KEMI
Swedish Chemicals Agency

Information on hazardous substances in articles

– a project in collaboration with Sweden's municipalities

ENFORCEMENT 9/20

kemikalieinspektionen.se

KEMI
Swedish Chemicals Agency

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

Article number: 511 367.

Preface

The Swedish Chemicals Agency (hereinafter the Chemicals Agency), together with inspectors from 71 municipalities, has conducted a national collaborative project that focuses on information about hazardous substances in articles. The project forms a part of the guidance on enforcement that the Chemicals Agency provides to the municipalities.

For a number of years, the Chemicals Agency has carried out collaborative projects with municipalities concerning the inspection of chemical regulations. Earlier collaborative projects have focused on controlling such things as pesticides, jewellery and chemical products.

The project comprised two parts, control of restricted substances in articles and control of articles treated with biocides. We checked for the occurrence of restricted substances by carrying out chemical analyses, primarily in plastic articles. In the case of articles treated with biocides, we checked if the active substance is permitted and whether labelling complied with legal requirements. We also visited the companies that sold the articles and checked how they work with chemical-related issues.

The part of the project that dealt with treated articles has been included in a joint EU enforcement project. The results from the inspections by the municipalities and the Chemicals Agency were reported to the EU project as part of Sweden's results.

The project managers at the Chemicals Agency were Frida Ramström and Mariana Pilenvik. Other project managers were Charlotte Rahm, Margareta Daho, Camilla Westlund, Amanda Rosen and William Morlin.

Many thanks to all the municipalities who participated in the project.

Swedish Chemicals Agency

Sundbyberg

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Glossary

Word/Abbreviation	Explanation
ADCA	Azodicarbonamide. The substance is used as a foaming agent in the manufacture of certain foamed plastics. When manufacturing is performed correctly, the substance should not remain in the end product.
Aluminium	A metal that has many different applications. In this project, we found it in toy slime.
Treated article	An article that has been intentionally treated with a biocidal product to achieve a biocidal effect.
Biocidal product	Substances and mixtures that contain or generate one or more active substances that are intended to prevent or render harmless the effects of harmful organisms such as bacteria, mould fungi and insects.
Lead	A metal with many applications including use as an additive in metal to make it more workable, and as an additive in plastic. The substance has harmful properties and can e.g. have a negative effect on the development of the central nervous system.
Boron	An element that may be found in e.g. toy slime.
Brominated flame retardants	There are various types of brominated flame retardants added to electronics and other articles to prevent fire. Polybrominated biphenyls (PBB) and polybrominated diphenyl ether (PBDE) are two groups of brominated flame retardants that have properties harmful to health and the environment.
ECHA	The European Chemicals Agency.
Phthalates	A group of substances that can be used inter alia as additives in plastic to make it soft. Certain phthalates have harmful properties and are therefore restricted in certain types of articles. The phthalates mentioned in this report are di(2-ethylhexyl)phthalate (DEHP), diisobutyl phthalate (DIBP), dibutyl phthalate (DBP) and diisononylphthalate (DINP).
ICSMS	Information and Communication System on Market Surveillance – a system in which enforcement authorities in the EU report controlled products.
Cadmium	A metal that is used among other things as an additive to metal and plastic articles. The substance has harmful properties and can e.g. have a negative effect on the kidneys and skeleton.
Candidate List	A list of substances with especially hazardous properties. If a substance is included in the list, certain obligations pertain under the REACH Regulation.
Short-chain chlorinated paraffins (SCCPs)	A group of substances used among other things for making certain types of plastic soft and flame resistant. The substances are difficult to break down in the environment, are harmful for aquatic organisms and are suspected to be carcinogenic.
Permethrin	A substance used as a biocide, inter alia to make textiles insect repellent. Among other things, the substance may cause allergic dermatological reactions and is toxic to aquatic organisms.
POPs	POPs is short for Persistent Organic Pollutants. They are regulated under the POPs Regulation.
PVC	Poly Vinyl Chloride – a kind of plastic that can be made soft by the addition of plasticisers.

RoHS	EU directive that regulates the occurrence of certain hazardous substances in electrical and electronics equipment.
Safety Gate	Safety Gate has previously been called Rapid Alert and Rapex. It stands for ”Rapid Alert System for non-food dangerous products” and is a system in which enforcement authorities in the EU report dangerous products.
SCIP database	A database at ECHA to which suppliers must notify articles containing substances in the Candidate List. The provision is in Waste Directive 2008/98/EC and takes effect on 5 January 2021.
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals – joint EU chemicals regulation (EG) no. 1907/2006
Active substances	The substances in biocidal products that give rise to the biocidal effect. Must be approved before use in biocidal product within the EU.
XRF	X-ray fluorescence - an x-ray-based screening technology for elements in the surface of a material.

Summary

The enforcement project was a collaboration between the Chemicals Agency and 71 Swedish municipalities. Its focus was to control whether hazardous substances were present in articles on the Swedish market, and whether consumers are able to get the information they are entitled to. The project forms a part of the guidance on enforcement that the Chemicals Agency provides to the municipalities.

The project has two parts; one where we used chemical analysis to check for restricted substances and substances on the Candidate List in articles made of plastic and metal, and another where we checked for active substances and the labelling of articles treated with biocides. The municipalities inspected articles in retail stores while the Chemicals Agency followed up on the suppliers with non-compliant articles. The Chemicals Agency also inspected some twenty retail chains and a few e-commerce companies.

Of the 323 articles analysed, 25 contained prohibited substances. The prohibited substance found in most articles was short-chain chlorinated paraffins (SCCPs), and it was found in different types of articles made of soft PVC plastic. In 43 of the articles, we detected substances on the Candidate List in concentrations above 0.1 per cent by weight, at which limit recipients of such articles must be provided with information about the substance to enable safe handling of the article. Prohibited substances were also found in 13 of these articles. The most frequently found substance from the Candidate List was bis(2-etylhexyl)phthalate (DEHP) used as a softener in PVC plastic.

In all, we checked 74 articles treated with biocides in the project. Of these, the majority had serious shortcomings concerning the labelling, such as where the active substance was not mentioned. The inspections showed a widespread lack of knowledge about legislation concerning treated articles, both in retail stores and with suppliers. It was also difficult for inspectors to get enough information about articles to make a correct assessment, as the information about biocidal treatment was often not available from the Swedish companies, but had to be requested from companies higher up the supply chain in other countries.

The results from local inspections at retail stores show that more than half of the companies were unaware of the Candidate List before the inspection visit. Furthermore, very few companies had been asked about the Candidate List by consumers, and none of the companies with articles in which we found substances from the Candidate List had received information about it from their suppliers. This shows major shortcomings in the transfer of information in the supply chain despite the duty to inform recipients about substances on the Candidate List having been in force more than 10 years.

Sammanfattning

Detta tillsynsprojekt har utförts i samverkan mellan Kemikalieinspektionen och 71 kommuner. Vårt fokus har varit att kontrollera förekomsten av farliga ämnen i varor som finns på den svenska marknaden och om konsumenter har möjlighet att få den information om dessa ämnen som de har rätt till. Projektet är en del av Kemikalieinspektionens tillsynsvägledning till kommunerna.

