Miljøministeriet
Miljøstyrelsen

Phthalate Strategy

Environmental Project No. 1488, 2013

Title:

Phthalate Strategy

Edited by:

The Danish EPA

Published by:

The Danish EPA
Strandgade 29
1401 Copenhagen K, Denmark
www.mst.dk

Year:

2013

ISBN no.

978-87-93026-22-3

Exclusion:

The Danish Environmental Protection Agency (Danish EPA) will, when the opportunity arises, publish reports and news articles regarding research and development projects within the environmental sector, funded by the Danish EPA research appropriation. It should be noted that such publication does not necessarily mean that the document in question expresses the views of the Danish EPA.
However, the publication means that the Danish EPA finds the content of this strategy to be an important contribution to the Danish environment policy debate.

Contents

Preface

Phthalates are a group of chemical substances with the same general structure. Some phthalates have proven to be of concern, but phthalates are different and therefore do not all have the same human and environmental impacts. This strategy has been launched in order to be pro-active regarding the potential risk of substituting phthalates of concern with other phthalates, which could prove to be of concern in the long term and hence address the whole group of phthalates from a horizontal approach. Managing phthalates must be based on comprehensive knowledge about the whole group of substances, so that some phthalates are not merely substituted by other others of equally high concern. This strategy examines generally the phthalates being used in Denmark and the European Union and describes the measures necessary to protect people and the environment against undesirable phthalates.

This national phthalate strategy was prepared by the Danish Ministry of the Environment collaboratively with the Danish Ministry of Health, which has contributed to the strategy with regard to the issue about phthalates in medical devices. The strategy identifies areas which need more knowledge, and in which activities must be launched in the short term as well as the long term to ensure sufficient protection of human beings and the environment.

The English version of the strategy is an unofficial translation.

Summary and conclusion

Objective

The objective of this strategy is to examine the entire group of phthalates to ensure that we manage phthalates on the basis of a horizontal approach, rather than managing phthalates substance by substance.

The aim of this strategy is to identify and manage the phthalates currently being used in Denmark and in the EU. The objective is to procure sufficient knowledge to conduct an evaluation of the phthalates being used as well as to identify whether there is a need for restriction, and if so propose such restriction. This will ensure protection of human beings and the environment against undesirable effects of phthalates.

This strategy gathers the knowledge we have today about the entire group of ortho(o)-phthalate esters (from now on called phthalates) and identifies areas in which we lack knowledge.

What are phthalates?

Phthalates are a family of substances with the same general chemical structure (1,2-benzenedicarboxylic acid), on which there are two carbon chains of different lengths. Many phthalates are documented endocrine disruptors, or are suspected of being endocrine disruptors and to affect the reproduction of human beings and animals. The problem is enhanced by the fact that a number of phthalates have similar modes of action, and that the overall risk therefore could increase when people and the environment are exposed to the different phthalates. Therefore, it is necessary to take into account the possible combination effects as a result of exposure to other phthalates and other substances.

Phthalates are primarily used to soften polyvinyl chloride (PVC). The substances can be released during production and when products are used, so both people and the environment can be exposed to the substances.

Status and ongoing activities

Current legislation of phthalates

EU legislation as well as Danish legislation has been laid down for phthalates, and this limits or in some other way affects the use of phthalates in Denmark:

- Classification: Twelve phthalates have EU-harmonised classification (of which 11 have been classified as toxic to reproduction), and additionally a number of phthalates have been self-classified by the industry.
- Authorisation List: Seven phthalates have been included in the EU Candidate List of Substances of Very High Concern, and four of these have been included in the EU Authorisation List with a deadline to apply for authorisation for continued use of 21 August 2013.
- Restrictions: At EU level, there are concentration limits for the use of six phthalates (DEHP, DBP, BBP, DINP, DIDP and DNOP) in toys and childcare articles. Moreover, four phthalates (DEHP, DBP, BBP and DIBP) have been banned in Denmark in products in concentrations higher than 0.1% in a wide range of consumer articles from December 2015, and all phthalates have been banned in Denmark in toys and childcare articles for children aged 0-3 years in concentrations higher than 0.05%.

Ongoing Danish activities

A survey of certain phthalates will be performed as part of the ongoing survey of substances included in the Danish EPA List of undesirable substances (LOUS). The objective is to evaluate use, quantities and knowledge available about the environmental and health impacts of the substances. However, since November 2012, four of the five phthalates in LOUS have been subject to Denmark's national ban on phthalates, and therefore further surveys are not necessary. Instead of the four phthalates covered by the national ban, other phthalates about which we lack knowledge, will be reviewed. These phthalates have been selected because they are used in large quantities, are included in the EU list of potential endocrine disruptors[1], or have a harmonised EU classification. The objective of the review is primarily to evaluate risks in using the substances, and where appropriate prepare strategies to manage these risks. However, needs for further knowledge may also be identified.

New activities

Focus on registered phthalates pursuant to the REACH Regulation

According to the REACH Regulation, industry must register all substances that are either produced in or imported into the EU in quantities of more than or equal to one tonne per year. So far 23 different phthalates have been registered, and at least three more phthalates are expected to become registered in the years to come. Registrations by industry must contain information available on the hazards the phthalates pose to human health and the environment, information on quantities produced and imported as well as if necessary documentation for safe production and use.

The Danish EPA will focus particularly on these phthalates, as these are the substances actually being used to produce products in the EU. In addition to this, there may be other phthalates in products imported to the EU.

Of these 26 registered phthalates, special attention will be given to the phthalates that are considered the most harmful with regard to their endocrine disrupting effects. This could include phthalates which are classified as toxic to reproduction or which are suspected of having endocrine disrupting effects. In this context, a screening will also be carried out of the environmental effects of the registered phthalates. However, focus will not be on the four phthalates which have been banned in many products in Denmark, as these have already been thoruoghly described elsewhere unless there will be a need.

Screening of phthalates for endocrine disrupting effects

Common EU criteria for endocrine disruptors are currently under development, and these criteria are expected to be available by the end of 2013.

In 2013, the Danish EPA will initiate a screening of information available on the endocrine disrupting effects of phthalates which have been registered, with the exception of phthalates which have already been classified as toxic to reproduction, as these are expected to meet the future EU criteria for identification as endocrine disruptors. Consequently, a screening will be carried out for 20 phthalates, as six of the registered or pre-registered phthalates have been classified as toxic to reproduction. The onward process will then be decided, as substances may be nominated for substance evaluation under the REACH Regulation in order to procure further documentation, or a proposal for EU legislation (harmonised classification (in case the evaluation concludes the effects meet the classification criteria for e.g. reprotoxicity), inclusion in the Candidate List, restrictions) may be prepared.

[1] The list is a priority list of substances for further evaluation of potential endocrine effects. The list is converted into a database

Substance evaluation under REACH

Substance evaluations can be initiated under REACH, if there is reason to believe that a substance poses a risk to human health or the environment. Substance evaluations are conducted by the individual Member States.

Seven of the phthalates registered in the EU have already been selected for substance evaluation. In 2014-2015, Denmark will be responsible for five of the evaluations. If results show that there is insufficient data to evaluate whether the use of the substance poses a risk to human health or the environment, further data will be required from industry. Completion of substance evaluations will provide an overview of available knowledge and effects of the selected phthalates.

It is possible to nominate further phthalates for substance evaluation, if deemed necessary.

Harmonised classification

Phthalates that have endocrine disrupting effects and/or are toxic to reproduction, but do not have a harmonised classification must be assessed to determine whether they meet the criteria for classification. In this connection, it should be examined whether industry has self-classified the substances and whether it has done so uniformly and satifactory. If not, it will be evaluated whether or not proposals for harmonised classification are to be prepared.

For example, recent studies indicate that DINP has endocrine disrupting effects at high doses. In 2013, Denmark will assess whether the evidence of endocrine disrupting effects provides a basis for a harmonised classification or other measures, and, if so, start the work to this end.

Nomination of substances to the Candidate List

Chemical substances that have properties of very high concern, and the use of which should ultimately be phased out, can be proposed for inclusion in the REACH Candidate List of substances which can be prioritised for inclusion in the REACH Authorisation List. Substances that are included in the Authorisation List may only be used in future after authorisation has been granted for specific uses.

The Danish EPA will make an assessment of the phthalates which meet the requirements for inclusion in the Candidate List (i.e. in particular phthalates which are endocrine disrupting and/or toxic to reproduction) and, on this background, possibly propose additional phthalates for inclusion in the Candidate List.

Restrictions

If an assessment leads to the conclusion that the use of a certain substance poses a risk to human health or the environment, restrictions will be introduced on the manufacture, placing on the market or use of the substance. As mentioned above, restrictions have already been introduced for a number of phthalates in Denmark as well as at EU level. For other phthalates assessed to have endocrine disrupting effects and/or are toxic to reproduction, the Danish EPA will make a more detailed review in order to assess the need for further restrictions. In this context, possible combination effects associated with simultaneous exposure to several phthalates with the same mode of action will be taken into account.

Specifically with regard to phthalates in medical devices, the Danish Ministry of Health will closely monitor the work by the expert committee; the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in relation to the use of the phthalate DEHP. The Ministry will also encourage knowledge sharing with relevant players in Denmark as well as with other EU countries and the European Commission on possibilities and barriers for use of phthalate-free medical devices. Assessing the need to introduce restrictions in the use of phthalates in medical

devices therefore requires a solid decision base in the form of more knowledge and documentation in this area.

Breaking down barriers for substitution

If phthalates pose a risk and/or have been identified as substances of very high concern and therefore are to be substituted by other substances or materials, it is essential that other suitable alternatives exist. A number of alternatives have been placed on the market today, but different barriers may hinder or limit their use. Focus should therefore be on barriers for substitution of the most problematic phthalates and how to break down these barriers. Guidance on how importers and distributors can purchase products without the most problematic phthalates should also be developed. Focus must remain on collecting and disseminating knowledge about alternative substances and materials.

Green public procurement

The total public procurement volume is 290 billion DKK. This could be a factor to create a demand, and thus a larger market for products, without phthalates. The Ministry of the Environment works with different activities to focus on green procurement. This is among others through Partnership for Public Green Procurement, Forum for Sustainable Procurement and within EU, where there are ongoing work with the development of criteria for green public procurement.

The Danish EPA would like to investigate the possibilities to – on a voluntary basis - reduce and phase out phthalates in the public demand for products and services by initiating an analysis of where and how phthalates in the public procurement can be reduced and if possible be phased out. The analysis shall show the direction for the future work with public procurement of products without phthalates.

Close collaboration and dialogue with stakeholders

Ongoing dialogue with stakeholders is vital for all activities. This applies to stakeholders from industry, sector organisations, NGOs and other authorities. Stakeholders can contribute valuable knowledge about the phthalates and their alternatives, and the different parties can work together on phasing-out phthalates as well as other initiatives. Stakeholders should therefore be consulted in connection with new initiatives and stakeholders will be invited to participate in advisory groups. Regular meetings with stakeholders will be held to report on the status and exchange information and views. Stakeholders will be invited to a status meeting in 2014.

The possibility to engage in partnerships with different stakeholders must be further examined. For example, this may regard collection and dissemination of knowledge about the use of alternatives or other areas.

An example of close collaboration is the medical devices working group (*arbejdsgruppen om medicinsk udstyr*) set up by the Danish Health and Medicines Authority with participants from Danish Patients, the Danish Consumer Council, the Secretariat for the Organisation of Danish Medical Societies, Medicoindustrien (medical devices industry association), Danish Regions, Local Government Denmark and the Danish EPA. The working group is to propose and collaborate on specific initiatives to reduce the use of phthalates in medical devices. The working group will be replaced by the broader Standing Committee on Medical Devices chaired by the Danish Health and Medicines Authority.

With regard to medical devices, it is vital that the EU pushes to include phthalates on the agenda during the negotiations on new rules for medical devices. The EU must also work to reduce phthalates in medical devices, and if there are safe and effective alternatives, to phase out phthalates in medical devices.

Summary and status

In mid-2015, the Danish EPA will prepare a status report on the work on phthalates. By then, the work on preparing strategies for the LOUS substances will have been completed and substance evaluation of a number of phthalates will be at such an advanced stage that Denmark will have assessed whether there is reason for concern, or whether new studies are required. In connection with this status report, possible combination effects of the phthalates which have been identified will be taken into account.

Table of activities

		2013	2014	2015
LOUS	6 phthalates	Preparation of strategies	Implementation of strategy	
Substance evaluation under REACH	7 phthalates, of which DK is responsible for 5		X	March - DK submits nomination - expected EU opinion end of 2015
Evaluation of REACH registrations			X	X
EU criteria for endocrine disruptors		Expected to be available in late 2013	DK follow-up work on the new criteria in relation to specific phthalates	
Proposal for EU legislation, harmonised classification	Where relevant, proposal for e.g. harmonised classification or inclusion in the REACH Candidate List	X	X	
Green public procurement – analysis of product categories and use of phthalates		X		
Close contact with stakeholders, e.g. working group on medical devices	Regular involvement	X	X	X
Status of work				Mid/late 2015

Abbreviations

BBP: Benzyl butyl phthalate
CLP: EU classification rules (CLP Regulation)
CMR: Carcinogenic substances (C), mutagenic substances (M) and substances that are toxic to reproduction (R)
DAP: Diallyl phthalate
DBP: Dibutyl phthalate
DCHP: Dicyclohexyl phthalate
DEHP: Di(2-ethylhexyl)phthalate
DEP: Diethyl phthalate
DIBP: Diisobutyl phthalate
DIDP: Diisodecyl phthalate
DIHP: Diisohexyl phthalate
DINP: Diisononyl phthalate
DIPP: Diisopentyl phthalate
DITP: Diisotridecyl phthalate
DIUP: Diundecyl phthalate, branched and linear
DMEP: Di(2-methoxyethyl)phthalate
DMP: Dimethyl phthalate
DNHP: Di-n-hexyl phthalate
DNOP: Di-n-octyl phthalate
DPHP: Bis(2-propylheptyl)phthalate
DTDP: 1,2-benzendicarboxyl acid, di-C11-14-branched alkyl ester, C13-rich
DUP: Diundecyl phthalate
ECHA: The European Chemicals Agency
LOUS: List of Undesirable Substances
MEHP: Mono-(2-ethylhexyl)phthalate
PBT: Persistant, Bioaccumulative and Toxic
vPvB: very Persistant, very Bioaccumalative
RAC: The Committee for Risk Assessment under the European Chemicals Agency
RMO: Risk Management Options

Introduction

This strategy aims to review and summerise the knowledge we have today about the entire family of phthalates (in this strategy phthalates are defined as ortho(o)-phthalate esters), and to identify areas where we lack knowledge. Furthermore, this strategy helps to identify whether there are areas where we currently have sufficient knowledge to propose further regulation or in some other way limit possible risks.

The term phthalates covers a family of chemical substances that are primarily used as plasticisers in PVC plastics. In 1999, the Danish EPA published an action plan to reduce and phase out the use of phthalates in soft plastic materials. The action plan was prepared, because there were already several studies at that time that showed that some phthalates had harmful effects on the environment and human health. Other countries also had their eye on phthalates, and in 1999 several EU countries introduced a ban against some phthalates in certain types of toys and childcare articles intended for children below 3 years of age.

In 2003, the action plan was followed by a status report on phthalates, describing regulation, classification, status of EU risk assessments and consumer trends. The status report also described that Denmark should follow EU risk assessments and consider a national ban, if the risk assessments were not completed by 2004. Furthermore, the Danish Ministry of the Environment should continue to inform Danish enterprises about alternatives to phthalates. Finally the Ministry was also to provide information about these substances for procurement officers and the retail sector. Since then, there has been great focus on the use of phthalates in consumer products. This is due to the fact that more documentation about the adverse health effects of some phthalates was now available, and that analyses of air and dust from private homes showed that consumers were exposed to inhaling phthalates from the air and not only through direct contact with products containing phthalates[2].

Current population studies from Denmark show that four in ten young Danish men have such poor sperm quality that it is likely they will take longer to impregnate their partner than the average male, or in the worst case, they will not be able to have children naturally. Among young Danish men, 6% have such poor sperm quality that they are assumed not to be able to have children without help. Today, about 8% of Danish children are conceived through artificial fertilisation. Furthermore, in Denmark the occurrence of undescended testicles at birth has increased from 2% to 9% in baby boys over the past 50 years, girls develop breasts one year earlier than 15 years ago, and the occurrence of testicular cancer is one of the highest in Europe; 1 in 100 young men risk developing testicular cancer. Based on current knowledge, exposure to some phthalates are suspected to contribute to these effects.

