

Development of enforcement activities conducted by the Swedish Chemicals Agency with the help of Rapex



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Preface

This memorandum is a Master's thesis in Health and Environment Protection at Stockholm University written in collaboration with the Swedish Chemical Agency and this is a translation of the memorandum Tillsyn 4/10 (www.kemi.se). The background to the thesis is the EU warning system RAPEX, where dangerous consumer products can be notified by the Member States. This database contains much information concerning products which pose a risk to consumer's health. Several of these are articles containing high levels of toxic chemical substances that are in the area of the Chemical Agency's enforcement work. The purpose of this report is to investigate how this information can be used more efficiently in the Chemical Agency's enforcement work to protect human health and increase risk reduction.

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Summary

In a memorandum published by the Swedish Chemical Agency (Tillsyn 4/10, KemI, www.kemi.se) the use of RAPEX (Rapid Alert System for non-food consumer products) to identify dangerous products for subsequent prioritization in enforcement work has been investigated.

Present day use of chemicals is complex and extensive. It is estimated that there are around 30000 substances in current commercial use. Chemicals are released the whole time as they are produced, used and become waste: as such, man and the environment can be exposed to toxic chemicals. Consumers are a particular group which is subject to multiple exposures from many different chemicals and sources. KemI's enforcement work is divided into three product groups concerning pesticides, chemical products and articles. Traditionally, the first two groups have been the main work areas of enforcement, but recently the potential danger of chemicals in articles has received an increased focus as reflected in REACH and that enforcement is a top priority of the EU Consumer Policy Strategy 2007-2013. Articles, for example toys, are often complex products about which we lack information on their chemical composition and potential risks. The EU database RAPEX is a system whereby Member States can report (RAPEX notification) on dangerous consumer products, including restricted substances, and on a weekly basis inform other MS. This information is an important part of enforcement surveillance. Therefore, KemI has (i) investigated ways to more systematically use RAPEX information to increase its risk management goals via enforcement activities and (ii), via a questionnaire establish how other EU enforcement authorities use RAPEX in their work.

To investigate the usability of RAPEX five search strategies, based on information from RAPEX notifications, have been developed and evaluated. In the first strategy, products and materials containing selected dangerous and by law restricted substances were identified based on RAPEX notifications and general background information. Some examples of the results include the occurrence of phthalates in dolls and inflatable toys made of PVC plastics, and the frequent occurrence of lead in paint and plastics in toys made of wood and hard plastics. More examples include the occurrence of chromium in the paint in toy cars, nickel in metallic jewellery, cadmium in packaging made of plastics, toluene in glue, nitrosamines in balloons, dimethylfumarate in shoes, azo dyes in scarves and formaldehyde in toys made of wood. These types of results can be readily used for identifying the relative hazard/risk of articles and subsequent prioritization for enforcement work.

The second strategy investigates how the information from RAPEX can be used to track articles that have been imported to Sweden from non-EU countries by using custom declarations. Swedish customs information on nine selected products from RAPEX with information on manufacturers/exporters was compared. The result shows that six of these manufacturer/exporter names were found in the customs registers. This indicates that RAPEX information is relatively reliable for tracking imported products in Sweden; however, national customs declarations information is essential to ensure that all products can be tracked.

The usability of barcodes from RAPEX notifications has been investigated in the third strategy. Contact information on the registering company could be obtained from GS1 (the barcode distributing company) webpage from the database GEPIR. The barcodes could also be used in the search for Swedish resellers of the article on the webpage www.prisjakt.se. In a test search in GEPIR, contact information could be obtained on 15 of 35 RAPEX articles with barcodes, but there was no match in the test search with Prisjakt. The GS1 codes are country specific and therefore ten articles with codes starting with 73 (Sweden's prefix) were chosen and contact information from GEPIR could be obtained to nine (9/10) of them, but none of them were found in the search at Prisjakt. Since articles with barcodes starting with 73 are registered by Swedish companies and therefore are more likely to be found on the Swedish market, they should be prioritized.

The fourth strategy investigates which Member States that identify Sweden as another country of destination in their RAPEX notifications. The results show that Nordic countries, Germany and other West European countries most frequently identified Sweden. This suggests that these countries have a consumer products market similar to that in Sweden and therefore regular surveillance of these countries should be prioritized to identify the possible occurrence of hazardous products on the Swedish market.

The fifth search strategy evaluates the usability of image recognition techniques for tracking RAPEX notified articles. The web-based search engine Gazopa can be used to upload photographs of articles in RAPEX to search for similar photographs/images on Internet, for example in web shops. However, the result of a test search shows that at present, this technique is not useful since no positive matches were made.

The result of the questionnaire shows that toys, childcare articles, clothes/shoes, chemical products and cosmetics are the product categories that the participating EU authorities prioritize in their work. All the participants used RAPEX to notify newly identified dangerous products and also as a tool for tracking articles. Picture, product name, importer, manufacturer, distributor/retailer, country of origin, barcode and country of destination were information mostly used for tracking products. The participants also made suggestions on how to improve and increase the usefulness of the system. One proposal was that a risk assessment should be included in the notification so that the chemical risk of the article could be estimated more easily. Other suggestions concerned development of a more advanced search engine and the need of photographs of higher quality. The lack of resources to deal with all RAPEX notifications, especially with the increasing number of notifications in the weekly reports, was also mentioned.

The results from the search strategies and the questionnaire show that RAPEX is a widely used system with much useful information that may be used more systematically in enforcement work. There are intentions to expand RAPEX so that it also includes products with environmental risks and products intended for working environment. This expansion will require that the system is easily overviewable, user friendly and has reliable and relevant search functions.

Sammanfattning

I detta PM undersöks användbarheten av Rapex (Rapid Alert System for non-food consumer products) för att identifiera farliga produkter som bör prioriteras i Kemikalieinspektionens (KemI) tillsynsarbete.

Dagens användning av kemikalier är storskalig och komplex. Uppskattningsvis används i dagsläget 30 000 kemikalier kommersiellt. Dessa kemikalier sprids under tiden de tillverkas, används och när de blir avfall vilket leder till att människor och miljön kan bli exponerade för toxiska kemikalier. Konsumenter är en grupp som är särskilt utsatta för många olika kemikalier från olika källor. Kemikalieinspektionen har tillsyn över tre sorters produkter: bekämpningsmedel, kemiska produkter och varor. Traditionellt har arbetet i huvudsak fokuserats på de två första produkterna medan problemet med kemikalier i varor har uppmärksammats först på senare tid. Reach-lagstiftningen och EU:s prioritering av tillsyn i strategin för konsumentpolitik 2007-2013 återspeglar detta. Varor är ofta komplext sammansatta produkter, till exempel leksaker, och kännedomen om vilka ämnen de innehåller och riskerna med dessa är bristande. EU-databasen Rapex är ett system där medlemsländer kan anmäla (Rapex-notifiera) farliga konsumentprodukter, bland annat på grund av innehåll av begränsade kemikalier, och veckovis informera andra medlemsländer. Den här informationen är en viktig del av tillsynsarbetets kontroll. KemI har därför (i) undersökt hur Rapex-information kan användas mer systematiskt för att utveckla varutillsynen och (ii) genom en enkätundersökning undersökt hur andra myndigheter i EU använder Rapex i deras tillsynsarbete.

För att undersöka användbarheten av Rapex har fem sökstrategier, som baseras på information från Rapex-anmälningar, tagits fram och utvärderats. I den första strategin har ett antal hälsofarliga och reglerade ämnen valts ut och med hjälp av Rapex-notifieringar och ämnesfakta och det har det kartlagts i vilka typer av varor och material som dessa förekommer. Exempel på resultat från denna sökstrategi är att ftalater återfanns i bland annat dockor och uppblåsbara leksaker av PVC-plast och bly återfanns i träleksaker och hårda plastleksaker i plast- och färginnehållet. Fler exempel är förekomst av krom i färgen på leksaksbilar, nickel i metallsmücken, kadmium i plastförpackningar, toluen i lim, nitrosaminer i ballonger, dimetylfumarat i skor, azofärgämnen i sjalar och formaldehyd i träleksaker. Dessa resultat kan användas för att identifiera riskkategorier av varor och för att prioritera dessa vid tillsynsinsatser.

Den andra strategin undersöker hur information från Rapex kan användas för att hitta varor som har importerats till Sverige från länder utanför EU via tulldeklarationer. En tullbegäran gjordes där nio specifika Rapex-anmälda varor efterfrågades med uppgifter om tillverkare/exportör. Resultatet visar att sex av dessa tillverkare-/exportörnamn gav träff i Tullverkets register. Det här tyder på att dessa uppgifter kan användas för att hitta importerade varor och svenska importörer.

Användbarheten av streckkoder angivna i Rapex undersöks i den tredje sökstrategin. Genom GS1:s (det företag som distribuerar streckkoder) hemsida kan kontaktuppgifter till det företag som har registrerat koden erhållas genom sökning i databasen Gepir. Streckkoderna kan dessutom användas för att söka reda på svenska försäljningsställen via hemsidan www.prisjakt.se. I en undersökning gav 15 av 35 Rapex-varor med streckkoder kontaktuppgifter via Gepir men ingen återfanns vid sökning på Prisjakt. Eftersom GS1koderna är nationsspecifika valdes tio koder som

började med 73 (Sveriges landskod) ut och av dessa gav nio träff i Gepir men ingen på Prisjakt. Varor i Rapex med kod som börjar med siffrorna 73 bör prioriteras eftersom de är registrerade av svenska företag och därför har större sannolikhet att hittas på den svenska marknaden.

I den fjärde strategin undersöks vilka länder som Rapex-anmäler varor som även har Sverige som destinationsland. Resultatet visar att det framför allt var de nordiska länderna, Tyskland och andra västeuropeiska länder som angav detta. Det kan då antagas att dessa länder har en varumarknad som liknar den svenska mer än övriga länder och varor som Rapex-notifierats av dem bör prioriteras eftersom de har större sannolikhet att även finnas på den svenska marknaden.

Den femte sökstrategin utvärderar användbarheten av bildigenkänningsteknik för att spåra Rapex-notifierade varor. Via den webbaserade sökmotorn Gazopa kan bilder på Rapex-notifierade varor laddas upp och liknande bilder eftersöks, till exempel på webbutiker. Resultatet av ett försök visar dock att tekniken i dagsläget inte är särskilt användbar då inga positiva träffar erhöles.

Resultatet av enkätundersökningen visar att leksaker, barnvårdsartiklar, kläder/skor, kemiska produkter och kosmetika är de produktkategorier som de deltagande EU-myndigheterna prioriterade högst i sitt arbete. Alla deltagarna använde Rapex dels för att göra egna notifikationer när de upptäckte en farlig vara och dels för att spåra varor. Bild, produktnamn, importör, tillverkare, distributör/återförsäljare, ursprungsland, streckkod och destinationsland var de uppgifter som främst användes vid denna spårning. Av enkäten framkommer även förslag på förbättringar av systemet för att göra det mer användbart. En synpunkt var att en riskbedömning borde medfölja en notifikation så att det går lättare att avgöra graden av den kemiska risken med varan. Det framkommer även önskemål på en mer avancerad sökmotor och bilder av högre kvalitet. Det påpekas även att det saknas resurser för att kunna följa upp alla Rapex-notifikationer, speciellt i och med ett ökat antal notifikationer i veckorapporterna.

Resultaten från sökstrategierna och enkätundersökningarna visar att Rapex är ett väl använt system med mycket användbar information som borde kunna användas mer systematiskt i arbetet med varutillsyn. Det finns även planer på att utvidga Rapex till att omfatta även produkter som kan innebära risker för miljön samt produkter för yrkesverksamma. Denna utökning av systemet kräver dock att det är lätthanterligt och överskådligt, med exempelvis en tydlig sökfunktion samt fullständiga och korrekta uppgifter.

1. Introduction

The Swedish Chemical Agency's enforcement work is divided into three categories of products: pesticides, chemical products and articles. The regulation for pesticides is relatively strict with rules concerning authorization, registration and labelling. Registration and labelling are also required for chemical products. For articles there is no demand for registration and classification/labelling¹. Due to this, there is a lack of knowledge about chemicals in articles and the enforcement work has not been concentrated on this area. The lacking knowledge concerns which chemicals there are in articles and their toxic effects on health and environment. This is, according to the Swedish Government (Regeringens proposition 2000), a fundamental problem for reaching the environmental quality objective "A non-toxic environment" (KemI 2002). These factors are why the enforcement work concerning articles is so important and needs to be developed. The companies also desire an improved enforcement work concerning articles in the EU to establish a more harmonized market and more fair conditions between different Member States (Svensk Handel, Teknikföretagen 2009).

The need to develop the enforcement work concerning articles has posed the question to how the Swedish Chemical Agency can more efficiently use the information from the RAPEX system to identify harmful articles and to choose areas for enforcement. A number of search strategies to track articles with information from RAPEX have been developed and evaluated. Some of the strategies are more focused on tracking specific articles while others give a more general overview of the types of articles that can pose a risk to consumer's health. To investigate how other EU Member States use the RAPEX system, a survey with a questionnaire was also performed.

1.1 RAPEX

The Rapid Alert System for non-food consumer products (RAPEX) is a system under the EU Commission where Member States can report dangerous products to a database. The system was adopted in 1984 and since then the number of notified products has increased steadily from 139 notifications in 2003 to 1997 notifications in 2009 (Europeiska Kommissionen 2010b). One notification can include several products and the number of notifications is therefore not the same as the number of reported products. The products vary from cars to cosmetics and the most common product type is toys. Food and pharmaceutical and medical devices have separate warning systems and are therefore excluded from RAPEX. The information in RAPEX has been used as the basic information to create the statistics shown in the figures and charts in this report.

Notifications for products with serious risk to consumer's health are called article 12 notifications due to article 12 in the General Products Safety Directive (EC directive 2001/95). When the risk is not considered serious, the notifications are defined article 11 notifications. If an authority does not have all the required information to make a complete

¹ Christina Larsson, The Swedish Chemical Agency

notification there is a possibility to submit a "for information only" notification (EC directive 2001/95).

The dangers that are related to the products are, for example, risk of fire, suffocation or chemical risk. The chemical risks that are reported today are only health risk, but there are discussions to expand the system to include environmental risks. Figure 1 shows which types of products that where notified due to chemical risk during 2005 to 2009. Some of the products are not within the Swedish Chemical Agency's enforcement jurisdiction, for example cosmetics and materials that come into contact with food.

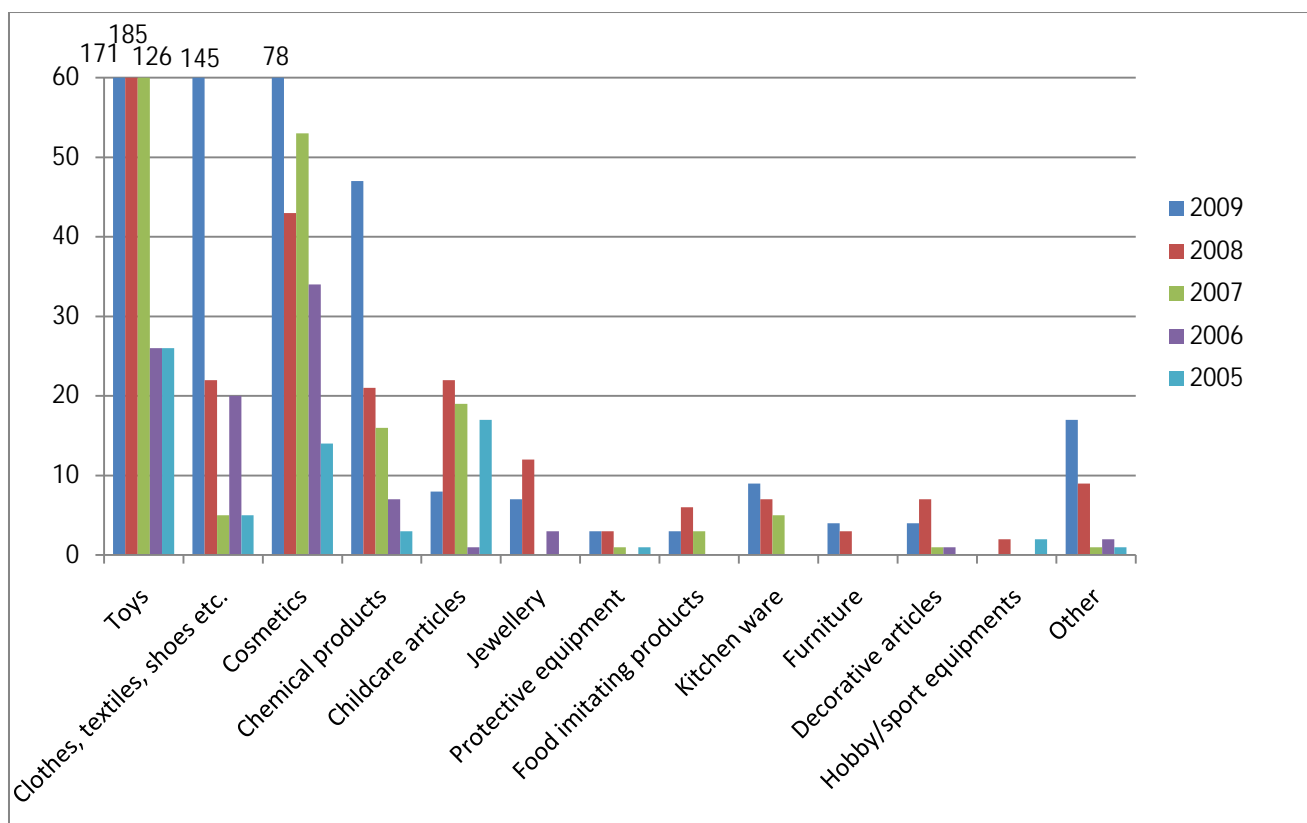


Figure 1. Different types of products and the number of notifications due to chemical risk between 2005 and 2009.

There is a national contact for RAPEX in each Member State and in Sweden that authority is the Swedish Consumer Agency. Except distributing the RAPEX information to other authorities, the Consumer Agency is also responsible for submitting Swedish notifications to the RAPEX system.