Projektet har bestått av två delar. I en del har vi kontrollerat förekomst av begränsade ämnen och ämnen på kandidatförteckningen i plast- och metallvaror med hjälp av kemiska analyser. I den andra har vi kontrollerat verksamt ämne och märkningen på biocidbehandlade varor. Kommunerna har fokuserat på varor i detaljhandeln medan Kemikalieinspektionen har följt upp de leverantörer som hade brister. Kemikalieinspektion har även inspekterat ett tjugotal butikskedjor samt några e-handelsföretag.

Av de 323 varor som vi analyserade var det 25 stycken som innehöll förbjudna ämnen. Det förbjudna ämne som vi hittade i flest varor var kortkedjiga klorparaffiner (SCCP) och det hittade vi i olika sorters varor av mjuk plast. I 43 av varorna hittade vi ämnen på kandidatförteckningen i halter över 0,1 viktprocent, vilket innebär att mottagare ska få information om ämnet för att kunna hantera varan säkert. 13 av dessa varor innehöll dessutom förbjudna ämnen. Det vanligaste ämnet på kandidatförteckningen som vi hittade var di(2-etylhexyl)ftalat (DEHP) som används för att göra PVC-plast mjuk.

Totalt kontrollerade vi 74 biocidbehandlade varor i projektet. Av dessa hade merparten stora brister i märkningen, till exempel angavs inte det verksamma ämnets namn. Inspektionerna visade på en utbredd okunskap om regelverket gällande biocidbehandlade varor i både butiksled och hos leverantörerna. Det var även svårt för inspektörerna att få fram tillräckligt med information om varorna för att kunna göra en korrekt bedömning, då information om biocidbehandlingen ofta inte var tillgänglig hos de svenska företagen utan behövde kommuniceras med företag högre upp i leverantörsledet i andra länder.

Vid kommunernas inspektioner hos butiker var det drygt hälften som inte kände till kandidatförteckningen före kommunens besök. Det var dessutom väldigt få som hade fått frågor om den från konsumenter och inga av de företag som hade varor där vi hittade ämnen på kandidatförteckningen hade fått information om det från sin leverantör. Detta visar på stora brister gällande informationsöverföringen inom leverantörsledet trots att informationsplikten för ämnen på kandidatförteckningen har funnits i drygt tio år.

1 Introduction

In this project, we have chosen to control articles available on the Swedish market. Articles are objects whose shape, surface or design is more important for the function than its chemical content. Examples of articles are clothes, dolls, electronics and jewellery. Objects that are not articles are defined in chemicals legislation as substances or mixtures of substances. Glue, paint and cleaning agents are good examples. The legal requirements for these various types of product differ greatly and in general articles are less regulated than substances and mixtures.

Treated articles are articles that have been intentionally treated with biocidal products or received them as additives. Biocides are substances and mixtures that contain or generate one or more active substances that are intended to prevent or render harmless the effects of harmful organisms such as bacteria, mould fungi and insects. The articles are treated with biocides to achieve a specific function such as preventing bacterial growth that causes undesirable odours in fabrics.

1.1 About the Swedish Chemicals Agency

The task of the Chemicals Agency is to reduce the risks of chemicals harming people and the environment. The agency is an authority under the Swedish government and we work within Sweden, the EU and the world. We monitor compliance with applicable rules on chemical products, pesticides and substances in articles and we carry out inspections. We review and authorise pesticides before they can be used. We also provide inspection guidance for municipalities and county councils. Our environmental quality objective is A Non-toxic Environment.

1.2 Description of the problem

We are often told that everyday articles in our homes and immediate surroundings may contain hazardous chemical substances. Certain substances are prohibited, and for others there is a requirement for the recipient to be informed about them. The substances are regulated under several different EU legal acts, and it can be difficult for businesses and consumers to form an idea of which regulations apply.

Earlier inspections by the Chemicals Agency concerning information about the presence of substances on the Candidate List in articles, and about the labelling of treated articles, showed there to be major deficiencies in the way companies handle these issues. Knowledge of applicable rules has fallen short in many companies, and the dissemination of information and the labelling of articles have not met requirements. There is a problem with consumers not receiving the hazardous substance information they are entitled to, leaving them unable to make informed choices about the articles they buy. Our earlier inspections have also shown that prohibited substances occur in articles[1] relatively often (in 14-18 per cent of inspected articles).

Articles that contained prohibited substances or substances on the Candidate List as well as treated articles are widely available in retail, and the Chemicals Agency has not had the ability to check them all. Municipal enforcement authorities may also check such articles, but

[1] Inspection no. 9/19 – Swedish Chemicals Agency analyses in conjunction with inspections in 2018, October 2019 (https://www.kemi.se/global/tillsyns-pm/2019/tillsyn-9-19-kemikalieinspektionens-analyser-i-samband-med-tillsyn-2018.pdf)

this only takes place regularly in a small number of municipalities as inspections are labour intensive and require special skills.

1.3 Objectives

One objective was to increase compliance in companies that sell articles regarding their dissemination of information about the biocidal treatment of articles and the presence in them of substances on the Candidate List. Articles discovered by the project as failing to meet legal requirements were removed from sale or remedied by some other means.

Another objective was to raise the expertise of municipalities regarding these issues and to provide them with knowledge and materials to enable them to perform inspections in this area themselves even after the project had ended.

A major advantage of running this type of enforcement in collaboration with the country's municipalities is the ability to reach many more companies and operators that are not usually subject to Chemicals Agency inspections. We can reach the entire distribution chain by letting the municipalities inspect retail while the Chemicals Agency inspects suppliers. By participating in the joint EU project on treated articles, we facilitate communication with other national enforcement authorities in the EU, allowing measures to be taken also at suppliers located outside Sweden.

It is hoped that the project will also increase consumer awareness about their rights to receive information about hazardous substances present in articles. The long-term objective is to reduce the number of articles on the market that contain hazardous substances by raising consumer pressure and increasing knowledge in companies.

1.4 Legislation

The legislation governing hazardous substances in articles is found in several EU legal acts. Brief descriptions of the legislation checked in this project are provided below.

1.4.1 REACH Regulation EC no 1907/2006

REACH is the EU's most comprehensive chemical regulation and mainly concerns substances and mixtures. However, some parts of the regulation concern substances in articles. Annex XVII to the regulation contains some 70 restrictions on substances and groups of substances, where many limit the occurrence in articles. Examples of such substances which were checked during the project are phthalates in toys and lead in small articles that children might put in their mouths.

Article 33 of the REACH Regulation includes a requirement to inform of especially hazardous substances in articles. Article 33 describes the suppliers' obligation to provide information about hazardous substances on the Candidate List in concentrations greater than 0.1 per cent per weight in their articles. This information must always be submitted to commercial customers, while consumers have the right to the information on request free of charge and within 45 days. The list of substances is updated twice a year. There are currently (March 2020) 205 substances on the list. This project focused on substances from the Candidate List that may be present in soft plastic and metal.