Several phthalates have the same mode of action in the body, and this should be considered when calculating the risk of exposure to phthalates. Most recently, this has led to a Danish proposal for a ban on four phthalates in a number of consumer products in the EU, and now Denmark has introduced a national ban against the four phthalates.

[2] The term products used in this strategy covers articles and chemical mixtures as described in the REACH Regulation.

Five phthalates (DEHP, DBP, BBP, DINP and DIDP) have undergone risk assessment by the EU, and these phthalates have been relatively thoroughly investigated for their effects on the environment and human health as well as their use in different types of products. However, many other phthalates exist. For many of these phthalates, there is a lack of information about effects and use, and as the use of the now classified phthalates is generally declining, the use of more unknown phthalates and alternatives to phthalates is expected to increase. This will result in greater consumer exposure to phthalates for which we do not know the full extent of their effects on the environment and human health.

The purpose of this strategy is to examine the entire group of phthalates to ensure that we manage the phthalates on the basis of a collective approach, rather than managing the individual phthalates substance by substance.

The aim of this strategy is to identify and manage the phthalates currently being used in Denmark and in the EU. The purpose is to gather sufficient knowledge to conduct an evaluation of the phthalates used as well as to identify whether there is a need for regulation, and if so propose such regulation. This will ensure protection of human beings and the environment against the undesirable effects of phthalates.

Managing phthalates must be based on comprehensive knowledge about the entire group of substances to ensure that some undesirable phthalates are not merely substituted by alternatives about which we lack knowledge and which may prove to be of equally high concern at a later stage.

1. Goal and strategy

The overall goal of this strategy is to protect human beings and the environment against possible risks from phthalates mainly used as plasticisers in PVC plastics.

Phthalates must be managed on the basis of the existing knowledge about the entire group of phthalates, as some phthalates that have been identified as undesirable have merely been substituted by other phthalates. Therefore, it must be ensured that only phthalates or alternatives safe for human beings and the environment are used, also taking into account that we are exposed to several different phthalates with the same effects in the body.

The objective of this strategy is to review and summerise the knowledge we have today about the entire group of phthalates, and to identify areas in which we lack knowledge. Furthermore, this strategy helps to identify whether there are areas in which we currently have sufficient knowledge to propose further regulation or in some other way limit the possible risk.

As of December 2015, Denmark will ban sale of products containing four specific phthalates (DEHP, DBP, DIBP and BBP). These phthalates will not be covered by the activities in this strategy, as they have already been dealt with unless there will be a need. However, as the national ban against the four phthalates does not cover medical devices, this strategy does include management of these phthalates in medical devices.

New activities:

Focus on phthalates currently being used

According to the REACH Regulation, industry and importers must register substances produced or imported at quantities above 1 tonne per producer or importer. Overall, this strategy focuses on these phthalates that account for the majority of the tonnage. A total of 26 phthalates have been pre-registered, and information about the hazardousness and use of these substances has been, or will be, submitted in connection with the registration. The Danish EPA will focus particularly on the phthalates which have proven to have, or are suspected of having, endocrine disrupting effects.

Identification of phthalates with endocrine disrupting effects

Common EU criteria for when a substance is considered to have endocrine disrupting effects are expected to be ready in late 2013. In 2013, the Danish EPA will initiate a study of available information for the most used phthalates to evaluate these when the EU criteria on endocrine disruptors become available. A decision will then be made regarding whether further action is needed.

Substance evaluation under REACH

Substance evaluations may be initiated under REACH if there is reason to believe that a substance poses a risk to human health or the environment. Phthalates are nominated for substance evaluation if justified concern is identified. For example, this could be if a phthalate is evaluated to have endocrine disrupting effects according the future EU criteria.

Harmonised classification

It must be examined whether phthalates without harmonised classification, and which are suspected of having endocrine disrupting effects, are to be proposed for classification. Moreover, it

must be assessed whether the data which shows endocrine disrupting effects for the phthalate DINP gives rise to health concerns. If so, a proposal for harmonised classification must be prepared.

Nomination of substances to the Candidate List

The Danish EPA carries out an evaluation of the phthalates which meet the requirements for inclusion in the Candidate List with a view to proposing relevant phthalates to be included in the Authorisation List under REACH.

Restrictions (bans etc.)

A restriction proposal will be prepared at EU level for phthalates evaluated to pose a risk. Overall exposure to phthalates with the same mode of action in the body will be taken into account for phthalates with endocrine disrupting effects.

Specifically with regard to phthalates in medical devices, the Danish Ministry of Health will closely monitor the work by the expert committee; the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in relation to the use of the phthalate DEHP in medical devices, and encourage knowledge sharing with relevant players about the possibilities and barriers for use of phthalate-free medical devices. Assessing the need to introduce restrictions in the use of phthalates in medical devices therefore requires a solid decision base in the form of more knowledge and documentation in this area.

Breaking down barriers for substitution

Focus must remain on gathering and disseminating knowledge about alternative substances and materials to promote substitution and reduce costs in connection with the transition.

Green public procurement

The total public procurement volume is 290 billion DKK. This could be a factor to create a demand, and thus a larger market for products, without phthalates. The Danish EPA would like to investigate the possibilities – on a voluntary basis – to reduce and phase out phthalates in the public demand for products and services by initiating an analysis of where and how phthalates in the public procurement can be reduced and if possible be phased out. The analysis shall show the direction for the future work with public procurement of products without phthalates.

Collaboration with stakeholders

All activities must include regular and close dialogue with stakeholders from industry, sector organisations, NGOs and relevant authorities, as these can contribute valuable information and in many cases are vital for successful management of the risk.

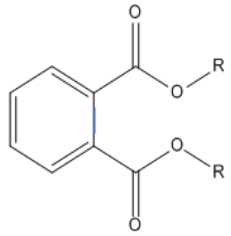
Summary and status

In mid 2015, a status report on the work on phthalates will be prepared. New knowledge will have been gathered from national surveys of selected phthalates and from the substance evaluations under REACH, and we will know whether some of the most used phthalates can be considered as endocrine disruptors according to the future EU criteria.

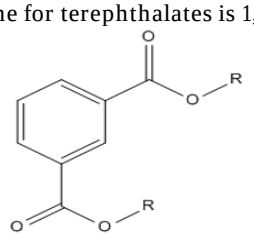
2. What are phthalates?

Phthalates are a family of chemical substances based on the same general chemical structure. In this strategy the term phthalates are used to refer to ortho(o)-phthalate esters (also called o-phthalic acid esters), where the ester groups are attached ortho to the benzene ring. The chemical name for o-phthalic acid is 1,2-benzenedicarboxylic acid.

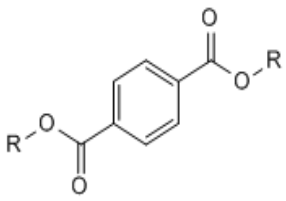
The structure below represent a phthalate. R represent ester groups that most often are alkyl groups and most often are identical. The two R functional groups can however also be different and may be an alkyl group, an aromatic ring or another functional group.



If the ester groups are attached to the meta- or para- positions on the benzene ring, the phthalates are called iso- or terephthalates, respectively. These types of phthalates are not included in this strategy. The chemical name for isophthalates is 1,3-benzenedicarboxylic acid and the chemical name for terephthalates is 1,4-benzenedicarboxylic acid.



Isophthalate



Terephthalate

The most widespread use of phthalates is as plasticisers in PVC, however phthalates are also used in other products such as paints and glues. Since the mid-1990s, phthalates have been the object of great attention, nationally and internationally, due to their suspected negative effects on the environment and the reproductive capacity, as well as their suspected carcinogenic effect. In recent years, their potential endocrine disrupting effects have been the centre of attention. Furthermore, it has been demonstrated that the mechanism by which cancer can be triggered in test animals is not relevant for humans.

There are many different types of phthalates, and there are indications that these do not have the same effects on the environment and human health. Phthalates can be divided into high- and low-molecular-weight phthalates. High-molecular-weight phthalates are often defined as phthalates with a carbon backbone in the main alkyl chain consisting of seven or more carbon atoms. These include e.g. the phthalates DINP, DIDP, DPHP, DIUP, and DTDP. Low-molecular-weight phthalates are often defined as phthalates with a carbon backbone in the main alkyl chain of three to six carbon atoms. These include e.g. the phthalates DEHP, DBP, DIBP, and BBP.

The phthalate DEHP has been the object of the greatest attention and is still the most commonly used phthalate globally. However, the use of DEHP in the EU and the US has decreased significantly after DEHP and other types of phthalates have been classified as toxic to reproduction and after their use has been banned in toys, childcare articles and food contact materials.

3. Status of regulation

3.1 Criteria for regulation

Phthalates can be regulated in several different ways. Regulation is divided into EU regulation and Danish regulation.

3.1.1 EU regulation

The overall regulatory framework for chemicals in the EU is the REACH Regulation and the CLP Regulation. The various elements of the REACH Regulation and the CLP Regulation have a direct influence on how the phthalates can be regulated.

An important aspect of the REACH Regulation is that it requires registration of all substances that are either produced or imported into the EU in quantities at more than or equal to one tonne per year. This registration must include documentation of the health and environmental properties of the substances, as the information requirements increase with the quantities of the substance produced or imported. The industry is responsible for submitting this documentation. If the documentation is not provided, the substance may neither be produced nor placed on the market within the EU. The authorities can assess whether the registrations contain data in an adequate quantity and quality (see part 4).

At EU level, there are a number of regulatory options under REACH and CLP (the classification rules). The most important are:

1. The authorisation scheme (including the Candidate List)
2. Restrictions (bans)
3. Harmonised classification

Re 1) Authorisation scheme including the Candidate List

The Candidate List is a list of substances of very high concern under the REACH Regulation which include carcinogenic and mutagenic substances and substances toxic to reproduction (CMR substances), as well as substances of very high concern for the environment (PBT and vPvB substances). Substances with other serious effects on humans and the environment, such as endocrine disruptors, can also be included in the list following case-by-case evaluation. Criteria for inclusion in the Candidate List are described in Article 57 of the REACH Regulation. The aim is that substances in the Candidate List will eventually be included in the Authorisation List with a view to being ultimately phased out.

Member States or ECHA, on behalf of the European Commission, can recommend substances for inclusion in the Candidate List. Proposals are processed by the Member State Committee under REACH. New substances are included in the Candidate List on a regular basis. If a substance is on the Candidate List, upon request, consumers are entitled to be supplied with information as to whether a given product contains more than 0.1% of the substance in question. Furthermore, the producer or importer must ensure that information about the content of the substance is passed on to professional users of a) the substance, b) any mixture in which the substance is a part, or c) a product containing the substance.

Candidate List substances can be prioritised for inclusion in the Authorisation List under REACH (Annex XIV); depending e.g. on the substances' uses. If a substance is on the Authorisation List, after a given cut-off date (the sunset date), companies will no longer be allowed to place on the market or use the substance, including any mixture containing the substance, unless the company has obtained authorisation for this purpose. This authorisation procedure covers only uses within the EU and therefore does not affect imports of products (articles) containing the substance, which means the substance may be imported in articles, even though it is illegal to produce the selfsame article within the EU.

Inclusion in the Authorisation List is based on a recommendation from ECHA and follows a procedure which includes public consultation and discussion in the Member State Committee, as described in Article 58 of REACH. It is up to the European Commission to submit proposals based on recommendations from ECHA. Thus there is no guarantee that a substance of concern will be included in the Authorisation List; it depends on whether the European Commission proposes its inclusion in the list and whether the REACH Committee endorses this proposal.

Inclusions in the Candidate List and in the Authorisation List are therefore two possible ways of regulating certain phthalates, if the criteria for inclusion, including the quantity and quality of data, have been met.

Re 2) Restrictions (bans)

Member States, or ECHA on behalf of the European Commission, can propose restrictions on a substance if they identify risks that are not being adequately controlled. Such restrictions may be broadly defined or very specific and may apply to individual substances or to several substances. Furthermore, restrictions may be in the form of a general ban with few or many exemptions, or a specific ban on use in toys, and this will depend on the specific use and risk, control options, etc. No specific criteria are mandatory; for example, the substance does not require a harmonised classification.

The proposal is processed in the context of ECHA by two scientific committees which consist of members appointed by ECHA upon recommendation by the Member States. The committees submit their opinion after they have processed the proposal and after a public consultation. On the basis of these opinions, and possible other concerns, the European Commission then decides whether to present a proposal. Restriction proposals are approved by the REACH Committee in accordance with the comitology procedure.

Restriction proposals should be considered in the light of the fact that inclusion in the Candidate List and the Authorisation List will not always provide adequate protection of the environment and/or human health, primarily because imported products are not covered by the authorisation scheme.

Re 3) Harmonised classification

Substances and mixtures placed on the market within the EU are subject to the requirements of the CLP Regulation (Regulation (EC) No 1272/2008) on classification, labelling and packaging. Substances that have already been classified as carcinogenic, mutagenic or toxic to reproduction (CMR) categories 1A or 1B may not be sold as either substances or in chemical mixtures to the general public (Annex XVII of REACH). Chemical mixtures could include paint, filler, etc. Whether placed on the market as a substance or a mixture, CMR substances in categories 1A and 1B must be marked on the packaging as follows: "Restricted to professional users".

If the substance has not been given a harmonised classification, a Member State or the industry may propose a classification for this purpose. This proposal will be processed by the Committee for Risk Assessment under ECHA and the European Commission will consider the Committee's final

opinion before presenting its proposal for a final harmonised classification. The classification will then be adopted by the REACH Committee through the comitology procedure. There is no guarantee the proposal will be adopted.

Other regulatory options

There are also a number of other regulatory options available, such as the Water Framework Directive etc., but these are less important in this context. In some situations, however, it may be relevant to use options other than those described above.

3.2 Classification of phthalates

Phthalates have long been an object of concern, primarily because of their effects on reproduction, and some phthalates have been classified as toxic to reproduction. When substances are classified as toxic to reproduction, they are divided into the following categories (see the CLP Regulation):

Category 1: Known or presumed human reproductive toxicants, including

Category 1A: Evidence of effects in humans
Category 1B: Evidence of effects in animals

Category 2: Suspected human reproductive toxicant. Substances are classified in this category when there is some evidence from animal studies or from human data but where the evidence is not sufficiently convincing (poor or insufficient data) to place the substance in category 1.

Reproductive toxicants are subdivided into substances with adverse effects on sexual function and fertility (allocated the letters F/f) and substances with adverse effects on development of the offspring (allocated the letters D/d). The classification system also contains a separate category for substances with adverse effects on or via lactation (breastfeeding).

Effects on sexual function and fertility can be: alterations to the reproductive system; adverse effects on onset of puberty; and effects on the reproductive cycle, parturition, gamete production or sexual behaviour. Effects on the development of the offspring can be adverse effects on normal development before or after birth. The primary effects on development are increased mortality of the foetus or offspring, structural abnormality, altered growth or functional deficiency. Effects on, or following from, lactation can be reduced quality or quantity of breast milk or effects on the offspring due to exposure to a substance via breast milk.

The majority of phthalates currently classified as toxic to reproduction have been so classified on the basis of their adverse effects on both fertility and development of the offspring. DEHP, for example, has been classified as a reproductive toxicant in category 1B based on animal studies which show reduced fertility (reduced number of offspring compared with control animals) as well as adverse effects on testicular development in the offspring.

There is no separate classification for substances with endocrine disrupting effects. Some endocrine disruptors will meet the criteria for classification as reproductive toxicants, however, endocrine disrupting effects can also lead to other types of effect which are not
covered by the classification rules.

Phthalates can also have other effects on either health or the environment. Examples of environmental effects include accumulation in the food chain and acute or chronic toxic effects on aquatic organisms. Several phthalates have thus been classified as e.g. environmental hazard, acute toxicity, skin sensitisation or skin, eye and respiratory irritation.

Some phthalates have a harmonised classification, which has been adopted and is binding at Community level. This classification appears from the list of harmonised classifications (Annex VI of the CLP Regulation), which includes 12 esters of o-phthalic acid which are classified for different effects, primarily reproduction toxicity and environmental hazard (November 2012). All but one of the 12 phthalates have been classified as toxic to reproduction.

A large number of phthalates have been self-classified by the companies who produce them or have placed them on the EU market. The self-classification by companies is available in ECHA's Classification and Labelling Inventory, the C&L Inventory. This C&L Inventory does not provide information about the specific use or volume of the notified substances. All classified substances that have been placed on the EU market must be notified to the C&L Inventory, regardless of the quantities placed on the market. Furthermore, all substances that are registered under REACH must also be notified to the C&L Inventory, regardless of whether they have been classified or not.

