KEMI
Swedish Chemicals Agency

Phthalates which are toxic for reproduction and endocrine-disrupting – proposals for a phase-out in Sweden

Report from a government assignment

REPORT 4/15

kemikalieinspektionen.se

KEMI
Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

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Order print from Arkitektkopia AB, Box 11093, SE-161 11 Bromma.
Order tel: +46 8 505 933 35, Order fax: +46 8 505 933 99, e-mail: kemi@cm.se.

Preface

The Swedish Government tasked the Swedish Chemicals Agency in June 2013 with conducting a survey into the use of phthalates suspected of being toxic for reproduction or endocrine-disrupting and the occurrence of alternative substances and materials. On the basis of the survey, the Swedish Chemicals Agency intends, for instance through dialogue with the industry, to endeavour to get companies to voluntarily substitute such phthalates for less hazardous substances or materials.

The assignment involved investigating the need and prerequisites for Sweden to introduce national restrictions on the use of phthalates suspected of being toxic for reproduction and endocrine-disrupting. Possible ways of influencing this development at EU level have also been investigated.

The task has been carried out by a project group comprising Erik Gravenfors (project manager), Karin Alkell, Gustaf Eskhult, Stellan Fischer, Lars Freij, Anna Nylander, Fredrik Olsson, Frida Ramström and Emma Westerholm.

The department manager responsible for the project was Kent Wiberg.

The assignment was conducted in close cooperation and dialogue with relevant authorities, the business community, environmental organisations and researchers.

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Summary

The Swedish Government has assigned the Swedish Chemicals Agency with the task to push for a phase-out in Sweden of phthalates suspected to be toxic for reproduction and endocrine-disrupting. The assignment included to carry out a survey, assess risks as well as to determine the need for action.

The greatest use of phthalates is as plasticisers in PVC (polyvinyl chloride). The trend for using plasticisers differs in separate parts of the world. On the EU market, the high molecular weight phthalates (DINP, DIDP and DPHP) dominate and the proportion of DEHP (low molecular weight phthalate) is relatively small, about 10 per cent. In the rest of the world market, it is instead DEHP which dominates with almost 50 percent of the market, while the proportion of high molecular weight phthalates and non-phthalates is roughly equal.

Phthalates are found in a large number of articles. Some examples where phthalates are used are: automotives, cables, wiring, flooring, wall coverings, sheets, film, tubing, gaskets, medical devices, toys, packaging materials for food, coated textiles / fabrics, garments with printing, sports equipment, leather, shoes , bags and furniture. What is common to these groups is that the articles are wholly or partly made of soft PVC. A large proportion of these articles are brought into Sweden via imports.

Many phthalates are classified as toxic for reproduction and thirteen phthalates are included in the candidate list of REACH. Four of these (DEHP, DBP, BBP and DIBP) are also on the authorisation annex (Annex XIV REACH). In addition to these four phthalates, it is only DIPP of the phthalates on the candidate list that has a registered use in the EU.

To be able to substitute phthalates in the diversity of uses, different alternative plasticisers are needed. Today, there are affordable alternatives for many applications and volumes increase significantly.

Within the framework of this assignment, the Swedish Chemicals Agency has carried on a dialogue with the industry, as a step to having companies voluntarily substitute such phthalates (i.e. suspected to be toxic to reproduction and endocrine-disrupting) with less hazardous substances or materials.

In this report, the Swedish Chemicals Agency is proposing a variety of measures driving the substitution of the most harmful phthalates. Since soft PVC, and thus phthalates, occurs in many different product categories, our proposals concern many different pieces of legislation. Proposals partly overlap, which means that developments within the area of one proposal could lead to other proposals becoming less relevant.

We want to prioritise the following:

<u>EU level</u>

- Sweden should work within the EU for a restrictive authorization of the four phthalates DEHP, DBP, BBP and DIBP in Annex XIV of REACH.
- Sweden should work within the EU for further restrictions in REACH of the four phthalates in specific articles.
- The Swedish Chemicals Agency will continue to work on the classification proposals for phthalates that are toxic for reproduction or are endocrine-disrupting, with the aim to having them included on the candidate list.

- Sweden should work within the EU to restrict the four phthalates in the Electronics Directive - RoHS.

National level

- The Swedish Government should appoint competent authorities to suggest national limitations of emissions from building materials of dangerous phthalates to the indoor environment.
- The Swedish Government should assign the Swedish Competition Authority with a similar mandate for the health care sector, which the Authority has already been given regarding the chemical requirements for procurement to kindergartens.
- The Swedish Chemicals Agency intends to promote measures that lead to improved compliance, effective enforcement and sanctions.

The Swedish Chemicals Agency intends to promote measures aimed to improve information on dangerous substances.

Sammanfattning

Regeringen har gett Kemikalieinspektionen i uppdrag att verka för en utfasning av misstänkt fortplantnings- och hormonstörande ftalater i Sverige. I uppdraget ingick att göra en kartläggning, bedöma risker och utreda behovet av åtgärder.

Den allra största användningen av ftalater är som mjukgörare i PVC (polyvinylklorid). Trenden för användning av mjukgörare ser olika ut i olika delar av världen. På EU-marknaden dominerar de högmolekylära ftalaterna (DINP, DIDP och DPHP) och andelen DEHP (lågmolekylär ftalat) är relativt liten, ca 10 procent. På den resterande världsmarknaden är det istället DEHP som dominerar med nästan 50 procent av marknaden, medan andelen högmolekylära ftalater och icke-ftalater är ungefär lika stora.

Några exempel på varugrupper där ftalater används är: fordon, kablar, ledningar, golv, våtrumstapeter, folier, film, slangar, packningar, medicintekniska produkter, leksaker, förpackningsmaterial för mat, belagda textilier/vävar, kläder med tryck, sportutrusning, konstläder, skor, väskor samt möbler. Det gemensamma för dessa varugrupper är att varorna helt eller delvis består av mjukgjord PVC. En stor andel av dessa varor kommer in i Sverige via import.

Många ftalater är klassificerade som fortplantningsstörande och tretton ftalater finns upptagna på kandidatförteckningen i Reach. Fyra av dessa (DEHP, DBP, BBP och DIBP) finns dessutom på tillståndsbilagan (bilaga XIV, Reach). Utöver dessa fyra ftalater är det bara DIPP av ftalaterna på kandidatförteckningen som har registrerad användning i EU.

För att kunna substitutera ftalater i mångfalden av användningsområden behövs flera olika alternativa mjukgörare. Idag finns det alternativ till överkomliga priser för många applikationer och volymerna ökar kraftigt.

Inom ramen för uppdraget har Kemikalieinspektionen genomfört dialoger med näringslivet som ett led i att få företag att frivilligt ersätta sådana ftalater (misstänkt fortplantningsstörande och hormonstörande) med mindre farliga ämnen eller material.

Kemikalieinspektionen föreslår i denna rapport en rad olika åtgärder som driver på utbytet av de skadligaste ftalaterna. Eftersom mjukgjord PVC, och därmed ftalater, förekommer i många olika varukategorier berör våra förslag många olika regelverk. Förslagen överlappar delvis varandra vilket innebär att utvecklingen inom området för ett förslag kan medföra att andra förslag blir mindre relevanta.

Följande förslag vill vi prioritera:

<u>EU-nivå</u>

- Sverige bör verka inom EU för en restriktiv tillståndsgivning av de fyra ftalaterna DEHP, DBP, BBP och DIBP på bilaga XIV i Reach.
- Sverige bör verka inom EU för begränsningar i Reach av de fyra ftalaterna för särskilda varugrupper.
- Kemikalieinspektionen avser att fortsätta arbetet med klassificeringsförslag av fortplantningsstörande eller hormonstörande ftalater samt få dem uppförda på kandidatförteckningen.
- Sverige bör verka inom EU för begränsning av de fyra ftalaterna i elektronikdirektivet – RoHS.

Nationell nivå

- Regeringen bör uppdra åt relevanta myndigheter att föreslå nationella begränsningar av emissioner till inomhusmiljön av skadliga ftalater från byggmaterial.
- Regeringen bör ge Konkurrensverket ett liknande uppdrag för sjukvården som det verket redan fått avseende kemikaliekrav vid upphandling till förskolor.
- Kemikalieinspektionen avser att verka för åtgärder som leder till förbättrad regelefterlevnad – effektivare tillsyn och sanktioner.

Kemikalieinspektionen avser att verka för åtgärder som syftar till att förbättra informationen om farliga ämnen.

Glossary and key terms

Annex XIV: Substances listed in this annex must not be sold or used in the production of articles within the EU without authorisation. Substances which require authorisation are listed in Annex XIV of REACH.

Antiandrogens: Substances that counter the biological effect of androgens and therefore can have an impact on both development and reproduction. The male sex hormone testosterone is an important androgen.

Authorisation list: Annex XIV: substances which require authorisation are listed in this annex of REACH.

BBP: Benzyl butyl phthalate is featured in the candidate list and in Annex XIV of REACH. Regulated in toys and childcare articles.

Candidate list: A list of substances of very high concern (SVHCs). If a substance is included in the list, the manufacturer and suppliers are required to provide relevant information.

CMR substances Substances which are carcinogenic, can cause harm to genetic material (mutagenic) or are toxic for reproduction.

DBP: Dibutyl phthalate is featured in the candidate list and in Annex XIV of REACH. Regulated in toys and childcare articles.

DEHT: Di-(2-ethylhexyl) terephthalate

DEHP: Diethylhexyl phthalate is featured in the candidate list and in Annex XIV of REACH. Regulated in toys and childcare articles.

DIBP: Diisobutyl phthalate is featured in the candidate list and in Annex XIV of REACH.

DIDP: Diisodecyl phthalate, a high molecular weight phthalate, regulated in toys and childcare articles.

DINA: Diisononyl adipate

DINCH: Di-isononyl-cyclohexane-1,2 dicarboxylate

DINP: Diisononyl phthalate, a high molecular weight phthalate, regulated in toys and childcare articles.

DNOP: Di-n-octyl phthalate, a high molecular weight phthalate, regulated in toys and childcare articles.

DPHP: Di-(2-propyl heptyl) phthalate, a high molecular weight phthalate

ECHA: European Chemicals Agency

Endocrine disruptor: Xenobiotic substance which can affect an organism's hormone system.

Harmonised classification: Classification at EU level at the request of EU Member States, importers or of companies/persons using the chemical.

High molecular weight phthalates: Phthalates which have 7 to 13 carbon atoms (C7-C13) in their ester groups' main chains, e.g. DINP, DIDP and DPHP.

Low-dose effects: Effects which arise in the case of very low concentrations of a substance, which are often close to the levels which people are actually exposed to.

Low molecular weight phthalates: Phthalates which have 3-6 carbon atoms (C3-C6) in their ester groups' main chains, e.g. DEHP, DBP and BBP.

Plasticisers: A plasticiser is an additive to a polymer (plastic), which acts as a softening agent. Plasticisers operate by being embedded between polymer chains, which separates them from each other and weakens the attractive forces between the polymer chains.

PVC: Polyvinyl chloride. The most common material containing phthalates. It occurs as both hard and soft PVC. Soft PVC contains a plasticiser, which is usually a phthalate.

Placing on the market: This term defines when certain regulations in EU legislation are applicable. Under REACH this term covers every delivery, whereas, according to the legislation on articles (e.g. the RoHS Directive and the Toy Safety Directive), it covers only the first point of access in the EU.

REACH: Common EU legislation governing general chemicals. REACH stands for the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals.

SVHC: Substances of very high concern. These substances have particularly dangerous intrinsic properties, which make them carcinogenic, damage genetic material and harm reproductive capacity. SVHC is a key term in REACH. Any decisions concerning new SVHCs are adopted by ECHA. SVHCs are therefore registered in the candidate list.

TDI: Tolerable daily intake, the highest quantity of a substance which a person can take in every day of their life without posing a health risk.

1 Summary of conclusions and proposals for action

1.1 Summary of conclusions

- The biggest use of phthalates is as plasticisers in PVC (polyvinyl chloride). High molecular weight phthalates are currently predominant on the European market and have replaced the low molecular weight and more toxic phthalates in a number of uses. However, in the rest of the world market, it is the low molecular weight phthalate DEHP which dominates.

- Phthalates feature in a large number of different groups of articles: construction products, vehicles, electronics, everyday goods, clothing, footwear, toys, packaging material, medical devices and more. A large proportion of these articles are brought into Sweden via imports from countries outside the EU.

- Serious health effects, such as impairment of reproduction and liver toxicity, have been reported in the case of a number of phthalates.

- Children have a high level of exposure to phthalates, which arises through food, dust and objects which they can put in their mouth. Not including toys and childcare articles, more than half the items mouthed by small children and which may contain plasticised materials are thought to be imported from countries outside the EU.

- In this report the Swedish Chemicals Agency is proposing a variety of measures driving the substitution of the most harmful phthalates. Since soft PVC, and therefore phthalates, occur in many different article categories, our proposals concern many different pieces of legislation. Proposals partly overlap, which means that developments within the area of one proposal could lead to other proposals becoming less relevant.
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  <u>EU level:</u>
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  - Sweden should work within the EU for further restrictions in REACH on the four phthalates DEHP, DBP, BBP and DIBP in specific groups of articles.
  - The Swedish Chemicals Agency intends to continue to work on the classification proposals for phthalates that are toxic for reproduction or are endocrine-disrupting, with the aim of having them included in the candidate list.
  - Sweden should work within the EU to restrict the four phthalates in the Electronics Directive - RoHS.

  <u>National level:</u>
  - The Swedish Government should appoint competent authorities to suggest national limitations of emissions from building materials of dangerous phthalates to the indoor environment.
  - The Swedish Government should assign a similar mandate to the Swedish Competition Authority for the healthcare sector, which the Authority has already been given regarding the chemical requirements for procurement in pre-school institutions.
  - The Swedish Chemicals Agency intends to promote measures that lead to improved compliance, effective enforcement and sanctions.
  - The Swedish Chemicals Agency intends to promote measures aimed at improving information on hazardous substances.

1.2 Surveying the occurrence of phthalates in products

The biggest use of phthalates is as plasticisers in PVC (polyvinyl chloride), which accounted for 93% of phthalate use in Europe in 2012. In 2012 phthalates accounted for just over 78% of the global consumption of plasticisers. More than 1.2 million tonnes of plasticisers are manufactured in Europe every year.

High molecular weight phthalates are predominant on the European market and have replaced low molecular weight phthalates in a number of uses, which are more toxic. However, in the rest of the world market, it is the low molecular weight phthalate DEHP which dominates.

Numerous phthalates are classified as toxic for reproduction, with 13 of them featuring in the REACH candidate list. Four of them (DEHP, DBP, BBP and DIBP) also appear in the authorisation list (Annex XIV of REACH). Apart from these four, DIPP is the only other phthalate in the candidate list which has a registered use in the EU. ECHA's database of registered substances features 26 phthalates. There is a higher number of phthalates registered in the Swedish Product Register (42 phthalates) as registration is required if 100 kg or more of the substance is used per year. Only a few of these phthalates are used in major volumes. This is the case with DIDP, DPHP, DEHP and DINP in Sweden and Europe, which are predominantly used.

Phthalates are found in a large number of different groups of articles. Some examples of these groups where phthalates are used are: vehicles, cables, wiring, flooring, plastic film, film, hoses, gaskets, wall coverings, medical devices, toys, food packaging materials, coated textiles/fabrics, garments with printing, sports equipment and leather in gloves, shoes, bags and furniture. What is common to these groups is that the articles are wholly or partly made of soft PVC. A large proportion of these articles are brought into Sweden via imports from countries outside the EU. Phthalates are also used in chemical products such as paint, sealants, adhesives and coating agents.

There are a number of different types of alternative plasticisers, many of which are used as special-purpose plasticisers. To ensure that any replacement can cover the wide range of applications offered by the most widely used phthalates, several different alternative substances are required. According to the Danish Environmental Protection Agency, alternative substances are available on the market. The following in particular can be used to replace DEHP: DINA[1], DINCH[2], DEHT[3], COMGHA[4], ATBC[5] and ASE[6]. According to the product register, the use of DINCH as an alternative has increased 47 times compared with last year. The volume used is now only 40% lower than the total quantity of phthalates registered in Sweden.

1.3 Health risks

Ortho-phthalates comprise a large group of substances presenting both different and similar toxicological effects. Impairment of reproduction, especially in men, is an effect which has been linked to a number of low molecular weight phthalates. Effects of this kind have been reported for DEHP, the most widely studied phthalate in the low molecular weight phthalate group, but also for DBP, BBP and DIBP. One feature these four phthalates have in common is

[1] Diisononyl adipate
[2] Di-isononyl-cyclohexane-1,2 dicarboxylate
[3] Di(2-ethylhexyl) terephthalate
[4] Glycerides, Castor-oil-mono-, hydrogenated, acetates
[5] Acetyl tributyl citrate
[6] Alkyl sulphonic acid phenyl ester

that they produce an antiandrogenic pattern of effects and should, therefore, also be assessed together. DEHP, DBP, BBP and DIBP are all classified as toxic for reproduction under EU chemicals legislation and their use is banned in toys and childcare articles.

Also in the case of the high molecular weight phthalate DINP, it is suspected of possibly being toxic for reproduction based on an antiandrogenic pattern of effects. However, DINP is not classified as toxic for reproduction. DIDP, another very common high molecular weight phthalate, is suspected ofbeing toxic for reproduction, but probably via a different type of mechanism. Therefore, DIDP does not contribute to the antiandrogenic effects.

Phthalates have a very wide area of application, featuring in many articles and products which we deal with every day, ranging from building materials and car fittings to electric cables and accessories. This wide use also means that we are constantly exposed to phthalates from a number of different sources. One way to study the combined exposure from several different sources is to measure the actual occurrence of phthalate metabolites in urine. Only a limited number of such studies have been conducted on children. But those which are available clearly highlight that children generally have higher concentrations than adults, which means that children take in phthalates to a greater extent.

One explanation as to why we observe a higher concentration in children is that children eat more in relation to their size than adults do and food is an import source of exposure. The use of a large number of phthalates is restricted in material coming into contact with foodstuffs, but still, due to the diffuse distribution in the environment relatively high concentrations continue to occur. Children also have a high respiratory rate, are often close to the floor and frequently put objects in their mouth. As a result, they are exposed, to a large extent, to phthalates in their indoor environment, both in the air and dust, as well as to phthalates which are released from mouthed objects. An assessment of the overall level of exposure indicates that the risk is not controlled to a sufficiently high extent.

An analysis of which objects children put in their mouth, combined with import/export figures showed that more than half of the mouthed objects are imported, which means that they are not covered by the authorisation requirement under REACH. There has been a sharp decline in the use of DEHP within the EU in favour of using high molecular weight phthalates. However, DEHP commonly occurs in other parts of the world, as well as in imported articles. As the occurrence of phthalates is regulated in toys and childcare articles, such objects are excluded from the analysis. However, the study also highlighted that children mouth other types of objects just as frequently, such as electronic items, accessories, home furnishings, office supplies and shoes. Mouthing objects can make an undesirable contribution to the high level of exposure which the child already has.

We have chosen to focus in the report on the exposure small children are subject to. However, the most sensitive group are developing foetuses where exposure is dependent on the mother’s exposure. By limiting small children’s exposure to phthalates which are toxic for reproduction, this will also reduce the exposure pregnant women and, therefore, their foetuses are subject to.

1.4 Action proposals

In this report the Swedish Chemicals Agency is proposing a variety of measures driving the substitution of the most harmful phthalates. Since soft PVC, and therefore phthalates, occur in many different article categories, our proposals concern many different pieces of legislation. Proposals partly overlap, which means that developments within the area of one proposal could lead to other proposals becoming less relevant.

1.4.1 Restrictive authorisation of the four phthalates in Annex XIV of REACH.

From 2015 authorisation will be required to use the phthalates DEHP, DBP, DIBP and BBP in the EU. Without this authorisation, the manufacture of articles in the EU which contain these phthalates will be prohibited. The purpose of this is for substances to gradually be replaced by safer alternatives or techniques.

Europe's DEHP industry has applied for authorisation covering a very wide range of uses, with there being a large risk that authorisation will be granted for broad, inadequately specified uses.

We consider that Sweden should establish contact with EU institutions at different levels in an effort to ensure that the authorisation provisions in REACH are applied with the intention of achieving a high level of protection for health and the environment by replacing substances of very high concern, including the most dangerous phthalates, with substances or technical solutions providing a safer alternative.

1.4.2 Restrictions on the four phthalates in Annex XIV of REACH

The EU chemicals agency ECHA must assess during 2015, after the authorisation requirement has come into force, whether a restriction is required on articles containing DEHP, BBP, DBP or DIBP.
If this is appropriate, ECHA must draw up a proposal for such a restriction. Sweden should work at different levels to restrict these four phthalates. The reason for this is that a large proportion of the phthalates to which EU consumers are exposed are not affected by the authorisation requirement as they are contained in articles imported from countries outside the EU. A restriction is also required to offset the competitive disadvantage which the authorisation requirement currently entails for articles manufacturers within the EU compared to manufacturers outside the EU.

However, Sweden cannot assume that the assessment carried out by ECHA will result in further restrictions, based on the extensive requirements which are imposed on the basis for making a decision during the ordinary restriction process. However, there is also an opportunity to introduce restrictions on specific groups of articles using the "fast-track" procedure contained in REACH Article 68.2. The fast-track procedure can be used to restrict the presence of CMR substances in consumer goods and does not require as extensive a basis as the standard restriction process.

Only the European Commission can formally initiate a fast-track restriction. However, there is nothing to prevent a Member State from suggesting that the Commission introduce such a process.

During our investigation we have identified a number of consumer articles which we consider may be suitable in terms of proposing phthalate restrictions using the REACH fast-track procedure. The starting point has been the risk to which children can be exposed. The groups of articles are:

- Accessories, including gloves and bags
- Clothing and shoes
- Sports and leisure articles
- Home furnishings
- Electronics (unless phthalate restrictions are introduced in the RoHS Directive)
- Vehicles
- Construction products for indoor environment

In the first five categories listed above, children are subject to exposure by being able to put the object in their mouth or by sucking it. Vehicles and construction products for the indoor environment, on the other hand, subject children to more general exposure. None of these groups of articles currently have any regulations restricting the use of phthalates. Apart from these categories, it may also be appropriate to restrict the use of phthalates in sex toys. This is supported by the risk assessment presented by Denmark in its proposal for restricting the use of phthalates in 2011.

Sweden can draft a proposal on restricting the use of phthalates in these groups of articles by using the REACH fast-track procedure, which can then be presented to the Commission and other Member States. Another conceivable alternative is to draft the proposal in collaboration with another or other countries which are well advanced in their efforts to phase out phthalates.

1.4.3 Harmonised classification of phthalates and compilation of the candidate list

Classification and labelling of chemicals constitute an effective means of control by providing the necessary information to end users about the chemicals' intrinsic hazardous nature and about how to provide protection aimed at minimising exposure. Classification information is also used by companies in their preventive efforts in replacing hazardous chemicals. How phthalates are regulated by restriction rules in the EU also largely depends on how the substance is classified according to the CLP Regulation. For example, a harmonised classification makes it easier for the substances to be included in the REACH candidate list.

When a substance is registered in the REACH candidate list, this means that it is a candidate for being listed in the annex for substances which require authorisation for use in the EU (Annex XIV). However, the fact that a substance is registered in the candidate list may have direct consequences for companies which import and sell articles containing this substance in a concentration above 0.1% due to them always having to inform their customers and consumers on request.

The Swedish Chemicals Agency will endeavour to ensure that a harmonised classification is granted to more phthalates which are potentially toxic for reproduction, are widely used in large volumes and are found in consumer articles if they fulfil the criteria, such as CMR category 1A or 1B. They should also be registered in the candidate list. Other serious features, such as endocrine-disrupting properties, may also provide a reason for registering substances in the candidate list.

1.4.4 Restriction on the four phthalates in the Electronics Directive - RoHS

The Commission is drafting a proposal on restricting the use of the phthalates DEHP, BBP, DBP and DIBP in electronics. The restrictions are intended to be introduced in the RoHS Directive, which currently restricts the use of certain chemicals in electrical and electronic equipment. A possible decision from the Commission is expected in early 2015, with the restrictions likely to start applying to consumer electronics around two years after this.

We can see that electronics is one of the categories with the largest proportion of imports from non-EU countries. Therefore, these articles will not come under the authorisation requirement which applies under REACH. Our general exposure assessment indicates that children put electronic items in their mouth to some extent. Therefore, the Swedish Chemicals Agency thinks that Sweden should work towards the Commission adopting a decision banning the use of DEHP, BBP, DBP and DIBP in electronics.

1.4.5 National restrictions on emissions of dangerous phthalates from building materials into the indoor environment

The construction industry is the sector where soft PVC and the associated phthalates are used most of all. Scientific studies show that there is a link between PVC flooring in the home environment and the volume of phthalates in dust. The Swedish Chemicals Agency has indicated in a previous report that children are exposed to phthalates in school, especially in pre-school institutions. One of the exposure sources is likely to be construction materials.

The EU Construction Product Regulation covers imported articles, but does not stipulate any requirements in terms of product features, but only states how construction products' features will be assessed and described when the products are placed on the market. Product requirements are generally stipulated instead at national level.

A number of countries have introduced emission limits for chemicals in construction products, the most recent being Belgium in 2012.

The Swedish Chemicals Agency is proposing for the government to appoint competent authorities how Sweden can introduce threshold limits for the most hazardous phthalates in construction products, similar to the system in force in other European countries. This is in line with what has already been proposed in the Chemicals proposal 2013/14:39. Given that such a regulation should probably cover more substances than just phthalates, we believe that it is not within the remit of this assignment to submit any completed statutory proposals.

1.4.6 Replacement of harmful phthalates by means of public procurement requirements

Chemical requirements for public procurement have proven to be an effective means of control, aimed at promoting the replacement of hazardous chemicals. By using green procurement, the public sector can take priority in terms of drafting legislation and steer developments towards a non-toxic environment. Procurement should be a particularly effective means of control in areas where the public sector accounts for a large proportion of the market, for instance, in the healthcare sector, education and care provision.

The Swedish Competition Authority is tasked with devising criteria for chemical requirements for procurement in pre-school institutions. The Swedish Chemicals Agency proposes that the government tasks the Swedish Competition Authority with a similar assignment for the healthcare sector.

1.4.7 Measures leading to improved compliance

As part of the ongoing market surveillance of articles, the checks for phthalates can be expanded. For instance, analyses can be conducted on articles for phthalates featuring in the candidate list. The Swedish Chemicals Agency can also provide surveillance guidance to support local authority market surveillance agencies, enabling them to increase their checks for phthalates in articles.

The phthalate regulations in REACH concerning toys and childcare articles are not complied with by all stakeholders in the EU. Market surveillance of the chemicals sector is carried out by each country within their own territory. There are currently different forms of cooperation available to market surveillance authorities in the EU. Harmonising market surveillance activities, for instance, by means of joint projects, gives the checks carried out greater impact, while also allowing countries, which are otherwise unable to enforce market surveillance, to carry out checks to a larger extent.

The Swedish Chemicals Agency will make every effort to continue to promote in-depth cooperation between market surveillance authorities in the EU.

We also believe that the sanction provisions in the chemicals sector should be revised to make them fairer and more effective. Some of the existing phthalate regulations are subject to criminal sanctions, which means that the Swedish Chemicals Agency (or local authority) reports breaches of the regulations to the regional public prosecutor's office. The prosecutor then assesses whether criminal intent or negligence can be proven. Between 1999 and 2013 the Swedish Chemicals Agency reported 596 cases to the prosecutor's office[7]. In the case of 67% of these reports, no judicial investigation was initiated or the case was dropped. Breaches considered to be of a less serious nature and where it is sufficient to state that the relevant provision has been breached (i.e. where the issue of wilful intent or negligence is not proven) are not subject to criminal sanctions but to environmental sanction charges, which are decided by the market surveillance authority. In practice, less serious offences generally result in a penalty in the form of an environmental sanction charge, whereas offences considered as being more serious rarely result in any penalty as judicial investigations into the matter are dropped or not started. This can be perceived as being both illogical and unfair.

The issue of whether some of the breaches which are currently subject to criminal sanctions should not be subject instead to administrative charges has recently been looked into in a government investigation into work environment regulations.

The Swedish Chemicals Agency believes that appropriate clarification and a review should be conducted of the regulations in the area of environmental criminal law.

1.4.8 Measures aimed at improving information on dangerous substances

There is still a great deal of ignorance today, most of all among companies involved in importing articles, about the chemicals contained in articles.

According to the provisions in REACH, there must be information provided if an article contains the hazardous substances featuring in the candidate list in concentrations above 0.1% by mass. Consumers are entitled to receive this information for free within 45 days of requesting it. As for store owners, they are entitled to receive similar information from their supplier immediately.

For instance, the Danish Environmental Protection Agency has produced guidelines advising companies on how they can replace dangerous phthalates and on what requirements they should stipulate for their suppliers. These guidelines have been produced in collaboration with a number of Danish organisations in the industry, which gives them greater clout. The Swedish Chemicals Agency has distributed Denmark's guidelines to the companies which have engaged in the dialogue that the Agency has been conducting in the industry. There is a link to these guidelines available on the Swedish Chemicals Agency's website.

The Swedish Chemicals Agency has recently set up a website completely devoted to consumers. Consumers can obtain from this site information about chemicals they encounter every day, enabling them to make an informed choice and handle products safely.

The Swedish Chemicals Agency intends to actively continue to improve the information it provides and convey more clearly the knowledge about the information requirements in

[7] The statistics include all the indictment notices issued by the Swedish Chemicals Agency and not only those relating to the regulations governing phthalates.

REACH so that commercial customers and consumers can have greater access to relevant information about the content of hazardous substances in articles, including phthalates.

2 Overview of assignment

The Swedish Government is tasking the Swedish Chemicals Agency with the assignment of conducting a survey into the use of phthalates suspected of being toxic for reproduction or endocrine-disrupting and the occurrence of alternative substances and materials. On the basis of the survey, the Swedish Chemicals Agency intends, for instance through dialogue with the industry, to endeavour to get companies to voluntarily substitute such phthalates for less hazardous substances or materials.

The assignment involves investigating the need and prerequisites for Sweden to introduce national restrictions on the use of phthalates suspected of being toxic for reproduction and endocrine-disrupting. Possible ways of influencing this development at EU level should also be investigated. The task should be carried out, taking into account EU initiatives on classifying, restricting or authorising phthalates. Any regulatory proposals must be submitted in the form of statutory proposals and be accompanied by both an impact assessment, which must be drafted as far as possible in accordance with Articles 6 and 7 of the ordinance (2007:1244) on impact assessments in legislation, and by a risk assessment. The impact assessment must also include an analysis of the impact on trade with other countries.

The Swedish Chemicals Agency must report on this assignment to the Swedish Government Offices no later than 30 November 2014.

The assignment is available in its entirety in Annex 1 (Government decision 27.06.2013; M2013/1736/Ke).

2.1 Project boundaries

The assignment is focused on the articles and products which are available to consumers or may affect the surroundings where children are present. One important starting point, which has served as a guideline for interpreting the assignment, is the action plan for creating a non-toxic everyday environment, which the Swedish Chemicals Agency is making every effort to work towards. One of the purposes of the action plan is to provide better protection for children against the risks which arise as a result of exposure to hazardous chemicals in their everyday life.

While carrying out this survey on the use of phthalates in society, it is important to look at the whole group of phthalates. But when looking into possible measures, we will start with the phthalates which we consider to be the most dangerous, posing the biggest risk of exposure.

2.2 Organisation of tasks involved, cooperation and consultation

The tasks involved have been carried out by a working group at the Swedish Chemicals Agency. The survey is being compiled by a consultant. An external reference group (see Appendix 2) made up of representatives from industry organisations, authorities and environmental organisations has supplied information and made it possible to establish proposals during the investigation. Members of the project group have met with officials from the Danish Environmental Protection Agency to exchange knowledge and experiences.

2.3 How the work is carried out

The project has been split into three subprojects:

1. Surveying the occurrence of phthalates in articles in Sweden
2. Dialogue with the priority industries in the sector
3. Drafting of action proposals

Subproject 1 was intended to survey the use of all phthalates, as well as the occurrence of alternative substances and materials. The Swedish Chemicals Agency has employed a consultant to carry out this task.

Subproject 2 was intended to establish a dialogue with relevant industries and work towards phasing out phthalates which are potentially endocrine-disrupting and toxic for reproduction. As the use of these substances is so common and widespread in a number of industries, we decided to conduct a cross-industry dialogue focusing on product development and purchasing. We have also engaged in separate dialogues with individual industries and companies.

Subproject 3 was intended to assess any health risks from using phthalates in society, which arose in the earlier subprojects, as well as to propose measures for reducing these risks.

3 Background

Phthalates are a group of chemicals which are used as plasticisers and are added to a material, usually PVC, to make it flexible, elastic and easy to process.

Phthalates are used primarily as plasticisers in PVC (soft or flexible PVC and metal surfaces with PVC coatings). They are used in a number of different articles, e.g. cables, hoses and pipes, flooring, medical devices, packaging material, sports equipment and leather. There are also many components used in cars which contain phthalates.

In 2012, 93% of all phthalates in Europe were used for softening PVC. Phthalates are used to a lesser extent in other polymers (e.g. rubber) and in chemical products (e.g. paints, plastic hardeners, sealants and adhesives).

The phthalates are not chemically bonded to the material. Therefore, they can leak from materials and be absorbed by the body. Foetuses and small children are considered to be a special risk group as young laboratory animals have shown to be more sensitive to phthalates than adult animals. We can also ingest some phthalates through direct contact, for instance, via dust in the air and sometimes indirectly via food. Phthalates have been detected in analyses of blood, breast milk and urine. Concentrations of phthalates have also been found in lakes and watercourses, as well as in rainwater and leachate from landfills.

3.1 General information about phthalates

Phthalic acid esters (phthalates) are manufactured by reacting phthalic anhydride with an alcohol or alcohol mixture, which ranges from methanol (C1) up to tridecyl alcohol (C13)[8, 9].

[8] Plasticisers.org, 2014. Not all phthalates are the same. Available: 12.03.2014 http://www.plasticisers.org/plasticisers/not-all-phthalates-are-the-same

[9] Godwin, A.D., 2011. Plasticizers (chapter 28). I: Kutz, M. (ed). Applied plastics engineering handbook. Plastics Design Library (pdl). E-book.

Phthalic acid esters comprise a phthalic acid main group (benzene dicarboxylic acid) to which two ester side chains (ester groups) are coupled[10]. There are three isomeric forms of phthalic acid (*ortho*, *meta* and *para*), which are used to produce the following three types of phthalic acid esters[11], see Figure 1:

- *ortho*-phthalates – phthalates – esters of 1,2-benzene dicarboxylic acid
- *meta*-phthalates – isophthalates – esters of 1,3-benzene dicarboxylic acid
- *para*-phthalates – terephthalates – esters of 1,4-benzene dicarboxylic acid

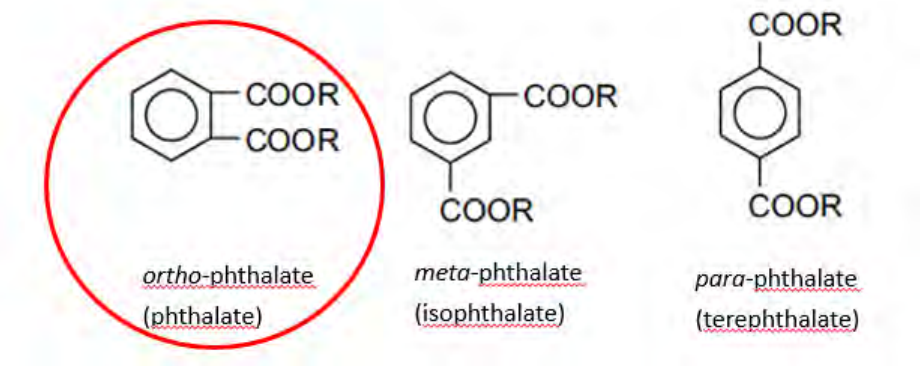


Figure 1: Three isomeric forms of phthalic acid esters. The R-group is the carbon chains from C1 to C13.

The isomeric form being investigated in this report is *ortho*-phthalates, which are esters of ortho-phthalate acid, which have the CAS name of 1,2-benzene dicarboxylic acid[12]. This isomeric form is very often simply called a "phthalate". From this point on, the word "phthalates" refers in this report only to ortho-phthalate acid esters based on ortho-phthalic acid (1,2-benzene dicarboxylic acid). See the structural formula in Figure 2.

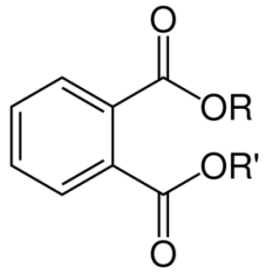


Figure 2: Basic structural formula for a phthalate where R and R' represent ester side chains (ester groups).

The other isomeric forms can also be used as plasticisers, but in this case, they are included in the group known as phthalate-free plasticisers. In particular, terephthalates are a popular alternative to ortho-phthalates [13]. One example of a terephthalate is dioctyl terephthalate (DOTP/DEHTP).

[10] Danish Environmental Protection Agency, 2013. Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013 http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf
[11] Wypych, G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.
[12] Danish Environmental Protection Agency, 2013. Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013 http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf
[13] Wypych, G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.

The most common ortho-phthalates have ester groups whose main carbon chain lengths vary from 1 carbon (C1) to 13 carbon (C13) atoms[14] and which derive from the alcohols methanol and ethanol (C1/C2) to tridecanol (C13)[15]. Ester groups can be linear, branched or a combination of linear, branched and ring structures[14].

Phthalates can be split into three groups based on the number of carbon atoms in the ester groups' main carbon chains[16]. This split is based on the phthalates' physical, chemical and toxicological properties. The naming convention used by the European industry organisation for plasticisers and in this report is high molecular weight phthalates, low molecular weight phthalates and other phthalates. The three groups have the following characteristic features:

- **high molecular weight phthalates** (HMW) - examples of these are DINP, DIDP, DPHP, DIUP and DTDP. They are produced from alcohols with linear carbon chains with carbon chain lengths > 7, or else from a benzyl alcohol combined with a diester group with a total carbon chain length > 7 [17]. They have 7 to 13 carbon atoms (C7-C13) in the ester groups' main chains[18]. Their solubility in water is very low.

- **low molecular weight phthalate**s (LMW) - examples of these are DEHP, DBP, DIBP, BBP. They are produced from alcohols with linear main carbon chains with 3-6 carbon atoms. They have 3-6 carbon atoms (C3-C6) in their ester groups' main chains[19]. Their solubility in water is slightly higher than that for high molecular weight phthalates, while human toxicity and toxicity for reproduction are usually present.

- **other phthalates (**with the lowest molecular weight) - examples of these are dimethyl phthalate (DMP) and diethyl phthalate (DEP). They are produced from alcohols with < 3 carbon atoms in the carbon chain[20]. They have a higher volatility, solubility in water and potential aquatic toxicity than the high and low molecular weight phthalates. They generally have a lower toxicity in humans than low molecular weight phthalates.

The level of toxicity usually depends on the carbon chains' length, with shorter carbon chains (LMW) having a higher toxicity[20]. In particular, phthalates with a carbon chain length of 4-6 carbon atoms (C4-C6) in the main chain have demonstrated toxicity for reproduction[21].

[14] NICNAS, 2008. Phthalates Hazard Assessment Reports. Available: 12.03.2014 http://www.nicnas.gov.au/chemical-information/other-assessment-reports/phthalates-hazard-assessment-reports
[15] Plasticisers.org, 2014a. Not all phthalates are the same. Available: 12.03.2014 http://www.plasticisers.org/plasticisers/not-all-phthalates-are-the-same
[16] US EPA, 2006. High production volume (HPV) Chemical challenge program. Test plan for the phthalate esters category. http://www.epa.gov/hpv/pubs/summaries/benzene/c13467rt3.pdf
[17] US EPA, 2006. High production volume (HPV) Chemical challenge program. Test plan for the phthalate esters category. http://www.epa.gov/hpv/pubs/summaries/benzene/c13467rt3.pdf
[18] Plasticisers.org, 2014. Not all phthalates are the same. Available: 12.03.2014 http://www.plasticisers.org/plasticisers/not-all-phthalates-are-the-same
[19] Plasticisers.org, 2014. High phthalates. Available: 12.03.2014 http://www.plasticisers.org/plasticisers/high-phthalates
[20] Danish Environmental Protection Agency, 2013. Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013 http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf
[21] NICNAS, 2008. Phthalates Hazard Assessment Reports. Available: 12.03.2014 http://www.nicnas.gov.au/chemical-information/other-assessment-reports/phthalates-hazard-assessment-reports

The most commonly used phthalates as PVC plasticisers are phthalate acid esters which have ester groups with a main carbon chain length of 6 to 13 atoms (C6-C13)[22].

3.2 Use in the EU and the rest of the world

The most common use of phthalates is as plasticisers in PVC. In 2012 phthalates accounted for just over 78% of the global consumption of plasticisers, which marks a 10% reduction compared to 2005. According to the forecast for 2018, there will be a further reduction in this proportion of global consumption to 75.5%. In spite of this reduction, the total global consumption of phthalates is expected to increase by a further 2.4% between 2011 and 2018 in line with the rising demand for plasticisers. The global consumption of low molecular weight phthalates is expected to fall in many regions as a result of being replaced mostly by non-phthalates[23].

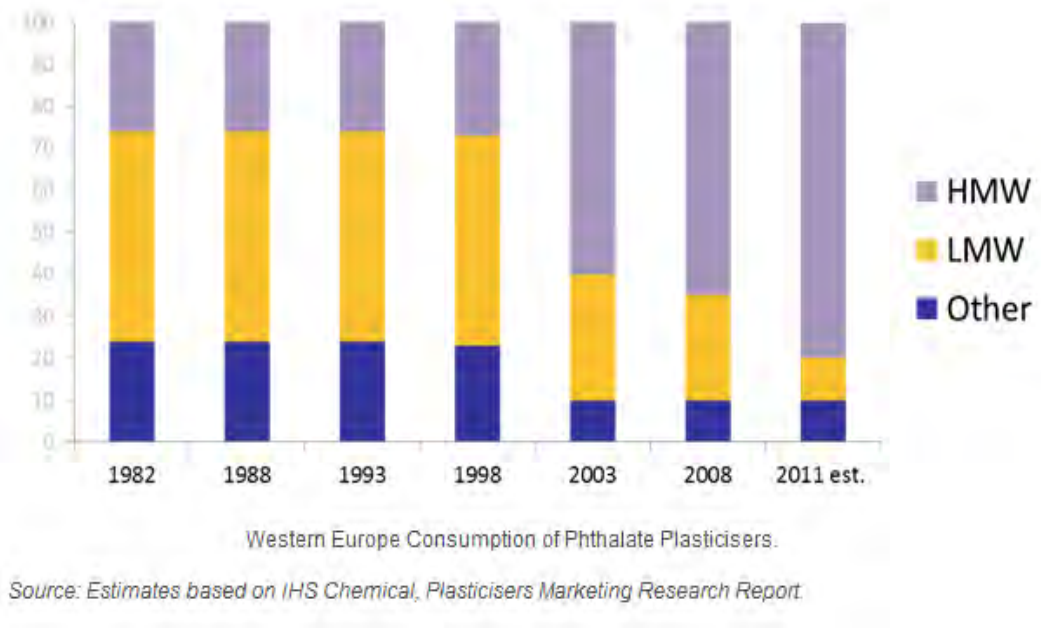
The trend for using plasticisers varies in different parts of the world. On the EU market, the high molecular weight phthalates (DINP, DIDP and DPHP) dominate and the proportion of DEHP is relatively small[24], only about 10 per cent[25]. In the rest of the world market, on the other hand, it is DEHP which dominates with almost 50 per cent of the market, while the proportion of high molecular weight phthalates and non-phthalates is roughly equal[26]. In this case, non-phthalates account for a higher proportion than they do in the European market. On a global scale, DEHP and DINP are the most important plasticisers [27].

Currently, high molecular weight phthalates account for around 85% of all phthalates manufactured in Europe[28]. ECHA's database of registered substances features 26 phthalates. There is a higher number of phthalates registered in the Swedish Product Register (42 phthalates) as registration is required if 100 kg or more of the substance is used per year. Of the 13 phthalates in the candidate list only five have been registered for use in the EU. These are the four substances in the authorisation list, plus DIPP. DIPP is only registered in quantities of 10-100 tonnes/year by a company which produces explosives and propelling charges[29].

There are a total of 41 phthalates registered in the EU, the product register (> 1 tonne/year) or in the candidate list.[30] The most commonly used high molecular weight phthalates in Europe

[22] Godwin, A.D., 2011. Plasticizers (chapter 28). I: Kutz, M. (ed). Applied plastics engineering handbook. Plastics Design Library (pdl) e-book.
[23] IHS Chemical, 2013. Plasticizers. Abstract from a market report on plasticisers published in January 2013. Available: 27.02.2014 http://www.ihs.com/products/chemical/planning/ceh/plasticizers.aspx
[24] Saykali, 2013. Dispelling myths and communicating science. Vinyl Sustainability Forum, Istanbul, 26 April, 2013. European Council for Plasticisers and Intermediates (ECPI) (PowerPoint presentation). http://www.vinylplus.eu/uploads/VSF13/Saykali_ECPI.pdf
[25] Plasticisers.org, 2014. DEHP. Available: 02.04.2014 http://www.plasticisers.org/en_GB/plasticisers/low-phthalates/DEHP
[26] Saykali, 2013. Dispelling myths and communicating science. Vinyl Sustainability Forum, Istanbul, 26 April, 2013. European Council for Plasticisers and Intermediates (ECPI) (PowerPoint presentation). http://www.vinylplus.eu/uploads/VSF13/Saykali_ECPI.pdf
[27] Godwin AD, 2011. Plasticizers (chapter 28). I: Kutz, M. (ed). Applied plastics engineering handbook. Plastics Design Library (pdl). E-book.
[28] Plasticisers.org, 2014. High phthalates. Available: 12.03.2014. http://www.plasticisers.org/plasticisers/high-phthalates
[29] Hagen Mikkelsen S, Maag J, Kjølholt J, Lassen C, Nylander Jeppesen C, Clausen AJ, 2014. Survey of selected phthalates. Part of the LOUS-review. Environmental Project No. 1541. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-95-7.pdf
[30] Swedish Chemicals Agency 2014 "Kartläggning av ftalater i varor" (Surveying the occurrence of phthalates in products). PM 2/14.

are DINP, DIDP and DPHP [31], while the most common low molecular weight phthalate is DEHP[25].



