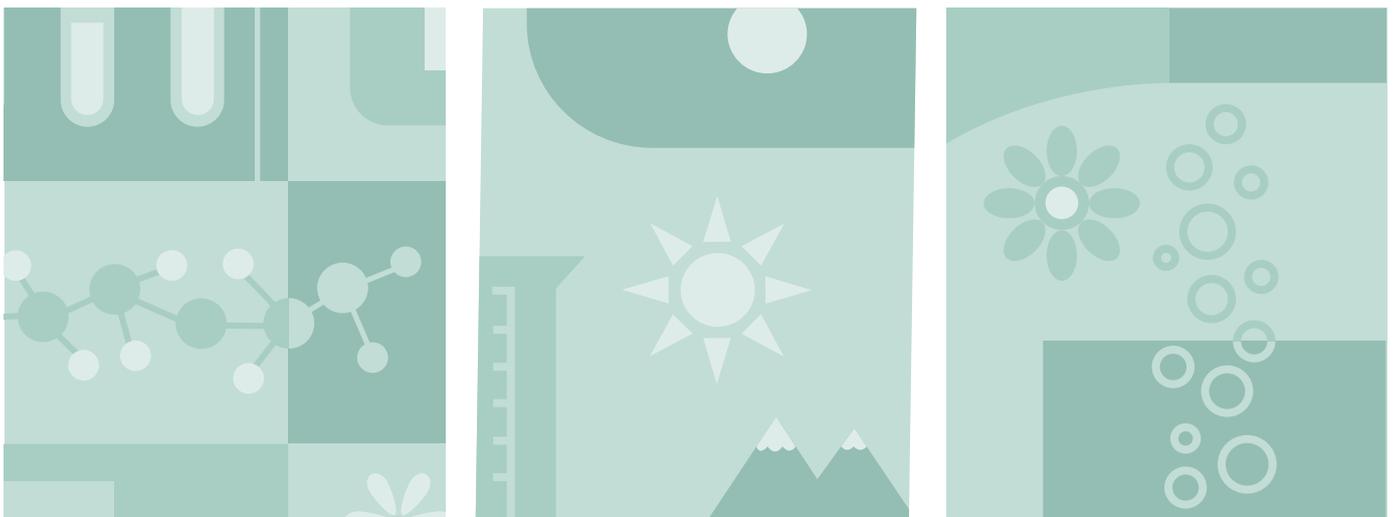


# **Enforcement of the information duty in REACH**

**Inspection project 2011-2012**





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**Inspection project 2011-2012**

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Publisher: Swedish Chemicals Agency©  
Order address: CM Gruppen, P.O. Box 11063, SE-161 11 Bromma, Sweden  
Phone: +46 8 5059 33 35, Fax +46 8 5059 33 99, E-mail: kemi@cm.se  
The report is available as a downloadable pdf on [www.kemikalieinspektionen.se](http://www.kemikalieinspektionen.se)

## **Preface**

An action plan for a toxic-free everyday environment has been launched by the Swedish Chemicals Agency, on assignment by the Swedish Government. Reducing risks from chemicals in the everyday life is one step towards reaching. One of the activities highlighted in the action plan is communication efforts and article inspections linked to the information requirement on substances of very high concern in articles. In this project, consumers have been informed about their right to information, and the work of companies on information concerning substances of very high concern has been checked. The Enforcement Department of KemI has been responsible for the project.



# Contents

|  |           |
|--|-----------|
| <b>Summary .....</b>                           | <b>7</b>  |
| <b>Sammanfattning.....</b>                     | <b>8</b>  |
| <b>1 Background.....</b>                       | <b>9</b>  |
| 1.1 Definitions.....                           | 9         |
| 1.2 Glossary .....                             | 9         |
| 1.3 Legislation .....                          | 10        |
| 1.4 Previous enforcements .....                | 12        |
| <b>2 The project .....</b>                     | <b>12</b> |
| 2.1 Purpose.....                               | 12        |
| 2.2 Selection.....                             | 12        |
| 2.3 Procedure.....                             | 13        |
| 2.3.1 Analyses of articles .....               | 13        |
| 2.3.2 On site inspections at retailers .....   | 13        |
| 2.3.3 Information to consumers.....            | 14        |
| 2.4 Results .....                              | 14        |
| 2.4.1 Analyses of articles .....               | 14        |
| 2.4.2 On site inspections at retailers .....   | 14        |
| 2.4.3 Information to consumers.....            | 15        |
| <b>3 Discussion.....</b>                       | <b>16</b> |
| <b>4 Advice to companies .....</b>             | <b>17</b> |
| 4.1 Knowledge.....                             | 17        |
| 4.2 Communication with supplier .....          | 18        |
| 4.3 Information to customers.....              | 19        |
| 4.4 Tests.....                                 | 19        |
| 4.5 The interpretation of 0.1%.....            | 20        |
| 4.6 Notification/registration to ECHA .....    | 20        |
| <b>5 Annexes.....</b>                          | <b>21</b> |
| 5.1 Annex 1 – Substances for analysis.....     | 21        |
| 5.2 Annex 2 – Questionnaire for consumers..... | 22        |



## Summary

In 2011 and 2012, the Enforcement Department of the Swedish Chemicals Agency (KemI) has undertaken an enforcement project focused on checking compliance by companies with rules on information duty in the REACH Regulation. In addition to the rules contained in the REACH Regulation, the RoHS Directive, the Toys Directive, the Environmental Code and the Product Safety Act have been checked.

