Work gloves are loose fitting, one size gloves in rough fabric or leather; may be reinforced in exposed wearing surfaces. Typically for outdoor use.
- allround gloves: gloves for work or leisure use. The glove is more tightfitting than the above work glove, and some are quite tight-fitting. The materials vary, but are typically provided with non-slip materials, also of variable character. The gloves can also be marketed as garden gloves, but here they will appear as an allround glove.
- garden gloves: garden gloves are gloves marketed as garden gloves, weed gloves or the like. The glove is typically made of fabric / knitwear with reinforcements either of leather, fabric, or anti-slip materials, such as rubber.
- knitted gloves: knitted gloves are soft, loose-fitting, one size gloves made of knitwear or soft fabric. Often with dots on the underside for a better grip.
- rubber gloves (household gloves): rubber gloves are long gloves in variations of rubber. Typically used in wet environments.
- disposable gloves: Disposable gloves are gloves made of different materials, but typically PE, vinyl or latex. The gloves fit both the right and the left hand.

3.3.4 Brands/products

In connection with web search and visits to the retail shops (DIY shops, garden centres), the survey showed a large number of products within the category of work gloves, and a smaller number of products within the category of rubber gloves (household gloves).

The covered products are far from exhaustive, but represent a wide range of what is available on the market. The products are selected to cover a wide price range, quality, brands and availability. Table 3-5 shows examples of the different types of identified gloves.

The identified products are based on availability on the market, i.e. the products have been observed in several places. Furthermore, some products are recognised in use tests and cover price levels, brands and materials.

The dominating brands/manufacturers are Ox-On/sækko, OS/Otto Schackner, Cliks/KCL for Bauhaus, Weibulls. Smaller foreign manufacturers are typically found with Internet retailers or in niche shops like arts and crafts shops etc.

Category	Example	Characteristics / typical material
Work gloves		Rough fabric or leather, may be reinforced in exposed wearing surfaces. Typically for outdoor use.
Rubber gloves (household gloves)	210	Rubber gloves are long gloves in variations of rubber. Typically used in wet environments.
Disposable gloves		Different materials, but typically PE, vinyl or latex.
Garden gloves		Typically made of fabric/knitwear with reinforcements either of leather, fabric, or anti- slip materials, such as rubber.
Allround gloves	B	These gloves are more tight-fitting than the work gloves, and some are quite tight-fitting. The materials vary, but are typically provided with non-slip materials, also of variable character.
Knitted gloves		Knitted gloves are soft, loose-fitting, one size gloves made of knitwear or soft fabric. Often with dots (PVC) on the underside for a better grip.

3.3.5 Price

The survey has shown that the products within this product group can be found within a price range of DKK 1,- to DKK 229,- per pair, but with the emphasis (> 50%) on a unit price of DKK 20-70 per pair.

Product category	Cheapest product found	Most expensive product
	(DKK per pair)	found
		(DKK per pair)
Work gloves	21.25	169.95
Garden gloves	4.00	229.00
Allround gloves	19.95	119.95
Knitted gloves	4.16	8.00
Rubber gloves	5.00	29.95
Disposable gloves	0.84	4.39

Table 3-6 Prices divided between the different glove types

Information on the prices is used in the selection of products for analyses, as we want to analyse both cheap and expensive products.

3.3.6 Where is it sold?

The survey has shown that the products are largely sold through DIY shops with Silvan and Bauhaus as the two DIY centres with the widest product range.

3.3.7 Market shares

Various vendors of work gloves/household gloves have been contacted, and the project team has obtained information on the best selling/most popular gloves. This information is confidential, but it has been used in connection with the selection of products for analysis. Thus, the best selling/most popular brands have been selected for analyses.

3.3.8 How much is sold?

Data from Statistics Denmark in the category resembling gloves, included in the survey, is divided in 2 groups a) Gloves, impregnated, coated with plastic or rubber, knitwear and b) Rubber gloves. The imported amount of these glove types for the Danish market is presented in Table 3-7.

Table 3-7 Import of work gloves / household gloves (incl. paint gloves) to the Danish market

Kilos, Import 2011M07	Gloves, impregnated, coated with plastic or rubber	Rubber gloves
Hong Kong	15 460	0
Indonesia	0	480
China	58 213	33 919
Malaysia	200	233 444
Norway	2	713
Pakistan	14 343	50
Switzerland	0	4
Sri Lanka	12 548	3 361
South Korea	15	0
Vietnam	0	3 826
Taiwan	0	220
Thailand	22	0
Total: 376,820 kg	100 803	276 017

This means that in 2010, 376,820 kg gloves were imported. It is assumed that of the approx. 4 mill. Danish adults, the elderly population is using this type of glove to a lesser extent. If the amount of gloves is assumed to be used by about 3 mill. Danish adults, it is approx. 0.13 kg glove/year per adult inhabitant, excluding the elderly. Many of the gloves weigh less than 100 grams per pair. Maxiflex weighs approx. 40 g/pair, so 0.13 kg corresponds to approx. 3-4 pairs of gloves/year on average per Danish adult. The figures cover, of course, major differences, as commercial use of the gloves is also covered by the statement. The statement, however, provides an idea of the number of pairs of gloves/year used in average per Danish adult, which provides a basis for assessing the exposure from here.

3.3.9 Selection of products for analysis

Work gloves containing rubber/plastic material, considered to be the most important in relation to exposure to the selected phthalates and D4, were selected. Experience shows that a variety of plastic materials besides PVC may contain phthalates, such as polyurethane (PU), but in lower concentrations than what may be the case in soft PVC. Therefore, the products have been selected in order to cover a wide range of rubber/plastic material types.

In order to accommodate a wide range of products on the market, the selection criteria take into account the following:

- price (analyses of both cheap and expensive products)
- brands/manufacturers (analyses of products from different manufacturers and/or of different brands)
- market shares (analyses of the best selling products)
- type of product (analyses of different types of products, e.g. knitted gloves and rubber gloves)
- relevant categories (analyses of both garden/work gloves and household gloves)

Based on information from the survey, products for analyses within all categories identified were selected, but with emphasis on garden gloves and allround gloves (most products analysed). A total of 11 products were analysed. The primary focus was on the analysis of phthalates, which is assessed to provide the highest exposure by use of gloves, based on the material type used in many gloves. Since it was not possible given the available information to identify the gloves, which might contain siloxanes (D4), all selected gloves, except disposable gloves, were analysed for D4 as well.

3.4 Sneakers

3.4.1 Definition of the product group

In this project, the product group sneakers covers roughly all types of closed comfortable shoes containing parts made of soft plastic/rubber. I.e. it is not just ordinary sneakers (used e.g. for aerobics) that are included. "Casual shoes" like Converse All Star, which are also used in everyday life, are also included.

For further information on the types of included sneakers, please refer to Section 3.4.3 Categories.

Shoes like plastic sandals, crocks, ballerina shoes, etc. are disregarded, as several of these have been examined earlier.

3.4.2 How is knowledge obtained?

Information for the survey has been found through the following sources:

- Internet search
- The Danish Shoe Merchant Association
- The Danish Shoe Supplier Association
- Sports Industry's Supplier Association
- interview with employees from Sportsmaster

In the following section, all information - except where otherwise indicated - has been obtained through Internet searches.

3.4.3 Categories

The survey has identified categories of sneakers, listed in Table 3-8. It should be noted that the categorisation is only a dividing, which has been found appropriate. A search on e.g. "sneakers" will result in shoes that fit under the "Trainers category" as well as shoes that fit under the "Casual shoes-category" and the "Short boots category". Characteristic for the category "Trainers" is that these shoes can be expected to be used in sports, while "Casual shoes" are primarily intended to be used as ordinary footwear - i.e. not in sporting contexts. Similarly, this applies to the category "Short Boots".

Category	Example	Typical material*	Typical material* Inner lining	Typical material*	Typical material* Outer sole
Trainers		Mesh (woven material) PU Gore-Tex Hide Leather Nubuck Synthetic hide Synthetic fabric Textile PVC 100% polyamide	Textile Mesh EVA (in the fore and rear foot) Neopren	TPU PU lightweight sole (possibly the outer sole?) EVA sole Antibacterial material Mesh	Rubber Padded EVA PU (guess outer sole)
Casual shoes		Hide Suede Canvas Hide-like PU Leather PU Syntheric leather	Hide lining Textile 100% cotton Synthetic fur	Textile Hide	Rubber
Short boots		Synthetic fabric Suede Canvas Linen Organically processed cow hide Hide	Lambskin and the like		Rubber Crude rubber
Five fingers		Nylon fabric Velcro straps Neopren for insulation TPU protection of the toes		3mm PU (thickest under the fore foot) EVA "footbed" (presume inner sole)	Rubber pads Rubber sole

Table 3-8 Examples of categories of sneakers

* according to the websites from which the products are sold.

3.4.4 Brands/products

The survey has identified the following brands of sneakers:

Adidas	Fred Perry	Pikolinos	
Alife	Generic Surplus	Playboy	
Asics	Gola	Pointer	
Ammann	Gram	Puma	
Bensimon	Gravis	Race Marine	
Björn Borg	G-Star	Ralph Lauren	
Blend	Guess	Reebok	
Boras	Henri Lloyd	Replay	
C1rca?	HUB	Rieker	
Camel	Hugo Boss	Salomon	
Clae	Hummel	Selected	
Converse	Jack & Jones	Shape-Ups	
Creative Recreation leathe	r HKangaroos	Shoe The Bear	
Cult	Карра	Simple	
DC Shoes	Karl Kani	Spalwar	
Diesel	Kawasaki	SpringCourt	
Dorotennis	Keds	Superdry Kanvas Hi	
DVS	LaCoste	Supra	
Ecco	Le Coq Sportif	TBS	
Ed Hardy	Levi's	The Hundreds	
Ellesse	Lyle & Scott	Timberland	
Energie	New Balance	Tommy Hilfiger	
Energy	Nike	Tone-ups	
Eser	Onitsuka Tiger	Tretorn	
Etnies	Original Penguin	Vans	
Feiyue	Palladium	Vibram	
Finn Comfort	Paul Smith	Victoria	
Fornarina		Viking	
		Warp	

Table 3-9 List of identified manufacturers of sneakers

The list is obviously not exhaustive, but gives a very good indication of the size of this market.

3.4.5 Price

A search on <u>www.pricerunner.dk</u> (keyword "sneakers") resulted in 5,649 products at prices varying from 49 DKK to 2,144 DKK.

A search on <u>www.findpriser.dk</u> resulted in 42 hits (on "sneakers") at prices from 199 DKK to 1,199 DKK. A search on "sneakers" resulted in 11,455 products at prices from 49 DKK to 2,940 DKK.

A typical average price of sneakers (type sneakers, casual shoes, short boots) can probably be assumed to be around *400-600 DKK*. The price is assumed, as it is impossible to calculate a genuine average via data from <u>www.pricerunner.dk</u> or <u>www.findpriser.dk</u>.

The average price of sneakers in the category "five fingers" can probably be assumed to be higher, as a search on "Five Fingers" on <u>www.pricerunner.dk</u> resulted in 15 products with prices from 799 DKK to 1,221 DKK. The 15 products had an average price of *1,039 DKK*, which is assumed to be the average price for Five Fingers.

Information on the prices is used in the selection of products for analyses, as we want to analyse both cheap and expensive products.

3.4.6 Where are they sold?

Sneakers can be purchased from the following shop types - the list is not exhaustive, but only indicates examples:

- shoe shops
 - Skoringen
 - TOPS
 - Bianco Footwear
 - Banks Detail
 - ZJOOS
 - EuroSko
 - Feet me
 - Riis Sko
 - Ecco
- sports shops
 - Stadium
 - Fjeld og Fritid
 - Intersport
 - Sportmaster
 - Spejdersport
 - Friluftsland
 - Eventyrsport
 - Lasse Hjortnæs Ski & Outdoors
- supermarkets
 - Bilka
 - Føtex
 - Kvickly
 - all major supermarkets
- webshops
 - <u>www.brandos.dk</u> (claims to be the largest shoe shop on the web).
 - <u>www.spartoo.dk</u>
 - <u>www.alun.dk</u>
 - <u>www.growingfeet.dk</u>
 - <u>www.zjoos.dk</u>
 - <u>www.youheshe.com</u>
 - <u>www.store.nike.com</u>
 - <u>www.sneakershop.dk</u>
 - <u>www.stadium.dk</u>
 - <u>www.cloggs.dk</u>

3.4.7 Market shares

Various vendors of sneakers have been contacted, and the project team has obtained information on the most popular types and brands.

It has not been possible to obtain information about the market shares of the various popular brands. This information is confidential, but it has been used in connection with the selection of products for analyses. Thus, the most popular brands have been selected for analyses.

3.4.8 How much is sold?

The following data on turnover of sneakers on the Danish market in 2010 were taken from Statistics Denmark.

Product	Import – DKK	Export – DKK	5	Total turnover in DK in 2010 - DKK
Sneakers*	3.464.090.124	2.221.827.835	107.128.000	1.349.390.289

* Sneakers cover more than 30 different subcategories, including "Sports footwear with outer soles of rubber, plastics, leather or synthetic leather and uppers of leather (excl. ski boots)." I.e., the figure is probably overestimated as it - for example for the said subcategory - cannot be excluded that the category contains shoes with outer soles of leather.

According to these data, sneakers for just over 1.3 billion DKK were sold on the Danish market in 2010. Assuming an average price of a pair of sneakers to be DKK 400-600, it corresponds to a sale of 2.25 to 3.37 million pairs of sneakers on the Danish market in 2010.

With a population of 5.53 million people (both men and women), it corresponds to every Dane buying between 0.4 and 0.6 pairs of sneakers in 2010. The market for sneakers is thus relatively high in Denmark.

3.4.9 Selection of products for analysis

In this project, 9 sneakers were analysed for the following substances:

- phthalates
- bisphenol A
- triclosan
- nonylphenol
- octamethylcyclotetrasiloxane (D4)

These substances can be found in the following relevant materials:

- textiles (both natural (wool, cotton) and synthetic textiles) (triclosan, phthalates and nonylphenol)
- synthetic leather (can be made of PU) (phthalates and D4)
- PVC (phthalates)
- canvas (textile) (triclosan, phthalates and nonylphenol)
- TPU (D4)
- nylon/polyamide (triclosan, phthalates and nonylphenol)
- material treated with antibacterial agent (triclosan)

Analysis for bisphenol A is done in the same analysis as for phthalates, which is why this substance is also included.

There are many different types of materials in sneakers. In relation to the selection of shoes for analyses, it is proposed to select shoes, for which it is described that

the inner sole and/or the inner lining is composed of the above relevant materials. Focus is on the inner lining and inner sole, because the highest exposure is found here. If there is no information about the material in the inner lining/inner sole, the material type in the upper part will be prioritised (as this often will be the same as on the inside of the shoe (at least for shoes that do not have lining).

According to a report from Greenpeace (2011), 14 international clothing producers have used nonylphenol in their production. This substance can degrade to nonylphenol which has endocrine disrupting properties. In total, Greenpeace tested 78 products - but mostly clothes - within 15 brands, and found NPE above the detection limit of 1 mg/kg in 52 of the products. The brands containing nonylphenol above the threshold limit were e.g. Adidas, Calvin Klein, Converse, G-Star RAW, H&M, Kappa, Lacoste, Li Ning, Nike, Puma,and Ralph Lauren. Only one shoe was examined, a traditional Converse boot, which was found to contain 140 mg NPE/kg. It was therefore suggested to select a Converse shoe for analysis in this project.

In the selection of sneakers for analysis, products of the above brands from the Greenpeace survey (2011) were purchased - giving priority to those brands mentioned both by the Danish Shoes Supplier Association as being the best known in Denmark and also mentioned in the report from Greenpeace (as producers with products (clothes) containing NPE), which means brands like Adidas, Converse and Puma.

Criteria used in the selection of sneakers for analyses were the following:

- 3 pairs of trainers, 3 pairs of casual shoes, 2 pairs of short boots, 1 pair of Five Fingers
- balance between price ranges
- he shoes represent the various, relevant types of materials (in the inner sole/inner lining)
- the most famous brands were represented to the extent possible with preference to the brands also mentioned in the report by Greenpeace (2011)
- then, the brands in which Greenpeace found NPE were prioritised
- furthermore, the priority was to purchase shoes marketed with antibacterial inner lining or the like, as triclosan is often used as an antibacterial substance
- the priority was also to purchase a Converse shoe, because it was shown to contain NPE in the Greenpease survey

3.5 Antibacterial clothing

Antibacterial clothing is clothes with added germicidal chemicals, e.g. to reduce perspiration odour in clothes.

Previous survey projects from the Environmental Protection Agency "Survey of triclosan" (Danish EPA 2006a) and "Antibacterial agents in clothing" (Danish EPA 2003) show that antibacterial clothes/products may be the following:

- clothes
 - "active wear" / sportswear (e.g. biking pants, sports bra, ski socks)
 - knitwear
 - underwear
 - socks/ski socks
 - leggings
 - gloves
 - hats
- work clothes
- bed linen
- sleeping bags
- mattresses (covers and fillings)
- padding and fabric for pillows

Triclosan was studied in 17 different pieces of clothing in the survey report from 2003 (Danish EPA 2003), and in 5 of these triclosan was identified by analysis. These five products were women's panties, biking shorts (2 pcs.), underwear and sandals.

In the EPA report "Antibacterial agents in clothing" (Danish EPA 2003), it is concluded that triclosan apparently is not used in the manufacture of clothing in Denmark. It should be noted, however, that other EU countries use several tons of triclosan in the manufacture of clothing, and that some triclosan-treated products may therefore find their way to Denmark, and the fact that a lot of clothing is imported from countries outside the EU. The results of the report indicate, however, that the content of triclosan in this type of products must be only 7 ppm (or less) to achieve the desired antibacterial effect.

According to the EPA report "Survey of triclosan" (Danish EPA 2006a), surveys in Denmark, Norway and Sweden have identified small amounts of triclosan in sports and casual wear. The same report refers to a Swedish report, which concludes that the use of triclosan appears to be declining in favor of silver compounds and silver threads. The survey in this project is trying to prove or disprove this. The product group has been selected, because the EPA has received information indicating that the use of triclosan is widespread.

The EPA report "Survey of chemical substances in textiles" indicates that there is no identified information indicating that triclosan is washed out of clothes by washing. However, it is indicated that the solubility of triclosan is not particularly high (10 mg/L), so it is expected that the washing out is not especially large (Danish EPA 2011b). This is an argument to involve antibacterial clothes treated with triclosan in this project, as exposure to triclosan is higher, if triclosan is not washed out of the clothes than if it is washed out of the clothes by washing.

Following initiation of this survey and chemical analysis of selected antibacterial clothing in this project, the Chemical Inspection in Sweden published a report on the antibacterial agents in clothing (KemI 2011). This Swedish study showed that

triclosan is not highly prevalent and is thus only identified in 2 out of 30 pieces of sportswear, while silver was identified in 16 out of 33 pieces of sportswear. The concentrations of triclosan in the two pieces of sportswear were 62 and 44 ppm, respectively.

3.5.1 Definition of the product group

Antibacterial clothing is clothes with added bactericidal chemicals to reduce perspiration odour in the clothes. Antibacterial chemicals can typically be triclosan or nano-silver (Danish EPA 2011b). Like triclosan and nano-silver, titanium dioxide has an antibacterial effect (Wu *et al.*, 2009), but is probably being used primarily as a UV-filter (protects against the sun's rays) (The NanoCare Consortium 2009).

This survey focused exclusively on antibacterial clothes treated with triclosan, because triclosan is one of the endocrine disruptors, which are the focus of this project.

Products treated with nano-silver or other substances were therefore deselected and are not discussed in this report. If there was no information about the identity of the antibacterial chemical used to treat the antibacterial clothing, the clothing was included in the survey.

Some products were indicated to contain natural materials such as wool and bamboo, which have a natural antibacterial effect. These materials were not included in this survey, as the focus was to identify and analysed products containing triclosan.

Moreover, the focus of this survey was on antibacterial clothing and products such as bed linen, sleeping bags, mattresses or the like.

3.5.2 How is knowledge obtained?

A search was made for antibacterial clothing on the Danish market using the following tools:

- internet search (webshops)
- contact to the branch (Danish Fashion & Textile)
- contact to selected Danish clothing manufacturers (primarily manufacturers of sportswear)
- examination of the range in retail (sports shops (Intersport, Sportmaster and Sportsman), lingerie shops (Hunkemøller etc.), special bike shops, supermarkets)

For the Internet search was used keywords such as "antibacterial," "mildew resistant", "bacteriostatic" or the like in combination with "clothes", "textile", "underwear", "bike pants", "socks", "bra", "pants" and the like.

3.5.3 Categories

3.5.3.1 Different types of antibacterial clothing

It is mentioned around the web that textiles of natural materials, such as peat fibers, bamboo, soy fibers, milk fibers, and sasawashi (bamboo type), are naturally antibacterial. Among other things, it is indicated that bamboo clothing added "the natural agent" "Bamboo Kun" gives the clothes an antibacterial and odour-free function". The survey also showed an application of antibacterial treatment with chitosan recovered from shellfish (okoliv.dk 2010; eco-info.dk 2011; friluftslageret.dk 2011; nordjyske.mobi 2011). This type of antibacterial therapy is not included in this survey.

In addition, the identification/search for antibacterial clothing identified some bacteria-resistant clothing, which specifically indicated the use of silver ions which reduce bacterial spread. This antibacterial clothing containing silver was, as previously stated, not included in this survey.

In other words, there are three different caterogies of antibacterial clothing:

- 1. clothing containing silver ions, which are antibacterial
- 2. clothing containing natural material of some form, which is bacteriaresistant or antibacterial (e.g. bamboo and wool, clearly the most frequently stated)
- 3. clothing reported to be antibacterial, but the antibacterial agent is not specified. This could be triclosan, but we do not know for certain

The Internet search showed that these three groups of antibacterial clothing are fairly evenly represented by number of hits. That is, basically the same number of pieces of clothing is found in the three categories. Whether they are also fairly evenly represented in terms of amounts and sales is not known. From the search in the retail sector, it is difficult to say which of the three different categories of antibacterial clothing is the most frequent. Generally, there is hardly found much antibacterial clothing in the retail sector (almost exclusively biking shorts).

Only category 3 is surveyed in this project, and described further below.

3.5.3.2 Different clothing categories

The Internet search showed the following types of clothing with the indication that the clothing had an antibacterial or bacteria-resistant effect:

- bra/sports bra
- underwear/panties (includes special ones for running, G-string panties)
- ski underwear (long underpants/long sleeved shirt)
- underwear (tank top/ Thigh high underpants)
- work clothes long sleeved shirt
- tracksuit bottoms
- running tights
- shorts
- biking pants/biking shorts (with or without pads, with or without straps/ belts, short or long)
- tank top (sleeveless T-shirt)
- T-shirt (short sleeves)
- running shirt (long sleeves)
- stockings/socks (typically sports socks, running socks, ski socks or hiking socks)
- pantyhose (both short to the thigh and long)

Common to the majority of the identified antibacterial clothing is that it can be found in shops, which have something to do with physical activity. I.e. sports shops, "Spejdersport" and outdoor stores or the like. Thus, only a few pieces of clothing were identified as antibacterial or bacteria-resistant, which are not sports and casual wear. This is the more "normal" underwear as panties, bras and pantyhoses.

The identified antibacterial clothing can be divided into the following overall, relevant categories:

- 1. "normal" underwear
- 2. ski underwear/work clothes
- 3. training pants/shorts
- 4. tights (for running or biking)
- 5. shirts (tops, T-shirts or long-sleeved)
- 6. stockings/pantyhose

Common for all these categories of clothing is that most of it fits tightly to the body and is worn as the innermost layer.

For the special biking pants with seat pad, it is typically the seat pad that has been treated antibacterially.

3.5.4 What brands / products are on the market?

The contact to the selected clothing manufacturers confirms that antibacterial agents do not exist in more normal clothing (i.e. non-sportswear). According to "Bestseller's Chemical Restrictions", it is Bestseller's official chemical policy that "Biologically active finishing products" (like triclosan) are not allowed (Bestsellers 2010).

The general picture from the selected clothing manufacturers was that triclosan is not used. One producer mentioned that they had previously used triclosan in some of their sportswear, but it was phased out several years ago. Another manufacturer told that they use silver salts exclusively in their antibacterial clothing.

Visits to selected shops in the retail sector have only identified one brand of biking pants as antibacterially treated clothing. And for biking pants, it is the only the seat pad that is antibacterially treated. Thus, it appears that there is a fairly limited range of antibacterially treated clothing in retail.

The Internet search confirmed, however, that there is antibacterial clothing on the Danish market - but it is typically found in sports/leisure/activity clothing. Via Internet search, the following brands of antibacterial clothing on the Danish market were identified. I.e. in Danish Internet shops (and partly in the Danish retail trade).

Table 3-10 Clothing brands with antibacterial clothing				
Addidas Techfit	Haglöfs	O' Glam		
BMW Danmark	Heatgear	ROGO		
Casall	Held	Sloggi		
Cette-Revelation	Houdini	Sup'air		
Craft	Hummel	Thoni mara		
DarmaSilk	Kari Traa	Under Armour		
Dream Ride	Kjus	Uvex		
Endura	MASCOT	Vangård		
Estella	Nannan	VIP Ergomed		
Everest	Newline			

3.5.5 Price

The price of the antibacterial clothing naturally depends on whether we talk about socks or special biking pants, used by women who engage in biking as a sport.

Below is stated the price ranges of the antibacterial clothing within the various categories of clothing.

Table 3-11		
Category of	Observed	Observed
antibacterial clothing	min price	max price
"Normal" underwear	99 DKK	375 DKK
Ski underwear/ work	199 DKK	799 DKK
clothes		
Training pants/shorts	449 DKK	649 DKK
Tights (for running or	199 DKK	799 DKK
biking)		
Shirts (tops, T-shirts or	50 DKK	800 DKK
long-sleeved)		
Stockings/pantyhose	69 DKK	139 DKK

Table 3-11

Information on the prices is used in the selection of products for analyses, as we want to analyse both cheap and expensive products.

3.5.6 Where is it sold?

Antibacterial clothing was primarily found in Internet shops. Antibacterial clothing in retail proved to be very limited - based on the individual shop visits made during the survey. We have only succeeded in identifying biking pants that were antibacterially treated in retail (sports shop) - and only one brand has been identified as being antibacterially treated. Another label described antibacterial treatment with silver (and is therefore not further described).

Antibacterial clothing was identified e.g. in the following webshops:

- <u>www.stadium.dk</u>
- <u>www.nelly.com</u>
- <u>www.outdoorrodovre.dk</u>
- <u>www.bodystore.dk</u>
- <u>www.shop.denintelligentekrop.dk</u>
- <u>www.aktivtraening.dk</u>
- <u>www.eventyrsport.dk</u>
- <u>www.jepsenhealthcare.dk</u>

- <u>www.workgear.dk</u>
- <u>www.maxpuls.dk</u>
- <u>www.netlingeri.dk</u>
- <u>www.friluftslageret.dk</u>
- <u>www.friluftsland.dk</u>
- <u>www.marathonsport.dk</u>
- <u>www.lingeri-online.dk</u>
- <u>www.skishop.dk</u>
- <u>www.runnerschoise.dk</u>
- <u>www.webshop-skikaelderen.dk</u>
- <u>www.skysport.biz</u>
- <u>www.stuff4bikes.dk</u>
- <u>www.runnur.dk</u>

The names of the various webshops also indicate that it is typically sports and casual wear that is sold as antibacterial or bacteria-resistant.

3.5.7 Market shares

No information was found about which brands of antibacterial clothing are the best selling. Therefore, the most famous brands have been selected for analysis.

3.5.8 How much is sold?

It is not possible via Statistics Denmark (Statistics Bank) to distinguish between clothing that is antibacterially treated and clothing that is not. Therefore, it is not possible to specify the percentage or the quantity of antibacterial clothing sold in Denmark.

Danish Fashion & Textile has been contacted during this survey and does not have any information in this area (there are no statistics). But they do not believe that this is an area which is particularly widespread.

The project "Survey of chemical substances in textiles" (Danish EPA 2011b) indicated the quantity of clothing (in terms of value of imports) annually imported and sold in Denmark. These quantities are given in Table 3-12.

The figures cover only clothing (which means that shoes, jewelry and leather goods are not included in the calculation). The figures cover all imports to Denmark - also sales via the Internet. The figures come from Statistics Denmark.

Table 3-12 The percentage of clothing and accessories imported to Denmark. Antibacterial clothing probably represents only a tiny fraction of the total imports. Source: (Danish EPA 2011b)

Value of imports (1000 DKK) Clothing and accessories			
Time	2007	2008	2009
Total imports to Denmark	24.169.936	24.131.465	21.170.743
% of clothing not coming			
from the EU	61%	63%	66%

It is seen that the share of clothes (clothing) sold in Denmark, produced in countries outside the EU, is steadily increasing over the period 2007 to 2009. In 2009, 66% of the imported clothing (specified as a value in DKK) originated from non-EU countries.

Imports from non-EU countries originate almost exclusively from the East. Danish Fashion & Textile has supplied data for 2009 (figures are from Statistics Denmark) showing that there was only imported for an amount of approx. 100 million DKK from countries other than the East. It is mainly from countries like the US, Egypt and the United Emirates. I.e. of the import of textiles outside the EU, imports from the East amount to approx. 99.3%. It is assumed that there may be triclosan in clothing from both EU and non-EU countries (Danish EPA 2003).

3.5.9 Selection of products for analyses

A total of 8 selected pieces of clothing containing antibacterial agents were selected for analyses. I.e. antibacterial clothing with possible content of triclosan, as we cannot see with certainty from the survey that triclosan is used. Every piece of clothing is analysed for content of triclosan and possible content of nonylphenol and octamethylcyclotetrasiloxane (D4), as it is expected that these substances may occur in the clothing. The Greenpeace survey (Greenpeace International 2011), as described earlier, confirms that nonylphenol ethoxylates can be found in clothing (identified in 52 out of 78 products).

The following parameters were used in the selection of the 8 pieces of antibacterial clothing to be analysed for the presence of triclosan, nonylphenol and octamethylcyclotetrasiloxane (D4):

- selected from the various categories of clothing, entirely consisting of clothing worn as the innermost layer. For example underwear, running shirt, tights, socks, etc.
- clothing selected from 8 different brands and the most famous brands are represented
- clothing selected, which probably is totally antibacterially treated. However, biking shorts have also been selected, even though only the "pad" is antibacterially treated
- selected from both the expensive and the cheap price level

3.6 Handbags made of synthetic leather

3.6.1 Definition of the product group

Synthetic leather bags mean bags consisting of leather or other plastic material. I.e. bags of leather, suede, textile (cotton, viscose, polyester, etc.) are not included.

Bags such as school bags, camera bags, sports bags, suitcases, etc. are disregarded. Also disregarded are bags with handles so small that they are impossible to carry on the shoulder, i.e. you must carry the bag by the handle.

The focus is thus exclusively on bags that can be worn by a strap over the shoulder (i.e. both neat small hand bags and larger bags (including computer bags and baby changing bags) - and bags in the form of "clutches", i.e. bags without handles, worn under the arm.

3.6.2 How is knowledge obstained?

For the survey, the following sources have been searched:

- Internet
- Scandinavian Shoe Center (also handles bags)
- Neye market-leading retail chain within bags
- Kaza one of the larger retail chains within bags
- www.bagcenter.dk (Centre that informs shops about new trends within bags, etc.)
- Føtex

In the following section, all information - except where otherwise indicated - is resulting from Internet searches.

Information regarding the identification of manufacturers (brands) is mainly obtained by Googling "bags of leather," "clutches synthetic leather", etc.

3.6.3 Categories

3.6.3.1 Different product categories

The survey has identified the following relevant categories of synthetic leather bags:

Category	Example	Typical material*
Shoulder bags (including changing bags)		PU leatherlook/synthetic leather 100% PU Skai (may contain PVC)** Various descriptions of synthetic leather: - Fabric with rubber effect - Embossed rubber material - Synthetic material - Leather look - Suede look - Soft hide look - Synthetic leather - Imitated leather
Clutches		Synthetic leather/Imitated leather Recycled candy paper (eco-friendly material with water repellent properties according to the manufacturer)

* according to the websites where the products are sold.

** according to telephone conversation with a purchaser from Kaza.

The above categorisation is used exclusively for this project. Kaza mentioned that they usually categorise bags in small, medium and large bags - a categorisation that does not make sense in this project, as we are looking for bags with relatively extensive skin contact. I.e. the category of small bags will probably contain small handbags (which can only be hand carried) - a group of bags that are not relevant for this project. Likewise, the big bags will probably include sports bags, a category that is not relevant for this project - due to the low skin exposure.

3.6.3.2 Different categories made of synthetic leather materials

It has been difficult to get information via the webshops about the nature of the synthetic leather on the bags. Most often expressions as "synthetic leather", "imitated leather" "embossed rubber material" and the like are used. In a few cases, however, it was evident that the synthetic leather was made of PU.

To get a better idea of the nature of the synthetic leather, further search was made on the Internet. The aim was to identify the types of synthetic leather containing large amounts of PVC, PU or PES, and thus should be prioritised in relation to the selection of products for analyses (if it is possible to identify synthetic leather bags consisting of these types of synthetic leather material).

A call to Kaza revealed that synthetic leather in their world often consists of "skai". According to www.forbrugerkemi.dk, skai is typically made of PVC plastic. Likewise, a distributor of synthetic materials states on a website that item number "6610 Leather look" consists of leather - skai - 100% PVC - with the reverse side of polyester/cotton (hecht-johan.dk 2011), which suggests that skai may contain PVC.

A further search via the internet on the typical ingredients in "synthetic leather" revealed the information displayed in Table 3-13.

Table 3-13 Examples of what synthetic leather materials may contain. The types of synthetic leather material marked in grey are those that seem to have the highest content of PVC, PES and/or PU.

Content of PVC, PES and/or PU. Name of Material/ Illustration Source						
Name of synthethic leather type	Material/ ingredients	lilustration	Source			
Gaucho	75.3% PVC and 24.7% cotton		http://www.qimova.dk/~/media/ Product%20sheets/PDF/DA/34 %20- %20Gaucho%20kunstlder.ashx			
Skai	100% PVC, reverse side of polyester/cotton		http://www.hecht- johan.dk/page.asp?sideid=148			
Synthetic leather	100% polyurethane (PU) However, mostly furnishing leather.		http://www.ballins.dk/KunstLae der.htm			
Ambla	Cotton with surface of PVC Antibacterial and therefore suitable for hospital and care furniture.		<u>http://www.schultz-</u> <u>kalecher.dk/?page_id=308</u>			
Stamskin Top	Polyamide-jersey with surface of PVC	No illustration	http://www.schultz- kalecher.dk/?page_id=308			
PM/MAH/Grif fine Neptune G	Polyester with surface of PVC	No illustration	http://www.schultz- kalecher.dk/?page_id=308			
Touch mee	Cotton with surface of 94% vinyl/PVC and 6% polyurethane	No illustration, but should resemble suede	http://www.schultz- kalecher.dk/?page_id=308			
Arelan Apollo	Polyester with surface of PVC	No illustration	http://www.schultz- kalecher.dk/?page_id=308			
Arelan Mobilia	Polyester with surface of PVC	No illustration	http://www.schultz- kalecher.dk/?page_id=308			
Mobilia Apollo Synthetic leather	Soft PVC and woven tricot PES. Has a buffalo-like structure.		http://www.tm- materialer.dk/product.asp?produ ct=485			

Name of synthethic leather type	Material/ ingredients	Illustration	Source
New York Synthetic leather	PVC with reverse side of woven PES.		http://www.tm_ materialer.dk/product.asp?produ ct=9988
FORTE Synthetic leather	PVC with woven tricot PES		http://www.tm_ materialer.dk/product.asp?produ ct=494
PISA Synthetic leather	PVC – 665 gr. M2		http://www.tm- materialer.dk/product.asp?produ ct=720
TECNOSKIN Synthetic leather	55% PU, 26% PL, 19% CO		http://www.tm_ materialer.dk/product.asp?produ ct=1815
CHICAGO – phthalate- free synthetic leather	No info on ingredients! For cars, planes and children under the age of 3.		http://www.tm- materialer.dk/product.asp?produ ct=6867
CORDOBA – phthalate- free synthetic leather	No info on ingredients! For cars, planes and children under the age of 3.		http://www.tm- materialer.dk/product.asp?produ ct=6929

NB: this list is not exhaustive, but shows examples of the kind of materials synthetic leather may consist of. It should also be pointed out that some of the identified synthetic leather materials had received flame-retardant treatment of some form!

3.6.4 Brands/products

The survey has identified the following different brands of synthetic leather bags:

Dixie	Zwei
Bjørn Borg	Vespa
Esprit (only makes synthetic	Friis & Company
bags)*	Mandarina Duch
Adax	Guess (only makes synthetic bags)*
Optipus	St. Sulpice (Neyes own brand only makes
Qnus	synthetic bags)*
byStroom	H&M
Stephanie	

* Information on the three brands only making synthetic bags originates from a sales clerk in a Neye shop.

We know for certain that the listed brands manufacture bags of synthetic leather. If all manufacturers of bags regardless of material are listed, the list will be considerably longer.

For many of the synthetic leather bags available for sale online, the name of the manufacturer is not disclosed. Thus, it has been difficult to identify manufacturers/brands of synthetic leather bags.

3.6.5 Price

A search on www.kelkoo.dk ("bags" as keyword) resulted in 2806 products with prices varying from 38 DKK to 10,417 DKK. However, this includes all kinds of bags and also bags made of leather, so the figures are somewhat misleading. Because it is not possible to search for synthetic leather bags only on "price-search engines", the data here cannot be used to estimate an average price.

The average price for the identified bags of synthetic leather (32 pcs) in this project is 305 DKK, varying from 45 DKK to 599 DKK.

An experienced sales clerk at Neye estimated that a typical average price for a synthetic leather bag is 400 DKK.

As the sales clerks are expected to have a pretty good idea of average prices, the average price for a synthetic leather bag in this project is assumed to be 400 DKK.

3.6.6 Where are they sold?

Synthetic leather bags are available in the following types of shops. Please note that this list is not exhaustive:

- bag shops
 - Friis & Company
 - Neye
 - Kaza
- other types of shops
 - Hennes & Mauritz
 - Various fashion/accessories shops
- department stores
 - Magasin
 - Illum

- supermarkets
 - Bilka
 - Føtex
 - Kvickly
 - all major supermarkets
- webshops
 - www.shopfriiscompany.com
 - www.regovs.com
 - <u>www.piaries.dk</u>
 - <u>www.importvarer.dk</u>
 - www.fashionteam.dk
 - www.sofiagaver.dk
 - <u>www.pribot.dk</u>

According to Scandinavian Shoes Center (sells bags themselves), the typical places to buy bags would be the large retail chains such as Neye, Kaza and Friis & Company, followed by the convenience industry.

According to an article from 2005, Neye is by far the largest leather goods chain in Denmark. The closest competitors are, according to the article, the convenience industry, which is consistent with the opinion of Scandinavian Shoes Center (Jessen 2005). Also according to Wikipedia, the chain (Neye) is leading in the market and has only a few minor competitors. Neye currently has 37 shops throughout the country and a turnover of approx. 200 million per year (Wikipedia 2011).

3.6.7 Market shares

Various vendors of bags have been contacted, and the project team has obtained information on the best selling/most popular types. This information is confidential, but information has been used in connection with the selection of products for analyses. Products for analyses have been selected among the most popular brands.

3.6.8 How much is sold?

The following data on sales of synthetic leather bags in the Danish market in 2010 originates from Statistics Denmark.

Product	Total quantity sold (pcs)
Handbags with/without straps – with outer surfaces of leather, synthetic leather or patent leather	1.030.519
Handbags with/without straps – with outer surfaces of plastic	1.390.921
Total	2.421.440 stk.

NB: Here, the industry's "own production" (i.e. production in Denmark) is disregarded, as it was minimal.

According to this data, about 2.42 million handbags were sold on the Danish market in 2010, corresponding to each Dane (older than 11 years) buying (2.421.440/4.811.581) 0.5 handbag in 2010. Thus, the handbag market in Denmark is relatively large.

3.6.9 Selection of products for analyses

The synthetic leather bags are analysed for content and release of phthalates and bisphenol A. Analysis for bisphenol A is done in the same analysis as for phthalates, which is why this substance is also included. According to the Chemical Analysis Division, these are the types of materials, in which phthalates are likely to be found:

- PU
- PVC
- PES
- TPE (TPE is a common name for thermoplastic elastomers PVC may be one)

However, the survey has revealed that it is difficult to obtain information on the exact constituents of the synthetic leather materials in bags. In a few places, it is reported that synthetic leather consists of PU, but otherwise terms like "imitated leather", "leather look", etc. are usually used

It is judged that there is a bigger chance of finding large quantities of PVC, PU and/or PES in certain types of synthetic leather, and therefore, some of the bags were purchased physically in shops, based on the above pictures of the material types.

The survey revealed 8 synthetic leather bags described as containing PU. The manufacturer/brand was only informed for 3 of these (2 of Esprit brand and one of EDC brand). As Esprit is one of the most famous brands, an Esprit bag of PU was bought.

Criteria for selection of synthetic leather bags for analyses are as follows:

- it is assumed that more women wear shoulder bags than clutches, and therefore 7 shoulder bags and 3 clutches were purchased. Of these, one of the shoulder bags was also a changing bag
- the bags represented cheap as well as expensive products
- the best selling/most popular brands have been selected
- 8 bags were purchased in shops where synthetic leather material resembled the synthetic leather material marked in grey in Table 3-13

The synthetic leather bags were purchased in the following shops:

- Neye
- Friis og Company
- Kaza
- Supermarkets
- Hennes & Mauritz
- Søstrene Grene
- And a few webshops

3.7 Pregnant belly creams/pregnancy oils and moisturising creams/lotions

For cosmetic products, there is a requirement to document the ingredients in the product in a list of ingredients. It is therefore possible simply by reading the list of ingredients to obtain knowledge of the contents of ingredients in cosmetic products. In this project, the list of ingredients was therefore perused closely for knowledge about the quantities of products containing one or more of the selected substances.

3.7.1 Definition of the product grop

The use of creams/lotions for the body is common for the target group of pregnant women and women who wish to become pregnant. It is therefore relevant to look at the amount and type of products available on the Danish market. As the project would like to include some of the specific products used by pregnant women, the category of "pregnant belly creams/pregnancy oils" is included in this survey. It is estimated that pregnant belly creams/pregnancy oils are mainly used in the latter part of pregnancy. However, products have been observed with recommended use in early pregnancy to prevent stretch marks, and are therefore relevant to include as a product group in the project.

The product group is limited only to address products that are not labeled with the Nordic Ecolabel. Nordic Ecolabelled cosmetics must not contain ingredients that are on the EU list of suspected endocrine disruptors. Therefore, Nordic Ecolabelled products are not relevant for this project.

The survey is divided in two parts with the following definitions:

- A. pregnant belly creams/pregnancy oils are not restricted further in the survey, as the aim is to identify a wide range of products available on the Danish market.
- B. moisturising creams/lotions are limited, as the survey only includes creams/lotions marketed for the whole the body, which exempts foot, face, and hand creams and the like from the survey.

Furthermore, besides Nordic Ecolabelled products, the survey will not include creams/lotions sold as "paraben free", as these are assumed to contain no parabens. Cosmetics sold as paraben free may, in some cases, contain one or more of the selected UV-filters.

3.7.2 How is knowledge obtained

The Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries (SPT) has been approached in order to survey the creams on the market and to gain a better knowledge of the amount (concentration) of the selected substances in the products. SPT asked their members on the content concentrations (in %) to be able to calculate in the risk assessment both the maximum allowed concentration and the most realistic concentration in the product group.

Coop, Dansk Supermarked, Matas and pharmacy chains (Apotekerforeningen, *dit*apotek and A-apoteket) were contacted regarding brands/trade names of the most frequently sold products.

Via Google was searched for information about pregnant belly creams/pregnancy oils and moisturising creams/lotions on the Internet. This was done in order to obtain general information about the types of pregnant belly creams/pregnancy oils and moisturising creams/lotions on the market, and also to identify a number of webshops selling these products.

The primary method of surveying the market for pregnant belly creams/pregnancy oils and moisturising creams/lotions has been to visit different shops, such as perfumeries, convenience shops and pharmacies, where relevant products have been photographed (front/back) to identify ingredients. A number of retail shops were visited:

- Føtex
- Bilka
- SuperBrugsen
- SuperBest
- Kvickly
- Netto
- Matas
- Apoteker
- Magasin
- Estethique
- The Body Shop
- Urtehuset
- Helsemin (Fields)

Then, the lists of ingredients were studied and the contents of the relevant, selected substances were listed.

3.7.3 Categories

3.7.3.1 Pregnant belly creams/pregnancy oils

Products marketed as creams/oils for "treatment of pregnant stomachs against stretch marks" are found only in very limited quantities. The products are different from one another either by being creams or oils. The products are marketed primarily for use on the stomach, but can also be used on breasts, hips and larger skin areas. Pregnant belly creams are seen marketed as "protecting the skin from drying out and irritation" or "increasing skin elasticity, thereby helping to prevent stretch marks", and it may be an extra rich cream with e.g. glycerine or cream with vitamin and mineral rich oil containing e.g. shea butter, avocado oil and coconut oil. Pregnancy oils are seen on the market with the effect that "the oil makes the skin and tissue supple thereby preventing stretch marks" and may be oils containing e.g. almond oil, jojoba oil, soy oil and wheat germ oil, as well as vitamins A and E.

3.7.3.2 Moisturising creams/lotions

The survey has identified the following typical categories of body creams:

- body lotion
- cream
- fatty cream

Whether the product is a body lotion, a cream or a fatty cream is decided by the water/fat content of the product. Lotion is more watery and less fat than cream and fatty cream, respectively. Fatty cream is highly viscous (paste) and has a high fat content. In the survey, an assessment was made of the categorisation of the products lotion, cream and fatty cream, respectively, as shown in Table 3-15. It is estimated, however, that there will be no significant differences between categories in terms of content of suspected endocrine disruptors. However, there may be differences in the amount used per application depending on the type, but that is not taken into account in this project.

3.7.4 Brands/products

3.7.4.1 Pregnant belly creams/pregnancy oils

Table 3-14 shows a list of pregnant belly creams/pregnancy oils surveyed in this project.

Table 3-14 Pregnant belly creams/pregnancy oils, found partly in shops, partly on the internet. For
each product, the presence of the selected ingredients, focused on in this project, has been stated

Category	Purchasing address (retailer)	Product name	Manufacturer / Importer	Cyclomethico	Propylparaben	Butylparaben	Isobutyl	Triclosan
Pregnant belly creams	http://www.rent- liv.dk/kropspleje/78-biosmetics- mavecreme.html http://www.biosmetics.com/mave creme-til-gravide/5-okologisk- mavecreme-100ml.html	Biosmetics Mavecreme	Biosmetics	-		-	-	-
	Matas*	Matas Mavecreme	Matas	-	-	-	-	-
	Matas*	Mor & Barn Mavecreme	Matas	-	-	-	-	-
	Estethique	Clarins Stretch Mark Control	Clarins	Х	-		-	-
Pregnancy oils	Matas * Bilka Føtex A-Z	Bio-oil	Bio-oil	-	-	-	-	-
	Matas http://www.helseriet.dk/shop/wele da-svangerskabsolie-456p.html	Weleda Svangerskabs olie	Weleda Marketed in DK by Dansk Helios, Østerskovvej 2, 7000 Fredericia.	-	-	-	-	-

* Matas, Borups Allé 132, 2000 Frederiksberg

"x" states that the substance is mentioned in the ingredients list of the product

"-" states that it is checked for the selected substance, but it is not mentioned in the ingredients list of the product

6 products are marketed in Denmark for use as pregnant belly creams/oil or for stretch marks. Only one of the products contains one of the 9 ingredients we focus on - cyclomethicone. None of the identified pregnant belly creams/oils contain propyl, butyl or isobutylparaben.

3.7.4.2 Moisturising creams/lotions

Table 3-15 shows a list of moisturising creams/lotions surveyed in this project.

