Nordic enforcement project on give-away products



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Report

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Definitions

CE marking	A legal marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing
CMR	Carcinogens, mutagenic (genotoxic) and reproductive toxicants that have such serious properties, which humans should not be exposed to. Theoretically, a single exposure to a very low dose (amount) can cause irreversible (permanent) damage. It can be hereditary mutations or damage to reproduction (on fertility or on the development of embryo / foetus / children) or injuries that can eventually develop into cancer
CLRTAP	Convention on Long-Range Transboundary Air Pollution
Code of Conduct	Guidelines for how a company or an organisation should conduct its business in an ethically, socially and / or environmentally correct manner
Distributor	Actor (natural or legal person) providing electrical and electronic products in one Nordic country, whom is not a manufacturer or importer
DoC	Declaration of Conformity
ECHA	The European Chemicals Agency
Economic operators	Manufacturers, importers and distributors, e.g. the companies controlled in the framework of this project
Enforcement authorities	In this project, it means the Nordic chemicals agencies
Flame retardants	Chemical compound that should protect goods from starting to burn
Internal control	Norwegian regulation according to which companies selling products in Norway need to have a legal quality insurance system.
ICSMS	Information and Communication System for Market Surveillance
Importer	Actor (natural or legal person) who places goods on the Union market from outside the EU
Manufacturer	Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark
Market surveillance authorities	In this project, the market surveillance authorities are the Nordic chemicals agencies.
NEG	Nordic Enforcement Group
NKE	Nordic Working Group for Chemicals, Environment, and Health
Nordic chemicals agencies	Kemiinspektionen (Swedish Chemical Agency), Tukes (Finnish Safety and Chemicals Agency), Miljøstyrelsen (Danish Environment Protection Agency), Miljødirektoratet (Norwegian Environment Agency), Umhverfisstofnun (Iceland Environment Agency)
Phthalates	Phthalates are used as plasticizers in plastic. Some phthalates have reproductive and environmentally harmful properties or may adversely affect the human body in another way.
Placing on the market	Delivery or provision to third parties, for payment or free of charge. Imports are considered to mean placing on the market
POPs	Persistent Organic Pollutants. Regulation EU 850/2004
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals. Regulation (EC) No 1907/2006
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user
Retailer	Actor who has suppliers within the country and sell articles to consumers or other actors within the same country
RoHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive 2011/65/EU
Safety Gate (previously RAPEX)	Rapid Alert System for dangerous non-food products / European platform to inform consumers and market surveillance authorities alike about dangerous products found on the EU/EEA market.
SCCP	Short Chain Chlorinated Paraffins
SVHC	Substance of Very High Concern
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market
Wholesaler	Actor who has suppliers within the same country and foreign suppliers and sells goods on the market
XRF	X-Ray Fluorescence

Summary

The Nordic chemicals agencies have jointly controlled the Nordic market of give-away products. 111 companies and 257 products (soft plastic gadgets, toys, EE-products, textiles, jewellery, batteries) were controlled. There were found in total 64 non-compliant products, i.e. 25 % of the total products controlled.

The products gathered from the Nordic market were controlled against the requirements in the following regulations and directives: REACH Regulation, Toy Safety Directive, RoHS Directive, POPs Regulation and the Battery Directive.

The analysis of the results showed that 35 % of the controlled toys and 12 % of the controlled EE-products were non-compliant due to the lack of CE-marking. We found 35 % non-compliant soft plastic gadgets, 25 % of non-compliant EE-products, and 17 % of non-compliant toys due to the content of chemicals in violation of the European chemicals legislation.

. 12 % of the controlled EEproducts were non-compliant

The Nordic chemicals agencies found phthalates and SCCP in toys and in soft gadget plastics, in addition to lead in metal solders and cadmium in EE-products and in toys. No chemicals in violation of the European chemical legislations for textiles and jewellery were found.

Our analysis of the results shows a lack of knowledge by economic operators. They lack understanding of the extent of their obligations and they are missing appropriate systems to comply with the rules. Nevertheless, the Nordic chemicals agencies have observed an interest from business organisations in the community to be better in understanding and complying with the applicable rules.

In this regard, it is of utmost importance that the companies selling giveaway products have internal procedures with a complete overview of the applicable chemicals legislations, as well as procedure to ensure that the company complies with these rules.

This joint enforcement project has contributed to better surveillance of giveaway products in the Nordic market, as well as creating closer collaboration between the Nordic chemicals agencies resulting in more data generated and better resource efficiency.

The project will also have a impact on the long-term collaboration between Nordic chemicals agencies with the help of mapping out the differences in carrying out market surveillance, as well as drafting best practices for surveillance in the Nordic countries (as well on how to best cooperate), written in the wake of this enforcement project. These two documents will be updated regularly so that we do our best to achieve the vision of the Nordic Council of Ministers who seek Nordic solutions wherever and whenever Nordic countries can achieve more together than on their own.

Preface

The Nordic Enforcement Group

The chemicals agencies in the Nordic countries have for many years worked together on enforcement projects to ensure greater impact and to obtain a better understanding of common EU legislation in the field of chemicals. The agencies also learn to carry out more effective market surveillance as a result from the exchange of information and experiences during these projects.

Joint enforcement projects, like this one on give-away products, are driven by the Nordic Enforcement Group (hereafter NEG), a subgroup under the Nordic Chemicals Group under the Nordic Council of Ministers. The main purpose of the NEG is to exchange experience on control and enforcement of the European chemicals legislation and to prepare and carry out common enforcement projects.

In June 2017, the NEG applied to the Nordic Council of Ministers for a joint enforcement project on the market of give-away products to be carried out in 2018 and completed in 2019. Give-away products are products used by companies for marketing purposes. They put their trademark and/or logos on a wide range of products (from toys, to electronic products), so-called give-away products, which are meant to be distributed for free to consumers.

"Give away products are broadly used as a way of marketing brands, trademarks and companies in the Nordic market. These articles are often cheap products with poor quality and they are not intended to be used over a long period of time."

The Norwegian Environment Agency has been the project leader and the representatives from Norway are Loella Bakka, Ingvild Kvien and Mathieu Veulemans. Participants from the other Nordic countries in the project group have been Karin B. Sorensen from the Danish Environmental Protection Agency, Charlotte Rahm and Camilla Westlund from the Swedish Chemicals Agency, Tiia Salamaki from the Finnish Safety and Eirikur T. Baldursson and Isak Sigurjon Bragason from the Environment Agency of Iceland.

Why do a joint enforcement project on give-away products?

Give away products are broadly used as a way of marketing brands, trademarks and companies in the Nordic market. These articles are often cheap products with poor quality and they are not intended to be used over a long period of time. The manufacturer, often located outside of the EU/EEA, delivers the products to a supplier who further customise them with trademarks or logos and then offer them to companies. The marketing for these products is therefore done by the suppliers, not the manufacturer.

It is worth noting that companies that distributes give-away products to promote themselves are encompassed by the European legislation and have clear obligations as distributors. Companies that distribute give-away products are considered distributors as defined in the European legislation as the concept of "distribution" also includes the distribution of products without compensation, i.e. for free. The obligations of distributors (as well as the obligations of other economic operators) are described in Appendix 2.

In 2017 Norway had an extensive surveillance campaign with focus on give-away products such as small electronics (mainly flashlights and USB flash drives), soft plastic products (beach balls, reflectors, etc.) and other products were part of this important surveillance project, where about 80 Norwegian companies were controlled.

