E·MAR·S
Enhancing Market Surveillance through Best Practice

A PROSAFE Project

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

BEST PRACTICE TECHNIQUES IN MARKET SURVEILLANCE

FOREWORD

By introducing the principle of New Approach Directives in 1985, the European Commission emphasized the importance of Market Surveillance as an important tool in ensuring the objectives of the inner market with respect to the free movement of goods. The objectives of market surveillance were initially recognized to improve product safety, the free movement of goods and equal conditions for the economical operators.

In 2005 the New Approach celebrated its 20th anniversary.

Even though several member states are very efficient and professional with respect to market surveillance, experiences gained from the first 20 years show that there is a need to enhance market surveillance within the member States to ensure a uniform approach to this important issue. Based on this experience, the Commission launched in 2005 a revitalisation of Market Surveillance as a part of the revision of the New Approach Directives.

Up to now market surveillance has mostly been undertaken at a national level and hence performed with respect to national interests.

Market surveillance at a national level will contribute to achieve EU objectives with respect to increase the free movement of goods to certain, but probably not sufficient degree. It is assumed that market surveillance at an EU level will increase the effectiveness and hence contribute to a greater extent to achieve EU objectives.

With respect to above mentioned assumption it seems clear that there are several issues that have to be improved on an EU-level. There is no common policy or strategy in EU giving recommendations on how to organise, plan, perform or report on market surveillance activities. The lack of such important common tools might lead to difficulties in the process of identifying dangerous products and an effective follow up in the market.

Furthermore, it seems necessary to give attention to the development of different procedures for the practical part of market surveillance actions; including cross border cooperation and cooperation with stakeholders. With the acknowledgement of above mentioned challenges, an idea was born; to develop a set of written recommendations to give aid to the enhancement of market surveillance in Europe.

The idea was initially presented in the Prosafe meeting in Vienna in 2005. This idea lead to an application from Voedsel und Waren Autoriteit (VWA)to DG Sanco in 2005 for the funding of a project, in which “Best Practices “ is one of 6 different topics, all of them dealing with different aspects of market monitoring and surveillance.

This project was named EMARS-Enhancing market surveillance in Europe. Since autumn 2005 a working group, Work package 3, has been occupied with collecting and collocating information on best practices in market surveillance from Member states related to market surveillance.

The result of this work is this document, named “Best practice techniques in market surveillance”. As mentioned above, there are several groups of users of this Book. Even though the main purpose is to give support to the enforcement authorities in Europe, the Book

will also be available for all stakeholders in order to ensure transparency and understanding between all parties which have some interest in the inner market.

This book is, as such, meant to be recommendations on best practices for the enforcement bodies in the Member States and EFTA.

DG Sanco has, through the financial programme under GPSD art. 10, contributed comprehensively to the EMARS project. The funding from DG Sanco has made it possible to achieve the objectives with respect to best practices in market surveillance.

EMARS will thank DG Sanco for their generosity in the funding of this project.

The financial contribution has made it possible to finalise this important work. EMARS will also thank participating member states for their efforts in developing this Book. EMARS wish you all luck and progress with the use of this “Best practice in market surveillance”.

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

On behalf of EMARS and Work Package 3

Gunnar Wold

Chair WP 3

DRAFT TABLE OF CONTENTS

PART A
INTRODUCTION

1 AIM AND SCOPE

This document focuses on market surveillance systems related particularly to safety of non-food consumer products. Member States within the European Economic Area have an obligation to ensure that only safe products are put in the market ensuring a fair playing field between businesses within the Single Market and contribute to increased flow of goods in the internal market.

The aim of this document is to try to assist policy makers, senior managers and practitioners within a given market surveillance system by describing the essential requirements needed for an effective surveillance system and by identifying best practice techniques in the various areas that are discussed and identified within the various chapters.

This document may be used as a guide and reference book by senior management to further enhance and develop their own surveillance strategies and at the same time it can also be used by market surveillance practitioners and inspectors as a handbook in order to improve their best practice techniques in a specific area.

All in all, this document may also be used by businesses and consumers to further understand how market surveillance is performed. Indeed, no market surveillance system can work effectively without instilling a high level of cooperation and coordination between government, businesses and consumers.

This book has been drafted in the view of being applied to products covered by GPSD, LVD, PPE and TOYS Directives; although in some parts of it reference is made to other Directives or products for the sake of more complete information. As consequences it has to be taken into account that it covers safety of products and doesn't concern other matters such as environment.

2 THE EC LEGISLATIVE BASES FOR MARKET SURVEILLANCE

2.1 Background

The establishment of a single market is a major achievement of cooperation in the European Economic Community and is the foundation of the European Union. By virtue of articles 28 and 29 of the treaty establishing the European Community quantitative restrictions on imports and exports and all measures having equivalent effect are prohibited between member states. Article 30 goes on to permit prohibitions or restrictions on an exceptional basis where this can be justified on grounds of inter alia the protection of health and life of humans.

The 1979 Cassis de Dijon ruling of the European Court of Justice was a landmark judgment in the Jurisprudence concerning the application of these Treaty provisions. It re-iterated that a product (in this case, a French blackcurrant liqueur) sold lawfully in one member state may not be prohibited in another member state (in this case, Germany) except on public health grounds – this is the so-called 'mutual recognition' principle.

Mutual recognition on its own however has not been sufficient to ensure the establishment of the single market. The basis of the single market and the free circulation of goods within the single market is the harmonization of product legislation throughout the European Union.

Article 14 of the Treaty set out the objective of having the Community adopt measures with the aim of establishing the internal market by 31st December 1992. Articles 94 and 95 empower the Council to issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market. Article 95(3) requires the Commission in its proposals concerning health, safety, environmental protection or consumer protection to take as a base a high level of protection taking account in particular of any new development based on scientific facts.

Initial efforts at harmonisation were rather slow for two reasons. First the legislation became highly technical as it addressed the individual requirements of each product category. Secondly at the time the adoption of technical harmonisation directives was base on unanimity in the Council. The creation of the internal market could not have been realised without the adoption of a New Approach to technical harmonisation. The New approach was adopted in 1985. Legislative harmonisation was limited to essential safety requirements and the technical specifications of products meeting these requirements were to be laid down in harmonised standards. The application of a harmonised or other standard would remain voluntary but products manufactured in compliance with harmonised standards would benefit form a presumption of conformity with the corresponding essential requirements.

In the field of consumer product safety the harmonization of product legislation has mainly been effected through new approach directives, but for specific product categories, like for example cosmetics, 'old approach' is also used and the directives address individual requirements of each product category. In addition to the harmonization of the product requirements the Directives are also one of the foundations of the high levels of health and consumer protection as required by articles 152 and 153 of the Treaty establishing the European Community.

The Member States are obliged to take all appropriate measures to ensure fulfilment of the obligations arising out of the Treaty (article 10) or resulting from actions taken by the institutions of the Community.

> **Article 10 of the Treaty establishing the European Community:**
> Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community. They shall facilitate the achievement of the Community's tasks. They shall abstain from any measure that could jeopardise the attainment of the objectives of this Treaty.

This not only includes the obligation to implement the Directives into their national legislation; in addition the member states are not allowed to prohibit or hinder the trade in products that are in conformity with the Directives and should take appropriate measures against products that violate the requirements in the Directives. These obligations imply enforcement of the Community product legislation, i.e. member states should organize some form of market surveillance. In fact, the Guide to the implementation of directives based on the New Approach and the Global Approach declares that "Market surveillance is an essential tool for enforcing New Approach directives, in particular by taking measures to check that products meet requirements of the applicable directives, that action is taken to bring non-compliant products into compliance, and that sanctions are applied when necessary".

The revision of the New Approach Directives focuses on several issues to be improved regarding the inner market. The Commission is, amongst other, seriously concerned about enhancing market surveillance and establishes this as a tool to improve the three pillars of market surveillance. Through developing and implementing best practices, member states will

be able to understand the importance of market surveillance as an important contributor to the free movement of goods in the inner market, equal conditions for the economical operators and more safe products for the consumers.

2.2 Additional requirements for market surveillance

In addition to the obligations derived from the Treaty, the Toys Directive and the General Product Safety Directive carry obligations with respect to market surveillance. Article 12 of the Toys Directive is concerned with market surveillance and requires the Member States to take the necessary measures to ensure that sample checks are carried out on toys which are on their market, so as to verify their conformity with this Directive and also provides for the Member States to make sure that the authority doing these checks has the necessary legal powers to perform the inspections and sampling. In addition, the Toys Directive requires the Member States to send the Commission a report on the application of this Directive every three years.

The General Product Safety Directive (GPSD) is more outspoken about market surveillance. It lays down the obligation for the member states to establish or nominate authorities competent to monitor the compliance of products with the general safety requirements and arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive and to define the tasks powers, organization and cooperation arrangements of these competent authorities. The GPSD also requires that the competent authorities have the legal powers to organize checks and take specific measures for products failing to comply with the safety requirements. Finally the GPSD requires cooperation and information exchange between the market surveillance authorities within the member states and between the authorities of the member states.

Particularly interesting in the context of the organization of market surveillance is Article 8,1 under a), where it says that the competent authority in the member state shall be entitled to:

for any product:

a) *to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;*

b) *to require all necessary information from the parties concerned;*

c) *to take samples of products and subject them to safety checks.*

The scope of the GPSD encompasses consumer products; in as far as they are not regulated by other Directives. Most of the new approach directives do not specify the way market surveillance should be performed which means that the provisions of the GPSD apply.

For consumer products the directions given in the GPSD provide to Market Surveillance Authorities a suitable model of the minimum requirements the harmonized legislation demands, which may be extended to the fields of the other new approach product directives to the degree that they regulate consumer products, too. In fact, parallel to the revision of the new approach a proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products1 is discussed, which devotes a whole chapter to market surveillance. Though not completely identical, the proposal brings the requirements to the way market surveillance for many new approach directives is performed in line with those in the GPSD.

Overall the treaty and legislation discussed define the preconditions market surveillance has to fulfil. The Guide to the New Approach summarizes the activities that follow from these obligations as follows:

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1 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS : {SEC(2007) 173}, {SEC(2007) 174}

Market surveillance involves two main stages:

- national surveillance authorities shall monitor that products placed on the market comply with the provisions of the applicable national legislation transposing the New Approach directives;
- subsequently, when necessary, they shall take action to establish conformity.

The guide specifies what is understood by monitoring as follows:

To be able to monitor products placed on the market, surveillance authorities shall have the power, competence and resources:

- *to regularly visit commercial, industrial and storage premises;*
- *to regularly visit, if appropriate, work places and other premises where products are put into service;*
- *to organise random and spot checks;*
- *to take samples of products, and to subject them to examination and testing; and*
- *to require all necessary information.*

Besides this 'core business', market surveillance organizations have obligations with respect to cooperation and information exchange with national and European market surveillance organizations and the European Commission and, when working in the area of consumer products, to investigate consumer complaints.

2.3 Cooperation with Customs

Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries lays down rules regarding the suspension of the release of products by customs authorities and provides for further proceedings including the involvement of market surveillance authorities.

The regulation prescribes that the customs authorities can block the releasing of goods that don't comply with the requirements from the directives. Goods can be blocked for three days for investigations. Often the three days are used for market surveillance authorities to investigate the products to decide if the goods can be released, if is must be blocked or if further investigations are necessary. If the goods are found to be non-compliant, import can be banned and customs will mark the consignment and the accompanying papers that imports of the goods were forbidden. Customs will also notify the customs authorities in the other Member States about the consignment.

2.4 The role of standards

Manufacturers frequently refer to voluntary standards in the design and production of their goods. As noted above harmonised European standards play a crucial role in the operation of the New Approach to technical harmonisation. Where a European standard has had its reference published in the official journal it is considered a harmonised standard and its use confers a legal presumption of conformity with the applicable legal requirements laid down in the new approach directives and under the General Product Safety Directive. This presumption can be rebutted by national authorities where products present an unacceptable risk to the public even when the products are made in compliance with the standard. The procedure is the so-called safeguard clause. Harmonised European standards thus form the basis of market surveillance activities for many products. Market surveillance authorities have traditionally participated in the development and revision of standards although their participation has waned in recent years. Standards committees with their mix of stakeholders do provide a unique forum within which to discuss product-related risks.

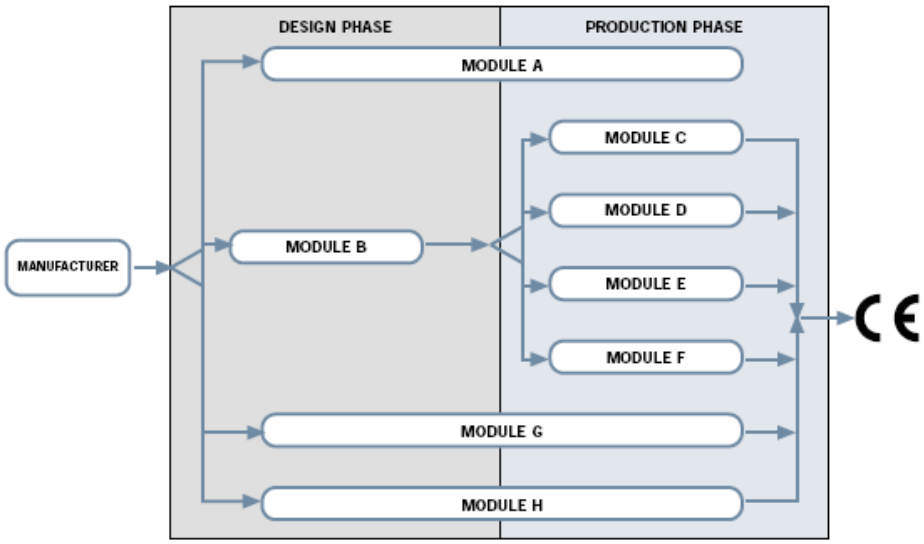
2.5 The Principles of conformity assessment and CE Marking

Before putting a product on the European market the manufacturer or importer is required to make sure that the product fulfils the essential safety requirements in the EU legislation. The process by which the producer or importer assures this is prescribed in the different European directives that apply for different kinds of products. This process is called conformity assessment.

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

The various procedures for conformity assessment are with only minor variations, more or less the same in all directives and are part of the “global approach”. They are subdivided in eight so-called “modules”:

The eight conformity assessment modules are:
Module A - Internal Production Control
Module B - EC Type Examination
Module C - Conformity to Type
Module D - Production Quality Assurance
Module E - Quality Assurance for Final Testing
Module F - Product Verification
Module G - Unit Verification
Module H - Full Quality Assurance



Some of these Modules (A, G or H) are normally applied individually, others like Module B to be applied in conjunction with one of Modules C, D, E or F. It is beyond the scope of this guide to fully discuss these procedures; details can be found in the "Guide to the implementation of directives based on the New Approach and the Global Approach" and in the specific Guides for other Directives. However, the differences between the modules required for the conformity assessment procedure for specific products are important for market surveillance organizations and should be taken into account when planning market surveillance on these products.

Module A – internal production control, for example, is more familiarly know 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 imprint the CE-marking on this product and put the product on the market. No independent third party is needed. This module has to be applied for electrical products under the LVD, for many machines under the Machine Directive and for most toys, for example.

Contrarily for products where third party intervention by a notified body is required for the conformity assessment, document checks are the primary instrument for market surveillance. For consumer gas appliances the Gas Appliances Directive and for personal protective equipment the PPE Directive require a type approval by a notified body, before the declaration of conformity can be issued and CE marking applied. The type approval generally involves checking the conformity of the appliance against the relevant European standard and the results of these tests and a 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 of such complicated appliances. The validity of the documents can easily be verified at the notified body that issued the certificate.

2.6 Revision of the New Approach

The adoption of the New Approach is generally qualified as a success and some of its important elements like the reference to standards have been adopted in the General Product Safety Directive. Experience with the implementation of the legislation has however shown that there is a certain lack of coherence in its implementation and enforcement. Furthermore there is a certain risk of distortion to competition as a result of unequal treatment in the case of non-complying and dangerous products through very different national market surveillance infrastructures rules and means.

The draft regulation setting out requirements for market surveillance seeks to ensure that national authorities are given equivalent means of intervention and the necessary authority to intervene in the market to be able to restrict or withdraw non compliant or unsafe products. Furthermore it seeks to ensure cooperation between the internal authorities and the customs authorities controlling products entering the market from third countries and sets the framework for the exchange of information between national authorities and cooperation between them in the case of products on the markets of more than one Member State. The regulation is expected to be adopted sometime in late 2008.

PART B
MANAGEMENT OF MARKET SURVEILLANCE ACTIVITIES

3 MARKET SURVEILLANCE ACTIVITIES - ORGANISATION & INFRASTRUCTURE

3.1 Introduction

Market surveillance authorities must be organized and equipped to cope with the obligations and requirements discussed in Chapter 2. However, the treaties do not prescribe how the member states have 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. The way they perform market surveillance falls under the principle of *subsidiarity*.

3.2 Subsidiarity

The considerable differences in the ways it is organized in the member states reflects the fact that market surveillance is a national responsibility. In some member states market surveillance is centrally organized, while in others market surveillance is operated regionally and decentralized. A vertical organization of market surveillance occurs, where for each directive (or groups of directives) specific market surveillance organizations exist, generally under the Ministries responsible for implementation of that particular directive. Other member states have a single organization for all regulations regarding consumer products (and often other legislation as well). In short, the ways in which market surveillance is organized and performed in the European Union varies greatly between the member states.

Subsidiarity allows the members states to organize market surveillance in such a way that it suits their cultural and political situation and their legal system. It seems fair, however, to note that in many cases the historical development of their enforcement organizations also played a role in defining the way member states organized their market surveillance. Furthermore, the organization of market surveillance is not static; in many member states the organization of market surveillance is frequently adapted to cope with new needs, a changing environment or a different political reality.

Where this chapter describes the organization of market surveillance it does therefore not describe a single ideal organization of market surveillance. No recipe can be provided that should be followed to install an organization that will perform 'state of the art' market surveillance. The differences between the member states are simply too large for a single organization model to suit all and the member states themselves are the best judge of what is suitable for their country.

Nevertheless performing market surveillance requires specific functions, knowledge and responses that all organizations performing this task have in common and which are useful to discuss. Not all of the subjects in this chapter may be relevant for al MS-organizations, but many will require some thought, even for those who are not directly affected. It is wise to realize that declaring a certain subject not relevant to the organization may implicitly boil down to a choice with consequences. As an example: If your organization is responsible for a single directive only prioritization across several directives might not appear to be relevant. On the other hand in such cases someone else will be doing the prioritization for you. Furthermore the arguments behind the prioritization might still be relevant because all directives requires a minimum level of market surveillance activity. It can perhaps be decided from the same arguments as those that decide the prioritization of the activity.

To fulfill the obligations arising from the European Treaties and Directives both hard and soft infrastructure is needed:

3.2.1 Hard Infrastructure

To perform the tasks required for effective and efficient market surveillance the organization needs accommodation, facilities and other means of production:

- office capacity
  Market surveillance authorities perform inspections, take legal measures following legal procedures, administrate the results of their activities, administrate their personnel and perform a lot of other activities involving paper work. Possibly some of these activities can performed by teleworking or can be subcontracted, but for the remaining activities sufficient office space should be available.
- lab capacity
  Monitoring the market involves taking samples and investigating those samples in order to determine their compliance with legislation. Therefore sufficient laboratory capacity is needed for market surveillance. Laboratory facilities can be part of the infrastructure of the authority itself, but laboratory investigations can also be subcontracted. Both alternatives are currently used in the Member states of the European Union.
- IT systems
  Though the administration involved in market surveillance can in principle be done using only paperwork, IT systems are mandatory from an efficiency point of view. IT helps efficient work flow and allows swift and easy retrieval of information needed for many tasks in the process. The role of IT in market surveillance will be extensively discussed later.
- Communication
  Both for internal and external communication infrastructure is necessary. Telephone and E-mail should be available to many of the employees involved in the activities.
- Transport
  Inspections are not performed in the office and field inspectors need a means of transport to reach the premises to inspect, most likely a car. Cars of suitable characteristics allow to take equipment required for field tests and to transport the samples taken.

Laboratory capacity and IT systems will be discussed more extensively later, because they are directly relevant to the functioning of the market surveillance processes themselves.

3.2.2 Legislative infrastructure

In order to establish proper and efficient market surveillance structure in each member state there is a need of looking into legislative structure, the nature and art of enforcement structure and the economical aspects of enforcement bodies. Since one of the main objectives of market surveillance is to ensure the economical operators equal conditions, it is very important to establish a structure that enables all enforcement bodies to carry out market surveillance under the same strategy. This means the same legal powers to act efficiently and sufficient financial support to perform efficient market surveillance within all product safety fields. The legislative framework regarding market surveillance in each member state should cover all market surveillance authorities and also be based upon the legislative framework of respective EU-directives.

3.2.3 Organizational (soft) infrastructure

Buildings, laboratories and computers do not make a market surveillance organization. More important are the people who work for the authority, their culture and customs, their knowledge, their contacts and the procedures and organization that structure their activities. Theory and literature about organizations and organization building is widely available and will not be discussed here. Nor is a model given of how market surveillance should ideally be organized. No single model could satisfy the particular needs and circumstances of all the member states.

