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Chemicals in toys
Inspection report 2005

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Chemicals in toys

Inspection report 2005

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Summary

Children are more sensitive than adults to chemicals. Toys therefore need to be particularly safe, in terms of both physical safety and chemical health risks, in comparison with other products.

There are around 70 companies in Sweden today that import and manufacture toys. The Swedish Chemicals Agency (KemI) inspected 30 of these companies in 2005 in a collaborative project with the Swedish Consumer Agency. KemI visited the companies and asked questions about the companies' operations, applicable rules on chemicals and the content of chemicals in their own toys. Toys from some of the companies were also analysed to establish their chemical content.

It was found that many companies had inadequate knowledge on the subject of the chemical content in toys. The inadequacies apply both to what rules exist and what chemicals the companies' own products contain. The companies rely on the CE mark and wrongly believe that it guarantees chemical safety. Many of the inspected companies did not either ask their suppliers whether the toys were free of prohibited or restricted chemicals or demand information on chemical content.

There is an information requirement in Chapter 14 Section 8 of the Environmental Code and Section of the Chemical Products and Biotechnical Organisms Ordinance (1998:941) for articles that contain or are treated with hazardous chemical products and that, on the basis of their properties, may be feared to cause harm to humans or the environment. This rule was only known to a third of the companies. Ignorance of this rule means that important information, for example on allergenic preservatives, does not reach consumers.

The Swedish Chemicals Agency's inspectors found three toys in the inspections that were unsuitable or directly hazardous. In a large company it emerged that all the air mattresses and large pools they sell contain the plasticiser DEHP in high concentrations (30 per cent). There will be a total ban on DEHP in toys from 17 January 2007 because this substance is judged by the EU to be toxic to reproduction.

One of the other large companies sold pens that contained free-flowing mineral oil. If it is very free-flowing, mineral oil can cause chemical pneumonia if swallowed.

However, the mineral oil in the pen was too viscous to be able to cause lung damage. The company nevertheless decided to stop selling the pen. In addition, high levels of lead and chromium were found in the analysis of pastel crayons.

The Swedish importer had certificates from the supplier showing that the crayons complied with the toy standard EN 71-3. Limit values for the migration of lead and chromium are specified in this standard. The migration values on the certificates were substantially lower than the permitted limit values. When the crayons were sent to an accredited laboratory for analysis, migration values were measured that were more than 20 times higher than the permitted value, according to the toy standard. The company decided to withdraw the crayons from the market.

The inspection reveals a clear need for increased information about chemicals in toys to prevent humans or the environment being adversely affected by chemical substances in toys.The industry organisations have an important role to play in disseminating information. But it is the companies themselves in particular that need to increase their knowledge, both about what rules apply to toys and about what chemicals the toys contain. Companies that actively seek knowledge are best equipped when new rules come along, including the new chemicals legislation.

1. Background

Toys are intended to be used by children and young people. As children are more sensitive than adults to chemicals, toys must be particularly safe, in terms of both physical safety and chemical risks to health. To ensure a high level of safety in toys, there is special legislation for toys and also certain other rules to restrict the use of chemicals in toys.

Both the Swedish Chemicals Agency (KemI) and the Swedish Consumer Agency have drawn attention to inadequacies in the control of chemicals in companies that place toys on the market. It is therefore essential to check that these companies comply with the legislation on chemical substances in toys. An inspection project targeted at toy companies was consequently conducted in 2005. This report presents the results of the project. To complement these results, a description is also given of the rules and environmental objectives that apply to chemicals in toys.

2. Toys

2.1 Definitions

Toys comprise a highly heterogeneous product group that contains both chemical products and other products (articles). This definition is significant as there is a mandatory system for labelling chemical products, but no systematic labelling requirement for chemical substances that form part of an article.

The term **toy** according to the Toys Directive[1] means any product or material designed or clearly intended for use in play by children of less than 14 years of age. The actual use of the article determines whether it is regarded as a toy.

The term **chemical product** means substances or preparations. Preparations are mixtures or solutions of two or more substances. Examples of toys regarded as chemical products are modelling clays and paints. Further examples can be found in the annex to the Chemical Products and Biotechnical Organisms Ordinance (1998:941) .

Most toys are regarded as articles according to the regulations. The articles consist of different materials and combinations of materials, which themselves contain chemical substances.

Childcare articles are defined as any product intended to facilitate sleep and relaxation on the part of children. See the full definition in Directive 76/769 on the restriction of phthalates in childcare articles.

Products other than toys

It should be noted that there are products other than those defined as toys that can be used by children and pose direct risks to children. Examples are mugs and toys that contain what are known as two-phase systems, a coloured liquid and an uncoloured liquid, which have been found to contain hazardous mineral oils. If one of these mugs breaks and the contents are swallowed, even in very small quantities, there is a risk of severe chemical pneumonia. There are strict rules on packaging for chemical

[1] Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys.

products containing free-flowing mineral oil with regard to child-resistant closures and tactile warning of danger when they are sold to consumers. This means that the suitability of a toy containing such mineral oil can be questioned if there is a risk of the toy breaking and the mineral oil escaping.

2.2 Chemicals in toys

Many chemical substances present in toys sooner or later come into contact with people and the environment. The greatest risk of dispersal obviously exists in those toys that are chemical products, such as paints and modelling clays, rather than toys (articles) in which the substances are bound to the material. In some cases the substances may nevertheless be unintentionally released from the material. Various types of external effect may have a significant bearing on whether the substances are released, such as washing, wear, UV radiation and various weather-related factors.

Toys often have a short life and are rapidly replaced. When toys are discarded, chemical substances may be released and pose risks to human health and the environment. It is therefore important that end-of-life toys are disposed of in a safe manner and that a life-cycle perspective is adopted when new toys are manufactured.[2]

There is no centrally gathered knowledge on what materials and chemical substances are contained in toys or what toys are treated with. Articles do not generally come with a list of ingredients that presents such information. The ones who are best placed to know the chemical composition of toys are the manufacturers themselves.

Additives

Toys may consist of various materials such as plastic, rubber, textile, metal, wood and paper. The material may contain substances that are added to endow the material with certain properties. Examples are additions of flame retardants and plasticisers in plastics, impregnating agents in textiles or tanning agents in leather. Certain toys may also contain chemical substances or preparations that are essential to the arti-

[2] See the Swedish Government's objectives on non-toxic and resource-efficient cycles and rules (Government Bill 2004/05:150).

cle's function. Examples are batteries that contain metals or light sticks of plastic that contain liquid with phthalates.