Each week the Commission comprises a list of the products with serious health risk (article 12 notifications) which have been reported to RAPEX. The products are described with information about, for example, country of origin, the risk, notifying country and what measures that have been adopted. It is also possible to see if another country has identified the same product and adopted measures and reported it to RAPEX. There is also extended information on every notification, for example information about the companies in the distribution link, which is restricted.

The intention of the system is to aid the Member States enforcement work with dangerous products. Today, the Swedish Chemical Agency notifies products with chemical risk to RAPEX and received information about dangerous products that have been reported in other countries via the Swedish Consumer Agency. An example of such a RAPEX notified article is a doll made of plastic that contains an excessive amount of phthalates. In the present situation, there are no routines to use the information with given resources in the practical enforcement work.

1.2 Substances in articles

The substances mentioned below have been chosen due to their well known dangerous health effects and their frequent occurrence in RAPEX notifications. All the substances are regulated in EU legislation and are therefore included in the Swedish Chemical Agency's enforcement work on articles. The substances are more extensively described in Annex 2 with information on sector of application, risk to health and environment and regulation.

Phthalates: DEHP (di(2-ethylhexyl)phthalate), DBP (dibutylphthalate), BBP (benzylbutylphthalate), DINP (diisononylphthalate), DIDP (diisodecylphthalate) and DNOP (di-n-octylphthalate)

Metals: Lead, Chromium, Nickel, Cadmium

Toluene

Nitrosamines

Dimethylfumarate (DMF)

Azo dyes

Formaldehyde

The occurrence of the substances in RAPEX has been studied and the result is shown in Figure 2. The most frequently notified substance is the phthalate DEHP followed by another phthalate, DINP. The heavy metals lead and chromium and the anti mould agent dimethylfumarate (DMF) and azo dyes also frequently occur.

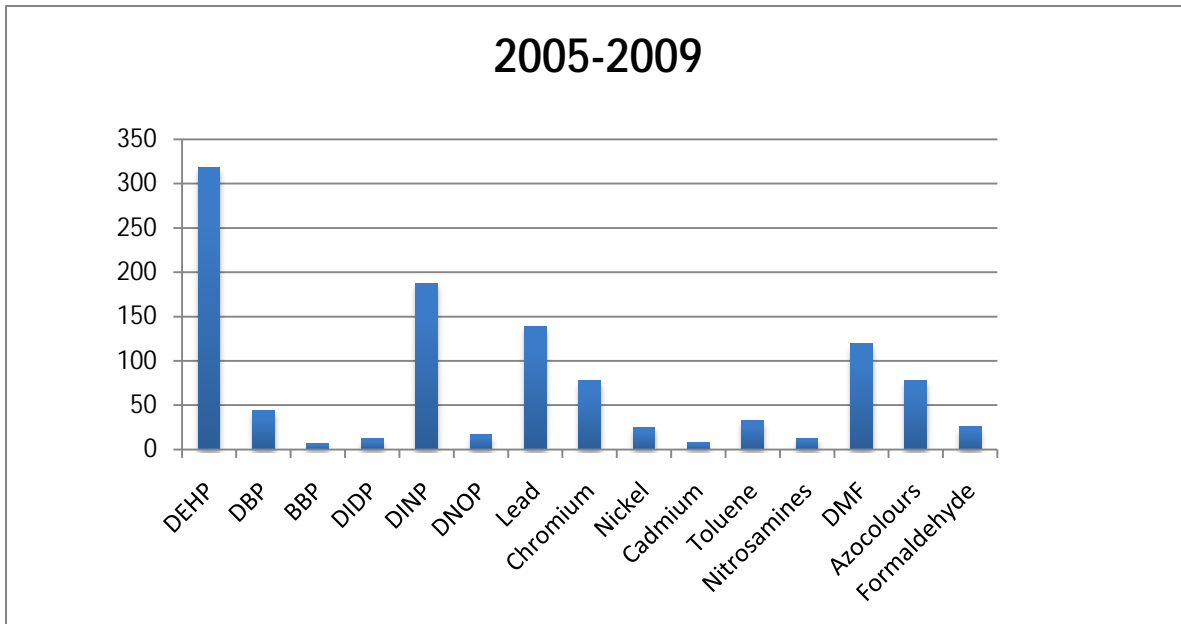


Figure 2. The number of RAPEX notifications from 2005 to 2009 where the chosen substances were considered to pose a chemical risk.

RAPEX notifications can also be ordered by year to visualized trends (Figure 3). For example, a dramatic increase of notifications concerning dimethylfumarate is seen in 2009, which is due to the occurrence of adverse human health effects and that a new regulation restricting DMF was adopted². The differences in which substances are reported can be due to specific enforcement projects in some Member States or due to a more frequent use of a substance in products.

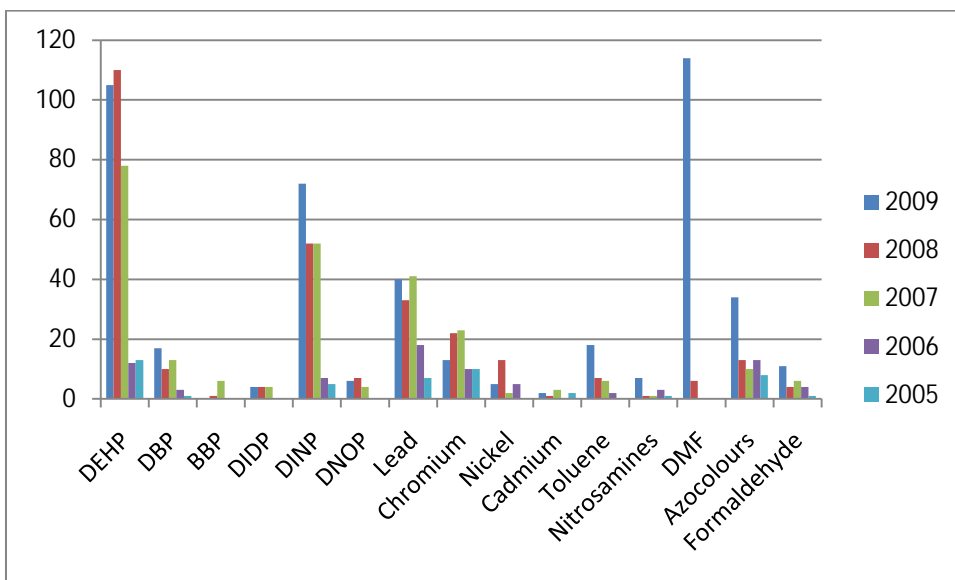


Figure 3. The number of RAPEX notifications with chemical risk sorted by substance and year.

² Marcus Hagberg, The Swedish Chemical Agency

1.3 Customs

The Swedish Customs is the authority that controls the flow of products in and out of Sweden. Importers/exporters have to fill out custom declarations which give the Customs information about the imported/exported products (Swedish Customs 2010).

Approximately 85% of the products that were RAPEX notified due to chemical risk during 2009 were of non-EU origin (Figure 4). When products from outside the EU are imported into a Member State it is called import. Due to the open market in the EU and the free movement of goods, trade between Member States is not defined as import. Hence, based on RAPEX information, the import is an important way for potentially dangerous products into the EU. China is the outstanding most frequently notified country of origin with 298 notifications during 2009 and a constant increasing trend for every year since the start of the RAPEX statistics in 2005 (see Figure 5).

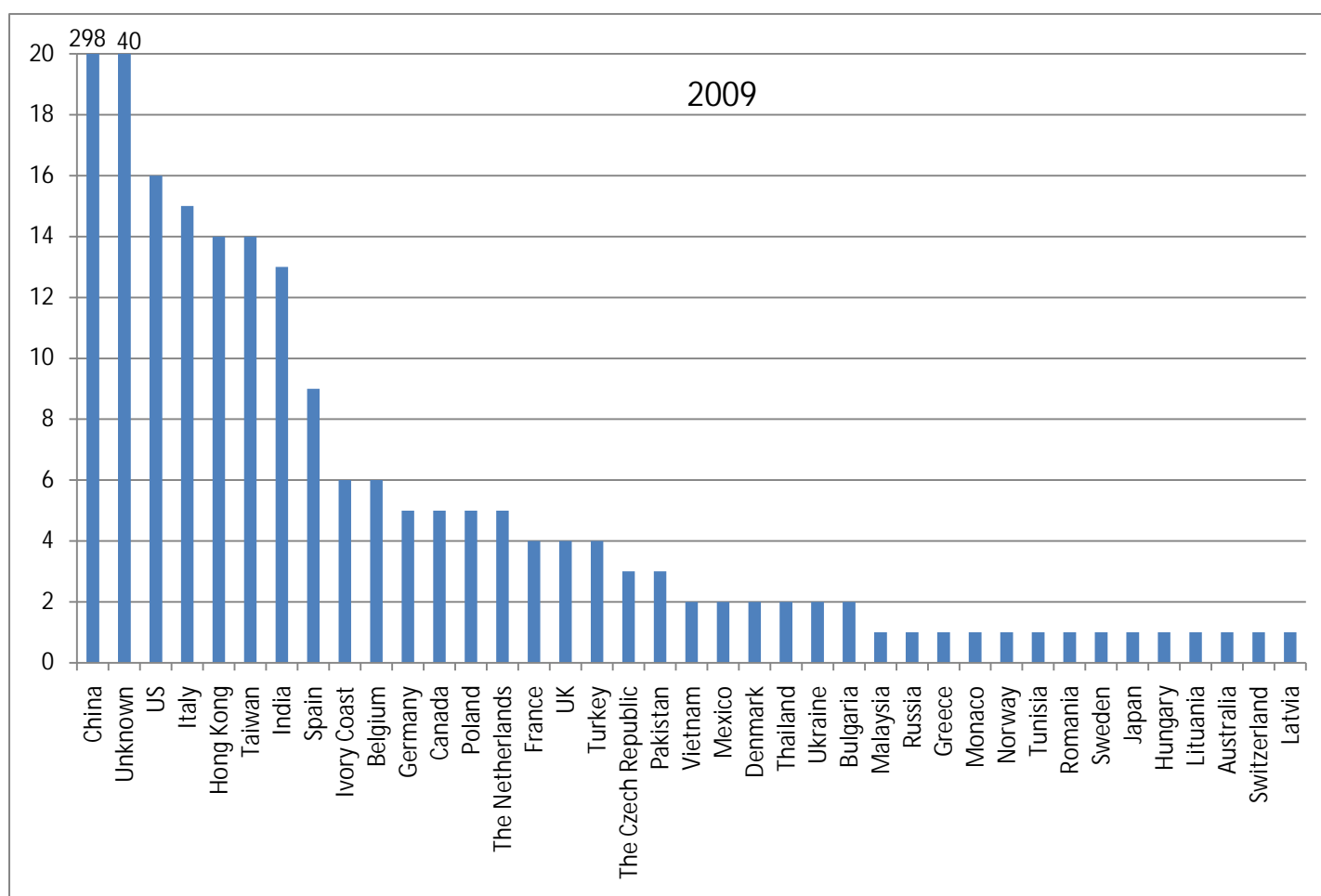


Figure 4. RAPEX-notified (chemical risk) products' countries of origin during 2009.

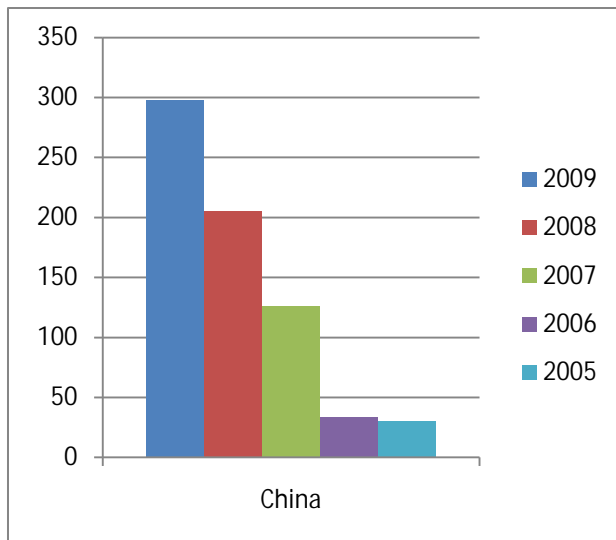


Figure 5. RAPEX-notified products (chemical risk) with China as country of origin 2005-2009.

When a product is imported to the EU it should be declared with a certain commodity code. This code is defined by a classification system called TARIC, Tarif Intégré Communautaire. The commodity code determines what duty and other fees that should be paid and if license or certain permission is needed for importing the product. There are approximately 13 500 different commodity codes to choose from. A commodity code consists of ten figures where there first four are called HS-number (HS stands for The Harmonized Commodity Description and Coding System). There are around 1200 HS-numbers with a description for every type of product. The HS nomenclature is international and is used in trade all over the world. Adding two figures gives a six figure code that is called the HS under number and gives approximately 5000 categories of products. In the EU, there is an extended system where two more figures are added which gives an eight figure CN number, where CN stands for Combined Nomenclature. There is around 10 000 CN numbers and these are used in trade between Member States and in export from an EU country to a non-member state. But there was need for additional specifications to meet some EU provisions, that led to an expansion of the code to ten figures and that is called TARIC code (Figure 6).

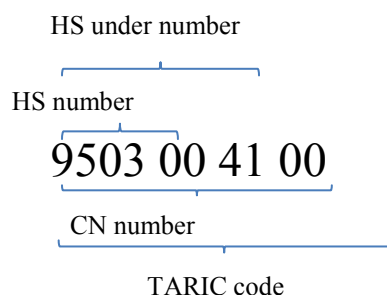


Figure 6. Explanation of how the commodity code for "soft toys" is put together from other codes.

The different types of products are sorted by material and function. There are 21 main categories and by specifying a product into subcategories the code increases to ten figures. The different types of products in RAPEX are classified in different ways and with a different level of specificity. The most frequently notified type of product in RAPEX is toys and they

are classified in Various Products Chapter 95 – Toys, games and sport equipments. There are several subcategories that can specify the product further, for example more elaborated, descriptive terms may be used: there is one called ”Toys that looks like animals and other non-human creatures, Stuffed” instead of ”soft toys”. This generates the commodity code 9503 00 41 00, see Figure 6. Dolls, puzzles and other types of toys can be specified in a similar way. For clothes there is the main category “Textile products” with several subcategories that specifies type of clothing, material and function. Shoes can be found in the main category “Shoes etc.” and can be specified by what material they are made of (Swedish Customs 2010).

The Swedish Chemical Agency is one of, at the moment, 15 market surveillance authorities in Sweden whose task it is to control the products safety of products on the market according to Förordning (2005:893) om marknadskontroll av varor. A market surveillance authority can request information about import and export from the Customs according to Tullagen (TL) 11:6 and then specify the products with, for example, manufacturer and commodity code³. A market surveillance authority can also request the Customs to hold a product at the border. When the Customs has done a requested control of the documentation about the products, the market surveillance authority is contacted. If the market surveillance authority is suspecting that the product does not comply with the product safety regulations, the Customs can postpone the releasing of the product by three work days. During this time the market surveillance authority has to decide what measures have to be taken.

1.4 Bar codes

There are relatively often barcodes mentioned in RAPEX notifications. These are often called bar code, EAN code or just EAN or code.

The bar code is placed on consumer products to give information about price in the counter at stores but can also give information about, for example, who has imported the product. The code including figures is called GTIN (Global Trade Item Number) or GS1 article number and is an internationally used code. This is translated into an EAN bar code (European Article Number). The most common code for consumer products is constructed of 13 figures, GTIN-13 and the bar code EAN-13. The six to nine first figures is a company prefix where the first two figures show in what country the code has been distributed. Swedish codes start with 73 (GS1 2010). After the company prefix, there is a three to six figure serial number that identifies the quantity of articles. The code ends with a control figure, see Figure 7. For products with limited space, there are also eight figure codes, GTIN-8 and the bar code EAN-8 (GS1 Sweden 2010).

³ Monica Fridolf, Tullverket



Figure 7. The construction of an EAN-13 code (Link 7).

GTIN and EAN codes are distributed by the global company GS1. In Sweden, it is GS1 Sweden that issues the codes. At the company's website there is a database called GEPiR (GS1 Electronic Party Information Registry) where it is, among other things, possible to search for whom is the owner of a code. It is an open database but the maximum number of searches is limited to 30 per day. Sometimes, the codes of some RAPEX notified products can not be found in the database which can be because of different reasons: the company has ceased to exist, that it is an American code, that the information is confidential in a specific country or that the code is false⁴. There is also other information available from an EAN code, for example suppliers, labelling and durability. This information is sent forward in the distribution chain during the trade and is called article information. This information may be purchased from GS1 (GS1 Sweden 2010).

1.5 Country of notification

In the RAPEX database, it is detailed what country made a notification, see Figure 8. This information can be used as a criterion when deciding which products that are the most interesting for the Swedish enforcement work. The background to this is that some countries markets are more similar to the Swedish market than others. For example, the Swedish market and markets in other Nordic countries can be expected to be similar. In some countries, there can also be large import companies that distribute products to Sweden that are not specified as importers and therefore cannot be found in the Customs registers. These countries can also be expected to have a similar market to the Swedish market. Examples of such countries where these import companies can be situated are Germany and England. If this assumption is correct, products from other countries that are expected to have a different type of market, for example Eastern Europe, do not need to be prioritized in the work with RAPEX⁵.

When notifying a product in RAPEX, additional countries of destination can be detailed (see Annex 1 – Notification form). If Sweden is identified as country of destination, the Swedish Consumer Agency distributes the information to the responsible authority and the authority makes a RAPEX reaction and adopts measures. For example, if the reason for the RAPEX

⁴ Bo Raattamaa, GS1 Sweden

⁵ Lena Bäcklund, Swedish Consumer Agency

notification is chemical risk, the Swedish Chemical Agency is contacted by the Swedish Consumer Agency. The Chemical Agency can also react on RAPEX notifications in the weekly report without the product being selected by the Consumer Agency.