Nevertheless, market surveillance organizations perform similar functions and activities. Therefore there are many issues they have to address and which they have in common. Some of these issues are discussed as follows, as far as they are typical issues market surveillance authorities have to cope with.

3.2.3.1 Personnel and Competences

The core processes of market surveillance are monitoring of compliance of products on the market with legislation and intervention when non compliances are found. To perform the tasks associated with these processes the market surveillance authorities need employees with a number of competences and skills that are particular for market surveillance. The competences required include specific legal and technical knowledge for the inspectors performing the actual inspections, but for the organization as a whole also knowledge of the markets where the authority operates, of hazard identification and risk analysis, etc. etc. are important.

3.2.3.2 Basic competences

Enforcement officers who carry out market supervision must have the necessary qualifications, experience and be fit for their tasks. They must have substantial legal knowledge, technical knowledge, personal behavior and administrative skills and the ability to use those in the daily practice of market surveillance.

Legal competences and skills

Enforcement officers and other personnel involved in the legal procedures following inspections need thorough knowledge of the applicable legislation and the legal structures in which they function. The national implementation of the European Directives varies considerably to suit the legal systems in 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.
- Thorough knowledge of the national product legislation involved
- Familiarity with the Directives and the Essential Requirements in the Directives

Technical competences and skills

Efficient and effective market surveillance also requires a good knowledge on the part of the enforcement officers of the markets involved, the properties of the products supervised and the risks of the products. Familiarity with technical issues relating to the legal product requirements and basic knowledge of the applicable standards is an additional necessity

Administrative competences and skills

To be filled in at later stage

3.2.3.3 Training of personnel

Examples of necessary competence are knowledge about risk assessments of products, familiarity with essential requirements in the directives, interpretation and use of standards as well as administrative knowledge. In addition inspectors responsible for market surveillance project should possess experience from previous projects. All these aspects have to be taken into account when designing a training project for inspectors.

Training Requirements for market surveillance inspectors

In order to prepare enforcement officers for market surveillance, a training program is envisaged to include legal aspects, technical issues as standards or other technical requirements, methods for risk assessment and skills regarding information, communication and relationship management.

On-going training and importance of cross-sharing of information/expertise

Experience from market surveillance projects should systematically be transferred to national and international colleagues. Transfer of experience regarding methodology and procedures is important to contribute to the development of market surveillance as an instrument and a profession. It is envisaged that market surveillance officers (MSO) meet regularly to share experiences, both at a national level and at a cross border level.

Ongoing training should include developments regarding directives, regulations, standards, result from scientific research and technological progress and finally cross border information related to dangerous products.

3.3 Approaches to market surveillance

This guide limits itself to the description of the practices used in the market surveillance of non food consumer products. It must be realized, however, that the activity of Market surveillance is broader in scope than what is discussed in this guide. Market surveillance is also done in the area of foods and products for professional use.

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For market surveillance of non food consumer products, roughly four approaches can be distinguished. These approaches differ in the way they deal with the monitoring of the market and they lead to difference in the way the activities involved are planned.

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3.3.1 Reactive market surveillance

Both the General Product Safety Directive and the regulations providing a framework for market surveillance require that consumer complaints are investigated and, where appropriate action is undertaken when the results of the investigation indicate that action is required.
Reports about possibly dangerous or non compliant products may come from other sources, too: complaints about products from competitors, notifications from other market surveillance authorities in the same or other member states, or reports in the media.
All these reports require similar reactions from the MS authority; they must be investigated, conclusions must be drawn, action taken when necessary and results must be reported back.
Because investigations are started by outside 'events', they cannot be planned in advance.
The authority therefore needs the capability to improvise and that capability has to be built into the organization. How to do this is described in section 4.6.1 on reactive market surveillance.

3.3.2 Product oriented market surveillance

Traditionally market surveillance on non food consumer products has been product oriented.
This approach to market surveillance comes naturally from the way legislation formulated product requirements. To prove that an offence has been committed by businesses, it must generally be shown that the product does not comply with the safety requirements of a given Directive.
Since demonstrating non compliance usually requires laboratory investigations, which can be done more efficiently when series of products are tested, there is a string incentive to work in projects on specific products.
This approach to market surveillance is pro-active. Projects can be selected for relevancy to consumer safety, can be planned in advance and can be tuned to be as efficient as possible.

Together with the obligatory reactive market surveillance this approach is the one that actually is most often used by the MS organizations in the European Union. The major part of this book describes the best practices in current use for product oriented market surveillance .

3.3.3 Business oriented surveillance

Especially in the market surveillance of legislation to safeguard the food chain insp ections are business oriented. That stands to reason, because businesses along the chain from production to delivery of foods can decisively influence the safety of the foods they are handling. Food legislation tends therefore to be system oriented and mar ket surveillance is also aimed at the operational management and the quality systems employed. Keywords are for example HACCP and system auditing.

Though not all lessons learned in the food terrain are relevant to product safety market surveillance, a number of recent developments are interesting for the product safety field, too. In particular a framework that takes into account the reasons businesses have for complying or not complying, in conjunction with approaches to improve the incentives to comply, g ives interesting handles for market surveillance to direct efforts at 'high risk' businesses [2]. Aiming the resources at those companies that do not comply improves efficiency of market surveillance and is also in line with the developments in several membe r states where the governments try to reduce the inspection burden for 'good' companies and direct market surveillance more precisely at the non compliers. A section in this guide will discuss these developments and indicate how product safety market surve illance can make use of this knowledge.

3.3.4 Risk oriented market surveillance

Market surveillance activities can also be guided via a risk oriented approach. Since the first priority of most market surveillance authorities is the protection of consumer safety and health, point of departure for prioritizing the activities can be the wish to reduce specific risks. Where information is available (for example form accident statistics) that specific hazards are prominent in determining the risks of products for con sumers, attention is pointed to reducing these hazards.

Fire hazard can serve as an example. Where casualties form the use of consumer products are relatively rare in Europe, fires of homes still cause many casualties and much damage. From some national available statistics it is found that a number of consumer products are potential fire sources and some are mentioned in the literature as having caused fires. Candles and electrical equipment, especially television sets, and gas appliances are mentioned regularly in this respect. The authority can then chose to aim market surveillance at reducing fire hazards by executing an activity program that concentrates predominantly on the surveillance of products that are potential fire hazards.

Of course, this approach converges with the product oriented approach, because it requires the identification of consumer products that might potentially originate fires and the subsequent market surveillance of these types of products.

In general most market surveillance au thorities are likely to use all of these approaches to a certain extent. Product oriented surveillance generally takes into account knowledge about the particular players in the market of which the authority knows they are 'high risk'. Similarly, when efforts are primarily directed at known offenders, offences of product legislation still has to be proven and for that sampling and testing of products is necessary. For reason of efficiency the choice for specific product categories is best made in advance, l eading to project similar in design as those in the product oriented approach.

[2] Business that are known from previous findings or from available data as potentially not following the regulations.

3.3.5 Importance of standard operating procedures

The basic market surveillance processes are always similar, regardless the organization that is performing them. All market surveillance authorities face essentially the same tasks and problems. Especially in larger market surveillance organizations, whose responsibility covers more Directives and product categories, care should be taken that the MS process maintains a high degree of uniformity and consistency to assure equality for the law for all businesses inspected. Similarly precautions must be taken to maintain proportionality and consistency in the interventions and sanctions imposed when offences are found.

The usual way to assure uniformity and consistency in the working processes is by adopting organization-wide standard operating procedures (SOPs) for these processes. Generally these protocols will be in the form of procedures that are part of the quality assurance system of the organizations.

Using SOPs will ensure that all actions are grounded on the same strategic principles and planned, performed, reported and analyzed within the same legal frames. A number of issues that should be addressed organization wide is discussed in the following sections.

3.3.6 Intervention policies

Market surveillance authorities intervene when non conformities are encountered. Generally the possible interventions range from giving information (compliance assistance), to formal warnings and fines, up to legal proceedings that can result in penalties. Other possible sanctions include the discontinuation of sales, seizure of products and forcing businesses to perform recalls. To make sure that all businesses are treated equally over the whole set of responsibilities, directives and product categories the authority covers, a number of principles should be adhered to.

a) Principles of proportionality and consistency.

The market surveillance authority must make sure that its interventions are:

- *proportional*
  Proportionality means that the severity of the intervention is in proportion with the severity of the offence; for small violations less strict measures are in order then for serious offences.

- *consistent*
  consistency in enforcement action means that for similar offences equally strict interventions are applied.

Many (but not all) market surveillance authorities monitor and enforce markets regulated by several directives and are consequently involved with a large variety of products. Since a single company frequently markets more types of products, consistency in the measures taken is important. Differences in the severity of measures taken for similar violations in different product categories will not be understood and will adversely affect confidence in the market surveillance system. The same is true when differences occur between the measures taken by different inspectors or where regional differences occur.

To preclude such differences as much as possible and to assure proportionality and consistence in the legal measures taken over the whole field covered, the market surveillance authority should define formal intervention policies and maintain their application throughout the whole organization. These issues are best addressed in a standard operating procedure, which could address the following issues:

b) *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 jeopardize the safety of the consumer and less stringent measures form non conformities that do not directly lead to great hazards. Article 8 of the General Product Safety Directive gives an indication of what is meant here, where it requires tougher action for increasingly dangerous products.

c) *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 int ervention policies should protocol this in such a way that repeated offences are treated equally.

d) *Intervention limit value*

In practice product requirements laid down in legislation and in (harmonized) 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 requirem ent.

Example to be introduced.

To determine if a quantitative requirement of a property is fulfilled, quantitative measurement of the property is necessary. The result of the measurement is a value that either exceeds or fulfils the limit value given in the requirement. Though that value can be said to either fail or pass the requirement, interpretation of the gravity of a failure to pass the requirement is not straightforward. In general a small deviation from the limit value of the requirement seems less of an offence than grossly exceeding the value and it is unlikely that a small deviation would lead to a sharp increase in the risk presented by the product.

Example the requirement in EN 71-3 for the maximum migration of heavy metals in toys, which requires for lead that the amount released for migration is less than 90 ng/mg. Clearly an amount of 90,2 ng/mg 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 agreement with the requirement. However, if the amount released for migration were 450 ng/mg, the risk on poisoning of course does 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, which risk gradually increases with increasing deviation from the limit value.

In the interest of consistency and proportionality the intervention policy of the market surveillance authority should provide general guidelines relating the degree of exceeding of the limit value to the sanction taken.

Measurement uncertainties must be taken into consideration when setting the intervention limit values. No physical property can be measured with absolute accuracy. There will always remain some uncertainties even if small and often the inaccuracies are in the magnitude of some percent. It doesn't make much sense to take action against a product if the measured value does not exceed the threshold value plus the uncertainty.

e) classification of shortcomings against standards and gravity of offence

Some authorities have developed the idea of intervention limit values into an entire scheme that assigns a given exceeding of a threshold value from a given test requirement with a severity. One example of such a scheme is the Nordic Failure Code List which has been discussed in LVD ADCO. (The list is annexed in Annex X.)

The idea behind such a list is that a given excess of a threshold value for a test requirement is assigned with a severity (a "code") which in turn is translated to the necessary measure. The lists can be shared with e.g. test laboratories.

Example: in electrical products live wires must be separated from touchable parts with a distance that is called the creepage distance. For many appliances the requirement is that this distance exceeds 5 mm.

The failure code list prescribes the following scale.

- *Creepage distance between 4.5 and 5.0 mm (a deviation of 10 % from the requirement) – code 1.*
- *Creepage distance between 2.5 and 4.5 mm (a deviation of 10 - 50 % from the requirement) – code 2.*
- *Creepage distance under 2.5 mm (a deviation of more than 50 % from the requ irement) – code 3.*

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

The intervention policy should prescribe how the different codes are translated to measures.

f) decision making on sanctions after determining of offences

Once it is determined that the legal requirements are violated, the authority must decide if a sanction will be imposed and, if it is, what sanction will be imposed. The sanction should of course fulfil the requirements of proportionality and consistency as discussed above. 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 authorized to t ake the final decision. Good practice is to involve the field officer who did the inspection leading to the sanction and the laboratory in the decision. Good practice is 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 senior officer. Where possible the legal department can also be involved. Such a procedure avoids that individual prejudices against a business or about the violation in questi on determine (height of) the sanction and advances equality for the law.

g) *Follow-up inspection*

When an inspection and the associated investigations result in an intervention or sanction, good practice requires follow-up after the sanction has been effect ed.

Since the intervention was because of a non compliance either in 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.

The necessity extends to even the lightest measures taken. A warning that a product is not in compliance must be taken seriously by the offender and he has either to discontinue the sale of the offending product, or bring it in compliance.

If on renewed inspection the offenc e still continues, a new stricter sanction should be taken. This is reasonable: the business was aware of the non conformity and is therefor e more culpable and recidivist.

3.3.7 Notifications and consumer complaints

Both the GPSD and the proposed *regulation*[1] *providing a framework for market surveillance* require that complaints about products available on the market submitted by consumers are investigated. Consumer complaints deserve attention for other reasons than the legal obligation to investigate them alone; they serve as an important antenna for safety problems in products on the market. This is especially true when the number of investigated complaints increases and obtains some statistical significance.

Repeated consumer complaints about the same product indicate a possible problem with that product, in particular when the complaints concern similar deficiencies or incidents with the product. Such a product should be carefully investigated and subjected to risk analysis. When necessary, test should be performed. Depending on the result intervention may be initiated.

The information obtained from investigating consumer complaints can also contribute to the sensible prioritizing of pro active market surveillance activities, because those complaints indicate with which categories of products consumer experience (safety) problems. The value of such information for this purpose increases with the number of complaints investigated.

Besides consumer complaints market surveillance authorities deal in a similar way with complaints from other sources, like for example complaints about competing products from traders and manufacturers, and with RAPEX notifications and safeguard clauses. In all these cases investigations are initiated because of information coming from outside the market surveillance authority. Reacting on consumer complaints, notifications and other reports from outside sources can be characterized as “reactive market surveillance”. A more elaborate discussion of reactive market surveillance is given in paragraph 4.6.1.

The Market surveillance authority should approach consumer complaints uniformly and consistently. The methods defined to handle complaints must be imbedded in the market surveillance organization.

h) How to handle consumer complaints and notifications

i) 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. Reports from other sources may also be of little relevance from the point of view of the market surveillance authority and even RAPEX notifications vary in the urgency with which they have to be handled. The investigation of irrelevant reports and incidents requires resources that cannot be spent on more useful activities.
An operational procedure should therefore be provided that allows filtering of incoming reports. The method of filtering should be capable to distinguish between irrelevant and relevant complaints/reports and should classify the urgency of the relevant reports. Conscientious judgement is imperative, because misclassification of a serious problem as irrelevant or unimportant fails to deliver good market surveillance and is likely to result in bad publicity. The system must assure that the initial classification and the decisions about the follow-up are taken by personnel well qualified to do this job. Initial assessment would normally involve risk assessment, but familiarity with the technical properties of the products involved and the applicable legislation is also indispensable. Where after the initial assessment there remains doubt, the possibility to consult a specialist should be incorporated in the procedure.

j) *Follow-up*

Follow-up obviously depends on the assessment of the complaint or report. Incidents about products that present high risks for the public or that potentially attract high media attention need more urgent reactions than simple consumer complaints that are likely to results in minor legal sanctions. For the critical cases it is advisable to have a contingency plan

available. This plan should address the responsibilities of key personnel involved, which relations have to be contacted (prosecutor, Ministries, media, etc), how the investigation is to be handled, etc.

Depending on the results of the investigation intervention may be necessary. In principle the course followed here does not deviate from the general and specific intervention policies defined in section 3.3.6, even where in cases with intense media attention outside pressures for specific interventions may be strong.

Follow up should always include reporting the results back to the consumer (or organization) 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. Determining issues are legislation, the way the legal procedures have to be handled and confidentiality requirements.

k) Examples of implementation: call centres; decentralized handling, E-mail entry

The way the European market surveillance authorities in Europe are organized varies greatly and the best way to organize the handling of consumer complaints and other reports obviously depends on the organization of the authority.

In decentralized organizations 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 for example food safety, and do not have all the required knowledge in house. They should then be able fall back to colleague authorities that do posses the required expertise and equipment to handle such cases.

In centralized organizations consumer complaints and reports may still be handled regionally, but central handling is an alternative which can have 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 assess them for analysis, which is important for planning future activities.

An example of centralized handling of consumer complaints and reports in one of the member states is centred around a call centre, where consumers can submit complaints over a toll free number. The centre is a small department, which also handles reports that come in via mail or E-mail. 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 terrains 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 3.4.4.2.a.

3.3.8 Quality assurance

A number of member states require conformity assessment bodies to be accredited before they can be notified in the framework of one or more new approach directives. Accreditation then testifies that the conformity assessment body fulfils the requirements for such bodies, as formulated in the Directives. In the present proposal for the review of the New Approach the requirements for conformity assessment bodies are harmonized for many new approach Directives3.

When this is asked from notified bodies, the market surveillance authorities themselves should also pursue accreditation

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3 Proposal for a DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a common framework for the marketing of products

a) Of inspections
b) Of sampling
c) Of tests and laboratory investigations
d) Of intervention procedures
e) Of complaint and notification handling

Reference to the 17000 series of standards

3.3.9 External relations

Market surveillance authorities perform a specific function as part of a set of wider policies aiming to establish the single market and the free circulation of goods while at the same time ascertaining a high level of product safety in the Union. The set of policies include 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. Important players with whom communication is required include:

3.3.9.1 Ministries

The Ministries responsible for the implementation of the Product Directives the authority has to 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 and that in turn determines the ease with which the legislation can be enforced. 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 group consisting of enforcement bodies. Such cooperation groups should ideally have the power to establish procedures for practical cooperation both nationally and on a European level.

3.3.9.2 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 zones' in the division of responsibilities, where there is uncertainty about which authority is responsible. Regular communication between the authorities to coordinate the activities in these areas is highly desirable.

However, even where no grey zones 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 which translate into extra costs. Political consensus is that these costs should be minimized. This calls for a coordinated approach of the authorities, which can only be reached with regular communication and coordination between the authorities. Authorities whose main task is not market surveillance of product legislation, but which also perform inspections at the same businesses, like labour and environmental inspectorates, should also be involved.

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

3.3.9.3 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 the sanction policies. Also, work flow should be coordinated with the prosecution to assure minimum turnover times. Intervention of the prosecutor may also be required when stocks are to be seized or destroyed.

3.3.9.4 Standardization

Though the new approach directives give the legal framework for the product requirements by formulating and imposing essential safety requirements, technical product requirements are specified mainly in European harmonized standards. These harmonized standards determine to a large degree not also the actual safety level of the products manufacturers according to these standards, but also how easy or different it is to enforce the requirements. Market surveillance authorities influence standardization on the European level via the AdCo's and the Commission. However, interaction with the standardization institutes at the national level is well advised, if only to monitor the developments in the most important standards. Participation in the working committees can also be considered.

3.3.9.5 Stakeholders:

Business

It is of vital importance to have stakeholders like business onboard on the issue of market surveillance. We shall remember that business is the main operator in trading goods and thus has the opportunity and possibility to influence the free movement of goods in Europe. In addition to this business is responsible for product safety and good national relations between business and enforcement bodies will clearly ease the work of product safety. Good national linkage with business on a regulatory basis will surely have a positive effect on the occurrence of dangerous products in Europe.

Consumers' associations

Consumers associations represent a very large group of European citizens and their main task is to ensure the consumers safety towards injuries and economical losses.

Consumers' organisations hold considerable expertise in several product fields. As a consequence of this fact it is envisaged to establish national cooperation with consumers organisations on a regulatory basis regarding product safety. Issues for such cooperation might be information to consumers, market surveillance campaigns, publishing in consumer's magazines etc. National cooperation will also have linkage to international consumer organisations as ANEC etc.

Periodic meetings

In order to establish good relations with all stakeholders it is recommended to arrange regulatory meetings on a national basis. The frequency of such meetings depends on the legislative and technical development both nationally and internationally. It is envisaged to arrange at least one meeting per year with different stakeholders. Meetings may have the form of workshops, seminars or be of another kind depending of 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

3.3.9.6 Media

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

3.3.10 The role of IT systems

Though all processes involved in market surveillance can be administrated in principle without the aid of information technology, efficiency is greatly enhanced by using electronic data reduction systems. In fact, the significance of the use of IT systems for market surveillance can hardly be underestimated. Besides the facilitation of the administrative processes information technology can contribute added value, because it makes possible analysis of the data obtained in a way that a system based on paper would never allow. The main roles of information technology in market surveillance can be summarized as follows:

- Facilitating the market surveillance processes

The core of market surveillance is a chain of processes depending upon each other, which may culminate in imposing sanctions or other interventions. Constituent processes are inspections, sampling, laboratory testing, interpretation of results, decision making, intervention and the executing of the legal processes that result. In all these processes data are generated, which are required in the next step (or parallel steps) in the chain. Both collecting and administrating the information required and its distribution within the organization are greatly facilitated and quickened by using well designed IT-systems.

IT-systems can also serve to assure the quality of the data obtained. By forcing entry of specific data, administrating the history and who and when of data entry and change and by monitoring process progress, more homogenous data are administrated and better control of data integrity can be obtained.

