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Guide on Market Surveillance and Safety of Consumer Products

Best practices in the Nordic countries

Nordic Council of Ministers
Committee of Senior Officials for Consumer Policy

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Consumer Co-operation in the Nordic Countries
The aim of the co-operation in the Nordic Committee of Senior Officials on Consumer Affairs is to promote consumer safety, protect their financial and legal interests, inform consumers and promote their education, and promote consumer influence in society. Exchange of information, reports, and research will contribute to the Nordic consumer policy and provides a platform for joint Nordic presentation in international contexts.

Nordic co-operation

Nordic co-operation, one of the oldest and most wide-ranging regional partnerships in the world, involves Denmark, Finland, Iceland, Norway, Sweden, the Faroe Islands, Greenland and Åland. Co-operation reinforces the sense of Nordic community while respecting national differences and similarities, makes it possible to uphold Nordic interests in the world at large and promotes positive relations between neighbouring peoples.

Co-operation was formalised in 1952 when *the Nordic Council* was set up as a forum for parliamentarians and governments. The Helsinki Treaty of 1962 has formed the framework for Nordic partnership ever since. The *Nordic Council of Ministers* was set up in 1971 as the formal forum for co-operation between the governments of the Nordic countries and the political leadership of the autonomous areas, i.e. the Faroe Islands, Greenland and Åland.

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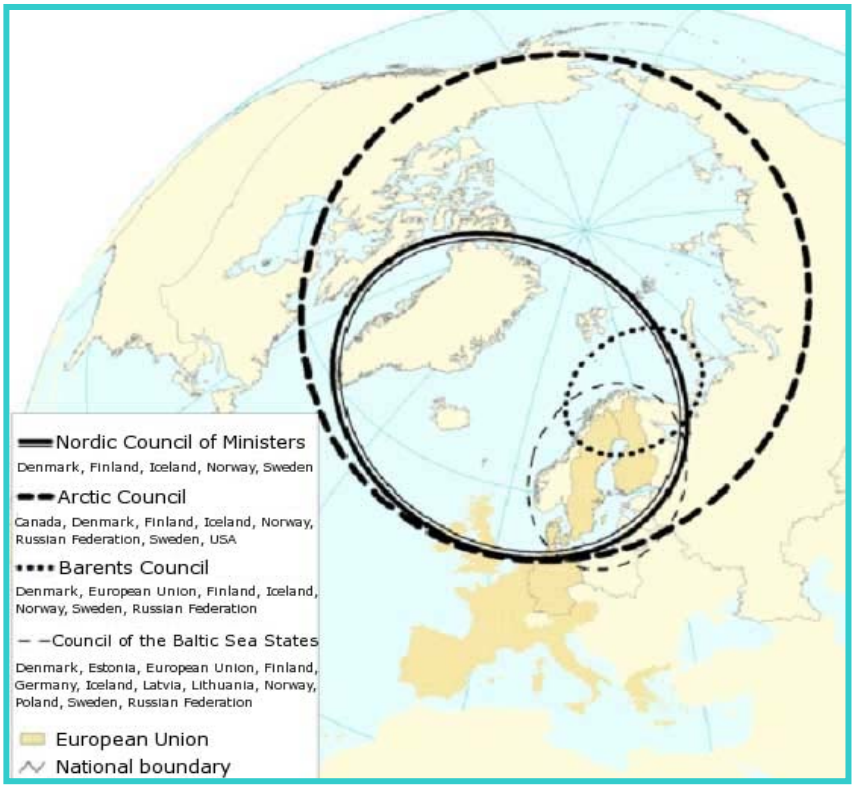


The Nordic Council of Ministers[1] engages in extensive cooperation with other international organizations and regional authorities in various fields of activities. Since 1990 there has been a special policy for the Adjacent

[1] www.norden.org

Areas, namely Estonia, Latvia, Lithuania and Northwest Russia. Activities in these areas account for about 20% of the Nordic Council's budget.

The projects undertaken by the Nordic Council of Ministers are based on experience from the Nordic countries aimed towards improving living conditions in the region and promoting shared values and closer economic ties.

The overall goal is to promote security and to contribute to stable and secure development, while at the same time assisting the regions in developing market economies and encouraging networking.

As the Baltic States (Latvia, Lithuania and Estonia) joined the European Union on 1 May 2004, the Nordic Council of Ministers intends to shift their emphasis to projects in Northwest Russia. Valuable experience gained from projects completed in the Baltic States form an important basis for this cooperation.

The Northwest region of Russia (yellow)

In May 2003, the Nordic Council of Ministers organized a seminar at Petrozavodsk, Karelia for Northwest Russia on Nordic/European perspectives on market surveillance and safety of consumer products. Delegates from Kaliningrad, Murmansk, Arkhangelsk, St. Petersburg and Karelia took part in the seminar along with Nordic market surveillance experts.

At the seminar, delegates from the region expressed concern over the lack of trust between consumers and economic operators, i.e. manufacturers/importers/distributors/retailers in the area of consumer product safety. An evaluation of information presented lead to the main conclusion that the transition to a market economy has highlighted the need for enforcement structures in the field of market surveillance, to ensure the safety of consumer products placed on the market.

On this basis, the Nordic Committee of Senior Officials for Consumer Policy, established by the Nordic Council of Ministers, decided to adopt a guide reflecting the principles of market surveillance and consumer product safety as well as those for the operations of national enforcement authorities in the Nordic countries.

In the "Framework programme 2003-2005 for the Nordic Council of Ministers Activities in the Adjacent Areas", the focus is directed on four main topics, one of them being market economy and consumer protection. The present guide serve both of these aspects. They are intended to encourage authorities in Northwest Russia to further develop their own market surveillance systems for the benefit of the consumer, thus contributing to further economic progress in the region.

The aim is to demonstrate how market surveillance is handled in the Nordic countries with special emphasis on the importance of national and cross border cooperation between interested parties.

A project group was established consisting of the following experts from the authorities in the Nordic countries: Ms. Eeva-Liisa Koltta-Sarkanen (Finland), Ms. Fjola Gudjonsdottir (Iceland), Mr. Hardy Balle (Denmark), Mr. Gunnar Wold (Norway) and Ms. Lotten Strindberg (Sweden). Project leader was Ms. Liselotte Widing (Iceland) and lead author and editor Ms. Birna Hreidarsdottir (Iceland).

2. Aim and Scope of the Guide

The purpose of this guide is to explain in general terms the main principles behind market surveillance activities and safety aspects of non-food consumer products in the Nordic countries. Further, to inform authorities in the Northwest region of Russia on the regulatory framework and practices in this area and explain the procedures which are designed to safeguard consumers from products that do not achieve a reasonable level of safety. Finally, the aim is to assist authorities in developing national market surveillance structures and procedures as well as to encourage them to establish effective national and regional cooperation to facilitate trade in safe consumer products across borders.

Target groups

The guide is primarily intended for national enforcement authorities in the Northwest region of Russia that have responsibility for implementing laws on market surveillance and consumer product safety on a regional and national level.

A market surveillance monitoring system that takes into account diverse criteria for safe consumer products is essential in improving consumer confidence and the well being of citizens. Consumers are exposed to various products on a daily basis. They should be able to assume that these products are safe.

A well functioning market surveillance system also benefits manufacturers and distributors. They recognize that it is in their interest to have a level playing field, without unfair competition from those that do not adhere to existing rules on consumer product safety.

European aspects

Denmark, Sweden and Finland are members of the European Union (EU), as Iceland and Norway are part of the EU Single Market through the European Economic Area Agreement (EEA). The EU Single Market will also be referred to here as the European internal market or the EU/EEA market.

In order to facilitate trade in the internal market, the European Union created common rules on market surveillance and safety of consumer products, which apply in all of the Nordic countries, as well as the other EU/EEA member states. The EU rules in this area apply to a market of 450 million consumers and are inevitably quite complex. This Guide is intended to explain the basic principles on which the systems in the Nordic countries are based, and at the same time the EU system.

Nordic aspects

There has been a relatively high level of consumer protection in all of the Nordic countries dating back several decades. At the same time there is a long history of cooperation between the Nordic countries in consumer product safety matters, both in general product safety and in sector specific matters.

This cooperation, as well as European harmonization, has lead to a similar level of consumer safety in the Nordic countries. But it has to be stressed that there is some divergence in the approach towards market surveillance and consumer product safety in these same countries, which will be described in this guide.

International aspects

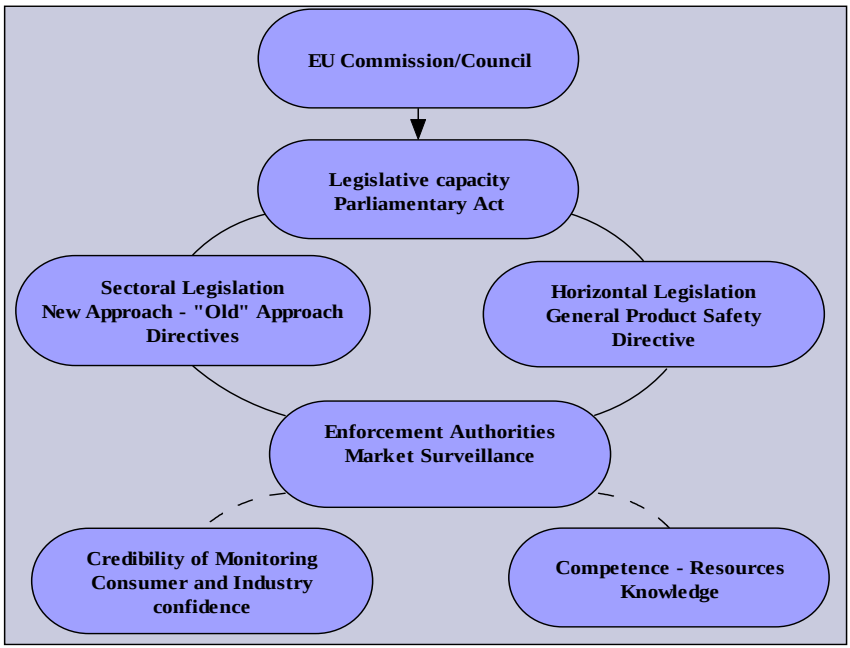
With globalisation and ever increasing movement of consumer products across borders, it has become much more important for authorities to establish a mechanism to control the safety of consumer products on their market, both for locally manufactured consumer products and imported products

Scope

Counterfeit goods are a major international problem, as it is estimated that around 5–7% of international trade is in counterfeit and pirated products. This guide does not, however, deal with problems relating to counterfeit products, which are covered by different legislation. The same applies to misleading advertising of consumer products.

