Regulatory Toxicology and Pharmacology 62 (2012) 523–531

Contents lists available at SciVerse ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Narrow-and-sharp or broad-and-blunt – Regulations of hazardous chemicals in consumer products in the European Union

Linda Molander *, Christina Rudén

Royal Institute of Technology, Dept. of Philosophy and the History of Technology, Teknikringen 78B, 10044 Stockholm, Sweden

ARTICLE INFO

Article history:
Received 27 March 2011
Available online 15 November 2011

Keywords:
REACH
Toys Safety Directive
RoHS Directive
Risk management
Consumer products
Hazardous chemicals

ABSTRACT

Chemicals are incorporated into a vast number of consumer products, and it has been recognized that considerable exposures of humans and the environment to chemicals are due to diffuse emissions from everyday products. Different approaches to the management of risks concerning chemicals in products are discussed on the international arena, but no general strategy has yet been adopted. The aim of this study is to investigate how health and environmental risks associated with chemicals in consumer products are currently managed in European Union legislations, mainly by the Toys Directive, the RoHS Directive, and REACH. Significant differences were found between the risk reduction strategies in these legislations, including substance prioritization, type of restrictions and requirements, and information dissemination to consumers. REACH regulates chemicals in products to a limited extent, and via quite complicated processes. Product-specific rules are therefore useful supplements to REACH for regulating chemicals in products. The combined effects of the RoHS and WEEE directives seem to be effective in promoting substitution of substances identified as problematic in electrical and electronic equipment, and it is recommended that the possibility to develop similar systems should be considered also for other product categories.

1. Introduction

Chemicals are incorporated into millions of manufactured products, such as building materials, textiles, toys, vehicles and electronics (Bengtsson, 2010; Swedish Chemicals Agency, 2009), and it has been recognized that significant exposures of both humans and the environment are due to diffuse emissions from products that include or have been treated with chemicals (e.g. The Swedish Environmental Objectives Council, 2008).

The new European chemicals regulation REACH (Registration, Evaluation, Authorization and restriction of CHemicals) has been criticized for being inadequate in regulating the use of hazardous chemicals in consumer products (e.g. Rudén and Hansson, 2010; Swedish Chemicals Agency, 2009). In addition to REACH there are also a limited number of legislations in the European Union (EU) covering specific types of consumer products and their chemical content. Different approaches to the management of risks associated with the use of hazardous chemicals in products on a global level are discussed by international actors. The Strategic Approach to International Chemicals Management (SAICM) highlights for instance the importance of increasing access to information of the chemical content of products (SAICM, 2009).

Controlling the use of hazardous chemicals in products is a complex issue and currently no general strategy for risk management exists. To develop a system that effectively handles problematic combinations of chemical substances and products is a considerable challenge. One important question is what different regulatory approaches to use in order to successfully promote risk reduction, including substitution, information dissemination, and other risk management actions such as improved waste management.

1.1. Aim of this study

The aim of this study is to investigate how risks associated with chemicals in consumer products during the use phase are currently managed in EU legislations and to discuss different aspects of these

Abbreviations: CMR, Carcinogenic, Mutagenic, Reprotoxic; DEHP, bis(2-ethylhexyl)phthalate; ECHA, European Chemicals Agency; PBB, polybrominated biphenyls; PBDE, polybrominated diphenyl ethers; PBT, Persistent, Bioaccumulative, Toxic; PVC, polyvinyl chloride; (Q)SAR, (Quantitative) Structure–Activity Relationship; REACH, Registration, Evaluation, Authorization and restriction of CHemicals; RoHS, Restriction of Hazardous Substances; SAICM, the Strategic Approach to International Chemicals Management; SVHC, Substance of Very High Concern; vPvB, very Persistent and very Bioaccumulative; WEEE, Waste Electrical and Electronic Equipment.

* Corresponding author. Fax: +46 8 790 95 17.
E-mail address: linda.molander@abe.kth.se (L. Molander).

0273-2300/$ - see front matter © 2011 Elsevier Inc. All rights reserved.
doi:10.1016/j.yrtph.2011.11.003

legislations in relation to their ability to promote risk reduction. The present analysis contributes with new knowledge to the ongoing discussion on developing more protective legal risk reduction strategies for the use of hazardous chemicals in consumer products with regard to human health and the environment.

2. Method

2.1. Selection of legislations

Three EU legislations have been selected for this comparative analysis: the Toys Safety Directive (European Council, 2009a), the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (both the current Directive: European Council, 2003a, and the revised Directive: European Union, 2011a), and REACH (European Commission, 2006) (Table 1). These legislations were selected with the aim of covering (1) the major European legislations that address the use of hazardous chemicals in consumer products, (2) product categories that have a widespread use, and (3) product categories known to include hazardous and/or high-volume chemicals. It is recognized that all life cycle stages of a product, including manufacturing, use, end-of-life and reuse, recycling and disposal, are important to take into account in evaluating potential risks to human health and the environment and for risk reduction. However, the emphasis of the present analysis is on hazards and risks associated with the products' use phase.

The initial identification of these legislations was based on the list of legislations restricting the use of substances in articles in Appendix 7 of the REACH "Guidance on requirements for substances in articles" (ECHA, 2008).