- Making data available where they are needed

For efficient market surveillance quick access to required information is a necessity in many of the stages of the process. This holds true for the field officer, the laboratory and for the departments involved in the legal follow-up.

Information technology 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 the results of the investigation on those samples. This information can be retrieved from the IT system before setting out for an inspection, but better still this is downloaded to the field officer's lap top, either directly from the system or via the internet. Lap tops for field officers are also useful to administrate the data from the inspection and the data on the samples. Such information is then available directly after uploading to the laboratory and the other departments involved.

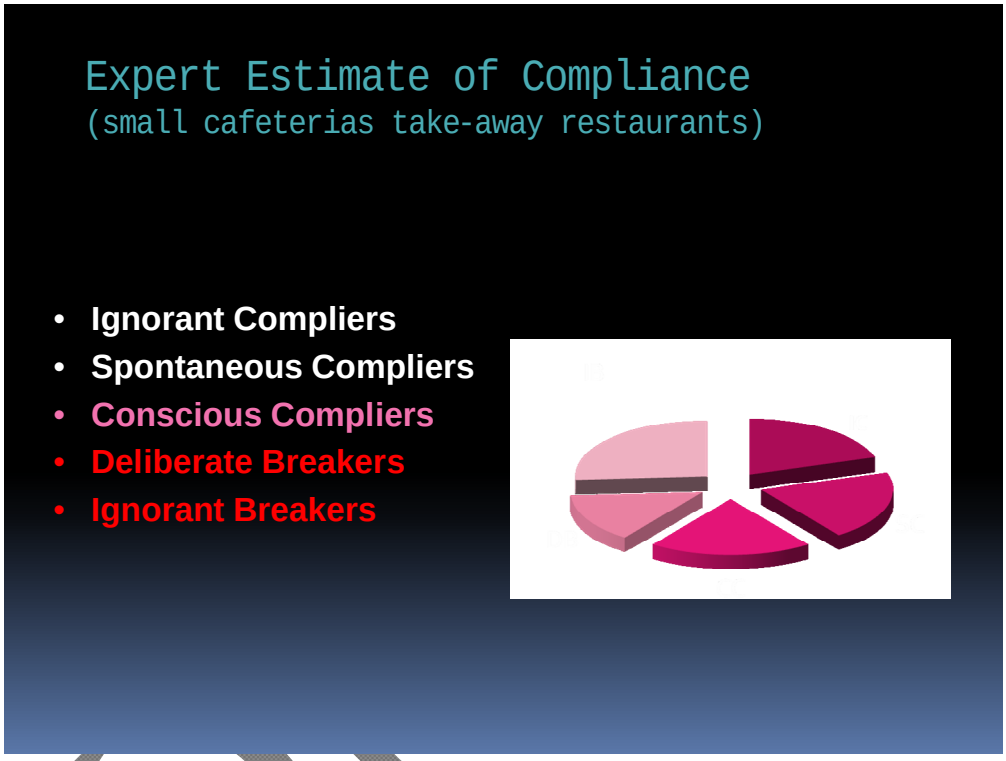
- Management tool

Besides its roles in facilitating the core processes of market surveillance the easy access to the information collected in these processes makes information technology an important management tool. When implemented appropriately the system can deliver instantaneous quantitative information on the progress and results of all market surveillance activities.

- ICSMS

3.3.11 Targeting of market surveillance To be written

- Willingness to comply of businesses
- Reasons for businesses to comply
- Reasons not to comply



What factors influence compliance behavior of businesses?

3.3.12 Effectiveness of interventions on breakers

Sanctions

- Effective for (deliberate and ignorant breakers)

Education of the target group

3.3.13 Legal actions to be taken by the enforcement bodies

When a product has been declared to be non compliant with the general safety requirements related to a specific product directive, legal actions has to be taken by the enforcement body towards retailer, importer or producer. The proportionality principle states that any legal actions taken must be proportional to the violation and be a reflection of the gravity of the violation.

Several legal actions have been utilized regarding market surveillance.

- Additional documentation of safety

If there are indications of lack of conformity with essential safety requirements additional documentation should be requested. Such documentation can be test reports, risk assessment etc. Discussions with the operator are recommended before any decisions are taken. If operator voluntarily proposes fair measures, a letter of agreement from the enforcement body should conclude such an agreement.

- Decision on temporarily sales ban and corrective actions.

The authority may temporarily ban the sales of a product by legal decision and oblige the operator to improve a product if there is a disagreement on corrective measures. This is the

case when shortcomings are of less serious character (lack of instructions or warnings or minor dangerous properties).

If lack of warnings or instructions, it is recommended not to recall.

If dangerous properties may affect a lot of consumers it is recommended to decide on a recall in order to carry out necessary corrective measures.

- Decisions on sales ban

If there is clear evidence that a product may impose a serious risk to the consumer sales ban should immediately be decided by the authority. Such a decision has to be formalised

In a letter with necessary documentation of evidence.

- Decision on withdrawal

If minor shortcomings are found in a product, this product should be temporarily withdrawn until corrective measures have been undertaken.

If major shortcomings are found, it is recommended to withdraw the product on a permanent basis.

- Decisions on recall

If a product imposes serious risk to the consumers, recall should be requested immediately.

In all aspects of legal actions it is necessary to remind all persons involved that the economical operator has the right to be informed of the current procedures and the right he or she has to make a complaint on a decision taken by the authority.

4 MARKET SURVEILLANCE - THE PLANNING STAGE

4.1 Planning and Control, introductory remarks

Market surveillance plays an important role in the European policies establishing the common market and free circulation of goods, while maintaining a high level of protection for the European citizens. Where the foundations of the common market are laid by the harmonization of legislation over the European union, market surveillance can be seen as tailing the efforts of the Union to establish the single market. Market surveillance serves to detect and sanction the operators that will not comply, despite all other policies aimed at making the single market function. In that way market surveillance contributes to ensuring free movement of goods in the internal market and to the desired high protection level for the European citizens.

Market surveillance is expensive and the member states spend considerable financial resources to organize and perform market surveillance. Since market surveillance is generally paid for from taxes, spending the money made available as optimal as possible is a major concern. The main keys to use resources to obtain maximal efficiency are setting the proper *priorities,* careful *planning and*, the twin brother of planning: *control of activities*.

prioritizing

Market surveillance authorities face the choice of where to put their resources to obtain maximum result from their resources. Making such choices is inevitable, because the numbers of different products in the market is such, that with the resources available it is impossible to cover all parts of the market at the same time. Therefore part of the planning process is choosing which terrains have priority and what share of the resources will be spend

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 priority and priorities are mainly set with this factor in mind. There are good arguments for this choice: all activities performed to promote product safety by market surveillance automatically contribute to establishing the “level playing field” and fair competition. The other way round is not necessarily true. Nevertheless it should be kept in mind that a level playing field for business competition remains an important corner stone for the proper functioning of the common market and therefore deserves due attention of the market surveillance authorities.

Planning

The activity of market surveillance requires a number of processes, which must be carefully tuned to make the overall effort efficient. Constituent processes include inspections, sampling, laboratory testing, evaluating results and legal follow-up. Each of these requires preparation individually and has to be worked out depending on the specific businesses or products under consideration. Though applying to all processes mentioned, this is best illustrated by considering the preparations involved in setting up a test program for a specific product in the laboratory, which requires the selection of suitable tests from the standard, setting up the measuring equipment and taking precautions for quality assurance.

Clearly, it is much more efficient to test series of products with identical test programs, because the preparations have to be done only once for the whole series. Similar argum ents hold for nearly all of the constituent processes. Therefore efficiency benefits when surveillance activities on similar products or businesses are performed in series, which almost naturally leads to working in well defined projects. A large part of the rest of this book will therefore be devoted to how market surveillance projects are planned and organized. Careful planning is also necessary to gear all the interconnecting processes in time. Interventions work best when the time between inspection and the intervention is short, which is the reason that some organizations set restrictions to the period in which the whole process has to take place. To fulfill these time restrictions the partial processes need to interconnect flawlessly, which can only be realized by careful planning. Again, adopting a working method centered on projects facilitates the planning process.

Control of the activities

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 is monitored, to see if the execution needs adjustment or if adjustments in the planning are necessary. Similarly it is wise to monitor budget spending to avoid overspendi ng.

In order to monitor the progress of the planned activities information about the progress should be fed back to the management at regular intervals. To be useful that information should summarize the progress of the activities in a way that is comprehensible for the management, without causing information overload. Reporting the results of all inspections, lab tests and legal cases by transmitting the case files is not useful for control purposes. What is needed is a set of parameters that is useful as an indicator for the progress.

Which parameters constitute suitable indicators depends on the organization of the market surveillance authority and the goals set in the planning. When planning is in terms of the number of inspections and lab tests the obvious indicators are the number of inspections and lab tests, possibly as a percentage of the scheduled output of these parameters. The number if sanctions imposed may also be a useful indicator, as it gives additional information about the effect of the efforts undertaken.

Since most market surveillance authorities have to justify their spending to the authority they work under (often a Ministry), the same indicators used to monitor progress of the planned activities may also be useful for purposes of accountability.

4.2 Planning cycle

Careful planning of activities is crucial for the efficient use of resources in market surveillance. The following paragraphs discuss a systematic approach to the planning process and the issues particularly relevant for planning in market surveillance organizations. The way market surveillance is organized varies considerably between the member states and consequently the market surveillance organizations themselves show big differences. This may be with respect to the scope of their tasks, with authorities covering many directives and authorities that are responsible for only one or two directives. Other differences include the availability of resources, their legal position and the way they have to account for their activities. Of course the way authorities plan is dependent on their specific position, tasks and organization and not all aspects discussed in the following sections will be relevant for all authorities. Neither is this discussion meant as a recipe of how planning should be done. However, many of the issues discussed will be relevant in one form or another and deserve consideration by every organization involved in the market surveillance of consumer products.

Figure 1 summarizes the main steps and relationships in the planning process. In general all these steps carry importance, even when they are not consciously addressed by the authority. It should be realized that failure to address any one of these issues means that implicit choices are made without one being aware.

The planning process as a whole ultimately leads to an operational activity program, which defines the specific market surveillance activities and actions for a certain period of time, usually one year. This activity program specifies the projects and actions for this period, which products and companies will be investigated, how many inspections and tests will be performed in each actions, etc, etc. In short is specifies what has to happen, how often, when and where.

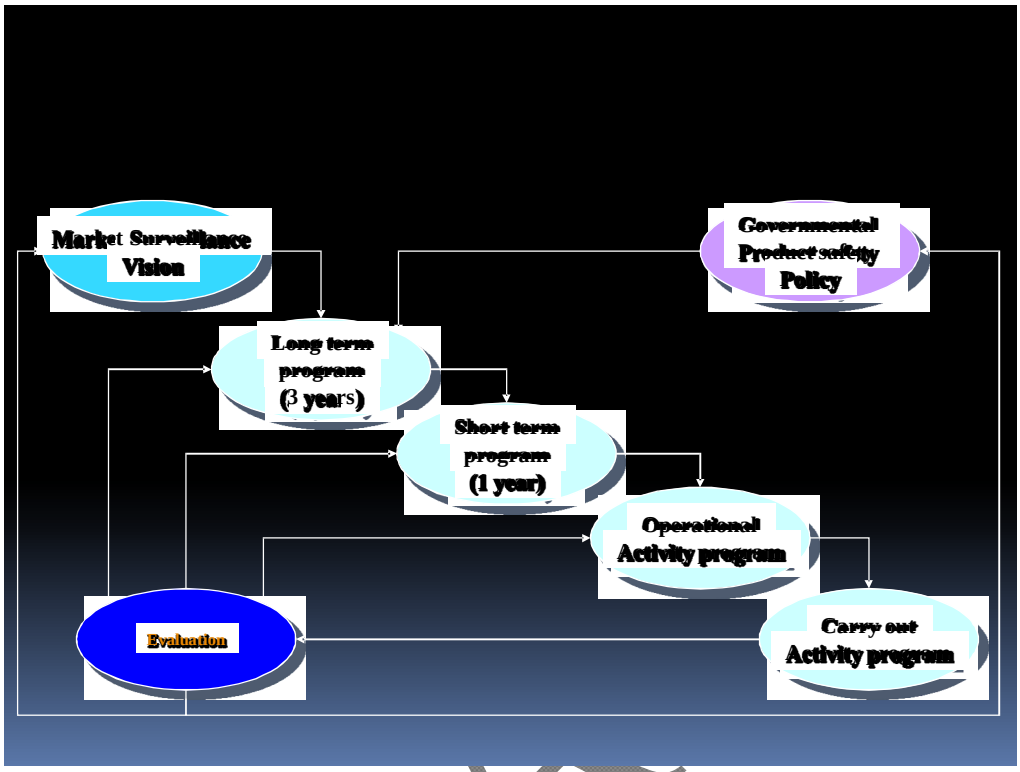


Figure 1: framework for the planning cycle

4.2.1 Vision on market surveillance

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 are outside the control of the market surveillance authority itself, because they are determined by EU policies, governmental policies and organizational boundary conditions. Partly, however, the approach to market surveillance can be defined by the market surveillance authority itself. Because these philosophies and assumptions determine partly the effectiveness of their activities and because they influence the position of the authority consideration of these basic assumptions is important for the authority.

Presently the set of basic presumptions underlying market surveillance varies considerably between the member states and between the market surveillance authorities, but for one of these assumptions exist general agreement. There is wide agreement between the authorities involved in the market surveillance of consumer product that consumer protection is the primary aim of the market surveillance activities.

Examples:

- Enforcement or compliance assistance?

The role of market surveillance can be seen primarily as the enforcement of legislation. When enforcement is the starting point the organization is likely to gear itself to trace and sanction offences and offenders as efficiently as possible. It will spend few resources to make the

target groups aware of their legal obligations or help offenders to comply. In planning and control goals will be formulated and success measured in terms of the number of offences to be identified and the number of sanctions that should be taken.

An alternative perspective is when market surveillance authorities acknowledge that overall compliance of companies might be better served if sanctions are applied to businesses not willing to comply and that the businesses that do want to comply but lack the competence are supported in obtaining the required knowledge (compliance assistance). Obviously that approach leads to different working methods and different control parameters than in the first approach.

- Product, business or risk based approach?

Product, business or risk based approach?

In section several approaches to market surveillance are discussed. Though in practice most authorities will use a mix of all these approaches, market surveillance of consumer products has traditionally leaned against a product-oriented approach. For that reason it is also the approach that receives most attention in the handbook. It should be realized that the unconscious adoption of this approach ("that is the way we have always been doing market surveillance!") might blind the eye for alternative approaches.

Presently the possibilities of market supervision via system audits in businesses are investigated in several member states and indeed system auditing is already routinely applied in the field of food safety. In product safety the possibilities of such an approach are limited at present, because the new approach legislation and that fact that most manufacturing occurs outside the European Union hardly allows system audits. However, system audits are routinely done in the cosmetic industry in some member states and there are possibilities to shift focus to checks of the administrative requirement, including the obligatory technical file.

If there are no possibilities to perform system audits with the producer as mentioned above, attention may be changed from producer to importer. In performing system audit it is of importance to audit importers with reference to products already put in the market and thus available for the consumer. By following this strategy all audits will have relevance to the importers procedures for ensuring that only safe products are put in the market. One major advantage with system audit is that it covers the importers 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 importers procedures related to safety of products.

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

- the position with respect laboratory test, i.e. if these are done "in house" or outsourced,
- the position of the authority with respect to outside pressure to decrease the inspection burden of industry,
- the position with respect to the confidentiality of the information obtained, Should information obtained in inspections and from laboratory tests be made available to the general public, which as tax-payers paid for the gathering of this information? Note that attitudes and also national legislation about this subject varies wildly in Europe and hence the some member states publish much information, while others hardly do.
- The degree of transparency the authority wishes to live up to.

Checking of documents or checking of products

Two different approaches to market surveillance are checking of documents vs. checking of products.

The idea behind the first approach is that checking of documents is a very cost efficient way of doing market surveillance. One officer can check many products in a single day and

documents can be “sampled” by email or mail. Furthermore documentary checks will reveal shortcomings in the administrative procedures which in general mean that the safety is endangered. It is also a well-established fact that most of the dangerous products also have shortcomings in the administrative procedures.

The idea behind the second approach is that it is easy to write papers that show that anything conforms to the legal requirements and that the ultimate way to check this is to test the product itself. Such an approach is more costly and time consuming than documentary checks as testing will most often involve test laboratories and an officer will only be able to check a few products per week (excluding the follow-up activities).

In general both approaches should be applied as documents should indeed be checked as part of any kind of market surveillance activity. The authority should however decide on the prioritisation of the two activities – e.g. if project just aiming at checking documents should be executed and to what extent. Other aspects that relate to the basic market surveillance vision of the authorities include:

- the position with respect laboratory test, i.e. if these are done “in house” or outsourced,
- the position of the authority with respect to outside pressure to decrease the inspection burden of industry,
- the position with respect to the confidentiality of the information obtained, Should information obtained in inspections and from laboratory tests be made available to the general public, which as tax-payers paid for the gathering of this information? Note that attitudes and also national legislation about this subject varies wildly in Europe and hence the some member states publish much information, while others hardly do.
- The 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 other national policies restrict the choices market surveillance authorities can make. They all have (major or minor) implications for the way the market surveillance authority approaches its tasks and operates, however, and therefore deserve consideration. Where possible the vision deserves to be explicitly formulated in a ‘vision document’, if only because it can provide guidance for the processes of planning and prioritizing.

4.2.1.1 Long term program

In an ever changing environment adapting the market surveillance organization to keep it in line with the vision and to cope with expected future developments is a necessity. Market surveillance organizations are generally fine tuned to do their present job, with personnel trained to optimally do that job and frequently an infrastructure of laboratories and IT-systems that is optimal for the present. The whole infrastructure is difficult to restructure in the short term, because, if tasks change radically, personnel needs to be re-educated and the hard infrastructure needs readjustment. Both processes require time (and money).

MS organizations should therefore continually 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 would be described in a long term program.

The long term program then describes the projected development of the organization over a longer period and gives indications of the direction in which the organization moves and adapts to expected new circumstances, environments and priorities. It is leading for drawing up the short term programs, that should reflect the directions indicated in the long term program.

The time frame for the long term program can vary; common periods are 3 and 5 years. Less than a 3 years horizon is probably too short to be able to adjust the organization in time, while over periods of more than 5 years extrapolation is unsure. Good practice is also to review the

long term program annually and correct the program when new information calls for adjustments.

Typical issues to address in the long term program 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 the 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 puts on issues like 'compliance assistance instead of sanctions' and directing market surveillance not at companies that comply (to diminish the administrative burden for the good companies) but instead to the non compliant companies. Another (always popular) initiative of the government bureaucracies in many member states is the relocation of services and resources.
This kind of developments can have great consequences for the working methods of the MS Authority, for the resources available and for the training requirements of its personnel. The long term program should where possible attempt to proactively address this kind of developments by planning the necessary adaptations over a number of years.

- Internal developments

Changing perspectives and visions on market surveillance within the organization may also give reason to make long term adjustments. Examples of internally initiated changes are a change from output managed organization to an outcome managed organization or a shift in focus from product oriented approaches of market surveillance to system oriented approaches. Such long term developments are of related to the vision and should also be addressed in the "vision document".

Radical changes in priorities may also require long term planning, because they may well need retraining of personnel and restructuring of the infrastructure, in particular of the laboratories.

- Changing environment

The environment in which MS surveillance functions continually changes and proactive MS 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 because of immigration may have effects on the priorities for market surveillance, but also on the possibilities to engage personnel.
  - - possibility of climate change and its effect on consumer behavior.

- 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".

Long term programming is a necessity because organizational adaptations to new circumstances require time. For example: retraining of personnel and necessary investments for change. The long term program also allows recalibration of the priorities. The result should be a document defining the long term program, to be adapted (bi)annually

4.2.1.2 Short term program

Long term programs lay down how the market surveillance organizations thinks it will develop over a longer period and how priorities are to be shifted in the long run. Long term programs are quite abstract and focus and major changes in the organization. They may set concrete aims, but it does not describe how these aims can be attained. Long term programs may call

for shifts in the allocation of resources, they generally do not precisely allocate resources for specific tasks and for the daily practice of market surveillance.

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

Short term programs plan concrete activities and attribute resources to these activities. Planning should of course optimize the results obtained from the available resources, while keeping in line with the terms of the long term program. Where necessary, they could address organizational issues as personnel management, IT management, budgeting, training, etc.

However, the main purpose of the annual program is allocating the resources over the different market surveillance activities. In other words: the short term program defines which areas will get priority in the following period. , which product categories will be subject to market surveillance actions, and determine which products and/or businesses get more attention

4.2.1.3 Activity program

a) precisely described activities and market surveillance projects.

b) specific actions

c) reactive market surveillance

4.3 Prioritizing

For most market surveillance authorities setting priorities is a process taking place at two distinct levels. Where they are responsible for a wide variety of different kinds of products under different legislation, the first question is how to divide resources over these product categories. **E.g., to answer the question which deserves most attention: toys, electrical appliances or cigarette lighters?**

When these choices have been made, similar decisions must be made within these categories. Staying with toys as an example, the question must be answered if consumer protection is best served with the surveillance of jig-saw puzzles, dolls or toy guns.

