BEST PRACTICE TECHNIQUES IN MARKET SURVEILLANCE

product safety

safeguarding consumers

supporting fair competition

effective consultation

A **PROSAFE** *Project*

Supported by the European Commission
DG-SANCO, Consumer Affairs Directorate

FOREWORD BY THE EUROPEAN COMMISSIONER FOR CONSUMERS, MRS. MEGLENA KUNEVA

Efficient and effective market surveillance is the cornerstone of a successful consumer product safety policy in the EU. Without the Member States' efforts to find and remove unsafe products from our markets, our policy framework can not be properly implemented and enforced. This is not only to the benefit of European consumers. Reputable businesses require a level playing field to innovate and flourish.

With product supply chains increasingly spanning the globe, coordination of market surveillance across national borders is not a luxury – it is a must. Without such collaboration scarce resources are wasted and unsafe products that are refused at one entry point could easily find access somewhere else, to the detriment of our citizens.

I am therefore delighted that the market surveillance authorities involved in the Enhancing Market Surveillance through Best Practices (EMARS) project have succeeded in gathering a wide range of best practices in market surveillance from across Europe. This project, which has been financially supported by the European Commission, has shown that cross-border cooperation between the Member States is not only highly desirable but also eminently feasible.

I hope that this best practice Book[1] will be an inspiration for all those involved in ensuring consumer product safety, be they public authorities, regulators or businesses. Only by strengthening our cooperation and raising our game can we ensure that global markets deliver safe products and that the health and safety of European consumers is protected.

Meglena Kuneva
European Commissioner for Consumers

1 The information contained in this Book does not necessarily reflect the opinion or the position of the European Commission. Neither the European Commission nor any person acting on its behalf is responsible for any use that might be made of the information contained in this Book.

FOREWORD BY CHAIRMAN OF WORK PACKAGE 3, MR. GUNNAR WOLD

Enhancing and protecting the welfare of European consumers has been the cornerstone of the EU Consumer Policy strategy 2007 – 2013, as is clearly shown by its subtitle: 'Empowering consumers, enhancing their welfare, effectively protecting them'.

Market surveillance is an important tool to achieve the aims of this strategy. Consumer protection is the most immediate outcome of market surveillance activities, when dangerous products are removed from the hands of consumers. But market surveillance also plays an important role in ensuring a well-functioning Internal Market with fair and open competition.

Market surveillance is the responsibility of the Member States, who conduct their activities in an efficient and professional way. However, experience has shown the need to enhance market surveillance and to encourage a more uniform approach. In fact, this is the aim of several of the European Commission's initiatives. The General Product Safety Directive 2001/95/EC sets up the Member States' obligations with respect to market surveillance of consumer product safety. The recent revision of the New Approach builds upon and complements the existing framework for consumer products and establishes a comprehensive system for industrial products.

The need for cross-border cooperation has become increasingly evident. The EU Consumer Policy Strategy aims at increasing cross-border trade in Europe. As a result, the fragmented national market will gradually be replaced by an EU-wide market, the biggest retail market in the world. This process necessitates a reinforced EU-wide cooperation between market surveillance authorities.

Furthermore, the fact that the resources available for consumer protection are limited should call for Member States to exchange experiences and best practice examples, so as to ensure that existing resources are spent effectively and the highest level of consumer protection possible is attained. Thus, it seems necessary to focus on developing procedures for the practical part of market surveillance actions, including cross-border cooperation and cooperation with stakeholders.

On the national level market, surveillance will contribute to achieving EU objectives with respect to increasing the free movement of goods. On the EU level, this will increase the effectiveness of EU legislation and hence contribute to a greater extent to achieve EU objectives.

In light of the above-mentioned challenges, the idea to develop a set of recommendations to assist and enhance market surveillance in Europe was conceived. It was first presented at the PROSAFE meeting in Vienna in 2005, leading to an application from Voedsel en Waren

Gunnar Wold
Chair WP 3

Autoriteit (VWA) to the Directorate-General for Health and Consumers of the Commission (DG SANCO) in 2005 for the funding of a project. Of the overall scope of this project, developing 'Best Practices' would be one of six topics, all of them dealing with various aspects of market monitoring and surveillance. This project was named EMARS (enhancing market surveillance in Europe).

Since autumn 2005, a working group called 'Work Package 3' has been collecting and compiling best practices in market surveillance from Member States. The result of this work is the 'Best practice techniques in market surveillance' (hereinafter, this Book). Even though the main purpose of this Book is to support the market surveillance and enforcement authorities, the Book will also be available to all stakeholders to ensure transparency and understanding between all interested parties.

This Book contains recommendations on best practices for the authorities in the Member States and EFTA/EEA countries concerning consumer products. The recommendations reflect the 'state of the art' existing at the time this Book was written.

Through the financial programme under Article 10 of the GPSD, DG SANCO has contributed comprehensively to the EMARS project. The funding from DG SANCO has made it possible to achieve the objective to provide the best practices in market surveillance.

EMARS would like to thank DG SANCO for their generosity in the funding of this project and also the participating Member States for their efforts in developing this Book. EMARS is also grateful for comments received from stakeholders representing businesses, standardisers and consumers.

We sincerely hope that this Book will guide and inspire you in your future work regarding market surveillance.

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EXECUTIVE SUMMARY

In 2006, the Product Safety Enforcement Forum of Europe (PROSAFE) started a three-year project aimed at ensuring a basic level of expertise and practical experience within the market surveillance organisations of the Member States of the European Economic Area (EEA). The project, entitled EMARS ('Enhancing Market Surveillance through Best Practices in Europe'), received financial support from the Directorate General for Health and Consumers as well as from the European Free Trade Association (EFTA) and several other European countries. Fifteen Member States were involved as full participants and several more contributed actively to the work.

This Book is one of the main deliverables of the project, which also developed a number of other tools including a forum providing rapid, practical advice to market surveillance officers and a knowledge base of documents related to market surveillance.

The purpose of the Book is to present information on best practices in market surveillance that has been collected from Member States as well as other countries. The main target audience is the enforcement authorities in Europe who will find descriptions of procedures and best practices to inspire their organisations' continuous development. Nevertheless, other interested parties including policymakers, regulators, businesses and consumer representatives will find that this Book provides them will additional insights into the practice of market surveillance.

The approach adopted in this Book is based on the following principles:

1. Taking a preventive approach to enforcement and employing effective communication strategies to advise and to protect consumers and businesses.
2. Using data capture and risk analysis to target unsafe products, services and practices and to establish enforcement priorities.
3. Taking a coordinated approach to enforcement programmes and practices across the EU to ensure greater operational efficiency and consistency.
4. Dealing swiftly and proportionately with problems identified to ensure offending products, services and practices present minimum risk.
5. Resolving problems at source and in a co-ordinated manner by adopting a home/lead authority approach.
6. Ensuring that market surveillance officials are appropriately trained, are aware of the economic context in which they operate, employ best practices and are supported by continuing professional development.
7. Ensuring that all policies and strategies are relevant and clearly understood by a process of appropriate consultation.

The following overview summarizes the contents for quick reference on where to find what.

The contents of the chapters are introduced below to allow the reader to focus on the parts of the Book that are of particular interest.

Part A of the Book introduces the legislative background for market surveillance and the framework for non-food consumer product safety in the EU. The basis for the discussion is the provisions as laid down in the General Product Safety Directive.

Part B discusses the management of market surveillance activities. The discussion follows a top-down approach beginning with the management level (in Chapters 3 and 4) and moving towards the operational level (Chapters 5 through 10).

Chapter 3 presents the organisational issues that must be addressed when setting up a market surveillance organisation. The chapter includes discussions of infrastructure, approaches to market surveillance, competences, external relations (to stakeholders, media and others) and operational risks. It also discusses the considerations behind a number of essential standard operating procedures, e.g. quality assurance, intervention policies, handling of notifications and consumer complaints, and procedures for inspections, sampling and testing.

Chapter 4 describes the planning cycle in market surveillance and how the market surveillance vision is broken down into long term programmes and further down into short term programmes (or annual plans). It also discusses the prioritising of market surveillance activities, including a presentation of tools that can be used for this purpose, and it discusses where to focus the activities to ensure the largest effect. The chapter finally includes a description of how key performance indicators can be used by management to monitor the progress in the activities.

Chapter 5 shifts the perspective to a more operational one. It describes how a project plan is developed and outlines a number of issues to be considered when planning the project, e.g. the setup of the investigations in the project, the use of check lists, the involvement of test laboratories, the risks that are addressed in the project and how they are evaluated, the staffing of the project and the financial aspects. The chapter also addresses the communication from the project including the cooperation with different stakeholders.

Chapter 6 discusses reactive market surveillance. Reactive market surveillance is defined as the market surveillance activities that can not be planned, e.g. investigation of accidents, notifications, consumer complaints, etc. The chapter outlines the differences between reactive market surveillance and planned (or proactive) market surveillance and it discusses the different sources that trigger reactive market surveillance and the measures

that the authority can apply to prioritise. It also discusses the organisational impact i.e. the financial and human resources required for reactive market surveillance.

Chapter 7 discusses implementation of a market surveillance project plan. The chapter presents examples of procedures and checklists for the inspectors. It also describes the basic equipment to be used by market surveillance inspectors and gives examples of how to make screening tests for consumer products, electrical products, toys and personal protective equipment for consumers. It describes practical ways to handle samples, including procedures for sampling, registration, packaging and labelling of collected samples. It discusses cooperation with test laboratories and addresses the necessary involvement of the economic operators in the investigations and the follow-up.

Chapter 8 describes how to report, analyse and follow up the results from market surveillance operations. It discusses different applicable measures including destruction of dangerous products as well as the follow-up in the market in general and for the specific product. The chapter also includes a description of the Member States' obligations to exchange information. Finally it discusses the information that must be retrieved from a project to allow reporting and analysing the outcome.

Chapter 9 discusses how to review, report and analyse a market surveillance project. This discussion includes a generalised table of contents for a final report. A significant part of the analysis is an evaluation of the effects of a project and the need for further measures. This is addressed in the part of the text that also considers the need to profit from the experience gained in the project, which will ensure that the authority learns from the project. Finally the chapter addresses considerations regarding the publication of a final report from the project.

Chapter 10 discusses risk assessment of consumer products. The chapter is closely linked to the revised RAPEX guidelines and it utilises the method from these guidelines. The chapter contains an introduction to risk assessment and it discusses how and why risk assessment is applied in the context of market surveillance (e.g. as opposed to production control). It describes the data that are necessary and discusses how they can be obtained. A large part of the chapter is devoted to a thorough presentation of a case of a risk assessment of a dangerous product, a hammer with a broken shaft. The chapter discusses a number of pitfalls in risk assessment and presents guidance and useful tools to avoid them and it presents an example of a risk assessment report. Finally it introduces two other common risk assessment methods, the original RAPEX method and the nomograph method.

Part C of the Book discusses cross-border market surveillance activities, in particular the role of customs in market surveillance. It introduces the legal basis and presents several examples of best practices in cooperation between customs and market surveillance authorities, e.g. exchange of information about dangerous products, setting up risk profiles, customs' inspection of products and notification of arriving consignments. The chapter also discusses counterfeiting and its relevance for market surveillance.

The Book contains ten annexes presenting miscellaneous information that was found relevant for the reader but so detailed that it did not fit into the flow of the main text of the Book:

- **Annex A** discusses mechanisms that can be applied in cross-border market surveillance actions and gives examples taken from three joint actions.
- **Annex B** presents different frameworks of risk assessment.
- **Annex C** presents six examples of 'model risk assessments'.
- **Annex D** discusses risk communication and presents miscellaneous tools and other ways to exchange information on dangerous products.
- **Annex E** presents a theory on the targeting of market surveillance.
- **Annex F** gives an example of how intervention limit values for electrical products have been set up by the Nordic countries in a 'Failure Code List'.
- **Annex G** introduces the main European and international stakeholders within market surveillance.
- **Annex H** gives detailed descriptions of a number of cross-border information systems.
- **Annex I** includes the legislative references and gives a list of appropriate literature to consult.
- **Annex J** contains an overview of standards applicable to quality assurance.

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PART A – INTRODUCTION

1 AIM AND SCOPE

In 2006, PROSAFE (The Product Safety Enforcement Forum of Europe), with support and funding from the European Commission, established the EMARS project ('Enhancing Market Surveillance through Best Practices in Europe').

The project's goal was to help increase safety for consumers and enhance operational efficiency in market surveillance with minimal encumbrance of good business. This will enhance enforcement efficiency and collaborative impact and contribute to consumer and business confidence in the European market.

This Book focuses in particular on market surveillance systems related to the safety of non-food consumer products as covered by the General Product Safety Directive (GPSD[1]), Low Voltage Directive (LVD[2]), Personal Protective Equipment Directive (PPE[3]) and Toys[4] Directive, although in some parts reference is made to other Directives or products for the sake of more complete information.

1 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [5] – OJ L 11, 15.1.2002, p. 4.

2 Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits [6] – OJ L 374, 27.12.2006, p. 10.

3 Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment [9] – OJ L 399, 21.12.1989, p. 18.

4 Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys [7] – OJ L 187, 3.5.1988, p. 1.

As such, the content does not address other issues such as environment or workplace safety. The Book's purpose is to share and disseminate best practices and hands-on advice to officials charged with market surveillance activities. Nonetheless, it is not only aimed at practitioners but also at senior managers of the Member States' market surveillance authorities, by describing the necessary elements of an effective surveillance system and by identifying best practices in this field. This Book will play a significant role in underpinning effective and informed implementation of EU legislation on market surveillance.

It can therefore be used as a guide and reference book by senior management in the Member State authority to further enhance and develop their own surveillance strategy. At the same time, it will also be helpful to market surveillance practitioners and inspectors as a reference for improving their surveillance approach in specific areas.

The Book has been prepared on the basis of practical experience and the up-to-date knowledge of officials from across Europe. Moreover, it is intended to be continually updated and revised according to the most recent experience and developments. Therefore the audience is cordially invited to contribute in this process by submitting comments and ideas. Feedback will be validated and used as appropriate.

Finally, this Book may also be used by businesses and consumers to enhance their understanding of the way market surveillance is carried out. Indeed, no market surveillance system can work effectively without introducing a high level of cooperation and coordination between government, businesses and consumers.

2 THE EC LEGISLATIVE BASES FOR MARKET SURVEILLANCE

2.1 Background – the framework for non-food consumer product safety in the EU

The legislative framework for the safety of non-food consumer products in the EU is to be found in the General Product Safety Directive (GPSD). The Directive lays down a general safety requirement whereby producers are obliged to place only safe products on the market.

The provisions of the GPSD apply generally except insofar as there are more specific provisions laid down in other Community laws covering the same aspects and risks or categories of risks. Such provisions can be found in certain sector-specific Directives such as those for toys, electrical equipment (LVD) and cosmetics.

The GPSD lays down many requirements for the various participants in the supply chain:

- producers may place only safe products on the market;
- all economic operators are responsible for the safety of the products that they market;
- economic operators must inform the authorities if they have placed unsafe products on the market and cooperate with authorities to remove unsafe products from the market.

The producer has the responsibility to verify and declare compliance with all European legislation applicable through a process of Conformity Assessment. The responsibility of the market surveillance authorities extends to the surveillance of products that are about to be or have already been placed on the market, performing a so-called Compliance Assessment. The responsibilities and roles of economic operators and market surveillance authorities before and after placing a product on the EU market are shown in Figure 1 below:

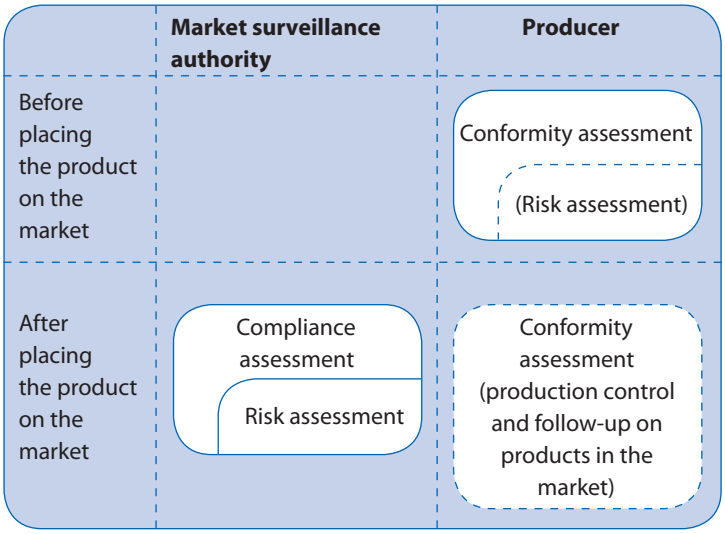


Figure 1: Responsibilities and role of economic operators and of market surveillance authorities before and after placing a product on the EU market.

2.2 Ensuring the safety of products

The ultimate purpose of market surveillance is to ensure the safety of products placed on the market. The GPSD provides some guidance for the process of determining compliance with the general safety requirement contained in the Directive. In the absence of specific Community provisions relating to the safety of the product, it is deemed safe if it complies with specific rules of national law of the Member State in whose territory the product is marketed. There is also a presumption of safety extending over the risks and risk categories that are covered by relevant national standards which transpose harmonised European standards, the reference of which have been published by the Commission in the Official Journal of the European Communities. In all other circumstances the following elements must be considered in particular when carrying out the conformity and compliance assessments:

(a) voluntary national standards transposing relevant European standards other than those referred to above;
(b) the standards drawn up in the Member State in which the product is marketed;
(c) Commission recommendations setting guidelines on product safety assessment;
(d) product safety codes of good practice in force in the sector concerned;
(e) the state of the art and technology;
(f) reasonable consumer expectations concerning safety.

Please note that the competent authorities of the Member States may take action if there is evidence that the product is dangerous even though it conforms to the above mentioned criteria.

Product-specific legislation may contain further provisions to guide the assessment of the safety of a product. New Approach Directives contain essential safety requirements. Under the New Approach, standards can also provide the basis of a presumption of the safety of a product with respect to the risk and risk categories addressed by the standard.

Where a European standard has had its reference published in the Official Journal, it is considered a harmonised standard; compliance with such a standard gives presumption of conformity with the applicable legal requirements laid down in the GPSD and in product-specific legislation. National authorities can rebut this presumption where products present an unacceptable risk to the public even when the products are manufactured in compliance with the standard. Harmonised European standards thus form the basis of market surveillance activities for many products.

The Commission can propose standardisation mandates to the relevant European Standardisation Organisations

and invite them to develop a new standard or to improve existing standards.

When there is no relevant standard or the safety of a product can not be adequately determined simply with regard to the compliance to harmonised standards, risk assessment plays an important role in conjunction with the elements laid out in the GPSD or in the essential safety requirements contained in the New Approach Directives. Risk assessment is covered in greater detail in Chapter 10.

2.3 Market surveillance authorities and standardisation

Participation of Member State authorities in the standardisation working groups that deal with product safety is highly desirable. Market surveillance authorities play an important role in the 'product safety learning loop' (see Figure 2 below) since they can share their experience on the actual performance of standards.

The standardisation bodies develop standards setting safety provisions, based on the essential requirements laid down in EU legislation. The manufacturers apply these legal requirements and safety standards when developing new products. The consumers buy and use the products. Finally, the market surveillance authorities analyse and report the experience with the functioning of standards expressed in accidents, incidents, nearby accidents, consumer complaints, etc. and can feed this into the standardisation work.

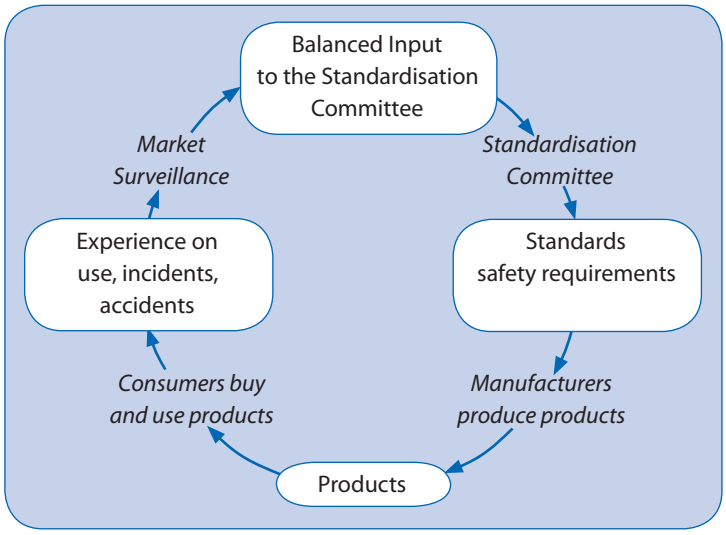


Figure 2: Product safety learning loop with mutual influence between market surveillance and standardisation.

Market surveillance authorities are considered to be impartial as they have no direct economic interest in standards. Furthermore, market surveillance authorities actively collect experience from the market on the practical functioning of standards. They have a broader picture than the other stakeholders as market surveillance covers many different products and the experience of the stakeholders should be taken into account in the standardisation work. This will subsequently also facilitate the work of the surveillance authorities themselves.

Participating in standardisation work increases the market surveillance authorities' knowledge of standards and their interpretation, which is of value in their daily work applying the various safety standards. Furthermore, standardisation committees produce valuable documents and information representing state-of-the-art knowledge concerning a particular product, class of risk or hazard. Cooperation in standardisation work enhances the flow of information.

2.4 Market surveillance provisions

The provisions of the GPSD provide a framework for the enforcement of the Directive through market surveillance. As noted above, the GPSD encompasses all non-food consumer products insofar as sector-specific directives do not regulate them. Most of the product-specific directives do not specify the way market surveillance should be performed. As a result the market surveillance provisions of the GPSD fully apply.

The GPSD lays down the obligation for the Member States to do the following:

- Establish or nominate authorities competent to monitor the compliance of products with the general safety requirements;
- Arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive;
- Define the tasks, powers, organisation and cooperation arrangements of these competent authorities;
- Grant the competent authorities the legal powers to organise checks and take specific measures for products failing to comply with the safety requirements;
- Encourage cooperation and information exchange between the market surveillance authorities within the Member States and between the authorities of the Member States.

Article 8(1)(a) of the GPSD provides that the competent authority in the Member State must take appropriate

actions, depending on the risks posed by the product under certain conditions or for certain persons or on the fact that it can be considered dangerous. In particular, the competent authorities must take the necessary actions, such as those mentioned in paragraph 1(b) to (f) of the GPSD, in a case where products pose a serious risk. For detailed information on risk evaluation see Chapter 8 of the GPSD.

Article 9 requires that appropriate means and procedures are put in place for the establishment, periodic updating and implementation of surveillance programmes, the follow-up and updating of scientific and technical knowledge concerning the safety of products, and the periodic review and assessment of the functioning of the control activities and their effectiveness and, if necessary, revision of the surveillance approach and organisation put in place. In addition, authorities responsible for market surveillance activities must give consumers and other interested parties the opportunity to submit complaints concerning product safety, as well as to follow up on such complaints.

For consumer products, the provisions contained in the GPSD provide the market surveillance authorities with the minimum requirements necessary to meet their obligations. On 23 June 2008, the New Internal Market Goods Package[1] was adopted by the European Parliament and Council. Part of the Package addresses the revision of the so-called New Approach to technical harmonisation. Much of the product-specific European legislation has been promulgated under the New Approach. A new Decision lays down a general framework for future legislation harmonising the conditions for the marketing of products and a reference text for existing legislation. A new Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, contains provisions on market surveillance, accreditation and control of products entering the EU. The Regulation comes into force on 1 January 2010. Though not completely identical, the new provisions bring the requirements for market surveillance under the New Approach in line with those in the GPSD.

1 The New Internal Market Goods Package, also known as New Legislative Framework (NLF) is composed of the three following legislative acts published on OJ L218, 13.08.2008, p. 30:
– Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.
– Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [4].
– Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

2.5 The legal basis for cooperation with customs

Council Regulation (EEC) No 339/93[1] regulates checks on products imported from third countries. It defines rules regarding the suspension of the release of products by customs authorities and further proceedings involving market surveillance authorities.

The Regulation aims to provide market surveillance authorities and customs with the legal basis to intervene and stop the release of unsafe products and to introduce rules regarding the suspension of the release of products and the subsequent procedure.

1 Council Regulation (EEC) No 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries [12]– OJ L040, 17.02.1993, p. 1.

From 1 January 2010, this Council Regulation will be replaced by the new Regulation 765/2008 mentioned above.

The new Regulation prescribes that the customs authorities can block the release of products that do not comply with legal requirements for three days. Generally the three days are used by market surveillance authorities to investigate the products to decide if they can be released, if they must be blocked or if further investigations are necessary. If the products are found to be dangerous import can be banned and customs will mark the consignment and the accompanying papers with a notice that import of the product is forbidden. Customs will also notify the customs authorities in the other Member States of the consignment.

At a major international conference on preventing imports of dangerous products held in Saalfelden, Austria in April 2008, a number of concrete actions were agreed in order to improve target customs controls via increased cooperation between customs and market surveillance authorities, particularly in the area of risk management. Among other things, it was agreed:

- to enhance the cooperative network between customs and market surveillance authorities;
- to improve targeting of controls of unsafe products by greater exchange of risk information;
- to share experience, knowledge and best practices on co-operation and controls.

2.6 Sources of further information

Further information on the relationship between the GPSD and other directives can be found in the 'Guidance Document on the Relationship between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety'[1]. Further information on the New Approach can be found in the Guide to the implementation of Directives based on the New Approach and the Global Approach (the so-called 'Blue Guide'[2]). This document contains further information related to market surveillance and producer obligations with respect to conformity assessment.

Following the adoption of the New Internal Market Goods Package, these guidance documents will be revised.

1 Guidance Document on the Relationship between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety [15]– Directorate General Health and Consumer Protection (DG SANCO) November 2003.

2 Guide to the implementation of directives based on the New Approach and the Global Approach [1], published by European Commission in 2000.

2.7 The principles of conformity assessment and CE marking

Before putting a product on the European market, the manufacturer or importer is required to make sure that the product fulfils the safety requirements in the EU legislation. This process is called conformity assessment.

The process by which the conformity with legislation is verified varies between the different directives and sometimes between the categories of products within a directive. In general, the requirements for conformity assessment procedures provided for by the directives depend on the hazards the specific product categories covered, with stricter requirements for products presenting greater hazards.

The various procedures for conformity assessment under the New Approach directives can be divided into eight 'modules'.

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

The following Figure 3 gives an overview of the procedures for conformity assessment.

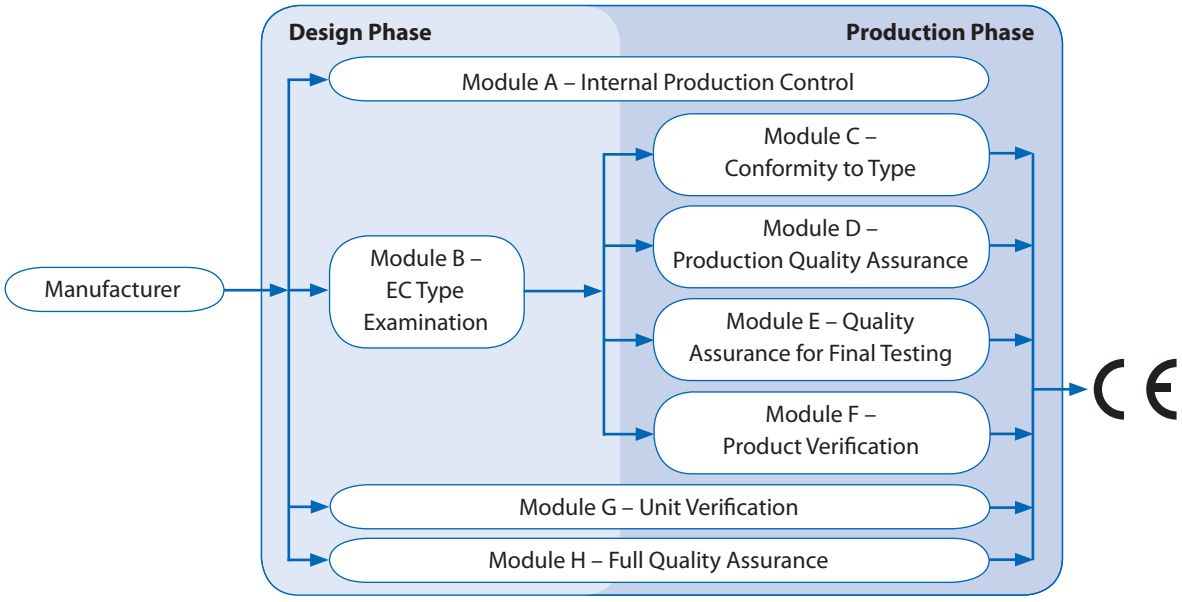


Figure 3: Modules of conformity assessment for CE marking.

Some of these Modules (A, G or H) are normally applied individually, while others like Module B are applied in conjunction with Modules C, D, E or F. It is beyond the scope of this Book to fully discuss these procedures; details can be found in the 'Blue Guide' and in the specific guides for individual directives. However, the differences between the modules required for the conformity assessment procedure for specific products are important for market surveillance authorities and should be taken into account when planning market surveillance on these products.

Module A – Internal Production Control is more familiarly known as 'self-declaration'. Essentially, the manufacturer or importer is required to assert the conformity of the product with the applicable directive(s), generally via assessment of conformity with a European or other standard, after which he writes the required declaration of conformity. He can then affix the CE-marking on this product and place the product on the market. No independent third party verification is needed. This module is applied for electrical products under the Low Voltage Directive, for many machines under the Machinery Directive and for most toys, for example.

However, declarations of conformity can be easily falsified and CE-marking can be affixed unlawfully. It is not therefore possible to rely on document checks alone to assess the safety of the products for which self certification is allowed. Further investigations are thus needed, including sampling and laboratory testing of the products themselves. The GPSD recognises this by imposing an obligation for market surveillance to include sampling and safety testing.

If third party intervention by a notified body is required for the conformity assessment, document checks are the primary instrument of market surveillance. For example, the Gas Appliances Directive[1] and the Personal Protective Equipment Directive require a type-approval by a notified body, before the declaration of conformity can be issued and CE-marking affixed. The type-approval generally involves checking the conformity of the appliance against the relevant European standard and the results of these tests and the type-approval certificate are forwarded to the manufacturer and added to the technical file. Checking these documents is far easier and cheaper than laboratory testing. The validity of the documents can easily be verified at the notified body that issued the certificate.

1 Directive 90/396/EEC on the approximation of the laws of the Member States relating to appliances burning gaseous fuels [8] – OJ L 196, 26.07.1990, p 15.

PART B – MANAGEMENT OF MARKET SURVEILLANCE ACTIVITIES

3 MARKET SURVEILLANCE ACTIVITIES – ORGANISATION & INFRASTRUCTURE

3.1 Introduction

Market surveillance authorities must be organised and equipped to cope with the obligations and requirements discussed in Chapter 2. However, the EU legal framework does not prescribe how the Member States are to implement the directives or how the legislation should be enforced. How the requirements in the treaties are to be fulfilled is up to the Member States, since market surveillance is a national responsibility and falls under the principle of subsidiarity.

Subsidiarity allows the Member States to organise market surveillance in a way that suits their own particular cultural and political situation, as well as their legal system. Moreover, in most countries the current organisational structure also reflects the historical development of their enforcement organisations. In many Member States the organisation of market surveillance is frequently adapted to cope with evolving needs, changing environment or different political conditions.

As a result, there is no single organisational model that fits all individual needs of the Member States and consequently the ways in which market surveillance is organised and performed in the European Union varies greatly between the Member States. In some, market surveillance is centrally organised while in others it is decentralised and operates regionally or locally. A vertical organisation of market surveillance occurs where for each directive (or groups of directives) specific market surveillance organisations exist, typically under the Ministries responsible for the implementation of that particular directive. Other Member States have a single organisation for all legislation regarding consumer products (and often other legislation as well).

3.2 Infrastructure for market surveillance activities

Performing market surveillance requires specific functions, knowledge and responses which are basically the same for all market surveillance organisations. The following issues should be considered when setting up such organisations or when the aim is to secure and enhance market surveillance authorities' effectiveness and efficiency.

3.2.1 Legislative infrastructure

To establish a proper and efficient market surveillance structure in each Member State requires looking into the legislative and enforcement structures, and the economic aspects of enforcement bodies. Since one of the main objectives of market surveillance is to ensure equal conditions between economic operators, it is very important to establish a structure that enables all enforcement bodies to carry out market surveillance under the same conditions. This means the same legal powers and sufficient financial support to perform effective market surveillance within all product safety fields. The legislative framework regarding market surveillance in each Member State should cover all market surveillance authorities and be based upon the legislative framework provided for by the relevant EU legislation.

3.2.2 Hard infrastructure

To perform the tasks required for effective and efficient market surveillance the organisation needs facilities and equipment:

- Information Technology (IT) systems and applications
  Although in principle the administration could be paper-based, IT systems and applications are mandatory from an efficiency point of view. IT enables efficient work flows and allows swift and easy retrieval of information needed for many tasks in the process. The role of IT in market surveillance can be summarised as follows:

1. *Facilitating the market surveillance processes*
   The core of market surveillance is a chain of interdependent processes such as inspections, sampling, laboratory testing, interpretation of results, decision making, intervention and the execution of ensuing legal processes, which may culminate in imposing sanctions or other interventions. In all these processes data are generated which are required in the next or in parallel steps. Collecting, administrating and distributing the information required within the organisation can only be efficiently done with the support of suitable IT systems. IT systems also serve to assure the quality and integrity of the data obtained. Software can for example require mandatory input, record metadata (history, date, time, operator references, create/change information etc.) and monitor process progress.

2. *Making data available where they are needed*
   Quick access to information is a necessity in many of the stages of the process. This applies to the field officer, the laboratory and the departments involved in the legal follow-up. IT can greatly speed up and improve the accessibility of the required information. It enables field inspectors to access the histories of the businesses they inspect, to be aware of previous samples taken and of the results of the investigation of those samples. This information can be retrieved from the IT system before setting out for an inspection, but better still this can be downloaded to the field officer's laptop, either directly from the system or via the Internet. Laptops for field officers are also useful to administrate the data from the inspection and the data on the samples. Such information can then be made available directly to the laboratory and the other departments involved.
3. *Management tool*
   Easy access to the information collected in the processes makes IT an important management tool. When implemented properly, the system can deliver instantaneous quantitative information on progress and the results of all ongoing and past market surveillance activities.
4. *Exchanging information*
   IT systems are also crucial for facilitating the exchange of information between different applications, including RAPEX, ICSMS, CIRCA and others. There are several existing systems which require almost the same data in slightly different formats. To avoid entering the same information repeatedly for each application or database, the authority should aim for a compatible IT system which can communicate with the existing applications.

- Laboratory capacity
  Monitoring the market involves taking product samples and investigating those samples in order to determine their safety. For this purpose, sufficient laboratory capacity must be available. Laboratory facilities can be part of the infrastructure of the authority itself or can be subcontracted.

- Tests
  For assessing the safety properties of products, the authority needs tools and tests enabling it to carry out the more basic investigations on site or during desk examinations. Laboratory capacity and test probes will be discussed more extensively in Chapter 7.

In addition, other basics such as office infrastructure (office space, office equipment), communication infrastructure (Internet, email, telephones) and suitable means of transport (motor vehicles suited for moving equipment and samples) are needed to be able to perform tests and investigations.

3.2.3 competences and skills

Buildings, laboratories and computers do not make a market surveillance organisation. More important are the people who work for the authority, their culture, their knowledge, their contacts and the procedures and organisation that govern their activities.

The core processes of market surveillance are the monitoring of legal compliance and safety of products on the market and intervention in case of non-compliance. To perform the tasks associated with these processes, the staff of market surveillance authorities needs particular competences and skills. These include not only specific legal and technical knowledge necessary for performing the actual inspections, but also, for the organisation as a whole, knowledge of the markets and an understanding of hazard identification and risk analysis.

Personnel involved in market surveillance activities must have a suitable educational or professional background and/or the necessary experience to deal with the tasks they perform in the enforcement body.

In particular enforcement officers who carry out market supervision must have the necessary qualifications and experience, must show exemplary behaviour, and have good administrative skills and the ability to use those skills in the daily business of market surveillance.

1. *Legal competences and skills*
   Enforcement officers and other personnel involved in the legal procedures need thorough knowledge of the applicable legislation and the legal framework in which they operate. The national implementation of the applicable legislation varies considerably between the Member States. Therefore, much of the expertise required depends on the national situation, but in general the following aspects need attention:
   - Knowledge of the national legal framework, including the relations of national product legislation to criminal law and/or administrative law;
   - Knowledge of the legal procedures and relationship to other institutions involved in the legal procedures, e.g. prosecution office, courts;
   - Thorough awareness of legal powers and the conditions under which these can be used;
   - Familiarity with the relevant Directives and the Essential Requirements in those Directives; and
   - Knowledge of the relevant (European and national) standards and their interpretation.

2. *Technical competences and skills*
   For efficient and effective market surveillance, enforcement officers must have profound knowledge of the relevant markets involved, the characteristics of consumer/user groups, the properties of the products supervised and the risks of the products.

3. Administrative competences and skills

Staff should also be instructed regarding their role in the organisation and taught the administrative skills required. For enforcement officers this would for example include knowledge of the internal procedures used in connection with their tasks, awareness of the roles of other departments in the processes they are part of, the ability to draft letters to external stakeholders, and the skills to collect and process the data required. Enforcement officers should also master the skill of writing the legal documents required for the follow-up of investigations, such as reports for the prosecution, etc.

4. Personal competences and skills

Market surveillance officials must also possess a number of personal skills such as the ability to interact and communicate with consumers and business representatives in a professional and diplomatic way under all circumstances. Furthermore, in today's working environment language skills are an important asset.

3.2.4 Training of personnel

Market surveillance authorities should set up a training programme specific to enforcement officers covering amongst others legal aspects, technical issues such as standards or other technical requirements, methods for risk assessment and skills regarding information, communication and relationship management.

Moreover, it is important to organise continuous training on developments regarding legislation, standards, results from scientific research and technological progress, and cross-border information related to dangerous products. This includes familiarity with the roles of administrative cooperation and the functions of RAPEX (Annex H.1.1).

Ideally, practicing inspectors convey their knowledge and experience to newcomers. Next to incorporating their experiences in course material, they can also be important for additional training on the job and mentoring of new personnel.

There should be an active and systematic exchange of experience from market surveillance projects between national and international colleagues. Transfer of experience regarding methodology and procedures is important to advance the development of market surveillance as an instrument and a profession. Market surveillance officers should meet regularly to share experiences, both at a national and international level.

3.3 Market surveillance strategy

The way market surveillance is performed is heavily influenced by a set of underlying assumptions and philosophies about its position, its role and the functions it performs in a Member State. Partly, these assumptions and philosophies lie outside the control of the market surveillance authority as they are determined by EU and national policies and organisational limitations. Because they affect the authority's effectiveness and position, consideration of these basic assumptions is important. Within these boundaries the authority itself defines the approach to market surveillance.

Market surveillance plays an important role in implementing the EU policy objectives regarding consumer protection and establishment of the single EU market. Whereas there is wide agreement between the market surveillance authorities for consumer products that consumer safety is the primary aim of the market surveillance activities, there are different views with respect to the exact role of market surveillance in achieving this policy objective: from a role that is restricted exclusively to law enforcement to a broader vision that sees market surveillance as a complex of activities that ultimately aims to promote consumer safety. In the latter case other approaches besides law enforcement, for example compliance assistance and consumer education, are considered part of the activities.

The vision and goals of a market surveillance organisation largely determine the choice of strategies it will follow to achieve results. Typical examples of strategic choices for which the market surveillance vision gives a framework include:

- Enforcement or compliance assistance?
  - Enforcement approach:
    The role of market surveillance can be seen primarily as the enforcement of legislation. If enforcement is the starting point, the organisation is likely to focus on tracing and sanctioning offences and offenders as efficiently as possible. It will expend few resources to make the target groups aware of their legal obligations or help offenders to comply. In planning and controlling, goals will be formulated and success measured in terms of the number of offences identified and sanctions taken.
  - Compliance and compliance assistance approach:
    An alternative view holds that overall compliance of companies might be better served if sanctions are applied to businesses not willing to comply and that the businesses that want to comply but lack the competence are supported in obtaining the required knowledge (compliance assistance). Obviously such an approach leads to different working methods and different control parameters than in the enforcement approach.

- Product, business or risk focused approach?
  - In practice most authorities will use a mix of all these approaches; market surveillance of consumer products has traditionally focused on the products themselves. For that reason it is also the approach that receives most attention in this Book. It should be realised that the unconscious adoption of this approach ('That is the way we have always been doing market surveillance') might blind the eye to alternative approaches, such as business oriented and risk oriented approaches (a detailed discussion on the different approaches to market surveillance can be found in 3.5).
  - Presently the possibilities of market supervision via system audits in businesses are investigated in several Member States. System auditing is already routinely applied in the field of food safety and in the cosmetics industry. At least one market surveillance authority performs system audits at importers in the product safety area.
  - If there is no possibility to perform system audits at the producers site, as is the case where manufacturing takes place outside the European Union, attention may be shifted from producer to importer. When performing system audits it is important to audit importers with reference to products already on the market and thus available for the consumer. By following this strategy all audits will have relevance to the importer's procedures for ensuring that only safe products are placed on the market. The major advantage of system audits is that they cover the importer's quality and safety procedures regarding products on a generic basis. Any findings reported back from such an audit will ultimately lead to improvement in the importer's procedures related to product safety.
- Document checks, product tests, or both?
  - The checking of documents approach is a very cost efficient way of doing market surveillance. A single officer can check many products per day and documents can be 'sampled' by email or mail. Furthermore, documentary checks will reveal shortcomings in the administrative procedures, which are an indicator of compromised product safety. It is also a well-established fact that most dangerous products also have shortcomings in the administrative procedures.
  - The checking of products approach stipulates that the only way to check product safety is to test the product itself. Such an approach is more costly and time consuming than documentary checks, since testing will often involve test laboratories and an officer will only be able to check a few products per week (excluding the follow-up activities).

In practice the two approaches are almost always used complementarily. Most authorities will include some rudimentary testing in their sampling procedure. This is to ensure that the products sent for laboratory testing are more likely to be found unsafe. Many authorities will send sampled products for laboratory testing to challenge the compliance assessment carried out by the producer. If, on the other hand, the testing of a product reveals non-compliances, the natural first step in the dialogue with the producer would be to request the technical file and examine the documents to find out if the shortcomings are due to design faults or production errors. This will have an impact on the question of which corrective measure will most efficiently fix the shortcoming.

Therefore, in general both approaches should be applied simultaneously, as documents should in fact be checked as part of any kind of market surveillance activity. The authority should however decide on the priority between the two approaches.

The choice will also depend upon the kind of products to be checked. The requirements for technical documents are in general more detailed for products falling under the New Approach Directives (e.g. electrical products and toys) whereas they are more general for products falling under the GPSD.

Other aspects that relate to the authorities' basic market surveillance vision include:

- Position on laboratory tests, whether performed in-house or outsourced;
- Position of the authority with respect to outside pressure to decrease the inspection burden on industry;
- Position on confidentiality of the information obtained: should results from inspections and laboratory tests be made available to the general public, since market surveillance is funded by taxpayers' money? Views and national legislation on this vary enormously across Europe: some Member States publish a lot of information, while others hardly do at all; and
- Degree of transparency the authority wishes to live up to.

Not all of these issues are under the control of the market surveillance authority itself; for some there are boundaries defined by EU or national legislation, for others national policies restrict the choices market surveillance authorities can make. Nevertheless, they all have (major or minor) implications for the way the market surveillance authority approaches its tasks and therefore deserve consideration.

The vision of the authority on these issues deserves to be explicitly formulated in a 'vision document', as it provides guidance for the processes of planning and prioritising. The 'vision document' is considered a best practice.

3 MARKET SURVEILLANCE ACTIVITIES – ORGANISATION & INFRASTRUCTURE (Continued)

3.4 Approaches to market surveillance

The primary goal of market surveillance in the consumer product area is the reduction of the risks these products present to the consumer. At present for market surveillance of non-foods consumer products, five approaches can be discerned. They differ in how they deal with the monitoring of the market and may cause differences in the way the activities involved are planned and in the organisational framework.

3.4.1 Reactive market surveillance

Both the GPSD and the Regulation EC 765/2008 require that consumer complaints be investigated and, where appropriate, action taken. Reports on potentially dangerous or non-compliant products may come from other sources too, including complaints about products from competitors, notifications from other market surveillance authorities in the same or other Member States or from the media.

All these reports require similar reactions from the market surveillance authority; they must be investigated, conclusions must be drawn, action must be taken if necessary and results must be reported back.

As such investigations are started by outside 'events', they can not be planned in advance. The authority therefore needs the capability to improvise and that capability must be built into the organisation. How to do this is described in Chapter 6 on reactive market surveillance.

3.4.2 Product focused market surveillance

Traditionally market surveillance on non-foods consumer products has been product focused, due to legislation that formulates product requirements. To prove an offence, it must generally be shown that the product does not comply with the safety requirements of a given directive.

Demonstrating non-compliance usually requires laboratory investigations, which can be performed more efficiently when a series of products is tested. Therefore, there is a strong incentive to work in projects on specific products. This approach is proactive as projects can be selected for their relevance to consumer safety, planned in advance, and tuned for maximum efficiency.

Together with reactive market surveillance, the product focused approach is currently the one most often used by market surveillance organisations in the European Union. The major part of this Book describes the best practices currently in use for product oriented market surveillance (See also the 'Joint action on cigarette lighters' described in A.2 as an example of a product focused market surveillance action).

3.4.3 Risk focused market surveillance

Market surveillance activities can also follow a risk based approach. Since the first priority of most market surveillance authorities is the protection of the consumers' safety and health, the goal of prioritising the activities can be the reducing of specific risks. Where information is available (for example from accident statistics) indicating that specific hazards are prominent in determining the risks of products for consumers, attention can be directed towards reducing these hazards.

An example of a risk focused approach is the current activities in several Member States to decrease the fire hazards in private houses. While casualties from the use of consumer products are relatively rare in Europe, home fires still cause many casualties and significant economic and property damage. Nationally available fire statistics show that a number of consumer products are potential fire sources and some of these products are mentioned in the literature as having caused fires. Candles, electrical equipment, especially television sets, and gas appliances are mentioned regularly in this context. The authority can target market surveillance at reducing fire hazards by undertaking activities focused mainly on products with a potential fire hazard.

Of course, this approach converges with the product oriented approach, because it requires the identification of consumer products that are potential fire sources and the subsequent market surveillance of these types of products.

3.4.4 Business focused market surveillance

Especially in the context of market surveillance of the food chain, inspections are business focused, since businesses along the chain from 'farm to fork' decisively influence the safety of the foods they are handling. Food legislation tends therefore to be system oriented and market surveillance is also targeted at the operational management and the quality systems in place. An example of such an approach is the so-called HACCP (see box below).

HACCP (Hazard Analysis and Critical Control Points) is a systematic preventive approach to assure food safety and pharmaceutical safety, which addresses physical, chemical and biological hazards during the production phase as a means of prevention rather than finished product inspection. HACCP is used in the food industry to identify potential food safety hazards, so that key checks and actions, known as Critical Control Points (CCP's) can be taken to reduce or eliminate the risk of the hazards being realised. Inspections of this system by market surveillance authorities are the best example of system oriented market surveillance.

A number of recent developments in this area could be important for the non-food product safety field as well. Most interesting in this context is an emerging theoretical framework that is based on the reasons businesses have for complying or not complying, in conjunction with approaches to improve the incentives to comply. This provides important levers for market surveillance to direct efforts at those 'high risk' businesses more likely to violate the applicable requirements. A high risk business in this context is defined as being known from previous findings or from available data as potentially non-compliant with the rules. Aiming resources at those businesses that are most likely not in compliance improves the efficiency of market surveillance and is also in line with the developments in several Member States where the governments try to reduce the inspection burden on 'good' companies and direct market surveillance towards the non-compliers. Chapter 4.3 will discuss these developments in more detail and indicate how product safety market surveillance can make use of this knowledge.

Several Members States are also investigating the possibilities of a system oriented approach in the consumer product safety field. At present the legal possibilities for performing for example system audits in companies producing or importing non-food consumer products are limited, but document checks and checks of the obligatory technical file underlying the conformity assessment procedure can generally be performed, especially when there is a legal cause justifying the action.

As an example the Norwegian authorities run audits of importers based on the national 'internal control regulation' which obliges the importers to monitor all safety aspects of imported products. For cosmetics, system checks are explicitly allowed and system audits are performed by several Member States in this field.