Table 3-15 Moisturising creams/lotions, found partly in shops, partly on the internet. For each product,
the presence of the selected ingredients, focused on in this project, has been stated

Category	Purchasing	Product name	Manufacturer /	_				
	address (retailer)		Importer	Cyclomethicon e	Propylparaben	Butylparaben	lsobutyl paraben	Triclosan
Cream	Magasin	Acqua Di Parma Colonia	-	-	-	Х	Х	-
Cream	Apoteker	A-Derma Creme De Soin	Apotekernes A.M.B.A	Х	-	-	-	-
Lotion	BodyShop	Africa Shea Butter & sesam oil Body Balm	BodyShop	-	х	х	х	-
Fatty cream	BodyShop	Aloe Body Butter	BodyShop	-	-	-	-	-
Cream	Matas	Australian Body Care Intensive skin Cream	Australian Bodycare	-	-	-	-	-
Lotion	Pharmacies	Avène Cold Cream Body Lotion	Avène	Х	-	-	-	-
Lotion	Pharmacies	Avène Moisturising Body Lotion	Avène	Х	-	-	-	-
Cream	Magasin	Baylis & Harding	-	-	Х	-	-	-
Cream	Matas	Beautée Pacifique	Beautée Pacifique	-	-	-	-	-
Cream	Bilka	Biotherm	Biotherm	-	-	-	-	-
Cream	Estethique	Biotherm Beurre Corporel	Biotherm	-	-	-	-	-
Fatty cream	BodyShop	Body Butter Duo	BodyShop	-	-	-	-	-
Lotion	Føtex	Budget - Bodylotion	Produced for Danish supermarket	-	-	-	-	-
Cream	Magasin	Calvin Klein Euphoria Sensual Skin	Calvin Klein	-	х	Х	Х	-
Fatty cream	Netto	Careful Kopattesalve	Produceret for Netto	-	х	-	-	-
Cream	Estethique	Chanel Allure Creme pour le corps	Chanel	-	х	-	-	-
Cream	Estethique	Chanel Body Excellence	Chanel	-	Х	-	-	-
Lotion	Estethique	Clarins Lotion Tonique Toning Lotion	Clarins	-	-	-	-	-
Lotion	Magasin	Clarins Satin Smooth Body Lotion	Clarins	-	-	-	-	-
Cream	Estethique	Clarins Serum Corps Peau Neuve	Clarins	Х	-	-	-	-
Cream	Estethique	Clarins Silky-smooth body Cream	Clarins	Х	-	-	-	-
Lotion	Magasin	Clinique Body Lotion	Clinique	-	-	-	-	-
Lotion	BodyShop	Cocoa Butter hand & body lotion	BodyShop	-	х	-	-	-
Fatty cream	BodyShop	Coconut Body Butter	BodyShop	-	х	-	-	-
Lotion	BodyShop	Coconut Milk Body lotion	BodyShop	Х	-	-	-	-
Cream	Matas	Comwell Spa Philosphy	-	-	-	-	-	-

Category	Purchasing address (retailer)	Product name	Manufacturer / Importer	Cyclomethicon e	Propylparaben	Butylparaben	Isobutyl paraben	Triclosan
Cream	Pharmacies	Cosmea BODY fugtighedscreme	Cosmea Aco A/S	-	Х	-	-	-
Lotion	Pharmacies	Cosmea BODY hudlotion	Cosmea Aco A/S	-	Х	-	-	-
Cream	Pharmacies	Decubal Body Cream	Actavis Danmark A/S	-	-	-	-	-
Lotion	Pharmacies	Decubal body Lotion	Actavis Danmark A/S	-	-	-	-	-
Cream	Pharmacies	Decubal Intensive Cream	Actavis Danmark A/S	-	-	-	-	-
Cream	Pharmacies	Decubal originally Clinic Cream	Actavis Danmark A/S	-	-	-	-	-
Cream	BodyShop	Deep Sleep Peaceful body moisturizer	BodyShop	-	-	-	-	-
Cream	http://www.d ermalogica.d k/	Dermalogica body hydrating cream	Derma¬logica	-	Х	х	х	-
Cream	http://www.d ermalogica.d k/	Dermalogica Stress Relief Treatment Oil-	Derma¬logica	-	Х	х	х	-
Cream	http://www.d ermalogica.d k/	Dermalogica Ultra rich Bodycream	Derma¬logica	-	Х	-	-	-
Lotion	BodyShop	Dewberry Bodylotion	BodyShop	-	-	-	-	-
Lotion	BodyShop	Divine Calm Sublime Bodylotion	BodyShop	-	-	-	-	-
Cream	Bilka	Dove Body cream oil	Unilever	-	-	-	-	-
Lotion	SuperBest/Føt ex	Dove Body Milk	Unilever	-	Х	-	-	-
Lotion	Bilka	Dove Body Silk	Unilever	-	-	-	-	-
Cream	SuperBest	Dove Essential Nourishment	Unilever	-	-	-	-	-
Lotion	Kvickly	Dove Proage Nourishment	Unilever	-	X	-	-	-
Cream	SuperBest	Dove Silky Nourishment	Unilever	-	Х	-	-	-
Lotion Lotion	Netto	Dove Supreme Silk Lotion	Unilever Dr. Hausabka	-	Х	-	-	-
	Magasin	Dr. Hauschka Lemon body Lotion	Dr. Hauschka	-	-	-	-	-
Lotion	Magasin	Dr. Hauschka Quince body Lotion	Dr. Hauschka	-	-	-	-	-
Lotion	Magasin	Dr. Hauschka Rose body Lotion	Dr. Hauschka	-	-	-	-	-
Lotion	Matas	Dr. Scheller 24-hour intensive moisture body lotion	Dr. Scheller	-	-	-	-	-
Cream	Magasin	Eau de Rose	Crabtree & Evelyn	-	X	Х	Х	-
Cream	Føtex	Elisabeth Arden – Green Tea	Elizabeth Arden	-	X X	X X	X X	-
Cream Cream	Magasin Matas	Elsa Heronimus Embryolisse Lait Creme Fluide	Elsa Heronimus	-	^	- -	-	-
Cream	Estethique	Estee Lauder Body	Estee Lauder	_	-	-	_	-
C * 0			Fatalla O Thill					
Cream Lotion	Magasin Bilka	Estelle & Thild GOSH Classic Bodycare -	Estelle & Thild GOSH	-	-	-	-	-
		Moisturizing body lotion		-	-	-	-	-
Cream	Magasin	Heavenly Gingerlily	Molton Brown	Х	Х	Х	Х	-
Cream	Magasin	Helena Rubinstein	Helena Rubinstein	-	-	-	-	-
Cream	Matas	Helosan	-	-	Х	-	-	-
Fatty cream	BodyShop	Hemp Body butter	BodyShop	Х	Х	-	-	-
Cream	Magasin	Inspiring Wild Indigo	Molton Brown	Х	Х	Х	Х	-
Cream	Magasin	Iris	Crabtree & Evelyn	-	-	-	-	-

Category	Purchasing address (retailer)	Product name	Manufacturer / Importer	Cyclomethicon e	Propylparaben	Butylparaben	Isobutyl paraben	Triclosan
Lotion	BodyShop	Japan Yuzu & Rice body milk	BodyShop	Х	-	-	-	-
Lotion	Netto	Jeune Intensiv pleje Body lotion Ekstra	Jeune	-	-	-	-	-
Cream	Urtehuset	John Masters Organics	-	-	-	-	-	-
Cream	Magasin	Jojoba	Crabtree & Evelyn	-	Х	Х	Х	-
Cream	Magasin	La Praire	La Praire	-	Х	-	-	-
Lotion	Magasin	La Source body lotion	La Source	-	Х	Х	Х	-
Cream	Matas	Lancome Baume Corps	Lancome	-	-	-	-	-
Cream	Estethique	Lancome Nutrix Body Body	Lancome	-	-	-	-	-
Cream	Estethique	Lancome Nutrix Royal body	Lancome	-	-	-	-	-
Lotion	Matas	LdB Creme Rich Body Lotion	LdB	-	Х	-	-	-
Cream Cream	Magasin Apoteker http://www.r en- velvaereshop	Lily Locobase Fedtcreme	Crabtree & Evelyn Astellas Pharma a/s	-	-	-	-	-
Cream	.dk http://www.p ureshop.dk/kr op/velvet- moisturizing- cream	Logona - velvet moisturizing cream	Logona	-	-	-	-	-
Lotion	http://www.p ureshop.dk	Logona Daily Care - Body Lotion Organic Aloe & Verbena			-	-	-	-
Lotion	http://www.p ureshop.dk/kr op/free- body-lotion	Logona Free Body lotion	Logona	-	-	-	-	-
Cream	Matas	L'Oréal NutriLift	L'Oréa	-	-	-	-	-
Cream	Netto	Malaja Lotion til Tør hud	-	-	-	-	-	-
Fatty cream	BodyShop	Mango Body Butter	BodyShop	Х	х	-	-	-
Cream	BodyShop	Maroccan Argan oil & orange blossom Body Souffle	BodyShop	-	-	-	-	-
Cream	Magasin	Massage From heaven	Rituals	-	Х	Х	Х	-
Lotion	Helsemin	Melissa Bodylotions	Melissa	-	-	-	-	-
Lotion	Føtex	Nivea Body Milk	Beiersdorf	-	-	-	-	-
Lotion	Føtex	Nivea Bodylotion	Beiersdorf	-	-	-	-	-
Cream	SuperBest	Nivea Happy Time	Beiersdorf	-	Х	-	-	-
Cream	SuperBest	Nivea Soft Careing	Beiersdorf	-	Х	-	-	-
Cream	Matas	No 7 Protect and Perfect	Boots	-	Х	Х	-	-
Cream	Matas	Nuxe body	Nuxe	-	-	-	-	-
Cream	Estethique	Ô de Lancôme lait Pour le Corps	Lancome	-	-	-	-	-
Lotion	Matas	Olay quench plus firming Body lotion	ay quench plus firming Body X		-	-	-	
Lotion	Estethique	Ole henriksen Body Sleek Hydrating lotion	Ole Henriksen	-	-	-	-	-
Fatty cream	BodyShop	Olive Body Butter	BodyShop	Х	х	-	-	-
Lotion	Matas	Organic Goodies Seize the day Body Lotion	-	-	-	-	-	-
Cream	Magasin	Origins	Origins	-	-	-	-	-
Cream	Estethique	Origins A perfect world	Origins	-	-	-	-	-
Cream	Estethique	Origins Modern Friction for the	Origins	-	-	-	-	-

Category	Purchasing address (retailer)	Product name	Manufacturer / Importer	Cyclomethicon e	Propylparaben	Butylparaben	Isobutyl paraben	Triclosan
		Body						
Cream	Magasin	Paradisiac Pink Pepperpod	Molton Brown	-	Х	-	-	-
Fatty cream	BodyShop	Pink Grapefruit Bodybutter	BodyShop	Х	х	-	-	-
Cream	Matas	Plaisir Body Cream	Plaisir	-	-	-	-	-
Lotion	Matas	Plaisir Body Lotion	Plaisir	-	-	-	-	-
Cream	Matas	Professor Lange Lavandal Skin Treatment	-	-	-	-	-	-
Cream	Matas	PSO lotion No 12	-	-	-	-	-	-
Cream	Matas	Ren Clean bio active Skincare Marroccan Rose otto Body Cream	-	-		-	-	-
Lotion	Føtex	Revlon Natural Honey - moisturing lotion	Revlon	-	х	-	-	-
Lotion	http://www.t heorganicph armacy.com /shop/body/r ose_body_loti on	Rose Body Lotion	The Organic Pharmacy 		-	-	-	
Lotion	Brugsen	Sanex – Bodylotion	Colgate Palmolive Europe	-	-	-	-	-
Fatty cream	BodyShop	Satsuma Body Butter	BodyShop	х	х	-	-	-
Lotion	Matas	Seba Med Moisturizing Body lotion	-	-	-	-	-	-
Fatty cream	BodyShop	Shea Body Butter	BodyShop	Х	х	-	-	-
Cream	Magasin	Shiseido Replenishing Body Cream	Shiseido X		-	-	-	
Fatty cream	SuperBest	Skin O'care – Kopattesalve	Unknown	-	х	-	-	-
Cream	Magasin	Summerhill	Crabtree & Evelyn	-	Х	Х	Х	-
Cream	Magasin	travel Reviving Cempaka	Molton Brown	-	-	-	-	-
Cream	Netto	Vanderbilt	-	-	-	-	-	-
Lotion	Brugsen	X-tra – hudlotion	Produced for Coop	-	-	-	-	-

"x" states that the substance is mentioned in the ingredients list of the product

 $"\mathchar`-"$ states that it is checked for the selected substance, but it is not mentioned in the ingredients list of the product

The list is not exhaustive but gives a very good indication of the size of this market.

A total of 116 moisturising creams were surveyed. Nordic Ecolabelled products or products marketed as "paraben free" have not been included (although other suspected endocrine disruptors might be found in the "paraben free" ones).

6 moisturising creams/lotions were found containing cyclomethicone corresponding to14% of the surveyed products.

43 moisturizing creams/lotions were found containing parabens corresponding to that 37% of the surveyed products contain one or more of the parabens focused on in this project. 42 creams/lotions containing propylparaben corresponding to 36%,

15 creams/lotions containing butylparaben corresponding to 13%, and 14 creams/lotions containing isobutylparaben corresponding to 12%.

No moisturising creams/lotions were found with a content of the ingredient triclosan, and the four UV-filtres OMC, 4-MBC, 3-BC and BC-3.

3.7.5 Price

The price for each product is used to ensure that both cheap and expensive products are collected for analyses, but since these products are not being analysed because the information can be found by reading the lists of ingredients, the price is not relevant.

3.7.6 Where is it sold?

It appears from Table 3-15 that the products are sold in a variety of different types of shops such as supermarkets, pharmacies, department stores, health shops, and Internet purchases are also very much a possibility.

3.7.7 Market shares

Figures from the Trade Association SPT show that sales of the group of skin care products, ie. both face products and body lotions in the cosmetics industry in 2010, are divided as follows among the different brands. The figures show turnover in DKK:

1.	Biotherm:	53,326
2.	Clinique:	41,415
3.	Lancôme:	36,488
4.	Clarins:	31,573
5.	Origins:	26,781
6.	Elizabeth Arden:	17,059
7.	Estée Lauder:	16,788
8.	Christian Dior:	8,146
9.	Shiseido:	7,906
10.	Helena Rubinstein:	5,408

Body lotions constitute approx. 32% of the group of skin care products.

Various distributors of this product group were also contacted, and this way the project group has obtained information on the best selling/most popular types. This information is, however, confidential.

3.7.8 How much is sold?

It is not possible via Statistics Denmark (Statistics Bank) to see the number of body lotions/moisturising creams sold every year. Figures for lotions/creams could not be found in the Statistics Bank. But figures from the Trade Association SPT show that the cosmetics industry in 2010 sold skin care products for 1,517 million DKK. Skin care products account for 28% of the market share among other groups, which constitute skin care for men (2%), make-up (21%) women's fragrance (28%) and men's fragrance (21%) (SPT 2011a; SPT 2011b).

3.7.9 Selection of products for analyses

It was decided not to analyse pregnant belly creams and moisturising creams for their content of the selected ingredients, as the maximum allowed concentrations in cosmetic products are used in the risk assessment as a rule.

It is desirable, however, to make an analysis of the products containing the ingredient cyclomethicone in order to assess the products' contents of D4, in the absence of a maximum allowable concentration for cyclomethicone/D4 in cosmetic products in the Cosmetics Directive. To be able to make an exposure assessment of this substance, an analysis is necessary.

16 products with a content of cyclomethicone were found, of which 10 were analysed. Critera for the selection of the 10 products are:

- at least 1 product per manufacturer is analysed
- in case of fragrance variants, only 1 product is selected for analysis, because the basic recipe for the product is presumed to be the same for all fragrances, and thus most likely also the concentration of cyclomethicone

3.8 Sunscreen

3.8.1 Definition of the product group

Sunscreen may be used by the target group during the summer periods and may also be used when skiing. Exposure to the substances contained in the sunscreen lotion takes place via a large contact surface.

This survey only focuses on sunscreens for adults, which means that products sold specifically for children, ie. "kids", "children", "baby" or "junior", are excluded from the survey. The target group may have contact with sunscreens marketed for children, if they already have a child or by other means, but this exposure is not addressed in this project.

The survey is limited only to address products that are not labeled with the Nordic Ecolabelled. Nordic Ecolabelled cosmetics must not contain ingredients included on the EU list of suspected endocrine disruptors. Therefore, Nordic Ecolabelled products are not relevant for this project.

As a basis has been used a survey conducted by Information Centre for Environment and Health (IMS) in spring 2011 of sunscreens on the Danish market, in which 32 sunscreens have been surveyed and their ingredients assessed (IMS 2011). Eight of these sunscreens are Nordic Ecolabelled and are therefore not included in this survey. The survey of this project complements IMS' survey with additional products found on the market in autumn 2011.

3.8.2 How is knowledge obtained

The Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries (SPT) was approached in order to survey the sunscreens on the market and to obtain a better knowledge of the amount (concentration) of the selected suspected endocrine disruptors in the products. This unfortunately gave no results.

The Trade Association also informed that sunscreens typically have a new formulation each year; i.e. the identified sunscreens might be obsolete next year by the time of the information campaign.

Coop, Dansk Supermarked, Matas and pharmacy chains (Apotekerforeningen, *dit*apotek and A-apoteket) were contacted regarding brands/trade names of the most frequently sold products.

Via Google was searched for information about sunscreens on the Internet. This was done in order to obtain general information about the types of suncreens on the market, and also to identify a number of webshops selling sunscreens.

The primary method of surveying the market for sunscreens has been to visit different shops, such as perfumeries, convenience shops and pharmacies, where relevant products have been photographed (front/back) to identify ingredients. A number of retail shops were visited:

- Føtex
- Bilka
- Kvickly
- Aldi
- Matas
- Apoteker

- Magasin
- Illum
- Estethique
- Urtehuset
- Helsehuset

Then, the lists of ingredient were studied and the contents of the relevant, selected substances were listed.

3.8.3 Categories

There are two general groups of sunscreen: lotion/cream or spray. In the survey there has been no further categorisation of the products.

3.8.4 Brands/products

Sunscreens typically contain either a physical UV-filter (titanium dioxide), a chemical UV-filter or a combination of both for protection against UV-radiation from sunlight.

Table 3-16 shows a list of the surveyed sunscreens of this project. Autumn is not a good time for identifying sunscreens, because many convenience stores have taken sunscreens off the shelves at this time. Therefore, parts of the survey are based on a survey of sunscreens on the Danish market in spring 2011 conducted by the Information Centre for Environment and Health (IMS 2011), which identified a total of 24 products falling within the criteria of this survey. By visits to several different shops, the survey from spring 2011 was expanded by 9 other sunscreens, so now there is a total of 33 sunscreens included in the survey.

Table 3-16 Sunscreens found partly in shops, and partly on the internet in spring 2011 and	
autumn 2011 (some data is based on a survey of sunscreens made by IMS(IMS 2011))	

Purchasing address (retailer)	Product name	Manufacturer / Importer	Cyclo- methicone	Propylparaben	Butylparaben	Isobutyl paraben	Triclosan	OMC	4-MBC	3-BC	BC-3
Pharmacies	Aco Moistudrising Sun Spray	Aco Hud Nordic AB	-	-	-	-	-	-	-	-	-
Føtex	Ambre Solaire Clear Protect Transparent Body Protection	Garnier Paris	-	-	-	-	-	-	-	-	-
Mornatur.dk	AnMa Sololie SPF 14	AnMa Naturprodukt	-	-	-	-	-	-	-	-	-
Urtehuset*	Annemarie Börlind Sun Fluid SPF 10	Annemarie Börlind	-	-	-	-	-	-	-	-	-
Pharmacies	Avène EAU Thermale Moderate Protection Spray SPF 20	Pierre fabre/ Apotekernes A.M.B.A	Х	-	-	-	-	-	-	-	-
Magasin	Biotherm Lait Solaire	Biotherm	-	-	-	-	-	-	-	-	-
Estethique*	Christian Dior Beautyfying protective Suncare SPF 15	Christian Dior	-	-	-	-	-	Х	-	-	-
Estethique*	Clarins Sun care soothing cream moderate protection SPF 20	Clarins	x	-	-	-	-	Х	-	-	-
Cliniderm	Cliniderm, Clear protection Transparent Sun Spray	Aco Hud Nordic AB	-	-	-	-	-	-	-	-	-
Matas	Clinique Face/Body Cream SPF 20	Clinique/Estee Lauder	-	-	-	-	-	-	-	-	-
Illum	Decléor, Protective hydrating milk	Decléor	-	-	-	-	-	х	-	-	Х
Magasin	Dermalogica Multivitamin Sunblock	Dermalogica	-	Х	-	-	-	-	-	-	-
Urtehuset*	EcoCosmetics Solcreme SPF 15	EcoCosmetics	-	-	-	-	-	-	-	-	-
Estethique*	Estee lauder Bronze Goddess SPF 15	Estee Lauder	-	-	-	-	-	-	-	-	Х
Helsehuset	Juhndahl Sollotion	CosMedic Care/PharmaScandi a	-	-	-	-	-	Х	-	-	-
Pharmacies	La Roche-Posay, Sun Sensitive skin	La Roche-Posay	-	-	-	-	-	-	-	-	-

Purchasing address (retailer)	Product name	Manufacturer / Importer	Cyclo- methicone	Propylparaben	Butylparaben	Isobutyl paraben	Triclosan	OMC	4-MBC	3-BC	BC-3
Estethique*	Lancaster fast Tan optimizer Shimmering velvety cream SPF 15	Lancaster	-	-	-	-	-	-	-	-	-
Matas	Lancôme Sôleil DNA Guard SPF 15	Lancôme	-	-	х	-	-	-	-	-	-
Føtex	L'Oréal Solar Expertise, Milk Spray Mist SPF 20	L'Oréal Paris	-	-	-	-	-	-	-	-	-
Lrworld.dk	LR Aloe Vera Sun Care SPF 20	LR health and Beauty systems GmbH	-	-	-	-	-	-	-	-	-
Matas*	Matas Sol Lotion SPF 30	Matas	-	-	-	-	-	-	-	-	-
Urtehuset	Melissa Solbeskyttelses- creme SPF 20	Melissa NaturKosmetik ApS	-	-	-	-	-	-	-	-	-
Bilka	Nivea Sun Invisible Prtotection Transparent Spray SPF 20	Beiersdorf	Х	-	-	-	-	-	-	-	-
Aldi	Ombra Sun Care Sol Spray	Emil Kiessling GmbH	-	-	-	-	-	-	-	-	-
Matas	Piz Buin Allergy Lotion SPF 15	Johnson & Johnson UK	-	-	-	-	-	-	-	-	-
Matas	Rieman P20 solfilter	Riemann & CO A/S	-	-	-	-	-	х	-	-	-
Estethique*	Shiseido Extra Smooth Sun protection Cream spf 30	Shiseido	Х	-	-	-	-	-	-	-	-
Illum	Shiseido Sun protection Sol Lotion	Shiseido	х	-	-	-	-	-	-	-	-
Føtex*	Sun Balance Sunlotion SPF 30	Dansk Supermarked gruppen	-	-	-	-	-	-	-	-	-
Mlmodel.dk	TIO-Solcreme "middelblocker"	Shangri-La	-	-	-	-	-	-	-	-	-
Urtehuset	UV Bio Økologisk solcreme SPF 20	UV Bio/ Alpha Cosmetics A/S	-	-	-	-	-	-	-	-	-
Pharmacies	Vichy Capital Soleil SPF 20	VICHY	-	-	-	-	-	-	-	-	-
Yves-Rocher.dk	Yves Rocher, Fugtgivende beskyttende Lotion	Yves Rocher, France	-	Х	-	-	-	Х	-	-	-

* Sunscreens identified autumn 2011 and thus extended for the survey from spring 2011

"x" states that the substance is mentioned in the ingredients list of the product "-" states that it is checked for the selected substance, but it is not mentioned in the ingredients list of the product

Six sunscreens contain the UV-filter OMC corresponding to 18% of the identified products, and two sunscreens contain the UV-filter benzophenone-3 corresponding to 6% of the identified products. No sunscreens containing the UV-filters 4-MBC and 3-BC were found. Therefore, 4-MBC and 3-BC are deleted from the following exposure calculations and the overall risk assessment.

Two sunscreens contain propylparaben, and one sunscreen contains butylparaben corresponding to that 9% of the identified sunscreens contain one of the selected parabens.

It is likely that many will be exposed to substances in sunscreens bought abroad, as the need for sunscreens typically arises during stays in countries where the solar radiation is considerably stronger than in Denmark. Here, the ingredients may be different from those seen on the Danish market.

3.8.5 Price

The price for each product is used to ensure that both cheap and expensive products are collected for analyses, but since these products are not being analysed because the information can be found by reading the lists of ingredients, the price is not relevant.

3.8.6 Where is it sold?

It appears from Table 3-16 that the products are sold in a variety of different types of shops such as supermarkets, pharmacies, department stores, health shops, and Internet purchases are also very much a possibility.

3.8.7 Market shares

Various vendors of this product group have been contacted, and the project team has obtained information on the best selling/most popular types. This information is, however, confidential.

3.8.8 How must is sold?

It is not possible via Statistics Denmark (Statistics bank) to see the amount of sunscreens sold each year. No figures for sunscreens were found in the Statistics bank.

3.8.9 Selection of products for analysis

It was decided not to analyse pregnant belly creams and moisturising creams for their content of the selected ingredients, as the maximum allowed concentrations in cosmetic products are used in the risk assessment as a rule.

It is desirable, however, to make analyses of the products containing the ingredient cyclomethicone in order to assess the products' contents of D4, in the absence of a maximum allowable concentration for cyclomethicone/D4 in cosmetic products in the Cosmetics Directive. To be able to make an exposure assessment of this substance, an analysis is necessary.

All products in the survey with cyclomethicone stated in their ingredients lists are analysed for their content of D4.

4 Exposure considerations

4.1 Relevant data for use in the migration analyses and the exposure considerations

In connection with migration analyses and exposure calculations, it was considered in which exposure scenarios the 6 tested product groups will be included (migration analyses have not been performed on cosmetic products), and also the duration of exposure for the target group (Table 4-1). These time estimates have been used in the migration analyses (see Section 5.2.3).

Table 4-1 Overview of relevant migration analyses compared with the exposure period of the 6 product groups, for which analyses are carried out. Surface areas are based on (Nordic Exposure Group 2011)

Product groups	Relevant migration analyses	Exposure period ¹⁾ (Application/contact, how often?)	Which/how extensive a part of the body is exposed?
Sneakers	Sweat (inside of shoe)	Analysis for a total of 10 hours ²) <u>Contact time:</u> Minimum: ½ hour per day. Maximum: 10 hours per day. 10 hours a day for persons, who always wear sneakers, cover on average an 8 hour working day and transportation to/from work and shopping and sports/leisure. In addition, 10 hours/weekend day for activities outside the home (gardening, shopping, sports, transportation, visiting, cafe visits, etc.). The estimate is based on the following figures: On average, people stay indoors between 80 and 90% of the day (Danish EPA 2007). This corresponds to between 19.2 and 21.6 hours per day.	Feet = 0.122 m ²
Handbags of synthetic leather	Sweat (outside of shoe)	Analysis for a total of 2 hours ²) <u>Contact time</u> 2 hours per day 1 hour average daily skin contact with hand + forearm in connection with transportation to/from work, shopping and sports/leisure	$\frac{1}{2}$ hand = $\frac{1}{2}$ x $\frac{1}{2}$ x 0.089 m ² = 0.022 m ² $\frac{1}{2}$ forearm = $\frac{1}{2}$ x $\frac{1}{2}$ x 0.099 m ² = 0.025 m ² $\frac{1}{2}$ hand + $\frac{1}{2}$ forearm = 0.047 m ²
Sleeping mat Sports use	Sweat (outside/cros s section of sleeping mat)	Analysis for a total of 2 hours ²) <u>Contact time:</u> 1 hour per day 1 hour average daily skin contact with the upper or lower side of the body in connection with sports/leisure covers on average 1 hour of daily exercise during the week (or a total of 7 hours/week) (DHI estimate)	½ x ½ body surface = 0.46 m ²

Produc	t groups	Relevant migration analyses	Exposure period ¹⁾ (Application/contact, how often?)	Which/how extensive a part of the body is exposed?
Sleeping mat Tent recreational use		Sweat (outside/cros s section of sleeping mat)	Analysis for a total of 8 hours ²⁾ <u>Contact time:</u> 8 hours per day for 7 days 56 hours within a short period or per year average skin contact with ½ body surface (upper or lower side), equivalent to one week of vacation/year (tent camp, etc.) sleeping on air mattress/sleeping mat	Area corr. to ½ x ½ body surface = 0.46 m ²
		Sweat (outside/cros s section of covers)	Analysis for a total of 3½ hours ²) <u>Contact time:</u> 3½ hours per day. 3½ hours average daily skin contact with the inside of the hand, and also the cheek, in connection with text messages, phone calls, online searches, etc.	Area corr. to the lower side of a hand, i.e. ½ x ½ x 0.089 m ² = 0.022 m ²
Antib acteri al clothi ng	Panties	Sweat	Analysis for a total of 23 hours ²⁾ <u>Contact time:</u> Maximum: 23 hours per day Maximum 23 hours average daily skin contact with panties, exclusive dressing, bathing, sex, etc.	Calculated as 1/5 part of the body = 0.131 m ² (1/5 x 0.654 m ² = 0.131 m ²)
	Stockings	Sweat	Analysis for a total of 16 hours ²) <u>Contact time:</u> Maximum: 16 hours per day Maximum 16 hours per day wearing stockings based on 24 hours minus 8 hours of sleep. It also covers an average for an 8 hour working day and transportation to/from work and shopping and sports/leisure. Furthermore, weekend days for activities in/outside the home (gardening, shopping, sports, transportation, visiting, cafe visits, etc.)	Feet = 0,122 m ² Lower legs = 0,18 m ² Feet + ½ lower leg = 0.212 m ²
	Biking pants	Sweat	Analysis for a total of 5 hours ²) <u>Contact time:</u> Maximum: 1 hour per working day. Maximum 5 hours per week wearing cycling shorts covering on average 1 hour daily biking to/from work on weekdays (or total of 5 hours/week).	18% of the body surfact for sports pants = $0.18 \times 1.85 \text{ m}^2 = 0.333 \text{ m}^2$ (ASHRAE, 1984, s. 67 of 161) Calculated as 1/5 parts of the body + 2/3 of the thigh = 0.246 m^2 (1/5 x 0.654 m ² = 0.131 m^2 ; 2/3 x 0.172 m ² = 0.115 m ²)
	Sweat underwea r/ski underwea r	Sweat	Analysis for a total of 9 hours ²) <u>Contact time:</u> 2 scenarios: Maximum: 1 hour per day (sports) Maximum: 9 hours per day (skiing) Maximum ½ hour per day wearing sweat underwear covers the average for ½ hour of daily exercise/manual work during the week (or a total of 3 ½ hours / week).	Calculated as the whole body surface minus feet, hands and head = 1.525 m ² (The whole body surface = 1.85 m ² , feet = 0.122 m ² , hands = 0.089 m ² , head = 0.114 m ²)

Product groups	Relevant migration analyses	Exposure period ¹⁾ (Application/contact, how often?)	Which/how extensive a part of the body is exposed?
Work gloves/ household gloves Professional use	Sweat (inside/cross section of glove)	Analysis for a total of 6 hours ²) <u>Contact time:</u> 6 hours daily for 5 days per week 30 hours average per week skin contact with the whole hand in connection with professional work (e.g. painting, cleaning, etc.)	Hands = 0.089 m ²
Work gloves/ household gloves Leisure use	Sweat (inside/cross section of glove)	<u>Contact time:</u> 7 hours per week 7 hours average per week skin contact with the whole hand in connection with gardening, DIY work at home, washing, cleaning, etc. 6 hours/week on average, from persons with frequent use of gloves per day for cleaning, washing, gardening, etc. to rare use of gloves.	Hands = 0.089 m ²

The longest exposure time is used in the analyses. Based on the results from these, the shorter exposure times are calculated. E.g. for the gloves, the migration analyses are performed for 7.4 hours/day and on the background of these results, the corresponding exposure for 6 hours/week is calculated.
 Indicates the exposure time used for the migration analysis. E.g. "Analysis for a total of 3 ½ hours" for sleeping mats: to ensure a migration from the material, which is also adequate for a concentrated total weekly use. When the calculations are carried out, the migration will be distributed on ½ hour per day to accommodate the average.

5 Analyses

5.1 Quantitative analyses

The aim of the performed analyses is to examine whether the selected product groups contain the selected chemical substances. The analysis program consists of quantitative analyses of extractable substances and of quantitative determination of substances migrating out of the products in sweat. The program is set out in relation to different exposure scenarios depending on the specific products, so the focus is on the parts of the products with the most frequent skin contact.

Quantitative content analyses have been made of selected substances and products in order to obtain knowledge of the contents of the selected substances in the products, and migration analyses to know the quantities of the selected substances for which the target group is likely to be exposed in contact with the product (i.e. what migrates out of the product).

In each exposure scenario, contact with skin is simulated using artificial sweat.

Table 5-1 shows an overview of which substances have been analysed for in which products. Duplicate determinations have been made for all analyses.

Product group	Phthalates and bisphenol A	Triclosan	Nonylphenol	Octamethylcyclotetra- siloxane (D4)	Parabens	Sun filters	Sum quantitative analyses
Sleeping mats	10						10
Cell phone covers	20			20			40
Work gloves/household gloves	11			8			19
Handbags of synthetic leather	10						10
Rubber shoe	9	9	9	9			36
Antibacterial clothing		8	8	8			24
Sunscreens/body lotion							
Pregnant belly creams/ pregnancy oils				15			15
Total							154

5.1.1 Analysis method – quantitative analysis of extractable substances

5.1.1.1 Various consumer products – not cosmetic products

GC/MS was used to test for the presence of extractable volatile and semi-volatile organic ingredients in various selected groups of consumer products.

In Table 5-2 the analysis method is described with the calibrated individual substances.

substances	
Sampling	Refer to the sections for the products.
Sample preparation for	Extraction agent: dichloromethane, 4-20 ml.
analysis of extractable substances from the	Extraction: Min. overnight at room temperature. Then 1.5
	ml extraction liquid is extracted, 13.5 ml methanol is
materials	added to precipitate possible dissolved polymer material.
Internal standard	
Internal standard	DEHP-d4 (deuterated DEHP)
Standard series	Standard series of the following substances were
	prepared for the quantification of the substances:
	DEHP, DiNP, DBP, BBP, DNOP, bisphenol A, D4,
	nonylphenol and triclosan.
	If the extracts contained other phthalates, they could
	be quantified by one of the known ones with good
	approximation.
GC/MS-instrument	Perkin Elmer Clarus 600/MS
GC-parametres	Kolonne Elite-5 MS, 30 m x 0.25 mm id., 0,25 µm film
	thickness
	Carrier gas: Helium, constant pressure.
	Oven program: 80 °C for 2 min., 10 °C/min. to 150 °C, 18
	°C/min. to 300 °C
	Injection: 325 °C, split 20
MS-parametres	Scan mode: 45-650 m/z + SIMmode
	Solvent delay: 5 min.
Quantification limit	Refer to the tables stating the quantification limits
(estimated)	

Table 5-2 Method for quantitative analysis of selected extractable substances

When carrying out the quantitative analyses, problems occurred in some of the analyses - the sample material swelled in the extraction agent. To get a correct extraction, it was necessary to add much more extraction agent than normal, which means that the quantification limit was significantly higher than expected.

That does not mean, however, that it has been impossible to detect the selected substances in this quantification limit. The detection limit is lower than quantification limit, so for some samples the substances could be detected, but not quantified. In general, the detection limit is at least three times lower than the quantification limit; the exact value depends on the individual samples.

In the tables below, the selected substances detected at levels below the quantification limit have been marked. But the general picture is that none of the selected substances have been detected below the quantification limit (with the exception of bisphenol A in cell phone covers).

Bisphenol A and phthalates are investigated by the same analysis method. Therefore, all the product groups, which have also been examined for phthalates, have been analysed for bisphenol A, despite the fact that content of bisphenol A is only expected in the products of the polycarbonate plastic (which some cell phone covers consist of).

5.1.1.2 Cosmetic products

15 cosmetic products have been analysed for content of D4 (octamethylcyclotetrasiloxane, CAS 556-67-2).

The analysis method is an internal method of Eurofins, using extraction with subsequent analysis using GC/MS.

A known quantity of a representative sub-sample is taken from the sample. The sub-sample is extracted with dichloromethane added internal standards. The extract is analysed by gas chromatography with mass selective detection (GC/MS). The results are calculated with the response factor from a run of a standard series with octamethylcyclotetrasiloxane.

The detection limit for D4 in cosmetic products is set to 0.8 to 1 mg/kg with an analytical uncertainty Um (%) of 20-30%.

5.1.2 Results - quantitative analyses

The tables below show the results of the GC/MS analyses. The results are given in percentage of weight. Only substances identified in one or several of the products have been listed in the tables.

5.1.2.1 Cell phone covers

20 cell phone covers and/or screen protectors were examined for contents of:

- phthalates
- bisphenol A
- octamethylcyclotetrasiloxane D4

Where the cell phone covers are made of different materials, pooled samples were taken for the analyses.

The analysis results are shown in Table 5-3. The results are only mentioned, if content has been detected. The values for most products are below the quantification limit. The quantification limits were calculated individually per sample depending on the amount of sample and quantity of solvent used for analysis.

DEHP is only found in five products and DINP in one of these - all five products with contents above the quantification limit. Products with contents of DEHP or DINP are marked with dark grey background colour in the tables below. No other phthalates (DBP, DIPB, BBP, DPP, DnHP, DnOP) have been found in any of the products. D4 is not detected in any of the products. Depending on the product, the quantification limit for D4 is 0.05 to 0.4%.

There are trace amounts (amounts above the detection limit, but below the quantification limit) of bisphenol A in the extraction liquid from the following cell phone covers: M7, M8, M10, M12, M18 and M19. This is marked with light grey background colours in the row for bisphenol A in the tables below. A (very uncertain) level is stated in parentheses. There is a higher detection limit for the following cell phone covers: M4, M11, M14, M16, M18, M19 and M20 resulting from the swelling of the sample or use of a larger amount of solvent in order to cover the sample. The detection limit of these samples is approx. 0.05%.

			Product no								
Substance name	CAS-no	M7	M8	M10	M11	M12	M14	M16	M18	M19	M20
DEHP in %1	117-81-7	-	-	-	8	-	6	13	-	9	0.12
DiNP in %1	28553-12- 0	-	-	-	-	-	1,4	-	-	-	-
Bisphenol A in % ²	80-05-7	(0.08)	(0.1)	(0.1)	-	(0.06)	-	-	(0.16)	(0.05)	-

Table 5-3 Analysis results for extractable substances in cell phone covers. Results are given in percentage of weight

¹ Depending on product and phthalate the quantification limit is 0.04 - 0.15%.
² Depending on product the quantification limit for bisphenol A is 0.2 - 2%.
Bisphenol A was detected in some samples, but at much lower levels than the specified quantification limit.

Samples with phthalate levels above the quantification limit are marked with dark grey background colour. Samples with bisphenol A levels above the detection limit, but below the quantification limit, are marked with light grey background colour, and a probable level is indicated in parentheses.

5.1.2.2 Work gloves/household gloves

11 work gloves were examined for contents of:

- phthalates
- bisphenol A

Furthermore, 8 work gloves were examined for contents of:

• octamethylcyclotetrasiloxane D4

By analysis of work gloves made of multiple materials, sub-samples were taken for each of the different materials. If a glove consisted of three different materials, a sample from each of the three materials was mixed together into one sample, which has been analysed for contents of the selected substances. As far as possible, the sizes of the individual material parts represent the ratio between the material parts of the total product. This means that if a glove mainly consists of a given material, this material is represented by a larger sub-sample in the pooled sample. The reason for the pooling of the materials was the lack of funds in the project to conduct quantitative analyses for each material for all the selected products.

The results of the quantitative analyses of extractable substances are shown in Table 5-4. Results are only given when contents have been detected. H8, H9 and H10 were not analysed for D4, as these only contain plastic. In products H9 and H11, high contents of DiNP and DEHP, respectively, have been found. Products with identified contents above the quantification limit are marked with grey background colour in the table below. Neither DBP, DiBP, BBP, DPP, DnHP nor DnOP have been found in any of the products. Bisphenol A and D4 have not been found in any of the products. Depending on product the quantification limit for bisphenol A is 0.5 - 1%. Depending on product the quantification limit for D4 is 0.12 - 0.15%.

Table 5-4 Analysis results for work gloves/household gloves

		Proe	duct no
Substance name	CAS-no	H9	H11
DEHP in % ¹	117-81-7	-	26
DiNP in %1	28553-12-0	> 30	0.9

¹ Depending on product and phthalate the quantification limit is 0.1 – 0.2%. Samples with values above the quantification limit are marked with dark grey background colour. With the applied analysis method, it is possible to identify more phthalates than the selected substances. The chromatograms show that there is probably a terephthalate plasticiser in sample H10. This content has not been quantified.

5.1.2.3 Sleeping mats

10 sleeping mats were examined for contents of:

- phthalates
- bisphenol A

Samples for analysis of sleeping mats, representing all materials, were taken.

Only in product L5 content of one phthalate was found: DEHP. Neither DiNP, DBP, DiBP, BBP, DPP, DnHP nor DnOP have been found in any of the products. Depending on product and phthalate the quantification limit is 0.12 - 0.2 Bisphenol A has not been found in any of the products. Depending on product the quantification limit for bisphenol A is 0.6 - 1%.

Content of DEHP in L5 was 14%.

With the applied analysis method, it is possible to identify more phthalates than the selected substances. The chromatograms show that there is probably a terephthalate plasticiser in samples L1 and L7. This content has not been quantified.

5.1.2.4 Antibacterial clothing

8 pieces of antibacterial clothing were examined for contents of:

- triclosan
- nonylphenol and nonylphenolethoxylates
- octamethylcyclotetrasiloxane D4

Products made of more than one substance were analysed as follows:

- product AT7, the bra fabric was analysed, but not the straps
- product AT8, Biking pants: For examination of triclosan, only the padding material was analysed. For examination of nonylphenol and D4, the padding material and the standard fabric were pooled to a total sample

All values were below the quantification limit 0.15% for triclosan, nonylphenol and D4. Trace amounts of the substances below the quantification limit have not been found. Furthermore, nonylphenolethoxylates has not been found in any of the products.

5.1.2.5 Handbags of synthetic leather

10 handbags of synthetic leather were examined for contents of:

- phthalates
- bisphenol A

Samples for analysis of the synthetic leather bags were taken from the outside of the bag, i.e. the back and front of the bag, from the domination material of the bag.

The analysis results of the quantitative analyses of extractable substance are shown in Table 5-5. In HT7 contents of DEHP was found and in HT9 small amounts of DEHP and DBP were detected, and trace amounts of DiBP. This has been marked with grey background colour in the table below. Neither DiNP, DiBP, BBP, DPP, DnHP nor DnOP were found in any of the products. Bisphenol A was not found in any of the products. Depending on product the quantification limit for bisphenol A is 0.6 - 0.75%.

		Product no					
Substance	CAS-no	HT7	HT9 ²				
name							
DEHP	117-81-7	0	0.07				
in %1		ð	0.07				
DBP	84-74-2		0.04				
in %1		-	0.06				

Table 5-5 Analysis results for handbags of synthetic leather

¹ Depending on product and phthalate the quantification limit is 0.06 – 0.15%.

² Furthermore, trace amounts of DiBP was found.

5.1.2.6 Sneakers

9 sneakers were examined for contents of:

- phthalates
- bisphenol A
- octamethylcyclotetrasiloxane D4
- triclosan
- nonylphenol and nonylphenolethoxylates

Samples for analysis were taken from the inside of the sneakers, i.e. the inner sole and the inner lining. Material from the inner sole and the different types of inner lining materials were pooled to a total sample. However, with the exception that a maximum of two of the materials from the inner lining of the rubber shoe were taken for analysis. In the few cases where not all inner lining materials were analysed, the two main materials (in terms of area) were selected for pooled analysis.

The only phthalate found in product G7 was DEHP in trace amounts – level 0.06%.

Neither DiNP, DBP, DiBP, BBP, DPP, DnHP nor DnOP were found in any of the products. Depending on product and phthalate the quantification limit is 0.05 - 0.15%. Bisphanol A, D4, triclosan and nonylphenol were not found in any of the products. Depending on product the quantification limit for bisphenol A is 0.6 - 0.75%. The quantification limit for D4, triclosan and nonylphenol is 0.09 - 0.15%.

Nonylphenolethoxylates were not found in any of the products.

Besides the selected phthalates, the analyses showed possible trace amounts of DIDP, i.e. below the quantification limit of < 0.2 % in sneaker G4.

5.1.2.7 Cosmetic products

A total of 15 cosmetic products were analysed for the quantitative content of D4. The cosmetic products are selected based on the survey (as previously described). The only products selected for contents analysis are the ones stating "Cyclomethicone" on the list of ingredients, which may contain D4, as previously mentioned, but not necessarily do so (see Table 2-2).

The cosmetic products were divided in the following categories:

- body lotions (KB) 9 of the 16 products containing cyclomethicone were analysed
- pregnant belly creams (KM) 1 product was analysed
- sunscreens (KS) all 5 products containing cyclomethicone were analysed

The analysis results for the quantitative content of D4 in body lotions, pregnant belly creams and sunscreens appear from Tables 5-6 and 5-7. It is seen that for five products (all body lotions) a content of D4 could not be measured (i.e. levels were below the detection limit, which is between 0.8 and 1 mg/kg depending on the product), in spite of the declared content of cyclomethicone. A declared content of cyclomethicone, however, only means that D4 *may* be contained.

Nine other products had a low content of D4 of below 30 ppm or 0.003%. Only one product (a sunscreen) had a higher content of D4 of 3400 ppm or 0.34%.

			Product no								
Substanc	CAS-	KB1	KB2	KB3	KB4	KB5	KB6	KB7	KB8	KB9	
e name	no										
D4 in	556-	2.2	~ 1	<	3.4	0,8	~ 1	~ 1	2.6	/ 1	
mg/kg	67-2	2.2	~ 1	0.9	5.4	0,0	\ 1	\ 1	2.0	\ 1	

Table 5-6 Analysis results for body lotions (KB)

Table 5-7 Analysis results for pregnant belly creams (KM) and sunscreens (KS)

		Product no									
Substanc	CAS-	KM10	KS11	KS12	KS13	KS14	KS15				
e name	no										
D4 in	556-67-	30	3400	4.1	12	1.9	4.3				
mg/kg	2	50	5400	7.1	12	1.7	4.5				

5.2 Migration analyses

5.2.1 Selection of products for migration analyses

All products with identified contents of the selected substances – even in trace amounts – were selected for migration analyses. Table 5-8 shows the number of products in the individual product groups, for which migration analyses have been made. Since only contents of phthalates and bisphenol A were observed in the products, the analyses are calibrated for these substances only.

Table 5-8 Overview of the number of migration analyses carried out for the various product groups

	Phthalates and
Product group	Bisphenol A
Sleeping mats	1
Cell phone covers	11
Work gloves/household gloves	2
Handbags of synthetic leather	2
Sneakers	3
Antibacterial clothing	0
Sunscreens/body lotions	0
Pregnant belly creams/pregnancy oils	0
Total number of migration analyses	19

5.2.2 Description of migration analyses

The artificial sweat simulant used is described in ISO 105 E04, which is used in connection with the ØKO-TEX certification, and which is used in former EPA projects. The sweat simulant in ISO 105 EO4 consists of 1-histidine-monohydrochloride-1-hydrate, sodium chloride, sodium dihydrogenphosphate and sodium hydroxide for adjustment of pH to pH 5.5.

The migration was carried out at 37 degrees, which is close to the body temperature and is used in EN-71-3 and ISO 105 E04. When carrying out the migration tests, the simulant is preheated before being added to the products. Samples are placed in a temperature controlled oven $(37 \pm 3 - 3 \text{ degrees})$ by stirring for the number of hours described in Section 7.3 regarding relevant data for exposure calculations. Stirring was used to simulate a dynamic extraction.

A sample of approx. 25 cm² surface area (normally both front and back contribute to the area) for 50 ml of simulant, which is the amount used during the migration analyses carried out in a similar EPA project on 2-year-old children's exposure to chemicals. Samples were withdrawn in one piece, to simulate the use situation in the best way. The volumes of the samples ranged from 0.1 to 4 g depending on the material being analysed. The aqueous phase was decanted from the sample pieces and examined with GC-MS with solid phase micro extraction (SPME) of compounds migrated into the aqueous phase with 7 μ m PDMS fibre, after the addition of 25% w/v NaCl. Roughly the same GC MS method was used as indicated in Table 5-2, with the necessary modifications.

5.2.3 Results - migration analyses

The result of the migration analyses was that all values were below the quantification limit. No traces of phthalates or bisphenol A were observed in the migration liquids for any of the products. The quantification limit typically was approx. $4 \mu g/cm^2$. Further details are given in Table 5-9.

Product group	Products selected for migration analyses	Quantification limit for phthalates and bisphenol A
Cell phone cover	M7, M8, M9, M10, M11, M12, M14, M16, M18, M19, M20	The quantification limits were calculated individually per sample depending on the test area. Typically, the level was 4 µg/cm ² , for M8, however, 6.5 µg/cm ² .
Work gloves	H9, H11	The quantification limits were calculated individually per sample depending on the test area. Typically, the level was 4 µg/cm ² .
Sleeping mats	L5	The quantification limit was 4 μ g/cm ² .
Handbags	НТ7, НТ9	The quantification limits were calculated individually per sample depending on the test area. Typically, the level was 4 µg/cm ² .
Sneakers	G7 (inner sole), G7 (heel), G7 (sides/flap)	The quantification limits were calculated individually per sample depending on the test area. Typically, the level was 4 µg/cm ² .

Table 5-9 Products selected for migration analysis

6 Hazard assessment

6.1 Selection of No and Lowest Observed Adverse Effect Levels (NOAELs and LOAELs)

The focus of the cumulative risk assessment in this project is substances with potential endocrine disrupting effects. Therefore the assessments of NOAELs (No Observed Adverse Effect Levels) and LOAELs (Lowest Observed Adverse Effect Levels) are based on animal studies showing endocrine disruption. Therefore the NOAELs/LOAELs used in the risk assessment do not originate from the critical effects of the substances, which are normally used in the surveys on chemicals in consumer products conducted by the Danish EPA. It has been prioritised to use NOAELs/LOAELs used for endocrine disrupting effects in EU risk assessments, EFSA's opinions or other official risk assessments.

In the risk assessment, we have focused on the total evidence of the endocrine disrupting effect of each of the selected substances. Therefore, the selection of data was carried out in several stages:

- from the total available literature on the substance, it was determined whether the substance meets the criteria for endocrine disrupting effects, as described in Section 2. Relevance and sensitivity of the available studies and information from available risk assessment reports were evaluated
- NOAEL or LOAEL was selected based on the study or studies showing relevant effects at the lowest dose levels. In the following text and in Table 6-2 only data from the selected study/studies of each substance is presented, while the remaining evaluated background knowledge is not reviewed here
- using correction factors (further described below), NOAEL or LOAEL for a given effect was converted to the derived no-effect level (DNEL)

6.2 Assessment of endocrine disrupting effects

For <u>antiandrogenic effect</u>, NOAELs/LOAELs are based on different types of effects, all of which can be caused by an antiandrogenic mode of action. In male rats, these may be

- changes in testosterone production,
- changes in weight of male reproductive organs,
- histological changes in male reproductive organs,
- reduces semen quality
- or
- changes in some of the very sensitive early markers for antiandrogenic mode of action, namely reduced anogenital distance in males at birth or increased number of retained nipples in young animals
- Malformed genitals (hypospadia)

Some effects may be associated with both antiandrogenic and estrogenic mode of action (e.g. delayed puberty, changes in testicular weight or semen quality), but appear here as an antiandrogenic effect, provided it is also shown that the substance has other effects that are clearly attributable to antiandrogenic mode of action, possibly at higher doses. Preferably, studies showing effects following exposure to the substance in fetal life have been applied. For a few substances, the NOAEL/LOAEL is selected based on studies with exposure of young or adult animals due to lack of specific studies of antiandrogenic effects in animal studies with exposure of pregnant animals. In these cases, there is also knowledge of antiandrogenic effects in other studies, such as screening test for antiandrogenic effect (the Hershberger assay) or cell-based studies. For other substances, it has been shown that if antiandrogenic effects are observed when exposing adult animals, antiandrogenic effects will also be observed by exposure during fetal life, and most often the effect will be observed at lower doses than by exposure of adults (Mahood et al., 2007). Therefore, it is considered relevant to use NOAELs / LOAELs for antiandrogenic effects in studies of young or adult animals. It may also be appropriate to include an additional assessment factor to extrapolate from a study with exposure of adult animals to a study with exposure of fetuses, which in some cases are more sensitive than adults. Such an additional assessment factor is however *not* used in the DNEL calculations, as fetuses in other cases may be partially protected from substances, to which the mother is exposed.

For <u>estrogenic effect</u>, NOAELs/LOAELs are based on different types of effects, which can be caused by an estrogenic mode of action, i.e.:

- changes in estrous cycle,
- reduced uterine weight in the uterotrophic assay and
- changes in the male reproductive system (e.g. changes in testicular weight, decreased semen quality or delayed puberty) for substances shown to be estrogenic in other studies, such as the uterotrophic assay or cell-based studies

Studies have been used, in which the effects are observed after exposure to the substance in utero, if they are found relevant. For several of these substances, however, NOAELs/LOAELs are from studies of animals dosed as young or adults, including so-called screening studies (e.g. the Uterotrophic assay). For other substances, it has been shown that if estrogenic effects of exposure of adult animals are observed, estrogenic effects will also be observed after exposure during fetal life. Therefore, it is considered relevant to use NOAELs/LOAELs for estrogenic effects from studies of young or adult animals. It may also be appropriate to include an additional assessment factor to extrapolate from a study with exposure of adult animals to a study with exposure of fetuses, which in some cases are more sensitive than adults. Such an additional assessment factor is however *not* used in the DNEL calculations, as fetuses in other cases may be partially protected from substances, to which the mother is exposed.

For <u>thyroid disrupting effects</u>, NOAELs/LOAELs are based on effects, which can be caused by a thyroid disrupting mode of action. The effect observed in most studies at the lowest dose is a reduction in the total T4 (thyroxine) levels in the blood Therefore a significant decrease in T4 has often formed the basis for selection of the NOAEL/LOAEL value. Substances that lower T4 in the blood can do so through a variety of thyroid disrupting mechanisms, and for most of the substances it is shown, that they at higher doses result in more and more severe thyroid disrupting effects, such as reduced T3 (triiodothyronine) levels, elevated TSH (thyroid stimulating endocrine) levels, increased weights and histological changes of the thyroid. For determination of NOAELs/LOAELs, both studies showing effects in pregnant and studies showing effects in non-pregnant animals are used, as the effects of thyroid hormones are assumed to occur at the same dose levels, independent of whether the animals are pregnant or not. Due to differences between the rat and the human thyroid systems, it has long been debated whether T4 reductions in laboratory animals are at all relevant to humans. However, experts in the field have in recent years argued that, especially when it comes to the potential impact of thyroid disruptors on the developing nervous system, measurements of T4 reductions in animals are guite relevant (Zoeller et al., 2007). Although significant physiological differences between the rat and the human thyroid systems, such as the type of binding proteins in the blood or the thyroid storage capacity of thyroid hormones, results in an observed faster reduction in T4 in the rat after exposure to a given endocrine disruptor than in humans, we do not know enough at present about the animal models to assess whether rats are more or less sensitive to the effects of reduced T4 (Crofton et al., 2005; Zoeller et al., 2007). As both species appear to be quite sensitive to the lack of T4 during brain development, and some of the same mechanisms seems to apply to both rats and humans (Crofton et al., 2005; Crofton 2008), this report rely on results showing reduced T4 levels in the selection of LOAELs and NOAELs.