Theoretically the two step process described above could also be done in a single step. All different product categories should then be analyzed at once and the results compared. In practice the number of different kinds of products, each requiring different test programs and therefore differing in the resources needed, is so big that this is practically impossible.

Ultimately these choices result in a surveillance program, which preferably contributes maximally to product safety and fair competition. A fail safe procedure to arrive at an optimum market surveillance program does not exist, but standing practice in many member states is that several considerations and sources of information should be taken into account when prioritizing

4.3.1 Accident reports

Accident statistics can show how frequently specific kinds of product are involved in accidents, what kind of injuries result from the accidents and which groups of people are most frequently victims. Up to a certain extent they allow comparing kinds of products and products themselves with respect to the frequency with which they are associated with accidents. This is useful, because when a specific category of products is hardly involved in accidents that cause injury, market surveillance on that product is unlikely to contribute significantly to improved consumer safety and need not have a high priority from that point of view.
Depending on the 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.

It should be realized, however, that a specific product is often related to accidents, does not imply that market surveillance on that kind of product automatically contributes to increased consumer safety. Accidents do happen even with products that are in conformity with the standards and regulations and market surveillance cannot hope to reduce all the accident incidences in such cases. Prime examples are ladders, which cause notoriously many accidents, but which hardly ever fail to comply. The reason to this is that the standard nort reflects essential requirements in the General Product Safety Directive.

Injury statistics are compiled by various organizations. The European Commission has initiated the Injury Database (IDB), previously known as ISS or EHLASS ('European Home and Leisure Accident Surveillance System') https://webgate.cec.eu.int/idb. Note: *In the Netherlands the Stichting Consument and Veiligheid adminsitrates LIS (letsel informatie systeem, injury data system), which registrates accident injuries of victims treated at the emergencies departments of a representative selection of Dutch hospitals.* *http://www.veiligheid.nl/csi/websiteveiligheid.nsf/wwwVwContent/l2onderzoekenregistratiesregistratieslisseh-behandelingen.htm*

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

Analysis of accident reports augments the results of accident statistics. It can show how products are involved in accidents and clarify what role failure to comply with the regulations plays in the occurrence of accidents. In that way it gives valuable information about the possible contribution market surveillance of this product groups can contribute to consumer protection.

Analysis of accident reports is also valuable for the selection of those requirements in standards that could be investigated in the market surveillance action.

Accident reports from consumers or media should be continuously assessed in order to be able to monitor the market. It is envisaged that 3 or more accidents connected to one product should undergo a closer examination towards producer or importer. To perform a risk assessment on the actual product should also include number of products in the market in order to conclude on the total injury potential present in the market. If risk assessment reveals a high probability of severe injuries to the consumer, measures should be taken towards the importer or producer according to national legislative sanctions

It has to be noted, however, that caution is called for when extrapoling accident statistics from one region to another. The frequency of causes of accidents is related to lifestyle, and lifestyles vary considerably between the European countries, because of differences in culture, climate, income per capita, etc.

4.3.2 Reports from consumers or media

Reports from consumers on potentially dangerous products are a valuable source of information, because they may point to safety issues in specific products and product categories. Such information is useful to indicate the fields where surveillance action should be undertaken. The usefulness of the information from consumers 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 that market. It should be investigated whenever possible, because the results of the investigations may indicate the need for direct measures against the product (reactive market surveillance). However, with a rising number of investigated reports about numerous products, information is gained about

the kinds of products the population complains, if these complaints concern a safety issue and which groups of the population are affected. All this information is valuable for pri oritizing market surveillance.

Another important source of information are the reports issued from Consumers Organisations that will have the advantage of having the situation already pre-analysed.

4.3.3 Reports from manufacturers, importers or retailers.

Manufacturers, importers and retailers regularly complain about products traded by competitors. Because market surveillance has the task to promote fair competition too, such complaints should be investigated If they poses any risk to the consumer. Because these economic operators are familiar with the market such complaints may well point to serious deficiencies in products otherwise undetected by the market surveillance authorities. The information obtained may be valuable for defining market surveillance programs. On the other hand it must also be realized that the operator who complains, has an economic interest that might well be (and is) regularly the source of the complaint.

Reports from manufacturers, importers and retailers are to be managed by these stakeholders in accordance with guidelines for notification of products for business, published and envisaged by DG-Sanco. Follow up on notifications by enforcement bodies shall follow above mentioned guidelines and reactions to shortcomings shall follow national regulations.

4.3.4 RAPEX notifications or other information systems

The importance of using IT as tool for continuous mutual information/communication is inestimable. There is a possibility to use any already established system for information (Circa, ICSMS, Rapex, Notification procedure). However, these systems seem to be developed for certain tasks and will probably not satisfy the needs of national information and communication. It is envisaged to establish different ways of communication and mutual information (E-mails, Web-sites etc). One requirement is that the information circulated should be stored and made available for participating bodies.

Though RAPEX and similar information systems (safeguard clause notifications-different?) are primarily meant to inform the authorities of the other member states about specific products that have been found unsafe or not to comply, analysis of the notifications also reveals which product categories regularly give problems.

Cross border information exchange between member states and EEA countries is an important tool in preventing the presence of dangerous or possibly dangerous products in the market. Product notifications systems used in a proper way may ease communication between stakeholders and enforcement bodies. Such systems should therefore be applied uniformly in Europe and, if possible be linked together.

Data based information systems are also important for the planning of market Surveillance; especially in the daily monitoring of the market. Enhancement of the efficency of information systems is a common responsibility and each member state is expected to share experiences in order to make such systems a living part of the market surveillance.

Existing product safety information systems are:

- ICSMS
- Rapex (non-food sector)
- Rassf (food-sector)

4.3.5 Data from previous market surveillance activities

Over time market surveillance organizations gather lots 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 in 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 in the selection of requirements from the applicable standards that should be investigated. Also, information can be extracted about which businesses frequently violate the legal requirements and which businesses remain in accordance with regulations.

4.4 Basic Risk Identification

Methodology for basic risk identification can include:

- Compliance or non-compliance with harmonized standards
- Risk assessment methods to reveal any possible injuries
- Safeguard clause notifications
- Rapex notifications
- Notification by business

Determining the market surveillance program

After evaluation of the information in the previous paragraphs the market surveillance program can be determined. The program should list the activities that should take place over the coming period and roughly divides the available resources between the different terrains that must be covered, product categories, directives, target groups, etc. Usually such a program would have a time span of a definitive period.

In many market surveillance organizations it is considered good practice to discuss the proposed program with stakeholders. These may include the ministries responsible for product safety policies and the legislation the market surveillance authority has to enforce, trade and industry representation and consumer organizations. Possibly these discussions suggest adaptations, after which the program can be finalized.

4.4.1 Particular human resources and competences needed

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

The competence needed depends on the art of the project, types of products or product groups, number and art of stakeholders and art of communication and information. Competence needed will have to be clarified as a part of planning in the first stage.

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

Resources needed to perform a project have to be sorted out at the start of the project. It is of vital importance that those persons involved commit themselves to the project and have necessary support by their leaders. A project plan should include all persons involved and amount of resources committed to the project.

4.4.2 Basic financial requirements for a project and how to minimise costs

Market surveillance projects have to be planned in order to, at an early stage, establis h a complete overview of all economical aspects. The intended use of this overview is to establish a cost benefit analysis that visualises possible economic effects for all stakeholders including the authority itself.

Before establishing a national collection of enforcement bodies, the market situation should be analyzed with respect to the possible presence of dangerous products, the origin of the products, overview of producers and importers. Another important factor that should be assessed is consumers' behaviour. Consumers' awareness of risk of products may influence the instruments to be used in product safety work.

An injury database or other knowledge about injuries is a very good source for finding out where resources have to be allocated in order to optimize the efforts in injury reduction work.

There will also be a need of examining the legal framework on a national basis to se if this is in accordance with the European framework (Regulations, Directives, Decisions) in different product safety fields.

4.4.3 Decision making and project identification

- Overall assessment of the market situation with respect to products or product groups
- Definition of hazardous products or groups of products
- Design of types of actions to develop (Nar4ket surveillance actio ns, info campaigns etc.)
- Assessment of available resources
- Final prioritization of actions

4.5 PROJECT PLAN SETUP

This chapter deals with the details concerning the practical projects that are decided to be carried out. It is necessary to develop a plan on or der to clarify and define all relations with and connections to the practical performance of any project.

For the purpose of:

- Management Quality Assurance
- Any market surveillance project should undergo supervision from the authority's management at certain points in the project. It might be appropriate to report to the management in connection with reporting on important milestones. Transparency towards the "world"

Market surveillance projects should not be kept as a secret within the authority itself. With reference to information and transparency principles the project plan could be published or announced after the performance in a way that gives evidence regarding the intention and the scope of the project.

- Historical data

Project plans are a source of kn owledge and experience. Future projects within the same field might benefit to a great extent in the planning process for new projects if made available.

The reader should note that it will in general be beneficial to adopt the below suggestions in a couple of different versions, e.g. project models for small, medium and large projects. The differences would be in the requirements for details in the descriptions and the budgets in the

three project types. For very small project it might even be feasible to leave out some of the points completely.

4.5.1 Project description

The following headings must all be considered in the project -planning phase. Some of the issues might be left out if there are obvious reasons; for example in very small projects involving very few persons.

The first paragraph in the project plan must give an overview of the project. It would often comprise a (short) description of the background for the project, the mandate, the scope and the objectives as well as a short description of the extent of the project and the test methods.

Definition of essential requirements, standards and compliance criteria to be applied for the checks/tests and reference to list of standards published according to UE Directives are also to be taken into account when relevant.

- Overview and main principles of the project
- Background-explanatory why this project
- Mandate and scope –terms of reference
- Market review: Producers, importers, distributors and retailers
- Objectives- what do you want to achieve
- Target groups- who are the actual stakeholders
- Methodology- the way to perform the project (sampling, testing etc)
- Essential requirements with reference to legislation and standards

4.5.2 Cooperation with different stakeholders

Any market surveillance project will certainly create interest with other organisations and stakeholders. It is of vital importance to assess possible interested parties in advance in order to establish necessary relations for the benefit of the outcome of the project. This paragraph should include who will be involved, in what way they are involved and when they are to be involved.

This paragraph presents the identification of stakeholders that must be considered in the context of the project. They should be described if their involvement goes beyo nd receiving general information from the authority.

Examples could be business associations that are involved to ensure a general support to the project, the European Commission in case of joint actions, or people from the political hierarchy if the project deals with sensitive issues.

- 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
- Strategy for contact with media
- Strategy for information within EU.

4.5.3 Project organisation

This paragraph presents the responsibilities and tasks for the people involved in the project. Included in this paragraph you also may include time frame and how and when to report oh the progress of the project.

It is particularly important when the project is big. It can be short () when one or two inspectors undertake the project.

- Definition of personnel involved
- Tasks, responsibilities and commitment for personnel involved
- Time frame and milestones
- Reporting procedures; content and time frame.

Market surveillance projects commonly involve inspections, testing and follow-up. 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 time major events that could be defines are:

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

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 dependencies in the markets. Especially in seasonal products, like 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 realized that imports and manufacture of such products may precede the actual selling season considerable and that inspections at importers or manufacturers must be done earlier. Time schedules for actions should take this into account.

4.5.4 Risk assessment principles

This paragraph should describe the major risks that are addressed by the project and how they are evaluated in general. It should also identify the basic risk assessment techniques to be adopted.

Harmonised standards exist for a number of products, especially products under some of the new approach directives such as the Low Voltage Directive or the Toys Directive. In such cases, risk assessment is closely linked to the conformity of the product. I.e. if the product conforms to the standard, it is presumed to represent a sufficient safety level. Therefore the purpose of the investigation is to find out if the product meets the requirements in the standard, and the authority should mainly decide which paragraphs in the standard are applied. The conclusion should be reflected in the project plan.

In other cases there are no harmonised standards. Then, the project plan should describe what parameters are tested, what test method is applied, what the requirements is for the product to comply and what the risk is if the product does not comply.

The description should be fairly broad and general.

- Description of major risks in concern
- Methodology of RA, risk assessment methods to reveal any possible injuries
- Compliance or non-compliance with harmonized standards
- Safeguard clause notifications, Rapex notifications and Notification by business
- Injury data
- Possible impact on consumers
- Historical data and experiences from other similar actions

4.5.5 Human resources

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

The competence needed depends on the art of the project, types of products or product groups, number and art of stakeholders and art of communication and information. Competence needed will have to be clarified as a part of planning in the first stage.

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

Resources needed to perform a project have to be sorted out at the start of the project. It is of vital importance that those persons involved commit themselves to the project and have necessary support by their leaders. A project plan should include all persons involved and amount of resources committed to the project.

- Personnel resources needed
- Competences needed
- Skills needed
- Availability and reliability of resources

4.5.6 Financial aspects

The plan must also present a budget broken down in number of man-days to be spent and all kind of external costs.

Budget plan should cover:

a) Cost of personnel
b) Expenses regarding
    - Travel
    - Purchase of products
    - Testing
    - Information

- Gathering of data
- Analysis of results

4.5.7 Project methodology

When deciding on the methodology to be applied in a project the projec t plan should take into account that the demand for resources increases with the level of detail that is requested from the project.

Decision has to be taken on the following questions when deciding on the methodology:

- Are products to be sampled in shops or at the importers?

  If products are sampled in the retail stores it would often be possible to do it quickly and less costly (especially if the importer is located remotely). It is also important to do it anonymously.

  If the products are sampled at the importers it is possible to have the discussion with the importer immediately and perhaps even decide on measures immediately if a screening test on the spot reveals shortcomings. Furthermore the sampling is then done at the start of the supply chain, which means that non-complying projects can be taken efficiently of the market should that be necessary.

- Is the focus on new or used products?

  Normally market surveillance will deal with new products but it might be preferable to check old products that are bought from consumers. This is especially the case in research projects where the authority would check if for instance products wear out in a safe way or if they catch dangerous non-compliances over time which must lead to changes in the standard or the design of specific products.

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

  If products are sampled at random the result from the project will immediately say something about the status on the market, e.g. the share of non-compliant products, the level of non-compliance, etc. On the other hand market surveillance authorities will then find that they spend a lot of efforts checking safe products (which one could argue is a waste of time).

  Alternatively the market surveillance officer may want to do an initial check on the spot so that he or she only picks out products that are dangerous. This will lead to an efficient use of the resources in the authority but the results from the project will only say little about the status on the market – and may even cause trouble if taken up by the press.

- Are products taken for testing at a laboratory?

  Often a market surveillance authority may want to consult an independent laboratory with the relevant accreditation to have a product tested. On the other hand this is not mandatory and in some cases it is not necessary depending upon the legislation, the competences of the market surveillance officer and the traditions and culture.

  In some Member States it is required to have a formal decision backed up by a test report from a laboratory.

  In some Member States the market surveillance inspector has the powers and the ability to take action in case of severe and obvious shortcomings.

  In some Member States there is a strong tradition for consultations between th e economic operators and the authorities. In such cases it might be sufficient to have a screening test as the basis for the consultation and “negotiation” on the proper measure.

- Are products collected (bought) or does the authority write to the economic o perators requesting for samples?

  National legislation and tradition often prescribe how to get samples. Normally the authority has the legal powers to obtain samples for free. It might however be preferable to deviate from this practice, especially in the case of very inexpensive products, where it might not be worth the efforts to do anything but buy the products.

The authority may also want to write to the producer requesting him to send in samples for testing instead of paying a visit to the operator. This decision should also 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 the samples carefully to ensure that only compliant ones are chosen, whereas a market surveillance inspector would go for the non-compliant ones.

- Are products tested physically or is the investigation limited to documentary checks (please also refer to 4.1.2.1)?

  A physical check of the products will be the best way to check that a product is actually safe and fulfils all legal requirements. On the other hand it is costly and time-consuming.

  Market surveillance based on documentary checks only is very cost efficient but will only catch those products where errors are found in the technical file.

  A different approach to documentary checks is an assessment of 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.

  Often the choice will not be between the one approach or the other but rather be a decision of which documents and which physical properties that should be checked for each product.

- Documentary check – Declaration of conformity (NA directives) or type approval.

  Once it has been decided that documentary check will be part of a particular market surveillance program, it must also be decided which documents should be requested and checked. For Global Approach directives it is obvious to acquire the declaration of conformity, but the authority might want to go further than that and request e.g. test reports, type approval or other documents depending upon the legal requirements that are to be checked.

  The checkpoints should be included in a checklist.

- Check points on standards with reference to risk assessment/dangerous properties.

  If a market surveillance action includes testing of physical properties (according to a standard), the test points should be decided and included in a checklist. It would also be a good idea to decide on intervention limit values for each test point. Such a list of intervention limit values must be in accordance with the intervention policy as described in section 3.

- Reports on complaints from consumers with importers/producers.

  Any intervention from the authority in the market will most likely cause a reaction form the market. The reaction may be complaints from producers (“If my product is dangerous, why don’t you do something about my competitor’s then ?”) or from consumers if the activity has raised the awareness of the public.

  Ideally the authority should decide beforehand how to handle such complaints.

- Testing on spot(tools & training)

  The authority should consider what kind of on-site testing is 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 test 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 X.X.X.

- Sampling and testing in laboratories

  The authority should decide on the number of samples and which test points that should be tested in the laboratory.

  Once this has been laid down, the authority can select the best laboratory to do the testing. The authority may want to run a call for tender procedure to do this.

- Check lists

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

  The results from the checks should be stored in the case.

- Report forms

  The authority might want to develop report forms to report the results from the tests. This is particularly important if the tests are made by the market surveillance officers themselves as there will be no test reports from any laboratories to capture the results.

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

4.5.8 Test labs

This paragraph identifies the laboratories that will be involved in the project.

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

Some authorities cooperate with one or the same few laboratories for a long period of time. In that case the selection of laboratory is obvious. Other authorities "shop around" or use different laboratories depending upon 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.

It might also be important to discuss if the laboratory should have an accreditation or not.

- Overview of possible test houses. Consider Round Robin tests in prequalification.
- Quality check of TL's (competence, equipment, references, procedures)
- Call for tenders
- Agreement incl. Costs and deliverables
- Follow up and actions to take

Authorities in several (neighbouring) Member States would most likely 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 under LVD several times by the Nordic countries in the NSS cooperation.

4.5.9 Information strategy

The project description should include a paragraph about the information and communication that is foreseen or planned during and after the project, e.g. information or "pre-warning" of industry, communication with other stakeholders (consumer organisations, business associations, the general public) during the project, publishing of results afterwards, etc.

- Awareness campaigns
- Information on web
- Communication with consumers associations previous to and during projects
- Information through media
- Meeting or conferences with stakeholders
- Direct mail

4.6 PROJECT PLAN APPROVAL

The project plan should undergo a formal approval. This implies a support for the project team and will facilitate the implementation.

Usually inspectors, lawyers or engineers propose projects; they are 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.

The process and the status should be indicated in the final paragraph that would often be fairly short.

Example 2: "This plan has been prepared by the market surveillance department. It is presented to the 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.

The market surveillance authority might find it beneficial to use the above headings as a "skeleton" all through a project.

The market surveillance authority might find it beneficial to use the above headings as a "skeleton" all through a project.

This should include:

- Procedures for the approval process and a approval document.
- Project plan-summary including time frames and milestones
- Human and financial resources.
- Reporting procedures
- Summary of information activities and follow up.

4.6.1 Reactive Market Surveillance

Not all activities in the market surveillance can be planned. Market surveillance authorities are forced to react to events in the outside world such as accidents, political pressure, etc. This is referred to as "reactive market surveillance". This part of market surveillance is to a large extent carried out in the same way as the proactive part of market surveillan ce (the projects). There are however important differences, which will be the focus of this chapter.

4.6.2 Reactive vs. proactive market surveillance

The following figure (Figure 2: reactive vs proactive market surveillance) presents an outline of two examples of reactive and proactive market surveillance to illustrate the difference between the two.

Reactive market surveillance is normally initiated by an outside event, e.g. an accident. The market surveillance authority has to decide if it will take up the case or leave it (a choice that sometimes must be taken under a considerable pressure from e.g. media). If the case is taken up, an investigation follows, then 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; firstly there is a sense of urgency as the product is most likely dangerous (it is suspected of having caused an accident), and secondly there may be attention from the general public (if the case has been noticed by the media). So the authority might find itself forced into taking decisions on strong measures rapidly.