The project has consisted of three parts, one of which focused on analyses of articles with regard to substances on the Candidate List. The results were then followed up by inspections by letter. In another part of the project, ten general retailers were visited, and these inspections were supplemented by analyses of articles. In addition, information for consumers has been published on the KemI website to make it easier for them to request information on substances of very high concern in articles.

The analyses showed that 18 of the 50 purchased articles contained more than 0.1% by weight of one or more substances on the Candidate List. In most cases this was unknown to the companies, partly because of inadequate procedures at the companies and partly because of incorrect information from suppliers.

Half of the ten companies visited were deemed to have relatively good knowledge of the rules contained in REACH. Some issues where deficiencies were common were knowledge of the requirement of notification in Article 7 of REACH, information to professional customers in stores, information about safe use and knowledge about the two differing interpretations of how 0.1% is to be calculated.

The project has resulted in increased knowledge at KemI on the presence of substances of very high concern in articles and greater knowledge among companies of the rules contained in the REACH Regulation. The companies that have been inspected by letter or visit have received information about the rules and gained greater awareness of these. This had led to improved transfer of information in several distribution chains and voluntary phasing-out of articles containing hazardous substances.

During the project, KemI has gained greater knowledge of the way in which companies work on issues that relate to chemicals in articles. This has pointed to many good solutions, and on this basis advice to companies has been collated in section 4.

## Sammanfattning

Under 2011 och 2012 har Kemikalieinspektionens (KemI) tillsynsavdelning bedrivit ett tillsynsprojekt som har fokuserat på att kontrollera företags efterlevnad av regler om informationsplikt i Reach-förordningen. Förutom reglerna i Reach-förordningen har även RoHS-direktivet, leksaksdirektivet, miljöbalken och produktsäkerhetslagen kontrollerats.

Projektet har bestått av tre delar varav en fokuserade på analyser av varor med avseende på ämnen på kandidatförteckningen. Resultaten följdes därefter upp med brevinspektioner. I en annan del av projektet besöktes tio återförsäljare inom diversehandeln och dessa inspektioner kompletterades med analyser av varor. Dessutom har information till konsumenter publicerats på KemI:s webbplats för att underlätta för dem att begära information om särskilt farliga ämnen i varor.

Analyserna visade att 18 av de 50 inköpta varorna innehöll mer än 0,1 viktprocent av ett eller flera ämnen på kandidatförteckningen. I de flesta fall var detta okänt för företagen, dels på grund av bristande rutiner hos företagen och dels på grund av felaktig information från leverantörer.

Hälften av de tio företag som besöktes bedömdes ha relativt god kännedom om reglerna i Reach. Några frågor där brister var vanligt rörde kännedom om kravet på anmälan i artikel 7 i Reach, information till yrkesmässiga kunder i butiker, information om säker användning samt kännedom om de två olika tolkningarna av hur 0,1 procent ska beräknas.

Projektet har resulterat i en ökad kunskap hos KemI om förekomsten av särskilt farliga ämnen i varor samt företagens kunskaper om reglerna i Reach-förordningen. De företag som har inspekterats via brev eller besök har fått information om reglerna och ökad medvetenhet om dessa. Detta har lett till förbättrad informationsöverföring inom flera distributionskedjor samt frivillig utfasning av varor som innehåller farliga ämnen.

Under projektet har KemI fått en större kännedom om företags sätt att arbeta med frågor som rör kemikalier i varor. Detta har visat på många goda lösningar och utifrån detta har råd till företag sammanställts i avsnitt 4.

# 1 Background

The Swedish Chemicals Agency is a central regulatory authority under the Ministry of the Environment and is responsible for A Non-Toxic Environment – one of Sweden's 16 environmental quality objectives. The Enforcement Department of the Swedish Chemicals Agency (KemI) inspects companies that manufacture and import chemical products, biotechnical organisms and other articles that have been treated with or contain chemical products to check that applicable rules are followed. The inspections are performed pursuant to the Environmental Code, and enforcement generally takes place in project form.

A large part of the EU's chemicals legislation is brought together in the REACH Regulation<sup>1</sup>(REACH). Most of the rules apply to substances and mixtures, but some relate to substances in articles. Among other things, there are rules stating that companies selling articles that contain substances of very high concern must inform their customers of this fact.

During previous inspection projects, the Swedish Chemicals Agency has observed deficiencies with regard to the companies' knowledge and their compliance with the requirements contained in REACH, among other things regarding the information duty. It is therefore crucially important to make further checks that this legislation is complied with at a larger number of companies. This report presents the background to and results of an inspection project carried out by the Swedish Chemicals Agency in 2011 and 2012.

## 1.1 Definitions

There are a large number of definitions and terms concerning substances in articles in the REACH Regulation and this report.

*Article*: an object which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition.

*Substance*: chemical element and compounds of this element in natural or manufactured form, including any additives necessary to preserve their stability and such compounds as originate from the manufacturing process, but excluding any solvents that can be separated without affecting the stability of the substance or altering its composition.

*SVHC substance*: substances that fulfil the criteria of Article 57 of REACH. These are carcinogenic, mutagenic, toxic for reproduction, environmentally hazardous (persistent, bioaccumulative, toxic or very persistent and very bioaccumulative) or have other serious properties, for example endocrine-disrupting. SVHC stands for “substances of very high concern”.