1.4.2 EU Biocidal Products Regulation 528/2012

This regulation governs biocidal products, but there are also certain regulations applicable to articles treated with biocides (referred to in the regulation as *treated articles*). Treated articles may only contain active substances that are permitted for the type of product, and in some cases articles must also be labelled. The labelling must include information stating that the article has been treated with a biocide, the name of the active substance, its biocidal properties and in certain cases risk management measures and information about nano materials. The language in the labelling must be Swedish if the article is sold in Sweden.

1.4.3 POPs Regulation EU no 2019/1021

This regulation governs persistent organic pollutants, and it is the EU's way of incorporating two global conventions, one of which is known as the Stockholm Convention. The Chemicals Agency found a great deal of short-chain chlorinated paraffins (SCCPs) in articles. SCCPs form a group of substances used to make plastic soft and flame resistant.

1.4.4 RoHS Directive 2011/65/EU

There is an EU directive that governs the occurrence of certain hazardous substances in electrical and electronic products. The substances concerned are lead, cadmium, mercury, hexavalent chromium and the flame retardants polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). Since 22 July 2019, the directive has also governed four phthalates (substances used to soften plastic), but the articles checked in this project were on the market before this date and are not subject to the phthalate restriction. The directive also includes requirements for labelling (including the CE mark) and documentation.

1.4.5 The Toy Safety Directive 2009/48/EC

The directive is the most comprehensive legislation for toys within the EU, but there are also rules that concern toys in other legislation. The directive concerns various safety aspects for toys, one of which is chemical risks. The directive limits the occurrence and emission of a number of different substances and also includes requirements for labelling (including the CE mark) and documentation.

2 Method

2.1 Inspections by the municipalities

In the autumn of 2018, all municipalities were invited to participate in the collaborative project. In January, we arranged four training sessions for the inspectors participating in the project. Training was conducted in Malmö, Gothenburg, Sundsvall and Stockholm. The training reviewed the regulations that would be subject to controls by the project and addressed practical issues about the inspections and sample articles for analysis. The municipalities that participated in the project are listed in Appendix 1.

On completion of training, the municipalities began their inspections in retail stores by looking for treated articles and articles that would be sent for chemical analysis. Treated articles found in retail stores by the municipalities were photographed. The municipalities sent the photographs to the Chemicals Agency for joint assessment. Each municipality could submit at a maximum five articles to the Chemicals Agency for chemical analysis. It was mainly articles made from soft plastic or metal that we suspected the occurrence of substances from the Candidate List or other restricted substances. We carried out a screening analysis of the articles using the Chemical Agency's in-house XRF equipment[2] and based on the results, we submitted the articles for analysis at an external laboratory.

The municipalities were able to choose whether to conduct inspections concerning restricted substances and substances on the Candidate List and/or treated articles. Two different checklists were used during inspection visits; one concerned restricted substances and the other treated articles. The checklist we used during visits to retail stores selling treated articles was drawn up in a joint EU project concerning treated articles.

When the results of the analysis were ready, we passed them on to the municipalities, who in turn informed the companies they had inspected. In cases where the articles contained prohibited substances, the companies were themselves asked to take measures, which they did in those cases where the articles remained on sale. The companies were also informed about the assessments of treated articles. In many cases, the municipalities had to ask further questions about the articles in order to make a full assessment. In the cases where treated articles did not meet legal requirements, the companies voluntarily removed them from sale or corrected the labelling.

2.2 Inspections by the Chemicals Agency

In parallel with the inspections conducted by the municipalities, the Chemicals Agency carried out its own inspections at certain major retail chains, primarily those with treated articles for sale. Several of these retail chains had been inspected previously, and the inspections functioned as follow-ups of previous inspection visits. We also visited a small number of e-commerce companies. During the inspections, we selected articles for chemical analysis and treated articles to check the active substance and labelling.

We informed the companies of analysis results as soon as the latter were ready. In cases where the articles contained prohibited substances, the companies were themselves asked to take measures, which they did in all cases. We also informed the companies about our assessment of their treated articles. In many cases, we had to ask further questions about the

[2] XRF (X-Ray Fluorescence) is an X-ray based technology that measures the content of elements in certain materials.

articles in order to make a full assessment. The companies remedied the non-compliant labelling or voluntarily removed the articles from sale. Because the articles no longer remained for sale in a number of cases, the companies did not have to take any action.

The Chemicals Agency then opened cases against the companies who had supplied articles containing prohibited substances or non-compliant treated articles (retail suppliers). In every case, the articles which did not meet legal requirements were removed from sale by the companies without the need to issue a sales prohibition. We also opened cases against companies that had supplied articles that contained substances from the Candidate List in concentrations greater than 0.1 per cent by weight, to investigate whether they had informed the recipient of the contents.

The Chemicals Agency reported suspected environmental offences to the public prosecutor in cases where companies had sold articles with prohibited substances or where they had produced or imported treated articles with prohibited active substances or incorrect labelling. We also reported suspected offences in a case where a company had supplied an article that contained more than 0.1 per cent by weight of a substance from the Candidate List to a commercial recipient (e.g. a retail store) without having informed the store of the content.

For certain offences, such as incorrectly labelled electronics or the wrong language when labelling treated articles, we decided on environmental penalty fees. The municipalities also reported suspected offences and issued decisions on environmental penalty fees in applicable cases.

2.3 Selection of articles

The articles we analysed when looking for substances from the Candidate List or other restricted substances were mainly those made from soft plastic. We also chose to analyse a number of brass articles, as this material may contain lead. Typical articles tested were sports equipment, electronics with soft plastic parts, plastic toys, animal toys made from soft plastic and gloves. Distribution by the number of articles in the different categories is shown in figure 1 below.

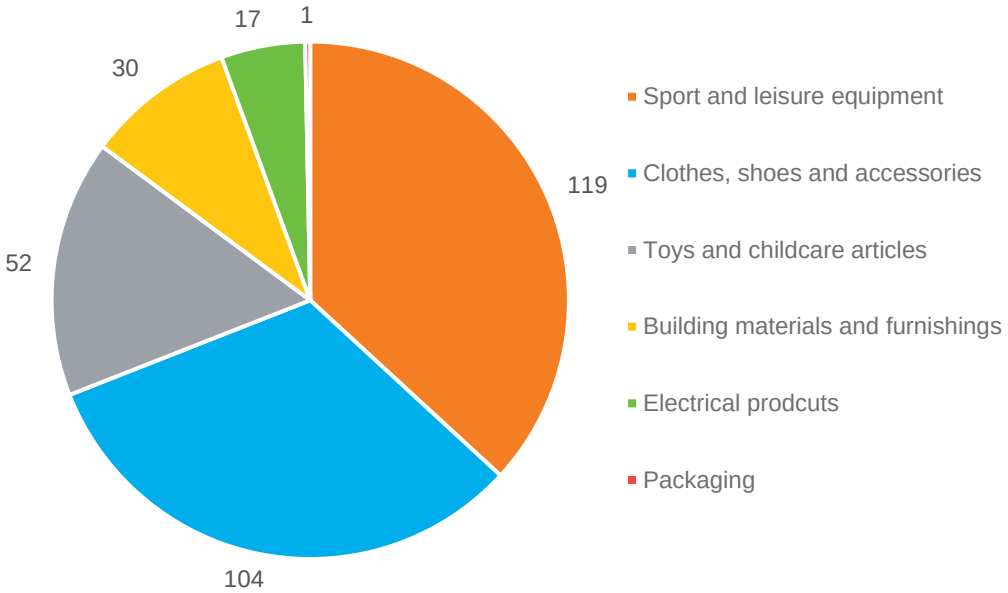

Figure 1. Articles analysed; number of articles across different categories.