3. The trade in toys

There are around 70 companies in Sweden that supply toys. Only a small proportion of the toys are produced in the country. Most toys today are imported into Sweden from China. For further details on where Swedish companies import their toys from, see 9.1 *The companies.*

As Swedish production of toys decreases and the flow of articles from other parts of the world increases, product knowledge in companies in Sweden is also declining. The Swedish companies are becoming dependent on the expertise of their foreign parent companies and suppliers and the information they provide. This makes new demands on companies in Sweden to critically examine and check data and assess the information about the products they receive from their suppliers. Otherwise there will be an increased risk of substances that are restricted or prohibited in Sweden and the EU coming back into circulation and, in the worst-case scenario, causing health and environmental problems.

4. Rules that apply to toys

There are several different sets of rules relating to toys. All products with which consumers come into contact must be safe in use under the Product Safety Act (SFS 2004:451). In addition, there are separate rules on toys in the Toys Directive that have been transposed into Swedish Consumer Agency's regulations (see 4.1).

Certain particularly hazardous substances are restricted by chemicals legislation, and these rules, where appropriate, also apply to toys. With regard to cosmetic products intended for children, such as stage make-up, rules on cosmetic and hygiene products apply alongside the rules on toys. There are also special rules for electrical and electronic products in addition to the rules on toys.

4.1 The Toys Directive

The law (SFS 1992:1327) on the safety of toys (the Toys Act) and the Toy Safety Ordinance (SFS 1993:971) apply to toys. The requirements that a toy must fulfil with respect to protection of health and safety are described in the Toys Directive (88/378/EEC). This Directive has been transposed into the Swedish Consumer Agency's regulations (KOVFS 1993:9).

Under the Toys Directive, toys may not contain hazardous substances or preparations in amounts that can pose health risks to children who use the toys.

The Toys Directive refers to the EU's Dangerous Substances Directive[3] and Dangerous Preparations Directive[4] to specify what is meant. Both directives have been transposed into the Swedish Chemicals Agency's Regulations (KIFS 2005:7) on the Classification and Labelling of Chemical Products.

Standards

The Toys Directive is what is known as a new-approach directive. This means that the essential safety requirements stated in the Directive can be made specific by European standards formulated by standardisation bodies on behalf of the European Commission.

The standards lay down requirements that deteremine the use of both materials and certain chemicals in toys.

A significant standard for toys is SS-EN 71-1, which stipulates the mechanical and physical properties of toys (Annex 2). The standard on Safety of Toys: Flammability (EN 71-2) stipulates general requirements that toys must be difficult to ignite, with limit values for burning time, rate of spread of flame and how large a part of the toys is to remain after any fire. Another standard covers the migration of eight substances (EN 71-3), where specific requirements are laid down for how much of a particular substance may be released from the toy.

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[3] Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances.

[4] Directive 1999/45/EEC on the classification, packaging and labelling of dangerous preparations.

There are also standards linked to the Toys Directive that relate to chemical substances in toys, see Annex 2.

CE marking

By CE-marking a toy, the manufacturer guarantees that it fulfils the essential safety requirements of the Toys Directive. If the standards linked to the Directive are fulfilled, it is presumed that the essential safety requirements are also fulfilled. However, standards are lacking in important areas of safety.
In some cases there is discussion as to whether a standard provides such protection that the essential safety requirements are met. A discussion of this type is taking place on standard SS-EN 71-9 on organic chemicals in toys. In such cases the toy has to be EC-type-approved by a notified body before it may carry a CE mark and placed on the EU market.

Note that CE marking does not guarantee that toys are safe with regard to chemicals. It has happened that toys have carry the CE mark without the appropriate obligations having been met.

Provisions on CE marking are contained in the law (1992:1534) on CE marking.

4.2 Chemicals legislation

The Swedish Environmental Code (1998:808) contains basic environmental provisions, and chemical products are governed by Chapter 14 of the Code. On the basis of this Code, the Swedish Government has issued a number of different ordinances, such as the Chemical Products and Biotechnical Organisms Ordinance (1998:941) and the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944)[5]. The Swedish Chemicals Agency, pursuant to authorisation under the ordinances mentioned above, has issued binding regulations in KIFS (1998:8) on Chemical Products and Biotechnical Organisms and KIFS (2005:7) on the Classification and Labelling of Chemical Products.

[5] There are more government ordinances in the area covered by the Swedish Chemicals Agency, but these are not touched on here, as they are judged to be less relevant in this particular context.

The Swedish provisions in the area of chemicals largely represent implementation of various European Community rules aimed at total harmonisation within the EU. Certain Swedish detailed provisions in the area of chemicals that are solely of national origin still exist, principally rules still in force that date back to the time before Sweden's accession to the EEA and the EU. As European Community regulations become more wide-ranging, previous national rules in the area are being superseded.

A brief synopsis of rules on chemicals that affect toys is presented below. For the full wording of the statutes, see www.kemi.se /legislation.

Chemical products

For chemical products there are detailed rules on the assessment of hazardous properties, product information given through labelling on the packaging of products hazardous to health or the environment or safety data sheets. There are also requirements relating to the design of packaging. Chemical products have to be notified to the KemI products register.

Chemical products intended for consumer use must not contain substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR substances), categories 1 and 2.

Articles

In Chapter 2 of the Environmental Code there are general rules of consideration, with requirements to be met by operators in relation to knowledge, precautions and choice of less hazardous products. Section 2 requires everyone to acquire the knowledge needed to protect human health and the environment against damage or detriment.

The general duty-of-care rule in Section 3 requires all operators to take precautions that are necessary in order to prevent, hinder or combat damage to human health or the environment.

The product selection rule in Section 6 stipulates that products that may be feared to cause harm to human health or the environment must be avoided if they can be replaced by less hazardous products.

If articles or chemical products may be feared to cause harm to human health or the environment, manufacturers and importers are required to supply information on this.

Particular restrictions

Certain hazardous chemical substances have been prohibited or severely restricted on the European Community market. Provisions on this have been collated in what is known as the Marketing and Use Directive[6]. In Chapter 10 of KIFS 1998:8, Sweden has introduced the restrictions on certain chemical substances the EU has agreed on in the Marketing and Use Directive.