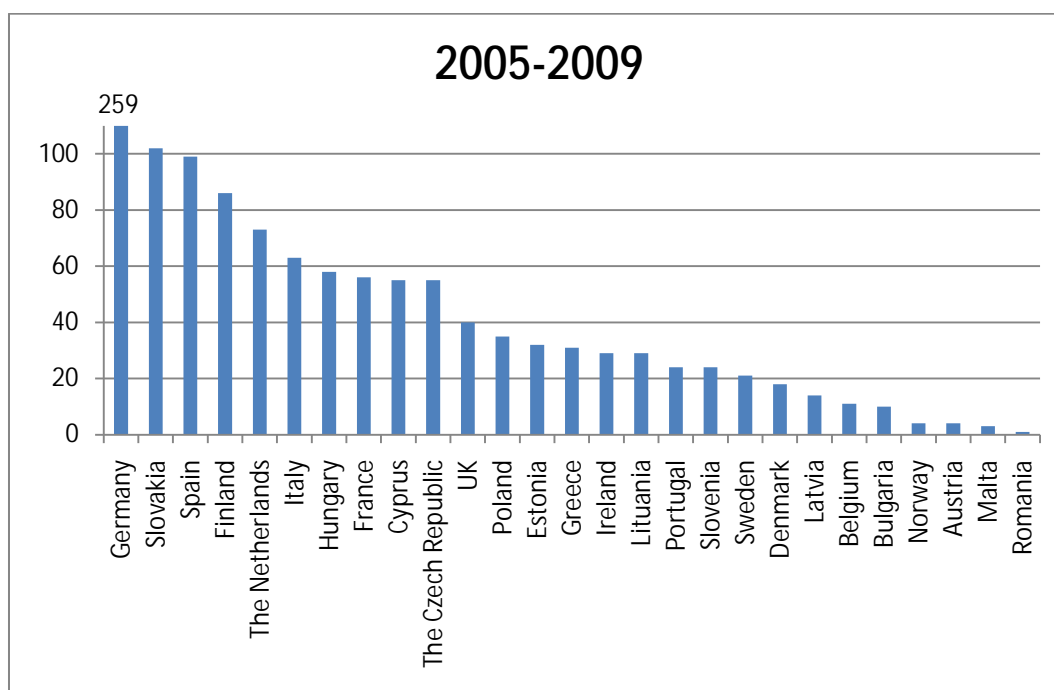


Figure 8. The number of RAPEX notifications (chemical risk) that different countries have made during 2005-2009.

1.6 Image recognition

Image recognition is a relative new technique that is based on a computer programme that recognizes characteristics, for example shape and colour, in an image and search for similar images on the Internet. Many RAPEX notifications contain an image of the product and the goal is that the same picture can be found in, for example, a web shop at a company's website.

Today there is a web-based image recognition program, Gazopa, available as a test version. This programme works as a search engine where the image is uploaded and the programme searches for similar images on the web.

1.7 Questionnaire survey

RAPEX is an EU database used by all Member States. There is no summary on how the countries use it in their practical work with enforcement. This is the reason why a questionnaire has been developed and sent to the RAPEX national contact points and to members of the CLEEN network (network for authorities that work with chemical issues in the EU).

The questionnaire is web-based and has been designed to be user friendly. Most of the questions are yes - no or multiple choice questions (see Annex 3). The hypothesis is that RAPEX is not used much to track products but rather for making notifications when the authority finds a product which is considered to pose a serious risk. This is how the Swedish Chemical Agency has worked with RAPEX to date. Some of the reasons for the hypothesis

are believed to be lack of resources, that the information is not considered useful and/or lack of knowledge about the system. This is investigated in the questionnaire in a question for the participants that do not use RAPEX in enforcement work. Another hypothesis is that authorities with much resource for enforcement work with articles use RAPEX more extensively because it is relatively time consuming. This can be investigated by linking questions in the questionnaire.

The answers give a general view of how the authorities in the EU work with enforcement of articles and how they use RAPEX. The answers can contribute to the development of the Swedish Chemical Agency's enforcement work with articles. A summary will be sent back to the participants to communicate the results and to raise attention to these questions.

2. Results

2.1 Substances in articles

An investigation of the chemical risk notifications in RAPEX for selected substances has been performed and the results for each substance are presented below (see Table 1). In brief, the investigation showed what types of products each substance has been found in. In addition, more detailed information about the substances is detailed in Annex 2 – Facts about substances, including information about what materials the substances can be used in.

Table 1. Table of the products that have been most frequently notified due to content of certain substances and the materials that the substances are likely to be found in.

Substance	Products	Material
Phthalates	DEHP: "Barbie dolls", inflatable toys, bathing and squeeze toys, hard plastic toys, bibs, balls, soft toys, erasers DBP: "Barbie dolls", hard plastic toys, soft toys BBP: Bathing and squeeze toys, baby dolls, hard plastic toys DIDP: Hard plastic toys, "Barbie dolls", changing mats DINP: "Barbie dolls", inflatable toys, hard plastic toys, bathing and squeeze toys, bibs, masks, balls DNOP: Inflatable toys, hard plastic toys, bathing and squeeze toys, changing mats	PVC plastics, rubber, solvent
Lead	Toys made of wood, toy cars, hard plastic toys, crayons and paint, soft toys, jewellery	Plastics, metal alloys, crystal glass, paint
Chromium	Toy cars, hard plastic toys, toys made of wood, crayons and paint, gloves, shoes, soft toys	Metal alloys, paint, leather, wood
Nickel	Jewellery, clothes with metal details, watches	Metal alloys
Cadmium	Plastic packaging, toy boxing bag, jewellery	Metal alloys, PVC plastics, paint
Toluene	Bike repair kit, glue, spray paint, plastic toys	Solvent
Nitrosamines	Balloons	Rubber
Dimethylfumarate	Shoes, furniture	Textile
Azo dyes	Scarves, gloves, dolls, clothes, underwear, soft toys, tattoo ink	Textile, leather
Formaldehyde	Toys made of wood (puzzles), clothes, underwear, shoes	Wood, textile

2.1.1 Phthalates

DEHP and DINP are the two substances that occur most frequently in the RAPEX system for notified products (chemical risk) between 2005 and 2009. Figure 9 – 14 show the distribution of the six phthalates in different types of products. The products that phthalates commonly occur in are most toys and childcare articles made of soft plastics. Dolls of the type "Barbie doll" are common but also softer, larger "baby dolls" contain phthalates. DEHP, DINP and DNOP are often found in inflatable toys such as swimming rings. Also smaller bathing toys and squeezing toys are notified due to content of phthalates. Examples of other toys where phthalates have been found relatively often are different hard plastic toys, balls, soft toys and masks for children. Childcare articles where phthalates have been notified are, for example, nappy changing mats and tables, bibs, soothers, feeding bottles and strollers.

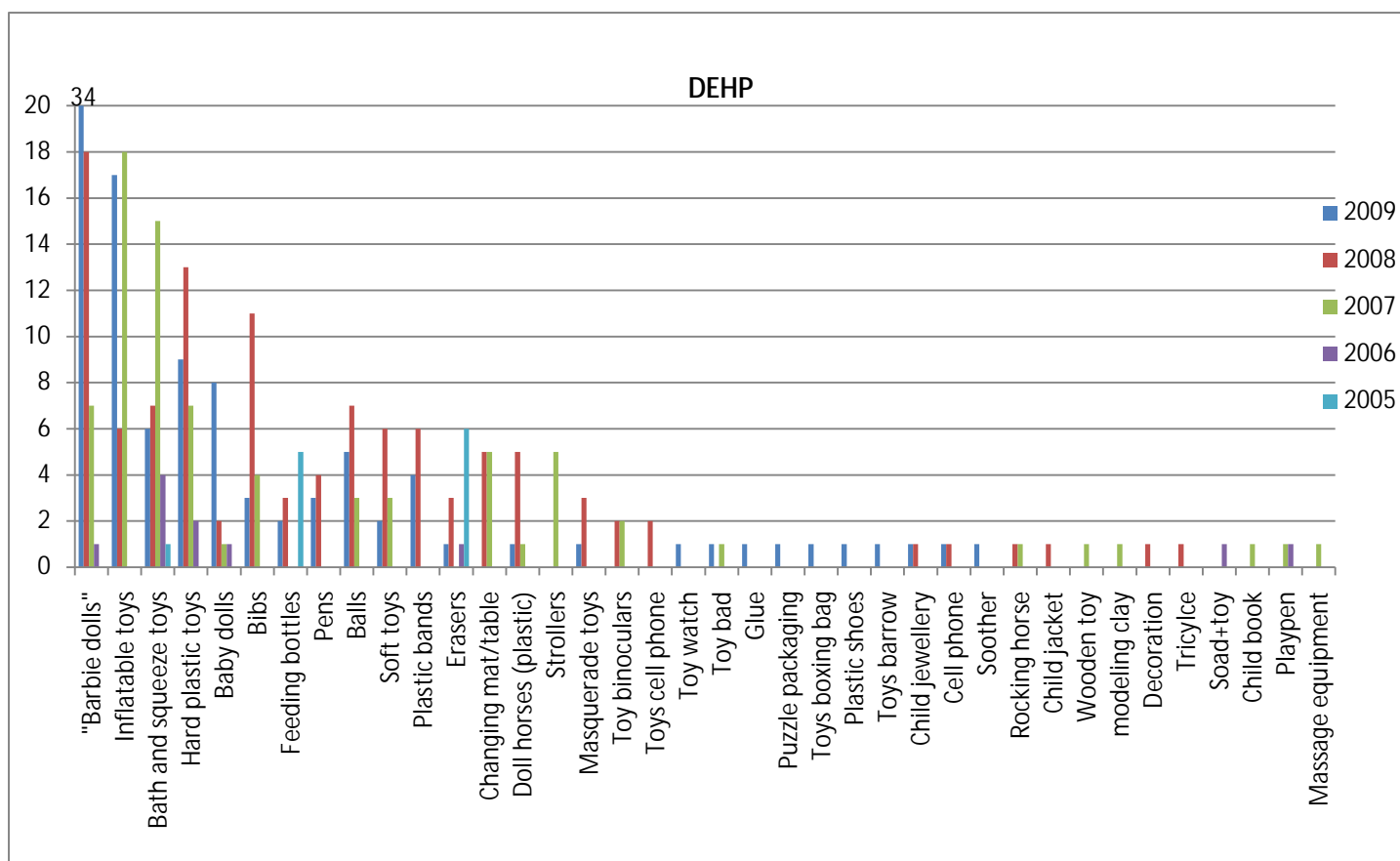


Figure 9. The distribution of DEHP in different types of products during 2005-2009.

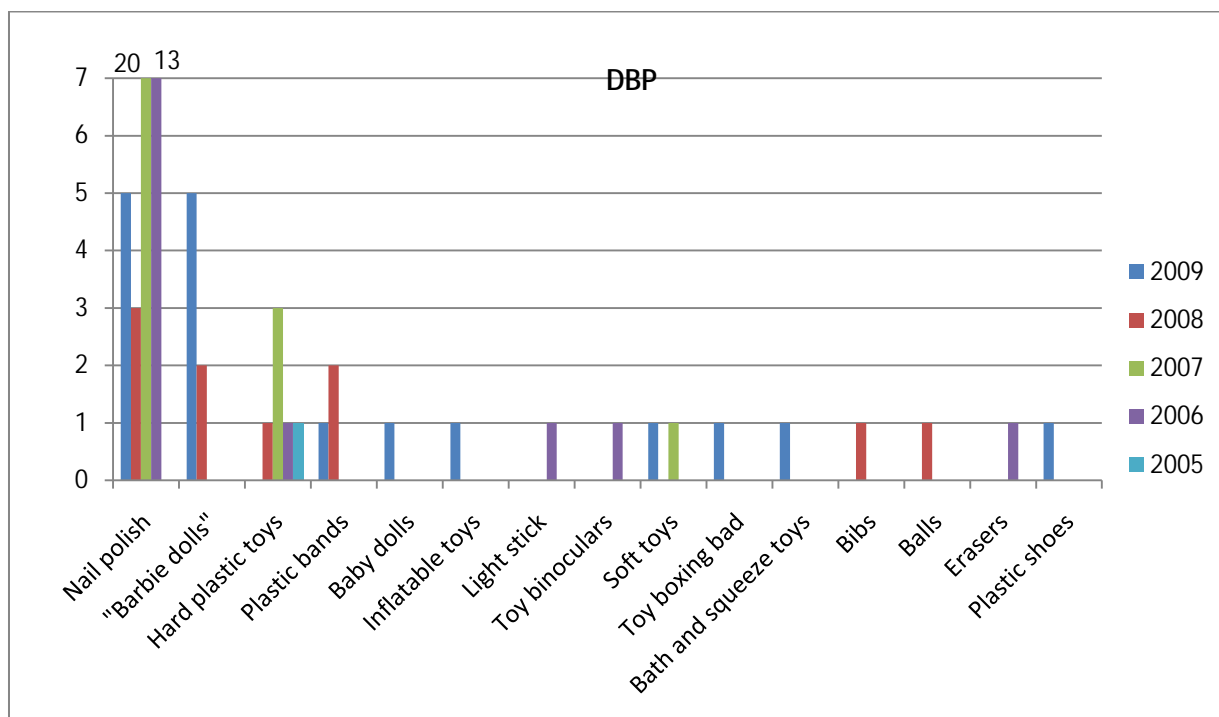


Figure 10. The distribution of DBP in different types of products during 2005-2009.

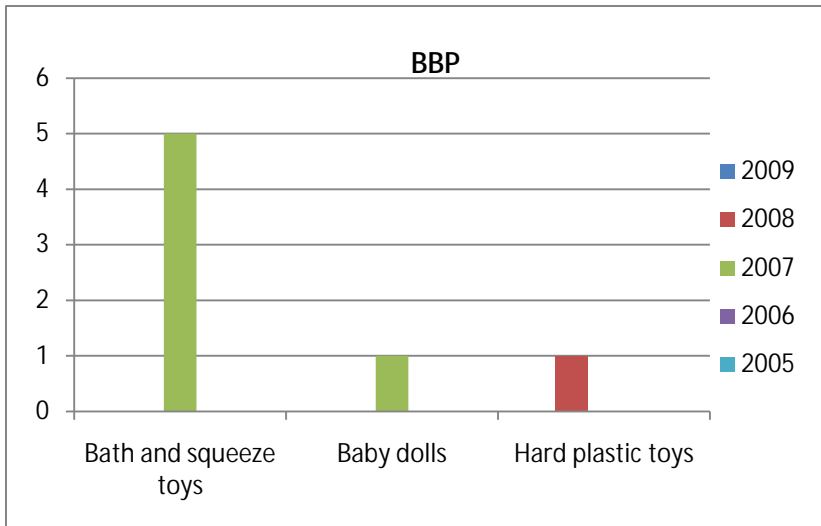


Figure 11. The distribution of BBP in different types of products during 2005-2009.

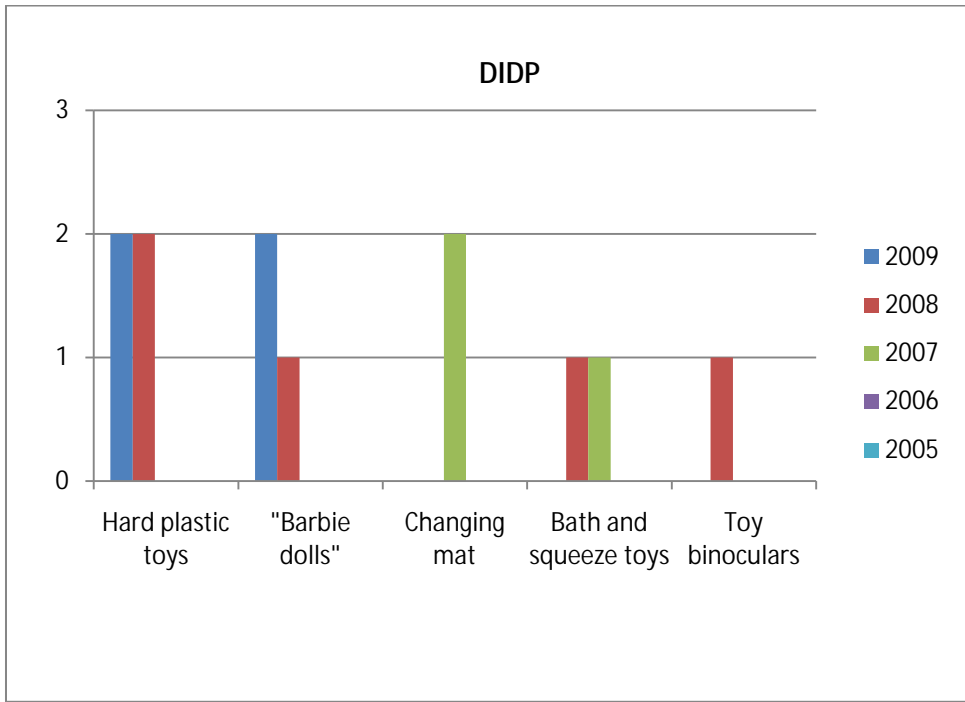


Figure 12. The distribution of DIDP in different types of products during 2005-2009.