*Substances in the Candidate List*: The SVHC substances that have been placed on the Candidate List in accordance with Article 59(1) of REACH. There are 73 such substances at present. These are candidates for inclusion in Annex XIV of REACH, which means that authorisation will be required for use of these substances.

## 1.2 Glossary

SVHC = Substances of Very High Concern.

PVC = polyvinyl chloride

ECHA = European Chemicals Agency

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<sup>1</sup> (EC) No 1907/2006

RoHS = Restriction of certain Hazardous Substances  
CMR = carcinogenic, mutagenic, toxic for reproduction  
DBP = dibutyl phthalate  
DEHP = di(2-hexyl ethyl) phthalate  
BBP = benzyl butyl phthalate  
DUBP = diisobutyl phthalate  
DIHP = di-C6-C8-branched alkyl phthalates  
DHNUP = di-C7-C11-branched and linear alkyl phthalates

### 1.3 Legislation

The focus in the inspections has been put on the rules applicable to articles in REACH. The rules contained in the RoHS Directive<sup>2</sup>, the Toys Directive<sup>3</sup>, the Environmental Code<sup>4</sup> and the Product Safety Act<sup>5</sup> have also been discussed in the on site inspections.

#### **The REACH Regulation (EC) No 1907/2006**

The REACH Regulation is the chemicals legislation that has replaced large parts of the rules on chemicals that applied prior to 1 June 2007 in the EU and Sweden. REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH primarily covers chemical substances and mixtures of chemical substances, but a few provisions also apply to articles, and these are described below.

Article 7 contains provisions that certain substances in articles must be registered or notified. This means that companies that manufacture or import an article containing a substance intended to be released from the article under normal or reasonably foreseeable conditions of use must register such a substance at the ECHA if the total quantity of the substance per producer or manufacturer exceeds 1 tonne per year (Article 7(1)). A substance that has already been registered for the use concerned does not need to be registered. Article 7 also contains a provision that an article containing a substance included in the Candidate List at a level exceeding 0.1% must be notified to the ECHA, provided that the total quantity of the substance is over one tonne per producer or importer per year (Article 7(2)). This duty of notification also applies if the substance is not released. If the substance has already been registered for this use or if exposure to humans or the environment can be excluded, no notification need be made. A notification only contains very limited information and is not to be confused with the more extensive registration notification to be made for chemical substances that are manufactured or imported.

Article 33 of the REACH Regulation contains a duty to communicate information on hazardous substances in articles. This article describes suppliers' obligations to communicate information on the substances in the Candidate List contained in their articles at levels of more than 0.1% by weight. The information must always be supplied to professional customers. Consumers also have the right to receive the information, but on request and within 45 days. The substances regarded as being of very high concern and covered by the information requirement are included in what is known as the Candidate List. Member States

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<sup>2</sup> 2002/95/EC

<sup>3</sup> 2009/48/EC

<sup>4</sup> Swedish Code of Statutes 1998:808

<sup>5</sup> Swedish Code of Statutes 2004:451

can propose substances regarded as being of very high concern, and the substances are then included in the list. This means that new substances are added to the Candidate List, and 73 substances are included at present (May 2012). The substances in the list can then be added to Annex XIV, which lists substances covered by authorisation rules. Companies wishing to use these substances, for example in manufacturing articles, must apply for authorisation for a specific use. The requirement for authorisation for use of these substances only applies to those articles that are manufactured in the EU, which means that imported articles can continue to be allowed to contain these substances. Fourteen substances are currently contained in Annex XIV.

Annex XVII contains a number of restriction rules, around thirty of which restrict the use of substances in certain articles. Examples of such substances and articles are phthalates in toys, nickel in jewellery and azo dyes in textiles.

### **The RoHS Directive 2002/95/EC**

The RoHS Directive (Restriction of certain Hazardous Substances) limits the use of lead, cadmium, mercury, hexavalent chromium and the brominated flame retardants PBDE and PBB in electrical and electronic equipment. The rules apply with effect from 1 July 2006 and cover the equipment stated in categories 1-7 and 10 of Annex 1A of the WEEE Directive (2002/96/EC). The limit values for lead, mercury, hexavalent chromium and PBDE/PBB are 0.1% by weight and the limit value for cadmium is 0.01% by weight.

A revision of the RoHS Directive has been in progress, and the new rules are due to come into force on 2 January 2013. The same substances are still regulated with the same limit values as previously, but the equipment covered has been extended. However, there are transitional periods of up to eight years for the new equipment that is to be covered. The requirements for documentation will be strengthened, and CE marking will additionally be required, to show that the requirements of the Directive are met.

### **Old and new Toys Directives (88/378/EC and 2009/48/EC)**

The old Toys Directive limits the migration of eight metals, including lead and cadmium. A standard, EN71, is linked to the Directive, and CE marking on a toy has to certify that it fulfils the requirements of the Directive. The Directive also contains a general requirement that toys must not contain chemicals that can harm children's health.

The new Toys Directive came into force on 20 July 2011. However, the rules on chemicals in the Directive do not need to be applied until 20 July 2013. The rules on chemicals are significantly more extensive than in previous directives, for example the migration of 19 metals, the content of CMR substances, 55 allergenic fragrances and nitrosamines and nitrosable substances in certain toys are regulated. In addition, there is an information requirement for a further eleven fragrances and an expanded requirement for documentation of chemical content.