Source: Estimate based on *IHS Chemical, Plasticisers Marketing Research Report 2013. Plasticisers.org, 2014. High phthalates. http://www.plasticisers.org/plasticisers/high-phthalates, Available: 12.03.2014*

Figure 3: Consumption of high molecular weight (HMW) and low molecular weight (LMW) phthalates in Western Europe as a percentage between 1982 and 2011.

3.2.1 Use and trends – plasticisers

The global consumption of plasticisers was approximately 6.4 million tonnes per year during 2011[32]. Of these 54.7% (3.5 million tonnes) were used in Asia and the Pacific Region, 15.6% (1 million tonnes) in Europe and 12.5% (0.8 million tonnes) in North America.

It is not completely unexpected that China is the largest market for plasticisers in the world, accounting for almost 38% of the global consumption of plasticisers in 2012[33]. Other Asian countries, including Japan, accounted for the next largest proportion (21%) of global consumption, followed by Western Europe (16%) and North America (13%).

The forecast demand for plasticisers between 2011 and 2018 varies for different regions. China has the largest forecast growth, which is driven by an increased consumption of plasticisers in articles for both the domestic market and export. Demand in North America is expected to rise by around 2.2% per year, whereas it is expected to increase in Europe only by 1.2%, with approx. 1% of this in Western Europe and approx. 1.9% per year in Central and Eastern Europe[33].

[31] ECHA, 2014. Registered substances (database) last updated 19.03.2014. http://ECHA.europa.eu/en/information-on-chemicals/registered-substances

[32] Cullen S, 2012. Global plasticizer update. SPI flexible vinyl products conference, July 2012. Eastman Chemical Company. (PowerPoint presentation (calculations from Eastman)). Available: 12.03.2014 http://www.plasticsindustry.org/files/events/Stephen%20Cullen_Tuesday.pdf

[33] IHS Chemical, 2013. Plasticizers. Abstract from a market report on plasticisers published in January 2013. Available: 27.02.2014. http://www.ihs.com/products/chemical/planning/ceh/plasticizers.aspx

The global consumption of plasticisers other than phthalates (i.e. terephthalates, aliphatic dibasic esters, trimellitates, epoxy esters, polymeric plasticisers, benzoates and phosphate esters) is expected to rise by around 5.7% per year between 2011 and 2018. It is primarily the use of terephthalates, benzoates and some aliphates (mainly hydrogenated phthalates) which is expected to increase quickly as they replace phthalates, but also other aliphatic plasticisers such as citrates and aliphatic phenyl sulphonic acid esters are expected to rise significantly, although in a smaller volume[33]. There is concern about the increase in the use of alternative plasticisers being restricted by a capacity shortage[34]. One of the alternative plasticisers whose use is growing rapidly is DINCH.

According to the same reference, non-phthalates accounted for around 22% of plasticiser demand in Europe in 2011, which was then a total of 1.2 million tonnes, marking a rise compared with the 2011 figures. The largest was the use of non-phthalates in North America where they accounted for approx. 30%, whereas non-phthalates in China only accounted for 5% of plasticiser consumption[34].

3.2.2 Use and trends globally – PVC

The information about PVC consumption which has been demonstrated varies somewhat. According to the PVC organisation, the global consumption of PVC comes to more than 35 million tonnes/year, with approx. 6 million tonnes/year of this being consumed in Europe. The global demand for PVC will probably rise to 49 million tonnes in 2017, with the largest growth being seen in the developing countries in the Asia-Pacific Region and Middle East[35], but no direct growth is expected in Europe and North America[36].

Out of the total PVC production in Europe approx. 30% is used to produce soft PVC[37]. At a global level, the proportion is higher, around 36%[38] which then gives a global consumption of about 12.2 million tonnes of soft PVC.

3.3 Current legislation

3.3.1 EU regulations

Hazard classification of chemicals (CLP)

The CLP Regulation[39] contains rules for classifying, labelling and packaging chemicals. The hazard classification of chemicals provides a foundation for chemical legislation. Some substances have an EU-harmonised classification, in which case they feature in Annex VI of CLP. If this harmonised classification is available, it must be used for chemicals. For

[34] Weeks H, 2012. Market Growth Seen for Non-Phthalate Alternatives. Chemical Week; Jul 16-Jul 23, 2012; 174, 19.
[35] PRWeb, 2012. Global Polyvinyl Chloride (PVC) Market to Reach 49 Million Tons by 2017, According to New Report by Global Industry Analysts, Inc. San Jose, California (PRWEB April 13, 2012 (news article) Available: 09.04.2012. http://www.prweb.com/releases/polyvinyl_chloride/PVC_market/prweb9400344.htm
[36] Research and Markets, 2010. Polyvinyl Chloride (PVC) Supply Dynamics to 2020 – China Emerges as the Leader in Global Production. (description of market report from GBI research). Available: 09.04.2014. http://www.researchandmarkets.com/research/a11d5c/polyvinyl_chloride
[37] Plasticisers.org, 2014. Not all phthalates are the same. Available: 12.03.2014 http://www.plasticisers.org/plasticisers/not-all-phthalates-are-the-same
[38] Emanuel C, 2011. Plasticizer market update. SPI Vinyl Products Division, 22nd Annual Vinyl Compounding Conference, July 10-13, 2011. BASF Corporation. http://www.cpsc.gov//PageFiles/126090/spi.pdf
[39] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

chemical products lacking a harmonised classification, anyone releasing the product on the market must classify it themselves based on given criteria featuring in relevant regulations (CLP or older regulations being applied during a transition phase).

The hazard classification of phthalates is of great importance in terms of how these substances can be used in articles, based on the legislation on articles generally referring to the CLP classification. All the phthalates in the candidate list (see Table 1) are classified under CLP as belonging to the category toxic for reproduction 1B and all have the hazard statement "H360D: May damage the unborn child". Most of them also have the hazard statement "H360F: May damage fertility" or "H361f: Suspected of damaging fertility".

A substance can be given a harmonised classification by the authorities and manufacturers in individual EU Member States, importers or downstream users requesting for classification and labelling of the substance to be harmonised within the whole EU. This can be done if, for instance, the substance has CMR properties.

Proposals for a harmonised classification and labelling of a substance (CLP proposal) must be submitted to ECHA along with proof of the scientific reasons for the request. ECHA then organises a public consultation. Once the consultation process is over, ECHA forwards all the comments which have been received to the Member State or the companies which have submitted the proposal.

The proposal, comments and response from whoever submitted the documentation are passed on to ECHA's Committee for Risk Assessment (RAC), which is made up of experts who have been nominated by EU Member States and appointed by ECHA's Management Board. The Committee prepares a scientific opinion on the proposal. The Commission then decides, assisted by REACH's regulatory committee, on the harmonised classification and labelling of the relevant substance.

REACH

One of the purposes of REACH[40] is to produce information about substances' properties, use and risks to ensure a high level of protection for human health and the environment. Substances involving unacceptable risks may be regulated via requiring authorisation and/or imposing restrictions/bans.

Registration

Any manufacturer or importer of chemical substances in quantities of at least 1 tonne per year must register them with the European Chemicals Agency (ECHA). Registration must include a variety of data, including details about the substance's hazardous properties. In the case of hazardous substances in volumes exceeding 10 tonnes, a special risk assessment must be carried out (Chemical Safety Report) covering every area of use. A substance which is not registered within the specified timeframes cannot be manufactured or released on the EU market.

Authorisation

Substances which may have a serious impact on human health or on the environment may be included in Annex XIV of REACH, making them subject to authorisation. The aim is for substances requiring authorisation to be replaced by less hazardous substances or other techniques when financially and technically possible. Substances featuring in Annex XIV

[40] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals.

cannot be used or released on the market without authorisation. The decision to include substances in Annex XIV is made by the Commission based on a vote in a regulatory committee where the Member States vote for the proposal. Authorisation may be requested by the manufacturer, importer or user of the substance. The first step in including a substance in Annex XIV is to include the substance in the candidate list. ECHA selects a number of substances from the candidate list which the authority recommends the Commission to register in Annex XIV.

Candidate list

The candidate list contains substances which can have a serious impact on human health and the environment, known as Substances of Very High Concern (SVHCs). ECHA published the first candidate list in October 2008. Identifying substances which can be included in the candidate list is an ongoing process. When a substance is included in the candidate list, certain requirements are imposed on companies manufacturing, importing or using the substance. If the substance has a concentration above 0.1% in an article, the supplier must advise of this. Consumers are entitled, upon request, to receive appropriate information free of charge within 45 days. In some cases, the manufacturer/importer must also make an application to ECHA about which articles the substance is contained in.

Restriction

REACH includes a process allowing the EU Commission to restrict or ban the manufacture, release on the market and use of a substance within the EU. A restriction may also extend to articles containing the substance. Restrictions and bans are listed in Annex XVII of REACH. To have a substance included in Annex XVII, the material in the proposal needs to indicate that using the substance entails an unacceptable risk to health and/or the environment which must be regulated at EU level and that the proposed measures are justified from a socio-economic perspective. Restriction proposals can be drawn up by responsible agencies in EU Member States or by ECHA (at the EU Commission's request). A restriction may be applied to the individual substance or to the substance as a constituent component of an article or mixture and cover specific areas of use or any use of the substance. A national authority must register its proposal with ECHA before submitting it. The proposal is examined and assessed by ECHA's Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC), and published for public consultation on the ECHA website. The next step is for the EU Commission to draw up a restriction proposal to be put to a vote in the Commission's regulatory committee where Member States will vote on the proposal.

Fast-track process for restriction

The task of producing a restriction requires great effort in terms of time, expertise and of gathering data. However, according to REACH Article 68.2 (known as the "fast track"), it is possible to apply a simplified process for restricting substances meeting the criteria for classification as CMR substances in category 1A or 1B according to the CLP Regulation and which consumers may be exposed to. Such a process waives the requirement for risk assessment and socio-economic analysis and therefore, for any review and assessment by the RAC and SEAC. This simplified process can be applied to both chemical products and articles.

In the case of substances featuring in chemicals intended for consumer use, the restriction process under Article 68.2 already applies. Based on the EU Commission's proposals and after the vote in the Commission's regulatory committee, the substances are registered in Annex XVII. Consequently, the substances will be banned for consumer use in chemicals. On the other hand, when the substances are contained in an article, the procedure involved is not

as clear-cut. At the Commission's initiative, discussions are in progress about the criteria and design for material used to draw up a restriction proposal, as well as about the extent to which an individual Member State can require a restriction. However, it is the Commission which enjoys the right of initiative to propose a restriction. The Commission has taken the initiative to commence work on restricting CMR substances in textiles, based on Article 68.2.

Existing REACH regulations on phthalates in articles

Phthalates are regulated in different ways by REACH's provisions. The following 13 phthalates appear in the SVHC candidate list:

Table 1: Phthalates in the candidate list for autumn 2014. Substances highlighted in bold also appear in Annex XIV of REACH (Authorisation list)

CAS No.	Name
117-81-7	**Di(2-hexyl ethyl) phthalate (DEHP)**
117-82-8	Bis(2-methoxyethyl) phthalate; Di(2-methoxyethyl) phthalate (BMEP; DMEP)
131-18-0	Dipentyl phthalate (DPP)
605-50-5	Diisopentyl phthalate (DIPP)
68515-42-4	1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)
71888-89-6	Di(C6-8-branched) alkyl phthalates (DIHP)
776297-69-9	N-pentyl-isopentylphthalate
84-69-5	**Diisobutyl phthalate (DIBP)**
84-74-2	**Dibutyl phthalate (DBP)**
84-75-3	Di-n-hexyl phthalate (DnHP)
84777-06-0	1,2-benzenedicarboxylic acid, dipentylester, branched and linear
85-68-7	**Benzyl butyl phthalate (BBP)**
271-093-5	1,2-benzenedicarboxylic acid, dihexylester, branched and linear

Four phthalates (highlighted in bold) are listed in Annex XIV. This means that the use of these substances will be banned in the EU from 21 February 2015 unless authorisation has been obtained to use them for a specific purpose. The deadline for requesting authorisation has passed (21.08.2013).

Only the substances' use as such is covered by the authorisation requirement. This means that authorisation is required to import these phthalates into the EU, to produce them and to use them, for instance, in manufacturing articles in the EU. The remaining phthalate in the candidate list which has a registered use in the Europe, DIPP, has a registered use of only 10-100 tonnes per year. Consequently, the authorisation requirement largely covers the significant phthalates toxic for reproduction used in the EU. However, the authorisation requirement does not affect the use of these phthalates in imported articles.

In order to manage exposure to phthalates in imported articles, a restriction is required to be included in Annex XVII of REACH. There are no general bans against phthalates in articles. A proposal was tabled by Denmark in 2011 on banning the use of DEHP, BBP, DBP and DIBP in consumer products. However, the proposal failed to receive the backing of the EU's Committee for Risk Assessment (RAC) as it believed that the available data failed to show there was any risk from combined exposure from phthalates.

On the other hand, the use of certain phthalates is restricted in toys and childcare articles. DEHP, DBP and BBP must not be used in toys and childcare articles at concentrations exceeding 0.1% in total by mass of the plasticised material. Furthermore, DINP, DIDP and DNOP must not be used in toys and childcare articles which children can put in their mouth at concentrations exceeding 0.1% in total by mass of the plasticised material. This ban extends to all articles released on the EU market, which also includes imported articles. These bans supplement the restrictions on phthalates which already apply under the Toy Safety Directive (see below). However, the REACH restrictions have another area of application as they not only extend to toys but also to childcare articles. The restrictions on phthalates featuring in Annex XVII (points 51 and 52) include a review clause, tasking the Commission with re-evaluating the need to make changes to the restriction by 16 January 2010 at the latest. This review has been carried out, but did not produce any proposals for changes. DEHP, DBP and BBP are listed in Annex XIV and will therefore be subject to an authorisation requirement and a requirement for ECHA to consider the need to propose a restriction on the three phthalates in imported articles. With regard to DINP, DIDP and DNOP, ECHA's Committee for Risk Assessment has been unable to prove that other uses would entail a risk. Therefore, the Commission did not propose that the restriction would extend to any new uses in addition to those which already apply.

The Toy Safety Directive

The Toy Safety Directive[41] was renegotiated during 2009, which led to the chemical requirements being tightened significantly. The Directive contains a general restriction on CMR substances. This means that the toy's accessible parts must not contain the substances at concentrations exceeding the classification level. The Directive covers all categories of CMR substances: 1A, 1B and 2. It can be compared with REACH, which only defines the first two categories as SVHCs.

As all the phthalates in the candidate list come under CMR classification 1A or 1B, they are covered by the ban in the Toy Safety Directive. Since the regulations in the Toy Safety Directive are based on the CLP classification, a number of phthalates will be covered if they were to be classified as CMR in categories 1-2.

EU Regulation on plastic materials and articles intended to come into contact with food

In the case of plastic materials and articles intended to come into contact with food, an EU regulation imposes restrictions on DEHP, DBP, BBP, DINP and DIDP.[42] These restrictions apply to the total phthalate concentration in plastics which come into contact with food and to specific migration limits (SMLs).

RoHS directive (electrical equipment)

The RoHS Directive[43] restricts the use of certain hazardous substances in electrical and electronic equipment. The aim is to reduce the risks to human health and the environment by replacing hazardous substances with less hazardous alternatives or alternative technology. The substances which are currently restricted by the RoHS Directive are mercury, cadmium, lead, hexavalent chromium and the brominated flame retardants PBB and PBDE.

[41] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.
[42] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.
[43] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The RoHS Directive does not currently contain any restrictions on phthalates. However, the Commission is preparing a proposal on restricting the use of a number of substances. The new substances which may be restricted are DEHP, BBP, DBP and DIBP. The Commission is expected to make a decision on the proposed substances in early 2015.

If the proposal is adopted, this means that these phthalates will no longer be allowed to feature in electrical and electronic equipment released in the EU market above the specified limits. However, there is an option to apply for a temporary exemption from the restrictions based on a special procedure in the Directive.

Medical Device Directive

EU regulations governing medical devices are split into three directives. There is one for medical devices[44], one for active implantable medical devices[45] and one for in vitro diagnostic medical devices[46]. These regulations stipulate that medical devices which are released on the market and used must be safe and fit for their purpose and that the risks involved in using the products must be acceptable in terms of the benefits for the patient and compatible with a high level of health and safety protection.

There are currently no bans applied to phthalates in medical devices. On the other hand, medical devices are required to be designed and manufactured in a manner that minimises as far as possible the risks of substances, especially CMR substances, leaking out of the products.

Only a labelling requirement applies to medical devices containing phthalates classified as category 1 and 2 CMR substances. The labelling requirement applies to medical devices or components of medical devices which are used to administer and/or remove medicines, bodily fluids or other substances from the body, or to devices intended for transporting or storing these bodily fluids or substances. The labelling must indicate that the product contains phthalates. If the medical device is to be used for treating children, pregnant women or breast-feeding mothers, the manufacturer must give a special reason for using these substances.

These three medical device directives are currently under renegotiation. During the Council negotiations, Sweden has proposed a ban on the use of CMR and endocrine-disrupting substances in the REACH candidate list in certain medical devices. According to the proposal, the Commission must be able to permit exemptions from the ban in certain cases.

Cosmetic Products Regulation

Substances which have been classified as category 1A or 1B CMR substances, including all phthalates on the REACH candidate list are usually banned under the Cosmetic Products Regulation.[47] The substances may be used in exceptional cases if a number of conditions are met. These conditions are briefly the following:

- The substance must meet food safety requirements.
- There are no alternative substances, which must be confirmed by a special analysis.
- The use relates to a specific product category with known exposure.
- The substance has been assessed by the Scientific Committee on Consumer Safety (SCCS) and found to be safe in a number of circumstances.

[44] Directive 93/42/EEC of the European Parliament and of the Council concerning medical devices.
[45] Directive 90/385/EEC of the European Parliament and of the Council relating to active implantable medical devices.
[46] Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.
[47] Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, Article 15.

There are also specific labelling requirements for products containing CMR substances. Category 1A or 1B CMR substances which are authorised must be re-assessed as soon as there are any doubts concerning their safety or, otherwise, at least every five years. By adding numerous conditions to the exemption rule, it is assumed that only a few substances will be granted an exemption.

Construction Products Regulation

The EU's Construction Products Regulation[48] is intended to facilitate the free trade in construction products on the internal market. This regulation governs how construction products' features will be assessed and described when the products are placed on the market. The regulation is not intended to impose requirements on the actual products, for instance, in terms of health or environmental properties. These requirements feature instead at national level or in other EU regulations.

The Construction Products Regulation stipulates that construction products covered by a harmonised standard must, from 1 July 2013, be provided with a declaration of performance and CE marking, permitting them to be sold within the EU. Harmonised standards are drawn up for the EU Commission based on Member States' requirements. The standards contain methods and criteria for assessing and describing the details of products' properties in the manner required under the relevant Member State's national legislation.

The Construction Products Regulation also stipulates how information about hazardous substances should, in accordance with Article 33 of REACH, be provided to those receiving construction products. This regulation states that the information must accompany the declaration of performance. The regulation also goes further than REACH as it requires this information to be supplied for every delivery, including to consumers. According to REACH, consumers will only receive this information on request and then within 45 days.

3.3.2 Other initiatives

Regulations governing the production, distribution, use and waste management for articles are of an increasingly global nature. Therefore, as part of the UN's global chemicals strategy, SAICM (Strategic Approach to International Chemicals Management), an initiative has been adopted to promote a programme (Chemicals in Products - CIP), providing information about chemicals in products where all the stakeholders must have access to information enabling them to handle chemicals safely throughout the life cycle.[49]

One aim of the CiP is to promote material cycles which are resource-efficient and free from hazardous substances as far as possible. Access to information is important not only in terms of protecting the environment and health, but also for creating efficiently operating markets.

The CiP is run by the UN's environmental programme UNEP. The project has prioritised four product groups so far: toys, electronics, textiles and construction products.

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[48] Regulation (EC) No 305/2011 of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products.

[49] SAICM Overarching Policy Strategy, Article 15 (b): "To ensure, for all stakeholders: i. That information on chemicals throughout their life cycle, including, where appropriate, chemicals in products, is available, accessible, user friendly, adequate and appropriate to the needs of all stakeholders. Appropriate types of information include their effects on human health and the environment, their protective measures and regulation; ii. That such information is disseminated in appropriate languages by making full use of, among other things, the media, hazard communication mechanism's such as the Globally Harmonized System of Classification and Labelling of Chemicals and relevant provisions of international agreements".

UNEP establishes a voluntary programme targeted at industry. The programme is intended to facilitate the distribution of information about chemicals in articles. The draft programme is intended to be negotiated and adopted during 2015.

3.3.3 National regulations

Legislative initiative in Denmark

A proposal was tabled by Denmark in 2011 on banning the use of DEHP, BBP, DBP and DIBP in consumer products throughout the EU, based on a REACH restriction. These phthalates are already included in the REACH authorisation list. However, the proposal failed to receive the backing of the EU's Committee for Risk Assessment (RAC) as it believed that the available data failed to show there was any risk from combined exposure from phthalates. Therefore, Denmark went ahead and imposed a national ban. The ban, which was to apply to concentrations above 0.1% in articles for internal domestic use and in articles which may come into direct contact with the skin or mucous membranes, was intended to come into force from 2015.

In August 2014, Denmark advised that it was withdrawing the national ban in the wake of criticism from the Commission. The Commission believed that the national ban could not be justified in light of the earlier statement made by the RAC and of the Commission's own decision not to adopt a restriction in REACH. In the Commission's view, the restriction process in REACH also means that Member States are not allowed, in principle, to proceed with national chemicals restrictions. This is an interpretation which has been criticised and is not shared by the Swedish Chemicals Agency, see Appendix 5.

Labelling regulations in France for volatile organic compounds (VOCs)

France has introduced a requirement for certain construction products to be labelled with regard to emissions of volatile organic compounds (VOCs). This compulsory labelling applies to construction products for internal domestic installations, flooring and wall coverings, paints and varnishes in emission classes. It is based on measuring any discharge.

Manufacturers or distributors classify their products at their own risk of liability. The regulation stipulates that all relevant products should be labelled with the emission class which the product belongs to from 1 September 2013. There are four classes: C, B, A and A+. The regulation specifies the concentrations marking the boundaries between the individual classes.

The labelling requirement only applies to certain, specifically identified VOCs, and does not currently apply to phthalates.

Emission limits in France, Germany and Belgium for CMR substances

With the aim of minimising exposure in an indoor environment, specific limits apply in France for CMR substances, including DEHP and DBP, used in building and decorating materials. Since 1 January 2010, only construction products with an emission level below 1 $\mu g/m^3$ can be used in France. Belgium also decided in 2012 to impose binding emission limits on substances, including CMR substances, in specifically identified construction products.

There are similar regulations in Germany, but only in the form of guidelines. They apply to guideline values for VOC emissions, with special values for carcinogens. There is also a

restricted list in Germany featuring indicative values linked to guidelines on sustainable construction.

Restrictions in France on use of DEHP in certain medical equipment

From 1 July 2015, there will be a ban in France on the use of tubes/pipes containing DEHP in paediatric, neonatal and maternity departments in hospitals. The law also paves the way for a future ban on DEHP, DBP and BBP in all medical devices if alternative materials are available and the equipment's safety can be guaranteed.

Current EU regulations on medical devices only feature a labelling requirement for phthalates. However, Sweden has drafted proposals, including one on banning the use of the phthalates in the REACH candidate list in medical devices.

3.3.4 National market surveillance

The task of supervising the application of the regulations restricting the occurrence of phthalates in articles is performed by the Swedish Chemicals Agency, along with local authority environmental and health protection boards. The regulations which are monitored are restrictions on the use of phthalates in toys and childcare articles in the REACH Regulation[50], as well as the duty to inform in REACH, which applies to particularly hazardous substances occurring in articles[51]. The Swedish Chemicals Agency's market surveillance may also include phthalates in toys, which are classified as CMR substances, which means that they come under the scope of the general CMR restriction featuring in the toy safety law[52].

The market surveillance of phthalates is often based on chemical analyses which the authorities have had carried out on articles. If analyses indicate the presence of a phthalate which is restricted at concentrations exceeding a limit, the companies who have released the article on the market are contacted with a view to examining what measures they will take. The company may be forced to recall the articles from its customers if they are resellers. The authorities may decide on a sales ban in cases where the company does not stop voluntarily selling the article. The market surveillance authorities and company discuss which processes the company needs to develop to avoid any recurrence of the breach. If any phthalates in the candidate list are detected in articles with a concentration above 0.1% by mass, companies in the supplier chain are contacted to verify whether the duty to inform under the REACH Regulation has been fulfilled. Checks may also be initiated on the basis of information received by the authorities via, for instance, reports from consumers or organisations which have had tests carried out.

Any suspected breach of the Swedish Environmental Code is reported to the environmental prosecutor if a restricted phthalate has been found in a concentration exceeding the limit or when a company is considered to have failed to inform its recipients about the content of

[50] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Annex XVII, points 51-52.
[51] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 33.
[52] The Swedish Safety of Toys Act (2011:579), the Toys Ordinance (2011:703), as well as regulations from the Swedish Consumer Agency, National Electrical Safety Board and Swedish Chemicals Agency implement EU Directive 2009/48/EC on the safety of toys. These regulations contain a restriction on substances classified as carcinogenic, mutagenic or toxic for reproduction, based on the rules for classifying chemicals. These substances must not be used in toys' accessible parts at concentrations exceeding the limits applicable to classifying mixtures. Some phthalates may be affected by this restriction.

substances in the candidate list. The environmental prosecutor then assesses whether a preliminary investigation should be initiated. The appropriate scale of sanctions for the two offences – environmentally hazardous handling of chemicals[53] and incomplete environmental information[54] – are a fine or up to two years' imprisonment. The market surveillance authorities have a duty to report any suspected breach. If the CMR restriction on toys is not observed, no report is submitted to the prosecutor as this is not a punishable offence under the Safety of Toys Act. But, in this case, the authorities only take the measures required to prevent the relevant article from being released on the market any longer. However, the authorities may request the court to impose a sanction charge on a trader. Such a request may be submitted if a trader has wilfully or neglectfully breached certain clearly specified provisions in the act, for instance, recurring offences.

While carrying out analyses as part of its market surveillance, the Swedish Chemicals Agency has found phthalates in a wide variety of articles made from soft plastic. Examples of such articles are dolls and other plastic toys, gloves and shoes, exercise equipment, furniture upholstery and flooring.

4 Survey of phthalates

4.1 Phthalates in chemical products

Data from the Swedish Chemicals Agency's Product Register has been used to obtain some idea of the volumes of phthalates derived from manufacturers and importers of chemical products. It is based on information supplied by those applying to the register in 2012.

The total volume of phthalates reported to the product register in 2012 was 34,130 tonnes/year, 76% of which or 25,826 tonnes was exported.

The total volume of phthalates in Swedish chemical products when exports have been deducted: 8,304 tonnes/year.

Their key function (product area) is as a plasticiser, with the sector using the most phthalates being plastic manufacturers ("Manufacture of plastic products").

Table 2 shows the volumes of the relevant phthalate types which are used in the "Manufacture of plastic products" sector in products available on the Swedish market.

Table 2: Use of phthalates for the sector "Manufacture of plastic products" C22.2 according to the 2012 Product Register.

CAS No.	Common name	Quantity tonnes/year 2012
68515-49-1	Diisodecyl phthalate (DIDP)	2504
117-81-7	**Di(2-hexyl ethyl) phthalate (DEHP)**	**941**
53306-54-0	Di (2-propyl heptyl) phthalate (DPHP)	784
68515-48-0	Diisononyl phthalate (DINP)	635
28553-12-0	Diisononyl phthalate (DINP)	585
..		363

[53] Chapter 29 Section 3, point 9 of the Swedish Environmental Code
[54] Chapter 29 Section 6, point 5c of the Swedish Environmental Code

26761-40-0	Diisodecyl phthalate (DIDP)	106
68442-70-6	1,2-benzenedicarboxylic acid, mixed cetyl and stearyl esters	52
84-69-5	Diisobutyl phthalate (DIBP)	10
Total		***5980***

Orange highlighting indicates phthalates which were in the candidate list on 15.10.2014. **Bold type** indicates phthalates which were in the authorisation list on 15.10.2014.

DIDP is the most commonly used phthalate in the "Manufacture of plastic products" sector, followed by DEHP, DPHP and DINP.

4.1.1 Use of phthalates for different functions and sectors according to the Swedish Product Register

This section describes the volumes of phthalates reported for different functions (product areas) and for different sectors in Sweden in 2012, according to the Product Register.

Table 3 shows the volumes of phthalates reported for different functions (product areas). The total volume of phthalates reported to the Product Register in 2012 was approx. 34,130 tonnes. Plasticisers accounted for the largest function by far with 29,446 tonnes, equivalent to 86% of the phthalates used. The next largest function (which was much smaller) was raw materials for manufacturing plastics, followed by paints and paint thinners, hardeners for plastics, sealants, adhesives and glues and raw materials for rubber manufacture. The remaining 1% is split between 25 different functions where small quantities are used (< 1 tonne).

Table 3: Volumes of phthalates reported in Sweden in 2012 for different functions (product areas) according to the Product Register.

Function (product area)	**Quantity (tonne)**	**Proportion (%)**
Softeners	29,446	86.3
Raw materials for the manufacture of plastics	1,903	5.58
Paints and paint thinners	1,042	3.05
Hardeners for plastics	772	2.26
Sealants	403	1.18
Adhesives and glues	165	0.48
Raw materials for rubber manufacture	105	0.31
Lubricants, other (e.g. ski wax)	53.0	0.16
Stabilisers	43.2	0.13
Other additives	27.8	0.081
Gunpowder, explosives, fireworks	24.0	0.070
Plastic construction material	21.5	0.063
Hardeners, other	20.6	0.060
Other non-specified functions	20.5	0.060
Catalytic agents, other	13.1	0.038
Pigment paste, pigments and colorants	12.1	0.035
Flame retardants and fire retardants	11.1	0.033
Base, motor and gear box oil	10.6	0.031
Floor coverings and seamless flooring	9.4	0.028
Antidegradant, antifouling, disinfection and biocidal products	7.8	0.023

Cutting fluids, cooling oil and coolant	7.4	0.022
Insulation material, electricity and others	4.5	0.013
Coating agents for metal	1.3	0.004
Binding agents, paint, adhesives etc.	1.0	0.003
Mortar, plaster, cement, concrete and putty	< 1	< 0.003
Wax	< 1	< 0.003
Curing agents	< 1	< 0.003
Car and boat care products	< 1	< 0.003
Castable resins, in general	< 1	< 0.003
Construction materials	< 1	< 0.003
Fillers	< 1	< 0.003
Cleaning agents, scourers and fabric conditioners	< 1	< 0.003
Raw materials for cosmetics/personal hygiene industry	< 1	< 0.003
Total	***34,130***	***100***

If they are broken down according to the aggregated product areas, the following phthalates are the most widely used within the relevant area:

- DPHP for plasticisers
- DIDP for paints and varnishes, sealants, as well as adhesives and glues
- DMP for hardeners for plastics
- DEP for thinners (for paint and others)

Table 4 shows the volumes of phthalates recorded in 2012 according to the Product Register instead of by industry in Sweden. This table highlights that the export volume is very large, around 25,826 tonnes/year. This means that most of the volume of phthalates recorded, i.e. 76%, is exported either as phthalates or in chemical products.

Exports are presented in a manner so that they are deducted from other industry codes shown in the table. Therefore, this leaves the products sold on the Swedish market, i.e. 8,304 tonnes. The biggest of these industries is the manufacture of plastic products with 5,977 tonnes, equivalent to 72% of the phthalates used for products intended for the Swedish market. This is followed by a group comprising merged industry codes: manufacture of pesticides/other agrochemical products/wholesale trade of chemical products. It is not known in this investigation which type of products contain phthalates in this group. This group is followed by the "manufacture of rubber articles" and the manufacture of electrical appliances from phthalates used for products on the Swedish market.

Table 4: Phthalates recorded according to the Product Register broken down by exports and the various industries in Sweden.

Industry code (SNI)	**Industry**	**Quantity (tonnes/year)**
Export, total	Export, total	25,826
C22.2	Manufacture of plastic products	5,977
C20.2/G46.75	Manufacture of pesticides and other agrochemical products and wholesale of chemical products	570
C22.1	Manufacture of rubber products	434
C27	Manufacture of electrical equipment	331
F41, F42, F/F43	Construction and civil engineering	268
C25.6	Treatment and coating of metals; machining	192

C20.3	Manufacture of paints, varnishes, printing ink etc.	160
C29	Manufacture of motor vehicles, trailers and semi-trailers	88.9
C16	Manufacture of wood and of products of wood, cork, rattan etc., except furniture	50.1
C20.16	Manufacture of plastics in primary forms	39.1
C20.51	Manufacture of explosives	26.7
S/Q	Other service activities/Human health and social work activities	21.8
G47.523	Retail sale of paints in specialised stores	17.3
G47	Retail trade, except of motor vehicles and motorcycles	15.7
G45.2	Maintenance and repair of motor vehicles	15.3
G45	Wholesale and retail trade and repair of motor vehicles and motorcycles	14.7
C30	Manufacture of other transport equipment	14.2
C20.52	Manufacture of glues	13.0
C18	Printing and reproduction of recorded media	11.4
C32/C26.3/C20.12	Other manufacturing	10.3
G46.9/G46.12	Non-specialised wholesale trade	10.1
C20.59/C21.1/C20.41	Manufacture of chemical products and pharmaceutical products	< 10
C25	Manufacture of fabricated metal products, except machinery and equipment	< 10
C28	Manufacture of other machinery and equipment	< 10
C23.1/C23.4	Manufacture of glass and glass products/Manufacture of other porcelain and ceramic products	< 10
C17	Manufacture of paper and paper products	< 10
C23.31/C19/C23.6	Manufacture of ceramic flags and tiles, concrete, cement etc.	< 10
L/I	Real estate activities/Accommodation and food service activities	< 10
G45.3	Sale of motor vehicle parts and accessories	< 1
G47.3	Retail sale of automotive fuel in specialised stores	< 1
G47.64/G47.643	Retail sale of boats, as well as sports and leisure equipment in specialised stores	< 1
G47.531	Retail sale of carpets, rugs, wall and floor coverings in specialised stores	< 1
C20.42	Manufacture of perfumes and toilet preparations	< 1
P/O84.2	Public services, education	< 1
C31	Manufacture of furniture	< 1
H	Transportation and storage	< 1
C24	Manufacture of basic metals	< 1
D35	Electricity, gas, steam and air conditioning supply	< 1
C13	Manufacture of textiles	< 1
N81.2	Cleaning activities	< 1
C10/C20.14/C21.2	Manufacture of food products/pharmaceutical preparations/other organic basic chemicals	< 1
M71.2	Technical testing and analysis	< 1
A01/A02/B/S96.01/M72	Other use	> 1
Total excluding exports		***8,304***

In the "Manufacture of plastic products" industry where exports have not been counted, the follow phthalates were dominant:

- DIDP (CAS No: 68515-49-1) 2,504 tonnes/year
- DEHP (CAS No: 117-81-7) 941 tonnes/year
- DPHP (CAS No: 53306-54-0) 784 tonnes/year
- DINP (CAS No.: 68515-48-0) 653 tonnes/year
- DINP (CAS No.: 28553-12-0) 585 tonnes/year

4.2 Phthalates in cosmetic products

DEP (diethyl phthalate) is currently the only ortho-phthalate used in cosmetic products in the EU. Other phthalates have either been phased out or banned under the Cosmetic Products Regulation (see Chapter 3). According to the Swedish Medical Products Agency, there is no reason to suspect companies of using banned phthalates in their products. The samples along with the chemical analyses carried out on the contents of cosmetic products have shown that the list of contents which the products carry does tally with the actual contents.

DEP is not used in cosmetics as a plasticiser but mainly as a denaturant, solvent or scent-bearer. DEP has been used in cosmetic products for a long time. However, it is difficult to obtain information about how much DEP is used as it can appear in the list of contents as "alcohol denat". This means that the list does not indicate whether a DEP has been used in the product or some other denaturant.

The Swedish Medical Products Agency used to have a national register of cosmetic products, but this has been discontinued. This has been replaced nowadays by an EU product register managed by the Commission, the "Cosmetic Products Notification Portal" (CPNP), which supervisory authorities and poison centres have access to. The CPNP contains certain information about the products' contents which are linked to the risk of poisoning incidents. Therefore, details of these contents are only available to the poison centres. The EU Commission also has an open database of cosmetic ingredients called CosIng. CosIng does not contain any product information. Neither the CPNP nor CosIng contains large volumes of information or ingredients for the products.

The Swedish Cosmetics, Detergents and Toiletries Association (KTF) compiles figures every year for the sales and value in the product categories, including cosmetics and hygiene products, but not for the substances they contain. A report published by the Swedish Medical Products Agency in 2000 indicated that the consumption of DEP in cosmetic and hygiene products in Sweden amounted to between 3 and 10 tonnes. DEP frequently occurs in "leave-on" products (e.g. perfumes, skin creams and deodorants)[55].

Greenpeace conducted a survey in 2005 investigating the occurrence and concentrations of phthalates in 36 different perfumes. The survey indicated that DEP featured in 34 perfumes, with concentrations varying between 0.4 and 22,299 mg/kg. A number of other phthalates were also found in this study in low concentrations[56].

When very low concentrations of phthalates are discovered in cosmetic products, the Swedish Medical Products Agency believes that it is most likely that these are not ingredients which

[55] Swedish Medical Products Agency, 2000. Ftalater i läkemedel, läkemedelsförpackningar, teknisk sprit, och kosmetiska/hygieniskaprodukter – redovisning av ett regeringsuppdrag (Phthalates in medicinal products, medicinal packaging, synthetic alcohol and cosmetics/hygiene products – government commission report). Ref. no. 291:2000/8257

[56] Greenpeace International Report, 2005. Perfume, an Investigation of Chemicals in Perfumes

have been deliberately added, but contaminants originating from raw materials, manufacturing equipment or packaging material.

In the Swedish Medical Products Agency's view, DEP has been thoroughly investigated and safety assessments have been carried out, showing that it is safe to use in cosmetic products. However, the safety assessment is 10 years old and new material may be available, requiring DEP to be investigated again. According to the Swedish Medical Products Agency, the use of DEP causes concern among consumers as there are so many questions raised nowadays about phthalates as a substance group. Therefore, the Swedish Medical Products Agency advises companies against using DEP as there are alternative ingredients available at present.

4.3 Phthalates in articles

To carry out a proper survey on phthalates used in articles, it is not sufficient to rely on the information featuring in the Swedish Chemicals Agency's Product Register as it only covers chemical products. Articles which are imported in many cases as finished articles are not subject to any duty to register. The survey of articles in this report is based instead on information from different industry associations and similar sources. The most common areas of use for plasticisers are[57]:

- Automotive industry
- Building and construction
- Cables and wires
- Flooring
- Wall coverings
- Packaging – (cling film)
- Toys
- Medical devices

According to data from 2008, the use of plasticisers in Europe was distributed as follows[58]:

- Film and disks 28%
- Cables and wires 22%
- Flooring 13%
- Profiles 11% (e.g. for windows and doors)
- Coatings 13%
- Other 13%

According to data from the PVC Forum[59], the distribution among the PVC products manufactured in Sweden was as follows (data from 2012):

- Plastic flooring 39%
- Pipes 17%
- Cables 11%
- Covered fabric 6%
- Other 11%

The bullet points above feature both hard and soft PVC and only indicate the distribution for items manufactured in Sweden. Among these listed items, PVC mainly occurs in plastic

[57] Plasticsisers.org, 2014. Applications. Available: 19.03.2014 http://www.plasticisers.org/en_GB/applications
[58] Wypych G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.
[59] PVC Forum, 2013. Dagens PVC är ett bra miljöval (Modern PVC is a good environmental option). Version 15.11.2013

flooring, cables and covered fabric. As exports are not included in the calculation, these figures cannot be used to indicate the distribution of PVC articles available on the Swedish market.

The task of quantifying the volumes of phthalates imported into Sweden through articles wholly or partially made of soft PVC is difficult and fraught with a series of uncertainties. There are no data sources available either enabling us to provide detailed information about which phthalates occur in which articles.

In the impact assessment we have used as the basis for this task the information available in the Swedish Chemicals Agency's product guide, based on trade statistics from Statistics Sweden. The Swedish Chemicals Agency has also had a consultation study carried out which provides an overall figure for the volume involved. Based on a rough estimate, the total volumes of phthalates used in chemical products and articles is approx. 20,000 tonnes/year, of which approx. 10,000 tonnes features in imported articles.

Table 5 provides a summary showing examples of articles which contain phthalates within different groups of articles. The data for this table has been extracted from the sources referred to in Chapter 4, i.e. from Appendices 3 and 4, which are based on data from Swedish market surveillance reports and tests on articles, ECHA notifications and Danish surveys.

Table 5: Summary showing examples of articles which contain phthalates within different groups of articles

Use/article group	**Examples of articles which may contain phthalates**
Accessories	plastic combs, watchstraps, belts, umbrellas
Children's articles	prams, changing tables, cots, baby carriers, children's chairs, bibs, aprons, teething toys, soothers, activity mats, child car seats
Plastic-coated fabrics	tarpaulins, awnings
Automotive	underbody coatings (anti-corrosion) and sealants, instrument and door panels, passenger compartment components, window profiles and body sill protectors, cable harnesses, seat covers and mud flaps, car mats, steering wheel covers/sleeves
Building and construction	covering on building facades *(cladding)*, membrane roofing, roof sheets, cables and wires, flooring, wall covering, coated panels, sealant tape, plastic laminate, flexible plastic hoses and pipes, insulating material, protection tape and plastic film, sandpaper, sealant strips for windows and doors, roll-up garage doors, water hoses, valve connectors, tools with plastic handles, toolboxes, as well as chemical products, sealants and adhesives, and paint and varnish.
Electrical and electronic products	PVC cables in domestic appliances (e.g. CD players, TVs and kitchen appliances) and office equipment (e.g. computers, fax machines, copiers and telephones)
Plastic film	for flooring, decorative surfaces (e.g. wall material in ships), furniture film for internal doors and kitchen cabinet doors, swimming pools, textile lamination (e.g. bed underlay), urine bags, blackout curtains, cinema screens, industrial films, weaving tape for plastic mats
Packaging	PVC cling film for packaging food, plastic packaging and blister packaging
Flooring	PVC flooring
Rubber products	rubber-coated fabrics, rubber bellows, rubber or rubber/metal spare parts
Cables and wires	cables for buildings, industries, electrical work, vehicle industry, electrical and electronic products
Toys	dolls, plastic balls, inflatable toys/animals, paddling pools, dressing-up clothes and masks, beads, floor puzzles, play swords
Medical devices	blood bags, infusion fluid bags, probes and catheters, heart-lung bypass and ECMO (extracorporeal membrane oxygen) equipment, gloves, resuscitation dolls, dental composites, dental cement, prosthetics
Furniture and furnishings	leather furniture (e.g. sofas, armchairs, pouffes and covered chairs), plastic furniture, shower curtains, shower hoses, plastic mats, undersides of mats, lampshades, anti-slip devices, Christmas decorations, oilcloths

Shoes	leather shoes, plastic shoes/sandals, boots and soles or other plastic components
Protective equipment	laboratory gloves, oven and cleaning gloves, other protective gloves, earmuffs, insect nets
Sport and leisure	mattresses with PVC covers (e.g. pre-school institutions and gymnastics), trampolines (spring and side protection), Pilates balls, training balls, balls, sports shoes, airbeds, inflatable flotation equipment (armbands, rings, boats, lilos and animals), diving equipment (e.g. snorkel and mask and flippers), cycle handlebars, gazebos, tents, boat fenders
Textiles, clothing	printed or coated textiles and clothing (e.g. printed T-shirts, oilcloths, rainwear) and accessories for textiles, such as buttons, reflectors, zips, badges, sequins and stickers
Garden items	water hoses, garden binding wire, gardening gloves
Wall coverings	PVC coverings, wall coverings
Bags and gloves	bags and gloves made of leather or soft plastic, e.g. wallets, school bags and rucksacks, travel bags watertight bags, computer bags, wallets, cases for tablets and mobile phones
Other articles	Sex toys, hand warmers, animal toys, soap packaging, erasers, storage boxes, manicure sets, soft plastic reflectors

4.3.1 Construction products

The construction industry is the sector where PVC is used most of all[60]. PVC is the most commonly used polymer in building and construction applications[61]. More than 60% of Europe's annual PVC production is used in this sector, which includes a large volume of soft PVC[61]. According to earlier information supplied by the PVC Forum (2007), more than 80% of the PVC manufactured in Sweden is used in the construction industry[60]. Examples of the uses in the building and construction industry include cladding *(facing for buildings)*, as well as roofing membranes, in cables and wires, flooring and wall coverings[61], profiles for doors and windows, coated panels[60] as well as PVC sealant tape and sealant between concrete blocks in dyke structures[62]. Other examples are plastic laminate, flexible plastic hoses and pipes, paint and varnish, insulating material, protection tape and plastic film, sandpaper, sealant strips for windows and doors, roll-up garage doors, water hoses, valve connectors, tools with plastic handles and toolboxes.

Chemical products are also used within the construction sector, such as paints, sealants and adhesives, which may contain phthalates.

The following information emerged from interviews conducted with companies in the sector.

Phthalates are used in PVC roof sheets, but roof sheets based on other plasticisers are also used. An example of a plasticiser used in roof sheets is DINP at concentrations of approximately 30%.

Alternative: Alternative plasticisers in roof sheets which are used are polyolefin plasticisers, for instance. One company mentioned that sales of the more expensive phthalate-free roof sheet are higher.