The treated articles controlled were those marketed with claims of a biocidal effect. Typical treated articles assessed were sports clothes, gloves, shoes and soles. Figure 2 below provides an overview of the types of treated articles checked in the project.

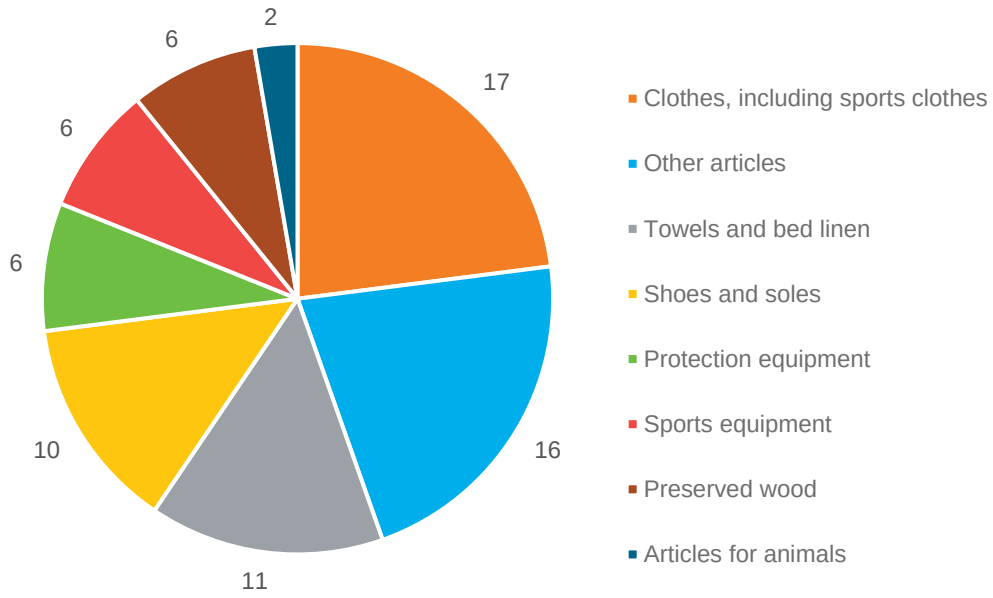

Figure 2. Treated articles checked in the project; number of articles across different categories.

3 Results

3.1 Articles analysed

In all, in the project we analysed 323 articles. Of these, 232 were from municipal inspections and 91 from the Chemicals Agency's inspections. All of the articles analysed are listed in appendix 2.

Of the articles analysed, 25 contained prohibited substances, and 13 of these also contained substances from the Candidate List in concentrations above 0.1 per cent by weight. In addition to these, a further 30 articles contain substances from the Candidate List in concentrations above 0.1 per cent by weight. In 47 of the articles, we either found substances that were not restricted for that type of article or we found restricted substances but in concentrations below the limit value. We found none of the target substances in 221 articles. Figure 3 below provides an overview of the analysis results.

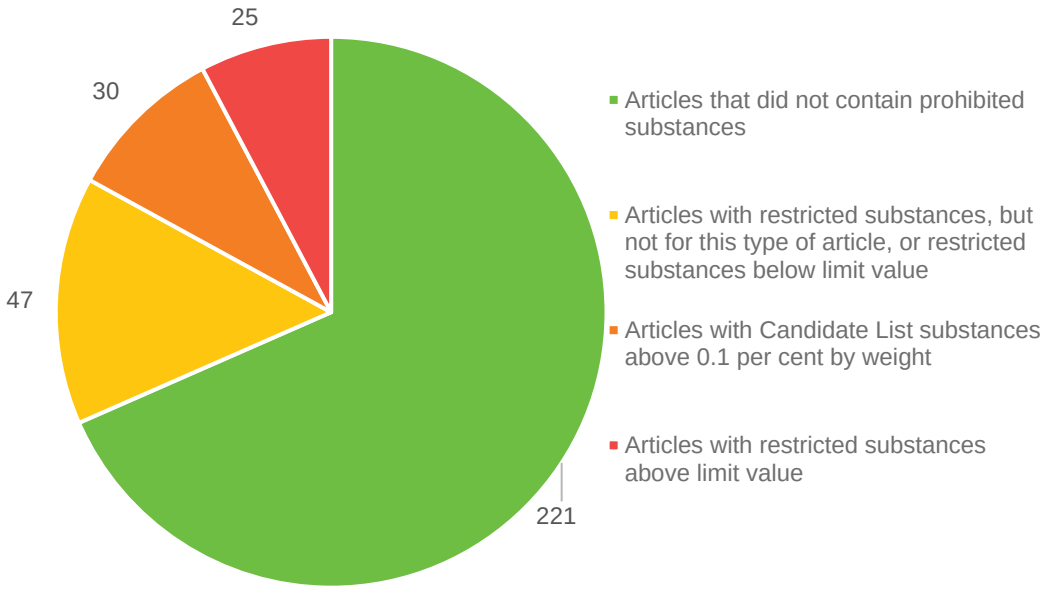

Figure 3. Articles analysed in the project; number of articles by results.

We have divided the articles tested during the project into different categories: *sports and leisure equipment*, *clothing, shoes and accessories*, *toys and childcare articles*, *building materials and furnishings*, *electrical products* and *packaging*[3].

All categories except *building materials and furnishings* included articles that contained prohibited substances; see figure 4 below. Substances from the Candidate List occurred in *sports and leisure equipment*, *clothes, shoes and accessories* and *building materials and furnishings*. The category with the highest proportion of articles containing prohibited substances and substances on the Candidate List was *sports and leisure equipment*. In *packaging*, we have only reported the instances where we found a prohibited substance, as this was the only case registered even though several other types of packaging were checked.

[3]These categories are based on our article inspection strategy. Inspection 4/16 Strategy for the inspection of chemicals in articles, March 2016 https://www.kemi.se/global/tillsyns-pm/2016/tillsyn-4-16-strategi-for-tillsyn-over-kemikalier-i-varor.pdf

Figure 4. Number of articles in the various categories tested during the project and results by category.

3.1.1 Prohibited substances

Restricted substances were found in 25 articles in concentrations above limit values, i.e. prohibited substances. This is equivalent to approx. 7 per cent of the articles checked. The restricted substances we found most of were short-chain chlorinated paraffins (SCCPs) used as softeners and flame retardants in PVC plastic. We also found lead in nine plastic articles and in soldering in electrical products, and we found cadmium in soldering in three electrical products. From two types of toy slime, the migration of boron was too high, and one of these also had too high migration levels of aluminium. Furthermore, we found excessively high concentrations of the phthalates DEHP, diisononylphthalate (DINP) and diisobutyl phthalate (DIBP) in three plastic toys. A summary of prohibited substances is shown in figure 5. Note that a single article may contain multiple prohibited substances.