3.3 Specific regulation of individual phthalates

Phthalates are regulated both via national and EU regulation. The following section describes national bans and EU regulation of phthalates.

3.3.1 National regulation

Since 1999, Denmark has had a national ban on all phthalates in toys and childcare articles intended for children under 3 years old. The Danish Statutory Order No. 855 of 5 September 2009 prohibits all phthalates, defined as esters of o-phthalic acid, in concentrations above 0.05%.

Furthermore, 2012 saw the introduction of a national ban on the four phthalates DEHP, DBP, DIBP and BBP in concentrations above 0.1% in products for indoor use and products that can come into direct contact with the skin or mucous membranes (Statutory Order no. 1113 of 26 November 2012). This ban is applicable from 1 December 2015, however for electrical and electronic equipment covered by the RoHS Directive (Directive 2011/65) not until 1 December 2016.

Any Danish regulation must be in accordance with EU legislation. Although this does not prevent more strict national rules than EU rules, it does mean that the national room for manoeuvre depends on whether there are already rules in the area at Community level, and, if so, whether these rules are subject to minimum harmonisation or maximum harmonisation.

3.3.2 EU regulation

Since 2007, there has been a ban in the EU on DEHP, DBP and BBP in all toys and childcare articles in concentrations above 0.1% (entry 51 of Annex XVII of the REACH regulation), as well as bans on DINP, DIDP and DNOP in toys and childcare articles that can be placed in the mouth in concentrations above 0.1% (entrance 52 of Annex XVII of the REACH Regulation). The ban on DINP, DIDP and DNOP is currently being evaluated and a result is expected in 2013 following an opinion from the Committee for Risk Assessment (RAC) under ECHA and processing and proposal from the European Commission.

Phthalates which are classified as CMR substances will be banned in all accessible components of toys in concentrations above the specific classification limit, once the new rules for toys enter into force on 20 July 2013 (Statutory Order no. 13 of 10 January 2011).

3.3.3 Phthalates in the Candidate List

At present, seven phthalates are included in the Candidate List, see Table 1**.** (ECHA 2012a). All of these phthalates have been included in the list because they are toxic to reproduction.

Table 1 Phthalates in the Candidate List (November 2012).

Substance	CAS number	Date of inclusion	Reason for inclusion
Bis(2-methoxyethyl) phthalate (DMEP)	117-82-8	2011/12/19	Toxic to reproduction (REACH Article 57 c)
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	2011/06/20	Toxic to reproduction (REACH Article 57 c)
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	2011/06/20	Toxic to reproduction (REACH Article 57 c)
Diisobutyl phthalate (DIBP)	84-69-5	2010/01/13	Toxic to reproduction (REACH Article 57 c)
Benzyl butyl phthalate (BBP)	85-68-7	2008/10/28	Toxic to reproduction (REACH Article 57 c)
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	2008/10/28	Toxic to reproduction (REACH Article 57 c)
Dibutyl phthalate (DBP)	84-74-2	2008/10/28	Toxic to reproduction (REACH Article 57 c)

3.3.4 Phthalates subject to authorisation

At present, four phthalates are included in the Authorisation List, see Table 2 (ECHA 2012b). Three of these phthalates are exempted from the authorisation requirement for uses in the immediate packaging of medicinal products.

Table 2 Phthalates in the Authorisation List (November 2012).

Substance	CAS number	Sunset date	Latest application date	Exempted uses
Benzyl butyl phthalate (BBP)	85-68-7	21/02/2015	21/08/2013	Packaging of medicinal products
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	21/02/2015	21/08/2013	Packaging of medicinal products
Dibutyl phthalate (DBP)	84-74-2	21/02/2015	21/08/2013	Packaging of medicinal products
Diisobutyl phthalate (DIBP)	84-69-5	21/02/2015	21/08/2013	-

3.3.5 Other regulation

There are specific EU rules on the content and migration of phthalates in packaging and other food contact material made from plastic. These include restrictions on the maximum content of certain

phthalates in the plastic material itself (QM values of 0.05-0.1%) as well as specific migration limits in food simulators (SML values of 0.3-30 mg/kg). The rules to be complied with depend on the type of food product and whether the material is intended for single or multiple use. The rules cover the phthalates BBP, DEHP, DBP, DINP and DIDP.[3] In the rules covering use of plastic in food contact materials (EU no. 10/2011) the exposure of phthalates from other sources than food contact materials are taken into account. This is taken into account by only using 10% of the TDI for each substance. This is a special case for the restriction of phthalates in food contact materials.

These rules apply only to plastics. Other types of material are subject to specific assessment of their migration to food pursuant to Article 3 of Framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

As of March 2010, certain types of medical devices have been subject to a phthalates labelling requirement covering phthalates that are classified as CMR substances (i.e. carcinogenic, mutagenic or toxic to reproduction) in category 1 or 2 (Statutory Order no. 1263 of 15 December 2008). This labelling requirement applies to medical devices, or components of medical devices, which are used to administer and/or remove medicine, body fluids or other substances to or from the body, or devices intended for transport and storage of these body fluids or substances. If the device is intended for use in the treatment of children, pregnant women or breastfeeding women, the manufacturer must state a special reason for using these substances in its technical documentation. Furthermore, the manufacturer must provide information in the instructions for use about the remaining risks for these patient groups and about any appropriate safety measures.

3.4 Other measures

Other measures than the three types of regulation mentioned above, in the form of authorisation, restriction and classification, may be relevant in connection with the regulation of chemical substances and chemical substances in products. Some of the measures that could be relevant in this context are described below.

3.4.1 Ecolabels

The purpose of ecolabelling (i.e. environmental labelling) is to contribute to production and consumption with less negative impacts on the environment. The way to do this is by developing criteria for more environmentally friendly goods and services for consumers (private as well as professional consumers). The ecolabel criteria are based on the individual area of products/goods and they determine the environmental impact of these in a life-cycle perspective (a life-cycle or cradle-to-grave analysis). The aim is to determine criteria which cover the best percentage of the market (20-30%). The task is to encourage environmentally adapted product development and to exploit market forces to achieve environmental benefits. Ecolabelling should be seen as a supplement to other environmental and consumer policy instruments (e.g. legislation and voluntary agreements).

The EU Flower and Nordic Swan ecolabels follow the ISO 14.024 standard and are subject to independent third-party control. The ecolabel criteria for a given area of goods are updated regularly, typically every four to five years, in order to follow developments in the market.

As a general rule, phthalates are not prohibited in ecolabelled products. Phthalates are being limited either by replacing materials or plasticisers, or by excluding the use of the most dangerous phthalates.

[3]Substances not on the positive list may be used in the plastic layers of multi-layer materials, however not in layers that come into direct contact with food. There must be a functional barrier between the food and the plastic layer which prevents the substances from migrating to the food (or a food simulator) at traceable levels above the migration limit of 0.01 mg/kg. Furthermore, even if they are not in direct contact with the food, the substances used must not be classified as CMR substances.

As more of the Flower label's criteria are being revised, phthalates on the Candidate List will be excluded.

3.4.2 Taxes

Pursuant to the Danish PVC Tax Act (Act no. 253 of 19 March 2007) certain goods are subject to taxation when they contain phthalates. This Act requires Danish companies that manufacture goods which are covered by the scope of the Act and companies that receive such goods from abroad, to pay a tax. The tax on phthalates is based on the weight of the phthalates in the goods. The Act covers a large number of goods categories, including flooring material, cables, ring binders, gloves etc.

3.4.3 Green public procurement and partnerships

The total public procurement volume of DKK 290 billion could help increase the demand for products without phthalates, thereby also helping to build a larger market for these products. Many products in demand by the public sector could potentially contain phthalates, e.g. furniture, cables and leads, work clothes and cloves, toys for care institutions, office supplies and medical devices.

By requiring phthalate-free products and by introducing competition parameters in favour of phthalate-free products in public tenders, the public sector can use its procurement volume as an incentive for producers to develop and carry out research into phthalate-free products. For example, medical devices developed without phthalates. There are already many phthalate-free products available on the market within the area of medical devices, however price differences and the functionality of the devices may keep public procurement officers from demanding phthalate-free alternatives.

The Ministry of the Environment is working to spotlight green procurement through various activities. For example the Partnership for Green Public Procurement and the Forum for Sustainable Procurement. Furthermore, at EU level criteria for green public procurement are being developed on an ongoing basis. Several analyses show that some of the greatest barriers to green public procurement are higher prices and lack of knowledge. Efforts must therefore be targeted at these areas.

For example, tools could be developed for public procurement officers, such as lists of products within a category which are free of phthalates. A list already exists of medical devices which do not contain phthalates subject to compulsory labelling. Public procurement officers can use this list to easily find medical devices without phthalates subject to compulsory labelling. Guidelines on reduction of certain phthalates in procurement of medical devices are currently being prepared for Danish regions and municipalities.

3.4.3.1 Partnership for public green procurement

The partnership for public green procurement is a partnership between the Ministry of the Environment, several municipalities and Region Midtjylland. The partners in the partnership develop and negotiate jointly binding procurement targets and these have a positive effect on the environment at global as well as local levels. The municipal members of the partnership account for 20% of total local-government procurement and several municipalities and regions have shown an interest in joining the partnership. In March 2012, the Minister and the respective mayors put their signature to new targets in the following areas: food, building and construction, and transport.

Within additional product areas procurement targets on phthalate free products could be relevant. The partnership already has a target for procurement of phthalate-free toys. Furthermore, the partnership can choose to develop new targets, e.g. in the healthcare sector. Medical device is a possible future target area which is supported by the the steering committee.

For more information about the partnership see www.gronneindkob.dk (only available in Danish). This website (only available in Danish) contains additional information about the specific procurement targets, which e.g. entail specific requirements and recommendations for building and renovation (e.g. concerning choice of materials), and that nappies must meet the criteria for the Swan ecolabel.

3.4.3.2 Forum for Sustainable Procurement

The Forum for Sustainable Procurement was established by the Minister for the Environment to promote responsible and environmentally conscious procurement of goods and services by procurement officers, in both public-sector and private-sector companies. The forum focuses on awareness boosting, networking and exchange of experience relating to the benefits and opportunities in sustainable procurement. The forum structure includes a steering committee with representatives of political organisations, working groups, and individual members. The forum hosts seminars and an annual conference, and submits regular newsletters to its approx. 700 members. Danish Regions, Local Government Denmark, the Danish Construction Association, Ecolabelling Denmark and the Capital Region of Denmark are among the organisations with representatives in the steering committee.

The forum could help support a possible initiative for phthalate-free products in the healthcare sector by disseminating knowledge and experience about including requirements in public tenders. In February 2013, the forum hosted an after-work meeting on phthalate-free medical devices in collaboration with Danish Regions. The steering committee and all forum members have moreover been informed about the list of medical devices not containing phthalates subject to compulsory labelling via steering committee meetings and a newsletter issued in December 2012.

Read more about the forum at www.ansvarligeindkøb.dk (only available in Danish).

3.4.3.3 Criteria for green public procurement

In 2008, the EU adopted a 50% goal for green public procurement within ten selected product groups. Medical devices were initially among the product groups selected, and for which criteria were to be developed for green public procurement. However, for various reasons medical devices were replaced by another product group. Sweden has in the meantime placed itself at the head of an initiative to develop criteria for electrical and electronic equipment in the healthcare sector in consultation with the European Commission. For more information, visit www.msr.se/en/green_procurement/criteria/Ongoing-criteria-work/Medical-devices/

It is still not clear whether criteria will be developed specifically for healthcare-sector products, which will have relevance for phthalate-free products. The Danish EPA has asked the European Commission on several occasions to develop criteria for medical devices according to the Commission Communication (COM (2008) 400) “Public procurement for a better environment”.

Ecolabelling Denmark is participating in a Nordic project to develop procurement criteria for public procurement officers based on ecolabel criteria. One of the selected product groups is potential phthalate-containing medical devices and these are defined as disposable bags and tubes, and accessories for healthcare use, e.g. products for peritoneal dialysis (PD) and intravenous (IV) infusion treatment.

In spring 2013, the Danish EPA will launch intensified efforts to communicate the EU's green public procurement criteria as well as national recommendations and guidance to Danish procurement officers in the form of a tool box on the *Udbudsportalen*, an information and advisory portal on tendering etc.

3.5 Recommendations

When adequate knowledge is available about one or more phthalates, there must be an assessment of whether steps should be taken to introduce one or more of the regulatory measures mentioned above.

Phthalates that cause endocrine disrupting effects and/or are toxic to reproduction, but which do not have a harmonised classification, must be assessed in order to determine whether they meet the criteria for classification. In this connection, it should be examined whether industry has self-classified the substances and whether it has done so uniformly. If not, a decision will have to be made as to whether or not proposals for harmonised classification are to be prepared.

For example, recent studies show that DINP has endocrine disrupting effects at high doses. In 2013, Denmark will assess whether the evidence of endocrine disrupting effects provides a basis for harmonised classification or other measures, and, if so, instigate work to this end.

Chemical substances that have properties of very high concern, and the use of which should ultimately be phased out, can be proposed for inclusion in the REACH Candidate List of substances which can be prioritised for inclusion in the REACH Authorisation List. Substances that are included in the Authorisation List may only be used in future after authorisation has been granted for specific uses.

The Danish EPA will make an assessment of the phthalates which meet the requirements for inclusion in the Candidate List (i.e. in particular phthalates which are endocrine disrupting and/or toxic to reproduction) and, on this background, possibly propose additional phthalates for inclusion in the Candidate List.

If an assessment leads to the conclusion that the use of a certain chemical substance poses a risk to human health or the environment, restrictions will be introduced on the manufacture, placing on the market or use of the substance. Restrictions have already been introduced for a number of phthalates in Denmark as well as at Community level. For other phthalates assessed to have endocrine disrupting effects, the Danish EPA will make a more detailed review in order to assess the need for further restrictions. In this context, possible combination effects associated with simultaneous exposure to several phthalates with the same mode of action will be taken into account.

The Danish EPA wishes to examine the possibilities for voluntary phasing out of phthalates in the public request for products and services by carrying out an analysis of phthalates and public procurement. This analysis will provide a knowledge base for how and where phthalates can be reduced and, possibly, phased out all together in public procurement. The analysis will identify the product areas in which the public sector buys and which may include phthalate-containing products. For the individual product area, there will be analyses to identify procurement volume, environmental impact, market possibilities, as well as any additional costs of buying phthalate-free alternatives. The purpose of the analysis is to point the way forward for efforts by the Danish EPA to green the public procurement. The analysis work should also serve as a knowledge and decision base for public procurement officers, in general, and for the Partnership for Public Green Procurement specifically, in order to reduce phthalates in public procurement and, if safe and effective alternatives exist, phase them out all together in the long term.

4. Phthalates registered under REACH

4.1 Registered phthalates

The obligation to register substances under the REACH Regulation applies to substances that are produced in or imported to the EU in quantities > one tonne/year per producer or importer. With regard to substances in products, there is a registration obligation if the substance is intentionally released from the product during use (e.g. fragrances), if the quantity of the substance in the products produced or imported exceeds one tonne/year, and if the use of the substance has not already been registered. Currently, 23 esters of o-phthalic acid have been registered under REACH in connection with the first registration deadline for high-tonnage substances (> 1,000 tonnes/year). In addition to high-tonnage substances, the first registration deadline also covered CMR substances (> 1 tonne/year) as well as substances that are classified as very toxic to aquatic organisms, and which can cause long-term effects on the aquatic environment ((R50/53) (< 100 tonnes/year). Three additional esters of o-phthalic acid have been pre-registered and are likely to be registered in connection with the next registration deadline for medium-tonnage substances (> 100 tonnes/year) in 2013. Three other additional esters of o-phthalic acid were also pre-registered before the 2010 deadline, however these substances were neither registered in 2010 nor pre-registered for the 2013 deadline. Table 3 gives an overview of registered and pre-registered phthalates (ECHA 2012c).

Table 3 Registered phthalates (November 2012).