3.4.5 Screening projects – market monitoring

Screening projects are a special category of market surveillance actions. The main purpose of a screening project is to monitor the status of a particular part of the market, for example a product category, a category of businesses or a category of risks. Even though the main purpose of such projects is not to remove all dangerous products, the authority most likely will come across non-conforming products that can not be left in the market.

Screening projects will often form the first part of a market surveillance action to allow the authority to gather knowledge about a particular area and thus increase the efficiency of the action. Screening projects can also be a useful tool for checking the effectiveness of new legislation, a new standard or previous market surveillance activities.

3.5 Quality management

Quality management systems originated in industry to assure the quality of manufactured products. The usefulness of such quality management systems for improving and substantiating the results of clinical laboratory tests was recognised, and laboratories for clinical and analytical chemistry adopted quality management systems. These systems developed over the decades and have been codified, inter alia, in the ISO 9000 and ISO 17000 series of standards (see Annex J).

3.5.1 Quality management system

In essence, a quality management system can be summed up as a verifiable organisation of activities where the validity and quality of the processes involved in producing the output of the activities can be demonstrated. This implies amongst others that:

- All key processes are meticulously described in procedures and are documented;
- Indicators are defined to monitor these processes; and
- Corrective procedures are implemented in case the processes are found to be out of control.

Implementation requires an independent quality manager who, under the control and with the support of the top management, is responsible for the whole quality management system, including the execution of internal audits to verify that the system is well implemented, the preventive actions based on the feedback from internal audits, management reviews or customer complaints and the actions undertaken to correct deviations found. Part of the system should also address policies and procedures that ascertain the (documented) competence of the personnel involved in the processes.

Generally, a central part of a quality system is a 'quality manual' which describes:

- Management statements concerning quality assurance policies of the organisation and the support of these policies by the management;
- Standard operating procedures;
- Responsibilities of personnel involved;
- Procedures detailing the processes running in the organisation; and
- Mechanisms to intervene if deviations from the procedures are detected.

An important part of the quality manual is formed by the description of the main processes in the form of 'standard operating procedures'. Standard operating procedures include the following:

- Meticulous description of the process steps;
- How to perform and document the process steps;
- How to measure and report; and
- Steps to take if process is found to be out of control.

3.5.2 Certification and accreditation

Organisations working on the basis of a quality system which conforms to the ISO 9001 standard can have this formally checked by a 'third party' certification body. The certification body performs an audit during which the conformity of the procedures, the work processes and the quality assurance manual are checked. In case of a successful audit, the certification body issues a certificate of compliance with ISO 9001. To be able to issue certificates of compliance the certification body must be accredited by an accreditation body.

Accreditation bodies are independent bodies that are allowed to accredit organisations against the ISO 9001 and the relevant ISO 17000 series of standards. In Europe nearly all Member States have established a single national accreditation body that performs a public task and operates relatively independently. Presently, the European accreditation bodies operate a peer evaluation system to safeguard the quality of their activities. Under the New Legislative Framework [4] a number of legal precautions are to be implemented assuring the public character of the accreditation bodies, as well as a number of other measures to assure independence and responsibility. Further, the Member States are required to monitor the functioning of their national accreditation bodies.

3.5.3 Quality management in market surveillance organisations

The basic market surveillance processes are always similar, regardless of the organisation that is performing them. Especially in larger market surveillance organisations that cover a wider range of Directives and product categories, the market surveillance processes have to maintain a high degree of uniformity and consistency to assure the equality before the law for all inspected businesses. Similarly, precautions must be taken to maintain proportionality and consistency in the interventions and sanctions imposed in case of offences. To accomplish this while operating under a quality management system is of increasing importance for market surveillance authorities.

Offenders are sanctioned based on the results of inspections and laboratory tests and, considering the economic interest involved, the authority must be able to substantiate the validity of its findings. Many manufacturers have their products certified by notified bodies. There are an increasing number of such bodies that are able to substantiate the validity of their results in turn. In case of conflicting evidence, working under a quality management system strengthens the position of the authority in court. Indeed, operating under such a system may be a prerequisite for market surveillance authorities.

Market surveillance authorities are engaged in enforcement of product legislation. No specific standard for the quality management for such organisations is available, but the general principles of quality management as stipulated in the ISO 9000 series apply. Furthermore, the processes are closely related to those performed in the field of inspections for which ISO 17020 applies.

For authorities operating their own testing facilities and laboratories, best practice dictates that these be operated under a quality system according to ISO 17025. It is recommended that those authorities have this system certified. Increasing numbers of notified bodies are accredited, which strengthens the need for the market surveillance authorities to be able to demonstrate the validity of the test results. Where lab tests are outsourced, the authority should ascertain that the test laboratory has been certified according to ISO 17025 for the tests performed.

ISO 17025 addresses both management requirements (comparable with the ISO 9000 series) as well as technical requirements. These technical requirements address, amongst other, the competence of staff, methodology and test/calibration equipment. Typical requirements include monitoring the test methods to assure their performance is controlled, following standard operating procedures for sampling and testing, validating the methods used, and calibrating test instruments.

3.6 Standard operating procedures

The usual way to assure uniformity and consistency in the working processes is by adopting organisation-wide standard operating procedures (SOPs). The SOPs are an important part of the quality system of the organisation. Using SOPs will ensure that all actions are based on the same strategic principles and are planned, performed, reported and analysed within the same legal framework. A number of critical issues for which standard operating procedures should be developed are detailed below.

3.6.1 Intervention policies

Market surveillance authorities intervene if non-conformities are encountered. Such interventions and sanctions typically include:

- Providing information (compliance assistance);
- Issuing formal warnings and fines;
- Initiating legal proceedings resulting in penalties;
- Discontinuing sales;
- Seizing products; and
- Enforcing recalls.

To make sure that all businesses are treated equally across all directives and product categories under the responsibility of the market surveillance authority, they must adhere to a number of intervention principles including:

– Proportionality: the severity of the intervention corresponds to the severity of the offence; for small violations less strict measures are applied than for more serious offences.
– Consistency: for similar offences equally strict interventions are applied.

Many market surveillance authorities monitor and control markets regulated by several directives and are thus dealing with a large variety of products. Since a single company may market various product types, consistency in the measures taken is important. Diverging measures issued by the market surveillance authority for comparable violations in different product categories are not understood; it will adversely affect confidence in the market surveillance system. The same applies for inconsistent measures taken by different inspectors or for regional differences.

To assure proportionality and consistency in the legal measures taken over the whole field covered, the market surveillance authority should define formal intervention policies. The intervention policies must apply for the entire organisation. These issues are best addressed in standard operating procedures. They may include the following elements:

1. *Proportionality between offence and sanction*
   – Where product safety is the first priority, intervention policy should evidently be based on risk analysis: stringent measures for non-conformities that immediately jeopardise the safety of the consumer and less stringent measures for non-conformities that do not directly lead to major hazards. Article 8 of the GPSD clearly supports this principle: the more dangerous the product the tougher the intervention.
2. *Recidivism*
   – It is common practice in nearly all fields of law that repeated offences are sanctioned more severely than first offences. Again, in the interest of equality before the law, the intervention policies should address this in such a way that all repeated offences are treated equally.
3. *Intervention limit value*
   – In practice product requirements laid down in legislation and in (harmonised) standards are either qualitative requirements or quantitative limit values for selected parameters. Qualitative requirements are either assessed as being fulfilled or as failing to fulfil the requirement.

Example 'qualitative requirement':
A typical qualitative requirement is the tilting test in Clause 20.1 of EN 60335-1.
The appliance is placed in its normal position of use on a plane that is inclined at an angle of 10 degrees. The appliance should not overturn.

   – Quantitative requirements necessitate the measurement of the relevant product properties. The result of the measurement is a value that either exceeds or fulfils the limit value given in the requirement. The interpretation of the gravity of the failure to pass the requirement is not straightforward. In general, one way to verify the gravity is to apply risk assessment as described in Chapter 10 or to compare the results with examples of classification of non-compliances, for example as given in the 'Failure Code List' in Annex F.

Example 'quantitative limit value':
EN 71-3 for the maximum migration of heavy metals in toys requires that the amount of lead released for migration is less than 90mg/kg. Clearly an amount of 90.2 mg/kg does not fulfil the requirement, but the exceeding of the limit is small. In fact, it is so small that the risk of lead poisoning hardly increases in comparison with a sample which is just in compliance with the requirement. However, if the amount released for migration is 450 mg/kg, the risk of poisoning of course would increase notably. Similar reasoning holds for most quantitative limits: a small exceeding of the limit value corresponds to a small increase in the risk presented by the product. The higher the deviation from the limit value is, the higher is the risk emanating from the product.

– In the interest of consistency and proportionality of the intervention activities, the market surveillance authority should provide general guidelines relating to the degree of exceeding of the limit value and to the sanctions imposed.
– Measurement variability must be taken into consideration when setting the intervention limit values. No physical property can be measured with absolute accuracy. Before taking action against a product, the inaccuracy of measurement methods should be considered.

4. Classification of shortcomings against standards and gravity of offence

– Some authorities have developed the idea of intervention limit values into systems linking a given 'distance' from a threshold value of a given test to a severity 'code'. The code itself is linked to the necessary measure. The intervention policy should prescribe how the different codes are translated to measures. The lists can be shared with test laboratories, for example. One such case is the Nordic Failure Code List (see Annex F) which has been discussed in The Low Voltage Directive Administrative Co-operation Group (LVD ADCO). (See box below and Annex F for more details about the Failure Code List).

Example 'Failure Code List':
In electrical products live wires must be separated from touchable parts with a distance that is called the creepage distance (d). For many appliances the requirement is d > 5 mm.
The Failure Code List prescribes the following scale:
- *d between 4.5 and 5.0 mm (deviation of 10% from requirement) – code 1.*
- *d between 2.5 and 4.5 mm (deviation of 10–50% from requirement) – code 2.*
- *d < 2.5 mm (a deviation of more than 50% from the requirement) – code 3.*

(Code 1 being the least severe and code 3 the most severe.)

5. Deciding on sanctions after detection of offences

– Once it is determined that the legal requirements are violated, the authority must decide if and what sanction will be imposed. The sanction must fulfil the requirements of proportionality and consistency. Also it must be asserted that the process leading to the proposed sanction fulfils all the requirements defined in the intervention policies.
– The intervention policies should clearly identify how decisions to impose sanctions are taken and which employees are authorised to take the final decision. Good practice is to involve in the decision the field officer who did the inspection leading to the sanction and the laboratory. Good practice is also to have a proposal for the sanction drawn up (for example by the head of laboratory in consultation with the field officer) and to have the final decision taken by a senior officer. Where possible the legal department should be involved. This procedure enhances impartiality and equality before the law.

6. Follow-up inspection

– If an inspection and the associated investigations result in an intervention or sanction, good practice requires follow-up after the sanction has been made.
– Since the intervention was made because of non-compliance either of a product or in the way the business is run, an inspection must be made after a certain period of time to check that the non-compliance has indeed been discontinued.
– This necessity extends to even the lightest measures taken. A warning that a product is not in compliance must be taken seriously by the offender. He must either discontinue the sale of the offending product or bring it in compliance.
– If on renewed inspection the offence still persists, a repeated and stricter sanction should be issued. This is reasonable: the business was aware of the non-conformity and is therefore more culpable and recidivist.

3.6.2 Notifications and consumer complaints

Both the GPSD and the New Legislative Framework require that consumer complaints be investigated. Consumer complaints call attention to safety problems with products on the market, especially if there is a significant increase in the number of complaints.

Repeated consumer complaints about the same product indicate a problem, in particular if the complaints concern similar deficiencies or incidents. This product should then be carefully investigated and subjected to risk analysis, tests and intervention if necessary.

Data from investigating consumer complaints also contribute to the prioritising of proactive market surveillance activities: complaints indicate categories of products where consumers' safety and health may be compromised. The more complaints are investigated, the more valuable such information.

Reports from other sources, for example traders' and manufacturers' complaints about competing products, RAPEX notifications and safeguard clauses, are dealt with in a similar way. Reacting to consumer complaints, notifications and other reports from outside sources is called 'reactive market surveillance'. See Chapter 6 for details on reactive market surveillance.

1. How to handle consumer complaints and other external reports

The market surveillance authority should approach consumer complaints uniformly and consistently. The methods defined to handle complaints must be imbedded in the market surveillance organisation, ideally by using a standard operating procedure. RAPEX notifications and information from safeguard clauses may be addressed in a separate standard operating procedure. The latter may

be the case if RAPEX notifications and safeguard clauses need to be channelled through a central coordinating point for European notifications.

The procedure should address the collection of complaints (see also below), actions to be taken, reporting and follow-up. Other issues that may be addressed are the filtering of incoming reports and complaints, as well as confidentiality issues.

a) Collecting consumer complaints and other reports
The procedure that describes the way in which consumer complaints are collected and accepted for further investigation may address the following items:

- Regardless of the entry point used by the consumer (i.e. telephone, mail, fax or email), the organisation should make sure that it is forwarded to qualified personnel that is familiar with the procedures and processes for the handling of complaints.
- The information needed to start the investigation has to be collected. This includes name and address of the complaining consumer (or other complaining source), the particulars of the product involved, the complaint in as much detail as possible and any information available about the source (retailer, distributor or importer) of the product.
- If and how consumer complaints and other reports are submitted to an initial assessment in order to decide on the follow-up (see also b) below: filtering complaints and notifications).
- The administrative procedures; i.e. what information is stored and how.
- The procedure for forwarding the dossier for further investigation.

b) Filtering complaints and notifications
Consumers not only complain about products because of safety deficiencies or because they suspect non-conformities. Frequently complaints concern disappointing product performance or lack of expected quality of the product. Poor performance or lack of quality do not necessarily imply safety problems or non-conformities. Reports from other sources may also be of little relevance from the point of view of product safety and even RAPEX notifications may vary in the urgency with which they have to be handled. The investigation of irrelevant reports and incidents wastes resources which could be spent on more useful activities.
An operational procedure should be established that allows filtering of incoming reports. The filtering method should distinguish relevant from irrelevant complaints/reports and classify the relevant reports' urgency. Conscientious judgement is imperative, because misclassification of a serious problem as irrelevant or unimportant fails to deliver good market surveillance and could result in negative publicity. The system must assure that the initial classification and the decisions about the follow-up are taken by competent personnel.

Initial assessment would normally involve risk assessment. Familiarity with the technical properties of the products involved and the applicable legislation is also indispensable. If there are still doubts after the initial assessment, the possibility to consult an expert should be provided for in the procedure.

c) Follow-up
Follow-up obviously depends on the initial assessment of the complaint or report. Incidents with products that present high risks for the public or which potentially attract significant media attention need more urgent reactions than simple consumer complaints that are likely to result in minor legal sanctions.

For the critical cases it is advisable to have a contingency plan available addressing the responsibilities of key personnel involved, people and organisations to contact (prosecutor, ministries, media etc.) and handling of the investigation.

For normal consumer complaints that are initially judged not to be critical, follow-up would usually involve a hearing of the consumer by a field officer who can also sample the product involved for investigation. Note that the consumer must be informed that further investigation of the product may damage the product. Therefore the consumer's formal consent and possibly a statement that he cedes his possession of the product should be requested befor the investigation.

Standard procedure should also be that a second sample of the product be obtained from the regular trade channel for comparison. It is after all possible that the sample obtained from the consumer was damaged for unknown reasons or was tampered with.

Depending on the results of the investigation, intervention may be necessary. In principle, the course of action followed in these cases does not deviate from the general and specific intervention policies defined in 3.6.1, even if outside pressure for specific interventions may be strong in cases with intense media attention.

Follow-up should always include reporting the results back to the consumer (or organisation) who submitted the complaint in the first place. The extent to which this can be done should be carefully considered and may vary between the Member States, depending on the applicable legislation, the way the legal procedures have to be handled and confidentiality requirements.

d) Confidentiality issue
Although Member States differ in their approach to confidentiality in the handling of consumer complaints, the confidentiality of the consumer submitting the complaint may need particular protection.

e) Organisation
Examples of implementation: call centres, decentralised handling, email entry.

The best way to organise the handling of consumer complaints and other reports depends on the organisation of the authority. In decentralised organisations complaints and reports can (and for legal reasons sometimes must) also be handled regionally, provided the required expertise is available.

Chances are that regional authorities combine product safety surveillance with other tasks, like food safety, and do not have all the required knowledge in-house. They should then be able to fall back on colleague authorities that do possess the expertise and equipment to handle such cases.

In centralised organisations consumer complaints and reports may still be handled regionally, but central handling can have considerable advantages. Uniformity in handling is easier to attain and efficiency is likely to benefit, too. Central handling makes it also much easier to archive complaints in a way that makes it easier to analyse them, which is important for planning future activities.

Example: the centralised handling of consumer complaints and reports in one of the Member States is organised around a call centre, where consumers can submit complaints via a toll free number. The centre is a small department, which also handles reports that arrive via mail or email.

Complaints handled include reports on food safety, product safety and veterinary notifications. The centre is staffed by a small number of specially trained employees, with all areas of expertise covered. The department itself is responsible for the first assessment of the incoming reports. Simple questions are answered by the employees of the centre, who also forward routine complaints to the (regional) departments which can handle them according to the procedures described in 3.6.2.a.

3.6.3 Inspections, sampling and testing

Inspections, sampling and testing are part of the primary working processes of market surveillance. Meticulous execution of these steps is decisive for a reliable outcome of the market surveillance process. Reliable results are necessary to assure fair and equal treatment of economic operators and ultimately determine the reputation of the market surveillance authority.

It is highly recommended to include standard operating procedures for inspections, sampling and testing in the quality management system. Relevant standards that provide a framework for drafting these procedures and the requirements which they must adhere to are the ISO 17000 series. For laboratories ISO 17025 is particularly relevant, while ISO 17020 provides guidelines on how to handle inspections.

1. Inspections
Inspections must be properly executed in order not to jeopardise the potential legal follow-up. Attention should be paid to the following items:

- how to issue an advance warning that an inspection will take place (required in some jurisdictions),
- formal identification of the field officer to the spokesman of the business,
- adherence to any legal requirements to inform the business,
- identification of the legally responsible representative of the business,
- handing over of information material (letters or leaflets),
- collecting and recording of information required in the possible legal follow-up (who, where, when etc.),
- instructions as to when and how immediate sanctions have to be taken,
- administrative settlement of the inspection,
- when, what and how to report to the manufacturer after the inspection, and
- whom else to report to (i.e. importer, producer, others)

2. Sampling
Market surveillance requires sampling of products for investigation. How to take samples should be prescribed in a standard operating procedure defining the following (where applicable and depending on national legislation):

- the number of samples,
- whether the sample is paid for, borrowed or taken without payment,
- documents to request along with the samples (i.e. Declaration of Conformity, technical file etc.),
- selection of samples after a pre-check or screening test or without, and
- information to be handed to the manufacturer (i.e. receipt, information on the procedures followed).

And make sure that:

- the samples taken are packaged in a way that precludes tampering on the way to the laboratory,
- the samples are unequivocally identified,
- all required information about the samples is collected and recorded properly,
- the proprietor of the business can have a reference sample taken for second opinion testing where legally required or prescribed by the authority, and
- the proper procedure for forwarding the samples to the laboratory is respected.

Since sampling generally takes place during inspections, one may choose to make these procedures part of the SOP for inspections. In addition, it may be preferable to formalise in the SOP only the general aspects valid for the whole organisation for inspections, sampling and laboratory tests. Aspects related only to single projects or actions can be standardised in specific SOPs.

3. Tests and laboratory investigations

Laboratory tests for market surveillance purposes are either performed in the authority's laboratories or are subcontracted to private or other state laboratories. In the latter case the authority must assure that the laboratory operates under a quality management system and preferably that it is accredited. In particular cases it may be necessary for quality management reasons to make sure that tests are witnessed by a representative from the authority. Chapter 5.7 gives additional information on the selection of laboratories.

Authorities that operate their own laboratories bear the responsibility for quality management and should preferably be accredited as well. In all cases the handling of the samples during the laboratory investigations should be the subject of a standard operating procedure, i.e. collecting samples, records to keep for the samples, responsibilities of personnel etc.

Test methods should be described and applied according to the relevant standard if available. If there are no standard based test methods available, standard operating procedures covering testing procedures must be developed and validated.

3.7 External relations

Market surveillance authorities perform a specific function within a set of wider policies aimed at establishing the single market and facilitating the free circulation of goods while at the same time ensuring a high level of product safety in the European Union. The set of policies includes legislation, dissemination of information to stakeholders, promoting consumer awareness, etc. Market surveillance authorities are therefore part of a wider social system where other actors play important roles, too. To function properly in that system communication with the other players is a necessity. It is necessary for the authority to communicate with other relevant players including:

3.7.1 Ministries

The ministries responsible for the implementation of the Product Directives that the authority must enforce are important partners. Depending on the responsibilities of the authority this may be one or more ministries. The ministries determine the way legislation is implemented which in turn determines the ease with which the legislation can be enforced. Therefore, input and feedback from the market surveillance authority is advisable. Frequently the ministries will also determine part of the priorities and the enforcement policies for the authority or have at least a say in them.

It is recommended to establish close national cooperation on market surveillance between ministries and to establish a network of enforcement bodies. Such cooperation groups should ideally have the power to establish procedures for practical cooperation both nationally and on a European level.

3.7.2 Other authorities

In most Member States product legislation is the responsibility of more than one market surveillance authority. The authorities are then each responsible for one or more directives, or cover for example consumer or professional markets for certain directives. Frequently this leads to grey areas in the sharing of responsibilities. Regular communication between the authorities to coordinate the activities in these areas is highly desirable.

However, even where no grey areas exist, coordination between the market surveillance authorities is needed, because the division in responsibilities between the authorities is unlikely to be reflected in the market. Many companies are therefore confronted with inspections by multiple market surveillance authorities. Inspections are a burden for businesses because they translate into extra costs. Political consensus is that these costs should be minimised. Reduction of administrative burden calls for a coordinated approach of the authorities which can only be achieved through regular communication and coordination between the authorities. Authorities which perform inspections at the same businesses, like labour and environmental inspectorates, but whose main task is other than market surveillance of product legislation, should also be involved.

Ideally this leads to cooperation between the authorities, which minimises the number of inspections in a business, for example by agreement to perform inspection tasks for the colleague authority or by combining inspections.

3.7.3 Legal authorities, prosecution

Depending on the legal systems and procedures used in market surveillance, close cooperation and coordination with the legal authorities handling the prosecution and the courts may be needed. Where the prosecutor is instrumental in imposing sanctions, the intervention policies should be discussed with the prosecutor's office. Indeed, the prosecutor should agree with such policies. Intervention of the prosecutor may also be required when product stocks are to be seized or destroyed. The work flow should be coordinated with the prosecution to assure minimum turnover times.

3.7.4 Standardisation organisations

Although the New Approach Directives provide the legal framework for certain consumer products by establishing essential safety requirements, technical product

requirements are specified mainly in European harmonised standards. These harmonised standards determine to a large degree not only the actual safety level of the products manufactured, but also how easy or difficult it is to enforce the requirements.

Market surveillance authorities influence standardisation on the European level via the AdCo's and the European Commission. However, interaction with the standardisation institutes at the national level is recommended, if only to monitor the developments in the most important standards. Participation in the standardisation committees responsible for drafting standards should also be considered as this would be the most effective and direct way to apply the practical experience gained through market surveillance into the standardisation process.

3.7.5 Notified Bodies

Market surveillance authorities should have good working relationships with the notified bodies in their Member State. Regular contacts are desirable to align differences in the interpretation of legislation and standards. Such differences are highly undesirable, because businesses should rightly be able to trust that products certified by a notified body do comply with the applicable requirements. It is also important to feed back and discuss with the Notified Bodies information about products found to be non-compliant, even though they were certified by them to comply with the relevant standard (N.B., notified bodies and test laboratories frequently also give out 'safety marks', for which it is also important to provide feedback with regard to non-compliances that have been determined). Note that this need not always involve mistakes from the notified body, because changes in product specifications after the tests frequently occur, as do downright falsifications. Feedback allows the notified body to rectify such a situation, or to discontinue the certificates.

3.7.6 Media

Professional interaction with the mass media is increasingly important. The media are the means to inform the public of safety problems in products and of recalls and are the main channel for public relations. On the other hand mass media can be very critical towards the authorities when there is a general feeling that they are not handling incidents properly.

3.7.7 Business

It is of vital importance to have stakeholders like manufacturers or importers on board on the issue of market surveillance. Business is responsible for product safety and good relations between business, and national enforcement bodies will clearly ease the work of product safety authorities.

Good national contacts with business on a regular basis will surely have a positive effect by reducing the occurrence of dangerous products in Europe.

3.7.8 Consumer associations

Consumer associations hold considerable expertise in several product areas. Therefore, it is useful to establish national cooperation regarding product safety with consumer associations on a regular basis. Issues for such cooperation might include information to consumers, market surveillance campaigns, publishing in consumer magazines etc.

3.7.9 Co-operation with stakeholders

In order to establish good relations with all stakeholders it is recommended to arrange regular meetings at national level. It is envisaged to arrange at least one meeting per year with different stakeholders. Meetings may have the form of workshops, seminars or any other setting, depending on the nature of the content of meetings.

Issues for regular meetings may include:

- Legal development nationally and in Europe
- Report from enforcement bodies on product safety activities
- Report from stakeholders on safety promoting activities
- Discussions on how to improve safety aspects, challenges and problems
- RAPEX
- Notification activities by business

3.8 Integrity policies

The daily practice of market surveillance regularly leads to interventions with considerable economic consequences. It is therefore conceivable that in some cases bribes could be offered in order to influence those involved in making the decisions about the interventions. Market surveillance authorities should be aware of these risks and formulate policies to minimise these risks and preferably avoid them completely.

The possibility of fraudulent behaviour of employees should be taken into account; this can range from accepting bribes to taking advantage of benefits. The management should be transparent with regard to procedures for investigating suspected cases and decision making. To underline the importance of integrity in dealing with trade and industry the formulation of a 'code of conduct' or an 'ethical declaration' in which it is made clear what is allowed and, in particular, what is not, needs to be contemplated.

To minimise the risk of falling prey to corruption several practical measures can also be taken. Firstly, decisions on interventions should not be taken by a single employee, but always require a second opinion to confirm the decisions.

It is also advisable to regularly shift the work districts of the inspectors, to avoid the development of a an overly close relationship between the inspector and the businesses surveyed.

3.9 Operational risks

Market surveillance authorities take measures to protect the consumer from risks associated with products found to be unsafe. These measures are based on non-conformities found in tests and risks assessments, which constitute part of the legal basis to impose these measures. The measures imposed may cause significant financial damages and pose reputational risks to the companies involved. Especially sales bans and mandatory recalls may cause considerable costs and loss of profits to the businesses affected.

Whenever taking measures, the authority risks that those measures can not be upheld in court. If by that time damages have occurred to the interests of the company, it may well demand compensation.

The authority should always aim to minimise the risk of being held liable for damages. The first safeguard against such liability is to perform a proper job, which means getting the facts right and following procedures meticulously. Tests should be reliable, substantiated by the use of accredited laboratories where possible. If in any doubt, have the results checked.

It is sometimes advisable to have risk assessments carried out by a second independent institution. Risk assessment is based on (subjective) estimates of the severity of injuries and their probability of occurring. A second opinion can then support the conclusions drawn from the assessment, making a stronger case in court.

One must verify that all official documents fulfil the legal requirements and that references to standards and legislation are correct. A double check made by a second person can be useful.

Especially when the stakes are high the legal department or an expert lawyer must be involved in all the steps taken. The company involved in the proceeding will probably refer to expert lawyers and the market surveillance authority has to consider the need to be ready to react properly.

The precautions above are always applicable, but they are especially important in trade bans and recalls, because the damages may be particularly large.

Despite all precautions and procedures safeguarding against the eventuality, the authority may still be put in the wrong and (in some jurisdictions) is ordered to pay compensations. The authority must prepare for that eventuality. How this is done depends on the situation. It may be possible to insure against damages caused, as the notified bodies are obligated to do. The government of the Member State may also cover the liability of the authority. If none of this is possible, the authority could designate part of its budget for a fund to cover such (and other) eventualities.

4 MARKET SURVEILLANCE – THE PLANNING STAGE

The Member States expend considerable financial resources to organise and perform market surveillance. These resources must be spent properly and efficiently. Therefore, careful planning, setting the proper priorities, and controlling the planned activities are an important part of the market surveillance authority's task. A large part of the rest of this Book will be devoted to the way in which market surveillance projects are planned and organised.

4.1 Planning

Market surveillance activities include a number of processes which must be carefully planned to make the overall effort efficient, including inspections, sampling, laboratory testing, evaluating results, legal follow-up and communication about the project. They require meticulous preparation and need to be set up depending on the specific businesses or products under consideration.

This is best illustrated by considering the preparations involved in setting up a test programme for a specific product in the laboratory. This requires the selection of suitable tests from the standard, setting up the measuring equipment and taking precautions for quality management. It is much more efficient to test an entire series of products at once. The preparations have to be made only once for the whole series. Performing surveillance activities on similar products or businesses in series almost naturally leads to working in well-defined projects.

Interventions work best when the time between inspection and intervention is short. This is why some organisations define a time span in which the whole process has to be accomplished. To achieve this goal, the sub-processes need to interconnect smoothly. This can only be realised with careful planning. Adopting a project-centred working method facilitates the planning process.

The following paragraphs discuss a systematic approach to the planning process and to the issues particularly relevant for planning in market surveillance organisations. Figure 4 summarises the main steps and relationships in the planning process, including:

- long term planning
- detailed planning of activities for restricted time periods (annual programmes)
- planning of specific projects
- feedback loops which allow control of the progress of the planned activities as well as adaptation of the plans where needed

The steps differ in the time frames and issues they address and in the level of detail of the plans. Long term planning covers the way the market surveillance organisation reacts and adjusts to long term developments and changes. Within a long term programme, the short term programme defines which activities receive priority in a shorter time frame, usually a year. The short term programme also roughly divides the available resources over the planned priorities.

Once fixed, the short term programme must be planned in detail. The planning process as a whole ultimately leads to a set of project plans and other scheduled activities (routine inspections, estimated capacity for consumer complaints and notifications etc.) which define the specific market surveillance activities and actions for a certain period of time, usually one year. This programme specifies at a higher level of detail than the short term programme the projects and actions for this period: what has to happen, how often, when and where.

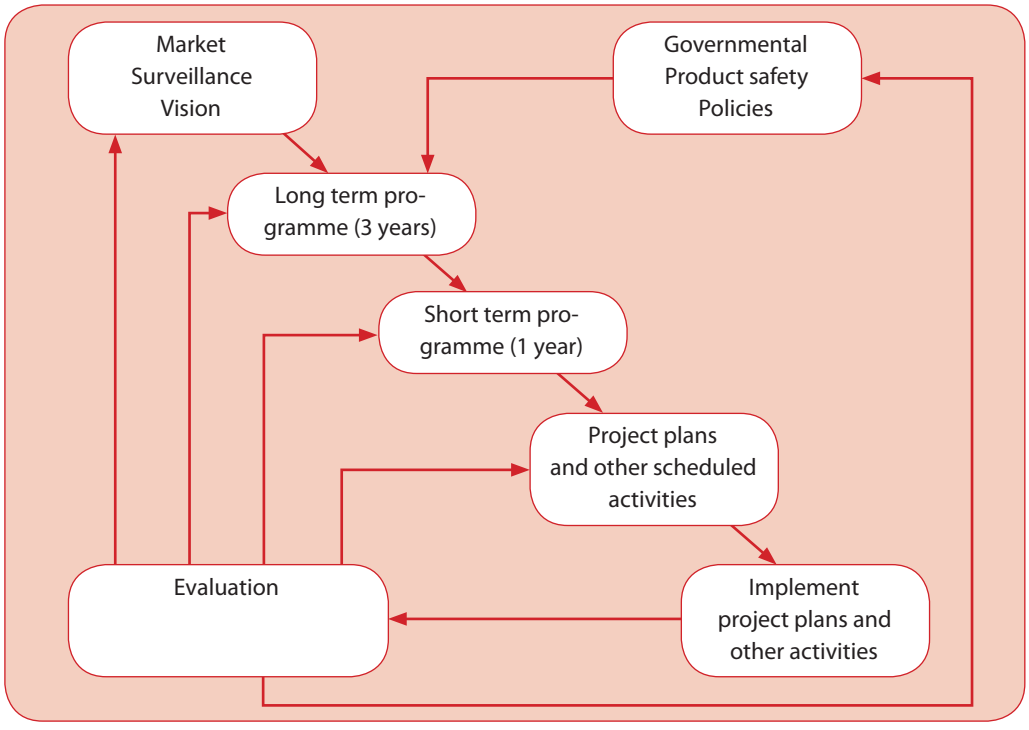


Figure 4: Framework for the planning cycle.

4.1.1 Long term programme

In an ever changing environment, adapting the market surveillance organisation to keep it in line with its vision and to cope with expected future developments is a necessity. Market surveillance organisations are generally fine-tuned to do their present job, with personnel trained to do that job optimally, and frequently have an infrastructure of laboratories and IT systems that is suitable for the present situation. It is difficult to restructure the whole organisation at short notice, because personnel may need to be retrained and the hard infrastructure needs adjustment. Both require time and money.

Market surveillance organisations should therefore continuously investigate both internal and external developments in order to plan adaptations necessary for the long-term well in advance. Normally such developments and long term plans are described in a long term programme.

The long term programme then describes the projected development of the organisation over a longer period and indicates the direction in which the organisation is moving and adapting to expected new circumstances, environments and priorities. Typically, such programmes are quite abstract and focus on major changes in the organisation, including major shifts in the allocation of resources. They may set concrete aims, but do not describe how these aims can be attained.

The time frame can vary; common periods are 3 and 5 years. Less than 3 years may be too short to be able to adjust the organisation in time, while extrapolations for periods exceeding 5 years are uncertain. It is good practice to review the long term programme annually and correct it if new information justifies this.

Typical issues to address in the long term programme include:

- Political developments
  Changing political priorities may force market surveillance authorities to adapt.
  A current example is the political aim to diminish the administrative burden and costs to businesses of conformity checks and inspections by multiple surveillance authorities. Other trends that have recently been initiated in several Member States include the emphasis politics has been putting on issues like 'compliance assistance instead of sanctions' and not to direct market surveillance at companies that comply (to lower the administrative burden for the good companies) but instead at the non-compliant companies. Another initiative of governments in many Member States is the relocation of services and resources.
  This kind of developments can have significant consequences for the working methods of the market surveillance authority, for the resources available and for the training requirements of its personnel.
- Internal developments
  Changing perspectives and visions on market surveillance within the organisation may also give reason to adjust the long term programme. Examples of internally initiated changes are a shift from an output-managed organisation to an outcome-managed organisation or a shift in focus from product-oriented approaches to market surveillance to system-oriented approaches. Such long term developments are often related to the vision and should also be addressed in the 'vision document', as introduced and described in 3.3 – Market surveillance strategy.
  Radical changes in priorities may also require long term planning, because they may well require retraining of personnel and restructuring of the organisation, in particular of the laboratories.
- Changing environment
  The environment in which market surveillance functions continually changes and proactive market surveillance adapts to these changes. Example of trends that need long term adaptations in priorities and possibly knowledge infrastructure include:
  – demographic changes: both the aging of the western European population and the demographic changes due to immigration may have effects on the priorities for market surveillance, but also on the possibilities to engage personnel.
  – global developments like climate change and its effect on consumers.
- New emerging safety issues
  Examples of such developments include nanotechnology which may hold as yet unidentified risks, the possibility to remotely control household appliances via the Internet, and the marketing of so called 'intelligent appliances'.

4.1.2 Short term programme

Resources are usually allocated over relatively short periods of time in short term programmes. Mainly for practical administrative reasons short term programmes usually span a period of one year, as they can then be synchronised with the bookkeeping of the Ministries and the State.

The main purpose of the short term (annual) programme is to allocate the resources over the different market surveillance activities. The short term programme defines which areas will get priority in the following period and which product categories will be subject to market surveillance actions.

Short term programmes describe concrete activities and attribute resources to these activities. Planning aims to optimise the results obtained from the available resources, while keeping in line with the long term programme.

Where necessary, they can also address organisational issues such as personnel management, IT management, budgeting, training etc. The drafting of the short term programme is a management task.

The short term programme generally takes the form of a document that defines the priorities and any other issues requiring capacity in general terms, while attributing capacity to the different activities. The way to determine priorities is discussed in detail in 4.2.

The process of prioritising does not directly result in fully developed project plans and a second step is needed to translate the global priorities determined in the short term programme into projects ready to be executed. Project specifications describe the activities to be undertaken in detail, including how many inspections and lab tests will be performed, which kind of companies will be inspected, what lab tests will be performed etc. The drafting of the projects must necessarily involve personnel with expert knowledge of the markets, products and tests involved, with management monitoring as to whether the projects designed reflect the aims of the short term programme. The end result is a detailed programme of all the activities the authority plans to undertake in the planning period: the activity programme. Note that it may be preferred to combine the short term programme and activity programme, instead of seeing them as separate phases of the planning process.

4.2 Prioritising

Market surveillance authorities must make a choice on where to allocate their resources to obtain maximum results. This prioritisation is necessary, because the available resources can not cover every product and all parts of the market at the same time. Therefore one part of the planning process involves choosing areas of priority and which share of the resources will be spent there.

The main objectives of market surveillance in the EU are consumer protection and ascertaining fair and free circulation of goods in the common market. These two objectives define the boundaries within which priorities must be chosen. For most of the market surveillance authorities in the EU consumer protection is the more important objective and priorities are chosen with this in mind. There are good reasons for this. All activities performed to promote product safety by market surveillance automatically contribute to establishing the 'level playing field' and fair competition. Nevertheless, it should be kept in mind that a level playing field for business competition is also an important corner stone for the proper functioning of the internal market and therefore deserves due attention.

For most market surveillance authorities setting priorities is a two-step process. The first step is to divide resources over the variety of product categories covered by the authority (e.g. which category deserves the most attention: toys, electrical appliances or cigarette lighters and how much resources should be allocated to the priorities).

Having made these choices for the top level categories, similar decisions have to be taken for the sub-categories (e.g. is consumer protection best served with the surveillance of jig-saw puzzles, dolls or toy guns). The process is complicated by numerous constraints such as available human resources, technical capacities and funding.

Theoretically, the two-step process described above could also be accomplished in a single step; all different product categories should then be analysed at once and the results compared. In practice, the number of different kinds of products or surveillance to be made, each requiring different planning and/or test programmes and therefore differing in the resources needed, is so high that this is impracticable.

Ultimately, these choices result in a surveillance programme. The surveillance programme preferably contributes maximally to product safety and fair competition. There is no fail-safe procedure to arrive at an optimum market surveillance programme, but best practice in many Member States is that several considerations and sources of information are taken into account when prioritising. The following chapters describe some of the sources of information relevant for prioritising:

4.2.1 Accident reports & accident statistics

Product failure causing an accident or injury will often be reported to the authority either by the injured party or by the producer as part of the obligation to report safety problems with products. Regardless of how the authority is notified, such reports are important indicators of dangerous shortcomings, for example the product may not comply with the safety requirements or the safety requirements are not sufficient.

Accident statistics can show how often specific (kinds of) products are involved in accidents, what kind of injuries result from the accidents and which groups of people are most frequently affected. Accident statistics allow the comparison of frequencies and accident outcomes for products and product categories. Depending on the level of detail of the data, they may also be used to assess which products are most often associated with accidents in specific target groups, like children and older people.

The data is also useful to identify products and product categories rarely involved in accidents causing injury. Market surveillance programmes for these products and categories do not contribute significantly to consumer safety and therefore do not deserve a high priority. On the other hand, the fact that a specific category of products is frequently related to accidents does not imply that market surveillance focussing on that product category automatically contributes to increased consumer safety. Accidents do happen even with products that are in conformity with legislation and standards, and market surveillance can not hope to reduce the number of accidents in such cases. Prime examples are ladders which notoriously cause many accidents, but not because they fail to comply.

Analysis of accident reports augments the results of accident statistics. It reveals how products are involved in accidents and clarifies how a failure to comply with the legislation plays in the occurrence of accidents. In that way it gives valuable information about the possible contribution that market surveillance of these product groups can make to consumer protection. Analysis of accident reports is also valuable for the selection of those requirements in standards to be investigated in the market surveillance action.

Caution is called for when extrapolating accident statistics from one region to another. The frequency of particular causes of accidents is related to lifestyle, and lifestyles vary considerably between the European countries because of factors such as differences in culture, climate and income per capita.

Injury statistics are compiled by various organisations. The European Commission has initiated the Injury Database (IDB), previously known as ISS or EHLASS (European Home and Leisure Accident Surveillance System) for more information see: https://webgate.cec.eu.int/idb.

Additional sources of statistics that are relevant in certain fields of consumer protection include fire statistics (for electrical products, lighters etc.) and statistics on work related accidents (machines, garden equipment), which are being gathered in many countries.

4.2.2 Reports from consumers, consumer organisations or media

Reports from consumers are useful to indicate the fields where surveillance action should be undertaken. The usefulness of the information from consumer reports increases with the number of reports investigated. A single isolated consumer report about a specific product may indicate a problem associated with the product but gives little information about the overall situation in the market. Nonetheless it should be investigated whenever possible; the result of the investigation may indicate the need for direct measures against the product (reactive market surveillance). With growing numbers of investigated reports on various products, information is collected on the kinds of products the population complains about, whether these complaints concern safety issues, and which target groups are affected. All this information is valuable for prioritising market surveillance.

Accident reports from the consumers or the media should be continuously assessed for market monitoring purposes. A fatal accident or more than two accidents connected to a single product merit serious investigation anyway. This investigation would include risk assessment on the product, also taking into account the number of products sold to estimate the potential for injury present in the market. If risk assessment reveals a high probability of severe injuries to the consumer, the product category should receive high priority. Also reactive market surveillance may be required immediately (direct measures against the importer and producer according to national legislation).

Consumer TV programmes are a valuable source of information, too. Many such programmes test various products and give recommendations to consumers. Often such testing includes safety aspects. The results can be the starting point for the authority to follow up.

Another important source of information are the reports published by consumer associations (e.g. the studies issued by ANEC on balcony barriers and pool fences, child exclusion clauses survey and those published in consumer magazines).

Consumers may also report shortcomings in a product that has caused near-accidents, e.g. appliances that emit smoke but could be disconnected from the mains before catching fire. Media and consumer associations' reports on comparable incidents with products require serious attention. Media attention raises consumer awareness of possible safety problems and it may be necessary to react to problems pointed out in the media.

4.2.3 Reports from manufacturers, importers or retailers

Manufacturers, importers and retailers regularly complain about products traded by competitors. Since market surveillance also has the task of promoting fair competition, these complaints have to be investigated to see if these products pose any risk to the consumer. Since the complaining entities are familiar with the market and the potential risks, their complaints may well point to serious deficiencies.

The information obtained may be valuable for defining market surveillance programmes. Note however, that the complaining entity has an economic interest, which might have motivated the complaint.

4.2.4 Data based information systems

Although RAPEX (Rapid Exchange of Information on Products posing a Serious Risk) is primarily meant to inform the authorities of the other Member States about specific products that have been found dangerous, analysis of the notifications also reveals which product categories regularly give rise to safety problems. Moreover valuable information on the specific shortcomings can be obtained which is useful for determining the test programme for projects concerning such products.
Other systems where such information may be found include (see Annex H for more detailed information):

- CIRCA (platform for exchange of information within the ADCO groups)
- The safeguard clause procedures (often exchanged via the CIRCA system)
- ICSMS (IT tool for cooperation between authorities)
- IT system for economic operators' notification of voluntary measures
- The EMARS knowledge base

4.2.5 Data from previous market surveillance activities

Over time, market surveillance organisations gather large amounts of data on the product categories and businesses they inspect. Generally this data is filed in databases and can be retrieved for analysis. Such analyses can give insight into the percentages of non-conformities for specific product categories in the market and thus allow the identification of problem areas. Further analysis can also indicate which kinds of non-conformities exist and thereby facilitate the choice of tests for the product category to be investigated.

Also, information can be extracted as to which businesses frequently violate the legal requirements and which businesses comply with legislation.

4.3 Targeting of market surveillance

The major part of the discussion on prioritising in this chapter has centred on the selection of product categories for market surveillance actions in such a way that the market surveillance contributes maximally to product safety. Making the right choice avoids expending resources on activities that only marginally contribute to product safety.

After selecting what to do the question of where to do it has to be addressed. The practice of market surveillance comprises checks at economic operators that trade the products. Limited resources generally do not allow checking all the operators active in the market segments that need to be covered. The market surveillance authorities must therefore decide which operators should be checked. The choices made determine the effectiveness of the market surveillance efforts to a considerable extent. After all, market surveillance practice indicates that some operators follow the rules while others frequently break them. Targeting market surveillance at those operators that are most likely to break the rules is more effective than inspection of randomly selected businesses. This is also in line with political priorities concerning 'better regulation' like those established at EU Level (see http://ec.europa.eu/enterprise/regulation/better_regulation/index_en.htm) and the wish to reduce the administrative burden on European industry.

Most market surveillance authorities are aware of this fact and take their previous experiences about the behaviour of specific economic operators into account when targeting their actions. However in most cases the approach adopted is rather ad hoc and systematic analyses are hardly ever performed. A systematic approach is desirable and also possible aided by the fact that over the years a consistent empirical basis regarding the likelihood for economic operators to comply with legislation has been compiled. This research has aimed to identify and describe the variables and parameters determining the level of compliance with legislation from the perspective of behavioural sciences.

The legislation investigated in this context varied from compliance with tax legislation to compliance with traffic regulations, with product safety legislation being practically absent. However, the findings are quite general and can be extrapolated to compliance with product safety legislation. The scope of this research is not limited to law enforcement, but addresses the whole chain from definition of policy aims, design of legislation, communication of the legislation and law enforcement.

Although law enforcement in the strict sense restricts itself to the identification of violations and imposing sanctions, there are many market surveillance authorities who go beyond sanctioning by applying alternative intervention methods. The variables and parameters not directly related to law enforcement are therefore also of interest, if only because they can help to determine the optimal intervention mix. A typical example of such studies is presented in detail in Annex E.

Taking into account the ideas described above is in line with other developments, such as the programmes to decrease the administrative burden to economic operators, the better regulation initiatives across the EU and the realisation that compliance assistance contributes to improved compliance levels. To apply methods like those described in Annex E deserves consideration.

4.4 Decision tools for selecting priorities

Evaluation of available information allows selecting the priorities for the short term programme. Once agreement has been reached about the priorities, the available resources can be divided. Depending on the responsibilities of the authority an initial division can be made between the areas covered, i.e. between the different directives, and subsequently between the different product categories. Constraints should be taken into account at this stage, i.e. the necessity to keep up a minimum effort for all the directives, constraints related to the possibilities of the testing facilities or the availability of expertise in the different areas.

4.4.1 Decision tools

When done conscientiously the choice of priorities and the resulting distribution of resources can be soundly argued. Nevertheless, the process leading to these choices can be criticised for making quantitative choices based on qualitative arguments and for being rather subjective. Especially with regard to accountability and justification of the choices made in expending resources, a more objective and transparent procedure is highly desirable. Due to the lack of reliable quantitative statistics on the relation between the occurrence of injuries and product non-conformities, a fail-proof quantitative method for prioritisation is unlikely to emerge in the near future. However, attempts to develop more objective and transparent procedures have been undertaken. Three approaches will be briefly discussed.

1. Group decision support systems

Group decision support systems (GDSS) are based on the use of computers to support decision making by groups. These systems vary in the way they support access to data and the way they structure the communication processes leading to decisions. A typical setup, experimentally used in one of the Member States for deciding on the general high level priorities for market surveillance, makes use of a system that allows the participants of a session to immediately express their opinion on questions or statements via a sort of 'remote control' to the computer. The computer then evaluates the results for the whole group in the form of statistics about the reactions. The decision process can be carried out in a meeting room or via the Internet. Initially, the main issues and data about the market surveillance performances in the previous year are made available to the participants, and in open discussions proposals and ideas from all experts are collected. The ideas and proposals are then structured so that they can be submitted to the group via the GDSS. In a series of such sessions the decision is reached by the group.

Participation in group decisions is not limited to experts and managers of the market surveillance organisation itself. Involving outside experts and stakeholders, such as policy makers from the ministry and experts from external institutions, broadens the outlook and precludes tunnel vision.