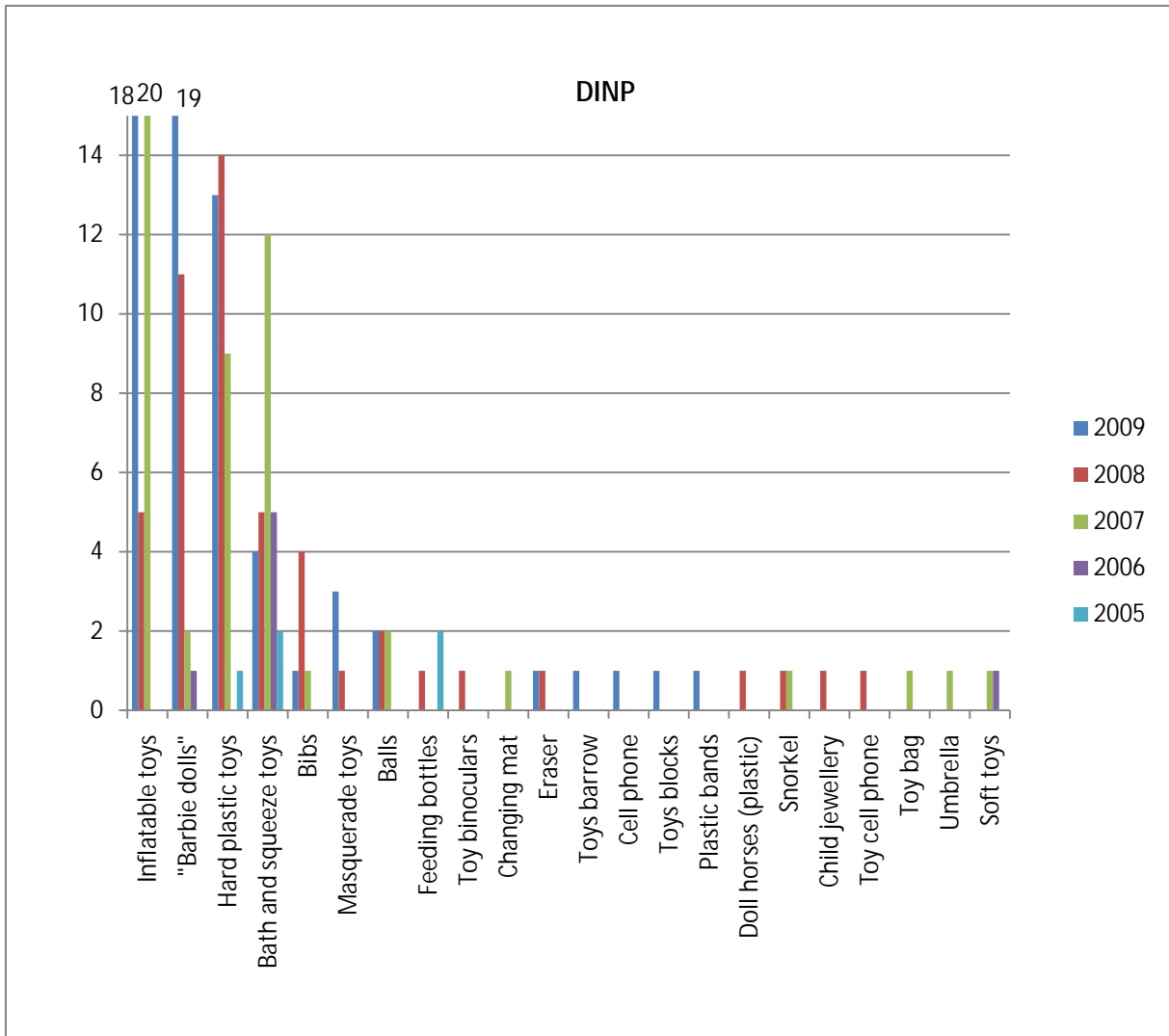


Figure 13. The distribution of DINP in different types of products during 2005-2009.

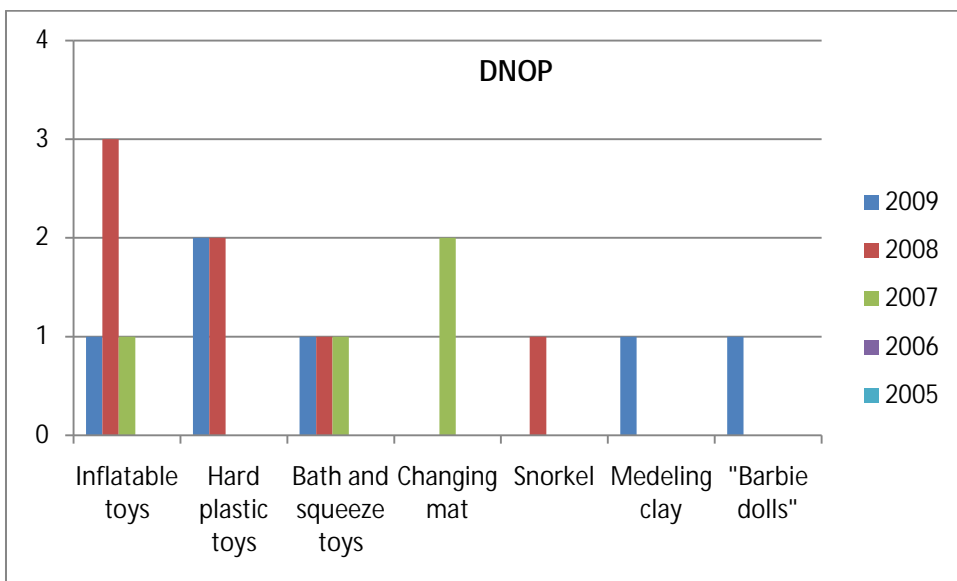


Figure 14. The distribution of DNOP in different types of products during 2005-2009.

2.1.2 Lead

Lead was the most frequently notified metal in the RAPEX system. Products containing lead were mostly toys and cosmetic products (see Figure 15). Common toys are wooden toys with plastics or paint that contain lead, toy cars and other hard plastic toys, crayons and paint and soft toys. Cosmetic products are mostly those intended for use by children.

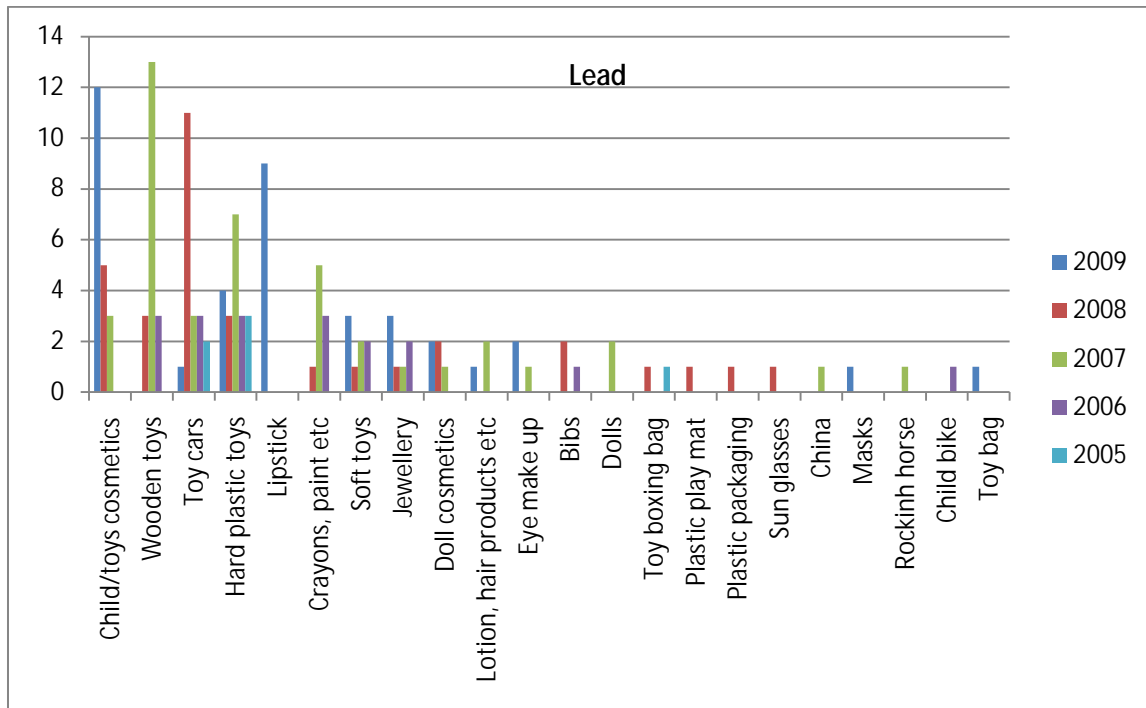


Figure 15. Chart showing the occurrence of lead in different types of products in RAPEX during 2005-2009.

2.1.3 Chromium

Chromium was the second most frequently notified (after lead) metal occurring in notified products. Different types of products containing chromium are shown in Figure 16.

Chromium is mostly found in the plastic parts and/or paint in toys such as toy cars, wooden toys and other hard plastic toys. It can also be found in crayons and paint and cosmetics.

Leather products such as gloves and shoes have also been RAPEX notified due to content of chromium.

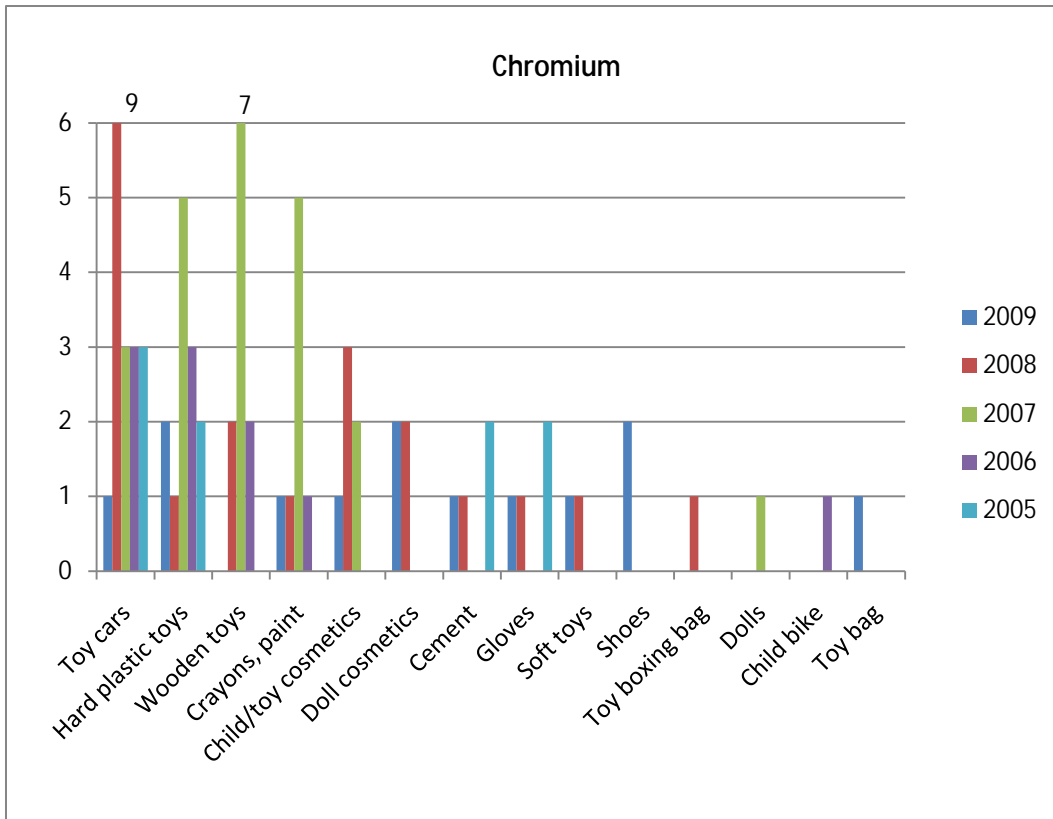


Figure 16. RAPEX notified products due to content of chromium during 2005-2009.

2.1.4 Nickel

Figure 17 shows the results for nickel in notified products. RAPEX notified products mostly contained nickel in the metal parts on clothes and in jewellery such as earrings, necklaces, rings and watches.

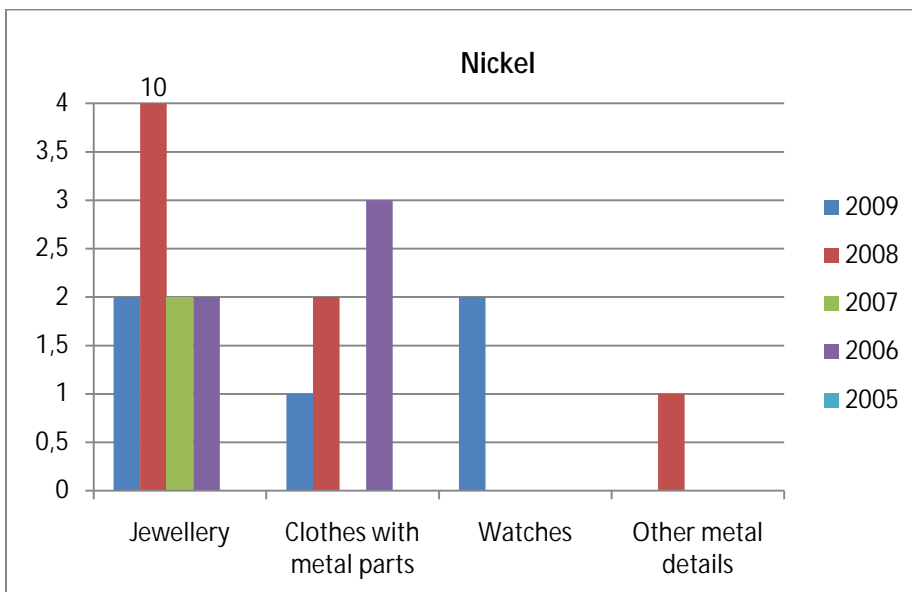


Figure 17. The occurrence of nickel in RAPEX notified products during 2005-2009.

2.1.5 Cadmium

Figure 18 shows the results for cadmium in notified products. Cadmium has mostly been found in plastic materials such as plastic packaging and in toy boxing bags made of artificial leather. There are also two notifications for cadmium in jewellery and china.

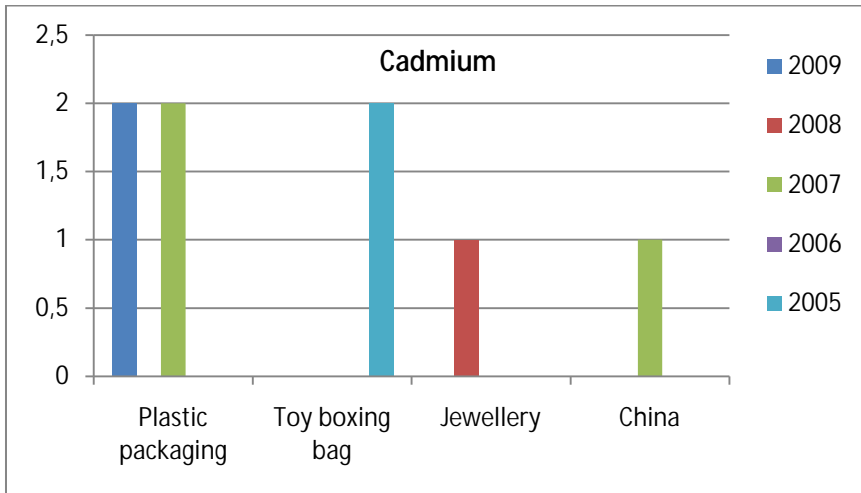


Figure 18. Chart showing the occurrence of cadmium in RAPEX notified products during 2005-2009.

2.1.6 Toluene

Figure 19 shows the results for toluene in notified products. The products are mostly bike repair kits, glue and spray paints where toluene is present as a solvent. There are also notifications for plastic toys, shoes and toy binoculars.

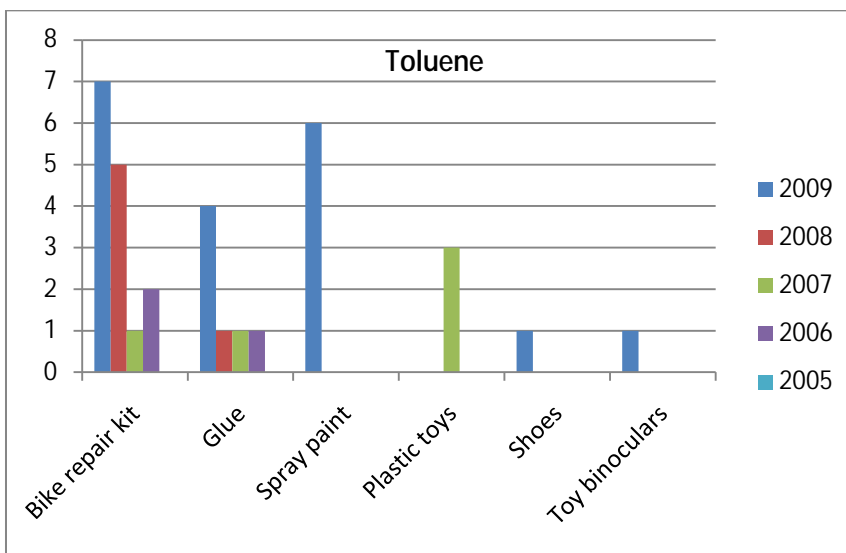


Figure 19. Chart showing the occurrence of cadmium in RAPEX notified products during 2005-2009.

2.1.7 Nitrosamines

The products that have been found to contain nitrosamines are mostly balloons where the nitrosamines occur as a by-product in the rubber. There are also notifications with nitrosamines in some cosmetics and in a plant protection product (see Figure 20).

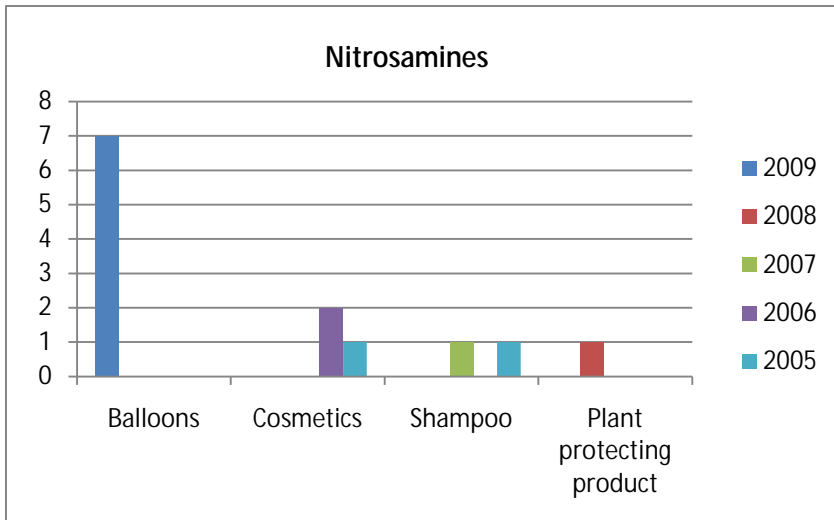


Figure 20. Chart showing the RAPEX notified products containing nitrosamines during 2005-2009.