Substance name	CAS number	Total tonnage level tonnes/year	Harmonised classification (CLP Annex VI)**
Diethyl phthalate (DEP)	84-66-2	1,000-10,000	
Diisobutyl phthalate (DIBP)*	84-69-5	1,000-10,000	Repr. 1B; H360Df
Dibutyl phthalate (DBP)*	84-74-2	1,000-10,000	Repr. 1B; H360Df Aquatic Acute 1; H400
Benzyl butyl phthalate (BBP)*	85-68-7	1,000-10,000	Repr. 1B; H360Df Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Bis(2-ethylhexyl) phthalate (DEHP)*	117-81-7	100,000-1,000,000	Repr 1B; H360FD
Dimethyl phthalate (DMP)	131-11-3	10,000-100,000	
Diallyl phthalate (DAP)	131-17-9	100-1,000	Acute Tox 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

Substance name	CAS number	Total tonnage level tonnes/year	Harmonised classification (CLP Annex VI)**
Diisopentyl phthalate (DIPP)	605-50-5	10-100	Repr. 1B; H360FD Aquatic Acute 1; H400
Diundecyl phthalate (DUP)	3648-20-2	1,000-10,000	
Benzyl 3-isobutyryloxy-1-isopropyl-2,2-dimethylpropyl phthalate	16883-83-3	1,000-10,000	
Diisotridecyl phthalate (DITP)	27253-26-5	1,000-10,000	
Di-''isononyl'' phthalate (DINP)	28553-12-0	100,000-1,000,000	
Bis(2-propylheptyl) phthalate (DPHP)	53306-54-0	100,000-1,000,000	
1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	68515-40-2	10,000-100,000	
1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	68515-43-5	1,000-10,000	
1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (DTDP)	68515-47-9	1,000-10,000	
1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich	68515-48-0	100,000-1,000,000	
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP)	68515-49-1	100,000-1,000,000	
1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5	100-1,000	
1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters	71662-46-9	100-1,000	
1,2-Benzenedicarboxylic acid, di-C1-13 alkyl esters, manuf. of, by-products from, distn. lights	84852-02-8	Can only be used as an intermediate	
diundecyl phthalate, branched and linear (DIUP)	85507-79-5	1,000-10,000	
1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters	90193-76-3	1,000-10,000	
Dicyclohexyl phthalate (DCHP)	84-61-7	Pre-registered (2013)	

Substance name	CAS number	Total tonnage level tonnes/year	Harmonised classification (CLP Annex VI)**
Disodium phthalate	15968-01-1	Pre-registered (2013)	
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	Pre-registered (2010), but not registered	
1,2-Benzenedicarboxylic acid, mixed decyl and lauryl and myristyl diesters	90193-92-3	Pre-registered (2010), but not registered	
Di-''isodecyl'' phthalate (DIDP)	26761-40-0	Pre-registered (2010), but not registered	

** The substance is on the Candidate List and the Authorisation List*
*** Complete wording of the hazard statements (H statements):*
H360 DF: May damage the unborn child. Suspected of damaging fertility.
H360 FD: May damage fertility. May damage the unborn child.
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects
H302: Acute toxicity (oral)

A registration must contain information about tonnage produced/imported of the substance, substance identity, use and intrinsic properties (hazardousness). This includes documentation of a range of environmental and health properties in the form of results from animal studies, human data and other documentation. If data is unavailable, the registrant has a duty to obtain the relevant data and to have the substances examined in closer detail. A chemical safety report must be prepared for substances that are produced or imported at quantities > 10 tonnes/year. If the substance is classified as hazardous or is considered to be a PBT or a vPvB substance, the chemical safety report must also include an exposure assessment with exposure scenarios, as well as a risk assessment of its uses. This requirement covers the registrant's own use of the substance as well as all identified uses by downstream users. The report must also provide recommendations on managing possible risks identified. Data on the substance's identity, use and environmental and health properties, including classification, is available via the registration portal on the ECHA website. The chemical safety report (with a safety assessment) is confidential.

4.2 Notified products containing phthalates

Companies that produce and/or import products containing Candidate List substances must notify the use of the substance if it is used in quantities > 1 tonne/year, and if the concentration of the substance exceeds 0.1%. If the use of the substance in a product is already covered by a registration dossier, the producer or importer will not be required to notify the use of the substance in the relevant product.

At present, four phthalates in products have been notified, see Table 4 (ECHA 2012d).

Table 4 Notified phthalates in articles (November 2012)

Substance name	CAS number	Number of notifications	Product category
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	92	Electrical batteries and accumulators Fabrics, textiles and apparel Machinery, mechanical appliances, electrical/electronic articles Metal articles Plastic articles Rubber articles Vehicles Wood articles Other
Dibutyl phthalate (DBP)	84-74-2	16	Electrical batteries and accumulators Fabrics, textiles and apparel Machinery, mechanical appliances, electrical/electronic articles Paper articles Plastic articles Rubber articles Vehicles Other
Diisobutyl phthalate (DIBP)	84-69-5	7	Fabrics, textiles and apparel Plastic articles Rubber articles Other
Benzyl butyl phthalate (BBP)	85-68-7	3	Plastic articles Rubber articles

4.3 Which phthalates are not covered by the registration obligation in REACH?

Substances that are produced or imported into the EU at quantities < 1 tonne/year are not covered by the registration duty under REACH.

If one of the following conditions is met, substances in products need not be registered:

- there is no intentional release of the substance from the product;
- there is intentional release but the use of the substance in the product is less than 1 tonne/year (production and import);

If one of the following conditions is met, substances in products need not be notified:

- the substance is not on the Candidate List;
- the substance is on the Candidate List but its concentration is < 0.1% in the article *or* the quantity of the substance in all imported products is < 1 tonne/year.

For phthalates which meet the above conditions there will not necessarily be information about whether and to what extent they are being imported into the EU as a component in products. Phthalates are primarily used as plasticisers in plastic (products) in which there is no intentional

release and therefore no requirement for registration. However, phthalates may be registered if they are produced or imported into the EU as an individual substance.

4.4 Recommendations

A total of 23 esters of o-phthalic acid are currently registered under REACH and an additional three esters of o-phthalic acid have been pre-registered and are expected to be registered in connection with the next registration deadline for medium-tonnage substances (100-1,000 tonnes/year) in 2013. Furthermore, notifications have been made of four Candidate List phthalates in products either produced or imported into the EU and where the concentration of the individual substance in the product exceeds 0.1% and the total quantity of the individual substance in all products exceeds 1 tonne/year. For the phthalates that are not covered by the requirement for registration, or where the use in the product does not trigger the notification requirement, no information is available as to the extent to which these phthalates are present in products that have been placed on the market in the EU. Since phthalates are primarily used as plasticisers in plastic products, it cannot be ruled out that other phthalates are being used in the EU than those which have already been registered and notified. In future, special attention will be given to registered phthalates, as these are the phthalates actually being used. Of the registered phthalates, special attention will be given to the phthalates that are considered the most harmful with regard to their endocrine disrupting effects. This could include phthalates classified as toxic to reproduction or which are suspected of having endocrine disrupting effects. However, only the phthalates DEHP, DBP, DIBP and BBP will be in focus in relation to medical devices. These phthalates are already being managed in Denmark through a ban on their use in a large number of consumer products, however excluding medical devices.

5. Brief description of the use of phthalates

Phthalates are mainly used as plasticisers in plastics, primarily PVC. However, certain phthalates are also used in cosmetics to ensure that perfumes adhere longer to the skin, or they are used to improve dyes and paints etc.

- Development trends

The Danish proposal for EU regulation of four phthalates includes a brief description of development trends (Danish EPA, 2011).

In Europe and the US, use of the low-molecular-weight phthalates has gone down slightly in recent years, and these phthalates now constitute 10-20% of the total use of phthalates. However, this downward trend is not seen at global level, and the use is still very high in Asia, where DEHP accounts for more than 50% of the total use of phthalates. This means that quite a lot of products with contents of e.g. DEHP are being imported into the EU.

However, there is only very limited data available on the use of individual phthalates worldwide (apart from DEHP, DBP, BBP, DIBP and DINP/DIDP). The use of DINP is increasing, not least because it can be used to replace DEHP without greater costs or changes to production. It is recognised that the development of the alternatives when introduced to the market has been supported by industry who according to ECPI over a 30 years period has invested over 2 billion Euros to meet the demand. Within the EU, according to the industry, DINP/DIDP/DPHP have become the dominant phthalates, accounting for approximately 70% of the plasticisers used.

The specific use of other phthalates is only known to a very limited extent, globally as well as in the EU level and Denmark. Since the use does not cover imports of substances in products from e.g. Asia, and since we know even less about these imports than about use in the EU and Denmark, our knowledge about the possible exposure from the different phthalates is very incomplete.

The registration process under REACH will provide knowledge about current and expected production, export and import of the substances to the EU. The deadline for which this information must be available depends on the volume produced/imported. The most common substances, with imports/production above 1,000 tonnes annually (and for CMR substances > 1 tonne), were registered in 2010. These include the four low-molecular-weight phthalates (DEHP, DBP, DIBP and BBP), as well as DINP and DIDP. Phthalates with imports/production above 100 tonnes annually must be registered in 2013, while substances that are produced or imported at quantities above 1 tonne need not be registered until 2018.

There will be no information about the total quantity in products imported into the EU, and, as mentioned above, there are large imports of PVC products from Asia.

As expected, large imports of products are taking place from Asia, in particular, and mainly from China. Even for products such as flooring, these imports are above 20-30% at EU level, however the picture may be somewhat different for the Danish market. For some product categories, the EU

market contains almost only imported products. Unfortunately, however, no information is readily available about the Danish market.

Recent years' Danish EPA surveys of the different consumer products have included analyses for phthalates. The results confirm that phthalates are present in a large number of different products, including, not least, products from Asia. A brief review of selected results is in Table 5 below. Data is from the Danish EPA database of chemical substances in consumer products (http://www.mst.dk/Virksomhed_og_myndighed/Kemikalier/Stoflister+og+databaser/Database_forbrugerprodukter/).

Table 5 Products containing phthalates.

Substance name	Selected products/product groups
DINP	Sex toys Lamination material Packaging for cosmetic products Erasers Swords and masks for role playing Pet toys Floor puzzles Sealants/fillers Christmas decorations Bath mats
DIDP	Swords for role playing Sealants/fillers Ear plugs
DMP	Swords for role playing Wooden toys Fluorescent products
DEP	Skin glue (role playing) Essential oils Perfumes in toys etc. Televisions Animal care products Incense Ear plugs Soap packaging
DEHP	Shower curtains Vinyl flooring Sex toys Textiles Gloves Lamination material Vinyl wallpaper Bags Air mattresses Swimming equipment etc.

Substance name	Selected products/product groups
BBP	Ear plugs Gloves Bags
DBP	Vinyl flooring Plastic tube beads Erasers Animal care products Ear plugs Plastic sandals Furniture
DIBP	Footwear Flooring Furniture Shower curtains Gymnastics balls Bags Swimming equipment

In addition to the above, other phthalates have been found in small quantities in a number of products. These include the phthalates DNPP, DCP and DNHP. The overall impression is that the phthalates mentioned in the table are clearly dominant and that the phthalates DEHP, DINP and DIDP are most widespread. This concurs with the information available on the use of phthalates on the global market. Studies have analysed primarily for the phthalates DEHP, DINP and DIDP.

It can be concluded that phthalates are being used in a large number of very different products. It should also be noted that some phthalates are more suited as plasticisers in PVC than others, while other phthalates are the best choice in chemical products, such as glue. Not all phthalates are equally suitable for the very broad applications. Some phthalates, such as DINP, can be used in many types of product, while other phthalates, such as DIDP, can only be used in more specific products.

5.1 Phthalates in medical devices

An initiative is in progress under the Danish EPA to prepare a list of medical devices that do not contain any of the phthalates that are subject to compulsory labelling. This list is evidence that phthalate-free medical devices exist to a certain extent. The list is available on the Danish EPA website. The purpose of the list is to serve as inspiration for procurement officers in local and regional governments, providing them with the possibility to buy medical devices on an informed basis. The list can also serve as inspiration for private hospitals and other stakeholders.

The most commonly used phthalate for softening PVC in medical devices is DEHP. It is not known to which extent other phthalates are being used in medical devices. Similarly, there is a lack of knowledge about alternatives to medical devices containing phthalates, which are also safe and effective in the treatment of patients and which do not have any adverse effects on humans and the environment.

The Ministry of Health has acted on this lack of knowledge about the use of certain types of phthalates in medical devices, and possible alternatives, by establishing a working group on medical devices under the Danish Health and Medicines Authority. This working group includes representatives from Danish Patients, the Danish Consumer Council, the Secretariat for the Organisation of Danish Medical Societies, Medicoindustrien (medical devices industry association),

Danish Regions, Local Government Denmark and the Danish EPA. The working group has addressed phthalates as its first area of focus and its ambition is to ensure individual or joint initiatives that further reduce the use of phthalate-containing medical devices in the Danish healthcare sector. The working group will from Summer 2013 be replaced by the broader Standing Committee on Medical Devices which in Spring 2013 was formed by the Danish Minister for Health and is to be chaired by the Danish Health and Medicines Authority.

Medical devices are covered by the EU Treaty's rules on the free movement of goods (Articles 34 to 36). More detailed regulations on requirements for medical devices have been set out in the Medical Devices Directive (Directive 93/42/EEC). According to this Directive, Member States may not prevent medical devices from being placed on the market and put into service within their area if the medical device bears CE marking that indicates it has been subject to a conformity assesssment pursuant to the rules of the Directive. Medical devices may only be placed on the market and put into service if they meet the requirements for safety and performance set out in the Directive. Thus, it is implicit that Member States may not prevent the placing on the market or putting into service of medical devices which meet the requirements of the Directive. There is no ban on the use of phthalates in medical devices in the EU.

It is therefore not possible to introduce a general ban on certain types of phthalates in medical devices, in Denmark, as this would be in conflict with EU law.

As stated under 3.3.5 above, EU regulations require that the device itself, or the packaging for each unit, is marked so that it is evident which phthalates are contained within the product. This labelling requirement applies to products which are used to administer and/or remove medicine, body fluids or other substances to or from the body, or devices intended for transport and storage of these body fluids or substances, and if the device contains specific phthalates (e.g. DEHP, DBP, DIBP and BBP) which are classified as carcinogenic, mutagenic or toxic to reproduction.

Thus, phthalates in medical devices are also in focus at EU level. In August 2012, the European Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to re-assess the safety aspects of phthalates used in medical devices. SCENIHR is to assess e.g. whether the phthalate DEHP poses a risk to certain patient groups and to propose possible alternatives to DEHP in medical devices. This work is expected to be completed by October or November 2013.

SCENIHR has previously assessed the risks of using phthalates in medical devices. In a report from 2008, SCENIHR concluded that, at the time, there was no conclusive documentation that exposure to phthalates of the DEHP type via medical devices has adverse effects on humans, but that additional studies were required in order to confirm or reject this.

In November 2012, the Ministry of Health encouraged the European Commission to consider having the SCENIHR study include an additional five phthalates suspected of having endocrine disrupting effects, that is the phthalates DBP, DIBP, BBP, DMEP and DPP. The Ministry of Health also encouraged the European Commission to share any knowledge about possibilities and barriers using phthalate-free medical devices with the competent authorities of EU countries.

In September 2012, the European Commission presented a proposal for a revision of the EU medical devices legislation (two new regulations on medical devices and in vitro diagnostic medical devices, respectively). The proposed regulation on medical devices includes a proposal to extend the obligation to label certain products that contain phthalates. In negotiations the Ministry of Health will focus generally on the issue of the use of phthalates in medical devices.

See 3.4.3 above on medical devices in a green public procurement context.

5.2 Phthalates in medicines

Phthalates are used in medicinal products chiefly as excipients in enteric-coated capsules/tablets where they make sure the medicinal product itself is not released until the capsule has passed through the highly acidic environment of the stomach. Furthermore, phthalates can be used to protect the active substance in medicinal products against humidity, ensure the flexibility of a capsule or tablet (so that it will not break) or cover up the smell or taste of the product.

The following phthalates are the most widely used in medicinal products: diethyl phthalate (DEP), cellulose acetate phthalate (CAP), hydroxypropyl methyl cellulose acetate phthalate, dibutyl phthalate (DBP) and polyvinyl acetate phthalate (PVAP). For medicinal products, it is only acceptable to use an excipient associated with CMR findings, if the toxicological effects seen in animals do not apply to humans (e.g. species-specific effects, very large safety margin), or if the benefits outweigh the risks associated with use of the medicinal product in question. It is well-documented that DBP has toxic effects on reproduction and prenatal and postnatal development in animals. As it cannot be ruled out that these findings have clinical relevance, the European Medicines Agency (EMA) is in the process of preparing limits for the use of DBP in medicines. Furthermore, the Agency will probably also establish limits for the use of DEP and PVAP in medicines.

5.3 Recommendations

Phthalates are present in many different PVC products; it is a market prone to regular change and new (types of) articles are introduced on a regular basis. Therefore, there is need for systematic and regular testing for phthalates in PVC products in the Danish market. Such testing could also help provide information about the use of alternatives to phthalates.

In the area of medicines, the European Medicines Agency's ongoing work should be backed, see 5.2.