[60] PVC Forum, 2007, PVC idag och imorgon (PVC today and tomorrow). http://www.plastkemiforetagen.se/Material/PVC_12_sid_A5_004.pdf

[61] Plasticisers.org, 2014. Building & construction. Available: 02.04.2014 http://www.plasticisers.org/en_GB/applications/building-construction

[62] Blomfeldt T, Bergsjö P, 2013. Utvärdering av egenskaperna hos fogband i mjukgjord PVC för betongkonstruktioner – Korrelation mellan accelererad åldring, långtidsexponering och fogband i drift (Assessment of properties of soft PVC sealant tape for concrete structures – Correlation between accelerated ageing, long-time exposure and sealant tape in operation). Elforsk Report 13:39

Flooring

Most PVC floor coverings are manufactured by combining phthalates with PVC powder to form a liquid paste known as "plastisol". It is applied in several layers to build up the floor, which comprises a foam core and a decorative and protective layer[63]. PVC floors often have a service life of more than 20 years. As PVC flooring provides a level, smooth surface, making it easy to clean, it is often used in hospitals and other healthcare institutions, as well as in other public buildings such as schools and pre-school facilities, and also in offices and bathrooms. PVC flooring is also cheaper than many other options.

It was estimated that in 2012 5.7 million m^2 of[64] plastic flooring was sold in Sweden.

The following information emerged from interviews conducted with the flooring industry's national association and companies operating in this sector.

Most of the production in the flooring industry has shut down in Sweden recently in 2011 and 2010, with just one large flooring manufacturer remaining. According to the flooring industry, the trend is that the phthalates used nowadays in flooring are not those in the candidate list. DINP and DIDP are mainly used, but other phthalate-free plasticisers are also used, such as DINCH. The last few years have started to see the introduction of other types of plastic flooring, such as polyolefin flooring. Occasionally, a very thin surface layer of polyurethane is applied or polyurethane is combined in the PVC flooring. An example of the phthalate concentration range in PVC flooring is 15-20%. Examples of other plasticisers used for flooring are vegetable plasticisers and DOTP. One company has phased out DINP and switched to Mesamoll (*alkylsulphonic acid esters*). The concentration of the alternative plasticiser is the same as for phthalates (approx. 15-20%).

According to Tarkett's website in 2014, Tarkett removed phthalates from all its homogeneous plastic flooring used in public environments at its factory in Skåne in 2011. During 2014 Tarkett has also gradually switched to phthalate-free plasticisers in manufacturing plastic flooring for both the home and public environments at all its production facilities throughout Europe. Following on from this, it plans to start substituting phthalates at its plants outside Europe as well[65]. Tarkett is switching from DINP to the phthalate-free plasticiser DINCH.

Alternative: Examples of alternatives used are DINCH, vegetable plasticisers, DOTP and Mesamoll (*alkylsulphonic acid esters*). Alternative materials include tiles, epoxy coatings, compound flooring, laminate, textile and linoleum flooring.[66]

Wall coverings

Most PVC wall coverings are composed of three layers: a decorative layer, which has prints and colours applied, an intermediate layer, which is soft, and a backing, which provides the covering with strength[67].

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[63] Plasticisers.org, 2014. Flooring. Available: 02.04.2014 http://www.plasticisers.org/en_GB/applications/flooring

[64] Flooring industry, 2012. Textila golv ökade starkt (Textile flooring saw strong growth). Flooring industry activity report 2012. http://www.golvbranschen.se/media/30951/golvbranschens-verksamhetsberattelse-2012-endast-statistik.pdf

[65] Tarkett, 2014. Vi tar bort ftalater ur våra plastgolv (We're removing phthalates from our plastic flooring). Available. 18.11.2014 http://proffs.tarkett.se/content/vi-tar-bort-ftalater-ur-v%C3%A5ra-plastgolv

[66] Response to questionnaire from the Swedish Construction Federation, 07.10.2014

[67] Plasticisers.org, 2014. Wall coverings. Available: 02.04.2014 http://www.plasticisers.org/en_GB/applications/wall-coverings

It was estimated that in 2012 approx. 1.1 million m^2 of plastic wall covering was sold in Sweden.

PVC wall coverings come in different thicknesses and can last for 20 years. As no cracks appear on the covering and it is easy to keep clean, this makes it suitable for places where there is a great deal of wear and tear or there are stringent hygiene requirements, such as in hospitals and schools.

One example of phthalate concentration in a wet-room wall covering is: 13% DINP.

Alternative: One example of an alternative material which can be used in a wet room is tiles.

4.3.2 Automotive industry

An average car in Europe is made up of more than a thousand plastic components, with roughly 12% of them being made of soft PVC[68]. Soft PVC is used in the automotive industry as underbody coatings (anti-corrosion) and sealants, for instrument and door panels, passenger compartment components, window profiles and body side protectors,[69] cable harnesses, seat covers and mud flaps[70]. Other examples include car mats and steering wheel covers.

This information is corroborated by the Swedish car association BIL Sweden, with the additional point that soft PVC is mainly found in cabling, plastic-coated fabric such as vinyl coverings, see-through protection etc, and underbody coatings.

Based on a source from 2007, a private car contains around 3-4 kg of PVC[71], but the most equipped cars can have up to 10 kg of PVC. A truck or bus contains around 20 kg of PVC[72].

According to a US source[73], phthalates may be found in foam used in car fittings. The following examples of phthalates used in the automotive industry are from another US source[74], which can be confirmed by BIL Sweden:

- Car fittings: DIDP, DPHP, linear (C9-11)
- External components: DINP, DIDP, DPHP, linear (C9-11)
- Underbody coating and sealant: BBP, DEHP, DINP, DIDP, DPHP
- Paint (external): BBP
- Wires: DIDP, DPHP, linear (C9-11), DTDP

[68] Plasticisers.org, Applications. Automotive. Available. 19.03.2014 http://www.plasticisers.org/en_GB/applications/automotive

[69] PVC Forum, 2013. Dagens PVC är ett bra miljöval (Modern PVC is a good environmental option). Version 15.11.2013

[70] British Plastic Federation, 2014. PVC explained. Available: 15.04.2014 http://www.bpf.co.uk/Press/PVC_Explained.aspx

[71] PVC Forum, 2007, PVC idag och imorgon (PVC today and tomorrow). http://www.plastkemiforetagen.se/Material/PVC_12_sid_A5_004.pdf

[72] Response from BIL Sweden to questionnaire, 03.10.2014

[73] Wypych G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.

[74] Godwin AD, 2011. Plasticizers (chapter 28). I: Kutz, M. (ed). Applied plastics engineering handbook. Plastics Design Library (pdl). E-book.

The following phthalates occur in trucks/buses according to BIL Sweden:

- Seats, seat coverings: DINP, DEHP, DPHP
- Components in braking system, starter motor: DEHP
- Fifth wheel, oil cooler, power transmission: DEHP
- Lamps, Loudspeaker: DEHP
- Wires, Wiring harness: DEHP
- Engine unit, fuel tank, main switch: DBP
- Starter motor: DEHP, DBP
- Doors, cab roof: DIBP

Alternative: Trimellitates can be used instead of phthalates in the car's fittings and can reduce the problem of fogging on windows because of their low volatility[75]. Trimellitates and polymeric plasticisers can be used in external components and wires[74].

4.3.3 Electronics

Phthalates can occur in a large number of products and components. The most widely used insulating material for electrical cables and wires is soft PVC. According to the plasticiser industry association, around 25% of all soft PVC is currently used in Europe for manufacturing electrical cables and wires.

The high molecular weight phthalates DINP, DIDP and DPHP mostly feature in power cables which are used in buildings and for power distribution wires underground. In the case of certain special applications requiring resistance to high temperatures, fire and oil, the high molecular weight phthalates can be combined or substituted with other special-purpose plasticisers[76].

There are six major cable manufacturers in Sweden. Some of them produce their own PVC compounds. Phthalates which are not in the candidate list are used in the PVC cables. Around 50% of cables are PVC cables, with the other half being halogen-free (i.e. containing no PVC). However, the process of substituting phthalates has been a slow one. Cross-linked polyethylene (PEX) is used in the halogen-free cables. The prices are roughly equivalent. PEX cabling is used within the electrical market. Based on a very rough estimate, around 20,000 tonnes of PVC cable are used in the Swedish cable industry. Cables are roughly 50% plastic by weight.

Examples of phthalates used by Swedish cable manufacturers are DIDP, DPHP and diundecyl phthalate (DUP). The concentration range for phthalates in cabling is 20-30% by weight. The cables are used in buildings, industry, power stations and the automotive industry, to name a few areas.

Most of the products in the consumer electronics sector are supplied with PVC cables. These products include CD/DVD players, TVs, computers, projectors, fax machines, copiers, telephones, kitchen appliances, hairdryers, shavers, sewing machines etc.

DEHP may occur in all these groups.

It is estimated that 80-90% of all IT products are manufactured outside the EU.

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[75] Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish Ministry of the Environment. http://www2.mst.dk/udgiv/publications/2010/978-87-92708-00-7/pdf/978-87-92708-01-4.pdf

[76] Plasticisers.org, 2014. Cables & wires. Available: 02.04.2014 http://www.plasticisers.org/en_GB/applications/cables-wires

4.3.4 Packaging

According to Sweden's National Food Agency[77], the majority of cling film used in Sweden is made from polythene and does not contain any plasticisers. On the other hand, PVC cling film of different qualities can be used for store-packaged food which is used, depending on the type of food to be packaged. For instance, low-migrating PVC film must be used for fatty foods. Other examples are blister packaging, which is sealed by melting[78].

PVC is used for two types of medicine packaging: blister packaging for tablets/capsules and bags for different types of infusion fluids. Only these bags are manufactured from PVC softened with DEHP. Based on data from 1999, around 800 tonnes of PVC is used per year to manufacture medicine packaging, with around 10% of this made from soft PVC. The content of DEHP in plastic packaging may be as high as 40%. The current products used are all aqueous solutions, which do not release any major quantities of DEHP. Nutrition solutions containing fat, which may be considered as having a strong capacity for releasing DEHP, are not packaged in soft PVC bags. Glass or specially developed phthalate-free bags are used for these instead. Infusion fluids are nowadays often packaged in bags made of plastic laminate rather than in soft PVC bags [79].

4.3.5 Toys and childcare articles

Phthalates may occur in toys and childcare articles made in particular from soft PVC and which may be relatively cheap. The majority of toys and childcare articles in Sweden which may contain banned phthalates are imported, mostly from China. Examples of childcare articles in which phthalates may occur are: prams, changing tables, cots, baby carriers, children's chairs, bibs, aprons, teething toys, soothers, activity mats and child car seats.

There are various types of restrictions on the use of certain phthalates in toys and childcare articles. In spite of these restrictions, concentrations above permissible levels for these substances are often discovered during market surveillance and other tests.

PVC can occur in a number of different toys. Examples of toys in which high concentrations of banned phthalates have been discovered are: dolls, plastic balls, inflatable toys/animals, paddling pools, dressing-up clothes and masks, and toy swords. Phthalates can also be found in paints and cable sheathing (electric toys).

The following points emerged from consultations with toy companies. According to several large toy importers, they do not import any toys containing phthalates; they request phthalate-free articles. Others stipulate as a requirement that phthalates in the candidate list must not feature in the products. Some companies choose to avoid PVC completely as it makes their job easier by reducing the number of checks and analyses involved.

Suppliers sign an agreement undertaking to comply with the company's requirements. Companies are requesting laboratory analyses from the supplier and are sending samples themselves for analysis. Alternatively, the company can carry out simpler analyses.

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[77] National Food Agency, 2012. Är det olämpligt att förpacka livsmedel i plastfilm av PVC? (Is PVC cling film unsuitable for packaging food?) Available: 10.04.2014 http://www.slv.se/sv/Fragor--svar/Fragor-och-svar/Hygien-och-hallbarhet/Ar-det-olampligt-att-forpacka-livsmedel-i-plastfilm-av-PVC/

[78] ECHA, 2014. Data on Candidate List substances in articles. Last updated 18.03.2014. https://echa.europa.eu/documents/10162/13642/data_candidate_list_substances_in_articles_en.pdf

[79] Swedish Medical Products Agency, 2000. Ftalater i läkemedel, läkemedelsförpackningar, teknisk sprit, och kosmetiska/hygieniskaprodukter – redovisning av ett regeringsuppdrag (Phthalates in medicinal products, medicinal packaging, synthetic alcohol and cosmetics/hygiene products – government commission report). Ref. no. 291:2000/8257

Alternatives: e.g. DINCH, DEHT and ESBO[80].

4.3.6 Medical devices

DEHP is the most commonly used phthalate in medical devices[81]. PVC plasticised with DEHP is used for such articles as blood bags, infusion fluid bags, probes and catheters, heart-lung bypass and ECMO (extracorporeal membrane oxygen) equipment, gloves[82] and resuscitation dolls[83].

The county councils in Dalarna, Sörmland, Uppsala, Västmanland and Örebro have entered into an agreement on a joint provision of articles. This means that procurement, warehousing and distribution of consumables are carried out jointly. Since 2005 active efforts have been made to attempt to reduce the volumes of products containing phthalates[84]. The register for the provision of articles contained almost 8,000 different articles types in 2013. Roughly 7% of these contained PVC with phthalates, while there was no information for around 6% of them, see Figure 4.

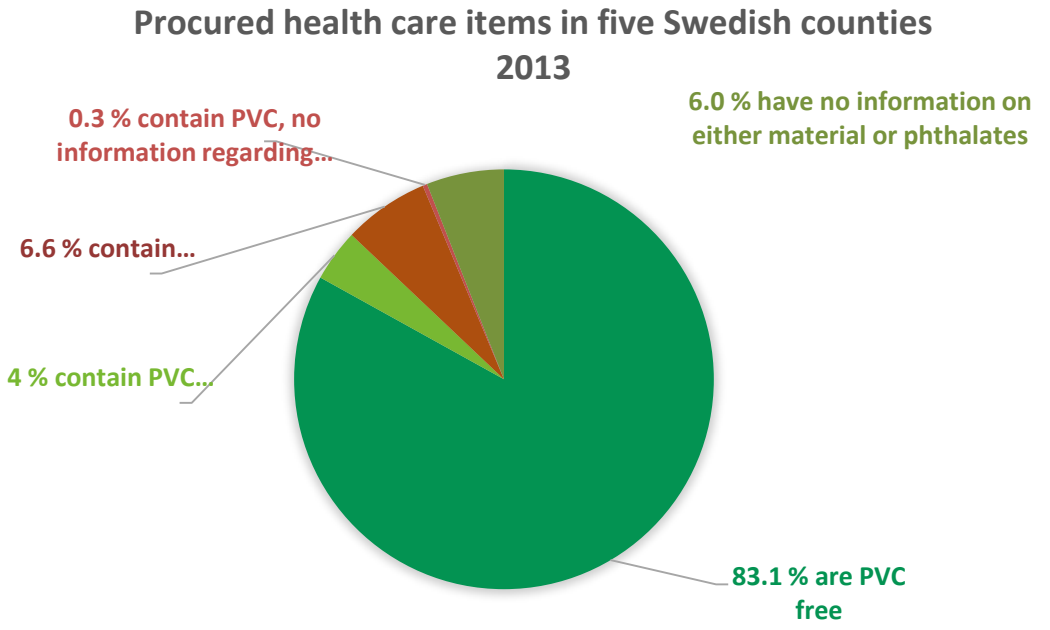

Figure 4: Proportion of medical consumables in the five councils' procurement in 2013

Among the medical consumables which contained phthalates in the 2013 procurement in the five county councils, most belonged to the article groups "intubation and accessories" and "anaesthesia and intensive care equipment". Examples of articles in these groups are different tubes, larynx masks, catheters, hoses, oxygen nasal cannulas, oxygen and anaesthetic masks

[80] Epoxidised soybean oil
[81] Danish Environmental Protection Agency, 2013. Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013 http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf
[82] Swedish Medtech, 2010. Fakta om PVC i medicintekniska produkter (Facts about PVC in medical devices), Information sheet. www.swedishmedtech.se/Files.aspx?f_id=38528
[83] ECHA, 2014. Data on Candidate List substances in articles. Last updated 18.03.2014. https://echa.europa.eu/documents/10162/13642/data_candidate_list_substances_in_articles_en.pdf
[84] Högdin K, Varuförsörjningen, Landstingen i Dalarna, Sörmland, Uppsala, Västmanland och Örebro (Provision of articles, county councils in Dalarna, Sörmland, Uppsala, Västmanland and Örebro). personal communication, 20.03.2014.

and resuscitators. Table 6 shows the distribution among the various groups of articles which contained phthalates.

Table 6: Distribution among various groups of medical consumables in the county areas of Dalarna, Sörmland, Uppsala, Västmanland and Örebro, which contained phthalates in 2013

Group of articles with phthalates	**No. articles 2013**	**Percentage of products with phthalates**
Intubation and accessories	149	27.6
Anaesthesia and intensive care equipment	101	18.7
ECG equipment, blood pressure gauges, register paper	45	8.3
Machine-connected infusion-transfusion-anaesthesia equipment	42	7.8
General operating equipment	36	6.7
Urological equipment	35	6.5
Local anaesthesia and central lines	28	5.2
Dialysis equipment	19	3.5
Blood establishment equipment	14	2.6
General hospital equipment	14	2.6
Vacuum-assisted wound treatment	14	2.6
Injection, infusion and transfusion material	11	2.0
Heart/lung equipment	7	1.3
Sampling material, including vacuum tube	6	1.1
Other (1-4 articles): Materials for dressings, bed equipment, customised operating set, enteral nutrition equipment; plaster, including accessories, incontinence equipment, intervention and surgical instruments, office equipment (general), eye operation equipment and implants	19	3.5
Total	***540***	***100***

In analyses vinyl gloves proved to have high concentrations of phthalates (e.g. Testfakta, 2013). It is worth noting that all the operating and examination gloves in the provision of articles procurement register are phthalate-free.

Alternative: The National Substitution Group (2013) for chemicals in articles (made up of representatives from Sweden's county councils and regions) has drawn up a substitution list for chemicals featuring in healthcare articles[85]. This list contains both alternative materials and plasticisers for various healthcare articles. The list is not completely up to date, but reflects the situation as it was in 2013.

During the review of options for replacing phthalates on the candidate list in medical devices, the following were considered as the most promising alternatives:

- COMGHA - glycerides, castor-oil-mono-, hydrogenated, acetates (CAS No 736150-63-3)
- DEHT - Di(2-ethylhexyl) terephthalate (CAS No 6422-86-2)
- DINCH - Diisononyl cyclohexane dicarboxylate (CAS No 166412-78-8)

[85] National Substitution Group (2013) for chemicals in articles 2013, Substitutionslistan för ersättning av hälso- och miljöfarliga kemikalier inom sjukvården (Substitution list for replacing chemicals hazardous to health and the environment in the healthcare sector).
http://www.msr.se/PageFiles/293/substlista_130529.pdf

This assessment was based on the fact that these substances have more extensive data which does not raise concerns about being toxic for reproduction or endocrine disruptors[86].

4.3.7 Coated fabrics and mats

Phthalates can occur in coated fabrics, such as tarpaulins and awnings. According to the PVC Forum (2013), coated fabrics account for 6% of PVC manufacture in Sweden.

Tarpaulins can be made of pure PVC. As part of the consultations which the Swedish Chemicals Agency has had during the project, it has transpired that several companies are choosing to stop purchasing these items as they can nowadays manufacture them in different materials, such as HD-PE (High-density polyethylene). Avoiding the use of PVC completely simplifies the situation for companies as this will involve less work for them and make it easier for them to exercise control.

4.3.8 Textiles, clothing and shoes

Phthalates can occur in textiles, clothing and shoes where soft PVC is used. For instance, phthalates can occur in printed or coated textiles and clothing (e.g. rainwear),textile accessories (buttons, reflectors, zips, badges, sequins and stickers),leather shoes, plastic shoes/sandals, boots and soles.

A large Swedish company has answered that around 95% of the articles for this particular company are imported from Asia. The remaining volume is manufactured in the EU.

The companies with a ban on PVC and/or phthalates do not have any information about alternative phthalates. Examples of options which have been highlighted are: DINCH, adipates and citrates.

4.3.9 Rubber products

Phthalates can be used for certain rubber articles. According to the product register, there are 11 phthalates registered for use in the manufacture of rubber articles in Sweden. DINP and DEHP are examples of phthalates used according to the product register. The manufacture of rubber articles accounted in the product register for only 0.3% of the registered volume of phthalates in Sweden in 2012.

Phthalates have been found in rubber from car tyres. In a study carried out[87], DBP was the phthalate found in the highest concentration. According to another reference[88], it is mainly in polar elastomers e.g. nitrile rubber and chloroprene rubber that phthalates are used. In non-polar types of rubber, such as natural rubber (NR), butadiene rubber (BR), polybutadiene rubber (SBR) or in polyolefins (e.g. EPDM) mineral oils are used as plasticisers[89]. Phthalates can also be used to enhance low-temperature properties in certain rubber applications[88].

Interviews conducted with the industry did not produce any comprehensive picture of the extent to which phthalates occur in car tyres. According to the response received from STRO

[86] Nielsen BS, Nørgaard Andersen D, Giovalle E, Bjergstrøm M, Larsen PB, 2014. Alternatives to classified phthalates in medical devices. Environmental Project No. 1557, 2014. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/03/978-87-93178-27-4.pdf

[87] Rakkestad KE, Dye CJ, Yttri KE, Holme JA, Hongslo JK, Schwarze PE, Becher R, 2007. Phthalate levels in Norwegian indoor air related to particle size fraction. Journal of Environmental Monitoring, 9: 1419-1425.

[88] Godwin AD, 2011. Plasticizers (chapter 28). I: Kutz, M. (ed). Applied plastics engineering handbook. Plastics Design Library (pdl). E-book.

[89] Rosca C, Giese U, Schuster RH, 2006. Investigation of Diffusion of Phthalates in Nitrile Rubber by Means of FT-IR-Spectroscopy. http://www.plastverarbeiter.de/ai/resources/a9afd4ea36d.pdf

– The Scandinavian Tire & Rim Organization – which represents a large proportion of the imports and sales of tyres in Sweden, they do not use phthalates in their tyres. However, there may be other "smaller" tyre manufacturers whose tyres are imported into and sold in Sweden, but we did not obtain any information about them in this study.

No car tyres are produced any more in Sweden. According to one European manufacturer which exports to the Swedish market, their tyres are completely phthalate-free as other types of plasticiser are used instead. Rubber bellows may contain DIBP[90]. Rubber or rubber/metal spare parts may contain DBP[90]. Technical rubber products, such as rubber-coated fabrics, may contain phthalates. DINP, DBP and DEHP are examples of phthalates used.

4.3.10 Furniture and furnishings

Examples of the furnishings which may contain soft PVC and phthalates are leather furniture, e.g. sofas, armchairs, pouffes and covered chairs, plastic furniture, shower curtains, shower hoses, plastic mats, underside of mats, lampshades, anti-slip devices, Christmas decorations, oilcloths (Sources: Appendix 3 and 4).

Alternative: There are numerous alternative materials to choose from in this category, such as furniture covered with fabric, wooden furniture, shower cubicles or nylon shower curtains, and phthalate-free cloths.

4.3.11 Sports and leisure articles

Phthalates can be found in many different products made from soft PVC or other type of soft plastic. The Swedish Chemicals Agency's market surveillance department has, for instance, carried out analyses on different sports articles and found that several of them contained DEHP and DIBP, which both feature in the candidate list. Sports articles are mostly imported from Asia.

Examples of sports articles which may contain phthalates are: mattresses with a PVC cover, trampolines (spring and side protection), Pilates balls, training balls, other types of balls, sports shoes, dumbbells, airbeds, inflatable flotation equipment, diving equipment, cycle handlebars, gazebos, tents, boat fenders (Sources: Appendices 3 and 4).

4.3.12 Bags, gloves, accessories etc.

It is common for these products to be available very often in retail stores and major department stores and to be relatively cheap.

The Swedish Chemicals Agency market surveillance department has carried out analyses on mobile phone cases, bags, pen cases, makeup bags, wallets and purses. The results showed that the phthalate DEHP was found in concentrations above 0.1% in 30 of the 62 articles analysed.

For instance, phthalates can be found in articles made of leather or soft plastic for a number of different products, such as bags, accessories, belts, watches and packaging. (Sources: Appendices 3 and 4)

DEHP may occur in all these products.

Many Swedish companies which sell clothing also sell products in this category. Therefore, the task of substituting phthalates and PVC is being carried out in the same way in the textiles

[90] ECHA, 2014. Data on Candidate List substances in articles. Last updated 18.03.2014. https://echa.europa.eu/documents/10162/13642/data_candidate_list_substances_in_articles_en.pdf

and footwear industries. Several major companies in Sweden use ban or restriction lists featuring chemicals, including a number of phthalates. Some companies have even imposed a blanket ban on PVC. Refer also to Appendix 7 for a more detailed description of companies' efforts.

4.3.13 Sex toys

In the restriction proposalwhich has been drafted by Denmark[91], it is concluded that the use of sex toys can result in a very high exposure to phthalates. Sex toys may contain, for instance, DEHP and migration can occur from products of this kind.

The Danish Technological Institute conducted a study in Denmark in 2006 on sex toys[92]. According to the study, sex toys are mainly made of vinyl (soft PVC) and latex. There are also silicone-based sex toys, along with thermoelastic (SEBS) or TPE (thermoelastic polymer) products available on the market.

Gel is a generally used product designation, but is often actually soft PVC. Phthalates can be found in these products at concentrations as high as up to 70%. This means that more than two thirds of the product is made up of plasticisers. Screening was carried out in Denmark to identify what phthalate concentrations occurred in different products. According to the results, 10 of the 15 samples tested contained phthalates. The concentrations varied from 0.12 g/kg to 702 g/kg. The phthalates which occurred were DEHP, DEP, DNOP or DINP[92].

It is likely that more than 90% of all sex aids are manufactured in China and by a total of 4-5 plants.

4.3.14 Other articles

Medicinal products

DBP and DEP may occur in medicinal products and are, according to the Swedish Medical Products Agency[93], the only phthalates used. When it comes to medicinal products, there are no general limits for permitted volumes without being exposed to risk. It is a matter of using personal judgement. There are efforts being made in the EU to table guidelines on the use of phthalates in medicinal products. They will lead to establishing limits (based on daily dose) which, when exceeded, must be reported, along with an indication of known risks in the product information sheet. The limits will probably coincide with the values produced by the EFSA. This is likely to have minor consequences for DEP as the value will probably be higher than that for existing medicinal products. This is not the case for DBP. Efforts are being made to substitute DBP for other less dangerous additives, mainly on companies' own initiative, following reminders from the authorities. There are very few products in Sweden containing DBP in these quantities, but there are still products in the EU with a higher DBP content. The possibility of such products reaching the Swedish market cannot be excluded. The new guidelines are likely to result in the efforts to remove DBP from medicinal products being speeded up.

[91] REACH Annex XV dossier (2011), Proposal for a restriction, Substance name: Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP). http://echa.europa.eu/documents/10162/c6781e1e-1128-45c2-bf48-8890876fa719

[92] Danish Technological Institute, 2006. Survey and health assessment of chemicals substances in sex toys, No. 77

[93] Swedish Medical Products Agency, personal communication, 16.10.2014.

With regard to packaging, the Swedish Medical Products Agency's view is that the authorities do not consider the packaging poses any risks except when there is a risk of the substance leaking into the product.

Protective equipment

Laboratory gloves, oven and cleaning gloves, other protective gloves, earmuffs and insect nets.

Garden items

Water hoses, garden binding wire and garden gloves.

Dental care articles

Phthalates may occur in dental composite, dental cement and prosthetics[94].

Other articles

Oil pipes and swimming pools.

4.4 Confirmed occurrence of phthalates in articles in Scandinavia based on market surveillance reports and other tests

As some phthalates are restricted to certain uses, in particular in toys and food packaging, and in view of the concern about human health and the environment due to exposure to different types of phthalates, a series of various tests have been carried out on articles, including in Sweden and Denmark. They have been included in market surveillance activities carried out by the Swedish Chemicals Agency and individual local authorities, in surveys commissioned by the Danish Environment Protection Agency, or they have been carried out on the initiative of green organisations or other stakeholders.

Appendix 3 contains a summary of the results from some of these tests. Examples of the groups of articles which have been tested and where phthalates have been discovered are accessories, children's articles, lighting, construction products, cycles, swimming equipment, flooring, furnishings, cables, clothing, toys, furniture, sex toys, shoes, protective equipment, sports equipment, garden items, wall coverings, bags and gloves. DEHP is the phthalate detected in most samples. Table 7 shows which articles produced the readings for the highest concentrations of the phthalates analysed.

Table 7: Articles in which the highest concentrations of phthalates have been discovered, based on tests conducted in Sweden and Denmark.

Type of phthalate	Concentration (g/kg)	Articles
DEHP	300-461	shower curtains, doll's head, plastic ball, airbed, plastic sandals (for children and adults), gloves, Pilates balls
BBP	20-33	gloves, flooring
DBP	283-345	plastic sandals (for children and adults)
DIBP	2150 – 355	gardening gloves, toy dolphin, Pilates balls
DINP	500 – 800	vinyl gloves, gloves, bath mat
DIDP	600 – 660	gloves, sex toys
DNOP	150	soap packaging

[94] Wypych G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.

4.4.1 Phthalates in articles based on the EU Commission's Rapid Alert System for non-food dangerous products (RAPEX) and ICSMS

The EU Commission's Rapid alert system for non-food dangerous products (RAPEX) allows participating countries (EU Member States, Norway, Iceland and Liechtenstein) to exchange information about products entailing a risk to consumer health and safety[95]. The database also reports what measures have been adopted by authorities or "voluntarily" by companies to avert the danger.

RAPEX also covers products which entail a health and safety risk to professional users and other stakeholders protected by EU legislation (e.g. environment and safety). Foodstuffs, medicinal products and medical devices, which are covered by other legislation, do not come under this system.

RAPEX was set up as part of the General Product Safety Directive (GPSD). New notifications are published every week and can also be received on a subscription basis. The database can be accessed via the following link:
http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.search

Searches carried out on registered articles containing phthalates in RAPEX generated a total of 1,176 hits for EU countries between 2005 and 2014. 112 of these have been registered from Sweden in recent years.

The largest and most common category of articles in which phthalates have been discovered and registered in RAPEX is toys, in particular dolls, plastic animals, bath toys, balls, dressing-up clothes, but also feeding bottles, erasers, pens, airbeds, teething toys and beads. Other categories include childcare articles and children's equipment (e.g. prams, changing tables, cots, baby carriers, children's chairs, bibs and aprons), clothing, textiles and fashion clothing (e.g. rainwear, T-shirts, children's shoes, baby shoes, slippers and sandals) and cosmetics (e.g. false nails, nail varnish and nail adhesive).

Not every EU country reports to this system and there is also another system available: the Information and Communication System on Market Surveillance (ICSMS). ICSMS is an IT-system also owned by the EU Commission, which provides a communication platform between the authorities in the Member States using market controls[96]. The system enables information about products/articles failing to meet requirements to be quickly shared among the authorities. A section of the platform is also available for consumer users and manufacturers[96].

4.4.2 Notification to ECHA in accordance with Article 7.2 of the REACH Regulation

Under the REACH Regulation, producers and importers of articles must submit a report (*notification*) to ECHA about substances featuring on the candidate list being contained in their articles at a concentration above 0.1% by mass. Liability comes into play if the total volume exceeds 1 tonne/year and if the substance has not already been registered for the same use. If the manufacturer or importer is able to demonstrate that humans and the environment will not be exposed to the substance in question under normal or reasonably foreseeable

[95] EU Commission, 2014. RAPEX- latest notifications. Available 11.04.2014 http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.listNotifications&CFID=6089141&CFTOKEN=77346147&jsessionid=09005deedc05e16121e4682475924131419a

[96] EU Commission, 2013. Information and Communication System on Market Surveillance. Available: 18.11.2014 http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/icsms/index_en.htm

conditions of use, no notification is required. Notification of the content of phthalates in articles has only been made for the four phthalates in the authorisation list.

Appendix 4 contains a list of all the notifications which have been made so far to ECHA for phthalates. Most of the notifications so far have been for DEHP (123), followed by DBP (19), DIBP (18) and BBP (4).

5 Alternatives to ortho-phthalates

Alternative options take the form of other external plasticisers (non-phthalates), internal plasticisers and alternative materials which have similar properties to soft PVC or which have totally different properties to PVC but provide the same function.

5.1 Alternative plasticisers

There are many groups of alternative plasticisers, many of which are used as special-purpose plasticisers. To ensure that any replacement can cover the wide range of applications offered by a number of large phthalates, several different alternative plasticisers may be required.

Table 8 shows the percentage distribution among the various plasticisers based on global consumption in 2009.

Table 8: Percentage distribution of global consumption in 2009 among various plasticisers[97].

Plasticiser	Percentage
Phthalates	85
Aliphatic dicarboxylic acid esters	3
Trimellitates	2
Epoxy esters	2
Polymeric plasticisers	2
Benzoates	1
Terephthalates	1
Cyclohexane dicarboxylic acid esters (DINCH)	1
Phosphate esters	< 1
Citrates	< 1
Other	2

According to IHS Chemical, the demand for non-phthalate plasticisers in Europe in 2011 was around 22% of plasticiser consumption, which is equivalent to 264,000 tonnes. The following is a list of non-phthalate alternatives available on the European market in descending order[98]:

[97] Godwin AD, 2011. Plasticizers (chapter 28). I: Kutz, M. (ed). Applied plastics engineering handbook. Plastics Design Library (pdl). E-book.
[98] Weeks H, 2012. Market Growth Seen for Non-Phthalate Alternatives. Chemical Week; Jul 16-Jul 23, 2012; 174, 19.

- Epoxy esters
- DINCH
- Other aliphates
- Adipates
- Trimellitates
- Polymeric plasticisers
- Phosphate esters
- Terephthalates
- Citrates
- Benzoates

A number of alternative plasticisers are special-purpose plasticisers[99] which have a narrow use, and some within these groups are less suitable for soft PVC. According to the ECPI (European Council for Plasticisers and Intermediates), the principal commercial alternatives to phthalates can be grouped as follows[100]:

- Terephthalates (DOTP, DEHT)
- Cyclohexanoate diesters (DINCH®)
- Citrates (ATBC)
- Trimellitates (TOTM)
- Aromatic sulphonates (phenol esters)
- Dicarboxylic acid esters (DINA, DOA; DEHA, DOZ, DOS)

5.1.1 Description of alternative plasticisers

This section describes a number of alternative plasticiser groups and examples of their use.

DINCH - 1,2-cyclohexane dicarboxylic acid, diisononyl ester – Hexamoll®

According to the Swedish Product Register, the use of DINCH (CAS 166412-78-8) in Sweden is large and increased 47 times between 2011 and 2012 from 427 to 20,077 tonnes. During 2012 the registered volume of DINCH, according to the product register, was only 40% lower than the total volume of registered phthalates. In addition, the use of DINCH in chemical products in Sweden, discounting exports, was much higher than it was for all phthalates in total. The registered use of DINCH according to the ECHA database of registered substances is > 10,000 tonnes/year.

Furthermore, there is another CAS number for DINCH (474919-59-0), but the use of this form is significantly less and it does not feature in the ECHA database of registered substances.

Recommended polymers are PVC and other polar polymers[101].

Recommended uses are medical products, toys, food packaging and sports and leisure articles.

[99] Plasticisers.org, 2014. Speciality plasticisers. Available: 01.04.2014 http://www.plasticisers.org/en_GB/plasticisers/specialty-plasticisers

[100] Saykali, 2013. Dispelling myths and communicating science. Vinyl Sustainability Forum, Istanbul, 26 April, 2013. European Council for Plasticisers and Intermediates (ECPI) (PowerPoint presentation). http://www.vinylplus.eu/uploads/VSF13/Saykali_ECPI.pdf

[101] Wypych A, 2013. Plasticizer Databook. ChemTech Publishing. E-book.

Dicarboxylic acid esters

This group includes adipates and sebacates.

Adipates (e.g. DEHA, DOA and DINA)

Adipates have a higher volatility and migration speed than phthalates, but enhance low-temperature properties and produce lower viscosity in plastisols, compared with phthalates[102]. Adipates are often used in mixtures with phthalates.

Examples of adipates used in PVC are di-2-ethyl hexyl adipate (DEHA), also known as dioctyl adipate (DOA) and diisononyl adipate (DINA)[103].

Recommended polymers are PVC, NBR, SBR, polyvinyl acetate (PVAc), cellulose acetate butyrate CP, CN, vinyl chloride vinyl acetate copolymer, polystyrene[104].

The main areas of use for adipates are plastisols[102], film, cables and wires, coatings, master batches, nail care, belts, printer rollers, boots, gloves, inner layer in tanks, food packaging film, adhesives, water pipes[104].

Sebacates (e.g. DOS and DOZ)

Sebacates are used in the same area as PVC where particularly good low-temperature properties are required[103].

Examples of sebacates are di-2-ethylhexyl sebacate (DOS) and di-2-ethylhexyl azelate (DOZ), which are the most common, with di-isodecyl sebacate (DIDS) also being used.

Recommended polymers are PVC, polyvinylidene chloride, acrylic acid derivate, EC, CN, PMMA, polyvinyl acetate (PVAc), polyvinyl butyral, nitrile rubber, neoprene rubber, chlorinated rubber.

The main areas of use are frost-resistant cables, aircraft and car fittings, flooring, film, paint, food packaging film, outer layer of medicines, packaging material and leather[104]**.**

Trimellitates (e.g. TOTM)

As trimellitates have a low volatility and less tendency to migrate than phthalates, they are suitable for any purpose where these properties are especially important, such as in car fittings[105].

Examples of trimellitates used in PVC are tri-octyl trimellitate (TOTM) and L79TM[105].

Recommended polymers are PVC, PS, CN, CA, cellulose acetate butyrate, EC, PMMA, rubber[106].

The main areas of use are cables and wires, disks, film, vehicle fittings, medical hoses, blood bags, gaskets, profiles, anti-fogging coating, furniture, leather, adhesives and tape[106].

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[102] Plasticisers.org, 2014. Speciality plasticisers. Available: 01.04.2014 http://www.plasticisers.org/en_GB/plasticisers/specialty-plasticisers

[103] Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish Ministry of the Environment. http://www2.mst.dk/udgiv/publications/2010/978-87-92708-00-7/pdf/978-87-92708-01-4.pdf

[104] Wypych G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.

[105] Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish Ministry of the Environment. http://www2.mst.dk/udgiv/publications/2010/978-87-92708-00-7/pdf/978-87-92708-01-4.pdf

[106] Wypych G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.

Terephthalates (e.g. DEHT, DOPT)

Terephthalates are used most in the US[105] and are chemically very like phthalates. Terephthalates exhibit slightly lower levels of compatibility with PVC than phthalates, which limits their use in products with a long service life, but offers better low-temperature properties instead[107].

An example of a commonly used terephthalate is di-(2-ethylhexyl) terephthalate (DEHT, also called DOPT), which is chemically like DEHP[105].

Recommended polymers are: PVC

Recommended areas of use are, for instance, bottle caps and seals, coatings, fabric coverings, electrical contacts, flexible film, medical devices, plasticisers, PVC flooring, toys, traffic cones, vinyl gloves, vinyl products, PVC water barriers and doormats[108].

Citrates (e.g. tributyl citrate)

One of the benefits of using tributyl citrate is that it is thermally stable and does not discolour so easily[105].

An example of citrates used in PVC is tributyl citrate[105].

Recommended polymers are PVC, polyvinylidene chloride, nitrocellulose, acrylic plastic, polyvinyl acetate (PVAc), polyvinyl butyral, cellulose acetate butyrate, cellulose nitrate and polyurethane[108].

The areas of use for acetyl tributyl citrate are medical plastics, medical devices, food packaging, toys, printing ink, metal covers, bottle tops, paper and aluminium foil coverings[108], soothers, cables, flooring and roofing membranes[107].

Benzoates (e.g. DGD known as Benzoflex® 9-88)

Benzoates are effective solvents and are therefore used most in PVC flooring[105].

Examples of benzoates used in PVC are di-propylene glycol dibenzoate (DGD), commercially known as Benzoflex® 9-88[109] and isodecyl benzoate[109].

Recommended polymers for DGD are PVC, SBR, polyvinyl alcohol, EVA and acrylates[110].

Uses för DGD include flooring, adhesives, paints and chalk[110].

Phosphate esters (e.g. 2-ethylhexyl diphenyl phosphate)

Apart from functioning as a plasticiser, phosphate esters also have a flame-retardant effect and can also be used along with other plasticisers to reduce costs[109].

One example of a plasticiser which has been widely used in soft PVC is 2-ethylhexyl diphenyl phosphate as it is an effective plasticiser, can be used in low-temperature

[107] Plasticisers.org, 2014. Speciality plasticisers. Available: 01.04.2014 http://www.plasticisers.org/en_GB/plasticisers/specialty-plasticisers
[108] Wypych A, 2013. Plasticizer Databook. ChemTech Publishing. E-book.
[109] Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish Ministry of the Environment. http://www2.mst.dk/udgiv/publications/2010/978-87-92708-00-7/pdf/978-87-92708-01-4.pdf
[110] Wypych A, 2013. Plasticizer Databook. ChemTech Publishing. E-book.

applications, has a low migration speed and has a flame-retardant effect[109]. Other examples are tris (2-ethylhexyl) phosphate and tricresyl phosphate (TCP).

Recommended polymers are PVC and numerous others, including rubber[111].

Areas of use include: film, foam, paper coverings, textile coverings, latex paints, varnishes, disks, cables and wires, hoses, sealants, PCBs, photographic film base, leather, wall coverings, flooring and tarpaulins[111].

Polymeric plasticisers (e.g. polyesters)

Polymeric plasticisers for PVC usually comprise polyesters[109]. The higher the molecular weight, the better it handles losses via diffusion and evaporation. Polybutenes can also be used for rubber[111].

The main areas of use are vehicle parts, flooring, decorative stickers, liners (film) in tanks, refrigerator gaskets, shoes, adhesives, sealants, external coatings, cables and wires, varnishes, printer rollers, garden hoses, seals, belts, vinyl tape, electrical insulation and furniture[111].

Castor oil derivative (e.g. COMGHA)

COMGHA (glycerides, castor-oil-mono, hydrogenated, acetates) with CAS No 736150-63-3 and the common name "Soft-n-Safe" is a plasticiser which has a similar function to DEHP[112]. Its primary use is in PVC (e.g. film, pipes, bottles and sealants), but it can also be used in other polymers such as polyolefins, polystyrenes and PET[112]. Its use is permitted in the EU in material designed to come into contact with food. COMGHA has a low migration potential and is highlighted as one of the three most promising alternatives to DEHP in medical devices[113].

COMGHA is a mixture of two components[114]:

- Component A: Approx. 84%: 12-(Acetoxy)-stearic acid, 2,3-bis(acetoxy)propyl ester – CAS No 330198-91-9
- Component B: Approx. 10%: Octadecanoic acid, 2,3-(bis(acetoxy)propyl ester – CAS No 33599-07-4.

5.1.2 Investigations into alternative plasticisers

The Danish Environmental Protection Agency has reviewed alternatives to phthalates, including in the following reports:

[111] Wypych, G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.
[112] SCENIHR, Scientific Committee on Emerging and Newly-Identified Health Risks, 2008. Preliminary report on the safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk. Health & Consumer Protection Directorate-General. EU Commission. Approved for public consultation by the SCENIHR during the 19th plenary of 21-22 June 2007.
[113] Nielsen BS, Nørgaard Andersen D, Giovalle E, Bjergstrøm M, Larsen PB, 2014. Alternatives to classified phthalates in medical devices. Environmental Project No. 1557, 2014. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/03/978-87-93178-27-4.pdf
[114] SCENIHR, Scientific Committee on Emerging and Newly-Identified Health Risks, 2008. Preliminary report on the safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk. Health & Consumer Protection Directorate-General. EU Commission. Approved for public consultation by the SCENIHR during the 19th plenary of 21-22 June 2007.

- Identification and assessment of alternatives to selected phthalates[115]. This report lists 25 potential non-phthalates as an alternative to DEHP, DBP and BBP, 10 of which have been selected for detailed description and assessment.
- Phthalate strategy. Chapter 8. Review of alternative substances[116]
- Survey of selected phthalates. Chapter 7. Information on alternatives[117]
- Alternatives to classified phthalates in medical devices[118]

The 10 options for replacing phthalates which were studied in greater depth by Maag et al.[115] were:

- ASE – Alkyl sulphonic acid phenyl ester
- ABTC – Acetyl tributyl citrate
- Bensoflex 2088 (with DEGD - diethylene glycol dibenzoate)
- COMGHA - glycerides, castor-oil-mono-, hydrogenated, acetates
- DEHT – Di(2-ethylhexyl) terephthalate
- DINA – Diisononyl adipate
- DINCH – Diisononyl cyclohexane-1,2-dicarboxylate
- DGD – Dipropylene glycol dibenzoate
- GTA – Glycerol triacetate
- TXIB – Trimethyl pentanyl diisobutyrate

These include both plasticisers with specific areas of use and more general plasticisers[116].

The alternative substances available on the market and which have mainly been suggested as substitutes for DEHP are DINA, DINCH, DEHT, ATBC and ASE[116]. The alternative which offers the widest coverage for replacing conventional DEHP areas of use is DEHT[117]. Two options to replace DBP and BBP, which are available on the market, are DEGD (DEGDB) and DGB (DPGDB)[116]. In the case of several of the options, there is lack of data accessibility for assessing the substances' technical suitability and suitability from an environmental and health perspective[116]. In a recently published survey, DINCH, DEHT and COMGHA were regarded as the most promising options for replacing DEHP in medical devices[119].

5.2 Alternative phthalates

The substitution of certain phthalates involves replacing them with other phthalates. DINP is a general plasticiser used in numerous products as a direct alternative to DEHP[120]. It also

[115] Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish Ministry of the Environment.
[116] Danish Environmental Protection Agency, 2013. Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013 http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf
[117] Hagen Mikkelsen S, Maag J, Kjølholt J, Lassen C, Nylander Jeppesen C, Clausen AJ, 2014. Survey of selected phthalates. Part of the LOUS-review. Environmental Project No. 1541. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-95-7.pdf
[118] Nielsen BS, Nørgaard Andersen D, Giovalle E, Bjergstrøm M, Larsen PB, 2014. Alternatives to classified phthalates in medical devices. Environmental Project No. 1557, 2014. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/03/978-87-93178-27-4.pdf
[119] Nielsen BS, Nørgaard Andersen D, Giovalle E, Bjergstrøm M, Larsen PB, 2014. Alternatives to classified phthalates in medical devices. Environmental Project No. 1557, 2014. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/03/978-87-93178-27-4.pdf
[120] Hagen Mikkelsen S, Maag J, Kjølholt J, Lassen C, Nylander Jeppesen C, Clausen AJ, 2014. Survey of selected phthalates. Part of the LOUS-review. Environmental Project No. 1541. Danish Ministry of the Environment. http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-95-7.pdf

emerged from interviews with Swedish manufacturers that DINP is an alternative that many manufacturers have used as a substitute for DEHP for a number of years.