A preliminary analysis was carried out including also the Construction Products Directive (European Council, 1989), the Medical Devices Directive (European Council, 1993) and the Cosmetic Products Regulation (European Commission, 2009). These were however excluded in the final selection from inclusion into the more detailed analysis. The essential requirements of the Construction Products Directive include a short paragraph on chemicals stating that construction products must not emit toxic gases, dangerous particles to the air or cause pollution of water or soil when they are part of a building (Annex I). The Construction Products Directive is a so called *New Approach* directive, and it refers to certain harmonized standards for the practical implementation of the health and environmental aspects (European Union, 2003). These standards have, however, not yet been developed and as long as they are lacking, this paragraph is not effective. As a result, the use of chemicals in construction products is at present primarily regulated by REACH. (Freilich, The Swedish Construction Federation, Personal Communication, 2010–04-23) The Construction Products Directive is furthermore under revision and major changes have been suggested (Government Offices of Sweden, 2008). Therefore, the Construction Products Directive is not further discussed in the more detailed comparisons presented below. How chemicals are regulated in medical devices was excluded because medical devices have a rather limited use application; the general population is not the target for exposure and the exposure route generally differ from that of other consumer products, i.e. the second criteria is not met. The reason for not including cosmetics is that their function, contrary to that of "articles", is determined by their chemical composition. The requirements in the Cosmetic Products Regulation were therefore not considered relevant to the present analysis. The Energy-related Products (ErP) Directive (European Council, 2009b, formerly the Energy-using Products (EuP) Directive 2005/32/EC) is currently not regulating the chemical content in those products, and was therefore not included in the analysis.

For the purpose of this paper the terms *product* and *consumer product* will be used synonymously with *article* as defined in REACH: "an object which during production is given a special shape, surface or design which determines its function to a larger degree than does its chemical composition" (European Commission, 2006, Article 3).

Table 1
Selected legislations and examples of consumer products that are within their respective scope.

Legislation	Products	Examples
Toys Safety Directive 2009/48/EC	Toys	Teethers, plastic cars and dolls
RoHS Directives 2002/95/EC and 2011/65/EU	Electrical and electronic equipment	Computers, phones, TV screens
REACH 1907/2006/EC	Any product except medical devices	Textiles, shoes, furniture

2.2. Characterization of regulatory strategies

A number of characteristics were selected for comparison of the legislations (Table 2). These characteristics were chosen to systematically describe central issues in the legislations including the prioritization of substances, types of requirements and restrictions and information and communication of the chemical content and chemical properties of incorporated chemicals. The characteristics were considered important as a basis for discussing the capacity of the legislations to promote risk reduction, and they were identified based on the authors' previous research in regulatory risk assessment (e.g. Beronius et al., 2009; Hansson and Rudén, 2006; Hansson et al., 2011).

One key in the risk management of chemicals is substitution. To substitute one hazardous chemical by a less hazardous chemical requires, as a minimum, that the relevant chemical content of the product is known and that the properties of the chemicals are described in sufficient detail. There are a number of regulatory measures that can encourage substitution. For the purpose of this paper we will focus on restrictions and information. These measures will be discussed in relation to the major identified characteristics of each of the legislations.

3. Description of the legislations

In this section the characteristics (Tables 2 and 3) are used to describe the selected legislations. The results are summarized in

Table 2
Description of the characteristics identified for comparison of the selected legislations.

Regulatory characteristics	Explanation
Aim	The aim of the legislation
Scope	The products covered by the legislation
Regulatory approach	Whether the legislation is *substance-specific*, i.e. regulates particular identified substances that are listed in the legislation, or *criteria-based* i.e. defines a set of criteria that need to be applied in order to identify substances that are eligible for regulation
Substance priority criteria	The criteria used to prioritize which chemicals are regulated
Prioritized substances	The substances and/or categories of substances that are regulated
Test requirements	Whether generation of data is required or the system relies solely on available data
Information requirements	The type of information required from the producers/importers to be conveyed to consumers and users, and for which chemicals/products this information is required
Information format	Whether the information is communicated in the form of labeling, use instructions or in other ways

Tables 4–6 (Section 4). All references in the following sections are to the main directives/regulations respectively, unless stated otherwise.

3.1. The Toys Safety Directive

A revised directive on the safety of toys (Directive 2009/48/EC) went into force on July 20, 2009 (hereafter referred to as the Toys Directive). This directive is replacing the former Toys Safety Directive (European Council, 1988), and most of its provisions shall be incorporated by the European member states no later than January 20, 2011.

3.1.1. Aim

The objective of the Toys Directive is "to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market [...]" (Paragraph 48). In this context, one important purpose of the Toys Directive is to limit the use of certain chemicals in toys. The restrictions relating to the chemical content in toys will not apply until July 20, 2013 (Article 53 and 55). During the transitional period, the particular safety requirements concerning chemical properties in toys (Annex II, Part 3) of the previous Directive (88/378/EEC) will continue to apply.

3.1.2. Scope

The Toys Directive applies to "products designed or intended, whether or not exclusively, for use in play by children under 14 years of age" (Article 2). "Whether or not exclusively" is an addition to the 1988 Toys Directive and means that products do not have to be intended for playing purposes only to be considered a toy (Toy Industries of Europe, 2009a). The Toys Directive applies to toys both produced in and imported to EU.

3.1.3. Regulatory approach

Annex II of the Directive constitutes particular safety requirements that concern the chemical content of toys. The chemical content is regulated using both a criteria-based and a substance-specific approach, meaning that the Toys Directive regulates substances that satisfy certain criteria as well as specific substances identified as being of concern.

3.1.4. Substance priority criteria and prioritized substances

The main criteria used in the Toys Directive to prioritize substances for restrictions are the CMR criteria for category 1A, 1B and 2 (according to European Commission, 2008a; European Council, 1967, 1999). The CMR-classified substances and mixtures may however be exempted from restrictions if the potential for exposure is considered to be insignificant or very low (Annex II, Part III).