- **Flame retardants** are restricted in Section 4 a, where it is stated that articles, or flame-retardant parts thereof, which contain pentaBDE (pentabrominated biphenyls: $C_{12}H_5Br_5O$) or octaBDE (octabrominated biphenyls: $C_{12}H_2Br_8O$) in concentrations higher than 0.1% by weight may not be placed on the market.
- **Nickel** is restricted in Section 9, where it is stated that nickel and its compounds may not be used in articles intended to come into direct or prolonged contact with the skin if the rate of nickel release is greater than 0.5 $\mu g/cm^2$/week.
- **Azodyes** which may can be broken down into carcinogenic aryl amines may not be present if the concentration of aryl amines is greater than 30 ppm (Section 11 a). A specific azodye, known as blue dye, is regarded as particularly hazardous and may not be used in concentrations greater than 0.1 per cent by weight (Section 11 c).

For the plasticisers phthalates, the EU has decided on joint prohibitions and restrictions that come into force on 16 January 2007. These rules are contained in Directive 76/769/EEC and are transposed into Chapter 10 Section 4 b of KIFS 1998:8.

[6] Directive 76/769/EEC

Rules will mean:

- Total bans on the three **phthalates DHEP, DBP and BBP** in all toys and childcare articles.
- Prohibition of the use of another three **phthalates, DINP, DIDP and DNOP,** in toys and childcare articles that can be placed in the mouth.

Swedish special rules that will shortly cease to apply

Swedish special rules are contained in the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944). It is stated in Section 16a that toys and childcare articles intended for children under three years of age may not be sold or transferred professionally if they contain plasticisers in the form of phthalates and are capable of being placed in the mouth. This rule will cease to apply when the EU-wide rules on phthalates referred to above come into effect on 16 January 2007.

In the text that follows it is stated that "nor may toys and childcare articles otherwise be offered for sale or transferred if they contain or have been treated with chemical products and may therefore cause harm to humans". The companies must, in other words, obtain knowledge of the chemical contents of toys and what chemicals they are treated with before they are placed on the Swedish market.

New rules for electrical and electronic products

The RoHS (2002/95/EEC) came into force on 1 July 2006. The rules are transposed into the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944). The electrical and electronic articles covered by the rules are listed in Annex 1 to the WEEE Directive (2002/96/EC). Toys are included in category 7 under the heading of Toys, Leisure and Sports Equipment.

The rules mean that the use of lead (Pb), mercury (Hg), cadium (Cd), hexavalent chromium ($Cr^{(VI+)}$) and the flame retardants polybrominated biphenyls (PBB) and polybrominated diphenylethers (PBDE) in electrical and electronic products is restricted.

The maximum permitted concentration of these substances in homogeneous material is 0.1 per cent by weight, except for cadmium, where the maximum permitted concentration is 0.01 per cent by weight.

4.3 REACH – new chemicals legislation in the EU

New harmonised chemicals legislation, REACH, is being prepared in the EU. REACH is an acronym of Registration, Evaluation, Authorisation and restrictions of Chemicals. An important implication of the future legislation on chemicals is that companies that manufacture chemical substances are given clear responsibility to test their chemicals with respect to properties hazardous to human health or the environment before the chemicals are allowed to be placed on the market, as well as responsibility for assessing the risks in use of the chemicals.

The current legislative proposal contains certain requirements that apply to substances of very high concern[7] , including when these are contained in articles. One requirement signifies that information on the presence of substances of very high concern in the article must be passed on along the production chain. This may lead to substances of very high concern in articles being substituted by less hazardous alternatives to a greater extent than is done today.

4.4 Cosmetics Directive

Make-up for children, like other cosmetics, is governed by the Cosmetics Directive[8]. The same applies to toy make-up intended for example for dolls. There are specific rules for make-up, for instance regarding what chemical substances and fragrances may be used. The rules can be found on the Medical Products Agency's website www.mpa.se.

[7] Substances of very high concern (SVHC): substances posing a serious hazard to the environment and health

[8] The EU's Cosmetics Directive 76/768/EEC, transposed into the Swedish Medical Products Agency's regulations LVFS 2003:5.

5. A Non-Toxic Environment

The Swedish Parliament has adopted the environmental quality objective A Non-Toxic Environment as a long-term environmental objective for Sweden to attain within a generation. Interim targets have been formulated so that we can attain this ultimate objective. According to interim target 3, newly produced articles must as far as possible be free of substances of very high concern. These are substances that are:

- persistent and bioaccumulative
- carcinogenic
- mutagenic and toxic to reproduction
- endocrine disrupting
- severely allergenic
- the metals mercury, cadmium and lead.

Articles already in existence that contain substances with the above properties or mercury, cadmium and lead must be handled in such a way that the substances do not escape into the environment.

According to interim target 4, the health and environmental risks in the use of chemical substances (not covered by interim target 3) must be continuously reduced. Over the same period, the occurrence and use of chemical substances that impede recycling of materials must decrease.

For further details on the objective, see www.kemi.se / A Non-Toxic Environment. For a list of substances of very high concern, see KemI's PRIO database.

6. KemI’s supervision of companies

The legislation assumes that companies are aware of their responsibility and follow the rules. This is checked by the supervisory authorities, who can apply sanctions in the event of contraventions, for example notifying the police of contraventions of rules that carry penal sanctions or levying environmental sanction charges.

Checks on compliance with legislation on toys are made by the Swedish Consumer Agency through market checks, tests and various information activities. The Swedish

Consumer Agency also receives reports from the public and consumer advisors on products that are not safe. These reports may, for example, relate to toys in which small parts work loose, but they may also concern objects that contain or have been treated with a chemical product. When reports are received of products with suspected hazardous chemical contents, the matter is generally passed to KemI for further action. KemI investigates whether companies that place products on the market live up to their responsibility and comply with the rules on chemicals under Chapter 14 of the Environmental Code and the Product Safety Act.

The supervision KemI usually performs is regulatory supervision of chemical products. In regulatory supervision, KemI checks that companies comply with rules and regulations on chemical products. An important element in this work is ensuring that the companies have the correct labelling and correctly designed safety data sheets for the chemical products that are professionally transferred, as well that the products have been notified to the KemI products register. If the product is of very high concern, the company additionally has to be able to show that it has received permission for transfer from the county administrative board.

6.1 System supervision for articles

As mentioned previously, there are no rules for articles corresponding to those for chemical products, and the regulations apply more on an item-by-item basis. The supervision of articles is therefore focused on company’s own systems for chemicals control, in other words how a company works and is organised to meet its obligations with regard to its own control of chemicals. In inspections of this type questions are asked about the company's system for the control of chemicals, company structure, routines for purchasing and sale and requirements in relation to suppliers. The replies give an indication of the company’s expertise on chemical issues and of whether they set sufficiently strict requirements regarding the chemical content of their articles. An important element in the inspections is that importers/manufacturers can state that the articles they sell are not hazardous to human health or the environment.