2.1.8 Dimethylfumarate

The majority of the products notified containing DMF are shoes. There are also some notifications concerning furniture, soft toys and a riding helmet, see Figure 21.

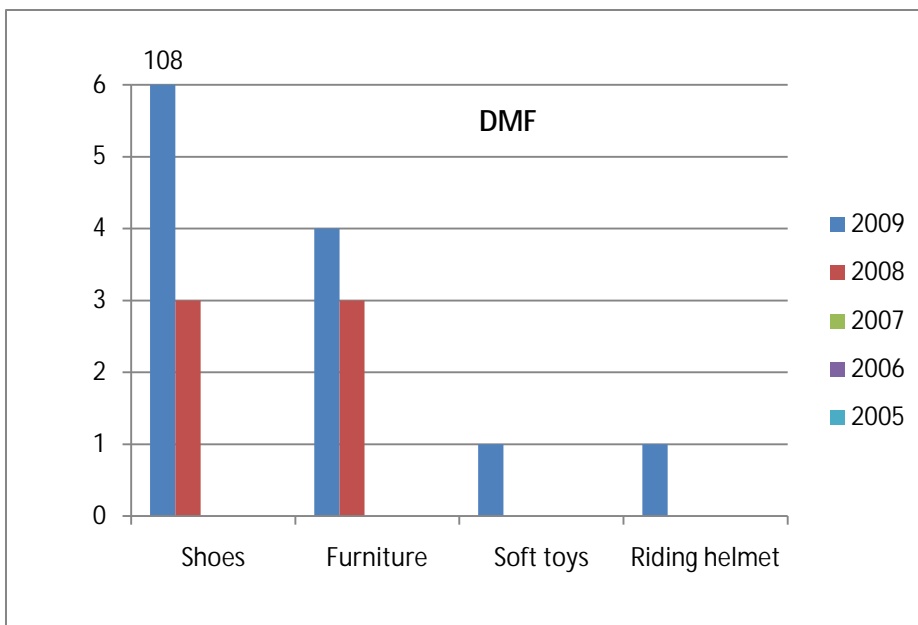


Figure 21. The distribution of DMF-containing products in RAPEX during 2005-2009.

2.1.9 Azo dyes

There are several different types of products that contain azo dyes in the RAPEX database, (see Figure 22). The most common products are scarves but also gloves, dolls, clothes, underwear and soft toys have been notified several times. In addition, there are also tattoo inks, baby scarves, jeans, caps, bibs, wallets, wooden toys and jewellery notified a few times.

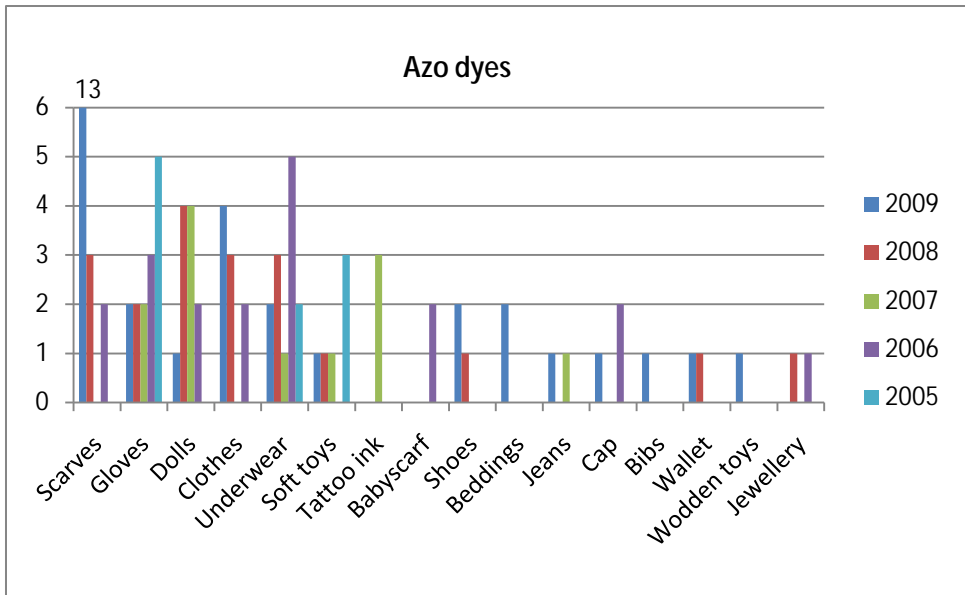


Figure 22. A chart that shows which types of RAPEX notified product azo dyes have been found in during 2005-2009.

2.1.10 Formaldehyde

Formaldehyde is mostly found in wooden toys, such as puzzles, in notified products. Other products that have been notified due to content of formaldehyde are clothes, underwear, shoes, bibs, soft toys and gloves. The results are shown in Figure 23.

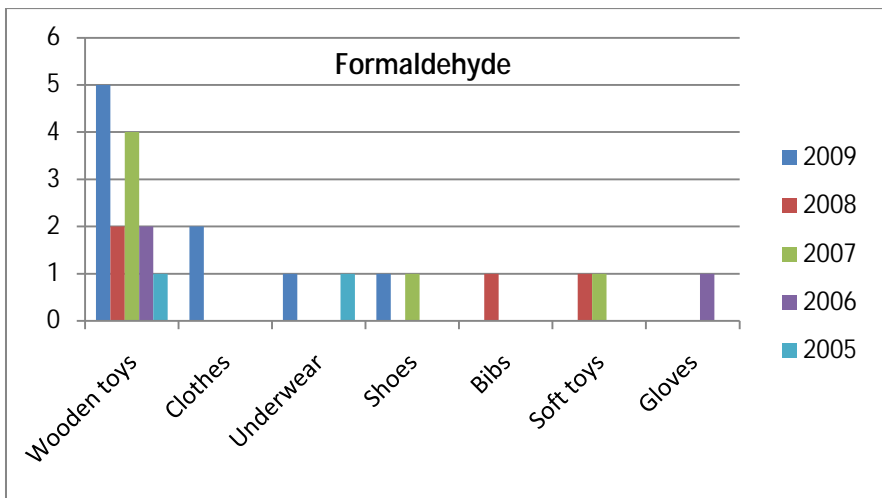


Figure 23. The chart shows which products that have been RAPEX notified because of content of formaldehyde during 2005-2009.

2.2 Customs

To investigate how the information in the Customs registers can be linked to the information from RAPEX, a request according to “Tullagen 11 kap 6⁶” was sent to the Swedish Customs. In that request, nine selected chemical risk products from RAPEX with information about manufacturers and/or exporters (from the extended RAPEX information) were listed

⁶ Tullag (2000:1281) 11 kap 6 §

(see Table 2). The products were assigned a commodity code to simplify the identification. All nine products had been notified by countries that can be expected to have a market similar to the Swedish market (see search strategy Country of notification) and therefore it can be interesting to see if they reached the Swedish border.

Twelve companies were identified as manufacturers and exporters in the extend RAPEX information for the nine products. Of these twelve, six were found in the Customs registers of companies exporting to Sweden during 2009/2010. The information from the Customs contained information from custom declarations about all the products that had been exported to Sweden by these companies during the given time period. The information also detailed custom ID, day of assessment, sender (exporter), sending country, declarant's organization number, name of declarant, number of package, commodity code, country of origin, statistical values, weight and description of product for every product.

The results of the information request are shown in Table 2. In the first column it is shown what type of product the nine products were. The second column shows what role the companies had according to the RAPEX notification. The third column shows if the company could be found in the custom declarations at the Swedish Customs during 2009/2010. If they could be found, the fourth and fifth column say how many custom declarations the manufacturer/exporter were mentioned in and what type of product that was mentioned in the product description. In some cases, the Customs' search for a company name has resulted in several alternatives. Then the companies most likely to correspond to the company in the RAPEX notification have been chosen.

Table 2. Results from request of information from the Customs.

RAPEX product	Manuf./Exp.	Export 09/10?	Number of declarations	Description of product
Inflatable chair	Manuf.	Yes	1	Beach ball
	Exp.	No	N/A	N/A
Wooden puzzle	Manuf. + exp.	Yes	2	Puzzles of metal, puzzles
Scarf	Exp.	Yes	4	Scarves
Plastic toys	Manuf.	No	N/A	N/A
	Exp.	No	N/A	N/A
Toy cars	Manuf.	No	N/A	N/A
Soft toys	Manuf.	Yes	2	Toys, soft toys
	Exp.	Yes	1	Set of pens
Wallet	Manuf. + exp.	Yes	1565	Bags, wallets etc.
Balloons	Manuf.	No	N/A	N/A
Toy purse	Exp.	No	N/A	N/A

2.3 Bar codes

In several RAPEX notifications, the bar code on the product is mentioned. By searching for the code in the GEPIR database on the website of GS1, a verification to see if the code is correct can be made. If the code can be found in the database with information about registering company, a search at www.prisjakt.se was conducted to investigate if the product can be found at a Swedish reseller.

To ensure that the products were as current as possible, RAPEX products (all risks) from Weekly Report 7 2010 were used in the investigation. Of the total number of 73 notifications, 35 had the products bar codes mentioned. Of these 35 bar codes, 15 were found in the GEPIR database. None of the 15 codes could be found in the search using the Prisjakt website.

The products that have been registered by a Swedish company receive a GS1 code (EAN code) that starts with the figures 73. To investigate that GSI codes are used, ten bar codes that start with 73 have been selected from RAPEX notifications from 2009 and search for in the GEPIR database. The bar codes that produced a hit in GEPIR were also search for at www.prisjakt.se.

Of the ten bar codes that start with 73, nine were found in GEPIR with information about registering companies. However, none of these gave a hit at the search at the Prisjakt website.

2.4 Country of notification

To establish which countries have similar products on the market, RAPEX notifications with Sweden mentioned as Country of Destination have been investigated. There are relatively few notifications with this information: for chemical risk the products only numbered 14 notifications (see Figure 24). These are made by five countries: Finland, the Netherlands, Germany, Norway and the UK.

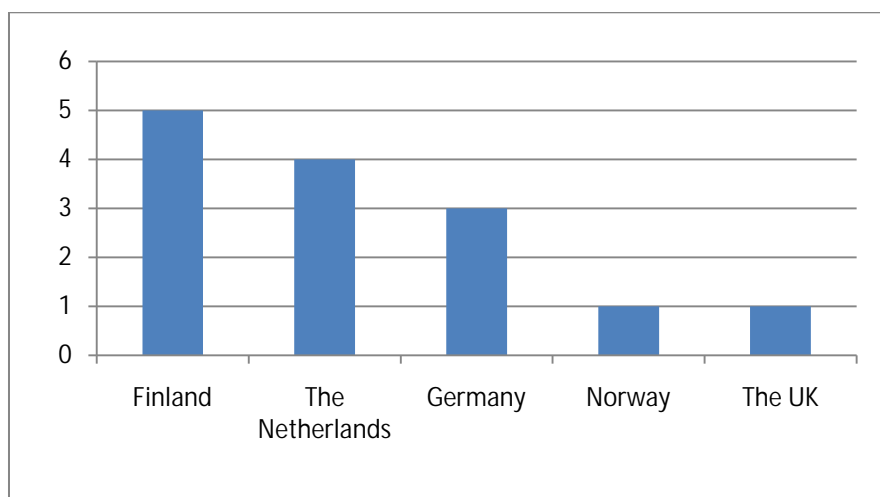


Figure 24. The number of RAPEX notifications (chemical risk) with Sweden mentioned as country of destination.

To get a wider set of data than 14 notifications, the notifications with Sweden mentioned as Country of Destination for products with all risks have been investigated and the result is

shown in Figure 25. The countries that occur most frequently (more than ten times) are Denmark, Germany, Finland and the UK.

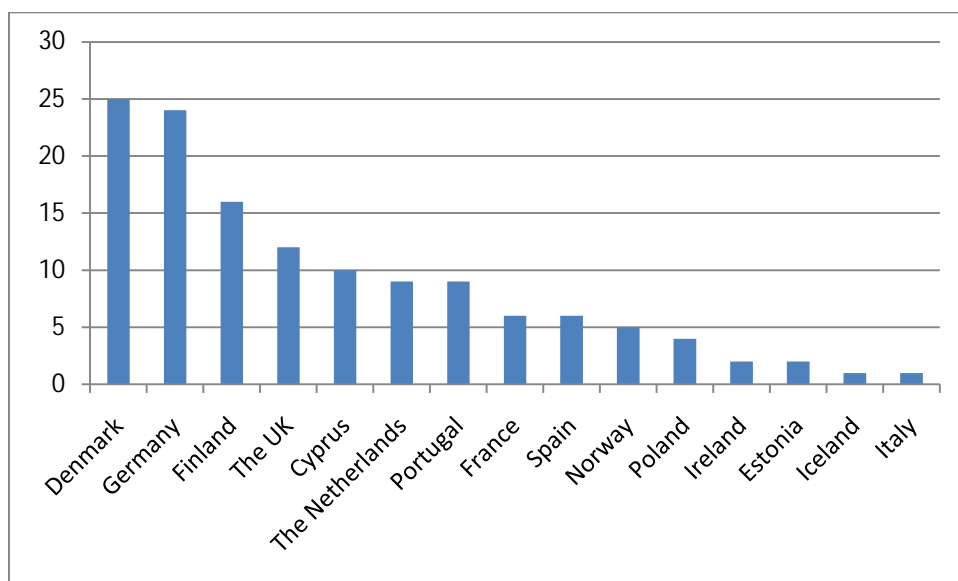


Figure 25. The number of RAPEX notifications (all risks) with Sweden mentioned as country of destination.

2.5 Image recognition

To investigate how the search strategy Image recognition works, a research was performed where ten images of RAPEX notified products (chemical risk) were uploaded in the search engine Gazopa. The selected products had characteristic looks which eases the search. However, none of the images gave a result where the same product, or even a similar one, was matched.

2.6 Questionnaire survey

A web-based questionnaire concerning 15 questions was sent to different authorities in the Members States whose work concerns chemicals. All answers were treated confidentially.

The first question concerned what proportion of an authorities' enforcement work was spent on consumer products with chemical risks. The answers varied from less than 1% up to 75%, the average was around 28%.

The second question asked about what types of products were prioritized in the authority's work with enforcement. Categories for these are toys, clothes/shoes, chemical products, childcare articles, cosmetics, jewellery and hobby/sport equipment and could be chosen by the participants but it was also possible to add own categories. These results are shown in Figure 26, the most frequently prioritized were toys, childcare articles, clothes/shoes, chemical products and cosmetics but jewellery was also common.

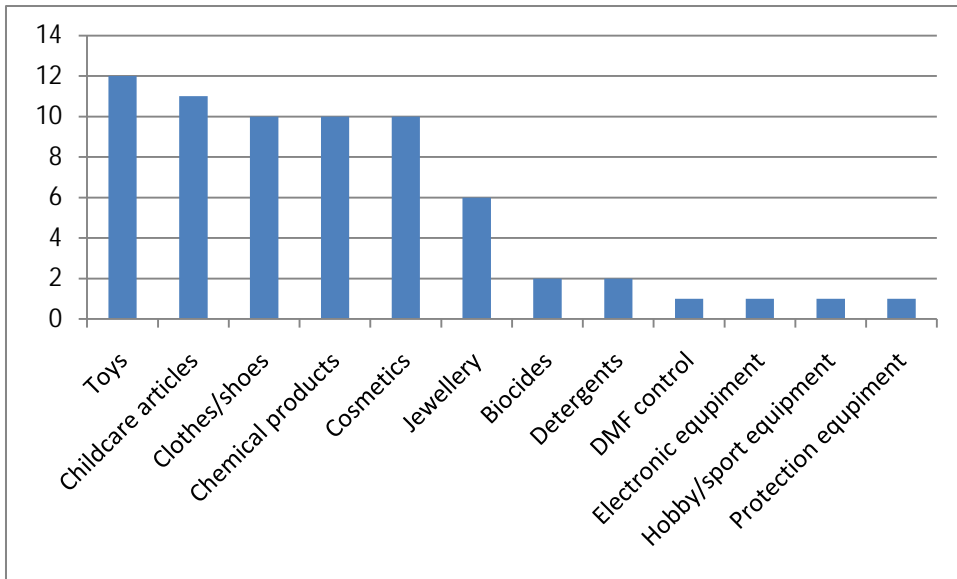


Figure 26. Chart showing the number of questionnaire participants that says that their authority prioritizes different types of products in the work with enforcement.

The third question investigated how many RAPEX notifications with chemical risk (estimated) the authority had processed during 2009. The results are shown in Figure 27. Of 15 answers, 0-5 notifications was the most common answer followed by 21-50 notifications.

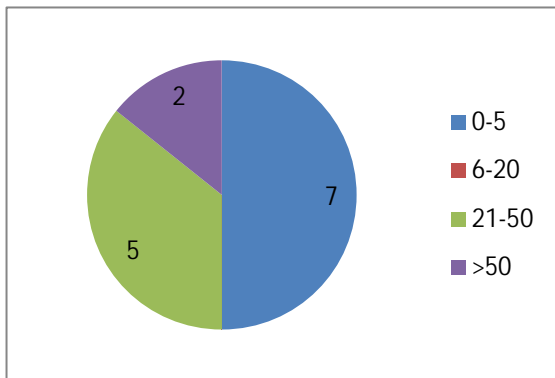


Figure 27. The number of authorities that had done a certain number of RAPEX notifications due to chemical risk during 2009.

The fourth question asked is if RAPEX is used by the authority (except for making own notifications) as a tool for tracking products with chemical risk. All 16 participants answered Yes.

If the participant answered Yes to the previous question, this was followed up in question 5 concerning if RAPEX was used to track specific products with chemical risk. All except one answered Yes.

Question 6 asked: "Is the information in RAPEX used to identify general product categories with chemical risk?" and the result was Yes from all participants.

Question 7 asked if the information from RAPEX had been successfully used to track a specific product, 14 of 16 participants answered Yes and two No.

The eighth question concerned what information contained in RAPEX was used for tracking products. The results are shown in Figure 28 where all alternatives except “Test results” were checkbox answers. The alternative “Image” was the one selected by most participants but also product name, importer, manufacturer, distributor/reseller, country of origin, bar codes and country of destination were chosen in more than half of the answers.