The Toys Directive also includes a ban of 55 fragrances identified in the Directive as allergenic. In addition, there are information requirements for another 11 fragrances identified as allergenic, and maximum migration limits for 19 metals. There are no criteria stated in the Directive explaining how these allergenic fragrances and metals were prioritized.

3.1.5. Test requirements

The manufacturer is obliged to make a safety assessment which includes identifying potential hazards associated with the use of the toy and assessing the nature of the exposure to those hazards (Article 18). The outcome of the safety assessments will determine if any risk reduction measures or further testing is needed (Toy Industries of Europe, 2009b). Although further testing is not explicitly required in the Toys Directive, this could potentially create incentives for generation of new toxicity and/or exposure data. To what extent this is actually the case in practice is not known to the authors.

3.1.6. Information requirements

Manufacturers and importers of toys are obliged to provide consumers with instructions and safety information on their products (Articles 4 and 6). If a toy contains any of the 11 fragrances identified as allergenic, the name of the substance should be listed on the toy if the concentration exceeds 100 mg/kg of the toy or a component thereof (Annex II, Part III).

Warnings should accompany a toy when considered appropriate (Article 11, and Annex V, Part A). For certain categories of toys specific warnings are required. One such category is chemical toys, e.g. chemistry sets, plastic embedded sets, and miniature workshops for ceramics (Annex V, Part B). If these toys contain dangerous substances or mixtures, instructions for use shall include a warning of the dangerous properties of these substances or mixtures. The user instruction shall also contain recommendations about precautious measures to be taken by the user, and the first aid to be given in the event of a serious accident. In addition, chemical toys shall bear a statement that the toy must be kept out of reach of children under a certain age (decided by the manufacturer). Information about user limitations should at least state the minimum or maximum age of the user (Annex V, Part B).

3.1.7. Information format

The warning should be conveyed in the form of a phrase or pictogram on the toy, on a label or on the packaging. The warnings should be clearly visible, easily legible and understandable. Toys also need to bear a CE mark when placed on the market. The CE marking shows that the toy fulfills the essential safety requirements and the particular safety requirements in the Toys Directive (Articles 4 and 15).

3.2. The RoHS Directives

The RoHS Directive (2002/95/EC) was adopted in February 2003 and took effect on 1 July 2006. A review of the RoHS Directive was completed in November, 2010 (Council of the European Union, 2010), and in May 2011, the EU council had decided on a new directive. The new RoHS Directive (2011/65/EU) will start to apply in autumn 2012 (Swedish Chemicals Agency, 2011). For the present analysis both the current legislation and the revised RoHS Directive have been considered.

3.2.1. Aim

The aim of both the current and the revised RoHS Directive is to harmonize the laws of the European member states on the restrictions of use of hazardous substances in electrical and electronic equipment to help protect human health and the environment, and ensure the sound recovery and disposal of electrical and electronic waste (Article 1). It is not specified what level of protection is aimed for.

3.2.2. Scope

The current RoHS Directive applies to the following categories of electrical and electronic equipment: large and small household appliances, IT and telecommunications equipment, consumer equipment, lighting equipment, electronic and electrical tools, toys, leisure and sports equipment, and automatic dispensers. These comprise categories 1–7 and 10 as set out in Annex IA of Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) (European Council, 2003b). Electric, light bulbs and luminaries in households are also included (Article 2). The revised Directive also includes category 8, 9 and 11, i.e. medical devices, monitoring and control instruments including industrial monitor-

ing and control instruments, and other electrical and electronic equipment not covered by any of the categories above. RoHS applies to electrical and electronic equipment whether produced in or imported to EU.

3.2.3. Regulatory approach

Both the current and the revised RoHS Directive restricts the use of certain identified substances; hence it uses a substance-specific regulatory approach. However, in the latest review of the directive, a new methodology has been introduced for the identification and future addition of substances to be restricted, which is based on four criteria (see below).

3.2.4. Substance priority criteria and prioritized substances

Four metals: lead (Pb), mercury (Hg), cadmium (Cd), hexavalent chromium (Cr^{6+}), and two groups of flame retardants: polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE), are restricted (Article 4 in the current RoHS Directive, Annex II in the revised RoHS Directive). These prioritizations were partly based on risk assessments made within the previous Existing Substances legislation (Ekblom, Swedish Chemicals Agency, Personal Communication, 2010–05-19; European Commission, 2000). The maximum permitted concentration is 0.1% by weight of homogenous material except for Cd, for which the limit is set to 0.01%. A homogenous material is a material being "of uniform composition throughout" (Nordic Council of Ministers, 2010). According to the methodology in the revised RoHS Directive, substances may be prioritized for restriction that during waste management could (1) negatively impact on the possibility for reuse or recycling of EEE waste and materials, (2) give rise to uncontrolled or diffuse release to the environment or to hazardous residues, transformation or degradation products, (3) lead to unacceptable exposure of workers, and (4) be replaced by substitute substances or technologies which have less negative impacts (Article 6). The review and amendment of the list of restricted substances should take "substances of very small size or with a very small internal or surface structure, or a group of similar substances" into special account (Article 6).

3.2.5. Test requirements

The RoHS Directives do not include any test requirements.

3.2.6. Information requirements

The RoHS Directives contain no requirement to inform consumers about the chemical content or hazardous properties of substances in electrical and electronic products. Since the substance restrictions are directed at the level of homogenous material it is necessary that data on substance concentrations are transferred down the supply chain to the final producer.