A potential replacement phthalate, for instance, for the six phthalates banned in toys would be, according to the EU Commission (2009), di-2-propyl heptyl phthalate (DPHP)[121].

5.3 Reactive plasticisers and internal softening

Phthalates are used as external plasticisers, which means that the plasticiser is not chemically bonded to the polymer structure and can therefore leak out. Polymers can also be made soft through internal softening. Internal softening means that functional groups are incorporated instead in the polymer structure or are bound to the polymer. PVC can be given enhanced process and elastomer properties by being modified with acrylonitrile butadiene rubber, nitrile butadiene rubber (NBR), styrene acrylonitrile rubber, styrene acrylonitrile (SAN), ethylene vinyl acetate copolymer (EVA) and acrylic copolymers[122]. For instance, the quantity of DEHP in flexible water hoses can be reduced if PVC is mixed with EVA.

5.3.1 Epoxy esters

Other examples of internal plasticisers are epoxy plasticisers, which go through side chain binding with the PVC polymer, e.g. epoxidised soybean oil (ESBO; ESO) or epoxidised linseed oil (ELSO)[123]. Problems can occur in PVC material with ageing if epoxy esters are used[124].

5.4 Alternative polymers/materials for soft PVC

There are a number of flexible polymers which can substitute many conventional uses of soft PVC, as well as replacement materials other than flexible polymers[125]. Examples of flexible polymers are polyethylene, polyolefin elastomers, various polyurethane forms, ethylene vinyl acetate (EVA) and different rubber types[125].

Examples of materials which can replace soft PVC are: tiles (instead of PVC flooring and carpet) and cross-linked polyethylene (PEX) instead of PVC cabling. Even if phthalates are discounted, PVC is the plastic type which requires the biggest quantity of additives by far[126].

5.5 Options for using alternatives in different applications

The Danish Environmental Protection Agency has asked the various industries questions in a survey[127] about whether alternatives to the harmful phthalates can be used. The results of the study highlighted that it is technically possible for the majority of products containing PVC to

[121] EU Commission, 2009. Directive 2009/48/EC on toy safety. Technical documentation. http://ec.europa.eu/enterprise/sectors/toys/files/technical-documentation-guidance/20110405_technical_documentation_guidance_document_rev_1-0_sv.pdf
[122] Wypych, G (ed.), 2012. Handbook of plasticizers. 2nd edition. ChemTech Publishing. E-book.
[123] Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish Ministry of the Environment. http://www2.mst.dk/udgiv/publications/2010/978-87-92708-00-7/pdf/978-87-92708-01-4.pdf
[124] Plasticisers.org, 2014. Speciality plasticisers. Available: 01.04.2014 http://www.plasticisers.org/en_GB/plasticisers/specialty-plasticisers
[125] Danish Environmental Protection Agency, 2013. Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013 http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf
[126] Murphy J. 2001. Additives for plastics handbook. Elsevier Science Ltd, Oxford.
[127] Danish Environmental Protection Agency, 2014. Identification of difficulties in acquiring articles without the phthalates DEHP, BBP, DBP and DIBP, Survey of chemicals in consumer products no. 127.

replace DEHP, BBP, DBP and DIBP with other plasticisers. On the other hand, it is difficult for a Danish importer to request modifications to a design simply to suit the special requirements of the Danish market. The product types which were analysed were lawnmowers, cycles, camping equipment, construction products, jumpers and textiles, rainwear, furnishings, electronics, electrical hand tools, ironwork, doorknobs, handles, zips, trim, ornaments, wheels, office equipment, mats, shower curtains, artificial flowers and other decorations, cleaning equipment - brushes, rags, brooms etc., reflectors, hand tools, packaging, training mats, exercise bikes, treadmills, rowing machines, furniture, spare parts and recycled plastic.

6 Phthalates which are potentially endocrine-disrupting and toxic for reproduction

6.1 Health impact

Ortho-phthalates comprise a large group of substances presenting both different and similar toxicological effects. In general, phthalates with 4-6 carbon atoms in the longest side chain, known as low molecular weight phthalates, are considered to pose the greatest toxicological risk. Impairment of reproduction is considered to be the critical effect of the use of phthalates, but liver effects have also been observed at levels which are only slightly higher than those seen for the impairment of reproduction. The phthalates which cause impairment of reproduction and liver effects overlap to a certain extent. Phthalates can also be a potential contributory factor to other kinds of effects on public health. Appendix 6 contains a list of the phthalates mainly mentioned in this chapter.

6.1.1 Reproductive effects

Impairment of reproduction, especially in men, is an effect which has been linked to a number of low molecular weight phthalates. Effects of this kind have been reported for DEHP, the most widely studied phthalate in the low molecular weight phthalate group, but also for DBP, BBP and DIBP. These four phthalates are all classified as toxic for reproduction under EU chemicals legislation and their use is banned in toys and childcare articles. DEHP, DBP and BBP also feature in the EU's list of potential endocrine-disruptors[128]. Other phthalates, apart from DEHP, DBP, BBP and DIBP, are also suspected of producing effects which are toxic for reproduction, thereby adding to the overall impact.

One feature the four phthalates DEHP, DBP, BBP and DIBP have in common is that they produce an antiandrogenic pattern of effects and should, therefore, also be assessed together. Antiandrogenic effects from these phthalates have been observed in both animal experimental studies and epidemiological studies. In other words, links have been seen between phthalates in humans and effects of an antiandrogenic nature[129]. In humans this pattern of effects is usually called testicular dysgenesis syndrome (TDS) and includes, for instance, altered levels of the sex hormone testosterone, deformation of the male sexual organs and impaired sperm quality. The underlying mechanism for effects of this kind is not clear. Different phthalates

[128] European Commission DG ENV, 2000. Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting; Annex 15. M0355008/1786Q/10/11/00

[129] Kay VR, Bloom MS, Foster WG. Reproductive and developmental effects of phthalate diesters in males. Crit Rev Toxicol, 2014; 44(6): 467-498.

may also act via different mechanisms even if the effects are ultimately similar. Proposed mechanisms include effects on different parts of steroid hormone production, including testosterone, effects on sex cells and altered metabolism of key trace elements[129]. There are also indications, albeit more tenuous, that phthalates may affect hormone levels and impair the development of female reproduction organs and oestrogen-sensitive tissue[130]. The studies also show that foetuses are especially sensitive to exposure as it is occurring during the gestation period when hormone and reproduction systems are developing. It is also suspected that the effects can be transferred between generations via epigenetic changes, where the instructions on how genes should be read are altered.

Also in the case of the high molecular weight phthalate DINP, it is suspected of possibly being toxic for reproduction based on an antiandrogenic pattern of effects[131, 132]. However, the effects are seen at higher doses than for DEHP, and DINP is not classified as toxic for reproduction. DIDP, another very common high molecular weight phthalate, is suspected of being toxic for reproduction, but probably via a different type of mechanism. Therefore, DIDP does not contribute to the antiandrogenic effects[131]. This is also supported by recently published data showing that DINP, as well as DIBP, DBP, BBP and DEHP, can lower the testosterone production while no significant effect was observed for DIDP and DPHP[133]. In the case of the phthalate DPHP, which has started to be used increasingly as a substitute for DEHP, an in-depth assessment of existing information has been launched in the EU with the focus on any reproduction and endocrine-disrupting effects, as well as effects on the different organs of the body[134].

High molecular weight phthalates, such as DINP and DIDP, are generally regarded as having a lower toxicity than phthalates with 4-6 carbon atoms in the longest side chain. The use of these high molecular weight phthalates has increased over recent years (see also Chapter 4), as the chemical industry believes that they can provide suitable alternatives to the low molecular weight phthalates which have been regulated. Some phthalates are manufactured using a reaction process (see also Chapter 3 on this), which may produce reactants with a varying carbon chain length for the main carbon chain. The occurrence of low molecular weight substances in DINP, for example, could at least partly explain the antiandrogenic effects observed.

6.1.2 Liver effects

In the case of the high molecular weight phthalates DINP and DIDP, the risk-limiting measures which have been introduced in toys and childcare articles derive from effects which have been seen on the liver[135] (see also Chapter 3). The liver is a vital organ in the body, whose function includes maintaining the hormone balance. However, it has not been shown

[130] Kay VR, Chambers C, Foster WG. Reproductive and developmental effects of phthalate diesters in females. Crit Rev Toxicol, 2013; 43(3): 200-219.
[131] ECHA, 2013. Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. ECHA-13-R-07-EN.
[132] Bornehag CG, Carlstedt F, Jönsson BAG, Lindh CH, Jensen TK, Bodin A, Jonsson C, Janson S, Swan SH. Prenatal phthalate exposures and anogenital distance in Swedish boys. EHP 2014, http://dx.doi.org/10.1289/ehp.1408163.
[133] Furr J, Lambright C, Wilson VS, Foster PM, Gray Jr EL. A short-term *in vivo* screen using fetal testosterone production, a key event in the phthalate adverse outcome pathway, to predict disruption of sexual differentiation. Toxicol Sci, 2014 Aug 1;140(2):403-24.
[134] Justification document for the selection of a CoRAP substance, Germany 2014. http://echa.europa.eu/documents/10162/41dd4a44-fc5e-4006-b2ed-ef3ca805245a
[135] ECHA, 2013. Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. ECHA-13-R-07-EN.

that the reported liver effects are due to hormone disruption. Liver effects have also been linked to a certain extent to other phthalates, such as DEHP and DPHP[136], and even if the mechanisms involved are not clearly explained either in this case, a joint assessment of phthalates based on the liver effects may be required. Liver effects are generally observed at levels slightly higher than the levels where reproductive toxicity is observed.

6.1.3 Other effects

Chemical exposure has recently been suggested increasingly often as a contributory factor to a number of commonly occurring effects on public health. We are exposed to a large quantity of chemicals in our everyday life, with phthalates being one group of substances which has been found in humans. Elevated concentrations of phthalates could be a possible contributory factor to an increased incidence of asthma and allergies among children, as well as to the occurrence of different degrees of functional impairment within the autistic spectrum, ADHD-type behaviour or effects on motor development[137]. However, it is difficult to see clear links as effects of this kind on public health are collective diagnoses for a number of different effects of varying degrees of severity. Apart from chemical exposure, a number of other complex factors can also contribute to the occurrence of these issues, which further complicates the picture. However, exposure to phthalates cannot be excluded as being a contributory cause.

6.2 Exposure

Phthalates have been found as contaminants in both the environment and in humans. In humans phthalates are metabolised relatively quickly and most of the phthalates we take in have been excreted within a few days[138]. In the environment, the decomposition of phthalates is a slower process, which means that they can remain for a lengthy period of time. In spite of the rapid metabolism in humans, concentrations are commonly found in analyses of blood, breast milk and urine, thereby indicating that we are constantly exposed to phthalates. Exposure can occur from a variety of sources via inhalation, ingestion, permeation via skin and from contact with mucous membranes. The principal sources of exposure are probably articles containing phthalates, food and the indoor environment. Therefore, to obtain a comprehensive picture of the level of exposure, the contribution of a number of different sources needs to be factored in. As an alternative to looking at the contribution made by each source, the concentration of phthalate metabolites in urine can be measured. This is known as bio-monitoring and will produce a measurement for the entire volume of phthalates which a person has been exposed to.

Phthalates also commonly occur in medical equipment and, even in some cases, in medicinal products. This can produce a very high level of exposure for patients receiving intensive care treatment, as well as, for instance, for very premature babies. However, this type of care is vital and efforts are being made to phase out phthalates and other harmful substances in the healthcare sector (see Chapter 4). Therefore, there will be no further discussion of this type of exposure in this chapter.

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[136] REACH registration file for DEHP and DPHP, available via the ECHA website (http://echa.europa.eu), 17.10.2014.

[137] Braun JM, Sathyanarayana S, Hauser R. Phthalate Exposure and Children's Health Curr Opin Pediatr. 2013;25(2): 247-254.

[138] Anderson WAC, Castle L, Hird S, Jeffery J, Scotter MJ. A twenty-volunteer study using deuterium labelling to determine the kinetics and fractional excretion of primary and secondary urinary metabolites of di-2-ethylhexylphthalate and di-iso-nonylphthalate. Food and Chemical Toxicology, 49 (2011) 2022-2029.

6.2.1 Exposure via food

Food is a key source of exposure to phthalates. It is the main source of exposure for adults, whereas exposure via the indoor environment is considered to be the biggest contributory factor for children, even though children eat more in relation to their body weight than adults. The European Food Safety Authority (EFSA) carried out an assessment in 2005 of the use of the phthalates BBP[139], DBP[140], DEHP[141], DINP[142] and DIDP[143] in materials in contact with foodstuffs. These assessments also determined tolerable daily intake (TDI) levels, i.e. the quantity of the respective phthalate which a person can take in every day of their life without suffering any harmful impact on their health. EFSA considered that it was not possible to determine a jouint TDI for the phthalates which were assessed as the effects were too diverse[144]. However, it might still be considered possible to do this using the knowledge we currently have at least of the low molecular weight phthalates BBP, DBP and DEHP, based on antiandrogenic effects. EFSA's summary indicated that the intake of BBP and DBP mainly comes from food of vegetable origin, whereas food of both vegetable and animal original is an important factor for DEHP. In the case of DBP and DEHP, the estimated daily intake at the time when the summary was compiled was close to or, in certain cases, above the TDI, whereas the daily intake for BBP, DINP and DIDP was lower than the TDI.

Since EFSA carried out its assessment in 2005, restrictions have been introduced on phthalates in materials in contact with foodstuffs (see also Chapter 3). Reports of limits being exceeded for the migration from plastic in contact with foodstuffs indicate that prohibited concentrations of mainly DEHP and DINP are occurring. These breaches apply most often to PVC seals in jar lids, PVC film and some household utensils made of PVC[145].

Even though the use of a number of phthalates is now restricted in materials in contact with foodstuffs, concentrations are being reported in food which are still making a major contribution to the overall exposure[146, 147]. The occurrence of phthalates in food could be due

[139] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food (AFC) on a request from the Commission related to Butylbenzylphthalate (BBP) for use in food contact materials, The EFSA Journal 2005; 241, 1-14.
[140] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food (AFC) on a request from the Commission related to Di-Butylphthalate (DBP) for use in food contact materials, The EFSA Journal 2005; 242, 1-17.
[141] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food (AFC) on a request from the Commission related to Bis(2-ethylhexyl)phthalate (DEHP) for use in food contact materials, The EFSA Journal 2005; 243, 1-20.
[142] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food (AFC) on a request from the Commission related to Di-isononylphthalate (DINP) for use in food contact materials, The EFSA Journal 2005; 244, 1-18
[143] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food (AFC) on a request from the Commission related to Di-isodecylphthalate (DIDP) for use in food contact materials, The EFSA Journal 2005; 245, 1-14
[144] EFSA, 2005. Statement of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on the possibility of allocating a group TDI for Butylbenzylphthalate (BBP), di-Butylphthalate (DBP), Bis(2ethylhexyl) phthalate (DEHP), di-Isononylphthalate (DINP) and di-Isodecylphthalate (DIDP). http://www.efsa.europa.eu/en/search/doc/747.pdf
[145] National Food Agency, 2011. Riskprofil för material i kontakt med livsmedel (Risk profile for material in contact with foodstuffs). Report 5/2011.
[146] Umwelt Bundesamt 2012, Phthalate levels in the German population: Exposure-relevant sources, intake pathways and toxicokinetics based on the example of DEHP and DINP. Volume I: Exposure through consumption of food and use of consumer products, http://www.uba.dr/uba-info-medien/4326.html
[147] Lee J, Lee JH, Kim CK, Thomsen M. Childhood exposure to DEHP, DBP and BBP under existing chemical management systems: A comparative study of sources of childhood exposure in Korea and in Denmark. Environment International 63(2014) 77-91.

to a wide distribution of phthalates in the environment. Concentrations of mainly DINP, DEHP and DIDP have been reported in water being discharged from sewage treatment plants, in sludge and in sediment[148]. The concentrations in sediment dropped the further away the samples were taken from densely built-up areas, which indicates that human activity is an important source of phthalates in the environment, which, in turn, can produce phthalate concentrations in food. The concentrations in the environment and, therefore, also in food originate from the production, use and waste management for articles containing phthalates. To reduce the phthalate concentrations in food further, restrictions may need to be imposed on phthalates in several types of articles. It is also important not only to restrict the use of phthalates in newly manufactured articles, but also to look at ways how we can handle existing articles when they have been disposed of and to take into account the occurrence of phthalates which are hazardous to health in the event of any recycling or reuse[149]. It has been shown that the use of recycled material can increase the level of exposure[150].

6.2.2 Exposure via indoor environment

Phthalates in the indoor environment are the main source of exposure for small children where a considerable contribution is made, above all, by the occurrence of phthalates in dust. Children have a higher respiratory rate than adults, they are often close to the floor and have a habit of putting hands and objects in their mouth. This means that children have a high intake of dust, estimated at up to 100 mg/kg body weight per day.

The presence of PVC flooring has been linked to an increase in the occurrence of phthalates in the home environment[151], but phthalates contained in other types of articles can also be a contributory factor. Concentrations of phthalates in dust are generally higher in the pre-school environment, up to five times higher than in the home or other public environments[152]. This can be attributed to the desire to have easy-to-clean surfaces in pre-school institutions, which means that PVC material is often used. Measurements taken for the occurrence of phthalates in dust from pre-school institutions indicated higher total concentrations in older buildings than in newly built premises. DEHP occurs to a larger extent in older pre-school institutions than in newly built ones, even though DINP generally occurred in the highest concentrations, followed by DEHP and DIDP. In an analysis of 11 different flooring samples during 2014, DIBP was found in one sample, DIDP in four samples and DINP in all samples[153]. DEHP was not found in any sample, which may indicate that DEHP has been phased out in flooring, mainly to the benefit of DINP. One explanation for the higher concentrations in older pre-school institutions may be that there is a higher level of wear and tear. Based on children's intake of dust and the phthalate concentrations measured, dust gave an exposure of children to DEHP equivalent to roughly half the limit value set based on reproductive effects[151]. Dust also made a significant contribution to the exposure to DINP, while there was a somewhat lower level of exposure to DIDP, BBP and DBP from dust.

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[148] TemaNord 2013:505, Selected Plasticisers and Additional Sweeteners in the Nordic Environment.
[149] Swedish Chemicals Agency, 2014. Response to the European Commission's proposal (COM(2014)397 final) amending a number of EU waste directives (Framework Waste Directive, Packaging Directive, Landfill Directive, ELV Directive, WEEE Directive and Battery Directive). Reference number 4.2.3a-H14-03884.
[150] Lee J, Pedersen AB, Thomsen M. The influence of resource strategies on childhood phthalate exposure–The role of REACH in a zero waste society. Environment International, 2014; 73:312-322.
[151] Carlstedt F, Jonsson BA, Bornehag CG. PVC flooring is related to human uptake of phthalates in infants. Indoor Air, 2013;23(1):32-9.
[152] Swedish Chemicals Agency 2013, Barns exponering för kemiska ämnen i förskolan (Children's exposure to chemicals in pre-school institutions). Report No 8/13.
[153] Analysis report from SP Technical Research Institute of Sweden 2014, Reference 4F019007-02.

6.2.3 Exposure via articles

Plastics which are plasticised using phthalates have a very wide area of application, featuring in a large number of articles and products which we deal with every day, ranging from building materials and car fittings to electric cables and plastic combs. The phthalates are loosely bonded to the plastic material, which means that they leak from the articles into the environment. This continuous leaking of phthalates from articles can contribute to concentrations of phthalates in dust or indoor air, as well as to direct exposure to people coming into contact with these articles. In the case of adults, for instance, the use of sex toys has been shown to create a high level of exposure to DEHP[154].

In the case of small children, the behaviour involved in them exploring their environment by putting objects in their mouth can produce direct exposure to phthalates. The phthalates BBP, DBP and DIBP are not allowed at all in toys and childcare articles, whereas DINP, DIDP and DNOP must not feature in toys and childcare articles which children can put in their mouth. However, a study into which type of articles children mouth indicated that they explore just as often other types of objects as toys and childcare articles[155]. We analysed the study on which additional objects children mouth and found that the main types of articles in terms of phthalates are electrical and electronic articles, clothing, shoes and accessories, home furnishings and office supplies. A comparison with the import/export figures for different sectors indicated that more than half the items which small children mouth and which may contain plasticised materials are imported[156]. There has been a sharp decline in the use of DEHP within the EU in favour of using high molecular weight phthalates, but DEHP is still very commonly found in other parts of the world and therefore, also in imported articles (see also Chapter 3). Mouthing objects can give an undesirable contribution to the high level of exposure which the child already has.

6.2.4 Bio-monitoring

Bio-monitoring surveys measure the occurrence of phthalate metabolites in urine. This produces a measurement of the actual exposure without depending on whether all the different sources of exposure have been included in the calculation or whether the importance of different sources has been over- or underestimated. However, in some cases, it may be of interest to analyse the significance of the various sources. The sampling equipment used has previously been suspected as a possible source of contamination of the sample, as phthalates usually occur in medical equipment, which would therefore give an incorrect picture regarding exposure. However, it has been shown that sampling equipment mainly causes contamination with phthalates in their original form and not with phthalate metabolites as metabolism primarily occurs in biological systems. This should therefore not affect the analysis[157].

The metabolism of phthalates into different metabolites occurs in several steps, producing both primary and secondary metabolites. It is important to include both primary and secondary metabolites in any analysis to give a fair picture of the level of exposure, especially

[154] REACH Annex XV dossier (2011), Proposal for a restriction, Substance name: Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP). http://echa.europa.eu/documents/10162/c6781e1e-1128-45c2-bf48-8890876fa719

[155] Consumer and Competition Policy Directorate 2002. Research into the mouthing behaviour of children up to 5 years old. URN 02/748

[156] Swedish Chemicals Agency, Varuguiden (Article guide). Available. 01.11.2014 http://webapps.kemi.se/varuguiden/.

[157] Barr DB, Silva MJ, Kato K, et al. Assessing human exposure to phthalates using monoesters and their oxidized metabolites as biomarkers. Environmental Health Perspectives 2003; 111(9) 1148-1151.

for high molecular weight phthalates. Different phthalates can also be metabolised into the same metabolite, which means that it can be difficult to ascertain which phthalate is the source of exposure. Rapid metabolism can cause a variation in metabolite concentration in the short term. However, the constant exposure that we have been subject to means that the levels are relatively similar over time. Differences in exposure level among different people can however be observed as a consequence of different habits or different external conditions producing variations in exposure, for instance, the occurrence of materials containing phthalates in the home environment.

The majority of bio-monitoring surveys analyse concentrations in adults, while there are only a few studies on children and an extremely small number of studies on children under the age of three. However, the studies available indicate that children are subject to higher exposure levels than adults. As described in previous sections, children have a higher level of exposure via food and indoor environment, as well as through their habit of mouthing objects.

A study conducted on children in Denmark and Korea compared calculated exposure levels from indoor and outdoor environments, as well as from food, with exposure based on the measurement of metabolite levels in urine for the phthalates DEHP, DBP and BBP[158]. The assessment of exposure based on metabolites in urine was higher, which may be due to articles not being included in the calculation model. In the case of the children subject to the highest exposure level, an overall assessment of the three phthalates DEHP, DBP and BBP indicated that concentrations were above what is considered a safe level.

6.3 Concluding summary

A number of the phthalates are regulated to different degrees in different types of articles, such as toys and childcare articles or in materials in contact with foodstuffs. However, there is no blanket regulation in place for governing harmful phthalates, which still occur in a large number of articles. Even the phthalate DEHP, which is well on its way to being phased out within the EU, occurs to a large extent in imported articles, which do not come under the authorisation requirement in REACH (see also Chapter 3). The widespread occurrence of phthalates causes constant exposure to both humans and the environment, which is a reason for continuing to phase them out. Additional restrictions may also be required for DEHP as high concentrations still occur in a large number of imported articles. According to Sweden's environmental quality objective of a Non-Toxic Environment, articles have to be free as far as possible of substances which are toxic for reproduction[159].

Phthalates contained in articles can cause direct exposure to humans, for instance, to children mouthing objects, and this also results in the spread of phthalates in both the indoor and outdoor environments. Concentrations in dust, the indoor environment and in food are likely to be originally linked to the production, use and waste management for articles containing phthalates. Therefore, restricting the occurrence of phthalates in various articles would, in the long term, also reduce the concentrations of phthalates in the indoor and outdoor environments, as well as in food.

The information available indicates that the level of exposure to phthalates is generally below the limits in relation to different sources of exposure and comprehensive bio-monitoring

[158] Lee J, Lee JH, Kim CK, Thomsen M. Childhood exposure to DEHP, DBP and BBP under existing chemical management systems: A comparative study of sources of childhood exposure in Korea and in Denmark. Environment International 63(2014) 77-91.
[159] Environmental objective of a Non-Toxic Environment. Available. 30.10.2014 http://www.miljomal.se/sv/Miljomalen/4-Giftfri-miljo/.

studies, even if children, who are subject to the highest level of exposure, are close to the limit in some cases and even occasionally above the limits considered to be safe. A joint assessment of the phthalates DBP, BBP and DEHP, which cause similar effects, indicates that the overall level of exposure and the ensuing risk are not controlled to a sufficiently high degree.

Efforts are continuing in the EU to establish criteria for when substances need to be identified as endocrine-disrupting. If these phthalates are also considered to be endocrine-disrupting, additional assessments and tighter restrictions may be required, if applicable.

As already discussed in this chapter, small children are subject to the highest exposure to phthalates, while the most sensitive group regarding reproductive effects are developing foetuses. In the case of foetuses, their exposure is determined by the mother's exposure. But by limiting small children's exposure to phthalates which are toxic for reproduction, this will reduce the level of exposure pregnant women and, therefore, their foetuses are subject to.

7 Possible measures

7.1 International conventions and agreements

7.1.1 SAICM - Global initiative on providing information about hazardous substances in articles

SAICM "Strategic Approach to International Chemicals Management" is a politically binding agreement within UNEP.

The task of distributing information more widely about the content of hazardous substances in articles is important for a number of reasons. Companies which sell articles, but do not have a direct insight into the process for manufacturing them must be aware of the substance content in them to be able to enforce the regulations which apply in the EU regarding, for instance, substance restrictions and the distribution of information. This information is also important to companies which actively want to reduce the content of hazardous substances in their articles by means of substitution. Better information about the content of hazardous substances is also required for the waste disposal phase in order to prevent the risk of recirculating hazardous substances through recycling, for instance. Clear and simple information about hazardous substances is also required for consumers so that they can make well-informed choices when they are purchasing articles.

The current CiP project (Chemicals in Products), which is an ongoing project within the UN, is important in terms of facilitating the distribution of information about hazardous substances in articles, including phthalates. As mentioned earlier, there is already a requirement in the EU under the REACH Regulation to provide such information to recipients of articles[160]. During its market surveillance, the Swedish Chemicals Agency has been able to notice that this requirement is far from met all the time. The explanation often given is that companies selling articles which have been imported from a non-EU country have not received any information about the content of hazardous substances from their suppliers. Therefore, a voluntary global system facilitating the distribution of information could mark an important step in spreading information more widely about hazardous substances in the EU as well.

[160] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 33.

Sweden should endeavour to make sure that the voluntary programme within the CiP will not be too narrow in terms of which substances are included. One proposal is that the scope of application is at least linked to the substance categories defined in SAICM, which have been prioritised with minimising risks and phasing the substances out in mind[161]. One such category which has been defined is CMR substances.

7.2 EU regulations

7.2.1 Hazard classification of chemicals (CLP)

Classification and labelling of chemical products is an effective instrument to provide the necessary information to end users about the chemical products' intrinsic hazardous nature and about how to provide protection aimed at minimising exposure. Classification information is also used by companies in their preventive efforts in substituting hazardous chemicals. How phthalates are regulated by restriction rules in the EU also largely depends on how the substance is classified according to the CLP Regulation. For example, harmonised classification makes it easier to include them in the candidate list under REACH.

A substance can be given a harmonised classification by the authorities and manufacturers in individual EU Member States, importers or downstream users requesting for classification and labelling of the substance to be harmonised within the whole EU. This can be done if, for instance, the substance has CMR properties.

By assessing new data and making comparisons with known substances which have a similar chemical structure, new classification proposals can be drafted by Member States.

The Swedish Chemicals Agency considers that Sweden should endeavour to ensure that a harmonised classification is granted to more phthalates which are potentially toxic for reproduction, are widely used in large volumes and are found in consumer articles, if they fulfil the criteria, such as CMR category 1A or 1B. As classification is a basic factor in determining how phthalates are regulated in the EU, this is one measure which we think should be made a priority.

7.2.2 REACH

Striving for restrictive authorisation according to REACH requirements

As already mentioned, from 2015 authorisation will be required to use the phthalates DEHP, DBP, DIBP and BBP. The purpose of this is for these phthalates to gradually be replaced by safer alternatives or techniques. Authorisation may be granted if the application can indicate that the health and environmental risks can be sufficiently kept in check or if it can be proven that the socio-economic benefits outweigh the health or environmental risks linked to the substance's use, and if there is no suitable alternative substances or techniques available.

The Commission has so far granted one authorisation for the use of DEHP. Its use is restricted and applies to the manufacture of fan blades for aircraft engines. There is no DEHP left in the

[161] SAICM Overarching Policy Strategy, Article 14: "Groups of chemicals that might be prioritized for assessment and related studies include: persistent, bioaccumulative and toxic substances (PBTs); very persistent and very bioaccumulative substances; chemicals that are carcinogens or mutagens or that adversely affect, inter alia, the reproductive, endocrine, immune, or nervous systems; persistent organic pollutants (POPs), mercury and other chemicals of global concern; chemicals produced or used in high volumes; those subject to wide dispersive uses; and other chemicals of concern at the national level."

end product. However, several applications have been submitted to the Commission for phthalates. This has included the European DEHP industry requesting authorisation covering a very broad scope of application. The Commission will decide whether to grant or reject authorisation after a public consultation process concerning alternatives has been carried out, after ECHA's scientific committees have issued statements and after Member States have voted via the regulatory committee.

As the authorisation requirement has not yet come into force, it is difficult to assess the authorisation process. However, we can already see problems and shortcomings now, which risk to prevent the objective of phasing out substances requiring authorisation being achieved.

One shortcoming in the authorisation management process is that it is difficult to obtain independently information about alternative substances and techniques. This particularly applies to alternatives in the form of other technical solutions which are normally supplied by companies other than the company which is applying for authorisation. Therefore, there is the risk that the decision-making process will largely be based on information from those actually requesting authorisation.

We have also noticed that applications have been let through the first check, even though the intended use has been specified in a very broad and vague manner. This is contrary to the requirements to describe the substance's use very precisely, as stated previously.

There has also been some uncertainty about whether and how the authorisation provisions should be applied to recycled material. Some believe that it should be exempted from authorisation[162]. The question has also become topical in connection with a specific case where a recycling organisation applied for authorisation to recycle PVC plastic containing DEHP. In the Swedish Chemicals Agency's view, recycled materials cannot be exempted from authorisation in general. We do not think either that particularly hazardous substances should be granted authorisation in recycled materials without verifying the substances in the same way as applies to uses in newly manufactured materials.

We consider that Sweden should establish contact with EU institutions at different levels in an effort to ensure that the authorisation provisions in REACH are applied in line with the intention of achieving a high level of health and environmental protection by substituting substances of very high concern, including the most dangerous phthalates, with substances or technical solutions providing a safer alternative[163]. As the authorisation management process is at an early stage, decisions have been made in only a few cases. Efforts are continuing in establishing good practice for managing them. Therefore, current authorisation cases are very important to how authorisation is managed in the future. It means that this is one of the measures we must regard as being a priority.

Efforts required for ECHA to propose restrictions under REACH

The authorisation requirement under REACH does not apply to articles containing phthalates subject to authorisation when these articles are imported from non-EU countries. In order to regulate imports, a restriction is required under REACH[164] or in some other EU legislation

[162] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 58(2).
[163] More proposals about how, for instance, the authorisation process under REACH should develop feature in the Swedish Chemicals Agency rapport "Utveckla och effektivisera Reach – en handlingsplan" (Developing and streamlining REACH - an action plan), report 4/14.
[164] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Annex XVII.

governing articles, targeted at articles containing these substances. One requirement under REACH stipulates that, after the authorisation requirement has come into force for a substance, the chemical agency ECHA must assess whether a restriction is also required for articles containing the substance. If this is appropriate, ECHA must draw up a proposal for such a restriction[165].

There are several reasons why a restriction should be considered for the phthalates which are subject to authorisation. Firstly, the procedure for handling the risks associated with phthalates in public will not be comprehensive if it only applies to articles manufactured in the EU. Our survey also indicates that there is a significant use of phthalates in articles in non-EU countries, which can be imported into the EU in spite of the authorisation requirement. Therefore, an authorisation requirement cannot handle in a comprehensive manner the environmental and health risks which these phthalates entail in the EU.

Secondly, this puts article manufacturers in the EU at a competitive disadvantage when manufacturers outside the EU, who then export their articles to the EU, can ignore the same stringent phthalate regulations. This is unlikely to be the intention behind the REACH legislation.

Compensating for the competitive disadvantage for EU industry is one factor which may justify regulations aimed at imported articles. This has been noted by the European Court of Justice in a ruling from 2009 concerning the duty to register polymers under REACH[166]. An importer believed that the requirement to register as well the constituent monomers in imported polymers contravened the principle of equal treatment as it is easier for EU polymer manufacturers than importers to register these substances. However, this was confirmed by the Court of Justice to be justified since it prevented importers from having an advantage over EU manufacturers. Therefore, this requirement was compatible with the principle of equal treatment.

Consequently, we consider that Sweden should endeavour at different levels to persuade the Commission and ECHA to give consideration to the following during the next assessment of the need for restrictive regulations for phthalates:

- a huge proportion of the phthalates which EU consumers are currently exposed to are not affected by the authorisation requirement as they feature in imported articles and
- the competitive disadvantage which the phthalate provisions under REACH currently entail for articles manufacturers within the EU compared to manufacturers outside the EU.

Proposing restrictions via REACH fast-track procedure

A proposal was submitted by Denmark to the EU in 2011 on banning the use of DEHP, BBP, DBP and DIBP in consumer products throughout the EU, based on a REACH restriction. However, the proposal failed to receive the backing of the EU's Committee for Risk Assessment (RAC) as it believed that the available data failed to show there was any risk from combined exposure from phthalates.

To ensure Sweden's success in promoting a restriction under REACH on these phthalates, such a proposal must either contain new data capable of changing the RAC's assessment or be made narrower in relation to the Danish proposal. The latter can be achieved by simply

[165] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 69(2).
[166] Case C-558/07, paragraphs 73-81.

selecting one or more of the phthalates and/or by targeting the restriction at certain, specific categories of articles. Furthermore, as the main thrust of our action proposal, we can, instead of referring to the standard restriction process, suggest that the Commission make a decision on a restriction based on the "fast-track" procedure under REACH, with the aim of restricting the presence of CMR substances in articles which may be used by consumers[167].

The REACH fast-track procedure has not been used yet to restrict the presence of CMR substances in articles. However, there are currently discussions in progress about using this mechanism to restrict certain CMR substances in textiles. As its name indicates, this restriction process will be faster than the standard process as the same material is not required in terms of risk and socio-economic analysis. The RAC and SEAC do not need to be involved in the process either.

Only the European Commission can formally initiate a fast-track restriction. However, there is nothing to prevent a Member State from suggesting that the Commission introduce such a process. On the contrary, the Commission has described in a document when it considers the use of the fast-track process appropriate in order to make it easier for countries wishing to propose such restrictions[168].

Based on what the Commission has stated about the fast-track process in REACH, we can say that the restrictions proposed by Member States will probably need to be clearly defined and justified, even if in-depth analyses are not required, as in the case of the standard restriction process. The most successful proposal is likely to be one for a relatively narrow restriction aimed at specific categories of articles where we can demonstrate the occurrence of phthalates and there may be concern about particular exposure risks.

We have identified a number of groups of articles which we consider may be suitable in terms of proposing phthalate restrictions using the REACH fast-track process. The starting point has been the risk of exposure to children. The groups of articles are:

- Accessories (including gloves and bags)
- Clothing and footwear
- Sports and leisure articles
- Home furnishings
- Electronics (unless phthalate restrictions are introduced in the RoHS Directive)
- Vehicles
- Construction products for indoor environment

In the first four categories listed above, children are subject to exposure by being able to put the object in their mouth or suck it. Vehicles and construction products for the indoor environment, on the other hand, subject children to more general exposure. None of these groups of articles currently have any regulations restricting the use of phthalates. Apart from these categories, it may also be appropriate to restrict the use of phthalates in sex toys. This is supported by the risk analyses presented by Denmark in its proposal for restricting the use of phthalates in 2011[169].

Sweden can draft a proposal on restricting the use of phthalates in these groups of articles by using the REACH fast-track process, which can then be presented to the Commission and

[167] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 68(2).
[168] CACS/13/2014, Use of article 68(2) for CMRs in articles.
[169] REACH Annex XV dossier (2011), Proposal for a restriction, Substance name: Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP). http://Echa.europa.eu/documents/10162/c6781e1e-1128-45c2-bf48-8890876fa719.

other Member States. However, one alternative is to draft the proposal in collaboration with one or more other countries which are well advanced in their efforts to phase out phthalates, such as Denmark and France. A joint proposal may possibly place greater political pressure on the Commission to proceed with the proposal and adopt a decision about further restrictions under REACH.

It is important that the REACH fast-track process starts to be used as intended for phasing out CMR substances in articles. So far, there has been no practice established for this. Therefore, we see the proposal on restricting phthalates in this way as an important step towards establishing such a practice. This is why we wish to highlight this proposal as one of the priority proposals.

Adding more phthalates to the candidate list

When a substance is registered in the REACH candidate list, this means that it is a candidate for being listed in the annex for substances which require authorisation for use in the EU. However, the fact that a substance is registered in the candidate list may also have direct consequences for companies which import and sell articles containing this substance in a concentration above 0.1%. It must specifically provide information about the substance's content to commercial users and consumers[170]. This means that the candidate list has several functions: it lists substances which may be subject to authorisation and it provides the basis for an information system for substances of very high concern featuring in articles. The Swedish Chemicals Agency has found in its experience that many companies choose to phase out the substances which have been included in the candidate list, even if this is not a statutory requirement.

The candidate list is constantly evolving, which means that new substances are gradually being added to it. There are currently 13 phthalates registered in the candidate list. Thanks to the candidate list's efforts promoting substitution, Sweden should endeavour to ensure that more phthalates are registered in the list, when these have been given a harmonised classification at EU level as substances that are toxic for reproduction or have other severe properties, such as endocrine-disrupting features. Therefore, this is a measure which we want to prioritise.

7.2.3 General Product Safety Directive

Under the General Product Safety Directive, the Commission has an option to make a decision quickly at EU level on banning a product which poses a serious risk to consumers' health and safety[171]. These bans are valid for one year, with an option for extension. The intention is for the ban to be subsequently incorporated into the legislation it is closest to, such as REACH, the Toy Safety Directive or any other relevant legislation. One example from the chemicals sector where the Product Safety Directive is used to impose a temporary ban on a substance is the ban on certain phthalates in toys. This ban was subsequently assigned to the REACH Regulation. Another example is the biocide dimethylfumarate, whose use is banned in consumer products. A ban on dimethylfumarate has now been adopted under REACH. There are also discussions in progress on restricting CMR substances in tattoo inks.

[170] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 33.
[171] Directive 2001/95/EC, Article 13. Under the Product Safety Directive, a product is considered to be a chemical product and article.

7.2.4 RoHS Directive

The Commission is drafting, at the time of writing, a proposal on restricting the use of the phthalates DEHP, BBP, DBP and DIBP in electronics. The restrictions are intended to be introduced in the RoHS Directive, which currently restricts the use of certain chemicals in electrical and electronic equipment. A possible decision from the Commission is expected before late 2014/early 2015, with the restrictions likely to start applying to consumer electronics around two years after this. In the case of medical equipment and control instruments, the restrictions are expected to come into force only after four or five years because a longer transition period is required[172].

The Swedish Chemicals Agency is optimistic about the use of phthalates being restricted in electronics. We can see that electronics is one of the categories with the largest proportion of imports from non-EU countries. Therefore, these articles will not come under the authorisation requirement which applies to these phthalates under REACH from 2015. Our clear assessment of the exposure level indicates that electronics is a category of articles which children put in their mouth to some extent. Therefore, we think that Sweden should work towards the Commission adopting a decision banning the use of DEHP, BBP, DBP and DIBP in electronics. We see this as a priority action proposal in the report.

7.2.5 The Toy Safety Directive

Toys are one of the categories of articles protected by the most far-reaching EU regulation on phthalate content. As mentioned in Chapter 3, there are restrictions on the use of phthalates in both the REACH Regulation and Toy Safety Directive. This means that toys are not an area where we see an immediate need to tighten controls on phthalates either at EU or national level. In principle, there is no scope either for tighter regulations at national level because of the harmonised EU regulations in this area.

However, what we have noted is that regulations on chemicals in relation to toys have been found to be difficult to access as they feature in different pieces of legislation. The restrictions and information requirements under the REACH Regulation are directly applicable in Sweden and have therefore not been implemented in Swedish legislation. On the other hand, the chemical regulations in the Toy Safety Directive need to be implemented in each Member State. This has been done in Sweden via the Swedish Chemicals Agency regulation (KIFS 2008:2) on chemical products and biotechnical organisms. Furthermore, there are substance restrictions in the POPs Regulation[173], which is directly applicable in Sweden just like the REACH Regulation[174]. This means that a company selling toys in Sweden needs to comply with several different pieces of legislation just relating to chemicals.

We believe that making it easier for the operators on the market to comply with the chemical regulations for toys by clarifying the legislation is an important step in increasing the regulations' impact. As the regulations currently apply, to a large extent, at EU level, the task of simplifying them should be carried out first and foremost on EU level. However, we see opportunities for also clarifying Sweden's implementation of EU legislation, mainly the Toy

[172] As there is an option to apply for an exemption from a substance restriction in the RoHS Directive, it is important to find an ideal time for entry into force. If the restriction comes into force before manufacturers have managed to adapt their production, there is a risk of companies applying for and being granted exemptions for numerous applications.
[173] Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants.
[174] The companies selling electric toys also need to be familiar with the RoHS Directive, those selling cosmetics need to be familiar with the Cosmetic Products Regulation, while the CLP Regulation is also applicable to chemical toys. In some cases, other legislation also needs to be applied.

Safety Directive[175]. This task of simplifying regulations is part of the Swedish Chemicals Agency's ongoing review of the authority's code of statutes.

7.2.6 Medical Device Directive

There are currently no bans applied to phthalates in medical devices (see Chapter 3). The only requirement is for certain products to be labelled if they contain phthalates. Sweden is involved in the renegotiation in progress on the Medical Device Directives, aimed at banning CMR substances, including phthalates in the REACH candidate list, with the option of an exemption under certain conditions. However, it is still not certain whether Sweden's proposals will be successful during the negotiations.

Therefore, there is a risk that the use of phthalates will continue to be allowed in all medical devices even after the renegotiation of the EU Directives. If this is the case, alternative instruments should be considered for phasing out phthalates in medical devices, especially in hospitals, where premature babies and pregnant women are at risk of exposure. One way of achieving this, as in France, may be to introduce a national ban on using certain medical devices if they contain DEHP in certain hospital environments (see section 3.3.3)[176]. Another way, which we suggest in this report (see section 7.5), is to develop a method of working with public procurement as a substitution instrument.

7.3 National regulations – Limit on phthalates in articles used in an indoor environment

7.3.1 The need for emission limits for construction products

Six research articles have been published on the subject of PVC flooring as a source of exposure to phthalates in the home environment in Sweden and about whether these factors can be linked to an increased risk of asthma and allergies in children. The publications are based on a large epidemiological study "Dampness in Buildings and Health" (DBH) whose aim was to analyse risk factors contributing to asthma and allergies in the indoor environment. The DBH survey started in 2000 and included more than 10,000 children and their parents. The studies indicated overall that there is a link between PVC flooring in the home environment and the volume of phthalates in dust. The intake of dust was identified as a key means of exposure to phthalates for children aged between one and three years old. A connection was also observed between exposure to phthalates and an increased risk of asthma and allergies. DEHP and BBzP were measured at the highest concentrations of dust, of which PVC flooring is one of the main sources. Researchers also observed a direct link between the quantity of DEHP and BBzP in children's bedrooms and an increased risk of asthma and allergies.

[175] On the other hand, the chemical restrictions in the EU regulations should not be implemented in Swedish legislation.

[176] However, this would require a thorough legal analysis of whether such a restriction on medical devices is compatible with the EU Medical Device Directive, which actually bans Member States from restricting the marketing of specified products. It can possibly be argued that the Directive does not prevent a national restriction being imposed on these substances' use as it does not have a direct impact on the marketing of the products.

7.3.2 Need for national regulations

There are currently no EU-wide regulations governing emissions from construction products in an indoor environment[177]. As mentioned above, it will be necessary from February 2015 to obtain authorisation for producing articles containing the most dangerous phthalates in the EU. However, a large number of articles on the EU market containing phthalates are imported from third countries, which are therefore not subject to the authorisation requirement. This means that the regulations will not be comprehensive, especially in those areas where a large proportion of the articles being sold in the EU are manufactured in third countries. This also puts European industry at a competitive disadvantage as it has to give consideration to more stringent regulations than the corresponding industry in the third country needs to take into account to gain access to the European market.