With regard to medical devices, as mentioned in 5.1 above, a general picture is needed of the use of the different types of phthalates in medical devices and of possible alternatives. This should be acquired through dialogue and information sharing with the European Commission, the competent authorities of other EU countries and Standing Committee on Medical Devices charied by the Danish Health and Medicines Authority. At EU level, the ongoing negotiations on a new set of rules for medical devices should be exploited to introduce to the European agenda the issue of phthalates and their reduction in medical devices. The SCENIHR report, expected to be issued in October or November 2013, could help in achieving this. The goal is therefore concrete initiatives to continue reducing the use of phthalate-containing medical devices in the Danish healthcare sector, without otherwise compromising patient safety and treatment.

6. Health assessment of phthalates

6.1 Effects of phthalates

For many years, phthalates have been suspected of having endocrine disrupting effects. For several years, the phthalates DEHP, DBP, DIBP and BBP have been hazard classified as toxic to reproduction, and animal studies have now shown that the endocrine disrupting properties of these phthalates are what causes the damage to reproduction. These phthalates are among the most thoroughly documented, however other phthalates have also been hazard classified as toxic to reproduction (table 3), even though the evidence base for the health effects of these substances is not as extensive.

The information on health assessement of phthalates described in this section is generally based on the previous work by the Danish EPA with respect to phthalates, and in particular the work on the restriction proposal for 4 phthalates. Reference is therefore made to the reference “Danish EPA, 2011”, unless otherwise stated.

An endocrine disrupting chemical is defined by WHO/IPCS as an ‘exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub) populations.’ When assessing chemicals One of the aims of the strategy is, among other things, to gain more knowledge about the potential of the different chemicals of the group of phthalates to either cause endocrine disrupting effects or affect the endocrine system. The difference in these types of effect will be assessed in the assessment of the individual phthalates.
Many phthalates have no hazard classification. This is because they have not been assessed with a view to determe whether they meet the criteria for classification; because there is not enough data about their effects; or because they do not meet the criteria for classification.

Some phthalates also have other adverse effects than endocrine disruption. For example, DAP is classified as acutely toxic and the EU risk assessment of DINP is initially based on this phthalate's critical effect on the liver.

In general, the adverse health effects of some phthalates are well-documented, whereas other phthalates have not been as thoroughly documented with regard to their health effects.

Annex 1: includes a table of phthalates which are registered, classified, on the Candidate List or on the EU list of potential endocrine disruptors. The table indicates where to find literature on the health effects of these phthalates. All phthalates that have been given a hazard classification for their health effects, exept DAP, have been classified as toxic to reproduction, which can often be attributed to their anti-androgenic effects. These effects can be tested for in an OECD two-generation reproduction toxicity study (TG416), and recently in the OECD extended one-generation reproduction toxicity study (TG443) which includes more endocrine sensitive endpoints. The effects are often related to an endocrine disrupting mode of action, and the more knowledge is obtained in general about the mode of action and effects of endocrine disruptors, the more knowledge will be available about the endocrine disrupting effects of phthalates, including an indication of whether

they affect other hormone-sensitive endpoints and, thus, whether they cause other (types of) effects than those about which knowledge is available today.. The EU strategy on endocrine disruption (Community Strategy for Endocrine Disruptors) is currently being revised and is expected to be available in the upcoming years.

The EU has yet to set up criteria for when a substance is to be considered an endocrine disruptor, and, today, management of endocrine disruptors in a regulation context is therefore only possible through case-by-case assessment of the endocrine disrupting effects of individual substances. The European Commission is expected to submit a proposal for horizontal criteria for endocrine disruptors by no later than December 2013.

6.2 Combination effects

Normally, risk assessment is based on exposure from a single substance and often only for one use at a time. However, we are exposed to many different products daily, of which several contain either the same chemical substances or substances that may have the same toxicological effect. Combination effects, or cocktail effects as they are also called, occur when a subject is affected by several different chemical substances, and these effects are exhibited in many different ways. However, combination effects often denote a situation in which exposure to small quantities of several substances together causes undesired effects that do not occur from exposures to the substances individually at the same doses.

An increasing number of studies highlight the necessity of taking simultaneous exposure to several substances with the same mode of action into account when assessing the risk of e.g. endocrine disruptors, and that combination effects of chemical substances with the same mode of action must be included in risk assessment.

In risk assessment of chemical substances, human exposure to a single substance is normally compared to a so-called zero-effect level. The zero-effect level is the highest dose of the substance which has not given rise to adverse effects in animal studies. The risk assessment is usually performed for one substance at a time.

A series of calculation methods has been developed to predict what will happen when a test animal is exposed simultaneously to several substances. One of these methods is based on the concept of dose addition, which has been applied and described in detail in the Danish proposal for restrictions on the phthalates DEHP, DBP, BBP and DIBP under REACH. These four phthalates all show evidence of anti-androgenic effects in animal studies (Danish EPA, 2011). In this proposal for restrictions, the contributions from the various sources of exposure are added up for all four phthalates to a single, combined exposure for the four phthalates.

6.2.1 Dose addition

The concept of dose addition is well established and is the recommended method in risk assessment for taking account of combination effects of chemical substances with the same mode of action (Kortenkamp and Hass 2009).

Dose addition can be applied if a group of substances have the same mode of action in the organism, e.g. affect the same organ. Dose addition prerequires that all simultaneous occurrences of several substances (with the same mode of action) can give an effect corresponding to an increased dose of the individual substance. This same model can be applied in risk assessment of chemical substances' significance for health effects in humans. In this context, mode of action should be understood broadly as a number of cellular or biochemical events that may differ from substance to substance but which lead to the same type of effect in animals or humans.

Combination effects of phthalates and other anti-androgenic substances can be calculated by applying the concept of dose addition (Danish EPA, 2011) in a modified version of the Hazard Index (HI) method. In general, this method can be described by the following formula:

$$HI = \sum_{I=1}^{n} ELi/ALi$$

Where EL is exposure level and AL acceptable level. In this case, DNEL is used as the acceptable level, and the the fraction EL/AL thereby corresponds to the calculated RCR for each substance. This method makes it possible to use specific uncertainty factors for the individual substances, which is advantageous when DNEL for the individual substance is based on different types of animal study.

The total, i.e. additive, risk is thus calculated by adding the individual substances' RCR values together:

$$RCR_{Total} = RCR_1 + RCR_2 + RCR_3 + ... + RCR_n$$

RCR_{Total} is therefore an expression of the total (cumulative) risk to which the human body is exposed when exposed to the entire group of suspected endocrine disruptors, with e.g. anti-androgenic effects included in the calculation.

6.2.2 Recommendations for use of dose addition

There is scientific evidence for and agreement among authorities and experts that chemical substances with the same type of effects (including anti-androgenic, estrogenic and thyroid endocrine disrupting effects) can cause combination effects which can be predicted using the concept of dose addition.

In January 2009, the Danish EPA hosted an international experts workshop on combination effects of chemicals with special focus on endocrine disruptors and regulatory aspects. At this workshop, the existing knowledge about combination effects of chemical substances, including large EU-funded research projects, was assessed with special emphasis on endocrine disruptors.

The workshop concluded that the concept of dose addition can generally be recommended until possible better alternatives become available; and that grouping criteria should focus on the same type of effects and or modes of action and the likelihood of combination exposure. The workshop also concluded that it is already both possible and necessary to take account of combination effects when carrying out risk assessments of chemicals, in order not to underestimate the total risk(Kortenkamp and Hass, 2009.).

In 2012, three EU scientific committees (SCHER, SCENIHR and SCCS - Opinion on Toxicity and Assessment of Chemical Mixtures (1 February 2012)) put forward a joint opinion about the risk associated with chemical mixtures. In this opinion, they conclude e.g. that there is scientific evidence that exposure to several substances simultaneously may affect the total toxicity and that the current risk assessment paradigm does not sufficiently take account of this change in total toxicity. The scientific committees emphasise that the concept of dose addition should be used in order to take account of the total toxicity; that dose addition is the recommended method for estimating combination effects both for substances with the same mode of action and for substances the mode of action of which is unknown, and that any amendment of current legislation to take account of combination effects will improve the level of protection for the public and the environment.

The European Commission [4] also recognises that, today, chemical risk assessments do not take sufficient account of combination effects underlines the importance of a horizontal legislative approach. On the basis of the Council conclusions on combination effects of chemicals from December 2009 and the opinion of the three scientific committees from 2012, in June 2012, the European Commission submitted a Communication which 1) calls attention to limitations in the existing legislation with regard to the assessment of combination effects; 2) specifies a method for how combination effects can be assessed; and 3) outlines new initiatives to ensure that assessment of combination effects is included to a greater extent in chemical risk assessments within current legislation. In the Commission press release regarding the Communication, the Commission includes a reference to a Danish study of the exposure of toddlers (two-year-olds) to endocrine disruptors.

In practice, the Danish EPA has used the concept of dose addition in a cumulative risk assessment of the total exposure of two-year-olds to chemical substances (2009); in a cumulative risk assessment of pregnant women's exposure to suspected endocrine disruptors (2012); and in its proposal for restrictions on four phthalates (2012) (Annex VX dossiers for DEHP, DBP, BBP, and DIBP). In all of these projects, for selected scenarios, the cumulative risk assessment combination effects showed that combination effects posed an unacceptable health risk.

At present, knowledge is still unavailable as to possible combination effects from exposure to e.g. anti-androgens and estrogens simultaneously. More information on whether a combined effect from simultaneous exposure to anti-androgens and estrogens due to changes in the sex-hormone balance caused by anti-androgens as well as estrogens, could affect reproduction would be valuable.

It is possible, that chemicals that impact the sex hormone balance should in future be included in a cumulative risk assessment.

6.3 Using biomonitoring data

For ethical and scientific reasons, the regulation of chemicals is normally based on data obtained from animal testing. In a few cases regulation is solely based on the effects seen in humans, e.g. in cases of poisoning. Data from studies involving human beings, e.g. biomonitoring studies, can contribute new knowledge about the impacts of exposure to specific chemicals, however such studies are not needed in order to be able to regulate chemical substances. Moreover, biomonitoring studies have proven to have several limitations, as biomonitoring data for e.g. phthalates is subject to some uncertainty due to the rapid breakdown of phthalates in the human body, and therefore such data only offers a snapshot picture of dosage levels. Furthermore, human biomonitoring studies are resource-demanding, and as the number of test subjects is often limited, results do not always give a fair representation of the highest exposure to which a given part of a population has been exposed.

Both within the EU and at international level, focus is on carrying out biomonitoring studies on human beings with a view to gaining insight into the exposures of chemical substances on human populations. In recent years, the Danish EPA has increased its funding to biomonitoring studies, both with regard to Arctic, European and national projects, and the findings from these studies are published regularly. Human biomonitoring studies can contribute to identifying the level of chemical substances to which populations are exposed.

However, in order to be able to use the findings from these biomonitoring studies in risk assessments, the levels measured must be converted to estimated daily intake. This may prove to be challenging, for example with regard to phthalates, as these substances undergo rapid breakdown in the human body, and because phthalate levels in human beings vary depending on behaviour.

[4] Communication from the Commission to the Council, COM/2012/0252, The combination effects of chemicals, Chemical mixtures.

Moreover, not enough is known about the sources of exposure. With regard to phthalates that are rapidly broken down in the body, biomonitoring data only offers a snapshot picture and does not offer any insight into possible exposure in e.g. the prenatal stage which is thought to have significant impact on development of effects later in life.

In general, biomonitoring studies show that almost all test persons excrete measurable concentrations of phthalates in their urine (Danish EPA, 2011). Recent Danish studies have also shown that there is a correlation between phthalate excretion and age (children have higher excretion rates than adults), however it is difficult to correlate phthalate excretion with specific effect parameters. For example, phthalate excretion is correlated with delayed pubic hair growth in girls, whereas it does not seem to effect the onset of puberty in boys (Mieritz et al. 2012; Frederiksen et al. 2012). There are still many unresolved questions about the effects of phthalates on the level of male sex hormones (the androgen level) in human beings.

New data indicate a close correlation in phthalate exposure between mothers and their children and that persons being highly exposed to one phthalate also is likely to be highly exposed to other phthalates (Frederiksen et al., 2013) making high-end exposure estimates relevant in cumulative assessments.

All in all it can be concluded that biomonitoring studies can contribute with valuable knowledge about exposure to these substances. However, animal testing that identifies at which levels effects are seen are still needed to support regulatory initiatives in order to fully prevent adverse health effects in human beings.

6.4 Exposure and risk

Human beings are exposed to phthalates when, for example, they touch products that contain phthalates. Phthalates can be extracted via sweat or saliva and can be absorbed via the skin or orally if the product is placed in the mouth. Furthermore, phthalates can be transferred via dust particles, thus entailing risk of exposure when dust is inhaled or consumed.

As phthalates constitute a large group of many different substances, there are variations in the levels transferred to the surroundings (air, dust, saliva, sweat, etc.). Overall, low-molecular-weight phthalates are transferred more easily than high-molecular-weight phthalates, as high-molecular-weight phthalates have a higher boiling point and thus have a lower evaporation rate at indoor temperatures.

Several assessments have been made of which sources cause the greatest exposure to phthalates, and whether these sources constitute a risk. Most of these assessments are based on exposure to a single phthalate from a single source, and in most cases they disregard the cumulative exposure to phthalates. Exposure to phthalates and other substances is determined by calculating the overall exposure and collating this with the hazardous effect of the specific substance (its intrinsic properties). Exposure is calculated on the basis of a number of assumptions, including how a product is used, whether exposure is oral, through the skin or airways, how long exposure lasts, user age group etc. The results of an exposure assessment and the associated risk assessment are therefore always open for debate. Most often, a worst-case calculation is done first. If this calculation shows that concerns are unfounded, there is no reason to progress with additional calculations. On the other hand, if the worst case calculation gives reason for concern, the parameters used are refined in order to assess whether there is still reason to be concerned. That is, a risk assessment does not always provide a clear and unambiguous answer.

6.4.1 EU risk assessments of DEHP, DBP, BBP, DINP and DIDP

Risk assessments of the phthalates DEHP, DBP, BBP, DINP and DIDP have been made in the EU. The risk assessment for DEHP concluded that there was reason for concern with regard to

children's oral exposure to phthalates in toys and childcare articles as well as in cases where children and premature infants receive blood transfusions over a longer period of time. This concern regarding exposure to DEHP from toys and childcare articles has led to the introduction of limit values in the REACH Regulation (see section 3.3.2). The EU risk assessments for DBP, BBP, DINP and DNOP showed that the level of exposure to these substances did not give rise to concern. However, these EU risk assessments did not assess possible exposure to other phthalates with the same mode of action. That is, only exposure to a single phthalate at a time was included in each assessment. The use of these phthalates in toys and childcare articles is, however, regulated in the REACH Regulation (see section 3.3.2).

6.4.2 ECHA review of DEHP, DBP, BBP, DINP, DIDP and DNOP (July 2010)

In 2009 the European Commission asked ECHA to review the new available data on these phthalates and to appraise whether further restrictions on their use were required for areas that were not already covered by the REACH Regulation.

All six reports conclude that legal use of these substances does not entail a risk to human health. Moreover, the reports conclude that any final decisions regarding whether the restrictions on the use of these substances as laid down in the REACH Regulation are still well-founded should not be made until registration dossiers for these substances have been submitted.

6.4.3 ECHA draft review of DINP and DIDP

At the end of 2010 the European Commission asked ECHA to assess whether the information from the registration dossiers submitted for the six phthalates offered cause to reassess the restrictions on these substances. The objective was to assess whether the review reports from July 2010 should be amended.

As three of the six phthalates were already included in the Danish restriction proposal, ECHA was only asked to review the remaining three non-classified phthalates (DINP, DIDP and DNOP). However, no registration dossier including new information since the July 2010 report had been submitted for DNOP. Therefore ECHA has prepared a draft for a new report for DINP and DIDP.

The ECHA report assesses what the exposure to DINP and DIDP would be if use of these two phthalates were not restricted under REACH. The report concludes that there would be a risk of damage to the liver in children under the age of one if there were no restrictions on the use of these two phthalates. On the other hand, the report concludes that there is no risk involved for older children with regard to oral exposure to erasers that contain DINP or DIDP. With regard to adults, the report concludes that there may be a risk of adverse health effects involved in using sex toys that contain DINP and DIDP, however the assessment is subject to some uncertainty, and new data is needed to reduce these uncertainties. The ECHA report concludes that the current ban in the REACH Regulation on the use of DINP and DIDP is well-founded, and that if there were no ban, this would entail a risk of adverse health effects in children younger than one year old.