3. Regulatory Framework

As the illustration below indicates, the basic regulatory and control system for market surveillance and safety of consumer products is based on the EU/ EEA membership of the Nordic countries.



Current Nordic legislation is mainly based on EU consumer product directives (legal acts), which have been incorporated into national law.

In order to develop the full potential of a consumer safety system, national authorities need to create an environment where adequate resources are secured and emphasis is put on cooperation of all interested parties.

Experience has shown that political support is absolutely vital in building up a well functioning market surveillance system. During this building phase, individual aspects must be prioritised, as it is not possible to achieve everything at the same time.

Main principles

"Horizontal" legislation in the Nordic countries, on the main principles of market surveillance and general (consumer) product safety, is largely based on the European General Product Safety Directive (GPSD, 2001/95/EC), which became applicable as of 15 January 2004.

The GPSD repealed Directive 92/59/EEC on the same subject, which was the first common European legislation in the field of market surveillance of general products.

The new directive applies to products intended for or likely to be used by consumers. When the manufacturer is not based in the EU/EEA market, this obligation applies to his representative or, in the absence of a representative, to the importer.

The principal rule of the GPSD is that manufacturers and distributors may only place safe (consumer) products on the market.

In order to safeguard that only safe products are put on the market, the directive contains detailed provisions on market surveillance activities, which enforcement authorities must carry out.

The GPSD also covers safety aspects of general (consumer) products that are supplied to consumers for their private use. Examples are household goods, child care articles and baby products, tools, equipment and clothing.

As mentioned earlier, the directive is horizontal in nature as opposed to sectoral consumer product legislation, which only covers certain product types.

However, in the absence of provisions on market surveillance and product safety in sectoral legislation, the provisions of the GPSD apply in

general. The same applies in most cases when the GPSD offers further protection than provisions in existing sectoral legislation.

Nordic legislation

Before the introduction of harmonized European legislation in this area, all of the Nordic countries had general legislation in force relating to the monitoring of safety consumer products on the market.

> **In Finland**, The Act on General Safety of Products entered into force in 1987. As there are some similarities between the Act and the first GPSD, it is assumed that the Finnish Act influenced to a certain extent the first GPSD.

When preparing to implement the revised GPSD of 2001, Nordic market surveillance experts held consultative meetings with the aim of harmonizing the implementation of the directive in the legislation of the respective countries.

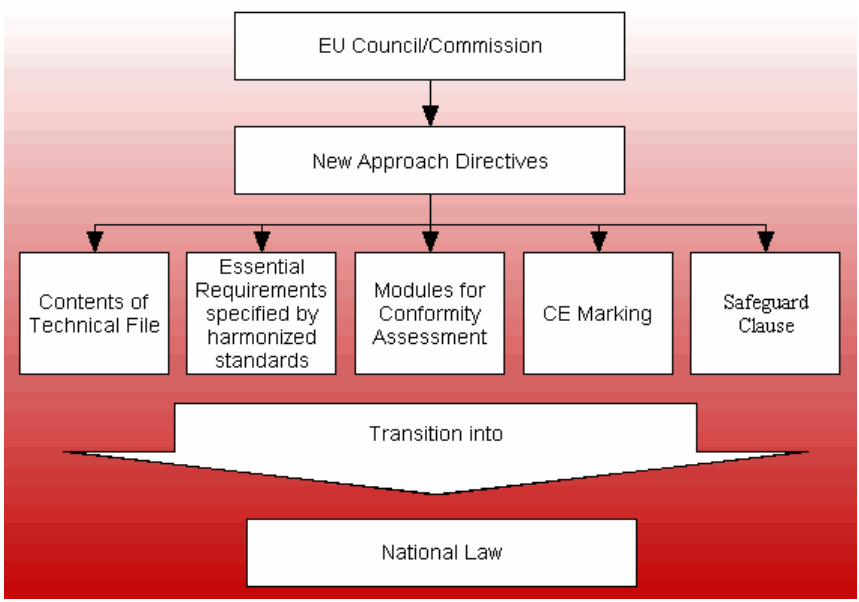
The main differences in the Nordic legislative acts is that Norway, Finland and Sweden opted to encompass safety of services along with consumer product safety in their respective legislation while Denmark and Iceland do not cover safety of services in present legislation.

“New Approach” directives

For specific types of consumer products there is harmonized legislation in force in the Nordic countries based on sectoral EU/EEA directives covering different (consumer) products, such as toys, electrical equipments, machines and personal protective equipment. These are the so-called *“New Approach” directives.*

The “dual” purpose of the "New Approach" directives is to establish one set of regulations for all to follow, to facilitate free movement of goods throughout the EU/EEA market and at the same time to safeguard the health and safety of consumers.

Apart from provisions on market surveillance, the main areas covered in the New Approach directives (with several variations according to the type of products) are as follows:



Please refer to list of New Approach directives, appendix 7

The essential requirements

The “New Approach” directives only set out the essential safety requirements which a product must fulfil in order to be considered safe in general terms. They do not contain information on how the essential requirements could or should be met nor do they contain the technical specifications needed to manufacture a product that will comply with the "essential requirements" listed in each of the directives.

Manufacturers who trade in Europe must demonstrate that their products meet the essential requirements of the directives. Harmonized standards provide the manufacturer with one solution for satisfying the essential requirements of the directives. Manufacturers are recommended to use European harmonized product standards (EN standards) to de-

monstrate compliance with the "essential requirements" set forth in each product directive.

However, according to the “New Approach”, manufacturers are not obliged to apply a harmonized standard. A solution, alternative to harmonized standards can be used provided it can be demonstrated that equivalent safety is secured through an EC-type approval supplied by a designated notified body.

The CE-marking

The "New Approach" directives establish a uniform marking system known as the CE- Marking.

Affixing the CE marking to a product is a declaration by the manufacturer (or the distributor) that the product in question has been designed and manufactured to meet the essential safety requirements and creates a presumption that the product is entitled to free circulation within the EU/EEA market.

However, it must be remembered that the CE marking is not a quality mark aimed at consumers**.** Its main purpose is to indicate to enforcement authorities that the products are intended for sale on the EU/EEA market and guarantees that at least the minimum essential requirements for health and safety of the consumers have been met.

As the General Product Safety Directive imposes a general safety requirement for a wide range of consumer products and does not specify any essential safety requirements as the sectoral (vertical) directives do, there are no provisions for CE marking on products falling under the scope of the GPSD.

Conformity assessment procedures

The essential objective of a conformity assessment procedure is to enable public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the applicable directives, in particular with regard to the health and safety of consumers.

Conformity assessment is based on the manufacturers' internal design and production control activities and third-party examinations by conformity assessment bodies, which are "notified" on the basis of harmonized criteria.

The applicable directive will be the guide to the level of risk involved and the methods of conformity assessment that may be employed. Conformity assessment modules are specified in each directive.

If a harmonized standard is used to meet an essential requirement of a New Approach directive, and if the risk of injury is low, no third party conformity assessment procedure is required, regardless of the nationality of the manufacturer. Therefore, for most consumer products under the New Approach directives, it is sufficient that the manufacturer (or his representative) certifies that the product complies with the directive(s)/harmonized standards. Very risky products on the other hand require an approved quality assurance system to be put in place and reviewed by a notified body.

The use of conformity assessment is designed to promote the removal of barriers to trade in the EU/EEA market and worldwide. Further, it provides confidence for consumers/users that the requirements applicable to products have been met. As technology becomes more complex, consumers are becoming more aware of their dependence on products whose design and construction they may not understand. Manufacturers must verify that all stages of product manufacturing (design, construction, presentation and marketing) fulfil legal requirements in order for their products to provide the safety consumers and other users are reasonably entitled to expect.

Cooperation among conformity assessment bodies can further contribute to mutual recognition and promotion of each participant's work across borders.

For information on the conformity assessment modules, please refer to appendix 4

Technical file

It is the responsibility of the manufacturer to draw up a technical file, which is the written justification that all aspects of a product are safe. The technical file includes information that demonstrates the technical basis for conformity of the product to the applicable requirements of relevant directive/s.

When questions arise as to the safety of a product, a technical file must be presented upon request by enforcement authorities. Technical files, for certain products, may be maintained for up to 10 years from the time the product was placed on the market.

Depending on the complexity of a product, the following elements should be present in a technical file:

- Design and production drawing and diagrams
- A general description of the product
- A list of standards and or/solutions applied
- Detailed technical data for essential aspects of the product
- Risk assessment
- Reports of calculations and tests that have been carried out
- Certificates and inspection reports
- User's manual
- Declaration of Conformity

In Norway the principle of internal control complements existing regulations. This principle states the obligations for manufacturers, importers and retailers to systemize and establish documents concerning the safety of any product under any directive.

Timing of inspections of consumer products

According to the GPSD post-market inspection is the general rule. Therefore, as a main principle, monitoring and inspection of consumer products by enforcement authorities takes place after the product is placed on the market.

Pre-market certification is, in principle, no longer applied. However, there are all kinds of exceptions to this rule as there are different legal requirements regarding inspection for certain consumer product groups such as medicines, some machines and electronics which employ specific regulatory mechanisms.

Pharmaceuticals and food products come under completely different rules such as on pre-marketing assessment and post-marketing obligations on manufacturers and authorities.

The Safeguard clause

In some cases, the European standards bodies have failed to elaborate adequate harmonized standards in compliance with the essential requirements of the product directives. As a consequence, consumer products made according to these standards are not in conformity with the essential requirements of the applicable directive, despite the fact that harmonized standards are used.

In this case, authorities in the EU/EEA member states have the possibility to intervene by making use of the so-called safeguard clause. The safeguard clause requires the EU/EEA Member States to take all appropriate measures to withdraw unsafe products from the market, even though they have been manufactured according to harmonized standards.