The results of the Norwegian surveillance showed that 77 % of the give-away products controlled had no or incorrect labelling and that 43 % contained dangerous substances in conflict with the applicable legislations. At the April 2017 meeting of the NEG in Stockholm, it was decided to carry out a joint enforcement project that focused on give-away products. None of the other Nordic countries had carried out a specific enforcement project on give-away products before, and all the Nordic countries saw the benefits of doing it in the framework of a joint enforcement project.

The market for give-away products

The market for give-away products has some specific features, described below:

- Most of the give-away products controlled in this joint enforcement project are manufactured in China.
- Some of the give-away products, especially jewellery with a known brand, are manufactured in the Nordic countries.
- The top of the national supply chain usually consists of a few big importers selling to the same retailers.
- These companies often use online platforms and catalogues, which can be common to several importers and retailers.
- Many companies advertise give-away products on their websites, including articles that are not necessarily sold.
- Several companies operate throughout the Nordic countries.
- The give-away products are delivered on demand.
- Many give-away products are delivered from outside EU/EEA to a few big warehouses often located in Eastern European countries, and then shipped to the Nordic countries
- Some of the give-away products are delivered directly from the warehouses in Europe to the customers.

EU Regulations controlled in the framework of this project

The European legislations that have been controlled in the framework of this project are described below.

REACH Regulation EC 1907/2006

The REACH Regulation is the chemical legislation that has replaced large parts of the chemical regulations that applied before June 1, 2007 in the EU. The REACH Regulation stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. The regulation primarily covers chemical substances and mixtures of chemical substances, but a few provisions also apply to articles.

Substances on the Candidate List	Substance on the authorisation list	Substance on the restriction list
Some of the chemicals are assessed to be Substances of Very High Concern (SVHCs)	Some of the chemicals in the production of articles can be used only when authorised by the European Chemicals Agency (REACH Annex XIV)	Some of the chemicals cannot be used in articles, unless used under a certain concentration or for special use (REACH Annex XVII).
Article 33 of the REACH Regulation contains information requirements linked to hazardous substances in articles. Article 33 describes suppliers' obligations to provide sufficient information to allow the safe use of the hazardous substances contained in their articles in excess of 0.1% by weight. This information should always be provided to professional users, while consumers are entitled to receive the information free of charge within 45 days		In REACH Annex XVII, there are several restrictions entries, of which several restrict the use of substances in certain articles.
In this project, give-away products were analysed for some of the substances on the Candidate List and the focus was mainly on phthalates.		In this project, we have not focused on a specific entry in Annex XVII, but adapted the analyses based on which product we requested.

POPs Regulation EC 850/2004

The European Regulation on Persistent Organic Compounds is based on the Global Stockholm Convention and the Convention on Long-range Transboundary Air Pollution (CLRTAP). The regulation contains a number of Persistent Organic Pollutants (POPs), which are considered very dangerous for human health and the environment. Articles must not contain the substances listed in the regulation, such as hexachlorobenzene, short-chain chlorinated paraffins (SCCPs) and certain brominated flame retardants.

RoHS Directive EC 2011/65

The RoHS directive (Restriction of use of certain Hazardous Substances in Electrical and Electronic Equipment) is an EU-wide regulatory framework that limits the presence of certain hazardous substances in electrical and electronic products. The limiting substances are lead, cadmium, mercury, hexavalent chromium and two groups of brominated flame retardants, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs).

Toy Safety Directive EC 2009/48

The Toy Safety Directive contains, among other things, certain specific chemical requirements: restrictions on CMR substances, certain allergenic fragrances and metals. The directive also contains rules on how a technical documentation for toys should be designed. It is the manufacturer who is responsible for producing technical documentation. Importers and distributors must ensure that the manufacturer has made the documentation available to them and that it is correct. The Toy Safety Directive has been introduced in the Nordic countries' national legislations. Some toys are classified as chemical products according to the chemical legislation and are therefore subject to special rules. Examples of toys that are chemical products are slime, soap bubbles, crayons, pens, paint and modelling clay.

Battery Directive EC 2006/66

The Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators, commonly known as the Battery Directive, regulates the manufacture and disposal of batteries in the EU/EEA. Batteries commonly contain hazardous elements such as mercury, cadmium and lead, which when incinerated or landfilled, present a risk to the environment and human health.

The Battery Directive:

- · Sets maximum quantities for certain chemicals and metals in certain batteries.
- Sets our rules covering labelling, marking, documentation and reviews.
- Sets out clear obligations to economic operators in the supply chain.



Close collaboration between the Nordic chemicals agencies

Joint Nordic enforcement projects contribute to ensure:

- · A uniform application of the EU legislation in the Nordic countries.
- A closer cooperation between market surveillance authorities in the Nordic countries.
- The exchange of information and experience.
- A bigger impact by coordinating surveillance of the same market segment throughout the whole Nordic market.

An important focus in this project was to ensure a very close collaboration between the Nordic chemicals agencies. We wanted this close cooperation to be efficient, and contribute to higher efficiency. This is why we decided to:

- Share the experience from the Norwegian enforcement project (sharing the results, check-lists, letters, presentations from seminars, way to proceed).
- Exchange the list of companies to be controlled in the framework of the project.
- Exchange the list of products to be controlled in the framework of the project.

These simple and practical measures allowed us to avoid unnecessary controls of the same companies operating across the Nordic countries.

The same has been achieved by exchanging the list of products to avoid testing of the same products from the same manufacturers by two or more market surveillance authorities in the Nordic countries.

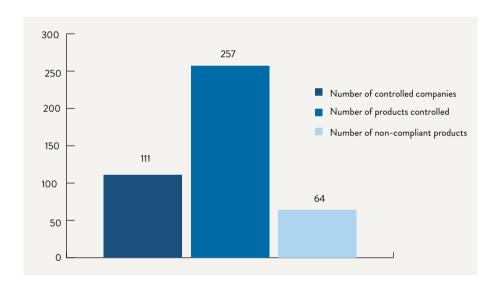
Because of the clear benefits from these three measures, the NEG decided to apply these measures to other parallel enforcement projects as well. The NEG is positive to regularly inform about planned controls and to exchange information on companies between the Nordic chemicals agencies, so we can ensure an effective cross-border surveillance.

We shared information by using the Nordic Sharepoint, which proved to be very efficient. The use of regular but short Skype meetings was also seen as very effective by the participants, in addition to reducing travel expenses and the carbon footprint of the project.

The results of the joint enforcement

This part of the report provides the aggregate results of this joint enforcement project. Please consult Appendix 1 for more detailed information about the results of the national campaigns.

Figure 1: General overview of the results of the joint enforcement project. The number of noncompliant products encompasses both non-compliance regarding the labelling as well as the content of chemicals



The role(s) of the companies controlled

The EU regulation differentiates clearly between different roles, which companies (economic operators) may have. Companies can be manufacturer, importer, or distributor, but they can also have several of these roles at the same time.

Importers or distributors who are selling products under their own trade mark/brand are considered by the European law as manufacturers, i.e. they have the same obligations as a manufacturer have. The reasoning behind this rule is that by affixing a trade mark/brand on products, companies are signalling to customers that the products are "their products". Therefore they are considered as manufacturers.

In the figure below there is an overview of the distribution of the type of roles the companies we controlled had. For those companies that had multiple roles, our goal was to count only the highest one it had in the supply chain (manufacturer > importer > distributor).