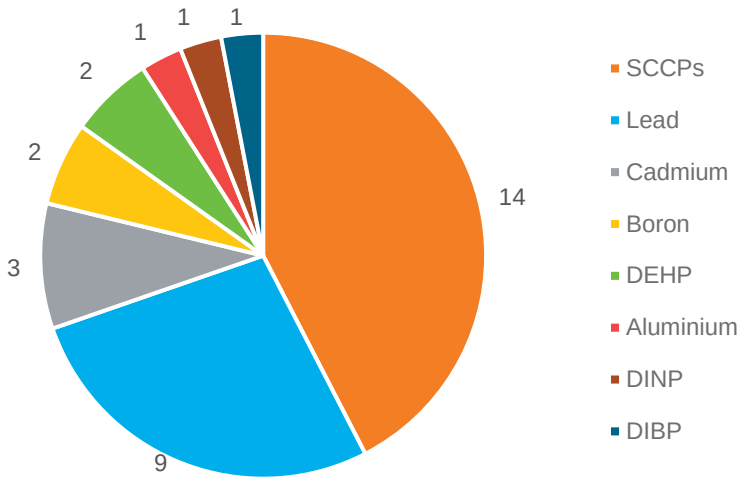

Figure 5. The figure shows the prohibited substances found in the articles analysed, and the number of articles in which each substance was found.

3.1.2 Substances on the Candidate List

Substances on the Candidate List were detected in 43 articles in concentrations above 0.1 per cent by weight, at which point recipients must be provided with information about the contents. These articles constitute around 13 per cent of the articles checked, and 13 of these 43 articles also contained forbidden substances. The substances from the Candidate List found were the phthalates DEHP, DBP (dibutyl phthalate) and DIBP, the softener and flame retardant SCCPs, lead and the plastic additive azodicarbonamide (ADCA). The most common substance found was DEHP, which was present in concentrations above 0.1 per cent by weight and in 36 of the articles.

Many articles contained several different substances from the Candidate List. SCCPs are prohibited in articles in concentrations above 0.15 per cent by weight, but they are permitted in concentrations between 0.1 and 0.15 per cent by weight. However, the recipient of the article must then be informed about its contents. Lead is prohibited above 0.05 per cent by weight in articles that children are able to put in their mouths. Lead in articles that children are considered unable to put in the amounts are only covered by a duty to inform at contents above 0.1 per cent by weight. The articles that contained phthalates and SCCPs were made from soft PVC plastic, e.g. soft plastic fishing lures, dog toys and the plastic parts of shoes and gloves. The articles that were discovered to contain lead were made from brass, e.g. wall hooks and door handle components. ADCA was detected in one article, a foam plastic nap mat. Figure 6 provides an overview of the substances from the Candidate List detected.

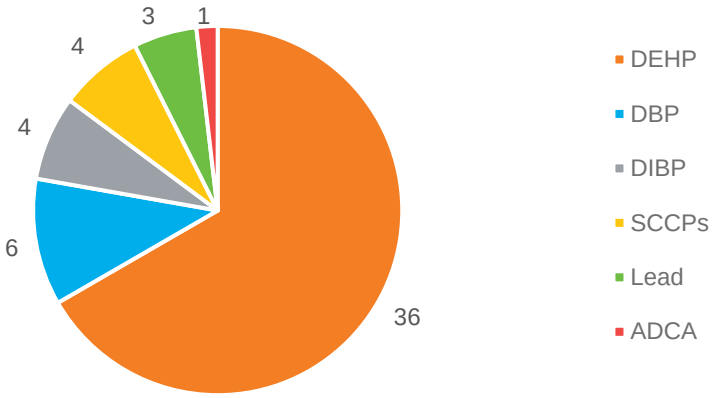

Figure 6. The figure shows the substances from the Candidate List found in the articles analysed, and the number of articles in which each substance was found.

3.2 Treated articles

In all, we checked 74 articles treated with biocides during the project, of which 35 were from the Chemicals Agency's inspections and 39 were from the municipal inspections.

The municipalities submitted photographs of a further 83 products that may have been treated articles, but which were not considered to be treated articles within the scope of the project. Some of these were chemical products categorized as treated articles and as such were beyond the scope of the project. Certain products were deemed biocidal articles, while others were "regular" articles or chemical products. In many cases, it was necessary for the municipalities and the agency to contact companies higher up in the distribution chain to gain more information to correctly assess the article.

When we assessed treated articles, we checked whether the active substance was permitted for the type of article and if the labelling was correct. Of the 74 articles checked, 59 had some

type of non-compliance, which corresponds to 80 per cent of the articles. Eight of the treated articles were assessed as meeting all legal requirements, and in four cases we were unable to make a full assessment as it was not possible to obtain further information. Three of the articles were released on the market before 1 September 2013, which means they are not subject to the legal requirements.

Figure 7 below provides an overview of the types of non-compliance the treated articles had. The most common was where we deemed an article to have seriously non-compliant labelling (30 articles). Most cases concerned articles whose packaging claimed biocidal effects, e.g. articles marketed as "antibacterial", but where e.g. the name of the active substance was missing entirely.

Another relatively common non-compliance (14 articles) was where the content of the labelling was correct but the language was not Swedish, which is a requirement if the article is sold in Sweden. In some cases, there was a QR code on the article that led to information in Swedish on a website, but we deemed this to be insufficient to meet the legal requirements for labelling.

Seven articles were assessed as having minor non-compliances in labelling. The most common was where the words *biocide* or *biocidal product* were lacking. When minor non-compliances in labelling were discovered, we did not demand that they be rectified on existing articles in retail stores, but in articles produced in the future.

In seven cases, claims about biocidal effect could only be found on the retailer's website, but not on the actual article. Under the applicable legislation, it is not the claim about the biocidal effect per se that requires it to be labelled on the article itself, but its presence in advertising or other information related to the article. In these cases, the manufacturer had chosen not to market the article to the end consumer as treated with biocides, but the retailer had been given information and made claims about the biocidal effect in Internet sales. This entails a requirement for labelling on the article, and such labelling was not present. In most of these cases, the retailer chose to remove the claim about the biocidal effect from the website, which is a permissible solution.

Three articles were released to market before 1 September 2013, and as such were not subject to the legal requirements. One article contained a prohibited active substance, and further sales were therefore banned.