The rules contained in the Toys Directive are transposed in Sweden through the Act (SFS 2011:579) on the Safety of Toys, the Ordinance (SFS 2011:703) on the Safety of Toys and the regulations of the Swedish Consumer Agency, the Swedish National Electrical Safety Board and KemI. The three agencies have joint responsibility for enforcing the rules, with KemI being responsible for the parts concerning chemicals and flammability.

### **Environmental Code (1998:808)**

The Environmental Code contains the collective Swedish environmental legislation. The Code contains regulatory and penal provisions relating among other things to the REACH

Regulation and the RoHS Directive. In addition to specific rules, there are the general rules of consideration relating among other things to substitution and the precautionary principle.

### **Product Safety Act (2004:451)**

The Product Safety Act is based on EU Directive 2001/95/EC (the Product Safety Directive). This Act contains general provisions stating that all products sold to consumers must be safe. There are also rules concerning withdrawal from the market of hazardous products.

## **1.4 Previous enforcements**

In 2010 KemI had an enforcement project aimed at examining how the information requirement contained in Article 33 of REACH was complied with. Fourteen articles were purchased in this project, and five of these were identified as containing substances included in the Candidate List at concentrations of more than 0.1%. These five articles consisted of three different tools with plastic handles, a pair of boots and a dumbbell. By contacting retailers and importers of these articles, KemI examined what information had been provided in the supply chain in Sweden and how the information had been asked for. Three companies had not provided information on the content of these substances in accordance with Article 33 and were reported to the prosecution authority as there were suspicions that a criminal offence had been committed. The project pointed to inadequate knowledge and procedures at certain companies selling articles. It was also clear that substances included in the Candidate List are present in articles sold to consumers, but there is little knowledge of where they are at present, either at KemI or at companies.

## **2 The project**

In 2011 and 2012 KemI has undertaken an enforcement project that has focused on the rules that apply to substances contained in articles under REACH, focusing in particular on the information requirement for articles containing substances in the Candidate List. There have been three parts to the project: one where articles have been purchased and analysed with respect to the Candidate List, one where retailers of articles have been inspected through visits and an information part aimed at consumers.

### **2.1 Purpose**

The purpose of the project has been to increase knowledge of the presence of hazardous substances in articles and of applicable rules at companies that manufacture, import and sell articles. Another aim was to check companies' procedures for information transfer. The focus in the contacts with the companies has been on informing about and checking compliance with the information requirement contained in Article 33 of REACH. In addition, the companies' compliance with other rules in the area of chemicals has been checked. A further aim has been to make consumers more aware of their right to request information about substances of very high concern in articles.

### **2.2 Selection**

The articles selected for analysis were those where it was likely that substances in the Candidate List were present. In particular, articles with parts made of soft PVC plastic or other soft plastic or rubber material were chosen. Twenty-six composite articles or articles that may be included in a composite article were purchased. These included various car parts,

household appliances, tools, boat accessories and weight-training equipment. In addition, 24 articles were bought from the ten stores that were inspected to check their self-monitoring.

Ten companies with stores that sell car accessories, tools, home furnishings and various other articles were selected for on site inspections. The companies were chosen because it was considered likely that their articles might contain substances in the candidate list and as they sell directly to consumers and may therefore need to fulfil the obligations set forth in Article 33(2) of REACH.

## **2.3 Procedure**

### **2.3.1 Analyses of articles**

Based on the selection criteria indicated above, 26 articles were purchased and an assessment was made of what substances could be imagined to be appropriate to search for. The articles were sent for analysis at an external laboratory. The substances selected for analysis were DBP, DEHP, BBP, DIBP, DIHP, DHNUP, short-chain chloroparaffins and anthracene (see Annex 1). In cases where none of the substances looked for had been detected, the company that had sold the article and the Swedish supplier, if any, were informed of the analytical result and the case was closed. In cases where the level of a substance was over 0.1%, a request was sent to the retailer and the Swedish supplier, if any. The retailers were asked to state what information they had received from their supplier about the article concerned. In addition, it was asked how the retailer in general requests information about substances in the Candidate List from its suppliers. When sale to professional customers took place, they also had to state how they ensured that professional customers would receive the information. The suppliers were to state what information they had given to the retailer, how they requested information from their suppliers and who their suppliers were. In some cases it was also asked how they ensured that they fulfilled the requirements of Article 7(2) regarding notification to the ECHA if the volume of any Candidate List substance in their articles was more than one tonne per year.

### **2.3.2 On site inspections at retailers**

To check retailers' self-monitoring, ten companies were selected according to the selection criteria mentioned above. Twenty-four articles from these companies were purchased and sent for analysis according to the same procedure as above. The companies were first contacted by telephone and then received a notification letter where it was stated that KemI would be booking an inspection and what it would be concerned with. They were also informed that they would have to provide information about the content of substances in the Candidate List in the articles that KemI had purchased and that this would be reported during the inspection. In the inspections, questions were asked about the companies' procedures for dealing with chemical issues, and what they did to fulfil the requirements of REACH regarding substances and also the RoHS Directive where relevant. In addition to this, the general principles of the Environmental Code and the Product Safety Act were discussed. The analytical results for the designated articles were also compared during the inspection with the information the company had received from its supplier or its tests. In cases where the information did not agree with a Swedish supplier's information, cases to address this were initiated afterwards. Following the inspection a request or case closure was sent to the inspected companies. When the companies that received a request had provided the report or information asked for, these cases were also closed.