The safeguard clause is in fact the counterweight to the rule of presumption of conformity.

“Old approach” directives

Product directives written prior to the New Approach do not take into account CE Marking and are known as *"Old Approach" directives*. These directives tended to include precise technical details within the text of the legislative document.

This made assessment against the legislation relatively easy; however the directives necessitated continuous adaptations to technical progress. Technical specifications for specific products needed frequent updating, which proved to be complicated and time consuming.

A new material or novel product that was not foreseen at the time of writing the legislation might not fit the technical requirements of a directive and would therefore not fulfil requirements according to existing legislation, even if the product was perfectly safe.

The “Old Approach” system is still in force for various products covering areas such as cosmetics, transportation equipment and pharmaceuticals.

This guide is not a legal instrument and have no legal force. Please refer to EU and existing legislation in the Nordic countries for legal acts.

4. Enforcement

In order to safeguard that only safe products are placed on the market, national authorities in the EU/EEA member states are obliged by law to carry out market surveillance activities for consumer products.

The main aim is to ensure that consumer products are only put on the market if they do not endanger the health or safety of consumers. This is not only for their protection and that of other users, but also to protect the interests of economic operators from unfair competition.

Institutional framework

Implementation of market surveillance and consumer product safety legislation is the responsibility of *"enforcement authorities"*, that is national market surveillance and consumer product safety authorities.

One of the most important tasks of enforcement authorities is to ensure that manufacturers observe the laws and rules of the market which apply to consumer product safety, thereby safeguarding that the rights of the consumer, in that field, is respected.

Enforcement authorities monitor that consumer products placed on the market comply with provisions of the applicable national legislation. The main emphasis is on identifying potentially dangerous products and assessing compliance with information provided by manufacturers, having the products inspected and tested and investigating consumer complaints. The enforcement authority must be in a position to justify all measures taken.

Organizational structure

In all of the Nordic countries there are central market surveillance authorities that are responsible for the implementation of the GPSD. In most cases these enforcement authorities are entrusted with market surveillance of other consumer product groups as well, not covered by the GPSD. The advantages are mainly better use of human and financial resources.

Certain differences exist in the Nordic countries' approach to the organizational structure for market surveillance activities, as shown below.

In Finland, the Finnish Consumer Agency is the central enforcement authority and as such directs inspection and monitoring duties nationally. The agency arranges training for people who monitor product safety at regional and local levels. It also participates in international cooperation. The agency operates as a centre of expertise in product safety matters. Local authorities monitor the safety of consumer goods and services, including locally produced goods, under the direction of state provincial offices. Monitoring is generally the responsibility of municipal health inspectors, which also handle food control and public health tasks.

In Sweden, market surveillance is the responsibility of some 15 public authorities, among them the Swedish Consumer Agency, the Swedish National Electrical Safety Board and the Swedish Work Environment Authority.

The Swedish Board for Accreditation and Conformity Assessment, SWEDAC, is the appointed national and international coordination and contact body with the basic objective to ensure consistent interpretation and application of overall market surveillance principles. SWEDAC aims to ensure a clear division of responsibility between public authorities and it monitors and evaluates the national market surveillance. This is manifested in, among other things, annual reports. An important basis for SWEDAC's coordination activities are the views expressed in the Market Surveillance Council, for which SWEDAC provides the secretariat. This Council consists of representatives from the relevant sector authorities, ministries, industry and consumer organizations as well as labour market unions. All issues connected to market surveillance are discussed in the Council with the aim of creating a common ground for market surveillance in Sweden as well as Swedish policy in an international context.

In Iceland, a new enforcement authority, the Consumer Agency, is responsible for overall coordination of market surveillance activities of consumer products in Iceland. The aim is to ensure that all products on the market are covered and no "grey" areas exist, as well as safeguarding the economic aspects and effectiveness of market surveillance in general.

Regarding consumer products, the agency is responsible for market surveillance of general products: toys; personal protective equipment for private use; construction products; electrical appliances and playground equipment.

In Denmark, a new, centralized market surveillance authority has recently been established - the Danish Technical Safety Authority.

A Committee on market surveillance matters advises the Danish Safety Technology Authority on the following market surveillance areas: electrical and gas appliances; fireworks; toys and consumer products in general. The mandate of the Committee is to:

- assist in ensuring general support among stakeholders for market surveillance;
- ensure a dialogue with all stakeholders;
- give advice on important areas in relation to market surveillance;
- give advice and contribute in specific areas and concrete projects;
- follow market surveillance activities in general and monitor withdrawals of dangerous products from the market and the application of sanctions.

What constitutes a safe product?

In assessing whether an enforcement authority shall take action against a consumer product on the market it has to have the right criteria to deem that the product is safe or not.

A safe product is one which poses no threat or only a reduced threat in accordance with the nature of its use and which is acceptable in maintaining a high level of protection for the health and safety of consumers.

A product is deemed safe once it conforms to the specific legislation governing its safety. In the absence of such provisions, the product must comply with the specific national regulations of the country in which it is being marketed or sold, or with the voluntary national standards, which govern the European standards.

A dangerous product is defined as one where the safety of the product is not that which consumers generally expect. This definition provides for an objective test of the defective product.

A product will not be considered defective solely because it is of poor quality nor will a product be considered defective simply because a safer version is subsequently put on the market.

Other aspects to look at in determining safety of consumer products:

- The product's characteristics
- Instructions for use, assembly and maintenance
- Packaging
- Labelling and other relevant information
- The categories of consumers at risk when using the product, particularly children and the elderly. "Migration" of products

When products, which are safe in the hands of trained professionals and indeed designed with such groups in mind, are being supplied to untrained consumers, it is said that they have "migrated".

Examples are fireworks (for professional use), laser pointers and some DIY (do-it-yourself) tools, where considerable skill is needed to use them correctly. In this case the GPSD applies to the safety aspects of the products.

The powers of enforcement authorities

In order to safeguard that only safe consumer products are circulating on the market, enforcement authorities have a wide range of powers at their disposal to perform their tasks. They include:

- To carry out inspections without interference
- Request all relevant information

- Ask for documentation
- Take samples
- Have the product tested
- Require that the product comply with essential requirements

Types of inspections

Enforcement authorities do not inspect every product nor do they give pre-market approval for safe products. Responsibility for the safety of products lies with the manufacturer.

As there are thousands of consumer products available on the market, it is not possible to check all of them. But random inspection is a powerful tool in monitoring safety of consumer products on the market. Enforcement authorities will visit commercial, industrial and storage premises on a regular basis and take random samples of certain product groups. The samples are then tested to see if they fulfil requirements according to relevant consumer product safety directive/legislation.

Apart from random inspection on the market, enforcement authorities will also perform inspections based mainly on the following criteria:

- Consumer reports, complaints or accidents in relation to consumer products
- Reports from manufacturers and importers on dangerous products
- Surveys (in cooperation with laboratories), where applicable
- European notifications - RAPEX

Measures

When a dangerous/defective consumer product is found on the market, a procedure is triggered in which enforcement authorities will select action based on the circumstances and severity of the defect.

Possible actions by enforcement authorities include:

- Ordering withdrawal from the market
- Imposing a (definitive/temporary) sales ban

- Suggesting methods to fix the product
- Ordering destruction of the product
- Ordering the revision of future deliveries
- Ordering a recall from consumers
- Issuing warnings
- Distributing relevant information to economic operators/consumers
- Ordering a ban on the export of dangerous products to third countries

In the legislation of the Nordic countries there are provisions for imposing fines on the manufacturer if decisions by enforcement authorities are not observed.

Voluntary actions

Voluntary actions by manufacturers are especially encouraged in law as an alternative to formal enforcement actions.

Dialogue with manufacturers, when possible, as well as allowing them the opportunity to take steps to correct any faults before applying legal action are considered to be more effective and produce better results than direct enforcement of consumer product legislation.

Private inspection bodies

The use of private inspection bodies to perform certain market surveillance tasks has, in recent years, gained ground in the Nordic countries as an alternative to inspection by enforcement authorities themselves.

Private inspection bodies are usually required to be accredited according to EN/ISO 17000 standards to ensure competence, impartiality and integrity of their work.

Inspections are only performed at the request of the enforcement authority, which monitors the market and requests actions based on their evaluation. The enforcement authority decides which products that should be checked by the inspection body. However, full responsibility for the market surveillance activities rest with the enforcement authority.

The inspection body reports back to the enforcement authority, which then takes appropriate measures, based on information derived from the inspection operation.

One of the advantages of using private inspection bodies is that the impartiality of the enforcement authorities is safeguarded. They have no contact with suspected offenders before getting the results from the inspection bodies.

In Iceland, legislation allows for the use of accredited inspection bodies to carry out market surveillance operations on specific product groups under a special contract between the enforcement authority and the inspection body. The enforcement authority draws up a contract with the relevant inspection body and issues an operational guide to ensure consistency and specifications of work methods.

Financing of enforcement activities

There is no uniform approach to the financing of market surveillance activities in the Nordic countries. Contributions from the state budget are the most common form, but in some instances financing comes from a yearly fee or special taxes imposed on manufacturers

It can be safely said that lack of resources, both financial and in terms of manpower, is a constant problem facing enforcement authorities throughout the Nordic countries.

It would be logical to assume that financing should come from fines imposed on those who place dangerous products on the market. But as it can be argued that effective market surveillance activities can prevent accidents and even death, it is in the public interest that financing be secured without relying on fines as a means to finance market surveillance activities.

Examples of financing of market surveillance activities of electrical appliances

Denmark

Additional tax on electricity (appendix 0.1 cent/KWH).

Norway

Financing from state budget.

Iceland

Up to 0.15% fee on imported electrical appliances and a comparable fee on electrical appliances produced in Iceland.

Finland

If the equipment is in violation of the Electrical Safety Act or the provisions or regulations issued under it, the Electrical Safety Authority may oblige the entrepreneur to pay compensation for the costs arising from testing and research.

Sweden

The Swedish National Electrical Safety Board is financed by a flat fee from the electricity subscribers. The annual fee is 6 SEK for domestic electricity subscribers and 500 SEK for high voltage subscribers.