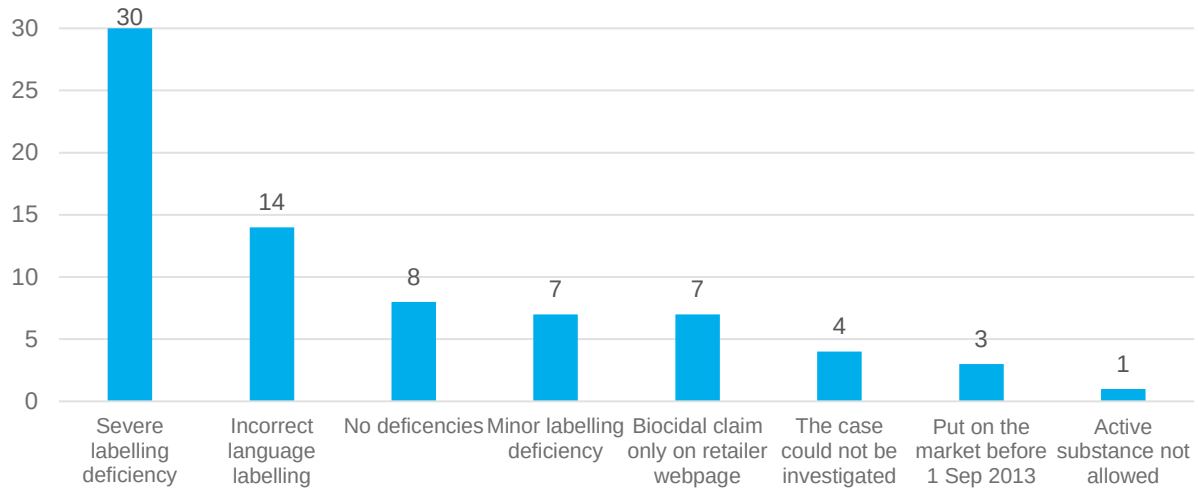

Figure 7 Overview showing our assessment of treated articles checked during the project.

3.3 Inspections by the municipalities

The municipalities reported that they had inspected 308 companies concerning the duty to inform under the REACH Regulation and the occurrence of prohibited substances. In cases where the municipalities discovered treated articles in companies, they also included this regulatory area in their inspections.

Of the companies inspected, 302 (98 per cent) sold articles directly to consumers, while the other six companies only sold to commercial customers.

During the inspections, the inspectors asked whether the responsible person in the company knew about the duty to inform in the REACH Regulation and the Candidate List; 86 companies (29 per cent) responded that they did (figure 8), 57 (19 per cent) responded that they were partially aware, and a further 57 said that they were aware now but had not been until the municipality contacted them prior to the inspection. No fewer than 100 companies (33 per cent) replied that they were unaware of the duty to inform in the REACH Regulation and the Candidate List.

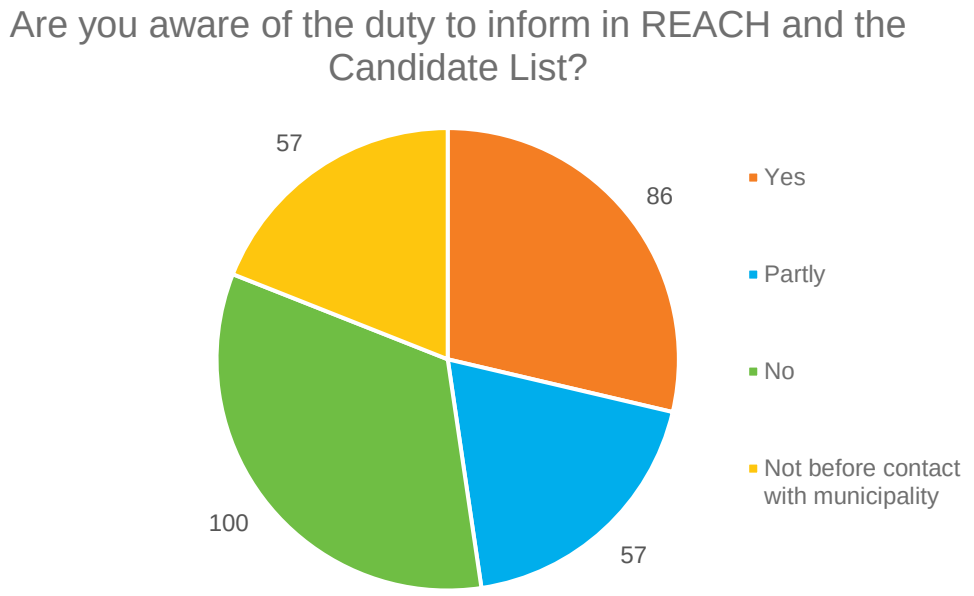

Figure 8. Number of companies and their responses when asked if they were aware of the duty to inform in REACH and the Candidate List.

When asked if their companies had received information about the presence of substances on the Candidate List in any of the articles they purchased, the majority – 278 companies (93 per cent) of the 300 who responded – replied that they had not received any such information; see figure 9. The remaining 22, corresponding to 7 per cent, replied that they had received such information. Of the companies receiving information, 18 said they had received it automatically, while four received it in response to a request.

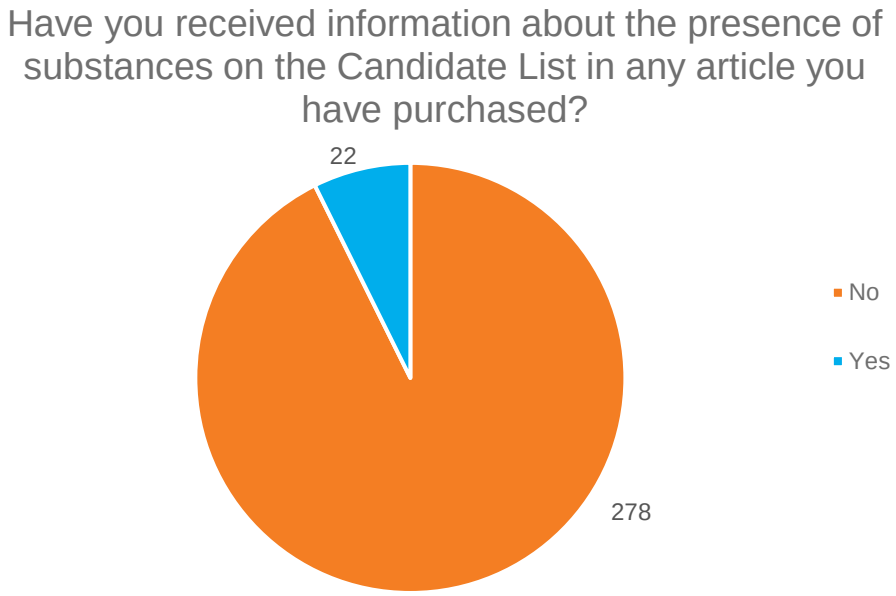

Figure 9. Number of companies and their responses when asked if any articles they had purchased contained substances on the Candidate List.

The inspectors also asked the companies if consumers had asked questions about substances on the Candidate List (figure 10); 182 companies (61 per cent) answered that they had not been asked such questions, while 86 companies (29 per cent) replied that they had not been asked questions about substances on the Candidate List, but rather other questions about chemicals in articles. The remaining 32 companies (11 per cent) had received questions from consumers about substances on the Candidate List.