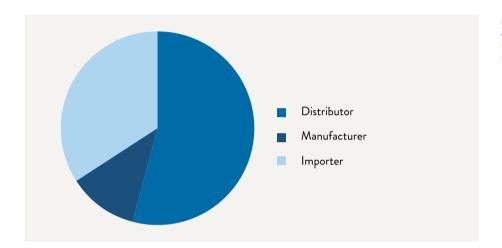


Figure 2: Overview of the companies controlled in relation to their legal role as defined in the European legislation

Overview of the type of products controlled

Give-away products cover a wide range of products. In this joint enforcement project, we tried to cover a wide range of products. Therefore we did control several product categories, such as EE-products, soft plastic gadgets, toys, textiles and other products (among others jewellery, batteries, products with hard plastic).

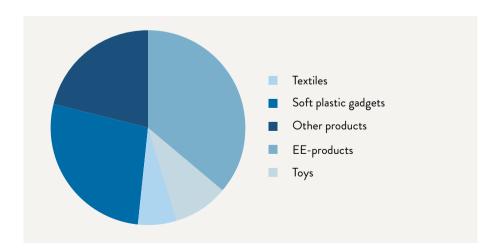
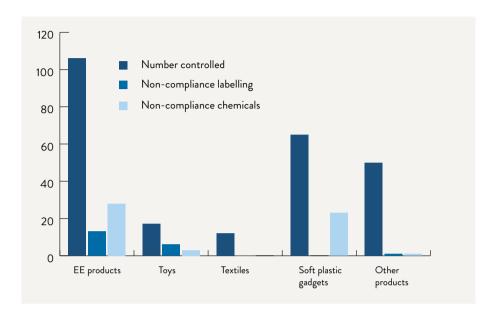


Figure 3: Overview of the type of products controlled

General overview of non-compliances per type of products

Figure 4: General overview of noncompliances per type of product



The non-compliance for labelling encompasses cases where the Nordic chemicals agencies found EE-products and toys that lack the CE marking. According to European law, EE-products and toys which are not CE marked cannot be distributed on the EU/EEA market.

The results show the following: 35 % of the controlled toys were non-compliant because they lacked CE marking. 12 % of the controlled EE products were non-compliant because they lacked CE marking.

There is no doubt that CE-marking should be affixed when required by law, i.e. for toys and EE-products. The high percentage of non-compliance of CE-marking may be due to the fact that companies selling give-away products will spare place to affix the logos or trade-marks/brands on the give-away products.

The non-compliance regarding the content of chemicals can be summarised as follows:

- 35 % of soft plastic gadgets were non-compliant due to the content of chemicals.
- 25 % of the controlled EE-products were non-compliant due to the content of chemicals.
- 17 % of the controlled toys were non-compliant due to the content of chemicals.
- 2 % of the other products were non-compliant due to the content of chemicals
- There were not found any non-compliances regarding give-away products made of textile.

More detailed overview of the non-compliances regarding chemicals

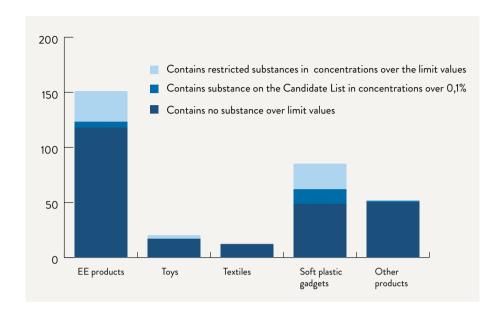


Figure 5: Detailed overview of non-compliance due to the content of chemicals

The content of chemicals in products is regulated by several European legislations (described in part 2 of the report), depending on the type of products. Chemicals in articles can be part of two different categories: Candidate List substances or restricted substances, depending on the product category.

The chemicals used can be regulated differently depending on which articles they are used in. For instance, phtalates are restricted in toys (Annex XVII of REACH, entry 51 and 52), but only listed in the Candidate List when used in soft plastic gadgets. It is also important not to forget the Persistent Organic Pollutants (regulated by the PoP-regulation, among others SCCP).

In the framework of this enforcement project we found the following chemicals in violation of the applicable EU chemicals regulation.

Product types	Chemicals	Chemicals regulated by	Products regulated by
Soft plastic gadgets	Phtalates	REACH Substances on the Candidate List (SVHC)	REACH, POP
	SCCP	POP	
Toys	Phtalates	REACH Annex XVII entry 51 and 52	Toy Safety Directive
	Cadmium	REACH Annex XVII entry 23	
EE-products	Lead	2011/65/EU	RHOS
	Cadmium	2011/65/EU	

The Nordic Chemicals Agencies did not find:

- Azo dyes in textiles in violation of the applicable regulation
- Cadmium and mercury in batteries in violation of the battery directive
- Chrome VI in EE-products.



Analysis of the results

Lack of knowledge by economic operators

Based on the controls carried out in this project, our assessment is that on average companies selling give-away products have little knowledge of the applicable regulations. This lack of knowledge includes both the requirements to chemicals and the extent of companies' responsibility according to European law.

Regarding the knowledge of the requirements, our assessment is that many companies are aware of the REACH Regulation, but not aware of the whole set of legislations. Companies have especially lack of knowledge of the POPs Regulation.

The joint enforcement also showed that only in few cases, the manufacturers of the give-away products provide information on SVHCs (Substances of Very High Concern on the Candidate List) when in a concentration over 0,1%. In other words, few companies are aware of the rules regarding SVHCs.

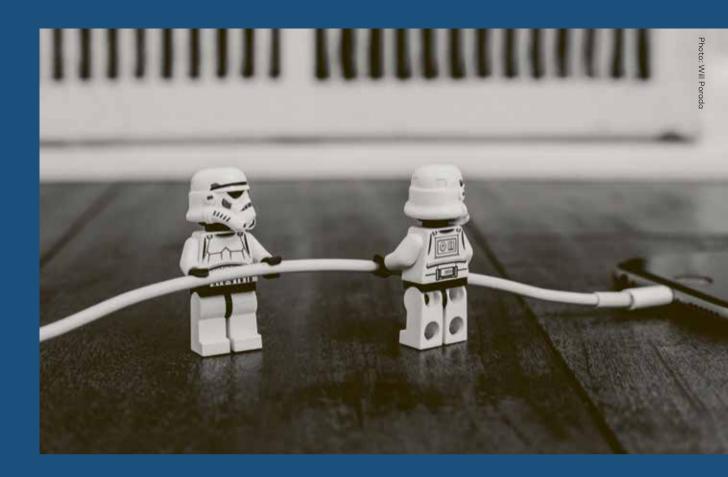
Economic operators lack understanding of the extent of their obligations

The controlled companies are not fully aware of the extent of the obligations that falls on them. The extent of obligations depends upon which role companies have. These obligations are listed in Appendix 2. Some of the economic operators are not aware that they have to conform with the applicable legislation. This especially applies to the importers or distributors that should be considered as manufacturers as they affix their trade mark or brand on the product. This includes ensuring the necessary technical documentation, to draft the Declaration of Conformity in its own name and to affix the CE marking, and upholding its guarantee, on the give-away products.

"Based on the controls carried out in this project, our assessment is that on average companies selling give-away products have little knowledge of the applicable regulations."

Furthermore many companies selling give-away products market these products through catalogues available on-line. Many of these products are not in stock, because they will be delivered on demand. Many of these companies are not aware that all the products that they make available in these catalogues are being made available on the market. The companies should therefore be able to demonstrate the compliance of these articles with the applicable legislation, even when these product are not ordered by the customers.