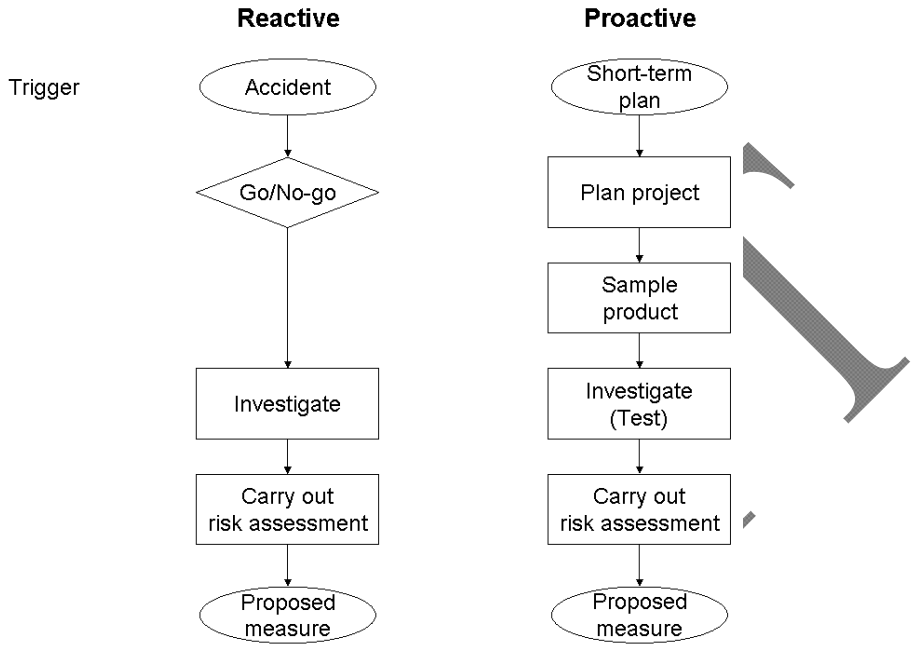


Figure 2: reactive vs proactive market surveillance

In contradiction, proactive market surveillance is a planned activity derived from the long - and short-term plans in 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 proportion ate measures are decided.

The differences between the two are outlined in the table. 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 – also if the authority decides not to take up the case. (In that case, the authority must be prepared to explain to the general public why it was decided not to run the case.)

	Reactive market surveillance		**Proactive market surveillance**
	Critical cases	Other cases	

	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.
What triggers the action?	Accident (fatality) – perhaps in other Member State	Accident, incident Complaint Notification from other Member State	The long-term or short-term plan.
Focus of the activity	To solve the potential problem with the individual product.		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	Few days.	Weeks, (few months)	Weeks, few months (for each individual product).
Implications for economic operator	Potentially large Magnified by attention from media.	Depending upon the non-conformities found.	Depending upon 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

A few comments to the table.

It is important to realise that the market surveillance authority always has the opportunity to decide if it will run a given case (even if this is not felt always). 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 "critical cases. Such cases should be assessed individually and the authority should prepare an explanation if it is decided not to take up the case.

It is also important to have efficient tools 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 might decide to spend a certain amount of resources on the activities or it might have objectives to investigate a given number of accidents each year. Furthermore the flow of complaints or accident reports may be fairly stable or vary in a predictable manner, which means that the authority could plan 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 potential safety problems. 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 that property – and of course to solve any encountered safety problems with tested products.

The most important characteristics for critical cases is the attention from media, which causes a high pressure on the authority to "do something quickly". Often such cases are started because of (serious) accidents. That 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 be very strong and have a high impact on the industry – an impact that is magnified by the attention from the media. Furthermore the authority must act legally correct to avoid trouble afterwards with the producer. These contradictory conditions possess a dilemma for the authority and necessitates that the authorities master communication – communication with the general public, the media, the producer, etc.

4.6.3 Risk Management background

The reactive market surveillance activities are initiated from:

- *Accidents and fires*

When a product fails and causes an accident or a fire, the authority will often be notified. Sometimes by the person who has suffered from the accident because he or she feels that it is right to report to the authorities, sometimes by the producer as part of the obligation to report safety problems with products and sometimes by consumers who have found it impossible to report the case to the producer. There might even be other reasons.

No matter how the authority is notified such reports should be interesting because accidents most likely are signs of dangerous shortcomings in a product – either because the product does not comply to the safety requirements or because the requirements are not sufficient or because the product has been used in a wrong way. Therefore it seems likely that such cases could be interesting to investigate.

- *Reports from consumers or media*

Consumers may also report to the authorities when the notice shortcomings in a product that are not necessarily dangerous but rather annoying or caused by nearby-faults, e.g. appliances that begin to smoke and are disconnected without catching fire.

Furthermore consumer programs in media are a valuable source of information. Many such consumer programs test various products to guide consumers in their choice of the given product. Often such testing includes a test of the safety of the product and it is obvious for the authority to follow up such investigations.

- *Reports from manufacturers, importers or retailers*

If a safety problem is found in a product the manufacturer, the importer or retailer is obliged to report this to the national authority together with a plan for correcting the problem. This will most often not necessitate anything but administrative follow-up from the authority's side.

However producers also report products from their competitors. Such reports could be valuable as the producers for sure know the market and the potential problems with products on the market very well. On the other hand it is also realised that producers definitely have an economic interest in disturbing competitors.

- *Notifications from other Member States (RAPEX and safeguard clauses)*

Note that the sources are the same as in chapter 4.2. The difference is that projects (the proactive market surveillance) deal with major trends that are derived from a number of events. The reactive market surveillance deals with the individual cases. Often these cases are found to represent products that are so dangerous that the authority has to investigate that specific product.

4.6.4 Basic Risk Identification

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

Firstly it is important to "spot" critical cases among the huge number of complaints, accident reports, enquiries, RAPEX-notifications etc. that the authority receives. As mentioned such cases must be handled to avoid increasing trouble at later stages.

Secondly, it is important to have efficient mechanisms for filtering the rest of the information so that the authority can focus its attention on products with safety or conformity problems. To complicate matters, unimportant cases that were left firstly may come back as critical cases if they are taken up by media. The authority might also receive more complaints about the same product in which case it could be interesting to clarify the pattern beneath. Therefore it is best practice to register all complaints even if they are turned down.

4.6.5 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 react. The authority must be able to reallocate sufficient resources quickly to cope with emerging cases.

The amount of resources for reactive market surveillance can hardly be estimated beforehand. Experience however indicates that the share could be considerable – perhaps up to half of the resources for market surveillance. It will however largely depend upon how good the authority is to focus on the important cases.

One has to bear in mind that it might be necessary to shift resources from planned projects to the reactive market surveillance during the year. Reactive market surveillance tends to attract a lot of attention because it involves following up on accidents and other cases which are potentially interesting for the media. Therefore the authority must be prepared that something starting out as an investigation of a single product now and then will evolve into an entire project with many products being investigated.

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

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

- Skills in communication and handling of relations to the press are important – in particular when handling critical cases.
- Some inspectors will have to investigate fires caused by products and need an education for that. Such courses are available from commercial providers.
- It will also be important that the staff has good knowledge of interviewing consumers. When investigating accidents it is important to find out as much as possible about how the accident happened.

These competences could most likely not be combined in one person. Instead the authority would set up a team working together on critical cases.

4.6.5.1 Reporting

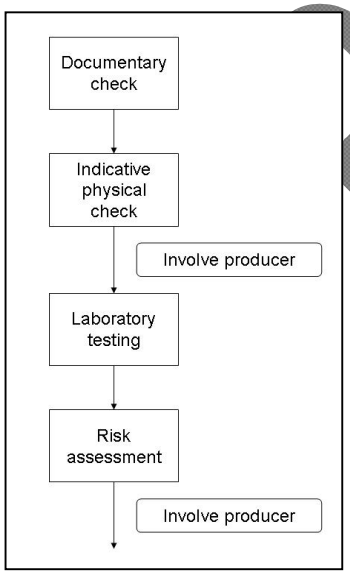
The authority will find it beneficial to report some statistics on the output and outcome from the reactive market surveillance in their annual report. Such statistics can be derived from the information that is registered for any product that is investigated (refer to chapter 7).

Furthermore the authority might want to report the number of fires and accidents investigated, the number of telephone calls answered, the number of complaints rejected and taken up, etc.

5 MARKET SURVEILLANCE PROJECTS - THE IMPLEMENTATION STAGE

5.1 Implementation of the project plan: On-site Market Surveillance Inspections & Sampling

The overall flow in the initial phase of any market surveillance case is presented in the following schema:



The initial phase consists of four tasks:

c) Documentary check
a) Indicative physical check
b) Laboratory testing
c) Risk assessment

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

It is considered best practice to involve the importer or producer in the case as early as possible to obtain input and to ensure that action can be taken quickly if dangerous short-comings are found.

5.1.1 Documentary Checks

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

Necessary documents normally comprise:

- 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 General Product Safety Directive covers a vary wide variety of products; from prams and battery operated electronic devices to wooden spoons. Therefore the level of documentation will vary considerably depending upon the complexity of the product. For very simple products (like the spoon) the producer may not be able to produce any documentation at all.

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

Often market surveillance inspectors would want 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 might prove beneficial to have a tool box with a few tools. The contents of the tool box depend upon the category of product that is investigated, i.e. the directive.

An indication about the contents of such a toolbox can be given here:

- 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.

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

As an example, stability tests of many products is carried out by placing the product on a well defined slope and observing if 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 differs.

5.1.3 Preliminary physical checks by use of the “toolbox”, instructions and tools required for checking.

Often market surveillance actions focus on sampling and testing the most dangerous products rather that products collected randomly. This means that the inspector should do some initial investigation 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 are saved.

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

5.1.3.1 Products under the General Product Safety Directive

Perhaps to be mentioned:

Typical potential injuries: Falls, squeezing, cutting, burns (fire) and fractures of limbs, strangulation and choking, electrical shocks, mechanical impact, etc.

General checkpoints are difficult to present as the directive covers a huge variety of products. However, the following checkpoints 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 sharp edges where users touch the product?
- Are there splinters? (Applicable to wooden products in particular)
- Does the product seem highly flammable?
- Does the product get very hot where users touches it (intentionally or unintentionally)?

A few other checkpoints can be indicated that apply to special product categories

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?

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 high products

- Is the stability of the product reasonable or does it fall over when tilted a few degrees?

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. 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 very 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).

5.1.3.2 Electrical products (under the Low Voltage Directive)

- Visual check of the product. Does it seem to have a 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?
- Is rated voltage and power indicated?
- Is there a CE mark?

- Are 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 sharp edges found around the supply cord? Or 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 luminaries in particular)

5.1.3.3 Toys (under the Toys Directive)

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

5.1.3.4 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.
- Is there a CE mark on the product and a reference to applied standard
- Doc of conformity
- Does the product have a product certificate (European test certificate for category 2 and 3)

It should be emphasised that such tests can only be indicative. I.e. they can given an indication of any non-compliances and the associated risk. If the risk is serious enough then the indication might be sufficient to justify a measure against a product but one should be aware that the test result is only an indication. In general such an indication would require further examination before measures are taken. In some countries, however, legislation obliges the inspectors to take action against obviously dangerous products on the spot.

5.1.3.5 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)?

5.1.4 Requirements for sampling and registration of samples.

At this stage it is assumed that the inspector knows the sampling criteria for the project meaning that he knows how to decide which specific products should be collected.

The authority must also define a general sampling policy, i.e. the number of samples that should be collected for each product.

Some authorities 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. This method ensures that all samples are taken from the same batch. That might be advantageous to know during the investigation and 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 will be quite difficult to argue against this for the authority unless it can find another non-compliant product on the market. This problem is however seen to be small in practice as the inspectors or the laboratory people can most often decide from the character of the short-coming 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 practices to leave a receipt where the product was collected as a 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 (digital) photos of all products; as a minimum the product itself, the marking of the product and the packaging should be photographed.

5.1.5 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 highly recommendable to identify each individual product with the same key or code all through the investigation. This key could be the case number from the document management system.

The products should also be packed in a way that doesn't 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 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 doesn't change the product. In extreme cases it might be impossible to send the product; one would have to take care to carry it to the laboratory.

5.1.6 Conclusions for follow-up towards economic operators (producers or importers or retailers).

The involved economic operator could be informed at this stage. It should be done in writing. The note could 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 process (the product will be tested; the producer will learn about the result and will be given the opportunity to comment it before any measures are taken).
- An indicative time schedule.
- A preliminary information on the steps that could be taken toward the economic operator concerned.

5.2 Testing in laboratories

5.2.1 Witness 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 want to check that the laboratory is keeping 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.)

5.2.2 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 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 non-compliances. However, access to live parts is considered to be a very serious risk whereas the missing marking is not seen to possess any 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 in a overall assessment of the risk of the product.

To do this the authority must do a risk assessment as described in chapter 9 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 it is done for instance for electrical products in the Nordic failure code list that describes the expected danger of different common faults found in electrical products. This list is shared with the Nordic laboratories and helps the authorities and laboratories to have a similar view on 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 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 chock." A reference to a failure code list is not sufficient in this sense.

5.2.3 Conclusions for further investigations.

The authority would seldom need a full test of a product for a market surveillance case. Rather the authority would want the laboratory to focus on finding the dangerous shortcomings. This is usually described in the contracts with the laboratory, which 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.

5.2.4 Conclusions for follow up towards producers and importers.

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 have the following contents:

- 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 authority's risk assessment.
- An invitation to the producer to comment the test results and a deadline for future measures to be taken.

6 MARKET SURVEILLANCE PROJECTS - THE ANALYSIS (REVIEW) STAGE: *(RESULTS & FOLLOW-UP, INCLUDING ACTION NEEDED)*

6.1 Decision on the necessary action to be taken; legal action, sales ban, withdrawal, recall

With the shortcomings of the product and the associated risks known, it can be decided which legal action has to be undertaken and if sanctions have to be imposed. Leading are the principles of 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.
Which specific measures can be imposed and how they can be imposed depend on the legislation of the particular member state. Fairly usual kinds of measures listed in increasing severity are:

Official warning

Official warnings are the least severe action authorities can take and cannot be considered a legal sanction, because no sanction is imposed. The 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, like non conformity with certain labelling requirements or shortcomings against a standard with little safety relevance. The company is supposed to rectify the shortcomings before further deliveries can be made and it should be checked if the product is indeed rectified. When this is not the case, stronger measures can be taken.

Formal warnings may also be useful, or even required, if the member states' legislation requires the company to be aware of the fact that it trades in violation of the law, before imposing more severe sanctions or taking additional measures. The official warning then proves knowledge of the violation and, when properly used and communicated, may be instrumental in convincing the company to take the required measures themselves voluntarily

Sales bans

The General Product Safety Directive requires that Market surveillance authorities have the power to temporarily suspend the supply of products that could be dangerous during the period of investigation needed to assess the risk of the product and to ban the marketing of dangerous products altogether. Unlike sanctions like fines, this power gives the possibility to

directly address (possible) risks for consumers by stopping the supply of products found to be dangerous.

The Directive limits the possibility to impose sales bans directly to products that are dangerous. A temporary ban may imposed for the time needed to investigate if products are suspected to be dangerous. This implies that risk analysis must demonstrate the product to be dangerous by not complying to the definition of a safe product under article 2 of the General Product Safety Directive. Because sales bans directly cause damages to 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 recalled too.

Recalls

According to the General Product Safety Directive the authorities can:

> "for any dangerous product already on the market:
> - to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;
> - to order or coordinate or, if appropriate, to organize together with producers and distributors its recall from consumers and its destruction in suitable conditions."

This gives the authorities the possibilities to protect the consumers against dangerous products by taking the products from the market in the whole supply chain. In cases were the product is very dangerous it also allows to warn consumers and recall the products from consumers.

The GPSD gives the authorities the power to organise recalls themselves, or to order a recall. Organizing a recall without cooperation of the company involved is an unattractive proposition for the authority, because the information required to efficiently recall from local distributors and retailers is not directly available and should be obtained from the company involved. This may be difficult if it is not cooperative.

Though the GPSD allows to enforce cooperation, because the manufacturer is obliged to recall when ordered by the authorities, the alternative, to organize the recall together with the producers and distributors, is a much better option. That way the actual recall is organized by the producers/distributors, who can recall much more efficiently. The whole process should be supervised by the authority, which can check if it is performed properly.

Practically this means that the company responsible for marketing the dangerous product should be contacted and informed about the hazard presented by the product and about the necessity of a recall. Since a recall is proposed when the product has been found to be seriously dangerous, organizing the recall is urgent. Contacting the company can be done by telephone or in person by a surveillance officer, but informing the company in writing will also be necessary in most jurisdictions (See also 6.2). Considering the urgency this should be done speedily.

Before initiating a recall the authority must decide what kind of recall is acceptable. Products may be recalled from distributors, from the whole of the supply chain, or, in serious cases, a recall from consumers may be required. The extent to which the product recall is imposed is of course 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 recall from the supply chain is sufficient, the manufacturer remains of course at liberty to extend the recall to consumers. If he does so, he should be facilitated by the authority.

How recalls are 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 the recall.

Fines

Fines are sanctions that can be applied for more serious violations. It should be realized, however, that sanctions punish the violator, but by themselves do not protect the consumer. In cases where the non conformities constitute a serious risk to the user of the product additional measures are therefore required.

Nevertheless, fines can be used as sanctions by themselves in cases where the risks are such that recalling from the retail channels or a full blown recall with publicity is disproportional. Imposing fines should stop further deliveries to retailers and this should be checked. If deliveries turn out to continue the initial fine can be raised; such deliveries aggravate the seriousness of the offence.

How fines are imposed is dependent on the legislation in the member state. Some authorities can impose fines directly. In other member intervention of the prosecutor is required, who may settle the height of the fine (in agreement with the offender) or decide to bring it to court to decide. Where the authority decides about the height of the fine the definition of a general policy about the way and conditions under which fines are imposed is desirable to guard against arbitrariness.

Other measures

In some jurisdictions legislation may allow other measures. For example, in the Netherlands legislations allows closure of businesses after intervention of the prosecutor. Meant to shut down filthy restaurants, the possibility also exist for other businesses, but is hardly used because of the proportionally requirement. For all alternative measures it is this principle that should be kept in mind.

6.2 Communication with importers and producers; test result and product information, voluntarily recall, pre-warning of sales ban, final reactions.

Reports from manufacturers, importers and retailers are to be managed by these stakeholders in accordance with guidelines for notification of products for business, published and envisaged by DG-Sanco. Follow up on notifications by enforcement bodies shall follow above mentioned guidelines and reactions to shortcomings shall follow national regulations.

Where market surveillance has revealed non conformities with legislation that require intervention, the violating company must be informed about the legal proceeding and actions that are undertaken.

The way this has to be done depends on the jurisdiction of the particular member state and may be subject to legal requirements in that 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 does not make formally informing in writing superfluous.

When the violations have been determined in products sampled at retailers it is normal to direct the measures against the original importer or manufacturer in the jurisdiction. This requires tracing back the product from retailer to its original source, which has to be done in a way that fulfils the legal requirements for evidence that can stand up in court. Note also, that when the product is imported by a local distributor from elsewhere in the European Union, the distributor/importer generally does not violate the European legislation, because he is not the first importer into the EU. Measures must therefore be based on legislation of the Member state itself that extends the requirements in the Directives to local distributors.

Note also that 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, etc.

Though the contents of the notification to the offender may vary depending on the legal requirements in the member state the following items are commonplace:

- *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 identifying 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 marks, signs of identifications, etc.

- Place and date of the inspection and sampling

Information about the inspection during which the products was 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 identification and the address of the retailer when the inspection was not carried out at the manufacturer or importer, as well as information that the sample was taken for testing.

- Results of testing and specification of the shortcomings found

The results of the tests of the products should be given in such a way that it is made clear why these results do not fulfil the requirements.

Generally this involves:

- Reference to the legislation involved and to the specific requirements violated

Reference must be made to the appropriate legislative acts and regulations of the member state and to the standards used in the testing of the product. The legal requirements that are violated should be clarified by referring to the appropriate sections in the acts and regulations and describing the failure to comply to these requirements. Often the basic non conformity is found in a failure to comply with the requirements of the applicable standard and it should be clearly demonstrated why the product does not meet the standard by giving the standard requirement and the test result 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 requirement should be linked to the specific requirement in the national legislation that implements the safety requirements of the Directive. Additional reference should be made to the specific essential requirement from the Directive (or its national implementation) that is violated.

- *Announcement of the measures imposed and the legal proceedings that will follow*

The communication should inform the recipient about 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 states, there may be great differences in the procedures to be followed. Some authorities can impose sanctions themselves, but often sanctions are imposed by a court. The latter usually requires very specific legal procedures, that vary between the member states and the legal system employed for product legislation. Also, the obligations of the recipient should be made clear; where sales are required to be discontinued, an obligations to recall or any additional measures are imposed, this should be

substantiated by reference to the specific national legislation applicable. Most likely that legislation will be the national implementation of the GPSD.

- *Information about the possibilities for appeal*

The recipient should also be informed about the possibilities to appeal against the decisions of the authority, or about the possibilities for appeal in the legal proceedings. Again, the possibilities for appeal differ between the member states.

In short: the communication to the responsible suspect of the offence should enable him to understand the nature of the offence (what it is that is wrong and why that is illegal), the measures he is obliged to carry out (what he has to do), what legal consequences there will follow and what possibilities he has for appeal. It is also important to formulate this message in a way that is legally acceptable, so that it does not interfere with the following legal procedures. In general this would require the communication to be accurate with respect to the facts and to the references to legislation and standards, as well as containing all the information that the national legislation requires for such messages.

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, by communication via telephone or directly by an inspector or other official.