### 2.3.3 Information to consumers

An information text and a form that consumers can use for enquiries to stores about Candidate List substances in articles have been prepared and published on the KemI website (see Annex 2). The purpose of the form was to make it easier for consumers to gain access to information about hazardous substances in the articles they buy.

## 2.4 Results

### 2.4.1 Analyses of articles

Six of the 26 analysed articles were found to contain more than 0.1% of some substance in the Candidate List, see the result below in Table 1. Three of these had been bought from Swedish companies, while three were bought from countries outside the EU. One of the Swedish companies was merely a sales agent, which led to the case being closed. The other two Swedish suppliers were reported to the prosecution authority as they had failed to provide information to the retailers. Cases involving other companies were closed, in some cases with comments.

Table 1. Articles containing more than 0.1% of any substance in the Candidate List.

| Article                  | Part/material            | DEHP (%) | DIBP (%) | SCC (%) |
|--------------------------|--------------------------|----------|----------|---------|
| Fuel hose                | Rubber inflator          | 2.5      |          |         |
| Fuel hose                | Rubber inflator          | 5.0      |          |         |
| Starter cables           | Red handle               | 11       | 6.1      | 0.12    |
|                          | Black handle             | 9.7      | 2.6      |         |
|                          | Red cable                | 12       |          |         |
|                          | Black cable              | 20       |          |         |
| Steering-wheel protector | Inner material           | 3.4      | 0.8      |         |
| Neck cushion for car     | Black plastic material   | 50       |          |         |
| Headsets                 | Black plastic on headset | 11       |          |         |

### 2.4.2 On site inspections at retailers

Great variation with regard to the companies' knowledge and procedures regarding chemical issues was noted in the inspections. For half the companies only a few details were lacking from the procedures to fulfil all the requirements in the legislation, while other companies barely did any work on chemical issues at all. The analytical results for the purchased articles were presented during the inspections, see Table 2. Deficiencies were found in several cases

in the comparison between the analytical results for the selected articles and the suppliers' information. This might be that the suppliers had failed to provide any information at all or that they had certified that the article did not contain any substances in the Candidate List although KemI's analyses pointed to such presence. In some cases such certificates were several years old. The retailers who had inadequate procedures were called upon to state, among other things, how they would ensure that they receive information on the content of Candidate List substances in articles and how professional customers gain access to the information. In cases where there were Swedish suppliers who had not provided information on the content of Candidate List substances in the articles KemI had inspected, these suppliers were contacted. In four such cases the companies were reported to the prosecution authorities and the cases were then closed.

*Table 2. Analytical results for the articles that had been purchased from the inspected companies and that contained more than 0.1% by weight of any substance in the candidate list.*

| <b>Article</b>               | <b>Part/material</b>  | <b>DEHP (%)</b> | <b>DIBP (%)</b> | <b>DBP (%)</b> |
|------------------------------|-----------------------|-----------------|-----------------|----------------|
| <b>Headsets</b>              | Cable                 | 18              |                 |                |
| <b>Aerial cable</b>          | Cable                 | 19              |                 |                |
| <b>Electric tape</b>         | Tape                  | 0.2-0.3         |                 |                |
| <b>CD sleeves</b>            | Plastic               | 26-31           |                 |                |
| <b>Seat</b>                  | Imitation leather     | 5.3-8           | 0.6             | 0.4            |
| <b>Wipe-clean tablecloth</b> | Wipe-clean tablecloth | 0.5             |                 |                |
| <b>Waders</b>                | Wellington boots      | 25-30           | 0.8             | 0.5            |
|                              | Trousers              | 0.2-0.3         |                 |                |
| <b>Work gloves</b>           | Blue plastic          | 29-30           |                 |                |
|                              | Red plastic           | 30-32           |                 |                |
| <b>Work gloves</b>           | Plastic               | 21-22           |                 |                |
| <b>Work gloves</b>           | Plastic               | 37-41           |                 |                |
| <b>Fender</b>                | Plastic               | 11-12           |                 |                |
| <b>Electric kettle</b>       | Cable                 | 16              |                 |                |

### **2.4.3 Information to consumers**

It is hoped, with the information effort aimed at consumers, that more consumers will become aware of their rights to information and start to make use of this right. In some cases it has happened that consumers who have not received a reply or where they feel that the replies they have received have been inadequate contact KemI, and this is then treated as a tip-off.

### 3 Discussion

Deficiencies relating to companies' knowledge of the requirements in REACH were observed both in on site inspections and in inspections by letter. Some companies did not know at all about the requirement in Article 33 that information has to be provided or the requirements in Article 7 about registration/notification, despite buying and selling articles that contained substances in the Candidate List. Knowledge appears to vary greatly between companies.

Several of the companies visited stated that they were members of industry organisations for retailers. They felt, however, that they did not receive much information or support regarding work on chemical issues from them even though it would be desirable to do so. Those companies that formed part of larger groups instead received better assistance from other companies within these groups.

The fact that the suppliers' information on the presence of substances in the Candidate List did not agree with the analytical results for the selected articles suggests that the companies must lay down requirements to be met by their suppliers, and also update these. For some articles, e.g. risk articles (plasticised PVC plastic, articles with substantial skin contact etc.) samples and analyses may be relevant to check that the information provided by the suppliers is correct.