We have observed that companies selling give-away products often ordered products from their suppliers on behalf of their clients, and the products are



delivered directly to the customers. This implies that companies ordering the products for their customers do not necessarily have the possibility to physically check the products before delivery to the customers. This fact cannot impact the obligations they have either as importers (if the products are directly delivered from suppliers from outside EU/EEA) or distributors (if the products are directly delivered from suppliers from within EU/EEA). Companies selling give-away products which are delivered directly by suppliers to the clients need to ensure that the products are in compliance with the applicable legislations.

Companies that distribute give-away products in order to promote themselves are not aware of the obligations they have. These companies are considered distributors with clear obligations to ensure that the give-away products are in conformity with the European chemicals legislation and to take necessary measures if they are not met.

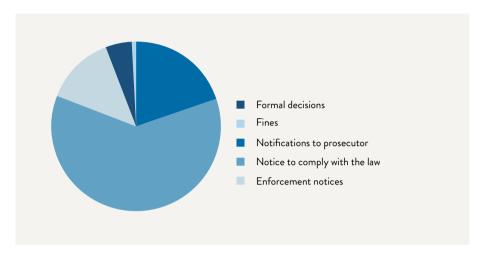
Lack of appropriate system to comply with the rules

Companies focus on having internal procedures (i.e. codes of conduct), which is a way for them to ensure compliance with the rules. However, these codes of conducts often do not cover the EU-legislation, and when they do, they are too general. There are for instance often no distinctions between the Candidate List and restrictions. Based on these internal procedures, companies accept reports from their suppliers with "REACH Pass. Ok". This is not sufficient to ensure a control by the importers that the products are in compliance with the applicable European chemicals legislation.

Sanctions

General overview of the sanctions used

Figure 6: General overview of reactions used for each controlled product



The general overview of the sanctions shows that in most cases, companies which were controlled took the necessary corrective actions when made aware of the non-compliances encountered.

The enforcement actions depend on the national legislation that the enforcement authority is required to comply with. The controlled companies are made aware of the non-compliances through two methods, either through a "notice to comply with the law" or through an "enforcement notice".

The purpose of "notices to comply with the law" and "enforcement notices" is the same: To make the companies aware of the non-compliances and requiring them to take corrective actions. The difference between the two instruments lies in their formal character. Notices to comply with the law are not considered as a formal proceeding. They only point out that the law requires the economic operators to comply with the rules, and in that context, it should be sufficient to point it out to oblige the economic operators to comply with the rules (because the obligation to comply with the law already lies in the law).

There is in other words no need to adopt a decision to oblige companies to comply with the law. Enforcement notices are formal proceedings to be taken prior to any decisions.

Corrective actions taken by the economic operators

On a general basis, when the companies are made aware of the noncompliances and the corrective actions to be taken they do implement them as instructed. The companies must inform the national enforcement authorities of which actions they have taken. They must also send documentation that confirms that the described actions are taken.

Corrective actions can for instance be the following:

List of corrective actions	Used in these cases:
Affixing or requiring the supplier to affix CE marking (if conditions for affixing the CE marking are met)	Lack of labelling
Sales ban	Missing CE marking and/or unlawful content of chemicals
Information to customers (including cases where companies using give-away products to promote themselves need to inform the consumers)	Unlawful content of chemicals
Withdrawal from the market (i.e that the products should be withdrawn from the supply chain (manufacturer-importer-distributor))	Unlawful content of chemicals
Recall (i.e that the products should be recalled from consumers)	Used in one case due to unlawful content of chemicals
Other corrective actions such as updating code of conducts, internal control systems, updating information on the products, ensuring that the next batch of products is in conformity with the applicable legislations	Minor shortage in internal control system/code of conduct. Minor failures of the products. Failure to ensure that information about the importer's name and contact addresses are affixed on the products.

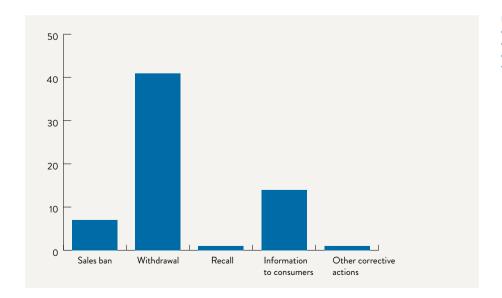


Figure 7: Overview of the corrective actions taken by companies after being made aware of the non-compliances and which reaction they needed to take

The results of the joint enforcement project show that withdrawal was more used than sales ban. This is the usual way of enforcing articles in several Nordic countries. This can also be explained by the fact that give-away products are distributed on demand based on a catalogue (on demand of the companies that wish to use give-away products to promote themselves), and are therefore not necessary in stock. When in stock, the unlawful products were subject to sales ban.

Many companies had to contact their customers and ask them to send back the non-compliant articles so that they could be properly destroyed. Giveaway products are mostly distributed as the consumers received them, so very few customers had any items left.

One recall from consumers was ordered by the Icelandic Environment Agency.

Fines and prosecution

In addition to these corrective actions, enforcement authorities did to a lesser extent impose fines and initiate prosecution. These forms for reaction are so-called penalties and are enforced according to and based on national legislations, proceedings and guidelines. Not all the Nordic chemicals agencies have a legal ground to impose fines and there are different practices regarding prosecution. It was imposed one fine in the framework of this project, by the Swedish Nordic Chemicals Agency.

The thresholds to submit cases for prosecution may vary within the different Nordic countries. Only the Swedish Chemical Agency submitted cases to the prosecutor (according to their internal guidelines).

ICSMS and Safety Gate

ICSMS is the Information and Communication System on Market Surveillance. It is an IT platform to facilitate communication between market surveillance bodies in the EU and in EFTA countries. It quickly and efficiently shares information on non-compliant products, avoids the duplication of work, and speeds up the removal of unsafe products from the market.

A goal of the joint enforcement project was to anchor the use of ICSMS. The exchange of information prior to the campaign (sharing the burden of control of the companies that operates cross-border in the Nordic countries) reduced to some extent the utility of using ICSMS as a platform to enhance cooperation between the Nordic chemicals agencies. However, 27 cases were notified in ICSMS to inform the other enforcement authorities in EU/EEA.

Every day the European Commission receives, through the rapid alert system for dangerous non-food products - "Safety Gate" (previously RAPEX), alerts from national authorities in the EU/EEA concerning dangerous products found on their markets. These alerts include information about the type of products found, the risks posed, and the measures taken at national level to prevent or

restrict their marketing. In the framework of the project 12 cases were notified through the Safety Gate.

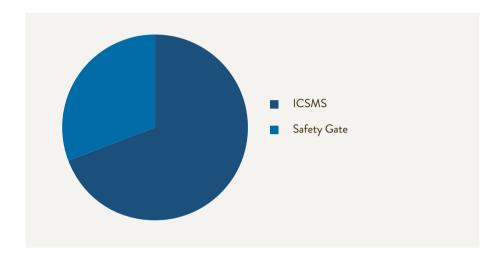


Figure 8: Overview of the cases submitted to ICSMS and to the European Safety Gate (previously RAPEX)



Different means to achieve the same goal

National legislations regarding enforcement

Enforcement is crucial to ensure the compliance with the European rules and to ensure the protection of the health of citizens as well as well as the protection of the environment. It also ensures a level playing field for the economic operators by ensuring that as many companies as possible comply with the rules. The basic rules of market surveillance are harmonised by Regulation (EC) 765/2008.