KemI annually carries out inspection projects focusing on chemicals in articles. Examples of the topics focused on in projects that have been carried out are flame retardants[9], antibacterial substances[10] and articles intended for children[11].

7. Inspection project in 2005 – Chemicals in toys

One of the inspection projects in 2005 relates to chemicals in toys. This project has been carried out in cooperation by KemI and the Swedish Consumer Agency. The Norwegian Pollution Control Authority (SFT) has also helped with XRF analyses of toys, to detect the presence of certain chemical elements.

The aim of the project has been to:

- check companies' awareness of and compliance with rules that cover toys
- analyse companies' awareness of the chemical content of their toys, as well as the risks these pose.

Another objective has been to increase the companies' knowledge through supervision, which results in improved control of chemicals among the companies. This in turn may lead to hazardous chemicals in toys being substituted.

As KemI is not responsible for the supervision of cosmetic products, this group has not been included in the project.

8. Implementation of the inspection project

8.1 Selection of representative companies

30 companies that manufacture or import toys were selected for inspection. The project began with consumer advisors around Sweden buying just over 80 toys and finding out who the importer or manufacturer of these was. The groups of toys the consumer advisors focused on were:

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[9]KemI (2004) Flamskydd 2003 (Flame retardants in 2003), PM no 2/04, Sundbyberg, Sweden.

[10] KemI (2005). Antibakteriella substanser och azofärgämnen i varor (Antibacterial substances and azodyes in articles). PM no.5/05, Sundbyberg, Sweden.

[11] KemI (2003) Varor och barn (Articles and children), PM no. 2/03, Solna, Sweden.

- plastic and rubber toys for children under three years of age (the phthalates rules)
- toys with electronic components, for example talking teddy bears and radio-controlled cars (RoHS)
- crayons, moulding clay and finger paints (Toys Directive)
- fragrant toys (allergy risk)

To complement this, KemI selected:

- three companies with a broad range of toys via the Formex trade fair in Älvsjö
- two companies that import and sell toys on markets
- two large restaurant chains that distribute toys through their children's menus

8.2 Inspection of the companies

All 30 companies in the project were visited by KemI. All the companies were asked general questions at the time of the inspection. These were concerned with the companies'

- operations
- knowledge of chemicals and applicable rules and
- knowledge of the chemical content of their own products and how they inform themselves about this.

At the time of the inspection the inspectors also requested that they be allowed if possible, to see the company's toy range. More specific questions were then asked on the basis of the companies' range of toys. The companies were asked, for example to state:

- what fragrances have been used in the fragrant toys with a possible risk of allergy in mind
- what heavy metals are present in crayons, finger paints and modelling clay
- what flame retardants have been used in soft toys
- how they ensure that toys made of soft plastic (e.g. bath toys, dolls and teething rings) do not contain phthalates as plasticiser

- how they are preparing for the new RoHS legislation (with effect from 1 July 2006) if they had electronic toys, for example talking teddy bears and toy phones
- what preservatives were contained in products such as finger paints and modelling clay
- the viscosity of the most free-flowing liquid for a pen that contained two differently coloured liquids.

At six of the 30 inspected companies KemI judged that the companies had good self-monitoring and the inspection was completed on site. The other 24 companies were asked to supply additional details. These reporting requirements were concerned for example with what plasticisers were present in toys made of soft plastic or what flame retardant had been used in flameproof textile toys (Figure 1).

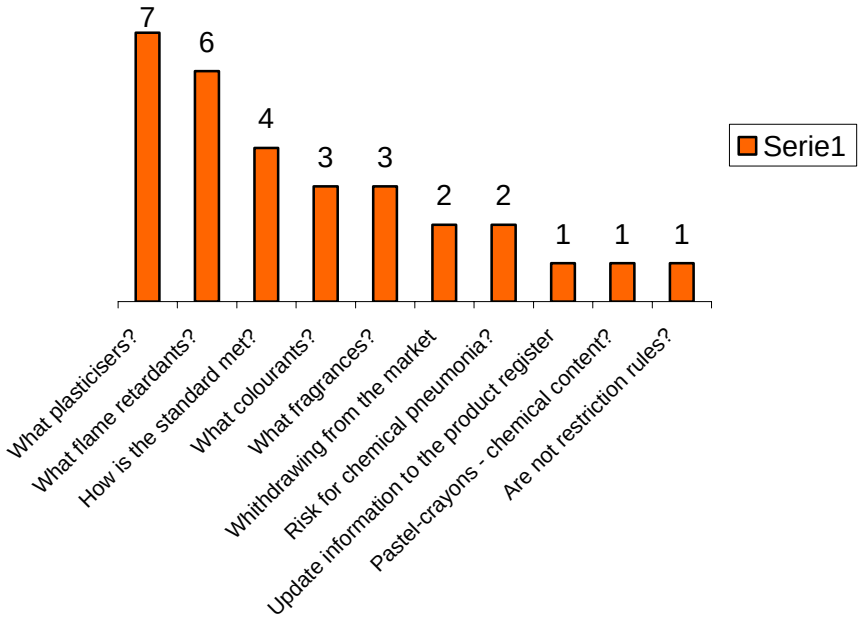

Figure 1: Requirements for additional information addressed to the inspected companies.

8.3 Analysis of chemical substances in certain toys

In cooperation with the Norwegian Pollution Control Authority, a selection of the toys were analysed using an X-ray fractometer (XRF). The XRF instrument shows the content of elements in the surface layer of an object. Energy transfers are measured by exposing the object to X-ray or gamma radiation. Each element creates a

unique pattern of energy transfers that can be regarded as a fingerprint of the substance.

There are certain limitations in this method of measurements. Only “heavier” elements can be measured by XRF. It is not possible to see, for example, whether an object contains phthalates as these are made up of “light” elements (carbon, hydrogen and oxygen). In addition, information is only obtained on the substances that are present in the surface layer of the toy with this method of analysis. More extensive analytical methods are required to obtain a measurement that reflects the total chemical content of the toy.

The selection of toys for analysis was based on the aspiration of covering the companies involved in the project and of analysing as great a variety of toys as possible. When it was found that some oil pastel crayons contained high concentrations of lead and chromium, KemI decided to purchase additional crayons for analysis. Various colours from 46 packs of finger paints, modelling clays and crayons[12] were analysed, as well as 14 other toys.

9. Results of the inspection project9.1 The companies

9.1 Size and sales

The size of the companies visited varied from small two-man businesses to large multinational corporations such as TopToy and McDonalds. Toys were the principal activity of just over half the inspected companies (Figure 2). In the case of the other companies, toys represent a small part of a wider range of articles, for example in ICA and Teknikmagasinet. Almost all the inspected companies are wholesaling businesses.