To ensure that the importation of articles is also covered, regulations are required at article level, unlike the REACH authorisation requirement, which applies at substance level. The EU Construction Product Regulation covers imported articles, but does not stipulate any requirements in terms of product features, but only states how construction products' features will be assessed and described when the products are placed on the market (see Chapter 3). Product requirements are generally stipulated instead at national level. The common EU assessment and description methods in the Construction Products Regulation are intended to prevent national product requirements creating unnecessary trade barriers by making companies re-test their products for different countries' markets.

Three EU countries – Germany, France and Belgium – have introduced national regulations on emissions of hazardous chemicals from construction products (see Chapter 3). At present, Sweden only has emission limits for formaldehyde from wood-based boards.

7.3.3 Legal scope for national chemicals restrictions for construction products

In July this year, Denmark's Ministry of the Environment rescinded its ban on the use of phthalates in articles (see Chapter 3)[178]. The reason for rescinding the ban was that the Commission had levelled criticism at it, believing that it contravened the REACH Regulation. In the Commission's view, Denmark was unable to introduce national regulations when a proposal on regulating phthalates under REACH had already been examined and rejected by the RAC. The Commission believed that national bans would create unlawful trade barriers within the EU.

The individual countries' option to go ahead with national chemicals bans has been debated in the EU ever since REACH was adopted in 2006. The slow processes involved in adopting an EU ban have also led to many countries choosing to go ahead with a national ban. Some examples include the restrictions imposed by France and Belgium on the endocrine-disruptor bisphenol A, Sweden's regulation on tattoo inks, the emission limits set for certain chemicals in construction products in Germany, Belgium and France, and reporting requirements in several countries for articles containing nanomaterials. Although the Commission has criticised proposals in many cases, none of them have progressed to an examination by the European Court of Justice. Therefore, at present, there is only the wording in REACH and

[177] The REACH Regulation (EC) No 1907/2006 contains some chemicals-related restrictions in relation to construction products, but none governing phthalates.
[178] Danish Environmental Protection Agency, 2014. Available. 19.11.2014. http://mst.dk/service/nyheder/nyhedsarkiv/2014/jul/forbud-mod-fire-ftalater-ophaeves/.

existing case-law from the European Court of Justice on related issues to use as a basis for settling the legal situation.

The Swedish Chemicals Agency's view has been that REACH does not prevent countries from going ahead with a national ban as long as there are no common EU regulations and provided that the regulations are compatible with EU free movement regulations[179]. However, in light of the criticism levelled at Denmark by the Commission, we have seen good reason to re-examine the legal situation. This legal examination is contained in Appendix 5.

Our conclusion is that REACH should not prevent Member States from imposing a national ban on hazardous chemicals when there are no restrictive regulations already in place at EU level. However, to guarantee a national restriction's compatibility with REACH, it must be ensured that there is no "duplication" or any conflict with any existing regulation for the same substance in REACH. If a substance is subject to an authorisation requirement under REACH, the national regulation, for instance, must be drafted taking this factor into account.

National requirements must obviously also be drafted to comply with Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) on the free movement of goods. During the drafting process, it must, for instance, be considered whether a certain substance or a certain use has already been subject to an EU restriction process. If, for example, it has been assessed as part of the REACH process that there is no unacceptable risk and that a REACH restriction has therefore not been deemed as justified, this may influence the opportunities of justifying national bans on the same substance or use.

In light of this, it would be difficult to justify a general national ban on the most dangerous phthalates, as was adopted in Denmark, since in June 2012 the RAC noted that such a restriction is not justified from a health protection perspective. In any case, new data would be required capable of demonstrating that the RAC's assessment is no longer relevant. On the other hand, the RAC's opinion should not prevent Sweden, if Sweden feels it is justified, proposing a national regulation governing phthalates, applying only, for example, to construction products as this was not one of the measure options tabled by Denmark.

As already mentioned above, the Construction Products Regulation does not prevent requirements being imposed on construction products at a national level, but actually requires national rules. We can also mention that a number of countries have introduced emission limits for chemicals in construction products, the most recent being Belgium in 2012 (came into force in January 2014), without the Commission having submitted the issue to the European Court of Justice. In the case of Belgium, the Commission did not level any criticism at all against the proposal.

7.3.4 Drafting regulations

We are proposing for the government to initiate an inquiry into how Sweden can introduce threshold limits for the most hazardous phthalates in construction products, similar to the system in force in other European countries. This is in keeping with what the government has already proposed in the Chemicals bill[180]. Given that such a regulation should probably cover more substances than just phthalates, we do not believe that it is within the remit of this report to submit any completed statutory proposals.

[179] See, for example, Swedish Chemicals Agency report 4/12, Bisfenol A i kassakvitton (Bisphenol A in cash receipts) – Report from a government commission.
[180] Government bill 2013/14:39, page 77.

To avoid any unnecessary trade barriers, it is important that the regulations take into account regulations already in force in other countries. This does not mean necessarily that the same limits should apply in Sweden as in other countries. It is up to each country to establish appropriate limits. What it rather means is that appropriate test and declaration methods should, where possible, apply in all national legislations to avoid companies selling construction products in several countries having to re-test their products. Therefore, from a commercial viewpoint, it is paramount to take into account the work currently being carried out in the EU on producing a harmonised standard for assessing and certifying emission levels for construction products. This work is in progress and is expected to be complete during 2015.

The emission regulations should be drafted so that they are transparent to all the operators on the market. The proposed enquiry should examine whether the regulations should apply when the products are released on the Swedish market or as performance requirements for the completed structure. Regulations governing the marketing of construction products are not common in Sweden. In the construction sector in Sweden, regulations are targeted instead mainly at the actual structure[181]. A construction product can only be included in a structure if it is suitable for the intended use[182]. The product is considered suitable if it has the properties to enable the structure which it is going to be used in to fulfil certain, specified technical property requirements, including protection in terms of hygiene, health and the environment.

A regulation restricting the sale of construction products in Sweden (possibly supplemented by a ban on use) could therefore be perceived as an oddity in Swedish building legislation. This may indicate that the regulation is targeted instead at the completed building. On the other hand, one argument in favour of a marketing regulation may be that this would bring the regulation into line with existing regulations in other countries. Harmonised regulations would probably make the situation easier for market operators and make it easier to justify from an EU legal perspective. This is an issue which any inquiry should take a closer look at.

The Swedish Chemicals Agency has called for this inquiry before and is optimistic that the government will put forward this proposal in the Chemicals bill. We are flagging this as a priority proposal in this report.

7.4 Positive eco-labelling/certification system

Ordinary consumers may find it difficult to make environmentally-friendly choices as it is not easy to obtain knowledge about hazardous chemicals and their use in articles. They are given some assistance in this matter by the ever-increasing number of articles with eco-labelling. In Sweden eco-labelling has made a major impact through the Nordic eco-label (The Nordic Swan) and the Swedish Society for Nature Conservation's Good Environmental Choice (Bra Miljöval) eco-label. The EU has been operating its EU Ecolabel system since 1992 which, in its present form, bears many similarities to the Nordic Swan scheme, but has not been given the same scope. These eco-labelling schemes provide an overall assessment, indicating that the article is environmentally sustainable, including the presence of hazardous chemicals. Eco-labelling guides consumers by "translating" complex information and scientific data into simple symbols.

There is no general ban on phthalates in the eco-labelling system. The use of phthalates in articles is controlled instead on a category-by-category basis, with far from all articles

[181] The basic technical requirements for structures are specified in Chapter 8, section 4 of the Swedish Planning and Building Act (2010:900).
[182] Swedish Planning and Building Act (2010:900), Chapter 8, section 19.

currently being covered by eco-labelling criteria. However, one example is the Nordic Swan label's requirement for dialysis bags used in the healthcare sector. To obtain the Nordic Swan label, these bags must not contain any phthalates[183]. As more categories of articles are covered by the eco-labelling system and the existing criteria are revised, more restrictions will be introduced on phthalates.

The EU and the Commission in particular have, in recent years, focused strongly on developing soft instruments such as eco-labelling criteria and green procurement criteria. It is important for Sweden to continue its involvement in this activity, where Swedish and Nordic criteria have often been used as models for common EU criteria.

Green activities are ambitious in many respects in the Sweden construction sector. Nowadays, there are voluntary systems for classifying and labelling buildings environmentally in both Sweden and abroad, such as: LEED[184], BREEAM[183] and Green Building[183]. There are environmental assessment systems for construction products: BASTA[185], Byggvarubedömningen[186] and SundaHus[187]. These systems are based on criteria, and construction products containing phthalates which are toxic for reproduction at concentrations above 0.1% are not approved under these systems. In order to document features in construction products, including chemical content, the Ecocycle Council has developed construction product declarations (BVD)[188].

7.5 Public procurement

Environmental and health protection requirements relating to public procurement are a market-based instrument whose potential for helping phase out hazardous chemicals in general and phthalates in particular can be developed. Procurement requirements can encourage both substitution and innovations in the chemicals sector. The value of goods and services in Sweden subject to the public procurement process in 2010 has been calculated at between SEK 560 and 670 billion[189]. Demand from customers can be a strong driver of companies' own efforts to reduce the risks.

Chemical requirements in public procurement can, for instance, be used as a suitable instrument for promoting substitution in this area where the process of formulating regulations at EU level is progressing slowly. In many cases Sweden does not have the opportunity to go ahead and impose tighter legislation when regulations are already in force at EU level, for instance, in the case of electrical equipment, toys and medical equipment[190]. By using green procurement, the public sector can go further than the legislation and steer

[183] The Nordic Swan, Criteria. Available: 10.10.2014. http://www.svanen.se/Foretag/Kriterier/kriterie/?productGroupID=61.
[184] Sweden Green Building Council. Available: 19.11.2014. http://www.sgbc.se/
[185] BASTA, assessment system for construction and installation products. Available: 19.11.2014. http://www.bastaonline.se/
[186] Byggvarubedömningen (Building product assessment). Available: 19.11.2014. http://www.byggvarubedomningen.se/sa/node.asp?node=455
[187] SundaHus. Available: 19.11.2014. http://www.sundahus.se/home.aspx
[188] Association of construction product declarations. Available: 19.11.2014. http://www.byggvarudeklarationer.se/
[189] Swedish Competition Authority, 2013. Figures and facts about public procurement; Statistics on procurement procedures carried out in 2012. Report 2013:9. http://www.konkurrensverket.se/upload/Filer/Trycksaker/Rapporter/rapport_2013-9.pdf
[190] Swedish Environmental Management Council. Available: 19.11.2014. http://www.msr.se/sv/Aktuellt/Press/Pressmeddelanden/Europeiska-miljokrav-for-sjukvard-framtagna-av-Sverige/

developments towards a non-toxic environment. Procurement should be a particularly effective instrument in areas where the public sector accounts for a large proportion of the market, for instance, in the healthcare sector and in pre-school institutions.

There has been a discussion about whether far-reaching environmental (chemical) requirements could result in restricting the market, contrary to EU regulations. For example, the question has been raised about whether procurers can impose chemical requirements which exceed harmonised EU legislation. In the view of the Swedish Chemicals Agency, based on factors including EU judgments and the existence of different EU criteria for green procurement, it is definitely possible to impose chemical requirements which go further than existing legislation. This interpretation is also shared by Sweden's specialist agency on procurement matters, the Swedish Competition Authority[191].

The EU's procurement regulations have just been revised and the new directives provide procurers with even more opportunities for taking into account green factors than under the previous directives[192]. This is naturally a positive development. However, procurers have occasionally experienced problems in setting out chemical requirements when there is often a lack of knowledge about the content of the substance in articles. Therefore, the need for effective tools and knowledge with a view to imposing relevant chemical requirements and monitoring them is vitally important to ensuring that the potential offered by procurement as an instrument is met[193]. Therefore, we believe that the task of the Swedish Competition Authority – previously known as the Swedish Environmental Management Council – in devising procurement criteria is particularly important.

In June 2014 the government tasked the Swedish Competition Authority with devising criteria for chemical requirements for procurement in pre-school institutions[194]. This assignment is being carried out as part of the government's action plan to create a non-toxic daily environment, and is due to be reported on in May 2015. The Swedish Environmental Management Council previously carried out, at the Swedish Chemicals Agency's request, a preliminary study on creating a non-toxic environment in pre-school institutions[195]. This will provide an important foundation for the work which the Swedish Competition Authority is going to complete.

The Swedish Competition Authority will join forces with experts in various fields to produce a package of requirements, followed by some guidelines, intended to make it easier for procuring authorities to impose sensible chemical requirements in the case of procurement for pre-school institutions. Sweden's local authorities have a great need for and are seeking support and advice on purchasing items for pre-school institutions and other environments where children spend a large part of their time. The desired aim is to produce a complete support package comprising a variety of tools. This will include criteria for health and

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[191] Swedish Competition Authority, 2014. Giftfri förskola är ett gemensamt intresse (Non-toxic pre-school institutions are in our common interest). Stakeholders meeting. http://www.kkv.se/upload/Filer/Press/Tal-artiklar/anforande_dan_sjoblom_giftfri-forskola_141924.pdf.

[192] SOU 2014:51, new rules on procurement.

[193] Swedish Environmental Management Council, 2012. Final report on chemical substitution through public procurement. Report 2012:4.
http://www.msr.se/Documents/publikationer/msr_2012_4_kemikaliesubstitution.pdf

[194] Swedish Ministry of the Environment, 2014. Assignment on procurement criteria for creating non-toxic pre-school institutions, Swedish Competition Authority.
http://www.konkurrensverket.se/upload/Filer/Om_Konkurrensverket/Regeringsuppdrag/regeringsuppdrag_giftfri_forskola_140626.pdf.

[195] Swedish Environmental Management Council, 2013. Giftfri förskola – Leka, äta, sova (Non-toxic pre-school – Play, eat, sleep). Report 2013:2. http://www.msr.se/Documents/publikationer/msr_2013_2_leka_ata_sova.pdf

environmental requirements in four different product areas: household utensils, toys, textiles and furniture. When criteria are actually in place, work will continue in 2015 in collaboration with the Swedish Chemicals Agency on marketing and publicising the established criteria.

It is our view that the systematic work going on in the pre-school area is the right way for us to develop procurement as an instrument in the chemical sector. However, we can see more areas where procurement can be used more than it currently is for phasing out hazardous chemicals. On the matter specifically of those phthalates which are toxic for reproduction and potentially endocrine-disrupting, we believe that the healthcare sector is one of these important areas. Most medical devices containing phthalates can be substituted fairly easily with less hazardous alternatives at an affordable cost, if requested during procurement.

In some cases, greater efforts may be required to make a substitution. At present, we know that, for instance, bags for red blood cells contain 30-40% DEHP and it is a known fact that DEHP migrates to blood. The amount of DEHP which migrates depends on such factors as time, temperature and fat content. Due to the fact that DEHP, apart from its plasticising properties, also interacts with components in the blood so that it can be stored for longer, the technical and financial obstacles are greater when it comes to substituting it in blood bags, for instance. Conventional procurement requirements and methods are not sufficient in this case to overcome all the obstacles. Therefore, direct support may be required in developing products or carrying out what is known as innovation procurement (procuring articles which are not yet available on the market). There is a project under way at the moment, aimed at developing a totally PVC-free blood bag, based on cooperation among six different operators in the EU and with financial support from the EU's Life+ programme[196].

Based on the toxicological effects of DEHP, the main concern is the most sensitive groups – newborn babies, children and pregnant women – being exposed via medical devices. Therefore, it is particularly important to phase out phthalates in hospital environments where premature babies and pregnant women are at risk of exposure. There are currently no bans applied to harmful phthalates in medical devices. During the current negotiations on new EU regulations, Sweden has proposed a ban, with the option of requesting an exemption, but it is not yet certain whether this proposal will gain support from the other EU countries. If Sweden's proposal is not adopted, we see the need to make it easier, for example, for county councils to choose when and how requirements with regard to phthalates should be imposed in the case of purchases for the healthcare sector. One suggestion is for the Swedish Government to task the Swedish Competition Authority with an assignment similar to the one the Authority has already been given regarding the chemical requirements for procurement in pre-school institutions. In the most complicated cases, support for innovation procurement, for instance via Vinnova, the Swedish innovation agency, may promote this development.

The work involved in devising chemical requirements for procurement in hospitals should obviously be based on the work already going on and completed in this area. Examples of this are the work involving the National Substitution Group[197], which is a national network focused on cooperation aimed at promoting the substitution of hazardous chemicals in the healthcare sector and, for instance, the ongoing cooperation between the county councils in Dalarna, Sörmland, Uppsala, Västmanland and Örebro on these matters (see section 4.3.6). One important aspect of the various forms of cooperation is the distribution of information about successful examples of substituting phthalates in a group of articles for other users of

[196] PVCfreeBloodBag.eu. Available: 19.11.2014. http://www.pvcfreebloodbag.eu/
[197] Swedish Environmental Management Council. National Substitution Group. Available: 19.11.2014. http://www.msr.se/sv/Upphandling/Kemikalier/Nationella-substitutionsgruppen/

the same articles. This will enable substitution to make an impact more quickly on the market. It is also important to dispel the myths that are often used as an argument by articles suppliers. One of these arguments is that Sweden is such a small market that it is not in the interest of manufacturers to change the material composition of their products. There are examples from the healthcare sector indicating both that suppliers have alternatives ready to produce when requested by Swedish care providers and that companies can manage to change their process during the time they have to produce a tender bid. Another common argument is that only one county council or only our country is asking for phthalate-free products. The agency itself has a global network of procuring agents with similar requirements for phthalate- and PVC-free products. This type of information also needs to be passed on to procuring organisations.

The final point to highlight is that the use of procurement as a tool for phasing out phthalates in hospitals must obviously not put patients' safety at risk. Procurement criteria must not result in a shortage of products for providing relevant care. Therefore, when devising procurement criteria, the individual area of use of each product/product group must be taken into consideration.

Applied properly, procurement requirements should provide an effective tool for phasing out hazardous substances. Therefore, we consider this action proposal a priority.

7.6 Communication/information support

There is still a great deal of ignorance today, most of all among companies involved in importing goods, about the chemicals contained in articles. The need for information has grown as authorities, researchers, environmental organisations and also the media have increasingly highlighted the risks involved with hazardous substances, including in consumer products.

To enable consumers and business to make informed decisions resulting in lower risks, information campaigns and educational activities need to be used to supplement other instruments. To make a great impact, information needs to be specific, adapted for a target group and highlight definite courses of action.

This section describes how the Swedish Chemicals Agency should continue its work in providing information about chemical regulations and risks, thereby making it easier for companies to do the right thing and for consumers, companies and the public sector to make informed decisions. We have highlighted in the report this action proposal, which therefore does not require any new regulations, as a priority proposal.

7.6.1 Right to information about substances featuring in articles

It is a key issue for actors in the management chain of an article to have access to information about the content of hazardous substances. Without this information, it is not possible to assess or manage risks or to avoid articles containing unwanted hazardous substances. Therefore, companies, agencies involved in public procurement and consumers need to have access to information about the content of hazardous substances featuring in articles to be able to handle the article safely and make informed decisions. This information therefore ultimately helps create incentives for substituting hazardous substances in articles with alternatives which are safer from an environmental and health perspective.

At present, there is a statutory requirement for information of approximately only one thousandth of all substances used commercially (i.e. substances registered in the REACH

candidate list[198]). There is no material available for estimating how many of all these substances on the market that are used in articles. Many companies attempt to find out what the content is, or at least parts of it, by asking its suppliers questions, with varying results. Without there being a statutory right in force, it can be difficult to exercise the right to obtain information about the content. Costly chemical analyses are often carried out instead, at least to ensure that banned substances or other known problem substances are not contained in the article. The biggest problem is encountered by commercial companies importing articles which are manufactured outside the EU, accounting for a large proportion of the articles consumed in Sweden. Therefore, it is vitally important to develop a global articles information system.

Right to information – Article 33 in REACH

According to this article, consumers can ask in the store or via a company's customer service whether an article contains substances featuring in the candidate list. If the article contains a substance at a concentration above 0.1% by weight, consumers are entitled to know about this and must be given adequate information to enable them to handle the article safely. However, the minimum requirement is to be informed about the name of the hazardous substance contained in the article. This information must be provided for free within 45 days of requesting it. As for store owners, they are entitled to receive similar information from their supplier immediately.

Monitoring has shown that these provisions are not always complied with. Neither consumers nor stores are very aware of this requirement either. Therefore, it is desirable to increase awareness about the information requirement in Article 33 of REACH so that commercial customers and consumers can have greater access to relevant information about the content of hazardous substances in articles. Pressure from consumers may succeed in reducing the risk from chemicals.

7.6.2 Information support

It is important to disseminate knowledge about chemicals and the laws pertaining to them. This is where authorities have a responsibility to disseminate knowledge and provide support to companies. For instance, the Danish Environmental Protection Agency has produced guidelines advising companies on how they can substitute dangerous phthalates. These guidelines have been produced in collaboration with a number of Danish industry associations, which gives them greater clout. This document has been translated into English to make it easier to use outside Denmark. The Swedish Chemicals Agency has distributed Denmark's guidelines to the companies which have engaged in the dialogue that the Agency has been conducting in the industry for this survey. There is a link to these guidelines available on the Swedish Chemicals Agency's website.

As part of the dialogue with the toys industry, the Swedish Chemicals Agency has launched an effort, with the help of companies and their industry association, to produce targeted information sheets. Information sheets will be distributed via the registers authorities have of the companies which are inspected, via the industry association's register, and will also be published on the participants' websites. The purpose of this information is to raise companies' awareness about the regulations they are obliged to observe. Information sheets will supplement the Swedish Chemicals Agency's factsheet on phthalates in toys, as well as the Toy Safety Directive and the REACH Regulation. Similarly, targeted campaigns could be run in other industries where additional efforts for supplying information are required.

[198] ECHA, Candidate list. Last updated 16.06.2014. http://Echa.europa.eu/web/guest/candidate-list-table

Another important issue is the support for local authorities and the public sector in relation to risks and handling the quantities of phthalates already present in public. Until now, the Swedish Chemicals Agency has not provided any recommendations concerning phthalates contained in articles already present in public, but has focused on preventive efforts. These issues will become more relevant as new alternative materials are produced. Therefore, there is a need to revise and consider recommendations and information support regarding how the public sector can use substitution.

7.6.3 Information on websites, via email and telephone

The Swedish Chemicals Agency currently has information available about chemicals, such as phthalates, on its website. However, this website is primarily geared towards companies and the issues which they are facing, such as legislation and demarcation issues. The Swedish Chemicals Agency obviously has an information service as well, which can be contacted by telephone or email.

The Swedish Chemicals Agency has recently set up a website completely devoted to consumers. Consumers can obtain from this site information about chemicals they encounter every day, enabling them to make an informed choice and handle products safely. The consumer website is still being developed.

At the start of 2014, the Swedish Consumer Agency was tasked by the Government with setting up a consumer information service. This information service is intended to provide information and guidance about consumers' rights and obligations. The service will also include information which will help make it easier for consumers to make well-considered choices. A number of different authorities share responsibility for this service, including the Swedish Chemicals Agency. The information service will be available via telephone, email and the Internet. Consumers must be able to contact the information service via a common access point for each means of communication. This service, which will be called "Hallå konsument" (Hello, Consumer), will be available from 1 April 2015.

7.7 Improved compliance with regulations

7.7.1 EU cooperation, more effective joint market surveillance of articles

There are currently different forms of cooperation available to supervisory authorities in the EU. Harmonising market surveillance activities, for instance by means of joint projects, gives the checks carried out greater impact, while also allowing countries, which are otherwise unable to enforce market surveillance, to carry out checks to a larger extent. This also results in more standardised and fairer controls in the various Member States. A description is given below of three networks offering the Swedish Chemicals Agency opportunities to cooperate with other countries in terms of supervising the use of phthalates in articles.

The REACH Regulation states that EU Member States must work together with regard to supervising REACH regulations by participating in the REACH Forum[199] within the ECHA. The REACH Forum is responsible for drawing up strategies for market surveillance, developing supervisory methodology, coordinating and evaluating joint EU supervisory projects and developing a training programme for

[199] The Forum for Exchange of Information on Enforcement. Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, Article 76(1)(f).

inspectors. The work done by the REACH Forum has been focused until now mainly on the provisions of the REACH Regulation on substances and mixtures. Therefore, it has not touched on the presence of phthalates in articles on a more general basis. However, it would be possible to promote joint supervisory projects within the REACH Forum which could focus on regulations restricting phthalates in articles or on the rules about providing information about substances of very high concern featuring in articles. Sweden should endeavour to expand the activities of the REACH Forum on monitoring articles.

ProSafe is a network of authorities in the EU dealing with product safety-related issues. The Swedish Chemicals Agency has been a member of the network since 2014. The network runs joint supervisory projects which may be focused on chemicals in articles. Sweden should endeavour to make sure that joint supervisory projects focusing on the presence of chemicals in articles, such as phthalates in toys, are run by ProSafe.

Joint supervisory projects are also run within the European network for monitoring the RoHS directive (which regulates certain substances in electrical and electronic articles). There are currently four phthalates which are being proposed for inclusion under the Directive. Sweden should continue to participate in joint supervisory projects run by the network. We would like to highlight more efficient EU cooperation on monitoring articles as a priority proposal.

7.7.2 National market surveillance, change to the system

The controls that supervisory authorities can carry out to check for phthalates in articles are restricted to the legislation in force. At present, there are mainly the six phthalates whose use is restricted in toys and childcare articles and the phthalates registered in the REACH candidate list which the Swedish Chemicals Agency and the local authorities can control. Other CMR-classified phthalates in toys can also be controlled to a certain extent. One option for extending the controls on the presence of phthalates in articles is if new regulations are introduced, such as restrictions on certain phthalates in the RoHS Directive. The allocation of responsibility for monitoring articles between the Swedish Chemicals Agency and local authorities may need to be reviewed, with the aim of achieving more effective market surveillance.

As part of the current monitoring of articles, the checks for phthalates can be expanded. For instance, analyses can be conducted on articles for phthalates featuring in the candidate list, with the main purpose of the check actually being to verify the presence of other restricted substances. The Swedish Chemicals Agency can also provide supervisory guidance to support local authority supervisory agencies, enabling them to increase their checks for phthalates in articles. One way of doing this is to expand the material included in the market surveillance guidelines available, by adding information about substances in articles, as well as to promote national cooperation projects with the local authorities concerning regulations for phthalates in articles. Supervisory checks often provide a great deal of knowledge about, for instance, which articles and materials can contain different substances. This information can be extremely useful to companies and the Swedish Chemicals Agency should therefore develop methods for distributing the results of the supervisory checks.

We want to continue with market surveillance on phthalates as a priority proposal.

7.7.3 More effective sanctions

Some of the existing phthalate regulations are subject to criminal sanctions[200]. This means that when the Swedish Chemicals Agency (or local authority) discovers a breach of the regulations, this is reported to the regional public prosecutor's office. The prosecutor then assesses whether criminal intent or negligence can be proven. Between 1999 and 2013 the Swedish Chemicals Agency reported 596 cases to the prosecutor's office[201]. In the case of 67% of these reports, no judicial investigation was initiated or the case was dropped.

Breaches considered to be of a less serious nature are not subject to criminal sanctions but to environmental sanction charges[202]. An environmental sanction charge is an administrative penalty determined by the market surveillance authority and targeted at traders. This entails strict liability, which means a presumption that the breach occurred due to criminal intent or negligence. This does not involve any actual investigation of the question of guilt, but it is sufficient, in principle, to confirm that the actual regulation has been breached. An appeal against the decision can then be lodged with the Land and Environmental Court.

The reason for the differentiation in sanctions is that serious offences should be criminalised, while less serious offences should be linked instead to an environmental charge. However, the consequence in practice is that less serious offences generally result in a penalty in the form of an environmental sanction charge, whereas offences considered as being more serious rarely result in any penalty as judicial investigations into the matter are dropped or not initiated. This can be perceived as being both illogical and unfair.

The issue of whether some of the breaches which are currently subject to criminal sanctions should not be subject instead to administrative charges has recently been looked into in a number of government investigations into work environment regulations[203]. The Swedish Chemicals Agency believes that appropriate clarification and a review of the regulations in the area of environmental criminal law would be desirable.

Any review should also include the issue of how to differentiate market surveillance and sanction provisions between different legislations and the chemicals sector. For example, if the Swedish Chemicals Agency finds phthalates in a toy, the REACH Regulation and Swedish Environmental Code are applicable. Any breach entails a suspected breach of the Environmental Code, which should then be reported to the regional public prosecutor's office. Any appeals against injunctions and bans are lodged with the Land and Environmental Court. However, if the Swedish Chemicals Agency finds barium in the same toy, the Toys Act is applicable, which provides the authority with opportunities to apply a ban and injunction along with a penalty, as well as a sanction charge in the event of breaches occurring. In this case, any appeals are lodged with the Administrative Court. It may, for obvious reasons, be considered as being difficult for a company to predict and understand why these variations exist.

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[200] Examples of these are breaches of the restrictive regulations in REACH (Chapter 29, Section 3, second paragraph, point 9 of the Swedish Environmental Code) and breaches of the obligation in Article 33(1) of REACH to inform the recipient of an article about the presence of substances of very high concern in the article (Chapter 29, Section 6, first paragraph, point 5c of the Swedish Environmental Code).

[201] The statistics include all the indictment notices issued by the Swedish Chemicals Agency and not only those relating to the regulations governing phthalates.

[202] Examples of this are breaches of the labelling and information regulations in the RoHS Directive (Chapter 7, Section 8-10 of ordinance (2012:259) on environmental sanction charges) and breaches of the registration requirement in REACH (Chapter 7, Section 2 of ordinance (2012:259)).

[203] For example, SOU 2011:57 on sanctions and the working environment and SOU 2013:38, known as the criminal law inquiry.

This highlights the need to investigate legislation concerning market control authorities' powers and sanction options, which has been requested by the Market Surveillance Council in a memo submitted to the government in December 2013. If the issue of criminalising offences versus imposing an environmental sanction charge is not covered by this horizontal survey, the issue should be dealt with instead by a special inquiry.

We consider this action proposal a priority.

7.8 Economic instruments

The economic instruments which we have considered include an environmental tax and producer's liability. A brief review is provided below of the tax rates considered by the report from the chemicals tax commission, along with an overview of producer's liability.

7.8.1 Taxes

Environmental taxes can generally be designed to be either financing or controlling. The choice of tax depends completely on whether the desire is to finance a transition process or whether there is a need to quickly phase out a substance[204]. It can work just as effectively as a restriction as the tax provides a strong incentive for modified behaviour.

The chemicals tax commission is currently examining a controlling environmental tax (Dir. 2013:127) for specific construction articles and across the board for a group of phthalates.

Without wishing to pre-empt the environmental tax inquiry, we are not highlighting this proposal as a priority in this report. However, the Swedish Chemicals Agency believes that reasonable, properly balanced environmental taxes can provide an effective instrument for reducing the use of harmful phthalates.

7.8.2 Extended Producer Responsibility/deposit

The term "extended producer responsibility" means that producers assume responsibility for the entire life cycle of an article to prevent any adverse environmental impact occurring. The following different aspects are covered by the term "extended producer responsibility" [205:]

- A producer can be held liable for environmental damage which has been verifiably caused by an article supplied by the producer. Whether the producer is liable for environmental damage depends on whether the producer can be linked to the parts of the life cycle where the environmental damage occurs.

- A producer bears financial responsibility for preventing any adverse environmental impact. This means that the producer will cover all or parts of the costs, for instance, for collecting, recycling or handling the definitive management of the articles manufactured by the producer. These costs may be paid directly by the producer or by means of a special charge included with the article, e.g. through a deposit system.

[204] Swedish Chemicals Agency, 2013. "När kan ekonomiska styrmedel komplettera regleringar inom kemikalieområdet?" ("When can economic instruments supplement regulations in the area of chemicals?"), Report 1/13.
[205] Lindqvist T, 2000. Extended producer responsibility in cleaner production: Policy Principle to promote environmental improvements of product systems, Doctoral Thesis, Lund University.

- A producer is responsible for physically handling the articles up until they are handed over and for the effects which handling the articles entail for the surrounding area and environment.

- A producer retains environmental liability for its articles throughout their whole life cycle, and can therefore be linked to the environmental problems caused by the article in different stages of the life cycle.

- A producer is responsible for advising as to what the product's environmental features are. Dealers and other market operators are obliged to pass on this information to customers.

The enforcement of extended producer responsibility will be more or less comprehensive with the producer being held liable for any indirect costs which the product can be considered as causing to society and the environment. Extended producer responsibility means that the producer is obliged to assume liability for these costs. These costs will also have a direct impact on the final price. This provides confidence that a purchased product covered by producer's liability will have already financed, through pricing, the measures required to prevent any environmental damage which the product may cause.

Extended producer responsibility offers, therefore, a financial solution without the need for high taxes.

It is difficult to apply extended producer responsibility to phthalates in articles as there is a lack of detailed knowledge about which products contain phthalates and about their distribution in public. In this case, more information is needed about the products' manufacturing processes.

7.9 Use of dialogue as an approach

Over the years the Swedish Chemicals Agency has engaged in dialogue with numerous different industrial sectors, ranging from the dye and detergent industry to the construction and food retail sectors. Dialogue as an approach has been viewed so far by those who have been involved in it as a positive experience, offering mutual benefit to both the relevant industries and authorities. Dialogue facilitates contacts between authorities and companies, as well as between companies. It also promotes an overall view by enabling important, common issues to be presented from several different perspectives. Dialogue also helps make companies aware early on of future regulations in the sector, which makes it possible to plan well in advance for their forthcoming application. Dialogue also enables individual companies to improve their environmental activities by learning from others and also by going further than the legislation. We are very keen to continue using dialogue as an approach in this area.

As part of the action plan for creating a non-toxic daily environment, the Swedish Chemicals Agency conducted dialogue with the business sector between 2011 and 2014. The industries which have been made the priority are the toy, cosmetics and textile industries. All industries have made it the goal of their efforts to reduce the risks present by substituting hazardous substances in their articles. This applies in particular to the occurrence of substances which can cause cancer, hereditary genetic damage or reproductive impairment. But it may also include substances capable of causing allergies, suspected of being endocrine-disrupting or accumulating in the environment. In its final report on the action plan, the Swedish Chemicals Agency will assess how effective industry dialogue is as an instrument and how it can be further developed. However, our preliminary assessment is that dialogue is, in general, an

important supplement to legislation and it should be planned in conjunction with other activities to a greater extent.

8 Dialogue conducted as part of the assignment

8.1 National cross-industry dialogue

As part of this assignment, the Swedish Chemicals Agency has conducted dialogues with the business sector as a means of getting companies to voluntarily substitute phthalates suspected of being toxic for reproduction and endocrine-disrupting with less hazardous substances or materials. We focused on the functions in companies with a direct influence on product choice and on the design of a product. This refined focus gave rise to a variety of interesting new discussions. In the dialogue on product development, our objective was for the discussions to touch on the difficulties/possibilities of substitution during the design phase. During the purchasing dialogue, the discussions were aimed at touching on finances, monitoring and requirement specifications. This new sharper focus with these dialogues would also clarify the situation in relation to our current dialogues which are targeted at whole industries.

With assistance from the previous survey that was carried out, we successfully identified in which article segment phthalates are mainly found. We identified the following industries as being relevant: automotive, construction sector, food retail sector, electronics, furniture,

sex toys, footwear, sports and leisure sector, plumbing and sanitation, bags and gloves, as well as watches and accessories.

Both dialogue meetings started with the Swedish Chemicals Agency advising about the completed survey on phthalates in Sweden, endocrine-disrupting substances, which statutory requirements apply and the results for phthalates from market surveillance activities. In both cases, Vinnova was involved in presenting different innovative project applications, as well as possible ways of seeking financial support from them. Some companies were invited to present the developments they are working on. In the case of the dialogue on product development, the following companies delivered their presentations: Perstorp (manufacturer of plasticisers in Sweden), Tarkett (substituting harmful phthalates in flooring) and the Jegrelius Institute (substituting harmful phthalates in blood bags). The following companies were involved in the purchasing dialogue: Hewlett-Packard (possibility of specifying environmental requirements for purchasing), Värmland county council (public procurement within the county council) and SundaHus (options in terms of selecting phthalate-free construction products).

Appendix 7 describes the industry dialogues carried out in greater detail.

9 Impact assessment

9.1 Introduction

The assignment description specifies that any regulatory proposals must be submitted in the form of statutory proposals and be accompanied by both an impact assessment, which must be drafted as far as possible in accordance with Articles 6 and 7 of the ordinance (2007:1244) on impact assessments in legislation. The impact assessment must also include an analysis of the impact on trade with other countries.

Article 6 stipulates that an impact assessment must contain:

- A description of the problem and the desired objective to be achieved
- A description of alternative solutions and of what the effects will be without a regulation (Baseline)
- Details of what is affected by the regulation
- Details of the powers on which the authority's right of decision is based
- Details of cost-related and other consequences which alternative regulations entail
- Compliance with EU regulatory framework
- Implementation time and any requirements for information campaigns

Article 7 complements Article 6 by stipulating the requirement that the report must also contain:

- Significant effects on companies' working conditions, competitiveness or other conditions
- The number of companies affected, the industry they belong to and size
- The time spent, as well as administrative and other costs incurred by the regulation for companies
- A description of the extent to which companies' competitiveness is affected by the regulation
- A description of the particular factors which should be taken into account for small businesses.

9.2 Issues and setting objectives

Effects which are toxic for reproduction have been reported for a majority of phthalates, with the low molecular weight phthalates DEHP, DBP, BBP and DIBP all being classified as toxic for reproduction according to the EU CLP regulation on classification and labelling. DEHP, DBP and BBP are also priority substances based on a likely endocrine-disrupting effect. Phthalates could also be a potential contributory factor to other types of diseases, such as asthma and allergies or different kinds of neurological diagnoses.

Phthalates are largely used as plasticisers for PVC, which can also lead to them being widespread in the environment and to continuous exposure for humans. Children in particular are exposed to a high degree via food, the indoor environment and articles which they can put in their mouth.

Further information about the occurrence of phthalates, their health impact and exposure to them is provided in chapters 4 and 6.

This impact assessment includes the measures which are described in Chapter 7 as a priority and are considered within the framework of this assignment as being reasonable and efficient to implement.

9.2.1 Restriction

The impact analysis will focus on the low molecular weight phthalates DEHP, DBP, BBP and DIBP based on the existing classification as being toxic for reproduction. In terms of other health effects, it is difficult to establish any causal link as the diagnoses are often complex and there is also simultaneous exposure to a large number of other substances. Chemical exposure

is rarely the predominant factor for different medical conditions. However, exposure to phthalates cannot be excluded as being a contributory cause.

It is a difficult task to perform detailed socio-economic benefit calculations due to the extensively wide distribution of phthalates and the uncertainty about how many cases involving the medical conditions described above can be put down to phthalates. Therefore, this impact assessment will involve a more detailed description of the cost involved, with indications of the impact on the main industries.

To enable us still to portray the socio-economic benefit of restricting the use of low molecular weight phthalates in public, we have chosen to compare the costs of the action proposals with the overall turnover and value added generated for the industries affected, as well as compare the costs of the measures with the socio-economic costs for certain types of health effects, such as deformities of the sexual organs, asthma and autism. In terms of assessing suitable measures and the costs of these measures, the focus is on the groups of articles containing a large quantity of plasticised PVC. The reason for this is that, according to the survey (see Chapter 4), phthalates are used extensively as plasticisers in PVC. Among the four low molecular weight phthalates (DEHP, DBP, DIBP, BBP), the use of DEHP is predominant. Therefore, the calculation of the costs of measures to be taken will be based primarily on the costs for substituting DEHP.

Based on the legal analysis in Chapter 7 and the results of the survey in Chapter 4, we have come up with six action proposals which we will look at in the following impact assessment:

- Introduction of an addendum to the RoHS Directive for low molecular weight phthalates;
- Introduction of an addendum to REACH by applying Article 68(2);
- Introduction of a limit on phthalates in articles used in indoor environments in Sweden;
- A national tax on construction articles containing phthalates;
- Public procurement focused on purchasing phthalate-free articles;
- Measures aimed at improved compliance with regulations in Sweden.

9.3 Description of the Baseline

The baseline or benchmark option describes what will happen if no further measures are taken. This involves analysing the consequences of the measures already implemented or decided upon, including voluntary measures. The baseline provides a benchmark against which the action proposals are compared.

In this section we will present data about the production, trade and consumption of articles containing DEHP in plasticised PVC in Sweden and the EU. Our assumption is that the commercial and production data for DEHP is representative of all four low molecular weight phthalates. The main reason for this is that DBP, DIBP and BBP are produced in small quantities which are too small to make a significant contribution to the total volumes involved.

It should be noted that from 2015 the production in EU of articles containing any of the low molecular weight phthalates DEHP, BBP, DBP or DIBP will be banned unless authorisation is granted for their use. This is expected to have an impact on the use of low molecular weight phthalates in the EU, but it is not clear how great this will be, as it depends on the authorisation which will be granted.

At present, there is little information about the precise volume of articles containing low molecular weight phthalates which are produced in Sweden or the EU. We know even less about the articles imported from outside the EU. There is no reliable information available about future trends in the use of phthalates. Therefore, we have assumed that the data and assumptions about the current use of phthalates in articles are acceptable assumptions to use for future use.

With regard to the production and trade at EU level of articles containing DEHP, there is a report compiled by COWI for ECHA describing the situation in 2007, although there is a lack of information in this report describing the trade aspect[206]. There is also a report compiled by COWI describing production and the substitution options available in the EU for 2012[207]. These reports mainly deal with the indoor environment and only include articles which are parts of an end product. One important conclusion from the COWI reports is that the production of DEHP fell from 282,000 tonnes in 2007 to 118,000 tonnes in 2012.

Trade is a difficult area to analyse. Sweden has the Varuguiden (Article guide), which has been compiled based on collaboration between the Swedish Chemicals Agency and Statistics Sweden. This contains production and commercial data from 2007 for products containing plasticised PVC and for the percentage of the group of articles containing plasticised PVC. The benefit of the data contained in the Varuguiden is that it provides plenty of details about plasticised PVC, as well as detailed information about 171 different groups of articles[208]. The groups of articles have been classified by industry to make the information contained in the Varuguiden easier to understand (Appendix 9).

As this report will analyse proposals at EU level, we also need to include the production and consumption of articles containing DEHP in the EU. We have made the assumption that Sweden has a similar output and trade in articles containing plasticised PVC as the rest of the EU. Therefore, the data contained for Sweden in the Varuguiden has been extrapolated to EU level by upscaling it with GDP.

The information shows that plasticised PVC usually contains between 5 and 40% plasticiser. In the following calculations we assume that the plasticised PVC contains 20% plasticiser[209].

The following equation is used to calculate the quantity of DEHP in each group of articles manufactured in Sweden and the EU:

$$\begin{aligned} &Tonne\ DEHP\ in\ article\ group \\ &\quad = Article\ group's\ production\ (tonnes) \\ &\quad * Share\ of\ plasticised\ PVC\ in\ article\ group \\ &\quad * Share\ of\ plasticiser\ (20\%) \\ &\quad * Share\ of\ DEHP\ of\ plasticisers\ in\ article\ group \end{aligned}$$

[206] ECHA, 2008. Data on manufacture, import, export, uses and releases of Bis(2.ethylhexyl)phthalate (DEHP) as well as information on potential alternatives to its use".
http://echa.europa.eu/documents/10162/13640/tech_rep_dehp_en.pdf
[207] ECHA, 2013. Estimating the abatement costs of hazardous chemicals, A review of the results of six case studies. http://echa.europa.eu/documents/10162/13580/abatement+costs_report_2013_en.pdf
[208] Swedish Chemicals Agency, Varuguiden (Article guide), category: "Polyvinyl chloride, plasticised". Available: 19.09.2014. http://webapps.kemi.se/varuguiden/MaterialVarugrupp.aspx
[209] Swedish Chemicals Agency, 2014. Kartläggning av ftalater i Sverige (Surveying the occurrence of phthalates in articles in Sweden), PM 2/14.

According to Emanuel (2011)[210], DEHP accounts for 16% of all plasticisers manufactured in Western Europe (Table 9). This information is assumed in this impact assessment to apply to the EU as a whole. This proportion is also used to calculate the quantity of DEHP in articles exported from Sweden and the EU.

Table 9: Percentage of market share for plasticisers in the US, Western Europe and Asia in 2010. Source: Emanuel, 2011

Plasticiser	**USA (%)**	**Western Europe (%)**	**Asia (%)**
DEHP	19	16	60
C9/C10 phthalates	33	63	21
Other phthalates	19	6	9
Total phthalates	*72*	*84*	*90*
Non-phthalates	28	16	10

To calculate the quantity of DEHP featuring in articles imported into Sweden and the EU, we need both details of the market share for DEHP among plasticisers used in plasticised PVC in different commercial regions and details of these regions' shares of the import market for articles containing plasticised PVC in Sweden and the EU respectively. We have no direct information about these import market shares. Therefore, we will make a rough calculation below in order to obtain an estimate for these shares.

The Vinyl Environmental Council[211] has details on the distribution of global PVC production among various regions (Table 10). As Asia, Europe and North America account for a good 90% of global PVC production, the estimate of the quantity of DEHP in imported articles is made based on these three regions. World Bank data for the share of GDP in exports in the relevant region[212] has been used to calculate the share of the import markets in Sweden and the EU respectively.

Table 10: Percentage of global PVC production distributed to different parts of the world, including percentage of these shares exported. Source: Vinyl Environment Council and own calculations.

Region	**Share of global PVC production**	**Calculated share of Sweden's import market**	**Calculated share of EU's import market**
USA	19%	10%	14%
Europe	18%	29%	-
Asia	54%	61%	86%
Other	9%	-	-

The market share in different regions accounted for by DEHP among plasticisers is shown in Table 9. North America is represented by the US in the calculations, while Western Europe, Europe and the EU are treated as a single unit. The import of DEHP per group of articles and exported region is calculated as follows:

[210] Emanuel C, 2011. Plasticizer market update. SPI Vinyl Products Division, 22nd Annual Vinyl Compounding Conference, July 10-13, 2011. BASF Corporation. http://www.cpsc.gov//PageFiles/126090/spi.pdf
[211] Vinyl Environmental Council, Statistics Data. Available: 28.10.2014 http://www.vec.gr.jp/english/pvc/statistics_data.html
[212] World Bank, Trade statistics, EXPORT of goods and services (% of GDP). Available: 19.11.2014 http://data.worldbank.org/indicator/NE.EXP.GNFS.ZS/countries

$$\begin{aligned} &Tonne\ imported\ DEHP\ per\ article\ group\ and\ exporting\ region \\ &\quad = Import\ for\ article\ group\ (tonne) \\ &\quad * Share\ of\ plasticised\ PVC\ in\ article\ group \\ &\quad * Share\ of\ plasticiser\ (20\%) * The\ exporting\ region's\ market\ share \\ &\quad * Market\ share\ of\ DEHP\ in\ exporting\ region \end{aligned}$$

By adding up the totals for all the export regions, you will then get the quantity of DEHP calculated as entering Sweden and the EU respectively via import.