However, it is the responsibility of the national authorities to decide how to ensure the best possible surveillance by deciding how to organise surveillance (by sector or horizontally), how much resources which will be reserved to it, but also to which extent complementary national legislations national authorities are appropriate or necessary.

In the framework of this joint enforcement project we have not observed any significant differences in the national enforcement legislations, which could lead to distortion of competition because companies would tend to locate in a specific Nordic country due to different enforcement legislation (so-called forum shopping).

We have observed differences in the national legislations concerning the possibility for the enforcement authorities to give fines, the possibility to claim testing expenses from the controlled companies or related to the application of the legislation (guidelines for submitting cases to prosecutors). However, we have no ground to affirm that these differences would contribute to any kind of forum shopping.

A mapping out of differences between the different national legislation in the wake of this report could be used by the Nordic chemicals agencies to argue for the use of more uniform enforcement instruments. Some of the discrepancies in the national enforcement legislation will be addressed by the proposal for a new regulation for market surveillance, and it is worth trying to ensure a uniform application of the new market surveillance regulation.

National legislation regarding Internal Control Regulations

Enforcement is of utmost importance for compliance, but it should not be forgotten that economic operators have the primary responsibility for complying with the applicable rules.

In Norway a specific national legislation, known as the Internal Control Regulation, which relates to systematic health, environmental and safety activities in enterprises, obliges all the relevant companies to have an internal control system (a kind of quality system) to ensure that they comply with the

applicable rules regarding health, environment (including European rules on chemicals) and security. The Internal Control Regulation emphasise that the main responsibility lies with the companies to comply with the rules to ensure a safe working environment, the prevention of damage to health or disturbances to the environment from products or consumer services and the protection of the external environment against pollution.

The internal control systems that companies must have, includes the following elements:

- Make sure the relevant acts and regulations in the field of health, environmental and safety legislation that apply to the enterprise are available. The enterprise also needs to hold an overview of the specific legal requirements that is relevant for the enterprise.
- 2. Employees shall have sufficient knowledge of and proficiency in systematic health, environmental and safety activities, including information on changes made.
- 3. Employee participation so as to utilise overall knowledge and experience within the enterprise.
- 4. Set out health, environmental and safety objectives.
- 5. Overview of the enterprise's organisational set-up, including allocation of responsibilities, duties and authority in regard to the work on health, the environment and safety.
- 6. Identify dangers and problems and assess the potential risks, in addition to draw up preventive plans and measures to reduce such risks.
- 7. Implement routines to uncover, rectify and prevent breaches of requirements established in or pursuant to the health, environmental and safety legislation.
- 8. Carry out systematic surveillance and reviews of the internal control system to ensure that it functions as intended.

Obligations covered by points 4 to 8 shall be documented in writing (written procedures). Obliging companies to have written routines is an appropriate way to facilitate compliance with the rules. We can draw a parallel with the code of conduct that many companies have on a voluntary basis in other countries which similarly facilitates compliance with written procedures. However, having the internal control integrated in the legislation ensures that the code of conducts/internal control system are completed and detailed enough.

For detailed information about the Internal Control Regulations, please consult https://www.arbeidstilsynet.no/contentassets/cf0737ad44a8497a8058731c-64cef64f/internal-control-regulations.pdf.

Effect of the project and way forward

First of all, we have observed improvement in terms of compliance from companies that were previously controlled in 2017 (as part of the Norwegian enforcement project) in terms of better compliance with the requirements. The joint enforcement project tends to show that surveillance has a positive and long-term effect on the compliance level of the controlled companies.

Both during and after the project there has been a huge interest at national levels for the control of give-away products. Activities such as information letters, conferences and seminars were carried out to inform actors in the give-away industry and it contributed to greater awareness of the legal requirements for this market segment. The industry was eager to learn more about the applicable chemical legislations and how to comply with them. This shows that the project not only uncovered important non-compliances from the controlled companies, but it also raised important awareness and enhanced the knowledge of compliance levels in an entire Nordic industry.

The results sparked a lot of interest among the industry in Finland, Sweden and Norway and not only were they presented at events by the Swedish and Norwegian chemicals agencies but they were also presented at several other events organised by business organisations (Sweden and Norway) and commerce federations (Finland).

"We do feel we have contributed to enhancing the knowledge and compliance level to a whole market segment in the Nordic countries."

It is important to raise awareness of these issues among companies and consumers alike in order to try to achieve a high level of protection of the consumers' health as well as the protection of the environment. Therefor the results of the campaigns were published by the Nordic chemical agencies and the results of this joint enforcement project were published by Bloomberg¹ and Chemical Watch², in addition to many national news publications.

To enhance attention of companies and consumers by publishing the results of market surveillance is an important part of the market surveillance activities. By doing this we try to extend the effect of the campaign by raising attention to both the industry but also to consumers.



In line with the practices at national level, the results of this joint enforcement project will be used to decide how the results of the campaigns should be followed up. The Norwegian Environment Agency will pursue its campaign throughout 2019 in order to achieve the follow-up of companies controlled in 2017. The Swedish Chemical Agency are planning to do a follow-up campaign on these products in 2021.

It is always important to carry out random checks to verify if companies that has taken voluntary actions have implemented these actions to the extent that the company describes, but also that these actions are not limited to the case at hand but are incorporated in the company's quality system or code of conducts so that the controls has the right impact on the companies.

 $\underline{\text{https://news.bloombergenvironment.com/environment-and-energy/nordic-nations-warn-of-swag-danger}}$

https://chemicalwatch.com/register/result?o=74581&layout=main&productID=1

¹"Nordic Nations Warns of Swag Danger"

^{2&}quot;Nordic inspections find phthalate, SCCPs in give-away items"

Our advice to companies

The Nordic chemicals agencies have been in contact with business associations either prior or after the joint enforcement project. We have observed that business organisations knew they did not know much about the applicable rules, but that they showed an interest to learn more about them. In other words, they are interested in doing better. In that context we have the following advice to companies and business organisations.

It is important for companies to communicate requirements for chemical content and inform their suppliers about these in order to have a functioning system for controlling chemicals in products. Sometimes it can be difficult to get the right kind of documentation from suppliers about the content of chemicals in products. Furthermore, several companies have described integrating the chemical requirements with other quality requirements as a successful way of ensuring compliance. In this way, the purchasing functions of the company are also involved in the chemicals requirements.

In the project we have encountered different types of agreements with suppliers regarding chemical requirements for products. In some cases, the agreements were generic and did not specify in detail the demands. BSCl's code of conduct (Business Social Compliance Initiative) was mentioned on several on-site inspections. However, this code of conduct does not point out specific chemical requirements.

Since the REACH Regulation contains many different parts, a code of conduct should be supplemented by an annex describing the chemical requirements in detail. It is also important to address all relevant legislation, the rules in the POPs regulation are often forgotten. A written agreement or certificate on chemical compliance does not disclose the companies from the responsibility that the contents of the articles must comply with the applicable legislation.

Spot check controls are a relatively simple way to monitor purchased products and the results should be used to ensure that the products are in accordance with what the company has ordered. The companies can also check whether the suppliers themselves perform spot check analyses and whether they can take part of the results or have this as a requirement for the supplier. Some companies in the project had this kind of internal procedures, and this measure is especially a good argument in the claim for chemical compliance.