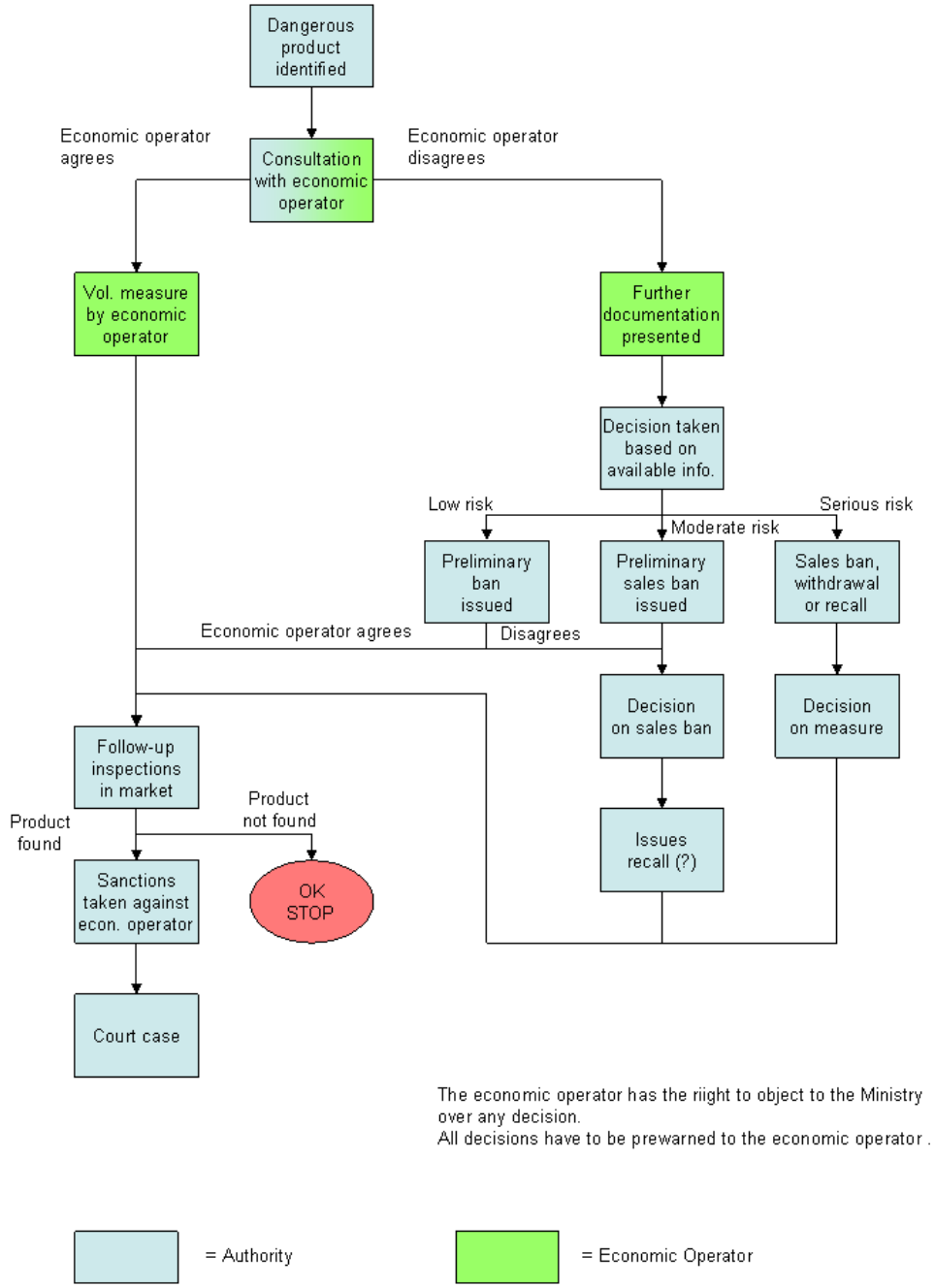


Figure 3 Actions flow in case of dangerous products

6.3 Operational risks

Market surveillance authorities take measures to protect the consumer from risks associated with products that do not comply with legislation. These measures are based on non conformities found in tests and risks assessments, which constitute p art of the legal basis to impose these measures. The measures imposed may cause appreciable damages to the

companies involved. Especially sales bans and obligatory recalls may cause considerable costs and loss of profits to the businesses affected.

Whenever taking measures the authority is at risk that these measures cannot be upheld in court. If by that time damages have occurred to the interests of the company, it may well request compensations.

It goes without saying that the authority should always minimize the risk to be held liable for damages inflicted. The first safeguard against such liability is to perform a proper job. Get the facts right and follow procedures meticulously. Tests should be reliable, substantiated by the use of accredited laboratories where possible. If in any doubt, have the results checked. For risk assessments that help decide over substantial interests it is sometimes advisable to have them done by a second independent institution. Risks assessment still depends partly on sometimes 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 court case.

Make sure that al official documents fulfil the legal requirements and that references to standards and legislation are correct. Check again.

Especially when the stakes are high: involve the legal department in all the steps taken when available, or contact a legal expert. If you don't do realize that the offending company very well might! 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, it may still occur that the authority is put in the wrong and (in some jurisdictions) has to pay compensations. For that eventuality the authority has to prepare. How this is done depends on its situation of the particular authority. It may be possible to insure against damages caused, like the notified bodies are obliged to do. Also the government of the Member State may take over 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.

6.4 Enforcement & Legal aspects; reference to regulations and standards

When an authority decides to take legal action against a product, this must always be done referring back to the legal requirements as they are laid down in the national legislation transposing the directives and not to requirements from e.g. harmonised standards.

The "legal" flow is as follows:

- The European parliament adopts a directive. The directive lays down specific requirements, e.g. the essential safety requirements to 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 pick an example from LVD.
- All Member State transpose the directives into national legislation by adopting national laws that basically repeats the requirements from the directives. In particular they also repeat the safety requirements.

Often the safety requirements are detailed and made more operational in (harmonised) standards. As an example the essential safety requirement from LVD that "the product must not cause electrical shock" can be found behind several more specific requirements from the European norms that are harmonised under LVD, e.g. the requirement that the creepage distance must be 5 mm or more.

Authorities will (almost) always assess the non-compliance of a product by testing it against miscellaneous requirements from a relevant standard. It must be realised that such tests only

reveals non-compliances to a standard. The authority has to "translate" this to a non-compliance with the essential requirements from the directive before action can be taken against a product. The usual way to do this is by indicating that a non-compliance with the essential requirements has been revealed by applying the method from the referenced standard.

Example: the minimum creepage distance in a luminaire is 2,4 mm when measured in accordance with EN 60598-1. The requirement is that the creepage distance must be 5 mm or more.
The authority writes a letter to the economic operat or that states that:
"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 Low Voltage Directive, article 2 referring to annex 1, item 1d and 2a because a creeeage distance lower than required in EN 60598-1 will cause a risk that the user gets an electrical shock 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 directive.

6.5 Follow-up within the market after final reactions

The legal routines that follow the assertion of serious violations of legislation would normally lead to sanctions like fines or sales bans. In a worst case scenario for the business the enforcement action could lead to a recall action for the non compliant product.

Almost always such cases require follow-up activity from the market surveillance authority:

- Recalls, whether organized on the initiative of the business or imposed on the company by the Market surveillance authority should be carefully monitored and supervised. This includes checking if the way the recall is planned suffices to accomplish the desired goal, monitoring of the contacts with distributors along the supply chain and checking if the action indeed results in the return of products from the retail chain and where applicable from the consumers. Checks at retailers are in order to ascertain that the recall has indeed resulted in the disappearance of the product from the supply chain. Where possible the success rate of the recall should be assessed. (The 'recall guide' gives a figure of 40% of umbrellas sold to consumers returned to the company in a recall action taken as an example, but also notes that this is an unusual high percentage).
- If the measure is a sales ban at the importer/manufacturer, the authority should check if sales of the product have indeed 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 reinvestigation after a short period of time should establish that the product is indeed in conformity and that the violation has been discontinued.

In general, if measures are imposed it should be checked that the economic operator does indeed comply with these measures. A good way to assure this routinely is by defining a standard operating procedures that prescribes renewed inspection and sampling after a reasonable period for every product that has been found not to be in conformity.

Besides the authority should be aware that the same product can also be available on the market via parallel imports. When found, similar enforcement must of course take place.

Where the measures concern first importers of manufacturers in the EU additional that have traded the product into other member states information should be sought to facilitate tracking the product for the authorities in those member states. This would include information on the identity and addresses of the buyers and the volumes sold into the other member states. Also, if enforcement took place against a local distributor who imported from another EU member state, the identity of the source of the products should be established. Such inf ormation must

be part of the information exchange via safeguard clauses, RAPEX notifications and or ICSMS.

6.6 Follow-up of project results.

All remarks in the previous paragraphs concern the follow up of cases from individual enterprises, which were found non compliant during the course of the project. The project as a whole should also be evaluated in order to see if follow-up is desirable or necessary. Despite the fact that often sampling will not have been random, the results give an indication of the situation in the specific part of the market for the investigated product.

Depending on the results the evaluation may lead to follow-up, which may take different shapes. If shortcomings are fairly common over the whole market it may be fruitful to meet with the stakeholders (companies, consumer organizations, industry & trade organizations) to discuss and implement ways to improve the situation. An educational campaign in cooperation with the associations for the industry involved may be beneficial to improve a wareness of the legal requirements.

Results may also lead to the conclusion that the project should be repeated after a certain period, to keep the industry under pressure and to bring about improved conformity. Analysis of the results may then indicate which safety requirements are frequently violated and tests in the follow-up project can restricted those requirements.

In chapter 7 under 7.3 evaluating the results of the project are discussed more extensively.

6.7 Additional Considerations

6.7.1 *Safeguard Clause notification*.

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. The first purpose of the safeguard procedure is that it allows the Commission to safeguard the free circulation of goods within the community by judging if the member states measure is justified. To do so it investigates the measure, contacting the manufacturer and member state(s) involved (and any expertise that may be required).

Member states are required to inform the commission of the reason for their decision, in particular whether non-conformity is due to:

a) failure to satisfy the essential requirements;

b) incorrect application of the standards;

c) 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 for the market surveillance authority that took the measure. 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. The latter is generally highly undesirable and probably only justified for very fundamental differences of opinion on the matter. It is also wise for the Market surveillance authority not to decide this on its own, but to consult the responsible Ministry.

The procedure described above is taken from the Machine Directive, but it is fairly typical for

the safeguard procedures in the New Approach Directives. A notable exception is the Low Voltage Directive (LVD), where the safeguard procedure requires the member states to inform the commission *and all the other member states*. Moreover, in the case of the LVD the Commission only investigates when the member state where the importer/producers is established protests the measure. [4]

Besides informing about 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 organization 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.

6.7.2 RAPEX Notifications

The RAPEX procedure is laid down by the General Product Safety Directive. It obliges Member State authorities to inform the European Commission when a product possessing serious risk is found on the market. The information will be a so-called RAPEX notification. The European Commission will then assess the completeness and the relevance of the notification. If the notification is judged to be complete and relevant to the other Member States it will be forwarded to all RAPEX contact points via the RAPEX IT system.

When a Member State receives a notification it is obliged to investigate the notification to see if the product is on their home market. If the product is found, the authority is obliged to take action and report back to the Commission. The procedures prescribe deadlines for these activities.

The entire RAPEX procedure is described in the guidelines issued by the European Commission. (Reference XX)

6.7.3 Destruction of high risk products

The General Product Safety Directive has provisions that allow the market surveillance authority to destroy products if they have been recalled. The authority must however realise that this is a very restrictive measure with a very high impact on the economic operator.

On the positive side counts that such a measure can be presented to the general public as the authority that “fiercely fights for the safety of the consumer” if destruction of products is done publicly.

The negative impacts of the measure can be huge, though. In principle, a producer may argue that the products will be modified so they become safe. Alternatively, the producer may argue that the products can be marketed legally in third countries. Both cases will leave the authority without arguments for the destruction. And if destruction is done anyway the economic operator may be in a good position to claim compensation because the authority has destroyed products that had a value.

Therefore, if an authority decides that a product is so dangerous that it seems relevant to destroy it, it will be particularly important that the authority consults the economic operator to ensure that modification or reexport of the product is not possible.

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[4] Note that this has consequences for the MS Authority. Good practice for the authority is to investigate LVD safeguard notifications directed against businesses in its own jurisdiction in order to assess whether objection against the measure is justified and to submit an objection to the Commission when it is the case.

(The provisions of the GPSD speaks about "to order or coordinate or, if appropriate, to organise together with producers and distributors (...) its destruction in suitable conditions". One may alternatively want to read this as an invitation to the authorities to assist economic operators with dangerous products with the destruction of the products.)

6.8 Gathering information for reporting purposes according to the project plan

It is important to have proper records, all authorities face the same questions:

Product:

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

Project:

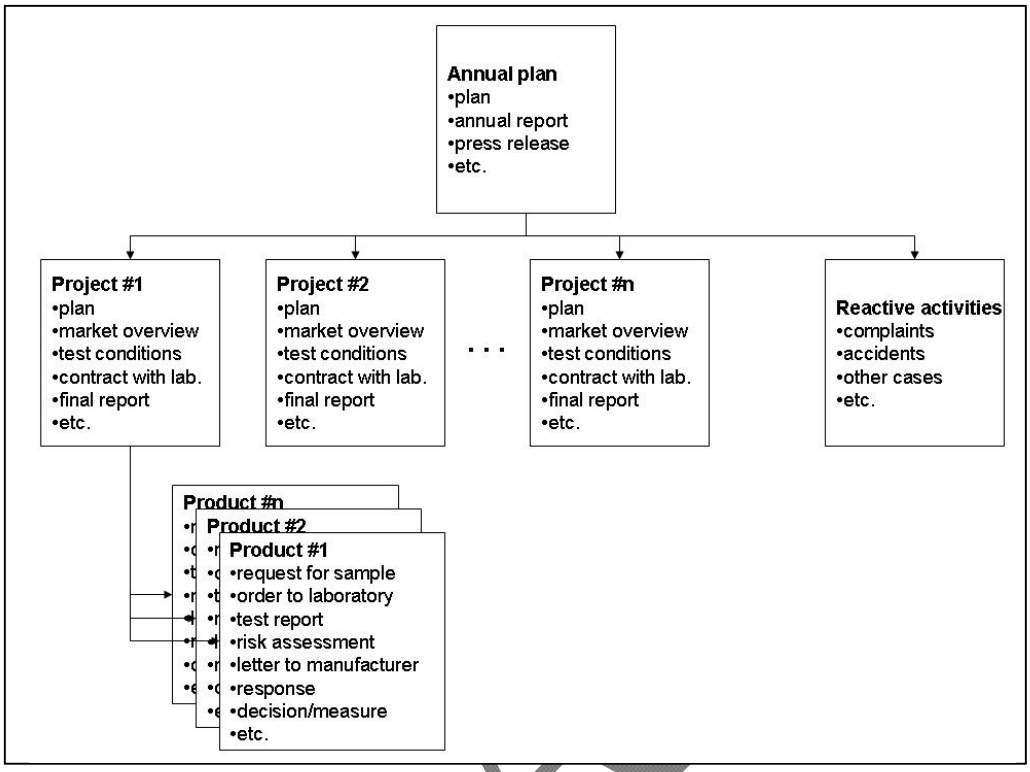
- What was the result of the project?
- What was the outcome of the project?

Annual plan or strategy:

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

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

The overall data structure in market surveillance can be presented as in the following schema:



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
- Perhaps a press release with a status for the year
- Other documents

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

The annual activities in a given year are a number of projects (each addressing a specific product category, a specific risk or something else) and the reactive activities such as following up on complaints, investigation accidents, running single product cases, etc. A number of documents will be produced in each project such as:

- 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
- Other documents

It will often prove useful to open a case in the document management system for each proj ect to collect all documents related specifically to that project.

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

- A request to the 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 with the result of the risk assessment
- Perhaps a response from the manufacturer
- The letter with the authority's conclusion
- Other documents

Normally a case is opened in the document management system for each specific product.

To ease the answering of the questions in the beginning of this paragraph the following information should be registered on each product case:

- Brand name, type name and model for the product.
- Product category.
- Project.
- Name and address of importer.
- Name and address of manufacturer.
- The result of the case (recall, sales ban, minor remark, etc.).
- (Perhaps also number of items sold and returned in recalls.)

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

More data would be useful but more data means more work. If a lot of information is required it is more likely that all information will not be provided or the quality will be lower. If data seems to be immediately useful for those who should provide it, it is more likely that he or she will spend the effort to provide the information.

There is one cross-border IT system available that could be used for storing information on products, the ICSMS system, described under 9.3.3.

7 MARKET SURVEILLANCE PROJECTS - THE REPORTING STAGE.

7.1 Final project report for internal use including analyzing project over all results (possible effects). Assess further measures to be taken.

When the project is finished it is considered best practice to report the results and to ev aluate the project. Reporting the results will ensure that the output from the project is kept for future reference. Evaluating the project will ensure that the authority learns from the project.

The reporting of the project should include reflections over the result of the project: Were the results different than expected ? What are the implications ? The reporting should also present suggestions for next steps.

The evaluation also means 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.

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

d) Project description.

e) Project setup.

f) The extent of the project (which could include something about the size of the project organisation).

g) Organisation of the project (which should include something about cross border cooperation, cooperation with customs, involvement of stakeholders and choice of test laboratories).

h) Methods (which should include something about sampling techniques, risk assessment techniques, use of standards and test methods).

i) 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).

j) Follow-up on time schedule and budget.

k) Evaluation of the project (which should reflect over the results and the method and present suggestions for next steps).

l) Communication (which should present suggestions for communication arising from the project and its results).

Such project reports could contain valuable information that other Member State authorities could learn from. Therefore it is strongly recommended that they are uploaded to the knowledge base that is being set up by EMARS WP1.

The structure of the final report and the structure of the project plan setup are quite similar. Therefore the authority might find it beneficial to use the above headings as a "live working paper" all through a project. The project plan setup is derived from this working paper at the early stage of the project. Results and information is filled into the paper as they are obt ained, and the final report is derived from the working paper at the end of the project.

7.2 Assess experience gained in the project.

The conclusion of a project should include an evaluation of the project to ensure that the authority learns from the project. This evaluation should comprise both the results and the method. (This follows the plan-do-check-act cycle that is well known from project management.)

When evaluating the results from a project a distinction is often made between "output" and "outcome". In the case of market surveillance project 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, the number of products recalled from consumers, etc.
- The outcome is the resulting implications on the level of safety.

The output can be measured from the data that is registered on 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 some kind of a database, perhaps simply as a few extra data stored in the document management system.

The outcome is (hopefully) an increased safety, which in principle means that a number of accidents are prevented and never happens. Thus the outcome is impossible to measure. But it is possible to measure some indicators that will allow the authority to express whether the project had a large or a small impact on the 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 number of items sold and returned to the authority 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 focussed on a new group of products that causes many accidents – e.g. the water yoyo balls or the mini motorbikes.)

The reporting of the project should include reflections over such subject if possible. This would imply that the authority reflects over 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. If the situation in much better that expected, the authority might want to shift focus to other areas for a longer time.

The reflections should present suggestions for next steps. A pitfall is that the most obvious "next step" is to suggest further activities in the area, but this will soon lead the authority into a situation where all resources are allocated to following up projects from the previous years. Other possible conclusions would be:

- 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 means 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 that other Member State authorities could learn from, it is strongly recommended that they are uploaded to the knowledge base that is being set up by EMARS WP1.

7.3 Final report for publishing.

It is often advisable to publish the results from the projects. (It might even have been foreseen in the project plan.) This will show the outside world what the authority is doing, which may in turn increase the awareness of consumers and industry on product safety.

The final report can be prepared by editing the internal report prepared by the authority. The edition 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 that is used.

During the process it must also be considered what the main message in the report will be. Endless tables with figures and detailed results only interest few people; 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 proves 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 handbook.

8 RISK ASSESSMENT

8.1 Introduction

8.1.1 Contents of this module

The focus in this module is entirely on the risk assessment of specific products in the context of market surveillance. It is based on the RAPEX guidelines containing a specific method for risk assessment in the revised version from 2008 [7] and it explains the practical arrangements an authority needs to make in order to do sound risk assessment.

The following sections of this module 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.

The knowledge base will contain examples of risk assessment reports that the WP4 team have developed as part of their work.

8.1.2 What is risk assessment?

Risk assessment is the process that estimates the risk that a product with dangerous non-compliances poses on people, animals or property. The process includes identification of potential hazards associated with the non-compliances and estimation of the probability that the non-compliances will lead to an injury.

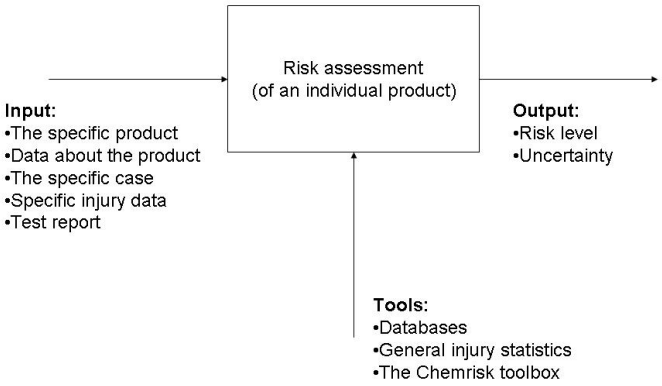
In general the following equation defines risk:

Risk = Severity x probability

In practice, this equation is difficult to apply as the severity and the probability are seldom well-defined numbers:

– The severity is often given as a verbal qualitative description of an injury caused by a given shortcoming in the product.
– The probability is normally difficult to estimate. Often the market surveillance officer can hardly 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 in the risk management and communication.