The ECHA report on DINP and DIDP only assesses the liver effects in cases where the lowest concentration that gives rise to an adverse health effect is present. Further, the report concludes: "DINP causes low incidences of similar permanent effects observed in with other phthalates likely via same modes of action including androgen deficiency" and "DINP has anti-androgenic properties and it could be appropriate to include this substance in a combined risk assessment of phthalates with anti-androgenic properties. DIDP, on the other hand, does not have similar properties/potency and it would not be justified to group DIDP in a combined risk assessment of phthalates on the basis of anti-androgenic properties". Furthermore, the report indicates that both DINP and DIDP have weak effects on the thyroid(iodine uptake) (ECHA, 2012g).

The report does not further address combined risk assessment of phthalates with anti-androgenic properties.

The ECHA report has been subject to public consultation and has been reviewed by the Risk Assessment Committee (RAC). In March 2012 RAC concluded that a health risk could not be excluded if children have oral contact with DINP/DIDP containing products and the current restrictions were lifted.

6.4.4 Exposure to phthalates from more than one source

The Danish EPA has assessed the risk for 2-year-olds, 6/7-year-olds, adults and pregnant women when exposed to a number of phthalates (Danish EPA, 2009; Danish EPA 2012; Danish EPA 2011). The assessment was based on phthalates that have anti-androgenic effects, and the total risk of exposure to all of these phthalates has been calculated for the different groups.

The assessments include exposure to a number of specific phthalates found indoors, in food and in consumer products. However, there may also be other sources of exposure to phthalates, e.g. from medicinal products and medical devices. This exposure has not been included in the calculations.

The assessments show that when calculating the risk of health effects in 2-year-olds, 6/7-year-olds and adults, there do not seem to be any effects when considering combined exposure to the four phthalates DEHP, DBP, BBP and DIBP from consumer products, the indoor climate and foodstuffs in realistic scenarios (an average scenario). A rather high exposure level was calculated for 6/7-year olds for consumer products in the realistic worst-case scenario. This level was based on the assumption that a 6/7-year-old consumes 8 mg eraser every day (corresponding to the weight of 2-3 sesame seeds daily), and this leads to a high exposure level. Assessment of consumer products shows that exposure to phthalates and the risk of adverse health effects are closely linked to which product is used. Several studies show that there are many products on the market that contain phthalates, and this means that some consumers have a high risk of exposure to these phthalates.

The risk characterisation ratio (RCR) has been calculated for the four phthalates found in consumer products, foodstuffs and the indoor climate in a realistic scenario and a realistic worst-case scenario. A realistic scenario includes the expected exposure for an average person, whereas a worst-case scenario includes the expected exposure for fewer, but individual persons, because of their use of the products. RCR values higher than 1 mean that the risk of adverse health effects is not adequately controlled. Table 6 shows the RCR values for combined exposure to the four phthalates from consumer products, the indoor climate and foodstuffs.

Table 6 RCR values for combined exposure to DEHP, DBP, BBP and DIBP from consumer products, indoor climate and foodstuffs

Age	RCR realistic scenario	RCR realistic worst-case scenario
2-year-olds	0.63	1.36
6/7-year-olds	0.88	6.25
Adults	0.19	1.14

As seen in Table 6, the risk is not adequately controlled for several age groups in the realistic worst-case scenario. Calculations show that some consumers will suffer exposure to too high concentrations of these four phthalates, as they have the same effect in the human body. If these combination effects are not included in the calculation, only the exposure of 6/7-year-olds to erasers poses a risk in itself. With regard to the remaining exposure factors, there is no risk with regard to the individual exposure factor or exposure to consumer products, the indoor climate or

foodstuffs. That is, the conclusions of the risk assessments can be changed if the combination effects are taken into account when the substances have the same effects on the body, as is the case for the four phthalates DEHP, DBP, DIBP and BBP. Therefore, risk assessments of phthalates that have the same effect should include combination effects.

The exposure of pregnant women to phthalates that have the same effect has also been calculated. Here exposure is calculated for consumer products, the indoor climate and foodstuffs. Seven phthalates with anti-androgenic effects (DEHP, DINP, DBP, DIBP, BBP, DPP and DNHP) were assessed. Total exposure to these seven phthalates is not great enough to give rise to concern with regard to pregnant women or the foetus in a realistic scenario or a realistic worst-case scenario. However, the RCR value increases from 0.2 in a realistic scenario to 0.63 in a realistic worst-case scenario. To this should be added the fact that there is risk of exposure to other substances that have the same effect. If a pregnant woman wears sandals that contain phthalates throughout an entire summer, there is a risk that she will be exposed to adverse health effects corresponding to the realistic worst-case scenario.

6.4.5 Results from biomonitoring

Biomonitoring studies can also be used to give a picture of the exposure to chemical substances. However there are some limitations when using the results from these studies, see section 6.3. Biomonitoring data was included in the calculation of the exposure to phthalates of 2-year-olds,6/7-year-olds, adults and pregnant women. There are not very many biomonitoring studies available for 2-year-olds, however, there are several studies available for slightly older children (approx. age seven). Table 7 shows the results of RCR calculations that are based on several studies covering various numbers of individuals. The results show that some children and adults are exposed to concentrations of phthalates that are so high that the risk is not adequately controlled. For pregnant women, biomonitoring studies show that exposure is not so high as to pose a risk of adverse health effects. This also applies to individuals who have the highest exposure.

Table 7 RCR values based on biomonitoring data as the sum of DEHP, DBP, DIBP and BBP.

	RCR average	RCR max
Children	0.43	1.59
Adults	0.39	1.23
Pregnant women	0.03	0.32

6.5 Recommendations

The adverse health effects of some phthalates (including phthalates with a hazard classification) are related to an endocrine-disrupting mode of action. When common EU criteria for endocrine disruptors become available, the phthalates in use that are not classified as being toxic to reproduction, should be assessed according to the EU criteria.

Internationally, there is focus on the importance of including the combined effects of chemicals that have the same mode of action in risk assessments of chemicals in order not to underestimate the total risk. Thus risk assessments of phthalates with anti-androgenic effects should include combination effects, and the concept of dose addition should form the basis of a cumulative risk assessment where all known contributions from all anti-androgenic phthalates are included. As we learn more about the endocrine disrupting effects of phthalates, it should also be considered whether it would be relevant to include other hormone-mediated effect parameters in a cumulative risk assessment. Biomonitoring studies may contribute to elucidating the exposure of the population to phthalates, however they do not provide the same knowledge about the effects and

the doses required to observe these effects, as can be obtained through animal studies. This is one of the reasons why animal studies are needed when assessing the need for regulatory measures.

7. Environmental impact assessment of phthalates

The Danish dossier concerning proposals for banning the four phthalates (DEHP, BBP, DBP and DIBP) includes a review of the environmental effects of these four substances as well as the most commonly used alternative, DINP (Danish EPA, 2011). The most important parameters are presented in Table 8 below.

It should be noted that little is known about the environmental effects of other phthalates. The registration process in the REACH Regulation includes important data, however the timing of the provision of this data depends on the tonnage produced/imported to the EU.

Table 8 Environmental properties of five phthalates (taken from the Danish proposal on restrictions on 4 phthalates)

Substance name	Environment			Ecotoxicity		
	Biodegradability	Bioaccumulation	Mobility	Fish	Crustaceans	Algae
DEHP	Moderate to low	Log KOW 7.5 BCF 2700	KOC 5.2 (estimated)	No effects at the solubility limit NOEC: 160 (mg/kg food (wwt)	No effects at the solubility limit NOEC: ND	No effects at the solubility limit NOEC: 1 mg/l
BBP	Readily	Log KOW 4.8 BCF 135-663 l/kg	KOC 10,500	LC50 0.51mg/L NOEC 0.14 mg/l	LC50 0.9mg/L NOEC 0.075 mg/L	EC50 0.64 mg/L NOEC/EC10 0.15 mg/l
DBP	Readily	Log KOW 4.6 BCF 1.8 l/kg (measured)	KOC 6.3 (estimated)	LC50(96) 0.4-3 (7,3) mg/L NOEC 0.1 mg/L	LC50 0.8 mg/L NOEC > 0.1 mg/L	ErC10 0.2 mg/L growth NOEC: ND

DIBP	No data	Log KOW 4.5 BCF 800 calculated	No data	LC50(96) 2.5-3.6	LC50 0.7-1.1 mg/L	EC50 (72 h) 1 mg/L NOEC 0.2 mg/L
DINP	Readily	BCF = 800-4000	KOC = 111,000-611,000 "very low mobility in soil"	No effects demonstrated for aquatic organisms at solubility limit.		

Of the five phthalates, BBP is classified as having acute and chronic toxicity in the aquatic environment, whereas DBP and DIPB are classified as having acute toxicity in the aquatic environment. None of the five phthalates can be categorised as having PBT or vPvB properties.

There is so little existing data for terrestrial organisms that an assessment is not possible.

As is seen in the table, both DEHP and DINP do not exhibit ecotoxicological effects at their solubility limit. The other three phthalates, DBB, DIBP and BBP, all demonstrate an effect on one or more of the test organisms at concentrations < 1 mg/l.

7.1 Recommendations

With the exception of the most commonly used phthalates, there is little available data and especially overviews on the environmental effects of phthalates. This is why public access to this kind of data is needed, with priority for the most commonly used phthalates in addition to the four phthalates that are already banned in Denmark (DEHP, DBP, BBP and DIBP). There is already some data available in the registration dossiers; it must be clarified whether this data can be made public and how this task should be approached.

8. Review of alternative substances

In 2010 the Danish EPA prepared a report about plasticisers that can be used as alternatives to the phthalates DEHP, DBP and BBP (Identification and assessment of alternatives to selected phthalates, Danish EPA 2010). As these phthalates are used for many diverse purposes, we assume that alternatives to these three phthalates can substitute most uses of phthalates.

Several of the possible alternatives have not been reviewed in this report. This is primarily due to lack of data or because the classification of a possible alternative renders it unsuitable for use, as it is assessed to constitute a risk. Moreover, use of these substances is limited and they can be replaced by other alternatives.

Alternative plasticisers have been identified to replace phthalates in most cases. Ten of the alternatives have undergone detailed assessment. Several of the alternatives assessed can be used in many areas of application, whereas others are more specialised.

Alternative non-phthalate plasticisers that can replace DEHP, most importantly the plasticisers DINA, DINCH, DEHT, ATBC and ASE, have been placed on the market at prices that range from being slightly higher to being significantly higher than the price of DEHP. Furthermore the assessment also shows that alternatives to DBP and BBP can be used in most cases where these substances are normally used and at a price that is very similar to the price of the actual phthalates.

Based on a number of animal studies, all of the substances assessed are expected to demonstrate low acute toxicity. For three of the alternatives assessed, data shows that these substances are not carcinogenic, mutagenic or harmful to reproductive capacity. Data regarding at least one of the the critical parameters is lacking for the remaining alternatives.

The toxicological data for DEGD (DEGDB) and DGB (DPGDB), two of the available alternatives to DBP and BBP used in polymers (plastics), indicates that these substances may have an effect on reproductive capacity, however these results are not statistically significant, and more data is needed to draw a clear conclusion.

As for their environmental properties, none of the ten alternatives examined have an environmental classification that complies with the criteria for PBT substances (persistent, bioaccumulative and toxic in the aquatic environment), or vPvB substances (very persistent and very bioaccumulative), although all of the substances, bar GTA, exhibit one or two of these properties.

See Table 9 below for a more detailed account of their effects on the environment and human health.

Table 9 Environmental effects of selected alternatives to phthalates (taken from the Danish proposal for restricting 4 phthalates)

Substance name	Environmental properties			Ecotoxicology		
	Biodegradability	Bioaccumulation	Mobility	Fish	Crustaceans	Algae
ASE CAS no. 91082-17-6	Not readily biodegradable (31% over 28 d)	Log K_{OW} >6	ND (log K_{OW} indicates low mobility)	LC_{50} (96 h) >100 mg/L	EC_{50} (48 h) >1,000 mg/L	EC50 (72 h) >10 mg/l
ATBC CAS no. 77-90-7	Readily biodegradable	BCF = 250 (calculated)	K_{OC} = 1,800 (estimated)	LC_{50} (48 h) = 2.8 mg/L LC_{50} (168 h) = 1.9 mg/L	EC_{50} (48 h) = 7.82 mg/L	EC50 (96 h) = 0.148 mg/L (calculated)
COMGHA CAS no. 736.150-63-3	Readily biodegradable	Log K_{OW} = 6.4	"Non-mobile in soil"	NOEC(LC_{10}) (96h) = 0.28 mg/L (attributed to a physical effect)	EC_{50} (48 h) = 0.92 mg/L (attributed to a physical effect)	EC_{50} (72 h) = 106 mg/L
DEGD/DEGDB CAS no. 120-55-8	Readily biodegradable	BCF = 120 (calculated)	K_{OC} = 540 (calculated)	LC_{50} (96 h) = 3.9 mg/L	EC_{50} (48 h) = 6.7 mg/L	EC_{50} (72 h) = 11 mg/L
DGD/DPGDB CAS no. 27138-31-4	Readily biodegradable	Log K_{OW} = 3.9	ND	LC_{50} (96 h) = 3.7 mg/L	EC_{50} (48 h) = 19.3 mg/L	EC_{50} (72 h) = 4.9 mg/L NOEC (72 h) = 1.0 mg/L
DEHT/DOTP CAS no. 6422-86-2		BCF = 393	K_{OC} = 2,000	LC_{50} (7 d) > 0.25 mg/L NOEC (71d) ≥ 0.28 mg/L	EC_{50} (48 h) > 1.4 mg/L NOEC (21d) ≥ 0.76 mg/L	EC_{50} (72 h) > 0.86 mg/L

DINA CAS no. 33703-08-1	*Readily biodegradable*	*BCF ≥ 1,100 BCF (calculated)= 3.2*	*ND*	*LC_{50} (96 h) > 500 mg/L (nominal) LC_{50} (96 h) > 2.6 mg/L (measured)*	*EC_{50} (48 h) > 100 mg/L NOEC (21 d) > 100 mg/L*	*EC_{50} (72 h) > 100 mg/L*
DINCH CAS no. 166412-78-8	*Not readily biodegradable (41% over 28 d)*	*BCF = 189*	*ND*	*LC_{50} (96 h) >100 mg/L*	*EC_{50} (48 h) >100 mg/L NOEC (21 d) ≥ 0.021 mg/L*	*EC_{50} (72 h) >100 mg/L NOEC (72 h) ≥100 mg/L*
GTA CAS no. 102-76-1	*Readily biodegradable*	*BCF = 1.3*	*K_{OC} = 10.5*	*LC_{50} (96 h) = 165 mg/L LC_{50} (14 d) > 100 mg/L*	*EC_{50} (48 h) = 380 mg/L NOEC (21d) = 100 mg/L*	*EC_{50} (72 h) > 940 mg/L NOEC (72 h) ≥556 mg/L*
TXIB CAS no. 6846-50-0		*BCF = 5.2-31*	*ND*	*LC_{50} (96 h) = 18 mg/L*	*EC_{50} (48 h) >1.46 mg/L NOEC (14 d) = 3.2 mg/L*	*EC_{50} (72 h) = 8.0 mg/L NOEC = 5.3 mg/L*

Whereas data for bacteria shows that there are no effects at relevant levels of exposure, data for terrestrial animals and plants is so sparse that it is not possible to make a comparison.

The report "Identification and assessment of alternatives to selected phthalates, Danish EPA 2010" includes a comparison of alternatives with the four phthalates (DEHP, DBP, BBP and DIBP) that Denmark banned in autumn 2012 (see chapter 6 for table with relevant data for the four phthalates).

As can be seen in the table above, most of the alternatives (except ASE and DINCH) are readily biodegradable compared with DEHP, which is classified as having low to moderate biodegradability.

The bioaccumulation properties of the alternatives are smaller or the same as those of the four phthalates; however, the majority of alternatives demonstrate significant bioaccumulation.

No ecotoxicological effects for either DEHP or the most commonly used phthalate, DINP, have been established below their solubility point, whereas such effects are seen for some of the alternatives (however, in general only at relatively high concentrations).

The report concludes that compared with the four phthalates, in general the alternatives do not exhibit more harmful effects on the environment than the four phthalates, even though some of them do have negative effects in one or two areas.

The most commonly used phthalates and their alternatives have been compared with regard to their effects on the environment and human health (taking into account the quality of the available data). Table 10 below is taken from the report "Identification and assessment of alternatives to selected phthalates, Danish EPA 2010".

Table 10 Overview of the most significant effects on the environment and human health of alternatives (taken from the Danish proposal for restricting 4 phthalates).