The companies' routines for fulfilling the requirements for registration and notification under Article 7 of REACH were also discussed in the inspection visits. Several companies, including those who were aware of the requirements, did not know that the volume of a substance in the Candidate List that has to be notified under Article 7(2) has to be calculated on all articles (imported or manufactured) containing more than 0.1% of the substance. Many companies had understood that the calculation only applied to one type of article. In order to be able to calculate the volume, the company that imports articles is required not just to find out that there is more than 0.1% of a Candidate List substance but also the level at which this substance is present. Several companies only stated requirements that suppliers should state whether the articles contained Candidate List substances or not. As well as how the calculation is to be done, it was unclear for some companies when the exemption (contained in Article 7(6) of REACH) for substances already registered for that use is to be applied. According to the ECHA guidance on articles, it is not sufficient for the substance to be registered with the "use descriptor system" for that use, and more is required for it to be possible for this exemption to be applied. This guidance advises an article importer to contact a supplier of the substance concerned to hear about their registration or to check exposure scenarios in safety data sheets. None of the companies inspected had done this. Article 7 is felt to contain difficult rules and in addition is complicated to enforce. Companies that had good knowledge of REACH in other respects appeared to be less aware of the requirements contained in Article 7. Experience from the project illustrates a great need for information and guidance on these obligations.

When the companies' procedures for information transfer under Article 33 were discussed, several companies were aware that consumers had the right to request information and that companies in the distribution chain have the right to receive information automatically at the time of purchase. When the right of professional store customers to information was raised, on the other hand, few of the companies were aware that these customers have the right to receive information without requesting it. Some companies had invoice customers they were aware of but they all also thought that they had professional "anonymous" customers who shopped directly in-store. It was discussed in the inspections how these customers are to receive information, and solutions such as labelling on the article, information on the website

and information on the invoice were discussed. At present there is no recommendation on how the companies are to proceed to fulfil these requirements. Good examples of how some companies have solved this are to post information on the website, enter information into the checkout system, label the articles and print out the information on the receipt.

Article 33 states that the supplier of an article containing more than 0.1% of a Candidate List substance has to provide the recipient with sufficient information, at least the name of the substance, so that the article can be used in a safe way. It is unclear what form such information is to take. In most cases when the inspected companies requested and/or received information on the content of Candidate List substances only the name of the substance was relevant. Only in one case there was a description of safe use, which advised pregnant women against using the article.

In the inspections information was given that there are two interpretations in the EU concerning how 0.1% by weight is to be calculated for composite articles (for the whole of the composite article or for individual components). Some companies were aware that there are two interpretations, while others were not. Among the companies that requested information from their suppliers, it was most common to do so based on the whole composite article and not at component level. It is possible that better communication is needed to companies on the fact that there are two interpretations and on KemI's interpretation in enforcement (the calculation is to be based on individual components).

The project has led to increased knowledge of the rules contained in the REACH Regulation applicable to Candidate List substances at companies that were inspected and among consumers. KemI and companies have also gained greater awareness of the presence of SVHC substances in various articles and materials through analyses of articles. This had led to improved transfer of information in several distribution chains and voluntary phasing-out of articles containing hazardous substances. However, the project has also identified deficiencies among companies selling articles with regard to knowledge, among other things, of the requirements of REACH. Awareness of the requirements of the Regulation varies greatly between companies and sectors. There is a great need for further information, and KemI should continue to undertake enforcement in this area.

## **4 Advice to companies**

### **4.1 Knowledge**

Companies that manufacture, import and sell articles often have to have knowledge of several pieces of legislation in the area of chemicals. These include the REACH Regulation, the RoHS Directive (for electrical and electronic products), the Toys Directive and the Product Safety Act. Companies can obtain information on these rules on the KemI website ([www.kemi.se](http://www.kemi.se)), from industry organisations and from other companies. For in-depth knowledge of the REACH legislation, there is the website of the European Chemicals Agency ([www.echa.eu](http://www.echa.eu)), which among other things contains guidance on the requirements in REACH applicable to articles<sup>6</sup>. By subscribing to KemI's newsletters, it is possible to obtain updates on new rules, enforcement projects and other developments in the area of chemicals<sup>7</sup>. Some consultancies also have services in which they offer updated lists of legislation adapted to the company's needs.

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<sup>6</sup> [http://echa.europa.eu/documents/10162/13632/articles\\_sv.pdf](http://echa.europa.eu/documents/10162/13632/articles_sv.pdf)

<sup>7</sup> [www.kemi.se](http://www.kemi.se) → Publications → Electronic newsletter

As well as knowledge of the rules, companies are required to know the content of chemicals in their own articles. This is required to enable them to know what legislation may be applicable to different articles. It also makes it possible to select articles where the risk of hazardous substances occurring is great and to focus chemical work on these. In the case of manufacturing companies, the person responsible for these issues is required to have an understanding of the manufacturing process and know what chemicals are used. In most cases manufacturing takes place at a different company in a different country, and communication with the supplier is then important. External consultants and test laboratories that know the industry may also have knowledge of what materials the articles are made of and what chemicals they may contain. Knowledge of what substances are present in articles also makes it possible to substitute hazardous substances.