Based on the data from the Varuguiden (see Appendix 9) for plasticised PVC and on the assumptions described above, we learn that approx. 4,000 tonnes of DEHP feature in articles manufactured in Sweden, while approx. 5,700 tonnes feature in articles consumed in Sweden (Table 11). This can be compared to one of the results featuring in the Swedish Chemicals Agency's Memorandum 2/14,"Kartläggning av ftalater i Sverige"[213], which gives a calculation of approx. 20,000 tonnes for all types of phthalates entering the Swedish market every year.

Table 11: Calculated production, trade and consumption of articles containing DEHP in Sweden, tonnes per industry and year.

Industry/sector	Production	Import	Export	Consumption
Construction sector	2,500	2,400	1,600	3,300
Automotive	700	600	400	1,000
Electronics	700	600	400	1,000
Other consumer articles[214]	70	500	100	500
Other products[215]	10	20	10	25
Total	**4,000**	**4,100**	**2,500**	**5,800**

The quantity of DEHP featuring in articles manufactured in the EU every year is calculated to be approx. 120,000 tonnes (Table 12). COWI (2012)[216] produces a similar result. The quantity of DEHP featuring in the articles used in the EU is calculated to be approx. 210,000 tonnes per year.

[213] Swedish Chemicals Agency, 2014. Kartläggning av ftalater i Sverige (Surveying the occurrence of phthalates in articles in Sweden), PM 2/14.
[214] Includes clothing, footwear, textiles, bags, kitchen utensils, furniture, household appliances, sports and leisure items and toys.
[215] Includes medicinal products and medical equipment, lighting articles, industrial machines, tools, food packaging, photo equipment and office items.
[216] ECHA, 2013. Estimating the abatement costs of hazardous chemicals, A review of the results of six case studies. http://echa.europa.eu/documents/10162/13580/abatement+costs_report_2013_en.pdf

Table 12: Calculated production, trade and consumption of articles containing DEHP in the EU, tonnes per industry and year.

Industry	Production	Import	Export	Consumption
Construction	77,000	94,000	50,000	120,000
Automotive industry	22,000	25,000	11,000	36,000
Electronics industry	22,000	25,000	11,000	36,000
Other consumer articles[213]	2,000	20,000	3,000	20,000
Other products[214]	300	700	200	1,000
Total	**125,000**	**165,000**	**75,000**	**215,000**

The figures in Tables 11 and 12 are sorted according to the size of the calculated consumption. These industry categories feature the 171 groups of articles which contain plasticised PVC according to the Varuguiden. The largest item among these groups of articles was cables and wires, which accounted for roughly 45% of the use of plasticised PVC. This group can belong to several different industries and there is insufficient information about the distribution across these industries. Therefore, the cables and wires article group was divided across three industries into sections of the same size: construction, automotive and electronics. Refer to Appendix 10 to see how all the industry categories were sorted.

It should be pointed out that all the figures for production, trade and consumption given above are based on an extrapolation of DEHP's share of the plasticiser market and on the data contained in the Varuguiden for production and trade involving articles containing plasticised PVC in Sweden. The results must be viewed as rough estimates and should therefore be interpreted with a certain degree of caution.

9.4 Costs for substituting phthalates

This section details the costs involved in substituting low molecular weight phthalates. The COWI report entitled "Abatement Cost Curves for the four phthalates DEHP, BBP, DBP, DIBP", compiled for and published by ECHA is used as the starting point for this.[217] For simplicity's sake, it has been assumed in the baseline for this impact assessment that DEHP is the main problem among the low molecular weight phthalates. The main reason for this is that the other three low molecular weight phthalates are produced in small quantities which are too small to make a significant contribution to the cost.

Costs involved with substituting DEHP include both the higher cost per tonne for alternative materials and the increased volume of plasticisers which are required to ensure that the material being plasticised will have the same nature as when the material is plasticised using DEHP, along with the one-off transition costs, mostly for research and development.

Low molecular weight phthalates are estimated to cost around SEK 14,000 per tonne to manufacture. Alternatives to DEHP are estimated to cost around 15% more per tonne. It is also assumed that 3-10% more material is required (which varies between groups of articles) when alternatives are used. The additional cost incurred for substituting DEHP with an alternative will be, on average, roughly SEK 3,200 per tonne.

[217] ECHA, 2013. Estimating the abatement costs of hazardous chemicals, A review of the results of six case studies. http://echa.europa.eu/documents/10162/13580/abatement+costs_report_2013_en.pdf

The R&D cost associated with a substitute is estimated to cost somewhere between SEK 270,000 and 1,400,000 per manufacturing site. COWI admits that there are major uncertainties with the figures. Research and development costs are estimated to amount to a total of SEK 200 million for the four low molecular weight phthalates, with DEHP responsible for roughly SEK 45 million. These costs are calculated with a depreciation period of 5 years. Therefore, the annual research and development (R&D) costs are estimated at SEK 35 million for the four low molecular weight phthalates, which includes SEK 9 million for DEHP. The R&D costs per tonne of manufactured low molecular weight phthalate are approx. SEK 300, while the cost for DEHP is approx. SEK 80 per tonne. The calculation does not include any major costs for replacing equipment to be able to manufacture the substitution for low molecular weight phthalates[216].

Given that the action proposals analysed below include all four low molecular weight phthalates, it is appropriate to include R&D costs for all of them. On this basis, we will reckon, overall, on R&D costs of SEK 300 per tonne for each article.

By way of summary, COWI (2012) indicates[216] that it will cost roughly SEK 3,200 per tonne to substitute DEHP with an alternative material. There is, in addition to this, a one-off R&D cost equivalent to SEK 300 per tonne. The total costs are roughly SEK 3,500 per tonne for substituted low molecular weight phthalates. We will use these costs when scaling up the calculations we have made for phthalate consumption using the baseline in Sweden and the EU (see Tables 11 and 12). The difference between the normal cost of phthalates in articles and the increased cost which is expected due to substituting phthalates with another plasticiser will be the cost for the measures which we will analyse.

9.5 Operators affected

We can see from Tables 11 and 12 in the previous section in which industries the operators are. In the next section we will describe the three largest industries affected and their use of phthalates. Apart from the construction, automotive and electronics industries, clothing, textiles, footwear, domestic and kitchen items will be discussed under the collective term “retail sector”. For more detailed information about the various articles which may be considered as containing phthalates among the various stakeholders, refer back to Table 5 in section 4.3. Refer to Appendix 10 to see the calculated quantities for each industry.

On the other hand, it is worth noting that as a group of articles, cables and wires, which have a separate heading in this section, account for 45% of PVC use, are difficult to define as a group and have therefore been assumed to feature in three industries: electronics, construction and automotive.

9.5.1 Construction sector

In this case, the construction sector is considered to be the part of the industry involved in building residential housing and housing for other uses. These sections of the construction sector generate a turnover of around SEK 4,100 billion every year in the EU and around SEK 210 billion in Sweden. This produces value added of around SEK 1,000 billion in the EU and around SEK 49 billion in Sweden. Roughly 90,000 companies operate in this industry in

Sweden[218]. This sector accounts for more than 60% of the plasticised PVC used in the EU (see Table 12 and section 4.3.1).

Of all the construction articles containing plasticised PVC manufactured in Sweden, around three fifths of them are for export. Of the construction articles containing plasticised PVC which are used in Sweden, around half of them originate from this (see Appendix 10). We assume that the ratios are similar at EU level, but this is an uncertain assumption as our data is mainly based on extrapolating the data contained in the Varuguiden for Sweden.

In dialogue conducted with the flooring industry in Sweden, it has emerged that sections of the industry have substituted DEHP and have successfully made the transition. The construction industry itself believes that it would be easier to substitute hazardous substances, such as phthalates, if the price of environmentally-friendly alternatives was lower. A transition period is expected to take a project cycle for building contractors, assuming that the manufacturers of the construction material have a substitute available[219]. A project cycle means the time taken to complete a construction project.

9.5.2 Automotive industry

This category includes every different type of vehicle: private cars, trucks, working vehicles etc. This sector generates an annual turnover of SEK 7,900 billion every year at EU level, and SEK 300 billion in Sweden[220]. The automotive industry produces value added of around SEK 1,400 billion in the EU and around SEK 48 billion in Sweden.

The automotive industry has a similar commercial ratio to the construction sector. Imports account for almost half of production. A large proportion of the articles manufactured are exported, which means that use in Sweden is largely down to imported cars. We can present a similar argument for the rest of the EU.

Cars can create exposure to phthalates as cars contain plasticised PVC, which can be found, for example, in instrument and door panels.

According to the phthalates survey, a private car contains around 3-10 kg of phthalates (see section 4.3.2.). Switching from phthalates to an alternative plasticiser has been considered in the automotive industry as costing car companies less, given that an alternative plasticiser is available. On the other hand, there is a research and development process carried out prior to substitution, which the car industry points out can incur high costs (Appendix 7). The car industry is considered to be an industry which monitors particularly well the substances used in its production.

9.5.3 Electronics industry

Manufacturers of electronic articles generate a turnover of around SEK 2,800 billion in the EU every year and value added of SEK 740 billion. In Sweden this industry generates a turnover of around SEK 160 billion, with value added of SEK 40 billion.

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[218] Eurostat, Annual detailed enterprise statistics for construction: Construction of residential and non-residential buildings. Available:
03.10.2014http://epp.eurostat.ec.europa.eu/portal/page/portal/european_business/data/database

[219] Swedish Chemicals Agency, construction industry questionnaire, response date: 06.10.2014

[220] Eurostat, Annual detailed enterprise statistics on manufacturing, subsections: Manufacture of motor vehicles, trailers and semi-trailers. Available:
03.10.2014http://epp.eurostat.ec.europa.eu/portal/page/portal/european_business/data/database

According to the Varuguiden, the quantity of plasticised PVC used in electronic products is proportionally small. On the other hand, if consideration is given to the fact that the "cables and wires" category of articles partly comes under the electronics sector (an assumption made in our description of the baseline), this gives the electronics industry a higher share of the plasticised PVC market.

Sweden exports the same volume of electronic articles which the country manufactures and has more imports compared with its production output. It is reasonable to assume that the electronic articles which we use in Sweden generally originate from outside Sweden (see Table 11).

During the dialogue which the Swedish Chemicals Agency has had with the industries, it has emerged that there is a difference between large and small operators in the electronics industry. Large operators usually have systems which monitor their products well and provide a good insight into which substances are used, whereas smaller operators generally do not have the resources for this. The large operators also check their products in terms of materials and chemicals, no matter where they have been manufactured in the world.

9.5.4 Manufacturers of cables and wires

Cable and wires is a large industry accounting for around 45% of the market share in Sweden in terms of use of plasticised PVC. In the EU this industry generates a turnover of around SEK 450 billion, with value added of roughly SEK 110 billion[221].

The survey featuring in the Swedish Chemicals Agency's Memorandum 2/14 indicates that this group of articles can feature in the construction sector, as well as in industry, the electrical sector and also in vehicle engines. The report mentions that the phthalates occur in imported electronic articles[222].

9.5.5 Retail sector

The retail sector is the collective term used in this report for commercial activity involving all the products containing plasticised PVC which are ineligible for any of the industries mentioned above. The articles included in this are of the type found in stores and can be used in the household environment. This includes household articles, clothing, kitchenware, toys, food items, furniture, sports and leisure items, footwear, textiles and bags. We would highlight three of these categories in relation to future action proposals, i.e. furniture, sports and leisure articles and clothing, footwear and accessories. We will use the Varuguiden to extrapolate so that we can calculate retail and product volumes in these three sectors[223].

Operators in the clothing, footwear and accessories sectors

The operators in the EU's clothing, footwear and accessories market generate a turnover of around SEK 1,400 billion every year, with value added of roughly SEK 370 billion[224]. This

[221] Eurostat, Annual detailed enterprise statistics for industry, Manufacture of wire and wiring devices. Available: 03.10.2014http://epp.eurostat.ec.europa.eu/portal/page/portal/european_business/data/database

[222] Swedish Chemicals Agency, 2014. Kartläggning av ftalater i Sverige (Surveying the occurrence of phthalates in articles in Sweden), PM 2/14.

[223] Varuguiden, Vilka material en varugrupp kan bestå av (Article guide, which materials a group of articles can comprise). Available: 10.09.2014. http://webapps.kemi.se/varuguiden/VarugrupperMaterial.aspx

[224] Eurostat, Annual detailed enterprise statistics for industry, Manufacture of wearing apparel except fur, Manufacture of footwear. Available: 03.10.2014

03.10.2014http://epp.eurostat.ec.europa.eu/portal/page/portal/european_business/data/database

group is largely an import sector, with almost no production at all carried out within the EU. According to Swedish Chemicals Agency report 6/14, roughly 80% of all textile articles in the EU are imported[225]. Major impact areas include mainly bags, where PVC accounts for the majority of the material used, which can therefore be assumed to contain phthalates.

Operators in the furniture industry

In the EU the furniture industry generated a turnover of around SEK 860 billion, with value added of SEK 270 billion. The volume of retail activity and production for the furniture industry is fairly large, but as the use of plasticised PVC is expected to be quite small in this group, it is not expected to account for a large use of phthalates.

Operators in the sports and leisure sector

Sports and leisure articles accounted for SEK 57 billion in 2012 within the EU, with a value added of approx. SEK 16 billion. This industry has almost no production output in the EU, exactly like the clothing sector. Typical articles which may be considered as sources of exposure include balls, tents and airbeds.

Purely in quantitative terms, sports and leisure products represent a fairly small sector. Based on data extrapolated from the Varuguiden and the assumptions we made, the quantity of phthalates originating from these articles should be less. But from an exposure perspective, there are a number of articles which children come into contact with and are exposed to.

9.5.6 Property owners

Any change to phthalate regulations governing construction products may be a factor for property owners, which may influence the cost of renovating properties. The costs which are reckoned to affect the construction sector will be passed on, to a certain extent, to property owners.

9.5.7 Consumers

The measures incurring costs for article manufacturers and the construction sector will be passed on, to a certain extent, to consumers.

In the case of an article where only a small proportion of plasticised PVC is used in the material and the price for this article is high, e.g. cars, changing plasticiser might not be expected to make a direct difference to the consumer price.

9.5.8 Public sector

The volume of the Government's transactions subject to procurement procedures amounted in 2012 to approx. 15-18% of GDP. If the Government were to start procuring articles using more stringent green and health criteria, this might entail increased costs for manufacturers targeting purchases made by the Government. This will be reflected in the prices of the articles included in the public procurement and, depending on the size of the purchase, will contribute to the Government increasing its revenue through tax and VAT hikes.

The public sector also has the additional responsibility of monitoring compliance with the regulations. This also includes administrative costs for the market surveillance activities run

[225] Swedish Chemicals Agency, 2014. Chemicals in textiles – Risks to human health and the environment, Rapport 6/14.

by the Swedish Chemicals Agency. This may also have a certain knock-on effect on local authorities. In the case of EU regulations, these administrative costs also apply to other Member States' supervisory authorities.

The Swedish Chemicals Agency is responsible for monitoring chemicals in articles in the first instance (i.e. when the article is released on the market). Based on six supervisory projects carried out in 2013, it is evident that the cost of the authority's supervisory effort was between SEK 0.2 and 3.6 million per supervisory project. This depends completely on the volume of activities which needed to be monitored, the number of supervisory visits and how frequent they were[226].

9.6 Identifying and assessing the consequences for various operators

This section will discuss expected consequences arising from the various action proposals. The various proposals are:

- Introduction of an addendum to the RoHS Directive for low molecular weight phthalates;
- Introduction of an addendum to REACH by applying Article 68(2);
- Introduction of a limit on phthalates in articles used in indoor environments in Sweden;
- A national tax on construction articles containing phthalates;
- Public procurement focused on purchasing phthalate-free articles;
- Measures aimed at improved compliance with regulations in Sweden.

9.6.1 Action proposal 1: Addendum to EU legislation

This option includes two action proposals. On the one hand, it involves introducing an addendum to REACH legislation via Article 68(2), as well as an addendum to the RoHS Directive for low molecular weight phthalates.

Action proposals 1.1: Addendum to RoHS Directive

The RoHS Directive will be able to incorporate the four low molecular weight phthalates into the legislation by 2017 at the earliest. This matter is already being discussed within the EU (see section 7.2.3), and this action proposal means that the Swedish Chemicals Agency is already endeavouring to incorporate low molecular weight phthalates in the RoHS Directive.

In the EU this industry generates a turnover of around SEK 2,800 billion every year, while the value added generated is roughly SEK 740 billion (see section 9.5.3).

The substitution cost per tonne for DEHP is roughly SEK 3,200 (see section 9.4), which, when multiplied by 31,000 tonnes, estimated to be the volume used every year in the European electronics sector (see section 9.3), gives a cost of SEK 102 million per year. Added to this are the transition costs of roughly SEK 9 million per year (for five years). Therefore, the total cost for this action proposal is estimated at SEK 125 million per year. The costs are 0.004% as a proportion of the electronics industry's turnover and the proportion of the value added produced is 0.01%.

[226] Swedish Chemicals Agency, Annual Report 2013.

Expanding the RoHS Directive may have a positive impact in reducing the exposure to phthalates. Restricting the use of DEHP in electronics is important as a large proportion of electronic products, including cables are used indoors. This should help reduce the exposure indoors (both in the home and workplace) through dust particles. Restricting the use of phthalates under the RoHS Directive therefore produces a similar effect to action proposal 2 below, which relates to construction products in an indoor environment. On the other hand, the RoHS Directive will only have an impact on the contribution made by electronics to exposure in the indoor environment.

Action proposal 1.2: Addendum to REACH legislation

A proposal on imposing a restriction, based on Article 68(2), must be properly justified. Therefore, the Swedish Chemicals Agency has monitored the areas where we consider the risk of exposure to be greatest. We have chosen to proceed with the following sectors:

- Electronics (unless phthalate restrictions are introduced in the RoHS Directive)
- Automotive
- Construction products for indoor environment
- Accessories (including gloves and bags)
- Clothing and footwear
- Home furnishings
- Sports and leisure articles

These industries generate together in the EU an annual turnover of roughly SEK 16,700 billion, including a total value added of SEK 3,700 billion.

An amendment to the law based on Article 68(2) means that the industries specified above would need to phase out the four phthalates. Based on the calculations in this impact assessment, this would mean that around 140,000 tonnes of DEHP would be phased out from products launched on the EU internal market.

The substitution cost per tonne for DEHP is roughly SEK 3,200 (see section 9.3), which, when multiplied by 170,000 tonnes gives a cost of SEK 660 million. Added to this are the transition costs of roughly SEK 51 million per year (for five years). Therefore, the total cost for this action proposal is estimated at around SEK 710 million per year. This amounts to roughly 0.004% of these sectors' turnover and 0.02% of their value added.

A description is given below for each group of articles. For electronics, see action proposal 1.1.

Automotive industry

In the case of the automotive industry, a restriction on low molecular weight phthalates is not expected to entail such a great difference. Given that a private car contains 3-10 kg of PVC (see section 4.3.2) and based on the substitution calculations performed in section 9.4, we assume that the cost per vehicle of a straight material substitution will be relatively low. On the other hand, it is not possible to predict the product development costs for producing an alternative plasticiser. In the dialogue being conducted by the Swedish Chemicals Agency (see Appendix 7), it has emerged that the costs for developing an alternative plasticiser to low molecular weight phthalates in vehicles can vary greatly. This variation in costs is dependent on the number of development cycles and tests required to establish that the plasticised material fulfils all the functional requirements which need to be met so that the material can be used in a vehicle.

Given that there already is a developed, proven substitute available and requirements are starting to be imposed by the EU on countries exporting vehicles to the EU, it is imaginable that foreign manufacturers will be able to switch without incurring any major costs.

Construction products

We assume that the prerequisites for the European construction sector are similar to those in the Swedish construction sector, which are looked at in more detail in action proposal 2. If a substitute is available, the process of phasing out phthalates in new products and renovations can take place over a project cycle, which will tend to accelerate the process, given that there is an alternative available to the low molecular weight phthalates.

Based on extrapolating the data from the Varuguiden (section 9.3) and the substitution cost per tonne for DEHP (section 9.4), it will cost roughly SEK 325 million per year to substitute low molecular weight phthalates which appear on the EU construction product market. Extrapolating the data for Sweden from the Varuguiden for the EU is unreliable, mainly with regard to the international trade in construction products. Therefore, the results must be interpreted with a certain degree of caution.

One upshot of EU countries forming one large economy together is that EU regulations can create standards regarding how production operates outside the EU's borders. This comes about as many countries are reliant upon trade with the EU. These countries will then adapt to the EU's regulations for economic reasons.

Clothing, footwear and accessories

In the case of industries selling or producing clothing, footwear and accessories, this will mean that a whole section of these articles will not be allowed to be imported into the EU. Based on the assumptions we made in section 9.3, a large share of imports contain DEHP. Measures recommended as part of any REACH restriction will mainly hit importers inside the EU. They will have to review their imports and replace manufacturers who are unable to switch to alternative plasticisers. This can lead, in turn, to amended prices for these articles in stores. Even the large retail chains which sell imported clothing will be hit due to articles possibly being more expensive.

This change in costs is not necessarily down to switching plasticiser, but is probably a result of transition costs. According to this analysis, the substitution cost will be roughly SEK 37 million. This amounts to around 0.003% of the industries' turnover and 0.01% of their value added throughout the EU. The costs of switching subcontractor (or else having existing suppliers supply phthalate-free articles) to someone who can supply articles free of low molecular weight phthalates can be considered as additional. It is difficult to assess the possible size of this transition cost. However, the impact of these transition costs can be contained by giving sufficient time to importers to implement the restriction so that they can smoothly make the transition.

Sports and leisure articles

Sports and leisure articles belong to an industry which is mainly focused on imports, where the majority of operators are located outside Sweden and very likely outside the EU as well. Just as in the case of clothing, footwear and accessories, we go on the assumption we made in section 9.3 that a large share of imports contain hazardous substances. Substitution is estimated to cost around SEK 3,700,000, which is 0.006 % of the industries' turnover and 0.02% of their value added.

It is mainly importers in the EU whose manufacturers cannot make a substitution for a less hazardous plasticiser who will be affected. The impact this will have on the article's cost follows the same argument as for clothing, footwear and accessories.

Home furnishings

Phasing out furniture and home furnishings in the EU is expected to incur fairly low costs as the categories of furniture which contain PVC are relatively large, but the quantity of PVC per article is relatively small. Substitution costs are estimated at around SEK 7,500,000, which is almost a negligible share of both the industries' turnover and value added. The majority of articles containing DEHP which end up on the EU market are assumed to be imports. The biggest substitution cost will be imposed on importers who import home furnishing articles into the EU.

Just as was mentioned in the earlier argument, it is not the actual cost of making the substitution, but rather the consequences which may result in switching to phthalate-free articles. Refer to the argument given in the clothing, footwear and accessories section.

9.6.2 Action proposal 2: National regulations for phthalate emissions from construction articles in indoor environments

This action proposal includes a limit on emissions in indoor environments. This mainly affects new and renovated buildings.

Phthalates occur in building materials which people come into contact with and can also contribute to exposure levels in indoor environments. Based on the calculations in section 9.3, the quantity of DEHP in products used in the construction sector in Sweden is roughly 3,300 tonnes per year. As exposure to phthalates in indoor environments is the main source of exposure for small children (see section 6.2.2) and our calculations indicate that a large proportion of harmful low molecular weight phthalates are found specifically in construction articles, we consider a measure in this sector will make an important contribution to reducing the level of exposure.

Sweden's construction industry has a turnover of around SEK 210 billion per year and the industry's value added is roughly SEK 50 billion per year.

The substitution cost per tonne for DEHP is roughly SEK 3,200 (see section 9.5), which, when multiplied by 3,300 tonnes, estimated to be the volume used every year in the Swedish construction sector, gives a cost of SEK 11 million. Added to this are the transition costs relating to the need for research and development, amounting to SEK 1 million a year. The total cost for this action proposal is therefore estimated at SEK 12 million per year.

Overall, the cost of substituting low molecular weight phthalates in the Swedish construction sector is estimated at around SEK 12 million per year. This amounts to 0.005% of the sector's turnover and 0.02% of its generated value added.

Our report has indicated that the substitute produces a very slight price disparity in articles costs per kg of article. Therefore, the price of the article is considered to be hardly affected.

A limit would be an effective way of reducing exposure from new articles on the market. This measure would also tackle exposure from low molecular weight phthalates from imported construction articles. Several operators in the Swedish market have already indicated possibilities for switching. For instance, the flooring industry has already, in large parts, switched to alternative plasticisers.

A restriction would impose the requirement for better reports on phthalate content in construction products. This may entail increased costs for companies in terms of not only analysing substances featuring in the articles they manufacture, but also of checking the content of the articles they import into Sweden.

The increased R&D costs are expected to be around SEK 1.2 million per year. The extent to which each company is affected by producing new substitutes depends on the market share the company has and how complex the process is of substituting harmful phthalates for the relevant article.

Monitoring compliance with legislation will be an administrative cost borne by the relevant authorities tasked with market surveillance of construction articles. The annual cost of the Swedish Chemicals Agency's market surveillance activities depends on the size of the project, but is expected to be less than SEK 1 million per year. This is relatively small in comparison to the cost of substitution.

The administrative cost incurred for both the authorities and companies is expected to fall once the new regulations have bedded in.

9.6.3 Action proposal 3: Public procurement

It is important that the government assumes environmental responsibility when procuring articles. In view of the size of the public sector, this can have a direct impact on certain industries in the sector. The requirement to phase out harmful phthalates in public procurement will potentially affect a number of different stakeholders.

For instance, the local authority's procurement of articles for schools and pre-school institutions may reduce the level of exposure children are subject to every day. This also applies to building project procurement in the case of building pre-school and school premises.

The same also applies to county councils when purchasing medical articles. A number of county councils have been actively involved for a long time in an attempt to reduce the volume of articles containing harmful phthalates. County councils deal with a number of articles which may contain harmful phthalates, such as blood bags, medicine packaging, healthcare instruments etc. At the same time, it is important that the articles used are safe to use over a long period of time. Satisfactory alternatives must be available for substitution.

This situation in terms of phthalate requirements also applies when the county council is purchasing new and renovated buildings.

Other organisations involved in government procurement for construction projects may also impose requirements for building materials to be free of harmful phthalates.

The consequences of this are generally that the Government will be made, initially, to pay more for articles in the sectors where existing articles containing harmful phthalates need to be substituted. One of the reasons for this is the higher R&D costs which the Government would possibly have to be involved in funding. On the other hand, the level of exposure which, for instance, children would be subject to in pre-school institutions would fall. This would also result in a general decrease in exposure to harmful phthalates in the public sector.

If we assume that the volume subject to public procurement proceedings amounts to 17% of GDP, we can assume that the Government is responsible for around 980 tonnes of the DEHP used in Sweden, based on the calculations in section 9.3. If we also assume from previous calculations that the cost of substituting a tonne of DEHP is roughly SEK 3,500 per tonne (including R&D costs), the substitution

cost in relation to public procurement is around SEK 3.4 million. The calculated substitution cost would be negligible in relation to the calculated cost for the volume subject to public procurement proceedings of SEK 560-670 billion per year. There are also the administrative costs on top of this.

In general, it is difficult to assess exactly how large a reduction would be achieved in the exposure level to harmful phthalates as a result of public procurement requirements. Even if many Swedish companies have moved away from using harmful phthalates such as DEHP, this substance will still occur in imported articles. It is also difficult to assess beforehand how much additional cost will be incurred by these procurement requirements. As described for the previous action proposals, it can be stated that the share of the price of a product dependent on which plasticiser is used is small and, in some cases, negligible. This means that, in general, phthalate requirements in public procurement will not change the cost very much at all.

9.6.4 Action proposal 4: Improved compliance with regulations in Sweden.

This option contains three different aspects:

- The Swedish Chemicals Agency provides more information about hazardous substances in articles;
- The Swedish Chemicals Agency expands its market surveillance activities and endeavours through market surveillance guidelines to ensure that local authorities also increase their market surveillance activities;
- Introduction of environmental sanction charges.

Communication

We want to be more active in ensuring information about products' content reaches consumers. This can be achieved by the Swedish Chemicals Agency adopting a more active role in providing information to industries and industry associations about low molecular weight phthalates, for instance. Communication is a good option from the point of view that it enables information also to be provided about the substances which the Swedish Chemicals Agency is considering introducing legislation against.

The financial consequences of this are mainly borne by the Swedish Chemicals Agency, which will need to allocate more resources to communication activities and providing information to companies.

Market surveillance

This action proposal could result in greater market surveillance of the regulatory areas including phthalates. There are currently provisions governing phthalates in two pieces of legislation – the Toy Safety Directive and REACH Regulation:

- Phthalates classified as CMR substances are subject to the restrictions in the Toy Safety Directive;
- The use of six phthalates is restricted in toys and childcare articles, according to Annex XVII of REACH;
- Article 33 of REACH means that a supplier must inform a customer if an SVHC in the candidate list is found in the article at a concentration above 0.1%;
- From January 2015, authorisation will apply under REACH to the four low molecular weight phthalates being examined in this report.

Increased market surveillance will mainly incur financially an HR cost for the Swedish Chemicals Agency. The Agency will therefore need a larger budget allocation from the Government or to reallocate resources in the Agency to cover the funding of the increased level of activity. According to an assessment from an earlier project, we reckon that a supervisory project costs in the region of SEK 1-3 million[227]. Given that the phthalate supervisory project will be carried out over a period of several years, the annual cost will be less than SEK 1 million a year.

If the Swedish Chemicals Agency and market surveillance officers with the local authorities receive additional resources for carrying out market surveillance of the articles specified in Article 33, the pressure will increase on those carrying out this activity to provide information about the presence of SVHCs in the articles. At present, this has already been perceived by many companies, subject to Article 33, as a ban and provided them with an incentive to change plasticiser from phthalates to an alternative which is less harmful to health. Increased market surveillance would result in more information being available to consumers about SVHCs and provide them with the chance to stop using products. It also provides companies with an incentive to switch articles.

Monitoring companies for production authorisation after the "sunset date" is expected to have a limited effect. In Sweden, a large proportion of the production of plasticisers has already switched from using low molecular weight phthalates to alternatives which are less harmful to health.

Environmental sanction charges

Switching from criminal provisions to environmental sanction charges means that a charge will be imposed by the Government for breaches of regulations which are currently linked to criminal provisions contained in the Swedish Environmental Code. An environmental sanction charge is a charge of between SEK 1,000 and 1 million paid by anyone committing breaches of the Swedish Environmental Code. The size of the charge is determined based on an assessment of the gravity of the breach committed[228]. An environmental sanction charge is paid to the Government.

As the Swedish Chemicals Agency is not proposing in this report which criminal provisions should be amended to environmental sanction provisions, which is being proposed as the subject of a separate review, it is not possible either to describe what the consequences of this may be.

Summary

Better compliance with the regulations in Sweden in terms of communication, market surveillance and sanction charges would help raise the profile of the phthalates issue. It is important that increased market surveillance forces companies to start providing information about the substances contained in their products. Providing more information may also result in companies voluntarily switching from articles containing phthalates to articles which are less harmful to health.

[227] Refer, for instance, to the Swedish Chemicals Agency, Annual Report 2013.
[228] Swedish Environmental Code (1998.808), Chapter 30, paragraph 1.

9.6.5 Summary of action proposals

Some comments are given below by way of summary of the actions proposed. We have decided not to weigh up the actions against each other, but to present them as a set of measures which we believe that the government should consider going ahead with.

Table 13: Summary of impact assessment results

Action proposal	Operators affected	Cost of measure	Cost of measure as share of relevant industries' turnover & value added
1.1: Addendum to RoHS Directive	EU Commission, electronics manufacturers in EU, importers of electrical and electronic products, consumers, national market surveillance authorities	SEK 125 million	0.004% of turnover, 0.02% of value added
1.2: Addendum to REACH via Article 68(2)	EU Commission, relevant sectors, importers, consumers, national market surveillance authorities	SEK 710 million	0.004% of turnover, 0.02% of value added
2: Limit in indoor environments in Sweden	Construction industry, importers, Swedish Chemicals Agency, consumers	SEK 12 million	0.005% of turnover, 0.02% of value added
3: Public procurement	Swedish Government, local authority care for the elderly, local authority schools, county council care activities, Government property administration	SEK 3.4 million	0.001% of the volume subject to public procurement proceedings
4: Better compliance with regulations	Swedish Chemicals Agency, local authorities, toy industry, industries requiring authorisation, consumers (children)	Roughly SEK 1-3 million	Not available

All the measures account for an equally small proportion of the industries' turnover and value added. Therefore, the cost of substitution would not impose any greater a burden on these sectors. On the other hand, it is worth pointing out that this breakdown is simplified and that some industries may be affected by this more than others, which means that they may be made to assume a larger proportion of the costs for these measures.

9.6.6 Brief overview of health-related costs

As mentioned in the introduction to the impact assessment section, it is difficult to establish any causal link between exposure to phthalates and different types of health effects, such as asthma, autism etc., as the diagnoses are often complex and there is also simultaneous exposure to a large number of other substances. However, effects which are toxic for reproduction have been linked to phthalate exposure in both animal experimental studies and epidemiological studies. In other words, links have been seen between phthalate concentrations in humans and effects which are toxic for reproduction. The effects observed in humans include deformities of male sexual organs and impaired sperm quality (section 6.1.1). The deformities of the sexual organs observed can entail, for instance, the urethra opening in the wrong place (hypospadias) or the testicles failing to descend into the scrotum (cryptorchidism).

To give an overall picture of the magnitude of the costs involved, we have compared them to the socio-economic costs associated with deformities of male sexual organs, but also to the

costs for asthma and autism. The costs for each of these health conditions are described in detail in Appendix 8.

The most costly measure at a national level is the one aimed at the construction sector, with a calculated cost of SEK 12 million per year. This is less than the cost of providing life-time care for an autism case. This indicates that if at least one autism case is prevented every year as a result of any of the national measures proposed, these measures are profitable to implement from a socio-economic perspective. The costs of the national measures targeted at the construction sector are equivalent to the costs of the life-time care for 30 asthma cases, 90 hypospadias cases or 230 cryptorchidism cases.

The estimate of the costs resulting from introducing an addendum to REACH via Article 68(2) is roughly SEK 710 million per year for the whole EU. This is equivalent to the cost of handling 1,600 asthma cases, 5,400 hypospadias cases or 35 cases of severe autism.

The estimate of the costs resulting from introducing an addendum to the RoHS Directive is roughly SEK 125 million per year for the whole EU. This is equivalent to the cost of handling 300 asthma cases, 1,000 hypospadias cases, 2,500 cryptorchidism cases or 6 cases of severe autism.

Appendix 1: Text of assignment agreement

REGERINGEN

Regeringsbeslut I:4

2013-06-27 M2013/1736/Ke

Miljödepartementet

Kemikalieinspektionen
Box 2
172 13 Sundbyberg

Uppdrag till Kemikalieinspektionen att verka för en utfasning av misstänkt fortplantningsstörande och hormonstörande ftalater i Sverige

Regeringens beslut

Regeringen ger Kemikalieinspektionen i uppdrag att göra en kartläggning av användningen av misstänkt fortplantningsstörande eller hormonstörande ftalater och förekomsten av alternativa ämnen och material. På grundval av kartläggningen ska Kemikalieinspektionen genom exempelvis branschdialoger verka för att företag frivilligt ersätter sådana ftalater med mindre farliga ämnen eller material.

I uppdraget ingår att utreda behovet av och förutsättningarna för Sverige att införa nationella begränsningar mot användning av misstänkt fortplantningsstörande och hormonstörande ftalater. Även möjliga vägar för att verka på EU-nivå bör utredas. Arbetet bör ske med beaktande av initiativ inom EU för att klassificera, begränsa eller tillståndspröva ftalater. Eventuella förslag om regelverk ska ske i form av författnings-förslag och åtföljas av dels en konsekvensutredning som ska utformas så långt som möjligt i enlighet med 6 och 7 §§ förordningen (2007:1244) om konsekvensutredning vid regelgivning, dels en riskbedömning. I konsekvensutredningen ska även ingå en analys av påverkan på handeln med andra länder.

Kemikalieinspektionen ska redovisa uppdraget till Regeringskansliet (Miljödepartementet) senast den 30 november 2014.

Bakgrund

Ftalater är samlingsnamnet på en grupp kemiska ämnen som är baserade på ämnet ftalsyra. Ett antal ftalater har dokumenterat fortplantningsstörande och hormonstörande egenskaper. Det finns anledning att misstänka att särskilt ftalater med en kolkedjelängd på 4–6 atomer har fortplantningsstörande och/eller hormonstörande egenskaper.

2

Ftalater används främst som mjukgörare i PVC-plast, där ämnena kontinuerligt frigörs under användningen. Den omfattande användningen av ftalatinnehållande mjuk PVC-plast i samhället innebär att ftalater påträffas i människor vilket framgår av analyser som gjorts av blod, bröstmjölk och urin. Ftalater används huvudsakligen i golvbeläggningar av plast inomhus. Ämnena finns också i lim, färg, tätningsmedel, tapeter, kabel, folie och vävplast.

Regeringen gav i december 2010 Kemikalieinspektionen i uppdrag att ta fram och genomföra en handlingsplan för en giftfri vardag. Uppdraget syftade bl.a. till att bättre skydda barnen från de risker som uppstår vid exponering för farliga kemikalier i vardagen. Barn och ungdomar är mer sårbara än vuxna under sin utveckling samtidigt som den växande konsumtionen av varor medför en ökande och diffus exponering. Kemikalieinspektionen redovisade uppdraget i rapporten Handlingsplan för en giftfri vardag 2011–2014: Skydda barnen bättre. I handlingsplanen gör Kemikalieinspektionen en genomgång av farliga ämnen som bör uppmärksammas i viktigare varugrupper. Ftalater pekas ut på ett flertal ställen i handlingsplanen.

Ftalater har p.g.a. av de risker de ger upphov till redan blivit föremål för olika regleringar. På EU-nivå har användningen av sex ftalater begränsats i leksaker och barnvårdsartiklar. Sju ftalater återfinns på den s.k. kandidatförteckningen till Europaparlamentets och rådets förordning (EG) nr 1907/2006 av den 18 december 2006 om registrering, utvärdering, godkännande och begränsning av kemikalier (Reach) varav fyra har blivit föremål för tillståndsprövning. Elva ftalater klassificeras som fortplantningsstörande i olika grad i Europaparlamentets och rådets förordning (EG) nr 1272/2008 av den 16 december 2008 om klassificering, märkning och förpackning av ämnen och blandningar (CLP). Danmark har utöver detta infört ett nationellt förbud mot användning av fyra ftalater i ett stort antal konsumentartiklar samt förbjudit användning av alla slags ftalater i leksaker och barnartiklar. Kemikalieinspektionen har tagit fram ett förslag om harmoniserad klassificering för en ftalat (DIHP) som skadlig för fortplantning och påbörjat arbetet med ytterligare ett förslag. Även om Danmark, Sverige och flera andra länder i EU arbetar aktivt med ftalaterna, både vad gäller förslag på harmoniserad klassificering i CLP och med upptag på kandidatförteckningen i Reach, är det fortfarande osäkert i vilken utsträckning dessa åtgärder kan komma att minska människors exponering för ftalater på kortare sikt.

Den danska regeringen har beslutat att genomföra en nationell ftalatstrategi med det övergripande syftet att ytterligare skydda de danska medborgarna från den sammantagna exponeringen för ämnena. Enligt strategin ska Danmark verka för att det på EU-nivå sker en systematisk genomgång och utvärdering, och vid behov även reglering, av samtliga 26 kända substanser. Utvärderingen kommer att ske inom ramen för

Reach och CLP, med utnyttjande av förordningarnas verktyg för riskbegränsning.

En tydlig utgångspunkt för den danska strategin är att det inte är tillräckligt att studera riskerna med ämnena vart och ett för sig. Eftersom de har likartade effekter på fortplantningen behöver också den kombinerade exponeringen och riskerna för kombinationseffekter bedömas. Arbetet kommer främst att riktas mot det 20-tal ftalater som hittills inte blivit klassificerade som reproduktionsstörande. Bland dem kommer det att ske en successiv prioritering utifrån vad registreringsunderlaget visar.

Uppdraget

Regeringen uppdrar åt Kemikalieinspektionen att verka för en utfasning av misstänkt fortplantningsstörande eller hormonstörande ftalater i Sverige. Kemikalieinspektionen ska göra en kartläggning av användningen av dessa ftalater och förekomsten av alternativa ämnen och material. På grundval av kartläggningen ska Kemikalieinspektionen verka för att företag frivilligt ersätter sådana ftalater med mindre farliga ämnen eller material.

I uppdraget ingår också att utreda behovet av och förutsättningarna för Sverige att införa nationella begränsningar mot användning av misstänkt fortplantningsstörande och hormonstörande ftalater. Även möjliga vägar för att verka på EU-nivå bör utredas. Eventuella förslag om regelverk ska ske i form av författningsförslag och åtföljas av dels en konsekvensutredning som ska utformas så långt som möjligt i enlighet med 6 och 7 §§ förordningen (2007:1244) om konsekvensutredning vid regelgivning, dels en riskbedömning. I konsekvensutredningen ska även ingå en analys av påverkan på handeln med andra länder.

Arbetet bör ske i beaktande av den kunskap och de erfarenheter som genereras i Danmark och med ambitionen att på lämpligt sätt stödja och komplettera de danska insatserna. Arbetet bör vidare ske med beaktande av utvärderingar inom EU av riskerna med ftalater, enskilt och i kombination, och eventuella initiativ inom EU för att klassificera, begränsa eller tillståndspröva ftalater.

Uppdraget ska utföras i en nära dialog med berörda statliga myndigheter och med berörda aktörer såsom kommuner, landsting, företag och

branschorganisationer inom industri och handel, konsumentorganisationer och miljöorganisationer.