		Health					The environment		
Substance name	CAS N No.	Acute, local and sensitising effects (A/L/S)	Carcinogenic effects (C)	Mutagenic effects (M)	Toxic to the foetus or the reproductive system (R)	Sub-chronic toxicity	Persistence *1	Bioaccumulation *2	Toxicity in aquatic environment *3
ASE	91082-17-6	○/○/○	-	○	○	●	● (Not readily)	● P_{ow}	○
ATBC	77-90-7	○/(○)/○	○	○	○	[●]	○	● BCF	●
COMGHA	330198-91-9	○/○/○	-	○	-	(●)	○	● P_{ow}	●
DEGD/DEGDB	120-55-8	○/(○)/○	-	○	(●)	●	○	(○) BCF	●
DGD/DPGDB	27138-31-4	○/(○)/○	-	○	(●)	●	○	● P_{ow}	●
DEHT / DOTP	6422-86-2	○/(○)/○	○	○	○	●	● (Inherently)	● P_{ow}	(●)
DINA	33703-08-1	○/○/○	-	○	-	●	○	(●) (contradictory)	○
DINCH	166412-78-8	○/(○)/○	○	○	○	●	● (Not readily)	● P_{ow}	○
GTA	102-76-1	○/○/○	-	○	○	○	○	○	○
TXIB	6846-50-0	○/(○)/○	-	○	●	●	● (Inherently)	○ BCF	●

Notes:

The intrinsic properties of the substances examined were summed up on the basis of the following key parameters: acute and local effects, sensitisation, carcinogenic effects (C), mutagenic effects (M), toxic to the foetus or the reproductive system (R), persistence,

bioaccumulation and and toxicity in the aquatic environment. If data is not available for all of the parameters, or only results from non-standard tests are available, a preliminary assessment has been made (shown in brackets). Symbols: potential hazard found, no potential hazard found, and - no available data. [] indicates that effects are negligible.

*1 Terms refer to different biodegradability tests:

"Inherently biodegradable": Does not comply with the criteria in a "inherently biodegradable" test

"Not readily biodegradable": Does not comply with the criteria in a "readily biodegradable" test

*2 is based on BCF > 100 or Pow > 3 (BCF is preferred to Pow when both values are available).

*3 is used for "very toxic" and toxicity < 10 mg/L.

● is based on BCF > 100 or Pow > 3 (BCF prevails over Pow where both values exist).

●● is used for very toxic and toxic < 10 mg/L.

Whether it is technically possible to use alternatives is described in the Danish proposal for a ban on four phthalates (DEHP, DIBP, DBP, BBP). This review is based on alternatives to these four phthalates, however the conditions described cover the general situation as DEHP has been by far the most commonly used phthalate for the past several decades. Today, the most commonly used phthalate is DINP (in the EU), however, as it is used as a direct replacement for DEHP, the present review can more or less be applied when assessing possible alternatives to DINP.

Use of non-phthalates is greatest in the US, where such substances constitute 25-30% of plasticisers, whereas they only constitute 15-20% in the EU according to data from the industry.

It should also be mentioned that DEHP is still the most commonly used plasticiser in PVC in Asia, including in China and Japan.

Below is an excerpt from the Danish phthalate dossier:

The technical descriptions of alternatives to phthalates are based on the manufacturers' assessment of relevant uses and experience from the market, especially from use in toys, food packaging and medicinal products, but also for other end-uses. Some of the alternatives have broad applications, whereas others are more specific. The information is from 2009, so there may be other experience with regard to application in other areas. However, this should be considered in the context of the relatively large quantities used which do not match the very few areas of application (for example, this applies for DINCH and DEHT, which according to industry are the two highest volume non-phthalate plasticisers in EU as of 2012).

The dominance of DEHP and other phthalates of the same type over the years has limited the development and not least the proliferation of alternatives. This is also seen in the proliferation of DINP and DIDP, which are often produced by the same enterprises that produce DEHP. The substances are placed on the market for the same uses, also because their chemical properties are very similar to DEHP, and they are only a little more expensive.

In some cases, a mixture of different alternatives must be used to achieve the same technical properties in the product. However, this is also necessary for many of the phthalates, including DEHP.

Table 11 shows a summary of the technical assessment of plasticiser alternatives in alphabetical order.

Table 11 Technical assessment of plasticiser alternatives (taken from the Danish proposal for restriction on four phthalates).

Substance name	Overall technical assessment
ASE	ASE is a general plasticiser alternative to DEHP. The producer has indicated significant market experience for most traditional DEHP, DBP and BBP uses.
ATBC	The performance of ATBC on some parameters seems similar to DEHP, indicating technical suitability for substitution of DEHP for some applications. The higher extractability in aqueous solutions and the higher volatility may reduce the performance of ATBC as a plasticiser in PVC. The data available does not allow a closer assessment of ATBC's technical suitability as alternative to DEHP, DBP and BBP.
Benxoflex 2088 (with DEGD)	The producer has indicated significant market experience in several of the traditional DBP and BBP specialty plasticiser applications and certain DEHP applications, notably in the non-polymer (adhesives, sealants, etc.) and PVC spread coating (plastisol) application fields. According to the producer, Benzoflex 2088 (with DEGD) has become the main non-phthalate alternative to DBP and BBP in vinyl flooring production in Europe. The higher extractability in water may limit use for some applications.
COMGHA	According to the producer, COMGHA still has relative moderate market experience, albeit with many examples of full scale usage and pilot/lab scale tests, and significant market experience in some plastisol application and cosmetics. The producer found good performance on key technical parameters indicating a potential for substituting for DEHP and perhaps for DBP and BBP in some traditional uses of these substances.
DEHT/DOTP	DEHT is a general plasticiser alternative to DEHP. Today, terephthalates like DEHT are more commonly used in the USA than elsewhere.
DINA	DINA has mostly been used for low temperature PVC applications and in PVC film/wrapping. The data available for this study does not allow clear-cut conclusions as regards DINA's suitability as alternative to DEHP.
DINCH	The producer's sales appraisal indicates a relatively wide usage of DINCH for general plasticiser purposes. DINCH was the most frequently found plasticiser in two European surveys of plasticisers in toys and childcare articles. The data available does not allow a closer assessment of DINCH's technical suitability as alternative to DEHP, DBP and BBP.
DGD/DPGDB	The fact that DGD for many years has been a well known and much used competitor to BBP, especially in PVC flooring and in PVA adhesives, indicates a clear potential for substituting DGD for BBP, from a technical point of view. DGD may probably also substitute for some traditional uses of DEHP and DBP.
GTA	According to a producer, GTA can substitute for DBP and BBP in adhesives, inks and coatings. The data available does not allow a closer assessment of GTA's technical suitability as alternative to DEHP, DBP and BBP.

TXIB	TXIB was found in more than 10% of the samples in surveys of plasticisers in toys and childcare articles. However, the producer does not consider an alternative to DEHP, DBP and BBP, and the usage of TXIB in vinyl flooring has declined in the 1990's due to high emissions from end products. Consequently, TXIB seems not to be a suitable alternative to DEHP, DBP and BBP.

Table 12 below shows a summary of information from producers of plasticisers contacted regarding alternatives to DEHP, BBP and DBP, broken down by application and with an indication of market experience.

Table 12 Summary of information from contacted producers of plasticisers (taken from the Danish proposal for restriction on four phthalates).

Application	Market experience (1 to 4) *1					
	ASE	GTA	DGD	Mix of DGD, DEGD, TGD	ATBC	COMGHA
As substitute for DEHP						
Polymer applications:						
Calendering of film, sheet and coated products	2	2	4	4	3	3
Calendering of flooring, roofing, wall covering	4	2	3	3		3
Extrusion of hose and profile	2	2	3	3	3	3
Extrusion of wire and cable	2	2	3	3		3
Extrusion of miscellaneous products	2	2	2	2	2	3
Injection moulding	?	2	2	2		3
Spread coating of flooring	2	2	2	2		2
Spread coating	2	2	2	2		3
Car undercoating	2		3	3		
PVC medical articles		2			2	
Toys and childcare articles		2			1	
Non-polymer applications:	0					
Adhesives/sealant, rubber	2	2	1	1	2	4
Lacquers and paint	2	2	2	2		4
Printing inks	2	2	2	2	2	3
Production of ceramics						
As substitute for DBP						
Polymer applications:						
Plasticiser in PVC	2		1	1	2	2
Plasticisers in other polymers	2					2
Non-polymer applications:						
Adhesives	2	2		1	3	4
Printing inks	2	3			2	3
Sealants	2				3	4

Application	Market experience (1 to 4) *1					
	ASE	GTA	DGD	Mix of DGD, DEGD, TGD	ATBC	COMGHA
PU foam sealants	2				4	
Nitrocellulose paints	2	3	2	2	2	
Film coatings	3				3	
Glass fibre production						4
Cosmetics						2
As substitute for BBP						
Polymer applications:						
General PVC (e.g. moulded plastic parts)	2					4
Plastisol coating for flooring	2		1	1		3
Extrusion or spread coating	2			2		2
Films, calendering	2		4	4		3
Non-polymer applications:						
Sealants	2		1	1		
Coatings and inks		2	1		3	
Adhesives	2			1		
Nail polish					1	

*1: Market experience categories interpretation: 1) Main alternative on market. 2) Significant market experience. 3) Examples of full scale experience. 4) Pilot/lab scale experience.

The tables above show a wide range of applications in which non-phthalate plasticisers are currently being used. However, the tables also show that there is no single alternative that covers all applications. This is because of the very broad application of DEHP and to some extent DINP/DIDP which are the most commonly used alternatives to DEHP. It also seems like there are other factors that act as barriers for substitution.

8.1 Recommendations

No alternatives to phthalates can be used for all applications in which phthalates are used today. In addition, the alternatives have different properties that prevent them from being optimal under all circumstances. Therefore, it is recommended that enterprises review alternatives to phthalates for different purposes.

Such a review should include an update of current knowledge about the environmental and health impacts of the alternatives. This could be used as a tool to assess what alternatives can be used safely. Especially with regard to medical devices, an obstacle is that producers are not confident with the alternatives available.

Work should be done to determine the barriers for substitution and how such barriers can be broken down.

9. Ongoing activities

9.1 Proposals for classification

The list of substances with harmonised classification (Annex VI of the CLP Regulation) is regularly expanded in line with work by the authorities and the industry to have new substances classified or to update existing classification. The Committee for Risk Assessment (RAC) under the European Chemicals Agency examines the proposals for harmonised classification in the European Union.

Proposals for classification of the two phthalates below as toxic to reproduction are being processed in the European Union:

- Diisohexyl phthalate (DIHP) (CAS no. 68515-50-4): Repr. 1B - H360 (Sweden)
- Di-n-hexyl phthalate (DnHP) (CAS no.84-75-3): Repr. 1B - H360FD (France). A vote among Member States are expected in the first half of 2013.

Moreover, on the ECHA website, Member States as well as enterprises can register whether they intend to submit new or updated proposals for classification of specific substances. Currently, there are no outstanding intentions to classify phthalates. However, Sweden has informed that they expect to prepare a proposal for classification for dicyclohexyl phthalate (DCHP).

9.2 Proposals for the Candidate List

In early September 2012, ECHA launched a public consultation on the proposal of 54 new substances to be included in the Candidate List. Table 13 shows the "new" phthalates which have been proposed for the Candidate List.

Table 13 New phthalates proposed for the Candidate List (September 2012)

Substance name	CAS number	Reason for inclusion
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	Toxic to reproduction (REACH Article 57 c)
Diisopentylphthalate (DIPP)	605-50-5	Toxic to reproduction (REACH Article 57 c)
N-pentyl-isopentylphtalate	-	Toxic to reproduction (REACH Article 57 c)
[Phthalato(2-)]dioxotrilead (dibasic lead phthalate)	69011-06-9	Toxic to reproduction (REACH Article 57 c)
Dipentylphthalate (DNPP)	**131-18-0**	Toxic to reproduction (REACH Article 57 c)

These substances are expected to be included in the Candidate List by the end of 2012 (ECHA 2012e).

On the ECHA website, Member States can register their intentions to have new substances included on the Candidate List (Registry of Current SVHC Intentions: http://echa.europa.eu/da/registry-of-current-svhc-intentions). Poland has registered intentions to have the following phthalate included on the Candidate List:

- Di-n-pentylphthalate (CAS no. 131-18-0). Reasons: CMR

9.3 Restriction proposal

In spring 2011, Denmark submitted a proposal to the EU to restrict the four phthalates DEHP, DBP, BBP and DIBP in articles intended for indoor use and articles that may come into direct contact with the skin. The proposal was based on a dose addition of the four phthalates in all articles intended for indoor use and articles that may come into direct contact with the skin or mucous membranes. The proposal was submitted under the REACH Regulation and was processed by ECHA's two scientific committees in 2011 and 2012. In June 2012, the Risk Assessment Committee (RAC) adopted an opinion which agrees with Denmark that dose addition is the right method to examine the effects of the four phthalates in relation to their combined effect. However, the RAC does not agree with Denmark that in 2012 people are being exposed to levels exceeding the level asummed not to give effects in humans.

Denmark does not agree with the RAC argument, which is based on a reduction in consumption of the four phthalates in Europe. The argument does not take into account that consumption in Asia, from where many of the products consumers buy in Denmark come, is not declining, and still accounts for more than 50% of total use of plasticisers in PVC. Therefore, Denmark assesses that exposure to the population is still of great concern.

Consequently, the Danish Minister for the Environment, introduced a national ban on the four phthalates in November 2012. The ban covers "articles intended for indoor use and articles that may come into direct contact with the skin or mucous membranes, containing one or more of these four phthalates in a concentration greater than 0.1% by weight of any component." The ban does not apply to 1) use in industrial manufacturing equipment and industrial manufacturing facilities, including mobile and fixed offshore installations, 2) use in motor vehicles, trailers, ships, trains and aircraft, and 3) use in military equipment and military facilities. The ban will enter into force on 1 December 2013, except for electronic and electrical products, for which the ban will enter into force on 1 December 2014.

9.4 Substance evaluation under REACH

As part of the implementation of REACH, Member States evaluate selected, registered substances. Substance evaluation is one of three types of evaluation process under REACH. The two other processes relate to proposals for testing by registration dossier and registrants with a view to evaluating environmental and health hazards; collectively referred to as dossier evaluation. The substance evaluation process is to clarify whether a chemical poses a risk to human health or the environment, and is initiated on the basis of risk-based considerations. Special areas of attention for substance evaluation are CMR substances, PBT/vPvB substances, and other similar substances of concern, such as endocrine disruptors.

The individual Member States propose which substances should undergo substance evaluation, and on this basis ECHA prepares a plan of the substances to be evaluated; the Community Rolling Action Plan (CoRAP). A number of phthalates have been proposed for the substance evaluation process and are to be evaluated in the years to come. Table 14 shows the phthalates selected for

substance evaluation in the period 2012-2014 (ECHA 2012f). It has not yet been established what substances are to be evaluated in the following years.

Table 14 Phthalates selected for substance evaluation 2012-2014

Substance name	CAS number	Background/ concern	Responsible Member State	Year
1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	68515-40-2	CMR	Denmark	2014
1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (DTDP)	68515-47-9	CMR/PBT	Denmark	2014
1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	68515-43-5	CMR	Denmark	2014
Diallyl phthalate (DAP)	131-17-9	CMR	Spain	2013
Diethyl phthalate (DEP)	84-66-2	EQC	Germany	2014
Diundecyl phthalate (DUP)	3648-20-2	CMR	Denmark	2014
Diundecyl phthalate, branched and linear (DIUP)	85507-79-5	CMR/PBT	Denmark	2014

Denmark has decided to propose a number of phthalates with 7-11 carbon atoms in the chain. For these phthalates, the available data for reproduction toxicity is either not sufficient (new studies have been planned) or is based on a read-across approach for other phthalates, see registration dossier of the substances. No own data for reproduction toxicity exists for the substances DTDP (CAS no. 68515-47-9) and DIUP (CAS no. 85507-79-5), and read-across has been carried out for other phthalates such as DINP (CAS no. 28553-12-0), DIDP (CAS no. 26761-40-0), in which more recent studies of DINP show that DINP can have endocrine disrupting effects in high concentrations. Common for DTDP and DIUP is that they have relatively specialised uses, and they cannot be used broadly as plasticisers (see information from the producer). Therefore, an evaluation of these phthalates can clarify whether the group of phthalates with 7-11 carbon atoms should be classified as toxic to reproduction.