It is important to have written, explicit procedures that describe the work to meet the requirements of the legislation and in Norway it is actually a legal requirement. To meet the requirement of Article 33 of the REACH Regulation, on substances of very high concern (SVHCs) in articles, it is required that those who sell articles have received information on SVHCs from their supplier. This is especially important if the goods are purchased from countries outside the EU/EEA because that supplier is not bound by any legal requirement to provide the

information. Another possibility is to agree with the supplier that the articles should not contain any substances on the Candidate List at all. It is important to know that substances on the Candidate List are substances that are candidates to be included on the authorisation list and that any substance or article could be subjected to the restriction process in the future.

Companies that distributes give-away products in order to promote themselves should be aware of their role (distributors) and of their obligations:

- · Act with due care in relation to the requirements
- Verify that the product is in conformity. In order to achieve conformity, check
 if the product needs to have markings, specific documentation set out in the
 relevant legislation, use instructions or safety information. Also make sure that
 this information is in a language which can be easily understood by consumers
 and other end-users in the Member State in which the product is to be made
 available on the market
- Refrain from making the product available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the companies shall inform their supplier (the manufacturer or importer) to that effect as well as the enforcement authorities
- Ensure safe storage and transport conditions
- Take corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities
- Collaborate with enforcement authorities

Many of the articles inspected contained some of the substances DEHP, BBP, DBP or DIBP at levels above 0.1%. These substances are on the Candidate List and recently also regulated in the RoHS directive. By July 7th 2020, these phthalates will also be restricted under REACH (under 0.1 % w/w) in consumer products. In order to ensure that these rules will be followed, companies whose articles contained one of these substances require more stringent and more specific requirements for their suppliers and ensure that their suppliers comply with the requirements.

In order to get information about the rules that apply, companies can search for information on the European Chemicals Agency (https://www.echa.europa.eu/), with trade organisations or with other companies. For in-depth knowledge of the REACH Regulation, the ECHA website provides guidance on the requirements of the REACH Regulation for articles.

In addition, by subscribing to the Nordic chemical agencies newsletter, it is possible to get updates on new rules, supervision projects and other things that are underway in the chemical field. Some companies also have services where they offer updated team lists adapted to the company's needs.

"It is important for compagnies to communicate requirements for chemical content to their suppliers."

https://echa.europa.eu/ regulations/reach/candidatelist-substances-in-articles/ notification-of-substances-inarticles

https://echa.europa.eu/ regulations/reach/candidatelist-substances-in-articles/ communication-in-the-supplychain

Conclusion

The results show that it was necessary to control the market for give-away products in the Nordic countries.

In our view, the level of knowledge of the companies operating in the Nordic market for give-away products has been greatly improved by this joint enforcement project. This is a prerequisite for ensuring a better compliance with the applicable European chemical legislation.

The project also focused on better cooperation between the Nordic chemical agencies both in the framework of this campaign and by applying some of the actions taken in this project at the level of the NEG. Some of the simple measures used in this joint enforcement project were:

- Exchange of information of companies to be controlled by the different Nordic chemical agencies
- Based on that, sharing of control efforts between the Nordic chemical agencies
- Exchange lists of products to be tested in order to avoid double testing and to avoid the risk of controlling the same manufacturers several times.

These measures should be implemented as good practices within the NEG.

We have also discussed the differences in the respective procedures used by the different chemical agencies. These differences are a source of inspiration for the Nordic chemicals agencies as it allows all the Nordic chemical agencies to use methods that have been successfully tested by other Nordic chemical agencies.

Combined with the measures used to ensure closer cooperation between the Nordic chemical agencies, we have drafted some best practices. We will continue to update these best practices based on the exchange of experience, inspector exchanges, and other enforcement projects, to have a solid base for a fruitful and effective cooperation between the Nordic chemical agencies. These best practices are not enclosed in this report, but is only accessible to the NEG, its members, as well as the Nordic Council of Ministers.

It is our opinion that the project was therefore fully in line with the mission of the Nordic Council of Ministers, which is to seek Nordic solutions wherever and



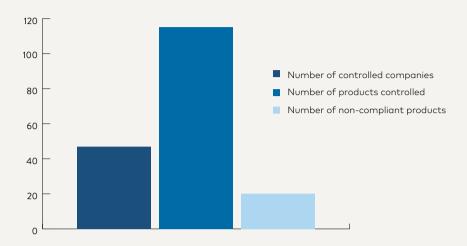
whenever the countries can achieve more together than by working on their own. We are of the opinion that in this project we have achieved much more by joining forces and carrying out the surveillance of give-away products available on the Nordic market. We have used simple measures endorsed by the NEG to better coordinate our efforts and used our resources in a more efficient way. We have also had a greater impact by joining forces and carried out controls throughout all the Nordic countries.

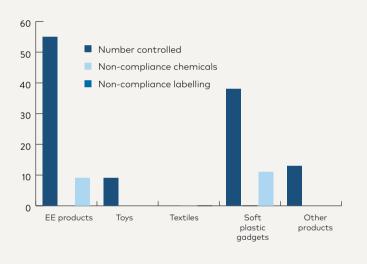
The enforcement of the European chemicals legislation and the closer cooperation between the Nordic countries will of course continue beyond the publication of this report, but we are confident that the project and this report have contributed to greater cooperation between the Nordic chemical agencies.

"In our view, the level of knowledge of the companies operating in the Nordic market for give-away products has been greatly improved by this joint enforcement project."