På regeringens vägnar

Lena Ek

Björn Dufva

Kopia till

Justitiedepartementet
Utrikesdepartementet
Socialdepartementet
Finansdepartementet
Landsbygdsdepartementet
Näringsdepartementet
Arbetsmarknadsdepartementet

Appendix 2: External reference group

Company/organisation	Description	Contact
BASTA	Assessment system for construction and installation products	Anna Widheden
BIL Sweden	Industry association for manufacturers and importers of private cars, trucks and buses	Anna Henstedt
National Board of Housing, Building and Planning	Government agency. Deals with issues relating to public planning, building and housing	Kristina Einarsson
ElektronikBranschen	Industry association for suppliers and traders in the consumer electronics, photography and service sectors	Klas Elm
Golvbranschen (GBR)	Industry association representing floor layers, dealers and suppliers	Jesper Nordlinder
Innovations och Kemiindustrierna i Sverige (IKEM)	Industry association for the chemistry, plastics and material sectors. Represented in this case by Perstorp	Anders Magnusson
Swedish Medical Products Agency (MPA)	Government agency for medicinal products, cosmetics, hygiene products and products used in the medical sector	Alicja Andersson
Swedish Society for Nature Conservation (SNF)	Sweden's largest environmental organisation	Cecilia Hedfors
Swedish Environmental Protection Agency (NV)	Government agency which oversees the state of the environment and any environmental activities being carried out. The NV is also tasked with coordinating, monitoring and assessing activities in relation to Sweden's environmental targets	Erik Westin
Perstorp	Chemicals company. Sweden's largest manufacturer of phthalates	Elna Nilsson
City of Stockholm	Local authority actively promoting chemical issues	Arne Jamtrot
Swedish Construction Federation	Industry and employers' association for the construction industry	Maria Brogren
Swedish Food Retail Association	Industry association for the food retail sector	Per Baumann
Swedish Trade Federation	Industry association for companies operating in the wholesale and retail sector	Ann Christiansson
Västra Götaland Regional Council	Council responsible for health and care issues in Västra Götaland region	Jens Strömberg

Appendix 3: Examples of occurrence of certain phthalates in articles based on supervisory projects in Sweden and other tests, as well as on the Danish survey of chemicals in articles

Article group	Article	DEHP (mg/kg)	BBP (mg/kg)	DBP (mg/kg)	DIBP (mg/kg)	DINP (mg/kg)	DIDP (mg/kg)	DNOP (mg/kg)	DPHP (mg/kg)	Source
Accessories	Plastic comb	160	n.d.	n.d	n.d	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Children's articles	Activity mat	42		23	1800					Market surveillance (Danish)
Children's articles	Children's car seats	11.3%								Market surveillance (Swedish Chemicals Agency)
Children's articles	Soothers	300				1600				Market surveillance (Danish)
Lighting	Bulb	365		719	337					Market surveillance (Danish)
Construction	Sealant, filler					16	32			Market surveillance (Danish)
Construction	Plastic laminate	760								Market surveillance (Danish)
Cycles	Cycle handlebars	11%			6.1%					Market surveillance (Swedish Chemicals Agency)
Miscellaneous	Heart-shaped hand warmer	510	n.d	n.d	n.d	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Diving and flotation equipment	Swimming equipment	333,000			1890					Market surveillance (Danish)
Diving and flotation equipment	Sports articles	48%			32%	28%	0.52%			Market surveillance (Swedish Chemicals Agency)
Flooring	Flooring	160,000	20000	16000		310000	310000			Market surveillance (Danish)
Flooring	Flooring	325	113	129	73650					Market surveillance (Danish)
Flooring	Flooring	17%				17%	5.3%			Market surveillance (Swedish Chemicals Agency)
Pet accessories	Pet toys, pet care articles	39				54				Market surveillance (Danish)
Hygiene articles	Soap packaging	200,000				200000		150000		Market surveillance (Danish)
Furnishings (bathroom)	Bath mats	220,000				800000				Market surveillance (Danish)
Furnishings (bathroom)	Shower curtains	296,000		63	173	88000	88000			Market surveillance (Danish)
Furnishings (bathroom)	"Yellow duck" anti-slip mat	24,000	n.d	n.d	n.d	1,200	0.015	n.d	-	Envir. admin. Gothenburg, 2014

Furnishings (decorations)	Christmas decorations	24,000				410000				Market surveillance (Swedish Chemicals Agency)
Furnishings (cloth)	Oilcloth	254,000			56					Market surveillance (Danish)
Furnishings (cloth)	Oilcloth	180,000	n.d	n.d	n.d	100	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Furnishings (mat)	Green anti-slip mat	68,000	n.d	27,000	23,000	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Furnishings (mat)	Black anti-slip mat	170,000	n.d	n.d	n.d	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014

continued

Article group	**Article**	**DEHP (mg/kg)**	**BBP (mg/kg)**	**DBP (mg/kg)**	**DIBP (mg/kg)**	**DINP (mg/kg)**	**DIDP (mg/kg)**	**DNOP (mg/kg)**	**DPHP (mg/kg)**	**Source**
Furnishings (mat)	White anti-slip mat	n.d	n.d	n.d	n.d	60,000	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Furnishings (mats)	Textile tiles					290,000	290000			Market surveillance (Danish)
Cables and wires	Cables	20%								Market surveillance (Swedish Chemicals Agency)
Clothing	Trousers	0.78%								Market surveillance (Swedish Chemicals Agency)
Clothing	Jackets	213,000		120						Market surveillance (Danish)
Clothing	Hestra children's mittens, plastic sticker	130,000	-	-	-	-	-	-	-	Testfakta, 2013
Clothing	Vossatassars children's mittens, plastic sticker	190,000	-	-	-	-	-	-	-	Testfakta, 2013
Clothing	Ellos E-protection overall with zipper	160,000	-	-	-	-	-	-	-	Testfakta, 2013
Clothing	T-shirts			38	23					Market surveillance (Danish)
Clothing	T-shirts	18,500			142	16790				Market surveillance (Swedish Chemicals Agency)
Office articles	Eraser	54				70				Market surveillance (Danish)
Toys	Doll's head (BraDeal)	400,000	n.d	60	1200	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Toys	Floor puzzle		355	780	315					Market surveillance (Danish)
Toys	Toy dolphin, plastic toy	56,000	n.d	90	250000	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Toys	Toys	39%		45%	42%	38%				Market surveillance (Swedish Chemicals Agency)
Toys	Toy spectacles, plastic	n.d	n.d	50	n.d	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014

Toys	“Angry Birds” plastic ball	460,000	n.d	n.d	200	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Toys	Plastic toy	374	< 1	21	28	230	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	34	< 1	< 1	< 1	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	5	1	3	3	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	< 1	< 1	< 1	< 1	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	25	< 1	3	6	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	< 1	2	129	110	1800	190	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	5	< 1	7	1	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
continued										
Article group	**Article**	**DEHP (mg/kg)**	**BBP (mg/kg)**	**DBP (mg/kg)**	**DIBP (mg/kg)**	**DINP (mg/kg)**	**DIDP (mg/kg)**	**DNOP (mg/kg)**	**DPHP (mg/kg)**	**Source**
Toys	Plastic toy	< 1	< 1	< 1	< 1	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	1	< 1	< 1	2	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Plastic toy	< 1	< 1	< 1	< 1	< 10	< 10	< 1	-	Environmental office, Örebro Council, 2012
Toys	Striped toy ball (foamed rubber)	n.d	n.d	n.d	760	n.d	n.d	n.d	-	Envir. admin. Gothenburg, 2014
Toys	Slimy toys	81				1800				Market surveillance (Danish)
Toys	Sword	76				935	25			Market surveillance (Danish)
Toys (bath)	Bath toys					25%	2.1%			Market surveillance (Swedish Chemicals Agency)
Toys (bath)	Child’s bath	258,000		10	18					Market surveillance (Danish)
Toys (bath)	“Floaties” inflatable plastic toy	310,000	-	-	650	100000	-	1,100	-	Environmental office, Luleå Council
Toys (bath)	Inflatable plastic toy crocodile	240,000	-	-	-	160,000	360	1800	-	Environmental office, Luleå Council
Toys (bath)	Inflatable plastic toy sea lion		-	-	-	< 400	-	-	-	Environmental office, Luleå Council
Toys (dressing-up clothes)	Red Grabbit - uniform, plastic	500	n.d	n.d	n.d	35,000	12,000	n.d	-	Envir. admin. Gothenburg, 2014

Mattresses	Airbeds	304,000								Market surveillance (Danish)
Furniture	Bar stool	15		335	16250					Market surveillance (Danish)
Furniture	Armchair	21			388					Market surveillance (Danish)
Furniture	Pouffe	35		11	38					Market surveillance (Danish)
Furniture	Chair	40		340	1140					Market surveillance (Danish)
Furniture (textiles)	Furniture textiles			0.17%		4.8%	9.5%			Market surveillance (Swedish Chemicals Agency)
Sex articles	"Black double dong" sex toy	n.d	n.d	n.d	n.d	2,600	37,000	n.d	-	Envir. admin. Gothenburg, 2014
Sex articles	8 pink G-spot, sex toy	n.d	n.d	n.d	n.d	25,000	660,000	n.d	-	Envir. admin. Gothenburg, 2014
Sex toys	Dildo							161		Market surveillance (Danish)
Sex toys	See-through bra	265								Market surveillance (Danish)
Sex toys	Vibrator	610				600		239		Market surveillance (Danish)
Footwear	Wellingtons									Market surveillance (Danish)
Footwear	Plastic sandals, children	344,500	79	282500	121000					Market surveillance (Danish)
continued										
Article group	**Article**	**DEHP (mg/kg)**	**BBP (mg/kg)**	**DBP (mg/kg)**	**DIBP (mg/kg)**	**DINP (mg/kg)**	**DIDP (mg/kg)**	**DNOP (mg/kg)**	**DPHP (mg/kg)**	**Source**
Footwear	Plastic sandals, adults	461,000	25	345000	116500					Market surveillance (Danish)
Footwear	Plastic shoes, lace	69%		36%	29%					Market surveillance (Swedish Chemicals Agency)
Footwear	Plastic shoes, sole	49%		0.67%	0.77%					Market surveillance (Swedish Chemicals Agency)
Footwear	Boot	30%		0.46%						Market surveillance (Swedish Chemicals Agency)
Footwear	Rubber clogs	50,000		51000	3000					Market surveillance (Danish)
Protective equipment (construction)	Ear protectors	11%								Market surveillance (Swedish Chemicals Agency)
Protective equipment (gloves, foodstuffs)	Kron vinyl gloves	11	-	-	-	500,000	-	-	-	Testfakta, 2013
Protective equipment (gloves: general)	Guide vinyl gloves	< 10	-	-	-	120,000	-	-	-	Testfakta, 2013
Protective equipment (gloves, foodstuffs)	Emotion vinyl gloves	240	-	-	-	150,000	-	-	-	Testfakta, 2013
Protective equipment (gloves, foodstuffs)	Evercare vinyl gloves	< 10	-	-	-	1,000	-	-	-	Testfakta, 2013

Protective equipment (gloves, foodstuffs)	Martin Olsson vinyl gloves	3,200	-	-	-	110,000	-	-	-	Testfakta, 2013
Protective equipment (gloves, foodstuffs)	Abena vinyl gloves	31	-	-	-	180,000	-	-	-	Testfakta, 2013
Protective equipment (gloves, foodstuffs)	Apoteket vinyl gloves	130	-	-	-	7,000	-	-	-	Testfakta, 2013
Protective equipment (gloves, foodstuffs)	Jula vinyl gloves	< 10	-	-	-	300,000	-	-	-	Testfakta, 2013

Appendix 4: Notified use of the phthalates DEHP, DBP, DIBP and BBP in articles in the EU.

The data is based on notifications and registrations to ECHA received before 17 February 2014.

Bis (2-ethylhexyl)phthalate (DEHP)

EC Number: 204-211-0
CAS Number: 117-81-7
Number of Notifications:123

Article Categories:
Electrical batteries and accumulators
Fabrics, textiles and apparel
Machinery, mechanical appliances, electrical/electronic articles
Metal articles
Plastic articles
Rubber articles
Vehicles
Wood articles
Other

Article types/use of articles, examples in alphabetical order:
Abrasive pads
Accessories for the following product ranges: Photo, Video, Audio, Computer, Telecommunication (e.g. Bags, Cables, Adapters, Tripods, Storage media, Picture frames, Mouse, Keyboard, Hub, Headsets, Cleaning Agents),
Accessories on textiles (such as buttons, reflectors, zippers, labels and paillettes),
Articles included in vehicles (wire harness, protector, column assy, stopper, cable sub-assy, cylinder and key set, motor assy, heater assy, sensor, power train, cap assy, hose assy, hose, plug plate, plug set, bearing assy, ventilation hose, gasket, cover hole, Accessories; ultrasonic sensor, ashtray, smoker kit, passenger lift-up, computer assy, turn signal sensor; service parts; ventilation hose, windshield glass stopper, plug plate, noise control plate, belt assy, speaker assy, check assy, hose assy, pipe, tube, switch assy, retainer, hose),
Artificial respiratory equipment
Backpacks,
Bags and carry sleeves for laptop computers and tablets (made of coloured jersey and polyurethane memory foam stuffed for protection, with a reinforcement pipe around the edges of the bag/sleeve),
Bags made of fabric,
Bathroom scales,
Bounce,
Building material
Bags,
Bracelets
Cable,
Cable insulations of PVC,
Cables in audio and video equipment,
Car mats

Decoration articles,
Decorative plastic tablecloths,
Diving flippers,
Diving mask,
Downlight
Electric cables,
Electric wire,
Electrical equipment,
Electrical lighting for outdoor use with PVC sheathing,
Electronic articles,
Electronic equipment,
Electronic equipment (such as washing machines, vacuum cleaners, scanners, printers, fax machines, network cameras, projectors, air conditioners, shavers, headphones),
Extension cord for domestic use
Fashion bags,
Faucets, basins, shower trays and racks made of plastic,
Fences (e.g. Oil booms, Oil fences, Roll doors, Dock seals),
Floor covering made by PC,
Flooring
Garden furniture (loungers, chairs, tables) made of plastic meshwork or plastic fibre fitted on a rack (steel/alu),
General purpose engines,
Glass fiber mesh insect screen, coated with grey PVC,
Goggles with plastic parts
Harnesses with plastic parts,
Household goods like lamps and microwave dishes
Industrial tank,
Inflatable articles (e.g. Inflatable boats, Ventilation ducts, Ventilation articles),
Inflatable mattress,
Insect frames
Laminated decorative PVC sheet,
Lamps,
Leatherette (synthetic leather),
Led strip,
Luggage containing elements of flexible plastic manicure sets
Massage units,
Mat,
Medical device,
Medical Devices: Adapters and Connectors,
Medical Devices: Blood Bags,
Medical Devices: Dialysis Fistula Needles,
Medical Devices: Dialysis Fistula Needles (for Hemodialysis treatment),
Medical devices including wrist stabilizers,
Medical Devices (Platelet bags, Arterial Venous Fistula needles, Bio hole Needle Set, Safety Arterial Venous Fistula needles, Blood Tubing Set (dialysis), Safety Blood Collection System, Safety Scalp Vein Set (Infusion), and Standard Infusion Set),
Medical devices such as tubing or backing for medical diagnostic devices or in optical films,
Metal lamps,
Motorcycles
Necklaces

Notebook with colored plastic cover
Off-road vehicles,
Organizer for storing things in the car,
Outboard engines,
Outdoor seating furniture (with seating made from fabric and frame made of aluminium, polypropylene or wood)
Packagings and products in plastic (mainly soft PVC),
Parts of vehicle (motor cycles),
Pavilion tent for outdoor use made of plastic canvas on a steel tube frame,
Pencil case and bag made of fabric coated with plastic,
Personal protective equipment, Personal protective equipment (Goggles),
Personal protective equipment: hearing protection, protective safety eyewear,
Personal watercraft,
Plastic air bed,
Plastic backed mat,
Plastic blister packaging,
Plastic chair,
Plastic floor tiles,
Plastic flooring,
Plastic foil,
Plastic foil,
Plastic packaging material,
Plastic packaging (transparent PVC bag),
Polybag and blister (packaging),
Portfolio in colored plastic material,
Power cord of electrical appliance,
Power supplying cable for buildings (supplying power e.g. to intrusion prevention, access control and gateway links systems),
Purses,
PVC adhesive film for labels,
PVC covered electrical cable,
PVC fabric,
PVC film for semiconductors,
PVC floor coverings (cushion vinyl),
PVC flooring,
PVC hairdryers (looks like a shower cap and has an extension to be connected to the hairdryer machine),
PVC packaging material,
PVC products used for insulation of cables and wires,
PVC profile and hose,
PVC shower curtains and mats,
PVC soap dishes and bath shower caps,
PVC/polyester/PVC three layer sheet rainwear
Pyjamas
Reflective films and labels,
Room air purifiers,
Rubber and rubber-metal parts for private repairing works
Scraper matting,
Seals (for e.g. windows, doors, ventilation conduits, metal sections, cabinet walls, furniture),
Sewing machines,

Shoes with plastic parts,
Shower hose,
Shower mat,
Signs,
Soft PVC tablecloth,
Steering wheels covers,
Suitcase made of fabric coated with plastic and handle of plastic and metal
Tapes for surface protection and bundling,
Tarpaulin,
Tarpaulin covers (that can be used e.g. as Pool covers, Tents, Roofing and so on),
Tent,
Textile products,
Textiles with printing,
Tool box (used to contain tools for mobile phones and electronics),
Tool with metal shaft and blade and a soft plastic handle (used to maintain mobile phones and electronics),
Torch led,
Training device for CPR (cardiopulmonary resuscitation) training
Umbrellas
Valve blister and flat plates for valve (packaging),
Vehicles and Power equipment products,
Vehicles with plastic and rubber parts (such as motor cycle, snow mobile, water vehicle or outboard motor)
Wallets,
Watches
Wallets,
Wide range of consumer products containing soft plastic, rubber or fabric parts,
Windscreen washer system,
Wire insulation in electrical articles,
Wooden doors

Dibutyl phthalate (DBP)

EC Number: 201-557-4
CAS Number: 84-74-2
Number of Notifications: 19

Article Categories:
Electrical batteries and accumulators
Fabrics, textiles and apparel
Machinery, mechanical appliances, electrical/electronic articles
Paper articles
Plastic articles
Rubber articles
Vehicles
Other

Article types/use of articles, examples in alphabetical order:
Accessories for the following product ranges: Photo, Video, Audio, Computer, Telecommunication (e.g. Bags, Cables, Adapters, Tripods, Storage media, Picture frames, Mouse, Keyboard, Hub, Headsets, Cleaning Agents),
Accessories on textiles (e.g. Buttons, Reflectors, Zippers, Labels, Paillettes),
Ammunition
Bags,
Belts,
Bounce,
Building material
Cables,
Car mats
Decoration articles
Extension cord for domestic use
Fences (e.g. Oil booms, Oil fences, Roll doors, Dock seals)
Head phones,
Household goods like lamps and microwave dishes
Industrial tank,
Inflatable articles (e.g. Inflatable boats, Ventilation ducts, Ventilation articles),
Inflatable mattress,
Insulation (sound and thermal) and sealing materials in air conditioning units and heat pumps
Mat
Outdoor seating furniture (with seating made from fabric and frame made of aluminium, polypropylene or wood)
Packaging material from plastic,
Pencil case and bag of fabric coated with plastic,
Plastic blister packaging,
Plastic foil,
Power cord of electrical appliance,
PVC packaging material,
PVC waterproof garments and bag
Rainwear,
Rubber and rubber-metal parts for repair of vehicles and machines
Shoe with plastic parts,
Shoes,
Signs,
Steering wheel covers,
Storage boxes,
Suitcase made of fabric coated with plastic and handle of plastic and metal
Tarpaulin covers (that can be used e.g. as Pool covers, Tents, Roofing and so on),
Tent,
Textiles with decorative printings on the outer side of the fabric
Wire insulation in electrical articles

Diisobutyl phthalate (DIBP)

EC Number: 201-553-2
CAS Number: 84-69-5
Number of Notifications: 18

Article Categories:
Fabrics, textiles and apparel
Plastic articles
Rubber articles
Other

Article types/use of articles, examples in alphabetical order:
Accessories on textiles (e.g. Buttons, Reflectors, Zippers, Labels, Paillettes),
Ammunitions
Bags,
Bellow (e.g. for encapsuling and guiding fluids or for covering mechanics like levers, adjustments and actuators),
Belts
Cables,
Car mats
Decoration articles
Extension cord for domestic use
Head phones
Outdoor seating furniture (with seating made from fabric and frame made of aluminium, polypropylene or wood)
Packaging material from plastic,
Plastic blister packaging,
Plastic foil,
Power cord of electrical appliance,
PVC floor coverings (cushion vinyl),
PVC packaging material
Shoes,
Steering wheel covers,
Storage boxes
Textiles with decorative printings on the outer side of the fabric
Wire insulation in electrical articles

Benzyl butyl phthalate (BBP)

EC Number: 201-622-7
CAS Number: 85-68-7
Number of Notifications: 4

Article Categories:
Plastic articles
Rubber articles

Article types/use of articles, examples in alphabetical order: -
Extension cord for domestic use
Medical disposables
Outdoor seating furniture (with seating made from fabric and frame made of aluminium, polypropylene or wood)
Plastic blister packaging, Plastic foil, Power cord of electrical appliance, PVC packaging material
Steering wheel cover
Wire insulation in electrical articles

Appendix 5: Can Sweden ban hazardous chemicals? A legal analysis

In early July this year, Denmark's Ministry of the Environment rescinded its national ban on the use of phthalates in consumer articles[229]. The reason for rescinding the ban was that the Commission had levelled criticism at it, believing that it contravened the EU's REACH Regulation. In the Commission's view, Denmark was unable to introduce national regulations when a proposal on regulating phthalates under REACH had already been examined and rejected by the EU. The Commission believed that national bans would create unlawful trade barriers within the EU.

The individual countries' option to go ahead with a chemicals ban has been discussed and debated in the EU ever since REACH was adopted in 2006. The slow processes involved in adopting an EU ban have also led to many countries choosing to go ahead with national restrictions. Some examples include the restrictions imposed by France and Belgium on the endocrine-disruptor bisphenol A, Sweden's regulation on tattoo inks and reporting requirements in France for articles containing nanomaterials. Although the Commission has criticised proposals in every case, none of them have progressed to an examination by the EU Court of Justice. Therefore, at present, there is only the wording in REACH and existing case-law from the EU Court of Justice on related issues to use as a basis for settling the legal situation.

The Swedish Government's view has been that REACH should not prevent countries from going ahead with a national ban as long as there are no common EU regulations. This is also an assessment shared and expressed by the Swedish Chemicals Agency, including when the Agency proposed how bisphenol A can be regulated in Sweden[230]. However, in light of Denmark rescinding its ban, we have felt it necessary to review our interpretation. In this legal analysis, we will explain the legal issues which are crucial and contribute to our assessment of the legal situation.

Background

In 2006 there was a fundamental change in the European legal landscape for chemicals with the adoption of the REACH Regulation. Existing chemical restrictions[231] and risk assessment rules[232] were merged and supplemented mainly by stringent registration requirements. One of the main objectives was to remedy the dearth of information available about chemicals on the European market. The bans and restrictions already in force under old provisions were incorporated into an annex to REACH[233].

REACH also introduced a process for determining how new restrictions are decided at EU level[234]. In a nutshell, the process is based on either the EU chemical agency ECHA or individual Member States compiling a restriction file, which is then reviewed by two

[229] Danish Environmental Protection Agency, 2014. Available. 19.11.2014. http://mst.dk/service/nyheder/nyhedsarkiv/2014/jul/forbud-mod-fire-ftalater-ophaeves/.
[230] See, for example, Swedish Chemicals Agency report 4/12, Bisfenol A i kassakvitton (Bisphenol A in cash receipts) – Report from a government commission.
[231] Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
[232] Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances.
[233] REACH ((EC) No 1907/2006), Annex XVII.
[234] REACH ((EC) No 1907/2006), Title VIII.

committees, the RAC[235] and SEAC[236]. Based on the opinion of these two committees, the Commission then decides on whether to impose any EU restriction[237]. Sweden is one of the countries which have been most active in proposing new restrictions via this procedure. However, in conjunction with proposals for EU restrictions, Sweden and numerous other countries have considered that national bans can be introduced where there is no restriction already in force under the REACH Regulation.

One relevant question on this subject is why some countries feel that it is important to proceed with national regulations. Most agree that common EU regulations are preferable to national requirements. The risks created by hazardous chemicals are generally handled more efficiently at a European level, or even better, at a global level. The application of common regulations also avoids the trade barriers which can result from different regulations in force in different markets. The focus of Sweden's efforts on chemical matters has also been to strive for tougher regulations at EU and global level[238]. However, in some cases, Sweden and other countries have chosen to go ahead with national bans where the EU has not yet successfully agreed on common regulations. National regulations have been regarded as better than no regulations at all in terms of combating risks from chemicals. National bans have also been used as a means of exerting pressure on the EU to introduce common EU regulations in the long term. Therefore, there are still grounds for Member States to want, in certain cases, to be ahead of the EU in terms of chemicals legislation.

However, there is still a difference of opinion regarding what harmonised effect the restriction process under REACH will provide and what scope is available for national bans. According to EU legal theory, some people, including Lucas Bergkamp in his reference work on REACH, have interpreted the restriction process in this regulation as not providing any scope for individual countries to go ahead and impose national bans or restrictions[239]. Based on this interpretation, the REACH procedure would offer not only an opportunity for countries to introduce EU restrictions but also to ban the introduction of national restrictions. This would mean, with only a few exceptions[240], full harmonisation of chemicals regulations in the EU.

What the legislation says

The REACH regulation is a single market act, with Article 114 TFEU (previously Article 95 TEC) providing its legal basis. Choosing Article 114 TFEU as its legal basis means that REACH has a harmonising effect unlike many other EU laws on environmental issues, which are more like a minimum standard. The harmonising impact of REACH is also expressed in Article 128(1) of the regulation, which states in simplified terms that Member States are not allowed to ban the manufacture, sale or use of a substance as such or as a constituent of a mixture or article if the requirements under REACH have been met. If a substance or a certain use of the substance is not banned under REACH, argues Bergkamp for example, it should be

[235] Risk Assessment Committee.
[236] Socio-Economic Analysis Committee.
[237] Through amendments to REACH ((EC) No 1907/2006), Annex XVII.
[238] This is evident from the Swedish Chemicals Agency's report "Handlingsplan för en giftfri vardag 2015-2020" (Action plan for a non-toxic everyday environment 2015-2020).
[239] Read Lucas Bergkamp's book, "The European Union Reach Regulation For Chemicals – Law and Practice" (2013), to see this interpretation.
[240] The safeguard clause in Article 129 of REACH, the so-called "environmental guarantee" in Article 114(5) TFEU and in rare cases where it has been established that EU regulations are inappropriate as the risk which needs to be managed only occurs in one particular Member State.

considered instead as being permitted under REACH[241]. This would mean that Article 128(1) bans countries from regulating this substance or its use at national level.

On the other hand, several Member States have felt that such an interpretation disregards Article 128(2) under REACH. This stipulates that REACH will not prevent countries from introducing their own regulations as a means of protecting, for instance, the environment and health where the regulation fails to harmonise requirements in terms of manufacture, sale or use. If REACH does not include regulations restricting the occurrence of phthalates in a particular article, to give one example, can it be considered that REACH has harmonised these requirements? A number of countries believe that the answer to this question is "no" and that Article 128(2) consequently allows countries to introduce national requirements in such a situation.

Alongside the chemical restrictions already introduced under REACH, there are also regulations governing the process for coming up with new, similar restrictions. They feature in Articles 67-73. Article 69 describes what action the Commission and Member States should take when they believe that there is an environmental and/or health risk which needs to be addressed. In this case, a Member State must notify the EU chemicals agency ECHA, prepare a dossier on the substance and its risks, and propose how a restriction should be devised at EU level[242]. The question is whether this should be interpreted as harmonising the option of restricting chemicals or only as a description of what action the countries must take if they want to strive for an EU regulation.

European Court of Justice case-law – Lapin judgment

When Denmark rescinded its ban on phthalates, one of the reasons mentioned was the judgment from the European Court of Justice in the Lapin case[243]. The Commission also referred to this judgment when criticising proposals for national restrictions. Other countries, including Sweden, have regarded this as an over-interpretation of the judgment. In these countries' view, the judgment should be interpreted instead as meaning that Member States are prevented from imposing further conditions when REACH has already introduced conditions for a particular substance or for a particular use of this substance[244]. On the other hand, this does not prevent countries from restricting substances and uses other than those which have been regulated under REACH. These are two opposing interpretations, which justifies a closer look at the judgment.

The Lapin case relates to bridgework which the Finnish rail authority in Lapland had carried out 2008-2009. The bridge had been constructed using poles impregnated with CCA solution (copper-chromium-arsenic) and previously used as telecommunications poles. The use of CCA for the preservation of wood is banned under REACH[245]. However, there are certain exemptions. CCA solution is occasionally used for preserving wood specifically in bridges and bridgework if the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely. However, CCA solution must not be used if there is a risk of repeated skin contact.

One question raised in the case was whether the Finnish authorities was allowed to impose further conditions on the use of the poles treated with CCA in the bridgework, in addition to

[241] Bergkamp (2013), pages 150-152.
[242] REACH ((EC) No 1907/2006), Article 69(4).
[243] Case C-358/11.
[244] REACH ((EC) No 1907/2006), Annex XVII.
[245] REACH ((EC) No 1907/2006), Point 19, Annex XVII.

the above-mentioned conditions featuring in REACH. Advocate General Kokott submitted her proposal for a decision in December 2012. Kokott indicated that Article 128(2) of REACH must not prevent Member States from maintaining or laying down national rules where this Regulation does not harmonise the requirements on manufacture, placing on the market or use. The question was "*whether the use of treated wood for the construction of duckboards was harmonised by Article 67 of and point 19 of Annex XVII to the* REACH *Regulation*"[246]. Since the REACH provisions on timber treated with CCA are exhaustive, Kokott considered that the regulations for this use had been harmonised, which meant that there was no scope provided for more stringent national regulations[247].

The European Court of Justice was, as usual, more succinct in its analysis than the Advocate General. Even though it came to the same conclusion - i.e. more stringent terms were not permitted in the current cases - the Court expressed a more general view. In the reasons for the judgment, the Court writes: "[Reach] *must be interpreted as meaning that European Union law harmonises the requirements relating to the manufacture, placing on the market or use of a substance such as that relating to arsenic compounds which is the subject of a restriction under* [Reach]."[248]

Our assessment

The Lapin judgment is of interest as it marks the first time that the European Court of Justice interprets the scope of a REACH restriction. Based on the circumstances of the case, the Court's conclusion did not come as a surprise. The requirements examined in the case, i.e. the Finns' requirements for using posts treated with CCA in bridgework, related exactly to the use already regulated under REACH. The regulation's harmonising effect means in all likelihood that additional national conditions governing the same use are incompatible with REACH.

However, the judgement raises questions about what applies to substances which have not been restricted under REACH and, in particular, what applies to substances which have only been restricted under REACH for certain, specific uses. If a substance is not *subject to a restriction under* REACH, requirements for manufacture, use or sale of the subject are therefore not likely to be regarded as harmonised. The same argument can be made for substances which are only restricted for certain, specific uses.

Phthalates is an example of a group of substances which are only restricted for certain uses. Although 13 phthalates have been identified in REACH as substances of very high concern[249] only some of them are banned from being used in articles. Bans also apply only in children's toys and childcare articles[250]. In other words, there are numerous aspects not covered by the existing phthalate regulation in REACH. In spite of this, can the phthalate regulation be considered as a whole to be harmonised through REACH?

In order to establish what has been harmonised via an EU legal act, the crucial factor is primarily the regulation's protective purpose. The principal objectives of REACH are, on the one hand, to guarantee a high level of protection for human health and the environment and,

[246] Paragraph 57 of the Advocate General's opinion.
[247] Paragraph 64 of the Advocate General's opinion.
[248] Paragraph 38 of the Court's judgment.
[249] SVHCs.
[250] REACH ((EC) No 1907/2006), Points 51 and 52, Annex XVII. Four phthalates will also require authorisation for their use in production in the EU from 21 February 2015. However, the authorisation requirement under REACH does not apply to articles which contain substances subject to authorisation and which have been imported from countries outside the EU, but only to the import of the substances themselves.

on the other, to enable substances to move around freely on the single market. These objectives must be achieved by regulating the manufacture, placing on the market or use of these substances as they are or as constituents of preparations or articles.

These objectives would normally mean that Member States no longer have opportunities to adopt national measures aimed at manufacture, placing on the market or use in order to protect human health and the environment[251]. However, REACH contains an exception to this main principle in Article 128(2)[252]. This article is in keeping with the European Court of Justice's previous case-law from the chemicals sector, which stipulates that the scope of the regulation must be examined to establish its harmonising effect[253]. If, for instance, the legal act only regulates when a particular substance itself can be sold, this has not prevented a Member State from regulating at a national level the trade in articles containing this substance [254]. In our view, Article 128(2) is crucial to determine the Member State's scope to retain or introduce new national requirements for chemicals in order to protect human health and the environment[255].

A restrictive view of what is harmonised by REACH seems logical as the regulation has such a broad area of application. This differentiates it from, for example, the Toy Safety Directive, Machinery Directive and the directive on medical devices, which is appropriate for each of these defined product areas. Our view is that if harmonisation is to be considered as covering every type of article this would result in an unreasonable impact if only a very restricted scope of use had been assessed in a restriction process in REACH. The phthalate restrictions in toys and childcare articles in Annex XVII can be referred to as examples of this. The process which brought about this restriction did not address other areas where phthalates can pose a risk, such as the use of phthalates in construction products. This is why several Member States have also chosen to regulate the phthalate content in construction products at a national level.

We believe that what has been said above indicates that REACH does not harmonise anything other than what specifically comes under the REACH restriction. However, the Lapin case has seemed, in certain respects, to contradict this interpretation. In the reason given for the judgment, it is stated that if a substance has been restricted under REACH, no national conditions are allowed to be imposed for the same substance. However, in our view, the verdict should be interpreted based on the circumstances in the specific case where the national conditions which were under examination clashed with the REACH restriction as

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[251] On the other hand, a Member State could regulate a substance with a view to protecting, for instance, animals' health as public interest is not addressed in the EU legal act. See case C-132/08 *Lidl Magyarország* where the Court stated that a Member State could ban the sale of an article which complied with a full harmonisation directive as the grounds for the ban were different to those which the directive was based on.
[252] See section "What the legislation says".
[253] The question has been raised about the extent to which the Court's interpretation of previous chemicals regulations (Limitations Directive) is relevant to the interpretation of REACH as the latter is far more extensive. However, the relevance of previous case-law was established by the European Court of Justice in the Lapin case (paragraph 37, see also paragraph 60 in the Advocate General's opinion).
[254] Refer also, for instance to case C-127/97 *Burstein* where the Court approved a German restriction on PCB content in *goods* even though there were EU legislative provisions restricting the sale of the *substance* PCB. See also case C-132/08 *Lidl Magyarország* where the Court stated that a Member State could ban the sale of an article which complied with a full harmonisation directive as the grounds for the ban were different to those which the directive was based on.
[255] David Langlet and Said Mahmoudi have also highlighted that a reasonable interpretation of Article 128(2) is that REACH's harmonising effect must not be interpreted in such a broad manner (EU environmental law, third edition (2011), pages 326-328). Therefore Article 128(2) should not, as Bergkamp asserts, only concern risks which do not need to be addressed at EU level, for instance, when the risk is restricted to only one country.

they related to the same area of use. The opinion of the Advocate General in the Lapin case also indicates that it is precisely the use regulated under REACH which would be regarded as harmonised[256].

The Commission has expressed its view in a manner, as we interpret it, which supports the conclusion that substances and/or specific uses of substances which have not been restricted under REACH cannot be regarded as harmonised under REACH[257]. Nevertheless, the Commission has criticised countries which have attempted to go ahead and introduce national legislation in these areas. We interpret this criticism to mean that the Commission believes that the harmonising effect applies not only to the "material restrictions" under REACH but also to the restriction process in Article 69 of REACH. As REACH stipulates that countries should initiate an EU restriction process if they believe that a chemical risk needs to be addressed, this means conversely that Member States are banned from taking action at a national level.

According to the EU's legal principle of loyal cooperation, Member States must not prevent EU law from being effective by their actions. The European Court of Justice has rejected national regulations in other areas on the basis that they stop EU law from being effective. For example, the Court has rejected national regulations which have not gone through the mandatory examination procedure under Directive 98/34/EC, whose aim is to prevent trade barriers in the EU. However, we believe that the articles in REACH governing the restriction process are not comparable with Directive 98/34/EC. The fact that a Member State introduces a chemical restriction at national level does not specifically prevent the state from, if necessary, also launching a restriction process at EU level[258]. Therefore, the effectiveness of the REACH restriction process is not jeopardised by a country being allowed to introduce a national restriction until a possible EU restriction is in place.

One of the main aims behind REACH is to create free movement within the EU. Would this purpose be undermined if Member States were allowed to introduce national chemical restrictions? We do not believe this would be the case as this purpose is guaranteed, in the non-harmonised area, by other EU legal mechanisms. Firstly, the above-mentioned examination procedure in Directive 98/34/EC applies, whose aim is to prevent national regulations from creating unnecessary trade barriers. Secondly, Member States need, even if REACH is not applicable, to justify a restriction based on the TFEU's provisions on free movement. A national ban which is more far-reaching and obstructive to trade than necessary may not be justified according to these regulations.

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[256] Paragraph 57 of the Advocate General's opinion.

[257] This can be inferred, for instance, from the Commission's opinion on Denmark's national mercury ban (notification procedure no 2013/0146/DK). The Commission expresses the following in its opinion: "Due to the very general and broad formulations of § 4 of the draft order, it is not clear whether it may still not interfere with the afore-mentioned existing restrictions, or derogations from them, laid down in Annex XVII to the REACH Regulation (whether e.g. the general ban in §4(3) of the draft order related to placing on the market of mixtures containing more than 100 ppm (mg/kg) does not interfere with derogations in entry 30 paragraph 2 of Annex XVII to the REACH Regulation etc.) It is equally unclear whether the ban to use mercury in substances or mixtures intended for paints, varnishes or similar in concentrations exceeding 1 ppm under § 6 of the draft order does not interfere with entry 30 of Annex XVII to the REACH Regulation." Therefore, the Commission is not criticising the national regulations on mercury per se, even though mercury is regulated by REACH Annex XVII, but only where the national regulations clash with the specific mercury restrictions featuring in Annex XVII. However, it must be mentioned again that there is no consensus on this view. Refer, for instance, to an opposing interpretation from Lucas Bergkamp in "The European Union REACH Regulation For Chemicals – Law and Practice" (2013).

[258] However, if the EU process results in a restriction at EU level, the country must obviously remove its own national regulation. This is how REACH requirements are harmonised.

We do not find any support either from the wording in Articles 68-69 for interpreting them as an obstacle to national bans. Article 69 describes the process for initiating a restriction process. However, these provisions only address restrictions at EU level, which is specified in the working of Article 68(1) ("*risk* [which] *needs to be addressed on a Community-wide basis")*.[259] This section of REACH makes no mention of national regulations at all and cannot be interpreted as a ban on them. In our view, Article 128(2) also loses its relevance completely if Member States were prevented from introducing national restrictions where there is no common EU restriction in place.

We believe that the Lapin case cannot be used as a pretext either for preventing Member States in general from introducing national chemical restrictions. The judgment seems rather to indicate the opposite. Since the Court confirmed in the Lapin case that Finland was prevented from introducing additional requirements for *substances which were already restricted* under REACH, conversely, it is likely to be the case that Member States are not prevented from introducing conditions for substances other than those which have been restricted under REACH.

Failing any explanatory statement from the European Court of Justice, it is not possible to say for definite how the Court would interpret the restriction process under REACH. However, by way of summary, our view is that REACH should not prevent Member States from imposing a national ban on hazardous chemicals when there are no restrictive regulations already in place in the REACH Regulation. However, to guarantee a national restriction's compatibility with REACH, it must be ensured that there is no "duplication" or any conflict with any existing regulation for the same substance in REACH. If a substance is subject to an authorisation requirement under REACH, the national regulation, for instance, must be drafted taking this factor into account.

National requirements must obviously also be drafted to comply with Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) on the free movement of goods. During the drafting process, it must, for instance, be considered whether a certain substance or a certain use has already been subject to an EU restriction process. If, for example, it has been assessed as part of the REACH process that there is no unacceptable risk and that a REACH restriction has therefore not been deemed as justified, this may influence the opportunities of justifying national bans on the same substance or use.

[259] See also the arguments in Articles 86-94 of REACH.

Annex 6: Overview of toxicological data for a number of phthalates

CAS No.	Molecular weight	Name	Abbreviation	Harmonised Classification[a]	Oral DNEL[b] Reproductive effects (mg/kg BW/d)	Oral DNEL[b] Liver effects (mg/kg BW/d)	TDI[c] (mg/kg BW/d)	Commission EDC priority list, Cat. 1[d]	REACH Regulations
Low molecular weight phthalates									
84-69-5	278.35	Diisobutyl phthalate	DIBP	Repro 1B	0.42	-	-		Candidate list[f] Annex XIV[g]
84-74-2	278.35	Dibutyl phthalate	DBP	Repro 1B	0.007	-	0.01 (Repro)	X	Candidate list[f] Annex XIV[g] Annex XVII[h]
85-68-7	312.35	Benzyl butyl phthalate	BBP	Repro 1B	0.5	-	0.5 (Repro)	X	Candidate list[f] Annex XIV[g] Annex XVII[h]
117-81-7	390.57	Diethylhexyl phthalate	DEHP	Repro 1B	0.034	-	0.05 (Repro)	X	Candidate list[f] Annex XIV[g] Annex XVII[h]
117-84-0	390.57	Di-n-octyl phthalate	DnOP	-	-	-	-		Annex XVII[h]
High molecular weight phthalates									
28553-12-0/ 68515-48-0	418.62	Diisononyl phthalate	DINP	-	0.25	0.075	0.15 (Liver)		Annex XVII[i]
26761-40-0/ 68515-49-1	446.68	Diisodecyl phthalate	DIDP	-	0.08[e]	0.075	0.15 (Liver)		Annex XVII[i]
53306-54-0	446.66	Di(2-propylheptyl) phthalate	DPHP	-	-	-	-		CoRAP 2016[j]

[a]Classification according to CLP ((EC) No 1272/2008), Annex VI.

[b]DNEL values according to ECHA/RAC/RES-O-0000001412-86-07/F (DIBP and BBP), RAC/24/2013/09_rev 2 (DBP), RAC/24/2013/08 rev. 2 (DEHP) and ECHA/RAC/A77-O-0000001412-86-10/F (DINP and DIDP).

[c]TDI values according to EFSA (The European Food Safety Authority), the EFSA Journal 2005, Volume 241-245.

[d]European Commission DG ENV, 2000. Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting; Annex 15. M0355008/1786Q/10/11/00DC

[e]Not based on an anti-androgenic effect

[f]Candidate list, substances identified as a Substance of Very High Concern (SVHC) are added to the list of candidate substances for possible inclusion in the Authorisation List (Annex XIV).

[g]Annex XIV, REACH Authorisation List.

[h]Annex XVII, REACH Restrictions List, Entry 51 banning the use in toys and child care products.

[i]Annex XVII REACH Restrictions List, Entry 52 banning the use in toys and child care products that can be put in the mouth.

[j]CoRAP 2016, Community Rolling Action Plan. Germany will evaluate the substance based on suspected organ and reproductive toxicity.

DNEL= Derived no effect level; TDI= Tolerable daily intake; CLP= Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures; REACH= Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals

Annex 7: Experiences from dialogues conducted as part of the assignment

Some case studies

A summary is provided below of the presentations made during the dialogues which were conducted as part of this project.

Perstorp

Perstorp started its presentation by indicating how widely the various plasticisers available on the market are used. There is an abundance of different alternatives, ranging from trimellitates, adipates, terephthalates, bio-based plasticisers and many, many more. Over the last 60 years, more than 30,000 compounds have been proposed as PVC plasticisers, but less than 100 have been given commercial status. Only around 10 of them are used as primary plasticisers and are considered to be easily accessible and cost-effective.

At present, almost 6 million tonnes of plasticisers are used worldwide every year, including around 1 million tonnes in Europe. Phthalates account for more than 80% of this volume.

Perstorp described some of the important factors when new plasticisers are manufactured. Technical performance needs to be assessed, products must comply with the regulations in place, the product must be sustainable, commercially viable and can be bought at an affordable price. It is important to be able to look at products over a life cycle. The challenging aspect is finding new general plasticisers to suit many different purposes.

Tarkett

Tarkett is one of the world's largest flooring companies and has manufactured flooring in Sweden since 1886. Tarkett currently offers in Scandinavia a wide selection of different types of flooring materials for the home environment, as well as total functional solutions for the public environment. Tarkett wants to assume serious environmental responsibility and manufacture products which operate in a modern circular economy without compromising on design and functionality. One example of this is the introduction of phthalate-free technology in the plants manufacturing plastic flooring.

Tarkett already started using phthalate-free technology in its Ronneby plant in Sweden in 2009. In 2011 it removed phthalates from all its homogeneous PVC flooring for the public environment. While the debate has been going on about phthalates' impact on health, Tarkett has decided to stop using phthalates. The company set as its mission to be the first to be phthalate-free and lead the trend. Starting in spring 2014, there will be a gradual transition to phthalate-free plasticisers in all production units worldwide. One of the plasticisers Tarkett uses instead is called DINCH, which is approved for use in food packaging and in toys for children under the age of 3, intended to be put in their mouth. Other alternative phthalate-free plasticisers have also been tested and used in production.

Tarkett's advice to other companies wishing to substitute phthalates is to start by carrying out a proper preliminary study. It is important to put a lot of work into this study. Two other success factors are good cooperation with key suppliers and active use of risks analyses. It is worthwhile companies carrying out their own analyses first and having good contacts with

suppliers of different plasticisers. Occasionally while work was in progress, the company was forced to go back and start again using a different plasticiser when they realised that it was not quite up to standard. On the other hand, the investment costs that the company had to make at the start of the job were recouped at a later stage. Tarkett wants to be a pioneer in sustainable development and adopt a responsible attitude to health and the environment.

Jegrelius Institute for Applied Green Chemistry

The Jegrelius Institute is a centre of environmental expertise and an independent agency working with consumers, businesses and the public sector to boost the demand and production of non-toxic products. Project managers spoke at the meeting about the EU PVCfreeBloodBag project, which intends to demonstrate that PVC-free blood bags can be manufactured, which meet the requirement specification produced, including CE marking. High demand is required from buyers to ensure that any future new bag will have the biggest possible market launch. Therefore, the project team is collaborating with the European healthcare sector to disseminate knowledge and raise awareness about this type of blood bag. PVC needs plasticisers to become soft. DEHP is classified as being toxic for reproduction and the risks from DEHP are highlighted in the directive on medical devices. Exposure to DEHP comes from numerous other sources. Nowadays, a number of healthcare organisations have a PVC policy. PVC can also cause waste and production problems on a global scale.

The main reason for choosing to move away completely from PVC is the precautionary principle. Demanding PVC-free articles means avoiding the risks with new plasticisers. The precautionary principle is important because it is difficult to predict the consequences of new plasticisers. The most likely alternative is polyolefin plastic.

At the moment, the most commonly used blood bags for red blood cells contain between 30 and 40% DEHP. Studies have shown that DEHP migrates to the blood, but the quantity depends on time, temperature, fat content, lipid content and other factors. Storage tests will be carried out at the Karolinska University Hospital in Sweden. There are stringent requirements for this and the testing will be carried out thoroughly. A prototype bag has been produced and we will know about its storage capabilities at the start of next year. If it transpired that there is a large cost difference between the new bag and a conventional blood bag, their use may be restricted to the most vulnerable patient groups, such as premature babies and chronically ill patients.

Värmland County Council

Värmland County Council in Sweden has been working successfully on procurement issues for some time. A consultant who was involved in the refurbishment of a neonatal unit spoke about some of the success factors relating to this task.

The first one, which is important, is to be involved early on in the process, in terms of influencing how the contract is drafted, what will be included in the construction and how the structure will fare at achieving the targets that have been set. Being involved at an early stage is a key factor if you want to be successful at making the substitution you want. It is paramount to be involved throughout the process to ensure that requirements are actually followed during the course of the work. Guidelines must be clear. It is important to have dialogue and good cooperation throughout the process.

In cases where other materials are available, they must be substituted with those which are greener and better for public health. Where there is a lack of information, the precautionary principle should be applied. In other cases, there may be issues which can be resolved in

different ways. It is very often possible to use alternative design solutions to avoid the need to use undesirable chemicals or a product with certain properties, without having a different solution devised.

To avoid problems, any material used should be documented, along with the possible deviations which are made. If a possible problem can be related to a particular substance, a check can be carried out for the presence of this substance.

In the case involving the refurbishment of the neonatal unit in Karlstad, a calculation was performed for the quantity of substances avoided by actively choosing materials: phthalates in electric cables - DIDP 14-31 kg and 177-288 kg of unspecified phthalates + PVC plastic, PVC-free installation pipes - 229 kg PVC plastic, PVC-free mat in the sections where this is possible 443 kg DINCH and 1172 kg PVC plastic, alternative roof covering 153 kg DINP and 197 kg PVC plastic. Actively choosing materials led to an overall reduction of around 1,600 kg of PVC and 800 kg of phthalates in a floor area of approx. 1,250 m2. All this was achieved at a cost of 0.33% of the total construction cost, excluding equipment.

Hewlett-Packard (HP)

One success factor with substitution is that it is best to engage in dialogue directly with those manufacturing chemicals and not with subcontractors. Subcontractors usually do not have the knowledge required to specify the correct requirements, i.e. to ensure that using an alternative is better. It is important to be aware of the high cost of substituting chemicals in articles. From the time a better alternative has been found, it takes a major company, due to the complex nature of the supplier chain, a minimum of two years to introduce the change.