## **4.2 Communication with supplier**

Most companies that sell articles have at least one supplier earlier in the distribution chain. It is common for suppliers to be in a country outside the EU and not to be subject to the same legislation as companies in the EU. It is therefore important to communicate requirements on chemical content and information clearly to these suppliers. One way that several companies have described as successful is to integrate the chemical requirements with other quality requirements. In that way the purchasing functions at the company also become involved in cases where chemical work is separated from the purchasing department.

In its enforcement, KemI has encountered several variants of contracts with suppliers regarding chemical requirements and REACH. In some cases the contracts are very general and do not specify in detail what they mean. Examples are certificates or contracts where the supplier has to sign that they “fulfil REACH” or “comply with all relevant legislation in the country where the article is sold”. As REACH contains many different parts, such a contract ought to be supplemented by an annex that describes the requirements in detail. There are no requirements in the REACH legislation on what form the communication between companies has to take, and it is important to emphasise that such contracts between companies are civil-law contracts. Such a contract thus does not relieve companies of responsibility for the contents of the articles complying with the legislation.

In some cases it may be relevant to require the supplier to have tests performed at an external laboratory and to report the results. This may, for example, be appropriate for “risk articles”, when a new supplier is appointed or when the design of an article is changed. However, expertise on the part of the recipient is required to understand the meaning of the test results.

If an article contains more than 0.1% by weight of a Candidate List substance, professional customers have to automatically receive information to this effect. Consumers have to receive information on request within 45 days. In order to be able to fulfil this requirement, it is required that those who sell articles in turn have received this information. It is therefore important to include a requirement that this information is provided in communication with the supplier. This is particularly important if the articles are bought from countries outside the EU, as the supplier does not have any legal requirement to supply the information. Suppliers outside the EU are, in fact, required to supply this information, but it has emerged during the course of the project that these rules in many cases are not known and implemented in the companies' procedures.

If articles are bought from countries outside the EU, the company that buys the article is defined as an importer of articles under REACH. An importer has an obligation to notify the ECHA if the goods they import during one year in total contain more than one tonne of a

Candidate List substance. To be able to decide whether this is the case, the company is required to know the level of the substance in its imported articles and not just the fact that the substance is present. The easiest way of finding this out is for the supplier outside the EU to state both the name and level of the substance and in which components it is present.

### **4.3 Information to customers**

Consumers have the right to receive information on whether an article contains more than 0.1% of a Candidate List substance if they request it. This information has to be supplied within 45 days. Nothing is written in the legislation about how this question has to be formulated or how the answer is to be given, other than that sufficient information has to be provided to enable the article to be used in a safe way. The customer must at least know the name of the substance. Questions put verbally in a store, on the telephone or by e-mail have to be answered if an article contains more than 0.1% of a Candidate List substance. As the rule is formulated, it is not clear that a reply is necessary in cases where no Candidate List substance is contained in the article at a level of more than 0.1%. KemI recommends, however, that such questions are always answered with a clear reply, even if the article does not contain any Candidate List substance.

Professional customers have the right to automatically receive information on whether an article they buy contains more than 0.1% of a substance in the Candidate List. This also applies to professional customers who shop in stores without identifying themselves as professional customers. This may signify some difficulty for the store as it can be difficult to identify these customers. The companies KemI has been in contact with have solved the problem in various ways, and examples of solutions have been printing the information on the receipt, informing through the invoice and labelling of the article. If sale only takes place through the Internet, the information can be clearly shown there.

### **4.4 Tests**

Analysing all articles for all substances that may be restricted or require information transfer is financially impossible for individual companies in most cases. Chemical tests may, however, be a good tool for checking selected samples. This can be done, for example, on identified “risk articles”, in cases where there is reason to check a supplier's certifications or if it can be suspected in some other way that the article may contain a hazardous substance. With the aid of knowledge on the materials in the articles, it may additionally be possible to reduce the number of analyses and only perform the analyses that are necessary. For example, testing need not be performed for all Candidate List substances in all materials in an article, and relevant substances for certain materials can be selected.

It is possible to test a limited number of substance oneself in ways other than by wet-chemical analysis. This applies for example to elements such as the metals lead and cadmium in plastic and metal. Using what is known as an XRF instrument (X-ray fluorescence), these substances can be detected in certain materials, and if an excessively high level is discovered, this component can be sent for external analysis. An XRF instrument can be a good way of screening a large number of articles but requires trained personnel who can handle it, as it emits some radioactive radiation. An XRF instrument is additionally a relatively expensive investment, costing around SEK 300 000. There is a cheap test from Apoteket for the testing of nickel release from jewellery and other objects.

## 4.5 The interpretation of 0.1%

There are two views in the EU on how the level of a substance in the Candidate List is to be calculated for composite articles. Sweden and some other countries consider that the level of the substance must be calculated on individual parts which earlier in production have been individual articles. An example is the handlebar grip on a cycle. The remaining countries consider that the level should be calculated on the whole of the composite article. The risk in calculating on the weight of the whole of the composite article is that the level of a substance may end up being below 0.1% despite the part that contains the hazardous substance and that may lead to exposure containing high levels. For a cycle containing 20% DEHP in the handlebar grip the level would probably end up below 0.1% if the calculation was based on the weight of the whole cycle. The requirement for information transfer would then disappear. If the handlebar grip were to be bought separately, however, information would need to be supplied, as the level is then more than 0.1% calculated on the whole article.