The process uses a number of data for input as indicated in the figure:

- The product itself.
- Data and further information about the product.
- Data about different possible injury scenarios and/or real accidents
- Injury data specific for the case.
- Test reports listing the non-compliances with the product.

A number of tools are identified in the figure

- Databases with e.g. anthropometric data, statistics on human behaviour, etc.
- General injury statistics
- Toolboxes like for instance the Chemrisk toolbox.

The output from the assessment will be

- The estimated risk level
- The estimated uncertainty in the risk level

8.1.3 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. We have decided to use the ISO definitions, as most RAPEX-notifications deal with mechanical risks. In an annex, we briefly explain the differences between these two frameworks, including illustrative schemes.

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.

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, c rushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).
(ISO/IEC Guide 51, definition 3.5)

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 fr om 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)

8.1.4 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, 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 tactic level (e.g. a project on sound levels in a particular year).

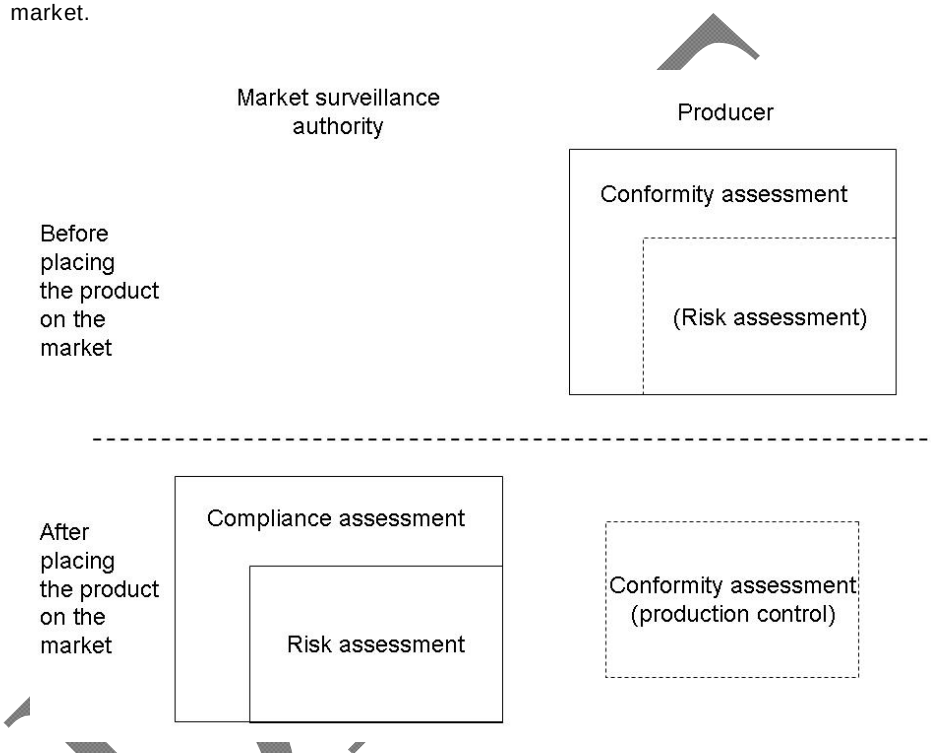
Secondly, it is necessary to determine the risk of specific products in the daily control actions. In particular, the effective operation of the system of rapid exchange of information on products presenting a serious risk (RAPEX) requires the authorities to use a fast, fact-based and consistent method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

(Risk assessment is also an important tool for product safety work outside the market surveillance authorities. As an 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.)

8.1.5 Risk assessment, conformity assessment or compliance assessment?

Risk assessment should not be confused with compliance assessment or conformity assessment (please refer to the figure:

- Risk assessment implies assessing the risk presented to consumers, property or environment by a given product. Risk assessment may be carried out by an authority or a producer when a dangerous non-conformity is found in a product to assist deciding on adequate and proportionate measures.
- Compliance assessment implies assessing if a given product complies with a given set of requirements (normally set out in a Directive and specified in harmonised standards). An authority will do a compliance assessment when they decide if a product meets all the requirements in a directive.
- Conformity assessment implies assessing if a given product conforms to a given set of requirements (normally set out in a Directive and specified in harmonised standards). A producer should carry out a conformity assessment before placing a product on the market.



As can be seen from the figure risk assessment is a part of both compliance assessment and conformity assessment. Thus, risk assessment is always carried out even if the user is not explicitly aware of it. Often conformity assessment is done using a harmonised standard. (This will be the case for a lot of products that are covered by New Approach Directives.) A harmonised standard can be expected to lay down all safety requirements, which means that the user can presume that the product conforms to the safety requirements if it complies with the standard. This implies that the 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.

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.

Compliance assessment is carried out by the market surveillance authorities to check if a given product (that is on the market) meets all requirements 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 a non-conformity in the product then the authority would have to carry out a risk assessment (using the methods from this module) to decide on the risk level associated with the non-conformity. If the producer discovers a 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 already being on the market.)

It is important to realise that a non-conformity does not necessarily imply a risk. Non-conformity to a standard might represent any level of risk as is shown in these 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 a 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:

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- *What is the potential hazard? Most likely it has to do with cutting of fingers but it might be worse depending upon the accessibility of the sharp edge, the sharpness and other geometrical data.*
- *How likely is it that the injury scenario will happen? This will also depend largely upon 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 an acceptable, moderate or serious risk?*
- *Based on the result of the analysis 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 that discovers this problem as part of a quality control programme will have to go through the same analysis to decide on the correct voluntary measure. (He or she 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 on 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 actions.

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8.2 Performing the risk assessment

8.2.1 When do you start a risk assessment?

The starting point for a risk assessment of a specific product can be an incident that happened with a product. A consumer may complain about it, a supplier may report a problem, or the media may signal safety problems. Another possibility is that your own 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.

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 we want to analyse whether it is likely to happen again. However, one should distinguish between risk assessment and accident investigation. The purpose of an accident investigation is to find out what happened and to clarify what the injury scenario was. Furthermore it usually includes a compliance assessment of the product in question. The purpose of a risk assessment to decide what level of risk is associated with the non-conformities in a product. Accident data is used in this analysis to define the injury scenarios and estimate the probabilities but in a general way.

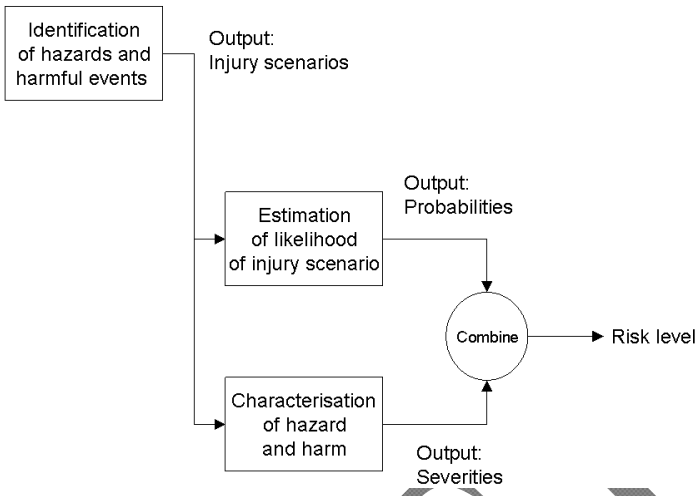
8.2.2 A presentation of the risk assessment process from the data collection to the resulting risk assessment

Risk assessment always focuses on three basic questions [6]:

1. What can go wrong?
2. How likely is it that it will happen?
3. If it does happen, what are the consequences?

In consumer product risk assessment, these questions can be translated to formal steps, using the terms defined in 9.1 (please refer to the figure):

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



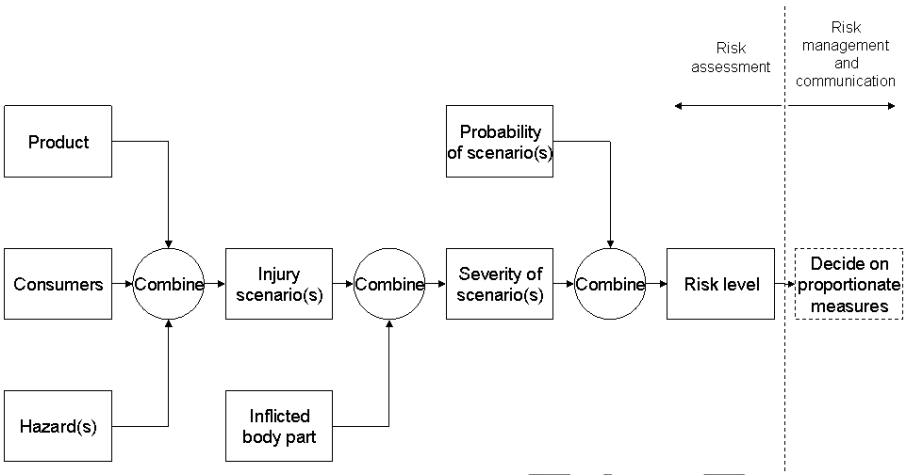
It is important to realise that risk is a combined measure of the likelihood and the severity. For example, all electric household appliances operate on 230 V. One injury scenario would be that the user touches a live wire and gets an electric chock, which can be fatal. However, the producer will normally work to make such a scenario very improbable by insulating the wires and keep all live parts inaccessible behind parts of insulating material. Therefore the probability of the harm and therefore the **risk** of the electrical equipment will be very low.

8.2.3 General procedure

The RAPEX Guidelines [7] constitute a harmonised procedure for supporting decisions on unsafe products. Its main features are:

1. product under assessment;
2. identify the type of consumer that is concerned;
3. identify the hazard(s) under consideration;
4. describe how the hazard inflicts on the consumer. This will usually result in several injury scenarios per product;
5. use the combination of injury type and body part to estimate the severity of each injury scenario (table of examples);
6. assess the likelihood 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;
7. combine severity and probability in a matrix to determine the level of risk.

The procedure is illustrated in the next figure.



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

Example: RAPEX notification no. 0125/06 deals with a cross pane hammer with metal handle and black plastic grip. The hammer has three shortcomings: The hammer head is insufficiently fastened on the handle, the plastic grip breaks under normal strain and 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 inflicts on 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 c and d is filled into the three first columns of the risk assessment table as shown in the figure:

	Product hazards	Injury scenarios	Type of injuries
7			
8	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 form 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.
12	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

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 subtable as shown in the figure.

Type of injury	Severity of injury			
	Slight	Moderate	Serious	Very serious
Laceration, Cut	Superficial	External (deep) (>10cm long on body)	Optic nerve	Bronchial tube
		(>5cm long on face)	Thyroid gland	Oesophagus
		Tendon or into joint	Bladder	Aorta
		White of eye	Nerve root cut	Spinal cord (low)
		Tongue (deep)	Brain	Deep lung laceration
		Cornea	Larynx	Deep laceration of intestines, kidney, liver, spleen
		Abdomen (deep but no organ damage)	Neck artery	Severed throat, high spinal cord
			Trachea	Completely severed aorta
			Intestines	
			Kidney	
			Liver	
			Spleen	
			Lungs (superficial)	
			Penis	
Burn/ Scald	1°, up to 100% of body surface 2° or 3°, <6% of body surface	2° or 3°, 6-15% of body surface	2° or 3°, 16-35% of body surface Inhalation burn	2° or 3°, >35% of body surface Inhalation burn requiring respiratory assistance
Bruising (abrasion/ contusion)	Superficial	Major	Trachea	Brain stem
	≤25 cm² on face	>25 cm² on face	Bladder, colon, kidney, liver, spinal cord (minor)	Spinal cord causing paralysis
	≤50 cm² on body	>50 cm² on body	Lung (minor)	
		oesophagus	Heart	
		larynx	Brain	
			Lung, with blood or air in chest	
Concussion		Under 1 hour	Over 1 hour	Coma

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 "slight" injury. Thus "slight" is chosen in the fourth column of the risk assessment table.

Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probablity 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 form 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: Very serious to Slight. Click into cell below.	For each hazar identified, estim the probability f each step in the scenario (even 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	Slight	
			Serious	
			Serious	
			Serious	

Select severity
Please select the appropriate severity level from the scale

6. Assess the likelihood 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 1/2).

Step 2: The upper parts hits the arm (with an estimated probability of 1/5).

The steps and their probability are noted in fifth column of the risk assessment table:

	Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probablity of factors	Calcu proba
8	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 form 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: Very serious to Slight. 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	Calcul value probal factor 1/10 x x 1/8 = 1/8.00
12	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	Slight	Handle breaking: 1/2 Hitting arm: 1/5	
13				Serious		

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 [7]:

Possible selections for severity and probability			
Severity		**Indicative statistical value of the proba**	**Description of the probability**
Very Serious		> 50 %	Almost certain, might well be expected
Serious		> 1/10	Quite possible
Moderate		> 1/100	Unusual but possible
Slight		> 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

The severity and the probability is combined to get the resulting risk level. The combination is done in the matrix in the RAPEX guidelines [7]:

Combination of severity and probability to risk level					
		Very Serious	Serious	Moderate	Slight
Almost certain, might well be e	> 50 %	Serious risk - r	Serious risk - r	Serious risk - r	Moderate risk
Quite possible	> 1/10	Serious risk - r	Serious risk - r	Serious risk - r	Low risk
Unusual but possible	> 1/100	Serious risk - r	Serious risk - r	Serious risk - r	Low risk
Only remotely possible	> 1/1.000	Serious risk - r	Serious risk - r	Moderate risk	Acceptable
Conceivable, but highly unlikely	> 1/10.000	Serious risk - r	Moderate risk	Low risk	Acceptable
Practically impossible	> 1/100.000	Moderate risk	Low risk	Acceptable	Acceptable
Impossible unless aided	> 1/1.000.000	Low risk	Acceptable	Acceptable	Acceptable
(Virtually) Impossible	< 1/1.000.000	Acceptable	Acceptable	Acceptable	Acceptable

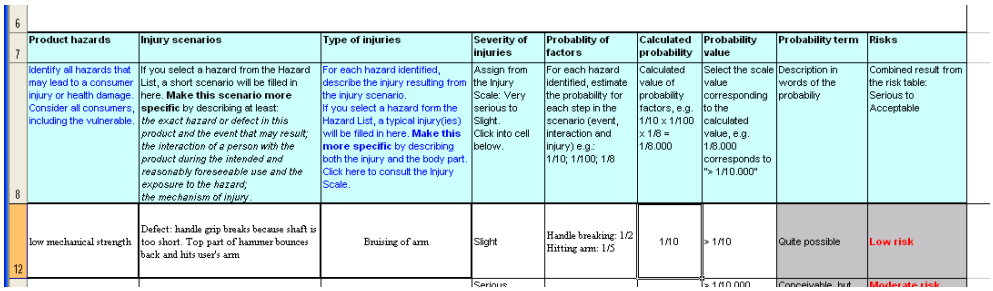
In this case the probabilities of each step in the injury scenario are multiplied to give 1/10.

This compares to an "indicative statistical value" of "> 1/10".

The severity of the injury was "slight" (step e).

The combination of "> 1/10" and "slight" gives "low risk" as can be seen in the table above.

These data appear in the Excel spreadsheet in the four last columns. The calculated, resulting probability is written in 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.



	Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probablity of factors	Calculated probability	Probability value	Probability term	Risks
8	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 form 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: Very serious to Slight. 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 = 1/8.000	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
12	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	Slight	Handle breaking: 1/2 Hitting arm: 1/5	1/10	> 1/10	Quite possible	Low risk

The detailed RAPEX guidelines can be found in [7].

8.2.4 Getting the necessary data for the risk assessment

At the beginning of section 9.2.2, we presented the three questions that are relevant in risk assessment. If we want to perform an evidence-based risk assessment, we need data for every question. Below we provide some suggestions for the type of data and how to access them.

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 a (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.

The answer to the question should be a list of injury scenarios. Often a product has several shortcomings that should all be analysed (unless it is immediately obvious that some of the shortcomings have no risk associated with them). You will also normally find that one specific shortcoming 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 decide the outcome of a scenario without doing the complete analysis.

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 of 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 of 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 most serious outcome. If a part of the hammer hits the user in the eye (the first scenario), the result might be blindness on that eye. This is in general 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 much lower than the probability of getting hit in the face, then the second scenario would turn out to have the highest risk level.

How likely is it that it will happen?

The probability that a given shortcoming will lead to an injury is often very difficult to estimate. In case of a reported injury, we know for sure 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, you should take into account that the data rarely relate to the exact type, brand and model of product that you are interested in. 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 types of steps can be distinguished:

1. Product characteristics.

How likely is it that the shortcoming will occur? (Example: What force is required to break the hammer head, 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 product.

How likely is it that people will actually use the product or be exposed to use of the product? (Example: How often is the hammer used during its lifetime? What share of the population does do-it-yourself-work? Is the hammer generally available through supermarkets or is it sold through specialised tool shops?)

Note that one may very well experience differences between different regions or Member States on this property. Snowboarding is for instance more frequent in the Alps than in the Mediterranean.

3. Behaviour.

Is a special behaviour required to cause the incident? How likely is it that people will behave in that specific way? What share of the population is actually able to behave in that way? (Example: Will all people be able to swing the hammer so fast that the impact breaks the hammer? What proportion of people will allow their children to watch them working with a hammer?)

In this step it might be necessary to include anthropometric data for groups of people, e.g. children and other vulnerable people.

4. Injury mechanism.

How exactly does the injury occur? What exactly is the injury? (Example: Will the broken part of the hammer hit the user? What part of the user? What kind of injury does that cause?)

The injury mechanism is often based on medical criteria. For instance, an estimate of the probability that an object hits the eye of a person can be made by comparison of the area of the eye to the area of the exposed body parts in total. Information about the probability of eye injury depending on energy and shape of objects could be available in medical literature.

It will be clear that data to estimate the likelihood 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.

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

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.

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

8.2.5 Sensitivity analysis

The estimate of the probability is often based on a number of assumptions and not only on exact numbers. 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 9.2.2 because the influence should be analysed in a sensitivity analysis.

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

A very practical way of doing the sensitivity analysis is to repeat the risk assessment as in paragraph 9.2.2 using the highest probabilities that one could estimate by combining the estimated probability and the estimated uncertainty. The resulting risk level will then be the highest possible level.

If it is the same as the originally estimated level, then the uncertainties on the probabilities do not have an impact on the result (which of course is 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.

8.2.6 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 an appearance so that it can be produced in a court case should that be requested.

To ensure that the reporting actually is done it is recommended to use a reporting form that is simple, easy to use and that does not require the user to fill in unnecessary information. The advantage of using a form is also that it 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 – rapid action required” or “moderate risk – action required”.

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.

NOTE Three examples are shown in section 8.5.

8.2.7 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 changing estimation into looking up values in a table and by forcing the estimates to be as transparent as possible. Still there is a risk for subjective judgements in the method.

The best way to handle this is by doing the risk assessment in pairs or groups where all participants in common carry out the risk assessment. To prepare the risk assessment it is recommended that all participants do individual risk assessments before the common assessment.

This might be difficult to achieve in practice. Often the authority would look for ways that take less time and are less resource demanding. 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 project where many similar products are investigated it might be possible to do the risk assessment of the first product in common in a group and use this as a base for the assessments of the other products. Again it is recommendable to have another person to check all the final risk assessments.

8.3 Pitfalls that may occur in practice and advice to avoid them

In this section, we address a number of practical problems that the EMARS Risk Assessment team has seen when performing the analysis for specific cases. We also suggest approaches to avoid these pitfalls.

Must I do a risk assessment every time?

Often the risks are so obvious that it seems superfluous to do a risk assessment using the method from 9.2. If the user can touch live parts in an electrical appliance, then “everybody” immediately knows that it is dangerous, so why bother about the paperwork?

We consider it best practice always to carry out a risk assessment.

Firstly, market surveillance authorities can only take measures against technical non-conformities if they are dangerous. The producer is not obliged to follow a standard and therefore non-compliance with a standard may not necessarily mean non-conformity with the requirements from the directives. Therefore the legal argument behind a measure against a 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 then proportionate measure was decided.

Off 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 over and over

again 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 that could go into the legal letter to the producer.

Serious injury = serious risk?

If an injury scenario can lead to serious injury, you might expect (or want?) to arrive at a serious risk.

As shown in paragraph 9.1.5 this will not necessarily be the case. It depends upon the probability of the scenario. If the scenario is virtually impossible t hen serious injuries might still lead to a moderate or even low risk.

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 doesn't work). This means that the person is exposed to the hazard that the equipment was supposed to protect from.

Small probability but many products

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 may seem unacceptable. If the product is sold in very large numbers then the exposure for society as a whole would be high. This would imply 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.

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.) The solution is to separate perception of risk from risk assessment and deal with the perception of the risk under risk communication (i.e. when deciding on adequate and proportionate measures).

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.

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How to avoid that the number of scenarios expl odes?

As we saw above, a major question is what can go wrong. In the RAPEX Guidelines this is implemented by developing an overview of scenarios that can happen with the product. If you have enough imagination, you may end up with a long list of scenarios that could happen. For

example, in a risk analysis of a chain saw you may imagine 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?

We emphasise that 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.

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, 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 feature such a special place for vulnerable people, but it is still *possible and desirable* to pay specific attention to them.

How can that be done?