6.3 Application of assessment factors

In previous surveys on chemicals in consumer products conducted by the Danish EPA, a calculation of the Margin of Safety (MoS) was used in the risk assessment of the estimated exposure concentration/dose in each study. Instead, REACH uses a Derived No Effect Level (DNEL)-value calculated from a dose factor (NOAEL or LOAEL) and relevant assessment factors (AF). The assessment factors to be used will depend on the study, on which the dose factor is based. From this, the effect specific DNEL value is calculated (ECHA 2010).

The effect specific DNEL value is calculated by use of the following formula:

Effect specific DNEL =
$$\frac{NOAEL}{AF_1 \cdot AF_2 \cdot ... \cdot AF_n} = \frac{NOAEL}{AF \ sum}$$

In certain cases where it has not been possible to determine a NOAEL value, a LOAEL value is used instead of a NOAEL value, and an assessment factor of 3 is applied for extrapolation from LOAEL to NOAEL. The calculated DNEL values can be found in table 6-2 and in the substance reviews on the following pages. The assessment factors are determined in accordance with the principles of the REACH guidance as indicated in Table 6-1.

Table 6-1 Assessment factors (AF) us	used in the calculation of DNEL
--------------------------------------	---------------------------------

Parameter	Value	Applied assessment factor
Interspecies	Allometric scaling.	4 for rats
	Correction for differences in	7 for mice
	metabolic rate per kg body weight.	2.4 for rabbits
		2 for monkeys
Interspecies	Remaining interspecies differences	2.5
Intraspecies	Intraspecies differences	10
Dose response	LOAEL to NOAEL, if LOAEL is used, because NOAEL has not been determined	3

6.4 Conversion to internal dose

When doses administered in animal studies are compared to human exposure data, it is relevant to use internal doses for both animals and humans. The internal dose is the amount of substance absorbed into the body, and an absorption fraction must be used to determine such an internal dose. For most of the substances in this project, there is insufficient data to determine internal doses in the animal studies. The ideal data material would be a calculation of the bioavailability of the substance by comparing the amount of substance in the blood by oral dosing with the amount of substance in the blood measured by intravenous dosing. This percentage of the bioavailability of the substance in the animals could then be compared with measurements of the amount of the substance in the blood of humans exposed to a known dose, e.g. orally or through the skin. Such data is, however, sparse for both animals and humans. In risk assessments the internal dose in laboratory animals is often assumed to be 100% of the dose given to the animal, e.g. through the feed.

In this project 100% absorption of substances in laboratory animals exposed by oral or subcutaneous dosing is generally assumed. For both humans and animals, 100% absorption of the substance by oral ingestion will presumably result in an overestimation of the internal exposure, but these uncertainties have opposite impact on risk assessment. An overestimation of internal exposure of laboratory animals will result in an underestimation of human risk, while an overestimation of internal exposure in humans will lead to an overestimation of human risk. An application of 100% absorption for both animals and humans is thus an assumption that the same oral absorption fraction is observed in animals and humans. For some substances, we used lower oral intake for laboratory animals, namely in the cases where an EU risk assessment of the substance uses a lower absorption than 100%. This applies to the following substances: DEHP, DINP, and nonylphenol. The used oral absorption fractions are specified for each substance in Table 6-2.

For substances with an oral exposure of humans (via food or dust), the oral absorption fractions specified in Table 6-2 will be used as well.

For dermal exposure of humans, the absorption fractions specified in the section on exposure from products are applied. It may be noted that for certain substances, with no data on oral bioavailability, an oral absorption fraction of 100% may be unrealistically high, and the calculated DNEL for the animal study thus becomes too high. This may result in an underestimation of the risk, when an absorption fraction of less than 100% for the dermal absorption in humans is used simultaneously (see further description of the risk assessment in section 8).

6.5 Data selected for hazard assessment

The following section shows the data used as the basis for calculating DNELs for each of the individual substances included in the project.

Table 6-2 gives an overview of the data used for the calculation of DNELs. A thorough review of the available literature concerning reproductive effects and endocrine disrupting effects has been conducted for all the substances. The experimental animal study underlying the DNEL determination is specified with the specification of NOAEL, LOAEL, observed effect and factors used for conversion of external to internal doses, where possible. In the text relating to the hazard assessments of each substance additional references relevant to the determination of the DNEL is included. Further references supporting the evidence for the endocrine disrupting effects of the individual substances, such as in vitro studies of interaction with hormone receptors, are also included. It should be emphasized that for the reproductive adverse effects, it can rarely be clearly determined, whether the effects are due to an antiandrogenic or estrogenic mode of action. Therefore, a choice has been made as to whether the determined DNEL is called:

- DNEL_E (for substances mainly with estrogenic effect)
- DNEL_{AA} (for substances mainly with antiandrogenic effect)
- DNEL_T (for substances disrupting the thyroid hormone system)

For each substance the robustness of the given data for the endocrine disrupting effects of the substance in laboratory animals is evaluated. Generally, the evidence is perceived as stronger when there are several suitable animal studies showing reproductive adverse effects, which are compatible with an endocrine mode of action, when there is no opposing evidence from other animal studies, and when appropriate *in vitro* studies also show endocrine disrupting effects. It must be emphasised that all the substances in question are *suspected* of being endocrine disruptors in humans, although robust data shows that they have endocrine disrupting effects in laboratory animals.

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
DEHP	117-81-7	AA	5	10	2.5*4*10 = 100	0.05	0.5	25	↓ AGD, ↑ Nipples, rat – Reduced testicular weight, histological changes in testes, rat	Combined NOAEL/LOAEL from two studies. Used in EU RAR and EFSA	(Wolfe et al., 2003; Christiansen et al., 2010)
DEHP	117-81-7	Т	37.6	375.2	2.5*4*10=100	0.376	0.5	188	Thyroid histology; 13-week study in rats		(Poon et al., 1997)
DiNP	28553-12-0	AA	300	600	2.5*4*10 = 100	3	0.5	1500	↑ Nipples, rat	Based on highest NOAEL under lowest LOAEL and because effects in EU RAR are not endocrine disrupting	(Boberg et al., 2011)
DBP	84-74-2	AA	ND	2	200 (cf EFSA 2005)	0.01	1	10	Histological changes in testes, changes in breast tissue, rat	EFSA 2005	(Lee et al., 2004)
Dibp	84-69-5	AA	125	250	2.5*4*10 = 100	1.25	1	1250	↓ AGD, ↑ Nipples, rat		(Saillenfait et al., 2008)
BBP	85-68-7	AA	50	250	2.5*4*10 = 100	0.5	1	500	↓ AGD, rat	EFSA	(Tyl et al., 2004)
DPP	131-18-0	AA	33	100	2.5*4*10 = 100	0.33	1	330	↓ AGD PND2, ↓ expression of steroid genes in fetal testes, rat	↑ Nipples at next dose	(Hannas et al., 2011b)
DnHP	84-75-3	AA	50	125	2.5*4*10 = 100	0.5	1	500	↓ AGD, increased frequency of malformations, rat	↑ Nipples, delayed sexual maturation, reduced reproductive organ weight at 250 and above	(Saillenfait et al., 2009b)

Table 6-2 Overview of endocrine disrupting effects, NOAEL, LOAEL, and internal dose DNEL for the substances included in the project (4-MBC and 3-BC have been excluded due to lack of exposure)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
DnHP	84-75-3	Т	Not deter- mined	1824	2.5*4*10*3=300	6.1	1	6100	Thyroid histological effects, hyperactivity, rat 3, 10, 21 days	Noted "Sufficient data" in the NTP monograph based on this study	(Hinton et al., 1986)
DnOP	117-84-0	T	36.8	350	2.5*4*10=100	0.368	1	368	Thyroid histological effects in 13 weeks study in rats	Cited in ECHA review and NTP_CERHR monograph 2003. Thyroid effects also observed in 21 days study at higher doses.	(Poon et al., 1997)
Dioxins and dioxin-like PCBs (foods and indoor air)	-	AA				2.0E-09	1	2E-06	Effects on reproduction compatible with an antiandrogenic mode of action.	DNEL is in TEQ (dioxin- equivalents) 2 pg TEQ/kg/day corresponds to TDI cf SCF (Scientific Committee for Food) 2001. Conversion to body burden has been taken into account.	(Faqi et al., 1998)
Dioxins and dioxin-like PCBs (dust)	-	AA	Not deter mined	0.0005	2.5*2*10*3=150	3.3E-06	1	3.3 E- 03	Effects on reproduction in monkeys	Conversion to body burden has been taken into account.	(Arnold et al., 1995)
Dioxins and dioxin-like PCBs (foods and indoor air)	-	T				6.0E-09	1	6E-06	Changed thyroid histology, reduced T4, increased TSH		(Sewall et al., 1995)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
Bisphenol A	80-05-7	E	ND	0.025	2.5*4*10*3=300	8E-05	1	0.083	Breast tissue changes, subcutaneous dosing during pregnancy	Studies not accepted in EU RAR addendum 2008.	(Durando et al., 2007; Murray et al., 2007)
Bisphenol A	80-05-7	E	50	500/60 0	2.5*4*10 = 100	0.5	1	500	Estrogenic effects in 2-3 generation study	EU RAR NOAEL of 5 mg/kg is based on effect on fetal development at 50 mg/kg, EFSA's NOAEL of 5 mg/kg is based on liver effect	(Tyl et al., 2008)
Nonyl- phenol	25154-52-3	E	15	50	2.5*4*10 = 100	0.15	0.1	15	Changes in oestrous cycle, time of vaginal opening, ovarian weight, sperm/spermatide numbers	Estrogen in vitro, but also slightly antiandrogenic acc. to 2 in vitro studies. There are several reproduction studies, but this is used in the EU RAR and has the lowest NOAEL below the lowest LOAEL of 2 studies	(NTP 1997)
TBBPA	79-94-7	E	ND	20	2.5*4*10*3 = 300	0.07	1	70	Increased uterus weight in uterotrophic assay	Also estrogenic in vitro	(Kitamura et al., 2005)
ТВВРА	79-94-7	T	30	100	2.5*4*10=100	0.3	1	300	28-day study and 1- generation study in Wistar rats. Mixed in feed. Reduced T4 in both studies, no effect on thyroid weight or histology.	NOAEL and LOAEL are determined from data in the paper, although the authors only calculate BMD. Also increased testes and pituitary size, but nothing on female reproduction.	(van der Ven et al., 2008)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
PFOA	335-67-1	AA	10	30	2.5*4*10 = 100	0.1	1	100	Delayed puberty, male and female rats in 2- generation study		(Butenhoff et al., 2004)
PFOA	335-67-1	Т	NA	3	2.5*2*10*3 = 150	0.02	1	20	Reduced T4 at 3 mg/kg/day after dosing of adult monkeys for 27 weeks.	Effect is also observed after just 5 weeks of dosing at 10 mg/kg	(Butenhoff et al., 2002)
PFOS	1763-23-1	AA	5	10	2.5*4*10 = 100	0.05	1	50	Reduced sperm count, reduced testosterone, and reduced expression of genes related to steroid synthesis after 21 days dosing of mice	Fall in gene exp from 5 mg/kg. Also reduced sperm count and testis weight in a Chinese study (only in Chinese). Reduced testosterone in goldfish exp to PFOS	(Wan et al., 2011)
PFOS	1763-23-1	Т	0.03	0.15	200 cf efsa	0.0001 5	1	0.15	Reduced T3 and T4 and increased TSH	NOAEL of 0.03 used by EFSA in opinion from 2008 to determine TDI on 150 ng/kg (UF 200)	(Seacat et al., 2002)
Octamet hylcyclote tra- siloxane (D4)	556-67-2	E	19.5	32.5	2.5*4*10 = 100	0.195	1	195	Reduced fertility and reduced litter size in a 2- generation study (inhalation) in rats	NOAEL 300 ppm in inhalation study, conversion cf SCCS 2010	(Siddiqui et al., 2007)
Propylpar a-ben	94-13-3	E	2	10-100	2.5*4*10 = 100	0.02	1	20	Reduced semen quality at exposure of young and pregnant rats, respectively; increased uterine weight in uterotrophic	SCCS uses the same NOEL for propyl- and butylparaben	(SCCS 2011)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
Butylpara- ben	94-26-8	E	2	10-100	2.5*4*10 = 100	0.02	1	20	(see propylparaben)	Overall assessment of several studies. There is equivocal data for LOAEL of 10 mg/kg bw/day, but robust data for LOAEL of 100 mg/kg bw/day. See text below.	(Fisher et al., 1999; Kang et al., 2002; Oishi 2002; Lemini et al., 2003; Lemini et al., 2004; SCCS 2011)
lsobutyl- paraben	4247-02-3	E	62.5	250	2.5*4*10 = 100	0.625	1	625	Uterotrophic, immature mice/rats, subcutaneous dosing	Highest NOAEL below lowest LOAEL of 2 studies	(Darbre et al., 2002; Vo et al., 2009)
OMC	5466-77-3	E	NA	500	2.5*4*10*3 = 300	1.6667	1	1667	Reduced testosterone (male PND16), progesterone (female PND28) and sperm count. At higher doses also reduced weight of testes and prostate and histological changes.		(Axelstad 2011)
OMC	5466-77-3	T	100	333	2.5*4*10 = 100	1	1	1000	Reduced T4	Effect observed after 5 days gavage dosing	(Klammer et al., 2007)
BP-3	131-57-7	E	937	1525	2.5*4*10 = 100	9.37	1	9370	Increased uterine weight in immature rats in the uterotrophic assay		(Schlumpf et al., 2001)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
Triclosan	3380-34-5	E	5	10	2.5*4*10 = 100	0.05	1	50	Reduced weight of several reproduktive organs, reduced FSH, LH, pregnenolone and testosterone after 60 days dosing of adult males. At higher doses also reduced sperm production		(Kumar et al., 2009)
Triclosan	3380-34-5	T	3	30	2,5*4*10 = 100	0.03	1	30	Reduced T4 after 31 days dosing of young male rats	Wistar rats, perhaps more sensitive to triclosan than LE rats.	(Zorrilla et al., 2009)
Resorcinol	108-46-3	T	1000 mg/l ≈ 78 mg/kg in males and 113- 220 mg/kg in female s	3000 mg/L ≈ 233 mg/kg in males and 340- 660 mg/kg in female s	2.5*4*10 = 100	1.1	1	1130	Thyroid histology affected in high-dose group in P males. Nothing on TH measured PND4 and 21, or on thyroid weight	Animals dosed via drinking water over 2 generations.	(Welsch et al., 2008)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
Dithiocar ba-mates: - mancoze b - maneb - propineb	8018-01-7 12427-38- 2 12071-83- 9	Т	4.8 (125 ppm)	28 (750 ppm)	2.5*4*10 = 100	0.048	1	48	Reduced T3 and T4, increased TSH and thyroid weight, changed thyroid histology in 2 years rat study, dosed in the feed	NOAEL for Mancozeb. Used by JMPR for mancozeb and Maneb	(Stadler et al. 1990)
Chloropyri fos	2921-88-2	AA	6	9	2.5*4*10 = 100	0.06	1	60	Reduces testes weight, sperm count, rats 90 days oral dosing		(Akhtar et al., 2009)
Chloropyri fos	2921-88-2	T	3	6	2.5*7*10=175	0.017	1	17	Thyroid histology, reduced T4 in mothers GD18, dosing subcutaneous, mouse, GD15 -18 and PND 11-14.	No thyroid disrupting effects in offspring PND15 but thyroid histology and T4 effects in 150 days old offspring postnatally dosed 3 mg/kg bw/d	(De Angelis et al., 2009)
Imazalil	35554-44-0	AA	20	80	2.5*4*10 = 100	0.2	1	200	Prolonged gestation and reduced ability to give birth		(Dirkx et al. 1992)
lprodion	36734-19-7	AA	15	30	2.5*4*10 = 100	0.15	1	150	Histological changes in testes, prostate, seminal vesicle, epididymis, rat 2 years chronic study	150 ppm assumed dose 15 mg/kg. Some reproductive effects shown in other studies in DAR	(Chambers et al. 1992)

Substance	CAS No	Ef- fect *	NOAEL (mg/ kg bw/ day)	LOAEL (mg/ kg bw/ day)	AF, 2.5 interspecies general and allometric scalation on 4 for rats and 7 for mice, 10 intraspecies, 3 from NOAEL to LOAEL	DNEL (mg/ kg bw/ day)	Absorp tion fractio n applie d	Interna I dose DNEL (µg/kg bw/ day)	Effect	Comment	Reference NOAEL/ LOAEL
Pirimiphos -methyl	29232-93-7	AA	62.5	125	2,5*4*10 = 100	0.625	1	625	Reduced semen quality, histological changes in testes, rat 90 days	AR antagonist and estrogen effect in vitro	(Ngoula et al., 2007)
Procymid on	32809-16-8	AA	ND	2.5	2.5*4*10*3*3 = 900	0.0028	1	2.8	↓ AGD, hypospadia, testes effect, rat exposed during pregnancy	Ekstra faktor 3 for "severity of effects"; 0,0028 is new ADI from 2009	(EFSA 2009)
Propamo- carb	24579-73-5	E	37.5	150	2.5*4*10 = 100	0.375	1	375	↓ Semen quality in offspring, rat 2-gen study. Reduced weight of epididymis and seminal vesicle at next dose, histological changes	Same effect in F0. Estrogenic effects in vitro	(Thorsrud et al. 2002)
Tebuco- nazol	107534-96-3	AA	NA	50	2.5*4*10*3 = 300	0.17	1	170	↑ Nipples, rat exposed during pregnancy	Higher DNEL than EU DAR NOAEL, but more relevant antiandrogenic effect than effects used in EU DAR	(Taxvig et al., 2007)
Thiaben- dazol	148-79-8	T	10	90	2.5*4*10=100	0.1	1	100	Low T3, high TSH, increased thyroid weight and hyperplasia. Male rat, 90 days, diet	2 studies	(Myers et al. 1990; Lankas et al. 1995)

* AA: antiandrogenic; E: estrogenic; T: thyroid disrupting. PND: postnatal day; GD: gestation day, TSH: thyroid stimulating hormone, FSH: follicle stimulating hormone, DAR: Draft assessment reports for biocides

6.6 Phthalates

Hazard assessments have been conducted for di-ethylhexyl-phthalate (DEHP), diiso-nonyl phthalate (DINP), di-n-butyl phthalate (DBP), di-iso-butyl phthalate (DIBP), butyl, benzyl phthalate (BBP), dipentyl phthalate (DPP), di-n-hexyl phthalate (DnHP) and di-n-octyl phthalate (DnOP). All the substances except DnOP affected the reproductive system, and DEHP, DnOP and DnHP all affected the thyroid hormone system. The effects observed on the reproductive system have been shown to be related to an antiandrogenic mode of action, as these phthalates reduce testosterone production in rat fetuses (Howdeshell et al., 2008; Hannas et al., 2011a). Some studies show that certain phthalates may have estrogen-like effects in cell-based studies (e.g. (Ghisari et al., 2009)), but the estrogenic effects observed are relatively weak. However, it cannot be excluded that some of the observed effects may be due to an estrogenic mode of action rather than an antiandrogenic mode of action. This also applies to other substance groups where the reproductive adverse effects cannot be sharply divided into estrogenic and antiandrogenic.

6.6.1 DEHP

DNEL_{AA} of 25 μ g/kg bw/day is based on a NOAEL of 5 mg/kg bw/day from a combined assessment of two studies examining the reproduction in male rats, including effect on testes weight and histology (Wolfe et al., 2003) and reduced anogenital distance and increased nipple retention in male rats exposed during pregnancy and lactation (Christiansen et al., 2010). There are plenty of other studies showing similar effects of DEHP_{AA}.

DNEL_T of 188 μ g/kg bw/day is based on a NOAEL of 37.6 mg/kg bw/day in a study with findings of histological changes in thyroid in rats exposed for 13 weeks (Poon et al., 1997). This finding of thyroid disrupting effects is supported by several other studies showing decreased T4 hormone in rats exposed to DEHP (NTP - CERHR 2003).

The data showing antiandrogenic and thyroid disrupting effects of DEHP is considered to be robust.

6.6.2 DINP

 $DNEL_{AA}$ of 1500 µg/kg bw/day is based on a NOAEL of 300 mg/kg bw/day in a study showing reduced semen quality and increased nipple retention in male rats exposed during pregnancy and lactation (Boberg et al., 2011). The antiandrogenic effect of DiNP is supported by studies showing reduced testosterone production in rat fetuses (Borch et al., 2004; Hannas et al., 2011a). DiNP is less potent than e.g. DEHP and DBP, which is also reflected in the higher DNEL.

 DNEL_{T} has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of DiNP is considered to be robust.

6.6.3 DBP

DNEL_{AA} of 10 μ g/kg bw/day is based on changed development of testes and changes of the breast tissue in rats exposed during pregnancy and lactation (Lee et al., 2004). This DNEL is also used by EFSA, and is based on a LOAEL of 2 mg/kg bw/day, which is somewhat lower than NOAEL for reduction of testosterone in rat

fetuses or reduced anogenital distance in males. The selection of this low DNEL in this project is due to the fact that EFSA uses this value. Several other studies show antiandrogenic effects of DBP. EFSA uses an assessment factor of 200, which is lower than the 300 used here for other rat studies, where DNEL is calculated by use of a LOAEL, because a NOAEL has not been identified. EFSA's arguments for this lower assessment factor is that the observed effects are reversible and that there is a big difference between this LOAEL and LOAELs from other studies, showing effects at about 30 times higher doses. Therefore we use the same assessment factor of 200.

 DNEL_{T} has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of DBP is considered to be robust.

6.6.4 DiBP

DNEL_{AA} of 1250 μ g/kg bw/day is based on a NOAEL of 125 mg/kg bw/day in a study showing reduced anogenital distance and increased nipple retention in rats exposed during pregnancy and lactation (Saillenfait et al., 2008) and is supported by findings of reduced testosterone production in rat fetuses (Howdeshell et al., 2008; Hannas et al., 2011a).

 $DNEL_T$ has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of DiBP is considered to be robust.

6.6.5 BBP

DNEL_{AA} of 500 μ g/kg bw/day is based on a NOAEL of 50 mg/kg bw/day in a study showing reduced anogenital distance in male rats exposed during pregnancy and lactation (Tyl et al., 2004) and is supported by findings of reduced testosterone production in rat fetuses (Howdeshell et al., 2008). Several other studies show similar antiandrogenic effects of BBP.

 $DNEL_T$ has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of BBP is considered to be robust.

6.6.6 DPP

DNEL_{AA} of 330 μ g/kg bw/day is based on a NOAEL 33 mg/kg bw/day in a study with showing reduced anogenital distance and reduced testosterone production in rats exposed during pregnancy (Hannas et al., 2011b). Older studies (Heindel et al., 1989) show that high doses of DPP cause total inhibition of fertility in mice when directly dosed in the feed, but no studies of reproductive effects of DPP at lower doses are known.

 $DNEL_T$ has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of DPP is considered to be robust.

6.6.7 DnHP

DNEL_{AA} of 500 μ g/kg bw/day is based on a NOAEL of 50 mg/kg bw/day in a study showing reduced anogenital distance and increased occurrence of malformations of reproductive organs in rats exposed during pregnancy and lactation, and is supported by other reproductive adverse effects at higher doses (Saillenfait et al., 2009a; Saillenfait et al., 2009b). An older study shows male infertility, reduced semen quality and reduced weight of reproductive organs at higher doses than the ones, on which this DNEL is based (Lamb et al., 1987).

DNEL_T of 6100 μ g/kg bw/day is based on a LOAEL of 1824 mg/kg bw/day in a study showing histological changes in thyroid in rats exposed for 3, 10 and 21 days (Hinton et al., 1986). This finding is noted to be "sufficient data" to show thyroid disrupting effect in NTP monografy (NTP - CERHR 2003), but very high doses were used, and no NOAEL determined, and therefore there is some uncertainty in this DNEL determination.

The data showing antiandrogenic effects is considered to be robust, while data for effects on the thyroid system is considered to be less robust.

6.6.8 DnOP

DNEL_T of 368 μ g/kg bw/day is based on a NOAEL of 36.8 mg/kg bw/day in a study showing histological changes in the thyroid in rats exposed for 13 weeks (Poon et al., 1997), and is supported by other studies showing reduced function of the thyroid in rats after exposure (NTP - CERHR 2003; ECHA 2010).

 $DNEL_{AA/E}$ has not been determined, as no data for effects on the reproductive system was located.

The data showing thyroid disrupting effects of DnOP is considered to be robust.

6.7 Dioxins and dioxin-like PCBs

In this project different DNELs are used in the assessment of dioxins (polychlorinated dibenzofurans, PCDF) and dioxin-like PCBs in dust, than for dioxins and dioxin-like PCBs in air and food. The reason for using another DNEL in the assessment of dioxins and dioxin-like PCBs in dust than in air and food is the fact that no data on measurements of the individual dioxin-like PCBs in dust is available; there is only available data for total intake of the PCBs. Therefore, it is necessary to assume that the composition of the dust has similarities to the original sources of pollution, i.e. commercial mixtures of PCBs (Aroclor mixtures), for which the reproductive effects can be attributed especially to the contents of PCDF and dioxin-like PCBs. Therefore, the risk assessment of PCBs in dust is based on toxicological studies of Aroclor mixtures, while the risk assessment of PCBs in air and food is based on the toxicity of the individual PCB congeners measured.

The risk assessment of dioxins and dioxin-like PCBs includes the concept of TEQ (toxic equivalents) as explained below.

Food and air:

DNEL_{AA} of 2 pg TEQ/kg bw/day has been determined based on a study showing reproductive adverse effects in male rats exposed to 2,3,7,8 Tetrachlorodibenzo-pdioxin (TCDD) during pregnancy and lactation (Faqi et al., 1998) at doses corresponding to a steady state body burden of 40 ng/kg bw. This DNEL has been selected corresponding to a tolerable weekly intake of 14 pg/kg bw/week determined by the EU Scientific Committee for Food (SCF) and the FAO/WHO Expert Committee on Food Additives (EC-SCF 2001) for 2,3,7,8-TCDD. In the study by Faqi et al., (1998), the animals are exposed to a single "loading dose" of 25 ng/kg bw and weekly "maintenance doses" of 5 ng/kg bw. The SCF considered that fetal exposure resulting from this dose would correspond to the exposure, the fetus receives from a steady state body burden of 40 ng/kg bw as a result of continuous daily intake. The SCF then made a convertion from the animals' body burden to daily dose in humans during continuous exposure, i.e. the dose (20 pg/kg bw/day) that by daily intake (over 30-40 years) will provide a steady state body burden of 40 ng/kg bw in humans (EC-SCF 2001). Next, selected assessment factors were used to arrive at the tolerable weekly intake of 14 pg/kg bw/week used here for determination of a DNEL_{AA} of 2 pg/kg bw/day.

For the individual dioxin-like PCB congeners, the dose is converted relative to potency by means of toxic equivalence factors (TEF) specifying the potencies of the different PCB congeners relative to 2,3,7,8-TCDD. As the most toxic congener, 2,3,7,8-TCDD, has been assigned a TEF of 1, while the dioxin-like PCBs measured in e.g. food, indoor air and dust have TEFs between 0.1 and 0.00003 (WHO 2005). In risk assessments of dioxin-like PCBs, a conversion of the measured values to TEQ values (dose multiplied by the TEF) is therefore conducted. Subsequently, a total toxic equivalent, TEQ, is calculated by summing up TEQs for all the substances. The total TEQ is compared with a DNEL of 2 pg TEQ/kg bw/day.

Air and food:

For dioxins and dioxin-like PCBs, $DNEL_T$ has been estimated to 6 pg TEQ/kg bw/day, which is 3 times higher than $DNEL_{AA}$. This is based on the fact that in order to observe thyroid effects, an animal must be exposed to TCDD body burdens which are 3 times higher than the body burdens causing reproductive adverse effects. The calculation is based on studies of chronic toxicity after dosing of laboratory animals to 2,3,7,8-TCDD for 2 years showing effects on the thyroid hormone system at a body burden of 127 ng/kg bw (NTP 2006), which is 3 times higher than the body burden of 40 ng/kg bw known to cause reproductive adverse effects in the study by Faqi et al (1998).

Dust:

DNEL_{AA} of 0.033 μ g/kg bw/day is used here for risk assessment of dioxin-like PCBs in dust. This DNEL has been determined based on a LOAEL of 0.005 mg/kg bw/day for a commercial PCB-mixture, Aroclor 1254, with respect to reproductive effects in monkeys (Arnold et al., 1995).

 $DNEL_T$ for dioxin-like PCBs in dust has not been calculated, because it is not currently possible to determine a NOAEL for thyroid disrupting effects of Aroclor-mixtures. Hereby the contribution from dioxin-like PCBs in dust will not be included in the overall risk assessment of thyroid disruptors, which may lead to an underestimation of the total risk.

The data showing antiandrogenic and thyroid disrupting effects for dioxins and dioxin-like PCBs is considered to be robust (EC-SCF 2000).

6.8 Bisphenol A

DNEL_E of 500 μ g/kg bw/day is based on a NOAEL of 50 mg/kg bw/day for reproductive effects compatible with an estrogenic mode of action (reduced fertility, delayed puberty, testes changes) in a multi-generation study in rats and a two-generation study in mice (Tyl et al., 2008). This DNEL is 10 times higher than EFSA's TDI (EFSA 2007), which was also used in the EU risk assessment of

bisphenol A (EU RAR 2003). This TDI is based on a NOAEL of 5 mg/kg bw/day for other effects than reproductive effects (Tyl et al., 2008).

In several studies, reproductive effects of bisphenol A have been found at lower doses than the effects shown in the study by (Tyl et al., 2008). These studies show effects at doses between 25 ng/kg bw/day and EFSA's used NOAEL of 5 mg/kg bw/day. Based on studies showing effects on breast tissue development at subcutaneous doses of 25 μ g/kg bw/day (LOAEL), an alternative lower DNEL of 0.083 μ g/kg bw/day can be calculated (Durando et al., 2007; Murray et al., 2007). Other studies show effects on breast tissue at oral doses of 10 to 250 μ g/kg bw/day. Particular note is taken of a study in rats orally dosed to bisphenol A in utero, followed by postnatal exposure to a carcinogenic substance (Betancourt et al., 2010). Among the animals receiving bisphenol A (250 μ g/kg bw/day), earlier appearance of breast tumours and a higher number of animals with breast tumours than in the control group were observed. Uncertainty about these low-dose effects makes it impossible to determine a reliable DNEL, and the use of the high DNEL_E of 500 μ g/kg bw/day thus does not consider the finding of effects in hormone-sensitive parameters, not included in the guideline studies.

DNEL_T has not been determined for bisphenol A in this project despite the fact that several studies show that bisphenol A inhibits the effect of thyroid hormones on the thyroid receptor. This inhibition of receptor activation will probably cause the same types of effects on the neurological development as the effects observed after exposure to substances that lower the level of thyroid hormones. But as increased T4 levels in animals exposed to bisphenol A are also observed, it is complex to predict the overall effect of thyroid receptor antagonists as bisphenol A and T4-lowering substances. DNEL_T for bisphenol A cannot be determined, and therefore bisphenol A is excluded from the group of substances affecting the thyroid hormone system in this project.

The data showing endocrine disrupting (estrogenic) effects of bisphenol A at high doses are considered to be robust. The determination of NOAEL is based on less robust data, i.e. subject to some uncertainty, which is very important for the size of the DNEL and thus for the risk assessment. Here, it has been chosen to start with the high $DNEL_E$, as data for determination of the lower $DNEL_E$ is not robust. This means that the risk of estrogenic effects will be underestimated, if low-dose effects actually occur, which are only not shown in robust studies with examination of hormone sensitive effects.

Although the alternative DNEL of $0.083 \ \mu g/kg \ bw/day$, which is based on lowdose effects, is not used in the quantitative risk assessment, it is used for perspectivation of the obtained results in the following sections.

6.9 Nonylphenol

DNEL_E of 15 μ g/kg bw/day is based on a NOAEL of 15 mg/kg bw/day for estrogenic effects on the reproductive system in male and female rats exposed to nonylphenol (NP) in a 2-generation study (NTP 1997). This study is also used in a EU's risk assessment, where a conversion to internal dose has also been conducted based on an assumed bioavailability of 10% resulting in an internal DNEL_E of 15 μ g/kg bw/day.

 $DNEL_T$ for nonylphenol has not been determined in this project, although there are signs that nonylphenol may affect the thyroid system. There is insufficient data for the determination of a $DNEL_T$.

Nonylphenol may originate from nonylphenol ethoxylate (NPE), which forms nonylphenol as a metabolite. Nonylphenol is more toxic than the mother substance NPE. (US EPA 2010) refers to studies which conclude that mammals metabolise NPE to NP. NPE is here assigned the same systemic toxicity as NP (measured as mg NP/kg body weight). Naturally, this is an approximation, since the NPE is not always degraded 100% to NP, and may be excreted from the body in the urine as short chain NPE. Due to lack of specific knowledge on kinetics, the 100% conversion of NPE to NP used here is a conservative estimate that may lead to an overestimation of the exposure, and thus overestimation of the risk of endocrine disrupting effect.

The data showing endocrine disruptive (estrogenic) effects of nonylphenol is considered to be robust.

6.10 Tetrabromobisphenol a (TBBPA)

 $DNEL_T$ of 300 µg/kg bw/day is based on a NOAEL of 30 mg/kg bw/day for reduced T4 in two studies in pregnant and non-pregnant rats, respectively (van der Ven et al., 2008).

 $DNEL_E$ of 66.7 µg/kg bw/day is based on a LOAEL of 20 mg/kg bw/day for increased uterine weight in a screening assay for estrogenic effect (uterotrophic assay) and cell based studies for estrogenic effect (Kitamura et al., 2005).

The data showing endocrine disruptive (estrogenic and thyroid) of TBBPA is considered to be robust, but the determination of DNEL is considered to be less robust, i.e. subject to some uncertainty.

6.11 Perfluoro octanoate (PFOA)

DNEL_{AA} of 100 μ g/kg bw/day is based on a NOAEL of 10 mg/kg bw/day for delayed puberty in male and female rats in a 2-generation study (Butenhoff et al., 2004) and reduced testosterone, reduced weight of male reproductive organs and occurrence of hormone related tumours in testes in rats dosed for 14 days and 2 years, respectively (Sibinski 1987; Cook et al., 1992).

DNEL_T of 20 μ g/kg bw/day is based on a LOAEL of 3 mg/kg bw/day in a single study in monkeys, where T4 is reduced after dosing for 5 or 27 weeks (Butenhoff et al., 2002). This finding is supported by a few human studies showing correlation between exposure to PFOA and reduced amounts of thyroid hormones in the blood (Knox et al., 2011), while other human studies do not find any correlation. Rat studies with examination of thyroid hormones have not been described in open literature.

The data showing antiandrogenic effects of PFOA are considered to be robust. Also the data for the purpose of $DNEL_{AA}$ determination is considered to be good. Regarding a thyroid disrupting effect, data is considered to be less robust, and therefore the $DNEL_T$ determination is subject to some uncertainty.

6.12 Perfluoro octane sulfonate (PFOS)

DNEL_{AA} of 50 μ g/kg bw/day is based on a NOAEL of 5 mg/kg bw/day in a study showing reduced sperm count and reduced testosterone levels in mice exposed to PFOS for 21 days. There is a lack of specific studies of parameters sensitive to antiandrogenic effects in animal studies, with exposure of pregnant animals , which would be helpful for determination of a DNEL more relevant for pregnant women.

DNEL_T of 0,15 μ g/kg bw/day corresponds to a TDI determined by EFSA in 2008 and is based on a NOAEL of 0.03 mg/kg bw/day in a study showing reduced thyroid hormone level in monkeys exposed to PFOS for 183 days. An assessment factor of 200 has been used cf. EFSA's opinion (EFSA 2008). EFSA substantiates the extra assessment factor with the wish to compensate for uncertainties, due to the relatively short dosing period in the study and internal dose kinetics (bioaccumulation).

The data showing thyroid disrupting effects of PFOS are considered to be robust and also the data for the purpose of $DNEL_T$ determination is considered to be good. Regarding the antiandrogenic effect, data are considered to be less robust, and therefore the $DNEL_A$ determination is subject to somewhat bigger uncertainty.

6.13 Octamethylcyclotetra-siloxane (D4)

DNEL_E of 195 μ g/kg bw/day is based on a NOAEL of 19.5 mg/kg bw/day for changed estrous cycle, reduced fertility and reduced litter size in a 2-generation study (inhalation) in rats (Siddiqui et al., 2007). The NOAEL of 19.5 mg/kg bw/day is an internal dose calculated from an inhalation dose of 300 ppm, and by means of a calculation method used in SCCS' risk assessment for D4 (SCCS 2010b). The estrogenic mode of action is supported by findings of increased uterine weight and reduced estradiol in the blood in screening studies for estrogenic effect in mice (He et al., 2003), and increased uterine weight and changed hormone levels and changed uterine histology in rats (McKim et al., 2001; Quinn et al., 2007).

 DNEL_{T} has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing endocrine disruptive (estrogenic) effects of Siloxane D4 is considered to be robust.

6.14 Parabens

6.14.1 Propylparaben

DNEL_E of 20 µg/kg bw/day is based on a NOEL of 2 mg/kg bw/day used by SCCS in opinion from 2011 for both propylparaben and butylparaben (SCCS 2011). This NOEL has been determined from a study by Fisher et al., 1999, where young male rats were dosed with 2 mg/kg bw/day of butylparaben from day 2 to 18, and no effects on the reproductive system of these males were observed on day 18. This NOEL is stated in SCCS' opinion to be conservative. In other studies, increased uterine weight at 10-20 mg/kg bw/day (LOAEL) has been observed in screening studies for estrogenic effect (Lemini et al., 2003; Lemini et al., 2004), and at 10 mg/kg bw/day reduced epididymis weight and reduced sperm production have been observed in young rats exposed to propylparaben (Oishi 2002). Several studies show that propylparaben has estrogenic and/or antiandrogenic effects in vivo and in vitro (described in SCCS' opinion 2010). However, the determination of DNEL_E for propylparaben is not robust, as the NOEL of 2 mg/kg bw/day is from a study of butylparaben, and as SCCS uses this NOEL for propylparaben as well due to lack of specific data. Generelly, propylparaben is considered to be less potent than butylparaben both in vitro and in vivo (SCCS 2011), which is not reflected in the chosen DNEL_E. Furthermore, there is a lack of specific studies of hormone sensitive parameters in animal studies with exposure of pregnant animals, which

would be helpful for the determination of a DNEL more relevant for pregnant women.

 $DNEL_T$ has not been determined, as no data for effects on the thyroid hormone system was located.

The data showing endocrine disruptive (estrogenic) effects of propylparaben is considered to be robust, but the determination of DNEL is considered to be based on less robust data, i.e. subject to some uncertainty, which will be discussed further in the section on discussion of the risk assessment.

6.14.2 Butylparaben

DNEL_E of 20 µg/kg bw/day is based on a NOEL of 2 mg/kg bw/day used by SCCS in the opinion from 2011 for both propyl and butylparaben. This NOEL is determined from a study by (Fisher et al., 1999), where young male rats were does with 2 mg/kg bw/day butylparaben from day 2 to 18, and no effects were found on the reproductive system of these males on day 18. This NOEL is stated to be conservative. The estrogenic effect is supported by findings of increased uterine weight in several screening studies for estrogenic effect (Hossaini et al., 2000; Lemini et al., 2003; Lemini et al., 2004; Vo et al., 2009). Furthermore, reduced sperm count is observed in offspring of rats exposed during pregnancy and lactation (Kang et al., 2002). No antiandrogenic effects were observed, as anogenital distance in males, in studies with dosing during gestation (Kang et al., 2002, Boberg J 2008; Taxvig C 2008). In other studies, reduced sperm production has been observed in young rats at 10-20 mg/kg bw/day (LOAEL) (Oishi 2001), but subsequent studies with the same study design have not shown the same type of effects (Hoberman AM 2008).

The study by Kang et al. (2002) specifically examines effects of butylparaben in offspring exposed during pregnancy and lactation, and is therefore particularly relevant for determination of DNEL_E for pregnant women. However, no NOAEL is determined in this study (effect at lowest dose of 100 mg/kg bw/day), and the lower part of the dose-response curve is thus poorly defined in studies with exposure during gestation and subsequent examination of semen quality. As in the SCCS opinion, a conservative approach for the DNEL determination was chosen (SCCS 2010), which takes into account possible effects in the low-dose area. A few studies of estrogenic effects in immature animals show effects at the same low doses (Lemini et al., 2003), while other studies only show effects at higher doses (Vo et al., 2009, Vo et al., 2010) or do not examine the low doses (Hossaini et al., 2000). Since there are doubts about the effects of butylparaben in doses at the low end of the dose-response curve, an alternative non-conservative $DNEL_E$ is calculated from the study by Kang et al., 2002, where effects are observed after exposure of pregnant rats to 100 mg/kg bw/day. Using the higher NOAEL of 100 mg/kg bw/day, an alternative DNEL_F of 330 µg/kg bw/day is obtained, i.e. 17 times higher than the one used here. This project generally uses the DNEL_E of 20 ug/kg bw/day to comply with the conservative approach, which also forms the basis of SCCS' assessments, but at the end of the report, an example is given of a calculation based on the alternative non-conservative DNEL_E.

Furthermore, there is a lack of specific studies of hormone sensitive parameters in animal studies with exposure of pregnant animals to be able to make a more certain $DNEL_E$ determination.

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data showing endocrine disrupting (estrogenic) effects of butylparaben is considered to be robust, but the determination of DNEL is considered to be based on less robust data, i.e. subject to some uncertainty, which will be discussed further in the section on discussion of the risk assessment.

6.14.3 Isobutylparaben

DNEL_E of 625 μ g/kg bw/day is based on a NOAEL of 62.5 mg/kg bw/day for increased uterine weight in immature female mice and immature female rats, respectively in screening studies for estrogenic effect (Darbre et al., 2002; Vo et al., 2009). Several studies show estrogenic effect in corresponding *in vivo* studies and in cell-based studies, and therefore it can be considered to be robust knowledge that isobutylparaben is endocrine disrupting (Koda et al., 2005). There is a lack of specific studies of hormone sensitive parameters in animal studies with exposure of pregnant animals, which would be helpful for the determination of a DNEL more relevant for pregnant women.

No $DNEL_T$ has been determined, as no data for effects to the thyroid hormone system was located.

The data showing endocrine disrupting (estrogenic) effects of isobutylparaben is considered to be robust, but the determination of DNEL is considered to be based on less robust data, i.e. subject to some uncertainty.

6.15 UV-filters

It should be noted that 4-MBC and 3-BC are excluded from the hazard and risk assessment because of lack of exposure (cf. Section 3.8.4).

6.15.1 Benzophenone-3

DNEL_E of 9370 μ g/kg bw/day is based on a NOAEL of 937 mg/kg bw/day for increased uterine weight in immature female rats exposed in screening studies for estrogenic effect (Schlumpf et al., 2001). In another study of benzophenone-3 (BP-3), no effects on the uterine weight were observed at doses of 250 and 1000 mg/kg/day (Schlecht et al., 2004). Furthermore, a number of cell-based studies have shown estrogenic activity of BP-3 or its decomposition product benzophenone-1 (Takatori et al., 2003; Matsumoto et al., 2005; Morohoshi et al., 2005; Suzuki et al., 2005).

No $DNEL_T$ has been determined, as no data for effects to the thyroid hormone system was located.

The data for benzophenone-3 relative to DNEL determination is considered to be subject to some uncertainty, as only one of two published studies, examining endocrine disrupting effects in rats, show an effect on the uterine weight.

6.15.2 OMC

 $DNEL_E$ of 1667 µg/kg bw/day is based on a LOAEL of 500 mg/kg bw/day for changed sex hormone levels and reduced sperm count in offspring dosed during fetal development and in the postnatal period (Axelstad 2011). Furthermore, at higher doses the substance induces increased uterine weight, changed uterine histology and changed gene expression in uterus in screening studies for estrogenic effect (Schlumpf et al., 2001; Klammer et al., 2005; Seidlova-Wuttke et al., 2006).

Estrogenic receptor activity has also been observed in cell based studies (Seidlova-Wuttke et al., 2006).

DNEL_T of 1000 μ g/kg bw/day is based on a NOAEL of 100 mg/kg bw/day in a study showing reduced T4 level in male rats dosed by gavage for 5 days (Klammer et al., 2007). Other rat studies show a corresponding effect on T4 levels after OMC dosing of pregnant (Axelstad 2011) and ovariectomised female rats, respectively (Seidlova-Wuttke et al., 2006). Furthermore, OMC has been shown to affect the deiodinase enzyme activity in the liver. This mechanism is one of the ways in which thyroid disrupting chemical substances may affect the thyroid hormone system.

The data showing endocrine disrupting effects on both the reproduction system and the thyroid hormone system of OMC is considered to be robust.

6.16 Triclosan

DNEL_E of 50 μ g/kg bw/day is based on a NOAEL of 5 mg/kg bw/day in a study showing reduced weights of several reproductive organs, histopatological changes in these, and reduced levels of FSH, LH and testosterone after 60 days dosing of adult males. At a higher dose, this study also shows reduced sperm production (Kumar et al., 2009). The estrogenic mode of action is supported by findings of estrogenic effects in cell-based studies (Gee et al., 2008; Jung et al., 2011); likewise studies in fish and amphibians have shown that the substance in high concentrations may induce estrogenic effects (Ishibashi et al., 2004; Raut et al., 2010).

DNEL_T of 30 μ g/kg bw/day is based on a NOAEL of 3 mg/kg bw/day in a study Showing reduced T4 levels after 31 days dosing of young male rats (Zorrilla et al., 2009). At higher doses, reduced T3 and changed thyroid histology were also observed. These observations are supported by several other studies showing that triclosan may affect the thyroid hormone system by reducing the levels of T4 in both young and adult pregnant rats (Crofton et al., 2007; Stoker et al., 2010; Paul et al., 2010b) (Axelstad et al., in prep), and that the effects are probably due to increased enzyme induction in the liver, which causes faster metabolism of the thyroid hormones (Paul et al., 2010a).

The data showing thyroid disrupting effects of triclosan is considered to be robust. Regarding the estrogenic effect, data is considered to be less robust, and therefore the $DNEL_E$ determination is subject to a somewhat higher uncertainty, and the selection of a low DNEL is conservative, and may cause overestimation of the risk of estrogenic effect.

6.17 Resorcinol

No DNEL $_{AA/E}$ has been determined, as no data for effects on the reproductive system was located.

DNEL_T of 1130 μ g/kg bw/day is based on a NOAEL of 113 mg/kg bw/day in a study showing changed thyroid histology in adult animals dosed with resorcinol in the drinking water (the parent generation in a two-generation study) (Welsch et al., 2008). Several other comprehensive animal studies have, however, not shown thyroid disrupting effects in exposed rats. Thus, the results from the studies examining the effect of resorcinol on the thyroid hormone system, point in different directions. The possible thyroid disrupting effect of resorcinol is supported by the fact that resorcinol has been shown to inhibit iodine absorption

and the TPO enzyme in cell-based studies, and that several clinical studies from the 1950es show that the use of ointment with resorcinol to cure skin ulcers caused thyroid problems among the patients.

The effects of resorcinol in cell-based studies and in humans, however, cause the substance to be considered a thyroid disrupting chemical.

The animal experimental data showing endocrine disrupting (thyroid) effects of resorcinol is considered to be subject to some uncertainty, and the determination of DNEL is subject to some uncertainty.

6.18 Pesticides

Hazard assessments have been made for Tebuconazole, Pirimiphos-methyl, Imazalil, Propamocarb, Iprodion, Chloropyrifos, Dithiocarbamates (Mancozeb, Maneb and Propineb), Thiabendazol og Procymidon. Tebuconazole, Pirimiphosmethyl, Imazalil, Propamocarb, Iprodion, Chlorpyrifos og Procymidon have effects on the reproductive system compatible with antiandrogenic or estrogenic modes of action, while Chloropyrifos, Mancozeb, Maneb, Proineb and Thiabendazol have effects on the thyroid hormone system.

6.18.1 Chloropyrifos

DNEL_{AA} of 60 μ g/kg bw/day is based on a NOAEL of 6 mg/kg bw/day in a study showing reduced sperm count, reduced testes weight and reduced testosterone level in rats exposed for 90 days (Akhtar et al., 2009) and is supported by corresponding findings in other studies. This study has not been conducted with exposure of pregnant rats, but it is likely that the effects are due to an endocrine disrupting mode of action, as a similar substance, chloropyrifos-methyl has been shown to have similar effects in offspring, when the substance is given during pregnancy and lactation, and furthermore to reduce the weight of sex organs in male rats in screening test for antiandrogenic effect (Hershberger test) (Kang et al., 2004; Jeong et al., 2006). Furthermore, chloropyrifos has shown antiandrogenic effect in cellbased studies. There is a lack of studies on antiandrogenic effects in animal studies with exposure of pregnant animals, which would be helpful for determination of a DNEL more relevant for pregnant women.

DNEL_T of 17 μ g/kg bw/day is based on a NOAEL of 3 mg/kg bw/day in a study showing histological changes in the thyroid and a reduced T4 level in pregnant mice dosed during pregnancy (De Angelis et al., 2009). This effect on thyroid is supported by similar findings when exposing animals to the related substance chloropyrifos-methyl.

The data showing antiandrogenic and thyroid disrupting effects of chloropyrifos is considered to be robust, but that data for determination of DNEL for antiandrogenic effects is considered to be less robust.

6.18.2 Dithiocarbamates (mancozeb, maneb, probineb)

An overall risk assessment has been made for the dithiocarbamates mancozeb, maneb and probineb. These three substances have similar modes of action, and in animal studies, exposure results in similar thyroid disrupting effects. The dithiocarbamates are metabolised to the known thyroid disrupting substances ethylenethiourea (ETU) and propylthiouracil (PTU), which, among others, inhibit formation of T4 in thyroid. Due to the similarities of the substances, the estimated intake of the different dithiocarbamates is summed up, and the DNEL determinations in this report are likewise based on a NOAEL value for mancozeb,

which has been selected to represent the group. The same method has been used in JMPR's (Joint Meeting on Pesticide Residues) assessments (JMPR 1993).

The common DNEL_T for the dithiocarbamates has been set to 48 μ g/kg bw/day based on a NOAEL of 4.8 mg mancozeb/kg bw/day in a study showing histological changes in thyroid, increased thyroid weight, reduced T3 and T4 levels and increased TSH in rats exposed for 2 years (Stadler et al. 1990). Similarly, maneb has been shown to cause histological changes in thyroid and increased thyroid weight after 14 weeks of dosing in the feed of rats (Trutter et al. 1988), while studies of propineb have shown increased thyroid weight and reduced T4 level in rats exposed for 62 days (Kroetlinger et al. 1980). Several other studies show effects on the thyroid hormone system of the dithiocarbamates and their metabolites ETU and PTU.

No $DNEL_{AA/E}$ has been determined for the dithiocarbamates, as no robust data for effects on the reproductive system was located.

The data showing thyroid disrupting effects of the dithiocarbamates is considered to be robust.

6.18.3 Imazalil

DNEL_{AA} of 200 μ g/kg bw/day is based on a NOAEL of 20 mg/kg bw/day in a 2generation study showing prolonged pregnancy and effect on the ability to give birth (Dirkx et al. 1992). This effect can be regarded as endocrine disrupting and is also observed for other pesticides of the azol-fungicide type (Jacobsen et al., 2010). At corresponding doses (NOAEL 14 mg/kg bw/day) reduced testes weight has been observed in rats dosed for 28 days (Gur et al. 1990). It is likely that these effects are due to antiandrogenic effect, as the substance has been shown to be a potent androgen receptor antagonist and to affect the steroid synthesis in cell-based studies (Vinggaard et al., 2000; Orton et al., 2011). There is a lack of specific studies of antiandrogenic parameters in animal studies with exposure of pregnant animals, which would be helpful for determination of a DNEL more relevant to pregnant women.