The principle of proportionality

One of the most important principles of market surveillance activities is that measures should be proportional to the objectives they seek to achieve. Enforcement authorities should act in such a way as to implement the measures in a manner proportional to the seriousness of the risk.

Products that severely infringe the objectives of the applicable consumer product legislation should be quickly identified and taken off the market. Minor deficiencies such as incorrect labelling and lack of documentation should be handled differently, for instance by having the manufacturers remedy the shortcomings.

Distribution of information

Enforcement authorities have to make available to the public any information about specific consumer products that pose risks to the health and safety of consumers and the measures that the authorities have taken to remove those risks.

Another important role of enforcement authorities is to provide general advice or guidance to economic operators, such as repairers, local representatives of manufacturers and trade associations.

However, in order to obtain adequate information, a balance must be struck between the interests of consumers and manufacturers. For instance, when consumer products must be tested to find out if they are dangerous or not, information might be withheld throughout the testing process, until the results are clear, in order to avoid harming the legitimate business interests of the manufacturer.

Role of the media

One of the most important roles of the media as regards market surveillance is in publishing information as a result of market surveillance activities and to focus attention on topics, which are of importance for consumers.

Interaction between the media and enforcement authorities creates a powerful tool deterring manufacturers/distributors from putting dangerous products on the market. Failure to comply with requirements will be publicized – an incentive to conform to applicable requirements.

Internet

The development of the Internet allows the consumer to browse through an incredible array of products; it also brings a wider range of products within easy reach of the consumer, regardless of the origin. This increases the importance of effective market surveillance activities and international cooperation, as all kind of products will “flow” from one country to another by means of the Internet.

5. Duty of Manufacturers and Distributors

The manufacturers and distributors of consumer products have an obligation to ensure that only safe products are placed on the market. In addition, they must provide consumers with the necessary information in order to assess a product's inherent threat, particularly when this is not directly obvious, and take the necessary measures to avoid such threats to consumers.

Responsibilities

Manufacturers and distributors are responsible for supplying only products that comply with general safety requirements. The main criteria are that only safe products should be placed on the market.

In addition manufacturers must provide consumers with the necessary information in order to assess a product's inherent threat, particularly when this is not directly obvious, and take the necessary measures to avoid such threats.

The manufacturer is responsible for designing and manufacturing of consumer products in accordance with the essential requirements of relevant directives and following the conformity assessment procedures, compiling a technical file and affixing the CE-marking.

For manufacturers and distributors of consumer products it is essential to know what safety aspects apply to a certain product category and the risks that their products might pose as they are legally responsible for ensuring that products placed on the market comply with provisions of general or sectoral legislation.

Distributors are also obliged to supply products that comply with the general safety requirements and to provide the necessary documents ensuring that the products can be traced.

Collaboration with enforcement authorities

Collaboration between manufacturers, distributors and enforcement authorities is especially encouraged in order for market surveillance systems to work smoothly.

One of the most important aspects of the revised GPSD is the post-marketing obligation on manufacturer/distributor to immediately report the risk of dangerous products that he has placed on the market to the relevant enforcement authority and, if necessary, cooperate with them.

That involves, among other things describing what actions he has taken to resolve those risks in order to protect consumers. If the enforcement authority deems the actions satisfactory, no further steps are required and the case is closed. The obligation to inform the competent authorities is clarified in Annex I of the GPSD.

Manufacturers are obliged to keep a register of safety complaints and to cooperate in the monitoring of the safety of products on the market.

In Finland, a report can be made by completing the accompanying form in app. 5 and sending it to the Consumer Agency. An interactive form can also be filled out. The same goes for Sweden where the form is available at www.konsumentverket.se.

6. Standards

Standards are able to facilitate trade and market access across borders, to improve the quality and safety of consumer products and services and create transparency. They have in fact become crucial element in economic integration and international trade.

Interoperability of products is possible because of standardization and it can be argued that almost everything in today's society is standardized. Standards can simplify everyday life; give consumers safer products as well as making design, production and distribution of a product more efficient and profitable.

Standards and market surveillance

As has been previously mentioned standards play a significant function in consumer product safety and means of market surveillance activities as they allow manufacturers to assume the conformity of their product with the requirements in applicable directive(s)/ legislation.

It is of crucial importance for the enforcement authorities to have a common base for evaluating the safety of consumer products. That can prevent unsafe products from cycling from one country to another, because different enforcement authorities evaluate the risks of unsafe products differently.

National standards bodies

In each of the Nordic countries there are national standards bodies that oversee the standardization work. These bodies are independent non-

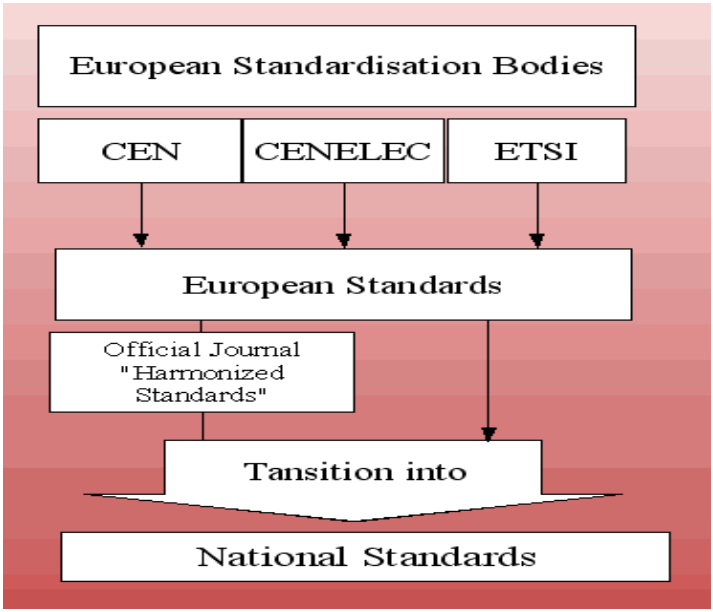
government organizations, financed by different stakeholders as well as proceeds from selling standards.

Prior to European integration in standardization, each country developed its own standards through the national standards bodies. There was considerable Nordic cooperation in the field of standardization and Nordic standards were in many cases identical.

But like differing and conflicting laws and conformity assessment procedures, standards were not only costly to produce, but also created technical barriers to trade with the outside world. It became necessary to create a new, integrated, European system of standardization.

Currently, most Nordic standardization work is done at the European level as Europe has taken the lead within international standardization. ISO, the International Standardization Organization and IEC, the International Electrotechnical Commission are international standards organizations, which play an important role in global standardization. All of the NBS in the Nordic countries are members of ISO and IEC (Iceland is an associate member of IEC) on behalf of their respective countries.

European standards organizations



Nordic standardization bodies are members of the three recognized EU standards development organizations responsible for creating European standards.

CEN[2] - The European Committee for Standardization is responsible for creating general standards.

There are around 10000 European (CEN) standards of which 30% are identical to ISO standards. Around 2000 harmonized CEN standards are cited in the OJ.

CENELEC[3] - The European Committee for Electrotechnical Standardization is responsible for creating electro-technical standards.

There are around 4500 European (CENELEC) standards of which 80% are based on IEC standards. Over 1900 harmonized CENELEC standards are cited in the OJ.

ETSI[4] - The European Telecommunications Standards Institute, responsible for creating telecommunications standards.

European product standards come in the prefix designation “EN” (European norm). “EN standards” are standards in which a broad consensus has been reached among all EU/EEA member states.

When a European standard (EN) has been approved by ETSI, CENELEC or CEN by weighted majority, it must be transposed into national standard within six months and the NBS must withdraw any conflicting national standards. Such standards are indicated with putting the abbreviation of the NBS in front of “EN”. For Iceland it is indicated with IST-EN, Finland STS-EN, Denmark DS-EN, Sweden SS-EN and Norway NS-EN.

> European standards are published in the three official languages of the European Union, English, French and German. It is up to each member state to decide which standards are translated into the national language in case it is not one of the official languages of EU/EEA states.

[2] www.cenorm.be
[3] www.cenelec.org
[4] www.etsi.org

Harmonized standards

The New Approach method means that only essential safety requirements are indicated in the directives, and the European national standards bodies are entrusted with the production of detailed technical specifications.

The European Commission can request the European standards bodies to prepare standards in order to implement European legislation. A contractual relationship is created, with the Commission providing financial support when needed. This standardization is 'mandated' by the Commission, through the Standing Committee of a certain product directive or GPSD, in support of the legislation.

The contract (or mandate) stipulates that a standard will be produced that will provide a technical solution, or a technical interpretation, of essential health and safety aspects.

In practise, this means that standardisation has taken on much of the authorities' previous provisional work. To participate in standardisation is therefore an important part of the consumer product safety work.

Main characteristics of harmonized standards are as follows:

- They have been mandated by the European Commission,
- They have been developed by the European Standards Bodies,
- They address essential requirements of New Approach directives,
- Notification of their acceptance has been published in the Official Journal of the European Communities (OJ).

Since harmonized, European standards have been transposed into national standards in a uniform way, a manufacturer may choose any of the corresponding national standards for his production**.**

The main advantage of European standardization is the mutual recognition of standards. A manufacturer that produces consumer products according to European standards can sell his products all over Europe without expensive re-testing in every country.

One of the most important aspects of harmonized standards is that they remain voluntary and as such can never replace legislation.

Presumption of conformity

Presumption of conformity is a legal concept surrounding harmonized standards, which denotes the relationship between the legislative and standardization processes.

Conformity with voluntary harmonized standards giving effect to such European standardization means the product will be presumed to be safe, so far as the risk is covered by the standards, that is, products will be presumed to be in conformity with the essential requirements set forth in the relevant directive.

When the standard is completed and the conditions of the Commission's mandate are met, the Commission publishes the notice of its completion in the OJ. Once the notice is published, the standard takes on the presumption of conformity mantle.

A manufacturer, therefore, using a harmonized standard in the design and/or production of the consumer product, is presumed to be in conformity with the essential requirements of the law.

The burden of proof lies with the relevant enforcement authority, which has to prove that a consumer product is not obliged to fulfil essential requirements as concerns safety if a manufacturer has produced it according to harmonized standards.