The advantages of the GDSS include more precise communication, synergies (members build on and extend ideas of other participants), improved objectivity in the evaluation of ideas and stimulation of individuals to increase participation. There are criticisms, too. Beside process oriented disadvantages such as information overload, lack of real participation, slower feedback and incomplete use of information, the main criticism when used in this context would be the reproach that the method exchanges the prejudices of a single expert for those of the group. It seems not unlikely that the outcome will be dependent on the composition of the group, with other groups leading to different decisions. Nevertheless, from a management point of view the group decisions, with the main stakeholders involved, have the advantage that they can claim wide support. The result of GDSS is a product of the views of the group members. A higher reliability and a wider support of the decision can be reached by involving participants from the relevant stakeholders.

2. Workshop

Planning in workshops is another way of applying a group decision approach. The general concept is that the planning takes place within a group of people with different perspectives on market surveillance. The workshop can be executed in a one-day meeting.

The decision workshop could include three main parts: generation of ideas, selection of the most promising ideas and drafting of outline project descriptions of the selected ideas.

a) Brainstorming

Ideas are generated in a brainstorming session. This part of the workshop could involve as many participants as practicable with as many different perspectives as possible. People working in market surveillance are obvious participants as they can contribute with knowledge from the market. Analysts that look at accident statistics will also provide valuable input. Representatives from stakeholders such as test laboratories, business associations or consumer associations may be invited to contribute with their knowledge of market trends. The focus of the brainstorming should be to come up with ideas for areas where market surveillance is needed.

b) Selection of the most promising ideas

A brainstorming session often produces hundreds of ideas. To reduce the scope of ideas to be discussed against a given set of criteria, the participants assign a finite number of points to a limited number of ideas they find most promising. When all participants have assigned their points, a list is generated with the ideas that have been given the most points. The participants should review the list to check for obvious omissions and to see if the ideas aim at building a plan for market surveillance activities. Again it is an advantage to have participants representing many different perspectives.

c) Drafting outline project plans

This phase should only involve people with experience in running or participating in market surveillance actions. Firstly, the group should agree on the headings for the project descriptions (see Chapter 5 for inspiration). Next, the group must go through the ideas one by one and provide input for each of the headings. The intention of this phase is to extract as much knowledge and experience as possible to include it in the final project plan.

After the decision workshop and as the output of it, project plans must be drafted from the outline plans.

3. Multi-criteria analysis

Prioritising implies that many conflicting interests and constraints must be taken into account. Prioritising therefore has all the features of a decision that must be made weighing multiple criteria. To support that kind of decision making a large number of multi-criteria evaluation methods have been developed and applied for different policy purposes in different contexts. In the selection of priorities for market surveillance of consumer products the goal of the multi-criteria analysis is the ranking of different groups of products in order of priority.

A crucial first step is the selection of the criteria relevant for assessing the order. These would of course include the (relative) risks of the product groups. There may be other criteria, derived from the market surveillance vision document or related to economical constraints. The latter would aim to avoid spending too much on very high risk items for which the situation can not be improved by market surveillance. Criteria found useful in this context that have been used in experiments with multi-criteria analysis in one of the Member States were risk, risk acceptance and cost. Each of these criteria itself actually represented a cluster of other more concrete criteria thought to provide a sound basis to score the cluster.

For the risk cluster the following criteria were used:

- risk assessment of the product group
- vulnerability of the user group (e.g. children or elderly population)
- accident statistics: the number of emergency treatments caused by incidents with the product group
- cost of the medical treatment after these incidences
- expected development of the risk in the near future (aging population, increasing possibilities to rent heavy equipment etc.)

The risk acceptance cluster provided an estimate of the priority given by society to the risks associated with the products. Risk acceptance comprised:

- political and media attention regarding the product category
- risk perception of the public with respect to the product
- frequency of consumer complaints

The cost cluster included:

- presence of useful legal and standard requirements
- observance level (from historical data)
- resources required to address the risk

Once the criteria are defined, the different risks associated with the specific product categories have to be scored on all sub-criteria in all clusters. Scoring can be done in different ways: ranking, relative scores, score tables. Where possible, scoring should be based on quantitative data, which is available in the form of accident statistics, historical data on observance levels etc. If no reliable quantitative data can be obtained, qualitative data or expert judgement is used.

The criteria have to be weighted. Weighting is done on the level of the criteria clusters, where the relative weight of the criteria clusters must be determined. To reduce the element of subjectivity in this step, performing a group decision process (see GDSS group decision support systems above) is advised. In the group decision process instantaneous feedback on the influence of different weighting of the criteria should be provided, so that the influence of the decisions made is immediately clear. The process is then iterated until satisfactory weighting factors are established.

For added confidence a sensitivity analysis can be performed in which the sensitivity of the final criteria values for changes in the weighting factors is investigated. This stage can be combined with the calculation of the overall product risks and their rankings, finally giving a list of priorities.

Table 1 below shows an example of a multi-criteria analysis. The table lists the scores for three clusters and the resulting score for the composite criterion for two product safety fields: products with chemical/toxicological risks and risks of Do-it-yourself products under the LVD. The conclusion is that the procedure is quite useful for prioritising within product groups. Indeed the high rankings of chain saws and circular saws, as well as that for rubber teats correspond to expectations.

4.4.2 Selection and prioritisation

The result of this stage of the planning effort is a division of resources between the different terrains and within these terrains between the different product categories which can serve as the basis for specifying the activities and projects for the coming period.

Table 1: Results of multi-criteria analysis for two product categories (example).

Product hazard				risk **0.50**	perception **0.25**	cost **0.25**
Rank		**Score**				
1	Rubber teats – plasticizers – toxicity	4.18		4	4.3	4.4
2	Toys for the bath – plasticizers – toxicity	3.30		3.4	3.9	2.4
3	Wood preservatives – toxicity	3.21		3.6	2.8	3.1
4	Dolls etc. – plasticizers – toxicity	3.02		2.9	3.9	2.4
4	Inflatable toys – plasticizers – toxicity	3.02		2.9	3.9	2.4
6	Phenol in floating toys – toxicity	3.01		3.6	3	2
7	Isophoron in floating toys – toxicity	2.88		3	3	2.5
8	Cadmium in wooden toys – toxicity	2.71		2.9	3	2.1
9	Scoubidou strings – organic tin – toxicity	2.69		2.4	3.5	2.4
10	Scoubidou strings – plasticizers – toxicity	2.45		1.7	3.9	2.4
11	Key rings – plasticizers – toxicity	2.22		2.3	1.9	2.4

Do it Yourself equipment				risk **0.50**	perception **0.30**	cost **0.30**
Rank		**Score**				
1	Circular saws – amputation	3.89		4.3	3.1	3.8
2	Chain saws – amputation	3.86		4	3.1	4.4
3	Electric grinders – eye injuries	3.43		3.6	2.1	4.4
4	Tile sawing machines – amputation	3.18		3.3	2.3	3.8
5	Wallpaper steamers – burns	2.78		2.9	2.5	2.9
6	Pneumatic jackhammers	2.73		2.8	2.1	3.2
7	Mitre saws – cuts	2.56		2.2	2.5	3.2
8	Circular saws – cuts	2.49		2.6	2.8	2.1
9	Tackers – eye injuries – finger injuries	2.29		2	2.5	2.6
10	Rough service luminaires – electrocution	2.29		1.4	1.9	4.4
11	Electric hedge trimmers – cuts	2.27		1.9	2.1	3.2

4.5 Overall planning – consolidation of project plans

Once the priorities have been selected and the short term programme finalised, it can serve as the basis for specifying the activities and projects for the coming period. To reach a detailed working plan, specific market surveillance projects must be developed, the resources need to be attributed to specific projects and personnel and laboratory resources must be assigned to these projects and activities.

The time frames during which the activities are performed are also important in this phase. Detailing the short term programme into a detailed 'activity programme' is a considerable planning effort. It will require expertise from all areas involved, not only management.

At this stage, it is necessary to obtain an overview of the total portfolio of activities for the coming period, their cross-links, and the demands they put on the organisation to ensure that the market surveillance organisation can manage all the activities foreseen for the coming period. This requires that project outlines are drafted and consolidated.

For many authorities, detailing the short term programme into specific activities and projects is considered part of the short term programme; the project plans are incorporated in the short term programme. Since the planning period is generally one year, the short term programme is in most cases an annual programme.

Drafting the project outlines requires a translation of the still rather general priorities defined in the short term programme into precisely defined activities. The activities specified can be well-described projects (as is customary with most authorities), specific enforcement actions, import controls in cooperation with customs or any other activity requiring resources and listed in the short term programme.

Similar outlines should be made for all activities including reactive market surveillance, as this also uses resources. Reactive market surveillance can not be planned in detail, but a good idea about the required capacity can be derived from historical data.

Where the short term programme attributes resources to market surveillance activities aimed at specific product categories (the priorities) these now have to be filled in, usually in the form of projects. At this stage it is not necessary to draft detailed project plans; project outlines (project summaries) will suffice as long as they include all information needed for fine tuning the overall planning:

- estimated number of inspections
- approximate number of samples taken
- initial estimate of tests needed
- estimated human resources and competences required to run the project; basic financial requirements for the project
- time constraints, time frames and deadlines (if necessary)

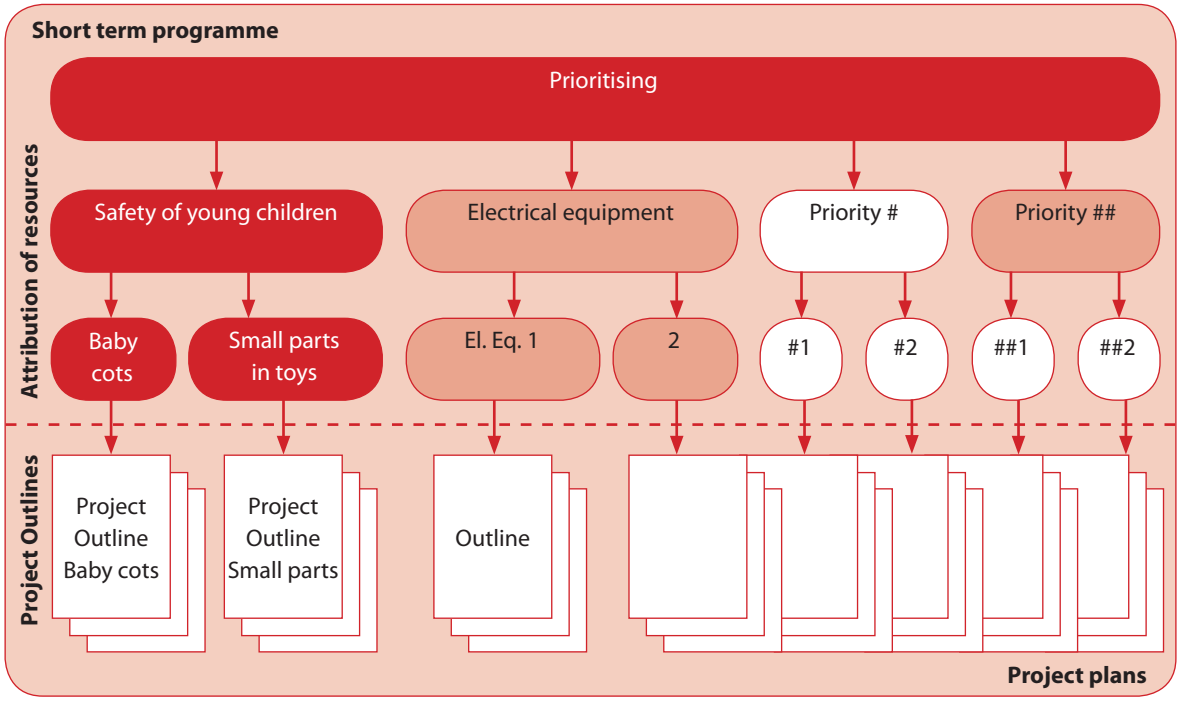


Figure 5: Process of translating a short term programme into project plans (Project outlines detailing the activity related to a priority).

Such project outlines must be compiled for all activities listed in the short term programme, including the expected activities for reactive market surveillance. Once available, the total resources needed can be compared to the resources available and a check can be made as to whether the attribution of resources is in line with the original intent. Further fine tuning can then be done in an iterative process, taking into account time constraints and phasing (i.e. not all activities can be done at the same time).

The finalised planning is best conceived as a document comprised of the short term programme and the catalogue of project outlines and other activities (i.e. reactive market surveillance estimates). It is then available for reference by all employees involved in the execution of the programme. The planning document also serves as basis for management control of the progress of the planned activities over the planning period and for purposes of accountability and justification. See also Chapter 5 for detailed project planning.

4.6 Controlling using key performance indicators

It is not uncommon for the execution of the planned activities to deviate from the schedules the planners had in mind. Therefore proper management requires that the execution of the activities be monitored, to see if the execution needs adjustment or if adjustments in the planning are necessary. Similarly it is necessary to monitor the budgets to avoid overspending.

Monitoring the progress of the planned activities can be seen as a cyclic process as depicted in Figure 6 for the annual programme. Information about the progress of the planned activities is fed back to the management at regular (monthly or quarterly) intervals. To this end data related to the progress of the processes involved are collected at regular intervals and reduced to information that summarises the progress of the activities for the management, without causing information overload.

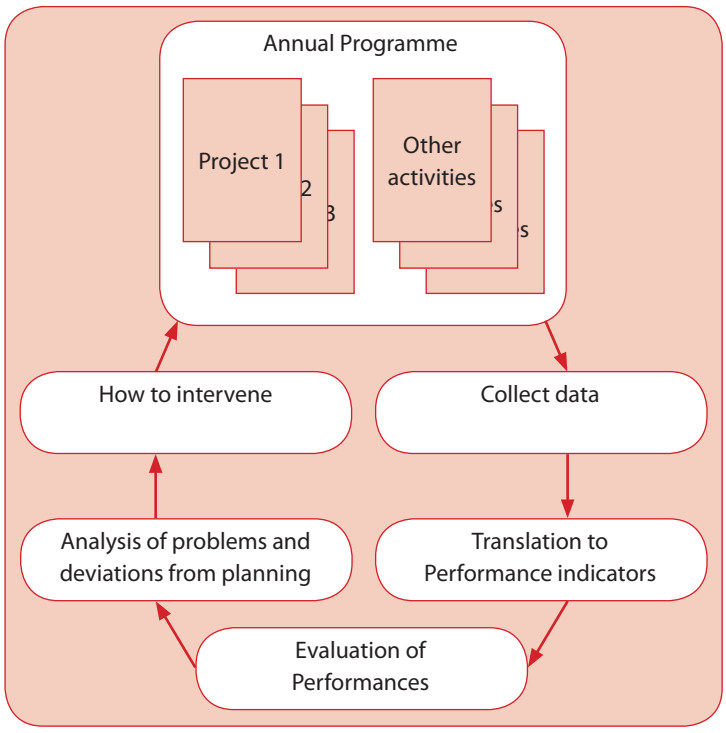


Figure 6: Control cycle of short term planning.

Reporting the results of all inspections, lab tests and legal cases by transmitting the case files is not useful for process control purposes. A set of parameters is required which can serve as an indicator for the progress; for this the data collected are translated into key performance indicators.

On the basis of the key performance indicators the performance of the organisation is regularly evaluated. When discrepancies with the planning are identified corrective action can be taken. Corrective action can involve:

- shifting manpower or other resources from one to another activity
- adaptations to the annual programme or the project plans

Performance indicators

Possible indicators to measure the performance of an organisation can be divided in output and outcome indicators. Output indicators are indicators that summarise the performance of the organisation. There is no direct relationship with the intended results of the activities in terms of output. Outcome indicators are indicators that focus on the intended effect of the activities by the organisation. Which parameters are useful in a specific case depend on the organisation of the market surveillance authority and the goals defined in the short term programme.

a) Output based performance indicators

Traditionally the performance of a market surveillance organisation is measured through output indicators as they are easy to obtain.

Typical output indicators are (in absolute figures or percentages):

- number of inspections
- number of products investigated
- number of laboratory tests
- number of measures taken against unsafe products
- number of voluntary actions taken by economic operators
- number of items withdrawn from the market
- number of sanctions imposed
- accumulated size of product batches affected by other measures
- processing time (from sampling a product to concluding the case)

All of these indicators measure output of the market surveillance organisation. Measured against the resources spent, such parameters also give an indication of the efficiency by which the activities are performed. The parameters can be used for reporting the activities of the market surveillance authority in general and they can immediately be used in the management's periodical follow-up on the activities.

The advantage of using numbers of inspections and laboratory tests as performance indicators is that they are generally easily available from the IT systems and that complicated translation from basic data is avoided. A disadvantage is that they do not directly relate to the effectiveness of the efforts, because they do not give any information on the influence of the activities on the compliance behaviour of economic operators. Another problem associated with using these indicators for controlling purposes is that they neglect the quality of the items measured. Steering on these indicators to bring results in line with the planning may result in increasing numbers of inspections and tests performed at the cost of reduced quality, i.e. the personnel 'work for numbers' instead of doing market surveillance.

Output indicators are assumed to correlate with the organization's impact on society. As an example, the number of measures taken by the authority against dangerous products is an output indicator. Taking measures against dangerous products reduces the exposure of consumers to those products, which is likely to decrease the number of accidents as well.

This output indicator may therefore provide an indirect measure of the impact or outcome of market surveillance.

b) Outcome based performance indicators

In a recent development several Member States are experimenting with outcome based performance indicators. Outcome based performance indicators are seen as being more relevant, because they measure the resulting effects of the activities of the organisation, rather than its output. Obviously outcome parameters used as indicators for the effects should be related to the policy aims of the responsible ministries and the authority.

Since most market surveillance authorities in the field of consumer products set product safety as their first priority, a suitable outcome parameter would be the reduction in product related injuries thanks to the activities of the authority. Regrettably there are no statistics available that directly relate changes in the number of injuries to specific market surveillance activities. Indeed even the statistics on product-related incidents do not identify the injuries directly caused by product non-conformities.

Although obtaining information about the effect of market surveillance activities on the general health and safety of the consumers remains important, at present there is no practicable performance indicator available based on this type of outcome.

Observance levels

A more useful outcome indicator is the ratio between compliant products and products that do not comply, hereafter called the observance level. Effects of enforcement actions are likely to be reflected in the observance levels measured, but measuring outcome in this way also has the advantage of measuring the effect of other activities designed to increase the observance levels. The capacity spent for awareness raising in industry and trade and the effort invested in compliance assistance may therefore contribute to the measured effects.

Moreover, measuring the observance level as an indicator of the effectiveness of market surveillance also provides a useful insight to the market situation and, when measured regularly, it can be used to direct activities and to measure the contribution to the goal of improving the safety of products on the market.

Example: The joint action on lighters (see Annex A) constitutes as indicators of the success:

- *The share of non-compliant lighters that are found on the European market;*
- *The share of non-compliant lighters that are imported to Europe;*
- *The share of non-compliant lighters that are produced in Europe;*
- *The share of shops that markets novelty lighters.*

All of these actually illustrate the use of observance levels as performance indicators, as the project also defines the ambition to reduce the percentages of non-compliance and compliance to be 2% and 98% respectively.

Though in principle this is a useful indicator suitable to optimize the efficiency and effectiveness of market surveillance, there are disadvantages, too. These are mainly associated with the difficulty of and the costs involved in the measurement of observance levels. Measuring the observance level for a specific product category requires the measurement of a sufficient number of randomly selected samples, the exact number depending on the number of different products for sale on the market and their market shares, as well as the observance level itself. In markets with a vast choice of products (like toys, for example) the number of samples may easily reach up to 50 if an accurate estimate is to be obtained. All samples must be measured. For an observance level of 96% (4% non-compliance) the large majority of samples comply. It can be argued that all these measurements do not lead to interventions and therefore hardly contribute to the efficiency of the market surveillance.

The planning, execution and follow-up of projects is further discussed in Chapters 5, 8 and 9.

4.7 Feedback from stakeholders

In many market surveillance organisations it is considered good practice to discuss the proposed programme with stakeholders. These may include the ministries responsible for product safety policies and the legislation that the market surveillance authority is required to enforce, trade and industry representation, and consumer organisations. Possibly adaptations are suggested at these discussions, after which the programme can be finalized.

5 PROJECT PLAN SETUP

This chapter describes the practical issues to be addressed in the planning of market surveillance projects. The development of a plan that clarifies and describes the practical steps to be taken in a project is considered best practice.

A proper project plan will serve as a good basis:

- to guide project execution
- to guide management's supervision of the progress in the project. It might be appropriate to report to the management in connection with important milestones.
- for the quality management of the project
- for transparency towards the 'outside world'. Market surveillance projects should not be kept confidential. Proper and timely information about the project and its results to stakeholders can be used to increase the impact of the activities before, during and after the project.
- for capturing historical data. Project plans are a source of knowledge and experience. Future projects within the same field might benefit from previous project plans if available.

5.1 Project description

The result of planning of a project is described in a project description.

The first paragraph in the project description must give an overview of the project. It would often comprise a (short) description of the background for the project, the mandate, the scope, the terms of reference and the objectives. The description of the background should include the rationale behind the project, e.g. reflections on the risk assessment.

Considerations that lay behind the steps in the project planning are given in 5.2 to 5.11 below.

The project description should address the following issues, but some can be omitted if there are obvious reasons; for example in very small projects involving very few people:

- Project description
- Project organisation
- Human resources
- Financial aspects
- Risk assessment principles
- Product investigation setup
- Test laboratories
- Communication strategy
- Cooperation with different stakeholders
- Internal communication
- Project plan approval

These issues and other relevant considerations are discussed in detail in 5.2 to 5.11 below.

5.2 Project organisation

The responsibilities and tasks of the people involved in the project must be clearly defined before execution of the project is started. The project description should also develop a time frame with decisions on how and when the progress of the project has to be reported. This is particularly important when the project is big.

The following issues must be considered during the planning:

- Staffing (number and competences)
- Tasks, responsibilities and commitment for staff involved
- Timeframe and milestones
- Reporting procedures; content and time frame.

Possibly there are time constraints between initial inspections and the initiating of the legal procedures that result when offences are found. Timing is therefore of great importance and the planning of the project should ascertain that the necessary resources in manpower and facilities are available at the time they are needed. To ascertain proper timing the following milestones are part of the project description:

- Visits to economic operators finalised
- Products sent to the test house
- Testing started
- Testing finished
- Risk assessment finalised
- Communication sent to general public
- Final report ready
- Reporting procedures; content and time frame

The above-mentioned issues are to be considered as examples. It is important to notice that the project management defines milestones within the scope of the project. A second consideration relates to time contingencies in the markets. Especially for seasonal products, for example products sold for Christmas or for summer activities, the products are available only in certain periods of the year. It should also be realised that imports and manufacture of such products may precede the actual selling season considerably and that inspections at importers or manufacturers must be made earlier. Time schedules for actions should take this into account.

5.3 Human resources

To succeed with market surveillance projects or activities it is of great importance to define the human resources needed and necessary competences.

The competences needed depend on the specifics of the project, types of products or product groups, the stakeholders concerned and the communication and information required. Necessary competences will need to be clarified as a part of planning in the first stage.

In complex projects it will be natural to work with a group of officers with different skills. It is recommended that all projects include legislative expertise in order to handle formal affairs with stakeholders.

The resources needed for the project must be determined and made available before the start of the project. It is of vital importance that those persons involved commit themselves to the project and have necessary support from their leaders. A project description should include all persons involved and amount of resources committed to the project. The planning should address the following issues:

- Personnel resources needed
- Competences needed
- Skills needed
- Availability and reliability of resources
- Particular training requirements for participants in the project

When special skills are within the framework of the project required from the field officers, for example because uncommon field tests need to be performed, training must be provided.

5.4 Financial aspects

Part of the planning is the budget broken down into number of man-days and external costs, itemised as detailed as practically possible.

Examples of important headlines in a budget for a market surveillance project are:

- Cost of personnel
- Expenses regarding
  - Travel
  - Purchase of products
  - Testing
  - Information
  - Gathering of data
  - Analysis of results

5.5 Risk assessment principles

The project description should describe which risks are addressed by the project and how the the risks of individual products are evaluated in general. It should identify the basic risk assessment techniques to be adopted.

Harmonised standards exist for many products, especially products under the new approach directives, such as the Low Voltage Directive or the Toys Directive. In these cases, risk assessment, although not being fully covered by the standard in some cases, is closely linked to the conformity of the product, i.e. if the product conforms to the standard, it is presumed to satisfy a sufficient safety level. Therefore the purpose of the investigation is to check if the product meets the requirements in the standard. The authority decides which requirements of the standard are applied. The conclusion should be reflected in the project plan.

If there are no harmonised standards applicable to the products investigated in the project, the project plan should describe which parameters are tested, which test methods are applied, which requirements have to be satisfied for the product to comply and which risks occur when the product does not comply.

The description should be fairly broad and general and discuss issues such as:

- Description of major risks
- Methodology of risk assessment
- Compliance or non-compliance with harmonised standards
- Safeguard clause notifications, RAPEX notifications and notification by business
- Injury data
- Possible impact on consumers
- Historical data and experiences from other similar actions

5.6 Product investigation setup

When planning the investigations to be carried out in the project one should consider that the demand for resources increases with the level of detail that is requested from the project.
Decisions need to be taken on the following questions discussed in detail in the following subsections.

5.6.1 Are products to be sampled in shops or at the manufacturers/importers?

Market surveillance actions generally involve inspections and sampling at facilities where products are traded. Therefore at some point one must decide which facilities will be inspected during the action and where (and which) samples should be obtained or checked.

For maximum impact a number of issues deserve consideration:
The product safety legislation in the EU directs most of its requirements to those manufacturers and importers that first place a product on the European Market.
Inspections aimed at these actors are a good choice, because the results of the action potentially extend further than just the local market. Indeed, taking action against unsafe products at companies that serve the European market benefits consumers across the entire European market.

Both for market surveillance projects aimed at the local market, as well as for cross-border actions, inspections are preferably aimed at manufacturers, importers or distributors. In other words, enforcement has to be made at the source. If non-compliances are found, further distribution of the product is easily stopped and the information regarding further measures that might be necessary, like withdrawal from the retailers or recall from the public, is likely to be available here. In comparison with non-compliances found during inspections at retailers, this avoids the necessity of tracing back the distributor. Moreover, if the products are sampled at the importers, the situation can be immediately discussed with the importer and, if a screening test on the spot reveals shortcomings, immediate measures can be taken. Furthermore, samples are taken at the beginning of the supply chain, which means that non-complying products can be removed from the market when needed.

However, there may be specific reasons to aim market surveillance at retailers, for example when the market is fragmented and the products are imported in small batches by many different small importers. In that case distribution over the retail market is not by a single actor but by many. The companies involved are generally small, may only import single batches and are not always known to the market surveillance authority. In such cases the advantage of enforcement at the source partially vanishes. In other cases (big) retailers operate as importers or market their own brand products. In such cases sampling may be done as efficiently in the retail market.

Sampling at retailers may also be preferred for other reasons. If products are sampled in the retail stores, it would often be possible to do so quickly and in a less costly way (especially if the importer is located remotely).

Visits to retailers can be performed anonymously if there is a risk of being misled by the retailer's staff. Usually however, for reasons of transparency the visit to retailers is performed in an official way by presenting the task and intentions. It must also be underlined that in some Member States anonymous sampling is legal, while in others, no legally valid samples can be taken anonymously.

The marketing of products is generally directed to specific groups of customers: manufacturers may aim at high sales by offering inexpensive products, or they may aim at high margins by selling expensive 'design' products for smaller groups of wealthy customers. It is argued that, compared to expensive products with high margins of profit, the small margins obtained with cheap products encourage compromises in design and production, which makes such products more likely not to comply. Therefore it may be effective to direct market surveillance activities to those products and companies that operate at the lower end of the market. It should be realised however, that upmarket products can also fail to comply and that the likelihood of such differences depends on the specific market or product.

Another factor deserving attention is market share. A fairly common situation is that a small number of brands from only a few manufacturers form the vast majority of sales of a category of products. The remaining share of the market is then divided by numerous small players and traders. Market surveillance directed at the market leaders then potentially forces the vast majority of products sold in compliance, but in most cases it is directed to the more reliable manufacturers, who are most likely to comply in the first place.

The same effort directed to the players with only marginal market shares might well yield more non-conformities or detect more non-complying products although it helps to improve the safety of only a minor number of consumers.

5.6.2 Which businesses are to be inspected

The ability to select companies for inspection presupposes that sufficient information about the market involved is available to the authority. The information should allow the selection of companies for inspection, while taking into account the relevant considerations in 4.3.

Market surveillance organisations operate in these markets and should have much information available from experience and previous activities.

When the knowledge required is not available it should be gathered systematically by performing a 'market survey'. The goal of the market survey is to obtain the information required to make a sensible selection of companies for inspection. This goal determines which information is required and how it can be obtained. For example, for steam irons on the European market the number of different brands is limited and it is easily possible to compile a complete overview of the brands and models offered for sale. Contrarily, the variety of (nameless) wooden jig saw puzzles is such that a complete overview would be hard to obtain. An approach that aims to find the main importers and key players, or on the other hand the importers or players which have had problems in previous market surveillance programmes in this market would be more useful.

Sources of information include advertisements and brochures, Google searches, websites of companies in the field, consumer organisations and their publications, direct mail etc.

Field inspectors can also play a major role in gathering information about the markets involved and can be asked to contribute their knowledge for the market survey, or to actively gather information.

Another good source of information is represented by well-known and reputable manufacturers associations, whose primary aim is to defend and increase the fair competition level through efficient market control of the so called 'free riders'.

5.6.3 Which products should be sampled: product specifications

A clear and precise definition of the type of products that is the subject of the action is important to avoid complications during the execution and reporting phases. The simple intention to enforce legislation for such-and-such products may well lead to a scope that is much wider than originally thought. For example, where luminaires are given as the subject of an action, inspectors are likely to sample a wide variety of luminaires: wall mounted and ceiling mounted luminaires, standing luminaires, luminaires with fluorescent tubes as the light source and luminaires with light bulbs, LED lighting etc.

Of course, this may be the intention, but such a variety of products complicates the action considerably. Probably different (sub) standards apply for these subcategories, multiple risk analyses have to be done for the different varieties of products, and the tests required may be different. The interpretation of results and reporting are also affected. Limiting the scope is then likely to lead to lower costs per checked product and will be more efficient.

Once the types of product have been decided upon, a good starting point for defining the scope precisely can often be found in the standards that apply for those products. Many European standards cover a wide range of similar products in a single standard. General requirements for the whole product group are then given in part 1, while specific varieties of this kind of product are covered more extensively and specifically in their own subparts.

Example: for luminaires, EN 60598 part 1 gives general requirements for luminaires, while part 2 gives the requirements for specific types of luminaries. Part 2 contains 25 sections, each for a different type of luminaire. These include diverse types as portable general purpose luminaires (IEC 60598-2-4), recessed luminaires (IEC 60598-2-2) and luminaires for use in clinical areas in hospitals and health care buildings (IEC 60598-2-2:1996). Since each section defines the luminaires for which it defines the specific requirements, they provide a useful means to precisely specify the scope of a project. Note, however, that it may be wise to further restrict the scope, when within sections different tests are required for differently built products. This avoids complications for the laboratory and increased expenses in the test phase.

Not all standards are equally suitable for this approach. Horizontal standards, which formulate requirements for specific safety aspects for a whole range of products, are hardly suitable to specify the product range precisely. The Toy Standard EN 71, for example, mixes horizontal safety requirements which hold for many kinds of toys, with specific requirements for subgroups of toys. If the project aims for a very specific type of toys, the standard itself may not give a suitable definition of the product type. While studying the standard remains useful, obtaining a good overview of what is on the market can then help to limit the scope of the project.

The risk focused approach is an alternative to the usual product focused approach. Market surveillance projects to tackle a specific risk in wide-range consumer products are feasible and have been carried out, especially in the field of toys and products for children. The issue can be, for example, strangulation risks, that can be found in clothing, toys and home decoration. Such an approach directly addresses risks in consumer products and so contributes to improved product safety. A standard like the toys standard is well suited to support this approach.

It is important to translate the product specifications defined for the project in such a way that the field officers involved in the inspections and sampling have a clear idea of what is expected. A guidance sheet for the inspectors, explaining the scope and where necessary illustrated with examples of what is intended, may be useful to avoid misunderstanding. Such guidance sheet may also be useful for customs officials who are asked to undertake initial product screening, as described in Chapter 11.

5.6.4 Are products tested physically or is the investigation limited to documentary checks?

The best way to check that a product is safe and fulfils all legal requirements is by physical (or chemical) tests. On the other hand physical tests are costly and time-consuming.

Market surveillance based exclusively on documentary checks is very cost-efficient but will only catch those products for which deficiencies are found in the technical file.

Often both approaches are combined and a decision must be made about which documents and which physical properties should be checked.

A recent best practice in some Member States takes a different approach to documentary checks and assesses the production control procedures at the producers or importers. This is also very cost-effective and will most likely reveal more shortcomings, but it will also only catch products with errors in the procedures of the papers.

For details on market surveillance strategies, refer to Chapter 3.3 and to Chapter 7.1.3 for information on documentary checks.

5.6.5 Documentary check – Declaration of conformity or type approval

When documentary checks will be part of a particular surveillance project, one must also decide which documents should be requested and checked. For Global Approach Directives, this obviously means acquiring the declaration of conformity, but the authority might want to go further than that and request test reports, type approval or other documents depending upon the legal requirements that are to be checked. Of course access to such documents is only obtained at the economic operator responsible for placing the product on the European market. Retailers and (national) distributors are not legally required to have such documents available.

The checkpoints should be included in a checklist.

If deficiencies are noted in the documents, or the product does not seem to be in accordance with the documents submitted, tests of the product should be required by the authority.

5.6.6 Are products sampled randomly or after an initial check on the spot?

Sampling at random immediately gives an idea about the condition of the market, e.g. the level of non-compliance etc. For this the sampling scheme must be designed taking into consideration factors such as the number of samples, price ranges, the geographical scope of the sampling, seasonal factors etc. On the other hand random sampling implies that the market surveillance authorities spend a lot of resources checking safe products.

Alternatively the market surveillance officer can do initial checks on the spot, so that only dangerous products are selected. This leads to a more efficient use of the resources in the authority, but the results will lack statistical significance and provide only a limited feedback on the condition of the market. The results of these preliminary checks, in general, will not be used to start any legal action.

5.6.7 Are products taken for testing at a laboratory?

Often a market surveillance authority may want to consult a laboratory to have the sample tested. On the other hand, this is not mandatory and it is not always necessary, depending on the legislation, the competences of the market surveillance officer and the traditions and culture of the Member State.

While in some Member States a formal decision backed up by a test report from a laboratory is required, in others the market surveillance inspector has the powers and the ability to take action himself in case of severe and obvious shortcomings.

Tradition in certain Member States calls for consultations between the economic operators and the authorities. In such cases a screening test may be sufficient as the basis for the consultation and 'negotiation' on the proper measure.

5.6.8 Are products collected (bought) or does the authority write to the economic operators requesting samples?

National legislation and tradition often determine how samples can be taken. In some Member States the authority may have the legal powers to take samples without payment, while in others, legislation requires that samples taken must be paid. Even in the first case it might however be preferable to deviate from this practice, especially in the case of very inexpensive products, where it might be easier to buy the products.

Instead of visiting the manufacturer, the authority can write to the manufacturer, requesting them to send samples for testing. This decision should be taken based on previous experience with the operators, taking the cost of a visit into consideration. The drawback of requesting samples in this way is that the producer may choose to send only compliant samples (so-called 'golden samples'), whereas a market surveillance inspector would go for the non-compliant ones.

5.6.9 Reports on complaints from consumers with importers/producers.

Any intervention by the authority in the market is likely to cause reactions. The reaction may include complaints from producers ('If my product is dangerous, why don't you do something about my competitor's then?') and from consumers, if the activity has raised public awareness.

Ideally, the authority should decide beforehand how such complaints are handled. (See also Chapter 6 on reactive market surveillance).

5.6.10 Testing on the spot (tools & training)

The project description lists which on-site tests are required. Often, the market surveillance officer can use some simple on-site tests to select the products from the shelf that will most likely fail in a laboratory test.

Such tests should be described beforehand and the field officers must possess the necessary competences when they are going to do the testing. This might necessitate training of the field officers.

Testing on the spot is described in further detail in 7.1.5 (Preliminary physical checks by use of the 'toolbox', instructions and tools required for checking).

The inspector must be able to identify himself as market surveillance officer and must be equipped to take samples. For sampling materials like sample packaging, sample labels and seals would be required. For identification of samples a camera should be available.

Specific projects may require additional equipment. If the project includes product tests in the field the necessary equipment must be made available. Examples include test fingers to check if live wires can be touched in electrical investigations and templates for testing small parts in toys (see also 7.1.5.3, Toys (under the Toys Directive)). For quality assurance reasons some of these instruments may require calibration which should then be facilitated, possibly by a notified laboratory.

Finally, one should determine whether personal protective equipment is needed for the field officers or laboratory personnel and whether this is available.

5.6.11 Sampling and testing in laboratories

The authority should decide on the number of samples and to which tests the samples will be subjected.

In defining the test programme one should realise that market surveillance is not the same as conformity assessment. Conformity assessment requires checking whether a product fulfils all requirements of the applicable standard. If it does it is considered to be in conformity with the Directive; it carries the presuntion of conformity.

Market surveillance on the contrary checks if the product is safe. This is generally more efficient if the resources are spent on the safety requirements on which products most commonly fail, i.e. not all requirements need to be tested. In that way the number of tests per sample is restricted and testing costs per sample decrease. More samples can then be investigated for the same amount of money, leading to increased enforcement pressure and greater visibility of the market surveillance authority in the target group.

Of course, decreasing the number of tests should not continue indefinitely; the test programme should be designed in such a way as to press economic operators into compliance as efficiently as possible. Ultimately this requires a conscious choice between 'in-depth' testing of only a few samples and restricted testing on many samples.

Where consumer safety is the first priority, the aim should be to select requirements and tests that are the most relevant for the safety of the product. It may be true that all requirements in a product standard have some significance for the safety of the product, but generally it is possible to make a selection of requirements that covers the most important safety aspects. The starting point to make the selection is the risk analysis of the product.

From the risk analysis the main hazards and their relative importance are identified. Once the hazards are known, the requirements in the standard that address these hazards can be identified.

Other consideration can also be taken into account. Data from previous actions can show where non-conformities are common and which requirements are hardly ever violated. Analysis of RAPEX notifications, safeguard clauses and ICSMS data of shortcomings found in the product category complement these data.

Example: Circular saws and mitre saws present several hazards, but the danger of cutting oneself is an important one. This is testified by the accident figures that show many cases where operators have cut themselves, often resulting in the loss of fingers and parts of the extremities. Harmonised standard EN 61029-1:2000 (Safety of transportable motor-operated electric tools), including the sections relating to circular saws and mitre saws, contains several requirements that explicitly address the cutting risks of these machines. Typical are the requirements that all cutting parts not involved in the cutting should be shielded so that they can not be touched. Partly the shielding is required to be fixed, but since the blade must come free to allow sawing, a part of the blade must be shielded by a movable hood. There are requirements for this hood, too. Clearly conformity to these requirements is important for the safety of the product and they are prime candidates to include in a testing programme for these kinds of saws.

It is important to consult the laboratory with regard to the design of the test programme. The laboratory can indicate if it is equipped to perform the tests proposed and can also tell how expensive and time-consuming the tests are, what capacity is available, when and what consequences these preconditions have for the programme.

The result should be a complete proposal, listing all requirements that are to be checked in the action.

5.6.12 Definition of intervention schemes for the project

Once the test programme is known there is a fair idea of the non-conformities that can be expected. Coupled to the information from the risk analysis already available in 4.2 (Prioritising) it is then possible to define the intervention schemes for the action, i.e. which interventions or sanctions will be applied for specific non-conformities.

Obviously the intervention schemes defined for the project should be in line with the general policies of the organisation as discussed in 3.6.1 (Intervention policies) in the context of broader principles of proportionality and consistency.

However, the general intervention policy describes in global terms the levels of risk and the corresponding sanctions to be used. For the action the interventions for very specific violations must be decided upon. In practice this amounts to deciding what level of risk a non-conformity with a specific standard requirement poses and which intervention or sanction it justifies.

5.6.13 Check lists

It is best practice to draw up check lists for those requirements that should be checked by the market surveillance staff. Such lists will help the staff in carrying out the right tests for all products.

The results from the checks should be stored in the 'case file' for each product or programme.

In general, the check list would normally include:

- clear identification of the product: product description
- clear identification of company under inspection (name, legal entity, address etc.)
- checks on the presence of CE-marking
- checks of the declaration of conformity: its availability and detailed specifications of the items required to be inspected (if applicable)
- availability of the technical file (if applicable)
- checks of the labelling requirements, with detailed specifications of all items to be checked (obligatory labelling, obligatory safety warnings etc.)
- any additional requirements, for example requirements for which measurements must be performed in the field
- name of the involved inspector

Similar preparations need to be made for other actors participating in the project, like the laboratories involved and possibly the communication department and administrative departments taking care of the legal arrangements.

5.6.14 Report forms

The project description can contain report forms to be used for reporting the results from the tests. This is particularly important if the tests are carried out by the market surveillance officers themselves as there will be no test reports from any laboratories to record the results.

Furthermore, it might be beneficial to develop further reporting forms to capture the results from visits to producers, screening tests etc.

5.7 Test laboratories

When deciding which laboratories should be involved in the project, a number of considerations must be made.

Some authorities have test facilities of their own whereas others rely on commercial test houses.

Some authorities cooperate with one or more laboratories for a long period of time. In that case the choice of the laboratory is obvious. Other authorities shop around or use different laboratories depending on the product that is investigated. In that case it is necessary to discuss why a specific test house is selected and what commercial conditions apply.

In some cases (in particular big projects) it could be relevant to compare several test houses and carry out so-called round robin tests where several test laboratories perform the same tests on the same products. Such a test could prove useful as a kind of pre-qualification.

It is also important to discuss whether the laboratory should have an accreditation. If the laboratory does not have an accreditation, the authority should undertake an investigation of the laboratory's competences, references, equipment, procedures etc. and document the results meticulously.

Authorities in several (neighbouring) Member States may find it advantageous to cooperate on testing. This is easiest to do when the Member States run joint projects – an approach that has been applied in the LVD area several times by the Nordic countries in the NSS cooperation[1]. The biggest advantage of doing joint testing is economic. It is easier to negotiate advantageous tariffs because the number of tests will be higher when more Member States join forces.

The authority may want to publish a call for a tender (or may be obliged to do so) to select the best laboratory for a project. If this route is followed, it is important, for reasons of transparency, to be careful in describing the criteria that the laboratory must meet to participate in the tender as well as the criteria that will be applied to make the final selection.

The final step is entering into a formal agreement with the selected test house(s) on the commercial agreements. This can be seen as a milestone that should be reported to the management and listed as such in the project description.

1 Nordisk Sikkerheds Samarbejde (the Nordic Safety Cooperation); a Nordic equivalent to PROSAFE.

5.8 Communication strategy

The project description should also define the information exchange and communication planned during and after the project. This includes for example informing or 'pre-warning' the industry, communication with other stakeholders (consumer organisations, business associations, the general public), the publishing of the results, etc.

Communication may flow via several channels:

- Awareness campaigns
- Information on the Internet
- Communication with consumers associations before and during projects
- Information through media
- Meeting or conferences with stakeholders
- Direct mail

The intended use of these channels must also be addressed during the planning.

5.9 Cooperation with different stakeholders

All market surveillance projects create interest among other organisations and stakeholders. The identification of interested parties in advance in order to establish good relations is important for the outcome of the project. The project description should address who will be involved, in what way and when they are to be involved and whether their involvement goes beyond receiving general information from the authority.

Typical stakeholders are business associations that are involved to ensure a general support to the project, the European Commission for projects with a European dimension and the political hierarchy if the project deals with sensitive issues.

Examples of cooperation with stakeholders are:

- Cross-border cooperation with other Member States
- National cooperation with other enforcement bodies
- Risk communication with stakeholders or other authorities
- Cooperation with business and consumers associations
- Cooperation with customs

The cooperation can use the channels described in the previous paragraph.

5.10 Internal communication

Before finalizing the project plan it is advisable to discuss the project design with the personnel participating in the project. Depending on the project design, participants in the discussion should include the field inspectors, the laboratories and the communications department. Sometimes it can also be useful to involve legal departments and the administrative departments in charge of legal follow-up.

The design of the project should be explained in detail. Topics to discuss are:

a) For the inspectors

- the guidelines for the project and the relevant check lists
- the intervention policy
- the suitability of the equipment
- the clarity of the inspection and sampling procedures

Also the need for additional training for the project should be discussed.

b) For the laboratory:

- laboratory programme and procedures
- information requirements

All parties involved must be informed and allowed to give feedback about the time schedule of the project, to make sure that the time schedule proposed is feasible. Intervention policies, communication aspects and follow-up are also of interest for all parties involved.

The main purpose of such a meeting is to make sure that everyone in the project knows what his expected contribution is, rule out misunderstandings from obscurities in the check lists, guide and procedures and agree on a feasible phasing of the project. It is also an opportunity to refine the design of the project.

Organizing market surveillance projects is mainly the job of well-educated higher officials. When done well and whenever full co-operation and understanding is sought, continual communication is needed with all layers of the working force involved in the project, and feedback has to be taken seriously.

The field inspectors know what problems they are likely to encounter during inspections and the laboratory knows what may become a bottleneck there. Thoroughly evaluating the feedback obtained is almost always well worth the effort: when taken seriously it makes it possible to avoid predictable hurdles at any stage of the project and thus contributes to the smooth execution of the project.

5.11 Project plan approval

The project plan should undergo a formal approval. Formal approval by the management implies support for the project team and will facilitate the implementation of the project.

Usually inspectors, lawyers or engineers propose projects, which are then prepared by a manager and approved by a director. Several Member States also have advisory boards or boards that must approve projects that exceed given limits.

Normally, a plan is prepared by the market surveillance department; it is then presented to an advisory market surveillance committee to obtain comments and advice. Afterwards, the plan will be adjusted according to the reactions from the committee and then be presented for the top management for final approval.

6 REACTIVE MARKET SURVEILLANCE

Not all activities in market surveillance can be planned. Market surveillance authorities are forced to react to events such as accidents, consumer reports, etc. This is referred to as 'reactive market surveillance'. The activities undertaken in reactive market surveillance correspond to the activities undertaken in the proactive market surveillance. There are however important differences, which are the focus of this chapter.

6.1 Reactive vs. proactive market surveillance

The following Figure 7 illustrates the difference between reactive and proactive market surveillance.

Reactive market surveillance is normally triggered by an outside event, e.g. an accident. The market surveillance authority must decide whether it will take up the case or leave it (a choice that sometimes must be made under considerable attention from parties such as the media). If the case is taken up, an investigation follows, and after that a risk assessment which leads to the risk communication phase.

Market surveillance authorities will often find themselves under pressure when working with reactive market surveillance; first, there is a sense of urgency as the product is most likely dangerous (it is suspected of having caused an accident), and second, the case may attract a lot of interest from the public (if it has been noticed by the media). In such cases the authority might find itself forced into taking decisions on strong measures rapidly.

Proactive market surveillance on the other hand is a planned activity derived from the long- and short-term plans of the organisation. The market surveillance officer will make a project plan and set up sampling criteria which will serve as the base of selecting a number of products for investigation. The investigation will usually comprise laboratory testing and documentary checks. The results will go into the risk assessment, and the results from that will in turn go to the risk communication where adequate and proportionate measures are decided.

The differences between proactive and reactive market surveillance are outlined in the Table 2. The column 'reactive market surveillance' is split in two columns describing 'critical cases' and 'other cases'. In this context, a 'critical case' is understood as a case that is based on a police enquiry or a case that involves (or might involve) the media. Critical cases always need attention from the market surveillance authority – even if the authority decides not to take up the case.

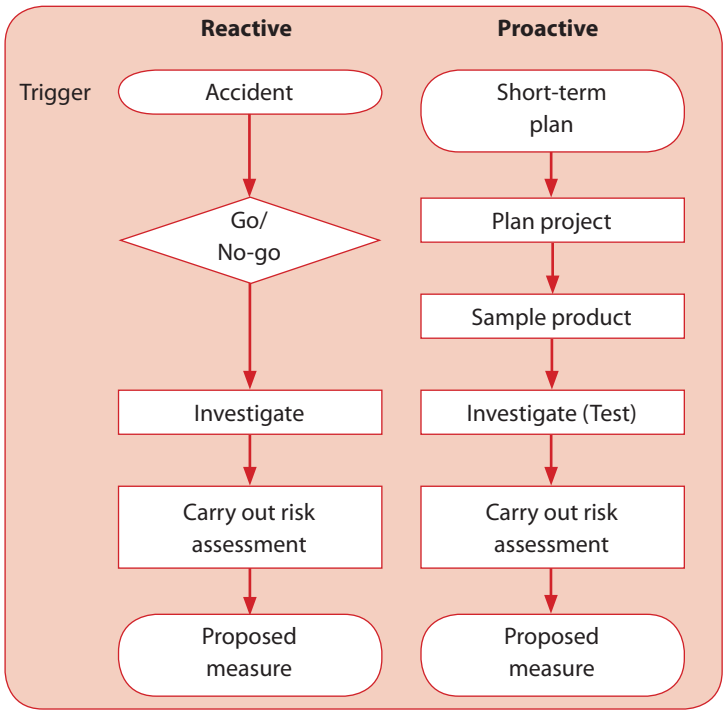


Figure 7: Reactive vs. proactive market surveillance.