[12] Both wax and oil pastel crayons were analysed, 31 being of the latter type. A billiard chalk was also analysed.

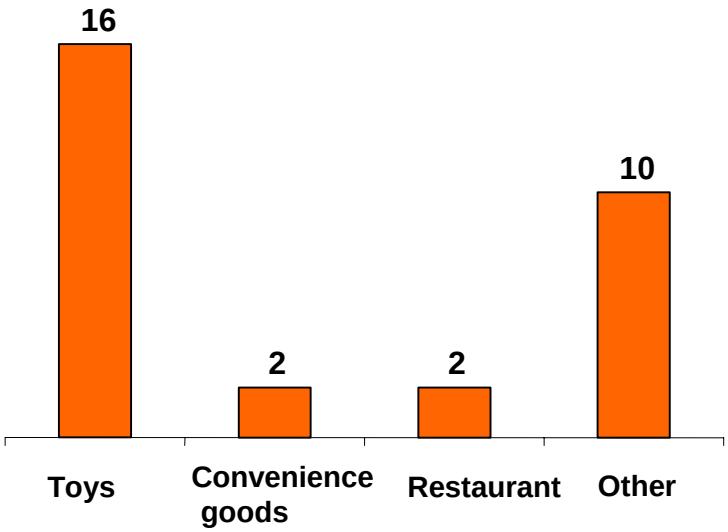

Figure 2. Principal activity of the inspected companies.

Membership of industry associations

Most of the toy companies, 20 out of the 30 companies inspected, are members of one of the Swedish toy industry associations, the Suppliers' Association for Games and Hobbies (LLH)[13], whose members are manufacturers and importers, the Swedish Toy Dealers' Association (SLR) for retailers, the Swedish Association of Wholesalers of Gift Items (PUFF) and/or the international industry association, the International Council of Toy Industries (ICTI). Some companies were members of El-Kretens, which is the trade and industry service company for the collection and recycling of electrical and electronic products.

Origin of the toys

Twenty-five of the 30 companies inspected do not have any manufacturing of their own, while another five have production as part of their business. What is made in Sweden is principally various types of wooden toys such as wooden jigsaw puzzles and various makes of classic wooden railway sets.

It emerged in the inspection that plastic toys, such as toys used in sand-pits and inflated plastic balls, are often manufactured in Europe. This manufacturing principally

[13] Has recently changed its name to the Swedish Toy Association.

takes place in Italy and Åland according to information from the inspected companies.

It was not always self-evident that companies that did not undertake their own manufacturing had less knowledge of the contents of the finished product. One company that does not produce any toys of its own, for example, has a department that creates ideas and drawings of the toys to be given away with the company's children's menus. A factory in southern China manufactures the toys according to the specified order. The whole series of toys is manufactured as a single order, and samples are taken and analysed, both on site in China and at a branch of an independent laboratory in the United Kingdom. As a result, the company has almost the same control over the finished product as it would have if it had its own production.

Toys imported into Sweden are often made in China. Several of the inspected companies themselves travel to southern China and Hong Kong, where large toy fairs are held twice a year. This is done to decide which toys to import. Some companies stated that during these trips they also travel to various factories in southern China where the actual production of the toys takes place. Other companies trade through what are known as trading houses in Hong Kong, which supply toys from a large number of different manufacturers. These companies have toy samples sent to them in Sweden.

Eight of the inspected companies form part of multinational chains, in which toy ranges are for the most part decided on centrally for the whole European market. The Swedish branches of these toy companies often do not themselves have any knowledge of the chemical content of the toys.

9.2 Knowledge of chemicals among the companies

The companies' expertise on chemical matters varies. In many of the larger companies there was an awareness that toys may contain chemical substances that can harm the user's health and that the use and content of some chemicals is restricted or prohibited in various laws. These companies were often part of multinational corporations that have separate departments to work on such issues.

The smaller companies were often found not to know that their articles may contain chemicals that are restricted by legislation. These companies were, however, aware that certain substances should be avoided in toys. This knowledge was chiefly based on information gathered through the media, for example on phthalates, see Figure 3. Several companies were not aware that certain toys, for example modelling clay and finger paints, are regarded as chemical products. As mentioned earlier, companies responsible for importing chemical products have to report their activities, and the products are covered by the legislation on chemical products and have to be classified and labelled.

It was found that information on chemical content from the foreign toy manufacturers to the inspected Swedish companies is often inadequate or non-existent. This is often due to the Swedish toy importers not having asked the supplier about the chemical content of the toys or not having stipulated requirements. Many of the Swedish companies wrongly believe that the CE mark is a guarantee that the toys entirely safe, including with regard to chemicals.

The rules the companies were most familiar with were the Swedish special rules for phthalates[15] and cadmium[16] , with 22 of the 30 inspected companies being aware of these bans (Figure 3).

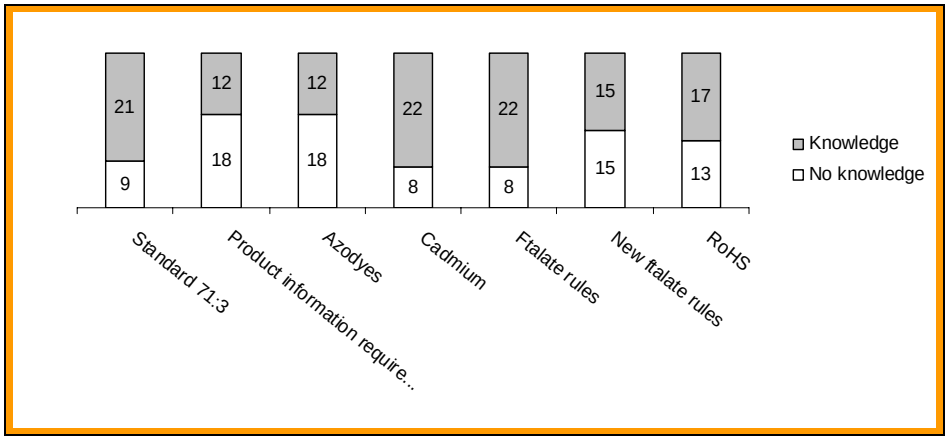

Figure 3. The inspected companies' knowledge of various rules on chemicals and of the standard that stipulates limits for the migration of certain substances (EN 71:3). The companies that lacked knowledge were divided into those that were or were not members of industry associations.

[15] Section 16a of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944). Toys and childcare articles which are intended for children under three years of age and can be placed in the mouth may not be sold if phthalates have been added.