National standards

The harmonization, or the “Europeanization”, of standards is an ongoing process. It is estimated that around 95% of the standards being adopted presently in the Nordic countries are common European standards.

There will, however, be instances where no European Standard (EN) is applicable to a consumer product that is unique, or innovative, or a product whose technology is developing rapidly. In this case, a manufacturer can make use of an existing national standard, which he considers relevant as a temporary solution to the proper implementation of the essential requirements.

In the absence of a European standard, the burden of proof that the consumer product meets all the essential requirements still rests with the manufacturer.

A national standard does not carry with it the presumption of conformity.

The standards making process

European standards are created in technical committees or working groups made up of experts from various interested parties. This work is done under the assumption that the experts are the ones most familiar with the problems to be solved. The process is quite unique in the way that it is highly transparent and the outcome is shaped by consensus.

An important element of the standards process is that all interested and materially affected parties must have the opportunity to actively participate in the standardization process. In practice, however, representatives from industry are the ones that most often have the necessary resources to participate in this work and thus influence the preparation of standards.

For flowchart of the standardization process, please refer to appendix 6

Consumers' participation in standardization

In principle anybody who is interested in an area may participate in the standardisation work. In practice, however, it is mainly the representatives of manufacturers, which have the necessary resources to participate in this work and thus influence the preparation of standards. Other interested parties, in particular the consumers, are often strongly underrepresented. In excess of making contributions in the form of work time and travel costs as a participant in a standardisation project, usually a fee has to be paid to the standards body to cover the administration costs of the national and international standardisation work.

As regards the role of consumer associations in standardization, consumer participation in the standardization process is crucial for many reasons, firstly because consumer representation counterbalances the industry view. Secondly, goods and services based on standards developed with consumer participation may be more easily accepted in the marketplace. Thirdly, consumers are the ones that are most affected by the

standards at the end of the process and finally, in the EU context, consumers ensure that the public interest is represented in standardisation work that complements European legislation under the New Approach to Technical Regulation.

The European standardization committees within CEN, CENELEC and ETSI usually correspond to national committees, the so-called mirror committees. The chances of exerting influence are better by actively participating in both the European and the national committee, but due to a lack of resources, this is not always possible for consumer's representatives.

If consumer representatives are to have any real influence on the work of European and national standards committees, it is necessary that they attend the meetings of the technical committees well prepared and, as far as possible, they agree beforehand on a common opinion on issues of importance to consumers.

ANEC

In order to coordinate the consumer influence in the European standardization work, the consumer organisations have established the cooperation body ANEC (European Association for the Co-ordination of Consumer Representation in Standardisation)[5]. ANEC was set up in 1995 as an international non-profit association and represents consumer organisations from the European Union Member States and the EFTA countries.

ANEC represent and defend consumer interests in the process of standardisation and certification, also in policy and legislation related to standardisation. The aim is a high level of consumer protection. The European Commission and EFTA fund ANEC, while national consumer organisations contribute in kind.

The General Assembly is composed of one national member per country. The Brussels-based secretariat co-ordinates a network of more than 200 consumer representatives across Europe. Experts contribute directly to the work of over 70 technical committees, working groups and political bodies of the European and international standard organisations. Research and testing projects underpin ANEC's activities at the technical level, as

[5] www.anec.org

the consumer representatives need scientific information to back up their arguments against strong industry interests in the standardisation committees and working groups.

Nordic consumers and standardization

Since 1990, the Nordic countries have successfully coordinated efforts in standardization in the interests of the consumer. A Nordic forum for consumer influence in standardization is funded by the Nordic Council of Ministers and administered by the Danish Consumer Council. In 2003 consumer product safety was added to the scope of the forum because of the very close link between standardization and consumer product safety.

The aim of the Nordic cooperation forum is to achieve more influence on the European standardization work via coordinated Nordic consumer cooperation and representation at European level. This cooperation to strengthen consumer influence in standardisation is in line with the EU policy within the standardization area.

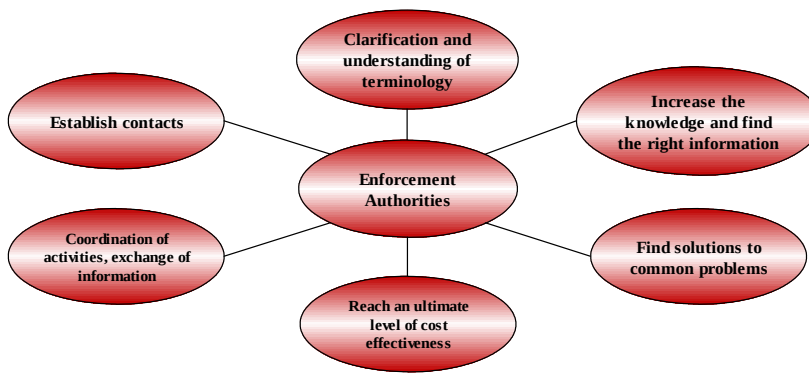
The Nordic co-operation forum gives, via co-ordinated co-operation, the Nordic consumer representatives the opportunity to achieve more influence on the contents of European standards and European legislation in the product area e.g. by working out a strategy before European meetings, co-ordination of comments on European standard proposals, preparation of standard proposals and development of test methods and test equipment. The standardisation work is organised in different ways in the Nordic countries, and the level of activity varies. In this connection the co-operation forum contributes towards ensuring that all the Nordic countries are involved at a certain level. The forum ensures the personal contact among the Nordic consumer representatives, which is an essential factor when the representatives are negotiating at the European level, and which also increases the competence. The Nordic co-operation forum works very closely with the European organisation for consumer representation in standardisation ANEC.

7. Cooperation and Exchange of Information

Cooperation in market surveillance activities is essential if progress is to be made in ensuring that only safe products are circulating on the market. Market surveillance is carried out at national level but it is vitally important that there is cooperation, both at national and cross border level, not least in the harmonized area.

The aim

Improving the effects of market surveillance activities must be a constant goal of enforcement authorities. Cooperation and coordination are the most important aspects towards that end as the illustration below indicates.



National cooperation

Exchange of practical experiences is vital in ensuring effective structure and operational arrangements thereby contributing to constantly improving methods and instruments for market surveillance activities.

In the Nordic countries, as in the rest of EU/EEA member states, authorities are obliged to keep a list of contact points for horizontal and sectoral enforcement authorities. The purpose is to facilitate contact with those that are responsible for administering different consumer product safety legislation.

In some instances consumer products, such as toys, machines and electrical appliances are covered by more than one directive which makes it all the more important that cooperation between different enforcement authorities takes place.

An exchange of information and experience between authorities in early stages of setting up structure for market surveillance activities is especially encouraged. Experience indicates that comprehensive application of terminology will make cross border cooperation more efficient.

Regional/cross border cooperation

As market surveillance activities cover basically all locally and imported consumer products on the market there is an obvious need for all nations/regions to do networking with other countries market surveillance systems. Often it makes sense to cooperate regionally as the systems might be similar at regional level.

At European level there is extensive cooperation in market surveillance and consumer product safety in which the Nordic countries take an active part. The same main principles apply and therefore cooperation is of crucial importance.

One of the advantages of cross border cooperation is in avoiding duplication of laboratory tests. It should be sufficient to test consumer products in one country and use those test results in other countries to save time and resources.

The Nordic cooperation forum (chapter 6) has given the Nordic consumer representatives the opportunity to achieve more influence on the

contents European product safety regulation. By working out a strategy prior to meetings, coordinating comments on proposals, preparing proposals and developing test methods and testing equipment, Nordic consumer demands can be presented and incorporated into the process at an early stage.

In order for cross border cooperation to be successful, there is a need for creating similar rules and safeguarding transparency as well as developing uniform terminology.

8. Notification Systems

As the EU/EEA member states form a common internal market, it is important that consumers enjoy the same level of protection from dangerous products, wherever they are located in the area.

The RAPEX system

Directive 2001/95/EC on general product safety establishes a notification system on dangerous products - the RAPEX system - for the rapid exchange of information between EU/EEA member states and the EU Commission. These pertain to measures and actions in relation to consumer products posing a serious threat to the health and safety of consumers in so far as there are no specific provisions in Community law with the same objective.

The objective of RAPEX is to ensure the rapid exchange of information among EU/EEA member states and the Commission on measures taken in the EU/EEA member states to prevent, restrict or impose specific conditions on the marketing or use of consumer products by reason of serious risk to the health and safety of consumers.

Information is circulated among the competent authorities, through a network of national contact points.

In order for the system to work smoothly, the revised GPSD provides for the establishment of a European Product Safety Network to organise administrative co-operation between the enforcement authorities of the member states which are responsible for the RAPEX system.

Product types

All non-food products intended for consumers, or likely, under reasonably foreseeable conditions to be used by consumers, are included within the scope of RAPEX, with the exception of pharmaceutical and medical products.

Procedures

As soon as an unsafe consumer product is found on the market in one of the EU/EEA member states, the national enforcement authority must consult the manufacturer (or distributor) of the consumer product concerned. Next, appropriate restrictions must be imposed and notification sent to the EU Commission. Finally, all the other EU/EEA member states are notified of the action taken so they can check if the same product is circulating on their respective markets and take appropriate measures, as necessary.

When submitting a notification via the RAPEX system, the following information must be submitted to the Commission:

- Information enabling the product to be identified;
- A description of the risk inherent in the product, and details of risk assessment studies;
- Details of measures already taken;
- Information on distribution of the product, including destination countries.
- Statistics (if available)
- Information on distribution of the product, including destination countries

RAPEX statistics

For the last four years the total number of RAPEX notifications has been as follows:

2001	2002	2003	2004
76	84	139	388

Three categories of risks represent more than 50% of the total notifications: risks of choking and suffocation, electric shocks and fires.

In 2004 the most frequently notified consumer products were electrical appliances (27%) and toys (26%). Of the total 388 notifications in 2004, 44 came from Nordic EU states.

Access to RAPEX

According to the GPSD (Art. 12.4), access to RAPEX shall be open to "applicant countries, third countries or international organizations", based on agreements between EU and interested parties.