6 REACTIVE MARKET SURVEILLANCE (Continued)

It is important to realise that the market surveillance authority always has the opportunity to decide if it will take up a given case or not. The authority is not obliged to investigate each and every complaint or enquiry that is presented to it. However, it will be wise to use transparent criteria in the prioritising of the enquiries. This is particularly important when dealing with potentially critical cases. Such cases should be assessed individually and the authority should prepare an explanation if it decides not to take up a case.

It is also important to have efficient tools in place for the risk identification and prioritising of complaints and enquiries to avoid overloading the authority with irrelevant cases.

Even if reactive market surveillance activities are triggered by outside events, it is possible to some degree to predict or plan the activities. The authority may beforehand decide to spend a maximum amount of resources on the activities or it may have objectives to investigate a given number of accidents each year. Furthermore, the

Table 2: Comparison of reactive and proactive market surveillance.

	Reactive market surveillance		**Proactive market surveillance**
	Critical cases	Other cases	
Who takes the initiative to the action?	The market surveillance authority (based on input from media, producers, consumers, police etc.).	The market surveillance authority (based on input from media, producers, consumers, police etc.).	The market surveillance authority itself based on criteria laid down in a plan. The authorities act independently from any kind of external inputs.
What triggers the action?	Accident (fatality) – perhaps in another Member State	• Accident, incident • Complaint • Notification from another Member State	The long-term or short-term plan.
Focus of the activity	To solve the potential problem with the individual product (group).		To get an overview of the market and solve safety problems with products.
How are products selected?	Products are given once the case is taken up.		Products that meet the sampling criteria for the project are selected for further investigation.
Planning horizon	Hours (if at all possible).	Days – weeks.	The project can be on the activity plan years ahead. The activities in the project can be planned months ahead.
Public attention (via media)	High or extremely high.	None or little.	The authority decides if and when to publish results from the project. This allows the authority time to prepare messages etc.
Time for administrative procedures	A few days.	Weeks, a few months.	Weeks, a few months (for each individual product).
Implications for economic operator	Potentially large Magnified by attention from media.	Depending on the non-conformities found.	Depending on the non-conformities found.
Critical issues	• Handling of media • Communication • Allocable human resources • Establishing good contacts with producer • Skills in risk assessment and legal procedures	• Risk identification • Prioritising of complaints • Establishing good contacts with producer	• Project planning • Skills in administrative procedures

flow of complaints or accident reports may be fairly stable or vary in a predictable manner which could also be taken into account when planning such activities.

The focus of reactive and proactive market surveillance is slightly different. The focus of reactive market surveillance activities will most often be on one specific product and the aim will be to solve a potentially emerging safety problem. The focus of a market surveillance project will be on a given product group or a given risk and the aim will be to clarify the status for the involved product group – and of course to solve any encountered safety problems with tested products.

Another issue that emerges more often in reactive market surveillance than in proactive market surveillance is that of critical cases. The most important characteristics for critical cases are the urgency, the nature of the hazard and the media attention which can cause high pressure on the authority to 'do something quickly'. Often, such cases are started because of (serious) accidents. This implies that the product might present a serious risk so the authority has to deal with it rapidly to prevent more accidents from happening. On the other hand the authority would want to investigate the case thoroughly as the necessary measure could have a high impact on the industry – an impact that is magnified by the attention from the media. Furthermore, the authority must act in a legally correct way to avoid trouble afterwards with the producer. These contradictory conditions pose a dilemma for the authority and require that the authorities master communication – communication with the public, the media, the producer etc.

6.2 Risk management background

The reactive market surveillance activities are initiated from different sources: accidents and fires, reports from consumers or media, reports from manufacturers, importers or retailers, notifications from other Member States (RAPEX and safeguard clauses).

The detailed description of the sources and the way they are considered and managed is given in Chapter 4.2 Prioritising.

6.3 Basic risk identification

Two aspects of risk identification are particularly important in the context of reactive market surveillance.

First, critical cases must be identified as such among the huge number of complaints, accident reports, enquiries, RAPEX notification the authority receives. These critical cases must be handled quickly to protect consumers as efficiently as possible.

Second, efficient mechanisms for filtering the rest of the information must be in place to focus the authority's attention on products with safety or conformity problems. Unimportant cases that were left initially may come back as critical cases if they are taken up by media or the authority may receive more complaints about the same product. In either case it will be important to be able to find all information about all previous cases to have a picture of the situation that is as complete as possible. Therefore, it is best practice to register all complaints even if no further handling takes place.

6.4 Identification of financial and human resources required for reactive market surveillance

The most important single aspect when discussing resources in the context of reactive market surveillance is the authority's ability to reallocate sufficient resources quickly to cope with emerging cases.

The amount of resources for reactive market surveillance is difficult to be estimated beforehand. Experience however indicates that the share could be considerable – perhaps up to half of the resources that are available for market surveillance. It will however largely depend upon the authority's ability to focus on the important cases.

One has to bear in mind that it might be necessary to shift resources from planned projects to reactive market surveillance activities during the year. Reactive market surveillance tends to attract a lot of attention because it involves following up on accidents and other cases where urgency is necessary. Another factor to be considered is that often such cases generate media interest. Moreover the authority must be prepared that something starting out as an investigation of a single product may evolve into an entire project with many products being investigated if it turns out that the underlying problem generally applies to an entire category of products.

The basic competences needed for reactive market surveillance are the same as those needed for proactive market surveillance. However, it is more important that reactive market surveillance cases are executed and followed up correctly, as they might more likely end up in court or could originate from police investigations.

Further to these competences are a number of qualifications that are particularly important in reactive market surveillance:

- Skills in communication to and handling of relations with the press are important – in particular when dealing with critical cases.
- Some inspectors will need to investigate fires caused by products and must be qualified for this purpose. Trainings are available from commercial providers.
- It will also be important to be skilled at interviewing consumers. When investigating accidents it is important to find out as much as possible about how the accident happened.

These competences would most likely not be combined in one person. Instead the authority should organise a team to work together on critical cases.

6.5 Ensuring collection of data for reporting

For purposes of reporting in its annual report, the authority will find it beneficial to ensure due collection of data in order to report some of the statistics on the output and outcome from the reactive market surveillance. Such statistics can be derived from the information registered for any product that is investigated (Chapter 7).

7 MARKET SURVEILLANCE PROJECTS – THE IMPLEMENTATION STAGE

7.1 Implementation of the project plan: On-site market surveillance Inspections & Sampling

7.1.1 Final preparations

It may be beneficial to run an information campaign towards all stakeholders, e.g. business associations and consumer organisations, before commencing any inspection activities. The purpose would be to provide general information on the project. One should also consider disseminating general information to all economic operators. Such information could be in the form of a letter that discusses the main features of the project including its background and objectives. In some Member States it is required by law to notify the economic operator before undertaking any kind of inspection or visit. Here it seems obvious to include information about the project in the notification.

Before starting the activities it is recommended to carry out a short training session for the staff involved in the project in order to harmonise the approach. The training may include a presentation of basic principles of the project, main tasks, a demonstration of test probes (if applicable) and a brief introduction of checklists and reporting forms.

It is highly recommendable to use inspection forms. It will support the inspector's work and help ensure uniformity in the inspector's approaches.

Such a form could be electronic or on paper. It should have the following items:

- Date and venue.
- Name and address of the economic operator (incl. contact details for the responsible person).
- Name of inspector and authority including contact details.
- A list of the products that were inspected including an overview of the checks that were undertaken.
- Clear identification of any products that have been taken for further investigation by the authority.
- If applicable, a reference to detailed test reports.
- Signature of both parties.
- The form should also present an overview of the further process in case products have been taken for further investigation, including references to relevant legislation and an outline of the rights of the economic operator.

7.1.2 Inspection process

Once the inspector goes to the premises of the economic operator to carry out an inspection, it is considered best practice to begin with a brief introduction of the project (its background, objectives, the underlying legislation, etc.). The purpose is to ensure that the economic operator will understand the aim of the inspection and hopefully be more engaged in any actions he is required to perform. The overall flow in the initial phase of any market surveillance case is presented in the following diagram:

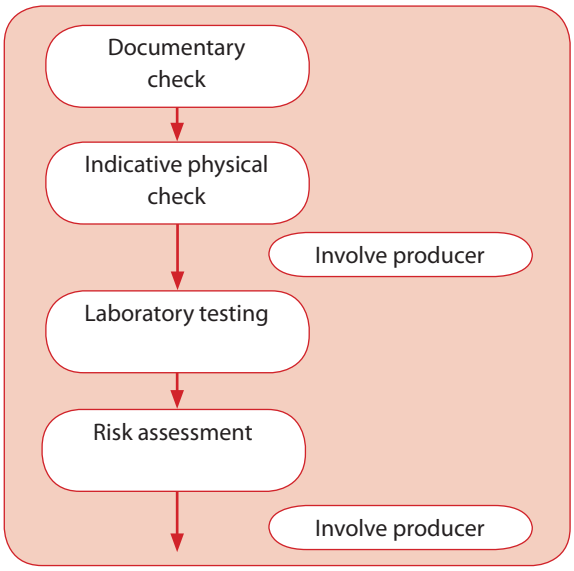


Figure 8

It consists of four tasks:

- Documentary check
- Indicative physical check
- Laboratory testing
- Risk assessment

Note that the first two tasks could be carried out in either order. Some authorities prefer to start with a documentary check before requesting samples, in order to avoid spending time on products that can be banned because of incomplete documentation. Other authorities prefer to start with an indicative physical check to focus their work on products with dangerous shortcomings.

It is considered best practice to involve the importer or manufacturer at the earliest possible stage in the case to obtain input and to ensure that action can be taken quickly if dangerous shortcomings are found.

7.1.3 Documentary Checks

The purpose of the documentary check is to find out if all necessary documents are available and correct.

Normally one would expect to find the following documents in a technical file:

- Technical documentation showing the construction of the product.
- Test reports or other documentation that demonstrates the conformity of the product.
- Products that fall under one or more new (or old) approach directives also have a declaration of conformity.

The GPSD covers a wide variety of products – from prams and battery operated electronic devices to wooden spoons. Therefore, the level of documentation will vary considerably depending on the complexity of the product. For very simple products (like the spoon) the producer may not be able to produce any documentation at all.

7 MARKET SURVEILLANCE PROJECTS – THE IMPLEMENTATION STAGE (Continued)

7.1.4 The toolbox: the basic checking and testing equipment to be used by market surveillance inspectors

Often market surveillance inspectors would like to carry out preliminary tests or investigations of a product to make an initial assessment of the risk of the product, to find out if the product should be taken for further investigations or to decide which properties should be tested at a laboratory.

For this purpose it is beneficial to have a toolbox with selected tools at hand. The contents of the toolbox depend on the category of product that is being investigated, i.e. the applicable requirements.

An initial description of the contents of such a toolbox can be given, however:

- A digital camera (preferably with the possibility of taking close-up photos at a distance of 20 – 25 cm)
- Folding rule or measuring tape
- Screwdrivers (different sizes and slots)
- Different pairs of tongs and a pair of nippers
- A pair of tweezers
- A small parts test cylinder (as defined in EN 71-1)

Further tools that could be considered would include:

- A finger-shaped test probe to test accessibility to live parts (as defined in EN 61032)
- A dynamometer (to test toys for loose parts)
- Small ball test probe (as defined in EN 71-1)
- Head and torso test probes (as defined in EN 1176) to test playground equipment, prams etc.
- Magnifying lens or jewellers 5x eye loupe (useful to read small print instructions and batch codes)
- Micrometer (useful for measuring the thickness of plastic bags)
- Circuit tester / voltmeter (useful to check for connections between electrical earthing and exposed live parts – only to be used after proper safety training!)

In practice further test equipment could be developed for specific purposes or projects.

As an example, stability tests of many products are carried out by placing the product on a well defined slope and observing whether the product is stable or falls over. Such a slope could be constructed from project to project as the required angle differs from one product category to the other and as the area that is necessary to carry out the test also varies.

7.1.5 Preliminary physical checks by use of the toolbox, instructions and tools required for checking

Normally market surveillance actions focus on sampling and testing the most dangerous products rather than sampling and testing products at random. This means that the inspector should carry out some testing of the products to make an initial assessment of the risk and to decide if the product should be taken for further investigations. Furthermore, such initial checks could focus the laboratory tests on the potential shortcomings, meaning that test costs can be saved.

Table 3: Risk types used for RAPEX notifications.

Ref	Type of risk	Notes
1	Burns	Tactile injury, heat, etc. – versus fire
2	Chemical	Including allergy, cancer, poisoning
3	Choking	Mechanical obstruction of the flow of air from the environment into the lungs. Choking prevents breathing and can be partial or complete. Prolonged or complete choking results in asphyxiation and is potentially fatal. Choking can be caused by, e.g., introduction of a foreign object into the airway.
4	Cuts	
5	Damage to hearing	
6	Damage to sight	
7	Drowning	
8	Electric shock	
9	Fire	
10	Health risk / other	
11	Injuries	External and internal
12	Microbiological	Including bacteriological, viruses, mould
13	Suffocation	Result of airway obstruction external to the mouth and nose or internal airway obstruction by closing off the flow of air from the mouth and nose by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

It is not possible to give a general description covering any kind of product for such investigations. Instead descriptions can be given for product categories:

7.1.5.1 Products under the GPSD

There are many ways in which injuries and associated risks can be described but one can get an indication of the possible risks from the list of risk types used for RAPEX notifications (see Table 3).

The GPSD covers a large variety of products. Therefore it is difficult to present a list of specific checkpoints but the following points apply to almost all products:

- Check the marking of the product. Can the name of the producer be found on the product?
- Is the product supplied with instructions for use?
- Are they in the language of the country?
- Are there any sharp edges in places where users touch the product?
- Are there any splinters (applicable to wooden products in particular)?
- Does the product seem highly flammable?
- Does the product get very hot in places where users touch it (intentionally or unintentionally)?

A few supplementary checkpoints can be indicated that apply to special product categories.
With regard to child care products:

- Does the product contain small parts?
- Does the product contain strings that could strangulate the child?
- Does the product have openings where children can get their heads or fingers trapped?

With regard to toys that are sold as other products, often marked 'This is not a toy' or 'Collector's item':

- Does that assessment seem correct compared to the use of the product and compared to the sales channel?
- Candle light holders and other long products:
- Is the stability of the product reasonable or could it fall over when tilted a few degrees?

7.1.5.2 Electrical products (under the Low Voltage Directive LVD)

- Visual check of the product. Does it seem to be of reasonable quality?
- Check the marking of the product. Can the name of the producer be found on the product?
- Is the product supplied with instructions for use?
- Are they in the language of the country?
- Are rated voltage and power indicated?
- Does the product have a CE-mark?
- Are any live parts accessible (after removal of parts that can be removed without use of tools)?
- Do the plug and the supply cord look correct? Or is the supply cord too thin?
- Pull the supply cord firmly: is it sufficiently fixed in the supply cord anchorage?
- Are any sharp edges found around the supply cord or around any other wires?
- Does the product look attractive to children? If so, is it powered through a transformer?
- Does the lamp fall over easily when tilted a few degrees? (Applicable to portable luminaires in particular)

7.1.5.3 Toys (under the Toys Directive)

- Check the marking of the product. Can the name of the producer be found on the product?
- Does the product have a CE-mark?
- Is the toy marked 'Not suitable for children under the age of 3 years'? Does that seem correct?
- Are there any small parts (which are easily detached)?
- Are there any sharp edges?
- Are there any splinters? (Applicable to wooden toys in particular)
- Does the toy have 'fur', 'clothes' or 'hair' that seem highly flammable?

7.1.5.4 Products under the Personal Protective Equipment Directive

- Check the marking of the product. Can the name of the producer be found on the product?
- Is there, if necessary, a warning text on the product?
- Does the product have a CE-mark and a reference to applied standards?
- Is there a document of conformity?
- Does the product have a product certificate (European test certificate for category 2 and 3)?

7.1.5.5 Instructions and warnings

- Are products accompanied with instructions for use?
- Are these instructions in the language of the country?
- Are they complete and clear (in particular translations have to be checked)?

7.1.5.6 Check list and reference to standards

It is recommendable to develop a checklist describing the most important checkpoints when a project concerning a specific product category is defined. Checkpoints and tests should always be developed from requirements laid down in harmonised standards whenever possible. If such standards do not exist it is advisable to use requirements that are generally accepted, e.g. requirements from European non-harmonised standards or commonly used national standards. It is important to recall that the test is only indicative, i.e. it indicates whether there might be a shortcoming in the product. Such tests can be used to discuss compliance with producers but it is unlikely that any measure can be taken based on indicative tests (unless the shortcoming is clear and obvious). In some countries, however, legislation obliges the inspectors to take action against obviously dangerous products on the spot.

7 MARKET SURVEILLANCE PROJECTS – THE IMPLEMENTATION STAGE (Continued)

7.1.6 Requirements for sampling and registration of samples

The sampling policy differs between authorities: some take three samples of each product. The first sample is sent for investigation. The second sample is kept to be investigated if the first sample turns out to have dangerous faults. The third sample is stored for reference should a court case arise from the case. If three samples of a product are to be taken, it is important that the inspector make sure they are taken from the same batch. This is fairly straightforward to do if the product is clearly marked with a batch or lot code, for example, cosmetics. Where products do not have batch or lot code marking it may be advisable to take the three samples from the same, ideally previously unopened, container. Alternatively the inspector may be satisfied that the products look identical and there is no reason to believe they are not part of the same batch. That might be advantageous to know during the investigation and for possible discussions with the producer.

Many authorities take only one sample of each product. This is simpler and less costly for the producer. If a shortcoming is found, the authority will contact the producer to resolve the case. The risk in such an approach is that the producer may claim that the product tested by the authority was the 'one-in-a-million' example that did not meet the safety requirements. It may be quite difficult for the authority to dispute this unless it can find another non-compliant product on the market. This problem is however seen to be minor in practice, as the inspectors or the laboratory people can most often decide from the type of the shortcoming whether it is a design fault or a single fault occurring during the production phase.

In some (rare) cases the number of samples is defined in the corresponding directive or standard. This is for instance the case for child-resistant lighters (EN 13869) and fireworks (EN 14035).

It is considered best practice to leave a receipt where the product was collected as proof that an authority has sampled the product.

When the products are collected, they must be registered. This implies that cases are opened in the document management system and all additional data are registered in the authority's system. The registration should include at least three (digital) photos of all products showing the product itself, the marking of the product and the packaging.

7.1.7 Packaging and labelling of collected samples

Once the products have been collected and registered they should be sent to the laboratory. During this stage it is important to mark all products carefully so that the tests afterwards can be easily assigned to the correct product. It is very important that products sent to test houses and laboratories can be properly identified and located at all stages of an investigation. The use of a standardised and recognisable unique identifier is highly recommended.

The identifier may be made up of different elements, for example:

- the inspector's initials
- the date of purchase/seizure
- the initials of the economic operator/business involved
- a sampling sequence number
- a case number

During the testing, the laboratory may also assign its own unique testing reference to the product.

The products must be packed in a way that does not affect the integrity and the safety of the product. It will most often be possible and preferable to use the original packaging. When products are not new (i.e. taken directly from the sales chain) and especially when they are investigated as part of a criminal court case, an accident or a fire, special attention should be devoted to packing the products in a way that does not change the product. In extreme cases it might be impossible to send the product; one would have to personally carry it to the laboratory.

7.1.8 Information to economic operators

At this stage the involved economic operator should be informed, preferably in writing. The information may be fairly short and general. It should present the following information:

- Information that a case has been opened
- Identification of the product
- The reason why the case was opened (e.g. as part of a project, as part of an investigation of an accident, or what would be the reason for collecting the product)
- An overview of the further process
- An indicative time schedule
- Preliminary information on the legal steps that could be taken toward the economic operator concerned.

7.2 Testing in laboratories

7.2.1 Extent of laboratory investigation

Most market surveillance actions include testing at a laboratory but it is important to realise that such testing is different from the testing a laboratory would do for a manufacturer to prove conformity. The authority would seldom need a full test of compliance with all safety requirements. Rather, the authority would want the laboratory to focus on finding the dangerous shortcomings. This is usually described in the contracts with the laboratory. They would typically allow the laboratory a few hours to test a few critical properties, find the most dangerous shortcomings and describe them in a short report.

7.2.2 Assess the test reports

There is an important distinction between the test report and what is needed to justify a measure against a dangerous product.

The test report from the laboratory describes a number of properties where the product does or does not comply with the standard. The test report in itself does not evaluate whether such non-compliances are dangerous. As an example, access to live parts in an electrical product and missing indication of country of origin are both considered to constitute instances of non-compliance. However, access to live parts is considered to be a very serious risk whereas missing marking is not seen to pose any direct safety risk at all. Thus, those two non-compliances would justify very different measures.

Therefore the authority, in consultation with the laboratory and/or technical experts, must evaluate all non-compliances described by the laboratory and assess the risk associated with each of them. This evaluation must conclude with an overall assessment of the risk of the product.

To do this the authority must perform a risk assessment as described in Chapter 10 of this Book. This method is general and can be applied to any kind of product and any kind of risk.

If the product is tested against a harmonised standard, it will be possible to describe the most common shortcomings and the severity of the associated risks in a table, as is done for instance for electrical products in the Nordic Failure Code List (Annex F). This list is shared with the Nordic laboratories and helps the authorities and laboratories get a similar view as to which faults are critical, which are major and which are minor.

Such lists can be developed for specific product groups or products and will ease the risk assessment. The user should however observe that the justification for a measure should still be described for the producer in terms that indicate the risk, e.g. 'The distance between live wires and the metal surface of the product is so small that there is a possibility that the wires over the lifetime of the product will move and touch the surface, meaning that the user can get a fatal electrical shock.' A reference to a Failure Code List is not sufficient in this sense.

7.2.3 Witnessed testing

Often, the authority has the possibility to monitor or even participate in the testing at the laboratory. Monitoring could be relevant if the authority wants to check that the laboratory is doing a satisfactory job. The authority's participation in testing would be relevant if there is uncertainty about what test is actually needed or if the test methods are to be developed. This could be the case if the authority wants to simulate an accident or if a (used) product is tested for a property that is not covered by the standard.

8 MARKET SURVEILLANCE PROJECTS – RESULTS & FOLLOW-UP, INCLUDING ACTIONS NEEDED

8.1 Decision on the necessary action to be taken

With the shortcomings of the product and the associated risks known, it must be decided which legal action has to be taken and whether sanctions must be imposed, based on the principles of effectiveness, proportionality and consistency. The measures imposed should correlate with the gravity of the risks associated with the offence and equally grave violations should lead to similar measures (see 3.6.1 Intervention policies).

The type of specific measures that can be imposed and how they can be imposed depends on the legislation of the particular Member State, taking primarily into account Article 8 of the GPSD and additional measures, if any, imposed by sectoral directives. Listed below are the measures that can be taken:

- Official warning
- Alert to consumers
- Sales bans
- Withdrawal from the market
- Recalls from consumers
- Destruction of the product
- Fines
- Other measures

In accordance with the criteria for different measures, the Member States' authorities must take the appropriate action.

8.1.1 Official warning

Official warnings are the least severe action authorities can take. A formal warning is a way to officially inform a company that it is violating the law. Obviously, this reaction is for small violations with little associated risk, such as non-conformity with certain labelling requirements or shortcomings with respect to a standard provision with little safety relevance. The company is supposed to rectify the shortcomings before further deliveries can be made and the authorities should then verify whether such shortcomings have indeed been rectified. When this is not the case, stronger measures have to be taken.

Formal warnings may be useful or even required, if the Member States' legislation requires the company to be aware of the fact that it is operating in violation of the law, before imposing more severe sanctions or taking additional measures. The official warning then serves as evidence of knowledge of the violation and, when properly used and communicated, may be instrumental in convincing the company to take the required measures themselves.

8.1.2 Alert to consumers

The GPSD contains provisions that allow a Member State authority to order an economic operator to publish warnings to the general public if the authority becomes aware that a certain product presents a risk to the consumers.

This measure is particularly useful under the following circumstances:

- When a product must be withdrawn and only part of the consumers are known to the economic operator (this is normally the case);
- If the potential safety issue with the product can be resolved by warning the consumers without modifying the product; and
- When a product is to be recalled and it is foreseen that the product is so inexpensive that the user will most likely just dispose of the product.

Alternatively, the authority may decide to publish such warnings itself. This could be necessary if:

- The responsible economic operator can not be identified (this is often the case for products sold on markets by many small individual traders);
- If the danger is so serious that consumers may be severely injured (or even killed) if they do not get the information quickly; or
- If the risk applies to a whole class of products rather than one particular make (an example being the water yo-yo ball case where all yo-yo balls were considered dangerous because the user could get strangled in the flexible cord).

8.1.3 Sales bans

The GPSD requires that market surveillance authorities have the power to temporarily suspend the supply of products that could be dangerous for the duration of the period of investigation needed to assess the risk posed by the product, and whether it is necessary to permanently ban the marketing of such products. Unlike sanctions such as fines, this power gives the possibility to directly address (possible) risks for consumers by stopping the supply of products that may be considered dangerous.

On the basis of the GPSD, only dangerous products can be subject to a sales ban. This implies that risk analysis must demonstrate that the product is dangerous by not complying with the definition of a safe product under Article 2 of the GPSD or under the relevant sector directives. Because sales bans directly cause damages to the economic interests of the company involved, the quality of the risk analysis should be high and the results acceptable to the courts, in case an appeal follows.

Sales bans are generally imposed at the manufacturer/importer or at the distributor in the Member State. This stops the delivery of products to the rest of the sales chain, but does not directly affect the products already in the supply chain (further distributors, retailers). If the risks associated with the product are such that this is unacceptable, the products in the supply chain should be withdrawn as well.

8.1.4 Withdrawals

The GPSD states that for any dangerous products already in the market, Member States' competent authorities can order or organise the withdrawal of such products. In addition, competent authorities can also order measures to be taken to alert consumers. In the case of withdrawals, the dangerous properties are not considered to be of a severity that requires recalls from the consumer or the product may not have been delivered to consumers yet.

Before initiating a withdrawal, the authority must decide what kind of withdrawal is acceptable. Products may be withdrawn from distributors or from the entire supply chain. The extent is determined by the danger of the product within the context of its use, as well as the number of units sold.

When the authority decides that a withdrawal is sufficient, the economic operators concerned remain of course at liberty to extend it to a recall from the consumers, e.g. to protect the brand. In such cases, the authority should facilitate this process.

The withdrawal process may involve a letter from manufacturer/importer to retailers which describes how to deal with the dangerous product.

8.1.5 Recalls

According to the GPSD, for any dangerous product already on the market, the authorities can order, coordinate or, if appropriate, organise together with producers and distributors its recall from consumers and its destruction under suitable conditions.

This gives the authorities the possibility to protect consumers against dangerous products by having the products taken back from the end user and from the market across the whole supply chain. Recalls also allow consumers to be alerted to the risks posed by the product.

The GPSD gives the authorities the power to organise recalls themselves but this is seen to be an unattractive measure for the authority because the information required to efficiently withdraw or recall a product is not immediately available to the authorities. It must be obtained from the company involved and that may be difficult if the company is not cooperative.

Although the GPSD provides authorities with the power to require cooperation, since the producer or distributor is obliged to recall a product when ordered by the authorities, the alternative, i.e. to organise the recall together with the producers and distributors, is a much better option. In that way, the actual recall is organised by the producers/distributors, who can recall products much more efficiently as they have information on their customers and can issue recall notices in their shops, websites and the media. The whole process should be monitored and supervised by the authority to ensure that it is performed properly.

In practice, this means that the company responsible for marketing a dangerous product should be contacted and informed about the hazard(s) presented by the product and about the necessity of a recall. Since a recall is required when the product has been found to be dangerous, organising the recall is generally urgent. Contacting the company can be done by telephone or in person by surveillance officer, but informing the company in writing is also necessary in most jurisdictions (see also 6.2).

The extent to which the product recall is imposed is of course determined by the health and safety risk posed by the product within the context of its use, as well as the number of units sold.

How recalls should be performed is described in the 'Guide to corrective action including recalls', which can be found at: http://ec.europa.eu/consumers/cons_safe/action_guide_en.pdf. This guide is primarily aimed at the business community, but the information it contains is also useful for the authorities in the supervision of a recall.

8.1.6 Destruction of high risk products

The GPSD gives the market surveillance authorities the power to destroy products if they have been recalled from consumers. When imposing this restrictive measure, the authority must take into account the economic impact it has on the economic operator.

An advantage of such a measure is that it can be presented to the general public as an example of how the authority 'fights for the safety of the consumer' if the destruction is undertaken publicly.

A disadvantage of this measure is the economic impact on the company. The economic operator may argue that the product could be modified to make it safe or that the product can be marketed legally in third countries. Both cases oblige the authority to provide convincing arguments to support the product's destruction. And if the products are destroyed despite the objections of the economic operator, he may be in a good position to claim compensation because the authority destroyed products that had economic value.

Therefore, if an authority decides that a product poses such a risk to the health and safety of consumers that it needs to be destroyed, it is particularly important that the authority consults the economic operator to ensure that modification or re-export of the product is not possible.

The GPSD's provision to 'order or coordinate or, if appropriate, to organise together with producers and distributors (…) its destruction in suitable conditions' also allows the authorities to assist economic operators with the destruction of dangerous products.

For example, in 2005, following the fireworks disaster in Kolding, the Danish Safety Technology Authority re-tested a large number of previously approved firework articles that were suspected to present an unacceptable risk of huge explosions when stored in large quantities. As a result of the investigation, the approval of a large number of fireworks was withdrawn. The authority also decided that the fireworks should be destroyed because there was a risk that the fireworks would end up in the illegal market. Therefore, orders were submitted to all importers that the approval of their articles had been withdrawn and that the articles had to be destroyed unless the importer could prove that the fireworks would be used in a safe manner e.g. by professionals in display shows.

8.1.7 Fines

Fines are sanctions that can be applied for more serious violations. It should be realised, however, that whereas sanctions punish the violator, they do not by themselves protect the consumer. Therefore, in cases where the non-conformities constitute a serious risk to the health and safety of the user of the product, additional measures are required.

Nevertheless, fines can be imposed in cases where the risks are such that withdrawing the product from retail channels or recalling it from consumers with the accompanying publicity is disproportional. In addition, further deliveries to retailers should stop and this should be verified. If deliveries continue, the initial fine can be raised as such deliveries aggravate the seriousness of the offence.

Note that in some cases fines can be imposed as a consequence of a failure to notify the authorities by the involved economic operator or for the lack of co-operation from its side.

How fines are imposed is dependent on the legislation in the Member State. Some authorities can impose fines directly. In other Member States intervention of the prosecutor is required, who may settle the amount of the fine (in agreement with the offender) or decide to bring the case to court for a final decision. Where it is the authority that decides on the amount of the fine, it is necessary to have in place procedures that guard against arbitrariness (see also 3.6.1).

8.1.8 Other measures

In some jurisdictions legislation may allow other measures. For example, in the Netherlands legislation allows the closure of a business after intervention of a prosecutor. Whereas this measure was originally aimed at shutting down filthy restaurants, it can also be used in other circumstances. However, it is almost never used because of the proportionality requirement. For all measures, the principles of effectiveness and proportionality should be kept in mind.

8.2 Communication with manufacturers and importers

Reports from manufacturers, importers and retailers are to be managed by these stakeholders in accordance with the 'Guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors in accordance with Article 5(3) of Directive 2001/95/EC [5] '. Follow-up to business notifications by enforcement bodies should follow the above mentioned Guidelines and reactions to shortcomings should follow national regulations.

Where market surveillance has revealed unsafe products that require intervention, the violating company must be informed of the legal proceedings and actions that will be undertaken.

Figure 9 gives a schematic description of the process that is applied in such cases.

The way in which this is to be done depends on the legislation of the particular Member State. The actual proceedings may therefore vary, but generally involve informing the violating company in writing about the non-conformities found and the measures imposed. For severe shortcomings that require immediate action, informing the company by telephone or direct visit may be advisable, but this should be done in parallel with written communication.

When violations have been determined in products sampled at retailers, it is normal practice to direct the measures against the manufacturer or the original importer in the jurisdiction. This requires tracing back the product from retailer to its original source which must be done in a way that fulfils the legal requirements for evidence in court proceedings. When the product is imported into the country by a local distributor from

elsewhere in the EU, the legal obligations set out for distributors in the GPSD or in a sector-specific directive apply. Measures taken by the authority must always be based on legislation of the Member State transposing the relevant EU directive and its requirements for producers and distributors.

Before taking measures and informing the person responsible for the offence, it may be necessary for legal reasons to formally question that person, assert his responsibility and follow the other requirements of national procedures.

Although the content of the notification to the offender may vary depending on the legal requirements in the Member State, the following information is generally required:

1. *Description and identification of the product involved in the offence*
   - The product involved in the offence must be unequivocally described and identified. This may for example be accomplished by referring to the brand name, type and batch codes, as well as by references to relevant labelling on the products and information on its origin.
   - This identification can be, in some cases, very difficult because some products are delivered to the market without any identification marks.
2. *Place and date of the inspection and sampling*
   - Information about the inspection during which the products were sampled and/or investigated should be given, including the exact date and information on the premises where it was carried out. This would include the name and address of the retailer when the inspection was not carried out at the premises of the manufacturer or importer, as well as information that the sample was taken for testing.
3. *Test results and specification of the identified shortcomings*
   - The results of tests of the product should be given in a way that it is clear why the product does not fulfil the legal safety requirements and safety standards.

Generally this involves:

1. *Reference to the legislation involved and to the specific requirements violated*
   - Reference must be made to the appropriate laws of the Member State and to the safety standards used in the testing of the product. The legal requirements that are violated should be clarified by referring to the appropriate sections of the law and describing how the product fails to comply with these requirements.
   - Often, the non-conformity is based on a failure to comply with the requirements of the applicable safety standards. The market surveillance authority should clearly demonstrate the ways in which the product does not comply with the safety standard by explaining the requirements and the test results for the offending product. Since non-conformity with the standard is not in itself a violation of the essential requirements of the directives, the violation of the standard should be linked to the specific requirement in the national legislation implementing the safety requirements of the relevant directive and explicitly referring to that standard.
2. *Announcement of the measures imposed and the legal proceedings that will follow*
   - The communication should inform the recipient of the legal procedures that will follow and the measures taken by the authority. Since the legal possibilities of the authorities depend on the legislation of the Member State, there may be great differences in the procedures to be followed. Some authorities can impose sanctions themselves, but often these are imposed by a court. The court procedures naturally vary between the Member States and depend on the national legal framework.
   - Also, the obligations of the recipient should be made clear in the communication. Where further sales are banned or an obligation to recall a product or any additional measures are imposed, this should be substantiated by reference to the relevant provisions of national legislation. Often, the applicable legislation is the national implementation of the GPSD.
3. *Information about the possibilities for appeal*
   - The recipient should also be informed of the possibilities to appeal against the decisions of the authority, or about the possibilities for appeal in the legal proceedings. Again, the modalities for an appeal differ between the Member States.

In short, the communication to the suspect of the product safety offence should enable to understand the nature of the offence, the measures to be carried out, the legal consequences that will follow and the possibilities for an appeal. It is also important to formulate this message in a way that follows the legal requirements. In general, this means that the communication is accurate with respect to facts and references to applicable safety legislation and standards, as well as contains all the information that the national legislation requires for such messages.

8 MARKET SURVEILLANCE PROJECTS – RESULTS & FOLLOW-UP, INCLUDING ACTIONS NEEDED (Continued)

Variations between different jurisdictions exist. Some authorities give the possibility to react to the measures within a certain time frame before actual enforcement of the measures and take the reaction into account in the further proceedings. Sometimes a pre-announcement is made before the actual measures are taken or the legal procedures are started. This can then be done either in writing, via telephone or directly by an inspector or other official.

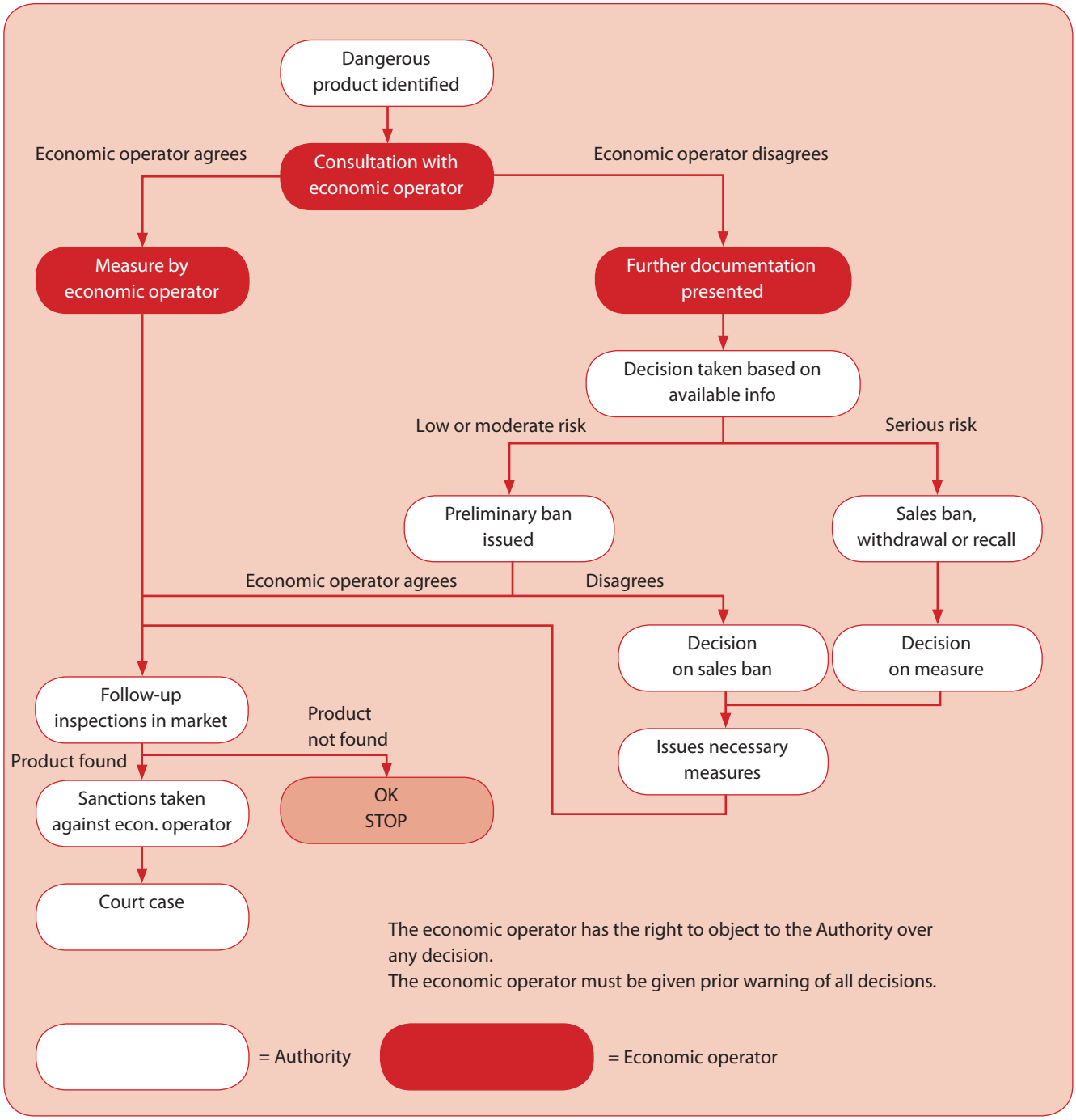


Figure 9: Actions flow in case of dangerous products.

8.3 Enforcement and legal aspects

When an authority decides to take legal action against a product, this must always be done by referring back to the legal requirements in the national legislation transposing the relevant EU directives and not merely to requirements in harmonised standards or technical specifications.

The 'legal' process is as follows:

- The European Parliament and the Council of Ministers adopt a directive. The directive lays down essential safety requirements for a group of products. The requirements are typically laid down in rather general terms such as 'Electrical products must not cause fire or electrical shock' to use an example from the LVD.
- All Member States transpose the directive into national legislation by adopting national laws that generally repeat the requirements of the directive.
- Often the safety requirements are explained in more detail and made more operational by safety standards. As an example, the essential safety requirement of the LVD that 'the product must not cause electrical shock' underpins several more specific requirements in harmonised European standards based on the LVD, e.g. the requirement that the creepage distance must be 5 mm or more.

Authorities will almost always assess the safety and non-compliance of a product by testing it against requirements from the relevant safety standard. It is important to highlight that such tests only reveal non-compliance with the standard. The authority must 'translate' this into a non-compliance with the safety requirements of the relevant national law implementing the EU directive before an action can be taken against a product. The usual way to do this is to indicate that a non-compliance with the essential safety requirements has been revealed by applying the method from a referenced and harmonised European standard.

Example: The minimum creepage distance in a luminaire is 2.4 mm when measured in accordance with the harmonised European safety standard EN 60598-1. The requirement in the standard is that the creepage distance must be 5 mm or more.
The authority writes a letter to the economic operator that states:
'The minimum creepage distance is 2.4 mm when measured in accordance with the harmonised standard EN 60598-1. The requirement in the standard is 5 mm or more.
This is considered to be a violation of the [national legislation transposing] the Low Voltage Directive, Article 2 referring to Annex I, item 1d and 2a, because the creepage distance is smaller than what is required in EN 60598-1. Therefore, the product poses a risk of electrical shock to the user during the lifetime of the product.'

Please note that the reference to the legislation must be to the relevant national legislation and not to the EU directive.

8.4 Follow-up within the market after final reactions

Once the test results have been evaluated by the authority the producer should be informed again. This should be done in writing.

In many countries this is required by law (a so-called 'hearing' of the producer). In those cases there are legal requirements to the letter. In general, the letter should contain the following:

- Information that the testing of the product is finished and that the authority has evaluated the test results
- Identification of the product
- A short overview of what has happened in the case until now
- Description of the test results
- The conclusion from the authority's risk assessment
- Proposed measures
- An invitation to the producer to comment on the test results
- Deadline for future measures to be taken

The legal procedure that follows violation of legislation normally leads to sanctions, such as fines or a sales ban. As a last resort, the enforcement action can involve a recall of the dangerous product from consumers.

Typically the following cases require follow-up action from the market surveillance authority:

- Withdrawals and recalls, whether organised on the initiative of the business or imposed on the economic operator by the market surveillance authority, should be carefully monitored and supervised. This includes checking if the way the withdrawal/recall of a product is planned suffices for accomplishing the desired goal, monitoring of the contacts with distributors in the supply chain and checking if the action results in the return of products from the retail chain and, where applicable, from consumers. Checks at retailers should be carried out to ascertain that the withdrawal has resulted in the disappearance of the product from the shelves. Where possible, the success rate of the withdrawal/recall should be assessed. The 'Recall Guide' gives, as an example, a figure of 40% for umbrellas sold to consumers returned to the company in a recall action but notes that this is an exceptionally high percentage.

- If the measure is a sales ban at the manufacturer/importer, the authority should check if sales of the product have been discontinued, either by administrative checks on the flow of products from and to the company, or by tracing back from retailers.
- If products are allowed back on the market after being brought in compliance, a re-investigation after a short period of time should be carried out to establish that the modified product is safe and that the violation has been discontinued.

In general, if measures are imposed, it should be verified that the economic operator complies with these measures. A good way to assure this is to define a standard operating procedure that prescribes new inspection and sampling after a reasonable period for every product that has been found to be unsafe.

Moreover, the authority should be aware that the same product can also be made available on the market via parallel imports. When such products are found, similar enforcement action must of course take place.

Where the measures concern manufacturers or first importers into the EU that have marketed the product into other Member States, additional information should be sought on the countries of destination to facilitate tracking of the product for the authorities in the Member States of destination. This includes information on the identity and addresses of the buyers and the volumes sold into those Member States. Also, if enforcement action takes place against a local distributor who imported the product from another EU Member State, the source of the product should be established. Such information on the supply chain must be part of the information exchange under RAPEX alert notification and the safeguard clause procedure.

8.5 Cross-border information

An important part of the authority's follow-up activities is the cross-border information exchange with other market surveillance authorities. This is a legal obligation under the GPSD when the product presents a danger to consumers but it is also considered to be best practice to exchange as much information as possible.

A number of tools exist for the exchange of information (see Annex H for a detailed description of the tools):

RAPEX
Measures ordered by the authorities, or actions taken by businesses in relation to a product that poses a serious risk must be notified via the RAPEX system to inform the other Member States so that they can take rapid actions in their national territories to prevent risks to the health and safety of consumers. Also measures ordered by the authorities in relation to products posing a moderate risk must be notified unless they are covered by the safeguard clause procedure (see Annex H.1).

The safeguard clause procedures
Member States must issue a safeguard clause when the free circulation of a product is stopped for technical reasons. Specific procedures establish whether a national measure restricting the free movement of a product is justified or not (see Annex H.2).

8.6 Obligation for businesses to notify

One likely outcome of a market surveillance activity is that the economic operator decides to initiate a voluntary action against his own product.

This is in fact a legal obligation of all economic operators. Article 5 of the GPSD states that 'where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof under the conditions laid down in Annex I, giving details, in particular, of action taken to prevent risk to the consumer'.

This obligation of the producers and importers is very important and the market surveillance authorities should inform them about their responsibilities. This can be done i.e. during the normal routine investigations by inspectors via direct communication, through the market surveillance authority's websites and/or with the use of brochures and seminars.

If the national authority receives such a notification from a manufacturer, an importer or a distributor, it is obliged to inform the European Commission about the products and the measures that are taken to prevent the risk. This information will then be disseminated between the EEA countries. Such information is exchanged through the RAPEX procedure.

One should note that economic operators may want to take voluntary measures even if the risk is low, if the operator wants to protect his brand name or for other similar reasons.

The European Commission has developed a set of guidelines addressed to producers and distributors of consumer products as well as national authorities on the management of the notifications of voluntary measures.

8.7 Gathering information for reporting purposes according to the project plan

One important aspect of all market surveillance activities is to ensure that the proper data are recorded so that the authority after the termination of the project can answer the questions that all authorities are faced with, including:

Questions related to specific cases:

- What was the resulting measure in a specific case?
- Do we have previous experience with this specific product? Or with similar products?
- Do we have previous experience with this specific manufacturer or importer?

Questions related to specific projects:

- What were the statistical results from the project?
- What impact did the project have on safety?

Questions related to the annual plan or strategy:

- What did we achieve in the past year?
- Do we still follow the strategy or do we need to make corrections?

Those questions can most easily be answered if certain supplementary information is registered together with the relevant documents.