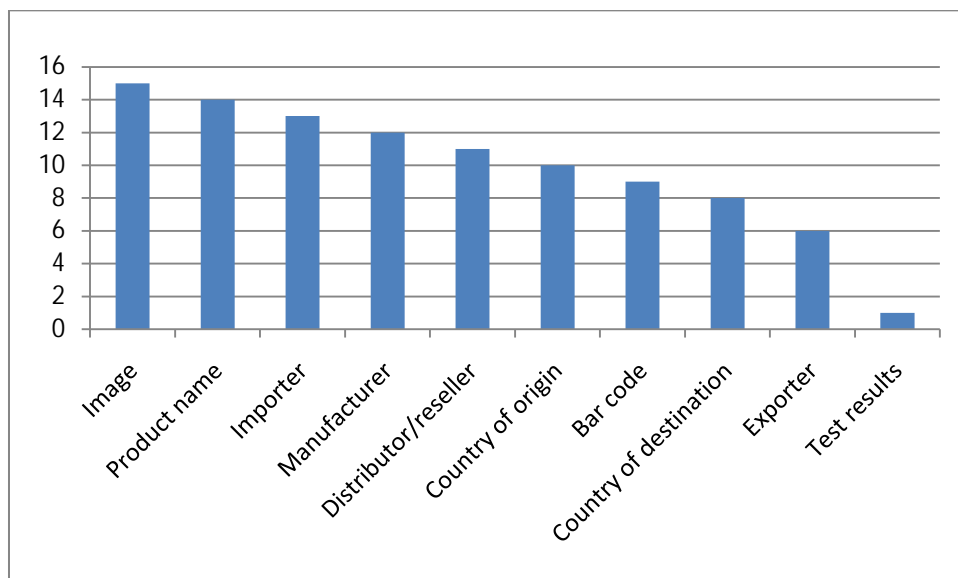


Figure 28. The chart shows how many of the participants that have mentioned what different types of RAPEX information that are used for tracking products.

Question 9, “Why is RAPEX not used in the enforcement work?” should be answered if the participant previously had answered that RAPEX was not used. But since all participants answered that RAPEX was used, no one answered to question 9.

In question 10 it was asked what the participants considered to be the advantages with RAPEX and included three checkbox answers and the possibility to provide free-text answers. 15 participants considered that one of the advantages was that it is a fast way to communicate about dangerous products with other Member States. 14 participants considered that the information in RAPEX could be easily used to track products. In addition, seven participants thought that it was an easy way to follow what other Members States are working with concerning products with chemical risks. Two participants provided free-text answers: “No advantages, it is just the system we are intended to use” and “the control gets more effective”.

Question 11 was “Is there a lack of information in RAPEX that could make the system more usable?” and the answers were given with free text. Several participants had suggestions: more detailed distribution list, custom code, more advanced search engine, more detailed images and risk assessment according to the new RAPEX guidelines.

To question 12, “Is there an intention to use RAPEX more in the future at your authority”, there were the answer alternatives Yes, No and Don’t know. The result in Figure 29 shows that several authorities (8 of 16) have those intentions.

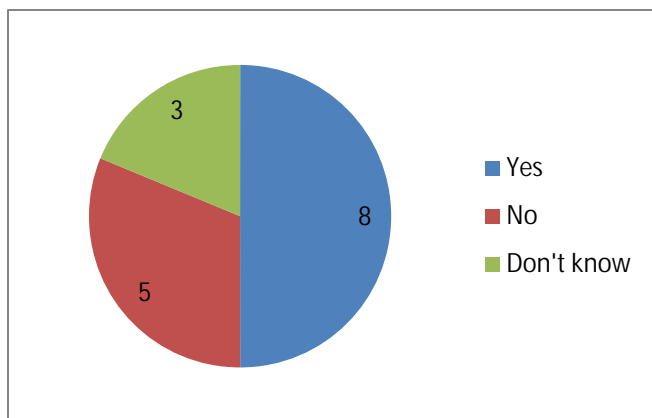


Figure 29. The answers to the question if there was an intention to use RAPEX more in the future at the authority.

Question 13 was "Is there collaboration between the customs authority and your authority concerning product safety and consumer products?". 14 participants answered Yes and two answered No.

Question 14 investigated if the authority uses bar codes to track products. Of the 16 participants, ten answered Yes and six answered No.

At the end of the questionnaire, the opportunity to provide additional comments was given. One of these considered that RAPEX is not useful any more because of the large number of notifications of products that are not on the country's own market. It was also pointed out that there is not enough resources to have time to follow up all notifications, just the ones with a known product name or if there are indications that the product is on the market in that country. It was also described that the customs authorities hold a lot of products at the border but that there are not enough resources to make RAPEX notifications about all of them. Another comment was that article 12 notifications should contain a risk assessment so that it can be verified that the product really is posing a "serious risk" to consumer's health. One participant made a comment that the authority would switch to another system for chemical products, ICSMS, in the future.

3. Discussion

3.1 Search strategies

3.1.1 Substances in articles

Articles are often complex products consisting of many different materials and the knowledge of the content of chemical substances is often limited. By investigating which selected substances have been found in different types of products in RAPEX, risk categories of products have been identified and connected to substances. These results can be used in future enforcement projects when choosing product types.

3.1.2 Customs

The result from the request of information from the Swedish Customs concerning nine RAPEX notified products shows that it is possible to identify manufacturers and/or importers

in the Customs' register of custom declarations. However, sometimes there can be an uncertainty about the company's name since the name given in the custom declaration do not always correspond to the name in the extended RAPEX information. To verify that it is the right company, the product description in the custom declaration can be used to see if it is the same type of products that has been exported to Sweden as the one from RAPEX.

Even though it is not exact the same products as in RAPEX that have been exported to Sweden, there can be reasons to pay attention to it. For example, in the case with a RAPEX notified inflatable chair there was an inflatable beach ball from the same manufacturer. It is then likely that the same materials have been used in the production and that the same chemical risk, in this case phthalates, can be suspected.

The information from the Customs also contains information about who has declared the product in Sweden. This can be used when contacting distributors and reseller when there is a need to adopt measures.

In the request to the Customs, proposals of commodity codes, relevant for the product according to the TARIC system, were given. But since there is a large uncertainty about what commodity code the declarant has chosen, the Customs search for all commodity codes. This increases the size of the search and covers more products but it also consumes more time which can be a problem.

A disadvantage with this search strategy is that it can be time consuming to sort out relevant information, both for the Customs and for the Chemical Agency. This is in particular true when there are a lot of custom declarations that matches the Customs search on company names. For example, in the case in the investigation with a wallet from RAPEX, 2115 custom declarations with manufacturer and exporter during 2009 and 2010 were found. Of these 1565 were considered to concern the same companies that were mentioned in the RAPEX notification.

At the present date (February 2010), there is an EU project going on where a number of Member States are developing work models that will simplify the collaboration between custom authorities and market surveillance authorities in each country. During an initial meeting, RAPEX has been mentioned and it has been pointed out that the information in RAPEX is not in a usable form for the custom authorities. Since import from countries outside the EU is the most important source to products with chemical risk in the EU, it is important that the collaboration between custom authorities and market surveillance authorities works well.

3.1.3 Bar codes

The investigation about bar codes shows that there is often a bar code mentioned in the RAPEX notifications but often, it is not possible to track the company with a search in the GEPIR database at the GS1 website. There are several reasons for this, among others the codes in RAPEX can consist of the wrong number of figures. A GS1 code mostly consists of 13 figures and when more or less figures are given in RAPEX, there is no search result in GEPIR. The reason why the wrong number of figures is used is most likely a mistake when

writing the notification but it is also possible that there is not a real GS1 code on the product. Another reason why a code does not give a hit in GEPIR can be that the company has ceased, that the code is American, the information is confidential in a country, or that the code is false. It was expected that none of the 15 codes that gave a hit in the GEPIR search would be found in the search at the Prisjakt website, since the products were notified by countries in the entire EU and the probability that the products are on the Swedish market is low. In addition, the products would need to be registered with an EAN code at a reseller at Prisjakt to be locatable in the search which lowers the probability even more.

A hit in GEPIR gives contact information to the registering company. This can be useful in some cases when a product's bar code is known but not the company that has registered it. A search in the GEPIR database is a quick way to provide contact information to a company when the search gives result.

Searching for an EAN code from a RAPEX notification at the Prisjakt website has a low probability to give a hit and can only be used in a few cases. To give a hit it is required that the product is registered with EAN code at the reseller listed at Prisjakt and that the product has been categorized. However, that approach is an easy and fast search and can in some cases give a result.

Products with codes starting with the figures 73 are registered by Swedish companies and are more likely to be found on the Swedish market and should therefore be prioritized. The result from the investigation of ten of these codes of RAPEX notifications in 2009 shows that it is easier to find contact information in GEPIR if the code starts with 73. The fact that none of these gave a hit in the search at Prisjakt additionally shows that finding products there has a low probability.

3.1.4 Country of notification

The search strategy Country of notification investigated which RAPEX products, with regard to the country of notification, are more likely to be found in Sweden and therefore should be prioritized. Using the extended RAPEX information on notifications, not only chemical risk products, a study has been performed to identify which countries that have identified Sweden as country of destination. This gives estimation about which countries that have a similar market and where it is likely to find the same type of products. The bar chart in Figure 34 shows that the adjacent countries Denmark, Germany, Finland and the UK are the countries that identify Sweden as country of destination most frequently when products with all types of risks are analyzed. Also some central and south European countries and some Baltic Sea countries identify Sweden as the country of destination. The result shows that products from these countries are more likely to be found in Sweden than products that have been notified by other European countries which supports the earlier mentioned theory.

However, it should be mentioned that only a small proportion of all RAPEX notified products have information about country of destination, information which this search strategy is based on. It should also be mentioned that some countries are more rigorous than other in reporting

the country of destination and therefore the investigation does not necessarily reflect the true flow of products.

3.1.5 Image recognition

The results from the investigation where ten images from the RAPEX database were searched for using a search engine for image recognition did not give a positive result. This was expected since the probability that the product can be found on a web page that Gazopa scans is not high. To get a positive hit with an image, the same product has to be on a web page that Gazopa scans and since the search engine is still a beta version, the supply of web pages is limited. In addition, the image has to be very similar, photographed from the same angle etc., as the images of the product on a web site.

At present, image recognition is not a useful method for tracking RAPEX notified products – this is confirmed by the results from this investigation. The probability that such a product should be found with an image on a web site, for example in a web shop, is low. If the product is in a web shop, then it is not certain that the search engine scans that web site. The quality of the image also plays an important part since an image taken from another angle or with another background would change the result of the search completely. However, image recognition is a relatively new technique and it is possible that this search strategy can be more useful in the future with refined search engines. A standardization of the images in RAPEX, for example using a white background for every image, would increase the effectiveness of an image recognition search.

3.2 Questionnaire survey

The questionnaire survey has provided a general view of how other chemical authorities in the EU work with questions concerning consumer products and RAPEX. Some of the questions had very varying answers while others had more similar answers.

In the first question, concerning what proportion of the authority's work that is spent on consumer products with chemical risks, the answers varied between less than 1% and 75%. The reason for this is probably that authorities in different countries have different organizations and not the same areas of responsibility. In addition, the prioritization of products can be different in different authorities.

Types of products that were mostly prioritized included toys, childcare articles, clothes/shoes, chemical products and cosmetics. Jewellery was also sometimes included. This answer corresponds to which products that have been most frequently notified in RAPEX (see Figure 1). These products (except cosmetics which are not a responsibility of the Swedish Chemical Agency) are the types of products that the Swedish Chemical Agency works with in its enforcement work.

The majority of the participants answered that their authorities had completed 0-5 or 21-50 RAPEX notifications (chemical risk) during 2009. Two answered >50 notifications. This shows that most of the authorities use RAPEX actively to notify dangerous products.

However, it should be considered that the more active RAPEX users can have been more willing to answer the questionnaire.

The high frequency of Yes answers to the question if RAPEX is used to track products, both specific products but also to identify general risk categories, shows that several authorities use the system not only for making own notifications but also to track products. The majority (14 of 16) had successfully tracked products using this information.

The most useful information for tracking products apparently is the image and product name. Furthermore, information about the distribution link, country of origin/destination and bar codes were also common answers. This shows that it is important that this information is included and is correct.

Many of the participants thought that RAPEX is a fast way to communicate about dangerous products with other Member States and that the information easily could be used for tracking products. But it was also pointed out that there is a lack of certain information. Suggestions about additional information that could facilitate the use of the system were: a more detailed distribution list, more custom codes, a more advanced search engine, more detailed images and a complementary risk assessment.

The need for images of higher quality with more details was discussed in the chapter about Image recognition. Better images are a demand for future search techniques but high quality images are already now useful for the enforcement work.

Recently, the EU Commission has announced new guidelines for RAPEX which among others contain a description of how to conduct a risk assessment to ensure identification of products posing a serious risk to consumers. One reason for this is to limit the number of weekly notifications in RAPEX. Presently it is questioned if all notified products do represent a serious risk. With an accompanying risk assessment, other authorities could make their own independent judgement.

The need for a more advanced search engine has also been shown during this work, both concerning the official weekly report database and the extended information. For example, it is not possible to search for a specific word in a specific field in the weekly reports, such as the number “73” in the field for EAN code. Instead, the result shows every notification that contains “73” somewhere in the whole text. These details in the search system make the procedure more time consuming than necessary and may also discourage users from searching for valuable information. Since some authorities (8 of 16 participants) intended to use RAPEX more in the future, it is important that it is possible to search effectively among the notifications.

Concerning the question about if there is collaboration between the authority and the customs authority in the country, most of the participants (14 of 16) do collaborate. This will probably increase in importance in the future due to the above mentioned new EU project where market surveillance authorities and customs authorities are required to develop their collaboration concerning consumer safety.

The information about bar codes is used by the majority of the participants (10 of 16) for tracking products. Today, the Swedish Chemical Agency does not use that information in the enforcement work and it would therefore be interesting to learn how the other authorities use the bar codes.

Other comments mentioned that there is often a lack of resources to be able to examine all notifications, especially when the numbers of notifications in the weekly reports are increasing. Instead, the products that are considered to pose the highest risk for consumers in their own country are prioritized. One purpose with this report has been to develop search strategies that can be used as tools for prioritization in the enforcement work. It is also pointed out that it is difficult to have time to do RAPEX notifications for all the products that the customs hold, which shows the need for an increased collaboration between the market surveillance and custom authorities.

3.3 Development of RAPEX

The number of RAPEX notifications has increased drastically during the last years, from 139 notifications in 2003 to 1997 notifications in 2009. As a result of new countries membership in the EU and a more well-known system, this development will probably continue. There are also discussions about including consumer products with environmental risks and products intended for working environment⁷, which would increase the number of notifications even more. Therefore it is significant that the system works well and that there is an easy access to important information without the system feeling unmanageable.

Recently (December 2009), there are new guidelines from the EU Commission concerning the risk assessment for RAPEX products. The reason for the new guidelines is the indication that many products are notified as posing a serious risk (article 12) while the lower level, not posing a serious risk (article 11), would be more appropriate. The disadvantage with too many notifications is that the weekly reports becomes too large and that the users have difficulties finding relevant and useful information. This has also been mentioned by participants in the questionnaire survey.

It was also suggested in the questionnaire that RAPEX should have a more advanced search engine. Today, sorting out desirable information can be difficult. It is for example not possible to search for a word in a specific field in the weekly reports, for instance "Sweden" in the field for Country of origin. Instead all notifications with "Sweden" somewhere in the text are shown. This is both time consuming and demands another step to sort out irrelevant notifications. This aspect should be regarded in the development of RAPEX and will be more important as the number of notifications increases.

3.4 Conclusions

The information from RAPEX notifications has been used to develop and evaluate a number of search strategies. In the search strategy Substances in articles, general risk categories of articles and material for a number of selected substances were identified. This can be used, for

⁷ Christina Larsson, Swedish Chemical Agency

example, when planning enforcement projects. The result from the request of information from the Swedish Customs shows that it is possible to get useful information from the Customs. This can be used for tracking specific RAPEX products or to identify similar products from the same exporter/manufacturer. Bar codes can be used to obtain contact information to registering companies. In some few cases, it can also be used for tracking products at the web sites like www.prisjakt.se. The RAPEX products that have an EAN code starting with the figures 73 should be prioritized since these have been registered by a Swedish company. The conclusion from the search strategy Country of Notification is that when looking in RAPEX for products that also can have been imported to Sweden, products notified by countries such as Denmark, Germany, Finland and the UK and other near Western European countries should be prioritized. The search strategy Image recognition is today difficult to use but a technical development could make it more useful in the future.

The questionnaire survey shows that the RAPEX system is used by several authorities in the EU although there is a large variation in what proportion of the enforcement work is spent on consumer products with chemical risks. The products that are prioritized in this work are above all the most frequently reported RAPEX products like toys and clothes. RAPEX is used for making own notifications but also for tracking specific products (often with success) and to identify general risk categories of products. The information that is used for tracking products is mainly images, information about product name, distribution, bar codes and country of origin/destination. It is therefore important that this information is complete and correct. There are several advantages with RAPEX but there is also a lack of some information that could improve the system. For example, detailed distribution lists, custom codes, more detailed images, a more advanced search engine and a risk assessment to be able to decide if the product is posing a serious risk or not. In several countries there are collaborations between market surveillance and customs authorities. It is important that this works well since the customs authorities often get in contact with the products that can pose a risk to consumers. Bar codes (EAN codes) are used for tracking products and this information could be used more in the Swedish enforcement work.