[16] Sections 1-4 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944). Prohibition on using cadmium as a stabiliser, colorant or surface treatment in articles.

The rules that were least known were the one about information requirements for articles that contain hazardous chemicals (product information requirements)[17] and the prohibition of various azodyes in textiles and leather articles[18]. Only 12 of the 30 inspected companies were aware of these two rules (Figure 3). Nine out of the 30 companies were not aware of the standard, SS-EN 71:3, which is associated with the Toys Directive, where the limit values for the migration of certain substances are specified.

Information on the rules for electronics and electronic products, the RoHS rules, was found to have reached the companies. Just over half the inspected companies have products that are covered by the new rules, and only two of these companies did not know of the new rules.

It was found to be easy for many of the companies to obtain information on the chemical content of toys from their suppliers when the Swedish Chemicals Agency requested additional details. It was usually sufficient to send an e-mail or fax, after which the company recieved within a few days. Further correspondence was sometimes needed, but the question was generally answered after two to three weeks. However, it happened that suppliers were not aware of the contents of the toy either, perhaps because they were only wholesalers.

9.3 Toys containing hazardous chemical substances

Crayons containing lead and chromium

Despite the CE mark, high concentrations of lead and chromium were found in green, yellow and orange crayons in XRF analysis of oil pastel crayons. Both these substances are severely restricted in the toys standard EN 71:3. As the restrictions in the Toys Directive apply to the migration of certain metals, four crayons (green, yellow, orange and red) were sent for further analysis to an accredited laboratory (the Swedish National Testing and Research Institute, SP). The surface content of lead and chromium was also measured at SP to give an idea of the accuracy of the XRF analysis performed by SFT in Norway and by KemI. The migration values measured

[17] Section 3 of the Chemical Products and Biotechnical Organisms Ordinance (1998:941).

[18] The EU's Directive 2002/61/EG and 2003/3/EEG

exceeded the limit value for migrationaccording to the toy standard by more than 100 times. The surface analyses showed good agreement between the portable XRF instrument at SFT and the accredited method of measurement at SP.

What happens if a child ingests these crayons is principally that the child suffers stomach ache. If the child ingests a larger quantity, the development of the nervous system may also be affected. The risk of a child ingesting such large quantities that health is affected is judged by KemI to be low. KemI has released information about the crayons, and the news has attracted media interest[19].

The Swedish wholesaling company that had been importing the crayons immediately stopped selling them voluntarily when it learned of the high lead and chromium concentrations in the crayons. KemI requested the company to contact the stores the crayons had been sold to, and the company the recalled the packs that were out in the stores and disposed of these as hazardous waste. A total of 266 packs of the crayons had already been sold to consumers.

After this discovery, KemI purchased another 30 or so different brands of oil pastel crayons. The crayons (green, orange, red and white) were analysed by SFT using XRF. Up to 18 per cent lead and high concentrations of chromium were found in two of the packs of crayons. When contact was made with the Swedish importer of the crayons, it was found that they had been purchased at a trade fair in southern China. The word *non-toxic* appeared on the packaging, so that the Swedish company had felt reassured and had therefore not asked for certificates. This company too withdrew its crayons from sale voluntarily. No non-permitted metals were found in the other packs of crayons.

KemI sent the information on the high lead content in the three packs of crayons to other countries in Europe. This was done through the CLEEN network[20], but also

[19] Ten newspaper articles and two television features.

[20] CLEEN - Chemicals Legislation European Enforcement Network - is an EU network to coordinate and improve the enforcement of EU chemicals legislation. For further information, see the website: www.cleen-eu.net

through a RAPEX notification[21] (ref. no. 0095/06) via the Swedish Consumer Agency.

Pens containing mineral oil

Pens containing two flowing liquids, a blue-coloured one and a transparent one, were encountered in the warehouse of a large toy company. Previous inspection projects have shown that similar articles have contained free-flowing mineral oil that can cause what is known as chemical pneumonia if ingested. The company was asked to report what liquids were contained in the two phases and their viscosity. At the time of the inspection, KemI explained to the company the risks associated with free-flowing mineral oil. The company decided to stop selling the pen as it did not wish to be associated with dubious toys.

The account given by the company showed that the mineral oil in the pen had a viscosity on the borderline for the liquid to have the properties that give rise to chemical pneumonia.

Inflatable mattresses with a high level of plasticiser

When information was requested from a large company that sells substantial quantities of air mattresses and large pools, it was found that their products contained very high concentrations, 30 per cent, of the plasticiser bis(2-ethylhexyl)ftalate (DEHP). This phthalate has been judged by the EU to be toxic to reproduction and may enter the body by absorption through the skin. DEHP will be banned in toys throughout the EU from 16 January 2007.

As the company that sells these products was not willing voluntarily to stop selling them, KemI imposed a ban on the company selling these air beds with hazardous plasticisers.

[21] RAPEX - Rapid Alert System for Non-Food Products - is an EU system for drawing attention to hazardous consumer products. For further information, see the website: http://europa.eu.int/comm/dgs/health_consumer/dyna/rapex/rapex_en.cfm

10. Discussion and conclusions

10.1 Inadequate knowledge of chemicals in many companies

The results of the inspection project showed that many companies had inadequate knowledge of chemicals in toys. The deficiencies relate both to rules and the chemicals content in their own products. It is a serious situation that many companies rely on the CE mark and believe that this covers all the risks associated with a toy.

The smaller toy importers generally had poor knowledge of chemicals legislation. Knowledge among the larger companies, which formed part of large multinational chains, was generally good, although the knowledge was not located in Sweden. This was due to the larger companies having one or more employees with responsibility for these matters. Smaller companies that cooperate with large multinational companies also had good knowledge of the chemicals legislation. These companies stated that they acquired their knowledge from working together with the large companies.

10.2 Toys containing hazardous substances

Despite the level of knowledge being higher in the larger companies, it was among the large and medium-sized companies that toys containing hazardous chemical substances were encountered. The two companies that sold pastel crayons with high lead concentrations were medium-sized and small. The pen containing mineral oil was encountered in one of the larger companies. The company that markets the air mattresses that contain DEHP is also a quite large company.

10.3 More information is required

It is important that knowledge of chemicals in toys increases among the companies concerned, so that children and the environment are not exposed to unnecessary risks. Children are generally more sensitive to chemicals than adults, and companies that supply toys therefore have particular responsibility to make sure that the products are safe.

Toy retailers should stipulate requirements to be met by their suppliers

The information that a toy contains hazardous chemical substances that accompany the article through the whole chain of supply puts importers of toys in a strong position to demand, for example, that hazardous chemicals be substituted. This improves the prospects of the products that reach consumers being safe.