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of imazalil is considered to be robust, but data for determination of the DNEL is considered to be less robust.

6.18.4 Iprodione

DNEL_{AA} of 150 μ g/kg bw/day is based on a NOAEL of 15 mg/kg bw/day in a study showing histological changes in the reproductive organs of male rats exposed for 2 years (Chambers et al. 1992). This study has not been conducted with exposure of pregnant rats, but it is likely that the effects are due to antiandrogenic effect, as the substance has been shown to reduce the weight of sexual organs in male rats in a screening test for antiandrogenic effect (Hershberger assay) and to reduce sexual maturation, reduce the weight of male reproductive organs and reduce testosterone levels in rats exposed around the time of sexual maturation (Blystone et al., 2007; Blystone et al., 2009).

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects of iprodione is considered to be robust, but data for determination of DNEL are considered to be less robust.

6.18.5 Pirimiphos-methyl

DNEL_{AA/E} of 625 μ g/kg bw/day is based on a NOAEL of 62.5 mg/kg bw/day in a study showing reduced semen quality and histological changes in testes in rats exposed for 90 days (Ngoula et al., 2007). This study is not conducted using exposure of pregnant rats, but it is likely that the observed effects are due to endocrine disruption, as the substance has been shown to be an androgen receptor antagonist and to have estrogenic effect in cell-based studies (Orton et al., 2011). Histological changes in testes in offspring of rats exposed in a 2-generation study have also been reported, but since there are conflicting interpretations of this study, it is not used for DNEL determination here. There is a lack of specific studies on antiandrogenic/estrogenic parameters in animal studies with exposure of pregnant animals, which would be helpful for determination of a DNEL more relevant for pregnant women.

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data showing endocrine disrupting (antiandrogenic/estrogenic) effects of pirimiphos-methyl is considered to be robust, but data for determination of the DNELs is considered to be less robust.

6.18.6 Procymidone

DNEL_{AA} of 2.8 μ g/kg bw/day is based on a LOAEL of 2.5 mg/kg bw/day in a study showing reduced anogenital distance, hypospadia (malformed sexual organs) and effects on testes in offspring of rats exposed during pregnancy (EFSA 2009). Several other animal studies and cell-based studies show that procymidone is a potent antiandrogen (EFSA 2009).

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data showing antiandrogenic effects for procymidone is considered to be robust, but data for determination of DNEL are considered to be less robust.

6.18.7 Propamocarb

DNEL_E of 375 μ g/kg bw/day is based on a NOAEL of 37.5 mg/kg bw/day for reduced semen quality in offspring in a 2-generation study of rats, and is supported by findings of reduced weight of male reproductive organs at higher doses and estrogenic effect in cell-based studies (Andersen et al., 2002; Thorsrud et al. 2002). It is not clear, whether the effects in the 2-generation study reflect the estrogenic or the antiandrogenic effects of propamocarb, but propamocarb has been chosen to be included in the group of estrogens, as there is specific knowledge of estrogenic mode of action, but no specific knowledge of possible antiandrogenic mode of action.

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data showing endocrine disrupting effects for propamocarb is considered to be robust.

6.18.8 Tebuconazole

DNEL_{AA} of 170 μ g/kg bw/day is based on a LOAEL of 50 mg/kg bw/day in a study showing increased nipple retention in male rats exposed during pregnancy and lactation, and is supported by findings of reduced testosterone production in fetuses at higher doses (Taxvig et al., 2007). Furthermore, substances with similar structures (azol-fungicides) are known for their antiandrogenic modes of action.

No $DNEL_T$ has been determined, as no data for effects on the thyroid hormone system was located.

The data for antiandrogenic effect of tebuconazole is considered to be robust.

6.18.9 Thiabendazole

DNEL_T of 100 μ g/kg bw/day is based on a NOAEL of 10 mg/kg bw/day for changes in the thyroid, increased thyroid weight and reduced T3 level in two studies of rats exposed for 90 days (Myers et al. 1990; Lankas et al. 1995). Several other studies show that thiabendazole may affect the thyroid hormone system.

No $\text{DNEL}_{AA/E}$ has been determined, as no data for effects on the reproductive system was located.

The data showing thyroid disrupting effects of tebuconazole is considered to be robust.

7 Exposure assessment

Based on analyses made on products relevant to the target group of this project, analyses of relevant products made in previous surveys published by the EPA, and estimates of exposure via indoor air and food, exposure calculations have been made for the chemical substances selected in section 2.

The exposure is divided into different scenarios. The reason for dividing the exposures into different scenarios is that there can be large differences in how and how much of the food/product you eat/use, and the time you spend indoors depending on your situation. Therefore, dividing the separate scenarios will give the most realistic picture of the different situations, in which a pregnant woman may be. It would be desirable to describe far more situations than is the case, but available data has not made this possible.

The following scenarios have been assessed in the project:

- basis scenario (indoor environment and food)
 - holiday scenario
 - work scenario (only related to consumer products)
 - transport scenario

All the scenarios also include an average and a maximum exposure.

Average and maximum exposure

The exposures are divided into an average and a maximum exposure, where the approach is that the exposure levels over a week of exposure, as exposure of pregnant women is considered here. In this situation it is interesting to look at a very short exposure period due to the short period of weeks during which the fetus is most sensitive to endocrine disruption, as described in Section 1. <u>Average exposure</u> describes the situation, by which many in the target group is expected to be affected, i.e. a **realistic scenario**, while <u>maximum exposure</u> describes the situation, while <u>maximum exposure</u> describes the situation, while <u>maximum exposure</u> describes the situation.

For consumer products, exposure scenarios have been defined based on EU's REACH guidelines for risk assessments (ECHA 2010). The scenarios are based on calculations of use and predictable handling of the products. Depending on the product group and the use, the exposure assessment is based on oral or dermal exposure or inhalation.

The exposure from indoor air is based on data from the literature. For foods, the basis is the average and maximum intake of food of the target group.

7.1 Method for calculation of exposure

The following sections will provide a description of calculation of exposure by inhalation, oral, and dermal contact.

7.1.1 Exposure from indoor environment

For exposure assessment of the selected substances via indoor environment, the general equations are used as described in the REACH guidelines "Guidance on Information Requirements and Chemical Safety Assessment" (ECHA 2008).

Total exposure indoor environment = Exposure via dust + exposure via air.

Exposure via air is assumed to be absorbed 100%, i.e. inhaled quantity is equal to the internal dose. For DEHP, DINP and nonylphenol, however, we use absorption via inhalation and oral exposure, which are lower, as lower fractions are listed in EU's risk assessments for these substances. The used dermal, oral and inhalation absorption fractions are shown in Table 7-2.

Exposure via dust

Exposure via dust for each substance x is calculated as the daily intake of dust times the fraction of the substance x in dust divided by female body weight (BW).

$$D(subst. x)_{DUST} = \frac{Intake_{DUST} \cdot f(subst. x)_{DUST} \cdot f(subst. x)_{ORAL}}{BW}$$

Where

D(subst. x)	Ingested daily dose of substance x	mg/kg
DUST		bw/day
Intake	Daily intake of dust	kg/day
f(subst. x) dust	Concentration of substance x in dust	mg/kg
f(subst. x) _{oral}	Oral absorption of substance x	%
BW	Body weight (bw)	Kg

Exposure via indoor air

Exposure is calculated acc. to the formula "Equation 15-2" from the REACH guidelines, chapter R.15 "Consumer exposure estimation" (ECHA 2010):

$$D(subst. x)_{inh} = \frac{F_{resp} \cdot C_{inh} \cdot IH_{air} \cdot T_{contact}}{BW} \cdot n$$

Where

D(subst. x) _{inh}	Inhaled daily dose of substance x	mg/kg bw/day
Fresp	Inhaled substance, i.e. respirable fraction (decimal fraction between 0-1)	
Cinh	Concentration of substance in the air of the room	mg/m³
Tcontact	Duration of exposure per incident	hours
IHair	The person's respiration volume	m ³ /day
n	Number of exposures (incidents)	per day
BW	Body weight (bw)	Kg

For dust, the content of the different substances is given as a fraction, i.e. amount of substance in μg or ng per gram of dust. For the indoor air, the content of the different substances is given as a concentration, i.e. the amount of substance in μg or ng per m³ air.

7.1.2 Dermal exposure

Exposure of the skin occurs by direct contact with the products, for instance when you hold your bag in the hand, when your clothes touch the body, when you use cosmetics on your skin, when you talk on the phone and it is in contact with the cheek, etc.

The possible absorption via the skin can be calculated acc. to the formula "Equation 15-7" from the REACH guidelines, chapter R.15 "Consumer exposure estimation" (ECHA 2010). A factor F_{abs} has been added as the fraction of the individual substance that is absorbable through the skin. Thus, the calculated D_{der} is the actual amount of substance, which can be absorbed per kg bw per day.

$$D_{der} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{abs} \cdot F_{contact} \cdot T_{contact}}{BW} \cdot n$$

Fc_{prod} • Fc_{migr} corresponds directly to the results from the migration analyses.

Where

D _{der}	Dermal daily dose (amount of absorbed chemical substance)	µg/kg bw/day
Qprod	Amount of product used per time	g
Fcprod	Weight fraction of substance in the product (decimal fraction between 0 and 1)	
FCmigr	Fraction of substance that migrates out of the product per time unit	µg/g per hour
Fabs	Fraction of applicated substance absorbed through skin (decimal fraction between 0 and 1)	
Fcontact	Fraction of contact area (to take into account that the product is only partially in contact with skin). For cosmetic products, this is set to1, as the assumed body area has been taken into account in the applied amount	m²/m²
Tcontact	Duration of exposure per incident	hours
n	Number of exposures (incidents)	per day
BW	Body weight (bw)	kg

If the dermal absorption of a substance is unknown, this survey uses as a worst case scenario, that the total amount of substance migrated from the product will be absorbed dermally. Where data for dermal absorption is available for a substance, this data will be used.

7.1.3 Oral exposure

It is assessed that oral exposure to consumer products occurs to a lesser extent, when the target group is adults. There is of course a possibility of oral exposure to endocrine disruptors via foods and some types of cosmetics (toothpaste, mouthwash).

The possible oral absorption can be calculated acc. to the formula "Equation 15-11" from the REACH guidelines, chapter R.15 "Consumer exposure estimation" (ECHA 2010). The formula has, however, been rewritten here to contain the possibility to introduce the actual measured migration from a product used in e.g. the mouth, such as a toothbrush.

$$D_{oral} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{abs}}{BW} \cdot n$$

where

Fc_{prod} • Fc_{migr} corresponds directly to the results of the migration analyses

D _{oral}	Dermal daily dose (amount of absorbed chemical substance)	µg/kg bw/day
Qprod	Amount of product used	g
Fcprod	Weight fraction of substance in the product (decimal fraction between 0 and 1)	
Fabs	Fraction of applied substance absorbed through skin (decimal fraction between 0 and 1)	
FCmigr	Fraction of substance migrating out of the product per time unit	µg/g per hour
n	Number of exposures (incidents)	per day
BW	Body weight (bw)	kg

7.2 Anatomic data used in exposure calculations

The anatomic data used for the exposure assessment is presented in Table 7-1.

Women's weight increase during pregnancy is also included in Table 7-1. This data has been included for information on weight changes during pregnancy and has been calculated from an average weight of women of 67 kg, and not the worst case scenario of 60 kg used in the exposure calculations.

Table 7-1 Overview of anatomic data etc. for the use of the exposure scenarios for pregnant women

Parameter	Value (+ comments)	Used (average)
Weight (Danish women)	A weight of 60 kg for a Danish woman is used as a worst case scenario, as this is the normal weight used in connection with risk assessment (Hesse 2007) The average for Danish women is however: 64 kg (average, 2005, 16-24 years) 69 kg (average, 2005, 25-44 years), (Nordic Exposure Group 2011)	60 kg
Weight increase during pregnancy	 13.5 kg (estimated average based on the following) 12-15 kg; 12.1 kg (average based on data from 2011), (Lofthus 2009) 10-15 kg (normal weight increase based on data from 2006), (National Board of Health 2006) 11.2 kg (weight increase alone as a result of pregnancy, child, placenta, etc.), (Bech 2011) 	13.5 kg
Weight increase 0- 12 weeks (approx. 0-2½ months)	1.5 kg (average, appropriate weight increase in the period from 0-12 weeks is 1-2 kg, (Bech 2011)	1.5 kg
Weight increase 12-28 weeks (approx. 2½ - 7 months)	5.6 kg (average, appropriate weight increase in the period from 12-28 weeks is 4.8-6.4 kg, (Bech 2011)	5.6 kg
Weight increase 28-40 weeks (appox. 7-9 months)	6.4 kg (average, appropriate weight increase in the period from 28-40 weeks is 2.5-7.5 kg and 6.4 in average, when a total average of 12.1 kg shall be reached for the total pregnancy period) (Bech 2011)	6.4 kg

Parameter	Value (+ comments)	Used (average)
Weight at birth	73.5 kg (estimated average weight of the pregnant woman just before birth, calculated as 60 + 13.5 kg = 73.5 kg)	73.5 kg
Body surface (for adult Danish women)	The total body surface area for adult women is 1.85 m ² , (stated surface area for 30 to 40 year old women), (Nordic Exposure Group 2011)	1.85 m ²
Head	1140 cm ² , (SCCS 2010c; Nordic Exposure Group 2011)	1120 - 1140 cm ²
Body	6540 cm ² , (Nordic Exposure Group 2011)	6540 cm ²
Arms (both)	2370 cm ² , (Nordic Exposure Group 2011)	2370 cm ²
Upper arms (both)	1240 cm ² , (ECHA 2010; Nordic Exposure Group 2011)	1240 m ²
Lower arms (both)	990 cm ² , (ECHA 2010; Nordic Exposure Group 2011)	990 cm ²
Hands (upper and lower side)	890 cm ² , (Nordic Exposure Group 2011) 860 cm ² (SCCS 2010c)	860 - 890 cm ²
Legs (both)	5980 cm ² , (Nordic Exposure Group 2011)	5980 cm ²
Thighs (both)	1720 cm ² (ECHA 2010; Nordic Exposure Group 2011)	1720 cm ²
Lower legs (both)	1800 cm ² (ECHA 2010; Nordic Exposure Group 2011)	1800 cm ²
Feet (both)	1220 cm ² , (Nordic Exposure Group 2011) Of this, feet soles, size 39, constitute 197 cm ²	122 cm ²
Height (Danish women)	168 cm (average, 2005, 16-24 years) 168 cm (average, 2005, 25-44 years) Average height: 168 cm (Folkesundhed 2007)	168 cm
"Stomach (heavily pregnant)"	To get a more accurate number for Danish women, the formula stated in (ECHA 2010; Nordic Exposure Group 2011) is used S der, tot = 0.0239 x BH ^{0.417} x BW ^{0.517} Where average height (168) and weight (60) of Danish women thus gives: S der, tot = 0.0239 x $168^{0.417}$ x $60^{0.517}$ = 16,800 cm ² The total body surface area for pregnant women at the time of birth corresponds to an average height of 168 and weight of 73.5, as follows: S der, tot = 0.0239 x $168^{0.417}$ x $73,5^{0.517}$ = 18,700 cm ² For heavily pregnant Danish women, the extra body area of the stomach and possibly slightly larger breasts and buttocks thus constitute the 1.87 m ² (body area pregnant)- 1.68 m ² (body area Danish woman)= 1860 cm²	1860 cm ²
½ body surface, front side with stomach or back side with back	 ½ x 18,500 cm² = 9,250 cm² (numbers are valid for a woman who has not yet increased the area of the pregnant stomach considerably) 	9,250 cm ²

7.2.1 Data for calculation of exposure via dust and air

In addition, the used calculation parameters needed to perform calculations for dust and air are the following:

- Intake of dust, i.e. the amount of dust assumed to be ingested by women each day
- Women's body weight (bw)
- Respirable fraction of the inhaled substance
- Duration, i.e. the time of the women's exposure to the substances via indoor air
- Women's respiration volume, i.e. the amount of air inhaled by women each day

These parameters are reviewed in details below.

7.2.1.1 Intake of dust

An RIVM (National Institute for Public Health and the Environment, Holland) report entitled "Exposure to chemicals via house dust" from 2008 concludes that a conservative, but realistic estimate of intake of dust in adults is 50 mg/day (Oomen et al., 2008). This report lists a number of studies related to intake of dust in adults. These studies state values varying from 0.56 mg/day to 100 mg/day. Most of the studies, however, presented a value around 50 mg/day, and therefore Oomen et al. (2008) chose to use this value in their assessments. One of the listed studies was US EPA (1997), which actually listed a value of 50 mg/day.

D'Hollander et al. (2010) choose to use an average value of 7 mg/day for intake of dust for adults and a 95% percentile value of 20 mg/day for adults. The value of 50 mg dust intake/day for adults is also used in "Annex XV Restriction Report" for the phthalates DEHP, BBP, DBP and DiBP (Danish EPA et al., 2011d).

Based on the above information, we chose in this project to set the value for intake of dust in adult women to 50 mg/day.

As stated in the chapter below on oral absorption rates, an oral absorption rate of 1 is generally used, i.e. 100% corresponding to the fact that the total ingested amount of the substance is also absorbed into the body. However, lower values are used for phthalates and nonylphenol based on information from the literature.

7.2.1.2 Respirable fraction of the inhaled substance

It is generally assumed that the respirable fraction of the inhaled substances is 1, i.e. 100%, due to the fact that the total inhaled amount of the substance is also absorbed into the body. For two of the phthalates, however, a value of 0.75 is used based on information from the literature.

7.2.1.3 Duration (staying indoor)

An ordinary Dane stays indoors for an average of between 80 and 90% of the time (Danish EPA 2007). This corresponds to between 19.2 and 21.6 hours per day. This covers the whole week and applies also to indoor staying in the work situation.

An average value is used in calculations, i.e. a value of 20 hours is used for indoor stays. We do not deliberately distinct between staying at home and staying indoors at work. Much of the presented data shows that there is no big difference between the concentration of substances in private homes and offices, day care centres and public buildings, where measurements have been taken. Therefore, we chose in the calculations to apply the maximum measured average values and maximum values regardless of whether it is data from private homes or data which may represent a work situation. The calculated values will thus represent indoor staying both in the home and at work.

7.2.1.4 Women's respiration volume

Adults inhale acc. to the REACH guidelines "Guidance on information requirements and chemical safety assessment", chapter R.15 "Consumer exposure estimation" (ECHA 2010), 18 m³ air per day. This value has been used in the calculations.

I.e. women inhale indoor air 20 hours - 24 hours per day x 18 m³ air per day = 15 m³ air while staying indoor either at work or at home.

7.3 Dermal and oral absorption rates and inhalation fractions

By dermal or oral exposure or by inhalation, the calculated exposure doses are corrected with the dermal absorption rate or inhalation fraction to find the internal dose.

Table 7-2 Statement of dermal and oral absorption and absorption by inhalation (fraction). Only substances have been included, for which exposure either via dermal or oral routes, or via inhalation have been included (therefore not all of the substances are mentioned here). The designation (1) means that no data was found and that the fraction therefore in worst cast is set to 1

Substance	Dermal abs fraction, humane	Oral abs fraction, humane	Inhalation abs fraction, humane	Reference	
Phthalates	numane		numarie		
DEHP	0.05	0.5	0.75	(RAR 2008)	
DINP	0.1	0.5	0.75	(RAR 2003)	
DBP	0.1	1	1	(EU RAR 2003)	
DIBP	0.1	1	1	(EU RAR 2003)	
BBP	0.05	1	1	(EU RAR 2003)	
BPP	(1)	1	(1)	Assumed; no data	
DnHP	(1)	1	1	(NTP - CERHR 2003)	
DnOP	(1)	1	(1)	Assumed; no data	
Other environmenta	lly hazardous	chemical sub	stances		
Dioxins and dioxin- like PCBs	(1)	1	1	Assumed; no data	
Bisphenol A	0.1	1	(1)	(EU RAR 2003)	
Nonylphenol	< 0.1	0.1	(1)	(Monteiro-Riviere et al., 2000; EU RAR 2002; Moody et al., 2010)	
TBBPA	(1)	1	(1)	Not sufficient data	
PFOA	0.5-0.7	1	1	(EFSA 2008; Franko et al., 2012)	
PFOS	(1)	1	1	(EFSA 2008)	
D4	0.005-0.01	1	(1)	(Reddy et al., 2007)	
Parabens					
Propylparaben	0.037	1	(1)	(SCCS 2011)	
Butylparaben	0.037	1	(1)	(SCCS 2011)	
lsobutylparaben	0.037	1	(1)	(SCCS 2011)	
UV-filters					
OMC	0.02	1	(1)	(SCCNFP 2001)	
BC-3	0.04	1	(1)	(SCCP 2008a)	
Substances relevant for other cosmetic products					
Triclosan	0.208	1	(1)	The dermal abs is for (deo and cream); from EU DAR	
Resorcinol	0.025	1	(1)	(SCCP 2008b; SCCS 2010)	
Pesticides					
Chloropyrifos	(1)	1	(1)	Not sufficient data	

DAR: Draft assessment report for biocides

7.4 Exposure via food

In the exposure assessment, it is assumed that ingestion of food belongs in the basis scenario. Generally, there are 2 exposure levels, average and maximum exposure. For the substances, where it has been possible to find 95 percentiles for exposure of the population, these values are stated, but in many cases it has been necessary to use other estimates for a maximum exposure representative for approx. a 95 percentile of the population. The aim has been to use Danish data for humane exposure of the substances, but where such data were unavailable, foreign data or exposure levels used in EU risk assessments or opinions published by the European Food Agency, EFSA have been used.

Values for exposure to phthalates from foods are shown in Table 7-3. For **DEHP**, **DBP**, **DiBP** and **BBP** intake was used based on measurement described by Fromme et al., 2007. These intakes were calculated based on measuring of phthalates in the total amount of foods ingested during a week for each of the 50 persons between the age of 14 and 60. The study took place in Southern Germany in 2005, and is thus based on newer data than other available studies. The values are lower than intake values calculated from Danish measuring in 1999 (Petersen et al., 2000) and calculations from 2006 based on measuring on foods from the US, EU and Asia during the period 1996 to 2002 (Wormuth et al., 2006).

In 2008, limitations in the use of DEHP, DBP, BBP, DiNP and DIDP food contact materials were introduced, while the other phthalates are not allowed in food contact materials. As there have probably been adjustments of the food production in order to reduce contamination of food with phthalates also in the period up to 2005, the latest measurings (Fromme et al., 2007) are assumed to be a suitable estimate for the present phthalate exposure from foods.

For **DiNP** an intake of 0.45 is used as average value. Intake has not been calculated in the study by Fromme et al., (2007), and data from the study by Wormuth et al., (2006), which is based on food measuring during the period 1996 to 2002, also shows exposure from foods close to 0. However, Wormuth et al., (2006), note that exposure to DEHP via environmental contamination of foods will be replaced with exposure to DiNP, and that foods in time are expected to be a significant source of DiNP. Clark et al., 2011, calculate intakes of DiNP from foods of 0.45 g/kg bw/day (average) and 1.4 g/kg bw/day (maximum) (Clark 2011).

DPP, DnHP and DnOP are assumed to have no exposure from foods, as these substances are not allowed in food contact materials. These phthalates may theoretically be found in foods due to background pollution in the environment, but as there are no specific data, the exposure is here set to 0.

For **dioxins and dioxin-like PCBs**, intake values from the Danish monitoring program for foods have been used. The latest available average values for intake is for the period 2005-2009 (Cederberg et al., 2010). As the most recent report does not include 95 percentiles, is the high intake used the 95 percentile from the survey of Danes' intake of dioxins and dioxin-like PCBs during the period 2000-2004 (Danish Ministry of Food 2005).

For **bisphenol A**, intake calculations from EFSA's opinion from 2007 (EFSA 2007) have been used.

For **nonylphenol**, intake from the EU risk assessment report (EU RAR 2002) has been used. Only one figure for intake has been given, and it is stated to be upper limit for intake, but here it is used both as average and high intake.

For **PFOA and PFOS**, the same intake data as in EFSA's opinion from 2008 has been used. This data is based on several European studies (EFSA 2008).

For **triclosan** the intake via food is set to 0, although triclosan is allowed for certain uses in the food production in the EU, but triclosan is not on the positive list of substances allowed in food contact materials in Denmark (Danish Ministry of Food 2011). However, no calculations of humane intake of triclosan from foods were found.

For resorcinol, octamethylcyclotetrasiloxane (D4), propyl, butyl and isobutylparaben and OMC and benzophenone-3, the intake via food is set to 0, as there is not assumed to be a significant exposure from food compared to the expected higher dermal exposure from cosmetic products. However, propylparaben has previously been allowed as a preservative in foods, and there might be some exposure to propylparaben from foods produced outside the EU. D4 is included in certain siloxane-based products allowed in food contact materials, but as this substance group has low migration (Helling et al., 2009), exposure via food has been assumed not to be relevant. For tetrabromobisphenol A (TBBPA), the intake from food is also set to 0.

Values for intake of pesticides via food are shown in Table 7-3. Generally, the basis has been substances found in the list from the Food Agency of the 20 pesticides, which have been ingested the most in 2009 based on measurements in the monitoring program from the Food Agency (Danish Ministry of Food 2009). These intakes have been used as an average value for pirimiphos-methyl, Imazalil, propamocarb, iprodione, chlorpyrifos, thiabendazol and the group of dithiocarbamates (mancozeb, maneb and probineb totally). Procymidone is not on the list from 2009, but instead intake calculations from 2007 (Danish Ministry of Food 2007) have been used. Tebuconazole is not on the lists from 2007 or 2009, but intake determined by probabilistic calculation made in another project made by DTU Food Institute for EPA (Pestimix 2011) has been used. For tebuconazole and procymidon 95 percentiles for intake determined by probabilistic calculation in the pestimix-project (Pestimix 2011) have been used as high value. For those substances, where no value was found as a representative for a 95 percentile level, a figure has been used as a high value, which is twice the average intake. This is based on calculations for dithiocarbamates, for which a probabilistic calculation has shown that the 95 percentile for intake for adults is almost the double of the average value (Jensen et al., 2008). Double average values have been used as high intake for pirimiphos-methyl, imazalil, propamocarb, iprodione, chlorpyrifos, and dithiocarbamates (mancozeb, maneb, propineb).

Table 7-3 List of intake of selected substances via foods

Substan	Intake	Intake		nces via foc reference	Comments
ce name	averge (µg/kg bw/day)	high high (µg/kg bw/day)	intake average	intake maximum	Comments
DEHP	1.2	2.2	(Fromme et al., 2007)	(Fromme et al., 2007)	
Dinp	0.45	1.4	(Wormuth et al., 2006)	(Clark et al., 2011)	DiNP not found in (Fromme et al., 2007), but biomonitoring shows increasing exposure
DBP	0.26	1.4	(Fromme et al., 2007)	(Fromme et al., 2007)	
DiBP	0.6	2.1	(Fromme et al., 2007)	(Fromme et al., 2007)	
BBP	0.2	0.4	(Fromme et al., 2007)	(Fromme et al., 2007)	
DPP	0	0			Not allowed in food contact materials and therefore assumed negligible exposure to foods
DnHP	0	0			Not allowed in food contact materials and therefore assumed negligible exposure to foods
DnOP	0	0			Not allowed in food contact materials and therefore assumed negligible exposure to foods
Dioxins and dioxin- like PCBs	1.00E-06	2.07E-06	(Cederbe rg et al., 2010) high mean	10% lower value than 95 percentile (Danish Ministry of Food 2005)	
Bis- phenol A	1.5	1.5	(EFSA 2007)	(EFSA 2007)	
Nonyl- phenol	0.2	0.2		(EU RAR 2002)	2 ug/kg/day dividet by 10 due to the bioavailability
TBBPA	0	0			Assumed negligible exposure from foods
PFOA	0.06	0.2	(EFSA 2008)	(EFSA 2008)	
PFOS	0.002	0.006	(EFSA 2008)	(EFSA 2008)	
D4	0	0			May be included in products used in food contact materials, but are there any exposure data?

Substan ce name	Intake averge (µg/kg	Intake high (µg/kg	reference intake average	reference intake maximum	Comments
Propyl- parabe n	bw/day) 0	bw/day) 0	Not allowed. Propyl P may occur from foreign foods	Not allowed. Propyl P may occur from foreign foods	
Butyl- parabe n	0	0			Assumed negligible exposure from foods
lsobutyl- parabe n	0	0			Assumed negligible exposure from foods
OMC	0	0			Assumed negligible exposure from foods
Benzo- phenon e 3	0	0			Assumed negligible exposure from foods
Triclosan	0	0			May be included in products used in food contact materials, but are there any exposure data? Decomposition products may be bioaccumulative (dioxins)
Resor- cinol	0	0			Assumed negligible exposure from foods
Tebuco- nazole	0	0.0246	Probabilis- tic calculatio n, (Pestimix 2011)	95 percentile , probabilist ic calculatio n, (Pestimix 2011)	
Pirimi- phos- methyl	0.1	0.2	(Danish Ministry of Food 2009)	Double of average, assumed same diff ml average and 95 perc as for dithio- carbamat es	
Imazalil	0.067	0.13	(Danish Ministry of Food 2009)	Double of average	

Substan ce name	Intake averge (µg/kg bw/day)	Intake high (μg/kg bw/day)	reference intake average	reference intake maximum	Comments
Propam ocarb	0.067	0.13	(Danish Ministry of Food 2009)	Double of average	
lprodion e	0.05	0.1	(Danish Ministry of Food 2009)	Double of average	
Chlorop yrifos	0.033	0.067	(Danish Ministry of Food 2009)	Double of average	
Procy- midone	0.012	0.044	(Danish Ministry of Food 2007)	95 percentile , probabilist ic calculatio n, (Pestimix 2011)	
Dithioca rbamat es (Manco -zeb, maneb, propine b)	0.1	0.2	(Danish Ministry of Food 2009)	Double of average	
Thiaben -dazole	0.05	0.14	(Danish Ministry of Food 2009)	(Danish Ministry of Food 2009)	

7.5 Exposure via indoor air

Our indoor air has been identified as one of the most significant sources of exposure to chemical substances. Our indoor air may contain significantly higher concentrations of chemical substances than the outdoor air. The most significant route of exposure for indoor air appears to be via house dust (Rudel et al., 2003).

A number of the selected substances are present in our indoor air, because they are released from various inventory and consumer products in the home, and can thus be measured both in dust and in the indoor air.

A study from 2003 found a significant correlation between exposure via the air and excretion of DBP and BBP in the urine of women (Schettler 2006). This indicates that inhalation and intake of dust may be significant routes of exposure in women for the lower molecular phthalates.

A general search for reports and articles regarding the selected potentially endocrine disruptors and their presence in our indoor air has been made. Focus has been on studies from private homes, but studies from offices, schools and daycare centres are also included, as these places very well may represent an exposure via indoor air for the target group, pregnant women and women who want to become pregnant.

Below, a series of studies of the contents of the selected substances in indoor air quality are reviewed, and further the tables below give an overview of the sources of the presented data.

Where possible, Danish figures have been used in the exposure calculations, but Danish figures only exist for PCB and phthalates (in dust).

The section is divided into two main sub-sections:

- 1) data regarding the selected substances in dust, and
- 2) data regarding the selected substances in indoor air

Substances – for which data about their presence in the indoor air has been found (both dust and indoor air) – are presented individually below. Please note that the measurements of the indoor air may include both airborne particles (e.g. stirred up) and gasses/vapours.

All identified studies have been stated in tables in the different sections below. In the table, the studies used for risk assessments are highlighted with grey background colour – and the individual values from this selected study are written in bold.

Generally, measurements from workplaces (offices, daycare centres etc.) are in line with measurements from private homes, although there is a tendency that the measurements of the workplaces are slightly higher than in private homes. But there are studies showing the opposite. Therefore, it has been deliberately chosen not to distinguish between occupational exposure and exposure in our private homes. Instead the highest values are used for the whole time women are assumed to stay indoors.

Overall, the following criteria have been used for selection of data for exposure calculations:

• Danish studies have been chosen rather than foreign studies

- studies with several measurements have been chosen rather than studies with few measurements
- new studies have been chosen rather than older studies
- studies with the highest measured values have been chosen

If described in the studies, it is shown when the measurements were made. Otherwise, the year of publication for the study is used as an indication of the age of the studies.

Generally, minimum and maximum values (range), the average, median (50% percentile), and 95% percentile are presented for the studies, if indicated. Based on this data, two values have been selected for each substance for both concentrations in dust and in indoor air, which are used in further exposure calculations:

- median values (or average, if median is not available). Median is selected rather than average, as average may be affected either by particularly high or particularly low values.
- maximum values, as by far the fewest studies indicate a 95% percentile. In some studies, where a 95% percentile is indicated, this is used rather than the maximum value, if the maximum value is extremely high compared to the remaining measurements.

7.5.1 Concentrations of the selected substances in dust

Data for concentrations in dust in the indoor air has been found for the following of the selected substances:

- phthalates (DEHP, BBP, DBP, DiBP, DiNP, DnOP, DPP, and DnHP)
- PCB
- bisphenol A
- nonylphenol
- TBBPA
- PFOS and PFOA
- parabens
- triclosan
- chloropyrifos

These substances/substance groups are presented individually below.

7.5.1.1 Phthalates in dust

A number of studies of different phthalates in house dust have been identified, but, however, most studies measuring on DEHP, BBP, DBP, and DiBP, minimum and maximum value (range), average, median (50% percentile), and 95% percentile are presented, if indicated in the studies.

As it appears from data in Table 7-4, there are very large variations between the 50 and 95 percentiles and the maximum values in the measuring of phthalates in dust. This illustrates the large differences in found levels and thus also in the levels that occur in Danish homes. Therefore, exposure calculations have been made for both the median (or average, where the median is not available), and maximum values to illustrate the large variations and their impact on the risk.

Data presented below is divided into two groups. Older data and newer data (2008) from a large Danish study and from a Swedish study measuring contents of phthalates in dust in 12 different countries (Bornehag et al., 2005; Langer et al., 2010; SSNC 2011).

Data is used from measurements of e.g. American, Bulgarian, German, Swedish, and Danish homes. A larger Swedish study is about 10-11 years old (sampling made in 2001-2002), (Bornehag et al., 2005). The latest Danish study is about 4 years old – sampling made in 2008 (Langer et al., 2010), and the latest Swedish study is from 2011, but it is not stated when the samples were taken (SSNC 2011).

The latter Swedish study (SSNC 2011) is not particularly comprehensive. Only one measurement has been made from each of 12 different countries. Except from the DBP levels, which are by far the highest measured, all other values are below the maximum values of the other studies. The high DBP level has been measured in the Czech Republic. The DBP values of all the other countries are on a level, which is at least 100 times lower. As it is a small study (12 samples in total from 12 different countries), the values from it are not used for the exposure calculations, as there is a Danish (relatively new) study with far more measurements.

This newer Danish study has gathered dust samples from 500 playrooms and 151 daycare centres from homes and buildings in Fyn in the spring of 2008 (Langer et al., 2010). In connection with this Danish study, the measured concentrations (medians) in dust for the phthalates have been compared with a large number of European and American studies (which are also presented in the table below). This comparison shows that the values measured in the previous foreign studies are at fairly comparable levels (within a factor 10) for the different phthalates (DEHP, DBP, DiBP, and BBP) in the different countries – except the Bulgarian study. The Bulgarian study deviates significantly from the others with far higher values. Langer et al. (2010) indicate that these Bulgarian values are unusually high, and are of the opinion that it may be due to analytical problems. Langer et al. (2010) conclude that the values for BBP, DBP and DEHP in dust in this Danish study are somewhat lower than measured in the previous studies. DiBP levels with the previous studies.

Langer et al (2010) make a comprehensive comparison of a Swedish study from 2005, which is also a comparatively extensive study (346 measurements) (Bornehag et al., 2005). The median for BBP is approx. 35 times lower than in the new Danish study compared with the Swedish one, DBP is approx. 10 times lower and DEHP approx. 3.5 times lower. The authors indicate the reasons for this as follows:

- 1. the lower values show that there has been a change to a use of other phthalates because of an EU prohibition of use of the phthalates in e.g. toys from 2007.
- 2. geographic differences (i.e. use of different products in Danish and Swedish homes). E.g. PVC flooring (containing phthalates) was found in much more Swedish homes (50%) compared with Danish homes (5%).

Langer et al (2010) therefore compare the Swedish and Danish data of the two studies for the homes without PVC flooring. And even in this comparison, the Danish median values for BBP are 24 times lower in the Danish study compared with the Swedish study, DBP is approx. 9 times lower, and DEHP approx. 3.3 times lower. This compared with the fact that the DEHP dust values from the new Danish study are 2.5 times lower than for the previous Danish study (Clausen et al., 2003), shows that the phthalate concentration in dust for these phthalates seems to have decreased.

It was decided only to use the Danish data from Langer et al (2010) for DEHP, DBP, DiBP, and BBP in the risk assessment, because this study is relatively new, is by far the most extensive, is Danish, and there is a chance that the phthalate prohibition may have had an effect in the form of lower phthalate values today than

earlier. For the other phthalates, values are used from non-Danish studies, because no Danish values were found:

- for DiNP, DnOP, and DnHP, available data is used, from one or two studies
 - for DiNP, 95 percentile is used instead of the maximum value, as the median value shows that only one or two measurements show these extremely high values
 - for DnOP, the geometric average is used, because median or normal average is not available
- for DnPP, no calculations are made, as the only study, which has measured for DPP has not identified DPP above the detection limit

Langer et al (2010) illustrate a small difference between the concentrations measured in Danish homes and in daycare centres. The average concentrations in daycare centres are a factor 1-4 higher than the average concentrations from the homes. As the difference is not significantly higher and to use a conservative approach, the highest concentration from the study is used whether or not the measurements are taken from the daycare centres or the homes. This concentration is used throughout the day – i.e. it is representing both staying indoor in a work situation and in a private situation (at home).

Table 7-4 Overview of content of phthalates in dust in indoor air. Highlights in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in indoor dust	Comments
(SSNC 2011)	House dust (bedrooms): DEHP: Range: 6.5 – 1670 μg/g Sweden: 121 μg/g Germany: 213 μg/g DBP: Range: < DL – 2900 μg/g	SSNC has measured on content of chemical substances in dust samples from 12 different countries: South Africa, Tanzania, Kenya, Uganda, the Philippines, Malaysia, Sweden, Belgium, Germany, the Czech Republic, Hungary, and Italy. It was not indicated when the sampling was performed The dust samples have been taken from bedrooms. Only three dust samples were taken from each bedroom, which are then pooled into a single sample for analysis The highest values were generally measuring in the Philippines for all substances Here a range is indicated for the different phthalates. This range thus illustrates the differences in the values from the 12 countries. Values from our neighbouring countries, Sweden and Germany are stated separately.

Source	Concentration measured in	Comments
	indoor dust	
(Langer et al., 2010; Weschler et al., 2010)	House dust (bedrooms): DEHP: Range: 12.7 - 6611 µg/g GM: 220 µg/g Median: 210 µg/g DBP: Range: < 0.18 - 253 µg/g	During spring 2008, 500 dust samples were taken from Danish homes (bedrooms), and dust samples from 151 Danish daycare centres. All the samples were taken in Fyn. DEHP was identified in all samples both in homes and daycare centres, while DnBP, DiBP, and BBP were detected in more than 75% of the bedrooms and more than 90% of the daycare centres. The article compares the found levels with some previous studies (also presented in this table), and concludes that the concentrations of BBP, DnBP, and DEHP are somewhat lower than in previous studies. The reasons for this, the author indicates as follows: 1) the values represent a change to use of other phthalates 2) geographic differences (different products are used in the homes of different countries) The article exclusively indicates average values – no maximum values for the substances. We have received raw data from the authors and can on thls background, indicate minimum and maximum values for the study. GM = Geometric Mean
(Hwang et al., 2008)	DEHP: ND – 40459 μg/g (95 percentile: 854 – 7980 μg/g) (Average: 192 – 3214 μg/g) (median* = 195 - 996 μg/g)	Among the phthalates, the source has just studieD DEHP. American study, but data from a number of other sources have been stated – incl. European sources (1997-2008). Between 5 and 376 samples in the different studies. The highest value was measured in the study with the 376 samples. Thus, data represents values from a number of different countries. The age of the data is not apperent.
(Becker et al., 2004)	DEHP: 22 – 5330 μg/g (95 percentile: 1840 μg/g) (50 percentile*: 515 μg/g) (Av. (geometric): 508 μg/g)	Only DEHP was measured in house dust from vacuum cleaner bags in Germany in 2001and 2002. 252 vacuum cleaner dust samples were analysed.
(Clausen et al., 2003)	DEHP: <u>Schools:</u> Av.: 3214 μg/g (95 percentile: 7063 μg/g) (50 percentile*: 858 μg/g) <u>House dust</u> : Av.: 640 – 858 μg/g (95 percentile: 2000 – 2600 μg/g)	Also states results from previous Danish (1991/23 samples), German (1997/272 samples, 2001/286 samples), and Norwegian (1997/38 samples) studies of house dust (vacuum cleaner dust). The latest study (2003) only includes schools, not private homes. Bornehag et al, 2005, have quoted the 50 percentile from this Danish study by Clausen et al, 2003.

Source	Concentration measured in indoor dust	Comments
(Bornehag et al., 2004; Bornehag et al., 2005)	DEHP: $0 - 40459 \mu g/g$ (Av.: 1310 $\mu g/g$, median: 770 $\mu g/g$) (95 percentile: 4069 $\mu g/g$) DBP : $0 - 5446 \mu g/g$ Av.: 226 $\mu g/g$, median: 150 $\mu g/g$) (95 percentile: 568 $\mu g/g$) DiBP : $0 - 3810 \mu g/g$ (Av.: 97 $\mu g/g$, median: 45 $\mu g/g$) (95 percentile: 311 $\mu g/g$) BBP : $0 - 45549 \mu g/g$ (Av.: 319 $\mu g/g$, median: 135 $\mu g/g$) (95 percentile: 599 $\mu g/g$) DiNP : $0 - 40667 \mu g/g$ (Av.: 639 $\mu g/g$, median: 41 $\mu g/g$) (95 percentile: 1930 $\mu g/g$)	346 measurings of surface dust from kid's room have been made in Sweden in 2001 and 2002. Data from the same study is presented in the two sources, but in Bornehag (2005) is also presented results from six German studies (1997/272 samples, 2001/286 samples, 2002/199 samples, 2003/65 samples, 2004/30 samples, 2004/252 samples), en Norwegian study (1997/38 samples) and a Danish study (2003/23 samples – only DEHP).
(Kolarik et al., 2008)	DEHP: 95 percentile: 1190 – 7980 µg/g (50 percentile = 340 - 990 µg/g BBP: 95 percentile: ND – 1560 µg/g (50 percentile = ND - 330 µg/g DBP: 95 percentile: ND – 30.800 µg/g (50 percentile = ND - 9850 µg/g DnOP: Geometric mean: 250 µg/g 95% CL: 200 - 300 µg/g Range: ND – 2510 µg/g	Dust samples have been made from 177 homes in Bulgaria in 2005. Furthermore, is shown results from nine other European studies (incl. Becker et al, 2004; Clausen et al, 2003; and Bornehag et al, 2004). There are results from Sweden (2004/346 samples), Germany (1997/272 samples, 2001/286 samples), 2002/199 samples, 2002/65 samples, 2004/30 samples, 2004/252 samples), Norway (1997/38 samples) and Denmark (2003/23 samples). Other phthalates have also been measured. Kolarik et al, 2008 refer to the same studies as other sources, but state exclusively 95 percentile and not maximum values, and therefore the high value of > 40,000 µg/g does not appear from this source. Measuring of DNOP in dust measured in 177 homes in Bulgaria. Number of samples above the detection limit: 143. Data is listed as: Geometric mean (95% CI; range).
(Rudel et al., 2003)	DEHP: $16.7 - 7700 \ \mu g/g$ (median = $340 \ \mu g/g$) DBP: $< 24 - 352 \ \mu g/g$ (median = $20.1 \ \mu g/g$) BBP: $3.87 - 1310 \ \mu g/g$ (median = $45.4 \ \mu g/g$) DiBP: $< 1 - 39.1 \ \mu g/g$ (median = $1.91 \ \mu g/g$) DnHP: $< 0.1 - 30.6 \ \mu g/g$ (median = $1.1 \ \mu g/g$)	Measurements have been performed in 120 American homes in 1999-2001. The dust sample has been collected via a vacuum cleaner from 4-5 of the most used rooms of the home.
(Watson 2009)	DEHP: Range: $10 - 2400 \mu g/g$ (median = $1355 \mu g/g$) DBP: $20 - 460 \mu g/g$ (median = $89 \mu g/g$) BBP: $< 2.6 - 20 \mu g/g$ (median = $< DL$) DiBP: $4.7 - 77 \mu g/g$ (median = $43 \mu g/g$) DPP (Dipentyl phtlatate): Range: $<1.3 \mu g/g - <3.3 \mu g/g$ (median = $< DL$)	4 dust samples taken in 2 offices in the Czech Republic and an observatory on the top of a mountain and an authority building, respectively. The mountain dust sample gave the value: < 1.5. Dust collected via vacuum cleaner. It has not been indicated when the samples were collected.

Source	Concentration measured in indoor dust	Comments
(HSDB 2009)	DnHP : Range: 0.308 – 3.14 µg/g	Data has been found in 5 of 6 dust samples from homes and offices. The complete reference cannot be provided, men the following site refers the data: (HSDB 2009). Original reference is from 2001. It has not been indicated when the samples were collected or where.
(NTP - CERHR 2003)	DnOP 40 μg/g (vacuum cleaner bag dust) 20 μg/g (dust sample from one of 3 houses)	(Pfordt et al., 1999) referred in (NTP - CERHR 2003) indicate that DNOP was found in the stated amounts in samples from Germany. However, only 3 homes were tested (allegedly). Referred on page II-2 in (NTP - CERHR 2003). The
	ated (below the date stice limit)	original source could not be provided.

ND = Not detected (below the detection limit)

DL = Detection Limit

Highlighting in grey and figures in bold illustrate the values used in the exposure calculations. *) Note that some studies indicate a median and others a 50 percentile. This is an expression of the same value.

7.5.1.2 PCB in dust

PCB in indoor air consists both of dioxin-like PCB and non-dioxin-like PCB. 12 of the 209 different types of PCB (congeners) are dioxin-like. The dioxin-like PCBs are interesting concerning endocrine disrupting effects. The problem is, however, that not all studies of PCBs in indoor air distinguish between non-dioxin-like and dioxin-like PCBs.

A couple of American studies have been found which measure PCB in dust. Furthermore, there is a Danish study of PCB in Danish building from 2009 (Gunnarsen et al., 2009). The new Danish PCB study of Farum Midtpunkt unfortunately does not measure PCB in dust (National Board of Health 2012). A Danish report made for the Danish Business Authority, the EPA and the Working environment Service (Jensen et al., 2009) picks up on indoor air measuring made in the US and Europe for PCB, but generally, only little information is indicated, such as maximum values. Data from Gunnarsen et al. (2009) is not included here, as the studies were made about the same time.

Common for many of the studies is the focus on measurements of buildings (e.g. schools) with known contamination of PCBs. For these buildings, the levels may be extremely high, e.g. 980 μ g/g in dust (Weis et al., 2003). There is some uncertainty in this exposure calculation for PCB, as no information of the specific dioxin-like PCB congeners has been shown in the sources. There is a big difference between whether the studies measure the individual specific PCB congeners, PCB7 (consisting of six non-dioxin-like PCBs and one dioxin-like congener) or total PCB (PCBn). Since there has not been found sufficient data to perform a risk assessment specifically for the dioxin-like PCBs, another DNEL for PCBs in dust than for PCBs in air and food has been used as specified in Chapter 6 "Risk Assessment". The DNEL_{AA} value for PCBs in dust has been determined based on a study of a mixture of dioxin-like and non-dioxin-like PCBs and an assumption that the composition of PCBs in dust reflects the composition of PCBs in the used study. Therefore, values of PCBs in dust as total PCBs or PCBn are selected for the exposure calculations.

Data stated by Jensen et al. (2009) shows the highest values measured in dust in a school in Denmark. Here is no data for PCBn, but PCB7, and the highest measured value for PCB7 is used as maximum value. As median value is used the median

Data from schools, public buildings, daycare centres etc. is used, because they may represent a work situation for the target group.

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Source	Concentration measured in indoor dust	Comments
(Rudel et al., 2003)	PCB 52: < 0.2 – 15.7 μg/g (median = < 0.2 μg/g) PCB 105: < 0.2 – 16.3 μg/g	120 American homes were measured in 1999-2001. The dust sample has been collected via a vacuum cleaner from 4-5 of the most used rooms in the home.
	(median = < 0.2 μg/g) PCB 153: < 0.2 – 35.3 μg/g	Of 120 homes, PCB in air was found in 32% of them and PCB in dust in 18% of them (Rudel et al., 2008).
	(median = < 0.2 µg/g)	PCB 105 is one of the dioxin-like congeners. PCB 52 and 153 are non-dioxin like.
(Rudel et al., 2008)	Sum of PCB 105 and 153: Maximum: 0.6 - 10 μg/g	The source follows up on the 2 of the 120 American homes with the highest measured PCB concentrations and the course is found (wooden floor finish). High PCB concentrations are still measured 5 years later. These measuring are from 2004-2005. It is shown that other American studies do not show the same high PCB concentrations (a study of 1000 vacuum cleaner bag samples). The dispersion thus indicates the level from "normal" to some high concentrations indicated in Rudel et al, (2008). PCB 105 is one of the dioxin-like congeners. PCB 153 is non- dioxin-like.
(Sullivan 2008)	Total PCB: Maximum 36 μg/g Αν.: 6.7 μg/g	19 dust samples in a school in the U.S. in 2007. PCB was found in 18 out of 19 samples from the school. Dust samples are from the ventilation system.
(Jensen et al., 2009)	PCB: Sweden: Maximum: 4 µg/g Denmark (school): Range PCB 7: 0.6 – 18.2 µg/g	A Danish report made for the Danish Business Authority, the EPA and the Working environment Service (Jensen et al., 2009). It follows up on indoor air measuring made in the US and different European countries for PCB. Data from Gunnarsen et al. (2009) is not included here. Generally, it is not stated when the samples were taken, and generally, single measurings are indicated. There is few data for PCB in dust, but dust measurements from a Danish school made in 2008 were used. Measuring of dust is for PCB 7. PCB 7 consists of six non-
(Gunnarsen et al., 2009)	Single-family homes/ residential floor: PCB 7: < $0.015 - 0.0899$ µg/g PCB n: < $0.015 - 0.171$ µg/g Public buildings: PCB 7: $0.0685 - 0.906$ µg/g PCB n: $0.119 - 2.054$ µg/g All 10 measurements: Median PCB 7: 0.09 µg/g Median PCB n: 0.152 µg/g	dioxin-like PCBs and the dioxin-like congener PCB 118. In this Danish study, buildings have been deliberately selected containing PCB in the building materials. The stated values are for single-family homes (4) and a residential floor (1), but but there is also measured in storage, office, college and university, which had between 1 and 100 times higher concentrations of PCBs in the dust. PCB7 = the sum of 7 congeners. PCB7 consists of six non- dioxin-like PCBs and the dioxin-like congener PCB118. PCBn = the sum of the n of the 22 congeners above the detection limit. Please note that no 95 percentile are stated for the few data (10 totally) measured. It has not been stated when the measuring was carried out, but the project started in 2006.

Tablel 7-5 Overview of content of PCB in dust in the indoor air. Highlighting in grey andfigures in bold illustrate the values used in the exposure calculationsSourceConcentration measuredComments

7.5.1.3 Bisphenol A in dust

Five studies have been identified concerning measuring of bisphenol A in dust. Three American studies (two of older date) and a newer Belgian and Swedish study (which has measured in 12 different countries. All studies show that the content of bisphenol A in dust is in the same relatively low level. The Swedish study, however, shows far lower values.

The values from the latest American study are used (Loganathan et al., 2011), because here relative many measurements have been made (56). The measuring was carried out in 2006. Median value and highest maximum measured concentration are used in the calculations.