The overall structure for data in market surveillance can be presented as in the following chart in Figure 10 below:

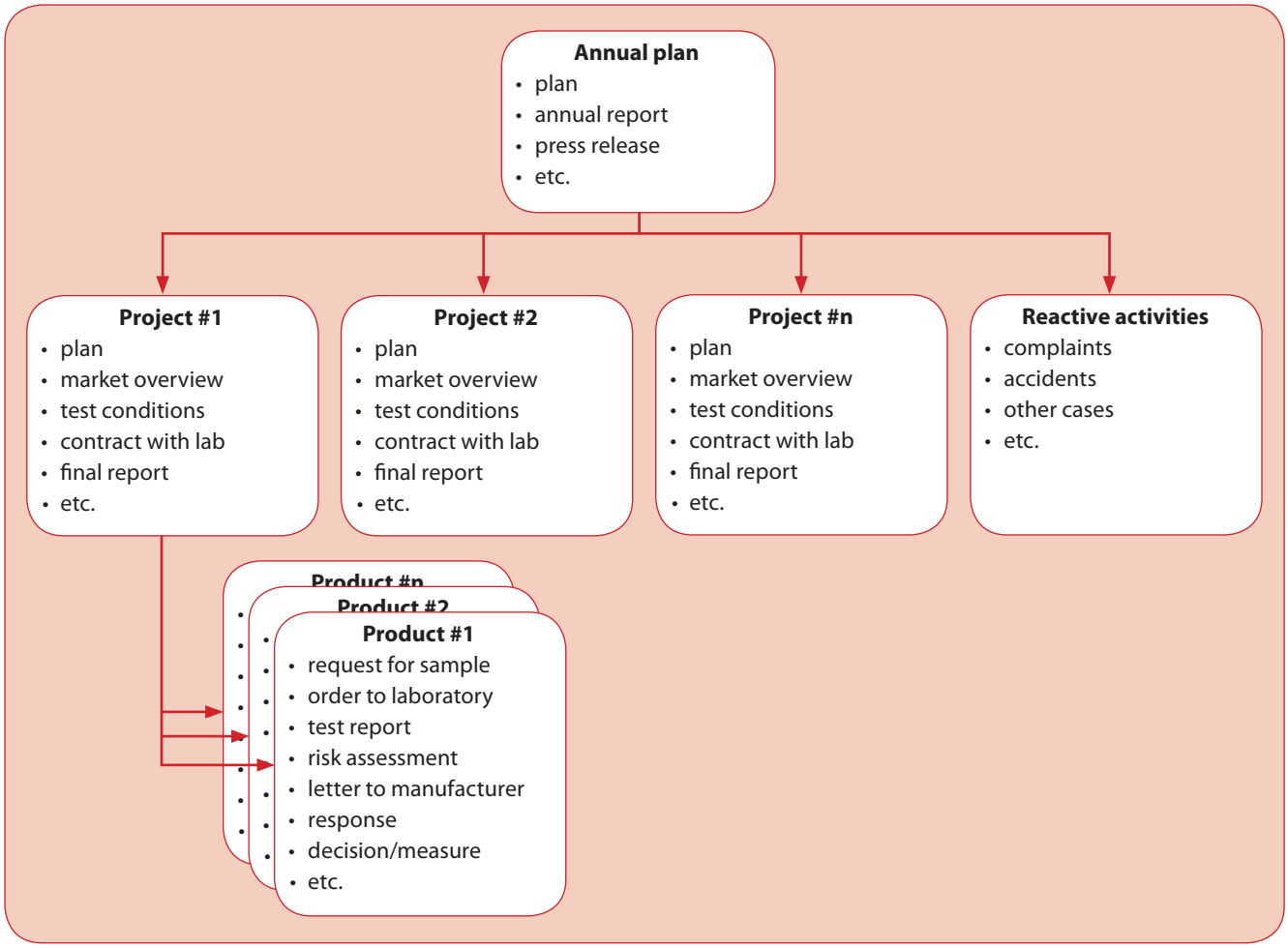


Figure 10: Actions flow in case of dangerous products.

Also reactive market surveillance could be conducted as one or more projects. Again all the individual case files should be linked to the project file. Best practice would be to have individual project files for consumer complaints, accidents, voluntary recalls and other major activities. This would allow the authority to easily identify for example the accidents that have been investigated during the year and analyse the data to reveal new accident patterns which in turn could provide input to the annual plan for the coming years.

The authority is supposed to work from an annual plan that sets out objectives for the authority and presents all the planned activities. A number of documents will be produced during the annual cycle:

- The annual plan
- The annual report
- A press release reporting the results achieved for the year and summing up the contents of the annual report

It will often prove useful to open a case file of its own in the document management system to collect all documents produced as part of the annual planning cycle.

The activities in a given year are a number of projects, each addressing a specific product category, a specific risk and the reactive activities such as follow-up to complaints, investigation on accidents, single product cases etc. Normally, a number of documents is produced in each project that includes:

- The project plan
- An overview of the market for the specific product
- A document with applicable tests and conditions
- Perhaps the resulting contract with the laboratory
- The final project report

It is generally useful to store all project-related documents separately in the document management system so that they are kept together.

Each project comprises a number of cases each concerning one specific product. A case comprises a number of documents:

- A request to the manufacturer/importer to send in a sample
- The specific order to the test laboratory
- The test report from the laboratory
- The risk assessment from the authority
- The letter to the manufacturer/importer with the result of the risk assessment
- Perhaps a response from the manufacturer/importer
- The letter with the authority's conclusion

Generally, a case is opened in the document management system for each specific product.
To assist in answering the questions set out in the beginning of this paragraph, the following information should be registered on each product case:

- Brand name, type name and model of the product
- Product category
- Project
- Name and address of the importer
- Name and address of the manufacturer
- Name and address of the distributor (where relevant)
- The result of the case (nature of the risk and measures taken; recall, withdrawal from the market, sales ban, minor remark, etc.)
- Perhaps also number of items sold and returned via corrective action

The data should be stored in a way that makes it is easy to search and to find the number of products with a given property (e.g. the number of products that were withdrawn from the market/recalled in the project on portable luminaries in 2007).

Currently there is one cross-border IT system available that can be used for storing information on products. This is the so-called ICSMS system, described under Annex H.2.3.

9 MARKET SURVEILLANCE PROJECTS – THE REVIEW, REPORTING AND ANALYSING STAGE

9.1 Final project report

When the project is finished, it is best practice to report the results and to evaluate the project. Reporting the results ensures that the output is kept for future reference. The evaluation helps the authority to learn from the project.

The reporting should include reflections on the result of the project, i.e. are the results different than expected or what are its implications, and should suggest next steps. The evaluation summarises lessons learned about the methods applied in the project and may form the basis for further improvements to the authority's project management. Such conclusions should also be reported in the final report.

The headings in the final report could follow the headings in the project plan proposal quite closely:

- Project description
- Project setup
- The extent of the project (which could include something about the size of the project organisation)
- Organisation of the project (which should include something about cross-border cooperation, cooperation with customs, involvement of stakeholders and choice of test laboratories)
- Methods (which should include something about sampling techniques, risk assessment techniques, use of standards and test methods)
- Results (number of products tested, result of test and risk assessment, resulting number of products recalled, banned from sales, corrected etc. as well as reflections upon the outcome of the effort)
- Follow-up on time schedule and budget
- Evaluation of the project (which should reflect on the results and the method and present suggestions for next steps)
- Communication (which should present suggestions for communication arising from the project and its results)

The structure of the final report and the structure of the project plan are quite similar. Therefore the authority might find it beneficial to use the above headings as a 'live working paper' throughout a project. The project plan is derived from this working paper at the early stages of the project. Results and information are reported on the 'live working paper' as they are obtained, and the final report is derived from the working paper at the end of the project.

9.2 Assess experience gained in the project

When evaluating the results from a project a distinction is often made between 'output' and 'outcome'. In the case of market surveillance projects those two terms could be defined as follows:

- The output is the immediate results, e.g. the number of products tested, the number of dangerous products found and the number of products recalled from consumers.
- The outcome is the effect on the level of safety.

The output can be measured from the data that is registered for each specific case. Such registrations would normally include all documents sent to or received from the economic operator which means that the resulting measure against the product can be found in the text. The authority would normally find it beneficial for this purpose to maintain the data in a database, i.e. as some extra data stored in the document management system.

The outcome should be an increased level of safety which in principle means that a number of accidents and injuries are prevented. While this outcome is very difficult to measure, it is typically easier to measure certain indicators that will allow the authority to express whether the project had a large or a small impact on safety. Examples of such indicators are:

- The share of recalled, withdrawn or banned products compared to the total number of products tested.
- The number of items that have been returned by the consumers in case of a recall (the importer or producer is often requested to report to the authority the number of items sold and returned as part of the follow-up on a recall).
- The trend in the number of accidents reported by a specific product or product category (It might be possible to see such changes if the project is focused on a new group of products that causes many accidents, e.g. water yoyo balls or mini motorbikes).

The authority should reflect on the result of the project: Were the results different than expected? If so why? What are the implications of the project? If the situation is much worse than expected, the authority might want to continue the activities in that area.

Depending on the results, the evaluation of the project may lead to follow-up, which may take different shapes. If shortcomings are common in the whole market sector, it may be useful to meet with the relevant stakeholders (companies, consumer organisations, and trade associations) to discuss and decide on ways to improve the situation. An educational campaign in cooperation with industry and trade associations may also be beneficial to improve awareness of legal requirements.

Results may also lead to the conclusion that the project should be repeated after a certain period of time, to keep the industry under pressure and to enhance the safety of products in question. Analysis of the results may also indicate the safety requirements which are most frequently violated and the follow-up project can be restricted to those requirements.

If the situation in much better than expected, the authority might want to shift focus to other areas for a longer time.

These reflections should include suggestions for next steps. One pitfall is that the most obvious 'next step' is to suggest further activities in the area, but this will soon result in a situation where all resources are allocated to following up projects from the previous years. Other possible conclusions are:

- An information campaign if the project has demonstrated that the products are safe but accidents are caused by misuse of the products.
- Shift the focus to other areas if the safety is better than expected.

The evaluation also ensures that lessons learned about the methods applied in the project are extracted from the project and possibly implemented as improvements to the authority's project handbook. Such conclusions should also be reported in the final report.

As such, project reports could contain valuable information from which other Member State authorities could learn. It is strongly recommended that they be uploaded to a common database accessible by other Member States' market surveillance authorities.

9.3 Final report for publication

Publishing project results provides transparency on the authority's work. This in turn increases the awareness of consumers and industry regarding product safety.

The final report may be an edited version of the internal report prepared by the authority. The editing must be carried out keeping the reader in mind: Is the report intended for professional readers (e.g. people from business associations) or is it intended for the general public? This should affect the way the report is written and the language and terminology used.

Consideration should also be given to the main message of the report. The report will gain a much larger audience if the conclusions are simplified and used as a platform for providing advice to the 'ordinary user'. This approach is especially fruitful when the conclusion from the project is that safety problems are caused by wrong use of the product.

Reports that are intended for the general public should be written in accordance with general journalistic rules – short, to the point, an interesting heading etc. Those rules will not be presented further in this Book.

10 RISK ASSESSMENT

10.1 Introduction

10.1.1 Contents of this chapter

The focus in this chapter is entirely on the risk assessment of specific products in the context of market surveillance. It is based on the revised RAPEX Guidelines containing a specific method for risk assessment. These Guidelines explain the practical arrangements an authority needs to make in order to do sound risk assessment.

The following parts are dedicated to:

- Data collection; what data are needed for an evidence-based risk assessment and how can you get access to them? Data on product use, injury data, test results of products etc.
- Practical recommendations to perform assessments; advantages and disadvantages of different methods.
- Reporting risk assessments.

10.1.2 What is risk assessment?

Risk assessment is the process that estimates the risk that a product with dangerous properties poses to people, animals or property. (Note that risk in the context of the GPSD and the RAPEX guidelines focuses on risk posed to people). Other directives, e.g. the low voltage directive have a broader definition that includes 'animals and property' as potential victims. Directives that deal with chemical risks often also consider the risk posed to the environment. The broader definition has been adopted in the presentation to make the concept of risk assessment as generally applicable as possible. The process includes identification of potential hazards associated in particular with the non-compliances against standards or legislation and estimation of the probability that the hazards will lead to an injury.

Definition of risk:
Risk = Severity x Probability
In practice, this equation is difficult to apply as the severity and the incidence probability usually are estimated figures:

- *The severity is often given as a verbal qualitative description of an injury caused by a given dangerous property in the product.*
- *The probability is normally difficult to estimate. Often, the market surveillance officer may find it difficult to decide on the most correct order of magnitude.*

Risk assessment is carried out for a specific product (that is under investigation by the market surveillance authority) and the output is an estimate of the risk level that can go into the further steps of risk management and communication.

Figure 11 below summarises the inputs, tools and output of a risk assessment process:

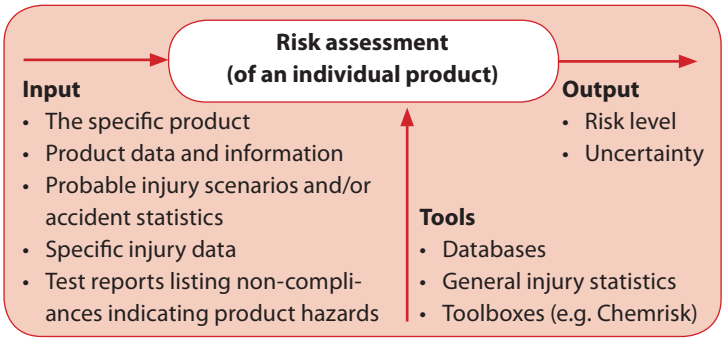


Figure 11: Input, tools and output from risk assessment of a product.

10.1.3 Definition of essential terms in risk assessment of consumer products

In order to be sure that different organisations and Member States understand each other's risk assessments, all parties should use the same terminology with the same definitions. Several different frameworks of risk assessment are used, each with its own definitions. Some are common in engineering and accident prevention, in particular the framework adopted by ISO for the safety of machines (ISO 12100); others are common in food and feed and in chemical safety. The ISO definitions are used in this Book, as most RAPEX notifications deal with mechanical risks. The differences between these two frameworks, including illustrative schemes, are described in Annex B – Different frameworks of risk assessment.

Risk: Combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51, definition 3.2).

Harm: Physical injury or damage to the health of people, or damage to property or the environment (ISO/IEC Guide 51, definition 3.3).

Harmful event: Occurrence in which a hazardous situation results in harm (ISO/IEC Guide 51, definition 3.4).

Hazard: Potential source of harm (ISO/IEC Guide 51, definition 3.5).
NOTE: The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

Hazardous situation: Circumstance in which people, property or the environment are exposed to one or more hazards (ISO/IEC Guide 51, definition 3.6).
NOTE: The combination of hazardous situation and harmful event is sometimes referred to as an (injury) scenario. It is recommended to include the qualification 'injury' (or something equivalent for non-mechanical hazards), to distinguish this term from expressions such as 'exposure scenario' and 'scenario analysis'.

Tolerable risk: Risk which is accepted in a given context based on the current values of society (ISO/IEC Guide 51, definition 3.7).

10.1.4 Why should you use risk assessment?

Risk assessment is a core tool for market surveillance of product safety.

First, every market surveillance authority will have to set priorities for its market surveillance activities, because the number of products on the market is enormous and the resources are limited. The risk associated with a product group will obviously be an important criterion when setting priorities. Priority setting can take place on a strategic level (e.g. long-lasting focus on toys) and on a more tactical level (e.g. a project on wooden jig-saw puzzles for children in a particular year).

Secondly, it is necessary to determine the risk of specific products in the daily control actions. In particular, the effective operation of the system of rapid exchange of information on products presenting a serious risk (RAPEX) requires the authorities to use a fast, fact-based and consistent method of risk assessment.

Risk assessment is also an important tool for product safety work outside the market surveillance authorities. For example, it should be used by designers, constructors and producers as part of the compliance assessment that ensures that only safe products are placed on the market.

10.1.5 How do you use the result of a risk assessment?

The result of a risk assessment is one important input in the risk management procedure. The purpose of the whole process is to control the risk. Examples of other inputs into risk management include the number of products on the market, the benefit of the product, the effort necessary to lower the risk etc.

Risk management varies in different sectors, and low risk does not mean that no action is necessary. Technical progress may have lead to a high safety level in certain sectors as defined and agreed upon in harmonised standards.

In general, the level of risks that society accepts is determined amongst others by culture, risk perception and technical development.

10.1.6 Risk assessment, conformity assessment or compliance?

Risk assessment should not be confused with compliance to legislation or conformity assessment (please refer to the 'Guide to the implementation of directives based on the New Approach and the Global Approach', also known as the 'Blue Guide'; and the detailed description of the differences in conformity and compliance assessment in Chapter 2.1):

- The basis of the New Approach is that only products in compliance with legislation or harmonised standards should be placed on the market. Authorities will take measures if products are found not to be in compliance after consultation with the producer. This is referred to as 'compliance assessment' in Figure 12 below.
- Conformity assessment is the process by which a producer verifies (or asks a third party to verify) the compliance in principle before the product is placed on the market; this verification process continues during production. Conformity assessment implies checking if a given product meets all essential requirements (normally set out in a Directive and specified in harmonised standards). Conformity assessment includes a risk assessment: according to the 'Blue Guide', manufacturers need to carry out risk assessment to determine the essential requirement applicable to the product.
- Risk assessment implies assessing the risk presented to consumers, animals or property by a given product. Risk assessment may also be carried out by an authority or a producer when a hazard is found in a product to assist deciding on adequate and proportionate measures. It can be a tool both before and after placing a product on the market.

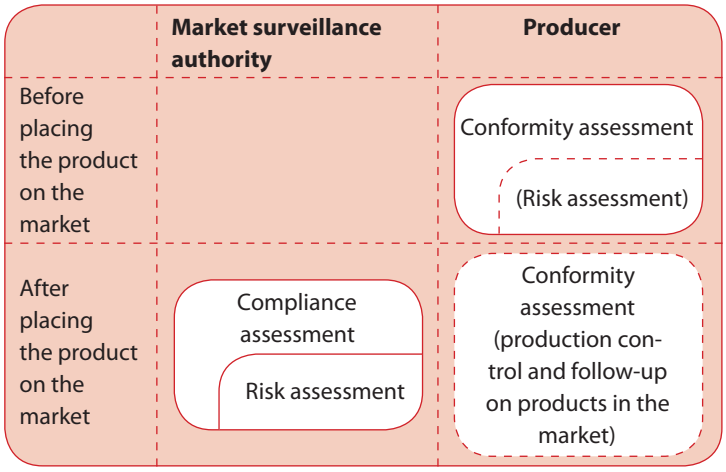


Figure 12: Relations between conformity assessment, compliance assessment and risk assessment.

According to the GPSD a 'producer' is either the manufacturer of the product, the manufacturer's representative, the importer into the EU or other professionals in the supply chain whose activities may affect the safety properties of the product. The complete definition is found in Directive 2001/95/EC, Article 2, item e.

As can be seen in Figure 12, risk assessment is a step in conformity assessment and also plays a role if non-conformity is found. Often, conformity assessment is done using a harmonised standard. This will be the case for many products that are covered by New Approach Directives. A harmonised standard can be expected to lay down safety requirements, based on the essential requirements provided for in EU legislation, as transposed into national law. This means that the user can presume

that the product conforms to the safety requirements if it complies with the standard. In this case, risk assessment is taken care of by the standard, i.e. the requirements in the standard set out a safety level that has been assessed to represent a satisfactory level of risk to the consumer. The advantage of standards is that they present very detailed definitions of the requirements given in the directives. This eases the risk assessment for the producer by changing it from an open and broad analysis to a simpler checking of fulfilment of a number of requirements. Nevertheless, it has to be checked in all cases whether the product has features that are not covered by the standard and which may require a risk assessment on their own.

Conformity assessment is carried out by the producer before a product is placed on the market but it will also be a part of the production control that the producer must undertake after the product has been placed on the market. The purpose of the production control conformity assessment is to ensure that all batches of a production stay in conformity. Risk assessment would in general play an insignificant role in this phase of the production unless the producer discovers an unsafe non-conformity with the product. In that case the producer would use risk assessment to decide on the correct (proportionate) voluntary measures to be taken.

Market surveillance authorities may check if a marketed product meets all requirements defined in a directive. This process includes among other things assessing a number of formal requirements as well as a number of safety related requirements. Again, the assessment would often be done using a harmonised standard. The major difference to the conformity assessment carried out by the producer is that if the authority finds non-conformity in the product then the authority would have to carry out a risk assessment based on methods from this chapter to decide on the risk level associated with the non-conformity. If the producer discovers non-conformity during the conformity assessment, the producer would have to modify the product to bring it in conformity. If the product was already placed on the market, then the producer would furthermore need to make a risk assessment to decide what measure should be taken against products already being on the market.

Still, non-conformity does not necessarily imply a risk as it is shown in the following two examples.

Example 1: A toy has been found by the market surveillance authorities to have sharp edges. A sharp edge in a toy presents non-conformity because the toy does not comply with the requirements laid down in EN 71-1. The market surveillance authorities need to do a risk assessment to decide which measure is proportionate to the risk:

- *What is the potential hazard? Most likely it has to do with cutting of fingers but it might be worse depending on the accessibility of the sharp edge, the sharpness and other geometrical data.*
- *How likely is it that the injury scenario will happen? This will depend largely on the accessibility of the edge but also on the exposure to the toy, the numbers it is sold in, the age of the users etc.*
- *Does this lead to a serious risk or another risk level requiring action?*

Based on the result of the risk assessment and the other elements mentioned in section 10.1.5 above it is decided what to do with the products on the market: do nothing, inform the consumers, stop the sales or recall the products from the consumers.

A producer who discovers a sharp edge as part of a quality control programme will have to go through the same analysis to decide on the correct voluntary measure (the producer might want to adopt more restrictive measures than required by the authority to avoid negative impacts on the brand).

Example 2: The CE-marking on a toy is 3 mm high. The Toys Directive requires a minimum height of 5 mm. Therefore, the product does not comply with the directive and it must not be placed on the market. If the producer discovers this non-conformity in the case of a toy that is placed on the market he would carry out the risk analysis. In this case, it will show that there is no immediate injury risk associated with the non-conformity. A producer might therefore choose to change the printing of the CE-marking on future deliveries without taking further action.

10.2 Performing risk assessment

10.2.1 When do you start a risk assessment?

The starting point for a risk assessment can be an incident: a consumer complaint, a producer's report on a problem or safety issues broadcast by the media. Alternatively, the market surveillance organisation systematically monitors trade, gathers information about certain products on the market and takes samples; in this process, a product may be found that looks unsafe at first sight initiating risk assessment procedures.

From each starting point the same approach can be followed: find more information about the product, request data from the supplier, possibly perform tests and start a risk assessment.

The main difference is that in case of an incident or complaint the focus will usually be on one scenario: something has already happened and the next step is to analyse whether it is likely to happen again. One must distinguish between risk assessment and accident investigation. The purpose of an accident investigation is to find out what happened and to clarify the injury scenario. Furthermore, it usually includes an assessment of the product in question. The purpose of a risk assessment is to decide what level of risk is associated with the hazards in a product. Accident data is used in this analysis to assist defining the injury scenarios and to estimate the probabilities.

10.2.2 Risk assessment process

Risk assessment always focuses on three basic questions:
1) What can go wrong?
2) If it does happen what are the consequences?
3) How likely is this to happen?

In consumer product risk assessment, these questions can be translated to formal steps, using the terms defined in 10.1.3:

- identification of the hazards, hazardous situations and harmful events (output: one or more injury scenarios);
- characterisation of the hazard and the harm (output: severity of consequence; measure of damage);
- estimate of the likelihood of the hazardous situations, harmful events and various types of harm (output: likelihood; level of exposure; probability of injury scenario).

Risk is a combined measure of the incident probability and the severity. Figure 13 below describes the risk assessment process:

Example: electric household appliances operate on 230 V. One injury scenario would be that the user touches a live wire and receives a potentially fatal electric shock (hazard and harm). The producer will normally work to make such a scenario very improbable by insulating the wires and keeping all live parts inaccessible (influencing likelihood of scenario). Therefore, the probability of injury and the risk posed by the electrical equipment will be very low.

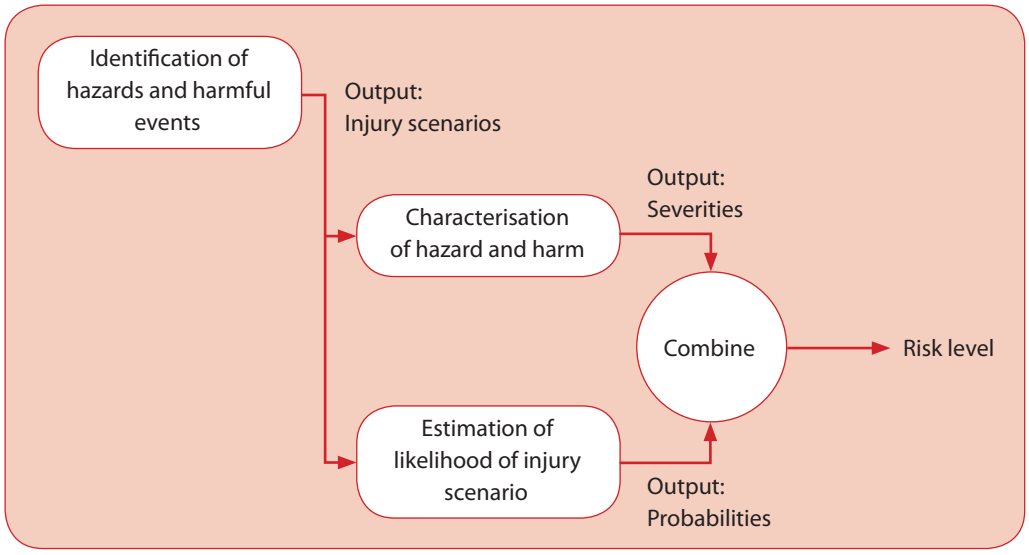


Figure 13: The steps in risk assessment.

10.2.3 General procedure

The RAPEX Guidelines [23] constitute a harmonised procedure for supporting decisions on unsafe products. Its main features are:

- defining the product under assessment;
- identifying the hazard(s) under consideration;
- identifying the type of consumer that is concerned;
- describing how the hazard harms the consumer. This will usually result in several injury scenarios per product;
- using the combination of injury type and body part to estimate the severity of each injury scenario (table of examples);
- assessing the likelihood of each injury scenario by breaking it up into smaller steps that are essential for the injury. Find data on the likelihood of each small step; and
- combining severity and probability in a matrix to determine the level of risk.

The procedure is illustrated in Figure 14 below:

The output from the risk assessment is an estimate of the risk level. The risk level goes into the further risk management process and the decision on proportionate and adequate measures.

Example: RAPEX notification no. 0125/06 deals with a cross pane hammer (see picture in Figure 15 below) with a metal handle and a black plastic grip. The hammer has three shortcomings:

1) The hammer head is insufficiently fastened to the handle.
2) The plastic grip breaks under normal strain.
3) The plastic grip is insufficiently fastened to the shaft of the hammer.

The steps in the risk assessment procedure for this example are as follows:

1. *Define the product under assessment*
   Cross pane hammer with metal handle and black plastic grip.
2. *Identify the type of consumer that is concerned*
   The product is normally used by adults. Children may want to stand nearby to watch the adult working.
3. *Identify the hazard(s) under consideration*
   The plastic grip has insufficient mechanical strength which means that it breaks under normal strain when the user hits a hard surface (only one hazard is considered in this example).
4. *Describe how the hazard harms the consumer*
   The upper part of the hammer bounces back and hits the user's arm. This causes bruising of the arm (only one injury scenario is developed in this example).

The information in 3) and 4) is filled into the three first columns of the risk assessment table as shown in the following Figure 16:

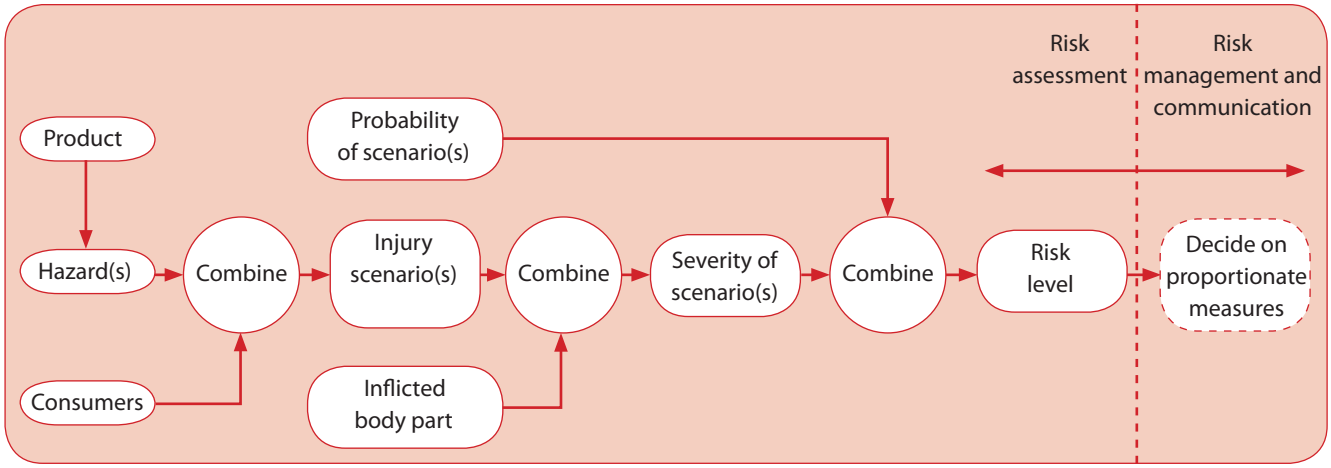


Figure 14: Overview of the risk assessment procedure.

Figure 15: RAPEX notification no. 0125/06 deals with a hammer where the handle breaks.

Product hazards	Injury scenarios	Type of injuries
Identify all hazards that may lead to a consumer injury or health damage. Consider all consumers, including the vulnerable.	If you select a hazard from the Hazard List, a short scenario will be filled in here. **Make this scenario more specific** by describing at least: *the exact hazard or defect in this product and the event that may result; the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.*	For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard from the Hazard List, a typical injury(ies) will be filled in here. **Make this more specific** by describing both the injury and the body part. Click here to consult the Injury Scale.
low mechanical strength	Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.	Bruising of arm

Figure 16: The three first columns in the risk assessment table show the injury scenario and the inflicted body part.

5. Use the combination of injury type and body part to estimate the severity of each injury scenario
The severity of the injury 'Bruising of arm' is looked up in a separate sub-table as shown in Figure 17.

The bruising of the user's arm if hit by the hammer head seems to fit best with the category '< 50 cm^2 on body', which translates to a level 1 injury. Thus '1' is chosen in the fourth column of the risk assessment table (see Figure 18).

6. Assess the likelihood of each injury scenario by breaking it up into smaller steps that are essential for the injury. Find data on the likelihood of each small step
The selected injury scenario is quite simple, as it only breaks up into two steps:

Step 1: Handle breaking (with an estimated probability of p=0.5 (50% probability): experts estimated that a large proportion of these products will break during their lifetime. Where possible, test reports should be taken into account to confirm such an estimate).

Step 2: The upper parts hit the arm (with an estimated probability of p=0.2 (20% probability, 1 out of 5): as the handle will usually break while someone is holding it and hits a hard surface, the hammer head will bounce back more or less in the direction of the user, but if the blow with the hammer was not perpendicular to the surface, the hammer head may also miss the arm. See also comment to Step 1).

The steps and their probability are noted in the fifth column of the risk assessment table as shown in Figure 19.

7. Combine severity and probability in a matrix to determine the level of risk
The resulting probability is calculated and compared to the scale with indicative statistical values, as shown in Figure 20.

The severity and the probability are combined to get the resulting risk level. The combination is done in the matrix in the RAPEX guidelines, as shown in Figure 22.

In this case the probabilities of each step in the injury scenario are multiplied to give p=0.1 (1/10).

This compares to an indicative statistical value of '> 1/100'.

Note that this category is chosen even though 1/10 is close to falling in the category '> 1/10'. This should be noted in the reporting of the result and it could be the basis for further investigation in the sensitivity analysis.
The severity of the injury was level 1 (step 5).

The combination of '> 1/100' and level 1 gives 'significant risk' as can be seen in the table in Figure 21.

These data appear in the Excel spreadsheet in the four last columns. The calculated, resulting probability is written into the sixth column. Next, the corresponding 'indicative statistical value' is chosen in the seventh column, and then the Excel sheet calculates the values in the eight and ninth column, see table in Figure 22.

The detailed RAPEX guidelines can be found on the EU website (see Annex I). In 2008, a revision of these Guidelines is under way.

10.2.4 Getting the necessary data for the risk assessment

Data and information are needed to answer the three questions that are relevant in risk assessment. The following provides some suggestions for the type of data and how to access it.

What can go wrong?
A first impression of actual product use can be obtained from the instructions for use, but this includes only the use as intended by the producer. In order to get a more realistic picture, you could start with questions such as: Will children or elderly people have access to this product and are they likely to use it for its purpose? How may a person be using a product in view of product functions and user goals? If there is a detailed description of near accident, this will obviously provide additional ideas of the use. In addition, it may be feasible to perform product use studies with the product or information about such studies may be available in the scientific literature. It might also be relevant to search for information in databases with accident statistics such as the European injury database, IDB (the public part of this database can be accessed on the website https://webgate.ec.europa.eu/idbpa/). A useful overview of questions that may help in finding relevant injury scenarios can be found on the EuroSafe website: http://www.eurosafe.eu.com (select Knowledge base and then Risk assessment).

The answer to the question should be a list of injury scenarios. Often, a product has several hazards that should all be analysed (unless it is immediately obvious that some of the hazards have very little risk associated with them). You will also normally find that one specific hazard may result in several likely injury scenarios. Again, one should analyse all scenarios unless it is obvious that some scenarios end up in an acceptable risk. However, one should be careful because it is usually complicated to anticipate the outcome of a scenario without doing the complete analysis.

If it does happen, what are the consequences?
It is essential to evaluate the final outcome of each scenario that has been identified. This requires qualitative data such as the type of injury that may result from a mechanism, and quantitative data such as the severity, medical treatment need etc. Preferably, a detailed injury mechanism should be given.

Type of injury	Severity of injury			
	1	2	3	4
Laceration, Cut	Superficial	External (deep) (> 10cm long on body > 5cm long on face) requiring stitches Tendon or into joint White of eye or Cornea	Optic nerve Neck artery Trachea Internal organs	Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/dysfunction)
Bruising (abrasion/ confusion, swelling, oedema)	Superficial ≤ 25cm² on face ≤ 50cm² on body	Major > 25cm² on face > 50cm² on body	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Brain stem Spinal cord causing paralysis
Concussion		Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma

Figure 17: The sub-table for the categories of severities of injuries.

Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probability of factors
Identify all hazards that may lead to a consumer injury or health damage. Consider all consumers, including the vulnerable.	If you select a hazard from the Hazard List, a short scenario will be filled in here. **Make this scenario more specific** by describing at least: *the exact hazard or defect in this product and the event that may result; the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.*	For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard from the Hazard List, a typical injury(ies) will be filled in here. **Make this more specific** by describing both the injury and the body part. Click here to consult the Injury Scale.	Assign from the Injury Scale: 1 to 4. Click into cell below	For each hazard identified, estimate the probability for each step in the scenario (event, interaction and injury) e.g.: 1/10; 1/100; 1/8
low mechanical strength	Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.	Bruising of arm	1	

Select severity
Please select the appropriate severity level from the scale

Figure 18: The severity level is entered in the fourth column.

Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probability of factors
Identify all hazards that may lead to a consumer injury or health damage. Consider all consumers, including the vulnerable.	If you select a hazard from the Hazard List, a short scenario will be filled in here. **Make this scenario more specific** by describing at least: *the exact hazard or defect in this product and the event that may result; the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.*	For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard from the Hazard List, a typical injury(ies) will be filled in here. **Make this more specific** by describing both the injury and the body part. Click here to consult the Injury Scale.	Assign from the Injury Scale: 1 to 4. Click into cell below	For each hazard identified, estimate the probability for each step in the scenario (event, interaction and injury) e.g.: 1/10; 1/100; 1/8
low mechanical strength	Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.	Bruising of arm	1	Handle breaking 1/2 Hitting arm: 1/5

Figure 19: The probabilities of the steps in the injury scenario are noted in the fifth column.

Indicative statistical value of the probability	Description of the probability
> 50%	Almost certain, might well be expected
> 1/10	Quite possible
>1/100	Unusual but possible
> 1/1,000	Only remotely possible
> 1/10,000	Conceivable, but highly unlikely
> 1/100,000	Practically impossible
> 1/1,000,000	Impossible unless aided
< 1/1,000,000	(Virtually) Impossible

Figure 20: The sub-table with indicative statistical values.

Combination of severity and probability to risk level					
		4	3	2	1
Almost certain, might well be expected	> 50%	Serious risk	Serious risk	Serious risk	High risk
Quite possible	> 1/10	Serious risk	Serious risk	Serious risk	Significant risk
Unusual but possible	>1/100	Serious risk	Serious risk	Serious risk	Significant risk
Only remotely possible	> 1/1,000	Serious risk	Serious risk	High risk	Low risk
Conceivable, but highly unlikely	> 1/10,000	Serious risk	High risk	Significant risk	Low risk
Practically impossible	> 1/100,000	High risk	Significant risk	Low risk	Low risk
Impossible unless aided	> 1/1,000,000	Significant risk	Low risk	Low risk	Low risk
(Virtually) Impossible	< 1/1,000,000	Low risk	Low risk	Low risk	Low risk

Figure 21: The matrix that is used for combining severity and probability.

Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probability of factors	Calculated probability	Probability value	Probability term	Risks
Identify all hazards that may lead to a consumer injury or health damage. Consider all consumers, including the vulnerable.	If you select a hazard from the Hazard List, a short scenario will be filled in here. **Make this scenario more specific** by describing at least: *the exact hazard or defect in this product and the event that may result; the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.*	For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard from the Hazard List, a typical injury(ies) will be filled in here. **Make this more specific** by describing both the injury and the body part. Click here to consult the Injury Scale.	Assign from the Injury Scale: 1 to 4. Click into cell below	For each hazard identified, estimate the probability for each step in the scenario (event, interaction and injury) e.g.: 1/10; 1/100; 1/8	Calculated value of probability factors, e.g. 1/10 x 1/100 x 1/8 = 1/8000	Select the scale value corresponding to the calculated value, e.g. 1/8 000 corresponds to '> 1/10 000'	Description in words of the probability	Combined result from the risk table: Serious to Acceptable
low mechanical strength	Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.	Bruising of arm	1	Handle breaking 1/2 Hitting arm: 1/5	1/10	> 1/10	Quite possible	Significant risk

Figure 22: The resulting description of the injury in the Excel sheet.

Example: The cross pane hammer from the previous example (RAPEX notification no. 0125/06). Analysing the product and its shortcomings will produce a number of possible injury scenarios, e.g.:

- *The hammer head breaks when a person uses the hammer and hits a hard surface. Parts of the head fly off and hit the user's eye.*
- *The hammer head breaks when a person uses the hammer and hits a hard surface. Large parts of the head fly off and hit the user's head.*
- *The hammer head breaks when a person uses the hammer and hits a hard surface. Parts of the head fly off and hit the user's hand, foot or other body part.*
- *The handle of the hammer slides off the shaft when a person swings the hammer. The upper part of the hammer flies off and hits the head of a nearby person (perhaps a child).*
- *The handle of the hammer slides off the shaft when a person swings the hammer. The upper part of the hammer flies off and hits the body of the user or a nearby person (perhaps a child).*
- *The handle of the hammer breaks when a person uses the hammer and hits a hard surface. The upper part of the hammer bounces back and hits the user's arm.*

Note that it is not immediately obvious which of these scenarios will lead to the highest risk. If a part of the hammer hits the user in the eye (the first scenario), the result might be blindness in that eye. This is generally considered to be a more serious injury than getting a scar in the face which might be the outcome of the second scenario. If, however, the probability of getting hit in the eye is sufficiently lower than the probability of getting hit in the face, then the second scenario would turn out to have the highest risk level.

The result should be that the injury scenario is linked to one of the four levels of severity in the RAPEX guidelines.

How likely is it that it will happen?

The probability that a given hazard will lead to an injury is often very difficult to estimate. In case of a reported injury, reality shows that it is possible, but could it happen again? Some Member States have a system for collecting accident and injury data. The authorities of those Member States should use these data wherever possible. However, one should take into account that the data rarely relate to the exact type, brand and model of product that you are interested in for your risk assessment. They usually refer to a complete class of products. Nevertheless, injury data may support the conclusion that a particular scenario is quite likely with this type of product.

In the approach of the RAPEX Guidelines, each scenario is broken up into smaller steps that are essential for the injury. Several considerations have to be made:

1. *Product characteristics*
   How likely is it that the hazard or shortcoming will occur during the lifetime of the product? (Example: What force is required for the hammer to break, and how does this compare to the forces that may occur when using the hammer? Do all products share the same characteristics, or is there a distribution of test outcomes?)
2. *Exposure to the hazard*
   How likely is it that people will actually be exposed to the hazard, again during the lifetime of the product? (Example: How likely is it that someone will be hit by pieces of the hammer head flying off?) Does exposure depend on specific behaviour or is it sufficient if the victim is near?
3. *Injury mechanism*
   How likely is it that the injury occurs given that the product fails? (Example: How likely is it that the broken part of the hammer hitting the user will cause the injury?)

In the example with the breaking hammer, the probability that an object that hits an eye actually causes an eye injury will depend upon the energy and shape of the object, and information on this probability could be available in the medical literature.

It will be clear that data to estimate the probability of each step may come from different sources: product tests can be performed to get information about the critical product characteristics; product use studies and ergonomics research may provide information about frequency of actions, forces used etc.

When building the scenarios and estimating the probabilities it may be helpful to recall the underlying principles as illustrated in Figure 23.

Draw up an event tree. Each step in the tree must list all possible outcomes so that the complete tree would describe all possible events and consequences of the particular product. In the last column of the event tree there is the complete list of all possible outcomes that would result if placing the specific product (or batch of products) on the market. Each scenario will be associated with an accident probability (pa). The probabilities are shown as p-values, where p=1 is a probability of 100%, p=0.1 is a probability of 10% or 1/10 (1 out of 10) etc.

The result of this should be that the injury scenario is linked to one of the eight levels of probability in the RAPEX guidelines.

The entire process appears at first sight to be rather complicated but is still realistic. Risk assessment is more comprehensive than conformity assessment and it is found to be important to make the outcome as objective and correct as possible. Therefore, it seems necessary to spend the effort to gather the background data. An authority should however observe that the time to carry out a risk assessment would decrease as experience with using the method is built up and as examples of 'standard risk assessments' are collected.

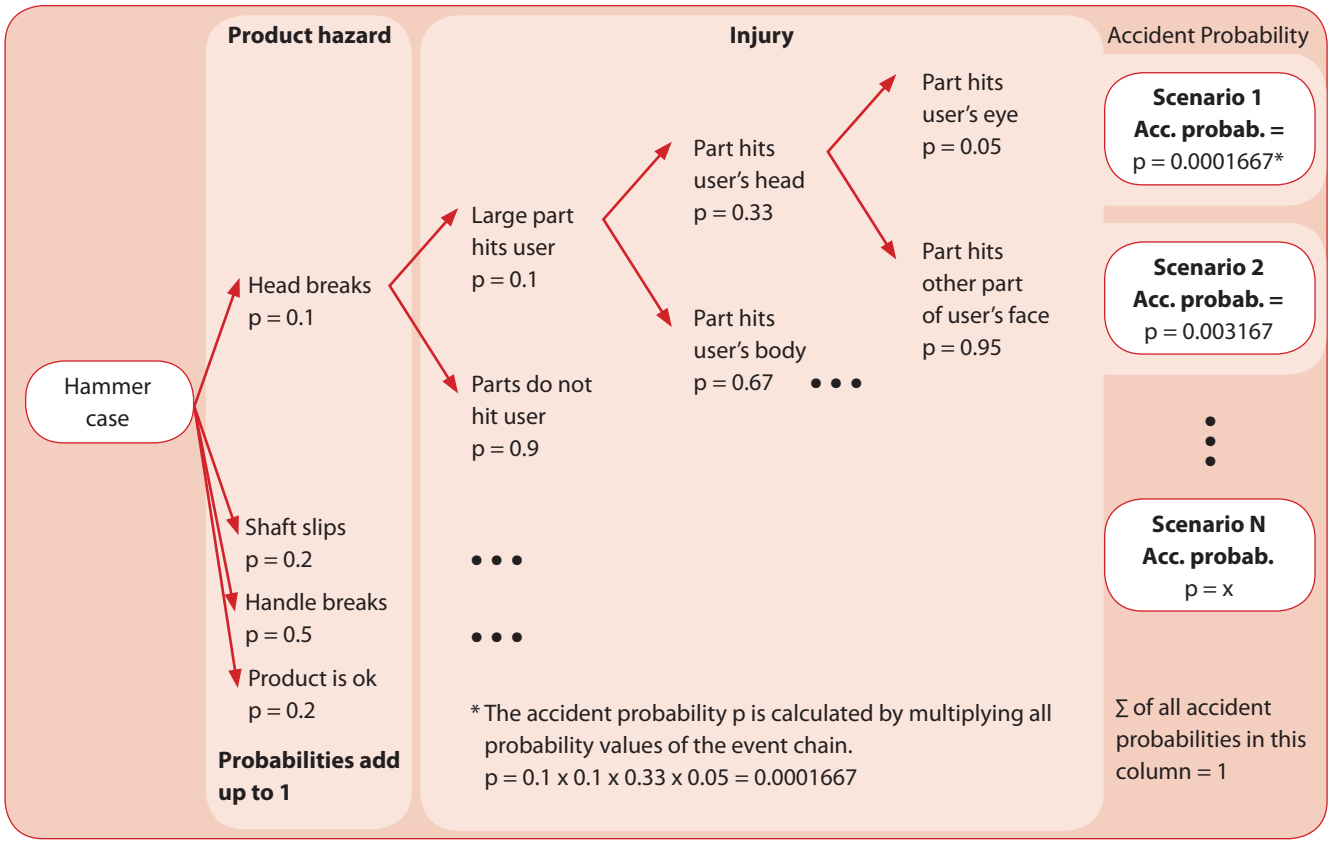


Figure 23: The Event Tree shows the sum of all possible outcomes of a product failure.
Note: the sum of the probabilities for each event/injury type (on the right side of the branching) is always p=1 (100%).

10.2.5 Sensitivity analysis

The probability is estimated most often based on assumptions rather than exact figures. Often, it is difficult to make a more precise estimate than an indication of the order of magnitude. Therefore, it is also important to state the level of uncertainty on each of the factors in 10.2.2 because the influence of such uncertainty should be analysed in a sensitivity analysis. Also the uncertainty in the severity of injury should be included in such an analysis.

The purpose of the sensitivity analysis is to clarify how sensitive the result of the risk assessment is to variations in the estimated probabilities or in the severities.

A very practical way of doing the sensitivity analysis is to calculate how much higher or lower the probability would be to change the risk level. Then you evaluate whether such a change in probability is realistic.

Another approach is to repeat the risk assessment as in 10.2.2 using the highest probabilities that one could estimate for each step (worst case approach). The resulting risk level will then be the highest level found in this assessment.

If it is the same as the originally estimated level, then the uncertainties on the probabilities or severities do not have an impact on the result (which of course would be the ideal case).

If the highest possible risk level is higher than the originally estimated level, one has to go back into the risk assessment to see if anything can be done to improve the estimates of any of the individual factors. If this is not possible, one should at least note that one of the injury scenarios might have a more severe outcome than estimated. This should be taken into account when drawing the conclusion of the whole risk assessment. If for instance the analysis has revealed several injury scenarios each with a moderate risk and the sensitivity analysis has shown that most of the injury scenarios could result in serious risk when the uncertainty is taken into account, then the most correct conclusion of the whole case might be that the product carries a serious risk.

10.2.6 Reporting a risk assessment result

The result from the risk assessment must be reported to ensure that the considerations are registered and that they can be used in the proper context. Normally, risk assessment is done as part of a market surveillance case or perhaps even an investigation of an accident. If the report has a suitable form, the market surveillance officer might be able to use it with little modification in the communication with the producer. On the other hand it is important that it has a quality level suitable to be produced in a court case if necessary.

To ensure proper reporting it is recommended to use a reporting form that is simple and easy to use. Furthermore, using a form assures that all necessary information is included.

A risk assessment report should as a minimum include the following headings:

1. *Identification of product and case, description of the context.*
   In most market surveillance cases most (or all) of this information is given if a reference is made to the case identification that the authority uses (e.g. a case number).
2. *Description of the hazards.*
   This could be a list with (verbal) description of the identified hazards in the product. The hazards are sometimes identified from a test report with non-compliances.
3. *Description of injury scenarios and sensitivity.*
   This could be given in a table with the following headings:
   - Injury scenario
   - Injury type and location
   - Severity of injury
   - Probability of injury
   - Resulting probability
   - Risk level
   - Sensitivity
   - Impact on risk level
4. *Conclusion*
   The conclusion should present the overall assessment of the product, e.g. 'serious risk' (requiring rapid action).

The conclusion should be drawn up to reflect as transparently as possible how the resulting overall risk level is derived from the estimated levels in the table.
Some examples are shown in Chapter 10.5.

10.2.7 Quality assurance

One of the drawbacks of the risk assessment method is that it includes a lot of estimation and individual judgements. The aim of the method is to support the market surveillance officer as far as possible by replacing estimation by looking up values in a table and by forcing the estimates to be as transparent as possible. Still, there is an intrinsic risk for subjective judgements.