The RoHS Directives refer directly to the WEEE Directive. The WEEE Directive requires that producers provide information about whether each type of new electrical and electronic equipment, which is put on the market within one year after the equipment is put on the market, contains dangerous substances or preparations. This information should be made available to reuse centers, treatment and recycling facilities in order to aid waste management (Directive 2002/96/EC, paragraph 22 and Article 11). The WEEE Directive also requires that users of electrical and electronic equipment in private households are provided with information about environmental and health effects potentially resulting from the presence of hazardous substances in these products (Directive 2002/96/EC, Article 10). As the consumer products covered by the RoHS Directives are also covered by the WEEE Directive, the requirement to provide information about chemical content and potential risks to human health or the environment thus exists for the products within the scope of the RoHS Directives.

3.2.7. Information format

Several manufacturers have voluntarily developed a compliance labeling to clarify which products have been manufactured in accordance with the RoHS Directives. According to the revised RoHS Directive the CE mark is required to show that the equipment meets the legal requirements (Article 7).

3.3. REACH

The European chemicals legislation, REACH (Regulation (EC) 1907/2006) went into force on the 1st of June 2007.

3.3.1. Aim

The overall aim of REACH is improved risk management of industrial chemicals produced in, or imported to Europe. The improved risk management is thought to rely on substitution by encouraging the replacement of identified substances of very high concern for human health and/or the environment by less dangerous substances or technologies, if economically and technically suitable alternatives are available (Paragraph 12).

3.3.2. Scope

REACH regulates production, placing on the market, and use of substances, mixtures (two or more chemical substances) and to a limited extent also substances and mixtures in consumer products. The requirements concerning substances in products apply to products whether produced in or imported to EU, except for the authorization requirement which is limited to substances when they are *used for manufacturing* of a product within EU. Imported products containing any of the substances on the so-called candidate list thus do not need to be authorized (Swedish Chemicals Agency, 2010).

3.3.3. Regulatory approach

The use of chemicals in consumer products can become regulated in five different ways under REACH (for a summary of these five approaches see Table 3). REACH uses both substance-specific and criteria-based processes.

Table 3
Summary of approaches used to regulate chemicals in articles under REACH.

Conditions	Consequence(s)	Possible consequence(s)
Import or production volume >1 tonne/year and intended release of the substance from the product	Registration of data	Restriction
Product includes a SVHC >0.1% of the weight of the product and import or production volume >1 tonne/year	Notification Provide information to professional users and to consumers on request	Registration and restriction
Product includes a SVHC on the candidate list	Producer/importer should show that risks are adequately controlled and/or show that socioeconomic benefits outweigh health/environmental risks	Restriction
Proposal from an EU member state to restrict a substance or mixture in a product	–	Restriction

Substances in products should be registered if the produced or imported volume of the substance exceeds 1 tonne/producer or importer/year and if the substance is intended to be released from the product "under normal or reasonably foreseeable conditions of use" (Article 7). The amount of data required for the registration depends primarily on the produced/imported volume (Annexes VII–X). Following the registration the European Chemicals Agency (ECHA) can propose restrictions (Paragraph 29).

Based on the information required in the registration dossiers a chemical may be classified as a Substance of Very High Concern (SVHC) and put on the candidate list. Before the first registration deadline in November 2010, around 143,000 substances had been pre-registered under REACH (ECHA, 2010). The identification of a SVHC is based on hazard criteria (CMR cat 1 or 2, PBT, or vPvB and/or substances "which give rise to an equivalent level of concern") (Article 57). The identification of substances to be put on the candidate list is performed in collaboration between interested parties using a case-by-case approach (Article 59). The first step in this process is thus criteria-based, while the second step is substance-specific.

If the concentration of a SVHC exceeds 0.1% of the product's total weight and if the total volume of the substance in all products exceeds 1 tonne/year/producer or importer, then a notification should be sent to ECHA, unless already registered for that use, or if it can be concluded that humans and the environment are not exposed to the substance during normal or reasonably foreseeable conditions of use (including disposal) (Article 7). The notification should include the identity and classification of the substance, identified use(s) of the substance in the product and produced or imported volume. Based on the notification information, ECHA can decide to require a registration (Paragraph 29).

For substances on the candidate list, which are present in products in concentrations exceeding 0.1% of the product's total weight, the supplier of the product is obliged to provide professional users with "sufficient information" for it to be handled in a safe way. As a minimum, the name of the substance must be provided. If requested, the same information should be given to consumers within 45 days (Article 33).

When a substance on the candidate list has been prioritized for authorization the producers of that substance must show that the risk of the substance will be adequately controlled and/or that socioeconomic considerations outweigh health and/or environmental risk (Article 60).

EU member states can also propose certain (uses of) chemicals to be restricted or banned regardless of whether there is a duty to register the substance or not. The restrictions also apply regardless of produced or imported volume, unless it is specified in the annex.

3.3.4. Substance priority criteria and prioritized substances

As described above, the following criteria are used as basis (often in combination) for selecting which chemicals are subject to registration, notification, information dissemination, and authorization when used in products:

- Produced or imported volume.
- Intended release of the substance from the product.
- SVHC-criteria (see above).
- Concentration limits (0.1% of the product on a weight basis).
- PBT or vPvB properties, wide dispersive uses, or high volumes (criteria for authorization prioritization) (Article 58).

The substances covered by the "intended to be released" criterion are e.g. fragrances.

The candidate list currently consists of 53 SVHC (ECHA, 2011). In addition to these, there are the over 50 substances on the list of restrictions. However, only a few of these are restricted for use in products. The substances on these two lists belong to different chemical use categories and have various hazardous properties.