Any such agreement shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the EU/EEA.

So far Bulgaria and Romania have joined the RAPEX system under Art. 12.4 of the GPSD and some other countries have expressed interest.

The TRAPEX system

Worth mentioning here is the so-called TRAPEX system (Transnational System for Rapid Exchange of Information on Dangerous Products)[6] which is a voluntary system of exchange of information on dangerous products.

The TRAPEX system was developed for the Eastern European accession countries, which, with the exception of Romania and Bulgaria, are

[6] For more information on the TRAPEX system, please see www.trapex.net

now EU member states. Consequently, this system will soon be discontinued. The goal is that Romania and Bulgaria will eventually join the RAPEX.

Ban on export to third countries

According to the GPSD, it is prohibited to export dangerous products, which have been the subject of a RAPEX notification, to third countries. Countries in Europe that are not members of the EU have to be particularly vigilant in order to prevent these products “migrating” across borders.

9. Accreditation, Notified Bodies, Testing and Certification

Accreditation

Consumers need confidence in the certification, inspection and testing of consumer products carried out on their behalf, which they cannot check for themselves. This is the responsibility of the accreditation bodies. The ISO/EN 17000:2004 standard series address criteria for accreditation, assessment, and operation of conformity assessment bodies.

Accreditation is a means of creating confidence on the market of products and services. It is an independent and impartial evaluation of the proficiency of the personnel and the bodies performing calibration, testing, and certification of products, processes, services, quality systems and surveillance.

More and more products are being made available. This means that the need for consumer protection has never been greater. Consumers can be protected by certification, inspection and testing of products and by manufacturing under certified quality systems.

But certifiers of systems and products as well as testing and calibration laboratories need to demonstrate their competence. They do this by being accredited by a nationally recognized accreditation body.

Accreditation delivers confidence in certificates and reports by implementing widely accepted criteria set by the European (CEN) and/or international standardization bodies (ISO). The EN/ISO 17000 standards address issues such as impartiality, competence and reliability; leading to confidence in the comparability of certificates and reports across national borders.

Notified bodies

Notified bodies are independent testing houses, laboratories, or product certifiers authorized by the EU/EEA member states to perform the conformity assessment tasks specified in the product directives. They must have the necessary qualifications to meet the testing and/or certification requirements set forth in the directives.

The primary task of a notified body is to provide independent verification that quality system conformity, the design or the manufacture of a certain product have been carried out by the manufacturer on the conditions set out in the product directive(s).

Most products within the scope of European product legislation (New Approach directives) can be self-certified by the manufacturer and do not require the intervention of a notified body.

For some products categories, as defined in the directives, the manufacturer must have the product design, production and/or quality assurance system approved by a European "notified body." Notified bodies are private agencies that have been appointed by a national government as the review experts for a particular directive.

There are no borders as notified bodies are free to offer their conformity assessment services, within their scope of notification, to any economic operator established either inside or outside the EU/EEA member states. They may carry out these activities also on the territory of other member states or of third countries. This implies that manufacturers may choose among the notified bodies, which are authorized to perform a particular conformity assessment procedure.

The use of conformity assessment and accreditation is designed to promote removal of barriers to trade in the EU/ EEA area and world wide.

Notified bodies are responsible for third party conformity evaluation procedures. Member states have to periodically verify the competence and the independence of these bodies.

The EC type-examination is a procedure by which the Notified Body ascertains and attests that a specimen representative of production meets the provisions of the directive that applies to it.

Testing and certification

Testing provides a 'snapshot' of the performance of a product, system or structure. It is often used to help develop new products, to evaluate product performance or as part of a requirement for CE marking or certification. It does not, however, always indicate whether the samples are representative of the final product, system or structure over a period of time. Testing consists of one-time verification of a product's performance**.**

Manufacturers can use the service of testing facilities anywhere in the EU/EEA member states.

Certification (or approval as it is also known) is an independent third party confirmation that products, systems and installers meet and continue to meet appropriate standards.

It is different from testing, as certification helps ensure, through regular audits, that the products continue to comply with the prevailing standards, which are themselves subject to revision and up-issue.

The auditing process also helps to confirm that the products available in the marketplace are exactly the same as those originally tested and approved.

Certification is always paid by the manufacturer.

The difference between accreditation and certification for laboratories and inspection bodies; Accreditation uses criteria and procedures specifically developed to determine technical competence. Certification demonstrates conformity to the standards requirements.

10. Toy Safety in the Nordic Countries

As children are viewed as an especially vulnerable group in society, the principles of toy safety in the Nordic countries will be demonstrated in this chapter as a model for a product group in the “harmonized” area.

Products for children

Over the years children have suffered injuries caused by products, which are designed for them. Special attention has therefore been focused on ways to protect them from unsafe products.

Apart from toys, other child care articles and baby products, such as soothers, baby beds, prams and playground equipment have to fulfil stringent safety requirements in order to be considered safe for children.

Legislation

The Toy Safety directive was the first New Approach directive (1988) to be adopted and has been incorporated into law in all of the EU/EEA member states as national toy safety legislation.

In some instances, toys must comply with other legislation, such as the Cosmetics directive for toys with cosmetics. Toys must comply with chemical legislation like other consumer products.

Recently, a ban on putting certain substances in toys was imposed in the EU/EEA market. Although this is an important step in securing the

environment for children, this is not directly linked to safety of toys as defined in the Toy Safety directive.

What products are toys?

The Toy Safety directive clarifies which products fall under the scope of the directive. A toy is defined as "any product or material designed or clearly intended for use in play by children of less than 14 years of age". Toys in kindergartens, day-care centres and other facilities must also meet the requirements in relevant legislation.

Products not regarded as toys, and as such excluded from the rules on toy safety, are listed in Annex I of the Toy Safety directive. They include Christmas decorations, scale models for adult collectors, folk dolls and decorative dolls for adult collectors, sports equipment, air guns and air pistols, for example.

What requirements must toys meet?

Manufacturers supplying toys on the EU/EEA market must ensure that toys satisfy the essential requirements in the Toy Safety directive and must take responsibility for the declaration, which the CE marking presents.

According to the directive, manufacturers of toys are required to supply products that are safe in normal and foreseeable use. Safety takes into account factors such as the product’s characteristics, instructions and warnings and the categories of consumers at risk when using the product, in this case children.

European harmonized toy standards (EN-71) contain detailed requirements concerning composition and labelling of toys. Essential safety requirements concerning toys' physical, mechanical, chemical and electrical properties and flammability are outlined in the directive and further materialized in the standards. These standards also present detailed information on test methods.

Nordic working groups on consumer safety and enforcement authorities have tirelessly campaigned for safety of toys and child care articles in order to protect children. One of the areas greatly emphasised in this campaign is the lowering of the noise limit for toys.

Tests indicate that exposure to just one shot from a toy cap gun can lead to permanent damage to the hearing capacity of children. After ten years of cooperation between consumer representatives, mostly from the Nordic countries, the toy standard now includes noise limits for certain toys.

Tips for assessing risk

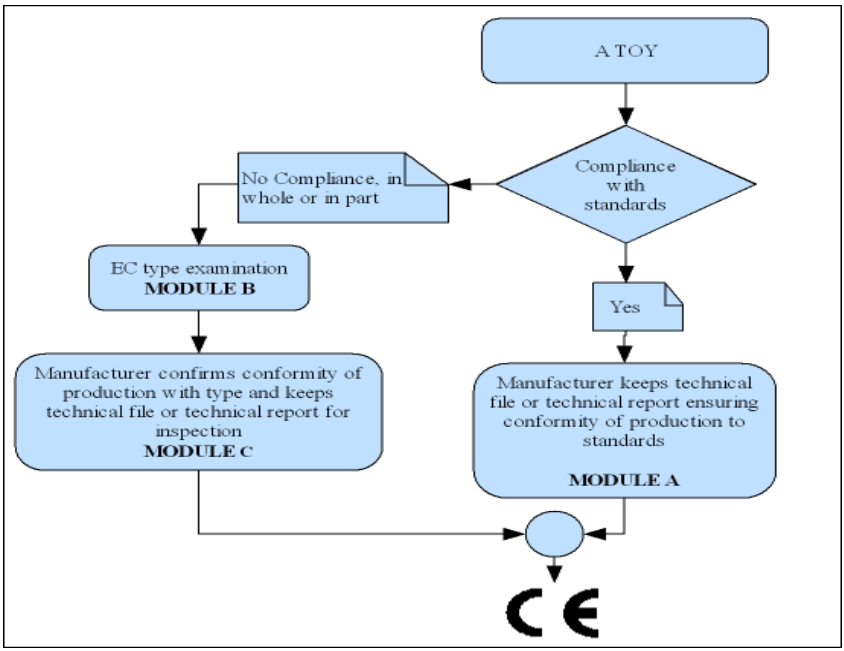
When attempting to figure out risks inherent in a toy there are many things to consider. First and foremost it must be decided what risks should be assessed. Those risks should then be documented together with reasons and consequences. Regular and non-regular use of the toy should be considered. Assembly and disassembly of the product and younger-than-intended users should be taken into account.

When the safety of toys is assessed, consideration must be given to the normal behaviour of children, who may not be as careful or have the same skills as adults. Risk refers to the chance of an unwanted event. It depends on the severity of the hazard and the probability of its occurrence.

Conformity assessment

As in other “new approach” directives, the toy safety directive lists the conformity assessment procedures that manufacturers need to go through in order to place toys on the EU/EEA market.

As the flowchart demonstrates, using harmonized standards gives the manufacturer presumption of conformity and he can “self-certify” his products. If he chooses not to make use of harmonized standards, the toy in question has to go through EC-type examination (module B).



For a flowchart of the conformity assessment modules, please refer to appendix 4.

Children under the age of three

Special attention is paid to children under the age of three. Toys intended for them, as well as any detachable parts from the toys must be of such dimensions as to keep them from being swallowed or inhaled. The toy standard (EN 71-1) contains a test method ("the small parts cylinder") to measure small parts that should be avoided.