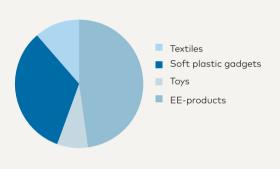
Appendix 1 Results by country

SWEDEN

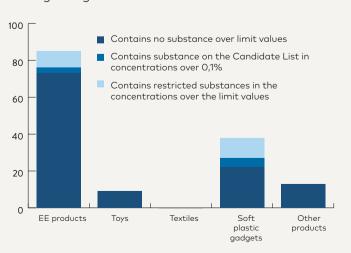




Products controlled



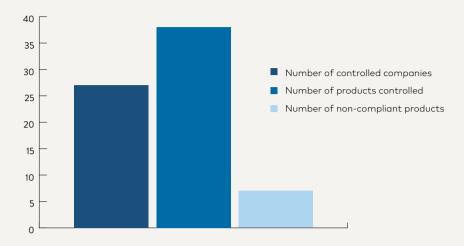
Regarding content of chemicals

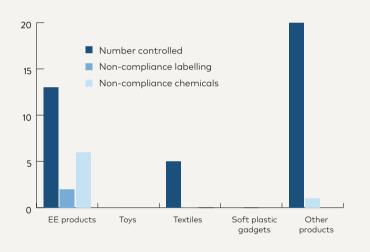


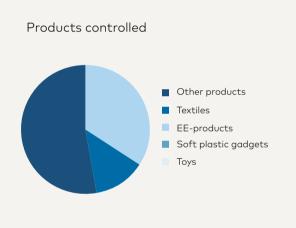
Type of companies controlled

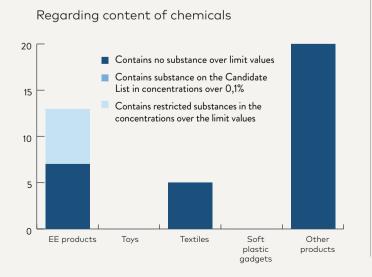


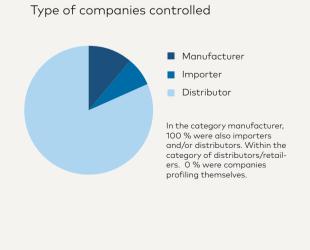
FINLAND



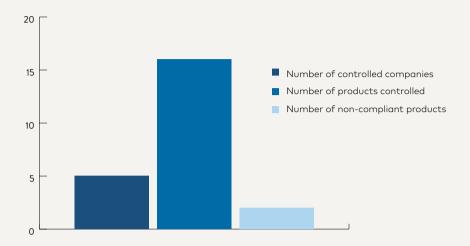


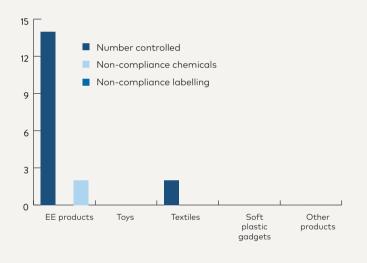




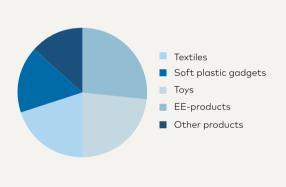


DENMARK

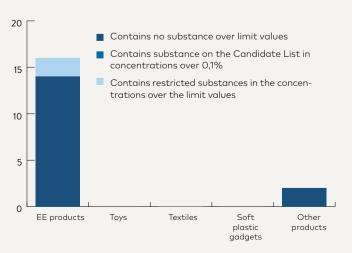




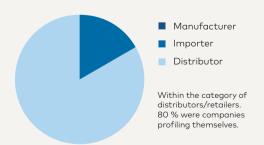




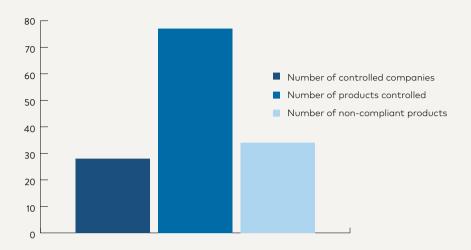
Regarding content of chemicals

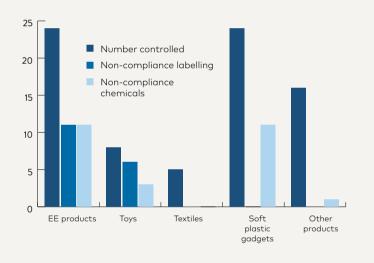


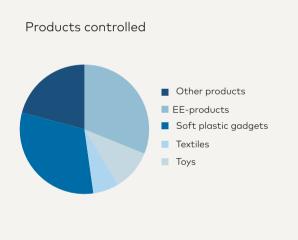
Type of companies controlled

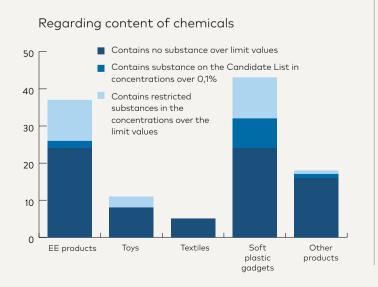


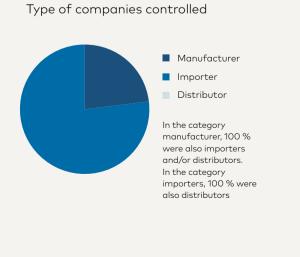
NORWAY



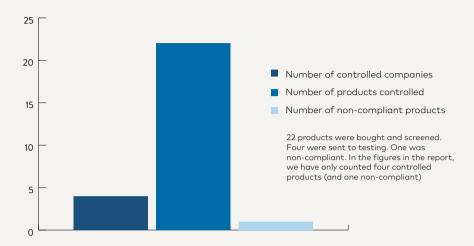


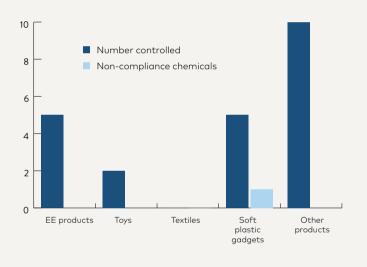


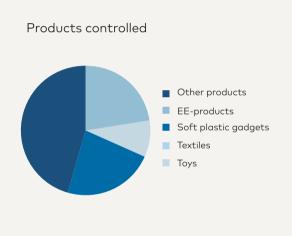


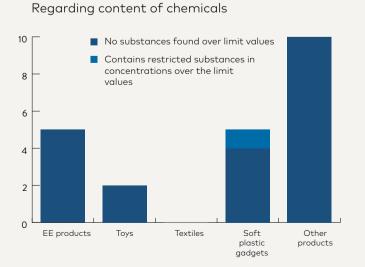


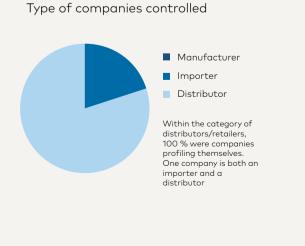
ICELAND











Appendix 2 Obligations of economic operators

Manufacturer's responsibility

Produce technical documentation.

Provide the finished product with CE marking after checking that all RoHS requirements are met

Draw up an EU Declaration of Conformity (DoC).

Provide the finished equipment with identification marking (eg item number or batch number).

Enter the company name, postal address and a contact address on the finished equipment, or if not possible, on the packaging or in an accompanying document.

Importer's responsibility

Make sure that the product meets the requirements of the RoHS directive and make changes or improvements if required.

Ensure that the manufacturer has prepared the technical documentation, that the product is CE-marked and that sufficient documentation is available and that the manufacturer's contact information is available.

Enter the company name, postal address and a contact address on the finished equipment, or if not possible, on the packaging or in accompanying documents.

Hold and save the EU Declaration of Conformity (DoC) ten years after the individual product has been placed on the market.

Distributor's responsibility

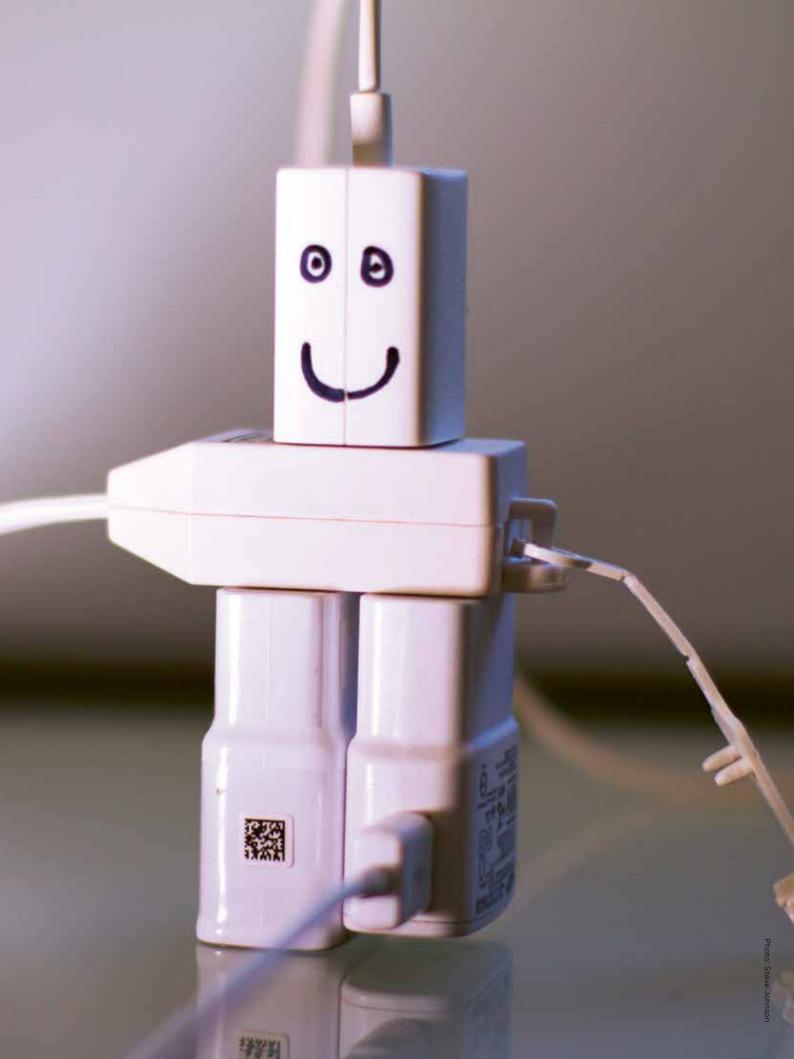
Make sure that the product meets the requirements of the RoHS directive and also make changes or improvements if required.