The best way to handle this is by performing risk assessment in pairs or groups. To prepare the risk assessment it is recommended that all participants do individual risk assessments before the teamwork assessment.

This might be difficult to achieve in practice. Often, the authority would look for ways that take less time and resources. Two methods are described here:

- The lowest recommendable level of quality assurance is to have one market surveillance officer to do the risk assessment and have another person to check the report afterwards. The second person should co-sign the risk assessment report or should file a note on the case with his or her comments to the report.
- In projects where many similar products are investigated, the risk assessment of the first product is done in teamwork. The teamwork risk assessment is then used as a template for the assessments of the other products. Again, it is recommendable to have another person to check all the final risk assessments.

10.3 Pitfalls and how avoid them

This chapter addresses a number of practical problems that the EMARS Risk Assessment team has seen when performing the analysis for specific cases and suggests approaches to avoid these pitfalls.

10.3.1 Must I perform a risk assessment every time?

Often the risks are so obvious that it seems superfluous to do a risk assessment using the method from 10.2. If the user can touch live parts in an electrical appliance, then 'everybody' immediately knows that it is dangerous, so why bother with the paperwork?

It is considered best practice to always carry out a risk assessment.

Firstly, non-conformities to harmonised standards are not sufficient for market surveillance authorities to take measures unless they make the product dangerous. The producer is not obliged to follow a harmonised standard and therefore non-compliance with such a standard may not necessarily mean non-conformity with the (safety) requirements of the directives. Therefore, the legal argument behind a measure against non-conformity must describe the associated risk.

Secondly, market surveillance cases end up in court now and then because the producer or importer may decide to challenge the opinion of the market surveillance authority. In such cases, the authority will have a stronger case if it can refer to a risk assessment that was carried out and documented when the proportionate risk management measure was decided.

Of course, many types of shortcomings are generally agreed to be dangerous (e.g. small parts in toys, accessible live parts in electrical appliances etc.) and many market surveillance inspectors would feel it unnecessary to go through the complete procedure repeatedly for the same type of shortcomings. An alternative would be to develop a list of 'standard risk assessments' for those common shortcomings, which the inspector could refer to. Such a 'standard risk assessment' could also include a standard phrase which is also introduced in the legal letter to the producer.

10.3.2 Serious injury = serious risk?

If an injury scenario leads to a serious injury, you might expect a serious risk.

As shown in 10.1.5 this will not necessarily be the case. Risk also depends on the probability of the scenario. If the scenario is virtually impossible, then serious injuries might still lead to a moderate or even low risk.

10.3.3 Risk due to a product hazard versus risk due to inadequate functioning

A special case is the risk assessment of products that are supposed to have a kind of protective function, for example personal protective equipment, socket protectors or fire extinguishers. These products do not necessarily have shortcomings that are dangerous in themselves (e.g. sharp edges where the user can get cut). Therefore, the primary hazard is not a property of the product. Rather, the risks are associated with a failing or insufficient protective function.

The approach to risk assessment is not fundamentally different, but you will need to include injury scenarios in which the product does not provide the required protection (e.g. the fire extinguisher does not work). This means that the person is exposed to the hazard that the equipment was supposed to provide protection.

10.3.4 Small probability but high quantities in the market

Some products may have shortcomings that can cause serious injuries but the associated probability is very low. Then, a risk assessment will reveal that the risk level is low or acceptable which nonetheless may seem unacceptable. If the product is sold in very large quantities, the exposure would be high implying that serious accidents might happen at regular intervals. If furthermore it is easy to make the product safer, the market surveillance authority would have a problem explaining its inactivity based on the low or acceptable risk level.

Such observations should be noted in the report and taken into account in the risk management phase when the authority decides which measures would be appropriate to deal with the risk. But the risk assessment and the resulting risk level should not be modified. The problem lies in the society's perception of a given risk which may be different from the objective result of the risk assessment (in general, people will not accept fatalities related to any consumer product – even though they live with several dozens of traffic fatalities per million per year). One solution is to separate perception of risk from risk assessment and deal with the perception of the risk under risk communication and management (i.e. when deciding on adequate and proportionate measures). It could also prove helpful to check the total exposure of the product to the population.

Example: Milk was sold in a milk carton which was closed with a lid that was small enough to fit into the small parts cylinder (defined in EN 71-1). Even though the risk level was estimated as very low, the producer and the authorities decided to take action by printing a warning on the milk carton.

10.3.5 How to avoid that the number of scenarios explodes?

A major question is: what can go wrong? In the RAPEX Guidelines this question is answered by developing an overview of scenarios that can occur with the product. If you make enough assumptions, you may end up with a long list of possible scenarios. For example, in a risk analysis of a chain saw you may assume that the user is standing on a stepladder; and also that the person may be wearing unsuitable shoes and standing on a stepladder. Where do you stop?

Every extra step you add in a scenario will lead to another factor in the likelihood that is less than 100%. The most likely scenarios will be those that 1) lead to the injury that you have chosen for the scenario and 2) present the shortest way to the injury. More complicated scenarios may normally be disregarded, unless they lead to new types of injury.

10.3.6 Vulnerable groups

In the first version of the RAPEX Guidelines, (very) vulnerable groups were given much attention. The matrix that was used to decide on the risk level contained specific columns for vulnerable and very vulnerable groups (defined as children, the elderly, people with handicaps etc.). The result of this approach was that even quite low risks could be labelled as unacceptable if the product could come into the hands of young children.

The current RAPEX Guidelines do not accord such a special place to vulnerable people, but it is still possible and desirable to pay specific attention to them:

- first, take into account any (very) vulnerable groups when describing scenarios;
- second, analyse if (very) vulnerable people could suffer more serious injuries in those scenarios, or whether the probability of any step in the scenario will be influenced by the vulnerability. Use this information for determining the risk level.

Example: A small part can be broken off a whistle. One injury scenario is that the user breaks off this part while he or she is blowing the whistle and the part gets into the user's mouth. From here, two developments are possible:

1. *If the user is an adult, then he or she would most likely spit out the part and nothing will happen.*
2. *If the user is a small child (i.e. a very vulnerable person), it is more likely that the child will swallow the part. This means that there is a risk that it ends up in the lungs, which in general is considered to be a serious injury.*

In this example the injury scenario worsens dramatically because the probability increases and the injury becomes much more serious. Both affect the risk level.

10.3.7 Subjectivity

If a single expert does an assessment, his or her personal experience may influence the estimation of injury severity and likelihood. The table of injury levels is intended to achieve higher consistency and standardisation in this estimation.

To avoid subjectivity:

- use quantitative measures and data;
- work with colleagues from the start or have them review the result.

10.3.8 Non-compliance to a standard means risk?

A shortcoming that is commonly found in RAPEX notifications is that no risk assessment is reported, but just a list of non-compliances to harmonised standards. The market surveillance officer might find the faults so obvious or well-known that it seems superfluous to describe the risk. Sometimes risk assessments are probably carried out to back up the notification or in reaction to it, but this information is not available in the public domain.

As explained in 10.1.3, the pure fact that a product does not comply with a standard is not sufficient to decide on the level of risk. The risk level depends upon the exact requirement and possibly also on how much the measured value deviates from the requirement. A risk assessment is necessary to decide the risk level (which in turn is necessary to decide if a RAPEX notification is at all required). The risk assessment could however be fairly short if the hazard and the injury is well-known. Alternatively existing risk assessments of such well-known hazards could be re-used to quickly decide on measures (this is the basis for so-called Failure Code Lists).

Example: Electrical lamps must meet the requirements of the Low Voltage Directive. The detailed safety requirements are given by standards in the EN 60598 series. One requirement is that the user must not be able to touch live conductors. If it is possible to touch live conductors in a specific lamp, a sufficient risk assessment would be: 'It is likely that a user can touch live wires thus risking a fatal electrical shock.'

10.3.9 Products causing damage to property

The risk assessment method in the RAPEX guidelines works on the assumption that products cause injuries to people. This is however not necessarily the case. If the product is a candle-light, then the most likely scenarios have to do with candles setting fire to property.

One approach to handling this is to write injury scenarios that imply that a person is injured (e.g. gets burns, is poisoned by the smoke, dies etc.). An example of such a scenario could be 'Candle sets fire to a curtain which ignites the room. A person is asleep and does not wake up. The person dies from smoke poisoning.'

The probability of this kind of scenario can be checked with data from fire statistics. The scenarios include the probability that someone dies in the case of a house fire. This probability can be estimated: dividing the number of victims by the number of fires. This estimate takes into account the probability of escaping in time.

Another approach to handling this is to categorise the fire (according to the extent and the resulting damage) in categories that fit with the scale from the revised RAPEX guidelines, for example):

Table 4: Example of how severity levels can be adapted to incidents that do not involve people.

Severity level	Description of fire
4	A whole building or several rooms are destroyed by the fire.
3	One room is destroyed by the fire or several rooms are affected e.g. by smoke.
2	Few pieces of furniture or curtains are destroyed or one room is affected e.g. by smoke or burn marks.
1	Few pieces of furniture are affected e.g. by smoke or burn marks.

Similar categorisations can be developed for damages to other kinds of property or injuries to animals.

10.4 Alternative methods

Several practical tools have been developed for performing risk assessment. A report compiled on behalf of the EU Commission lists six formal methods that were used recently in Europe, but probably more methods exist that had not been formally published (including the use of expert panels). The report further distinguishes between qualitative, semi-quantitative and quantitative methods. For example, the 'Nomograph' method is classified as semi-quantitative.

The EMARS Risk Assessment team has tested three methods for various cases to get an idea of their strengths and weaknesses:

- The 2004 RAPEX method as developed for the European Commission as modified and presented in 10.4.1.
- The Nomograph method (see 10.4.2).
- The (revised) RAPEX procedure (see 10.4.3).

10.4.1 The 2004 RAPEX method

The 2004 RAPEX method uses the red-yellow-green matrix that all market surveillance authorities should be familiar with (see Figure 24):

A couple of problems have been identified with the original method [5]. The primary problem being that the method quite often yields the result 'serious risk'. This has led to modifications of the method. The new method was found to provide higher transparency in the background of the results. It also seems to give more diversified (and realistic) results. Finally, the homogeneity in different experts' assessments of the same hazard seems to increase when using the method described in 10.2.3.

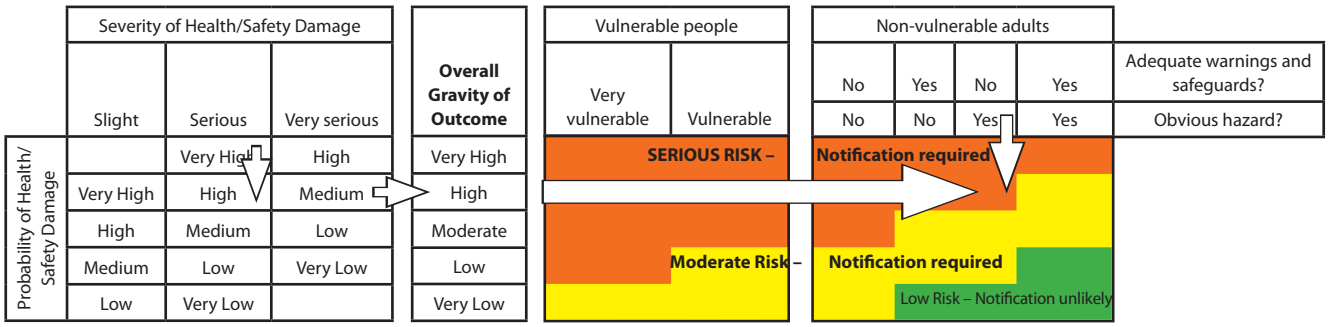


Figure 24: The matrix from the 2004 RAPEX guidelines.

10.4.2 The Nomograph method

The Nomograph method uses maximum potential injury (6 levels), probability of hazard occurrence (6 levels) and hazard recognition (5 levels) to make an initial (individual, or single product) risk assessment. This can be combined with the availability of the product (from Rare to Widespread) to arrive at the final (collective, or market) risk assessment. The risk estimation is made using a standardised graph.

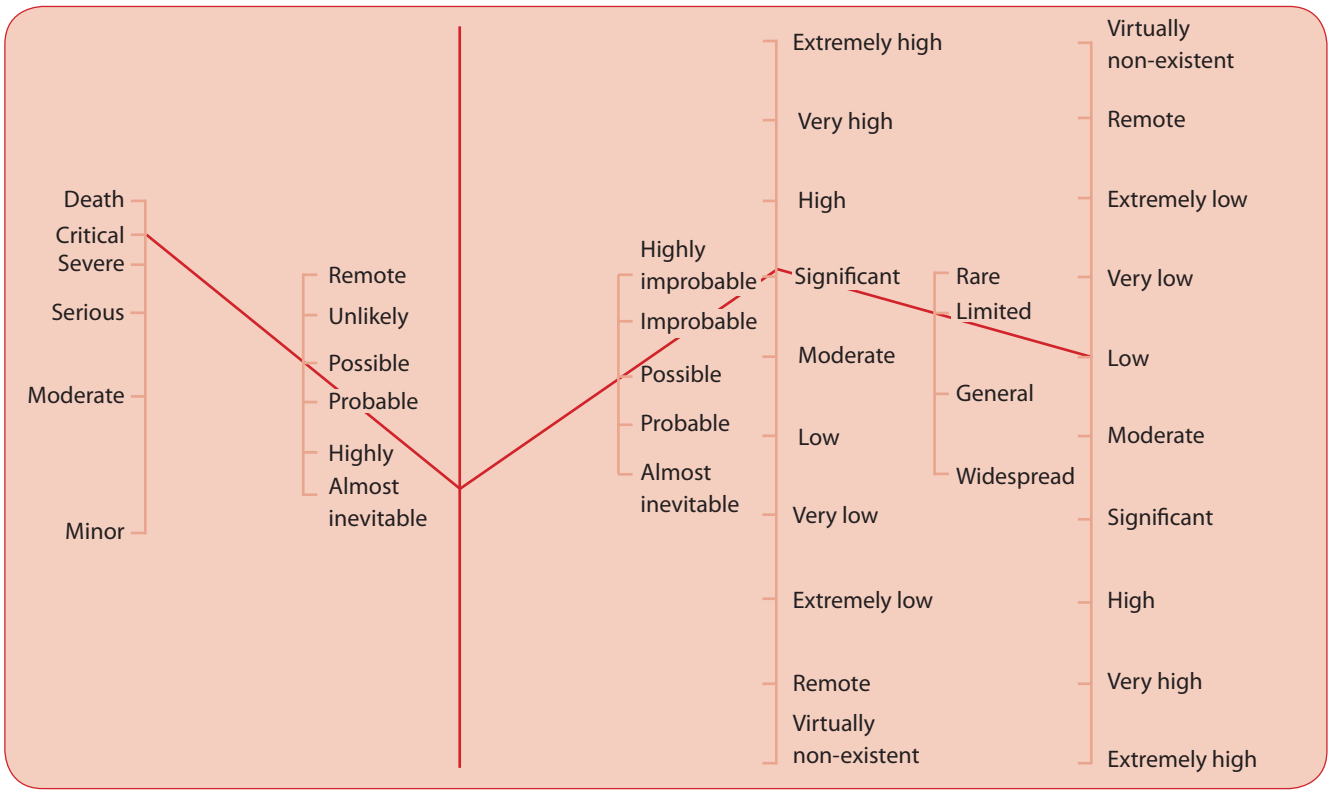


Figure 25: The nomograph that is used for risk assessment in the nomograph method.

The nomograph method gave a wide range of outcomes in each of the cases and also large variation between experts.

In the RAPEX system, hazard occurrence and hazard recognition can both be included in the injury scenarios. The RAPEX guidelines are found to provide more guidance on selecting the injury level and the probability factors.

10.4.3 The current RAPEX procedure

The RAPEX procedure is currently the most suitable tool for decisions on unsafe products. Its main features are highlighted above. The method was developed from the RAPEX guidelines by the Working Group for the Improvement of the Risk Assessment Guidelines WG IRAG (Working Group for the Improvement of the Risk Assessment Guidelines).

The basic instrument in the method is still a matrix but further guidance has been added to facilitate the choice of probabilities and severity of injury. Furthermore, risk for vulnerable consumers is dealt with in a different way: vulnerable consumers have to be taken into account when setting up the injury scenarios.

The method provides guidance on when to issue RAPEX notifications and serves as the preferred method when justifying RAPEX cases.

10.4.4 Why one common method?

Risk assessment can be done in numerous ways but the recommendation is to use the method from the RAPEX guidelines as modified by WG IRAG as the standard method for risk assessment in general in Europe.

The advantage of having one harmonised, commonly used method is that it introduces a common language to describe the phenomena associated with risk assessments. This means that problems can be more efficiently discussed and solved among experts in risk assessment. It also increases transparency so that it becomes more obvious why a specific product has been evaluated the way it has and so that differences can be tracked back to obvious reasons (such as differences in the climate in which the product is used).

Furthermore, the method from the RAPEX guidelines is seen to decrease subjectivity as subjective judgements are replaced to the largest possible extent by factors that can be found in tables. As experience with this method

grows, more and more exposure factors will be estimated and reported. These factors should be made accessible somehow to further assist in making risk assessments.

The method is harmonised, but it is not mandatory. Other methods can be applied if it can be justified that they giver better, more reliable results. This could be the case for specific sectors where other (and more complex) risk assessment tools exist. An example would be the FMEA method that is used to assess the risks associated with machinery; another example is the modelling and calculation of exposure to chemical substances emitted or migrating from consumer products.

10.5 Examples with model assessments

Six examples of risk assessments have been developed and are included in Annex C – Examples of risk assessment. They cover the following type of products:

- Hammers as an example of an assessment that is initialised because of a sample by a Member State
- A rubber luggage strap as an example of an assessment that is initialised by an accident with a product
- Socket protectors as an example of an assessment of protective products
- Bathing mattresses as an example dealing with a chemical hazard
- A toy with small parts as an example of a product covered by a harmonised standard
- A candle as an example of a product that is not covered by a standard

All examples are presented in the reporting format described in 10.2.6.

PART C – COMMUNITY & CROSS-BORDER MARKET SURVEILLANCE ACTIVITIES

11 CROSS-BORDER MARKET SURVEILLANCE ACTIVITIES

11.1 Introduction

Cross-border cooperation between market surveillance authorities is increasingly important due to the fact that product markets have changed significantly over the past decade. While previously, most of the products on the European market were produced by European manufacturers, nowadays a large percentage of products come from third countries. For example, China manufactures around 85% of all toys on the EU market. At the same time, container ships have grown, while the number of important harbours has decreased. As a result, consumer products are imported into Europe via a relatively small number of entry points. One can also observe a trend towards fewer and bigger importers that import goods from countries outside of the EU and smaller domestic importers that buy their goods from the EU importers.

Another trend is that big retailers tend to operate in more than one Member State, or even all Member States, which means that the same products are sold throughout the EU market.

This raises a number of issues that can best be handled in an international cooperation between authorities:

- There is a risk of double-testing products that are placed on the markets in several Member States. This means waste of market surveillance resources and it adds an unnecessary burden on the economic operators.
- Follow-up on dangerous products will be much more efficient if it involves the EU importer and the market surveillance authority in the same Member State.
- When the same products are marketed in many countries the sampling plans should allow for this to increase the efficiency of the sampling.
- When products are banned in one Member State or blocked by customs there is a risk that they will re-enter the market in another Member State or via another entry point.
- Lack of coordination will demonstrate any differences in Member States' approaches to economic operators that market products in several markets.

Furthermore, many stakeholders have organised themselves in European stakeholder organisations (please refer to Annex G). The dialogue with such parties requires coordination from the market surveillance authorities' side to prevent stakeholders from seeing a fragmented picture of the European market surveillance.

Chapter 3.4 discussed the approaches to market surveillance, including the choice between enforcement or compliance assistance. Compliance assistance may include inspections of production lines and production control systems. This is not in line with production facilities in third countries. It seems likely that such inspections at production facilities in third countries are undertaken most efficiently in cooperation between authorities rather than by a large number of individual Member States.

One should note that such cooperation calls for more than a coordination of the activities themselves. Some of the above-mentioned activities shift work between Member States or from inspections in the market to inspections at the border: one can imagine that neither the entry points nor the EU importers are distributed proportionately over the Member States. Therefore, a coordination of the demand for resources is also necessary.

11.2 Exchange of information

EU legislation contains provisions that oblige Member States to exchange information related to market surveillance. These obligations mainly focus on dangerous products:

- The RAPEX procedure under the GPSD obliges Member States to notify products that pose a serious risk to consumers.
- The new approach directives describe safeguard clause procedures that oblige Member States to notify when they take measures against a product.

Both procedures imply that the information is forwarded to the other Member States after having been assessed by the European Commission. More information on the two procedures can be found in Annex H.

Both procedures require a proper identification of the products which can be difficult when marking is lacking. Digital photos are of a great help. Three such photos are seen to be the minimum requirement: one photo of the product itself, one photo of the packaging it is sold in and one photo of the marking on the product (if the product has got a marking).

A number of other channels exist besides the two mandatory means stated above:

- ADCO meetings (ADCO stands for Administrative Co-operation and is the name of groups that are organised under most New Approach Directives). The meetings deal with legislation, standardisation and administrative procedures as well as practical issues related to the specific directive.
- The ICSMS system focuses on exchange of very detailed information about single products.
- PROSAFE meetings between enforcement officers of Europe (and from abroad). The meetings aim at exchanging information about market surveillance issues e.g. specific cases, products or actions.
- The tools developed under the EMARS project including a knowledge base that focuses on sharing of knowledge produced by the project participants and other parties and the Rapid Advice Forum that aims at ensuring rapid informal advice to issues raised by market surveillance officers.

More detailed information on these channels (and others) can also be found in Annex H.

It is seen to be beneficial for the Member States to exchange information beyond the information about dangerous products. A number of examples can be given:

- When following up recalls and other corrective actions the Member State authorities should ensure that they obtain relevant information for the whole EU market and not only for their own territory. They should in particular ensure that information about the presence of the products in other Member States is identified (this information is also required by the RAPEX procedure).
- Reports from finalised market surveillance actions, studies etc. This information is valuable because it may describe good or best practice that other Member States can learn from. Furthermore, information about the results will prove valuable for other Member States in their analysis and planning of upcoming activities.

11.3 Joint cross-border activities

When the cooperation between the Member States extends beyond exchange of information it takes the shape of joint cross-border activities. The cooperation can have many different appearances. Figure 26 illustrates a generic model of a (cross-border) market surveillance action and the necessary coordination activities.

Specific market surveillance actions can be designed by combining elements from the model according to the ambitions of the participants.

Table 5 outlines a number of potential levels of cooperation ranging from exchange of information to a joint action. The table also describes the coordination activities associated with each level of the scale. The table gives an outline of some typical possibilities. However, all kinds of intermediate solutions are possible depending upon the interests of the participants.

The involvement of the Member States could also vary depending upon the level of co-operation. Obviously, a number of the participants need to participate fully, i.e. in all of the activities including the coordination but at the same time other Member States could play a role without committing themselves to full participa-

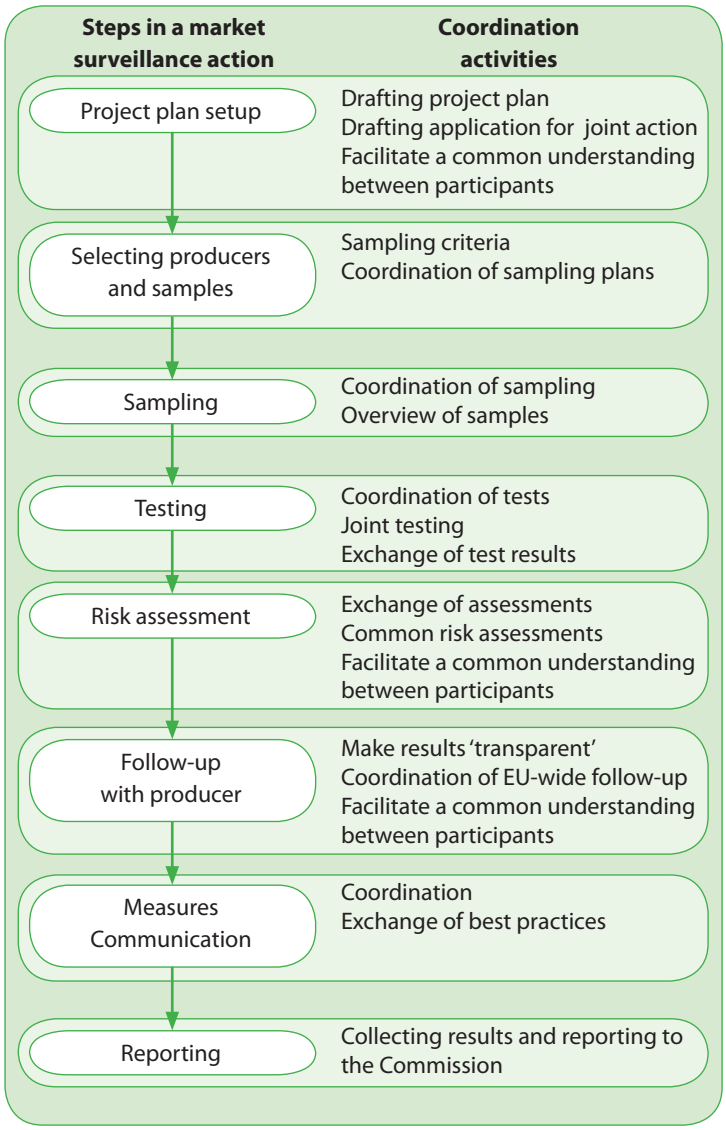


Figure 26: Outline of Cross-Border Market Surveillance Action.

Table 5: Different levels of cross-border market surveillance activities.

Level	Coordination activities
Exchange of product information and test results	Exchange of information on sampled products, tested products and test results.
Coordinated sampling and follow-up	Coordination of sampling plans so that products are only sampled at the European importer. Follow-up is undertaken at European level.
Coordinated information activity	Drafting of common information material (e.g. text for flyers, advertisements, press releases etc.). Coordination with the European Commission.
Coordinated testing	Collection and dissemination of information on sampled products to ensure that the same product is not tested (unintentionally) in parallel in two Member States. Exchange of information about test houses in different Member States.
Joint testing	Organisation of the testing, including call for tenders etc. to ensure that the test costs will be kept at a minimum level.
Cross-border market surveillance action	Organisation of the whole action, including drafting the project plan, organisation of project meetings, facilitating discussions on miscellaneous topics, coordination of sampling and testing, organisation and coordination of the follow-up at a European level and reporting to stakeholders (e.g. the European Commission).
Joint action under GPSD Article 10	This level includes the above activities plus the administration related to the EU funding, i.e. producing the application, doing the financial follow-up and reporting, doing the final reporting, administering payments and handling all other communication with the European Commission.

Table 6: Potential contributions from Member States during a cross-border market surveillance action.

Steps in a market surveillance action	Potential Member States contributions and participation
Project plan set-up	• Information on national market situation. • Technical information about the product. • Experience from previous (national) actions.
Selecting producers and samples	• Information from market survey on their national markets. • Developing screening criteria and procedures. • Experience from previous (national) actions.
Sampling	• Information about samples taken on their national markets. • Information collected during the national effort about products being on markets in other Member States. • Participation in coordinated sampling. • Information about test results from previous actions.
Testing	• Results and experience from tests carried out at national level. • Participation in coordinated or joint testing.
Risk assessment	• Participation in risk assessment. • Exchange of information on assessment of specific products.
Follow-up with producers	• Follow-up with producers and other operators on their territory. • Supply information about operators on other markets.
Measures	• Coordinate national measures with other Member States. • Exchange information about products and measures.
Communication and reporting	• Coordinate communication efforts. • Participate in a common reporting. • Develop a unified communication strategy.

tion. Table 6 illustrates the potential contribution from a Member State to the different steps in a market surveillance action.

The benefit of participating increases as the commitment increases. Basically, the benefit is an increased impact of the activity with a decreased effort from the market surveillance authority.

The increase of the impact is due to a number of reasons:

- Follow-up will be done at the European importer or manufacturer (or at least in parallel in all participating Member States).
- Re-entry of goods is less likely as a third country exporter will see an European-wide action rather than uncoordinated actions in individual Member States.
- Member States will react more uniformly because any doubts can be cleared quickly in the project group.
- The number of products that are investigated and followed up will be considerably higher than what can be achieved by one Member State.
- The need for resources decreases because:
- Double-testing of products is avoided.
- Often, the number of products to be sampled and tested per Member State decreases.
- Joint testing means larger volume of tests in total which would often mean that better prices can be negotiated with the laboratories.
- Contracts with laboratories are negotiated once (as part of the coordinated activities) instead of many times (by each individual Member State).
- Follow-up with the national importers will be much easier if the European headquarters is already involved (by another Member State).

Further information about cross-border cooperation can be found in Annex A which discusses cooperation mechanisms (section A.1) and examples of joint actions (sections A.2, A.3 and A.4.)

12 THE ROLE OF CUSTOMS IN MARKET SURVEILLANCE

Customs play a significant role in protecting the health and safety of European consumer. Indeed, its importance is increasing because more and more consumer goods are manufactured in countries outside the EU. A well-working cooperation with customs authorities ensures that a portion of these goods can be checked at the border before they enter the internal market. Customs checks provide a more efficient way of guaranteeing that only safe products reach the consumers than traditional market surveillance where products are generally checked only after they are placed on the market

12.1 Legal basis

The legal basis for customs involvement in market surveillance is the Council Regulation 339/93/EEC on checks for conformity with the rules on product safety in the case of products imported from Third Countries (see also 2.5). This Regulation will be repealed by Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (see also 2.4).

This regulation lays down provisions that give customs the powers to inspect the safety properties of products before being released for free circulation and to suspend the release of the product if it is suspected to present a serious risk or if it is not accompanied by the necessary documents (e.g. technical files, declarations of conformity etc.).

When the release of a product is suspended, the customs authorities must immediately notify the national market surveillance authority.

The market surveillance authority then has three working days from the day the release was suspended to react. If the market surveillance authority does not notify the customs within three working days about actions or precautionary measures, the products must be released.

12.2 Cooperation between customs and market surveillance in practice

To ensure efficiency, it is therefore essential to involve customs in market surveillance actions. This Chapter describes the practical ways to carry out such cooperation.

12.2.1 Exchange of information

Customs are a very valuable source of information on importers of products. The information in their possession is very detailed and provides a useful starting point for market surveillance authorities establishing the initial overview of the market for a given product in the start-up of a market surveillance action.

It is therefore recommendable that the market surveillance authority contacts the customs authorities in the first phase of the project plan set-up to benefit from this knowledge.

12.2.2 Setting-up risk profiles

The amount of products declared for release for free circulation in the EU is enormous and it is therefore not realistic to expect customs to check every single consignment. Instead, the customs authorities focus on risky products by applying 'risk profiles'.

A risk profile is a set of parameters that allow identifying products for further inspection. The parameters include the customs codes for the products in the consignment, the exporting country and the identification details of the exporter and the importer. The risk profile is applied to the customs declaration that must be presented to the customs authorities by the importer before the products are released. This is done automatically through an IT system which uses the profiles to scan the customs declarations for products to be checked. Consignments that meet the criteria laid down in the risk profiles will be notified to a customs officer who will have to decide what to do with the consignment.

It is considered best practice for market surveillance authorities to cooperate with the customs authorities when setting up the risk profiles.

The customs should also form part of the national RAPEX network and receive copies of RAPEX notifications.

The cooperation between market surveillance and customs authorities may also include exchanges such as information about product categories that are known often to present safety problems or basic knowledge on how to identify potentially unsafe products.

12.2.3 Inspection of products

The practical inspection of products can be carried out in several ways.

In cases where only one product category with straightforward safety requirements is targetted, it may be feasible to have the customs carry out the initial inspection of the selected products. Such an inspection can consist of checking the accompanying documents and the more simple safety requirements. The purpose of the initial inspection is to decide if the market surveillance authority should be involved or if the products can be released. The market surveillance authority should provide training to the customs authorities as well as necessary documents, such as check lists of easily detectable safety defects.

An example of well-working cooperation can be found in Denmark where the customs authorities have digital cameras and a list of contact persons in the Danish Safety Technology Authority. This allows the customs officer to take a digital photo of the suspect product and send it to the market surveillance officer who in most cases is able to decide on the basis of the photo alone whether the release of the product should be suspended or not.

In other cases where the safety requirements are more complex, the customs should suspend the release of all consignments that meet the criteria laid down in the risk profile and ask the market surveillance authorities to investigate the products.

12.2.4 The 3-day limit

In accordance with Regulation 339/93/EEC, the market surveillance authority must notify the customs within three working days if the products can be released. In practice, three working days is a short time if the market surveillance authority needs to take samples and perform laboratory tests, in particular if the country is big and there is a long distance between the import control point and the test laboratory.

Therefore, it is important to note that the Regulation provides several options for the market surveillance authority:

- If the initial inspection reveals that a product appears to be safe, it can be released immediately.
- If the initial inspection reveals that a product is obviously dangerous, the market surveillance authority can inform the customs authorities to maintain the suspension of the release and start the formal procedures against the importer, including consultation on the results of the investigation etc.
- If the initial inspection reveals that a product appears to be dangerous but further investigations are necessary, the market surveillance authority can inform customs that the release of the product must be suspended as a precautionary measure. The importer must be informed accordingly and consulted.
- If the initial inspection reveals that a product has shortcomings that are not suspected to present a serious safety risk, the market surveillance authority can contact the importer and inform him that the product will be released but it can be placed on the market only after having being brought into compliance.

12.2.5 Notification of arriving consignments

Customs are notified by the importer when the products are declared for release for free circulation. This means that the customs authorities know in advance that products are arriving in the EU. Market surveillance authorities may find it beneficial to receive notifications on arriving consignments from customs, in particular, in case of large consignments (complete containers).

Firstly, it allows the market surveillance authority to turn up at the premises of the importer to check the contents of the container when it is unpacked. In practice, this is often the most efficient way to carry out border controls because the inspection is carried out while the importer empties the container. This allows the importer to assist with the unpacking of the products and avoids repacking them into the container – a job that is rather cumbersome.

Secondly, intrinsically dangerous products such as fireworks must only be handled in suitable surroundings. This is seldom the case at the customs premises. Thus, it is often practical to use the premises of the importer to check such products.

12.2.6 Counterfeiting

Counterfeiting is a violation of a producer's intellectual property rights (IPR). In most Member States, counterfeiting is handled by units within the customs authorities and counterfeiting in itself is not an issue for market surveillance.

Nevertheless, counterfeit products may be of interest for market surveillance as such products are often of such poor quality that they pose safety problems in which case the market surveillance authority should be involved. However, it is not impossible that the counterfeit products have the same (or an even higher) safety level as the original product. In that case, the market surveillance authorities can not take measures against the product because of safety reasons but it is rather for the customs to tackle these products on the basis of IPR protection.

12.3 More information

More information about customs procedures can be found on the Commission's website:

http://ec.europa.eu/taxation_customs/customs/procedural_aspects/imports/free_circulation/index_en.htm.

ANNEX A – EXAMPLES OF MECHANISMS TO BE USED IN CROSS-BORDER MARKET SURVEILLANCE PROJECTS

A.1 Introduction

According to the GPSD, market surveillance programmes must be effective and based on risks assessment. At present, in all Member States and connected countries, market surveillance programmes are planned and executed. However, programmes and projects are planned individually, often without any connection with the programmes in other Member States.

The market for consumer products is global. Hence, market surveillance needs to have a broader focus than merely the home territory or even existing cooperation between neighbouring Member States. Often, products are brought on the market by a producer (manufacturer or importer) operating Europe-wide rather than by many domestic importers. Therefore, the most efficient way to solve a safety issue with a product is to co-operate cross-border so that the authority in the Member State where the producer is based resolves the issue together with the producer and the problem is taken care of at the source (the home authority principle).

Moreover, market surveillance faces challenges associated with a general outsourcing of production to third countries which necessitates a more intense control at the external borders and makes it more difficult for the authorities to perform controls of the production process. Such controls may be most efficiently carried out in cooperation between the Member States because industry outside the EU tends to see the European market as one single market and not one regulated by many individual authorities.

Furthermore, non-food consumer products do not have an expiry date, which means that they can be stored for a long time. Examples are seen where products that were banned in one country are moved to other countries to be sold after some time when the story has been forgotten. This is also a situation that can only be resolved through cross-border cooperation and exchange of information.

Market surveillance's aim to protect citizens against unsafe products necessitates cross-border cooperation to achieve an effective system of supervision and enforcement.

A.1.1 Ways to cooperate

Several forms of cooperation in market surveillance are possible and can be used separately or concurrently. However, methods and structures of cooperation are only successful when participants are proactive and really willing to work together. The motivation of market surveillance officers and their natural behaviour to think cross-border are the basis for a successful market surveillance system and optimal protection of citizens.

A.1.1.1 Cooperation in case of incidents (reactive)

RAPEX

If a dangerous or unsafe product is detected on the market, market surveillance officers must inform their colleagues in other countries where this product is sold or might be sold. For this purpose, Member States and EEA countries are required to use the RAPEX system under the provisions of the GPSD.

Bilateral

If a product is sold in only one other (neighbouring) country or in a country that is not licensed to use the RAPEX system, Member States should inform each other bilaterally. The aim of this cooperation is to ban the dangerous or unsafe product from the market as soon as possible.

A.1.1.2 Cooperation in case of no safety related non-conformities (reactive)

ICSMS

If a product is detected on the local market that is not immediately dangerous or unsafe but does not comply with all the aspects of the legislation, action must be taken to have the producer or importer correct the product or the attached user manual or safety descriptions. In those cases, market surveillance authorities should inform each other bilaterally (by letter, e-mail or phone), or use the ICSMS system (see H.2.3).

A.1.1.3 Cooperation in surveillance programmes (proactive)

Beside the reactive activities which take place after an unsafe product is detected, Member States can cooperate in surveillance programmes with the aim to check a specific group of products or to search for unsafe products. Because of the large diversity of consumer products and the large number of worldwide producers, market surveillance authorities should tune their programmes with each other to achieve the right spread across the range of products and producers to avoid inefficiency and waste of money.

A.1.1.4 Neighbouring cooperation

'Neighbouring cooperation' has been established by the Baltic Sea Initiative to adjust their import controls and is a good example of neighbouring cooperation in market surveillance. The agreement between Malta and the Netherlands where samples collected by the Maltese authority are tested in the Netherlands, is another example. Similar neighbouring programmes exist in Europe, i.e. Latvia and Lithuania, Poland and the Czech Republic.

A.1.1.5 Joint Actions

More formal and structural cooperation takes place in the 'Joint Actions' , funded by the European Commission (DG Sanco) under the framework of the GPSD. Under this programme, each Member State has the possibility to take the initiative to propose subjects for such Joint

Action which aim to promote and support cross-border market surveillance activities. Joint surveillance actions can be undertaken without co-financing from the Commission. Examples of such actions are those for soothers and soother holders, and luminaires.

A.1.1.6 PROSAFE Annual Plans collection programme

PROSAFE recently started the collection of all the annual plans of the Member States and connected countries, with the aim to set up an inventory of such plans and discuss the overview in the PROSAFE meetings and workshops. In the planning stage of their programmes countries should be transparent to their colleagues and make contributions to an Annual Plan Adjusting Programme that PROSAFE is developing.

A.1.1.7 Cooperation in development and improvement

Non-food consumer products are globally traded goods and in most cases produced, distributed or sold by many different companies. Those companies very often work in different countries in parallel and therefore have contact with several market surveillance authorities.

Because of the free market policy on the one hand and the professional image of market surveillance authorities on the other hand, interpretation of test results or risk estimations have to be consistent. Therefore, market surveillance authorities should cooperate in the development and use of risk assessment instruments (e.g. the RAPEX risk assessment model).

The Rapid Advice Forum of PROSAFE has been established to enable market surveillance authorities to consult experts from other countries to check their own opinion and outcomes of their risk assessment process. This should be made use of whenever a potentially hazardous product is identified or a potential new risk has been found.

A.1.1.8 Worldwide networks

Every year, market surveillance authorities from Europe, united in PROSAFE, meet colleagues from USA and Canada (ICPSC / ICPHSO). Guided by a common agenda, they share information and developments in production, products, politics etc. related to market surveillance.

A.1.1.9 Exchange of experts

The exchange of market surveillance officers is the latest form of cooperation. By sending people to other countries to help and to learn, market surveillance authorities work not only on the improvement of the procedures and structures, but also on the motivation and expertise of their officers. The European Commission (DG Sanco) stimulates the exchange of experts with coordination and funding.

A.2 The Cigarette-lighters Project

This annex will present an overview of the joint action for lighters as well as the best practices that will be or have been applied in the action.

A.2.1 Joint action on cigarette lighters – an overview

The action was proposed according to the 'Procedure for the awarding of financial contributions to specific joint surveillance and enforcement actions in the area of consumer product safety (non-food)' and is entitled 'Joint market surveillance Action on Child-Resistant Lighters and Novelty Lighters.'

The objectives of the project are to ensure that lighters placed on the EU market are safe and to gather experience related to best practice techniques with running a joint market surveillance action. The action marks a continuation of the activities that have taken place since 2005 in the so-called Working Group for lighters; a group that includes representatives from the Commission and the Member States as well as stakeholders (industry and consumer representatives).

The action is planned to run from September 2007 to December 2009 and involves 13 Member State authorities in the financial scheme plus a number of authorities outside the financial scheme. It will comprise safety tests of some 150 lighter models plus tests of the child-resistance of another four. The application was sent in by PROSAFE and the action will be coordinated by PROSAFE. The involvement of the Member States is foreseen to be around 2,000 working days. The activities in the Member States will comprise market surveillance authorities as well as customs authorities.

The progress in the project will be monitored in four indicators:

- The share of non-compliant lighters that are found on the European market.
- The share of non-compliant lighters that are imported to Europe.
- The share of non-compliant lighters that are produced in Europe.
- The share of shops that market novelty lighters.

The ambition of the project is to achieve a level below 2% for each indicator at the end of the project.

Regular contacts with industry and consumer organisations are foreseen. They might be scheduled via open parts of the project group meetings or via a continuation of the core group for lighters. Their meetings will be combined with project group meetings.

A.2.2 Best practice techniques applied in the action

Although the action is still ongoing, a number of best practices have already been applied in the project, including the following 6:

1. The action has common, ambitious objectives

From the start, four objectives were defined to 'shape' the ambition in the action. The objectives were ambitious, e.g. 'More than 98% of the lighters on the market in 2008 should comply with the safety requirement'.

The advantage of setting up such objectives was that they helped define the project and the activities, e.g. the necessary number of samples to be taken.

When finalising the application, the participants however found that it would be premature to state the objective too firmly. Therefore, the objectives were changed a bit; the indicators were kept, i.e. the number of lighters that comply with the decision is still traced but it is no longer an objective to reach a level of 98%. It is rather the 'ambition' of the action to achieve such a level.

2. Coordinated sampling plans

The project uses a coordinated sampling plan with common criteria for sampling for all participants. This means that the share of consignments that should be checked is the same in all Member States, the visits to the importers are coordinated at European level and the inspections in the entry points as well.

Furthermore, there will be an exchange of identification on sampled products. The idea is to coordinate the testing and to find out if it is also possible to exchange test results and use them in the follow-up in the different Member States.

It has turned out that those two issues encounter legal obstacles. Some Member States are obliged to observe very strict confidentiality, meaning that information on products under investigation can not be disclosed. Other Member States can only use test results of their own if a case ends up in court. Both questions will be explored further in the project.

3. Involvement of industry

The Commission has involved industry and consumer representatives from the beginning of the activities. The project foresees to continue this involvement as industry has the knowledge of the product, the market, the pitfalls, the risks etc.

It is of course an issue when to involve industry and when not to, because industry will have a different perspective to the activities than Member States, and Member States might want to have introductory discussions of various topics without the involvement of industry. This balance has however been maintained quite well in the working group for lighters.

4. The coordination function

The coordination in itself also seems to represent a step forward in European cooperation as it has meant that common procedures and tools have been developed to a much larger extent than in most other joint actions. In this way the action truly utilises the fact that lighters are produced overseas, are imported by rather few big European importers, and sold Europe-wide.

The tools developed include inventories with pictures that for instance are intended to help Member State authorities decide whether a given lighter design is a novelty lighter or not.

The coordination is also more comprehensive as it includes cooperation between market surveillance authorities and customs in more Member States, the European Commission and industry representatives.

The main challenge in this coordination is to find the balance between one coordinated approach and the procedures in the individual Member States; differences that are caused by tradition and differences in legislation.

5. The Rapid Advice Forum

The participating Member States have come across a lot of problems where the Rapid Advice Forum has proven useful and the procedures of the forum have been developed further to suit the needs of the joint action.

The main topic for discussion among Member States is which lighter designs are to be recognised as novelty lighters. Usually, the problem arises because a Member State authority comes across a new lighter design that is not in the inventory of novelty lighters. What happens now is that the market surveillance officers take a digital photo, attaches it to a mail and sends it to the other colleagues in the project group. They state their opinion (novelty or not novelty) in a few days which means that the officer can continue his procedures knowing the assessment of his colleagues.

Afterwards, the coordinator will enter the new design in the inventory of novelty lighters. The inventory will end up in the public part of the web site set up within the framework of EMARS project (http://prosafe.project.webexworkspace.com/) once it is approved by the participants in the joint action.

6. Joint testing
It has also been decided to do the testing jointly in the action. Therefore, a call for tender was issued to a number of European laboratories and two laboratories have been selected.

The coordination of the testing is presently done in such a way that a number of deadlines have been set over the course of the project when lighters must be submitted to the laboratory. In this way, Member States know beforehand when to have samples ready for testing.

The test reports are uploaded to a database that is established on the Webex system to allow all participants to make use of them.

A.3 The LVD-ADCO Projects (Luminaires and extension cords)

A.3.1 Cross-border market surveillance actions in the area of the Low Voltage Directive

In reaction to a growing realisation that cross-border cooperation in market surveillance of the LVD is becoming more and more a necessity, LVD AdCo initiated a first cross-border market surveillance action, to be performed in 2006.

The purposes of this action were:
- To gain experiences with cross-border market surveillance;
- to exchange information on market surveillance practices in the Member States in the area of the LVD;
- to collect information on the differences and similarities between the participating Member States with respect to the effects of differences in their market surveillance practice;
- identify obstacles that hinder cross-border market surveillance; and
- to raise the profile of market surveillance in the field of the LVD in the minds of consumer organisations and industry.

Within the context of this specific project the secondary goal was law enforcement in the cross-border setting.

A.3.1.1 Cross-border action luminaires – overview

Point of departure in designing the action was the desire to involve as many Member States as possible. To make participation as easy as possible:
- Member States were explicitly allowed to organise and manage their share in the action according to the procedures applicable for their organisation.
- Coordination and support was provided where needed.
- The action was designed such that Member States with only moderate means and infrastructure at their disposal could also participate. Thus the subject of the action was the category luminaires, for which a purposeful action could be designed using simple and inexpensive tests.

Coordination
The responsibility for the design and coordination of the cross-border action on luminaires was assigned to one of the Member States by LVD-AdCo, to be supported by a task force consisting of representatives of a number of the participating Member States. Besides assuring representation of the participants in the design and management of the action, the task force agreed to back up and help the project coordinator in refining the project description and development of the test programme, sampling requirements, organisation of information exchange, and compiling a practical project guide for inspectors and laboratories and a question and answer sheet. In addition, the task force was required to support the project coordinator in the practical coordination required during the execution of the project.

Participation
Market surveillance authorities of 15 Member States participated in the luminaire cross-border action. Two participants depended on other participants for testing; three of the participants were willing to assist in the measurements for these participants. Five of the 15 participants belonged to the so-called 'New Member States' and two were EFTA partners.

A.3.2 Best practice techniques applied in this action

Best practices were not an important concern in this first LVD cross-border action, though the design of the action incorporated several aspects that can be considered best practices such as the following seven examples:

1. Risk based selection of luminaires as the subject for the cross-border action
Although the primary objective was to select a product group which could be inspected and tested simply and inexpensively, the risk presented by the product group was the most important secondary consideration. Luminaires were chosen for the following reasons:
- Luminaires are the subject of many RAPEX notifications in the LVD field. Also luminaires often figure in safeguard clause procedures under Article 9 of the LVD.
- Previous experiences in several Member States indicated high levels of non-compliance.
- Non-compliances reported in RAPEX notifications and by Member States frequently concern serious safety shortcomings, possibly leading to risk of electric shock and fire hazards.
- Accident and fire statistics were studied, but regrettably no clear data linking these hazards to luminaires could be identified.