Table 7-6 Overview of content of Bisphenol A in dust in the indoor air. Highlighting in grey
and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured	Comments
	in indoor dust	
(Rudel et al., 2003)	Bisphenol A: < 0.2 – 17.6 μg/g (median = 0,821 μg/g)	120 American homes were measured in 1999-2001. The dust sample has been collected via a vacuum cleaner from 4-5 of the most used rooms in the home.
(Wilson et al., 2001)	Bisphenol A: 1.04 – 4.51 μg/g	Dust samples from 6 homes and offices in the US. (Wilson et al., 2001; Salthammer et al., 2009) Wilson, Chuang and Lyu (2001) referred in Salthammer and Udhe, 2009. It has not been indicated when the samples were taken.
(Loganathan et al., 2011)	Bisphenol A: Range: < 0.0005 – 2.95 μg/g Av.: 0.843 μg/g Median: 0.422 μg/g	56 measuring of dust samples from two different cities in Eastern USA were made in 2006. 44 measurements from houses, 6 measurements from laboratories, and 6 special measurements of dust in dryers and refrigerators. It is indicated that the average concentrations from the laboratories were higher than the concentrations from the private homes, but not statistically significantly higher. The highest measuring of10.2 μg/g originates from a dust filter in a laboratory, which dust has been accumulating for more than a year. This measurement is thus kept out of the study and is not considered to be representative for this project on pregnant women. The second-highest measurement is 2.95 μg/g.
(Geens et al., 2009)	Bisphenol A: <u>Private homes:</u> Minimum 0.535 µg/g Median: 1.461 µg/g 95%: 4.873 µg/g Maximum: 9.729 µg/g Mean: 2.001 µg/g <u>Offices:</u> In the two offices, just the following values are indicated: 4.685 µg/g 8.380 µg/g	Measured in dust samples from 18 randomly selected houses and 2 offices in Flanders, Belgium. The samples were taken in 2008. The samples consist of dust collected form living room, bedroom and kitchen.

Source	Concentration measured in indoor dust	Comments
(SSNC 2011)	Bisphenol A: Minimum: 0.00004 µg/g Maximum: 0.0247 µg/g Sweden: 0.0017 µg/g Germany: 0.0004 µg/g	SSNC has measured content of chemical substances in dust samples from 12 different countries: South Africa, Tanzania, Kenya, Uganda, the Philippines, Malaysia, Sweden, Belgium, Germany, the Czech Republic, Hungary and Italy. It is not indicated when the sampling took place. The dust samples were taken from bedrooms. Only three dust samples were taken from each bedroom, which have then been pooled into a single sample for analysis. The highest values have generally been measured in the Philippines for all substances. No range for bisphenol A has been indicated. This range thus illustrates the difference between values from the twelve countries. Values from our neighbouring countries Sweden and Germany are given separately.

7.5.1.4 Nonylphenol in dust

A number of studies of nonylphenol in indoor dust have been identified. However, data is primarily of older date (2000-2005). Some data is indicated as nonylphenol – others as nonylphenol and its ethoxylates. Both data from house dust and data from offices or daycare centres have been identified.

A Czech study and an American study are different by having maximum values and average values significantly higher than de remaining studies (approx. 1000 times higher). The Czech study, however, also covers other nonylphenols, and the American study is from way back in 2000.

Rudel et al. 2003 is by far the most extensive study with 118 dust samples from American households (made in1999-2001). The remaining studies exclusively cover a couple of samples (4-10 samples). Therefore, data from the most extensive study (Rudel et al., 2003) is used, even though the data is several years old.

The maximum values found in the calculations are used (i.e. the highest identified median values and maximum values).

Table 7-7 Overview of content of nonylphenol in dust in the indoor air. Highlighting in grey		
and figures in bold illustrate the values used in the exposure calculations		

Source	Concentration	Comments
	measured in indoor	
	dust	
(Rudel et al., 2003)	4-nonylphenol: Minimum: <rl Maximum: 8.68 μg/g Median: 2.58 μg/g</rl 	120 American homes were measured in 1999-2001. There is data for 4-nonylphenol (a synonym for nonylphenol). 4- nonylphenol was found in 80% of the 118 dust samples from households.
(Butte et al., 2001)	Nonylphenol Median: 6.2 μg/g 95%: 18 μg/g	Found in house dust from households (residents' own vacuum cleaners). Households in Schleswig-Holstein and Lower Saxony. It is not indicated when the samples were made.
(Watson 2009)	P-Nonylphenol: Range: 3300 – 20,000 μg/g Av.: 8675 μg/g.	4 dust samples taken in 2 offices in the Czech Republic and an observatory on the top of a mountain and an authority building, respectively. The mountain dust sample gave the value: < 4500 ug/g. Dust collected via vacuum cleaner. It is not indicated when the samples were taken. Data for the nonylphenol with the highest values is presented here.
		NB: nonylphenol covers here P-N-nonylphenol (104-40-5) and 4-Nonylphenol mono-ethoxylate (9016-45-9) and 4- nonylphenol di-ethoxylate (20427-84-3) and not Nonylphenol (with nos 25154-52-3 or 84852-15-3) which we have focus on in the project.
(Rudel et al., 2001; Salthammer et al., 2009)	Nonylphenol: Nonylphenol (og dets mono- og di- ethoxylates): Maximum: 14 µg/g i house dust	(Rudel et al., 2001)(Salthammer et al., 2009). The measuring has been taken in 7 samples of house dust in the US. It is not indicated when the samples were taken.
(Wilson et al., 2001; Salthammer et al., 2009)	Nonylphenol: Range: 4.16-13.8 µg/g	Dust samples from 10 daycare centres in the US. (Wilson et al., 2001; Salthammer et al., 2009). It is not indicated when the samples were taken.
(Costner et al., 2005)	Nonylphenol: Maximum: 10,500 μg/g Minimum: 3740 μg/g Av: 5141 μg/g	Data is for 4-nonylphenol. Found in 7 out of 7 dust samples (from vacuum cleaner bags) from 7 different US states (10 samples from houses in each state). It is not indicated when the samples were taken.
(SSNC 2011)	Nonylphenol: Maximum: 0.0038 μg/g Minimum: 0.0001 μg/g Sweden: 0.001 μg/g Germany: 0.0008 μg/g	SSNC has measured for content of chemical substances in dust samples from 12 different countries: South Africa, Tanzania, Kenya, Uganda, the Philippines, Malaysia, Sweden, Belgium, Germany, the Czech Republic, Hungary and Italy. It is not indicated when the sampling took place. The dust samples were taken from bedrooms. Only three dust samples were taken from each bedroom, which have then been pooled into a single sample for analysis. The highest values have generally been measured in the Philippines for all substances. Here is indicated a range for nonylphenol. This range thus illustrates the difference between values from the twelve countries. Values from our neighbouring countries Sweden and Germany are given separately.

7.5.1.5 TBBPA in dust

Only two newer Belgian studies have been identified, and an English study with measuring of TBBPA in dust. All three studies show fairly the same measured levels. One of the Belgian studies (Geens et al., 2009) however, is different with a maximum value approx. 3-5 times higher than the maximum value in the other two studies. The median value (which is low) from the Belgian study shows, however, that only a few measurements have so high values.

The results from the latest Belgian study (D'Hollander et al., 2010) are used (measurements made in 2008), as these are the highest maximum values of the remaining two studies. The median value from the Belgian study, however, is a factor 3-5 lower than the English study.

Source	Concentration	Comments
	measured in indoor	
	dust	
(D'Hollander et al., 2010)	TBBPA Range: < 3 – 419 ng/g Median: 12 ng/g	Belgian measuring from 45 homes and 10 offices. Dust samples were collected in 2008. The dust samples represent dust from living room, bedroom, kitchen and office.
(Geens et al., 2009)	TBBPA <u>Private homes:</u> Minimum: 0.85 ng/g Median: 10 ng/g 95%: 689 ng/g Maximum: 1481 ng/g Mean: 146 ng/g	Measured in dust samples from 18 randomly selected houses and 2 offices in Flanders, Belgium. The samples were taken in 2008. The samples consist of dust collected from living room, bedroom, and kitchen
	Offices: In the two offices, just the following two values are given: 100 ng/g 45 ng/g	
(Abdallah et al., 2008)	TBBPA Private homes (35): Range: <0,05 – 382 ng/g Median: 62 ng/g Av.: 87 ng/g	TBBPA in dust has been measured for in 35 private homes, 28 offices and 4 public places (3 pubs and 1 restaurant) in the UK. Sampling took place in 2007. Dust samples have been collected with vacuum cleaner. Air samples were collected in living rooms (private homes).
	<u>Offices (28):</u> Range: <0.05 - 140 ng/g Median: 36 ng/g Av.: 49 ng/g <u>Public places (4):</u> Range: 52 - 350 ng/g Median: 230 ng/g Av.: 220 ng/g	TBBPA was not detected everywhere. The article calculates the importance of intake via air, dust and foods for children and adults. For adults, food still is of the greatest importance (44-82% of the total exposure depending on whether you look at the 5 of the 95 percentile), whereas intake from dust represents between 12 and 50% of the total exposure (for the 5 and the 95 percentile, respectively). It is concluded in the study that the dust intake represents an important part of the total exposure.

Table 7-8 Overview of content of TBBPA in dust in the indoor air. Highlighting in grey and
figures in bold illustrate the values used in the exposure calculations

7.5.1.6 PFOS and PFOA in dust

Several comparatively new studies of the content of PFOS and PFOA in dust in the indoor air have been identified. A Norwegian study (Huber et al., 2011) also picks up on other previous dust measuring (from Belgium, Sweden, Canada, the US and Japan). Generally, there is no suggestion of large differences in the values from private homes or from offices. All values are therefore presented in total. Huber et al. (2011) indicate that the measured values in Tromsø, Norway generally are lower than observed in the other studies, but indicate that this may be due to geographic differences, cultural differences, and differences in the used sampling methods.

A Japanese study – also from 2011 (Liu et al., 2011) also picks up on previous studies. Here is also indicated that the new Japanese study has values, which are lower than previously measured values in e.g. the US, China, Australia, the UK, and Germany, but there are also other previous studies with lower values than the Japanese ones. The Japanese study exclusively measures PFOA and other PFC (perfluoroalkyl carboxylates) in dust. PFOS has not been measured.

A Swedish study measures PFOS and PFOA in dust in 12 different countries (SSNC 2011). Only one measuring has been made in each country, and PFOS and PFOA have only been identified in 5 and 2, respectively, of the 12 measurements.

Jogsten, Nadal et al. (2012) have measured PFOS and PFOA in 10 different houses in Spain. It is stated that the identified values are lower than the values from previous studies.

Goosey & Harrad (2011) represent by far the most extensive study of PFOS and PFOA in dust in private homes and work places (offices and classrooms). A total of 225 different measurings have been made in 8 different countries. This study also shows some of the highest measured values. The values from here are used in the calculations, as this is the most extensive study. The highest identified values and the highest median values are used for the calculations. These highest measured values have been measured either in the UK or in Germany. Therefore, it has been deliberately chosen not to distinguish between measurements from private homes and from work situations, since the values are reasonably at the same level – and in order to use a conservative approach, the highest concentrations from work situations or the homes are used throughout the day, i.e. they both represent staying indoor in a work situation and in a private situation (at home). It is however stated in the study that the levels from classrooms and offices are significantly higher than in private homes, even though the highest value found originates from a private home.

Table 7-9 Overview of content of PFOS and PFOA in dust in the indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in indoor dust	Comments
(Jogsten et al., 2012)	PFOS: Range: 1.1 – 12 ng/g Median: 2.5 ng/g Average: 3.5 ng/g PFOA: Range: 0.16 – 36 ng/g Median: 4.2 ng/g Average: 9.5 ng/g	PFOS and PFOA and a number of other PFCs have been measured for in house dust and indoor air in 10 different houses in Spain. Dust samples were taken from vacuum cleaner bags, og the air samples were collected in the height of 1 m in the homes in 2009. PFOS and PFOA were identified in all 10 samples of house dust, but PFOS only in three samples of the indoor air (but they could not be identified again by double determination). It is stated that the identified values are lower than values from previous studies. In the article, an assessment of exposure of adults and small children to different PFCs has been made. The exposure assessment shows that the food intake is the major source of exposure to PFCs. When using the highest measured values from this study, the indoor air constitutes maximum 4% of the total exposure of adults.

Source	Concentration	Comments
Jource	measured in indoor	Comments
	dust	
(Huber et al., 2011)	PFOS: Range: <0.1 – 5065 ng/g Median: 0.5 – 201 ng/g Average: 9.4 – 443.6 ng/g	PFOS and PFOA and a number of other PFCs have been measured for in house dust and indoor air in Tromsø, Norway. 12 dust samples were collected – of these 7 from living rooms, 1 from a bedroom, 2 from a carpet and a settee, respectively, and 2 samples from an office and store room. The samples were collected in 2007/2008.
	PFOA: Range: <0.05 – 3700 ng/g Median: 0.7 – 165 ng/g Average: 6.4 – 380 ng/g	The article picks up on other dust measuring from Belgium (45 measuring in homes), Sweden (10 measurements in houses, 38 in apartments, and 10 in an office), Canada (67 measurements in homes), the US (102 measurements in homes and 10 measurements in daycare centres), Japan (16 measurements in homes), Norway (1 measurement in an office) and Belgium (10 measurements in an office). Minimum, maximum, median and average values are presented for all these measurements, where Huber et al. (2011) have cited a number of sources.
		Generally, this does not suggest that a large difference between the values of private homes or of offices. All values have therefore been presented.
		Huber et al. (2011) state that the measured values in Tromsø, Norway, are generally lower than observed in the other studies, but state that this may be due to geographic differences, cultural differences, and differences in the used sampling methods.
(Liu et al., 2011)	PFOA: Range: 3.2 – 340 ng/g Median: 20.8 ng/g Average: 42.3 ng/g	PFOA and orther PFCs have been measured for in 77 samples of dust from vacuum cleaner bags from 4 different towns in Japan in 2010. It is stated that the measurings in this study have values, which are lower than the previously measured values in e.g. the US, China, Australia, the UK and Germany, but there are other previous studies with lower values than the Japanese ones. The article picks up on a number of previous studies (from 2003-2011) showing median values of between < 0.98 and 355 ng/g PFOA in dust. The highest median value referred to, 355 ng/g has, however, only made 4 measurements. Only median values from previous studies were indicated - not maximum values.
(SSNC 2011)	PFOA: Range: 1.1 – 3.4 ng/g Sweden: < DL Germany: < DL PFOS: Range: 0.7 – 7.6 ng/g Sweden: 1.6 Germany: < DL	SSNC has measured for content of chemical substances in dust samples from 12 different countries: South Africa, Tanzania, Kenya, Uganda, the Philippines, Malaysia, Sweden, Belgium, Germany, the Czech Republic, Hungary and Italy. It is not indicated when the sampling took place. Only three dust samples were taken from each bedroom, which have then been pooled into a single sample for analysis. The highest values have generally been measured in the Philippines for all substances. Here is indicated a range for PFOS and PFOA. This range thus illustrates the difference between values from the twelve countries. However, PFOS and PFOA were not detected in all 12 countries. Values from our neighbouring countries Sweden and Germany are given separately.

Source	Concentration	Comments
	measured in indoor	
	dust	
(Goosey et al., 2011)	dust PFOS: Private homes: Range: <0.03 - 7400	Measurings for PFOA and PFOS and other PFCs in house dust have been made in a number of countries from 2007- 2009. Australia (20 measurements), Canada (20 measurements), France (9 measurements), Germany (10 measurements), Kazakhstan (9 measurements), Thailand (20 measurements), the UK (45 measurements) and the US (10 measurements). Furthermore, measurements from cars (20 measurements), classrooms (42 measurements) and offices (20 measurements) have been made in the UK. The highest concentrationof PFOS was measured in the UK, the lowest was measured in Kasakhstan. The highest concentration of PFOA was measured in the UK, the lowest was measured in Kasakhstan and Thailand. The measured values were stastistically analysed and show the the values in the UK, Australia, Canada, France, Germany and the US are significantly higher than in Kasakhstan, and the values in the UK, Australia, Canada and the US are significantly higher than in Kasakhstan, and the values in the UK, Australia, Canada and the US are significantly higher than in Thailand when it comes to PFOS. Furthermore, the values in private homes for PFOS. The article also describes an exposure assessment showing that intake of food constitutes the largest contribution for PFOS and PFOA (which is in line with previous studies). But the intake of PFOS and PFOA from dust may be significant for particularly high values of PFOS and PFOA in dust.
(D'Hollander et al., 2010)	PFOS: Range: <0.1 – 211 ng/g	Belgian measurings from 45 homes and 10 offices. Sampling took place in 2008. It is stated that data observed for PFC in this study is on line with PFC levels observed elsewhere in Europe – however, median values are approx. 10 times lower in this study. It is stated that median PFC values in the US and Canada in dust samples generally are higher compared with European studies, in which PFOS and PFOA levels are min. 200 times higher relative to the values in this study. In this study, dust measurings of PFOS and PFOA are generally approx. 3-10 times higher for the office measurings relative to measurings in the homes.
(Bjorklund et al., 2009)	PFOS: Range: 8 – 1100 ng/g Median: 31 – 110 ng/g PFOA: Range: 14 – 850 ng/g Median: 41 – 93 ng/g	Measurings of PFOS and PFOA in Sweden. Dust measurings have been made in 10 houses, 38 apartments, 10 daycare centres, 10 offices and 5 cars in 2006/2007. The results have been examined by Huber et al. (2011) above. The results from cars are not included here. Levels in homes, offices and daycare centres are on fairly the same level and therefore all are included. Minimum and maximum values (range, and median for all measurements (except cars) are presented.

7.5.1.7 Parabens in dust

The only identified studies are an Amerian study (from 2003), a Spanish study, and a newer Swedish study, which examine the presence of parabens in dust (Rudel et

al., 2003; Canosa et al., 2007; SSNC 2011). The American study has only measured butylparaben in dust. Relatively low concentrations have been identified, and the fact that the median value is below the detection limit shows that only relatively few of the 120 studies have measured an actual content of butylparaben.

The Spanish study measures on methylparaben, ethylparaben, propylparaben, and butylparaben. All four parabens were identified in all 10 samples. In this project, however, focus is exclusively on propylparaben and butylparaben. It is shown that the values from the Spanish study are in line with the values from the American study. The Spanish study seems to be able to analyse lower levels than the American study.

The American study is – even though it dates back to 2003 – an extensive study with a total of 120 measurings. The newer Spanish study (from 2007) only covers 10 measurings. Therefore, the maximum value from the American study is used for butylparaben, as this is the most extensive study. However, the American study has not measured on propylparaben, and therefore the Spanish study is used here.

Table 7-10 Overview of content of butylparaben in dust in the indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in	Comments
	indoor dust	
(Rudel et al., 2003)	Butylparaben: Range: < 0.2 – 3.92 μg/g (median = < 0.2 μg/g)	120 American homes were measured in 1999-2001. The dust sample has been collected via a vacuum cleaner from 4-5 of the most used rooms in the home.
(Canosa et al., 2007)	Butylparaben: Range: 0.004 – 0.210 μg/g (av. = 0,076 μg/g) Propylparaben: Range: 0.016 – 1.05 μg/g (av.= 0.406 μg/g)	Dust measurements taken from private homes in Spain. 10 dust samples were taken from several private homes – the number is not indicated. It is not stated when the samples were taken.
(SSNC 2011)	Butylparaben : < DL for all measurings Propylparaben : Range: < DL – 0.0002 μg/g	SSNC has measured for content of chemical substances in dust samples from 12 different countries: South Africa, Tanzania, Kenya, Uganda, the Philippines, Malaysia, Sweden, Belgium, Germany, the Czech Republic, Hungary and Italy. It is not indicated when the sampling took place. The dust samples were taken from bedrooms. Only three dust samples were taken from each bedroom, which have then been pooled into a single sample for analysis. The highest values have generally been measured in the Philippines for all substances. Here is indicated a range for parabens. This range thus illustrates the difference between values from the twelve countries. However, the parabens were not detected in all 12 countries. Propylparaben was only detected in any of the 12 countries.

7.5.1.8 Triclosan in dust

Only one Spanish and one Belgian study of the content of triclosan in dust have been identified. The most recent study is used; this study also has the highest measurings of triclosan in dust.

Table 7-11 Overview of content of triclosan in dust in the indoor air. Grey highlighting and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in indoor dust	Comments
(Canosa et al., 2007)	Triclosan Maximum: 702 ng/g	Dust measurings made in private homes in Spain. 10 dust samples were taken from several private homes – the number is not indicated. It is not stated when the samples were taken.
(Geens et al., 2009)	Triclosan <u>Private homes:</u> Minimum: 25 ng/g Median: 220 ng/g 95%: 1733 ng/g Maximum: 1828 ng/g Mean: 484 ng/g <u>Offices:</u> In the two offices, the following two values are given: 305 ng/g 195 ng/g	Measured in dust samples from 18 randomly selected houses and 2 offices in Flanders, Belgium. The samples were taken in 2008. The samples consist of dust collected from living room, bedroom and kitchen.

7.5.1.9 Chloropyrifos in dust

Only a single study has been identified on the concentration of the pesticide chloropyrifos in dust (Rudel et al., 2003). Data originates from a larger American study from 2003 (measuring took place in 1999-2001). It is stated in the article the the pesticide is prohibited (or limited) at the time the samples were taken. This means that the levels may be somewhat higher than today – even though the median value from the study is below the detection limit.

The stated maximum measured value is used in the calculations. The median value is below the detection limit, and therefore the value null will be used as median value in the calculations.

Table 7-12 Overview of content of chloropyrifos in dust in the indoor air. Grey highlighting and figures in bold illustrate the values used in the exposure calculations

Source	Concentration	Comments
	measured in indoor dust	
(Rudel et	Chloropyrifos: < 1 – 228	120 American homes were measured in 1999-2001. The dust
al., 2003)	µg/g	sample has been collected via a vacuum cleaner from 4-5
	(Median = < 1 µg/g)	of the most used rooms in the home.
		The pesticide chloropyrifos has been identified in 18% of the
		120 samples. It is noted in the article that the pesticide was
		prohibited or limited at the time the samples were taken.

7.5.2 Exposure from the selected substances via dust

The exposure is calculated on the basis of the selected median and maximum values for the selected substances in dust. The daily exposure is stated in Table 7-13.

Calculation of the daily exposure was made as follows, as also described in Section 7.1:

$$D(DEHP)_{DUSTMAX} = \frac{0.05 \ g \ / \ day \ \cdot \ 6611 \ \mu g \ / \ g \ dust \ \cdot \ 0.5}{60 \ bw} = 2.75 \ \mu g \ / \ bw \ / \ day$$

Table 7-13 Overview of the selected median and maximum values, and calculated daily exposure to the selected substances in dust

Substance	Median/maximum	Intake of house dust (g/day)	Measured value (µg/g)	Oral absorption	Body weight (kg)	Daily intake (µg/kg bw/day)
	Maximum		6611	0.5	(0	2.7546
DEHP	Median	0.05	500	0.5	60	0.2083
DiNP	95% percentile	0.05	1930	0.5	60	0.8042
DINF	Median	0.05	41	0.5	00	0.0171
DBP	Maximum	0.05	440	1	60	0.3667
DDF	Median	0.05	38	I	00	0.0317
Dibp	Maximum	0.05	2496	. 1	60	2.0800
DIBP	Median	0.05	27	I I	60	0.0225
BBP	Maximum	0.05	293	1	60	0.2442
DDP	Median	0.05	17	I I	80	0.0142
DPP	Maximum	0.05	0*	1	(0)	0
DPP	Median	0.05	0*	1	60	0
	Maximum	0.05	30.6	1	(0	0.0255
DnHP	Median	0.05	1.1	1	60	0.0009
	Maximum	0.05	2510	1	(0	2.0912
DnOP	Geometric mean	0.05	250		60	0.2083
PCBs	Maximum	0.05	18.2	1	60	00152
PCBS	Median		0.152			0.0001
	Maximum	0.05	2.95	1	60	0.0025
Bisphenol A	Median		0.422			0.0004
Nandahanal	Maximum	0.05	8.68	0.1	60	0.0007
Nonylphenol	Median		2.58			0.0002
TBBPA	Maximum		0.419	1	60	0.0003
IDDPA	Median	0.05	0.012			0.00001
	Maximum		6	1	60	0.0050
PFOA	Median	0.05	0.3			0.0003
PFOS	Maximum	0.05	7.4	1	60	0.0062
PFUS	Median	0.05	0.84			0.0007
	Maximum	0.05	1.05	1	60	0.0009
Propylparaben	Mean	0.05	0.406	1		0.0003
Butylparaben	Maximum		3.92	1	60	0.0033
	Mean	0.05	0.076	1		0.0001
Triclosan	Maximum	0.05	1.828	1	60	0.0015
	Median	0.05	0.22	1		0.0002
Chloropyrifos	Maximum	0.05	228	1	60	0.1900
	Median	0.05	0*			0

* All values here were below the detection limit.

7.5.3 Concentrations of the selected substances in indoor air

Data for concentrations in indoor air was found for the following of the selected potentially endocrine disruptors:

- phthalates (primarily DEHP, BBP, DBP, DiBP DnOP and DnHP only in small amounts around th detection limit)
- PCB
- nonylphenol
- TBBPA
- PFOS og PFOA
- butylparaben
- chloropyrifos

These substances/substance groups are presented separately below.

No data for bisphenol A or triclosan i indoor air has been found.

7.5.3.1 Phthalates in indoor air

There are few studies of phthalates in indoor air compared with phthalates in dust. Four studies have been identified, and only four phthalates are measured in concentration above the detection limit (DEHP, BBP, DBP, and DiBP).

The identified American studies are relatively old (measuring took place in 2001 or before), and since then, certain phthalates (DEHP, DBP, BBP, DiNP, DiDP, and DnOP) have been prohibited in toys in Europe (Rudel et al., 2003; Adibi et al., 2008). The results from a newer study are therefore selected, even though this study is not as extensive (10 measurings), because the concentrations of phthalates in indoor air are expected to have decreased due to regulation.

Source	Concentration measured in	Comments
	indoor air	
(Adibi et al., 2008)	DEHP: 95-percentile: 0.49 μ g/m ³ (50-percentile: 0.19 μ g/m ³) DBP: 95-percentile: 1.04 μ g/m ³ (50-percentile: 0.48 μ g/m ³) BBP: 95-percentile: 0.27 μ g/m ³ (50-percentile: 0.04 μ g/m ³) DiBP: 95-percentile: 1.43 μ g/m ³ (50-percentile = 0.50 μ g/m ³)	96 American homes were measured over a period of 48 hours. Persons carried a device ensuring that the air around the person was measured (personal air). It is not stated exactly when the samples were taken, but the samples were analysed from 2001.
(Schettler 2006)	DBP: median 0,39 μg/m ³ BBP: median 0,01 μg/m ³ DEHP: median 0,11 μg/m ³	Phthalate concentration has been measured in indoor air in 27 houses in Tokyo. It is not stated when the samples were taken.
(Rudel et al., 2003)	$\begin{array}{l} \textbf{DEHP:} < 59 - 1000 \text{ ng/m}^3 \\ (\text{median} = 77 \text{ ng/m}^3) \\ \textbf{DBP:} 52 - 1100 \text{ ng/m}^3 \\ (\text{median} = 220 \text{ ng/m}^3) \\ \textbf{BBP:} < 31 - 480 \text{ ng/m}^3 \\ (\text{median} = < 31 \text{ ng/m}^3) \\ \textbf{DiBP:} 11 - 990 \text{ ng/m}^3 \\ (\text{median} = 61 \text{ ng/m}^3) \end{array}$	120 American homes were measured in 1999- 2001 over a period of 24 hours. A frequently used room was measured, i.e. the living room or family room. Air was drawn in a height of approx. 1.2 m above the floor (4 ft).

Table 7-14 Overview of content of phthalates in indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in indoor air	Comments
(Boast et al., 2010)	DEHP: 8.5 - 142.0 ng/m ³ Av.: 39.6 ng/m ³ Median: 16.5 ng/m ³ BBP: 0.5 - 15.2 ng/m ³ Av.: 6.8 ng/m ³ Median: 4.9 ng/m ³ DBP: 66.5 - 354,7 ng/m ³ Av.: 137.5 ng/m ³ Median: 106.8 ng/m ³ DiBP: 59.6 - 686.3 ng/m ³ Av.: 139.5 ng/m ³ Median: 61.7 ng/m ³ DnOP: <0.4 - <2 ng/m ³ Av.: <0.82 ng/m ³ DnHP: <0.1 - <0.2 ng/m ³ Av: <0.16 ng/m ³	Phthalate concentration measured in indoor air in 10 homes in Melbourne, Australia. It is not stated when the samples were taken. DNOP and DNHP are only identified in concentrations below the detection limit. The authors point out that the level of phthalates is lower in this study compared with other studies (ex. (Rudel et al., 2003)).

7.5.3.2 PCB in indoor air

PCB in indoor air consists of both dioxin-like PCB and non-dioxin-like PCB. 12 of the total 209 different types of PCB (congeners) are dioxin-like. The dioxin-like PCBs are the ones of interest concerning endocrine disrupting effects. The problem is, however, that not all studies of PCB in indoor air distinguish between non-dioxin-like and dioxin-like PCB.

It makes a big difference whether the studies measure the individual specific PCB congeners, PCB7 (consisting of six non-dioxin-like PCBs and dioxin-like congeners) or total PCB.

A couple of American studies measuring PCB in indoor air have been found. Furthermore, there is a Danish study of PCB in Danish building from 2009 (Gunnarsen et al., 2009). A Danish report made for the Danish Business Authority, the EPA and the Working environment Service picks up on indoor air measurings made in the US and Europe for PCB (Jensen et al., 2009). Data from Gunnarsen et al. (2009) is not included in the report from Jensen et al. (2009), as the studies have been prepared about the same time.

Furthermore, a few newer measurings of PCB in the indoor air of a number of public buildings in Denmark have been identified, such as municipal buildings (scholls, daycare centres, hospitals). Furthermore, PCB measurings of Farum Midtpunkt have recently been published in the start of 2012 (National Board of Health 2012).

There are a number of measurements of PCB concentrations in indoor air, but common to many of the studies is the fact that focus is on measuring of buildings (e.g. schools), where you are aware that the building is contaminated with PCB. For these buildings the levels can be extremely high, for example above $40 \ \mu g/m^3$ in the air (Weis et al., 2003).

For the PCB measuring in Farum Midtpunkt apartments, the special issue is that the indoor air measurements were made after the PCB joints had been covered with alutape, which is believed to reduce the exposure significantly and particularly reduce the heavier soluble (dioxin-like) PCB types' release from the joints to the indoor air. Furthermore, the measuring took place *after* the residents had received instruction on what to do in order to reduce exposure in the apartment (increased ventilation, vacuuming/drying and cleaning) (National Board of Health 2012).

In the exposure calculations of this project, we chose to use the values from the measurements in Farum Midtpunkt. It is the most recent and also the most extensive study, and furthermore it represents the highest values found in Denmark. Lars Gunnarsen of the Danish Building Research Institute refers to Farum Midtpunkt as "the largest and most severe PCB case so far identified in Denmark" (Bredsdorff 2012). Thus, it is a worst case using this data, as it is the highest levels identified in Denmark. However, the measurings were carried out after covering the joints and information on ventilation/cleaning, so it is possible that there may be even higher levels in other locations. The sum of dioxin-like PCBs is used from the study.

As stated in Section 6 "Risk assessment", the DNEL values are used for risk assessment for PCB in indoor air, determined exclusively for the dioxin-like PCBs, and DNEL i TEQ (dioxin-equivalent) are specifically calculated relative to the specific dioxin-like PCB derivatives identified in indoor air in the Farum study.

Table 7-15 Overview of content of PCB in indoor air. Grey highlighting and figures in bold
illustrate the values used in the exposure calculations

Source	Concentration measured in indoor air	Comments				
(Rudel et al., 2003)	PCB 52: < 1 – 25 ng/m ³ (median = < 1 ng/m ³) PCB 105: < 1 – 3.6 ng/m ³ (median = < 1 ng/m ³) PCB 153: < 1 – 6.7 ng/m ³ (median = < 1 ng/m ³)	120 American homes were measured in 1999- 2001 over a period of 24 hours. A frequently used room was measured, i.e. the living room or family room. Air was drawn in a height of approx. 1.2 m above the floor (4 ft). Out of 120 homes, PCB was found in the air in 32% and PCB in dust in 18% of them. (Rudel et al., 2008). PCB 105 is one of the dioxin-like congeners. PCB 52 and 153 are non-dioxin-like.				
(Rudel et al., 2008)	Sum of the three PCBs (52, 105 and 153): Max.: 7,3 ng/m ³	The source follows up on the 2 of the 120 American homes with the highest measured PCB concentrations and the cause is found (wooden floor finish). High PCB concentrations are still measured 5 years later. The measurings are from 2004-2005. It is stated that other American studies do not show the same high PCB concentrations. The spreading thus indicates the level from "normal" to a few high concentrations stated in (Rudel et al., 2008). PCB 105 is one of the dioxin-like congeners. PCB 153 is non-dioxin-like.				
(Sullivan 2008)	Total PCB: Range: 2.4 – 310 ng/m ³	Samples from a school in the US in 2007.				

Source	Concentration measured in indoor air	Comments				
In indoor air (Jensen et al., 2009) PCB: Sweden: Max: 1200 ng/m³ Max: 1200 ng/m³ Norway (private homes): Range: 6 - 429 ng/m³ Germany (220, publ. building): Range: 10 - 2880 ng/m³ Av.: 600 ng/m³ Germany (181, publ. building): Max: 2065 ng/m³ Median: 20 ng/m³ Germany (schools): More than half had conc. of > 300 ng/m³ Max.: 40,000 ng/m³ Max.: 40,000 ng/m³ Max: 10,000 ng/m³ Switzerland (700, private homes): Max: 10,000 ng/m³ Switzerland (160, publ. building): Max: > 3,000 ng/m³ Max: > 3,000 ng/m³ Av.: 790 ng/m³ USA (private homes): Range: 40 - 580 ng/m³ Denmark (schools, daycare centres): Range: 24 - 2701 ng/m³		Danish report prepared for the Danish Business Authority, the EPA and the Working environment Service (Jensen et al., 2009). It picks up on indoor air measurings made in the US and various European countries for PCB. It is not stated when the different measurements were made. Data from Gunnarsen et al., (2009) is not included here.				
(Gunnarsen et al., 2009)	<u>Single-family</u> <u>homes/residential floor:</u> PCB 7: < 1 – 5.6 ng/m ³ PCB n: < 1 – 11.9 ng/m ³ <u>Public buildings:</u> PCB 7: < 1 – 580 ng/m ³ PCB n: < 1 – 1153 ng/m ³	In this Danish study, buildings have been deliberately selected containing PCB in the building materials. The stated values are for 4 single-family houses and 1 residential floor, but measurings have also been made in storage, office, college, and university, which had between 1 and 100 times higher concentrations of PCB in the indoor air. PCB7 = the sum of 7 congeners. PCB7 consists of six non-dioxin-like PCBs and the dioxin-like congener PCB 118. PCBn = sum of n of the 22 congeners above the detection limit. It is not stated when the measuring were taken,				
(Boast et al., 2010)	PCB: 17 - 343 pg/m ³ Av.: 71 pg/m ³ Median: 44.18 pg/m ³	but the project started in 2006. Concentration of total PCB has been measured in indoor air in 10 houses in Melbourne, Australia. It is not stated when the samples were taken. The authors state that the measured concentrations in this study all are lower than corresponding measurings elsewhere.				
(Alectia 2011)	PCB: 85 – 600 ng/m ³	8 measurings of PCB in indoor air were made at Rigshospitalet. It is not stated when the samples were taken.				
(Alectia 2010)	PCB: 1 – 255 ng/m ³	7 measurings of PCB in indoor air were made at Brøndby Kommune's buildings (schools, daycare centres, care homes) in 2010.				
(Golder Associates 2011)	PCB: 2.9 – 600 ng/m ³	Measuring of PCB were made at one school in Humlebæk in 2011. 10 air samples were taken in different rooms.				

Source	Concentration measured in indoor air	Comments
(National Board of Health 2012)	PCB: <u>Contaminated</u> <u>apartments:</u> Range PCB total (6): 167.97 - 3842.88 ng/m³ Median PCB total (6): 861.95 ng/m³ Range PCB DL: 0.18 - 16.53 ng/m³ Median PCB DL: 0.18 - 16.53 ng/m³ Median PCB DL: 2.19 ng/m³ Median PCB DL: 2.005 - 253.63 ng/m³ Median PCB total (6): < 0.005 ng/m³	PCB measuring made in Farum Midtpunkt in the start of 2011. 83 PCB-contaminated apartments and 21 non-contaminated apartments were measured. It should be noted that the measuring in the contaminated apartments took place <u>after</u> the PCB joints had been covered with alutape, which is believed to reduce the exposure significantly. Furthermore, the measurings took place <i>after</i> the residents had been instructed on how to reduce the exposure in the apartments themselves (increased ventilation, vacuuming/drying and cleaning). It is therefore indicated that the concentration in indoor air may be higher, if alutape and ventilation/cleaning had not been done. Median value for PCB total in the joints was 21%. In this study, measuring of the PCB content in the residents' blood has also been made. The study both states the total concentration of PCBs (" PCB total (6) "), and the sum of the dioxin- like congeners is used in the exposure calculations.

7.5.3.3 Nonylphenol in indoor air

A couple of studies of nonylphenol in the indoor air have been identified. However, data is primarily of older date. Some data is stated as nonylphenol – others as nonylphenol and its ethoxylates. Both data from private homes and from daycare centres have been identified, i.e. data may represent a possible work situation.

Rudel et al. 2003 is by far the most extensive study with 120 samples from private American homes. The other American studies are only shortly mentioned by Salthammer and Udhe (2009). Therefore, data is sparse. Data from Rudel et al. 2003 is therefore used, because it is a larger study, even though it does not represent the maximum measured values (but values in the same scale as the maximum values).

Source	Concentration measured in indoor air	Comments				
(Rudel et al., 2001; Salthammer et al., 2009)	Nonylphenol Maximum: 118 ng/m ³	Rudel et al., 2001 referred in Salthammer and Udhe, 2009. 4-nonylphenol was found in air in concentrations up to 0.118 ug/m ³ in 7 samples in the US. It is not stated when the samples were taken.				
(Rudel et al., 2003)	4-nonylphenol: Minimum: 21 ng/m ³ Maximum: 420 ng/m ³ Median = 110 ng/m ³	120 American homes were measured in 1999- 2001 over a period of 24 hours. A frequently used room was measured, i.e. the living room or family room. Air was drawn in a height of approx. 1.2 m above the floor (4 ft). There is data for 4-nonylphenol (which is a synonym for nonylphenol). 4-nonylphenol was found in 100% of the 120 house samples.				

Table 7-16 Overview of content of nonylphenol in indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

(Wilson et al., 2001; Salthammer et al., 2009)	Nonylphenol Range: 52 – 527 ng/m ³ Av.: 203 ng/m ³ (covers sum of nonylphenol and its ethoxylates)	Samples of indoor air in 10 daycare centres in the US. The source is Wilson, Chuang and Lyu (2001) referred by Salthammer and Udhe, 2009. It is not stated when the samples were taken. The average value covers the sum of nonylphenol and its ethoxylates.
(Saito et al., 2004; Salthammer et al., 2009)	Nonylphenol Maximum: 680 ng/m³	It does not appear where or when the samples were taken, or the number of samples taken.

7.5.3.4 TBBPA in indoor air

Only a few studies have been identified, in which TBBPA in indoor air of offices and other work places was measured. A newer Finnish study has measured TBBPA in 6 different work places. Here very high concentrations were identified relative to the concentrations identified in private homes in other studies (Mäkinen et al., 2009).

As worst case, very high TBBPA values from work places are used in the exposure calculations as the level for 24 hours, knowing that it is probably an overestimation.

Table 7-17 Overview of content of TBBPA in indoor air. Highlighting in grey and figures in
bold illustrate the values used in the exposure calculations

Source	Concentration measured in indoor air	Comments				
(Mäkinen et al., 2009)	TBBPA: Range: < 4 – 14,600 ng/m³ Geometric mean: 970 – 1050 ng/m³	6 measurings have been made in work places in Finland. In a printed circuit board factory, in a furniture workshop, in two locations where electronics are dismantled, in a computer classroom, in offices of these factories. Both stationary measurings of TBBPA in air and airborn person measurings have been made. For TBBPA, the person borne measurings were approx. 10 times higher than the stationary measurings. The person born measurings are used here. It is not stated when the samples were taken.				
(Abdallah et al., 2008)	TBBPA Private homes (5): Range: 0.009 – 0.022 ng/m³ Median: 15 ng/m³ Av.: 16 ng/m³ Offices (5): Range: 0.0045 – 0.033 ng/m³ Median: 0.011 ng/m³ Av.: 0.016 ng/m³ Public places (4): Range: 0.017 – 0.032 ng/m³ Median: 0.027 ng/m³ Av.: 0.026 ng/m³	There is measured for TBBPA in indoor air in 5 private homes, 5 offices and 4 public places (3 pubs and 1 restaurant) in th UK. Sampling took place in 2007. Dust samples were collected with vacuum cleaner. Air samples were collected in living rooms (private homes). TBBPA was not detected everywhere. The article calculates the importance to children and adults of intake via air, dust and food. Intake from dust stands for between 12 and 50% of the total exposure (for the 5 and 95 percentile, respectively). Intake from indoor air stands for around 5-6% of the total exposure. It is concluded that the dust intake stands for a significant part of the total exposure.				

Source	Concentration measured in indoor air	Comments
(Sjødin et al., 2001; Destaillats et al., 2008)	TBBPA: Range: 0.01-0.07 ng/m ³ Av. = 0.036 ng/m ³	The concentration in air in offices with computers in Sweden. The study covers 4 measuements. Data for TBBPA in electronic recycling factories in Sweden is also given (6.9-61 ng/m ³ – 12 measurings) and electronic assembly lines in Sweden (0.11-0.37 ng/m ³ – 6 measurements). It is not stated when the samples were taken, but data originates from 2001.

7.5.3.5 PFOS and PFOA in indoor air

Only a few studies of the contents of PFOS and PFOA in indoor air have been identified. The latest source is Australian, and this source refers to an older Norwegian study from 2005 (Barber et al., 2007), in which only an average value for PFOA is stated, which is approx. 8 times lower than the Australian values.

The Australian study is used, because it is the most recent study, and it contains more measurements than the Norwegian study, and both median and maximum values are stated in the study. They are also the highest values.

Table 7-18 Overview of content of PFOS and PFOA in indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in	Comments
	indoor air	
(Boast et al., 2010)	PFOS: 4.8 – 349.5 pg/m³ Av.: 47.6 pg/m ³ Median: 12.8 pg/m³ PFOA: 6.9 – 109.9 pg/m³ Av.: 33.5 pg/m ³ Median: 21.6 pg/m³	Concentration of PFOS, PFOA and other perfluorinated substances measured in indoor air in 10 houses in Melbourne, Australia. It is not stated when the samples were taken. A single measurement stands out by having a significantly higher content of PFOS and PFOA relative to the 9 other measurings. The authors do not have an immediate explanation for this. Generally, higher concentrations of PFOS and PFOA were measured indoors relative to the outdoor measurings.
(Barber et al., 2007; Boast et al., 2010)	PFOA: Av.: 4.4 pg/m ³	PFOA and other perfluorinated substances have been measued in indor air in 4 houses in 2005. The measurings are from Tromsø, Norway. Data is cited in (Boast et al., 2010), where only an average value is stated.

7.5.3.6 Butylparaben in indoor air

Only a single American study (Rudel et al., 2003) has been identified, with measuring of butylparaben in indoor air. Relatively low concentrations are identified, and the fact that the median value is below the detection limit shows that it is only a few of the 120 studies, in which an actual content of butylparaben has been measured.

Table 7-19 Overview of content of butylparaben in indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured	Comments				
	in indoor air					
(Rudel et al., 2003)	Butylparaben: Maximum.: 3.2 ng/m ³ (median = < 4 ng/m ³)	120 American homes were measured in 1999- 2001 over a period of 24 hours. A frequently used room was measured, i.e. the living room or family room. Air was drawn in a height of approx. 1.2 m above the floor (4 ft).				

7.5.3.7 Chloropyrifos in indoor air

Only a single study has been identified on the concentation of the pesticide chloropyrifos in indoor air. Data originates from an older larger American study. It is stated in the article that the pesticide has been prohibited (or limited) at the time when the samples were taken.

The stated median value (below the detection limit) and the measured maximum value are used in the calculations. The median value is below the detection limit, and therefore the value null is used as median value in the calculations.

Table 7-20 Overview of content of chloropyrifos in indoor air. Highlighting in grey and figures in bold illustrate the values used in the exposure calculations

Source	Concentration measured in indoor air	Comments
(Rudel et al., 2003)	Chloropyrifos: Range = < 1 – 92 ng/m ³ Median = < 1 ng/m ³	120 American homes were measured in 1999- 2001 over a period of 24 hours. A frequently used room was measured, i.e. the living room or family room. Air was drawn in a height of approx. 1.2 m above the floor (4 ft). The pesticide chloropyrifos has been identified in 38% of the 120 samples. It is noted in the article that the pesticide is prohibited or limited at the time when the samples were taken.

7.5.4 Exposure from the selected substances via indoor air

The exposure has been calculated on the basis of the selected median and maximum values for the selected substances in indoor air. The daily exposure is stated in the table below.

Calculation of the daily exposure was made as follows, as also described in Section 7.1 and can be seen in Table 7-21:

$$D(DEHP)_{inh\,\max} = \frac{18\,m^3/day \cdot 20/24 \cdot 0.142\,\mu g/m^3 \cdot 0.75}{60\,bw} = 0.027\,\mu g/bw/day$$

Table 7-21 Overview of the selected median and maximum values, and calculated daily exposure to the selected substances in indoor air

Substance	Median/maximu m	Inhalatio n of air (m ³ /day)	Exposure time (hours/day)	Measure d value (µg/m³)	Inhalation fraction	Body weight (kg)	Daily intake (µg/kg bw/day)
DEHP	Maximum	- 18	20/24	0.142	0,75	60	0.0266
DLIIF	Median	10	20724	0.0165	0,75	00	0.0031
DINP	Maximum	- 18	20/24	None	0,75	60	None
DINP	Median	10	20724	None	0,75	00	None
DBP	Maximum	- 18	20/24	0.3547	1	60	0.0887
DBP	Median	10	20/24	0.1068	1	60	0.0267
Dibp	Maximum	- 18	20/24	0.6863	1	60	0.1716
DIBP	Median	10	20/24	0.0617	1	60	0.0154
	Maximum	10	20/24	0.0152	1	(0)	0.0038
BBP	Median	- 18	20/24	0.0049	1	60	0.0012
DPP	Maximum	10	20/24	None	1	(0)	None
DPP	Median	- 18	20/24	None	1	60	None
	Maximum	10	00/04	0*	1	(0)	0
DnHP	Median	- 18	20/24	0*	1	60	0
	Maximum	10	00/01	0*		()	0
DnOP	Median	- 18	20/24	0*	1	60	0
PCBs	Maximum	- 18	20/24	7.78 x 10 ⁻⁷	1	60	0.0000002
	Median		20/21	9.21 x 10 ⁻⁸			0.0000002
Bisphenol A	Maximum	18	20/24	None	1	60	None
	Median	10	20/24	None		00	None
Nonylpheno	Maximum	- 18	20/24	0.42	1	60	0.1056
	Median	10	20/24	0.11	1	00	0.0275
	Maximum			14.6			3.6500
TBBPA	Geometric mean	18	20/24	1.05	1	60	0.2625
PFOA	Maximum	- 18	20/24	0.00011	1	60	0.00003
110/1	Median	10	20724	0.00002	I	00	0.000005
PFOS	Maximum	- 18	20/24	0.00035	1	60	0.0001
1105	Median	10	20/24	0.000013	I	6U	0.000003
Propylpara	Maximum	- 18	20/24	None	1	60	None
ben	Average	10	20/24	None	1	00	None
Butylparabe	Maximum	- 18	20/24	0.0032	1	60	0.0008
n	Average	Ιð	20/24	0*	1	60	0
Triologen	Maximum	10	20/24	None	1	40	None
Triclosan	Median	- 18	20/24	None	1	60	None
Chloropyrifo	Maximum	10	20/24	0.092	1	10	0.0230
S	Median	- 18	20/24	0*	1	60	0

* All values were here below the detection limit.

7.6 Exposure via consumer products

In the project, quantitative analyses and migration analyses were made on cell phone covers, gloves, sleeping mats, handbags, antibacterial clothing and sneakers. Contents of some of the selected substances were measured in the quantitative analyses, but no migration in concentrations above the detection limit for the selected substances (refer to Section 5). The migration studies included below are therefore taken from a previous survey from the EPA.

The exposure via consumer products is divided into different scenarios. The background for this is that there may be a great difference in how and how much you use of the individual product depending on the given situation. To describe these situations in different scenarios will therefore give the most realistic picture of the different situations a pregnant woman may be in. It would be desirable to describe more situations than is the case, but the data basis has not made it possible.

The following scenarios have been assessed in the project:

- basis scenario
- holiday scenario
- work scenario
- transport scenario

The scenarios are further described in Section 8.2. For all the scenarios we also work with an average and maximum exposure (see below).

Categorisation of average and maximum exposure

The exposures are divided in average and maximum exposure, respectively, where the approach is that the exposure is evened over one week of exposure, as this is exposure of pregnant women. During pregnancy, it is interesting to observe the short period of a few weeks, in which the fetus is most sensitive to endocrine disruptors, as described in Section 1. It is less interesting in this case to observe a chronic exposure (e.g. exposure over a year), which is frequently used in risk assessments of single substances/products.

<u>Average exposure</u> describes the situation, which is believed to affect many in the target group, namely a **realistic scenario**. E.g. standing on a bath mat for 10 minutes per day, and wearing plastic sandals for 5 hours per day, and wearing a rucksack for 10 minutes per day, or have contact with other products giving a similar exposure.

<u>Maximum exposure</u> describes the situation, which is believed to affect fewer in the target group, namely a **realistic worst case scenario**. E.g. standing on a slip mat for $\frac{1}{2}$ hour per day, and wearing plastic sandals for 10 hours per day, wearing a rucksack for 1 hour per day or have contact with other products giving a similar exposure.

In Tables 7-22 - 7-24, the conditions for calculating exposure of a pregnant woman over a week are described for each of the included products. Available information, and an assumption of which products a pregnant woman is expected to use during a week are used as background. There will be differences, and many women will use products in other ways, but the assumption has been to be able to calculate an exposure. The target group may also use other products that are not included here, but may contain and release the selected substances.

The specific calculations of the exposures for each product are shown in Tables 7-25-7-39. For a few exposures, difference between average and maximum has not been stated, e.g. when using shampoo and toothpaste. This is due to the fact that the average exposure is assumed to be predominantly representative, and is therefore repeated in the maximum exposure.