3.3.5. Test requirements

One important objective of REACH is to increase the knowledge about the inherent properties and uses of chemical substances on the market. The registration dossier should include data on e.g. physico-chemical properties of the substance and for high volume substances also toxicity and ecotoxicity data. The required amount of data on toxicity is mainly determined by the produced or imported volume. A prioritization of which of the low-volume substances to test will be done, e.g. based on (Quantitative) Structure–Activity Relationship ((Q)SAR) data (see e.g. Rudén and Hansson, 2010).

3.3.6. Information requirements

As mentioned above, the producer or importer has the duty to provide information to professional users if the product in question includes a SVHC on the candidate list in concentrations above 0.1% by weight of the finished product. The information should be "sufficient" for the product to be handled in a safe way (Article 33). As a minimum, the name of the substance must be provided. The same information should be given to consumers within 45 days if requested.

3.3.7. Information format

No labeling or information system to inform the consumers about the chemical contents of products is integrated in REACH. The duty for suppliers to communicate information about e.g. composition, identified hazards and exposure control up and down the supply chain does not apply to products, but only to substances and mixtures (Articles 31, 32 and 34).

4. Comparative analysis

4.1. Aim and scope

REACH and the RoHS Directive aim at reducing risks to both human health and the environment. They regulate chemicals in consumer products in a general manner in the sense that no specific group of people or environmental compartment are in the focus of protection. In contrast, the Toys Directive focuses on the protection of health, and furthermore on a specific subpopulation, i.e. children (Table 4).

All restrictions in the Toys Directive and the RoHS Directive apply to consumer products whether produced within the EU or imported to the EU. On the contrary, the authorization requirement under REACH will not apply to products containing SVHCs on the candidate list when they are imported to EU.

4.2. Regulatory approach, priority setting and test requirements

4.2.1. Regulatory approach

The scrutinized legislations use different approaches in the way they regulate the use of substances in their respective product categories; some are general and criteria-based, meaning that they include processes for identifying new substances of concern based on specified criteria. In that way they cover, in principle, any substance. Other legislations focus on the risk management of particular substances identified as problematic, i.e. are substance-specific. REACH and the Toys Directive combine criteria-based and substance-specific approaches. In contrast, the current RoHS Directive uses a substance-specific approach (Table 5).

Table 4
Summary of the aim and scope of the legislations.

Regulatory characteristics	Toys Directive 2009/48/EC	RoHS Directives 2002/95/EC; 2011/65/EU	REACH 1907/2006/EC
Aim	Ensure a high level of safety of toys with a view to ensuring the health and safety of children	Protection of human health and the environment	Improve the protection of human health and the environment
Scope	Toys	Electrical and electronic equipment	Industrial chemical substances, mixtures and products (i.e. articles under REACH)

Table 5
Summary of the regulatory approach, priority setting and test requirements of the legislations.

Regulatory characteristics	Toys Directive 2009/48/EC	RoHS Directives 2002/95/EC; 2011/65/EU	REACH 1907/2006/EC
Regulatory approach	Substance-specific and criteria-based	Substance-specific and criteria-based[a]	Substance-specific and criteria-based
Substance priority criteria	CMR cat. 1 and 2, concentration limits, including migration concentration limits	Concentration limits (by weight in homogenous materials) Substances that could have a negative impact during waste management[b]	Concentration limits (by weight of the product), produced/imported volume, intended release, SVHC criteria (CMR cat. 1 and 2, PBT, vPvB, and "equivalent level of concern")
Identified prioritized substances	CMR cat. 1 and 2, 66 allergenic fragrances, 19 metals	Pb, Hg, Cd, Cr^{6+}, PBB, PBDE	53 SVHC, 58 restricted (groups of) substances some of which relates to consumer products (Annex XVII)
Test requirements	No	No	Yes

[a] The revised RoHS Directive also includes a criteria-based approach.
[b] These are included in the revised RoHS Directive.

Table 6
Summary of the information and communication requirements of the legislations.

Regulatory characteristics	Toys Directive 2009/48/EC	RoHS Directives 2002/95/EC; 2011/65/EU	REACH 1907/2006/EC
Information requirements	Yes	No	Yes
Information format	For chemical toys: use instructions and a warning phrase or pictogram		No general information system exists
	All toys: CE marking	The revised RoHS Directive requires the CE mark	Consumers can request information case-by-case

4.2.2. Substance priority criteria and prioritized substances

Two of the legislations under scrutiny use CMR-criteria for prioritization. Besides that, there are clear differences in their priority setting criteria and what substances that have become prioritized. This may seem inconsistent, but it could also be motivated given the complexity of the system to be regulated. Appropriate prioritization of combinations of consumer products, their chemical content, use pattern, exposure potential, and waste management is likely to require more or less tailored approaches for different product categories.

All legislations use concentration limits as a criterion for prioritization. These limits are, however, applied differently. In the Toys Directive, the concentration limits apply either to *the toy* or *components* of the toy. The maximum permitted concentration limits in the RoHS Directives should be applied to any *homogenous material* that the product consists of. In contrast, the general concentration threshold of 0.1% under REACH shall apply to the *entire complex product* as produced or imported (ECHA, 2008). The way in which the 0.1% concentration limit is used within REACH has led to an intensive discussion within the EU. The interpretation is considered unacceptable by six of the European member states (Austria, Belgium, Denmark, France, Germany and Sweden) since it will have consequences for the information dissemination about the presence of SVHC in products (Nordic Council of Ministers, 2010). The current interpretation of the 0.1% threshold will potentially lead to losses of important information since the requirements will cease to apply as smaller products are incorporated into complex products (Nordic Council of Ministers, 2010).

The production volume thresholds for test requirements and the "intended to be released"-criterion are unique to REACH. The latter criterion has, however, some similarity with the migration limits for metals in the Toys Directive which are based on the metals' bioavailability and hence their exposure potential.