2. Clear definition of the scope of the project
The scope of the action was limited to a subset of the luminaires standardised in EN 60598. Restricting the scope to a subset of this standard avoids a multitude of test programmes for different varieties of luminaires. Excluded were for example luminaires with fluorescent tubes and low-voltage luminaires with transformers.

Restriction of the scope allowed a standard testing programme for all samples which is more cost-effective per sample.

In order to facilitate the field officers to select the proper samples clear instructions on what to sample were issued, including instruction on how to administrate and evaluate administrative shortcomings.

3. Risk-based definition of the test programme
Compliance was tested against a restricted set of requirements from EN 60598. The requirements to be tested were selected on the base of the risks they addressed, so that all tests performed had direct bearing on the safety. Hazards addressed included the risk of electric shock, fire hazard and mechanical risks of injury. In effect, the tests performed comprised amongst others requirements for cord anchorage, earthing, cross-diameter conductors and insulation.

4. Selection of businesses for inspection and sampling
Inspections were to be aimed at EU importers and manufacturers and Member States were asked to take sales volumes into account. For that purpose a preliminary market analysis was scheduled in which the participating authorities were asked to identify the importers and manufacturers of luminaires and estimate their relative sales volumes. Inspections and sampling were requested to be performed proportional to sales volumes on the premise that cleaning up large volumes contributes more to consumer safety than measures against luminaires that hardly sell. Since the action was planned as enforcement, inspectors were instructed to select samples suspected of non-compliances.

5. Checklists and guide on how to sample and evaluate the conformity of samples
To assure uniformity of sampling with the project scope, of laboratory testing and of compliance evaluation guides for the field inspectors and laboratories were made available, describing what and how to sample; how to perform laboratory testing and how to evaluate the conformity of samples. Electronic data-entry sheets, functioning as checklist were also made available.

6. Information exchange
A mechanism for the exchange of information was set up using the CIRCA system. The system was meant to assure the timely exchange of information about samples and businesses inspected by the participants, in order to avoid double sampling and testing of identical luminaires, as well as a means for collecting the results of the action for reporting purposes. The system used provided for unique codification of the samples taken and was to make available pictures of the samples taken to the field inspectors.

7. Uniform codification of shortcomings
To assure uniform evaluation of the shortcomings found use was made of the Nordic Failure Code List. The list classifies specific shortcomings frequently found in electrical equipment in three categories of increasing severity (F1, F2, F3).

A.3.2.1 Summary of results of the cross-border action on luminaires

In the luminaires action the compliance of 226 luminaires against the administrative requirements of the LVD and against a number of requirements from the applicable standard were checked. Only 11 of the investigated luminaires showed no shortcomings at all. Products with only administrative shortcomings (CE-marking, DOC and TCF) were found 53 times, while 162 luminaires showed technical shortcomings.

More detailed results can be found in the final report on the luminaires action: http://ec.europa.eu/consumers/safety/projects/docs/report_international_cord_extension_en.pdf.

This report also discusses extensively the difficulties encountered in applying some of the practices requested in the project:

- The working methods and/or organisation of some participants did not always allow premarket orientation. Some Member States also reported that they do not usually sample at importers/producers.
- The information exchange mechanism did not function as intended which meant that inspections and sampling generally took place without awareness of what other authorities had already done.
- Although use of the Nordic Failure Code List indeed resulted in largely coherent classification of the shortcomings found during the action, agreement on classification did not always extend to the resulting legal measures taken. One reason is that legal follow-up after a specific shortcoming has been codified in the quality manuals used by the market surveillance authority in several Member States.

A.3.3 Joint action on multiple outlet cord extension sets – overview.

Grant under the joint action programme

The luminaire action was followed by a cross-border action on multiple outlet extension cords which took place during 2007. This cross-border action on extension cords

was partly financed by the European Commission under the joint action programme. The project application for the extension cord project was formally submitted by the Netherlands and included 15 participating Member States that applied for financial support from the Commission. Participating without being partner in the grant agreement for the action were five Member States/EFTA countries, bringing the total number of participants to 20.

Organisation and coordination
The general organisation and setup of this cross-border action closely resembled that of the luminaires action. Coordination and management were the responsibility of one of the Member States (Austria), supported by a task force consisting of seven representatives of the participants. Information exchange and data collection used the same CIRCA based system previously developed for the luminaire action.

Project design and development were largely comparable with the design and development of the luminaire project, except for increased complexity of this project and a few important differences in approach:

- Because there are four different system for plugs and sockets in use within the European union, each with corresponding national standards, comparable safety shortcomings in all the systems had to report and had to be coupled to comparable requirements in the standards for the different systems.
- The action aimed at obtaining a reliable estimate of the compliance levels in the market by prescribing quasi-random sampling.
- Instead of a restricted set of requirements, the action prescribed an almost complete conformity assessment, testing many of the standard requirements (22 test parameters).

The other best practices used in the luminaire action were also applied in the extension cord action, including risk-based selection of extension cords as the subject of the action, definition of a clear scope of the action, use of the Nordic Failure Code List and instruction on how to sample and collect and exchange data via the Circa system.

A.3.3.1 Summary of results of the cross-border action on extension cords

In the extension cords action a total of 209 extension cords were investigated by 20 participants. Since this action aimed to obtain reliable estimates of the observance levels, the results may be taken as indicative of the compliance levels of products in this market.

From the results it appears that a large proportion of the companies active in this market do not comply with the administrative requirements: for 74% of the samples tested CE-marking (13%), Declaration of Conformity (54%) or technical file (74%) were lacking.

The most frequent technical deficiencies were wrong shape and dimensions of plugs and sockets (43%), poor construction of the cord – i.e. inadequate insulation material (26%), and insufficient protection against electric shock (21%). Less frequent technical shortcomings were dielectric strength and material properties (resistance to ageing, temperature and fire) which did not meet the requirements in less than 10% of the cases. The report on the extension cord action can be found at CIRCA:

http://circa.europa.eu/Members/irc/enterprise/esg/library?l=/meetings_workshops/adco_meetings/administrative_2008-03-0/08-04doc_atpdfpdf/_EN_1.0_&a=d.

The clear conclusion drawn from this action was that compliance levels of extension cords are disappointingly low, leading to the recommendation to repeat the action in due time in a slightly trimmed form.

A.3.4 Cross-border market surveillance in the LVD area – ongoing developments

The cross-border market surveillance actions on luminaires and extension cords have produced a wealth of experiences about the organisation and running of cross-border reactions which LVD-AdCo intends to capitalise upon. The actions revealed a number of bottlenecks and obstacles which hinder the development of multinational market surveillance in the area of the LVD, but also showed that cross-border actions can be organised successfully. To further develop cross-border market surveillance in the area of the LVD several recommendations to LVD AdCo were extracted from the experiences:

- LVD AdCo was recommended to organise cross-border market surveillance campaigns regularly, at least once a year;
- LVD ADCO was recommended to stimulate small-scale co-operation between interested Member States by collecting the annual activity plans of its members, making them available to its members and encourage bi- or multilateral local co-operation;
- LVD ADCO was advised to set up a working group in order to investigate the possibilities for harmonizing the relation between the risk classification of common shortcomings found in electrical products under the LVD and the interventions the authorities decide upon; and
- LVD ADCO was recommended to investigate the requirements for an improved information exchange system to facilitate cross-border actions.

Currently LVD ADCO has acted on all these recommendations. Small working groups address the harmonisation of the relation between specific non-compliances and interventions and the need for better information exchange. New cross-border actions are scheduled (i.e. for lighting chains and sun beds) and the possibilities for small-scale cooperation are investigated in cooperation with the EMARS initiatives in that area.

A.4 The Playground equipment Project

The Polish authority OCCP (office of competition and consumer products) operates this project. The project start-up meeting was held in Warsaw in October 2007. The main objectives are to develop guidelines for economical operators and users of playground equipment. EMARS WP 3 is cooperating with the project in order to achieve feedback related to the Book. In the project start-up meeting the ideas of cooperation were presented. This will be followed up by a closer coordination with Chapters 4 to 7 in the Book.

The joint project 'safe play in the playground', initiated by the Polish OCCP (office for competition and consumer product), started in autumn 2007. This project was funded by the Commission under GPSD art. 10, and involves eight countries.

The deliverables of this project are twofold:

1. Inspectors' handbook for inspection of playgrounds.
2. Information to parents, operators and producers of safety of playground equipment by means of leaflets and brochures.

The playground handbook is based on the Belgian guide for inspection of playgrounds. This part of the handbook deals with technical aspects related to playground equipment.

The different stages of inspection programmes in playgrounds have links to this Book on best practice techniques. Chapters 6 to 9 of this Book, dealing with the planning stage, implementation, reporting, analyzing and information have been used as guide for writing the different chapters in the playground handbook and resulted in a practical approach for the performance of actions.

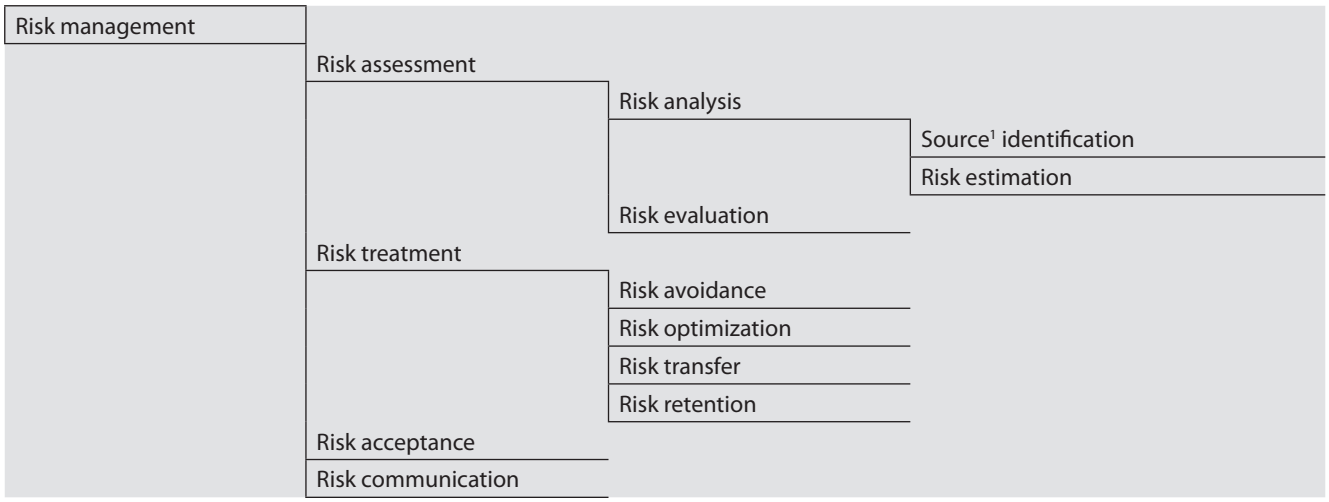
The contents of this Book have shown to be useful for both developing the guidelines for inspection and for the information actions that will be carried out at the end of the project.

ANNEX B – DIFFERENT FRAMEWORKS OF RISK ASSESSMENT

It may be confusing that at least two different risk assessment frameworks are used, each with its own definitions. One is common in engineering and accident prevention, in particular the framework adopted by ISO for the safety of machines (ISO 12100) and for product safety in general. Another is used for food and feed safety (adopted by the WHO and FAO), and for chemical safety (WHO IPCS, TGD). As RAPEX notifications may involve both physical hazards and chemical substances, market surveillance authorities may encounter both frameworks. In this annex, we briefly explain the differences between these two frameworks.

Schemes of the risk assessment process

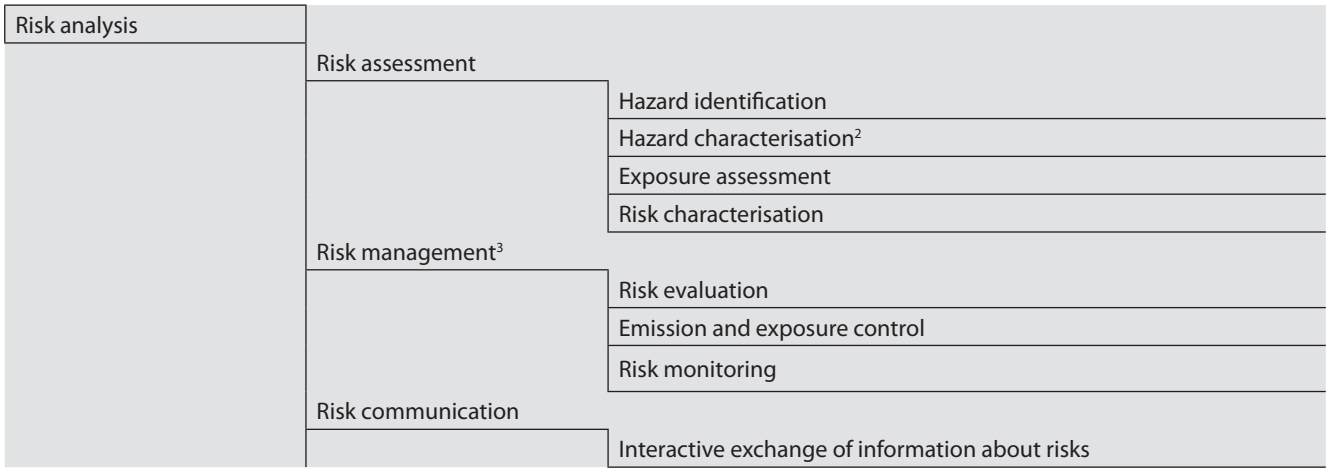
A. ISO 12100, ISO/IEC Guide 51 and ISO Guide 73



[1] In Guide 51, the term 'hazard' is used, defined as a potential source of harm.

The most general term here is 'Risk management' which consists of the elements 'Risk assessment', 'Risk treatment', 'Risk acceptance' and 'Risk communication'. Within 'Risk assessment' in turn two steps are distinguished: 'Risk analysis' and 'Risk evaluation' etc.

B. IPCS Risk assessment Terminology, Key Generic Terms used in Chemical Hazard/Risk Assessment; WHO/FAO framework for risk analysis in food; EU Technical Guidance document on Risk Assessment (TGD)



[2] Includes dose-response assessment; TGD uses 'effects assessment' as an overall term for hazard identification and dose-response assessment.

[3] WHO/FAO have four components here: preliminary risk management activities; evaluation of risk management options; implementation of risk management decision; monitoring and review.

Here, the general term is 'Risk analysis' consisting of the activities 'Risk assessment', 'Risk management' and 'Risk communication' etc.

Due to the different ways of dividing the process, it is not possible to simply make a correlation table to translate terms. For example, the ISO/IEC term *risk estimation*

is more or less a combination of *hazard characterisation* and *exposure assessment*. *Risk evaluation* in the ISO/IEC framework can be compared with *risk characterisation* combined with *risk evaluation* in the IPCS terminology.

The following definitions are used in the IPCS document:

Risk
The probability of an adverse effect in an organism caused under specified circumstances by exposure to an agent.

Agent
A chemical substance which may cause adverse effects such as injury or damage to health.
NOTE: In this definition, we extend the meaning of 'agent' from chemical substance to include physical hazards.

Risk assessment
A process intended to calculate or estimate the risk to a given target organism, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target organism.

The risk assessment process includes four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Hazard identification
The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system or (sub)population.

NOTE: The result of this step should be a number of scenarios that may occur including the health outcomes (endpoints).

Hazard characterisation
The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.

NOTE: The result of this step should be a justified conclusion about the severity of the adverse effects. The tool used for this in the RAPEX Guidelines is the injury table.

Exposure assessment
Evaluation of the exposure of an organism, system or (sub)population to an agent.

NOTE: General relevant parameters are frequency of contact with the product, exposure pathways and behaviour of person and vulnerability of person.

For chemical substances, exposure is usually expressed as mg substance per kg body weight that is taken up by inhalation, dermal contact or ingestion; specific parameters include evaporation or diffusion.

For physical hazards, relevant parameters can be the probability that a scenario will occur, energy transferred to a body part etc.

Risk characterisation
The qualitative and, wherever possible, quantitative determination, including attendant uncertainties of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions.

NOTE: The result of this phase is a conclusion on the expected risk level in terms of severity and probability. It may include a quantitative probability distribution of adverse effects and confidence intervals or sensitivity analysis.

ANNEX C – RISK ASSESSMENT EXAMPLES

C.1 Hammer (case taken from RAPEX notification number 0125/06)

C.1.1 Identification of product and case, description of the context

This case deals with a cross pane hammer with metal handle and black plastic grip. The hammer head is insufficiently fastened to the handle and the plastic grip breaks under normal strain.

C.1.2 Description of the hazards

The hammer has three dangerous shortcomings:

1. The hammer head is insufficiently fastened to the handle.
2. The plastic grip breaks under normal strain.
3. The hammer head is made of brittle material with insufficient dynamic impact strength.

All hazards may result in parts breaking off hitting the user or a bystander.

Table 7: Table of injury scenarios and associated risk levels for the hammer case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Defect: material of hammer head. Parts of head fly off when person uses hammer and hits hard surface. Part flies into eye.	Foreign body in eye, blindness in 1 eye	3	• Breaking: 1/10 (p = 0.1) • Hitting person: 1/10 (p = 0.1) • Hitting head: 1/3 (p = 0.33) • Hitting eye: 1/20 (p = 0.05)	1/6,000 (p = 0.0001667)	High risk
Defect: material of hammer head. Parts of head fly off when person uses hammer and hits hard surface. Large part hits head.	Fracture of nose or teeth, contusions	1	• Breaking: 1/10 (p = 0.1) • Hitting person: 1/10 (p = 0.1) • Hitting head: 1/3 (p = 0.33)	1/300 (p = 0.0033)	Low risk
Defect: material of hammer head. Parts of head fly off when person uses hammer and hits hard surface. Large part hits hand, foot or other body part.	Contusion of hand, finger etc.	1	• Breaking: 1/10 (p = 0.1) • Hitting person: 1/10 (p = 0.1) • Hitting body parts: 2/3 (p = 0.66)	1/150 (p = 0.0066)	Low risk
Defect: grip slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby).	Concussion < 1 hour	2	• Grip sliding off: 1/5 (p = 0.2) • Person nearby: 1/10 (p = 0.1) • Hitting person: 1/100 (p = 0.01) • Hitting head: 1/10 (p = 0.1)	1/50,000 (p = 0.00002)	Low risk
Defect: grip slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby).	Broken nose or teeth	1	• Grip sliding off: 1/5 (p = 0.2) • Person nearby: 1/10 (p = 0.1) • Hitting person: 1/100 (p = 0.01) • Hitting head: 1/10 (p = 0.1)	1/50,000 (p = 0.00002)	Low risk
Defect: grip slides off shaft. Hammer flies off when person swings hammer and hits body part of user or other person.	Contusion of hand, finger etc.	1	• Grip sliding off: 1/5 (p = 0.2) • Person nearby: 1/10 (p = 0.1) • Hitting person: 1/100 (p = 0.01)	1/5,000 (p = 0.0002)	Low risk
Defect: grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.	Contusion of arm	1	• Handle breaking: 1/2 (p = 0.5) • Hitting arm: 1/5 (p = 0.2)	1/10 (p = 0.1)	Significant risk

C.1.3 Description of injury scenarios and probability

A sensitivity analysis has not been carried out. However, the probability of the first injury scenario (which has the highest risk level) can be a factor of 6 higher before the risk changes to 'serious risk'. All other scenarios will not reach the 'serious risk' level with reasonable assumptions for the probability.

C.1.4 Conclusion

The result of this analysis is that one scenario has the outcome 'high risk' (which happens to be the most serious outcome). Five scenarios result in 'low risk' and the last one ends in 'significant risk'.

The overall outcome of the analysis it that the risk is high, i.e. action against the product should be taken, but there is no need for a rapid intervention and RAPEX notifications.

C.2 Rubber luggage straps (assessment initialised by an accident)

C.2.1 Identification of product and case, description of the context

This case deals with a rubber luggage strap with metal hooks on both ends. The strap is used for tying luggage to bicycles, motorcycles or to the roof of a car.
The case is provided by VWA in the Netherlands. In the Netherlands some 30 accidents are reported each year. Half of them result in eye injuries of which 50% result in permanent injury. There are even a few cases of lost eyes and blindness on one eye.

Figure 27: Rubber strap used for tying luggage to motorcycles or cars.

C.2.2 Description of the hazards

The hooks at both ends of the strap are of poor quality: the hooks bend open if the tension exceeds a certain level resulting in hitting the user with high force. The most severe injury will occur if the hook at the opposite end of the strap bends open.

(Outside the scope of this scenario: a number of accidents happen when the user attaches the hooks poorly, so that the hook comes loose while tightening the strap.)

C.2.3 Description of injury scenarios and probability

One injury scenario has been developed based on a case found in an article in a medical journal.

The estimate of the probability that a hook at the end of a strap will open carries the highest uncertainty in the calculation. If the resulting probability increases to 1/10,000 (a factor of 6) then the risk level increases to 'high risk'.

C.2.4 Conclusion

The result of the analysis is that the risk level is 'significant risk'.

A special problem arises because the probability of an accident might be low but the number of products is high. In the actual case, a low probability is 'multiplied' by a serious consequence and the result is a low risk. Still the fact is that the big number of products implies that there are quite a few injuries every year. These should be taken into account when deciding on the appropriate risk management measures.

Table 8: Most severe injury scenario and associated risk level for the rubber strap case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Person tries to fix luggage while standing in the line of the strap; hook on other end opens and hits person in the eye.	Permanent low vision in one eye	3	Person standing in line: 1/2 (p = 0.5) Hook opening: 1/100 (p = 0.01) Hitting head: 1/3 (p = 0.33) Hitting eye: 1/20 (p = 0.05) Eye injury: 1/5 (p = 0.2)	1/60,000 (p = 0.0000165)	Significant risk

C.3 Socket protectors

C.3.1 Identification of product and case, description of the context

This case deals with socket protectors – devices that users (parents) put on the electrical socket outlets. The

Figure 28: Socket protector that prevents children from sticking pointy things into power outlets.

socket protectors should ensure that small children can not get an electric shock (possibly fatal) by accessing live parts by introducing long metal objects into the power outlet.

C.3.2 Description of the hazards

The holes in this protector (where the pins of the plug go through) are so narrow that the pins might get stuck.

C.3.3 Description of injury scenarios and probability

There is the risk that the user will pull the protector of the outlet when the plug is pulled out. If the user does not notice this happening (or does not replace the protector), the outlet is not secured. Therefore, the product will not provide the protection that the parents rely on.

The outcomes of the analyses were one scenario resulting in 'serious risk' and one in 'low risk'. The calculations are based on an estimated probability that the protector can be removed unintendedly over the lifetime of the product of 90%. A sensitivity analysis revealed that only if this probability is less than 0.1%, the outcome would change to 'significant risk'.

Some homes have residual current breakers that will interrupt the power if a person touches the live wire. This is included in the analyses as an extra factor in the calculation of the probability in the three scenarios. It does not affect the outcome.

For comparison, we have made an analysis for an unprotected socket outlet. In this case, the parent does not expect protection and therefore it seems less likely that the child will be left unattended near the outlet.

Table 9: Table of injury scenarios and associated risk levels for the socket protector case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Protector is removed from the plug which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.	Electrocution	4	• removing of protector 9/10 (p = 0.9) • not noticing the removal of protector 1/10 (p = 0.1) • child is playing with thin conductible object 1/10 (p = 0.1) • child is unattended when playing 1/2 (p = 0.5) • child inserts the object into the socket 3/10 (p = 0.33) • access to voltage 1/2 (p = 0.5) • electrocution due to voltage (without circuit interrupter) 1/4 (p = 0.25)	27/160,000 (> 1/10,000 (p = 0.00017)	Serious risk
Protector is removed from the plug which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and sustains shock.	Burns 2nd degree	1	• removing of protector 9/10 (p = 0.9) • not noticing the removal of protector 1/10 (p = 0.1) • child is playing with thin conductible object 1/10 (p = 0.1) • child inserts the object into the socket 3/10 (p = 0.33) • access to voltage 1/2 (p = 0.5) • child is unattended when playing 1/2 (p = 0.5) • burn due to voltage (without circuit interrupter) 3/4 (p = 0.75)	81/160,000 (> 1/10,000) (p = 0.0005)	Low risk

Table 10: The injury scenario and associated risk level for an unprotected socket outlet.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Socket unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.	Electrocution	4	• child is playing with thin conductible object 1/10 (p = 0.1) • child is unattended when playing 1/100 (p = 0.01) • child inserts the object into the socket 3/10 (p = 0.33) • access to voltage 1/2 (p = 0.5) • electrocution due to voltage (without circuit interrupter) 1/4 (p = 0.25)	3/80,000 (> 1/100,000) (p = 0.0000375)	High risk

C.3.4 Conclusion

The product in itself is not dangerous. The risk arises because the product tempts the users to change their habits because they rely on the protective properties of the product.

The overall outcome of the analysis it that the risk is serious, i.e. rapid action against the product should be taken.

C.4 Bathing mattresses

C.4.1 Identification of product and case, description of the context

This case deals with a type of bathing mattress, an inflatable airbed for seaside and pools made from PVC.

C.4.2 Description of the hazards

The PVC contains a plasticiser: a substance to make the plastic flexible. In this case, the substance is bis(2 ethylhexyl)phthalate (DEHP). DEHP and other phthalates are classified in Annex I to Directive 67/548/EEC as a dangerous substance because of reproductive toxicity – Category 2 'Suspected human reproductive toxicant'; the packaging of this substance needs to carry the warning sentences R60-61 'R60: May impair fertility' and 'R61: May cause harm to the unborn child'.

Figure 29: Bathing mattress that emits phthalates.

C.4.3 Description of injury scenarios and probability

In order to assess the risk of this particular product, we need to know if DEHP can migrate out of the plastic and how much human exposure would take place. The first part of such a risk assessment is similar to the physical examples: describing one or more scenarios. After that, the probability is dealt with in a different way. We do not estimate how probable the scenario is, but how much of the substance the person is likely to get into his body. This can be done using (measured or estimated) data on release, transfer and absorption.

Table 11: Table of injury scenarios and associated risk levels for the bathing mattress case.

Injury scenarios	Injury type and location	Severity of injuries	Exposure parameters (Probability of injuries)	Resulting exposure (probability)	Risk
Use by a 5 year old boy. The DEHP present in the air mattress is released from the surface. The released amount of DEHP is transferred to the skin via direct physical contact and rubbing with the skin. The transferred amount of DEHP to the skin is absorbed.	Effects on reproduction	4	• Body weight: 16 kg • Release of DEHP: 7.4 µg/cm^2/h • Transfer to skin: all released DEHP gets on an area of skin of 1500 cm^2, during 2 h per day • Absorption of DEHP: 5%	104.6 µg/ kg$_{BW}$/day	Margin of safety insufficient, serious risk

The risk in chemical cases can not directly be derived from the risk table, because there is no probability class such as '>1/100.000'. Instead, we have a dose which is usually expressed in an amount per kg of body weight.

We then compare this dose with data on the levels that have been reported to produce the effect we mentioned under 'injury type'.

In this case, there are data on the highest tested level that did not produce the effect in rats: 4800 µg/kg_{BW}/day. Higher doses did give the effect of developmental toxicity. Toxicologists then say that the *No Observed Adverse Effect Level* (NOAEL) is 4800 µg/kg_{BW}/day.

The ratio between the NOAEL and the value calculated for the mattress is 4800/104.6 = 45.8. This ratio is called the Margin of Safety. A Margin of Safety of 45.8 is considered insufficient by toxicologists. It should be more than 100, because we need to take into account the differences in metabolism between rats and humans as well as between different persons (inter- and intra-species variability).

C.4.4 Conclusion

The Margin of Safety is not sufficient; therefore, the product poses a risk. Because the effect that may occur is in the highest category and the margin of safety is well below 100, we consider this a serious risk.

C.5 Toy with small parts

C.5.1 Identification of product and case, description of the context

This case deals with a push-along toy that was notified by Belgium in 2008 (RAPEX notification 0265/08).

Figure 30: A toy with detachable small parts.

C.5.2 Description of the hazards

According to the RAPEX notification the toy poses a serious risk of choking because the duck's beak can be detached at a force of 19 N (the requirement from EN 71-1 is 100 N). The detached part fits into the small parts cylinder.

C.5.3 Description of injury scenarios and probability

The outcome of the analysis is a scenario resulting in 'high risk'. The assumptions behind this calculation are:

- The beak is so poorly attached that it will sooner or later come off (all products in this batch affected);
- The child will be alone while playing with the toy in 50% of the cases when the beak detaches;
- It is considered to be normal behaviour for small children to examine objects by putting them in the mouth;
- It is assumed that the beak is so small that it does not get stuck in the larynx; only if it is aspired, it will cause (partial) blocking of the airways.

The resulting probability 1/2,000 falls in the category '> 1/10,000' but it is close to the category '> 1,000'. A sensitivity analysis revealed that using this category instead will change the outcome to 'serious risk'. Moreover, the severity could increase as well: depending on the shape, size and material of the beak, the part might cause complete blocking of the airways leading to permanent damage or death. Taking the uncertainties into account the result of the risk assessment is changed to 'serious risk'.

C.5.4 Conclusion

The overall outcome of the analysis it that the risk is serious, i.e. rapid action against the product should be taken.

Table 12: Injury scenario and associated risk level for the toy with a detachable small part.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
The child detaches the beak. The parents don't notice or don't react. The child puts the beak in his mouth. The small part goes into the child's airways and surgery is necessary.	Oxygen flows to brain blocked without permanent consequences	3	• Beak is detached 1/1 (p = 1) • Parents don't notice 1/2 (p = 0.5) • Child puts beak in mouth 1/1 (p = 1) • Beak gets in the child's airways 1/1,000 (p = 0.001)	1/2,000 (> 1/10,000) (p = 0.0005)	High risk

C.6 Candle

C.6.1 Identification of product and case, description of the context

Candles containing plant parts, e.g. sunflower seeds or coffee beans, have been reported to burn intensely with high flames. There have been at least two RAPEX recalls for candles in 2006: 0351/06 and 0563/06.

Figure 31: Candles containing plant parts may burn intensely with high flames and cause fires.

C.6.2 Description of the hazards

When the candle burns down melting the wax, the plant parts begin to float in the melted wax. At this stage the plant parts will heat up or get stuck to the wick which may cause the parts to catch fire. This fire will usually evolve rapidly, melt the rest of the candle and might put fire to the furniture where the candle is placed. If nobody is present at this stage this will most likely develop into a fire that can cause harm to people.

Another hazard is small plant parts easily detachable and fitting into the small parts cylinder. This will make them dangerous if small children swallow them.

C.6.3 Description of injury scenarios and probability

Several scenarios for these candles create a serious risk. A sensitivity analysis shows that these serious risk levels remain valid, even if the probability would be a factor 10 lower.

The uncertainty in this case is rather high because several steps in the scenarios depend on behaviour rather than physical parameters.

It is noted that fires often result in considerable damage to property, even when there are no people injured. This risk can not be estimated according to the standard RAPEX table. Instead, we have assumed for this assessment that a certain percentage of house fires leads to fatalities.

C.6.4 Conclusion

The overall outcome of the analysis is that the risk is serious.

Table 13: Table of injury scenarios and associated risk levels for the candle case.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Seeds or beans catch fire generating high flames. Person blows out flames and tries to move the candle. Hot wax flows over the hands of person.	Scalds on hands	1	• Seeds or beans catch fire: 9/10. (p = 0.9) • Person tries to move the candle: 1/4. (p = 0.25) • Hot wax flows over the hands: 3/4. (p = 0.75)	27/160 (> 1/10) (p = 0.16875)	Significant risk
Seeds or beans catch fire generating high flames. Person tries to extinguish flames by covering or pouring liquid. Flames reach the hands of person.	Burns on hands	1	• Seeds or beans catch fire: 9/10. (p = 0.9) • Person tries to extinguish flames: 9/10. (p = 0.9) • Flames reach hands: 1/20. (p = 0.05)	81/2000 (> 1/100) (p = 0.0405)	Significant risk
Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are not in room, but inhale toxic fumes.	Fatal poisoning	4	• Seeds or beans catch fire: 9/10. (p = 0.9) • People not in the room for some time: 1/3. (p = 0.33) • Furniture or curtains catch fire: 1/2 (depends on surface on which candle is placed) (p = 0.5) • Persons inhale toxic fumes: 1/20. (p = 0.05)	> 1/1,000 (p = 0.0075)	Serious risk
Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are in room and inhale toxic fumes.	Fatal poisoning	4	• Seeds or beans catch fire: 9/10. (p = 0.9) • Furniture or curtains catch fire: 1/2. (p = 0.5) • Persons are in room (e.g. sleeping): 1/100. (p = 0.01) • Persons inhale toxic fumes: 1/1. (p = 1)	> 1/1,000 (p = 0.045)	Serious risk
Seeds or beans catch fire generating high flames. Person sits close to the candle. Flames ignite hair or clothing of person.	Burns over large part of body, may include the head	3	• Seeds or beans catch fire: 9/10. (p = 0.9) • Person sits close to the candle: 1/1000. (p = 0.001) • Flames ignite hair or clothing of person: 1/1000. (p = 0.001)	< 1/1,000,000 (p = 0.0000009)	Low risk
Seeds or beans are attractive to children. Children pick them out of the candle, put them in mouth and it enters the trachea. Child is suffocated.	Suffocation	4	• Children pick seeds out of the candle: 1/10. (p = 0.1) • Seed put in mouth: 1/10. (p = 0.1) • Seed enters the trachea: 1/100. (p = 0.01) • Child is suffocated: 1/1 (p = 1)	> 1/10,000 (p = 0.0001)	Serious risk

ANNEX D – RISK COMMUNICATION

Risk Communication is recognised as an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties (FAO/WHO, 1997).

There are various reasons why risk communication is important. The European Economic Area (EEA) operates as a single market. Therefore, it is necessary that all its Member States harmonise actions that are taken with regard to dangerous products at national level. The objective of the GPSD and the New Approach Directives was to adopt a single set of rules applicable in all the Member States. Thus, action taken in one Member State to safeguard the health and safety of consumers can very well be adopted by the other Member States. This can only be achieved if there is a good communication infrastructure and network between the members.

Risk Communication is part of the Risk Analysis. Risk Analysis is the philosophy and the fundamental methodology underlying the development of legislation and product standards. It is composed of three separate but integrated elements: Risk Assessment, Risk Management and Risk Communication. Figure 33 introduces the WHO/FAO framework for risk analysis for food but the method may also be adopted in non-food product safety areas.

D.1 Fundamental Concepts

Following a proper 'Risk Assessment' (see Chapter 10) carried out by product safety experts in order to identify the risk level posed by a product, a strategy must be developed to identify the ways to eliminate or reduce the risk to an acceptable level. This is called 'Risk Management'. Managing the risk may consist of various kinds of actions depending on the outcome of the Risk Assessment (please refer to Part C of this Handbook). The final important step is to undertake an effective 'Risk Communication' to communicate the risk in the best possible manner and to reach all those who are exposed to the said risk. In order to control and minimise risks, all these steps have to be in place and interlinked.

Figure 32: The relationship between Risk Assessment, Risk Management & Risk Communication.

If the outcome of risk assessment is a low risk, authorities still have to impose corrective action but there is no need to implement a full blown information campaign or cause unwarranted alarm, although some information should still be communicated to consumers. Communication should rather consist of oral communication with the respective producers to reduce or eliminate the risk posed by a product.

On the other hand, if the outcome of risk assessment is a high risk, an immediate action has to be taken in order to eliminate the danger to consumers. First, it is necessary to identify who is in danger and to decide on the appropriate method of communication (refer to the following Figure 33):

The first column shows the origin of the risk identified. It is important to establish whether this risk has been identified through local inspections carried out by national market surveillance officers, in the EEA or by other organisations situated in other parts of the world such as the United States Consumer Product Safety Commission.

The second column, the risk identification column, shows the four different levels of risk, ranging from serious risk to low risk. In order to identify the risk level, an expert has to perform a systematic process called 'risk assessment' (refer to Chapter 10). This process should be repeated if the risk assessment process has been carried out by entities outside your territory, e.g. other Member State market surveillance authorities, to identify whether the risk is also applicable in your country. It is extremely important to categorise the risk associated with the product and to assess the exposure to the risk at local level. If the outcome of the risk assessment is high, it is obvious that immediate action has to be taken in order to eliminate or reduce the identified risk to an acceptable level. On the other hand, if the outcome is low, action may not be urgent but still must be taken.

After the risk identification process, it is necessary to assess the tools (column 3) available to communicate the risk with the entities involved (column 4), e.g. consumer segments at risk. A thorough analysis should be carried out in order to choose the best possible tool(s) to reach the target audience and to send them an accurate message. Such communication strategies can only be effective if they are planned carefully. Apart from reaching the target audience in the shortest possible time, choosing the best available tool(s) will also save costs for the authorities and affected businesses.

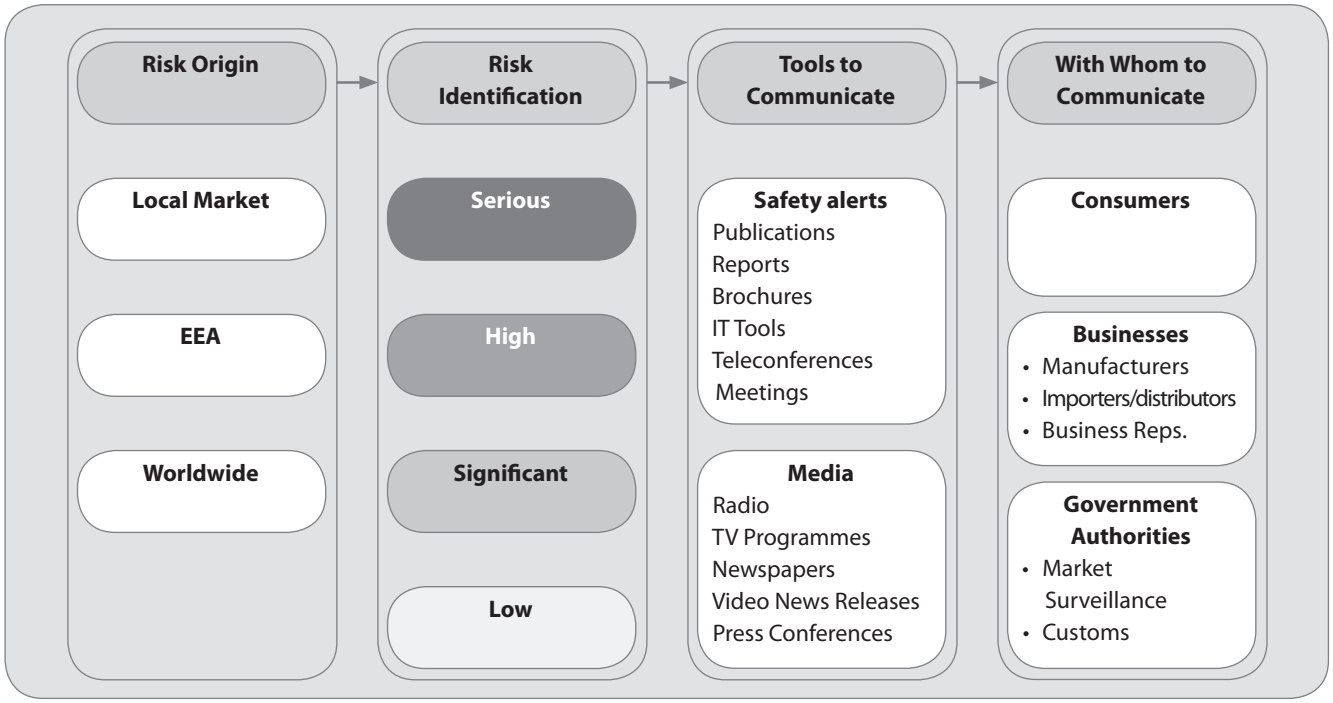


Figure 33: Risk Analysis and Risk Communication Steps.

The European Commission and the Member States are carrying out continuous research in order to improve the existing communication tools and to identify and develop new effective tools that will contribute to both faster and more efficient communication. The Internet is a valuable tool used for communication between Member States. Various IT systems have been created and are being used today. These can either be available to the public on the public domain such as the weekly RAPEX reports published by the European Commission on its website or they may be restricted to public officials within the Member States.

D.2 Communication in the field of product safety

In the field of product safety, communication is being carried out using the following methods:

- Regular meetings between the European Commission and the Member States
- IT Tools
- Media
- Reports
- Teleconferences
- Brochures

The use of the above mentioned methods of communication depends on the objectives of communication. For example, in case of a dangerous product posing a risk to the health and safety of consumers in a particular Member State, a rapid communication channel between all Member States is essential, so that they can take the necessary action to eliminate the risk or reduce it to an acceptable level.

The tools that are currently used for dissemination of information are the following:

- RAPEX
- Safeguard Clause Notification Procedure
- ICSMS
- CIRCA
- European Commission Website

Apart from the ICSMS system, all other systems are used by all the Member States and have their own objective and scope of application. Detailed descriptions of these systems can be found in Annex H.

D.3 How to inform consumers and media of dangerous products and instructions on how to react in order to avoid dangerous situations

If we work together in order to create the best market surveillance institutions with the best market surveillance officers having a brilliant and foolproof proactive market surveillance system, unsafe or non-conforming products would still be supplied to consumers. One has to keep in mind the considerable amount of products that are found on the European market and also the new importers who are not aware of the European legislation. This is the reason why the Market Surveillance organisations shall always have an effective readily available method so as to communicate with the people at risk when they encounter hazardous products. This may serve as a contingency plan.

Figure 34 on in the following page shows the strategy and methodology of a risk communication procedure. Reaching the target audience in the shortest possible time with clear objectives and instructions can save lives.

The first thing to tackle is to determine the importance of the information campaign, and whether this has to be carried out in order to recall a very hazardous product from the consumers or whether it is simply to obtain some information from the general public or a segment thereof.

Hence prior the communication strategy, there should be a clear objective why communication is necessary and clear goals have to be identified. The next step is to identify the kind of environment that the information will be introduced into and the target audience. In the field of product safety, the target audience of the market surveillance organisations can be either the Business sector (manufacturers/importers) or the consumers. The 'consumers' group can be subdivided into further segments (age group, class, lifestyle, gender or education) as shown in Figure 34.

Following the identification of the target audience, one must determine the most feasible and viable tool to communicate (please refer to Figure 32 Risk Analysis). Nowadays, there are various tools that offer effective and rapid communication throughout the entire spectrum and this depends on the particular situation and the target audience.

Prior to the communication step, it is important to identify any potential obstacles that may hinder the effectiveness of the communication. One must try to minimise these obstacles as much as possible. If there are doubts on the effectiveness of the method, the communication method may also be revised accordingly.

At this stage, the person communicating the risks with the target audience shall start anticipating any questions or possible reactions from the target audience and prepare the response beforehand. It is quite important to have technical officers that give complete, clear and reliable instructions when answering any questions from the target audience.

When all steps mentioned above have been tackled, communication has to take place. The effectiveness of the communication strategy can be assessed by various methods, for example, checking the feedback obtained from the target audience, the use of questionnaires / surveys or other methods.

The media is an important tool to be used when a dangerous product is distributed within the market. Before making the statements to the media, public officials have to be extremely careful. In order to effectively communicate, one has to establish clear communication goals and key messages. Once goals and messages have been established, the challenge becomes one of delivery and ensuring that messages are heard and goals are met.

The public should only be informed when one of the products encountered on the market poses a risk to the health of the consumer. The competent national authorities should take the immediate necessary actions to withdraw the product from the market and to order the distributor to recall the product from consumers. When the voluntary action is not immediately taken by the distributor/responsible person, the national authority should be responsible for withdrawing the product from the market and to issue the public statements in order to protect the health of the consumers.

When informing the general public the authority must consider that individuals, e.g. users of the product, might have further questions on the information given. Therefore, it is important to provide a contact person (or some other source) where such information can be obtained. One must also consider whether the number of reporting consumers will be higher than what one person can handle. It will rarely be the case provided that the information that is published is clear and sufficient.

Furthermore, the media will often want to follow up the case – especially when the hazard associated with the product is serious and obvious, if serious accidents have occurred, or if the product is widely in use. In such cases the contact person must be trained in contacts with the media or instructed how to handle a call from a journalist.

When communicating through the media the following have to be in place:

- Clear communication goals and key messages
- Information delivered with brevity, clarity, and effectiveness
- Accurate information

When issuing a press release, the officer should ensure that it has the following information:

- Contact details of the authority issuing the press release
- Contact person – head of unit
- Picture of the product
- Description of the product
- Model number and batch number
- The danger posed with the product without in-depth technicalities
- What to do with the product
- The contact details of the distributor or manufacturer

The individual or office sending a risk message or interacting with other individuals, groups or organisations in a risk communication process, may also be the risk manager, risk message preparer, risk analyst or other expert.

It is considered to be best practice that market surveillance officers working with the media get appropriate training. Courses are available through numerous commercial providers.

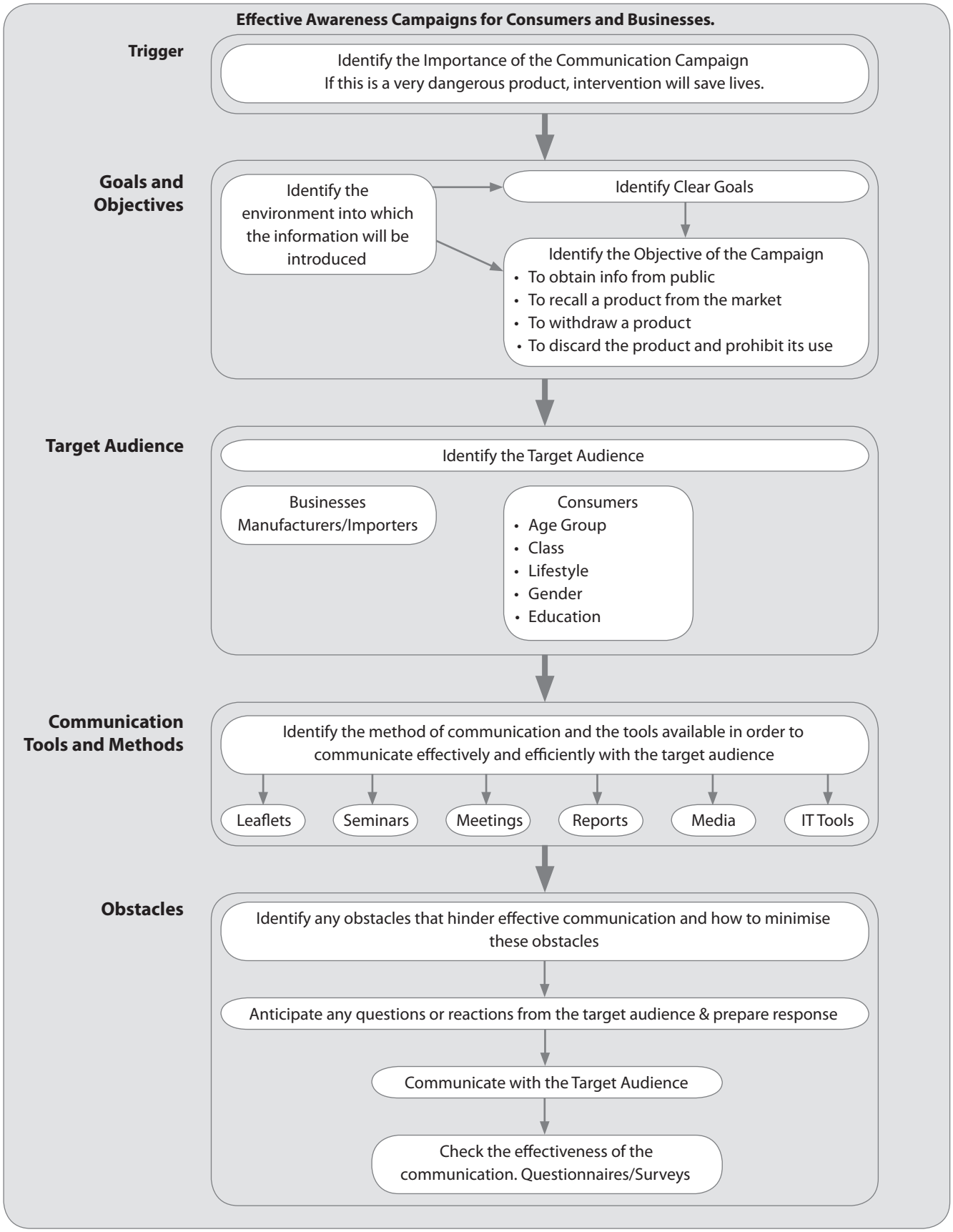


Figure 34: Effective awareness campaigns for consumers and businesses.