Product group	Relevant migration analyses	Average exposure – exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed*	Used referen ce
Consumer p	products				
Bath soap packagin g	Migration: 2 μg DEHP /g /0.5 hour for a product of 4 g corr. to 4 μg/g/hour	<u>Contact time:</u> 1 min corr. to 0.017 hour <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 4 g	<u>Contact time:</u> 5 min corr. to 0.083 hour <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 4 g	<u>Contact</u> <u>area:</u> Contact with 75% of the product via use is assumed	(Danish EPA 2009a)
Receipts	Migration: Migration is measured to 0.00103 mg bisphenol A/cm ² /sec for an average of receipts corr. to 3708 μg/cm ² /hour by migration to wet hands	Contact time: 10 sec corr. to 0.0028 hour. The receipt is held with both hands, and the fingers move down over the receipt while checking, and the receipt is subsequently folded <u>Times per day:</u> 4.6 times per day	Contact time: 10 sec corr. to 0.0028 hour. The receipt is held with both hands, and the fingers move down over the receipt while checking, and the receipt is subsequently folded <u>Times per day:</u> 4.6 times per day	Contact area: 10 cm ² of the finger pads (on 8 fingers) will be in contact with the receipt when checked and folded facing outwards	(Danish EPA 2011c)
Pilates ball	<u>Migration</u> : Migration of 1 pilates ball with a migration of 0.38 μ g DEHP/cm ² /hour corr. to a migration of 5.6 μ g/g/hour for one ball of 1.13 g and 16.8 cm ² With the assumed contact surface for use, in this case Q will be (500 cm ² /16.8 cm ² x 1.13 g) = 33.6 g	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 3 times per week corr. to 0.42 per day <u>Amount used:</u> Q = 33.6 g	<u>Contact time:</u> 1 hour per time <u>Times per day:</u> 3 times per week corr. to 0.42 per day <u>Amount used:</u> Q = 33.6 g	<u>Contact</u> <u>area:</u> 500 cm ² naked skin	(Danish EPA 2010b)

Table 7-22 Exposure considerations for products included in the **basis scenario**

Product group	Relevant migration analyses	Average exposure - exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed*	Used referen ce
Plastic sandals, adults	Migration:Plastic sandals' migration of DEHP, DIBP, and DBP has been measured previously in a number of products. In this project, an average of the migration has been calculated in 11 samples (7 soles and 5 straps)Sole:Migration was measured to 0.11 μ g DEHP/g/hour 1.56 μ g DiBP/g/hour 0.30 μ g DBP/g/hour All migration values were measured in sandal samples with average weights of 4.18 g and 18.14 cm².With the assumed contact surface for use, in this case Q will be (394 cm²/18.14 cm² x 4.18 g) = 90.74 gStrap: Migration was measured to 0.18 μ g DEHP/g/hour 0.58 μ g DiBP/g/hour 2.23 μ g DBP/g/hourAll migration values were measured in sandal samples with average weights of 2.77 g and 11.40 cm² With the assumed contact surface for use, in this case Q will be (100 cm²/11.40 cm² x 2.77 g) = 24.32 g	Contact time: 8 hours <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 90.74 g for sole Q = 24.32 g for strap	Contact time: 16 hours <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 90.74 g for sole Q = 24.32 g for strap	Contact area: 2 foot soles corr. to a shoe size 39: 197 cm ² x 2 = 394 cm ² and contact area with a strap corr. to 50 cm ² per foot. Totally 100 cm ² It is assumed that there is only contact with half a strap, and therefore the calculation is multiplied by a factor 0.5 (F contact)	(Danish EPA 2010)
Rucksack	Migration:Migration of 1 rucksack with amigration of 0.21 µgDEHP/cm²/hour corr. to amigration of 9.9 µg/g/hour forone rucksack of 0.33 g and15.8 cm²With the assumed contactsurface for use, in this case Qwill be (580 cm²/15.8 cm² x0.33 g) = 12 g	<u>Contact time:</u> 1 hour per time <u>Times per day:</u> 1 time per week corr. to 0.14 per day <u>Amount used:</u> Q = 12 g	<u>Contact time:</u> 1 hour per time <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 12 g	Contact area: 580 cm ² . In lots of cases, rucksack will not be in direct contact with the skin, but in this case we assume so (e.g. when wearing a bikini top)	(Danish EPA 2010b)

Product group	Relevant migration analyses	Average exposure – exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed*	Used referen ce
Sex toys – vibrator	Migration: Migration of DEHP from a vibrator was tested in a product with simultaneous use of lubricant. The value is 54.80 μg/cm ² /hour for a product with a size of 120 cm ² Migration of DnOP from a vibrator was tested in a product with simultaneous use of lubricant. The value is 0.21 μg/cm ² /hour for a product with a size of 120 cm ²	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 1 time per week corr. to 0.14 per day	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 2 times per week corr. to 0.28 per day	Contact area: Skin contact is assumed to be with 80% of the product corr. to 96 cm ²	(Danish EPA 2006b)
Sex toys – gag	<u>Migration:</u> 0.06 µg DEHP/cm²/hour for a product with a size of 38 cm²	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 1 time per week corr. to 0.14 per day	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 2 timer per week corr. to 0.28 per day	<u>Contact</u> <u>area:</u> This sex toy is for oral use, and therefore an oral exposure is calculated. Maximum contact is assumed to be with 50% of the product in use, corr. to 19 cm ²	(Danish EPA 2006b)
Slip mats for baths	Migration: 25 μg DEHP/g/0.5 hour for a product of 202.2 g corr. to 50 μg/g/hour	<u>Contact time:</u> 10 min per time corr. to 0.167 hour per time <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 202.2 g	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 202.2 g	Contact area: Exposure by contact with the foot soles, i.e. standing on the mat and being in contact with 25% of the mat	(Danish EPA 2009a)

Product group	Relevant migration analyses	Relevant migration analyses Average exposure – exposure time and amount used Maximum exposure – exposure time and amount used		Which/how big a part of the body is exposed*	Used referen ce
Toothbrus h	Migration: 4.29 µg BBP/toothbrush/10 hours corr. to a migration of 0.429 µg/toothbrush/hour. As worst case is assumed oral or skin contact with the whole toothbrush, and therefore Q is set to 1	4.29 μg BBP/toothbrush/10 hours corr. to a migration of 0.429 μg/toothbrush/hour.2.5 min per time corr. to 0.04 hour per time2.5 min per time corr. to 0.04 hour per timeAs worst case is assumed oral or skin contact with the whole toothbrush, and therefore Q isTimes per day: 2 times per dayTimes per day: 2 times per day		Contact area: Contact with the whole toothbrush is assumed, either via mouth or hand	(Danish EPA 2004)
Exercise ball	Migration on 1 exercise ball with a migration of 5.8 μ g DiBP/cm ² /hour corr. to a migration of 182 μ g/g/hour for one ball of 0.55 g and 17.3 cm ² With the assumed contact surface for use, in this case Q will be (500 cm ² /17.3 cm ² x 0.55 g) = 16 g	<u>Contact time:</u> 0.5 hour per time <u>Times per day:</u> 3 times per week corr. to 0.42 per day <u>Amount used:</u> Q = 16 g	<u>Contact time:</u> 1 hour per time <u>Times per day:</u> 3 times per week corr. to 0.42 per day <u>Amount used:</u> Q = 16 g	<u>Contact</u> <u>area:</u> 500 cm ² naked skin (legs and arms during training)	(Danish EPA 2010)
Clothing – jeans	<u>Migration</u> : Migration of NPE from two pairs of jeans was measured to 32 og 60 mg/kg textile/2 hours, respectively, corr. to an average of 23 µg NPE/g textile/hour. It is assumed that NPE is absorbed through the skin to the same degree as NP and that all NPE is transformed to NP in the body	<u>Contact time:</u> 14 hours per time <u>Times per day:</u> 1 time every 14th day corr. to 0.07** <u>Amount used:</u> Q = 450 g	<u>Contact time:</u> 14 hours per time <u>Times per day:</u> 1 time per week corr. to 0.14 <u>Amount used:</u> Q = 450 g	<u>Contact</u> <u>area:</u> Direct skin contact is assumed to be with 75% of a pair of jeans	(Danish EPA 2012)
Oilcloth	Migration: Migration on two oilcloths with an average migration of 0.07 μ g DEHP/cm ² /hour (0.05 and 0.09 μ g/cm ² /hour) corr. to 5.35 μ g/kg/hour for and average oilcloth of 0.24 g and 18.3 cm ² With the assumed contact surface for use, in this case Q will be (500 cm ² /18.3 cm ² x 0.24 g) = 6.6 g	Contact time: 0.5 time pr gang <u>Times per day:</u> fordelt over flere gange pr dag eller en gang <u>Amount used:</u> Q = 6.6 g	<u>Contact time:</u> 1 time pr gang <u>Times per day:</u> fordelt over flere gange pr dag eller en gang <u>Amount used:</u> Q = 6.6 g	Contact area: 500 cm ² naked skin corr. to 2 undersides of forearms	(Danish EPA 2010b)

Product group	Relevant migration analyses	Average exposure – exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed*	Used referen ce
Cosmetic p	roducts				
Facial cream	Leave-on product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	<u>Times per day:</u> 2 times per day <u>Amount used:</u> 1.54 g/day estimated by SCCS at 2.14 times/day corr. to 0.72 g/time	<u>Times per day:</u> 2 times per day <u>Amount used:</u> 1.54 g/day estimated by SCCS at 2.14 times/day corr. to 0.72 g/time	Body area: The face, i.e. 565 cm ²	(SCCS 2010c)
Body lotion/ cream	Leave-on product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	<u>Times per day:</u> Every other day corr. to 0.5 per day <u>Amount used:</u> 7.82 g/day estimated by SCCS at 2.28 times/day corr. to 3.43 g/time	<u>Times per day:</u> 1 time per day <u>Amount used:</u> 7.82 g/day estimated by SCCS at 2.28 times/day corr. to 3.43 g/time	Body area: The whole body, i.e. 15,670 cm ²	(SCCS 2010c)
Deodoran t	Non-spray product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	Times per day: 1 time per day <u>Amount used:</u> 1.5 g/day estimated by SCCS at 2 times/day corr. to 0.75 g/time	<u>Times per day:</u> 2 times per day <u>Amount used:</u> 1.5 g/day estimated by SCCS at 2 times/day corr. to 0.75 g/time	Body area: In both armpits, i.e. maximum 200 cm ²	(SCCS 2010c)
Hand cream	Leave-on product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	Times per day:2 times per weekcorr. to 0.29 perdayAmount used:2.16 g/dayestimated bySCCS at 2times/day corr. to1.08 g/time	<u>Times per day:</u> 1 time per day <u>Amount used:</u> 2.16 g/day estimated by SCCS at 2 times/day corr. to 1.08 g/time	Body area: Both hands, i.e. 860 cm ²	(SCCS 2010c)
Hand soap	Because hand soap is washed off, a dilution factor of 0.01 is added (SCCS 2010c)	Times per day: 5 times per day <u>Amount used:</u> 20 g/day estimated by SCCS at 10 times/day corr. to 2 g/time	Times per day: 8 times per day <u>Amount used:</u> 20 g/day estimated by SCCS at 10 times/day corr. to 2 g/time	Body area: Both hands, i.e. 860 cm ²	(SCCS 2010c)

Product group	Relevant migration analyses	Average exposure – exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed*	Used referen ce
Hair dye	Because hair dye is partly washed off, a dilution factor of 0.01 is added (SCCNFP 2003; SCCS 2010c)	<u>Times per day:</u> 1 time per week corr. to 0.14 per day <u>Amount used:</u> 35 ml semi- permanent hair day/time	<u>Times per day:</u> 1 time per week corr. to 0.14 per day <u>Amount used:</u> 100 ml permanent hair day/time	<u>Body area:</u> The head, i.e. 580 cm ²	(SCCS 2010c)
Pregnant belly creams/pr egnancy oils	Leave-on product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	Times per day:1 time per dayAmount used:It is assumed thatthe amount usedcorr. to 10% of theamount youwould use for thewhole body (3.43g/time) corr. to0.34 g/time	<u>Times per day:</u> 2 times per day <u>Amount used:</u> It is assumed that the amount used corr. to 10% of the amount you would use for the whole body (3.43 g/time) corr. to 0.34 g/time	Body area: The extra body area on the stomach and possibly somewhat larger breasts and buttocks etc. corr. to 10% of the body surface	
Shampoo	Because shampoo is washed off, a dilution factor of 0.01 is added (SCCS 2010c)	<u>Times per day:</u> 1 time per day <u>Amount used:</u> 10.46 g/time acc. to SCCS	<u>Times per day:</u> 1 time per day <u>Amount used:</u> 10.46 g/time acc. to SCCS	Body area: The head, the palm, corr. to about 1440 cm ²	(SCCS 2010c)
Toothpast e	Because toothpaste is partly spat out after brushing, a dilution factor of 0.05 is added (SCCNFP 2003; SCCS 2010c)	<u>Times per day:</u> 2 times per day <u>Amount used:</u> 2.75 g/day estimated by SCCS at 2 times/day corr. to 1.375/time	<u>Times per day:</u> 2 times per day <u>Amount used:</u> 2.75 g/day estimated by SCCS at 2 times/day corr. to 1.375/time	Possible exposure via mucosa in the mouth and oral exposure	(SCCS 2010c)

* Applies to both average and maximum exposure unless something else is stated **Here is deviated from the assumption that exposure is calculated for a short period per max one week

Table 7-23 Exposure considerations for products included in the holiday
scenario

	scenario				
Product group	Relevant migration analyses and size of the product (Q)	Average exposure – exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed *	Used referen ce
Plastic sandals, adults	Plastic sandals' migration of DEHP, DiBP, and DBP has been measured previously in a number of products. In this project, an average of the migration has been calculated in 11 samples (7 soles and 5 straps). By concurrent use of sunscreen, a higher migration was found for the substances DEHP and DiBP corr. to a factor 149 and 3.4, respectively, increased migration. These factors were multiplied to the migrations for DEHO and DiBP. <u>Sole:</u> Migration was measured to 0.11 μ g DEHP/g/hour x a factor 149 corr. to 16.39 μ g DEHP/g/hour 1.56 μ g DiBP/g/hour x a factor 3.4 corr. to 5.30 μ g DiBP/g/hour 0.30 μ g DBP/g/hour All migration values were measured in sandal samples with average weights of 4.18 g and 18.14 cm ² . With the assumed contact surface for use, in this case Q will be (394 cm ² /18.14 cm ² x 4.18 g) = 90.74 g <u>Strap:</u> Migration was measured to 0.18 μ g DEHP/g/hour x a factor 3.4 corr. to 1.97 μ g DiBP/g/hour 0.58 μ g DiBP/g/hour x a factor 3.4 corr. to 1.97 μ g DiBP/g/hour 2.23 μ g DBP/g/hour x a factor 3.4 corr. to 1.97 μ g DiBP/g/hour All migration values were measured in sandal samples with average weights of 2.77 g and 11.40 cm ² With the assumed contact surface for use, in this case Q will be (100 cm ² /11.40 cm ² x 2.77 g) = 24.32 g	Contact time: 8 hours <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 90.74 for sole Q = 24.32 for strap	Contact time: 16 hours <u>Times per day:</u> 1 1 time per day <u>Amount used:</u> Q = 90.74 for sole Q = 24.32 for strap	Contact <u>area:</u> 2 foot soles corr. to a show size 39: 197 cm ² x 2 = 394 cm ² and contact area with a strap corr. to 50 cm ² per foot. Totally 100 cm ² It is assumed that there is only contact with half a strap, and therefore the calculation is multiplied by a factor 0.5 (F _{contact})	(Danish EPA 2010)

Product group	Relevant migration analyses and size of the product (Q)	Average exposure – exposure time and amount used	Maximum exposure – exposure time and amount used	Which/how big a part of the body is exposed *	Used referen ce
Sunscreen s	Leave-on product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	Contact time: 1 time per day <u>Amount used:</u> SCCS states 18 g/day as the realistic daily consumption	<u>Contact time:</u> 2 times per day <u>Amount used:</u> 18 g is used twice a day corr. to 36 g/day, the EU Commission recommends 36 g/day	Body area: The whole body, i.e. 17,500 cm ²	(SCCS 2010c)

* Applies to both average and maximum exposure unless something else is stated

Product group	Relevant migration analyses and size of the product (Q)	Average exposure – exposure time and amount used	Maximum exposure - exposure time and amount used	Which/how beg a part of the body is exposed *	Used referen ce
Hand cream	Leave-on product (100% content considered available for absorption through the skin; the amount absorbed through the skin depends on the substance)	Times per day:3 times per dayAmount used:2.16 g/dayestimated bySCCS at 2times/day corr. to1.08 g/time	Times per day:3 times per dayAmount used:2.16 g/dayestimated bySCCS at 2times/day corr. to1.08 g/time	Body area: Both hands, i.e. 860 cm ²	(SCCS 2010c)
Receipts	Migrationen was measured to 0.00103 mg bisphenol A/cm ² /sec corr. to 3708 µg/cm ² /hours by migration to wet hands	<u>Contact time:</u> The receipt is held with one hand for 5 sec <u>Times per day:</u> Number of incidents per day: 100 receipts per day	<u>Contact time:</u> The receipt is held with one hand for 5 sec <u>Times per day:</u> Number of incidents per day: 100 receipts per day	Contact area: 5 cm ² of the finger pads (on 4 fingers) that will be in contact with the receipt	(Danish EPA 2011c)
Plastic sandals, adults	Migration: Plastic sandals' migration of DEHP, DiBP, and DBP has been measured previously in a number of products. In this project, an average of the migration has been calculated in 11 samples (7 soles and 5 straps)Sole: Migration was measured to 0.11 µg DEHP/g/hour 1.56 µg DiBP/g/hour 0.30 µg DBP/g/hour All migration values were measured in sandal samples with average weights of 4.18 g and 18.14 cm².With the assumed contact surface for use, in this case Q will be (394 cm²/18.14 cm² x 4.18 g) = 90.74 gStrap: Migration was measured to 0.18 µg DEHP/g/hour 0.58 µg DiBP/g/hourAll migration values were measured in sandal samples with average weights of 2.77 g and 11.40 cm² With the assumed contact surface for use, in this case Q will be (100 cm²/11.40 cm² x 2.77 g) = 24.32 g	Contact time: 8 hours <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 90.74 g for sole Q = 24.32 g for strap	Contact time: 16 hours <u>Times per day:</u> 1 time per day <u>Amount used:</u> Q = 90.74 g for sole Q = 24.32 g for strap	Contact <u>area:</u> 2 foot soles corr. to a shoe size 39: 197 cm ² x 2 = 394 cm ² and contact area with a strap corr. to 50 cm ² per foot. Totally 100 cm ² It is assumed that there is only contact with half a strap, and therefore the calculation is multiplied by a factor 0.5 (F _{contact})	(Danish EPA 2010)

Table 7-24 Exposure considerations for products included in the **work scenario**

* Applies to both average and maximum exposure unless something else is stated

Example of exposure calculation (DEHP in consumer product)

The calculated D_{der} will constitue the actual amount of substance that may be absorbed per kg bw per day, cf the colomn for internal dose (D_{der}) in Tables 7-23 -7-37. The calculation is based on parameters stated in Table 7-23. Calculating the DEHP impact from bath soap packaging in Table 7-23 shows:

Qprod	Amount of product used	4 g
FCprod	Weight fraction of the substance in the product (decimal fraction between 0 and 1) and here 1 because of measured migration.	1
FCmigr	Fraction of substance migrating out of the product per time unit	4 µg/g per hour
Fabs	Fraction of applicated substancd absorbed through the skin (decimal fraction between 0 and 1). 5% dermal absorption for DEHP cf Table 7-2	0.05
Fcontact	Fraction of contact area (taking into account that the product is only partially in contact with the skin). Contact is assumed to be with 75% of the soap packaging	0.75 m²/m²
Tcontact	Duration of exposure per incident	0.25 hours
n	Number of exposures (incidents) per day	1 time per day
BW	Body weight (bw)	60 kg
Dder	Dermal daily dose (amount of absorbed chemical substance = internal dose)	0.0025 µg/kg bw/day

Via:

$$D_{der} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{abs} \cdot F_{contact} \cdot T_{contact}}{BW}$$

Where $Fc_{prod} \cdot Fc_{migr}$ directly corresponds to the results of the migration analyses.

$$=\frac{4g \cdot 4\mu g / g / t \cdot 0.05 \cdot 0.75 m^{2} / m^{2} \cdot 0.25 hours / day}{60 kg} \cdot 1 time / day$$

 $= 0.0025 \ \mu g/kg \ bw/day$

7.6.1 Exposure calculation for the basis scenario – consumer products

The calculated exposure levels are determined providing that the migration from the product used, as stated in Tables 7-22 - 7-24, and the products actually used by the pregnant women are similar. The exposure will vary depending on which products are used. Some products will release higher concentrations, while others will release lower values. For several of the products included in Table 7-22, migration average has been used for a number of products. This means that when using the concerned product group, you may be exposed to products with higher or lower migration of the substance in question.

7.6.1.1 DEHP

DEHP is quantitatively determined in a number of different consumer products (see Table 2-3), but for several of the products there are no migration studies. The

available migration studies, measuring migration of DEHP in consumer products considered relevant to the target group, appear from the table below. In Table 7-25, an internal dose is calculated based on an assumed average and maximum exposure.

Table 7-25 Exposure by contact with different consumer products containing DEHP. The calculations are based on measured amounts of DEHP migrating out of the products. All values are for dermal exposure except for gag, which is a sex toy used in the mouth. An internal dose is calculated based on average and maximum esposure, respectively. Please refer to Table 7-22 for explanation of the used parameters and references

Product group	Weight product, (Q), (g) ¹	Weight fraction of substan ce in product (Fc prod) ²	Measured migration value, sweat (Fc migr), (µg/g/h, if nothing else is stated)	F abs	Part of product you are in contact with (F contact)	Conta ct time (T _{contact}), (h)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/day) (D _{der})
Average exposure									
Bath soap packaging	4	1	4	0.05	0.75	0.017	1	60	0.0002
Pilates ball	33.6	1	5.6	0.05	1	0.5	0.42	60	0.0329
Plastic sandals, adults, sole	90.74	1	0.11	0.05	1	8	1	60	0.0665
Plastic sandals, adults, strap	24.32	1	0.18	0.05	0.5	8	1	60	0.0146
Rucksack	12	1	9.9	0.05	1	1	0.14	60	0.0139
Sex toys, vibrator	120 cm ²	1	54.8 μg/ cm²/h	0.05	0.8	0.5	0.14	60	0.3069
Sex toys, gag (oral)	38 cm ²	1	0.06 µg/ cm²/h	0.5	0.5	0.5	0.14	60	0.0014
Slip mats for baths	202	1	50	0.05	0.25	0.17	1	60	0.3580
Oilcloth	6.6	1	5.35	0.05	1	0.5	1	60	0.0145
Sum; internal dose at	average ex	oosure							0.8087
Maximum exposure	•	1		1		1	r		r
Bath soap packaging	4	1	4	0.05	0.75	0.083	1	60	0.0008
Pilates ball	33.6	1	5.6	0.05	1	1	0.42	60	0.0659
Plastic sandals, adults, sole	90.74	1	0.11	0.05	1	16	1	60	0.1331
Plastic sandals, adults, strap	24.32	1	0.18	0.05	0.5	16	1	60	0.0292
Rucksack	12	1	9.9	0.05	1	1	1	60	0.0990
Sex toys, vibrator	120 cm ²	1	54.8 µg/ cm²/h	0.05	0.8	0.5	0.28	60	0.6138
Sex toys, gag (oral)	38 cm ²	1	0.06 µg/cm²/h	0,5	0.5	0.5	0.28	60	0.0027
Slip mats for baths	202	1	50	0.05	0.25	0.5	1	60	1.0531
Oilcloth	6.6	1	5.35	0.05	1	1	1	60	0.0290
Sum; internal dose at maximum exposure2.0								2.0265	

¹ Q (product weight) here is not indicative of the weight of the total product, but depending on the detected data relating to the weight of the part of the product, for which migration has been measured, or the weight corrected for the area you are in contact with (refer to Table 7-22)

² A weight fraction of substance in the product of 1 is here not indicative of the total product being made of DEHP, but that here is used the measured migration value, $F_{c prod} \times F_{c migr}$ equals the measured migration of DEHP from the product

7.6.1.2 DBP

DBP is quantitatively determined in a number of different consumer products (see Table 2-3), but for several of the products there are no migration studies. The available migration studies, where migration of DBP in consumer products was measured, and which are relevant for the target group, are shown in the table below. The exposure originates from skin contact with a plastic sandal containing DBP. The internal dose is calculated based on an average and maximum exposure.

Table 7-26 Exposure by contact with consumer products containing DBP. The calculations are based on the measured amount of DBP migrating out of the product in contact with sweat by dermal exposure. Please refer to Table 7-22 for explanation of the used parameters and references

Product group	Weight product, (Q), (g)	Weight fraction of substanc e in product (Fc prod)	Measured migration value, sweat (Fc migr), (µg/g/h)	F ab s	Part of product you are in contact with (F contact)	Contac t time (T _{contact}) , (h)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/day) (D _{der})
Average exposure									
Plastic sandals, adults, sole	90.74	1	0.30	0.1	1	8	1	60	0.3630
Plastic sandals, adults, strap	24.32	1	2.23	0.1	0.5	8	1	60	0.3616
Sum; internal dose	at average e	xposure							0.7245
Maximum exposure	9								
Plastic sandals, adults, sole	90.74	1	0.30	0.1	1	16	1	60	0.7259
Plastic sandals, adults, strap	24.32	1	2.23	0.1	0.5	16	1	60	0.7231
Sum; internal dose	at maximum	exposure							1.4490

7.6.1.3 DiBP

There are two available migration studies, where migration of DiBP in consumer products was measured, and which are relevant for the target group. In Table 7-27, the internal dose is calculated based on an assumed average and maximum exposure

Table 7-26 Exposure by contact with consumer products containing DiBP. The calculations are based on the measured amount of DiBP migrating out of the product in contact with sweat. Values are for dermal average and maximum exposure. Please refer to Table 7-22 for explanation of the used parameters and references.

Product group	Weight product, (Q), (g)	Weight fraction of substan ce in product (F _{c prod})	Measures migration value, sweat (Fc migr), (µg/g/h)	F abs	Part of product you are in contact with (F contact)	Conta ct time (T _{contact}), (h)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/day) (D _{der})
Average exposure Plastic sandals,	90.74	1	1.56	0.1	1	8	1	60	1.8874
adults, sole	70.71		1.00	0.1		U		00	1.0071
Plastic sandals,	24.32	1	0.58	0.1	0.5	8	1	60	0.0940
adults, strap									
Exercise ball	16	1	182	0.1	1	0.5	0.42	60	1.0192
Sum; internal dose	at average e	xposure							3.0006

Maksimaleksponer	Maksimaleksponering											
Plastic sandals, adults, sole	90.74	1	1.56	0.1	1	16	1	60	3.7748			
Plastic sandals, adults, strap	24.32	1	0.58	0.1	0.5	16	1	60	0.1881			
Exercise ball	16	1	182	0.1	1	1	0.42	60	2.0384			
Sum; internal dose at maximum exposure												

7.6.1.4 BBP

There is one available migration study, where migration of BBP in consumer products was measured, and which is relevant for the target group. It is shown in Table 7-28. Exposure originates from contact with a toothbrush containing BBP.

Table 7-28 Exposure by contact with consumer products containing BBP. The calculations are based on the measured amount of BBP migrating out of the product. The internal dose is calculated similar for average and maximum exposure. Please refer to Table 7-22 for explanation of the used parameters and references

Product group	Weight product, (Q), (g)	Weight fraction of substan ce in product (Fc prod)	Measured migration value (Fc _{migr}), (µg/g/hour)	F abs (oral)	Part of product you are in contact with (F contact)	Conta ct time (T _{contact}), (h)	Times per day (n)	Bw (kg)	Internal dose (μg/kg bw/day) (D _{der})			
Average and maximum exposure												
Toothbrush	1	1	0.429	0.05	1	0.04	2	60	0.00003			

7.6.1.5 DnOP

There is one available migration study, where migration of DnOP in consumer products was measured, and which is relevant for the target group. It is shown in the table below. Exposure originates from skin contact with a vibrator (sex toy) containing DnOP.

Table 7-29 Exposure by contact with consumer products containing DnOP. The calculations are based on the measured amount of DnOP migrating out of the product in contact with sweat by dermal exposure. The internal dose is calculated similar for average and maximum exposure. Please refer to Table 7-22 for explanation of the used parameters and references

Product group	'Weight product' (Q), (cm ²)*	Weight fraction of substan ce in product (F _{c prod})	Measured migration value, sweat (Fc migr), (µg/cm ² /h)	F abs	Part of product you are in contact with (F contact)	Conta ct time (T contac t)(hour s)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/da y)		
Average exposure											
Sex toys, vibrator	120	1	0.21	1	0.8	0.5	0.14	60	0.0235		
Maximum exposure											
Sex toys, vibrator	120	1	0.21	1	0.8	1	0.14	60	0.0470		

* For DnOP 'weight product' is, due to the available data for migration, instead the assumed area of the product you are in contact with, and the migration is measured in $\mu g/cm^2/hour$

7.6.1.6 Bisphenol A

There are two available migration studies, where migration of bisphenol A in consumer products was measured, and which are relevant for the target group. They are shown in Table 7-30. The highest exposure originates from skin contact with receipts containing bisphenol A during shopping.

Table 7-27 Exposure by contact with consumer products containing Bisphenol A. The calculations are based on the measured amount of bisphenol A migrating out of the product in contact with sweat. Please refer to Table 7-22 for explanation of the used parameters and references.

Product group	'Weight product', (Q), (cm ²)*	Weight fraction of substance in product (F _{c prod})	Measured migration value, sweat (Fc migr), (µg/cm ² /h)	F abs	Part of produc t you are in contac t with (F contact)	Contact time (T _{contact}), (t)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/day) (D _{der})	
Average exposure										
Sex toys, vibrator	120	1	0.21	0.1	0.8	0.5	0.14	60	0.0024	
Receipts	10	1	3708	0.1	1	0.0028 (10 sec)	4.6	60	0.7960	
Sum; internal dose	at average	exposure							0.7984	
Maximum exposu	re			-						
Sex toys, vibrator	120	1	0.21	0.1	0.8	0.5	0.28	60	0.0047	
Receipts	10	1	3708	0.1	1	0.0028 (10 sec)	4.6	60	0.7960	
Sum; internal dose	e at maximun	n exposure							0.8007	

* For bisphenol A 'weight product' is, due to the available data for migration, instead the assumed area of the product you are in contact with.

7.6.1.7 Nonylphenol

The available migration studies relevant for the target group are based on use of unwashed, new clothes. At average exposure, it is assumed that you wear unwashed, new clothes once a fortnight, while at maximum exposure, it is assumed that unwashed, new clothes are worn once a week (the parameters are described in Table 7-22). In this case we have deviated from the method that exposure is calculated over max one week for pregnant women. This is done, as it is considered most realistic that a pregnant woman only wears new, unwashed clothes once a fortnight or presumably even less. It is also assumed that direct skin contact is with 75% of a pair of jeans.

The migration to sweat is based on migration of nonylphenol ethoxylates, where an average migration of NPE to sweat of 23 μ g/g textile for jeans was found in the Danish EPA's survey on NP/NPE in textiles (Danish EPA 2012). It is assumed that the migration of NP from clothes is max of the same size as migration of NPE; it is likewise assumed as a rough estimate that all absorbed NPE from exposure via clothes will be transformed to NP in the body.

Table 7-28 Exposure by contact with consumer products containing Nonylphenol/nonylphenol ethoxylates. The calculations are based on the measured amount of NP/NPE migrating out of the product in contact with sweat at dermal exposure. Please refer to Table 7-22 for explanation of the used parameters and references

Product group	Weight produ ct(Q), (g)	Weight fraction of substance in product (F _{c prod})	Migration value, sweat (Fc migr), (µg/g/h)	F abs	Part of product you are in contact with (F contact)	Contact time (T _{contact}), (h)	Times per day (n)	Bw (kg)	Internal dose (μg/kg bw/day) (D _{der})*		
Average exp	osure										
Jeans	450	1	23	0.1	0.75	14	0.07	60	4.5281		
Maximum ex	Maximum exposure										
	450		23	0.1	0.75	14	0.14	60	9.0563		

* Absorption of NPE is thansformed to absorption of NP-units. It is assumed that NPE has 9 ethoxylate groups, and therefore the molweight of NPE₉ is 616 g/mol. As the molweight of NP is 220 g/mol, an NPE concentration of e.g. 25 mg NPE/kg corresponds tol 25/616×220 mg NP/kg = 8.9 mg NP/kg textile. I.e. that the absorption of NPE is transformed to an absorption of NP by dividing by 2.8. Therefore, the figure in this column appears by dividing the calculated D_{der} by 2.8.

7.6.2 Exposure calculation for the basis scenario – cosmetic products

The target group is expected to use the following cosmetic products daily or almost daily, and they will therefore be included in the exposure assessment:

- facial cream
- body lotion/cream (incl. pregnant belly creams)
- deodorant
- hand cream
- hand soap
- shampoo
- toothpaste

Some will also use make up on a daily basis, but make up is not included in the contribution to the exposure, because it is assessed that the used amounts for an average woman are minimal relative to e.g. the amount of creams and deodorants, and the fact that it varies a lot how frequently and in what amounts these products are used by women. It migh be considered to include exposure via the following other products: body soap, mouthwash, powder, foundation, covering pens, etc. In this project, however, we have chosen to select only the most commonly used products, for which it is expected that the majority of the target group is using them daily.

Other not daily used products might be:

- hair dye
- sunscreen (described under the holiday scenario in section 7.6.4.1)

Chemical analysis has only been made for one of the selected substances, which may appear in cosmetic products, namely octamethylcyclotetrasiloxane (D4). For the remaining selected substances, which may be present in cosmesic products, no analyses have been made in the individual product. The occurrence of the selected substances in the product group has however been examined in connection with the survey, solely based on the ingredients declaration (see Sections 3.7 and 3.8). The quantitative contents of the substances in the specific product groups are not known, and therefore the allowed maximum concentrations of the substances in cosmetic products are used for the maximum exposure (Table 7-32). For the

average exposure, it is assumed that only max half of the allowed amount of the individual substance is contained in the product (Table 7-33).

For the parabens, however, the average exposure is calculated with a value of 0.1% (as ester), for propyl and butylparaben, respectively. This is due to the fact that EU's Scientific Committee for consumer products (SCCS) has assessed that the sum of their individual concentration shall be set to 0.19% (as ester). Therefore, the EU is currently working on a proposal, which will reduce the concentrations of propyl and butylparaben, while prohibiting isopropyl and isobutylparaben.

cosmetic products (Council Substance	CAS-no	Maximum allowed concentration in
Substance	CAS-no	
		cosmetic products
Octamethylcyclotetrasiloxane	556-67-2	No maximum limit – the analysed
(D4)		substance concentration is used in the
		calculation
Propylparaben	94-13-3	0.4% for a single substance and 0.8% in
		total for all parabens in a product
Butylparaben	94-26-8	
Isobutylparaben	4247-02-	
	3	
OMC	5466-77-	10%
	3	
Benzophenone 3	131-57-7	10%
Triclosan	3380-34-	0.3%
	5	
Resorcinol	108-46-3	5% (hair dye)*,
		0.5% (hair lotion and shampoo)

Table 7-29 Maximum allowed concentrations of the selected substances in cosmetic products (Council Directive 1976)

* 5% is allowed in one half of the hair dye mixture, but as two substances are mixed subsequently, the maximum concentration is set to 2.5% for the ready-to-mixture that is applied to the hair (skin)

The DNEL_E values for the parabens (20 μ g/kg bw/day for both propylparaben and butylparaben, and 625 mg/kg bw/day for isobutylparaben, indicate that propylparaben and butylparaben are the most potent parabens of the three, and therefore it is assumed in the exposure calculations that for the maximum exposure in cosmetic products there is 0.4% propylparaben and 0.4% butylparaben in the products, i.e. the maximum allowed substance concentrations in the products. The survey showed that mainly propylparaben was added to the products containing paraben, while propyl or butylparaben in combination with isobutylparaben was rare. The combination of all three parabens was also observed. Therefore, it is assessed to be a realistic worst case scenario (maximum exposure) to assume that the allowed 0.8% consists of propyl and/or butylparaben. Daily exposure dose for isobutylparaben is thus not calculated.

Some of the products are bath products, and therefore we use a dilution factor (retention factor) of 0.1 (hair dye), 0.05 (toothpaste) or 0.01 (hand soap, shampoo) to account for products which are diluted during use and are washed out after use (SCCS 2010c).

Table 7-30 Daily internal doses of the selected substances occurring in cosmestic products (body weight 60 kg). The calculation is made with amounts of the selected substances in the products corr. to max half (i.e. average exposure) of the allowed amount in cosmetic products. For the parabens, 0.1% (as ester) is reckoned for each paraben, as the sum of their individual concentrations is allowed to be 0.19% (as ester) in the new proposition from the Commission.

For the maximum exposure, the calculations are made with amounts of the selected substances in the products corr. to the maximum allowed of the allowed amount in cosmetic products, except for D4, for which analysis data exist. The used parameters are described in Table 7-22

Product	n Table 7-22 Substance	Amount of product per time (Q) (g)	Weight fraction of substance in product (F _{Cprod})	Reten- tion factor	Dermal absorp tion (F _{abs})	Applic ations per day (n)	Internal dose (μg/kg bw/day)
Average exp	osure	.0,					
Facial	Propylparaben	0.72	0.001	1	0.037	2	0.8880
cream	Butylparaben	0.72	0.001	1	0.037	2	0.8880
	OMC	0.72	0.05	1	0.02	2	24.0000
	Benzophenone -3	0.72	0.05	1	0.04	2	48.0000
Body lotion	Propylparaben	3.43	0.001	1	0.037	0.5	1.0576
/cream	Butylparaben	3.43	0.001	1	0.037	0.5	1.0576
	D4	3.43	3.4E-06	1	0.01	0.5	0.0010
Deodorant	Propylparaben	0.75	0.001	1	0.037	1	0.4625
	Butylparaben	0.75	0.001	1	0.037	1	0.4625
	Triclosan	0.75	0.0015	1	0.20	1	3.9000
Hand	Propylparaben	1.08	0.001	1	0.037	0.29	0.1865
cream	Butylparaben	1.08	0.001	1	0.037	0.29	0.1865
Hand soap	Propylparaben	2.0	0.001	0.01	0.037	5	0.0617
	Butylparaben	2.0	0.001	0.01	0.037	5	0.0617
Hair dye	Resorcinol	35 ml	0.0125	0.1	0.025	0.033	0.0006
Pregnant belly creams/pre gnancy oils [*]	D4	0.34	0.00003	1	0.01	1	0.0017
Shampoo	Propylparaben	10.46	0.001	0.01	0.037	1	0.07
	Butylparaben	10.46	0.001	0.01	0.037	1	0.07
Toothpaste	Triclosan	1.375	0.0015	0.05	-	2	6.875
Maximum ex	posure						
Facial	Propylparaben	0.72	0.004	1	0.037	2	3.5220
cream	Butylparaben	0.72	0.004	1	0.037	2	3.5220
	OMC	0.72	0.1	1	0.02	2	48.0000
	Benzophenone -3	0.72	0.1	1	0.04	2	96.000
Body lotion	Propylparaben	3.43	0.004	1	0.037	1	8.4607
/cream	Butylparaben	3.43	0.004	1	0.037	1	8.4607
	D4	3.43	3.4E-06	1	0.01	1	0.0019
Deodorant	Propylparaben	0.75	0.004	1	0.037	2	3.7000
	Butylparaben	0.75	0.004	1	0.037	2	3.7000
	Triclosan	0.75	0.003	1	0.20	2	15.6000
Hand	Propylparaben	1.08	0.004	1	0.037	1	2.6640
cream	Butylparaben	1.08	0.004	1	0.037	1	2.6640
Hand soap	Propylparaben	2.0	0.004	0.01	0.037	8	0.3947
	Butylparaben	2.0	0.004	0.01	0.037	8	0.3947
Pregnant belly creams/pre gnancy oils [*]	D4	0.34	0.00003	1	0.01	2	0.0034

Hair dye	Resorcinol	100 ml	0.025	0.1	0.025	0.033	0.0035
Shampoo	Propylparaben	10.46	0.004	0.01	0.037	1	0.27
-	Butylparaben	10.46	0.004	0.01	0.037	1	0.27
Toothpaste	Triclosan	1.375	0.003	0.05	-	2	6.8750

* The survey did not find any parabens in pregnant belly creams/pregnancy oils

7.6.3 Exposure calculation for the basis scenario - other activities and sources

This subsection contains a description of studies on exposures for different other situations, which are part of the project, but where migration studies were not available to carry out the calculations.

7.6.3.1 DYI

During "DYI work" you will often be in contact with e.g. paint, cleaning products, joint fillers, masking tape/plastic and various equipment, such as knee pads and building materials. Household gloves and/or work gloves are often worn during the work.

This may cause exposure to e.g. phthalates, perfluorinated compounds (PFAS) such as PFOS and PFOA, and nonylphenol partly via direct skin contact with the products and partly via inhalation of the substances that evaporate from the products or are already present in the air.

Household gloves and work gloves have already been measured in the project, but migration above the detection limit of phthalates, bisphenol A or octamethylcyclotetrasiloxane (D4) has not been found, and as there were no suitable available migration data from previous projects either, this scenario cannot be used as an extra contribution. However, it is clear that products of this type containing one or more of the selected substances (e.g. phthalates) will contribute to the overall burden of these substances in our homes (indoor environment – dust and indoor air).

7.6.3.2 Sport during leisure time (exposure via training situations) During sports activities, you will frequently come into contact with e.g. yoga mats/sleeping mats, pilates balls, soft handles on equipment (bikes, exercise equipment), hand weights and elastics. Furthermore, biking gloves/pants, sneakers/five fingers and other sports equipment are frequently worn during training.

In this connection, you may be exposed to phthalates, triclosan, and nonylphenol partly via direct skin contact with the products and partly via inhalation of the substances evaporating from the products or are already present in the air.

Sneakers/five fingers and sleeping mats were measured, but no migration of the examined substances was found. There was, however, migration data for phthalates from previous studies, which has been used as a contribution to exposure to phthalates.

If products of this type, containing one or more of the selected substances (e.g. phthalates), are used in our private homes, they will contribute to the total burden of these substances in our homes (indoor environment – dust and indoor air).

7.6.4 Exposure calculation for the holiday scenario

Apart from the exposure, to which the target group is exposed in every day life, extra contribution may occur during holiday periods, e.g. a beach holiday, where the women use sunscreen and wear plastic sandals.

7.6.4.1 Sunscreens

Exposure to some of the selected substances via use of sunscreen occurs for most of the target group as a short limited exposure in connection with e.g. beach holidays or skiing holidays (face only). An exception to this is may be persons who stay much outdoors e.g. in connection with work . For these persons, a longer exposure period will be seen, but presumably with a significantly smaller contact surface (face and arms); however, no calculations have been made for this situation.

The exposure has been calculated:

- average exposure with the total amount of sunscreen used per day set to 18 grams (SCCS 2011) and the concentration for the UV-filter reduced to half the maximum allowed concentratio and for the parabens 0.1% (as ester) for propyl and butylparaben, respectively, as the sum of their individual concentrations must be 0.19% (as ester) in the new proposition from the Commission. Furthermore, results from the quantitative analyses on content of D4 in sunscreens are included (parameters described in Table 7-23)
- maximum exposure with the maximum recommended amount of sunscreen of 36 grams per day (Commission recommendation, 2006) and parabens and UV-filter in the product in their maximum allowed concentration, i.e. 0.4 % propylparaben, 0.4% butylparaben and 10% of a UV-filter. Furthermore, results from the quantitative analyses on content of D4 in sunscreens are included (parameters described in Table 7-23)

Table 7-31 Internal dose of selected substances occurring in sunscreens at maximum allowed amounts in the products and at half the maximum allowed amounts for UV-filters, while for the parabens at average exposure, 0.1% (as ester) is reckoned for each paraben, as the sum of their individual concentrations is allowed to be 0.19% (as ester) in the new proposition from the Commission

Product	Substance	Amount of product per time (Q) (g)	Weight fraction of substance in product (Fcprod)	Retention factor	Dermal absorp tion (F _{abs)}	Applic ations per day (n)	Internal dose (µg/kg bw/day)
Average e	exposure						
Sunscre	Propylparaben	18	0.001	1	0.037	1	11.1
en	Butylparaben	18	0.001	1	0.037	1	11.1
	OMC	18	0.05	1	0.02	1	300
	Benzophenon e-3	18	0.05	1	0.04	1	600
	D4	18	0.0034	1	0.01	1	10.2
Maximum	exposure						
Sunscre	Propylparaben	18	0.004	1	0.037	2	88.8
en	Butylparaben	18	0.004	1	0.037	2	88.8
	OMC	18	0.1	1	0.02	2	1200
	Benzophenon e-3	18	0.1	1	0.04	2	2400
	D4	18	0.0034	1	0.01	2	20.4

7.6.4.2 Plastic sandals

In survey no. 107 from the EPA (Danish EPA 2010), migration from plastic sandals has been studied with simultaneous use of sunscreen on the feet. It has been found that sunscreen on the feet will significantly increase the migration of several phthalates from the plastic sandal; that does not apply to all. For DBP, a lower migration is seen. In connection with a holiday, a situation with simultaneous use of sunscreen and plastic sandals may easily occur, and therefore a calculation of such an exposure has been made (Table 7-35). The used assumptions and conditions are described in Table 7-23.

Table 7-32 Exposure during a holiday with simultaneous use of plastic sandals and sunscreen on the feet. All values are for dermal exposure. Please refer to Table 7-23 for explanation of the used parameters and references

Product group	Weight produc t, (Q), (g)	Weight fractio n of substa nce in produc t (Fc prod)	Measured migration value, sweat (Fc migr), (µg/g/h)	F abs	Part of product you are in contact with (F contact)	Conta ct time (T _{contact}), (h)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/day)
Average exposure	e								
Plastic sandals, adults, sole, DEHP	90.74	1	16.39	0.05	1	8	1	60	9.9149
Plastic sandals, adults, strap, DEHP	24.32	1	26.82	0.05	0.5	8	1	60	2.1742
Total DEHP									12.0891
Plastic sandals, adults, sole, DBP	90.74	1	0.3	0.1	1	8	1	60	0.3630
Plastic sandals, adults, strap, DBP	24.32	1	2.23	0.1	0.5	8	1	60	0.3616
Total DBP									0.7245
Plastic sandals, adults, sole, DiBP	90.74	1	5.3	0.1	1	8	1	60	6.4123
Plastic sandals, adults, strap, DiBP	24.32	1	1.97	0.1	0.5	8	1	60	0.3194
Total DiBP									6.7317
Maximum exposu	re								
Plastic sandals, adults, sole, DEHP	90.74	1	16.39	0.05	1	16	1	60	19.8297
Plastic sandals, adults, strap, DEHP	24.32	1	26.82	0.05	0.5	16	1	60	4.3484
Total DEHP									24.1781
Plastic sandals, adults, sole, DBP	90.74	1	0.3	0.1	1	16	1	60	0.7259
Plastic sandals, adults, strap, DBP	24.32	1	2.23	0.1	0.5	16	1	60	0.7231
Total DBP									1.4490

Plastic sandals, adults, sole, DiBP	90.74	1	5.3	0.1	1	16	1	60	12.8246
Plastic sandals, adults, strap, DiBP	24.32	1	1.97	0.1	0.5	16	1	60	0.6388
Total DiBP									

7.6.5 Exposure calculation for the work scenario

In a workplace there are rules for the handling of substances and materials. In the work environment, you work with prevention steps, where the first step is to consider substitution. In this context, some substances and materials may be substituted directly (e.g. hand cream and plastic sandals), and some substances and materials may be very difficult or impossible to substitute. If substitution is not possible, technical measures must be taken to avoid exposure from substances or materials. If it is technically impossible to eliminate the exposure this way, personal protection must be used as the last of the prevention steps.

An employer must, when told that an employee is pregnant, take care that it is assessed in the workplace evaluation, whether the employee will be exposed to effects causing a risk during the pregnancy. Basicly, the imployer must always make a risk assessment concerning the hazard, the severity and the duration of the exposure. The employer's decision about whether a pregnant employee may perform a certain work task, therefore, must be made in connection with her actual work conditions. If the employer assesses that a risk will adversely affect the pregnancy, he/she must do the following in order of priority:

- take care of technical measures or changed design of the work place, or if this is not enough or impossible,
- change the planning and the organisation of the work, or if this is not enough or impossible,
- transfer the pregnant employee to other tasks, or if this is not enough or impossible,
- decide that the pregnant employee must not be occupied with the task in question

7.6.5.1 Exposure to individual consumer products via work environment As this project has not been able to generate specific data for the work environment, the following data is based on data from published literature and on an estimate of the exposure, which professionals may get via contact with individual consumer products. In this project, scenarios for exposure to suspected endocrine disruptors from products to professionals via the work environment have not been made.

Healthcare professionals, childcare professionals, etc.

Healthcare professionals and childcare professionals are assessed, e.g. due to frequent hand wash, to use hand cream more frequently than the general population. Furthermore, many people use soft plastic sandals/clogs to relieve shock impacts of feet/legs and back in connection with many hours of walking and standing work positions.

The extra exposure that women in these work situations may be exposed to via consumer products as plastic sandals and hand creams is clarified in Table 7-36.

Table 7-36 Exposure during a work day, wearing plastic sandals and using hand cream. Values are for dermal exposure. Please refer to Table 7-24 for explanation of the used parameters

dermal exposure. Please refer to Table 7-24 for explanation of the used parameters											
Product group	Weight produc t, (Q), (g)	Weight fractio n of substa nce in produc t (Fc prod)	Measured migration value, sweat (Fc migr), (µg/g/h)	F abs	Part of product you are in contact with (F contact)	Contact time (T _{contact}), (h)	Time s per day (n)	Bw (kg)	Internal dose (µg/kg bw/day)		
Average exposure						l	1		l		
Hand cream, propylparaben	1.08	0.001	not used	0.03 7	1	1	3	60	1.9980		
Hand cream, butylparaben	1.08	0.001	not used	0.03 7	1	1	3	60	1.9980		
Plastic sandals, adults, DEHP, sole	90.74	1	0.11	0.05	1	8	1	60	0.0665		
Plastic sandals, adults, DEHP, strap	24.32	1	0.18	0.05	0.5	8	1	60	0.0146		
Plastic sandals, adults, DBP, sole	90.74	1	0.30	0.1	1	8	1	60	0.3630		
Plastic sandals, adults, DBP, strap	24.32	1	2.23	0.1	0.5	8	1	60	0.3616		
Plastic sandals, adults, DiBP, sole	90.74	1	1.56	0.1	1	8	1	60	1.8874		
Plastic sandals, adults, DiBP, strap	24.32	1	0.58	0.1	0.5	8	1	60	0.0940		
Maximum exposure		1									
Hand cream, propylparaben	1.08	0.004	not used	0.03 7	1	1	3	60	7.9920		
Hand cream, butylparaben	1.08	0.004	not used	0.03 7	1	1	3	60	7.9920		
Plastic sandals, adults, DEHP, sole	90.74	1	0.11	0.05	1	16	1	60	0.1313		
Plastic sandals, adults, DEHP, strap	24.32	1	0.18	0.05	0.5	16	1	60	0.0292		
Plastic sandals, adults, DBP, sole	90.74	1	1.56	0.1	1	16	1	60	3.7748		
Plastic sandals, adults, DBP, strap	24.32	1	0.58	0.1	0.5	16	1	60	0.1881		
Plastic sandals, adults, DiBP, sole	90.74	1	1.56	0.1	1	16	1	60	3.7748		
Plastic sandals, adults, DiBP, strap	24.32	1	0.58	0.1	0.5	16	1	60	0.1881		

Cashiers

Cashiers are more frequently in touch with receipts than the general population and are assumed to be in touch with receipts up to 100 times per work day. This extra exposure is clarified in Table 7-37.

Table 7-33 Exposure by contact with receipts. Values are for dermal exposure. Please refer to Table 7-24 for explanation of the used parameters

Product group	Weight produ ct (Q), (g)	Weight fraction of substan ce in product (F _{c prod})	Measured migration value, sweat (Fc migr), (µg/g/h)	F abs	Part of product you are in contact with (F contact)	Contact time (T _{contact}), (h)	Times per day (n)	Bw (kg)	Internal dose (µg/kg bw/day)		
Average and m	Average and maximum exposure										
Receipts, bisphenol A, (Danish 2011c)	10 cm ²	1	3708 µg/cm²/h	0.1	1	0.0014 (5 sec)	100	60	4.3260		

7.6.6 Exposure calculation for work scenarios – examples of other work functions with risk of exposure

Exposure scenarios for the work environment have not been made, but instead a risk was calculated using individual consumer products used at work. The below mentioned sectors of trades are examples of trades (i.e. an incomplete list of trades) with risk of exposure to endocrine disruptors.