9.5 The SIN List

In May 2012, on behalf of the Danish EPA, the Danish Centre on Endocrine Disruptors tested the Danish proposed criteria for endocrine disruptors on the 22 substances on the SIN List 2.0, including three phthalates ((http://www.sinlist.org/). The substances were identified by ChemSec as substances of very high concern[5], based on their endocrine disrupting properties alone. In

[5] (SVHC, Art. 57 (f) in REACH)

addition to the 22 substances on the SIN List, four substances selected by the Danish EPA were evaluated (Danish EPA 2012).

The purpose of the study was to gain practical experience with different proposed criteria for endocrine disruptors. Using the Danish proposed criteria, 17 of the 26 substances were evaluated as endocrine disrupting, eight substances were suspected of being endocrine disrupting, while one substance could not be categorised as endocrine disrupting.

The three phthalates on the SIN List are dicyclohexyl phthalate (DCHP), diethyl phthalate (DEP) and dihexyl phthalate (DHP). According to the Danish proposed criteria for endocrine disruptors, DCHP and DHP are evaluated as endocrine disruptors and DEP as a suspected endocrine disruptor on the basis of a weight of evidence approach.

As a follow up to the SIN List evaluation, two phthalates (DCHP and DHP) are under consideration for a more detailed RMO (Risk Management Options) analysis of the possible need to regulate the substances.

9.6 List of Undesirable Substances (LOUS)

The List of Undesirable Substances (LOUS) is a list for producers, product developers, procurement officers and other players of recommendations and guidelines for chemicals, for which use should be limited or stopped entirely in the long term.

The list contains 40 substances/substance groups considered to have effects of concern by the Danish EPA, and which meet the criteria selected for the list. In order to adjust the list to the Danish market, only substances used for industrial purposes in large quantities in Denmark have been included on the list. The list includes the following phthalates: DEHP, DBP, BBP, DMEP and DIBP.

As part of the Danish Finance Act 2012, the Danish government and the Danish Red-Green Alliance agreed that all substances on LOUS should be reviewed, enabling the Danish EPA to subsequently assess for each individual substance or substance group the need for, for example, further regulation, substitution/phasing-out, classification and labelling, as well as waste management or information. This should be done by first surveying each substance/substance group in order to evaluate the need for measures. The group of phthalates on LOUS is to be surveyed in 2013, and this is expected to gather existing knowledge about the use, effects and risks of these phthalates. However, it was decided not to survey these four phthalates because a thorough study had already been conducted in connection with the proposals for EU regulation and national regulation. Instead, the following will be studied: DEP, DIPP, DPHP, 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich as well as the DMEP phthalate, which are registered under REACH, as these phthalates are known to be used in the European Union. A risk management strategy will be prepared subsequent to the mapping, which recommends how the substances are to be managed subsequently.

9.7 Recommendations

Focus is on phthalates' properties of concern at national level as well as at EU level. Therefore, a number of different activities have been launched, which aim either at procuring more knowledge or at regulating selected phthalates. These initiatives have been launched by Denmark, other Member States or by ECHA. It is recommended to ensure ongoing overview of ongoing activities. As for the Danish initiatives, coordination between the different activities must be ensured, including mapping any new phthalates through the LOUS project, description of risk management options (RMO) for phthalates on the SIN List and current and future substance evaluations under the

European Union. When phthalates are identified with properties of concern or as phthalates, about which there is a shortage of knowledge, through this strategy or through other activities, substance evaluation can be a tool to procure new knowledge about already registered phthalates.

References

Statutory Order no. 1263 of 15 December 2008 concerning medical devices

Statutory Order no. 855 of 5 September 2009 on ban on phthalates in toys and childcare articles

Statutory Order no. 13 of 10 January 2011 on safety requirements for toys

Statutory Order no. 1113 of 26 November 2012 on the ban on import and sale of products for indoor use containing the phthalates DEHP, DBP, BBP and DIBP, and articles, and articles which can come into contact with skin or the mucous membranes

CSTEE, 2001, Scientific Committee on Toxicity Ecotoxicity and the Environment (CSTEE), "Opinion on the results of the Risk Assessment of: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-"isononyl" phthalate", 2001.

The REACH Regulation (Regulation (EC) No 1907/2006) on Registration, Evaluation and Authorisation and Restriction of chemicals

The CLP Regulation (Regulation (EC) No 1272/2008) on classification, labelling and packaging

ECHA (2012a). Candidate List
http://echa.europa.eu/web/guest/candidate-list-table

ECHA (2012b). Authorisation List
http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

ECHA (2012c). Registered substances
http://echa.europa.eu/information-on-chemicals/registered-substances

ECHA (2012d). Information on Candidate List substances in articles
http://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles

ECHA (2012e). Proposal on 54 new substances on the Candidate List (September 2012).
http://echa.europa.eu/en/web/guest/view-article/-/journal_content/512b7526-9dd6-4872-934e-8c298c89ad99

ECHA (2012f). Community Rolling Action Plan (CoRAP).
http://echa.europa.eu/da/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

ECHA (2012g). Evaluation of new scientific evidence concerning the phthalates DINP and DIDP.
http://echa.europa.eu/documents/10162/13641/information_note_dinp_didp_en.pdf.

Frederiksen, H et al., 2012. High urinary phthalate concentration associated with delayed pubarche in girls. Int J Androl. 2012 Jun;35(3):216-26. doi: 10.1111/j.1365-2605.2012.01260.x. Epub 2012 Mar 19.

Frederiksen, H., et al., Urinary excretion of phthalate metabolites, phenols and parabens in rural and urban Danish mother–child pairs. Int. J. Hyg. Environ. Health (2013), http://dx.doi.org/10.1016/j.ijheh.2013.02.006

Kortenkamp and Hass, 2009. Expert workshop on combination effects of chemicals.http://www.mim.dk/NR/rdonlyres/C59693B7-2421-4748-89F0-5937496E0A28/0/BILAG_2_Expertworkshop.pdf

Mieritz, MG et al., 2012. Urinary phthalate excretion in 555 healthy Danish boys with and without pubertal gynaecomastia. Int J Androl. 2012 Jun;35(3):227-35. doi: 10.1111/j.1365-2605.2012.01279.x.

The Danish EPA, 2009, two-year-olds' exposure to chemical substances. Survey of chemical substances in consumer products, no. 103,2009.

The Danish EPA, 2010, Identification and assessment of alternatives to selected phthalates.

The Danish EPA, 2011, Annex XV Report, Proposal For A Restriction on DEHP, BBP, DBP and DIBP, http://www.echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals/-/substance/490/search/+/term

The Danish EPA (2012a). Evaluation of 22 SIN List 2.0 substances according to the Danish proposal
on criteria for endocrine disruptors. http://www.mst.dk/NR/rdonlyres/CDA4EB4F-1554-4754-A0F9-77D73BCA0228/0/SINreportandAnnex.pdf

The Danish EPA (2012b). Pregnant consumers' exposure to suspected endocrine disruptors. Survey of chemical substances in consumer products, no. 117, 2012.

The table contains esters of o-, m- and p-phthalatic acid. Substances marked with grey are esters of o-phthalic acid.

Annex 1: Table of phthalates which have a harmonised classification, are endocrine disrupting, are included in the Candidate List or in the EU list of potential endocrine disruptors

Substance name	CAS number	Endocrine disrupting effect	Harmonised classification (CLP Annex VI)	In the Candidate List	In the EU list of potential endocrine disruptors	Literary source
Diethyl phthalate (DEP)	84-66-2				X	Registration dossier
Diisobutyl phthalate (DIBP)*	84-69-5	AA	Repr. 1B; H360Df	X		Registration dossier, EFSA, restriction dossier, ECHA proposal for the Candidate List and Authorisation List
Dibutyl phthalate (DBP)*	84-74-2	AA	Repr. 1B; H360Df Aquatic Acute 1; H400	X	X	Registration dossier, EU RAR, EFSA, restriction dossier, ECHA evaluations
Benzyl butyl phthalate (BBP)*	85-68-7	AA	Repr. 1B; H360Df Aquatic Acute 1; H400 Aquatic Chronic 1; H410	X		Registration dossier, EU RAR, EFSA, restriction dossier, ECHA evaluations
Bis(2-ethylhexyl) phthalate (DEHP)*	117-81-7	AA and T	Repr 1B; H360FD	X	X	Registration dossier, EU RAR, EFSA, restriction dossier, ECHA evaluations
Dimethyl phthalate (DMP)	131-11-3					Registration dossier
Diallyl phthalate (DAP)	131-17-9		Acute Tox 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410			Registration dossier
Di-n-pentyl phthalate (DPP)	131-18-0	AA	Repr. 1B; H360FD Aquatic Acute 1; H400		X	
Diisopentyl phthalate (DIPP)	605-50-5		Repr. 1B; H360FD Aquatic Acute 1; H400			Registration dossier
Diundecyl phthalate (DUP)	3648-20-2					Registration dossier

Substance name	CAS number	Endocrine disrupting effect	Harmonised classification (CLP Annex VI)	In the Candidate List	In the EU list of potential endocrine disruptors	Literary source
Benzyl 3-isobutyryloxy-1-isopropyl-2,2-dimethylpropyl phthalate	16883-83-3					Registration dossier
Diisotridecyl phthalate (DITP)	27253-26-5					Registration dossier
Di-isononyl phthalate (DINP)	28553-12-0	AA				Registration dossier, EU RAR, EFSA
Bis(2-propylheptyl) phthalate (DPHP)	53306-54-0					Registration dossier
1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	68515-40-2					Registration dossier
1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	68515-43-5					Registration dossier
1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	68515-47-9					Registration dossier
1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich	68515-48-0					Registration dossier
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich	68515-49-1					Registration dossier
1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5					Registration dossier

Substance name	CAS number	Endocrine disrupting effect	Harmonised classification (CLP Annex VI)	In the Candidate List	In the EU list of potential endocrine disruptors	Literary source
1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters	71662-46-9					Registration dossier
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0		Repr. 1B; H360FD Aquatic Acute 1; H400			
1,2-Benzenedicarboxylic acid, di-C1-13 alkyl esters, manuf. of, by-products from, distn. lights	84852-02-8					Registration dossier
Diundecyl phthalate, branched and linear (DIUP)	85507-79-5					Registration dossier
1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters	90193-76-3					Registration dossier
Di-n-hexyl phthalate (DNHP)	84-75-3	AA and T				
Di-n-octyl phthalate (DNOP)	117-84-0	T				
Bis(2-methoxyethyl) phthalate (DMEP)	117-82-8		Repr. 1B; H360Df	X		ECHA evaluation
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6		Repr. 1B; H360D	X		ECHA evaluation
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4		Repr. 1B; H360Df	X		ECHA evaluation
Dicyclohexyl phthalate (DCHP)	84-61-7				X	
Mono-n-butyl phthalate	131-70-4				X	

Substance name	CAS number	Endocrine disrupting effect	Harmonised classification (CLP Annex VI)	In the Candidate List	In the EU list of potential endocrine disruptors	Literary source
Mono-2-ethylhexyl phthalate (MEHP)	4376-20-9				X	
Di-isodecyl phthalate (DIDP)	26761-40-0	T				EU RAR, EFSA
n-pentyl-isopentylphtalate	776297-69-9		Repr. 1B; H360FD Aquatic Acute 1; H400			

AA: Anti-androgen
T: Thyroid endocrine disrupting
Data in registration dossier is data submitted by the industry.

Annex 2: Table of phthalates and current and future initiatives

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
Diallyl phthalate (DAP) CAS no. 131-17-9	100-1,000	Acute Tox 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410		Spain 2013		X		
Diisopentyl phthalate (DIPP) CAS no. 605-50-5	10-100	Repr. 1B; H360FD Aquatic Acute 1; H400	Proposals for the Candidate List		X	X		
Bis(2-methoxyethyl) phthalate (DMEP) CAS no. 117-82-8		Repr. 1B; H360Df	C		X			
Diethyl phthalate	1,000-10,000			Germany	X	X		

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
(DEP) CAS no. 84-66-2				2014				
Diundecyl phthalate (DUP) CAS no. 3648-20-2	1,000-10,000			Denmark 2014		X		
Di-''isononyl'' phthalate (DINP) CAS no. 28553-12-0 / 68515-48-0	100,000-1,000,000					X		ECHA evaluation of the current restriction in REACH Annex 17. Evaluation of the need for harmonised classification or other
Bis(2-propylheptyl) phthalate (DPHP)	100,000-1,000,000				X	X		

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
CAS no. 53306-54-0								
1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters CAS no. 68515-40-2	10,000-100,000			Denmark 2014		X		
1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters CAS no. 68515-43-5	1,000-10,000			Denmark 2014		X		
1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl	1,000-10,000			Denmark 2014		X		

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
esters, C13-rich CAS no. 68515-47-9								
1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich CAS no. 68515-48-0	100,000-1,000,000				X	X		
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich Di-"isodecyl" phthalate (DIDP) CAS no. 68515-49-1	100,000-1,000,000				X	X		ECHA evaluation of the current restriction in REACH Annex 17.
Diundecyl phthalate,	1,000-10,000			Denmark 2014		X		

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
branched and linear (DIUP) CAS no. 85507-79-5								
Dicyclohexyl phthalate (DCHP) CAS no. 84-61-7	Pre-registered (2013)							Considerations on RMO analysis as follow up to SIN List project
Di-n-hexylphthalate (DnHP) CAS no. 84-75-3							Repr. 1B; H360FD France	Considerations on RMO analysis as follow up to SIN List project
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear CAS no. 84777-06-0			Proposals for the Candidate List					

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
N-pentyl-isopentylphtalate CAS no. 776297-69-9		Repr. 1B; H360FD Aquatic Acute 1; H400	Proposals for the Candidate List					
Diisohexylphthalate (DIHP) CAS no. 68515-50-4							Repr. 1B; H360 Sweden	
Diisobutyl phthalate (DIBP) CAS no. 84-69-5	1,000-10,000	Repr. 1B; H360Df	C, A			X		
Dibutyl phthalate (DBP) CAS no. 84-74-2	1,000-10,000	Repr. 1B; H360Df Aquatic Acute 1; H400	C, A			X		
Benzyl butyl phthalate (BBP) CAS no. 85-68-7	1,000-10,000	Repr. 1B; H360Df Aquatic Acute 1; H400 Aquatic Chronic 1;	C, A			X		

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
		H410						
Bis(2-ethylhexyl) phthalate (DEHP) CAS no. 117-81-7	100,000-1,000,000	Repr 1B; H360FD	C, A			X		
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich CAS no. 71888-89-6		Repr. 1B; H360D	C					
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) CAS no. 68515-42-4		Repr. 1B; H360Df	C					

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
Di-n-pentyl phthalate CAS no. 131-18-0		Repr. 1B; H360FD Aquatic Acute 1; H400						
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear CAS no. 84777-06-0		Repr. 1B; H360FD Aquatic Acute 1; H400						
1,2-Benzenedicarboxylic acid, di-C1-13 alkyl esters, manuf. of, by-products from, distn. lights CAS no. 84852-02-	Can only be used as an intermediate							

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
8								
1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters CAS no. 90193-76-3	1,000-10,000					X		
Disodium phthalate CAS no. 15968-01-1	Pre-registered (2013)							
1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters CAS no. 68515-51-5	100-1,000					X		
1,2-Benzenedicarboxylic acid, di-C8-10-	100-1,000					X		

Phthalate	Registered under REACH in tonnes	Harmonised classification	In the Candidate List (C) or Authorisation List (A)	Substance evaluation under REACH	Surveyed under LOUS	Consideration for evaluation in relation to criteria for endocrine disrupting substances (2014)	Proposals for classification	Other activities
alkyl esters CAS no. 71662-76-9								
Benzyl 3-isobutyryloxy-1-isopropyl-2,2-dimethylpropyl phthalate CAS no. 16883-83-3	1,000-10,000					X		
Diisotridecyl phthalate (DITP) CAS no. 27253-26-5	1,000-10,000					X		
Dimethyl phthalate (DMP) CAS no. 131-11-3	10,000-100,000					X		

Phthalate Strategy

Strategien håndterer ftalater som en gruppe af stoffer, da dette vil kunne tage hånd om, at sundhedsskadelige ftalater ikke erstattes med andre skadelige ftalater. Strategien har identificeret en række aktiviteter, der bør igangsættes over de kommende år, og som, hvis grundlaget er til stede, vil kunne medføre reguleringstiltag.

The strategy manages phthalates as a group of substances to ensure that some undesirable phthalates are not substituted by alternatives about which we lack knowledge and could be of concern as well. The strategy has identified activities that should be started within the coming years and which could lead to regulatory measures if the documentation shows that criteria are fulfilled.

Miljøministeriet
Miljøstyrelsen

Strandgade 29
1401 Copenhagen K, Denmark
Tel. +45 72 54 40 00

www.mst.dk