D.4 Additional practical ways of exchanging information on risk / product know-how

D.4.1 ADCO GROUPS

There are various Administrative Co-operation Groups (ADCO Groups) for the market surveillance of non-food products. These groups normally meet around twice a year and are normally composed of representatives of Member States' market surveillance authorities and were established to pursue the following objectives:

- to exchange information between Member States' authorities concerning the national market surveillance mechanisms and the adopted solutions;
- to achieve of a uniformly high level of enforcement of the relevant EU legislation;
- to reduce the overlapping of national surveillance operations;
- to diffuse good market surveillance practices; and
- to exchange views and solve practical problems.

These groups are chaired by different countries depending on who is elected for the position. In-house groups elections are conducted periodically in order to determine who will chair the meetings. The meetings are hosted in different Member States. The following are the existing ADCO groups according to the different directives;

- ATEX – Equipment to be used in explosive atmospheres
- Construction Products Directive
- Electromagnetic Compatibility Directive
- Toy Safety Directive
- Gas Appliances Directive
- Lifts Safety Directive
- Low Voltage Directive
- Machinery Directive
- Noise Emissions Directive
- Personal Protective Equipment Directive
- Pressurised Equipment Directive
- R&TTE (Radio & Telecommunications Terminal Equipment Directive)
- Recreational Craft Directive
- Medical Devices Expert Group

Those directives that do not yet have the ADCO group might have one in the future.

D.4.2 GPSD Committee and Network

The GPSD (GPSD) Committee is composed of the representatives of the Member States to the Committee created under Article 15 of the Directive 2001/95/EC of 3 December 2001 on general product safety. The objective of the Committee is to assist the Commission in the implementation and practical application of the Directive.
The GPSD Network is composed of the contact authorities in the Member States for the Network created under Article 10 of the Directive. The objective of the Network is to facilitate improved collaboration at operational level on market surveillance and other enforcement activities, in particular risk assessment, testing of products, exchange of expertise and scientific knowledge, execution of joint surveillance projects and tracing, withdrawing or recalling dangerous products.

D.4.3 PROSAFE – EMARS PROJECT

PROSAFE (the Product Safety Enforcement Forum of Europe) is an organisation established entirely by enforcement officers throughout Europe who deal with the safety of consumer products. The first formal meeting of the group was in 1990. Since that time, most EU Member States and EFTA (the European Free Trade Association) countries have been represented at meetings. The background of PROSAFE was a common recognition of the need to build links in operational understanding and trust between enforcement officials charged with the task of working together to enforce community law.

PROSAFE coordinates the project EMARS, 'Enhancing market surveillance through best practice' with financial support of the European Commission. The project aims to ensure a basic level of expertise and practical experience in most of the market surveillance organisations of Member States within the EEA.

This project has established a couple of tools for exchanging information between market surveillance officials. Further details on these systems can be found in H.2.4.

ANNEX E – THEORY ON TARGETING OF MARKET SURVEILLANCE

In this Annex the results of studies performed by the Law Enforcement Expertise Centre of the Dutch Ministry of Justice ('Table of Eleven'[1]) on the targeting of market surveillance are presented for reference.

The target group for the Table of Eleven included policy makers, jurists drafting legislation and enforcers for whom much of what is discussed is directly beneficial in helping them do their job.

1 Law Enforcement: Expertise Centre of the Dutch Ministry of Justice: The 'Table of Eleven' A versatile tool, November 2004: http://www.justitie.nl/images/English%20version%20versatile%20tool%20oct2006_tcm34-9098.pdf

The Table of Eleven distinguishes eleven dimensions which determine compliance with legislation. These are divided into two groups: spontaneous compliance dimensions and dimensions related to enforcement. Obviously, the latter are of direct interest to enforcement organisations. Nonetheless, awareness of the spontaneous dimensions is useful especially for market surveillance authorities focusing also on compliance assistance.

An overview of the compliance dimensions is presented in Table 14 where the enforcement dimensions have been subdivided in two categories: sanction dimensions and control dimensions. For the purpose of this discussion it shows clearly that the possibilities to influence behaviour are associated with market surveillance.

Table 14: overview of compliance dimensions.

Spontaneous compliance	Enforcement	
	Sanction dimensions	Control dimensions
Knowledge of the rules	Sanction Probability	Inspection Probability
Cost/Benefit	Sanction Severity	Detection Probability
Level of Acceptance	Quality of the rules	Selectivity
Loyalty of the target Group		Risk of being reported
Informal Control		
No or minimal influence	*Indirect influence*	*Direct influence*

E.1 Spontaneous compliance dimensions

1. Knowledge of the rules

When the target group for which the legislations are intended is unfamiliar with the rules, compliance or violation of the rules becomes more or less accidental. Being unaware of the rules, or when the rules are not well understood, violators may unknowingly break the rules, and those who comply may not even know that they are complying. Clearly an effort to disseminate information about the legislation to the affected group and 'compliance assistance' is indicated in this situation.

Besides familiarity with the legislation a second determinant is the clarity and/or complexity of the legislation. Complex legislation may require technical or legal knowledge which may not be present in (all of) the target group. This certainly holds true for parts of the product safety legislation (e.g. LVD, Machines, GPSD and most other directives which refer to standards) where it is not uncommon that the businesses involved lack the expertise to interpret the technical requirements. Here also straightforward law enforcement may well be less effective than compliance assistance.

2. Cost/Benefits

Compliance with legislation may induce costs but also benefits to the economic operator. The same applies for non compliance which may result in (short-term) financial and economical benefits, but carries the risk of financial penalties and other disadvantages.

Included in this dimension are intangible costs and benefits, like for example the image that a business wants to maintain, but not the costs and benefits due to inspections and sanctioning from the market surveillance authorities. These are discussed separately in the section on enforcement dimensions.

For economic operators in the field of consumer product falling under the New Approach Directives, obvious costs of compliance are those involved in maintaining the files and declarations of conformity and the costs involved in assessing conformity with the standard. Conversely disregarding the rules saves these costs at the risk of being caught and a deteriorating reputation. Having excluded the influence of law enforcement in the scope of this dimension, the significance of this dimension is mainly for legislators and policy makers, who can influence the balance between costs and benefits by designing legislation that takes this dimension into account. Possibilities include subsidies and levies, certification schemes etc.

Note, however, that the balance between costs and benefits may vary between economic operators; companies depending on their reputation (often big companies) are more inclined to spend in order to comply than those operators and traders that engage in short-term trade and frequently change identity. In the approach of such target groups such differences should be taken into account.

3. Extent of acceptance of policy objectives and of the effects of the policy, and the target group's respect for authority
Acceptance is related to the subjective view of the target group with respect to the reasonableness of the legislation and its consequences for the target group. Unwillingness to accept a rule is seen for example in young adults from certain regions who are obliged to wear helmets on mopeds under traffic laws. The degree of respect for authority is particularly difficult to influence. Acceptance can be raised by involving the target group and other stakeholders in developing the policies and making the target group itself partly responsible for the success of the policy by self-regulation.

These two dimensions are hardly relevant to market surveillance authorities in the field of consumer product safety. Because industry has been and is deeply involved in the development of regulations, both in the phase of developing the New Approach Directives and in the process of standard development, industry is in a sense committed to these rules. Moreover, market surveillance authorities have few means to influence these dimensions of target group behaviour.

4. Non-official (or social) control
Social control is the influence of the community, like friends, colleagues, auditors and other companies and competitors. The impact of social control is dependent on the perceived risk of detection, the degree of (dis)approval of the violating behaviour and the extent to which the community takes action (social sanctions).

Non-official control is the form of formal control that is accepted in certain groups and industries to raise their professional standards by codes of conduct, certification schemes and the adoption quality marks.

E.2 Enforcement Dimensions

The Table of Eleven distinguishes six dimensions that directly influence the impact of enforcement activities on the target group. Two of these dimensions are generally not under the direct control of the market surveillance authorities. The remaining three are directly influenced by the choices market surveillance authorities make with regard to their activities.

For the purpose of this discussion we will divide the enforcement dimension therefore into two groups: the sanction dimensions and the control dimensions.

E.2.1 Sanction dimensions

1. Risk of sanction
The perceived risk of sanction is that an inspection and the detection of a violation will actually be followed by a sanction. Lack of manpower in the juridical system and policies for dismissing charges are common reasons why violations in some cases do not result in punishment. Compliance is not encouraged when the target group is aware that the chance of sanction after detection of a violation is small.

2. Severity of sanction
The severity of the sanction and additional disadvantages of being sanctioned (loss of reputation, legal costs etc.) influence compliance behaviour. This parameter does not have the same impact on all offenders or target groups, however, and the speed and certainty of sanctioning may also influence the impact (tit-for-tat approach) (see 'risk of sanction').

Though increasing the risk of sanction and the severity of the sanction encourage compliance behaviour, they are largely outside the control of the market surveillance authority. The severity of sanctions is generally determined by legislation and the probability that violations are punished depends on the priorities of and capacities in the prosecution and court systems.

In some Member States the probability of sanctions has been raised by allowing the market surveillance authority to impose certain sanctions itself, bypassing the complicated legal procedures required by penal law. Depending on the jurisdiction this competence may for example be founded on administrative law which still provides appeal possibilities for the accused. Because administrative sanctions can be imposed quickly, such measures also raise the effectiveness of sanctions (tit-for-tat).

E.2.2 Control dimensions

1. Perceived risk of being reported
This dimension is concerned with the perception of the offender that violations are disclosed without the intervention of the authorities themselves – for example, tipping by competitors and the general public. In non-food product safety a good example is consumer complaints to the authority. Raising the perceived risk of being reported is clearly within the scope of the market surveillance authority. This can be done by running a well-organised and easily accessible consumer complaints system and widely advertising its accessibility (see 3.7.2).

2. Risk of inspection
Compliance behaviour is stimulated when the risk of being inspected is perceived as being high. The perceived risk of being inspected is of course largely under the control of the market surveillance authority which can determine the frequency of inspections in the target group. The effect on behaviour can be increased when the ac-

tivities to be undertaken are widely communicated in the target group, as this raises the perceived risk of being inspected (enforcement communication).

3. Risk of detection, either from inspection of the records or from physical inspection
Apart from the probability of being inspected it is useful to increase the probability of detection of violations during inspections. Inspections that do not uncover the violations of offenders do not impress the offenders. Therefore, it is important to think about the required 'depth' of the inspections and lab tests for a target group, in order to raise the detection rate of violations and, again, to communicate the high risk of detection.

4. Selectivity
Selectivity concerns the ability of the authority to inspect selectively those violating the rules, while leaving those that comply at ease. Improved selectivity increases the risk of offenders to be discovered.

Note that improving selectivity means concentrating on businesses that are more likely to be offenders and is therefore in line with the initiatives in some Member States (and also the EU) to reduce the administrative burden on industry. To raise selectivity, an analysis of the target groups is necessary. Data from previous inspections, generally available in market surveillance organisations, is useful information for this purpose.

E.3 Analysis of compliance in target groups

The dimensions described cover the main factors that determine compliance behaviour. These dimensions are relevant for a wide range of legislation, not only non-food product safety legislation. Indeed, they address not only market surveillance, but the many other underlying factors that stimulate or discourage compliance as well. As such, they are relevant for the legislator which can take these factors into account when designing legislation, for example by paying attention to the clarity of the regulations. Also, analysis of the target group against these dimensions may point to specific policies suited to encourage compliance. Such policies might include amongst others organisation of certification schemes, subsidies designed to encourage desired behaviour and to educate the target groups.

Until recently, most market surveillance authorities restricted their activities to enforcement of the legislation by performing inspections and intervening where non-compliances were found. Lately, however, several market surveillance authorities have embraced additional intervention methods which in specific circumstances are believed to be more effective in raising compliance levels than pure enforcement. Especially assisting businesses in compliant behaviour by providing the necessary information about the legal requirements (compliance assistance) is applied. Compliance assistance is useful for those operators that are unaware of the requirements, but willing to comply.

It is important to note that in the surveillance dimensions it is the perceived risk of being inspected or detected, not the actual risk that influences compliance behaviour. The perceived risks of detection and inspection can be influenced, for example by communicating planned surveillance action in advance. Informing the target businesses of enforcement actions aimed at them attempts raises the perceived risk of inspection which itself encourages compliant behaviour, because it shifts the cost/benefit balance.

Compliance behaviour is determined by a few core dimensions, rather than by the correlation of all dimensions, e.g. 80% of compliance behaviour is determined by 20% of the dimensions (see ref. 4). These core dimensions vary with the legal requirements and also with the target group. Identifying the core factors that determine the compliance behaviour in target groups allows tailoring a specific approach to raise compliance levels of the target group to specific legislation.

To perform this analysis the target group is scored on all the dimensions which for this purpose are grouped according to whether they encourage or discourage compliance. For example, increase of the enforcement pressure (the enforcement dimensions) encourages compliance, while unfamiliarity with the rules can be seen as encouraging violations. The other dimensions can both encourage or discourage compliance. Plotting the score against the dimensions then gives a compliance profile as shown in Figure 35.

Figure 35 is an example that shows an analysis performed on a target group consisting of operators/proprietors of amusement rides. The rides must be subjected to a safety test by a certification institute which checks if they comply with the safety requirements. If shortcomings are detected, these must be corrected, sometimes requiring substantial investments. The figure shows at a glance the strong and weak reasons for compliance in the target group and thus indicates which dimensions need attention in order to promote compliance. Note that some dimensions have been subdivided in more specific varieties.

Though the results of this analysis must be interpreted with care, it gives a useful indication of the possibilities for enforcement to improve compliance levels, or alternatively that other approaches are more likely to succeed. It is important to consider that behaviour is not determined by the actual factors themselves, but by the way those factors are perceived by the target group.

For meaningful scoring of the dimension for the target group knowledge of the target group is of course a necessity. The information required may partly be available from previous experiences of the market surveillance authority, but can also be obtained by questioning the target group. Since the latter may be expensive, questioning experts what they believe to be the reasons for a particular type of behaviour is sometimes used. A computer programme to facilitate the process for a group of experts is available: http://www.it11.nl/it11/login.jsp. Access can be obtained via the site by requesting a login code.

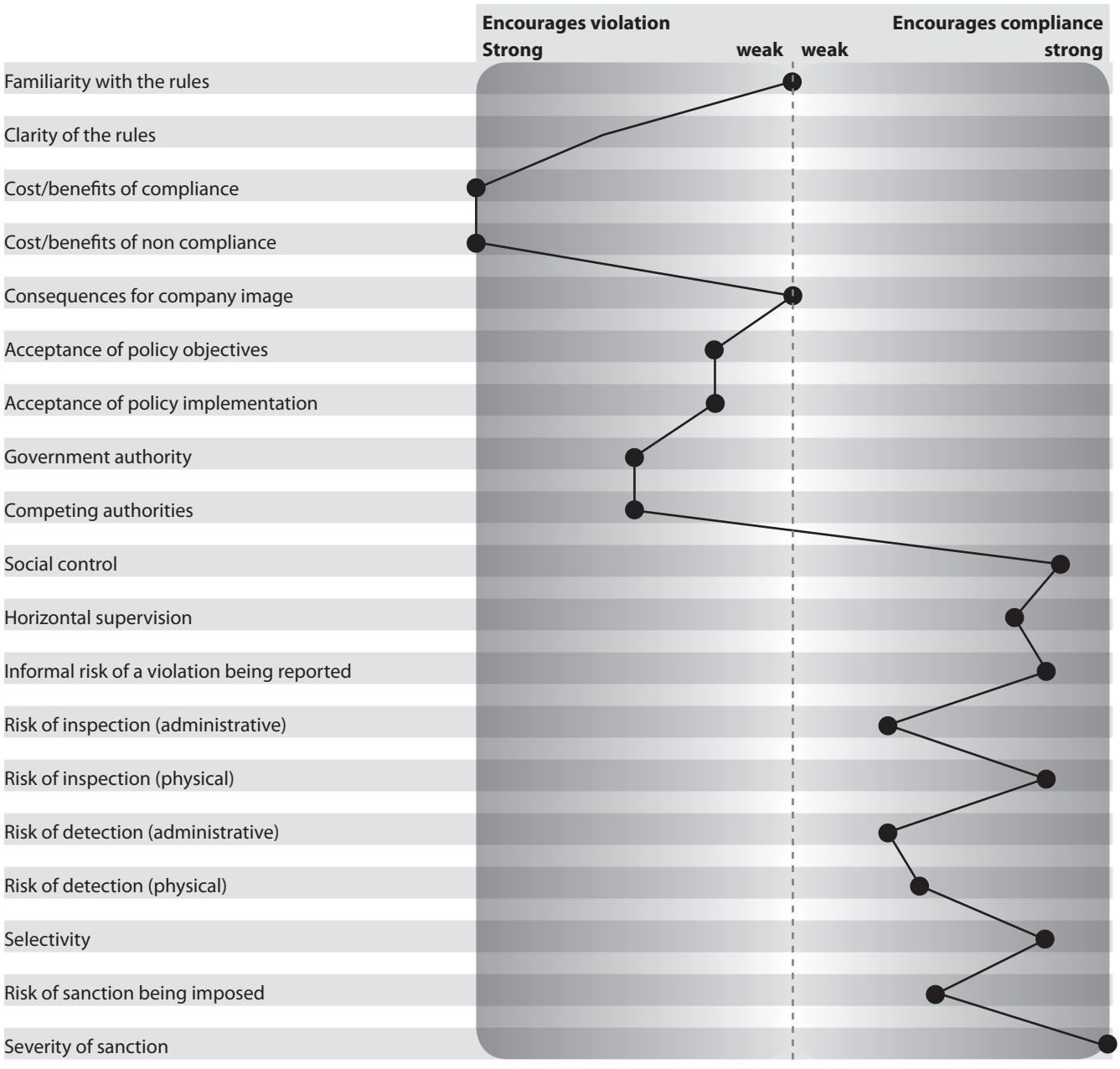


Figure 35: Compliance profile for operators/proprietors of amusement rides.

E.4 Characterisation of the target group

The target group is not homogenous; there will be economic operators that comply with the rules and operators that violate the rules. For both groups the reasons they behave the way they do may differ. The effectiveness of the interventions by market surveillance authorities is dependent on the reasons for compliance behaviour. Distinguishing sub-groups within the target group, on the basis of the reasons for their compliance behaviour, can then contribute to an approach tailored to give optimal effects.

The target group can for instance be distinguished into the following groups:

- *Unconsciously compliant people:* this group is unfamiliar with the rules, but unknowingly complies with them (more or less by chance);
- *Unconsciously non-compliant people:* this group breaks the rules unconsciously because they are not familiar with the rules;
- *Spontaneously compliant people:* those who know the rules and spontaneously comply. For this group no enforcement is needed;
- *Spontaneously non-compliant people:* those who know the rules but spontaneously break them, regardless of the risk of sanctions or punishment;
- *Calculatingly compliant people:* those people that know the rules and would break them, but who are deterred by the risk of inspections and sanctions;
- *Consciously or calculatingly non-compliant people:* those people that knowingly break the rules and consciously accept the risk of being caught.

Finally, there is a group that can not be or is very hard to influence. This group is either respectful to authority (and therefore complies) or disrespectful to authority, in which case they are likely not to comply.

The original purpose of this attempt to characterise the target group for a specific kind of legislation was to estimate compliance levels to be expected for this legislation. Proper characterisation requires insight into the target group. To facilitate obtaining that insight a complicated technique involving the answering of a large number of questions by experts, facilitated by software, was developed: http://www.it11.nl/it11/login.jsp. Eventually, the result can be a graph like Figure 36: Compliance estimates for operators/proprietors of amusement rides which shows the composition of the target group at a glance.

For market surveillance authorities collecting information that gives a reliable idea of the composition of the target group allows drawing up a more or less reliable image of the target group. This in turn helps in determining the proper intervention methods and to direct enforcement activities to those operators that are most likely to violate the legislation. For example, education of the unconsciously compliant group may initially be the preferred approach. The same kind of intervention may also help to improve the compliance behaviour of ignorant offenders that might well be willing to comply once they are aware of the rules.

Contrarily, enforcement by inspecting and testing is more likely to work for deliberate offenders and is required to keep the conscious economic operators complying.

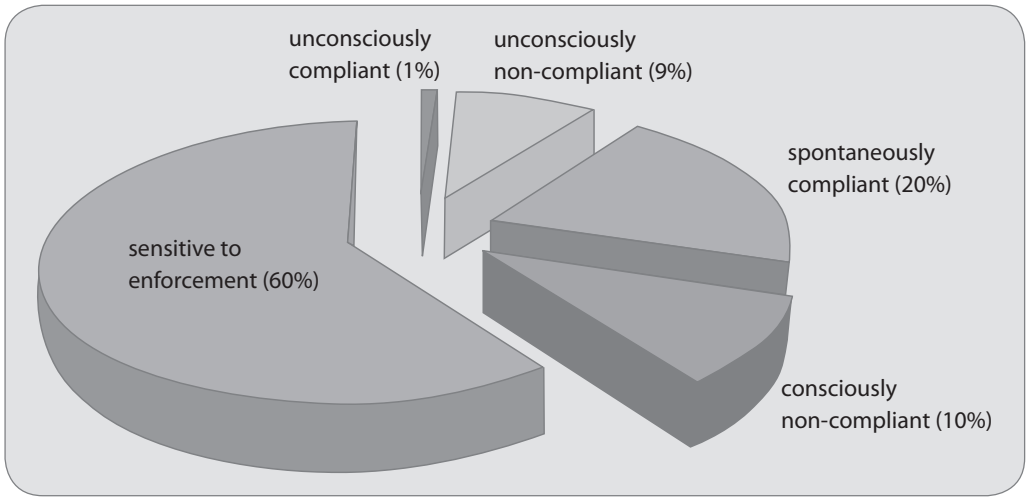


Figure 36: Compliance estimate for operators/proprietors of amusement rides.

ANNEX F – FAILURE CODE LIST

	Remark 1	Criticism 2	Serious criticism 3
Technical faults			
Accessible live part in normal use			3
Accessible basic insulated parts on class II products		2	
Luminaries and domestic equipment of class 0	1		
The creepage and clearance distance is less than 10% of the requirement in relevant standard			3
The creepage and clearance distance is more than 10% and less than 50% of the requirement in relevant standard		2	
The creepage and clearance distance is more than 50% of the requirement in relevant standard	1		
Cord extension set with class 0 plug and class 1 outlet	1		
Cord extension set with class 1 plug and class 0 outlet			3
Cord extension set with class 2 plug and class 0 or 1 outlet			3
Class 1 plug mounted on a supply cord without protective earth conductor, changing a class 1 appliance into a class 0 device			3
Phase and earth exchanged by mistake in earthed coupling			3
The equipment lacks thermal cut-outs and/or current cut-outs		2	(3)
The rated current in the equipment is one step too high	1		
The rated current in the equipment is more than one step too high		2	
The rated current in the equipment is so high that it is a fire hazard			3
Marking is incomplete or missing		2	(3)
CE-mark is missing	1	(2)	
Incomplete and wrongful instructions for use and/or mounting which can cause danger		(2)	3
National language operation instructions with necessary safety information are missing		2	
The design diverges from standard or technical documentation		2	(3)
Conductors not adequately attached		2	(3)
Risk of mechanical damage to conductor		2	(3)
Equipment with inadequate conductor (cross-section, insulation)		2	(3)
Cord anchorage is missing		2	(3)
Ip classification does not comply with the requirements		2	(3)
The design diverges from standard or technical documentation (great risk for electrical shock/fire)		2	(3)
Administrative procedures			
Declaration of conformity is missing		2	
Errors in declaration of conformity	1		
Technical documentation is missing		2	
Errors in technical documentation	1	(2)	
Modified product sold with the same type no. etc. as product where sales ban is issued	1		

(a parenthesis indicates that the code could be used in some cases)

ANNEX G – THE MAIN EUROPEAN / INTERNATIONAL STAKEHOLDERS WITHIN MARKET SURVEILLANCE

Besides national legislators, national policy makers, producers, distributors and individual consumers who complain about specific products, stakeholders' organisations can have a very important influence on the market surveillance policy in several ways.

In this Annex the main international and European stakeholders' organisations in the area of consumer product safety market surveillance are addressed. Follow the respective stakeholder's hyperlink to get more detailed information from their Website.

G.1 International / European Agreements and Treaties

International agreements on world trade (and especially the technical barriers to trade) and the European Treaties have a major impact on the national legislation and policies in the area of consumer product safety. The World Trade Organisation (WTO) and the European Commission act as 'guardians' of the agreements and treaties and both organisations promote the developments and elaboration of the substance of the agreements and treaties.

G.1.1 WTO (World Trade Organisation)

The hyperlink to the website of the WTO is: www.wto.org. Of special interest is the 'Agreement on Technical Barriers to Trade (TBT)' (see article 2.4): this agreement is available on: http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf.

G.1.2 European Commission

The hyperlink to the website of the European Commission is: http://ec.europa.eu. The hyperlinks to the most important Directorate Generals in the area of consumer product safety market surveillance are:

- DG SANCO's (http://ec.europa.eu/consumers/index_en.htm) mission is to help make Europe's citizens healthier, safer and more confident. Part of this task is to keep up to date European laws dealing with the safety of food and other products, on consumers' rights and on the protection of people's health. It is national, regional or even local governments in EU countries who actually apply the EU's health and consumer protection laws. It is their job to make sure traders, manufacturers and food producers in their country observe the rules. DG SANCO checks that this is really happening and that the rules are being applied properly in all EU countries. Moreover, it supports the Member States with these important tasks.
- DG ENTERPRISE (http://ec.europa.eu/enterprise/site-map.htm) has the role to ensure that businesses can compete openly and fairly. The aim is to make Europe an attractive place to invest and work in. Current priorities for Enterprise policy include: promoting entrepreneurship, contributing to the design, implementation and improvement of a flexible regulatory framework providing access to the single market, opening-up of and guaranteeing obstacle-free, fair access to the markets of non-EU countries, promoting European competitive performance.
- DG TAXUD: (http://ec.europa.eu/taxation_customs/taxation/index_en.htm) has the role to monitor the implementation of the EU Tax Policy Strategy and to ensure that tax policy supports broader EU policy objectives.

G.1.3 International and European technical standardisation

International and European technical standards provide the main reference sources for checking the conformity of consumer products. The International and European organisations engaged in standardisation are:

- ISO (International Organisation for Standardisation): http://www.iso.org/
- IEC (International Electrotechnical Commission): http://www.iec.ch/
- ITU (International Telecommunication Union): http://www.itu.int/
- CEN (Comité Européen de Normalisation): http://www.cen.eu/
- CENELEC (Comité Européen de Normalisation Electrotechnique): http://www.cenelec.org/
- ETSI (European Telecommunications Standards Institute): http://www.etsi.org/

G.2 General International and European Stakeholders Organisations

G.2.1 ICPSC (International Consumer Product Safety Caucus)

The ICPSC was founded in 2004 in order to facilitate the exchange of information on consumer product safety issues with a view to strengthening the collaboration and cooperation among governments and regulatory agencies around the world.

Members of ICPSC include: Asia (NITE, AQSIQ, KATS), Australia (Australian Competition & Consumer Commission), North America (CPSC and Health Canada), Europe (European Commission, DG SANCO and PROSAFE).

G.2.2 ICPHSO (International Consumer Product Health and Safety Organisation)

The International Consumer Product Health and Safety Organisation was founded in 1993. ICPHSO is an organisation dedicated to the health and safety issues related to consumer products manufactured and marketed in the global marketplace. The hyperlink to the website of ICPHSO is: http://www.icphso.org/.

ANNEX G – THE MAIN EUROPEAN / INTERNATIONAL STAKEHOLDERS WITHIN MARKET SURVEILLANCE (Continued)

G.2.3 EuroSafe

EuroSafe, the European Association for Injury Prevention and Safety Promotion, is the network of injury prevention champions dedicated to making Europe a safer place. The hyperlink to the website of EuroSafe is: http://www.eurosafe.eu.com/.

G.3 Business representatives

Most business sectors have specific trade organisations representing their interests. It has also to be noted that similar organisations exist at Member State level.

G.4 Consumer representatives

G.4.1 Consumers International (CI)

Consumer International (CI) is the only independent global campaigning voice for consumers. With over 220 member organisations in 115 countries, CI is building an international consumer movement to help protect and empower consumers everywhere. The hyperlink to the website of Consumer International is: http://www.consumersinternational.org/.

G.4.2 Bureau Européen des Unions de Consommateurs (BEUC)

BEUC's members include 40 reputed, independent national consumer organisations from some thirty European countries (EU, EEA and applicant countries). BEUC acts as a sort of 'embassy' for these organisations in Brussels and our main task is to represent our members and defend the interests of all Europe's consumers. The hyperlink to the website of BEUC is: http://www.beuc.eu.

G.4.3 European Consumer Consultative Group (ECCG)

In EC Decision (2003/709/EC) of 9 October 2003, the European Commission created the European Consumer Consultative Group (ECCG). This body replaced the Consumer Committee as the Commission's main forum for engaging with consumer organisations. The hyperlink to the webpage on the EU website of ECCG is: http://ec.europa.eu/consumers/cons_org/associations/committ/index_en.htm.

G.4.4 ANEC

ANEC (http://www.anec.org) is the European consumer voice in standardisation, representing and defending consumer interests in the process of standardisation and certification, also in policy and legislation related to standardisation.

ANEC was set up in 1995 as an international non-profit association under Belgian law and represents consumer organisations from the European Union Member States and the EFTA countries.

G.5 PROSAFE

PROSAFE is the forum where European Market Surveillance Authorities meet and inform each other of upcoming risks, developments in the Member States in relation to market surveillance, exchange best practices and discuss about the future of market surveillance.

The hyperlink to the website of PROSAFE (the Product Safety Enforcement Forum of Europe) is: http://www.prosafe.org/.

G.6 EMARS

EMARS is a project of PROSAFE, funded by the European Commission. One of the aims is to improve market surveillance in Europe by gathering and developing best practices in market surveillance. Most Member States participate and make contributions.

The hyperlink to the website of EMARS (Enhancement Market Surveillance, a PROSAFE project, partially funded by the European Commission) is: http://www.emars.eu.

G.7 Sectorial Administrative Cooperation Groups (ADCO's)

Further information on the activities of sectorial Administrative Cooperation Groups (ADCO's) can be retrieved from the 'Communication & Information Resource Centre Administrator' (Circa) of European Commission (access only for the members of the sectorial ADCO's): http://circa.europa.eu/Public/irc/enterprise/Home/main.

ANNEX H – CROSS-BORDER INFORMATION SYSTEMS

H.1 Systems based on legal obligations

For effective pan-European market surveillance close co-operation between the market surveillance authorities in the Member States is a necessity. A number of information systems are in place to facilitate this. The use of some of these systems follows from legal obligations laid down in the GPSD or sectorial directives, whereas the use of other systems is voluntary (even though highly recommended).

H.1.1 RAPEX

RAPEX is a European rapid alert system for dangerous non-food consumer products. It is used to disseminate information regarding dangerous products identified in one Member State. In accordance to Articles 11 and 12 of the GPSD, when a Member State takes measures to eliminate risks being posed by a dangerous product, it is obliged to inform the European Commission within a stipulated time frame (please refer to the Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC).

In this regard, the European Commission has established a network of National Contact Points. They are responsible at national level to handle such information, to distribute it to the competent authority responsible for the particular product (depending on the market surveillance structure at national level) and to report back to the Commission the action(s) taken by the competent authority to eliminate the communicated risk (if any).

When a Member State takes a measure to eliminate the health/safety risk posed by a dangerous product, it must immediately inform the Commission. The Commission evaluates whether the data is complete and the notification meets the legal requirements. If the information is pertinent and sufficiently complete, the notification is transmitted to the network of national RAPEX Contact Points. The Contact Points distribute the notification to the relevant national authority responsible for the particular product category for the necessary follow-up. After the national authorities have investigated the issue and, if the product is found, taken the necessary follow-up action to eliminate or minimise the communicated risk, the Contact Point reports back to the Commission and information on the follow-up is communicated back to all the other Member States via RAPEX. The procedure is illustrated in Table 15.

Table 15: The functioning of the RAPEX System

Step 1	RAPEX notification is sent to the European Commission by one Member State
Step 2	Data verification by the European Commission
Step 3	Validated RAPEX notification is sent to all Members of the EEA for the necessary follow-up
Step 4	The Member States that find the product on their national markets, have additional information on the product or the risk or contest an element of the RAPEX notification informs the European Commission as to their reaction.

Information on RAPEX notifications on products posing a serious risk to consumers are published weekly on the Commission's website at http://ec.europa.eu/rapex for the benefit of consumers, economic operators and other stakeholders.

Step 4 in Table 15 requires that Member States take actions to investigate the market for the presence of dangerous products notified in RAPEX. Experience shows that the follow-up to notifications can be a time-consuming and complicated process. Input from Member States also shows that practices vary between the Member States.

These methods can consist of:

- Visiting retailers on a random basis or more extensively can be performed as a short-term action. This method has a great chance of success since large parts of the market will be examined in a relatively short time period. The greatest disadvantage of this method is that it is resource-intensive, especially when larger parts of the market are to be investigated.
- Information on the product on the authority's website that is available to all interested parties, i.e. consumers, media and business. Experience shows that this method is not widely used. Efforts should therefore be made to enhance the use of this information channel. For consumers easy access and good usability are key issues. For businesses and other stakeholders, a subscription system is recommendable.
- Advertising or other actions in media, especially on products posing a very serious risk might create some interest with the consumers and businesses and consequently result in information of the presence of the product in the national market.
- Workshops and seminars intended for manufacturers, importers and possibly retailers increase awareness on the GPSD and the RAPEX system and the obligations this system poses for economic operators. Topics for such events can include risk assessment, RAPEX statistics etc. These events can be used as a means to inform these stakeholders of the presence on a given national market of a dangerous product inviting them to cooperate in monitoring and removing similar situations on other markets.

Link to list of national contact points: http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_weekly/contact_points_revised.pdf.

Link to weekly published reports of dangerous products: http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm.

H.1.2 Safeguard Clause Procedures

All the New Approach Directives include a 'safeguard procedure'. In many of the Directives this procedure is described in Article 7. In the Low Voltage Directive the procedure is under Article 9 and it is also slightly different from the template of the safeguard procedures in the other directives. The reason for this is that the LVD was originally conceived and adopted before the New Approach.

The safeguard procedure is not meant as an information exchange tool. The main aim of this procedure is to safeguard the free circulation of goods by providing the Commission with a means to analyse the justification of national measures restricting the free circulation of goods. The safeguard procedure may also play a role in the information exchange between the authorities on dangerous and non compliant products, and in the area of the LVD it indeed does so.

The safeguard clause procedure obliges Member States to take CE marked products that endanger the safety or health of their citizens (and sometimes also when they endanger domestic animals or property) from the market and to inform the Commission that they have done so.

Safeguard clauses must be invoked by the Member State for products falling under a New Approach directive that present a substantial hazard, even if the products are correctly constructed, installed and maintained and used according to their intended purpose. For this product the Member State must have taken national measures which restrict or forbid the placing on the market of the product, or have the product withdrawn from the market. Furthermore, these measures should have binding legal effects .[1]

Member States are required to inform the Commission of the reason for their decision, in particular whether non-conformity is due to:

- failure to satisfy the essential requirements;
- incorrect application of the standards;
- shortcomings in the standards themselves.

After investigation, the Commission informs the Member State about the conclusion reached, either that the measure was justified, or that it was not. When the Commission judges the measure justified the case is settled. If the Commission decides that the measure was not justified, the authority has to decide whether it wants to comply with the ruling of the Commission or not. When it does, it has to take the measure back and allow the continuing trade of the product on its market (and possibly pay compensations for lost profits and other costs).

When it upkeeps the measure despite the Commission opinion, it risks being called before the European Court of Justice, either by the Commission or the manufacturer/importer affected for imposing an illegal barrier to the free circulation of goods.

Besides informing as to the reasons for the measure, there are a few practical matters to consider when submitting a safeguard notification. The notification is a legal obligation of the Member State and should be handled as such. The exact procedure to submit is dependent on the organisation of the Member State, but commonly notifications should be forwarded officially through the Permanent Representations of the Member States. This official procedure must always be followed, in view of the legal significance the process may have. Because in some cases the official way may be a slow process, and may also be error prone, parallel direct delivery to the Commission official in charge of the Directive can help to prevent confusion.

Safeguard clause notifications for products that comply with the relevant European standard, but which do not comply with the essential safety requirements, require special attention. Because those products satisfy the standard requirements they enjoy the assumption of conformity. In all fairness their producers or importers can then hardly be blamed for the non-compliance. Where the product nevertheless is dangerous and does not comply with the safety requirements of the Directive, a safeguard clause notification can be issued which challenges the European standard directly. Of course, if the product presents a real risk measures to stop, its circulation also must be taken.

Safeguard clause notifications against (parts of) European standards require special care. It must be shown that the safety level the European standard concerned does not fulfil the essential safety requirements of the associated Directive. Plausible evidence that such is indeed the case will most likely be based on a risk assessment. The risk assessment should show that products fulfilling the standard requirements carry nevertheless unacceptable risks, and therefore do not comply with the requirements in the Directive. Since the Commission investigates the validity of the notification and checks the evidence on which it is founded, it will hear the stakeholders involved. This would generally include the affected company and the European standard organisation (CEN or CENELEC) which are given opportunity to react. It is therefore of paramount importance that the notification is soundly argued. In these circumstances getting a second opinion on the risks from an independent institute to substantiate the risk analysis is advised.

1 See: Guide to the implementation of directives based on the New Approach [1].

Relevant in this context is also the 'state of the art' in the field concerned. Though often a vague concept, it helps when products that do not share the same risk are sold on the market. These products should then be comparable, making them indicative for the 'state of the art'. Less useful in this argument are upmarket products which are much more expensive.

When after investigation the notifying Member State is put in the right, the Commission will publish this in an opinion and will probably draw back the assumption of conformity for (part of) the standard. Most likely the Commission will also draw up a mandate to the standard organisations to adapt the standard to the essential requirements for those risks not covered sufficiently.

In the area of the LVD good practice requires that, when a company within a Member State is the subject of a safeguard clause by another Member State, the Member States' authority carries out an inspection of that company. The company's comments on the safeguard clause should be heard and it should be investigated if the non-conformities indeed exist. If this is the case, proportional measures should be taken and further trade should be stopped. If the charges in the safeguard clause can not be confirmed and the company's defence against the charges is relevant, the Member State can object to the safeguard clause at the Commission. The Commission then investigates the legality of the original measure that spawned the safeguard procedure.

Further information about the operation of the safeguard clause procedure should be sought through the national representative in the relevant ADCO group.

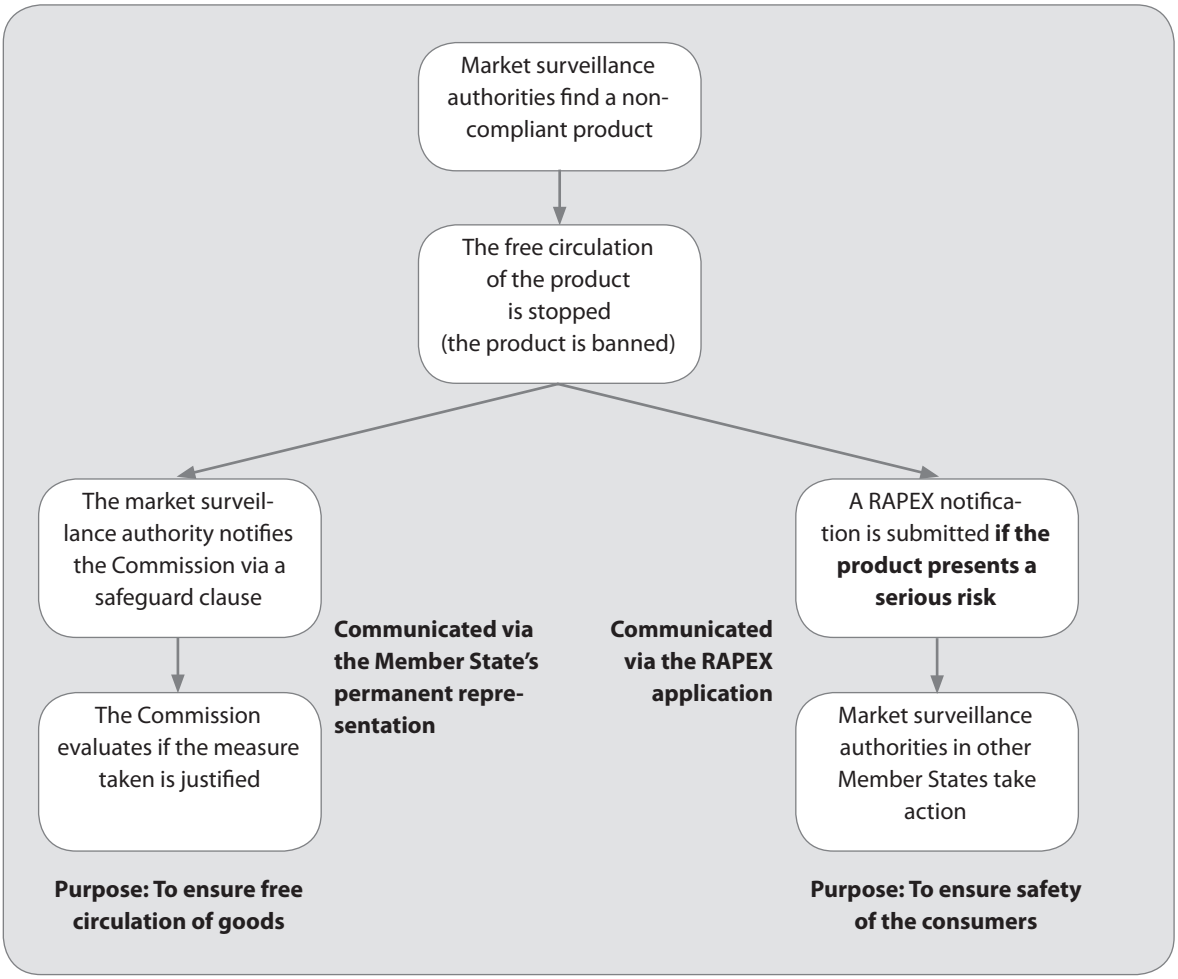


Figure 38: Interaction between the RAPEX procedure and the safeguard clause procedure.

H.2 Voluntary Systems

H.2.1 CIRCA

The Communication and Information Resource Centre Administrator (CIRCA) is a web-based environment, funded and developed, initially for Eurostat, under the European Union IDABC (Interchange of Data Between Administrations) Programme. As the name implies, it is a communication tool. CIRCA allows groups with common interests (working groups, project groups etc.) to share and exchange information and documents and to communicate in a private space on the Internet. CIRCA offers several additional functions.

CIRCA is divided in interest groups that allow public access and interest groups with restricted access. The groups with restricted access can be accessed after a user name and password are obtained. Access and navigation is done via any Internet browser and Internet connection. One member of the interest group plays the role of chairman or moderator; in CIRCA it is called a 'Leader'.

A large variety of interest groups uses CIRCA. These range from groups on specific industries to groups on specific legislation. Participants may be from industry, governments, consumers etc. For market surveillance authorities the restricted access groups set up for the Administrative Cooperation (Ad-Co's), expert groups and the working parties on new approach legislation are important:

- Low Voltage Directive Administrative Cooperation Working Group
- Machinery Administrative Cooperation Group
- LVD WG Update
- LVD Working Party
- Expert Group on Toy Safety
- LVD Notified Bodies Forum
- Machinery Directive

Most of these groups employ CIRCA mainly as a tool to exchange documents and information before their actual meetings. LVD AdCo has employed their CIRCA space also as a means to facilitate the information exchange in the framework of their cross-border actions, allowing the participant's access to the sampling data and test results of the other participants.

H.2.2 European Commission Website

Another very important database can be accessed from the European Commission Website, in the section of the Directorates for Health and Consumers and for Enterprise and Industry. Here, market surveillance authorities, industries, customs authorities and also the consumer can access all the enacted legislation and also the list of standards that are published under each directive.

The information is stored separate for each European Directive and all the recent developments with respect to the legislation itself or the publication of standards can be accessed on the website.

The links to the websites are:
Directorate for Health and Consumers:
http://ec.europa.eu/dgs/health_consumer/index_en.htm
Directorate for Entreprise and Industry:
http://ec.europa.eu/enterprise/index_en.htm.

H.2.3 ICSMS

ICSMS is a system with the main task to provide and exchange product information via the Internet. It is currently being used by eleven Member States; AT, BE, EE, DE, LU, MT, SL, SE, CH, NL and UK. The system is also being considered in the context of some of the joint actions for exchange of information.

ICSMS consists of a closed and a public area. The closed area is for the use of market surveillance bodies, customs authorities and the EU Commission – i.e. official agencies. It contains product information, test results, official measures taken etc. The public area is for the use of consumers and manufacturers. It contains, for example, official information about dangerous products, by manufacturers drawing attention to pirated copies. Here, the consumer can quickly find reliable information about unsafe products. All the information is presented in an easy to understand form; it is kept up-to-date, and can be accessed via an Internet address.

ICSMS enables all users to carry out a specific search. A search can be made, for example, according to individual products, and according to test results for entire product groups. Test results can be obtained for products from specific countries, information can be obtained for products coming under certain directives, safeguard clause notifications, as well as information about manufacturers, importers and dealers. Confidentiality aspects are protected by a complex system of access authorisations. Of course the system and the data contained in it are protected against unauthorised access.

In the EMARS project a survey was carried out to explore the use of the system in the Member States. The survey comprises 21 authorities in eight Member States. The conclusion was that the use of the system varies a lot between the responding organisations. One organisation responded that they had never used the system. Two organisations indicated that they mainly or only use the system to search for information on dangerous products. Five participants indicated that they file information on all investigated products on ICSMS. One more participant indicated that they expect to do so in the near future. Eleven organisations file information on all products with dangerous shortcomings. Three organisations have answered that they have uploaded a few cases to ICSMS for test purposes.

Even though some of the participants have indicated that they only file information sparsely in the system, almost all participants use it as a source of information. Eighteen of the 21 authorities search the database to gather information to be used in their investigations. Two of the eighteen only search ICSMS when planning a project whereas the remaining eight organisations also search ICSMS when products are investigated as part of a campaign, or because of complaints accidents.

Link to ICSMS: http://www.icsms.org/icsms/App/index.jsp.

H.2.4 Information systems under EMARS

The EMARS project has established a couple of tools to enhance the exchange of information between market surveillance officials:

- Knowledge Base

One deliverable of the EMARS project is a Knowledge Base; i.e. a body of knowledge on market surveillance. It is available for market surveillance officials (and the European Commission) via the Internet and is organised within a storage system with good retrieval functions. Furthermore, the Knowledge Base presents links to information about market surveillance on the Internet.

Information about the Knowledge Base and how to access the documents can be found on: http://www.emars.eu/Knowledge_Base.php.

- Rapid Advice Forum

The Rapid Advice Forum is a procedure whereby market surveillance officers can ask questions and get informal advice on market surveillance issues from colleagues throughout Europe.

The aim is to help market surveillance officials reach a correct and non-biased result in complex and complicated questions that the officials often face. The procedure offers rapid and informal first assessment and feedback from fellow officers (from other Member States). This assessment and feedback is given by individual market surveillance officers and is based on their personal experience and expertise. Answers must never be regarded as a binding opinion of a Member State and the person receiving the assessment is in no way obliged to take this assessment and feedback in consideration.

More information on the Rapid Advice Forum can be found on: http://www.emars.eu/Rapid_Advice_Forum.html.

ANNEX I – BIBLIOGRAPHY

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ANNEX J – STANDARDS APPLICABLE TO QUALITY ASSURANCE

Table 16: Overview of standards related to quality assurance in the ISO 9000 and ISO 17000 series.

ISO 9000:2005	Quality management systems – Fundamentals and vocabulary
ISO 9001:2000	Quality management systems – Requirements
ISO 9004:2000	Quality management systems – Guidelines for performance improvements
ISO/IEC 17000:2004	Conformity assessment – Vocabulary and general principles
ISO/PAS 17002:2004	Conformity assessment – Confidentiality – Principles and requirements
ISO/PAS 17003:2004	Conformity assessment – Complaints and appeals – Principles and requirements
ISO/PAS 17004:2005	Conformity assessement – Disclosure of information – Principles and requirements
ISO/IEC 17011:2004	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020:1998	General criteria for the operation of various types of bodies performing inspection
ISO/IEC 17021:2006	Conformity assessment – Requirements for bodies providing audit and certification of management systems
ISO/IEC 17024:2003	Conformity assessment – General requirements for bodies operating certification of persons
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories

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