The revised RoHS Directive states that "substances of very small size or internal or surface structure which may be hazardous due to properties related to their size or structure" should be taken into account when evaluating the need for future restrictions and substitutions (Paragraph 12). Although it is not clearly stated, REACH also covers substances at the nanoscale (European Commission, 2008b). However, there are no provisions referring specifically to nanomaterials in REACH (European Commission, 2008b).

The identification of SVHCs and the inclusion of these substances on the candidate list are crucial processes for risk management of chemicals in consumer products within REACH. These processes are complicated and concerns have been raised that they will be slow and bureaucratic (see e.g. the Substitute It Now (SIN) Reporter; International Chemical Secretariat, 2009). Therefore, even though REACH is a more comprehensive legislation with a wider scope than the product-specific legislations, it will most likely only affect the use of hazardous substances in consumer products to a limited degree, since most requirements only pertain to the identified SVHC on the candidate list. The criterion of "intended release" triggering the registration requirement also has a narrow scope and will likely not be applicable to very many substances. The Toys Directive, which regulate CMR classified substances as a group, will automatically include substances to the

extent that they undergo testing and become classified, for instance as a consequence of the test requirements under REACH. The number of regulated substances is however not the sole measurement on how extensive a legislation is with regard to risk management; it also depends on the type of measures and requirements that are associated with the regulated substances.

Many substances are used in consumer products which are within the scope of all legislations analyzed in the present paper. One such substance is bis(2-ethylhexyl)phthalate (DEHP) (Heudorf et al., 2007). DEHP is classified as toxic to reproduction, on the basis that it may impair fertility and may cause harm to the unborn child according to Annex I to Directive 67/548/EEC. It is regulated in different ways and to different extent depending on the type of product in which it is present. DEHP is currently still allowed to be used in products only regulated by REACH, e.g. clothes, shoes and furniture. In February 2011 the EU Commission decided to move DEHP from the candidate list to Annex XIV, which means that producers need to apply for its uses to be authorized no later than 21 August 2013 for these uses to continue to be allowed after 21 February 2015 (European Union, 2011b). Polyvinyl chloride (PVC) plastics are often used in toys and children's care products (European Chemicals Bureau, 2008), and DEHP was a commonly used plasticiser in such consumer products before the European Commission decided in 2007 to prohibit its use in toys and childcare products in concentrations exceeding 0.1% (European Commission, 2006, Annex XVII). The Toys Directive also prohibits DEHP in toys (European Council, 2009a, Annex II, Part III). The scope of the RoHS Directive covers among other things PVC cables, e.g. power cords to computers, which can contain DEHP. DEHP is not one of the restricted substances in the current or revised RoHS Directive. DEHP is thus banned in some product categories, such as toys and childcare products, while its use is unrestricted in others, such as PVC floorings and clothes. DEHP is prohibited in toys and childcare products as a means to protect those being particularly sensitive, but due to this inconsistency children may still be exposed to DEHP via its presence in PVC floors, clothes and other consumer products. Such regulatory diversity may be explained by variable exposure levels and/or sensitivity towards the substances in sub-populations identified as the primary recipients. However, in the case of DEHP, children may, as a consequence of the legislative inconsistency, still be exposed via emissions from other types of consumer products.

4.2.3. Test requirements

The RoHS Directive and the Toys Directive do not require any toxicity tests to be performed, but rely on available data for prioritizing substances for regulation. REACH is the only of these legislations that puts focus on the generation of new (eco-)toxicity data of previously untested or inadequately studied chemicals.

4.3. Information and communication to users

There is little coherence between the legislations concerning requirements to provide information to users about the chemical content and/or properties of incorporated chemical substances (Table 6).

First, all legislations include some requirement to provide information to consumers except the RoHS Directive.

Second, the type of information required by REACH and the Toys Directive differs. While REACH, as a minimum, only requires that the name of included SVHC is provided by the supplier, the Toys Directive requires that certain chemical substances in the product are clearly stated, and that use instructions and warnings are provided to the consumers.

Third, how that information is conveyed is also divergent. The responsibility for disseminating information about incorporated chemicals to consumers lies with the producers or importers according to the Toys Directive. In contrast, according to REACH, the consumers need to ask to get the information.

The CE mark, which is required by the new approach directives (the Toys Directive and the revised RoHS Directive), states that the product complies with the legal requirements. It is not primarily intended for consumers and it does not provide any information about which chemical substances a product contains.

5. Discussion

The aim of the present analysis was to identify which characteristics, included in the different legislations, are important for promoting substitution of hazardous substances in products to safer alternatives. This is of course different from a general appraisal of the quality of the different legislations.

5.1. Aim and scope

The authorization requirement under REACH does not apply to imported consumer products. Together with the restrictions, the authorization process makes up the main way in which substances can become banned or restricted by REACH. The authorization is thus a key process in current EU chemicals legislation for substituting SVHCs with less hazardous substances or other safer non-chemical alternatives. In contrast, the other legislations under scrutiny impose the same obligations for products imported from non-EU countries as for those produced within the EU. It has been stated that the RoHS Directive "has had profound impact on the global electronics industry" and that the Directive has led to, not only on a European, but also a more protective standard on hazardous substances in electronics on a global level (Tsydenova and Bengtsson, 2011). A significant amount of consumer products are imported to the EU from countries having less stringent chemicals control. In order to obtain the same protection for imported products as for those produced within the EU, the EU would have to implement the same requirements for imported products as for EU-produced products under REACH.