Toys which are intended for older children but appealing and unsuitable for children under the age of three must bear an age warning together with a brief indication of the specific hazard calling for this restriction (EN 71-1:1998 clause 7.2). It can be in the form of a text, "not suitable for children under 36 months" or " not suitable for children under three years" or the pictogram below.

Labelling and instructions for use

A toy or packaging must contain information regarding the manufacturer or his authorized representative or the importer.

All toys or their packaging must bear the CE marking in plain view. The CE marking is the manufacturer's assurance that a product meets the essential requirements in the Toy Safety directive. It is not a comprehensive guarantee of the quality or the function of the toy, however. Warnings and instructions for use and care must also be supplied with a toy.

Who is responsible for the safety of toys?

Manufacturers and others in the supply chain are responsible for safeguarding that toys, which they manufacture, market and sell are safe. This includes manufacturers, importers, distributors and sellers.

Manufacturers must show due care to prevent risks and dangerous situations and immediately report to the competent authority any risk observed in toys which they produce and place on the market.

Parents, teachers and educators can play an important role in providing information about toy safety but also about the safe use of toys and consumer rights and responsibilities.

Who monitors toys?

Enforcement authorities appointed to monitor safety of toys on the market in each of the Nordic countries are responsible for market surveillance

activities regarding toys on the market. The relevant enforcement authorities conduct market surveillance and have the products tested.

Technical file

Information on the construction of a toy must be maintained for up to ten years to be presented for inspection by enforcement authorities.

What happens when a toy is found to present a risk?

As with any consumer product if a toy presents a risk to consumers' health or safety, the relevant enforcement authority can ban the sale of the product. In addition to a sales ban the enforcement authority can require a manufacturer to recall products, which have already been sold and provide consumers with a replacement or refund.

The manufacturer can also withdraw the product voluntarily.

11. Role of Customs Authorities

Consumers are entitled to an equivalent level of protection regardless of the origin of available products on the market. The system of market surveillance of consumer products that has been described in these Guidelines is for consumer products that fulfil the entire requirements concerning safety in the Nordic countries as members of the EU/EEA internal market.

The "Third country" regulation

All the Nordic countries have transposed into their respective legislation EC regulation No. 339/93/EEC (Third Country Regulation) relating to safety of products imported from third countries. There is no uniform approach in the Nordic countries in tackling imports of dangerous products from third countries.

According to the regulation, customs authorities can detain goods from third countries at the external borders for up to three working days to permit checks by enforcement authorities.

This is the case when products bear the characteristics suggesting a serious and immediate risk to health and safety of consumers and/or they are not accompanied by required documents assuring their safety. Given these circumstances, customs authorities play an important role in market surveillance activities.

Cooperation

Cooperation between enforcement authorities and the customs authorities is a prerequisite for effective market surveillance of products coming from third countries. Customs authorities should be able to take samples, which are sent to laboratories for testing. Authorities should seek to ensure transparency of the measures taken in order to avoid reverse effects of the control.

Enforcement authorities can issue a sales ban on dangerous products. This ban can also be applied to the importation of a specific product. In this respect, customs authorities can monitor products that are being imported.

By activating customs authorities to check for safety of products, unfair competition from manufacturers/distributors that do not adhere to the rules on product safety is avoided.

In Denmark, when customs authorities discover that products being imported constitute a hazard, entry is halted and the case is handed over to the relevant enforcement authorities for further consideration.

Cooperation also takes place with customs authorities where relevant enforcement authorities participate in actions composed by customs authorities (for instance checking for safety of products on local markets).

12. Product Liability

The 85/374/EEC Directive on liability for defective products introduced (in the EU) the principle of objective liability or liability of the manufacturer in cases of damage caused by a defective product.

According to the directive, any manufacturer of a defective product must compensate any damage caused to the physical well-being or property of individuals, independently whether or not there is negligence on the part of the manufacturer or not.

All of the Nordic countries have legislation in force based on the product liability directive that gives consumers the opportunity to recover compensation in case they sustain injuries by defective products. In contrast to most other European countries, contract law has very limited scope in product liability cases in the Nordic countries.

The directive on product liability is applicable to all products covered by New Approach directives and GPSD.

It is in the interest of the manufacturer, the importer and the distributor to supply safe products in order to avoid the costs that liability places on them for defective product causing damages to individuals or property. People injured by defective products may have the right to sue for damages. If more than one person is liable for the same damage, there is a joint liability.

Overall it can be stated that the product liability directive has contributed to a higher level of safety of products placed on the EU/EEA market.

The directive has to be viewed as part of a broader system involving a wide variety of factors such as product safety and consumer protection laws.

13. Consumer Associations

Consumers need to look to the safety of themselves and their families by selecting products that are appropriate, using them in accordance with the manufacturer's instructions, maintaining products in good condition and taking notice of any safety warnings.

Nordic consumer associations are increasingly making efforts to ensure that consumer safety concerns are taken into account in product legislation.

Consumer associations and product safety

Consumer associations´ involvement in product safety matters is essential in ensuring a well functioning and efficient system. The main areas to focus on are the following:

- Inform consumers about their rights in relation to safety of consumer product legislation.
- Give consumers easy access to information about identified dangerous products.
- Be in close contact and co-operate with the national authorities responsible for the consumer product safety.
- Use consumer complaints, accident data, comparative testing and results to compile information for the benefit of the consumer.
- Use other countries experiences as input in proposals for reforms.

Contribute to the process of creation of standards under consumer product directives.

In Finland, the Finnish Consumers' Association is an independent promoter of the interests and rights of consumers.

The objects for which the Finnish Consumers' Association is established are: to encourage consumers to work actively for their interests and to promote this kind of co-operation, to promote and advance consumer interests in society and on the market by means of informal action, to further the principles of fairness and sustainable consumption, to promote consumer awareness and to work for environmental protection.

Members of the Finnish Consumers' Association are local and regional consumer associations, national federations, unions and associations, and private persons. The Finnish Consumers' Association participates in national, European and global-level cooperation on consumer protection matters.

Funding

The authorities in the Nordic countries have a long history of financially supporting consumer associations in order for them to work effectively in the interests of the consumer.

The result has been relatively efficient consumer associations in the Nordic countries, which have contributed to a high level of consumer protection as authorities have realized the benefit from powerful and independent consumer associations.

Publications

Consumer magazines regularly publish test results of comparative testing and in doing so introduce to the public the nature and the significance of quality investigations.

Through the consumer magazines, the consumer associations are able to inform consumers about consumer products that are unsafe (or of a low quality), thus contributing to more awareness among consumers. In some instances, magazines published by national consumer agencies serve the same purpose.

14. Appendixes

Appendix 1: Terminology

Accreditation

Third party attestation, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks (EN 45000/ EN ISO IEC 17000 standards series).

Information on accreditation: European Co-operation for Accreditation, www.european-accreditation.org

Conformity assessment

The demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000.)

Information on conformity assessment: www.conformityassessment.org

A mandate

A mandate is a political request by the EU (and EFTA) to develop voluntary standards based on consensus amongst all parties involved. In many cases, a mandate is given to support European legislation and to develop the technical specifications of the essential safety requirements. Mandates are mainly issued in the area of New Approach legislation.

Market surveillance

ISO Guide 74: The organized efforts of the government to ensure that products on the market comply with regulations on safety and the protec-

tion of health and environment. Market surveillance means the organized supervision of products on the market.

Risk

ISO/IEC Guide 51: The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm. (Hazard is defined as a potential source of harm).

Standardization

Activity of establishing, with regards to actual or potential problems, provisions in the form of standards for common and repeated use, aimed at the achievement of the optimum degree of order in a given context. Different stakeholders take part in the different project groups that develop the standard proposals that the member states then vote on.

Standards

ISO/IEC Guide 2: A standard is a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Appendix 2: GPSD enforcement authorities in the Nordic countries

Denmark

Sikkerhedsstyrelsen
Nørregade 63
DK-6700 Esbjerg
www.sik.dk

Finland

Kuluttajavirasto/Finnish Consumer Agency
Haapaniemenkatu 4, Box 5
FIN-005310 Helsinki
www.kuluttajavirasto.fi

Iceland

Neytendastofa/Icelandic Consumer Agency
Borgartun 21
IS-105 Reykjavik
www.ls.is

Norway

Direktoratet for Samfunnsikkerhet og Beredskap
Postboks 2014
NO-3103 Tønsberg
www.dbs.no

Sweden

Konsumentverket
Rosenlundsgatan 9
SE-118 87 Stockholm
www.konsumentverket.se

Appendix 3: Additional references

1. Product Safety in Europe: A Guide to Corrective action including recalls
http://europa.eu.int/comm/consumers/cons_safe/action_guide_en.pdf

2. Consumers safety in the European Union
www.eu.int/comm/consumers/

3. Guidance document on the relationship between the General Product Safety Directive (GPSD) and certain sector directives with provision on product safety
http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf

4. New Approach guide
http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm

5. The RAPEX system
http://europa.eu.int/comm/dgs/health_consumer/dyna/rapex/rapex_en.cfm

6. Guidelines for the management of the Community information system (RAPEX) and for notifications presented in accordance with article 11 of directive 2001/95/EC
http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/rapex_guid_en.pdf

7. Standardization policy
http://www.europa.eu.int/comm/enterprise/standards_policy/index_en.htm

8. List of references of harmonized standards published in the OJ
www.europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/index.html

9. Relations between New Approach directives/programs of standards/standards
www.newapproach.org

10. List of new approach directives and standardisation work
www.newapproach.org/directives/directivelist.asp

11. Council regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries
http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31993R0339:EN:HTML

12. EU aid
www.europa.eu.int/comm/europeaid/index_en.htm

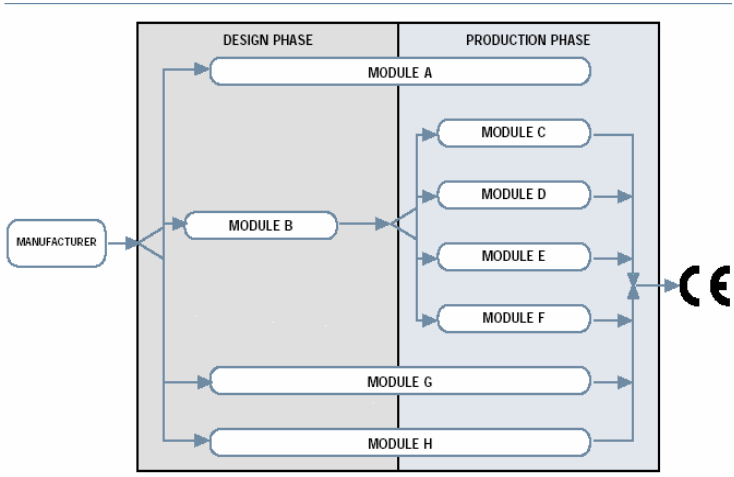
13. Trade and development
www.europa.eu.int/comm/trade/issues/global/development/trta/index_en.htm

14. EA European Co-operation for accreditation
http://www.european-accreditation.org

15. Implementation in Finland of the Community directive on general product safety act (92/59/EEC)
http://europa.eu.int/comm/dgs/health_consumer/library/surveys/sur13_07_en.pdf

Appendix 4: Conformity assessment procedure - the modules

The different requirements for an outside review have been codified into a system of "conformity assessment module(s)". There are eight basic procedures, labelled as modules A through H.