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Annex 1 – RAPEX notification form

Identification	
Notification number	
In application of Directive 2001/95/EC (art 11 information, art 12 serious)	
General information	
01. Notifying country	
Contact person	
The notifying company and contact person, address, telephone number and E-mail	
02. Date:	
Product	
03. Category (ex. toys, clothing, vehicles, electrical supplies):	
Customs code/Tullkod*	
04. Product name/Produktnamn:	
Brand/Märke:	
Price*	
Country of origin/Ursprungsland:	
05. Type/number of model/Typnr, modellnr, EAN-kod:	
06. Description/Beskrivning:	
Photos: (Jpg-format)	
07. Standards and regulations(ex.vis General Product Safety Directive 2001/95/EC):	
08. Proof of conformity/Märkning ex CE-märke:	
Producer	
09. Manufacturer/Tillverkare:	

10. Exporter:	
Importer:	
Distributor and Retailer	
11. Distributors or retailer/Distributör, återförsäljare, representant:	
12. Suppliers, (ex. shops, stores, supermarkets):	
Countries of destination/ Destinationsland:	
Danger	
13. Type of risk (ex. choking, internal injuries, poisoning, burns, electrical shock)	
14. Summary of the results of tests/analyses and conclusions (summering av resultat från tester/analyser och slutsatser):	
15. Description of accidents that have occurred:	
Measures adopted	
16. Voluntary measures (scope, nature, date of entry into force and duration) Frivilligt vidtagna åtgärder (på vilket sätt, när och hur länge?)	
17. Compulsory measures (scope, nature, date of entry into force and duration) Tvingande åtgärder (på vilket sätt, när och hur länge?)	
Other information	
18. Additional information/övrig information*:	

19. Confidentiality: (Yes or No)	
Additional information annexed	
Copy of test reports, certificates, examinations, etc (kopior på testrapporter, certifikat eller undersökningar):	

Annex 2 – Facts about substances

Phthalates

Phthalates are a group of substances that are composed by phthalic acid with two side chains in the ortho position. The side chains can be symmetrical or unsymmetrical and consist of straight, branched or cyclic/aromatic hydrocarbons (KemI 2010l). Phthalates are produced by a reaction between phthalic acid and alcohols to form the side chains. By varying the types of alcohols that are used, different phthalates with different properties can be produced. They are often divided into long and short chain phthalates. Longer side chains results in a more hydrophobic molecule but phthalates generally have low solubility in water and low volatility. The six phthalates that are regulated in REACH Annex XVII and are found in RAPEX notified products are DEHP (di(2-ethylhexyl)phthalate), DBP (dibutylphthalate), BBP (benzylbutylphthalate), DINP (diisononylphthalate), DIDP (diisodecylphthalate) and DNOP (di-n-octylphthalate). Figure 31 - Figure 36 shows the chemical structure of these phthalates. All these phthalates are long chained except DBP (KemI 2010d).

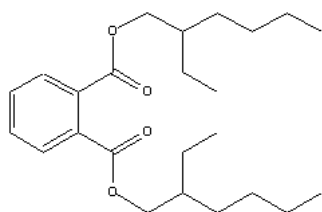


Figure 30. DEHP (Link 1).

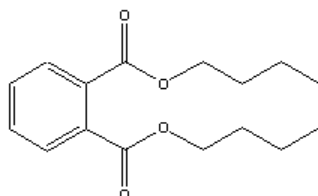


Figure 31. DBP (Link 2).

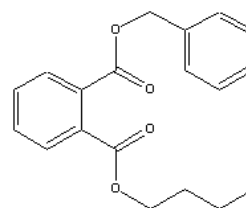


Figure 32. BBP (Link 3).

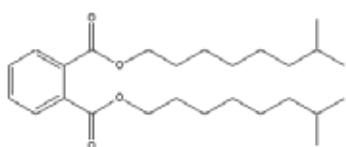


Figure 33. DINP (Link 4).

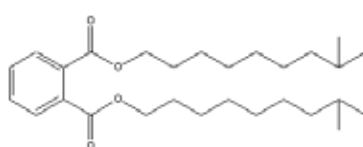


Figure 34. DIDP (Link 5).

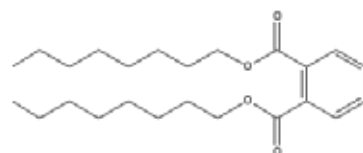


Figure 35. DNOP (Link 6).

Usage

The properties of the long chained phthalates make them suitable as softeners in different plastics, mostly PVC, and rubber. These materials have a wide use including floor covering, wall paper and cables but also in consumer products such as toys. Phthalates with short side chains are often used as solvents in paint, glue, perfumes and pesticides. Phthalates have been widely used since the 1950's when the manufacturing of PVC plastics began but the production started already in the 1920's (KemI 2010l).

Materials and products can contain up to 40 % by weight phthalates and they are added as additives to the plastics. As such, phthalates migrate from the materials and products with time to the surroundings and are bioavailable (KemI 2010g). Phthalates have been found in the environment and in human blood, breast milk and urine (KemI 2010d).

Health and environmental risks

DEHP is classified as toxic for reproduction category 2 (risk phrases R60 and R61). R60 means that the substance may impair fertility and R61 that the substance can cause harm to the unborn child. DBP and BBP are also classified as toxic for reproduction category 2 (risk phrases R61 and R62). R62 means that there is a possible risk that the substances may impair fertility. The other three phthalates (DINP, DIDP, DNOP) are not classified in the EU. Some phthalates can also be harmful to the environment. DBP and BBP are classified as harmful to the environment due to their toxicity for water organisms (EC regulation 1272/2008).

The different toxicities of the phthalates are due to the different structure of their side chains. When these are degraded (mostly to mono esters by hydrolysis) metabolites are formed with different toxicities than the parent substance molecule, which in some cases can be more harmful (Hauser & Calafat 2005).

Regulation

Due to established health effects caused by DEHP, DBP and BBP, toys and childcare articles cannot contain more than 0.1 percentage by weight of these substances. DINP, DIDP and DNOP are also regulated and are not permitted in toys and childcare articles that children can place in their mouth if the level exceeds 0.1 percentage by weight (EC regulation 1907/2006 Annex XVII).

Lead

Lead is an element and a metal that is not essential for animals or humans. Pure lead is classified as a heavy metal and has a high density and relatively soft consistency. The fact that it is also a good isolator, gives good protection against radiation and that it can resist impacts well makes it useful for many applications (KemI 2007).

Lead occurs naturally in the earth crust, often together with other metals as zinc, copper and silver. Hence, mining of lead is often more profitable since other metals are also recovered. Lead can be released into the environment naturally through erosion of rock and volcano eruptions. But human activities are the main sources of released lead into the environment. Mining is one source but lead is also released as a contaminant when mining coal and limestone (Nriagu 1989). The extraction of lead has decreased slightly between 1970 and 2000 but the total consumption has increased. This is due to improved recycling of lead, mainly from batteries (Nordic Council of Ministers 2003b).

Usage

Lead is used both as a pure metal and in many compounds, such as tetraalkyl lead in gasoline. When the metal corrodes, lead ions are released forming compounds or complexes with other molecules. Lead compounds occur as inorganic and organic compounds and organic compounds are the most harmful since they have a higher bioavailability. Due to lead's varying properties, the metal has been used by humans for a long time and in many appliances. Some products where lead has been mainly used is in batteries (60 % of the usage of lead in the EU), isolation of cables, roof cover panels, ammunition, protection against

radiation, weights, crystal glass, boat keels, electronics, fishing tools, plastic products, alloys and paints. The consumption of lead has decreased in some of these products during recent years while some uses have increased. A significant decrease in consumption of lead was shown when lead in petrol was forbidden in Sweden 1995 (Swedish Environmental Protection Agency 2010) and later in the whole EU, which has produced a noticeable decrease in the levels of lead in the environment and in humans. Some products where the consumption of lead has decreased (between 1995 and 2005) are pigments for paint, plastics, crystal glass, lead-covered cable, electronics and lead ammunition. The decrease is a result of new regulations but also voluntary measures to substitute lead in some businesses. Concerning batteries, boat keels, fishing tools, alloys, weights and protection against radiation, the usage of lead has been maintained or even increased. The increased consumption of lead is mostly due to increased production of a certain product but not due to an increased content of lead (KemI 2007).

Health and environmental risks

Effects on metabolism, the kidneys and the cardiovascular system are observed at low levels of lead in the blood, 0.3 $\mu\text{mol/l}$, but these effects are not considered dangerous for health. At 0.5 $\mu\text{mol/l}$ lead in the blood in young children and foetus, adverse effects on kidney development, decreased IQ and behaviour disorder have been seen. There are also indications that these effects do not have a threshold value, but rather start at a low level of exposure. Measures made in Sweden show that the average level of lead in the blood in men are 0.2 $\mu\text{mol/l}$ and slightly less in women and children (Swedish Chemical Agency (2007) Rapport nr 3/07 Bly i varor). The margin up to the level where the health is affected is small and it is therefore important that sensitive groups that can exceed these levels are identified so the health risks can be avoided.

The uptake of inhaled lead has been estimated to 50% where the uptake of lead from food is only approximately 10%. However, children have a higher dietary uptake (approximately 50%) because their stomachic-intestinal system is not fully developed (WHO 1995). Therefore it is extra important that lead does not occur in articles that children can easily swallow or put in their mouth, for example toys. A case where a child died from lead poisoning after swallowing a lead containing jewellery highlighted this in the US.

When lead is taken up in the blood, it can mimic other metals, for example calcium. Hence, lead stored in the bone tissue can be accumulated there. Later it can be released during pregnancy, breast feeding (Silbergeld 1991) and osteoporosis (Silbergeld, Schwartz & Mahaffey 1988). Lead can also be transferred from the mother to the foetus via the uterus (Bellinger 2005) which is very serious since the foetuses are very sensitive to lead toxicity.

All lead compounds are classified as toxic for reproduction in category 1 to 3 and can be harmful to the foetuses and a possible risk for impaired fertility. Most lead compounds are also classified as toxic to the environment since they can be harmful to aquatic organisms and to the aquatic environment (EC regulation 1272/2008).

Regulation

The REACH regulation (Annex XVII of (EC) No 1907/2006) specially regulates the use of lead carbonate and lead sulphate in paint. Although, there are exceptions for, among other, professional restoration and maintenance of historic buildings and works of art. In Annex XVII, there is also a restriction for selling products with substances that are classified as carcinogenic, mutagenic and/or toxic for reproduction (category 1 or 2) to the general public.

In the Toys Directive (EC) No 2009/48 there are certain safety requirements that need to be met. One of these is a limit of value of how much lead that is allowed to migrate from different material in toys. Lead cannot be added on purpose so the limits of value concern contamination. Since lead is classified as a CMR substance (carcinogenic, mutagenic or toxic for reproduction), it cannot be used in parts of the toy that a child can reach (EC directive 2009/48). In the European standard for toy safety (SS-EN 71-3) the minimum level of how much lead that is allowed to migrate from the material is specified (KemI 2006b).

Electric and electronic products are not allowed to contain lead (more than 0.1 percentages by weight) according to the RoHS directive. However, there are several exceptions where lead is allowed, for example in some solders and in optic glass (RoHS (EC) No 2002/95).

Lead is forbidden in cosmetics since it is considered that it can harm the human health through dermal uptake. However, there are exceptions for lead acetate that is allowed in hair preparations (ECC directive 76/768).

Chromium

Chromium in its pure form is a hard, white and shiny metal. It does not naturally occur in the pure form but in different minerals in the earth crust whereof chromite is the most common. Chromium and its salt are used in many applications. Chromium salts are often highly coloured. There are several different oxidation states but chromium(III) and chromium(VI) are the most common and occur naturally. The higher the oxidation state, the greater the solubility (KemI 2010m).

Usage

Chromium has many areas of usage, for example in alloys (stainless steel), pigment in paints, anti-rust agent (chromium plating) and impregnation of wood and tanning of leather (ATSDR 1998).

Health and environmental risks

The two most common forms of chromium have very different properties and toxicity. Chromium(III) is essential for the metabolism of glucose and fat in mammals. It has also been considered to be involved in the function of insulin and deficit of chromium has been connected to cardiovascular diseases (Anderson 1989). Chromium(VI) has a higher uptake in the body than chromium(III) is classified as carcinogenic (Sterner 2003). Chromium(VI) also causes dermal contact hypersensitivity and. This has mostly occurred in construction workers in contact with chromium(VI) containing cement (Lidén m. fl. 2008). In Europe, it is

estimated that 1-2% of the adult population and approximately 6 % of all allergic persons are allergic to chromium. Chromium in cement is regulated in the EU but leather tanned with chromium is now suspected to be another source of exposure (Lidén 2007).

In the EU, several chromium containing compounds are classified as harmful to the health. All chromium(IV) compounds that are not on the list (except barium chromate) are generally classified as carcinogenic (category 2) since they are considered to be able to cause cancer when inhaled. Specific chromium compounds have different classification that includes carcinogenic, mutagenic and toxic for reproduction. Several chromium compounds are also classified as toxic to the environment (EC regulation 1272/2008).

Regulation

The Toys Directive regulates the maximum level of chromium that is allowed to migrate from different materials in toys. Chromium cannot be deliberately added to toys, however there is limit value for the occurrence of chromium due to contamination. There are limit values for both chromium(III) and chromium(VI), but the value for chromium(III) is higher since it is considered to be less toxic (EC directive 2009/48). There is also an European standard for toy safety (SS-EN 71-3) that specifies a limit value of how much chromium is allowed to migrate from the material (KemI 2006b).

Levels of chromium(VI) greater than 0.002% dry weight is not allowed in cement. The chromium compounds that are classified as carcinogenic, mutagenic or toxic for reproduction (category 1 or 2) are forbidden in chemical products that are sold to the general public (EC regulation 1907/2006 Annex XVII).

Levels of chromium(VI) that exceed 0.1% by weight in homogenous material are not allowed in electric and electronic. Waste from these types of discarded products can pose a risk to health and the environment. However, there are several exceptions where the levels can be exceeded (EC directive 2002/95 RoHS).

Chromium levels in packaging are also regulated by the Packaging and Packaging Waste Directive (EC directive 94/62).

Nickel

Nickel is a hard, shiny and silver white metal that is commonly found in the earth crust in many minerals. Nickel can have several oxidation states but bivalent nickel is the most stable and common form. The hardness of nickel and its ability to resist corrosion make it useful in for example different alloys (ATSDR 2005). Nickel forms inorganic yellow green salts with, among other, nitrate, chloride, sulphate, fluoride, hydroxide, carbonate and oxides. These salts have different properties such as melting points and water solubility (KemI 2010n).

Usage

The area of application for nickel is stainless steel which consists of 18% nickel (Sterner 2003). Nickel salts are used for different applications; nickel oxide as pigment and for producing other nickel salts and magnets: nickel hydroxide; production of nickel-cadmium

batteries: nickel carbonate; metal coating and catalyst for refining and tempering of oils and fats within the food industry: nickel nitrate; pigment, metal coating and pesticide and: nickel sulphate and nickel chloride; production of other nickel compounds (KemI 2010n). Nickel is often used in alloys which can release different amounts of nickel ions. Some alloys that release high amounts of nickel ions are German silver, cupro-nickel and nickel-brass. Nickel in stainless steel is often more tightly bound and is therefore not as readily released from the object (Lidén & Norberg 2005). Many daily used objects contain nickel, for example coins, tools, buttons, jewellery and cell phones (KemI 2004a).

Health and environmental risks

The most well-known health effect in humans caused by nickel is contact skin allergy. A large part of the population (approximately 15% of the women and 2-5% of the men) in Sweden and Europe have nickel allergy, which is a lifelong disease. A common symptom is hand eczema that is both painful for the person and expensive for society. The allergy arises after exposure to nickel for a longer period of time, which is called sensitization. Once the allergy is established, only low amounts of nickel and short exposure is enough to trigger the symptoms (elicitation) (KemI 2004a). A skin rash arises much faster if the skin is already harmed or inflamed (Kitura, Yoshida & Yamada 2003). The allergy arises when nickel containing objects are in contact with the skin and nickel ions penetrate the skin and binds to proteins. This triggers the immune defence that identifies the nickel protein complexes as foreign and causes a skin rash. If a person already is allergic to nickel, it is believed that nickel in food can cause reactions. Examples of food that contains nickel naturally are cacao, nuts and soya beans (Sterner 2003). However, the levels of nickel in food and water are often low and should not be a problem for nickel allergists (National Food Administration 2010).

Some nickel compounds are also carcinogenic when inhaled by workers in nickel industries. The potential of a nickel compound to cause cancer is related to its ability to penetrate into the cells in the body. The water insoluble compounds often have a higher bioavailability and are therefore more carcinogenic due to uptake in the cells via phagocytosis. Once in the cell, nickel ions are released and can bind to the DNA. The mechanism for inducing of cancer by nickel is not fully known, but one theory is that the nickel ion increases the methylation of DNA. This in turn leads to more mutations than normally (Costa & Klein 1999).

Nickel and twelve other nickel compounds are classified as harmful to human health. All except one is considered able to cause allergy via skin contact and/or inhalation. Several are also classified as carcinogenic, by which five in category 1 with risk phrase R49 (may cause cancer by inhalation). Pure nickel metal is classified as carcinogenic in category 3 with the risk phrase R40 (limited evidence of carcinogenic effect). Several nickel compounds are also classified as harmful to the environment (EC regulation 1272/2008).

Regulation

Annex XVII of REACH regulation regulates the rate of migration of nickel from some objects. The limit value for how much nickel is allowed to migrate from piercing jewellery is $0.2 \mu\text{g}/\text{cm}^2/\text{week}$. In other articles that come into contact with skin (earrings, necklaces, watch

straps, rings etc) the value is 0.5 µg/cm²/week. This value also applies to articles that are in contact with the skin for at least two years of normal use which have an insufficient nickel free coating but it is not sufficient (during at least two years normal use). This means that jewellery is supposed to stand two years normal wear without exceeding the value.

The migration of nickel in toys is regulated in the new Toys Directive concerning toy safety (EC directive 2009/48).

Cadmium

Cadmium is a heavy metal that is extracted from the earth crust together with mining of zinc (OECD 1994).