In KemI's enforcement, information has been provided on the two different approaches, and it has been stated that KemI adopts Sweden's interpretation in its enforcement. This means that companies wishing to follow the Swedish interpretation must request information on the content of Candidate List substances in individual components of composite articles.

## 4.6 Notification/registration to ECHA

If a company manufactures or imports articles containing more than 0.1% of a Candidate List substance and the annual volume of this substance is more than one tonne, the substance must be notified to the ECHA. One of the purposes of this rule is to increase knowledge of where these substances are present.

To be able to decide whether such a notification is relevant, the company is required to know whether its articles contain Candidate List substances and, if so, at what levels. An approximate calculation can then be made to study whether the quantity is more than one tonne. The amount of the substance in all imported or manufactured articles where the level is more 0.1% must be added together in this calculation. For a company that imports work gloves, garden hoses and cables that all contain DEHP, for example, the amount of DEHP in all these articles must be added together.

If an article contains a substance intended to be released, this must be registered at the ECHA by the importer or manufacturer. This applies if the annual quantity of substance is more than one tonne for the imported and/or manufactured articles. This is conditional on the substance being intended to be released under normal or reasonably normal foreseeable conditions of use. Examples of such an article is fragrant rubber erasers.

There is an exemption from both these rules that can be applied if use of the substance is already registered for that use. This means that a company that has registered the substance as such may have covered use of the substance in the article concerned. A system of "use descriptors" is used in registration of the substance. DEHP, for example, has been registered with the use descriptor "plastic articles". The ECHA, in its guidance on articles, has considered such registration not to be sufficiently detailed for it to be possible for the exemption to be used. This is because "plastic articles" cover a large number of uses and possible exposures. If it is to be possible for the exemption to be applied, more detailed information on the use of DEHP is therefore required to be registered. This information may be difficult to obtain, and it is pointed out in the guidance that notification may be easier for a company than to examine whether the exemption is applicable.

## 5 Annexes

### 5.1 Annex 1 – Substances for analysis

The substances stated in the table below are looked for in the chemical analyses performed on the purchased articles in the project. The substances are included in the Candidate List, and the reason for this is shown in the right-hand column.

| Substance  | CAS number | Classification                        |
|--|------------|---------------------------------------|
| Dibutyl phthalate (DBP)                                | 84-74-2    | Toxic for reproduction <sup>8</sup>   |
| Di(2-ethyl hexyl) phthalate (DEHP)                     | 117-81-7   | Toxic for reproduction                |
| Benzyl butyl phthalate (BBP)                           | 85-68-7    | Toxic for reproduction                |
| Diisobutyl phthalate (DIBP)                            | 84-69-5    | Toxic for reproduction                |
| Di-(C6-C8 branched) alkyl phthalates (DIHP)            | 71888-89-6 | Toxic for reproduction                |
| Di-C7-C11 branched and linear alkyl phthalates (DHNUP) | 68515-42-4 | Toxic for reproduction                |
| Alkanes, C10-13 (short-chain chloroparaffins)          | 85535-84-8 | PBT <sup>9</sup> , vPvB <sup>10</sup> |
| Anthracene   | 120-12-7   | PBTs                                  |

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<sup>8</sup> Toxic for reproduction means that the substance may harm ability to reproduce.

<sup>9</sup> PBT = Persistent, Bioaccumulative, Toxic. Means that the substance breaks down very slowly, accumulates in biota and is toxic.

<sup>10</sup> vPvB = very Persistent, very Bioaccumulative. Means that the substance breaks down very slowly and accumulates in biota.

## 5.2 Annex 2 – Questionnaire for consumers

The text below is posted in Swedish on the KemI website and is intended to assist consumers in requesting information under Article 33 of REACH.

*Under the European chemicals legislation REACH (Regulation (EU) No 1907/2006), anyone who manufactures, imports or sells an article containing 0.1% or more of certain substances is obliged to provide information to this effect to consumers who request it. The information duty applies to substances included in the EU's Candidate List. These substances are of very high concern due to their properties hazardous to health and the environment. This rule is contained in Article 33 of REACH.*

*The Candidate List is updated regularly, and the latest list can be viewed on the website of the European Chemicals Agency (ECHA). <http://echa.europa.eu> (The Candidate List can be found on the ECHA's English website under ECHA CHEM, Authorisation, Candidate list.)*

*A Swedish version of the list can be found on the Swedish Chemicals Agency website: [www.kemikalieinspektionen.se](http://www.kemikalieinspektionen.se) (Search on "Kandidatförteckningen")*

*Please inform me whether your article (name): ..... contains any substance or substances included in the Candidate List mentioned above at a level of more than 0.1%. If the article contains any such substance, I wish to receive information on the name of the substance and information enabling me to handle the article in a safe manner.*

*The information has to be provided within 45 days, and I therefore expect a reply to my enquiry by (date):.....*

*Name:.....*

*Contact details (address/  
e-mail/telephone): .....*

*Questions concerning the chemicals regulation REACH can be put to the Swedish Chemicals Agency's REACH enquiry service [Reach-upplysning](#).*

*Read more at [www.kemikalieinspektionen.se/reach](http://www.kemikalieinspektionen.se/reach)*



**[www.kemikalieinspektionen.se](http://www.kemikalieinspektionen.se)**

**Swedish Chemicals Agency, P.O. Box 2, 172 13 Sundbyberg, Sweden  
Phone: +46 8 519 41 100, Fax: +46 8 735 76 98, E-mail: kemi@kemi.se**