The conformity assessment modules are:

Module A - Internal Production Control
Module B - EC Type Examination
Module C - Conformity to Type
Module D - Production Quality Assurance
Module E - Quality Assurance for Final Testing
Module F - Product Verification
Module G - Unit Verification
Module H - Full Quality Assurance Abbreviations

It is normal for Modules A, G or H to be applied individually and for Module B to be applied in conjunction with one of Modules C, D, E or F.

The conformity assessment procedures in most New Approach directives include three modules (D, E and H) that enable a manufacturer to

meet the requirements on the basis of an approved quality management system.

EN/ISO 9001:2000 quality assurance standard is now the harmonized standard for these three modules and as such will provide an element of presumption of conformity to the requirements in the applicable directive.

From design to placing on the market

A manufacturer that intends to place consumer products on the EU/EEA market will have to review the consumer product directives to determine which of them applies to the relevant product type.

Further it has to be decided upon which conformity assessment module(s) will be used to demonstrate that the product fulfils all requirements according to applicable legislation.

In some cases EN standards have not been developed for certain product types. If so, other standards must be identified to use that effectively address the same concerns.

Appendix 5: Manufacturer's complaint form

In Finland a report on potentially dangerous consumer product can be made by completing the accompanying form and sending it to the Consumer Agency. An interactive form can also be filled out.

The manufacturer must indicate what measures have been taken to eliminate the risk (Product Safety Act, section 3) - he can use the same form to reply to the Consumer Agency if a product has been found to violate regulations.

To register a safety complaint

Report must be made even if complete information on the risk is not available.

A report must be made if consumer products present a risk in the form of: damage to health - accident - a dangerous situation or - a serious near miss.

Even a small risk can require a report if - a product is broadly distributed - the risk is not obvious to consumers- the product is intended for children, young people or elderly adults.

A manufacturer must provide the supervising authority any information needed to monitor compliance with the product safety legislation. Filing a report does not eliminate responsibility for seeing that products are safe.

Kuluttaja virasto ● asiamies

Business operator's notification of actions in respect of products that do not comply with regulations

1. Information on the business operator: name, address, telephone and fax numbers, e-mail address:

_____

_____

Does this concern a manufacturer ☐, importer ☐ or shop/seller? ☐

2. Product information

Brand name:

_____

Trade name:

_____

Batch code or equivalent: --

_____

3. Information about the manufacturer if other than in question one.
Name, address, telephone and fax numbers, country of manufacture:

_____

_____

_____

_____

4. Number of items and dates:
Number imported (importer) and date. _____ pcs. _____._____ 200_
Number manufactured (Finnish manufacturer), and date.
_____ pcs. _____._____ 200_

Number in importers/manufacturer's stock, and date.
_____ pcs. _____._____ 200_
Number remaining in shops, and date.
_____ pcs. _____._____ 200_

5. Distribution channels for the products; list the wholesalers and retailers that have received deliveries of the product. Continue on a separate sheet if necessary.

_____
_____
_____
_____

6. What do you intend to do with the products that are in stock and in the shops?

_____

☐ Withdraw them from sale and distribution, date. _____ 200_
☐ Repair the products (details of the intended repairs and timetable attached)

7. What do you intend to do for the consumers with respect to the products already sold?
Actions and timetable:

_____
_____
_____

8. If you withdraw the products from the market voluntarily, what do you intend to do with the products that are in stock and that are returned to you?
Actions and timetable:

_____
_____
_____

9. If the product is manufactured in Finland, has the product been exported?

Yes ☐ No ☐

If yes, when and to which country/countries, and how many?

_____
_____
_____

10. How do you intend to give information about the matter?

To the shops:

_____

To consumers who have already bought the product (notification to be attached):

_____

Timetable for notification:

_____

11. Have you other products of a similar nature? Yes ☐ No ☐

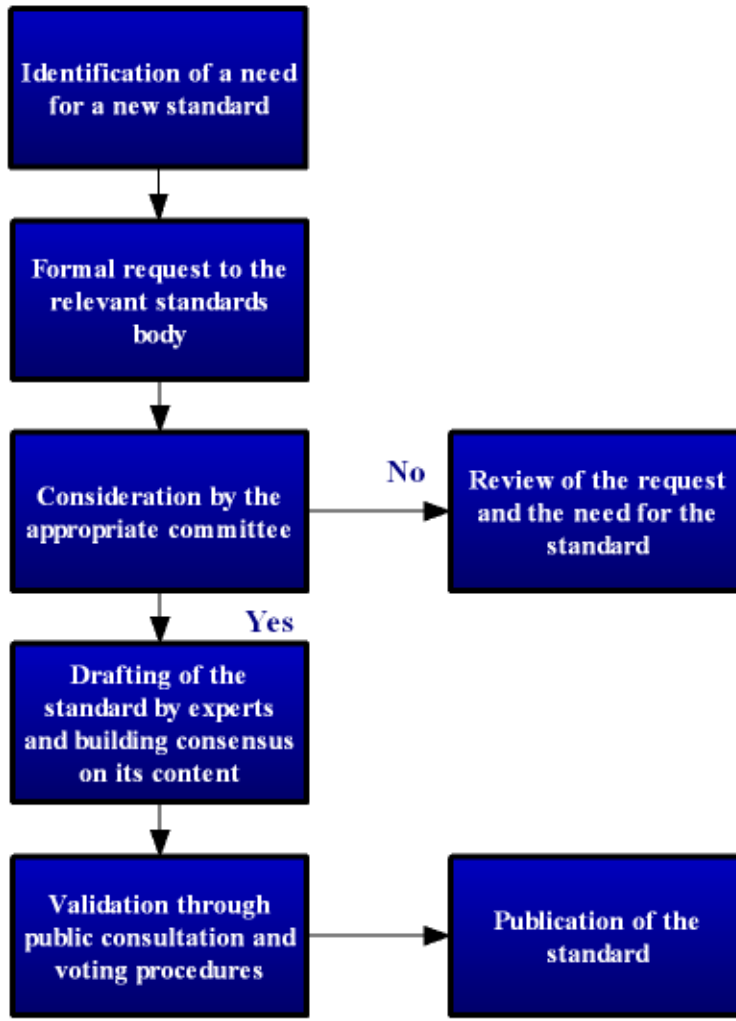
If yes, what do you intend to do about the matter?

12. Signature, name in block letters, date:

_____ _____._____ 200_

Return address: Consumer Agency, Haapaniemenkatu 4, PL 5, 00531 Helsinki, fax +358 9 7726 7586

Appendix 6: The European standardization process



1. The first stage is the adoption of a work item (WI) in the programme of a Technical Committee (TC) at CEN or CENELEC. This is normally done at the plenary meeting after the circulation of a proposal.

2. The creation of a Working Group (WG) to produce the standard - or the assignation of the work item to an existing WG.
3. The production of the draft standard leading to the CEN/CENELEC enquiry - the draft standard is assigned an EN number and sent to the NBS, national standards bodies, for comment. The enquiry period is normally 6 months.
4. The draft standard is revised by the WG accepting or rejecting the comments received.
5. The revised draft standard is then sent to the formal vote. The NBS vote yes or no on a weighted majority basis. NBS can appeal at this stage on matters affecting safety if they disagree with a positive vote.
6. If the vote is yes the standard is ratified by CEN/CENELEC and sent to the NBS for publication.
7. At the same time the CEN/CENELEC Secretariat send details of the ratified standard to the Commission for inclusion in the Official Journal (OJ). It is from this stage that EU/EEA member states can raise an objection to the inclusion of the reference to the standard in the OJ.
8. The standard becomes an "harmonized standard" when reference to it is published in the OJ and published by at least one NBS of CEN or CENELEC.

Appendix 7: List of directives based on the New Approach and the Global Approach

Directives based on the principles of the New Approach which provide for CE marking

I. Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to **electrical equipment designed for use within certain voltage limits**

II. Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to **simple pressure vessels**

III. Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the **safety of toys**

IV. 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**

V. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to **electromagnetic compatibility**

VI. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to **personal protective equipment**

VII. Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to **non-automatic weighing instruments**

VIII. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to **active implantable medical devices**

IX. Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to **appliances burning gaseous fuels**

X. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for **new hot-water boilers fired with liquid or gaseous fuels**

XI. Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of **explosives for civil uses**

XII. Council Directive 93/42/EEC of 14 June 1993 concerning **medical devices**

XIII. Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in **potentially explosive atmospheres**

XIV. Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to **recreational craft**

XV. European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to **lifts**

XVI. Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning **pressure equipment**

XVII. Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to **machinery**

XVIII. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on **in vitro diagnostic medical devices**

XIX. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on **radio equipment and telecommunications terminal equipment** and the mutual recognition of their conformity

XX. Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to **cableway installations designed to carry persons**

XXI. Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on **measuring instruments**

The General Product Safety Directive (GPSD)

A new revised directive for General Product Safety (GPSD) is applicable as of January 15th 2004. The new directive, 2001/95/EC was adopted on 3 December 2001 and published in the Official Journal L 011 on 15 January 2002. http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/index_en.htm