7.6.6.1 Painters

During paint work and the like there will be a risk of contact with e.g. paint, cleaning products, joint fillers, masking tape/plastic and various equipment, such as knee pads and building materials.

During paint work you may be exposed to endocrine disruptors partly via direct skin contact with the products and partly via inhalation of substances evaporating from the products.

The employee, however, has a duty to prevent the pregnant painter from exposures, which may be hazardous to the pregnancy. In this connection it may be necessary to consult a health and safety consultant, who may assist in assessing the products to which the pregnant painter may be exposed during pregnancy.

7.6.6.2 Hairdressers

Hairdressers use disposable gloves during wet work, if they follow and recommendations from the Working Environment Service. During handling of perm liquid, bleaching agents, hair dyes, etc., suitable gloves must be worn, protecting sufficiently against exposure to the substance.

It is likely that hairdressers will be exposed by e.g. contact with resorcinol in hair dyes and other substances in the cosmetic products, they are working with, thus potentially absorbing partly via dermal contact and partly by inhalation during the work day. There is no suitable available exposure data for this, so it has not been used.

7.6.6.3 Gardeners and gardeners' assistants

Gardeners and gardeners' assistants use personal protection during spraying, if they follow the demands from the Working Environment Service. Despite this, the study shows that the women are exposed to a number of pesticides through work, mainly by diluting fungicides or growth regulators (National Board of Health 2008). Pregnant women must not, according the rules from the Working Environment Service, mix or deliver pesticides or clean spraying equipment, neither must they remain in greenhouses where known or suspected teratogenic pesticides have been

placed. If a pregnant woman is working in a greenhouse after spraying, she must use gloves protecting against the pesticide in question.

7.6.7 Exposure calculation for the transport scenario

Information on the selected substances in vehicles (cars) has been searched for in the literature. Three studies have been identified as stated in Table 7-38.

The studies show that small amounts of phthalates, flame retardants and fluorine compounds can be found inside cars, i.e. in the car's indoor environment. Measuring has been made of the indoor air of cars, of dust from cars, and of grease/dirt/dust sitting inside the windshield of the car. The substances may originate from the materials of the car itself, but also from the products we as consumers choose to have in our cars, such as child safety seats, rear seat protectors (a product with storage compartments, which also protects the back of the front seat). Also impregnating agents used on the textiles of the car seats have been found to contain phthalates and fluorine compounds (Danish EPA 2009b).

Geiss et al. (2009) state the concentration of phthalates in indoor air of different cars, whereas Goosey & Harrad (2011) have measured on the contents of PFOS and PFOA and other PFCs in dust inside cars. The American study from Ecocenter (2006) has measured the contents of phthalates in dust and on the film of grease/dirt/dust on the inside of the windshield. Concentrations vary depending on car brand (and thereby interior) and age of the car.

Dust in cars

The dust values in cars for PFOS and PFOA (Goosey et al., 2011) are shown to be way below measured values from the indoor environment (homes and offices) made in the same source/study. The same applies to the dust values for the phthalates (The Ecology Center 2006), which are a factor 100 – 1000 lower than corresponding dust values from private homes or daycare centres. As the exposure calculations calculate on a daily contribution from dust of 50 mg/day for adults, this contribution is ignored both from PFOS/PFOA and phthalates in transport, as women are not assumed to have a higher intake of dust per day just because they drive a car. As worst cases, there is thus exclusively calculated on the higher PFOS/PFOA and phthalate values from the indoor environment for the full 50 mg dust intake/day.

Indoor air in cars

For indoor air in cars, however, we use the maximum values for DEHP and DBP measured in the study from Geiss et al. (2009). The contribution from indoor air in cars for these two phthalates is therefore calculated as an extra contribution relative to the indoor environment in the exposure calculations. The study is Italian but is expected to be transferred to Danish conditions. The measurings were made in the winter, and therefore the evaporation of phthalates may be expected to be higher at higher temperatures in the summer.

Table 7-34 Overview of content of selected substances in cars

Source	Concentration measured	Comments
Indoor air in cars		
(Geiss et al., 2009)	DEHP: Range: < DL – 3.656 μg/m ³	Measuring in 23 different Italian cars has been made for the concentration of three different phthalates. The measuring took place in
	DBP:	November and December of 2007.
	Range: < DL – 1.630 µg/m³	
Dust in cars		
(Goosey et al., 2011)	PFOS: Range: 20 – 1500 ng/g Median: 97 ng/g Average: 260 ng/g	There was measured on PFOA and PFOS, and other PFCs in dust in 20 cars in Birmingham, the UK in 2007-2009.
	PFOA: Range: <0.98 – 370 ng/g Median: 65 ng/g Average: 110 ng/g	
(The Ecology Center 2006)	Dust: DBP: 3 µg/g DiBP: 1 µg/g BBP: 6 µg/g DEHP: 49 µg/g <u>Windshield film:</u> DBP: 3 µg/m ²	An American study from 2006 has examined a number of cars in the American market for content of phthalates in dust inside the car (2 measurings) and from the film inside the windshield (13 measurings). It has not been stated when the samples were taken. The concentrations from the film in the windshield
	BBP: 2 μg/m ² DEHP: 5 μg/m ²	are stated per area of the windshield.

Highlights in grey and figures in bold illuestrate the values used in the exposure calculations.

The contribution from indoor air in cars for the phthalates DEHP and DBP (for which there is data) is calculated as an extra contribution relative to the indoor environment. It is assumed that we stay indoors for 20 hours (home and at work), but in addition it is assumed that we use $1\frac{1}{2}$ hours transport per day – which, if this transport is by car, may give the below extra contribution to the daily exposure to the two phthalates (see Table 7-39). In comparison it is stated in (The Ecology Center 2006) that the Americans spend minimum 100 minutes each day in their cars.

The calculation of the daily exposure was made as follows, as also described in Section 7.1:

$$D(DEHP)_{inh} = \frac{3.656 \ \mu g \ / \ m^3 \cdot 18 \ m^3 \ / \ day \cdot 1.5 \ / \ 24 \cdot 0.75}{60 \ bw} \cdot 1 = 0.027 \ \mu g \ / \ bw \ / \ day$$

Tablel 7 25 Evine autra ta	abth a lata a lay dr	ulag o corfor	11/ hours hor dou
Tablel 7-35 Exposure to	primalates by dr	iving a car ior	1/2 nours per day

Contribution from indoor air in cars	Maximum measured conc. in air (µg/m ³)	Daily inhalation of air (m ³ /day)	F inh (fraction of substance inhaled)	Contact time (T _{contact}), (h)	N	Bw (kg)	Exposure (inhalation) (µg/kg bw/day)
DEHP	3.656	18	0.75	1.5/24	1	60	0.0514
DBP	1.63	18	1	1.5/24	1	60	0.0306

8 Risk assessment

8.1 Method for calculation of risk

The pregnant woman can be exposed to the same substance via different routes of exposure as described in Section 1. According to the REACH guidelines for consumer exposure (ECHA 2010), the exposure dosage (D_{total}) for the three different routes to find the total exposure per substance:

$$D_{total} = D_{inh} + D_{der} + D_{oral}$$

According to the REACH guidelines for risk assessment (ECHA 2008), it shall be assessed in each case if there is a health risk according to the following formula, which calculates a Risk Characterisation Ratio (RCR) using the Derived No Effect Level (DNEL):

$$RCR = \frac{Exposure(D_{total})}{DNEL}$$

If RCR > 1 (i.e. exposure is higher than DNEL), there is a risk. If RCR is < 1 the exposure is not considered to be a risk.

For a single substance the total exposure values for various exposure routes followed by division by DNEL will correspond to RCR being calculated for various exposure routes and then combined:

$$RCR = \frac{Exposure (D_{total})}{DNEL} = \frac{D_{inh}}{DNEL} + \frac{D_{der}}{DNEL} + \frac{D_{oral}}{DNEL} =$$

$$RCR = RCR_{inh} + RCR_{der} + RCR_{oral}$$

In order to compare various exposure sources' contribution to a total RCR for a substance, calculations of RCR have been made in this project from various exposure routes and from various sources (e.g. oral exposure from dust and food respectively) and these RCR values for each substance have been added up to an RCR_{total}, as explained below.

8.1.1 Combination effects

Exposure to different substances with the same effect from various sources are characterised as combination effects. The Danish Working Environment Service recommends that at least an additive effect is taken into account, if no specific information about the co-effects of the substances is available (Arbejdstilsynet, 2005). Occurrence of several substances at the same time may also have an increased (synergistic) or reduced (antagonistic) effect. To demonstrate these effects, however, it requires thorough studies with the right detailed substance

combinations. In this project, only the additive effect is included by use of the dose-addition principle, as described in Section 1.

New tests show, that the combination effect of phthalates and other antiandrogenic substances can be calculated by using the dose-addition concept (NAP 2008; Benson 2009). This concept is also used here.

It is estimated, that the best method of calculating combination effects in this case is a modified version of the hazard index (HI) method. This method can in general be described with the formula:

$$HI = \sum_{i=1}^{n} EL_i / AL_i$$

Where EL is the exposure level and AL is the acceptable level. In this case DNEL is used as the acceptable level, and the fraction EL/AL therefore corresponds to the calculated RCR for each substance. This method allows for use of specific factors of uncertainty for the single substances which is an advantage, when DNEL for the single substances are based on different types of animal testing.

The total, i.e. additive risk is therefore calculated by adding up the single substances' RCR values:

$$RCR_{Total} = RCR_1 + RCR_2 + RCR_3 + \ldots + RCR_n$$

 RCR_{Total} is thus equivalent of the increased (cumulative) risk which the woman is exposed to by e.g. effect from the whole group of suspected endocrine disruptors with antiandrogenic effect.

RCR_{Total} is calculated:

- only for the antiandrogenic substances (RCR_{Total(AA)})
- only for the estrogen-like substances (RCR_{Total(E)})
- only for the substances with a thyroid disrupting effect (RCR_{Total(T)})

8.2 Exposure scenarios

8.2.1 Basis scenario

All humans are exposed to chemical substances in daily life, from food, indoor environment, cosmetics and other products surrounding us at home, at work and other places where we stay. In the project a basic exposure is used covering an average woman representing the estimated exposure, which the target group is exposed to through their normal day, to the extent that data to illustrate it has been available.

The basis scenario includes contributions from:

- indoor environment
- food
- daily life (including exposure from toothbrushing, cell phone covers, footwear/textiles, use of creams (pregnant belly creams and body lotions), sex toys, bath soaps, bath mats etc. as well as sport, leisure and shopping)

A realistic estimate for exposure (medium exposure) is included in the basis scenario as well as a realistic worst case estimate (maximum exposure). The two exposure situations within the basis scenario are determined by an estimate of contact period with the consumer products (medium/maximum), data from literature (medium/maximum), exposure from indoor environment and via intake of food (median and 95 percentiles as far as possible).

The exposures are based on the available data, i.e. contributions from consumer products are included, where migration data are available (e.g. oilcloth, Pilates ball, rucksack, bath soap packaging and plastic sandal) – and consequently do not include contribution from all consumer products you are in contact with in daily life. Data for consumer products, which have been chosen as part of the basis scenario, are described in Table 7-22.

8.2.1.1 Products particularly for the pregnant woman

Pregnant women may be exposed to the selected substances by using products especially targeted for pregnant women. Only data for pregnant belly creams/pregnancy oils are found, which to a high extent are meant for pregnant women. A risk assessment is based on consumption data from Table 7-33. It is assumed that the pregnant woman applies the cream to abdomen, bosom and buttocks corresponding to 10% of the amount used for the whole body. It is assumed, that the pregnant woman at a realistic scenario (medium) applies the cream to the abdomen once a day, while she at a realistic worst case scenario (maximum) applies the cream to the abdomen twice a day. Exposure from use of pregnant belly creams is included in the basis scenario.

8.2.2 Other exposure scenarios

Apart from the basis scenario, exposures may occur for only short periods of time, or special habits or special work may cause exposure beyond the basic one.

8.2.2.1 The holiday scenario

During the summer period the target group may be exposed to sunscreens for example in connection with summer holidays. Intense exposure may occur during two weeks' summer holiday, whereas the rest of the year gives no exposure. It is assumed that the target group at a medium exposure uses 18 gram of sunscreen per day in the holiday period, while at maximum exposure the consumption is 36 gram per day corresponding to applying the whole body twice daily in a thick layer. In addition it is estimated to be likely that the target group wear plastic sandals for up to 16 hours daily and in the holiday furthermore has applied sunscreen on the feet. It is hereby determined, that migration of some phthalates from plastic sandals has increased considerably.

The risk of such exposure to sunscreen and for use of plastic sandals at the same time as sunscreen is applied to the feet is calculated as the holiday scenario (Table 7-34 and 7-35) and the calculated risk appears in Table 8-2 for a medium and maximum exposure.

8.2.2.2 The transport scenario

In connection with transport (here cars, for which data are available) the target group may be exposed to certain of the selected phthalates which appear in small amounts in the indoor air in cars (Table 7-39). In the transport scenario a $1\frac{1}{2}$ hours' stay in the car per day is assumed. This is based upon an average assumption, but the exposure period may be very different from woman to woman. Some commuters have a long distance to work and spend longer time whereas others are far from spending $1\frac{1}{2}$ hours in the car on a daily basis.

Data has only been identified for cars, but a similar exposure could be estimated in connection with use of other means of transport such as train and bus. The risk of the average assumption for the transport scenario can be seen in Table 8-2, where the assumed risk is the same for medium and maximum exposure.

8.2.2.3 The work scenario

This project does not include scenarios with exposures in the work environment to suspected endocrine disruptors from professional products. However, exposure has been calculated for a few consumer products which can be used in connection with work (Tables 7-36 and 7-37). It is assumed, that selected working groups use more hand cream than the amount used in the basis scenario. Frequent washing of hands (e.g. health personnel at hospitals) is assumed to result in higher consumption of hand cream corresponding to 3 times extra a day compared to the basis scenario.

Furthermore it is estimated that several working groups use plastic sandals and therefore are exposed to phthalates. By use of plastic sandals in a work situation the contact period is estimated to be 8 hours. The risk of exposure for single consumer products used in work situations is seen in Table 8-2 for a medium and maximum exposure.

8.3 Results

The calculated internal doses of exposure for the selected substances in food, indoor environment and consumer products are presented in various scenarios. The results from the exposure calculations for the various sources of the basis scenario can be seen in Table 8-1, where the internal dose with which the target group is exposed from each of the three main sources (consumer products, indoor environment, food) in a medium and maximum exposure. Furthermore the RCR values per substance are indicated.

Exposure calculations for holiday scenario, work scenario and transport scenario are shown in Table 8-2.

It is also interesting, however, to add up the exposure calculations for selected scenarios in order to assess a total risk, if/when a person is exposed to many sources during a day.

Following scenarios are combined in order to estimate a total exposure:

- basis + holiday scenarios (medium and maximum exposure)
- basis + work + transport scenario (medium and maximum exposure)

8.3.1 The basis + work + transport scenarios

It is assumed to be a realistic estimate, that the target group could potentially be expose to suspected endocrine disruptors via the sources that are included in the basis scenario, as well as other sources via work and transport, where these scenarios are added up.

Since no work scenarios have been made on exposure from suspected endocrine disruptors from products to professionals, the only data from the work environment are exposure to a few consumer products such as extra hand cream in comparison to the basis scenario and exposure to phthalates from use of plastic sandals. As exposure to phthalates from use of plastic sandals is already included in the basis scenario (same exposure, 8 hours at medium exposure and 16 hours at maximum exposure as used in the work scenario) a direct combination of the two scenarios will result in a considerable overestimation of the risk. The additional exposure from the work scenario will therefore in this case in reality only be use of extra hand cream. Furthermore an extra contribution from the transport scenario is added. These data can be seen in Table 8-3.

8.3.2 The basis + holiday scenario

In connection with a holiday period it is estimated, that the target group will continue to be exposed from sources such as food and indoor environment (basis scenario) albeit one stays more outdoor than indoor during a summer period than during a winter period. In a holiday period the contribution from the basis scenario can therefore be somewhat over-estimated. Contact to various consumer products will in the holiday period often be the same as in daily life which is why it is found realistic to put the basis and the holiday scenarios together. However, in this report exposure to selected phthalates from plastic sandals are included in both the basis and the holiday scenario. It will not be realistic to experience a double exposure for this product since the contact period in both scenarios is set to be 9 and 16 hours

for medium and maximum exposure. The plastic sandals will therefore be left out from the basis scenario in this situation.

Table 8-1 Den total exposure per substance and per source (consumer products, indoor environment and food) is shown for the basis scenario. The calculated internal doses for consumer products, indoor environment and food are indicated in µg/kg bw/day. RCR is calculated as a sum of exposures divided with DNEL for each substance. RCR values above 0.1 are indicated in read figures, whereas RCR values above 1 are indicated in bold read figures and italic. The green colour indicates the source contributing the most for the single substance for realistic (medium exposure) and realistic worst case (maximum exposure) respectively in the basis scenario. Empty field means that no data have been identified for the substance in question

		L. C.	BASIC -	medium ex	kposure			BASIC -	maximum e	exposure	
Substance	DNEL (µg/kg bw/day)	Consume r products (µg/kg bw/day)	Indoor environm ent (µg/kg bw/day)	Food (µg/kg bw/day)	Sum (µg/kg bw/day)	RCR _{Total}	Consume r products (µg/kg bw/day)	Indoor environm ent (µg/kg bw/day)	Food (µg/kg bw/day)	Sum (µg/kg bw/day)	RCRTotal
DEHP (AA)	25.00	0.8087	0.2114	1.2000	2.2201	0.0888	2.0265	2.7812	2.2000	7.0077	0.2803
DEHP (T)	188.00	0.8087	0.2114	1.2000	2.2201	0.0118	2.0265	2.7812	2.2000	7.0077	0.0373
DINP (AA)	1500.00		0.0171	0.4500	0.4671	0.0003		0.8042	1.4000	2.2042	0.0015
DBP (AA)	10.00	0.7245	0.0584	0.2600	1.0429	0.1043	1.4490	0.4553	1.4000	3.3044	0.3304
Dibp (AA)	1250.00	3.0006	0.0379	0.6000	3.6386	0.0029	6.0013	2.2516	2.1000	10.3528	0.0083
BBP (AA)	500.00	<0.0000	0.0154	0.2000	0.2154	0.0004	<0.0000	0.2480	0.4000	0.6480	0.0013
DPP (AA)	330.00		<0.0000	<0.0000	0.0000	<0.0000		<0.0000	<0.0000	0.0000	<0.0000
DnHP (AA)	500.00		0.0009	<0.0000	0.0009	<0.0000		0.0255	<0.0000	0.0255	0.0001
DnHP (T)	6100.00		0.0009	<0.0000	0.0009	<0.0000		0.0255	<0.0000	0.0255	<0.0000
DnOP (AA)	368.00	0.0235	0.2083	<0.0000	0.2319	0.0006	0.0470	2.0917	<0.0000	2.1387	0.0058
Dioxins and dioxin-like PCBs (AA)	0.000002		0.00000002	0.00000100	0.00000102	0.5115		0.0000002	0.00000207	0.00000226	1.1322
Dioxins and dioxin-like PCBs (T)	0.000006		0.00000002	0.00000100	0.00000102	0.1705		0.0000008	0.00000207	0.00000285	0.4747
Dioxins and dioxin-like PCBs (AA) DUST	0.03		0.0001		0.0001	0.0038		0.0152		0.01517	0.4555
Bisphenol A (E)	500.00	0.7983	0.0004	1.5000	2.2987	0.0046	0.8007	0.0025	1.5000	2.3031	0.0046
Nonylphenol (E)	15.00	4.5281	0.0277	0.2000	4.7558	0.3171	9.0563	0.1057	0.2000	9.3620	0.6241
TBBPA (E)	66.70		0.2625	<0.0000	0.2625	0.0039		3.6503	<0.0000	3.6503	0.0547
TBBPA (T)	300.00		0.2625	<0.0000	0.2625	0.0009		3.6503	<0.0000	3.6503	0.0122
PFOA (AA)	100.00		0.0003	0.0600	0.0603	0.0006		0.0050	0.2000	0.2050	0.0021
PFOA (T)	20.00		0.0003	0.0600	0.0603	0.0030		0.0050	0.2000	0.2050	0.0103
PFOS (AA)	50.00		0.0007	0.0020	0.0027	0.0001		0.0063	0.0060	0.0123	0.0002
PFOS (T)	0.15		0.0007	0.0020	0.0027	0.0180		0.0063	0.0060	0.0123	0.0817
D4 (E)	195.00	0.0027			0.0027	<0.0000	0.0054			0.0054	<0.0000
Propylparaben (E)	20.00	2.7241	0.0003	<0.0000	2.7244	0.1362	19.0427	0.0009	<0.0000	19.0435	0.9522
Butylparaben (E)	20.00	2.7241	0.0001	<0.0000	2.7241	0.1362	19.0427	0.0041	<0.0000	19.0467	0.9523

			BASIC -	medium ex	posure			BASIC – I	maximum e	xposure	
Substance	DNEL (µg/kg bw/day)	Consume r products (µg/kg bw/day)	Indoor environm ent (µg/kg bw/day)	Food (µg/kg bw/day)	Sum (µg/kg bw/day)	RCR Total	Consume r products (µg/kg bw/day)	Indoor environm ent (µg/kg bw/day)	Food (µg/kg bw/day)	Sum (µg/kg bw/day)	RCR Total
lsobutylparaben (E)*	625.00										
OMC (E)	1666.70	24.0000			24.0000	0.0144	48.0000			48.0000	0.0288
OMC (T)	1000.00	24.0000			24.0000	0.0240	48.0000			48.0000	0.0480
Benzophenone 3 (E)	9370.00	48.0000			48.0000	0.0051	96.0000			96.0000	0.0102
Triclosan (E)	50.00	7.3375	0.0002	<0.0000	7.3377	0.1468	22.4750	0.0015	<0.0000	22.4765	0.4495
Triclosan (T)	30.00	7.3375	0.0002	<0.0000	7.3377	0.2446	22.4750	0.0015	<0.0000	22.4765	0.7492
Resorcinol (T)	1017.00	0.0006			0.0006	<0.0000	0.0035			0.0035	<0.0000
Chlorpyrifos (AA)	60.00		<0.0000	0.0330	0.0330	0.0006		0.2130	0.0670	0.2800	0.0047
Chlorpyrifos (T)	17.10		<0.0000	0.0330	0.0330	0.0019		0.2130	0.0670	0.2800	0.0164
Dithiocarbamates (T)	48.00			0.1000	0.1000	0.0021			0.2000	0.2000	0.0042
Imazalil (AA)	200.00			0.0670	0.0670	0.0003			0.1300	0.1300	0.0007
Iprodione (AA)	150.00			0.0500	0.0500	0.0003			0.1000	0.1000	0.0007
Pirimiphos-methyl (AA)	625.00			0.1000	0.1000	0.0002			0.2000	0.2000	0.0003
Procymidone (AA)	2.80			0.0120	0.0120	0.0043			0.0443	0.0443	0.0158
Propamocarb (E)	375.00			0.0670	0.0670	0.0002			0.1300	0.1300	0.0003
Tebuconazole (AA)	170.00			<0.0000	0.0000	<0.0000			0.0246	0.0246	0.0001
Thiabendazole (T)	100.00			0.0500	0.0500	0.0005			0.1400	0.1400	0.0014

* Cf. section 7.6.2 exposure has not been calculated for isobutylparaben

Table 8-2 the total exposure per substance per scenario (holiday, work, transport) is shown. The calculated internal doses are indicated in µg/kg bw/day. RCR values above 0.1 are indicated in read figures, whereas RCR values above 1 are indicated in bold read figures and italic. Only selected substances where a contribution to exposure has been found are included. Empty field means that no data have been identified for the substance in question and the source in question.

		Medium exposure							Maximum exposure					
Substance	DNEL (µg/kg bw/day)	Holiday (µg/kg bw/day)	RCRHOLI DAY	Work (µg/kg bw/day)	RCR WORK	Transpor t (µg/kg bw/day)	RCR TRANSPORT	Holiday (µg/kg bw/day)	RCRHOLID	Work (µg/kg bw/day)	RCR WORK	Transpor t (µg/kg bw/day)	RCR TRANSPORT	
DEHP (AA)	25.00	12.0891	0.4836	0.0811	0.0032	0.0514	0.0021	24.1781	0.9671	0.1623	0.0065	0.0514	0.0021	
DEHP (T)	188.00	12.0891	0.0643	0.0811	0.0004	0.0514	0.0003	24.1781	0.1286	0.1623	0.0009	0.0514	0.0003	
DBP (AA)	10.00	0.7245	0.0725	0.7245	0.0725	0.0306	0.0031	1.4490	0.1449	1.4490	0.1449	0.0306	0.0031	
Dibp (AA)	1250.0 0	6.7317	0.0054	3.9629	0.0032			13.4634	0.0108	3.9629	0.0032			
Bisphenol A (E)	500.00			4.3260	0.0087					4.3260	0.0087			
D4 (E)	195.00	10.2000	0.0523					20.4000	0.1046					
Propylparaben (E)	20.00	11.1000	0.5550	1.9980	0.0999			88.8000	4.4400	7.9920	0.3996			
Butylparaben (E)	20.00	11.1000	0.5550	1.9980	0.0999			88.8000	4.4400	7.9920	0.3996			
omc (e)	1666.7 0	300.0000	0.1800					1200.00 0	0.7200					
OMC (T)	1000.0 0	300.0000	0.3000					1200.00 0	1.2000					
Benzophenone 3 (E)	9370.0 0	600.000	0.0640					2400.00 0	0.2561					

Table 8-3 combination of scenarios. The basis scenario combined with the holiday scenario; exposures from plastic sandals have been removed from the basis scenario in this case. The basis scenario is combined with the work scenario and the transport scenario. In those cases the plastic sandals have been removed from the basis scenario. Only selected substances where a contribution to exposure has been found are included. Empty field means that no data have been identified for the substance in question and the source in question.

			Medium	exposure			Maximum exposure							
Substance	RCRBASIS	RCR _{HOLIDA}	RCR _{TOTAL} - basis + holiday	RCR WORK	RCR TRANSPORT	RCRTOTAL- basis + work + transport	RCRBASIS	RCR _{HOLIDA}	RCRTOTAL- basis + holiday	RCR WORK	RCR TRANSPORT	RCRTOTAL- basis + work + transport		
DEHP (AA)	0.0856	0.4836	0.5691	0.0032	0.0021	0.0909	0.2738	0.9671	1.2409	0.0065	0.0021	0.2824		
DEHP (T)	0.0114	0.0643	0.0757	0.0004	0.0003	0.0121	0.0364	0.1286	0.1650	0.0009	0.0003	0.0375		
DBP (AA)	0.0318	0.0725	0.1043	0.0725	0.0031	0.1073	0.1855	0.1449	0.3304	0.1449	0.0031	0.3335		
Dibp (AA)	0.0013	0.0054	0.0067	0.0032		0.0045	0.0051	0.0108	0.0159	0.0032		0.0083		
Bisphenol A (E)	0.0046	0.0000		0.0087		0.0132	0.0046			0.0087		0.0133		
D4 (E)	<0.0000	0.0523	0.0523			<0.0000	<0.0000	0.1046	0.1046			<0.0000		
Propylparaben (E)	0.1362	0.5550	0.6912	0.0999		0.2361	0.9522	4.4400	5.3922	0.3996		1.3518		
Butylparaben (E)	0.1362	0.5550	0.6912	0.0999		0.2361	0.9523	4.4400	5.3923	0.3996		1.3519		
OMC (E)	0.0144	0.1800	0.1944			0.0144	0.0288	0.7200	0.7488			0.0288		
OMC (T)	0.0240	0.3000	0.3240			0.0240	0.0480	1.2000	1.2480			0.0480		
Benzophenone 3 (E)	0.0051	0.0640	0.0692			0.0051	0.0102	0.2561	0.2664			0.0102		

The total, i.e. the additive risk, is calculated for antiandrogenic, estrogenic and thyroid endocrine disruptors respectively by categorising the substances according to their effect and add up the RCR values for the single substances.

8.3.3 Antiandrogenic substances

Contribution from various sources to the total RCR_{AA} for substances with antiandrogenic effects is based on a basis scenario, a holiday scenario, a work scenario and a transport scenario respectively. The values for the various exposures are based on a realistic medium scenario (medium exposure) for a pregnant woman (Table 8-4), and a realistic worst case scenario (maximum exposure) for a pregnant woman (Table 8-5).

Table 8-4 Total RCR_{AA} for substances with antiandrogenic effects based on a realistic scenario (medium exposure) for the basis scenario, the holiday scenario, the work scenario and the transport scenario as well as basis + holiday and basis + work + transport. For these scenarios exposure for plastic sandals have been removed from the basis scenario in order to avoid an overestimation of the risk. Red figures indicate an RCR_{AA} value above 0.1, while RCR_{AA} values above 1 are indicated with bold red and italic. Empty field means that no data have been identified for the substance in question and the source in question

	Medium exposure										
		RCR _{basis} -indoor							RCR _{basis +}		
	RCR _{basis}	environmen	RCR _{basis}	RCR _{basis}	RCR_{holid}		RCR _{transp}	RCR _{basis +}	work +		
Substance	-consumer	t	-foodstuff	-total*	ay	RCRwork	ort	holiday	transport		
DEHP	0.0323	0.0085	0.0480	0.0888	0.4836	0.0032	0.0021	0.57241	0.0941		
DINP		<0.0000	0.0003	0.0003				0.0003	0.0003		
DBP	0.0725	0.0058	0.0260	0.1043	0.0725	0.0725	0.0031	0.1768	0.1799		
DiBP	0.0024	<0.0000	0.0005	0.0029	0.0054	0.0032		0.0083	0.0045		
BBP		<0.0000	0.0004	0.0004				0.0004	0.0004		
DPP		<0.0000	<0.0000	<0.0000				<0.0000	<0.0000		
DnHP		<0.0000	<0.0000	<0.0000				<0.0000	<0.0000		
Dioxins and dioxin-like PCBs		0.0115	0.5000	0.5115				0.5115	0.5115		
Dioxins and dioxin-like PCBs DUST		0.0038		0.0038				0.0038	0.0038		
PFOA		<0.0000	0.0006	0.0006				0.0006	0.0006		
PFOS		<0.0000	0.0000	0.0001				0.0001	0.0001		
Chlorpyrifos		<0.0000	0.0006	0.0006				0.0006	0.0006		
Imazalil			0.0003	0.0003				0.0003	0.0003		
Iprodione			0.0003	0.0003				0.0003	0.0003		
Procymidone			0.0043	0.0043				0.0043	0.0043		
Pirimiphosmethyl			0.0002	0.0002				0.0002	0.0002		
Tebuconazole			<0.0000	<0.0000				<0.0000	<0.0000		
TOTAL sum	0.1072	0.0297	0.5815	0.7170	0.5614	0.0789	0.0051	1.2784	0.8010		

* Exposure for plastic sandals is excluded in this column

For the basis scenario most of the contribution is from food with a total RCR_{AA} of 0.58 for medium exposure and 1.29 for maximum exposure (Tables 8-4 and 8-5). The substance contributing the most to this RCR_{AA} is dioxins and dioxin-like PCBs, whereas other substances only contribute slightly (Figure 8-1). The consumer products contribute with an RCR_{AA} of 0.11 for medium exposure and 0.23 for maximum exposure respectively, whereas the indoor environment contributes with 0.03 for medium exposure and 0.72 for maximum exposure respectively.

Table 8-5 Total RCRAA for substances with antiandrogenic effects based on a realistic scenario (maximum exposure) for the basis scenario, the holiday scenario, the work scenario and the transport scenario as well as basis + holiday and basis + work + transport. For these scenarios exposure for plastic sandals have been removed from the basis scenario in order to avoid an overestimation of the risk. Red figures indicate an RCRAA value above 0.1, while RCRAA values above 1 are indicated with bold red and italic. Empty field means that no data have been identified for the substance in question and the source in question.

		Maximum exposure										
		RCRbasis										
		-indoor		DOD					RCR basis +			
Substance	RCRbasis	environmen	RCR basis		RCRholid		RCRtransp	RCR basis +	work +			
DEHP	-consumer 0.0811	0.1112	-foodstuff 0.0880	-total* 0.2803	ay 0.9671	0.0065	ort 0.0021	holiday 1.2474	transport 0.2889			
	0.0811				0.9071	0.0005	0.0021					
DINP		0.0005	0.0009	0.0015				0.0015	0.0015			
DBP	0.1449	0.0455	0.1400	0.3304	0.1449	0.1449	0.0031	0.4753	0.4784			
DiBP	0.0048	0.0018	0.0017	0.0083	0.0108	0.0032		0.0191	0.0115			
BBP		0.0005	0.0008	0.0013				0.0013	0.0013			
DPP		<0.0000	<0.0000	<0.0000				<0.0000	<0.0000			
DnHP		0.0001	<0.0000	0.0001				0.0001	0.0001			
Dioxins and dioxin-like PCBs		0.0972	1.0350	1.1322				1.1322	1.1322			
Dioxins and dioxin-like		0.0772										
PCBs DUST		0.4555		0.4555				0.4555	0.4555			
PFOA		0.0001	0.0020	0.0021				0.0021	0.0021			
PFOS		0.0001	0.0001	0.0002				0.0002	0.0002			
Chlorpyrifos		0.0036	0.0011	0.0047				0.0047	0.0047			
Imazalil			0.0007	0.0007				0.0007	0.0007			
Iprodione			0.0007	0.0007				0.0007	0.0007			
Pirimiphosmethyl			0.0003	0.0003				0.0003	0.0003			
Procymidone			0.0158	0.0158				0.0158	0.0158			
Tebuconazole			0.0001	0.0001				0.0001	0.0001			
TOTAL sum	0.2308	0.7161	1.2873	2.2278	1.1228	0.1546	0.0051	3.3506	2.3875			

* Exposure for plastic sandals is excluded in this column

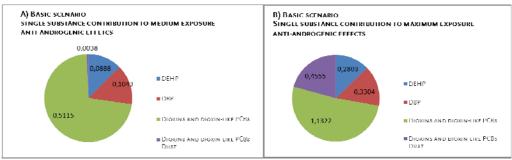


Figure 8-1 ratio of the substance contribution to the RCR values in the basis scenario at A) medium exposure and B) maximum exposure. Only substances with a considerable contribution are included

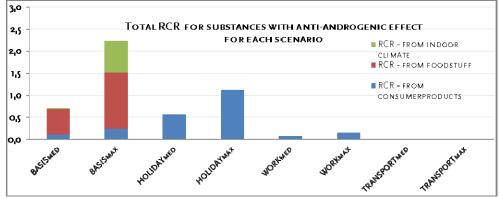
Totally the weight of the antiandrogenics in the basis scenario gives an RCR_{AA} below 1 for medium exposure and above 1 for maximum exposure (Tables 8-4 and 8-5 and figure 8-2). For the holiday scenario an RCR_{AA} of 0.56 is seen for the medium exposure and 1.12 for the maximum exposure, where the contribution

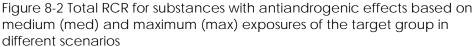
depends on exposure to phthalates from plastic sandals. The same exposure from phthalates from plastic sandals is seen for the work scenario (but without sunscreen so the exposure corresponds to the exposure in the basis scenario) with an RCR_{AA} of 0.08 and 0.15 for medium and maximum exposure respectively. It is seen that the phthalates in the indoor air from cars in total give a very small contribution to the total RCR_{AA} for the target group. Even if the stay in the car is increased considerably during a holiday (e.g. a driving holiday) the contribution will still be minimal. Besides, the contribution from the indoor environment during a holiday will decrease correspondingly because the person does not stay indoor but rather outdoor or in the car.

The exposure from transport is consequently minimal in the total exposure for the target group. Whether or not the same applies for other forms of transportation (train, bus, metro etc.) cannot be accounted for, since these transportation forms have not been examined, but it is expected to be approximately the same level.

Some working groups walk and stand a lot during a considerable part of the day, and it is therefore assumed that they use shock-absorbing footwear, e.g. plastic sandals/clogs. The plastic sandals are therefore included in the work scenario. The phthalates in the plastic sandals give a total RCR_{AA} contribution of 0.08 at medium exposure and 0.15 at maximum exposure in the work scenario.

In connection with holiday, use of plastic sandals for many hours (8-16 hours) may occur, and a higher migration of phthalates will occur because the feet is applied with sunscreen compared to when the feet is without sunscreen on (see Table 7-22). Such an exposure will consequently contribute additionally to the antiandrogenic effects (Tables 8-5 and 8-6), and in total the basis and the holiday scenarios will give an RCR_{AA} of 1.3 at medium exposure, when taken into consideration not to get a double exposure for the plastic sandals in the two scenarios. A risk is therefore seen in the medium exposure when combining the two scenarios will give an RCR_{AA} of 3.4.





8.3.4 Estrogenic substances

Contribution from various sources to the total RCR_E for substances with estrogenic effects based on a basis scenario, holiday scenario, work scenario and transport scenario is shown in Tables 8-6 and 8-7. The values for the various exposures are based on a realistic scenario (medium exposure) and a realistic worst case scenario (maximum exposure) of a pregnant woman.

Table 8-6 In total RCR_E for substances with estrogenic effects are based on a realistic scenario (medium exposure) for the basis scenario, the holiday scenario, the work scenario and the transport scenario as well as basis + holiday and basis + work + transport Red figures indicate an RCR_E value above 0.1, whereas RCR_E values above 1 are indicated in bold red and italic figures. Empty field means that no data have been identified for the substance in question and the source in question.

		Medium exposure									
		RCR _{basis} -							RCRbasis		
	RCR basis-	indoor	RCR _{basis} -	RCR _{basis} -	RCRholida		RCRtranspo	RCR _{basis}	+ work +		
Substance	consumer	environment	foodstuff	total*	У	RCRwork	rt	+ holiday	transport		
Bisphenol A	0.0016	<0.0000	0.0030	0.0046		0.0087		0.0046	0.0133		
Nonylphenol	0.3019	0.0018	0.0133	0.3170				0.3171	0.3171		
TBBPA		0.0039	<0.0000	0.0039				0.0039	0.0039		
	0.00001			0.00001					0.00001		
D4	4		<0.0000	4	0.0523			0.0523	4		
Propylparaben	0.1362		<0.0000	0.1362	0.5550	0.0999		0.6912	0.2361		
Butylparaben	0.1362	<0.0000	<0.0000	0.1362	0.5550	0.0999		0.6912	0.2361		
Isobutylparaben											
*		<0.0000	<0.0000								
OMC	0.0144			0.0144	0.1800			0.1944	0.0144		
Benzophenone											
3	0.0051		<0.0000	0.0051	0.0640			0.0692	0.0051		
Triclosan	0.1468	<0.0000	<0.0000	0.1468				0.1468	0.1468		
Propamocarb			0.0002	0.0002				0.0002	0.0002		
TOTAL sum	0.7422	0.0058	0.0165	0.7644	1.4063	0.2085	0.0000	2.1707	0.9730		

* Cf. section 7.6.2 an exposure for isobutylparaben has not been calculated

Table 8-7 Total RCR_E for substances with estrogenic effects is based on a realistic worst case scenario (maximum exposure) for the basis scenario, the holiday scenario, the work scenario and transport scenario as well as basis + holiday and basis + work + transport. Red figures indicate an RCR_E value above 0.1, whereas RCR_E values above 1 are indicated in bold red and italic figures. Empty field means that no data have been identified for the substance in question and the source in question.

		Maximum exposure									
		RCR _{basis} -							RCRbasis		
	RCR _{basis} -	indoor	RCR _{basis} -	RCR _{basis} -	RCR _{holida}		RCR _{transp}	RCR _{basis}	+ work +		
Substance	consumer	environment	foodstuff	total*	У		ort	+ holiday	transport		
Bisphenol A	0.0016	<0.0000	0.0030	0.0046		0.0087		0.0046	0.0133		
Nonylphenol	0.6038	0.0070	0.0133	0.6241				0.6241	0.6241		
TBBPA	-	0.0547	<0.0000	0.0547				0.0547	0.0547		
	0.00002										
D4	8		<0.0000	0.000028	0.1046			0.1046	0.000028		
Propylparaben	0.9521	<0.0000	<0.0000	0.9522	4.4400	0.3996		5.3922	1.3518		
Butylparaben	0.9521	0.0002	<0.0000	0.9523	4.4400	0.3996		5.3923	1.3519		
Isobutylparaben											
OMC	0.0288		<0.0000	0.0288	0.7200			0.7488	0.0288		
Benzophenone											
3	0.0102		<0.0000	0.0102	0.2561			0.2663	0.0102		
Triclosan	0.4495	<0.0000	<0.0000	0.4495				0.4495	0.4495		
Propamocarb			0.0003	0.0003				0.0003	0.0003		
TOTAL sum	2.9982	0.0621	0.0167	3.0769	9.9607	0.8079	0.0000	13.0376	3.8848		

* Cf. section 7.6.2 an exposure for isobutylparaben has not been calculated

For the estrogenic substances it is seen, that the biggest contribution in the basis scenario comes from consumer products with a total RCR_E of 0.74 and 3.0 respectively for medium and maximum exposure (Table 8-6 and 8-7 as well as figure 8-4). The substances, which are the main contributors to this RCR_E in the basis scenario is propyl- and butylparabens and triclosan from cosmetics (figure 8-3). Food and the indoor environment contribute very little to the estrogenic effects.

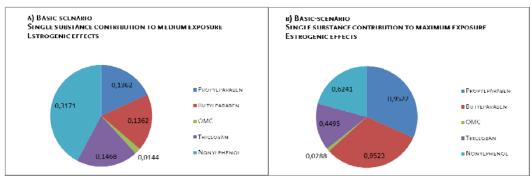


Figure 8-3 ratio of the substance contribution to the RCR values at A) medium exposure and B) maximum exposure. Only substances with a considerable contribution are included

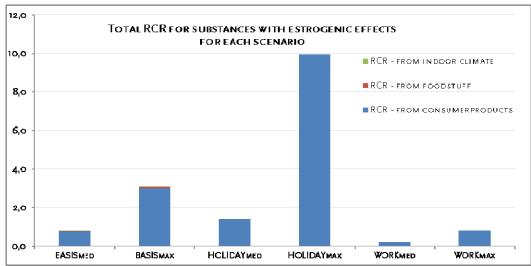


Figure 8-4 Total RCR $_{\text{E}}$ for substances with estrogenic effects based on medium (med) and maximum (max) exposure to the target group in different scenarios

In connection with summer holiday it is estimated, that the target group is exposed to products which may contain suspected endocrine disruptors. For this relatively short period, for most people, calculations have been made as to the level of exposure for the target group.

For the holiday scenario it is the exposure from sunscreens which are the basis for estrogenic effects. The mapping and the analyses showed, that sunscreen may contain the UV-filters OMC and benzophenone-3, parabens and D4. 18% contained the UV-filter OMC and 6% contained benzophenone-3.9% of the mapped sunscreens in this project contained one or more of the parabens included in this project, while 15% of the mapped sunscreens contained D4 in low concentrations (see Section 5.1.2.7). With the products available on the Danish market it is therefore possible to avoid the suspected endocrine disrupting contribution from these substances by buying and using cosmetic products without the selected substances, e.g. Nordic Ecolabelled products.

In order to make as realistic a scenario as possible for the medium exposure in the holiday scenario the basis for the calculation is made on the assumption that the sunscreens only contain 0.1% (as ester) of propyl- and butylparaben respectively as opposed to the allowed 0.4% (and as calculated in the maximum exposure for the holiday scenario).

It is estimated to be a realistic approach because it is under discussion in EU to reduce the allowed maximum concentration of propyl- butyl butylparabens so that the sum of their individual concentrations may be 0.19% (as ester) in cosmetic products just as the industry has expressed that many products do not contain the maximum concentration allowed. Furthermore, the amount of sunscreen used on a daily basis is reduced from 36 grams per day as recommended by the EU Commission to 18 grams per day, which is indicated as a realistic amount by SCCS (SCCS, 2010).

In Table 8-6 and in figure 8-4 it can be seen, that the contribution to RCR_E at the holiday scenario alone is above 1 (is 1.4) for medium exposure. In figure 8-5 it can be seen that the main contributor to the high RCR_E in the holiday scenario are propyl- and butylparaben. In connection with holiday and at continuous exposure to the "normal" sources from the basis scenario (i.e. body lotion, hand cream, facial cream etc. are used), will the use of sunscreen add a considerable exposure even at the realistic medium exposure, where the total $RCR_{basis+holiday}$ is 2.2.

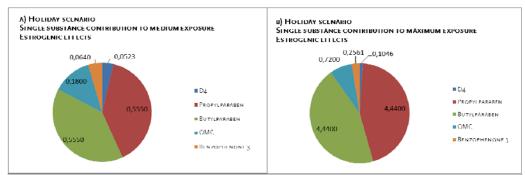


Figure 8-5 Ratio of the substance contribution to the RCR values at A) medium exposure and B) maximum exposure for the holiday scenario

D4 has been found in pregnant belly creams and pregnancy oil, body lotions and sunscreens. Assuming that pregnant women in a realistic scenario use pregnant belly creams once a day for the abdomen/bosom/hips at medium exposure and twice a day at maximum exposure in the basis scenario, it can be seen in Tables 8-6 and 8-7, that it contributes negligibly to the RCR_E both at medium and maximum exposure for use of pregnant belly creams and body lotion. At maximum exposure in the holiday scenario the considerable consumption of sunscreen contributes less. It was observed in the mapping of pregnant belly creams/pregnancy oil that only a few products are on the market and none of the mapped products were found to contain parabens.

The work scenario includes among others health staff in hospitals, who are estimated to wash hands more frequently and therefore estimated to have a higher consumption of hand cream.

Use of extra hand cream ((assumed to be three times extra during a working day) contributes with an extra RCR value of 0.2, if the cream contains propyl- and/or butylparaben at medium exposure and 0.8 at maximum exposure.

Moreover, cashiers may be exposed to bisphenol A via contact with receipts. It can be seen in Tables 8-6 and 8-7, however, that the contribution is negligible.

8.3.5 Thyroid disrupting substances

Contributions from various sources to the total RCR_T for substances with thyroid disrupting effects based on a basis scenario, a holiday scenario, a work scenario and a transport scenario is shown in Tables 8-8 and 8-9. The values of the various exposures are based on a realistic scenario (medium exposure) and a realistic worst case scenario (maximum exposure) for a pregnant woman.

Table 8-8 Total RCR_T for substances with thyroid disrupting effects based on a realistic scenario (medium exposure) for the basis scenario, the holiday scenario, the work scenario and transport scenario as well as basis + holiday and basis + work + transport. Red figures indicate an RCR_T value above 0.1. Empty field means that no data have been identified for the substance in question and the source in question.

		Medium exposure									
		RCR basis-									
		indoor							RCRbasis		
	RCR _{basis} -	environmen	RCR _{basis} -	RCR _{basis} -	RCR _{holid}		RCR _{transp}	RCR _{basis}	+ work +		
Substance	consumer	t	foodstuff	total*	ay	RCRwork	ort	+ holiday	transport		
DEHP	0.0043	0.0011	0.0064	0.0118	0.0643	0.0004	0.0003	0.0757	0.0121		
DnHP		<0.0000	<0.0000	<0.0000				<0.0000	0.0000		
DnOP	0.0001	0.0006	<0.0000	0.0006				0.0006	0.0006		
ТВВРА		0.0009	<0.0000	0.0009				0.0009	0.0009		
Dioxins and dioxin-like PCBs		0.0038	0.1667	0.1705				0.1705	0.1705		
PFOA		0.0000	0.0030	0.0030				0.0030	0.0030		
PFOS		0.0047	0.0133	0.0180				0.0180	0.0180		
OMC	0.0480		<0.0000	0.0240	0.3000			0.3240	0.0240		
Triclosan	0.2446	<0.0000	<0.0000	0.2446				0.2446	0.2446		
Resorcinol	<0.0000		<0.0000	<0.0000				<0.0000	0.0000		
Chlorpyrifos		<0.0000	0.0019	0.0019				0.0019	0.0019		
Dithiocarbamat es			0.0021	0.0021				0.0021	0.0021		
Thiabendazole			0.0005	0.0005				0.0005	0.0005		
TOTAL sum	0.2969	0.0111	0.1939	0.4780	0.3643	0.0004	0.0003	0.8423	0.4787		

Here it is indicated that the largest contribution comes from consumer products with a total RCR of 0.3 and 0.8 respectively for medium and maximum exposure (Tables 8-8 and 8-9). The substance, which is the main contributor to this RCR, is triclosan from cosmetic products (figure 8-6). Food contribute with 0.19 and 0.42 respectively for medium and maximum exposure (mainly from dioxins and dioxin-like PCBs), whereas the indoor environment contributes very little in medium exposure of 0.01 and a higher contribution of 0.22 in the maximum exposure. Contributions from the other scenarios for the thyroid disrupting effects are small. The only contribution higher than 0.1 is the contribution from the UV-filter OMC. OMC has an individual RCR from the holiday scenario of 0.3 at medium exposure but a contribution of 1.2 at maximum exposure and the substance thereby contributes considerably to the risk of thyroid disrupting effects. It is via the use of sunscreen in large amounts (36 grams per day) that the substance OMC in itself reaches an RCR_T above 1.

There is only an insignificant contribution to the RCR_T from work and transport scenarios at both the medium and maximum exposures.

Table 8-9 Total RCR_T for substances with thyroid disrupting effects based on a realistic scenario (maximum exposure) for the basis scenario, the holiday scenario, the work scenario and transport scenario as well as basis + holiday and basis + work + transport. Red figures indicate an RCR_T value above 0.1, whereas RCR_T values above 1 are indicated in bold red and italic figures. Empty field means that no data have been identified for the substance in question and the source in question

		Maximum exposure										
		RCR basis-										
		indoor							RCRbasis			
	RCR _{basis} -	environmen	RCR _{basis} -	RCR _{basis} -	RCR_{holid}		RCR _{transp}	RCR _{basis}	+ work +			
Substance	consumer	t	foodstuff	total*	ay	RCRwork	ort	+ holiday	transport			
DEHP	0.0108	0.0148	0.0117	0.0373	0.1286	0.0009	0.0003	0.1659	0.0376			
DnHP		<0.0000	<0.0000	<0.0000				<0.0000	0.0000			
DnOP	0.0001	0.0057	<0.0000	0.0058				0.0058	0.0058			
TBBPA		0.0122	0.0001	0.0123				0.0123	0.0002			
Dioxins and dioxin-like PCBs		0.1297	0.3450	0.4747				0.4747	0.4747			
PFOA		0.0003	0.0100	0.0103				0.0103	0.0103			
PFOS		0.0417	0.0400	0.0817				0.0817	0.0817			
OMC	0.0480		<0.0000	0.0480	1.2000			1.2480	0.0480			
Triclosan	0.7492	0.0001	<0.0000	0.7492				0.7492	0.7492			
Resorcinol	<0.0000		<0.0000	<0.0000				<0.0000	0.0000			
Chlorpyrifos		0.0125	0.0039	0.0164				0.0164	0.0164			
Dithiocarbamat es			0.0042	0.0042				0.0042	0.0042			
Thiabendazole			0.0014	0.0014				0.0014	0.0014			
TOTAL sum	0.8081	0.2168	0.4163	1.4410	1.3286	0.0009	0.0003	2.7696	1.4422			

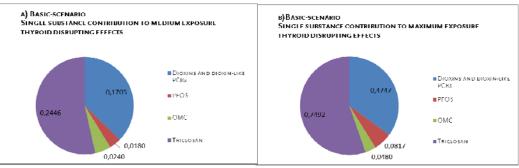


Figure 8-6 Ratio of the single substance contribution to the RCR for thyroid disrupting effects at A) medium exposure and B) maximum exposure. Only substances with a considerable contribution are included

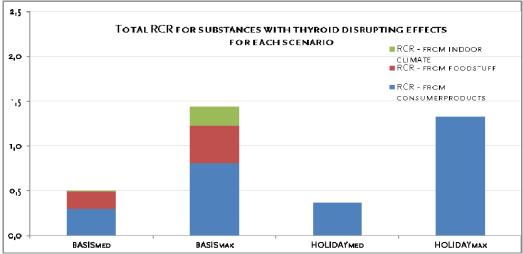


Figure 8-7 Total RCR for thyroid disrupting effects based on medium (med) and maximum (max) exposure of the target group in basis and holiday scenarios

8.3.6 Biomonitoring data

In the biomonitoring study 12 of the chemical substances included in this project were measured in urine samples from Danish pregnant women. The samples were collected in the period between 1 February and 7 June 2011. Phthalates (DEHP, DINP, DBP, DIBP, BBP, DPP and DnOP) and parabens (propyl- butyl- and isobutylparaben) were measured in the urine samples from 200 pregnant women, whereas bisphenol A, triclosan, benzophenone-3 and nonylphenol were measured in urine samples from 50 pregnant women. All these substances are relatively quickly metabolised and excreted from the body. The amount excreted during 24 hours is therefore a reasonable estimation of the daily exposure. The urine samples were taken as spot urine samples in week 28 of the pregnancy. Spot urine samples are urine samples taken some time during the day as opposed to 24 hour urine samples collecting all urine over 24 hours or morning urine samples taken at the first flow of urine in the morning.