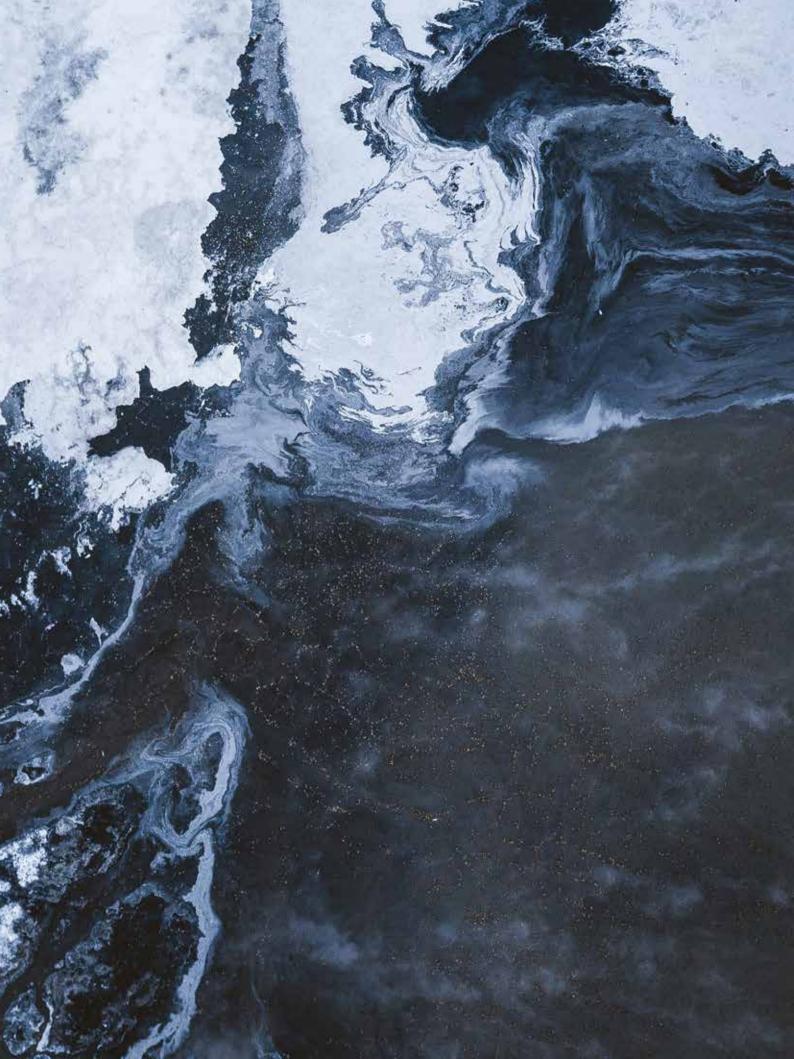
Ensure that the products have CE marking and identification marking, and the name and postal address of the manufacturer and importer.

Be able to show all relevant information and documentation if the supervisory authority so requests.

Appendix 3 Substances looked for and in which material

Substance	Example of material	Limit value and legislation (observe that some substances can be limited in other legislations as well
DEHP CAS: 117-81-7 DBP CAS: 84-74-2 BBP CAS: 85-68-7 DINP CAS: 28553-12-0 and 68515-48-0 DIDP CAS: 26761-40-0 and 68515-49-1 DNOP CAS: 117-84-0	Plastic	REACH article 33, Candidate List, 0.1 weight% Annex XVII art. 51 & 52 (toys)
Diisobutyl phthalate (DIBP) CAS: 84-69-5	Plastic	REACH article 33, Candidate List, 0.1 weight%
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich CAS: 71888-89-6	Plastic	REACH article 33, Candidate List, 0.1 weight%
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters CAS: 68515-42-4	Plastic	REACH article 33, Candidate List, 0.1 weight%
Dihexyl phthalate (DHP) CAS 84-75-3	Plastic	REACH article 33, Candidate List, 0.1 weight%
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear CAS 68515-50-4	Plastic	REACH article 33, Candidate List, 0.1 weight%
Dipentyl phthalate (DPP) CAS 131-18-0	Plastic	REACH article 33, Candidate List, 0.1 weight%
1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters CAS 68515-51-5 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	Plastic	REACH article 33, Candidate List, 0.1 weight%
Bis(2-methoxyethyl) phthalate CAS 117-82-8	Plastic	REACH article 33, Candidate List, 0.1 weight%
Alkanes, C10-13, chloro (SCCP) CAS: 85535-84-8	Plastic	POPs-regulation EC 850/2004, 0.15 weight%
Cadmium	Plastic	Annex XVII REACH, entry 23 0.01 weight%
Cadmium	Plastic	Annex XVII REACH, entry 23 0.01 weight%
Nickel (release)	Metal	Annex XVII REACH entry 27.b 0.2 µg/cm2/week
Lead	Metal	Annex XVII REACH, entry 63 0.05 weight%
Lead	Plastic	Annex XVII REACH, entry 63 0.05 weight%
4,4'-isopropylidenediphenol Bisphenol A; BPA CAS: 80-05-7	Plastic	REACH article 33, Candidate List, 0.1 weight%
Quicksilver	Different components in electric devices	RoHS-directive 0,1 weight%
Lead	Different components in electric devices	RoHS-directive 0,1 weight%
Cadmium	Different components in electric devices	RoHS-directive 0,01 weight%







Nordisk Ministerråd Nordens Hus Ved Stranden 18 DK-1061 København K www.norden.org

The Nordic chemicals agencies have jointly controlled the Nordic market of give-away products. These products were controlled against the requirements of several EU-legislations (REACH Regulation, Toy Safety Directive, RoHS Directive, POPs Regulation and the Battery Directive).

The results show that economic operators lack knowledge of the applicable requirements, as well as lacking understanding of the extent of their obligations. They are missing appropriate systems to comply with the rules. Nevertheless, the Nordic chemicals agencies have observed an interest from business organisations to be better at understanding and complying with the applicable rules.

This joint enforcement project has also contributed to creating closer collaboration between the Nordic chemicals agencies resulting in sharing more information and ensuring better resource efficiency.