5.2. Regulatory approach, priority setting and test requirements

The advantage of a criteria-based approach is that the legislation includes processes both for identifying and restricting substances of concern. The disadvantage of such a legislation is that it might become complex, and include several processes that could be time and resource consuming. One process that runs this risk is the REACH authorization process. So far, only some 50 substances out of the 143,000 pre-registered substances have been included on the candidate list.

The advantage of using a substance-specific approach is that it will have a direct effect on information dissemination and substitution. If a substance is prohibited for use in a particular consumer product then the responsible agent needs to acquire knowledge to ascertain that the product is in fact free of that compound. The RoHS Directive is an example of a regulation using such an approach. Identification of individual substances for restriction is perhaps better suited for product-specific than for general regulations, since in the former case the scope of products is more clearly defined, and typical chemical content and exposure routes can possibly be identified. Hence, the substances prioritized for restriction become better selected with regard to how they are used. The disadvantage is that the scope is fixed i.e. it covers a number of particular substances, and it does not, by itself, create incentives to generate information or risk management actions beyond what is currently required. Another difference between these two

regulatory approaches is that restrictions according to the substance-specific approach require substances to first be introduced into the legal act, while the criteria-based approach automatically includes substances as they have been identified to satisfy the criteria. The latter approach thus puts more responsibility on producers and importers.

5.3. Information and communication to users

The combined force of the RoHS and WEEE directives has created incentives to generate information about parts of the chemical content of electrical and electronic devices and to disseminate this information to the producer of the final product, reuse centers and recycling facilities.

The way information about chemical content is transferred to users/buyers of different consumer products differs. According to REACH consumers have to actively contact the manufacturer and request information about the contents of SVHC in their products. This seems to be an ineffective way of communication that is likely to limit the amount of information received by the consumers.

5.4. Conclusions and recommendations

The present analysis shows that there are significantly different approaches for regulating the chemical content in different categories of consumer products within the EU. These differences include which substances are restricted or banned, what type of restrictions and requirements are used, and what information is provided to the consumer.

REACH is the main driving force for generating data and increasing knowledge about the properties of industrial chemicals in the EU. In order for decisions on risk reduction to be based on adequate scientific data on all products that are potential targets of such measures the REACH legislation would have to be modified in several ways. As identified in the present study, such a modification would have to deal with the following five features of the current REACH legislation:

- REACH regulates chemicals in products only to a very limited extent, and
- Via quite complicated and time-consuming processes.
- The authorization requirement does not apply to SVHCs in EU-imported products.
- The 0.1% concentration limit applies to the entire, complex product, and
- Several of the requirements do not apply to low-volume chemicals (i.e. <1 tonne/year).

Given the nature of products (large number of diverse and often complex items) it seems unlikely that all products could be covered by a single regulation. Product-specific rules can therefore be a useful supplement to REACH for regulating chemicals in products. Based on the comparative analysis, five strengths of the product-specific RoHS Directive are that:

- The current RoHS rules are relatively uncomplicated.
- The RoHS Directives' requirements apply also to products imported to the EU.
- The concentration limit criterion applies to homogenous materials.
- The connection between the RoHS and WEEE directives requires that producers of electrical and electronic equipment take the environmental or health problems that can arise during the waste phase into greater consideration already at the design and manufacturing phase, and
- Together, the RoHS and WEEE directives have created incentives for generating information about the chemical contents of electronic devices and for disseminating this information to relevant supply chain actors.

The RoHS and WEEE directives are working together with the aim of preventing certain hazardous substance in electrical and electronic equipment from being released into the environment and reducing the risk of them causing harm to human health or the environment. While the RoHS Directives reduces the inclusion of hazardous substances in electrical and electronic equipment, i.e. at their source, the WEEE Directive seeks to prevent products to be sent to landfills after they have reached their end-of-life.

The number of regulated substances in the RoHS Directive is currently limited, but it is foreseen that the inclusion of additional chemicals will be a less complicated process under the revised directive. Inclusion of substances will probably partly be based on risk assessments performed within REACH. Given the amount of resources invested in REACH, it is crucial to utilize REACH data as they become available, but other sources of information should also be explored whenever this is possible and relevant. In our view, the combined effects of the RoHS and WEEE directives seem to be an effective way to promote substitution of substances identified as problematic in electrical and electronic equipment.

The introduction of directives, using a similar approach as the RoHS and WEEE-connected directives, also for other product categories may possibly be an efficient way to achieve some of the goals of the chemicals legislation.

6. Conflict of Interest statement

The authors declare that there are no conflicts of interest.

Acknowledgments

This work was performed within the ChEmiTecs (Organic Chemicals Emitted from Technosphere Articles) research programme, which is funded by the Swedish Environmental Protection Agency.

References

Bengtsson, G., 2010. Regulating chemical risks. In: Eriksson, J., Gilek, M., Rudén, C. (Eds.), Regulating Chemical Risks: European and Global Challenges. Springer, Dordrecht Heidelberg, London, New York (ISBN 978-90-481-9427-8, e-ISBN 978-90-481-9428-5).

Beronius, A., Rudén, C., Hanberg, A., Håkansson, H., 2009. Health risk assessment procedures for endocrine disrupting compounds within different regulatory frameworks in the European Union. Reg. Toxicol. Pharmacol. 55 (2), 111–122.

Council of the European Union, 2010. Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment – (RoHS) (recast) (2008/0240 (COD)), Brussels, 12 November, 2010.

European Chemicals Agency (ECHA), 2008. Guidance on requirements for substances in articles. Guidance for the implementation of REACH. <http://guidance.echa.europa.eu/guidance_en.htm> (accessed 20.08.10).

European Chemicals Agency (ECHA), 2010. List of pre-registered substances. <http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx> (accessed 06.06.11).