Spot urine samples give a picture of the concentration in the urine at the given time. In order to estimate a daily intake from this concentration it is necessary to extrapolate, either in terms of volume or in terms of creatinine. In this project creatinine is used, because this method – as opposed to the extrapolation in terms of volume – takes the differences of volume into account, which may occur because the individuals consume different amounts of fluid.

calculated RCR values in the project. Red figures indicate an RCR value above 0.1										
			Medium exp	osure	Maximum exposure					
Sudstance	DNEL	Estimated exposure from biomonito- ring	Sum (products, indoor environme nt, food) BASIS	RCR Biomo	RCRBASIS	Estimated exposure from biomonito- ring	Sum (products, indoor environme nt, food) BASIS	RCR _{Bio}	RCR _{BASI} s	
	(µg/kg bw/day)	(µg/kg bw/day)	(µg/kg bw/day)			(µg/kg bw/day)	(µg/kg bw/day)			
DEHP (AA)	25.00	0.2294	2.2201	0.0092	0.0888	2.64	7.0077	0.1055	0.2803	
DEHP (T)	188.00	0.2294	2.2201	0.0012	0.0118	2.64	7.0077	0.0140	0.0373	
Dinp (AA)	1500.00	0.0921	0.4671	0.0001	0.0003	22.93	2.2042	0.0153	0.0015	
DBP (AA)	10.00	0.2085	1.0429	0.0209	0.1043	1.86	3.3044	0.1860	0.3304	
Dibp (AA)	1250.00	0.5295	3.6386	0.0004	0.0029	4.11	10.3528	0.0033	0.0083	
BBP (AA)	500.00	0.0356	0.2154	0.0001	0.0004	3.45	0.6480	0.0069	0.0013	
DPP (AA)	330.00	0	0.0000	0	0.0000	0.051	0.0000	0.0002	0.0000	
DnOP (T)	368.00	0.0324	0.2319	0.0001	0.0006	2.925	2.1387	0.0079	0.0058	
Bisphenol A (E)	500.00	0.0140	2.2987	0	0.0046	0.0791	2.3031	0.0002	0.0046	
Nonylphenol (E)	15.00	0	4.7558	0	0.3171	0	9.3620	0	0.6241	
Propylparabe n (E)	20.00	0.0704	2.7244	0.0035	0.1362	5.19	19.0435	0.2595	0.9522	
Butylparaben (E)	20.00	0	2.7244	0	0.1362	0.941	19.0435	0.0470	0.9522	
lsobutylparab en (E)	625.00	0	0.0000	0	0.0000	0	0.0000	0	0.0000	
Benzophenon e 3 (E)	9370.00	0.0645	48.0000	0	0.0051	94.25	96.0000	0.0100	0.0102	
Triclosan (E)	50.00	0.0095	7.3377	0.0003	0.1468	17.24	22.4765	0.4924	0.4495	
Triclosan (T)	30.00	0.0095	7.3377	0.0005	0.2446	17.24	22.4765	0.5747	0.7492	

Table 8-10 Data for internal doses measured in a biomonitoring study in DK for a selection of the substances included in the project. RCR values are compared between biomonitoring data and the calculated RCR values in the project. Red figures indicate an RCR value above 0.1

Creatinine is a metabolite from creatinine phosphate, which is found in skeletal muscle. Creatinine in plasma is proportional with the muscle mass, i.e. it is typically higher with for instance young men than with women. Within the same population group with roughly the same body weight (here pregnant women) the creatinine levels generally varies very little. Creatinine is secreted by glomerular filtration in the kidneys, and a constant secretion rate is normally assumed.

Creatinine was measured in all urine samples and the average concentration of each single substance was indicated as quantity of substance per gram of creatinine. From the literature an average measurement for the daily secretion of creatinine by pregnant women was chosen (0,015 g/kg/d), which was used to estimate the daily secretion (and thereby the daily intake) of each single substance. The following formula was used for the calculations:

Estimated intake $(\mu g/kg/d) =$ urine concentration $(\mu g \text{ substance/g creatinine}) * 24$ hour creatinine (g creatinine/kg/d)

The urine samples were also tested for nonylphenol and isobutylparaben but all measurements were below the detection limit.

PFOA and PFOS were measured in blood samples from 199 pregnant women in the same cohort. Since these substances are only metabolised and excreted very slowly in the body, it has not been possible to convert the observed levels to estimates for daily intake.

The concentrations of DiHP, dioxins and dioxin-like PCBs, TBBPA, D4, OMC and resorcinol were not examined in the biomonitoring study.

Table 8-10 provides a summary of the estimates of daily exposure for the included substances based on the biomonitoring study as well as the RCR values calculated from this. Just as the RCR values for the estimated exposure, the RCR values from the biomonitoring study have been calculated by dividing exposure for a given substance with its DNEL value.

The estimated exposures and the RCR values are shown both as the medians and the maximum values. Use of the maximum values rather than e.g. 95 percentiles is chosen because this is a relatively small study, where it can be interpreted that each single woman represent a certain percentage of the population. For the substances only analysed in 50 women, the woman with the highest exposure level thereby represents the 2% women with highest exposure in the population.

A high maximum value will therefore be realistic for a number of women just as even higher maximum values might be expected if more women had participated in the study.

Chemicals in spot urine samples from pregnant women have also been measured in other countries, but comparison is complicated by the fact that some of the studies are older than the Danish one. It is particularly relevant to compare with European studies as American consumption patterns and exposure levels in general differ significantly from the European. The differences observed between the studies, may therefore both be explained by different consumption patterns between the countries and also by the fact that the exposure has been reduced during the years because of regulatory measures and/or public attention to the various substances. Furthermore, many of the studies are small (including the Danish one, in particular for the substances where only 50 samples are included), which makes the uncertainty of the results very high and complicates the comparisons further.

For the phthalates the measured levels in Denmark are in general lower than in e.g. Norwegian (samples from 2004) and Dutch (samples from 2002-2006) studies, except for MCPP (metabolite of DnOP), which are higher in the Danish study (Ye X 2008; Ye X 2009). A Spanish study (samples from 2004-2008) also finds higher levels of phthalates in general, except for MiBP (metabolite of DiBP) and MCPP (metabolite of DnOP) (Casas 2011).

For bisphenol A the measured levels in Denmark are at the same level as in a Dutch study (samples from 2004-2006), a little lower than in a Spanish study (samples from 2004-2008) and much lower than in a Norwegian study (samples from 2004)(Ye X 2008; Ye X 2009; Casas 2011).

For triclosan the measured levels in Denmark are lower than in a Spanish study (samples from 2005-2008) (Casas 2011).

For parabens there is no knowledge of other European investigating exposure of pregnant women.

For BP-3 the measured levels correspond to a Spanish study (samples from 2005-2008) (Casas 2011).

For PFOS and PFOA, which were measured in blood samples from the pregnant women, the levels from this study are lower than in previous Danish studies with samples taken in 1992-2002 (Fei C 2009; Vestergaard S 2011). A Norwegian study (samples from 2007-2008) found lower levels of PFOS and PFOA, whereas a Swedish study (samples from 2004) found higher levels (Karrman A 2007; Gutzkow KB 2011).

8.4 Discussion

In the project, the exposure is assessed based on the assumptions that during the day the target group will stay indoor for a number of hours and thereby potentially be exposed to the selected substances via the indoor environment, will consume an amount of food, which may potentially contain the selected substances and will handle a number of consumer products every day, which may potentially release some of the selected substances.

All these sources combined form a so-called basis scenario. The consumer products included in the basis scenario cover available data relevant to the target group. That e.g. sex toys are included in a basis scenario with a weekly use may for some women be an overestimation, whereas others probably will find it an underestimation, just as the use of cosmetics of course varies from woman to woman. The reason for assessing the estimated exposure in this way is that unfortunately not all exposure sources are known, just as the migration from all products known to contain some of the selected substances have not been examined. By this approach some of the sources to the various substances have been identified and assessed while others are still unknown.

Even if the whole target group perhaps do not use all the products included in the basis scenario it is assumed that they will use something else which potentially also may contain endocrine disruptors. In this way the exposure assessment gives the best idea of a typical exposure based on the available data.

For antiandrogenic, estrogenic and thyroid disruptors a total RCR below 1 at medium exposure in the basis scenario (0.48 - 0.76) is found. At maximum exposure an RCR above 1 for all three modes of action is found (1.43 - 3.08). For both medium and maximum exposures the RCR_E is the highest. For the holiday scenario an RCR_E between 0.36 and 1.41 is found at medium exposure. The value above 1 is only found for estrogenic effects and can be attributed to exposure to propyl- and butylparaben as well as the UV-filter OMC from sunscreen. At the maximum exposure for all modes of action an RCR above 1 (1.12 – 9.96) is found in the holiday scenario.

By combining the basis scenario and the holiday scenario and at the same time remove the plastic sandals from the basis scenario, RCR values above 1 are found for both antiandrogenic and estrogenic modes of action (1.20 - 2.18) for the medium exposure. By combining the basis scenario, the work scenario and the transport scenario, where the plastic sandals are removed from the basis scenario, RCR values below 1 for all three modes of action (0.48 - 0.97) are found for the medium exposure. For the maximum exposure RCR values above 1 are found for all three effects. The transport scenario, however, gives a negligible contribution to RCR.

The exposure assessments indicate that there can be an increased risk of endocrine disrupting effect for women who are exposed to several of the substances that contribute to the highest individual RCR at the same time. It appears that conducting cumulative risk assessment rather than risk assessment of each single substance is of major importance. It is clearly the total contributions from the various substance groups which lead to RCR values above 1, whereas the single substances alone all have RCR below 1 at medium exposure in the basis scenario and only dioxins and dioxin-like PCBs have an RCR above 1 at maximum exposure in the basic exposure.

The biggest contributions to the total RCR in the basis scenario are from dioxins and dioxin-like PCBs (food, dust), propyl- and butylparabens (cream), triclosan (deodorant and toothpaste) and phthalates (dust). The intake of dioxin-like PCBs from food cannot be changed notably by the individual. The possibilities to limit the risk of endocrine disrupting effects will mainly be to change the use of personal care products (avoid propyl- and butylparabens and triclosan in lotion and deodorant) and by limiting the impact from chemicals from the indoor environment, e.g. by frequent airing out and vacuuming (PCBs and phthalates in dust). Frequent vacuuming and airing out have in connection with PCB tests in indoor air turned out to be quite effective in terms of reducing the exposure (National Board of Health, 2012).

8.4.1 Discussion on contributions to RCR from the single substances/substance groups

In the following, the substances and substance groups are discussed one by one with respect to the risk characterisation ratios (RCRs) identified in this project.

8.4.1.1 Phthalates

For the phthalates the calculated RCR_{AA} values are all below 1 for the individual substances in the basis scenario both at medium and maximum exposure. The total RCR_{AA} for the group of phthalates is 0.20 at the medium exposure and 0.62 at the maximum exposure. Phthalates constitutes in both cases a considerable contribution to the total RCR for antiandrogenic substances. It must be noted that these calculations only include a limited selection of products containing phthalates as only data from products for which migration analyses have been conducted are included (plastic sandals, sex toys, slip mats, Pilates balls etc.) In this project the main source of exposure of phthalates from consumer products is found to be plastic sandals. It is estimated that this source is relevant in the summer period where a daily use of 8-16 hours is not unrealistic (both in connection with holiday and daily life). The exposure in the summer period may either be an exposure as estimated in the basis scenario or an exposure as estimated in the holiday scenario. In the holiday scenario an RCR_{AA} for the phthalates of 0.56 and 1.12 is found at medium and maximum exposure when using plastic sandals and sunscreen on the feet at the same time. Exposure to phthalates from plastic sandals will, combined with use of sunscreen on the feet at the same time, increase the migration of some phthalates from the sandals and thereby increase the contribution to RCR. For DEHP migration was observed to be 149 times higher when using sunscreen at the same time (Danish EPA 2010). Consequently a considerable contribution from antiandrogenic phthalates is seen in the holiday scenario (Tables 8-3 and 8-4). Holiday is normally for a limited period, but it may be a critical period for the development of the fetus. For the two phthalates, which contribute the most to the RCR, robust data exist for the endocrine disrupting effect.

In this project cell phone covers, work gloves, sleeping mats, sneakers and handbags of leatherette have been tested to assess the content of the 8 phthalates included in the project. Quantitatively phthalates have been found (only DEHP, DiNP and DIDP) in few products, whereas the migration tests did not find migration of phthalates from the products. (See section 5).

Apart from the included contributions there may be additional exposure from contact with other materials containing phthalates. In addition exposure from other phthalates with endocrine disrupting effect may occur.

DiNP contributes minimally to the total RCR_{AA} even though this phthalate is used more and more as a substitution for e.g. DEHP. The low contribution is partly due to the fact that DiNP has not been identified in analyses of food and dust, and that no contribution from DiNP in consumer products is included. In reality the amount of DiNP in food, dust and consumer products is expected to increase due to the phasing out of the phthalates which are classified as toxic to reproduction. DiNP, however, has a very high DNEL for antiandrogenic effect (60 times higher than DNEL for DEHP), which is why it takes a considerable increase in human exposure before a considerable increase of RCR for an antiandrogenic effect can be expected. Consequently it is of no immediate importance if the exposure for DiNP is under-estimated in this project.

8.4.1.2 Dioxins and dioxin-like PCBs

Dioxins and dioxin-like PCBs constitute a considerable part of the total RCR. The exposure comes mainly from food, but the indoor environment also contributes, particularly via dust in the realistic worst case scenario. The exposure via food is based on measurements in Danish food, where a decreasing content of dioxins and dioxin-like PCBs is measured over time. Part of the contribution to exposure of dioxins and dioxin-like PCBs in food come from fatty fish such as salmon from contaminated areas, which is why the Danish Veterinary and Food Administration (Danish Ministry of Food) recommends that women in the childbearing age, pregnant women as well as breast feeding women do not eat more than one portion of salmon from the Baltic Sea (approx. 125 g) once per month (Altomkost.dk). Other salmon is often breeded in Norway and is not contaminated with dioxin.

Exposure to this group of substances via indoor environment highly depends on whether a person lives or works in a PCB contaminated building. The value used in the realistic scenario for dust origins from a Danish study and is the median for PCB values in dust from 10 buildings, selected on the basis of their date of construction and type of sealants. Hereby a selection has taken place which probably makes the values higher than what most Danes are exposed to. The value in the realistic worst case scenario is the highest measured value in a Danish school. This value corresponds to maximum values from other studies but probably reflects what a minor part of the population may be exposed to.

The exposure via indoor environment to dust is based on an intake of dust of 50 mg/day for adults which is used in several studies (Oomen et al., 2008). But in literature, much lower daily intakes of dust for adults are found, e.g. between 7 mg/day (average) and 20 mg/day (95% percentile) in D'Hollander et al. (2010), which of course will have a major impact on the RCR value for dust for PCBs if the real value for intake of dust is much lower. An intake reduced by half means that the RCR value is reduced by half. Furthermore, PCBs on dust particles are probably less bio available than PCBs in indoor air and food. The above mentioned factors may imply that the calculated RCR is over-estimated, i.e. the risk applies only for a minor part of the population. However, some assumptions used for the calculations pull in the opposite direction, i.e. towards an under-estimation of the risk, as described in the following. The estimated exposure of PCB from dust is somewhat uncertain since there is no information about the amounts of the specific dioxin-like PCB congeners in the relevant literature. As indicated in the section about risk assessment the used DNELs for dioxins and dioxin-like PCBs in dust are different than for dioxins and dioxin-like PCBs in air and food. Furthermore, the work is based on the assumption that the composition of dust is somewhat similar to the original pollution sources, i.e. the commercial mixtures of PCBs (Aroclor mixtures). It is, however, important to note that toxic effects to reproduction from Aroclor mixtures are particularly attributed the dioxin-line PCBs. It has been chosen to use data for PCB n or PCB 7 as representatives for PCB data in dust. These PCB mixtures mainly consist of non-dioxin-like PCBs, but also dioxin-like PCBs. Particularly where data for PCB 7 content in dust and not total PCB (PCB n) is used there may be an under-estimation of the total PCB exposure and thereby of the RCR. Some choose to adjust PCB 7 in the risk assessment to an assumed total

PCB level by multiplying by 5, which may result in an over-estimation of the RCR. This potential under-estimation is, however, less important compared to the extensive variation in maximum PCB concentrations in dust in the mentioned studies.

A DNEL_{thyr} for dioxin-like PCBs in dust has not been calculated, as it was not possible at present to determine a NOAEL for thyroid disrupting effects of Aroclor mixtures. Consequently the contribution to RCR_T from dioxin-like PCBs in dust will not be included in the total risk assessment of thyroid disruptors which may lead to an under-estimation of the total RCR_T .

An under-estimation of the RCR may also occur as thes calculations only include dioxin-like PCBs in food and indoor environment and not the non-dioxin-like PCBs. Extensive knowledge exists, that also the non-dioxin-like PCBs may have endocrine disrupting effects, and it seems to be especially the thyroid disrupting effects which are observed with laboratory animals exposed to non-dioxin-like PCBs. At present a total TDI for the non-dioxin-like PCBs is not determined in the same way as for the dioxin-like PCBs. But literature gives various suggestions for how to determine toxic equivalence factors (TEFs) for the non-dioxin-like PCBs as it has been done for the dioxin-like PCBs (Simon et al., 2007; Yang et al., 2010). Such calculation methods will be usable for a refinement of the risk assessment for PCBs including the non-dioxin-like ones.

The contribution from non-dioxin-like PCBs in dust, indoor air and food as well as contribution from dioxin-like PCBs in dust will thus contribute further to the total RCR_T. All in all, this means that RCR_T may be under-estimated.

8.4.1.3 Bisphenol A

The contribution from bisphenol A to the total RCR for estrogenic effect is negligible when the high DNEL of 500 ug/kg bw/day is used. If a lower DNEL of 0.25 μ g/kg bw/day is used, which takes low dose effects of the substance into account, (alternative DNEL described in the hazard assessment, section 6), the total RCR_E will be 9.2, which lead to a concern for endocrine disrupting effects at bisphenol A exposure, mainly from food.

Bisphenol A is found in a variety of food contact materials, e.g. packaging, which is why it will be difficult for the consumer to avoid exposure to bisphenol A.

In this project, the content of bisphenol A in cell phone covers, work gloves, sleeping mats, sneakers and handbags made of leatherette was tested. The substance was only found in small amounts in a few products and analyses could not detect a migration (see Section 5). In previous surveys of chemicals in consumer products from the Danish EPA, bisphenol A has been found in various products of which most have not been found relevant for the target group in this project (e.g. baby dummies and baby bottles). Exposure from cash register receipts, which may contain bisphenol A, both for the normal consumer during shopping, and the cashier who is in contact with cash register receipts during the whole working day, also turned out to be negligible based on the high DNEL value. If the risk assessment is made with a DNEL bases on low dose effects, the exposure from cash register receipts will, however, be expected to represent a risk. In this project it cannot be determined, whether exposure to bisphenol A in food or products may cause endocrine disrupting effects in humans.

8.4.1.4 Nonylphenol

In this project, exposure to nonylphenol from food, indoor environment (dust) and consumer products in the form of clothes is examined. However, there are only few

available data. The calculated RCR_E is 0.32 and 0.62 at medium and maximum exposures in the basis scenario assuming that the pregnant woman will wear new unwashed clothes (only jeans) one time during two weeks at medium exposure and one time during one week at maximum exposure. Based on these assumptions nonylphenol contributes to the total RCR_E for estrogenic substances.

In this project nonylphenol was analysed in the product groups antibacterial clothes and sneakers. The substance was not found in any of the selected products in the two product groups. (See Section 5.1.2).

In a previous survey of chemicals in consumer products from the Danish EPA nonylphenol and nonylphenolethoxylates have been found in clothes (Danish EPA, 2012). The calculations in that report, however, are based on a small data set as only a limited number of samples of clothes were included in the test (migration tests on two pairs of jeans were made). The assessment of nonylphenol's contribution to RCR_E in this project is based on the assumption that nonylphenolethoxylates are absorbed via the skin at the same rate as nonylphenol and then converted to nonylphenol in the body. Thus the used migration data are for nonylphenolethoxylate. In the NP/NPE report from the Danish EPA the migration of nonvlphenol from clothes is found to be insignificant, but with the above assumption on the relationship between nonylphenol and nonylphenolethoxylates the exposure to nonylphenol becomes much more substantial (Danish EPA 2012). A test from Greenpeace shows that nonylphenolethoxylates occur in many products, as they found that 52 of 78 pieces of clothes from all over the world contained residues of nonylphenolethoxylates (Greenpeace International 2011). The relevance for human risk is not clarified in the report from Greenpeace. A Danish study has furthermore shown that a large part of nonylphenolethoxylates (17-49%) are washed out of the clothes during washing. (Danish EPA 2012).

8.4.1.5 TBBPA

Exposure to the brominated flame retardant TBBPA via the indoor environment contributes to RCR_E with 0.004 at medium exposure and 0.05 at maximum exposure in the basis scenario, which in itself does not lead to a concern, but which does contribute to the endocrine disrupting effect combined with other estrogenic substances. TBBPA contributes to RCR_T with 0.0001 at medium exposure and 0.0002 at maximum exposure in the basis scenario which does not lead to a concern but still contributes to the endocrine disrupting effect in combination with other thyroid disruptors. TBBPA is measured in air and come from electronic equipment and plastic in homes and workplaces.

It should be noted, that only TBBP is included in this assessment, whereas humans may be exposed to other brominated flame retardants with possible endocrine disrupting effects, e.g. PBDEs (polybrominated diphenylethers).

8.4.1.6 PFOA/PFOS

The exposure to PFOA adds only negligible to the total $RCR_{AA/T}$ values. The exposure to PFOS has insignificant importance to the total RCR_{AA} values for antiandrogenic effects, whereas PFOS contribute with an RCR_T of 0.08 for thyroid disrupting effects at maximum exposure in the basis scenario. This contribution to RCR_T reflects that a considerable exposure to PFOS is estimated via dust and food in spite of the fact that the substance is no longer used in products. Data from PFOS in dust are from the UK and obtained in 2007-2009. Since then the use of PFOS has been reduced, why the values today may be lower. The exposure from food is also expected to be decreasing.

PFOS and PFOA are accumulated in the body so an exposure will contribute to the amount accumulated in the body. In the calculation of DNEL, accumulation has been taken into account by use of an additional uncertainty factor.

In recent years a change from use of PFOS to other perfluoric and polyfluoric substances has occurred and some of these substances may also have endocrine disrupting effect. These substances are, however, not included in this project.

8.4.1.7 Octamethylcyclotetrasiloxane (D4)

In this project cell phone covers, work gloves, antibacterial clothes, body lotion/cream, pregnant belly creams and sunscreens were tested for D4. The substance was only found in small amounts in several of the cosmetic products (see Section 5). In previous surveys of chemicals in concumer products from the Danish EPA D4 has not been examined, why in this project only very few sources are included. The substance may occur in various hair products, and in detergents. At present, however, there is no available information on how widespread the use of the substance is and from which sources the population may be exposed.

D4 contributes insignificantly to the total RCR_E in the basis scenario for estrogenic effect, as only data for very small concentrations of D4 are found in body lotions and pregnant belly creams.

The contribution from use of pregnant belly creams/pregnancy oils is not included in the basis scenario but calculated separately. Even by use of pregnant belly creams twice per day (realistic worst case scenario) in the amounts and with the concentrations of D4 assumed in this project the use gives an insignificant contribution to RCR_E .

In sunscreen, however, higher concentrations of D4 have been found, which lead to a higher exposure in the holiday scenario and an RCR of 0.05 and 0.10 at medium exposure and maximum exposure respectively from use of sunscreen. In the holiday scenario, D4 therefore contributes a little to the total RCR_E but the contribution is however still negligible compared to the high RCR_E values for e.g. propyl- og butylparabens, UV-filters such as OMC and benzophenone 3 and triclosan.

8.4.1.8 Propyl- butyl- and isobutylparaben

At maximum exposure (realistic worst case) butyl- and propylparaben each contribute with high RCR_E values in both the basis scenario (0.95) and in the holiday scenario (4.44) (see Table 8-11).

At medium exposure in the basis scenario, the two parabens each contributes with an RCR_E of 0.14 whereas in the holiday scenario a contribution of 0.56 is found. These contributions to the total RCR_E are also considerable.

At medium exposure in both the basis and the holiday scenarios the concentration of propyl- and butylparaben respectively in the single products is assumed to be 0.1% (as ester), whereas at maximum exposure in both the basis and the holiday scenarios the current maximum concentration allowed of 0.4% is assumed for propyl- and butylparaben respectively.

	RCRBASIS-	RCRHOLID	RCRBASIS	RCRBASIS-	RCRHOLI	RCR _{BASIS+HOLI}
	MEDIUM	AY-MEDIUM	+HOLIDAY;	MAXIMUM	DAY-	DAY; MAXIMUM
			MEDIUM		MAXIMUM	
Propylparab en	0.1362	0.5550	0.6912	0.9522	4.4400	5.3922
Butylparabe n	0.1362	0.5550	0.6912	0.9523	4.4400	5.3923
Sum	0.2724	1.1100	1.3824	1.9045	8.8800	10.7846

Table 8-11 Calculated RCRE for propyl- and butylparaben for basis and

holiday scenarios respectively (medium and maximum exposure)

This approach to the calculation is used, since in the EU it has been suggested to reduce the maximum concentration allowed for propyl- and butylparaben (currently 0.4% for each paraben, 0.8% in total) to 0.1% (as ester) for each paraben and 0.19% in total. Even when assuming a concentration of propyl- and butylparaben in cosmetic products of only 0.1%, the RCR_E values from the parabens still contribute to the combined RCR with a total of 0.27. By use of sunscreen in the recommended amounts at medium exposure an RCR_E above 1 is found for the two parabens (1.11). Assuming that the target group uses the amount of cosmetic products included in the basis scenario and sunscreen at the same time, a total RCR_F of 1.38 at medium exposure and 10.78 at maximum exposure is found for the two parabens propyl- and butylparaben together. The high RCR_E for the combined exposure from the basis and holiday scenarios, requires that a number of different cosmetic products are used (primarily body lotion, facial cream and sunscreen which contribute with the highest exposures) that they are used in the amount described in Table 7-22, and that they all contain propyl- and/or butylparaben.

As doubts are raised about the effects in the low end of the dose response curve, a calculation of RCR_E at a non-conservative DNEL of 330 µg/kg bw/day has also been conducted based on a study of animals exposed in fetal life (Kang et al., 2002). This is a factor 16.5 higher than the determined DNEL for effects in the low end of the dose response curve. With the non-conservative DNEL and the maximum exposure values from the combined basis and holiday scenario, propyland butylparaben still contribute to the RCR_Ewith 0.65 for propyl- and butylparaben (assuming a total concentration of 0.8% parabens). This RCR_E is below 1 but still represent a considerable contribution to a total RCR_E. If the same calculation is conducted for the basis scenario at medium exposure, RCR_E will be 0.015 and thereby of much more limited significance. In other words, even if possible effects at lower doses than used in the study of Kang et al. are not taken into account, propyl- and butylparaben will contribute significantly to a total risk of endocrine disrupting effect in the realistic worst case scenario, but not in the realistic scenario.

The exposure from creams (body lotion, facial cream, hand cream, sunscreen) and deodorant contributes the most to RCR_E which is why the best possibility for risk-reduction will be to avoid use of especially moisturizers and sunscreens containing propyl- and butylparabens, since they contribute with the highest exposure due to the large contact surface. To avoid "rinse-off" products such as shampoo and soap containing propyl- and butylparabens will be less important for risk-reduction.

No calculation is conducted for worst case daily exposure to isobutylparaben, since a maximum exposure to propyl- and butylparabens has been assumed up to the maximum concentration allowed. If the maximum exposure to parabens was replaced by isobutylparaben instead of the two other parabens, the RCR_E value would be lower (approximately 30 times) due to the higher DNEL value for

isobutylparaben compared to butyl- and propylparaben. RCR_E value for isobutylparaben would therefore be 0.18 in the basis scenario (at maximum exposure) + use of sunscreen, if all parabens in the products were isobutylparaben. Isobutylparaben would consequently also contribute to a total risk of endocrine disrupting effects to women using creams containing high concentrations of this paraben, but still to a considerably lower degree than propyl- and butylparaben.

Finally it should be noted that the calculations are conducted assuming a dermal absorption of 3.7%. It is the official value used for normal skin, but it is still much debated (Harville et al., 2007). SCCS used this as a conservative value (SCCS 2010). The absorption may be higher if the product is applied to damaged skin.

8.4.1.9 The UV-filters OMC and BP3

The UV-filter OMC contributes with RCR_E of 0.014 and 0.03 at medium and maximum exposures respectively in the basis scenario for estrogenic effect. OMC contributes with an RCR_T of 0.02 and 0.05 respectively at medium and maximum exposures respectively for thyroid disrupting effect. Thereby OMC only contributes a little to the total RCR_E .

In the holiday scenario, however, OMC contributes considerably with 0.3 and 1.2 the total RCR_E and total RCR_T respectively at maximum exposure.

Exposure to BP-3 contributes less to RCR_E , as BP-3 contributes with RCR_E values of 0.005 and 0.01 at medium and maximum exposures respectively in the basis scenario for estrogenic effect. RCR_E for BP-3 is lower than RCR_E for OMC in spite of the fact that higher exposure to BP-3 is estimated. This is due to the fact that DNEL for BP-3 is much higher, and in terms of possible endocrine disrupting effects, BP-3 will thereby be preferred as UV-filter rather than OMC. It has to be noted though, that no studies investigating thyroid disrupting effects of BP-3 were located.

8.4.1.10 Triclosan

The calculated RCR_E is 0.15 and 0.45 at medium and maximum exposure respectively in the basis scenario. RCR_T is 0.4 and 0.75 at medium and maximum exposure respectively in the basis scenario. Triclosan contributes thereby considerably to the total RCR_{E/T} for both estrogenic thyroid disrupting effects.

Data concerning the estrogenic effect from animal studies is considered to be less robust, whereas data concerning the thyroid disrupting effect observed in laboratory animals are considered to be robust. It should be mentioned here, that the human relevance of thyroid disrupting effects observed in rat studies in general is not clarified (see Section 6.2). However, since it has been established, that the nervous system in both the human and the rat may be damaged from reduced T4 levels in fetal life, it is important to include results showing reduced T4 levels in the risk assessment of thyroid disruptors (Crofton et al., 2005; Zoeller et al., 2007). Because even if rats due to their thyroid physiology are perhaps more sensitive than humans to substances that reduce the T4 levels, then several studies show, that even moderate T4 reductions during pregnancy in humans may lead to inhibited brain development, reduced intelligence and delayed motor skill development in the children. (Haddow et al., 1999; Pop et al., 1999; Li et al., 2010). A careful approach to this problem will therefore be to seeks to take into account thyroid disrupting effects in the risk assessment.

The amounts and concentrations of triclosan used in the calculations cannot be considered to be unrealistically high, and the used dermal absorption fraction is similar to the one used by SCCS (SCCS 2010). Therefore the calculations are considered to be trustworthy and the use of triclosan in products such as toothpaste

and deodorant is considered to contribute to the total risk of endocrine disrupting effects. SCCS finds in their assessment from 2008, that exposure to triclosan from e.g. toothpaste and deodorant is considered to be safe, whereas exposure from other sources including mouth rinsing product and body lotion is not considered to be safe (SCCS 2010). SCCS, however, does not include endocrine disrupting effects in their assessment, which is further discussed below. It is described by SCCS, that the margin of safety (NOAEL divided by exposure) is at 200-400, which generally is interpreted as safe for a single substance, as a margin of safety above 100 is normally accepted in assessment of single substances. A margin of safety calculation for single substances, however, does not take combination effects of exposure to several different substances with the same effects from several different sources at the same time into account.

It can be noted that the DNEL used here is based on lower NOAELs (5 and 3 mg/kg bw/day respectively for estrogenic and thyroid disrupting effect), than the NOAEL, used by SCCS (12 mg/kg bw/day). The difference between these NOAELs is due to the fact that in this report more recent studies have been used (from 2009), in which particularly endocrine sensitive parameters have been investigated, and that these studies were not available for SCCS' opinion from 2008. SCCS furthermore choose to ignore the thyroid disrupting effects shown in animal studies due to the uncertainty connected to human relevance of these effects. But there is only a factor 2-4 between the NOAELs used here and in SCCS' opinion.

Triclosan was not found in the products analysed in this project (8 products within the category "antibacterially treated clothes", as well as 9 different sneakers) (see Section 5). As described in section 3.5 about antibacterial clothes, the Swedish Chemicals Inspectorate has published a report on antibacterial agents in clothes (KemI 2011) after initiation of the analyses in this project. This Swedish report shows that triclosan is not widespread. Triclosan has been identified in two out of 30 pieces of sportswear. The concentration found in the Swedish project is lower than the detection limit in the analysis conducted in this project. Therefore it is possible that lower values of triclosan may occur, which cannot be identified with the chosen method of analysis. If a risk assessment is based on levels at the detection limit and it is assumed that all the triclosan migrates from the clothes that are worn, the RCR value for clothes will be maximally 0.002, which is a minimal contribution to the total RCR.

Investigations of triclosan in cosmetic products on the Danish market indicate that only one toothpaste contains triclosan, whereas it is mainly deodorants in the expensive price range that contain triclosan (Danish EPA 2006). It is therefore considered to be possible for the individual consumer to avoid this exposure by buying cosmetic products without the substance, such as cosmetic products.with the Nordic eco-label

The exposure from food and from other products than toothpaste and deodorants is not completely investigated in this project and may lead to further contributions to the assessed risk.

8.4.1.11 Resorcinol

In this project use of resorcinol in hair dye is assumed to occur one time in a week, but the contribution to the total RCR_T is so small that even at daily use, resorcinol will not contribute considerably to the total RCR_T . Data for endocrine disrupting effects are furthermore subject to some uncertainty. It is considered that there is no immediate cause for concern in terms of endocrine disrupting effects in connection with exposure to resorcinol in hair dye. However, it is noted that resorcinol is an allergenic substance.

8.4.1.12 Pesticides

Only a very insignificant contribution to the total RCR values of endocrine disrupting effects from pesticides is found. This is due to low intake from food in the assessments conducted by the Danish Veterinary and Food Administration in 2007-2009 (Danish Ministry of Food 2007; Danish Ministry of Food 2009). In the realistic scenario medium exposure values are used, and in the realistic worst case scenario twice the medium value is used, since for pesticides no detailed calculations of e.g. 95 percentiles for intake has been conducted for most of the pesticides.

For tebuconazole and procymidon, however, 95 percentiles have been used. If calculations are conducted for the parts of the population whose consumption pattern lead to intakes at the 99.9 percentile for procymidon, an intake of approx. 0.058 μ g/kg bw/day is found leading to an RCR_{AA} of 0.02 (Pestimix 2011). Thereby the parts of the population with the highest intake of fruits and vegetables containing pesticides may reach a pesticide intake which can contribute slightly to the total risk of endocrine disrupting effect.

8.4.2 Discussion on biomonitoring data

The RCR values for the phthalates in the medium exposure (realistic scenario) are in general lower in the biomonitoring study than for the estimated values. For maximum exposure (realistic worst case scenario) in the basis scenario DEHP and DBP showed high RCR_{AA} values from the theoretically estimated exposure, and here there is a good consistency with biomonitoring data, which also lead to RCR_{AA} values above 0.1 for these two phthalates. For the women with maximum exposure the biomonitoring data underline that our exposure estimates are realistic and can be observed in parts of the population.

The major sources for exposure to DBP are the consumer products, in particular plastic sandals, and food. These sources lead to an RCR of 0.33 at maximum exposure the basis scenario, which corresponds well to the exposure estimated for the women with the highest DBP exposure in the biomonitoring study. In the biomonitoring study an RCR value of approximately half (0.18) of the theoretically estimated (0.33) is found. The difference may be due to an over-estimation of DBP exposure in the theoretical part of this project. The data material in the biomonitoring study is limited, though, and since the samples are collected between 2 February and 6 June, it is less likely that the participants walked barefoot in plastic sandals, than if the samples had been collected during the summer months. It is realistic though, that part of the high exposure of DBP observed as maximum values in the biomonitoring study may be caused by dermal exposure from products. In certain medical products, DBP may be used as a carrier and it is not determined whether such an exposure could lead to the high exposure level found in the biomonitoring study. In general, the consistency between theoretically estimated maximum exposures and maximum exposures estimated from the biomonitoring data for phthalates is good. This result confirms that several of the phthalates included in the project contribute to the total RCR_{AA} for antiandrogenic effect even though the RCR values are below 1 for each of the individual phthalates.

Nonylphenol was not found at concentrations above the detection limit in any of the samples from the biomonitoring study, which is not consistent with the considerable contributions to the combined RCR_E from nonylphenol in the theoretical part of this project. This may be because in this project it is assumed that the whole amount of nonylphenolethoxylates in the clothes is converted to nonylphenol, which is a worst case assumption. Furthermore, part of the nonylphenol in the clothes will be washed out, when the clothes are washed, so this may indicate that 1) women are good at washing their clothes before use, and/or 2) women do not have new unwashed clothes as often as once per week.

For bisphenol A there is a considerable difference between the theoretically estimated exposure compared to data from the biomonitoring study, since the theoretically estimated values are 160 and 30 times higher than the values estimated from the biomonitoring data at medium and maximum exposures respectively. This may be explained by the fact, that e.g. none of the test subjects had been particularly exposed to bisphenol A or e.g. that the theoretically estimated exposure over-estimates the amount which is actually absorbed in the body. RCR_E for bisphenol A is however small in calculations with the used DNEL, why a possible over-estimation in the exposure calculations is insignificant compared to the total RCR_E. It must be noted that possible endocrine disrupting effects at low doses of bisphenol A are not taken into account.

For BP-3, the theoretically estimated medium exposures are also considerably higher than the exposures estimated from the biomonitoring study, whereas

exposure estimated from the maximum levels in the biomonitoring study are very close to the theoretically estimated. This indicates that the theoretical estimation of the maximum exposure is likely and occurs for some women, but that most women are exposed to only limited amounts of BP-3. RCR_E for BP-3 is very small though and contributes only minimally to the total RCR_E .

Both propylparaben and butylparaben are in the theoretical estimations assumed to contribute equally to the RCR_E for estrogenic effect assuming that the concentrations of these two substances are the same in the cosmetic products. From the biomonitoring study, however, a considerable difference is observed between the two parabens. A similar difference was also observed in other biomonitoring studies (Boberg et al., 2010). Butylparaben was not identified at all at the 50% percentile, while the estimated exposure from the maximum levels in the biomonitoring study was 20 times lower than the theoretically estimated maximum exposure. Thereby the contribution from butylparaben to the total RCR_E is minimal according to the biomonitoring study. For propylparaben the contribution to RCR_E was also small when looking at the medium exposure estimated from the biomonitoring study, but for maximum exposure the difference between the theoretically estimated and the estimated exposure based on the biomonitoring study is only a factor 3, and the RCR_E value for propylparaben reaches 0.26 based on the biomonitoring data.

These biomonitoring data indicate that, even though the human exposure to propylparaben may be lower than theoretically estimated in the project, propylparaben contributes considerably to the total RCR_E value for estrogenic effect.

Triclosan is considerably higher than in the calculation of the report compared to biomonitoring data for the medium value. This could be because only very few of the examined test subjects have actually used personal care products containing triclosan. On the other hand the estimated maximum exposure in the basis scenario corresponds very well to what was measured in the biomonitoring study. This means that the RCR values from the biomonitoring study at maximum exposure in the basis scenario are relatively high, and therefore it seems that with the most exposed test subjects, triclosan contributes considerably to the total RCR_{E/T} both in terms of thyroid disrupting effect and estrogenic effect.

8.5 Significance of uncertainties

8.5.1 Dermal and oral absorption of substances in humans and laboratory animals, respectively

In the risk calculations, it is very important to compare internal doses of the substance in both animals and humans. This is, however, only possible for very few substances, for which there are detailed knowledge about oral absorption in the animal models underlying the NOAEL/DNEL determination, and also data for human absorption via skin, inhalation or oral intake. For all the substances in this project, knowledge of internal doses is inadequate, and we have used approximate values for absorption where such values are available.

For oral absorption in animal studies, absorption fractions are only used for DEHP (50%), DINP (50%) and nonylphenol (10%), as these are the only substances for which EU's risk assessments use oral absorption fractions. These absorption fractions are based on animal studies, but are subject to some uncertainty. For the remaining substances, the lack of inclusion of an oral absorption fraction is equivalent to an assumption of similar absorption and bioavailability in animals and humans. This is less important in the cases involving both oral exposure of the laboratory animal and oral route of exposure in humans. The uncertainty may, however, be important, when an animal study with oral dosing is compared to e.g. an internal dose calculated from dermal exposure of humans.

For dermal exposure of humans, absorption fractions of less than 100% are used for all substances with calculated dermal doses. There is some uncertainty of these absorption fractions, but in most cases the dermal dose is determined conservatively according to the EU risk assessments, which may lead to a higher calculated internal dose than is actually observed in humans, and thus an overestimation of the risk. However, the internal human dose is unlikely to be significantly more overestimated than the internal dose in the animal study. It should be noted that for certain substances, where we do not have data on oral bioavailability, an oral absorption fraction of 100% may be unrealistically high, and the calculated DNEL for the animal study thus becomes too high. This may lead to an underestimation of the risk, when at the samen time an absorption fraction of less than 100% for the dermal absorption in humans is used. All in all, the uncertainties about the internal doses in humans and laboratory animals are considered to lead an underestimation of the risk rather than an overestimation of the risk when it comes to dermal exposure.

8.5.2 Other uncertainties

Exposure via indoor environment for dust is based on an intake of dust of 50 mg/day for adults (Oomen et al., 2008). In the literature a lower intake of dust for adults is stated, e.g. of between 7 mg/day (average) and 10 mg/day (95 percentile) in D'Hollander et al. (2010), which of course will influence the total RCR value for dust markedly, if the actual value for intake of dust is far lower. Halving the dust intake means halving of the RCR value originating from dust in the indoor environment.

As mentioned in the introduction, it may also be relevant to include an additional uncertainty factor to extrapolate from studies with exposure of young and adult animals to studies with exposure of fetuses, which in some cases are more sensitive than adults. The use of an additional uncertainty factor would mean lower DNEL values and thus higher RCR values than the calculated ones. Such an additional uncertainty factor is, however, not used in the DNEL calculations, because fetuses in other cases may be partly protected from the exposure of the mother.

This risk assessment includes a number of substances assumed to be encodrine disruptors, and to which the target group may be exposed. In this project, migration analyses were made on cell phone covers, gloves, sleeping mats, handbags, and sneakers. Contents of some substances were measured in the quantitative analyses, but no migration in concentrations above the detection limits of the selected substances. This does not mean that there are no or will be no products on the market from which migration of these endocrine disruptors may result in an exposure. But it does mean that the selected products analysed in this project and representing some random samples from the product groups, are examples of products actually occurring on the market with minimal migration of these substances (i.e. below the detection limit). Whether there is a general tendency to a decline in the occurrence of the substances in consumer products is impossible to say based on the results of this project. Other studies show:

- a) that nonylphenol is still present in many products (Greenpeace International 2011; Danish EPA 2012) and
- b) that triclosan is only present in 2 of 30 tested antibacterially treated products on the Swedish market (KemI 2011) and
- c) that in 2009 phthalates are still found in a large number of consumer products on the Danish market (Danish EPA 2010; Danish EPA 2010b)

8.6 Other substances, which may contribute to endocrine disrupting effects

The selection of the 35 substances, included in the quantitative risk assessment in this report, reflects the knowledge we have in this area today. Many other substances are suspected to be endocrine disruptors. The EU list of potential endocrine disruptors, for example, includes almost 200 substances in category 1, but many were excluded from this project. The reason may be that the exposure of pregnant women to the substances is expected to be very low or nonexistent. Furthermore, only a small part of the approximately 50.000 chemical substances that surround us in everyday life are tested for endocrine disrupting effects. Among the substances showing endocrine disrupting effects in e.g. cell-based assays, only a small proportion has been toxicologically tested in laboratory animals as well. This risk assessment is based on endocrine disrupting effects shown in laboratory animals, which further limits the number of substances included. Therefore, the substances used in the calculations do not represent the total chemical universe, to which women are potentially exposed, and other substances are likely to further contribute to the overall risk, just as we do not have the full picture of the exposure sources for the included substances.

Below, some of the substances are described, which are likely to contribute to further increasing the overall risk.

8.6.1 Other potential endocrine disruptors

A number of other xenobiotic substances are used in the products surrounding us. Only a fraction of these have been examined for their possible endocrine disrupting effects. EU's list of potential endocrine disruptors includes a total EU list of 432 candidate substances to be further examined for endocrine disrupting effects. The list also includes e.g. certain flame retardants and organic tin compounds, which may also be present in consumer products. For the phthalates, besides the 8 reprotoxic and antiandrogenic phthalates examined here, it is also suspected that several others may be endocrine disruptors. The frequently used diethyl phthalate (DEP) may also have endocrine disrupting effects, but mechanism studies show that DEP does not have a similar mechanism of action as the testosterone synthesis-inhibiting phthalates. Dicyclohexyl phthalate is an example of another phthalate found in some consumer products, with the same types of effects as the phthalates included in the above calculations. This is one of several antiandrogenic substances with effects that are likely to further contribute to the overall risk of endocrine disrupting effects in humans.

The number of parabens included is limited to some of those with the strongest evidence of their endocrine disrupting effects, while other parabens (methyl, ethyl, isopropyl, benzylbutyl, and other parabens) may also have endocrine disrupting effects, but with a less evident data base for a risk assessment. Among the pesticides, only pesticides which the Danish Veterinary and Food Administration in recent years have included in the lists of pesticides contributing to the highest intake in humans are included.

Finally, there is the group of polyfluorinated substances, which has not yet been fully examined. PFOS and PFOA appear to be potential endocrine disruptors, but it is not yet known whether the large group of polyfluorinated substances used today will have similar effects.

In recent years there has been a change from the use of PFOS to the use of other perfluorinated and polyfluorinated substances, and some of these substances may also have endocrine disrupting effects. These other polyfluorinated substances are not among the selected substances in this project, as this substance group generally is not particularly well examined, and there are no published animal studies available for determination of NOAEL for endocrine disrupting effects. These substances may potentially contribute to the overall risk of both antiandrogenic and thyroid disrupting effects.

8.6.2 Phytoestrogens

Certain plants also contain substances with estrogenic effects, and there is basically no difference in the types of effects expected from exposure to xenobiotic estrogenic substances and the effects expected from exposure to naturally occurring estrogens (phytoestrogens) in the diet.

An American risk assessment report regarding phytoestrogens in soy was published by the National Toxicology Program, US Department of Health and Human Services (NTP - CERHR 2006). The risk assessment is based on animal studies of genistein, which is the substance mainly causing the estrogen-like effects of soy. In this report a NOAEL of 7 mg/kg bw/day and a LOAEL of 35 mg/kg bw/day were identified for endocrine disrupting (estrogenic) effects in a multi-generation study (NCTR, referred by (NTP - CERHR 2006b). Furthermore, intake for American vegetarians is assessed to be 0.1 mg genistein equivalents per kg per day, and for the adult Japanese population, an intake of up to 0.43 mg/kg bw/day is assessed. Based on this data, NTP concludes that there is no reason for concern for exposure to genistein in doses up to 0.43 mg/kg bw/day, as effects in rats are not observed until intake of 35-45 mg/kg bw/day.

However, it cannot be excluded that a high intake of e.g. soy products will increase the risk of adverse reproductive effects in sensitive periods of the development, i.e. pregnancy and early childhood (Jefferson et al., 2012; Wendy N. Jefferson in press).

8.6.3 Food supplements

Food supplements are different types of products containing a wide range of more or less known substances or food ingredients. These could include: vitamin and mineral pills, omega 3-fatty acids in fish oil products, different plants or herbs or other ingredients or substances derived from plants (vegetable), of ingredients from animals (animal) or other (mineral). Food supplements must contain vitamins and/or minerals, and/or other substances or ingredients in sufficient amounts in order to affect the body nutrionally and/or physiologically, but must not be harmful to health. However, today we only have limited knowledge on the potential risk of prenatal damage and fetal abnormalities (including endocrine disrupting effects) when it comes to food supplements containing e.g. plants and pure substances. Therefore, it is recommended by the Danish Veterinary and Food Administration that women, who wish to become pregnant, are pregnant or breast feeding, should take extra care before starting to use food supplements and follow the precautionary principle (Danish Ministry of Food 2010). The Danish Veterinary and Food Administration strongly discourages use of food supplements apart from these recommended by the authorities (folic acid, iron, vitamin D, calcium), unless it is used after agreement with the doctor, the midwife or the health nurse (Danish Ministry of Food 2010). Food supplements must also be labeled with the phrase: »Should only be used by pregnant women or children under 1 year after agreement with a doctor or a health nurse«.

8.6.4 Medicine

Medicine is used for diagnosing, prevention, treatment or alleviation of diseases or symptoms, including pain, in humans or animals. Because medicine is used specifically for their effects on the body, it is common knowledge that medicine may have adverse side effects to a greater or lesser extent, and that the use of medicine requires consideration of beneficial effects from the use relative to the known risks. This obviously also applies to pregnant women, who furthermore must be aware that the fetus may be particularly sensitive to exposure to certain medical products, including non-prescription medication such as headache pills. On this background, the Danish Board of Health and the Danish Medicines Agency recommend that pregnant women use as little medicine as possible during pregnancy. This also applies to non-prescription medication and herbal medicine. Furthermore, women who are being treated with medicine and are planning to become pregnant shold contact their doctor for advice.

8.6.5 Herbal medicine

Herbal medicine are typically produced from plant extracts or pulverised plants, and contain naturally occurring substances in concentrations, which are not significantly higher than the naturally occurring concentrations. A product can only be designated as herbal medicine if it has a proved effect on the body, and therefore it applies to herbal medicine, as well as to medicine, that it may have adverse side effects, including endocrine disrupting effecs. On this background, the general advice from the Danish Medicines Agency, to ingest as little medicine as possible during pregnancy, also applies to herbal medicine.

9 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 food 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 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.

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Resume

Pregnant women's exposure to potential endocrine disruptors from consumer products, indoor environment and food has been investigated. A risk assessment has been made, taken the total exposure of endocrine disruptors into account. A number of suspected endocrine disruptors were selected based on their endocrine disruptive effects in animal studies, and anticipated exposure of pregnant women to the substances through consumer products, indoor air or food. The selected substances are for example selected phthalates, parabens, pesticides, bisphenol A and triclosan. The content and migration of the selected substances were analysed in 8 product groups (for example, covers for mobilphones, gloves and shoes). The analyses showed that none of the selected substances migrated from the products. The risk assessment is based on data from earlier reports from the Danish EPA for consumer products and from literature data for indoor environment and food. The risk assessment shows that there could be a risk when the total exposure from consumer products, indoor environment and food is taken into account. There is a need for pregnant women to reduce the exposure to endocrine disruptors from food, indoor environment and consumer products, and it is important to take the total exposure into account.



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