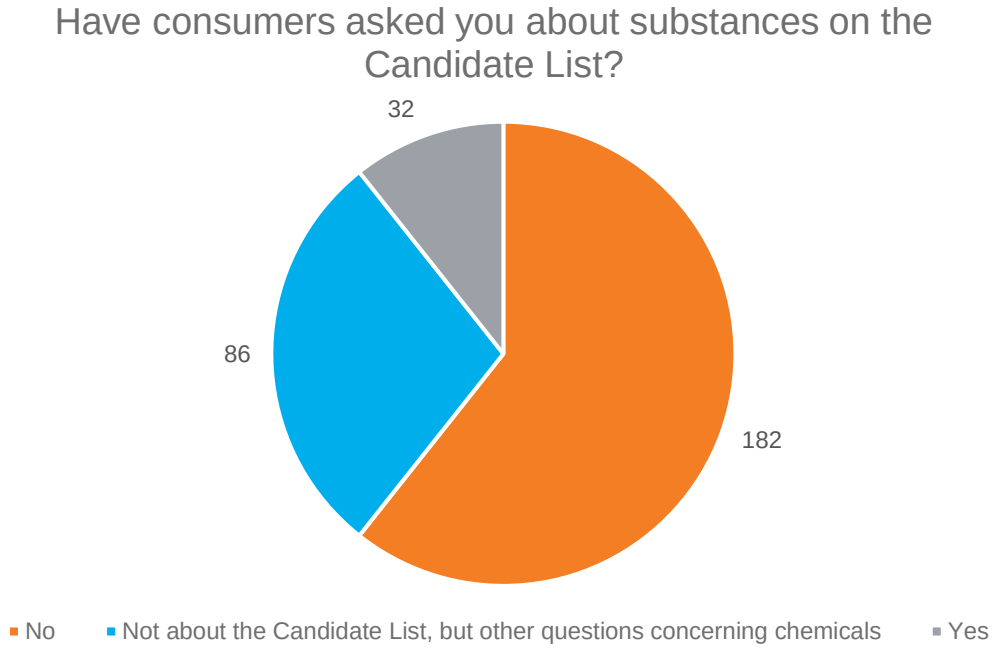

Figure 10. Number of companies and their responses when asked if consumers had asked questions about substances on the Candidate List.

The inspections also discussed how the companies placed demands on their suppliers in respect of chemicals. In the most common response (129 companies), the companies stated that they relied on suppliers to make sure all chemical requirements were met (figure 11). Almost as many (124 companies) responded that they were careful to choose the type of suppliers whom they considered capable of meeting requirements, while 110 companies replied that they had other methods. In many cases, these were retail stores that belong to a chain where the head office took care of such issues. Another 67 companies replied that they had actively deselected risk materials or risk products; 35 companies responded that they required substances on the Candidate List not to be present in their articles, and 26 companies replied that they demanded information about substances in the Candidate List. In response to this question, companies were able to say they used a number of these approaches. Of the companies that placed demands on their suppliers, 65 replied that they did so in writing and almost as many – 60 – stated that they had verbal agreements with their suppliers, while 20 companies replied they had their own lists with specific restricted substances for which compliance agreements were concluded with suppliers.

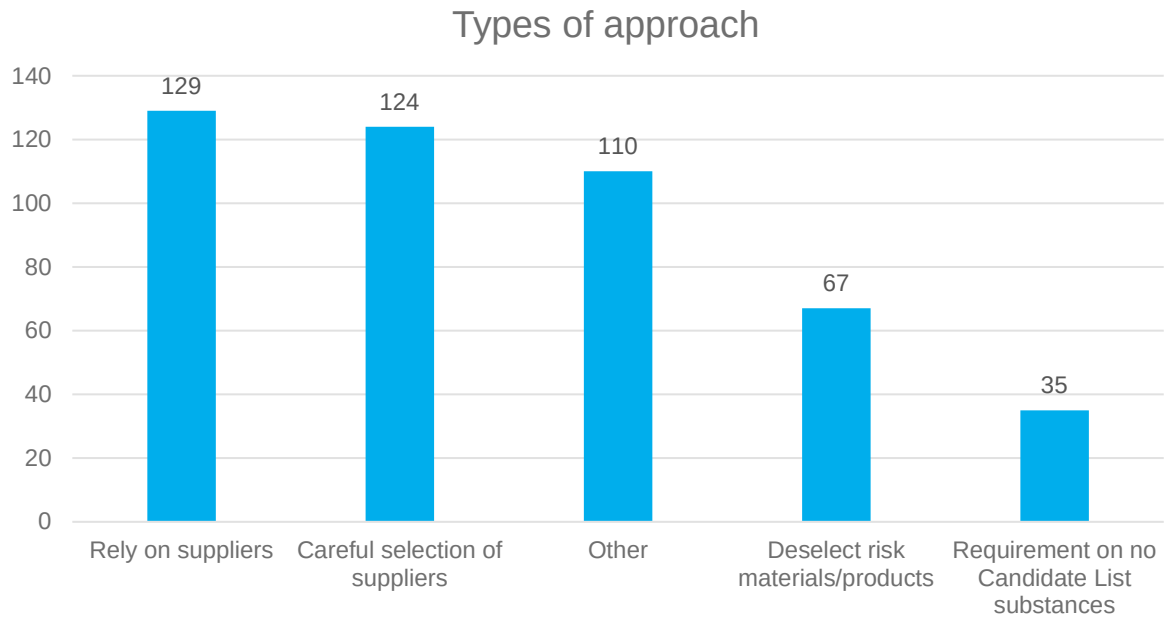

Figure 11. The figure shows how many companies had indicated the type of approach they used when working with matters concerning chemicals in articles.

During the inspections, the municipalities also asked the relevant companies if they were aware that their articles contained substances on the Candidate List. None of these companies had received this information from their suppliers.

3.4 Inspections by the Chemicals Agency

In all, the chemicals agency conducted 128 inspections during the project, of which 22 involved visits, the remaining 106 being conducted by letter and email. The inspections conducted by letter and email were primarily those where we followed up analysed articles containing restricted substances and non-compliant treated articles, and also inspections where we only informed suppliers that we had tested their articles and that we had not detected any prohibited substances.

The Chemicals Agency reported 33 cases of suspected offences to the environmental prosecutors. These mainly concerned companies that had sold articles containing prohibited substances or had supplied articles containing substances from the Candidate List without informing the commercial recipient. In some cases, it also concerned companies that had put incorrectly labelled treated articles on the market.

We decided on environmental penalty fees for 11 companies. Nine concerned the wrong language in labelling of treated articles and two concerned non-compliant labelling of electrical goods.

The companies located at the top of the distribution chain in Sweden were informed that they had to recompense our analysis costs for the articles that contained prohibited substances.

At the time of publication of this report, a few cases are still being processed, and this means the number of sanctions may change.

3.5 Communication with other countries

In many cases where we discovered non-compliant articles, companies higher up the distribution chain were located in other countries. Where necessary, we made contact with these companies to investigate the non-compliances further. In several cases, we also contacted the competent authorities in these countries.

Non-compliant articles were reported to the joint EU information system ICSMS[4] to enable enforcement authorities in other countries to share the results of our inspections. Articles with serious health and environmental risks (such as prohibited substances discovered in concentrations above limit values) were also reported to Safety Gate[5]. Safety Gate is a system whereby enforcement authorities in the EU report dangerous products discovered during their inspections. The products are published so that consumers, companies and other interested parties can share the results.

[4] Information and Communication system on Market Surveillance https://webgate.ec.europa.eu/icsms/
[5] Safety Gate was formerly known as Rapex.
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

4 Discussion

This section seeks to highlight a number of interesting observations made during the project. Some of the observations were such that we were positively surprised, while others are challenges both for companies and the enforcement authorities. These challenges require the continued efforts of both companies and the enforcement authorities.