The industry organisations have an important role to play

The inadequate knowledge of legislation among companies affiliated to industry associations shows that the organisations have an important role to play in disseminating information and supporting their members on issues concerned with chemicals. The industry organisation LHH developed a quick reference guide for its members on current legislation for various types of toys in the spring of 2006.

Information meeting in 2006

During the spring of 2006 KemI invited the industry to a dialogue on chemicals in toys, with the aim of providing information on applicable rules. However, it is also essential that the companies themselves active seek the knowledge they need and comply with applicable rules. The rules can be found, for example, at www.kemi.se

Information on substances

KemI's PRIO database contains information on substances and their hazardous properties for the environment and health. It is possible to search for information in the database on priortised health and environmental properties in risk reduction activity and to see which substances are of very high concern. The database can be consulted by anyone at www.kemi.se

10.4 Inspection of articles is important

This project has shown that it is important to check rules on chemical substances in articles, both to draw the attention of companies to the fact that there are risks associated with chemical substances in articles and to reduce such risks. The inspected companies receive information and knowledge on the legislation and many companies are improving their long-term work on control of chemicals. The authority ob-

tains a good picture of the companies' self-monitoring and the chemical contents of the articles. This is important as there is no register of the chemical contents of articles and it would otherwise be difficult to ascertain what substances are included. By inspecting companies that supply articles, KemI can stipulate requirements for substances contained in the articles to be reported and where appropriate also require that hazardous substances be substituted. Most companies consequently appreciate the need to specify requirements to be met by their suppliers with regard to the chemical content of products, keep themselves updated on rules relating to chemicals and start replacing/phasing out hazardous chemicals.

When goods containing hazardous chemicals are encountered, such as crayons with high concentrations of heavy metals and pens containing mineral oil, it becomes clear how important knowledge of the chemical contents of goods is. There is package labelling on chemical products that describes the dangers posed by the product, formulated according to detailed rules on the classification and labelling of substances. There are also strict rules on packaging for chemical products containing free-flowing mineral oil relating to child-proof closures and tactile warning of danger when they are sold to consumers.

If the crayons with a lead content are regarded as a chemical product, they are to be classified and labelled in accordance with applicable EU rules. A content of ten per cent lead would lead to the crayons being classified as toxic, with associated risk and safety phrases. Special permits are required to purchase toxic chemical products, which often means that private consumers have to refrain from making purchases. The rules in the area of articles do not afford the consumer the same level of protection.

10.5 Future trade with toys

By specifying requirements when purchasing, companies can prevent human health or the environment being adversely affected by chemical substances in toys. Knowledge is required to be able to stipulate requirements. A knowledge of applicable rules and regulations is important, but it is equally important to increase awareness of chemicals in a more general way. This can be done through choice of materials, and by investigating what the various materials contain and which chemical substances

are particularly hazardous. Companies that commit themselves to the environmental objective of A Non-Toxic Environment and actively seek knowledge on chemical substances are well placed. These are the companies that are best equipped when new rules come along, for instance through the new chemicals legislation REACH.

Cooperation is taking place under the Swedish Government's dialogue with the convenience goods trade, ***Framtida Handel – Future Trade*** between Swedish companies, local authorities, regions and the Government, to achieve sustainable development of trade in convenience goods. This cooperation can also be used as a source of inspiration for products not regarded as convenience goods. The cooperation is based on voluntary agreements and dialogue. Guidance has been drawn up in ***Framtida Handel - Future Trade*** to assist companies in stipulating product requirements with regard to chemicals. The guidance will be published in 2006.
Further reading at www.framtidahandel.se

Annex 1. Rules that cover chemicals in articles

A brief summary follows below of the most common rules that exist in the area of toys. The rules can be found on the Swedish Chemicals Agency website: www.kemi.se.

Environmental Code (1998:808):

- Chapter 2 General rules on consideration
- Chapter 14 Chemical products and biotechnical organisms

Product information requirements

It is stated in the Chemical Products Ordinance (1998:941) that the information requirement that applies to chemical products under the Environmental Code[22] also applies to articles. Examples of where the information requirement is relevant to toys are if they contain fragrances (information on allergy risk), preservatives (information on allergy and irritation) or formaldehyde (information on allergy and cancer).

Presence of chemicals

In Section 16 a of the same ordinance it is stated that nor may toys and childcare articles otherwise be offered for sale or transferred if they contain or have been treated with chemical products and may therefore cause harm to humans. Companies must, in other words, acquire knowledge of the contents of their toys and what they are treated with.

Restrictions under Chapters 9 and 10[23] of KIFS 1998:8 on Chemical Products and Biotechnical Organisms

Azodyes:

Section 11a, azodyes which, by reductive cleavage of one or more azo groups, may release certain prohibited aryl amines indicated in EU Directive 2002/61/EC in con-

[22] It is stated in Chapter 14 Section 8 of the Environmental Code that anyone who manufactures or imports chemical products or biotechnical organisms or places such products or organisms on the market must supply any information that is necessary in order to protect human health or the environment (product information) by labelling the products or by some other means.

[23] According to Directive 76/769/EEC

centrations above 30 ppm may not be used in textile and leather articles which may come into direct and prolonged contact with human skin or the oral cavity.
Section 11c, azodyes indicated in Directive 2003/3/EEC, known as blue dye, may not be placed on the market or used as a dye or as a constituent of preparations in concentrations higher than 0.1 per cent by weight in the colouring of textiles and leather articles.

Flame retardants:

Section 4a, articles, or flame-retardant parts thereof, which contain pentaBDE (pentabrominated biphenyls: $C_{12}H_5Br_5O$) or octaBDE (octabrominated biphenyls: $C_{12}H_2Br_8O$) in concentrations higher than 0.1% by weight may not be placed on the market.

Nickel:

Section 9, nickel and its compounds may not be used in articles intended to come into direct or prolonged contact with the skin if the rate of nickel release is greater than 0.5 µg/cm^2/week.

Cadmium

Chapter 9 Sections 1-5 of KIFS 1998:8 contains a prohibition on using cadmium for surface treatment, as a stabiliser or as a colorant. The prohibition also applies to professionally offering for sale, transferring or importing articles that have been surface-treated with a cadmium substance or contain such a substance as a stabiliser or colorant. Note that this a Swedish special rule. Under the EU Marketing and Sale Directive 76/769/EEC (amended by 91/338/EEC), there is a maximum permitted cadmium concentration of 0.01 per cent by weight.

Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944)

Phthalates

Section 16 a Toys and childcare articles which are intended for children under three years of age and may be placed in the mouth may not be offered for sale or transferred professionally if phthalates have been added.

New EU-harmonised rules on restriction of phthalates are formulated in the directive on phthalates in toys and childcare articles which comes into effect on 16 January 2007. These rules are transposed into Swedish law through Chapter 10 section 4b of KIFS 1998:8. The new rules impose a complete ban on the phthalates DEHP[24], DBP and BBP in all toys and childcare articles, as well as the phthalates DINP, DIDP and DNOP in toys and toy articles that can be placed in the mouth, in concentrations higher than 0.1 per cent by weight of the plasticised material in toys and childcare.

RoHS – restriction of certain substances in electrical products

Under the RoHS Directive (2002/95/EC), restrictions were introduced with effect from 1 July 2006 on lead, mercury, cadmium and hexavalent chromium, as well as brominated flame retardants polybrominated biphenyls (PBB) and polybrominated diphenylethers (PBDE) in electrical and electronic articles. The maximum concentration in homogeneous material, uniform composition, for example plastic, glass and metal, has been set at 0.1% by weight. The maximum limit for cadmium has been set at 0.01 per cent by weight.

RoHS has been transposed into Swedish law through Section 11 a-c of the Ordinance (2005:217) amending the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944) and through Sections 40-41 of the Regulations (KIFS 2005:6) amending the Swedish Chemicals Agency's Chemical Products and Biotechnical Organisms Regulations (KIFS 1988:8).

Electrical and electronic articles covered are enumerated in Annex 1 to another directive, the WEEE Directive (2002/96/EC). The rule has been translated into the Re-

[24] DEHP = bis (2-ethylhexyl)ftalate, CAS-nr: 117-81-7; DBP = dibuthylftalate, CAS-nr: 84-74-2; BBP = bensylbutylftalate, CAS-nr: 85-68-7; DINP = diisononylftalate, CAS-nr: 28553-12-0 resp 68515-48-0; DIDP = diisodecylftalate, CAS-nr: 26761-40-0 resp 68515-49-1; DNOP = di-n-oktylftalate, CAS 117-84-0

[25] DEHP = bis (2-ethylhexyl)ftalate, CAS-nr: 117-81-7; DBP = dibuthylftalate, CAS-nr: 84-74-2; BBP = bensylbutylftalate, CAS-nr: 85-68-7; DINP = diisononylftalate, CAS-nr: 28553-12-0 resp 68515-48-0; DIDP = diisodecylftalate, CAS-nr: 26761-40-0 resp 68515-49-1; DNOP = di-n-oktylftalate, CAS 117-84-0

sponsibility for Electrical and Electronic Equipment Ordinance (2005:209). Toys are included in category 7 under the heading of Toys, Leisure and Sports Equipment.

Annex 2. EN 71 standards on the safety of toys

A brief summary of the contents of toy standards, EN 71, on the safety of toys follows below. These can be ordered from the SIS website: www.sis.se.

SS-EN 71-1. Mechanical and physical properties

This standard relates to protection against choking, crush injuries, cuts, falls, eye damage, drowning, damage to hearing etc. and is concerned with loose and small parts that must be above a certain size. Test cylinders can be ordered through the Swedish Consumer Agency

SS-EN 71-2. Flammability

This standard is intended to eliminate toys that are highly flammable and consequently expose children to the risk of burns. The standard states the types of combustible material that are prohibited in the manufacturing of all toys, as well as the requirements that apply to the combustibility of certain toys when exposed to a small source of ignition.

The toys considered to pose the greatest hazards are wigs, masks, disguise costumes, play tents and soft filled toys. The standard indicates limit values for burning time, how large a part of the toy is to remain after any fire and the rate of spread of flame.

SS-EN 71-3. Migration of certain elements

This standard specifies requirements and test methods for the migration of antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium in different toy materials. The migration limits for the different substances are stated and the materials covered are indicated. The procedures for the analyses are also described for the various materials covered by the standard.

SS-EN 71-4 Experimental sets for chemistry and related activities

This standard enumerates the 50 substances/compounds that may be used for chemical experiments, in what are known as chemistry sets. Maximum concentrations are

also stated. Examples of substances/compounds that may be used are sodium hydroxide, hydrochloric acid, sugar, hydrogen peroxide, urea, zinc, and ammonium, iron, calcium, copper, sodium, magnesium and potassium compounds. Denatured alcohol may be sold, but in the same packs as the toy.

Requirements are specified for chemistry sets with regard to the labelling of containers and packaging with the names of the substances contained, hazard symbol and hazard designation. The name, address and telephone number of the manufacturer or importer must appear on the outer packaging. Directions for use must be enclosed with chemistry sets with risk and safety information, where appropriate, for the individual experiments. A listing of all substances included must also be given, with associated risk and safety phrases and first-aid measures. All information must be given in the national language.

SS-EN 71-5. Chemical toys (sets) other than experimental sets

This standard covers cernit clays of plastic (PVC), photographic development kits, sets for plaster casting and glues, paints and solvents for model buildings. Phthalates that may not be included are named in the standard. Positive lists of solvents that may be used in glues/paints are also given.

SS-EN 71-7. Finger paints

This standard defines finger paint as paste or jelly-like coloured preparations specially produced for children, which are applied directly to suitable surfaces with the fingers and hands.

The standard specifies stricter requirements with regard to limits for the migration of certain chemical elements than in EN 71-3. It contains a list of pigments that may be present in finger paints, a list of which preservatives may be present and in what concentrations, and what ingredients are commonly present in finger paints.

SS-EN 71-9. Organic chemical compounds – Methods of analysis

This standard relates to those organic chemicals that can be classified in the groups of solvents, preservatives, plasticisers, flame retardants, monomers, biocides (wood

preservatives), processing aids and colorants. It covers the migration of certain organic substances in toys that children may eat from, suck/chew on or inhale, and that may come into contact with the skin and eyes. Restrictions on specific substances are stated in tables for the materials concerned.

Liquids that are accessible in toys are specifically restricted. These must not be classified as highly toxic, toxic, harmful to health, corrosive, irritant or sensitising. In addition, these liquids may not contain substances that are classified as carcinogenic, mutagenic or toxic to reproduction (cat. 1 or 2). The liquids must not have a pH below three or above ten. Finally the toys may not contain liquids classified with R65.

The EN 71 series of standards on safety of toys also includes:

SS-EN 71-6 Graphical symbol for age warning labelling
SS EN 71-8 Swings, slides and similar activity toys for indoor and outdoor family domestic use.

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