If an investment is being made in no longer using a substance due to its adverse environmental and/or health properties, it is absolutely paramount to ensure that the alternative has evidence of better properties. In this case, there are different options to choose from. HP has chosen to assess chemicals' environmental and health properties by using Green Screen™. Since autumn 2013 it has published for the first time lists of plasticisers and flame retardants which have undergone the Green Screen™ assessment. They contain recommendations on which substances should not be used and which alternatives can be recommended. To gain access to this document, the relevant subcontractor must sign an agreement with HP.

Public procurement is another important tool for achieving substitution and can, in all likelihood, be used to a larger extent than it is at the moment.

SundaHus

SundaHus offers property owners, such as local authorities, local authority agencies, county councils and major private property owners a wide selection of services for making an informed choice of material. Past experiences have shown that the wrong choice of construction articles can cost large sums of money and entail health and environmental risks for those carrying out the construction, working in the building or due to demolish buildings. As a result, an increasing number of property owners are in the process of phasing out the substances which are now known to be hazardous. We are also aware that substances which are harmless today can become hazardous in the future.

Many also use different types of certifications for buildings nowadays. The concept behind most of these systems is often the same as above, i.e. to avoid hazardous substances, keep the health and environmental risks to a minimum and to document proof for the future. SundaHus

Miljödata (environmental data) can therefore be used as a tool for achieving objectives in terms of certification. The system offers functions to support property owners in their work. With a web-based system and expert advice, SundaHus is a total solution for supporting the task of systematically phasing out hazardous substances in a building's whole life cycle. Therefore, they have developed a system which rates building materials and products from an environmental and health perspective.

Other dialogues conducted during the project

Given that phthalates are used in a number of different industries, it has been paramount to contact as many industries as possible to obtain a complete picture. It has not been possible to bring all the relevant industries together at the dialogue meetings which have been held. Therefore, individual meetings have been held with some industries.

Toys industry

As part of the existing dialogue with the toys industry, a survey was presented at a meeting, followed by a discussion based on issues relating to the companies' use of phthalates.

To ensure legal compliance, companies feel that it is important, with clear consideration of all the legal requirements, to choose suppliers carefully, with testing and monitoring being a crucial part of this. Some random samples are taken and companies can sometimes test themselves using an XRF (X-ray fluorescence machine). It is costly and draws bad publicity if a RAPEX notification is used and products are recalled. Companies really want to avoid this situation.

Some companies choose to avoid PVC completely, which makes their job easier by reducing the number of checks and analyses involved. In some cases, it is impossible to avoid using PVC as a material as it is a good material and, for instance, retains colours well. The alternative, TPE, used by a company instead, does not work equally well, for instance, for all applications. The company therefore felt that it had no options in this case other than PVC.

Nowadays, there are standardised tests for checking for 28-30 different phthalates. Another strategy deployed in the toys industry is to avoid purchasing toys containing phthalates and to request phthalate-free articles instead. Otherwise, companies can stipulate as a requirement that phthalates in the candidate list must not feature in the products (does not only apply to toys).

The assurance that requirements are met is based on the supplier signing an agreement undertaking to comply with the company's requirements. Companies are also requesting laboratory analyses from the supplier and are sending samples themselves for analysis. If phthalates are being used, it is important to obtain information about what is actually being used and then try to evaluate the alternatives. What would be desirable is if a complete list of contents could be requested. Sometimes it is possible to go back in the chain to obtain the relevant information. If there is an increasing demand for this, it becomes more obvious that it is a high priority for companies to obtain this information.

If it is not possible to monitor all the requirements, the most important thing is to verify the requirements for the products involving skin contact and children. This is the biggest source of risk of exposure.

Many companies have problems handling the phthalate requirements. One reason for this is that companies purchase random batches which are not checked. But, there are also companies which have poor knowledge and do not set any chemical requirements. Some

companies are not aware either of all the requirements toys are subject to. Companies take chances and try to purchase and sell products without checking the supplier first. This is successful on many occasions, but it can also go wrong. There may also be traces of banned phthalates, which are not intentionally added. This is something which can be difficult to keep tabs on.

Alternative phthalates which companies can use include, for instance, DINCH, DEHT and ESBO.

Textile industry

As part of the existing dialogue on textiles, a survey was also presented, along with alternative phthalates and how companies can use phthalates. In this case too, there followed a discussion, raising similar issues to those facing the toy companies. The feedback from the meeting with textile companies is also included in the report.

Cosmetics industry

As part of the existing dialogue on cosmetics, the group has been informed about the Swedish Chemicals Agency's assignment on phthalates. However, this industry is not as affected by this task as DEP is the only phthalate currently used in cosmetics. Other phthalates are substituted or regulated.

Electronics industry

During the project the project group has met with a number of electronics companies to report on the assignment on phthalates which the Swedish Chemicals Agency is involved with, as well as to be able to share companies' experiences. The feedback contributed to the report by the electronics industry is described later on in this appendix.

Construction sector

A number of initiatives are in progress within the construction industry, aimed at phasing out hazardous substances. One of these is BASTA. As part of the BASTA system, a scientific committee has been set up where the Swedish Chemicals Agency is represented. During some of the meetings held by the scientific committee, the Swedish Chemicals Agency has provided information about its phthalate assignment. More information is provided later on in this appendix about the construction sector's efforts.

Axel Johnson Group

Early on in the project, the Swedish Chemicals Agency was contacted by this group with a request to collaborate on a seminar on phthalates along with IKEM (Innovation and Chemical Industries in Sweden) and Perstorp. The Swedish Chemicals Agency presented its assignment on phthalates, the regulations which currently apply to phthalates in the EU and the rest of the world, the outcome from market surveillance, current developments in other countries, as well as tips on how companies can phase out hazardous substances such as phthalates. Åhléns and Filippa K also described their efforts on substitution during the seminar.

The group includes a number of different types of companies, such as Mekonomen, Åhléns, Filippa K, Axfood, Kicks, Martin & Servera and Lagerhouse.

Prerequisites in different industries for acting on own initiative

Construction sector

The construction sector is large and complex, and can be split into a number of different industries. This sector accounts for around 40% of all the material and energy used in Sweden. Around 50,000 different materials and chemical products are used in the construction sector.

Imports from other countries

It most commonly seems that contracts are with Swedish dealers, but the number of contracts within the EU is increasing. This means that the actual product can be manufactured in different ways around the world, which is something that the end user generally knows very little about.

Product development cycle, transition time

The transition time for building contractors is generally a project cycle. Specified materials based on the design are purchased as early as possible in the project and are subsequently replaced only in exceptional cases. As there is a growing use of one of the environmental assessment systems, such as BASTA, Byggvarubedömningen (Building product assessment) or SundaHus for products, the supplier needs to be able to present validation of the content so that an assessment can be carried out. This process is carried out in slightly different ways in systems, but the requirement is for the supplier to carry out checks backwards in the chain. Requirements are set out in procurement/purchasing agreements for the products supplied to fulfil requirements based on criteria used in the environmental assessment system. This works with varying degrees of success in different sectors of the industry. But the trend is towards specific requirements being set and also monitored. Validation is also requested from the supplier in the form of Building product declarations (BPD) and the result of the assessment based on the chosen system.

Flooring industry[260]

The flooring industry has, to a large extent, switched over to phthalate-free alternatives. In normal circumstances, it takes 2-3 years to develop new products so as to establish the process and product characteristics. In some cases, switching to existing alternatives can have an impact on product characteristics and performance or it means that the product would fail to meet specific standards and requirements. In this case, the product development process takes longer.

With regard to the time required for introducing new requirements for suppliers, consideration should be given to contractual periods, which are at least 1 year long, but may vary and run for several years.

Environmental requirements

The construction industry is well advanced in terms of setting requirements for phasing out hazardous substances. There are currently three major environmental assessment systems on the market, with development in progress for around 10 years. The work has been carried out as a collaboration between the operators in the construction sector and requirements for

[260] Feedback from flooring industry based on questionnaire, 06.10.2014

materials are handled constructively among manufacturers, thereby promoting product development and the phasing out of hazardous substances. The focus is concentrated for the whole time on intrinsic property requirements rather than blacklists of individual substances, which has been positive and boosted progress more quickly.

Flooring industry

New local requirement specifications may generally be difficult to handle as the Swedish market is only a small part of the European/global market. Changes can mean in many cases that the entire manufacture of the product(s) is affected. Global suppliers also have a large volume of collections and colour variations which would be affected, as well as material variations and colours which are not sold at all on our market. In other words, it is difficult to get exporters to Sweden to switch to national requirements as Sweden is a small market. As there are phthalate-free plasticisers available on the market, there are no major problems in terms of them meeting the requirement to be phthalate-free.

Costs and barriers

Going ahead with particular requirements which entail necessary product development incurs costs, at least in the initial phase. It is important that the party imposing the requirements is aware of this and contributes to development. The contracting authorities have considerable responsibility in setting requirements and in monitoring that products are selected to facilitate the phasing out of hazardous properties as quickly as possible. Unfortunately, one factor slowing this process down is a deep-rooted perception that green products will be far more expensive. In certain cases, previous experiences of inferior products being marketed at a high price under the eco-label have damaged confidence in a way which requires time to be restored.

There are currently no clear descriptions of the differences in terms of cost between selecting green products and selecting traditional products without any particular requirements being specified. Comparisons have been made indicating increases amounting to a very small percentage of the overall project cost[261].

Flooring industry

If specific Swedish requirements were introduced, some operators reckon that it would be more difficult to switch to national requirements as production is geared towards global sales. Other operators are not affected at all as they have already adjusted. In cost terms, it may mean that the product will be 5-10% more expensive as the raw materials are more expensive. Switching part of production to a separate market would incur investment costs in facilities, higher production costs and increased storage costs.

In general, there is strong impetus for substitution in the environmental assessment systems which are commonly used in the construction sector. This is an absolute requirement in many projects.

The automotive industry

All components in the automotive industry must be rigorously tested to meet tough conditions.

[261] Feedback from Swedish Construction Federation based on questionnaire, 07.10.2014

Product development cycle

The product development cycle for both heavy and light vehicles is around 5 years. Development work involves carrying out a large number of tests on materials' properties, which need to meet the functional requirements which have been specified. This is followed by verification in many harsh environments. There are also statutory requirements stipulating that vehicle manufacturers need to provide spare parts long after the product has stopped being manufactured. In the best case scenario, transition can take place quickly and smoothly if switching material is desirable. If switching material definitely has no impact on performance and the material suppliers have already done the development work, the switch can be carried out quickly. A manufacturer of heavy vehicles replied that it still takes at least 2 years, even with a small modification. In the worst case scenario, switching is not even viable in terms of performance requirements and safety. In other words, in the extreme case, it may transpire at the end of the 5-year product development cycle that none of the performance requirements can be met, forcing the manufacturer to go back to the old material. Vehicle manufacturers are not actually always experts on materials. On many occasions, the vehicle manufacturer is reliant upon the plastics manufacturer not making a substitution which entails serious consequences.

Environmental requirements

Procedures for monitoring and communicating requirements specifications are well established. Apart from functional requirements featuring in the requirements specification, there is also the IMDS (International Material Data System) and GADSL (Global Automotive Declarable Substance List). The supplier enters the material's constituent substances in the IMDS reporting system. GADSL is a "blacklist" containing substances which either need to be declared or are restricted as agreed globally by the automotive industry. If such a substance is entered in the IMDS, it will be flagged there.

In the case of bus and truck manufacturers, there is very often a special process used for monitoring and ensuring that the supplier meets the basic requirements stipulated for being approved as a supplier. Bus and truck manufacturers develop their products for a global market and, therefore, apply uniform requirements and standards. This means for hazardous substances that there are black and grey lists which are combined with GADSL to help with substitution.

IMDS is used to ensure requirements are fulfilled. It usually provides information on the product's entire composition. This makes it considerably easier to identify where hazardous substances like phthalates can be found in components.

Phthalates have also been handled separately where all suppliers to truck and bus manufacturers have been requested via a circular to substitute and report changes in substance compositions in components.

The automotive industry does not oppose tighter statutory requirements in any area. On the other hand, difficulties arise with there being widely varying requirements between different continents and countries. The automotive industry is actively involved in trying to make requirements as globally harmonised as possible. Therefore, it is unfortunate if new national requirements are introduced. Vehicle manufacturers produce "global products" and should therefore agree on global requirements. National regulations can drive suppliers and their production abroad.

Costs and barriers

The cost of making a substitution can vary from almost nothing to a huge amount (if a switch is made to a new material which seems to have quality issues). As phthalates are fairly easy to substitute, this has already been done in many cases. The interpretation of the information requirement according to Article 33 of REACH and the authorisation requirement have jointly contributed to measures resulting in substitution.

As has already been described, huge costs may also be involved in substituting substances other than phthalates. When a substitution is made, it is often the cost of different tests which is expensive rather than the material cost itself.

In the case of private cars, there are no direct customer requirements to substitute phthalates. On the other hand, there are technical requirements which make substitution difficult in a number of cases.

Purchasers of trucks and buses are generally regarded as being well-versed in environmental issues, with companies themselves often having their own green policies. The environment is an important "core value" in certain respects. So, for instance, manufacturers of heavy vehicles are asked questions about substitution during the procurement process.

Requirements under REACH encourage substitution, but technical requirements may delay it happening.

Electronics industry

This is a global, complex industry with numerous subcontractors and products.

Product development cycle

Replacing or removing a substance should be examined carefully to ensure that a sufficient level of reliability, safety, performance and sustainability is retained.

The length of time required to substitute chemicals in articles varies according to the product category: around 18 months to 2 years for computers or smaller printers; 2-3 years for larger printers, 3-6 years for servers and digital printing systems. Most companies replied that the transition period is roughly 2-3 years, but this obviously depends on the complexity of the product, which means that it may take many more years than this in some cases.

Environmental requirements

The contacts made while compiling the report have shown that there is a huge number of companies in this industry and they have made varying degrees of progress in their efforts relating to material and chemical issues. According to one major electronics firm, there are generally no complete substance and material declarations for products at the moment. The IT- sector and basically all the other sectors regulate material and substance restrictions by means of control documents containing requirements regarding what the products cannot contain, i.e. blacklists. Each company then has different systems for checking that requirements are met. However, this process does not include any obligation to report which substances are used as alternatives to the materials and chemicals which are not permitted. These control documents vary greatly between companies. One company states that their suppliers must provide an assurance that the products are free of substances in the candidate list and, if this is not possible, information is requested about the type of substance and its concentration.

Many companies are actively conducting a dialogue with their suppliers on phasing out phthalates, with the majority of products on sale nowadays not containing phthalates. One company responded that they already decided voluntarily to phase out DEHP, DBP and BBP in new PCs from 2013 and in all other products from 2016.

There are several different projects going on in the US, such as Green Screen™ where alternatives can be assessed. There is a non-profit organisation, BIZ, which is focused on producing safer alternatives. The alternatives likely to be used most are DINCH and DEHT, which are also the most analysed alternatives.

The electronics industry does not object to more stringent chemical requirements, but they need to be at EU level. National regulations are not viable as the electronics industry is a global market. The electronics industry is not opposed to current proposals on regulating four phthalates under the RoHS Directive, but it feels that this is completely feasible only if there is a sufficiently long transition period and also the opportunity to apply for exemptions. On the other hand, if the ban was to be extended further to include phthalates as a "group", it would be extremely tough to come up with appropriate alternatives at current costs.

With regard to the information requirement under REACH, there are few customers at the moment requesting this information and it is also difficult to obtain this information outside the EU. The companies which receive queries think that providing this information is a time-consuming task.

Costs and barriers

The incentive to carry out substitution varies for different companies. The four biggest drivers are regulations, voluntary organisations, customer queries and public procurement.

Since 2012 there have been requirements specified for phthalates as part of certain eco-labelling procedures, such as the EU flower and German blue angel (substances in the candidate list) and the Nordic swan (phthalate-free power supply cables). TCO development is at the forefront when it comes to phasing out phthalates. Obviously, new statutory requirements provide strong impetus for substitution. In some cases, the customer's specification can provide the impetus for substitution.

There is great competition between companies on these issues. Those who are at the forefront of this can win market shares. However, the increase in costs is the main obstacle to substitution. This is particularly noticeable when competitors have not substituted hazardous substances in the same way, thereby enabling some companies to gain a competitive advantage as a lower price is assigned to a similar product. Making mistakes can also cost a great deal, which makes it worth to stopand think first.

It can also be difficult to gain support internally for voluntary substitution as it usually costs more.

It is paramount that when new regulations come into force that standardised metrics are available to prove that the requirement is being met.

Medical device sector[262]

Product development cycle

The product development cycle varies a great deal depending on the complexity and type of product. Medical devices span every technical area. It is estimated that there are around half a million medical devices in Sweden. The Medical Device Directive and suitable standards set out guidelines on how the work in this area should be carried out. This also means that there is a considerable variation in the product development cycle between product groups and that external organisations are frequently brought in to verify that the work has been carried out and documented properly.

In terms of transition time, it depends completely on the relevant product. There are some less complicated products which require a shorter period of time, but more complicated products take longer, which means that it is difficult to specify an exact time.

It generally takes 7-10 years, but it may take longer with the new Medical Device Directive, which has proposed that clinical studies should be carried out.

Costs and barriers

To enable a medical device to be sold on the European market, it must be CE-marked in accordance with the legislation. This factor must be taken into account when contacting subcontractors.

The profession guarantees what is best for the patient when it comes to product requirements. Many companies are actively involved in substituting substances which may be harmful, but it is not always the case that there are substitutions and the patient's needs must take priority. One example is urological material. Some products made from urological material are suitable for treating a condition where patients are unable to empty their bladder. A doctor's prescription provides the basis for using these products. It is important that patients follow the prescription to avoid any damage to their bladder and kidneys. The key aspect with the articles used is that they are safe to use over a long period of time. In some cases, for the rest of the person's life.

Any development of new products is carried out nowadays taking into account that substances regarded as being dangerous for humans and the environment should not be used. However, there are still products containing PVC and phthalates which still have not been phased out yet, as there are no satisfactory alternatives available which are PVC- and phthalate-free.

Procurement requirements aimed at phasing out substances must be specified, bearing in mind that they do not pose any risk to patient safety. There are several examples of procurement processes in Sweden where requirements for PVC- and phthalate-free products have resulted in a shortage of products for providing relevant care.

Consideration must be given to the specific area of use for each product/product group prior to setting such requirements.

For our own part, around 20% of our products contain PVC and phthalates within the products areas described in the material, while all new products being launched are phthalate- and PVC-free.

[262] Feedback from the medical device sector based on questionnaire, 13.10.2014

It can be stated in general that the procurement processes in Sweden which set requirements for products exceeding legislative requirements make it more difficult for companies in Sweden, which are often part of a global company selling products worldwide. This makes it difficult to gain support for modifications exceeding legislative requirements as Sweden is such a small market.

The best way to promote the process is if country councils attempt to make efforts to amend the legislation at European level.

There are different sources providing alternatives which can be used. For instance, the National Substitution Group, under the guidance of the Swedish Environmental Management Council, carried out an assignment showing that the alternatives highlighted in the Danish report on the use of alternatives in medical equipment can be used.

Clothing, textiles, footwear and accessories

Product development cycle, transition time

These vary for different products. There are several different stages in the process of creating a new product. This can take anything between 6 months and two years in total. The following example explains what can happen in the process. The actual product development phase lasts roughly 1 of the 6 months. Companies send a drawing and list of dimensions for the product, requesting a quoted price and a prototype using the correct material. The supplier selects materials based on the specification in terms of design, quality and chemical content requirements. The companies imposing more stringent chemical requirements than many others in the industry occasionally have problems with high minimum quantities, which they handle by making several products using the same material.

If a new requirements specification needs to be drawn up, this can take several months to a year, depending on how difficult it is to find new materials, suppliers or how easily accessible alternatives are. With regard to PVC and phthalates, this could go on for around 6 months in the case of common products where several other operators already have the same requirements and are purchasing similar products not containing PVC or phthalates.

Environmental requirements

Based on responses to the questionnaire from industry associations and some major companies in the textile and footwear industries, the following picture emerged. The task of substituting phthalates and PVC is being carried out in the same way in the textiles and footwear industries. Several major textile and footwear companies in Sweden use ban or restriction lists featuring chemicals, including a number of phthalates. Some companies have even imposed a blanket ban on PVC for their product range. One company replied that they had a PVC ban, except for plastic mats which have been manufactured in Europe. Another company also has a PVC ban in place, but with an exemption for soft plastic reflectors used as an accessory in the children's ward. The decision to purchase reflectors, even though they are made of PVC, was adopted as their function is to save lives.

The number of phthalates featuring on companies' blacklists varies between 7 and 16. Apart from the 13 phthalates in the candidate list, some companies have also included the high molecular weight phthalates DINP, DIDP, DNOP and DCHP in their restriction lists. In one case, the restrictions applied to all ortho-phthalic acid esters. The ban can take the form of a total ban or up to 0.1%.

During the procurement of products and articles, many companies request that the substances in their lists do not feature in the finished article. In some cases, a limit is specified for the highest permissible concentration (0.1%). In some instances, companies may get involved in developing the actual material, but this is most often not the case. However, checks are carried out, sometimes based on product and material analyses carried out in third-party laboratories in the manufacturing countries and sometimes based on analyses carried out in Sweden. One company responded that their production office has a burner and they carry out the Beilstein flame test on plastic components and products to examine whether the material is PVC.

Several companies are also working on developing coatings and print from materials which are already soft and do not need to be plasticised to obtain desirable properties. In both the textiles and electronics industries there is cooperation in the chemicals sector via Swerea IVF's chemical group. The chemical group helps the 80 member companies to reduce/prevent the occurrence of hazardous substances in products and provides support in meeting the requirements and wishes of consumers and the media.

In order to make an impact in a global market and in Sweden, which is a small country, and to prevent the need to check for and find banned chemicals in production, the same rules need to apply throughout the whole of the EU. If Sweden has national requirements, costs will be higher which, in turn, can result in articles being more expensive, in fewer articles being available or in articles not being able to be sold due to their chemical content. Therefore, national requirements need to have a great deal of information provided and some understanding about them, as well as controls being made.

Costs and barriers

Based on the experience of one company, it can take longer to achieve substitution when purchasing within the EU. It can depend on a number of steps and longer steps being required to access the manufacturer and the company not having direct contact with the manufacturer (which, in most cases, is in China/outside the EU).

The driving force behind this is to sell products which do not pose any risk to the customer's health. This is not actually what companies in the industry are marketing, but the assumption is that customers require products to be safe.

As a company, a great deal can be achieved on a voluntary basis, but substitution should always be benchmarked with costs, competitiveness and the use of human resources in the company (a great deal of time is required to substitute an existing product). It is easier to set requirements for new products. Statutory requirements cannot be discussed but need to be observed. Phasing out substances in the candidate list and SIN list is nevertheless a voluntary process. If a substance needs to be substituted, proof is required to show that the substance is hazardous.

If the article deteriorates as a result of a substance or function having been substituted, customers can approach other suppliers. It is a major obstacle if there is no good substitute available on the market and customers are used to a certain performance level.

It is mainly interest groups, the media and authorities which encourage substitution. It is extremely rare for customers to ask about chemical content, but it does happen.

Appendix 8: Health-related costs

The diagnoses below are considered relevant based on potential links to substances which are endocrine-disrupting and toxic for reproduction.

Autism

According to rightdiagnosis.com, there are around 18,000 people diagnosed in Sweden with autism, and a figure of 960,000 in the EU. However, these figures are extrapolated[263]. Roughly 0.67% of all newborns are born with some form of autism[264]. This means that around 35,000 babies are born every year with a diagnosis of autism, with the number in Sweden at almost 800.

For the socio-economic costs of an autism diagnosis, the UK study *"The Economic consequences of autism in the UK",* produced by the Centre for the Economics of Mental Health at Kings College, London, has been used.

This study classifies people with autism as having mild or severe autism, with roughly 45% and 55% respectively being born with high- and low-functioning autism. This entails different types of costs already from childhood. At a simplified level, all children live at home, regardless of the degree of autism they have. The costs will be higher for a child with severe autism compared with a child with mild autism, the older the child gets. The indirect cost, for instance, highlights this as the annual cost of staying at home with a child with severe autism amounts to a month's salary in Sweden. The fact that these costs are not incurred between the time of birth and the age of 3 is because, in this case, the child is so young that it still requires care from its parents to function in society.

Table 1: Annual costs for a child with autism (ASD) split into direct and indirect costs, indicating how the costs differ between mild autism and severe autism, given in euro

Direct costs	**Severe ASD**	**Mild ASD**
0-3 years old	900	1,800
4-11 years old	36,000	32,000
12-17 years old	55,000	32,000
Indirect costs		
Cost of time lost at work, age 4-17	EUR 3,100	300

All the above costs are taken from the UK study and scaled up to 2013 levels. Information has also been collected from the UK study about the living arrangements of those affected.

Table 2: Breakdown of living arrangements for people with autism (ASD) in the UK

Percentage of adults with ASD in different living arrangements	**Severe ASD**	**Mild ASD**
Percentage living in private household	35%	79%
Percentage living with support persons	7%	5%
Percentage living in sheltered accommodation	52%	16%
Percentage in hospital	6%	

[263] Right Diagnosis, Statistics by country for autism. Available. 19.11.2014. http://www.rightdiagnosis.com/a/autism/stats-country.htm

[264] Autism & Asperger Association, Hur vanligt är autism (How common is autism)? Available: 17.06.2014. http://www.autism.se/district_content.asp?nodeid=33592

Based on the details provided about living arrangements, the cost details can now be added. It is worth mentioning that an autistic person living in a private household will always cost the least compared with the cost of living in any kind of institution, regardless of whether the person has severe or mild autism. From an overall perspective, people with mild autism will always cost society less money.

Table 3: Annual costs for adults with autism in euro

Direct costs	**Severe ASD**	**Mild ASD**
Living in private household	21,000	20,000
Living with support persons	99,000	98,000
Sheltered accommodation	101,000	102,000
Hospital	115,000	
Indirect costs		
Lost annual income	34,000	30,000

A person with autism is expected to have a normal life expectancy, which means that the costs will be discounted at the age of 80, which is the average life expectancy for men and women born nowadays in the EU. The socio-economic costs spread over 80 years will then be EUR 1.5 million for a person with mild autism and EUR 2.5 million for a person with severe autism.

Deformity of sexual organs in newborn boys

Hypospadias and cryptotorchidism are congenital deformities. Both conditions can be remedied by visiting a doctor. Cryptotorchidism means that the child has at least one undescended testicle. The percentage of boys affected by cryptotorchidism in Sweden is around 600 a year and around 26,000 boys in the EU. The treatment involves a couple of days' medical treatment during the child's first year. Each intervention is estimated as costing around EUR 4,400 in direct care costs, plus EUR 1,100 in indirect costs, such as childcare.

Hypospadias is a deformity of the urethra occurring in both men and women, where the urinary hole (opening or male external urethral orifice) is abnormally placed. Instead of opening at the tip of the glans of the penis, a hypospadic urethra opens anywhere along a line (the urethral groove) running from the tip along the underside of the penis to the scrotum. The treatment for hypospadias entails both surgery and follow-up medical examinations several years apart. The cost for treating hypospadias is estimated at around EUR 9,000[265].

Asthma

According to the European Lung Foundation (ELF) and the European Respiratory Society (ERS) report *"Lung health in Europe: Facts and figures",* the direct costs of asthma per year are around EUR 19.5 billion, along with EUR 14.4 billion in indirect costs[266]. Based on data from the OECD in 2008 for the percentage of cases among the population in 17 EU Member States[267], we have estimated that around 14.6 million people have asthma. We have

[265] Nordic Council, 2014, Cost of inaction - A Socioeconomic analysis of health related costs linked to endocrine disrupting substances on male reproductive health, TemaNord 2014:557

[266] European Lung Foundation, 2013, "Lung health in Europe: Facts and figures".

[267] OECD, Health at a glance: Europe 2012, Asthma and COPD prevalence, Self-reported asthma 2008. Available: 28.10.2014. http://www.oecd-ilibrary.org/sites/9789264183896-en/01/16/index.html?itemId=/content/chapter/9789264183896-19-en

extrapolated this figure to EU28 level and have come up with, based on the calculations, a figure of around 22 million people with asthma.

Based on the number of cases in the EU, we have estimated that the cost care per person is around EUR 900, while the indirect cost and lost working time etc. cost around EUR 600 per year. According to studies carried out, with the right care being provided, asthma does not entail any change to anticipated life expectancy[268].

Given that we are estimating these costs for a whole lifetime, i.e. 80 years and then discount them, we come up with EUR 27,000 in direct costs and EUR 20,000 in indirect costs.

Summary

Table 4: Costs per case, discounted over the whole course of illness

Medical condition	Cost per case in EUR	Cost per case in SEK
Asthma	47,000	440,000
Mild autism	1,500,000	14,000,000
Severe autism	2,300,000	21,000,000
Hypospadias	9,000	80,000
Cryptotorchidism	4,500	40,000

The total amount of the costs, discounted from the time of the illness's diagnosis onwards, depends on whether the illness is curable or not.

[268] Greenberg M, Glick M, 2003. Burket's Oral Medicine: Diagnosis and Treatment 10th edition, page 354,

Appendix 9: Article guide, groups of articles containing plasticised PVC

An extract is provided below from the Swedish Varuguiden (Article guide), containing the production, commercial and consumer data which the impact assessment is based on. This data is from 2007, apart from for the groups "PVC floor, wall and ceiling coverings" and "Coated non-woven coverings", where it is taken from 2001. The reason for this is that the export volumes in 2007 were large, which generated high negative consumption figures. This is explained by the storage system, with 2007 being a year when large volumes were sold from warehouses, which meant that exports exceeded consumption. This is why the figures for 2001 have been used, so as to avoid these figures. In both 2001 and 2007 the volume for production + export will be around 90,000 tonnes for floor, wall and ceiling coverings. The production volume for coated non-woven covering was higher in 2001 than in 2007.

The market segment indicated in the left column of the table is the way in which the articles have been sorted for this report, so that we can sort various articles into what we consider as being a more general market segment. It should be noted on this point that the category for cables and wires has been split into three sections of arbitrary size, which have been placed in the construction products, electronic products and automotive categories.

Table 1: Article guide, groups of articles containing plasticised PVC

Market segment	Article group	Percentage of plasticised PVC	Import, tonne/year	Product, tonne/year	Export, tonne/year	Consumption, tonne/year
Automotive	Buses	0.50%	42	166	81	127
Automotive	Combustion engine generating set	4%	70	53	31	92
Automotive	Crane lorries, firefighting vehicles and other special-purpose vehicles	1%	35	26	32	29
Automotive	Diesel-electric trains	2%	0	0	3	-3
Automotive	Electric vehicles	1%	14	0	15	-1
Automotive	Excavators	0.50%	188	37	6	219
Automotive	Fuel pumps	2%	109	105	86	128
Automotive	Insulated wires and cables	51%	14,297	43,540	22,118	35,719
Automotive	Lorries and vans	1%	1,408	4,066	642	4,832
Automotive	Military vehicles	0.50%	0	0	0	0
Automotive	Non-motorised train coaches	1%	6	0	0	6
Automotive	Private cars and estate cars under 3,500 kg	1%	7,025	8,629	8,117	7,537
Automotive	Road-rollers etc.	0.50%	7	185	191	1
Automotive	Self-propelled bulldozers	0.50%	11	0	8	3
Automotive	Self-propelled loaders	0.50%	71	0	0	71
Automotive	Self-propelled railway or tramway coaches	3%	137	0	0	137
Automotive	Spark-ignition engines	2%	1,508	1,051	777	1,782
Automotive	Tankers	1%	184	1,844	734	1,294
Automotive	Tractors etc.	0.50%	161	217	684	-306
Automotive	Trucks	1%	540	944	1,265	219
Automotive	Vehicle fittings	0.50%	82	47	36	93

Market segment	Article group	Percentage of plasticised PVC	Import, tonne/year	Product, tonne/year	Export, tonne/year	Consumption, tonne/year
Automotive	Work and service wagons	1%	2	0	4	-2
Bags	Plastic and textile sleeves, bags etc.	8%	300	0	34	266
Bags	Plastic bags, cases, rucksacks etc.	59%	914	55	233	736
Bags	Plastic sleeves, bags, travel bags etc.	51%	1,677	0	314	1,363
Bags	Textile bags, rucksacks etc.	12%	612	0	130	482
Clothing	Clasps, loops, buckles etc.	1%	11	0	17	-6
Clothing	Clothing and plastic clothing accessories	39%	2,619	42	560	2,101
Clothing	Clothing made using coated textiles	16%	679	0	169	510
Clothing	Cotton stockinette baby clothing	2%	35	0	5	30
Clothing	Other men’s workwear	5%	52	5	20	37
Construction products	Boilers	0.50%	37	32	39	30
Construction products	Coated iron and steel cables, mesh etc.	2%	1,260	450	273	1,437
Construction products	Coated non-woven coverings	24%	4,208	11,443	6,888	8,763
Construction products	Electric radiators etc.	0.50%	36	34	24	46
Construction products	Electric water heaters and immersion heaters	1%	36	14	13	37
Construction products	Fire hoses and other hoses	2%	1	0	2	-1
Construction products	Flexible hoses	4%	57	106	15	148
Construction products	Flexible plastic hoses and pipes	65%	5,661	3,998	4,064	5,595
Construction products	Flexible PVC boards, sheets, film etc.	66%	5,060	10,012	5,949	9,123
Construction products	Insulated boards with two metal walls	1%	161	253	73	341
Construction products	Insulated wires and cables	51%	14,297	43,540	22,118	35,719
Construction products	Irradiation devices	0.50%	0	0	0	0
Construction products	Painted, varnished or plastic-coated iron boards	4%	5,824	3,976	5,422	4,378
Construction products	Plastic foam boards, sheets, film, tape etc.	20%	3,023	8,926	3,800	8,149
Construction products	PVC floor, wall and ceiling coverings	74%	11,937	55,004	38,924	28,017
Construction products	Reinforced flexible plastic pipes and hoses with couplings	77%	2,593	253	680	2,166
Construction products	Rigid PVC boards, sheets, film etc.	15%	0	0	0	0
Construction products	Self-adhesive plastic boards, sheets film etc.	19%	3,528	3,313	707	6,134
Construction products	Spray guns	1%	49	16	32	33
Construction products	Stoves etc. for solid and liquid fuel	2%	456	338	180	614
Construction products	Uncoated non-woven covering	10%	0	0	0	0
Electronic product	Cabinets and boards for controlling electrical equipment	3%	287	267	239	315

Market segment	Article group	Percentage of plasticised PVC	Import, tonne/year	Product, tonne/year	Export, tonne/year	Consumption, tonne/year
Electronic product	Cassette players and similar audio players	3%	20	0	8	12
Electronic product	Electric amplifiers	3%	31	1	10	22
Electronic product	Electric meters	1%	37	39	50	26
Electronic product	Electrical capacitors	2%	46	74	395	-275
Electronic product	Fax machines	1%	8	0	1	7
Electronic product	Insulated wires and cables	51%	14,297	43,540	22,118	35,719
Electronic product	Radio and telephone receivers	3%	226	14	69	171
Electronic product	Speakers	2%	198	29	60	167
Electronic product	Still cameras	3%	7	3	5	5
Electronic product	Telegraph devices	3%	314	2,098	1,187	1,225
Electronic product	Telephones	3%	521	450	905	66
Electronic product	TV and video devices with screen	2%	1,236	8	665	579
Electronic product	TV cameras	3%	74	1	56	19
Electronic product	TV satellite dishes etc.	2%	167	34	147	54
Engines	Compression-ignition engines	1%	433	1,733	1,165	1,001
Foodstuffs	Liver foodstuffs	0.50%	4	58	0	62
Foodstuffs	Non-electric bakery ovens	1%	0	9	9	0
Foodstuffs	Prepared meat and sliced meats	1%	130	307	27	410
Foodstuffs	Preserved fish	2%	420	77	207	290
Foodstuffs	Preserved fish products	1%	23	6	16	13
Foodstuffs	Preserved seafood apart from mussels and molluscs.	0.50%	0	0	0	0
Foodstuffs	Salted meat from mammals	1%	56	133	78	111
Foodstuffs	Sausages	1%	44	11	3	52
Foodstuffs	Smoked meat from mammals	2%	56	552	37	571
Footwear	Clogs	4%	0	0	1	-1
Footwear	Plastic waterproof footwear	73%	183	0	44	139
Footwear	Rubber or plastic sports shoes etc.	14%	1,211	4	136	1,079
Footwear	Textile footwear	4%	83	0	15	68
Furniture	Furniture for clinics	4%	58	120	44	134
Furniture	Furniture made of fibreboard	4%	5,333	9,101	4,696	9,738
Furniture	Metal furniture	5%	5,905	2,918	4,165	4,658
Furniture	Upholstered seats, sofa beds etc.	3%	3,029	1,130	802	3,357
Healthcare articles	Dentist drills	5%	5	1	1	5
Healthcare articles	Electrical diagnostic machines	1%	4	0	2	2
Healthcare articles	Mechano-therapy appliances and massage equipment	3%	128	2	22	108
Healthcare articles	Plastic stoma and urine bags	44%	0	0	0	0
Healthcare articles	X-ray machines etc.	1%	4	3	4	3

Market segment	Article group	Percentage of plasticised PVC	Import, tonne/year	Product, tonne/year	Export, tonne/year	Consumption, tonne/year
Household articles	Air pumps	3%	21	0	8	13
Household articles	Curtains, blinds etc.	0.50%	19	1	5	15
Household articles	Electric irons	3%	26	0	11	15
Household articles	Festive decorations, novelty articles etc.	2%	103	0	28	75
Household articles	Iron and steel household articles	0.50%	65	88	56	97
Household articles	Sewing machines	1%	29	10	32	7
Household articles	Shavers and haircutting appliances	1%	16	0	6	10
Household articles	Tarpaulins and awnings	49%	460	6	75	391
Household articles	Tumble-driers	1%	138	69	111	96
Household articles	Vacuum cleaners	8%	1,025	152	391	786
Household articles	Washing machines	3%	1,704	487	998	1,193
Household articles	Wooden decorations and boxes	4%	311	46	142	215
Industrial machines	Appliances for heating food	0.50%	0	0	0	0
Industrial machines	Hydraulic and pneumatic machines	1%	130	233	176	187
Industrial machines	Industrial ovens	0.50%	4	3	13	-6
Industrial machines	Machinery for making up paper pulp etc.	1%	91	109	153	47
Industrial machines	Machinery for treating textiles	0.50%	13	0	4	9
Industrial machines	Machines for producing paper and cardboard	2%	107	571	364	314
Industrial machines	Miscellaneous other machines	1%	2,508	3,471	2,525	3,454
Industrial machines	Non-electric industrial ovens	0.50%	4	10	5	9
Industrial machines	Non-electric melting furnaces	0.50%	0	0	1	-1
Industrial machines	Offset machines	1%	19	9	34	-6
Industrial machines	Other machines for handling materials	1%	332	125	284	173
Industrial machines	Other transformers (dry)	0.50%	49	12	11	50
Industrial machines	Printing machines	1%	22	212	62	172
Industrial machines	Transporters	1%	257	637	525	369
Industrial machines	Wind-power generators	1%	32	0	0	32
Industrial machines	Yarn-twisting machinery	2%	0	0	0	0
Kitchen articles	Plastic table and kitchen articles	5%	837	469	570	736
Kitchen utensils	Baking ovens and ovens for biscuits	1%	1	13	3	11

Market segment	Article group	Percentage of plasticised PVC	Import, tonne/year	Product, tonne/year	Export, tonne/year	Consumption, tonne/year
Kitchen utensils	Coffee- or tea-makers	3%	122	0	54	68
Kitchen utensils	Extraction hoods	2%	45	16	26	35
Kitchen utensils	Household cookers and ovens	2%	495	215	243	467
Kitchen utensils	Household microwave ovens	3%	276	463	384	355
Kitchen utensils	Table cloths made of coated textiles	58%	1,706	2,703	2,498	1,911
Kitchen utensils	Toasters	3%	26	0	7	19
Lighting products	Non-plastic light fittings for bulbs	4%	975	140	328	787
Lighting products	Other electrical lighting products	3%	301	119	251	169
Lighting products	Plastic light fittings for bulbs	9%	533	75	226	382
Lighting products	Plastic light fittings, not for bulbs	6%	171	86	38	219
Medicinal products	Medicinal products containing alkaloids, retail packs	3%	5	0	3	2
Medicinal products	Medicinal products with antibiotics	6%	61	219	183	97
Medicinal products	Medicinal products with vitamins, retail packs	6%	80	18	35	63
Medicinal products	Psychoactive drugs in retail packs	5%	0	0	0	0
Office articles	Books and exercise books	0.50%	57	5	25	37
Office articles	Felt-tip pens etc.	3%	24	0	4	20
Office articles	Office and school articles	9%	620	297	344	573
Office articles	Office chairs	0.50%	29	40	27	42
Office articles	Other office machines	1%	264	70	159	175
Office articles	Staples, paper clips etc.	0.50%	6	9	16	-1
Photography equipment	Badges	5%	31	64	20	75
Photography equipment	Photo laboratory equipment	1%	4	4	3	5
Photography equipment	Transfers	23%	17	9	7	19
Sport and leisure	Airbeds	27%	125	0	7	118
Sport and leisure	Golf equipment	9%	142	0	48	94
Sport and leisure	Gymnastics and sports apparatus	2%	10	0	3	7
Sport and leisure	Hunting and fishing equipment	3%	34	4	12	26
Sport and leisure	Play and sports balls	33%	572	0	325	247
Sport and leisure	Skates and rollerskates	8%	107	0	57	50
Sport and leisure	Tents	23%	585	42	71	556
Storage articles	Plastic bags, sacks etc.	2%	936	1,755	625	2,066
Storage articles	Sacks and bags for packaging articles	13%	1273	0	632	641
Textiles	Impregnated needleloom felt	25%	474	25	141	358
Textiles	Other made-up textile articles apart from knitwear and felt	6%	456	0	190	266
Textiles	Textile adhesive tape	2%	17	0	2	15
Tools	Cutting tools with a hard metal cutting blade	3%	105	3,005	93	3,017

Market segment	Article group	Percentage of plasticised PVC	Import, tonne/year	Product, tonne/year	Export, tonne/year	Consumption, tonne/year
Tools	Electric hand tools	1%	132	3	27	108
Tools	Screwdrivers, pliers, files etc.	9%	233	136	119	250
Tools	Sowing machines and manure spreaders	0.50%	7	45	33	19
Toys	Dolls and doll accessories	45%	659	0	126	533
Toys	Games equipment	2%	3	0	1	2
Toys	Materials for party games	2%	120	0	47	73
Toys	Miscellaneous metal toys	3%	16	0	1	15
Toys	Miscellaneous plastic and metal toys	3%	0	0	0	0
Toys	Miscellaneous plastic toys	4%	195	0	22	173
Toys	Paddling pools, play area equipment etc.	3%	401	0	254	147
Toys	Plastic building toys	3%	39	0	11	28
Toys	Plastic toy figures	34%	0	0	0	0
Toys	Toy cars	4%	90	0	30	60
Toys	Toy weapons	8%	35	0	2	33
Toys	Writing and drawing chalks	3%	15	0	3	12

Appendix 10: Calculations for DEHP in the article guide

The results are given below of the calculations we performed in the impact assessment as part of this assignment, sorted according to the market segments used in Appendix 9. To calculate these quantities, we have used the equations described in section 9.3, as well as the assumptions made in Tables 9 and 10 in this chapter. Therefore, the figures for production, imports and exports have been rounded to two significant digits.

It should be remembered that the calculations in this appendix are based on calculations using data from the Swedish Varuguiden (Article guide) from 2007, as well as being based on the assumptions made in section 9.3. Therefore, these figures should be regarded as estimates and not as absolute values.

Table 1: Summary of article guide *calculations per tonne of DEHP in articles in every market segment, at EU level, rounded figures sorted after net usage*

Market segment	**Production**	**Import**	**Export**	**Net**
Construction products	77,000	93,000	50,000	120,000
Automotive	22,000	25,000	11,000	36,000
Electronic products	22,000	25,000	11,000	36,000
Bags	30	5,000	300	4,730
Clothing & textiles	20	4,300	300	4,020
Kitchen articles	1,600	3,600	1,500	3,700
Furniture	500	2,000	400	2,100
Household articles	30	1,300	100	1,230
Sport and leisure	10	1,300	140	1,170
Toys	0	*	-	*
Footwear	1	1,000	50	951
Storage articles	30	600	100	530
Lighting products	20	400	50	370
Tools	100	90	10	180
Office articles	30	200	40	190
Industrial machines	60	100	40	120
Foodstuffs	20	40	10	50
Medicinal products	10	30	10	30
Photography equipment	5	20	5	20
Healthcare articles	0	10	0	10
Total:	**Approx. 124,000**	**Approx. 164,000**	**Approx. 75,000**	**Approx. 212,000**

*Occurs in imported toys in spite of ban

Table 2: Summary of article guide *calculations per tonne of DEHP in articles in every market segment, in Sweden, rounded figures sorted after net usage*

Market segment	**Production**	**Import**	**Export**	**Net**
Construction products	2,500	2,400	1,600	3,300
Automotive	720	640	360	1,000
Electronic products	710	640	360	990
Bags	1	130	10	121
Clothing & textiles	1	110	10	101
Kitchen articles	50	90	50	90
Furniture	20	50	15	55
Household articles	1	30	5	26
Sport and leisure	0	40	5	35
Toys	0	*	-	*
Footwear	0	25	2	23
Storage articles	1	15	5	11
Lighting products	1	10	1	10
Tools	5	2	0	7
Office articles	1	5	1	5
Industrial machines	2	5	2	5
Foodstuffs	1	1	0	2
Medicinal products	1	1	0	2
Photography equipment	0	0	0	0
Healthcare articles	0	0	0	0
Total:	**Approx. 4,000**	**Approx. 4,200**	**Approx. 2,400**	**Approx. 5,800**

*Occurs in imported toys in spite of ban

KEMI
Swedish Chemicals Agency

Box 2, SE-172 13 Sundbyberg
+46 8 519 41 100

Visitors' and delivery address
Esplanaden 3A, Sundbyberg

kemi@kemi.se
www.kemikalieinspektionen.se