4.1 Restricted substances

Of the 323 articles submitted for analysis, 25 contained prohibited substances, which corresponds to around 8 per cent. This is a relatively low percentage compared to our previous experience with this type of articles. The reasons for this are worth discussing. One likely explanation for the relatively low percentage is that the selection of articles for analysis was made by a large number of people with little experience of this type of inspection. This means many of the articles chosen were made of materials with a low risk of containing restricted substances. This is an area where the Chemicals Agency needs to improve its guidance to municipal inspectors to further our chances of reaching the companies that do not comply with legislation. Another reason could be that an improvement has taken place in the Swedish market and that fewer articles now contain prohibited substances. However, that conclusion cannot be drawn on the basis of this project.

4.2 Substances on the Candidate List

During the inspections, we noted that many companies do not differentiate between restricted substances and substances on the Candidate List, but treat them all as prohibited. This may be because they are not aware that the substances on the Candidate List actually may be used in articles (on the condition that the recipient is informed) or because they have actively chosen not to include the substances in their articles. It is good when companies deselect such substances as it leads to a substitution of hazardous substances beyond that required by legislation. However, we usually point out the importance of clearly communicating requirements and what they entail to suppliers. Merely requiring companies outside the EU to ensure articles to "comply with REACH" or to comply with "all relevant EU legislation," which is relatively common, risks lacking the necessary clarity. Such articles could easily contain substances on the Candidate List even if this was not what was intended.

We found substances from the Candidate List in 43 articles. In most cases, the articles were manufactured outside the EU and the companies that sold the articles were not aware of the contents. Several companies had also placed demands on their suppliers in respect of the REACH Regulation and substances on the Candidate List. For most articles, the companies we made contact with had not received information about the presence of substances on the Candidate List even when they had bought them from suppliers within the EU who have a duty to inform the recipient. This shows how important it is to follow up requirements, e.g. to perform chemical analyses of articles made from risk materials. This applies especially to articles manufactured outside the EU as regulations in the manufacturing countries often allow substances that are restricted within the EU. It is the duty of the importer to ensure that articles meet the requirements of EU legislation.

There will soon be a new reporting obligation[6] for companies that have substances on the Candidate List in their articles. Companies are required to report articles containing substances on the Candidate List to a new database known as SCIP. The requirement comes into force on 5 January 2021 and the database will be managed by ECHA, the European Chemicals Agency. In this project, few companies were aware of the presence of substances from the Candidate List in their articles. The new requirement will place further demands on companies to be aware of the presence of these substances in their articles in order to comply with their duty to report to the SCIP database.

Under article 33 of the REACH Regulation, suppliers of articles that contain more than 0.1 per cent by weight of a substance on the Candidate List must provide the recipient with sufficient information as available to the supplier, at a minimum the name of the substance, to allow safe use of the article. The wording is relatively unclear, especially where it concerns the information that must be provided in addition to the name of the substance. In most cases, it's extremely difficult for a company or an enforcement authority to determine which risk management measures are suitable for various types of substance and articles, and guidance is lacking in this area. This has meant that inspections have only been able to demand that the name of the substance be included in the information. However, in most cases and for most recipients, the name of the substance alone will not provide sufficient information on how to handle the article safely.

4.3 Treated articles

In many cases, a general conclusion drawn from our inspections of treated articles is that it is difficult for enforcement authorities to assess articles and interpret legislation. The high percentage of non-compliant treated articles detected shows that companies also have difficulty in complying with legislation. In many cases, we had to contact foreign manufacturers and they usually had poor knowledge about active substance additives and current labelling requirements. On many occasions, we initially believed an article to be treated with biocides but this later proved not to be the case, even though the marketing made this claim. This shows that identifying treated articles and collecting sufficient information about the articles to allow a correct assessment demands a lot of resources for enforcement authorities.

However, it was good that many of the companies we contacted had changed their labelling procedures and that some had even chosen to stop selling treated articles in cases where such treatment was not considered to add value to the article concerned, or quite simply to avoid the hassle with labelling.

Under the biocidal legislation, treated articles only need to be labelled if they are marketed with claims of biocidal effect. The exception concerned articles treated with certain active substances that always require labelling regardless of claims made (e.g. permethrin). This means companies can choose not to market articles treated with biocides with claims about the biocidal effect in order to avoid the labelling requirement. It is currently unknown how common this is, but companies do choose this solution during inspections, which is permissible from a legal standpoint. In such cases, the consumer receives no information about the biocidal additive and has no means of deselecting such articles.

[6] The duty is described in the Waste Framework Directive. Further information is available at the ECHA website: https://echa.europa.eu/sv/understanding-wfd

During the project, we inspected several companies who wholly or partially sold their articles via e-commerce. In several such cases, information online indicated that an article was treated with biocides e.g. with the text "treated with antibacterials". When we checked the labelling on the article itself, there was often no claim about biocidal effect on the article or its packaging. This may have two reasons. The online information may be erroneous, for example the article may previously have been treated with biocides, but when this treatment was discontinued the online text was not updated. It may also be due to the fact that the retailer has received information about the article from the supplier indicating that it is treated with biocides, and the information has then been used by the retailer in marketing, even if this was not the manufacturer's or supplier's intention. This indicates that there are articles on the Swedish market that are intentionally treated with biocide but where the manufacturer has chosen not to inform consumers. The only possibility for a consumer to find out whether these articles are treated or not is to specifically ask the retailer or supplier. Under article 58.5 of the Biocidal Product Regulation, the supplier of an article must, upon consumer request, provide the consumer with information about the biocidal treatment of the article within 45 days.

5 Conclusion

During the project, 25 articles were discovered to contain prohibited substances, and these have been removed from the market. We also found substances from the Candidate List in an additional 30 articles, and the companies can now inform their customers about this content. Many companies also chose to remove such articles from sale. Also, companies have remedied or removed from sale the non-compliant treated articles inspected during this project.

Through the inspections, many companies now have more information about chemical regulations for articles, which will hopefully enable them to place better demands on their suppliers and thus receive safer articles.

The municipalities that participated in the project have increased their know-how within the regulatory area and will hopefully be able to conduct similar inspections themselves moving forward. The materials used in the project will be made available for municipalities wishing to conduct such inspections themselves.

The information published in this report and the results from the inspections will also be made available to consumers to raise their awareness of the problems associated with hazardous chemicals in articles and to enable them to make demands of the companies they purchase articles from. When consumers place demands and ask questions about chemical contents, they motivate companies to check that their articles do not contain hazardous chemicals. At the end of November 2019, the so-called Chemicals App[7] was launched to make it easier for consumers to ask questions about substances on the Candidate List.

The results also lead us to conclude that it is important to continue inspections of labelling for treated articles. It can also be a good idea to target information to consumers, who in most cases are unlikely to be aware that they have the right to ask questions about any biocidal treatment of the articles they purchase.

[7] https://www.sverigeskonsumenter.se/vara-projekt/kemikalieappen/

Appendices

Appendix 1 – Participating municipalities

Appendix 2 – Analysed articles

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