European Chemicals Agency (ECHA), 2011. Candidate List. <http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp>. (accessed 22.11.11).

European Chemicals Bureau, 2008. European Union Risk Assessment Report, bis(2-ethylhexyl)phthalate (DEHP). <http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dehpreport042.pdf> (accessed 30.08.10).

European Commission, 2000. Proposal for a directive of the European Parliament and of the Council on waste electrical and electronic equipment/Proposal for a directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Commission of the European Communities, COM (2000) 347 final, Brussels.

European Commission, 2006. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Off. J. Eur. Commun. L396, 1–849.

European Commission, 2008a. Classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 Regulation (EC) No. 1272/2008 of the European Parliament and of the Council. Off. J. Eur. Commun. L353, 1–1355.

European Commission, 2008b. Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH): Nanomaterials in REACH. <http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf> (accessed 31.08.10).

European Commission, 2009. Regulation (EC) No. 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products. Off. J. Eur. Commun. L342 (59), 1–151.

European Council, 1967. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Off. J. Eur. Commun. L196, 1–98.

European Council, 1988. Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys. Off. J. Eur. Commun. L187, 1–13.

European Council, 1989. Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products. Off. J. Eur. Commun. L40, 12–26.

European Council, 1993. Directive 93/42/EEC of 14 June concerning medical devices. Off. J. Eur. Commun., L169.

European Council, 1999. Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. Off. J. Eur. Commun. L200, 1–68.

European Council, 2003a. Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Off. J. Eur. Commun. L37, 19–23.

European Council, 2003b. Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE). Off. J. Eur. Commun. L37, 24–38.

European Council, 2009a. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. Off. J. Eur. Commun. L170, 1–37.

European Council, 2009b. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products. Off. J. Eur. Commun. L285, 10–35.

European Union, 2003. A New Approach to Technical Harmonization. <http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/technical_harmonisation/l21001a_en.htm> (accessed 02.07.10).

European Union, 2011a. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Off. J. L174, 88–110.

European Union, 2011b. Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Off. J. L44 (2), 1–5.

Government Offices of Sweden, 2008. Faktapromemoria 2007/08:FPM123, Byggproduktförordningen [in Swedish]. <http://www.riksdagen.se/Webbnav/index.aspx?nid=251&dok_id=GV06FPM123> (accessed 31.08.10).

Hansson, S.O., Rudén, C., 2006. Priority setting in the REACH system. Toxicol. Sci. 90, 304–308.

Hansson, S.O., Molander, L., Rudén, C., 2011. The substitution principle. Reg. Toxicol. Pharmacol. 59 (3), 454–460.

Heudorf, U., Mersch-Sundermann, V., Angerer, J., 2007. Phthalates: Toxicology and exposure. Int. J. Hyg. Environ. Health 210, 623–634.

International Chemical Secretariat, 2009. 356 Substances of Very High Concern. <http://www.chemsec.org/list/about-sin/why-a-sin-list> (accessed 25.08.10).

Nordic Council of Ministers, 2010. REACH Trigger for Information on Substances of Very High Concern (SVHC) – An Assessment of the 0.1% Limit in Articles. TemaNord 2010:514, ISBN 978-92-893-1998-0. <http://www.norden.org/sv/publikationer/publikationer/2010-514?set_language=sv> (accessed 31.08.10).

Rudén, C., Hansson, S.O., 2010. Registration, Evaluation, and Authorization of Chemicals (REACH) is but the first step – how far will it take us? Six further steps to improve the European chemicals legislation. Environ. Health Perspect. 118, 6–10.

SAICM (Strategic Approach to International Chemicals Management), 2009. International Conference on Chemicals Management, Second session. Background information in relation to the emerging policy issue of chemicals in products, Geneva, 11–15 May 2009. <http://www.saicm.org/documents/iccm/ICCM2/meeting%20documents/ICCM2%20INF35%20products%20background.pdf> (accessed 31.08.10).

Swedish Chemicals Agency, 2009. Varor som innehåller farliga ämnen – underlag för utveckling av strategier för fortsatt arbete [in Swedish]. Reference number 630-826-09.

Swedish Chemicals Agency, 2010. REACH – Tillståndsprövning [in Swedish]. <http://www.kemi.se/upload/Forfattningar/Reach/REACH_Tillst%C3%A5nd.pdf> (accessed 02.07.10).

Swedish Chemicals Agency, 2011. Aktuellt om RoHS-direktivet [in Swedish]. <http://www.kemi.se/templates/Page____3794.aspx> (accessed 04.07.11).

The Swedish Environmental Objectives Council, 2008. Sweden's Environmental Objectives – No time to lose. ISBN: 978-91-620-1266-3, pp. 121–127. <http://www.naturvardsverket.se/sv/Nedre-meny/Webbokhandeln/ISBN/1200/978-91-620-1266-3> (accessed 31.08.10).

Toy Industries of Europe, 2009a. Factsheet: The Scope of the 2009 Toy Safety Directive, October 2009. <http://ec.europa.eu/enterprise/sectors/toys/files/factsheets/scope_of_toy_safety_directive_en.pdf> (accessed 01.06.10).

Toy Industries of Europe, 2009b. Factsheet: The 2009 Toy Safety Directive, Provisions on Conformity and Safety Assessment, October 2009. <http://ec.europa.eu/enterprise/sectors/toys/documents/pdf/tie_ec_factsheet_casa_october_2009_final_en.pdf> (accessed 01.06.10).

Tsydenova, O., Bengtsson, M., 2011. Chemical hazards associated with treatment of waste electrical and electronic equipment. Waste Manag. 31, 45–58.