Usage

The largest sector for the application of cadmium is nickel-cadmium batteries. It is also used as pigment in paint, as stabilizer in PVC, as a coating and in alloys (Nordic Council of Ministers 2003a). Jewellery in Switzerland have been found to contain high levels of cadmium (approximately 20%) which is believed to be due to that electronic waste is melted and used as metal for producing jewellery that is exported to Europe⁸. The American counterpart to the Swedish Consumers Agency, CPSC (Consumer Product Safety Commission), has found jewellery that contained cadmium levels above 10% in 12%. This was mostly jewellery intended for children that had the highest levels with up to 84-91 percentages by weight cadmium. The cadmium containing jewellery were manufactured in China but imported and sold in established chain stores. There are indications that manufacturers exchange lead in jewellery with cadmium, since lead is more restricted in the US and cadmium is also relatively cheap (Fox News 2010). Another usage that has gained attention is cadmium in artist paints that are excluded from the ban of cadmium in paint. Other cadmium salts, cadmium sulfoselenide and cadmium zincsulfide are used as pigments to produce the colours “cadmium red” and “cadmium yellow”. These compounds are mainly a problem in waste water treatment plants where cadmium ends up in the sludge making it unusable on farmland (KemI 2005).

Health and environmental risks

Cadmium has several known health effects in humans. One target organ is the kidneys where the tubular and glomerular functions are harmed and impair the kidneys ability to filter. Cadmium ions similarity with calcium ion results in the storage of cadmium in the skeleton and can cause osteoporosis and fractures in more severe cases. There are also indications that cadmium can have hormone disrupting effects by imitating estrogen⁹. Two common sources for exposure of cadmium are tobacco and vegetables/cereals since plants are good at absorbing cadmium. Except highly exposed persons as smokers, vegetarians and workers in the cadmium industry, women are a risk category since the enzyme DMT1 in the stomachic-

⁸ Lennart Dock, Swedish Chemical Agency

⁹ Agneta Åkesson, Institutet för miljömedicin, Karolinska Institutet

intestinal system that is activated at iron deficit and increases the uptake of bivalent iron including cadmium ions when available¹⁰.

Cadmium is a relatively readily soluble metal which makes it mobile in soil. As a consequence, it has a higher bioavailability than other heavy metals which leads to a higher bioaccumulation in organisms (Nordic Council of Ministers 2003a). Due to its toxicity, cadmium is classified as harmful to the environment.

Regulation

Annex XVII in REACH regulates the use of cadmium as a pigment in several plastic materials and in paints. In addition, cadmium cannot be used as a stabilizer in certain articles such as plastic packaging, clothes and accessories (EC regulation 1907/2006 Annex XVII).

Cadmium is one of several heavy metals which has a limit on migration in the new Toys Directive (EC directive 2009/48).

In the RoHS directive, the level of cadmium allowed in electric and electronic equipments are limited to 0.01 percentages by weight (EC directive 2002/95 RoHS).

Toluene

The chemical structure of toluene is a benzene ring with a methyl (see Figure 36). It is a colourless liquid at room temperature and is extracted from coaltar or petroleum products by extraction or distillation (KemI 2010o).

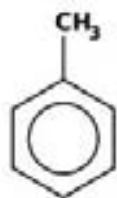


Figure 36. The chemical structure of toluene (Link 8).

Usage

Toluene is mainly used as a component in petrol but also as a chemical for synthesis for producing, among others, p-xylene and explosives. Another large application for toluene is as solvent in paint, car preservative agents and glue (KemI 2010o).

Health risks

One explanation of the toxicity of toluene is that a small fraction of the toluene that is taken up in the body is metabolized to reactive intermediates e.g. epoxides and electrophilic sulphate conjugates. These intermediates are similar to those formed when the toxic substance benzene is metabolized and that can react and damage the liver and the DNA. A higher exposure of toluene leads to a larger amount of these intermediates (Sterner 2003). Toluene is also

¹⁰ Maria Vahter, Institutet för miljömedicin, Karolinska Institutet

irritating to the skin, eyes and respiratory organs. Except inhaling and orally, toluene can also be taken up dermally (KemI 2001).

Toluene is classified as irritating, harmful and toxic for reproduction category 3 (risk phrase R63 – possible risk to harm the unborn child).

Regulation

Annex XVII in the REACH regulation defines the maximum level of toluene allowed (0.1 percentages by weight) in glues and spray paints intended to be sold to the general public.

The European standard for toy safety (EN 71-9) defines a maximum level of toluene that is allowed to migrate from toys (KemI 2006b).

Nitrosamines

Nitrosamines are a group of substances that have a chemical structure according to Figure 37.

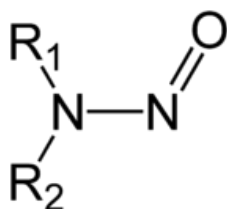


Figure 37. The chemical structure of nitrosamines (Link 9).

Usage

The presence of nitrosamines in food has received much attention. The nitrosamines are formed in food as a product from a reaction between secondary amines and nitrate or other nitric oxides during certain conditions (Scanlan 2000).

Nitrosamines can also be formed during the production of rubber and can therefore be found in rubber products (Balogh m. fl. 2003).

Health risks

Most of the tested nitrosamines have been shown to have carcinogenic effects in animal experiments and it is likely that they can cause cancer in humans. This is due to reactive metabolites formed during the digestion of nitrosamines in the body that can bind to proteins or DNA. Many nitrosamines have organ specific health effects, for example causing cancer in the liver (NE 2010).

Regulation

Some countries, for example the Netherlands and Germany, have national legislation that regulates the level of nitrosamines in balloons but there are no EU legislation concerning nitrosamines in balloons (Alltombarn 2007).

However, there is a regulation of how much nitrosamines or nitrosatable substances that is allowed to migrate from soothers of elastomer or rubber (EEC directive 93/11).

Nitrosamines are on the list of substances that are forbidden for use in cosmetics (LVFS 2004:14).

Dimethyl fumarate

Dimethyl fumarate is an ester that is formed when methanol and fumaric acid react. The chemical structure is shown in Figure 38 and the compound is a solid, white powder at room temperature.

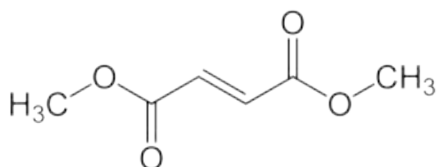


Figure 38. The chemical structure of dimethyl fumarate (Link 11).

Usage

The main application of dimethyl fumarate is as an anti-mould agent. It is often added to imported articles as furniture and shoes to protect them from mould during transport. The powder is packed in small bags similar to the anti-moisture bags, either in the same packaging as the article or sewed into the article. The bags can be labelled “anti-mould agent”.

Health risks

The carbon-carbon double bond of the dimethyl fumarate molecule is reactive, which leads to irritating reactions with skin and eyes. Skin contact can cause allergy with itching, irritation and burns.

Regulation

In the EU, dimethyl fumarate is forbidden in products (in levels above 0.1 ppm) of 1st of May 2009 after an EU decision the 17th March the same year. The regulation is implemented in the Swedish law in ”Förordning (1998:944) om förbud m.m. i vissa fall i samband med hantering, införsel och utförsel av kemiska produkter” (KemI 2010b).

Azo dyes

Azo dyes are a large group of organic compounds that all contain an azo function (see Figure 39). The bond enables, depending on the R-groups, a system of varied size with delocalized electrons which give rise to different colour properties. This bond can also be broken and then a so-called arylamine is formed if the R-groups are aromatic (KemI 2010f).

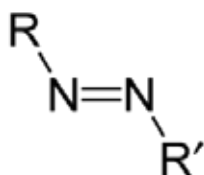


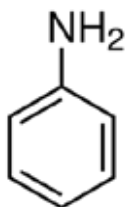
Figure 39. The chemical structure of an azo bond that has given the azo dyes their name (Link 13).

Usage

Azo dyes are used for colour textile and leather. The textile materials that are coloured are mostly cotton but also silk, wool, viscose and synthetic materials (KemI 2010f). Examples of articles where these materials are used are clothes, bedding, shoes, purses, toys, thread, wallets and watchband (KemI 2010a).

Health and environmental risks

One example of an arylamine is the substance anilin (Figure 40) that, like many other arylamines, has known toxic properties. However, all azo dyes are not metabolized to arylamines. Metabolism occurs following uptake in the body by enzymes or chemically by light or temperature during storage. Arylamines are considered to be carcinogenic but some can also cause allergic reactions or be directly toxic when inhaled. Several are also classified as dangerous for the environment due to their ability to harm aquatic organisms and the aquatic environment (KemI 2010f).



Figur 40. The chemical structure of anilin, an arylamine that can be formed during metabolism of certain azo dyes (Link 12).

Regulation

Of approximately 2000 substances on the market that contain an azo function, only those giving rise to 22 different arylamines (see Annex 2) are regulated in the EU. The level of these substances can not be higher than 30 ppm in the coloured article (KemI 2010a).

Formaldehyde

Usage

Formaldehyde is a common chemical in the chemical industry and has several applications. The chemical structure is shown in Figure 41. In pure form, it is used as preservative and antiseptic agent but also to prevent corrosion of metals and as hardener/stabilizer in photography. Formaldehyde is also an important chemical for synthesis of other chemicals: polymers of formaldehyde and other substances such as urea, melamine and phenol. Urea and melamine formaldehyde polymers are used as a binder for production of chip boards, laminate and lacquer. Phenol formaldehyde polymers are used as mentioned above and for production of pulp. Urea formaldehyde resins have an application as anti-wrinkling agent for clothes. These polymers can also be used for production of plastics. Oximethylene plastic is also made from formaldehyde and is used in construction and machine details. Formaldehyde can also be used as raw material for synthesis of polyols that are used when producing polyurethane plastic and alkydes. Another sector of application for formaldehyde is as raw material for production of the well-used chelating agents EDTA and NTA (KemI 2010k).

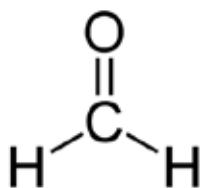


Figure 41. The chemical structure of formaldehyde (Link 10).

Articles that contain formaldehyde or substances that have been synthesized from formaldehyde can emit formaldehyde to the surroundings. One product that has been given attention is chip boards in houses that have led to high levels of formaldehyde in the indoor air (KemI 2010c). The materials that contain or have been treated with formaldehyde can also be found in consumer products. These are for example clothes and textiles for furniture that have been treated with anti-wrinkling agent and wooden products where formaldehyde has been used during manufacturing (KemI 2004b).

Health risks

The health risks with formaldehyde are mainly due to irritating effects in the eyes and the respiratory organs. But it is also suspected that formaldehyde can be carcinogenic (mostly in the mucous membrane in the nose) after animal experiments and epidemic studies of highly exposed workers (Swedish Environmental Protection Agency 2004).

In the EU, formaldehyde is classified as corrosive, toxic, irritating, can cause allergy and carcinogenic category 3 (risk phrase R40 – limited evidence of carcinogenic effect) (EC regulation 1272/2008).

Regulation

According to the Toys Directive (EC directive 2009/48), CMR-substances are not allowed in toys and since formaldehyde is classified as a possibly carcinogenic for humans, it is regulated in toys. The allowed amount of formaldehyde that can migrate from a toy is also regulated in the European standard (EN 71) for toy safety.

Annex 3 – Rapex questionnaire

Product safety and Rapex

Enforcement authority

What is the name of your enforcement authority?

Question 1

Approximately what proportion of the enforcement work at your authority is spent on consumer products with potential chemical risk? (0-100%)

Question 2

Which types of products are prioritized in this work?

- . Toys
- . Clothes/shoes
- . Hobby/sports equipments
- . Chemical products
- . Cosmetics
- . Childcare articles and children's equipments
- . Jewellery
- . Other:

Question 3

Approximately how many notifications (chemical risk) did your authority make during 2009?

- . 0-5
- . 6-20
- . 21-50
- . >50

Question 4

Is the Rapex database used in the enforcement work (except making notifications) as a tool for tracking products with chemical risk?

- . Yes
- . No

Question 5

If Yes on Question 4, is the information in Rapex used for tracking specific products with chemical risk?

- . Yes

. No

Question 6

If Yes on Question 4, is the information in Rapex used for identifying general categories of products of chemical concern?

. Yes

. No

Question 7

If Yes on Question 4, have the information from a Rapex notification been successfully used when tracking a specific product?

. Yes

. No

Question 8

If Yes on Question 4, what information (from a Rapex notification) is used for tracking Rapex notified products?

. Product name

. EAN/barcode

. Manufacturer information

. Exporter information

. Importer information

. Distributor/retailer information

. Picture

. Country of origin

. Country of destination

. Other:

Question 9

If No on Question 4, why is Rapex not used in the enforcement work?

. Lack of time/resources

. Other, better systems are used

. The information in Rapex is not useful

. Lack of knowledge about the information in Rapex and how to use it

. Other:

Question 10

What are the advantages with Rapex?

. Quick communication about hazardous products between member states

- . The information can be used for tracing products easily
- . An easy way to see what other member states are working with concerning products with chemical risk
- . Other:

Question 11

Do you miss any information in Rapex that could make the system more useful?

Question 12

Is there an ambition at your authority to use Rapex more frequently in the future?

- . Yes
- . No
- . Do not know

Question 13

Is there collaboration between the customs authority and your authority concerning product safety and consumer products?

- . Yes
- . No

Question 14

Are EAN codes or bar codes used for tracking products?

- . Yes
- . No

Question 15

Other comments

Annex 4 – Legislation concerning articles

The Swedish Parliament has defined 16 environmental quality objectives including "A non-toxic environment" which the Swedish Chemical Agency is responsible for. The overall goal is that "The environment must be free from man-made or extracted compounds and metals that represent a threat to human health or biological diversity." There are also complementary interim targets that describe the work more in detail and specify time frames. Some of these concerns articles, for example Interim target 3 "Phase-out of substances of very high concern (2007-2010)" which says that newly manufactured products will as far as possible be free from several substances with toxic properties (KemI 2006a).

In the enforcement work with articles, there are several different legislations that concerns chemicals. There is the national legislation with the Environmental Code (Miljöbalken) with complementary regulations and more detailed authority regulations. There is also the EU legislation with regulations, decisions and directives. The difference between these is that a regulation is applied in all Member States directly when adopted while directives and decisions need to be implemented into each state's national legislation to be adopted. The EU legislation can also have a great impact on manufacturing of articles in countries outside the EU if the article should be exported the EU and needs to meet the same demands. The most important legal frameworks concerning articles are described below.

The Swedish environmental legislation can be found in the Environmental Code (Miljöbalken). This is the law that is the basis of the Chemical Agency's legal work. Except the law, regulations and authority regulations are also used but these are below the Environmental Code (hierarchy: constitutional law > law > regulation > authority regulation). Mostly, it is Chapter 14 in the Environmental Code about chemical products and biotechnical organisms that concerns chemicals. The Chemical Agency has been given mandate by the Swedish government to write authority regulations and other regulations concerning chemicals. Among other things, these mention the risks with usage of chemical products, articles and pesticides and that it is the manufactures and importers that are responsible. In Chapter 2, the General rules of consideration describe, among others, the demand of sufficient knowledge and the substitution principle that are foundations in the Environmental Code but are more difficult to adopt practically in work with enforcement. There are also regulations in other chapters about enforcement, penalties and environmental sanctions that concern the Chemical Agency's work with enforcement (KemI 2010e).

The 1th of June 2007, a new EU regulation concerning chemicals was adopted; REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). In REACH, an article is defined as "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". Earlier, there was a directive that restricted certain substances in certain products, but that has been replaced with Annex XVII in the REACH regulation (KemI 2010h). An additional Annex XIV should also be added, where substances that are considered to have very toxic properties (SVHC – substances of very high concern) will be listed. The use of these substances for manufacture in the EU will require that certain permission in the future. A final date for

placing on market and using these substances will be stipulated. SVHC substances can either be toxic CMR substances (Cancerogenous, Mutagenic and Toxic for Reproduction) or environmentally harmful PBT substances (Persistent, Bioaccumulative and Toxic) or vPvB substances (Very Persistent, Very Bioaccumulative). Today, there is a Candidate List that is updated continuously with substances that may be included in Annex XIV. If a substance is on the Candidate List, this may have consequences for the user, for example, if an article contains these substances in levels > 0.1 %, information about the substance should be provided to the consumer if asked for¹¹.

In the Law of Product Safety (Produktsäkerhetslagen 2004:451) and the Regulation of Product Safety (Produktsäkerhetsförordningen 2004:469) it is described that products in general should be safe for consumers. These rules are applied when there are no applicable rules in other legislation. The Law of Product Safety says that an article or service should be safe for normal use and lifetime. These rules are in accordance with the General Product Safety Directive (EC directive 2001/95).

There is new EU directive concerning toy safety (EC directive 2009/48) and it should be implemented into Swedish legislation before the 20th of July 2011. It contains prohibition and regulation of certain hazardous chemicals in toys, for example odorants that can cause allergies and some heavy metals. The metals cannot be added to the toys on purpose, they may only be present as a contaminant. Also carcinogenic, mutagenic substances and substances toxic for reproduction (CMR substances) are forbidden in parts of the toys that children can come in contact with (KemI 2010i).

The RoHS directive (EC directive 2002/95 RoHS) regulates a number of substances in electric and electronic products. The metals cadmium, mercury, lead, hexavalent chromium and some brominated flame retardants are not allowed in levels above 0.1 percentages by weight (0.01 percentages by weight for cadmium) in homogenous materials in these products that are on the market after the 1st July 2006. However, there are several exceptions where the substances can be used. One problem that has been given attention is that fact that discarded electronic products often end up as waste in developing countries where appropriate care is not practised. There, these toxic substances can be released and harm both human health and the environment. This is one of the most important reasons for the restrictions in the RoHS directive. Another reason is that recycling of the products is facilitated if these substances can be avoided (KemI 2010j).

In the EU, there is a system for standards with criteria concerning product safety for articles. European Standards are composed from the EU legislation by three standard bodies; CEN, CENELEC and ETSI. There are different standards which concern different types of products and one of these standards is EN-71 about toy safety that concern many RAPEX notified articles. This consists of several parts with criteria for different areas, for example, the highest level allowed for migration of heavy metals and organic compounds. It is also specified which methods for analysis should be used (Europeiska Kommissionen 2010a). The standard label (CE label) is a way for the manufacturers of a product to show increased product safety and

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meets the safety requirements of the EU (but it is also allowed to prove that a product is safe in other ways)¹².

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