- first, take into account any (very) vulnerable groups when listing 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 of a whistle. An injury scenario is that this part is broken of by the user while he or she is blowing the whistle and gets into the user's mouth. From here two developments are possible:

a) If the user is an adult then he or she would most likely spit out the part and nothing will happen.

b) 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.

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Subjectivity

If an assessment is done by a single expert, his or her personal experience may influence the estimation of injury severity and likelihood. Furthermore it is easy to become misled by the names of the categories in the scale of injury severities in the RAPEX guidelines. As an example "loss of a toe" is called *moderate*. Personal preferences or the specific circumstances may lead the market surveillance officer to consider the injury unacceptable in any case.

To avoid subjectivity:

- use quantitative measures and data;
- work with colleagues from the start or have them review the result;

- don't put any value in the words for the injury levels.

The injury levels are grouped under four headings "slight", "moderate", "s erious" and "very serious". The risk assessor must not get confused by this terminology as it is only intended to distinguish four levels in a scale. (It is also important to stress that authorities should be cautious if they communicate the results of a risk assessment as the perception of the injury in the general public and by a victim will most likely be very different from the headings of the four levels.)

Non-compliance to a standard means risk?

A shortcoming that is commonly found in RAPEX notificati ons 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. Risk assessments are prob ably carried out sometimes to back up the notification or in reaction to it, but this information is not available in the public domain.

As explained in 9.1.3, 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 shortcoming and the injury is well-known. Alternatively existing risk assessments of such well-known shortcomings could be re-used to quickly decide on measures (this is t he 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 us er 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."

Products causing damage to property

The risk assessment method in the RAPEX guidelines works from 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 putting 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 smoke poisoning, dies, etc.). An example of such a scenario could be "Candle puts 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 these scenarios can be checked with data from fire statistics. The scen arios include the probability that someone dies in 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:

Severity	Description of fire
Very Serious	A whole building or several rooms are destroyed by the fire.
Serious	One room is destroyed by the fire or several rooms are affected e.g. by smoke.
Moderate	Few pieces of furniture or curtains are destroyed or one room is affected e.g. by smoke or burn marks.
Slight	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.

8.4 Alternative methods

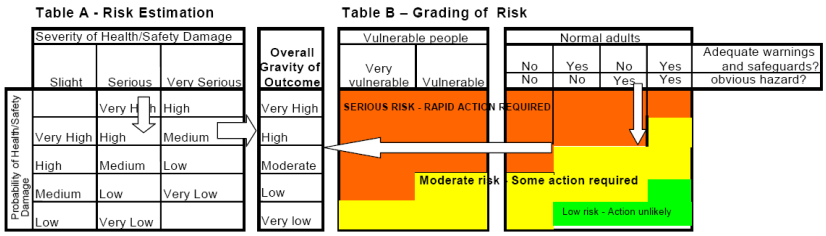
Several practical tools have been developed for performing risk assessment. A report compiled on behalf of the EU Commission lists six formal methods that were used recently in Europe [5], but probably more methods exist that had not been formally published (including the use of expert panels). The report further distinguishes between qualitative, semi-quantitative and quantitative methods. For example, a method that makes use of a nomograph is classified as semi-quantitative.

The EMARS Risk Assessment team has tried three methods for various cases to get an idea of the strengths and weaknesses:

- The RAPEX-method as developed in 2003 for the European Commission as modified and presented in [8].
- The (revised) RAPEX procedure [7].
- The Nomograph method [5].

8.4.1 The RAPEX method

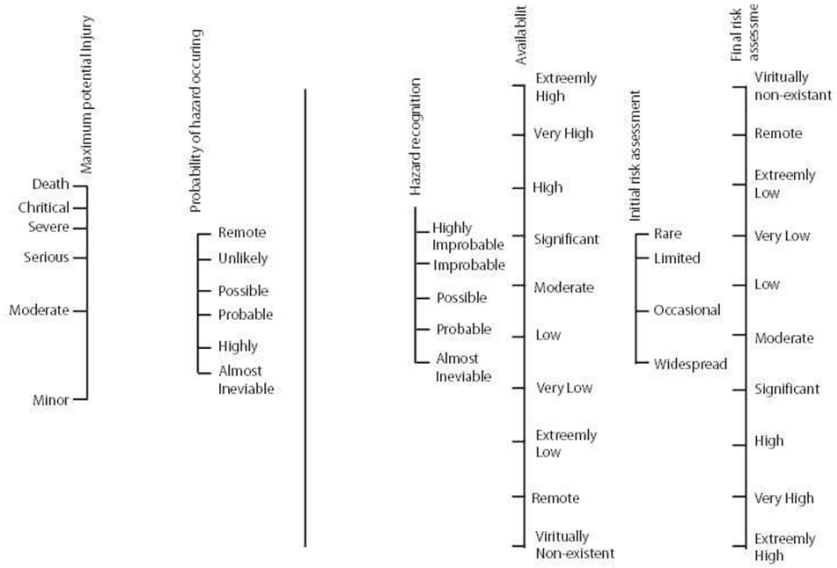
The RAPEX method uses the red-yellow-green matrix that all market surveillance authorities should be familiar with:



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. We found that there is a higher level of transparency, less often serious risk, and more agreement between experts when using the method as described in [8].

8.4.2 The nomograph method

The Nomograph method [5] uses maximum potential injury (6 levels), probability of hazard occurrence (6 levels) and hazard recognition (5 levels). The risk estimation is made using a graph.



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. In our opinion, the RAPEX guidelines provide more guidance on selecting the injury level and the probability factors.

8.4.3 The current RAPEX procedure

The RAPEX procedure [7] is currently the most suitable tool for decisions about unsafe products, and we have highlighted its main features above. The method was developed from the RAPEX guidelines by WG IRAG.

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: this condition has 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 in justification of RAPEX cases.

8.4.4 Why one common method?

Risk assessment can be done in numerous ways but we support using 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 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 explained from obvious reasons (like e.g. differences in climate).

Furthermore, the method from the RAPEX guidelines is seen to decrease subjectivity as subjective judgements to the largest possible extent are replaced with 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) 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.

8.5 Examples with "ideal" model assessments

This paragraph presents three examples of risk assessments:

- 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

All examples are presented in the reporting format described in paragraph 9.2.6.

8.5.1 Hammer

Identification of product and case, description of the context.

This case deals with a cross pane hammer with metal handle and black plastic grip where the hammer head can fly of. The hammer head is insufficiently fastened on the handle and the plastic grip breaks under normal strain.

The case is taken from the RAPEX notification number: 0125/06.

Description of the hazards.

The hammer has three dangerous shortcomings:

- The hammer head is insufficiently fastened on the handle.
- The plastic grip breaks under normal strain.
- The hammer head is made of brittle material with insufficient dynamic impact strength.

All hazards may result in parts that break of the hammer hits the user or on a spectator standing nearby.

Description of injury scenarios and sensibility

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	Serious	Breaking: 1/10 Hitting person: 1/10 Hitting head: 1/3 Hitting eye: 1/20	1/6.000	Moderate
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	Slight	Breaking: 1/10 Hitting person: 1/10 Hitting head: 1/3	1/300	Acceptable
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	Bruising of hand, finger etc	Slight	Breaking: 1/10 Hitting person: 1/10 Hitting body parts: 2/3	1/150	Acceptable
Defect: handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby)	Concussion < 1 hour	Moderate	Grip sliding off: 1/5 Person nearby: 1/10 Hitting person: 1/100 Hitting head: 1/10	1/50.000	Acceptable
Defect: handle grip of hammer 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	Slight	Grip sliding off: 1/5 Person nearby: 1/10 Hitting person: 1/100 Hitting head: 1/10	1/50.000	Acceptable
Defect: handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits body part of user or other person	Bruising of hand, finger etc	Slight	Grip sliding off: 1/5 Person nearby: 1/10 Hitting person: 1/100	1/5.000	Acceptable
Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm	Bruising of arm	Slight	Handle breaking: 1/2 Hitting arm: 1/5	1/10	Low

A sensitivity analysis has not been carried out. However, the probability of the first injury scenario (which has the highest risk level) can be raised 5 times before the risk changes to "serious risk". There is only this one scenario with a risk level above "acceptable".

Conclusion

The result of this analysis is that one scenario has the outcome "moderate risk" (which happens to be the most serious outcome). Five scenarios result in "acceptable" and the last one ends in "low risk".

The overall outcome of the analysis it that the risk is moderate, i.e. action against the product should be taken, but there is no need for a rapid intervention and RAPEX-notifications.

8.5.2 Rubber luggage straps

Assessment that is initialised by an accident with a product

Identification of product and case, description of the context.

This case deals with a rubber luggage strap with metal hooks in both ends. The strap is used for affixing 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 impairment. There are even a few cases of lost eyes and blindness on one eye.

Description of the hazards.

The risk with this product comes from the hooks in the ends of the strap being of so poor quality that they bend open if the tension in the strap is too high.

The result is that the hook hits the user quite hard. The biggest injury is supposed to occur if it is the hook in the opposite end of the strap that opens.

(Further to this scenario a number of accidents happen because the user attaches the hooks poorly, so that they loose their grip when the strap is tightened. These scenarios are not analysed here.)

Description of injury scenarios and sensibility.

One injury scenario has been developed based on a case found in an article in a medical journal.

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	Serious	Person standing in line: 50% Hook opening: 1% Hitting head: 1/3 Hitting eye: 1/20 Eye injury: 20%	1/60,000	Low risk

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 “moderate risk”.

Conclusion

The result of the analysis is that the risk level is “low 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.

8.5.3 Socket protectors

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 to avoid that small children access live parts by putting long metal object into one of the holes in the outlet and gets a (fatal) electric chock.

Description of the hazards.

The holes in this protector (where the pins of the plug go trough) are so narrow that the pins might get stuck. This would most likely mean that the user will pull the protector of the outlet when the plug is pulled out.

If the user doesn’t notice (or doesn’t put back the protector) then the outlet is left unprotected for the children. Therefore the product will not provide the protection that the parents rely on.

Description of injury scenarios and sensibility.

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk

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.	death	Very Serious	removing of protector 9/10 not noticing the removal of protector 1/10 child is playing with thin conductible object 1/10 child is unattended when playing 1/2 child inserts the object into the socket 3/10 access to voltage 1/2 electrocution due to voltage (without circuit interrupter) 1/4	> 1/10.000	Serious risk - rapid action required
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	Slight	removing of protector 9/10 not noticing the removal of protector 1/10 child is playing with thin conductible object 1/10 child inserts the object into the socket 3/10 access to voltage 1/2 child is unattended when playing 1/2 burn due to voltage (without circuit interrupter) 3/4	> 1/10.000	Acceptable

The outcomes of the analyses were 1 scenario resulting in “serious risk” and 1 in “acceptable”. The calculations are based on an estimated probability that the protector can be removed unintended 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 “moderate 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 doesn’t affect the outcome.

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.

9 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 is a single market, therefore it is imperative that all its Member States harmonize the actions taken at National level. The objective of the New Approach Directives is to adopt single pieces of legislation that are applicable to all the Member States, hence, the actions taken in one Member state in order to safeguard the health and safety of the consumers,

could very well be adopted by the other Member States. This can only be achieved if there are good communication infrastructures and networks between all the members.

In the area of food and feed safety, risk communication is part and parcel of the Risk Analysis. Risk analysis is the philosophy and the fundamental methodology underlying the development of the legislation and product standards. It is composed of three separate but integrated elements namely Risk Assessment, Risk Management and Risk Communication. The following table is the WHO/FAO framework for risk analysis in food but may also be adopted in other non-food product safety areas.

The linkage between Risk Assessment, Risk Management & Risk Communication

9.1 Basic Fundamental Concepts

Following a proper Risk Assessment (see Chapter 8) carried out by product safety experts in order to identify whether the product poses a HIGH, MEDIUM or LOW risk, a strategy to identify the ways and means to eliminate or reduce the risk to an acceptable level has to be carried out. This is called Risk management. Managing the risk may consist of various different kind of actions depending on the outcome of the risk Assessment (please refer to Part C of this handbook). The final important step is to do an Effective Risk Communication in order to communicate the risk in the best possible manner and to reach all those that are exposed to the said risk. To control and minimise the risks all these steps have to be in place and have to be interlinked.

When the outcome of the risk assessment is LOW, although one still needs to take action, there is no need to implement a full blown information campaign and therefore cause an unwanted alarm. This should be tackled by verbal communication with the respective manufacturers/importers/distributors in order to reduce or eliminate the risk. On the other hand, when the outcome is a very HIGH risk, an immediate action has to be taken in order to eliminate the danger. The first thing to think about is to identify who is in danger and the method of communication. Please refer to the following table.

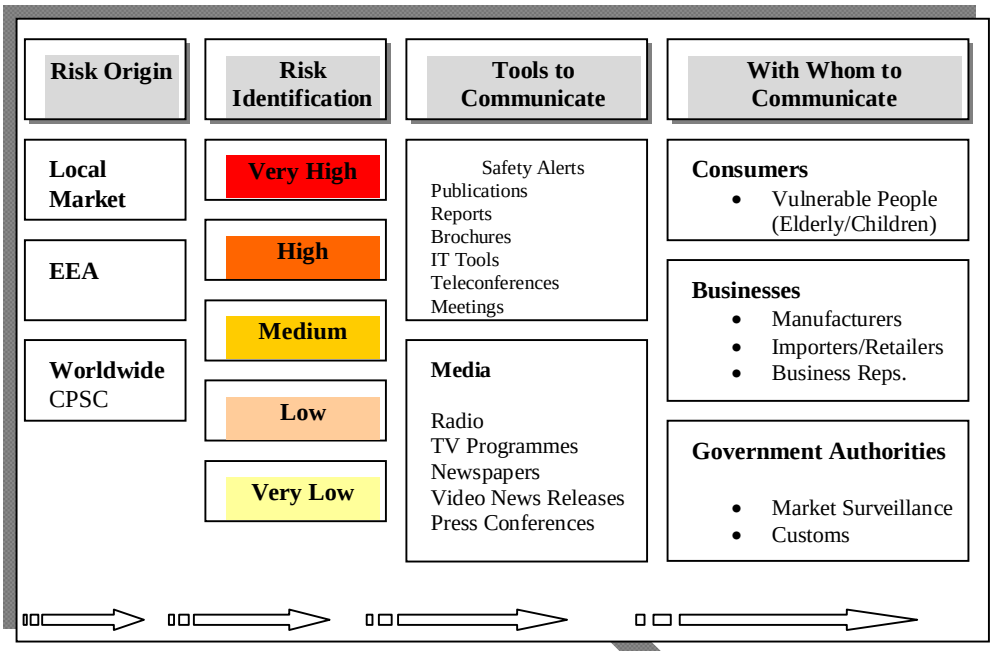


Table 1. Risk Analysis

The table above is divided into 4 columns, the first column shows the origin of the risk identified and to gather knowledge on whether this risk has been identified through local inspections carried out by the National Market Surveillance Officers, in the European Economic area or from other organisations situated in other parts of the world such as the CPSC. The second column shows the level of risk involved. In order to identify the risk level, an expert has to perform a systematic process called Risk Assessment (please refer to chapter……..). This process should be repeated if the risk assessment process has been carried out by other exterior entities (other Member States or other market surveillance organisations in order to identify whether this risk is applicable also in your country. It is extremely important to categorize the risk associated with the product and to discover its exposure at local level. The risk identification column (column 2) shows 5 different levels of risk, ranging from the very high risk to very low risk. When the outcome of the risk assessment is very 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 very low, there is no need of an immediate action but preferably this very low risk should also be eliminated.

After the risk identification process, one has to gather knowledge regarding the tools available to communicate the risk with the entities involved (consumer segments at risk), in the table above these are being referred to as column 3 and column 4 respectively. A thorough analysis should be carried out in order to choose the best possible tool/s so as to reach the target audience and send them accurate messages. Such communication strategies can only be effective if they are planned carefully. Apart from reaching the target audience in the least possible time, choosing the best available tool/s (column 3) will also save costs to the respective organisations.

Continuous research is being done by the European Commission and the Member States in order to improve the existing communication tools and to identify and develop other new effective tools that will contribute to either faster or 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 for the public on the public domain such as the weekly RAPEX reports (for consumers published by

the European Commission) or may also be restricted to public officials within the Member States.

9.2 Communication In the field of product safety

In the field of product safety communication is being carried out using the following methods:

- Continuous meetings between the European Commission and the Member S tates
- IT Tools
- Media
- Reports
- Teleconferences
- Brochures

The use of the above mentioned methods of communication depends on the objectives and goals of communication. For example in the case of a dangerous product posing a risk on the health of the consumer in a particular Member State a method of rapid communication between all Member States is essential, so that the latter take the necessary action/s to eliminate the risk or to reduce it to an acceptable level.

The tools that are currently used for the dissemination of information are the following;

- RAPEX
- Safeguard Clause
- ICSMS
- CIRCA
- European Commission Website

Apart from the ICSMS system all the other systems are used by all the Member Sates an d all have their own importance for their particular application. The use of such systems will be discussed in further detail in this chapter. The ICSMS is currently being used by these 11 Member States (AT, BE, EE, DE, LU, MT, SL, SE, CH, NL, UK).

9.3 Infrastructures for effective communication of risks

Importance of a rapid alert notification system (national & cross -border links)

There are various tools used as rapid exchange of information between members of the European Economic Area EEA. These tools are used in order to exchange the information very rapidly so that the contact points in each Member States can take the necessary action immediately.

9.3.1 RAPEX

RAPEX is a European rapid alert system for dangerous non-food products. It is used to disseminate information regarding dangerous product

s identified in one Member State to be quickly circulated between all the Member States and the Commission. In accordance to Articles 11 and 12 of the General Product Safety Directive, 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 Annex IV of 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).

To this regard, the European Commission has established a network of National Contact Points (please refer to the following website) http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_weekly/contact_points_revised.pdf

These contact points are the public officials who 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).

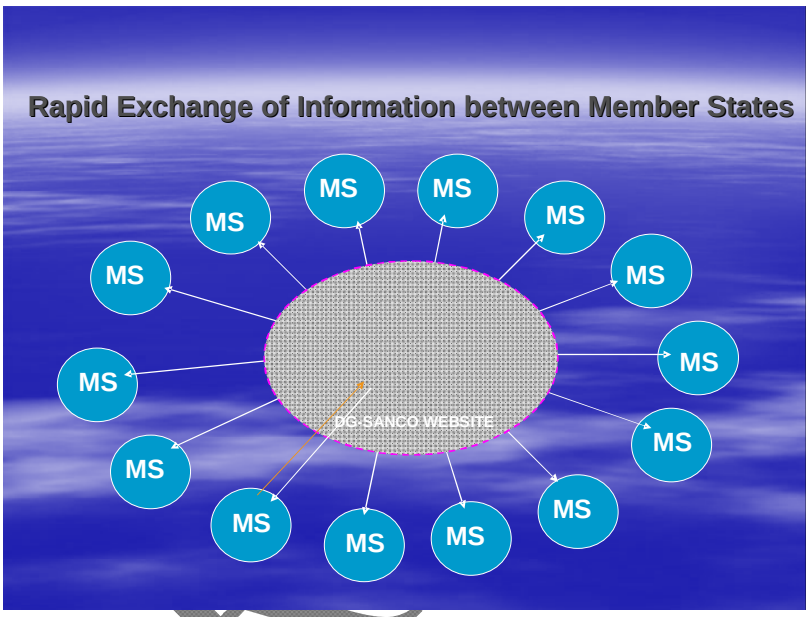


Table 2. The functioning of the RAPEX System

Step 1.	Rapid Alert Notification is sent to the European Commission by one Member State
Step 2.	Data Verification by the European Commission
Step 3.	The Rapid Alert Notification is sent to all Members of the EEA in order to take the necessary action/s if the notified product is found on their market

Link for Consumers – Weekly Reports

http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

Link for National Contact Points

https://reis.ec.europa.eu/reis/login.xml

Deadlines for National Contact Points

(These deadlines are established in 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)

Action	Deadline
Send notifications relating to emergency situations to the commission	ASAP or maximum 3 days
Notify the Commission of decisions and actions taken: By the authorities in case of serious risk; As agreed between authorities and producers and distributors.	ASAP or maximum 10 days
Notify the Commission of voluntary measures by producers and distributors	ASAP or maximum 10 days
Send the Commission information on serious risks liable to be exchanged under RAPEX	ASAP or maximum 10 days
Inform the Commission of decisions and actions taken by the authorities in case of products not presenting a serious risk	ASAP or maximum 15 days
Confirm or modify information already provided before the decision on the measure was taken	ASAP or maximum 45 days
Update the Commission on any modification of lifting of the notified measure or action	ASAP or maximum 5 days
React to a notification requiring emergency action from Member States	ASAP or maximum 20 days
React to a notification of decisions and actions taken by the authorities, of measures and actions agreed between authorities and producers and distributors, of voluntary measures by producers and distributors	ASAP or maximum 45 days
React to notifications related to products manufactured or first marketed in its territory	ASAP or maximum 15 days

9.3.2 Safeguard clause notifications

New approach directives provide for a "**safeguard-clause procedure"** which is designed to allow the Commission to verify the justification of national measures restricting the free movement of CE marked products. These measures are intended to protect public interests covered by the essential requirements (in most cases safety requirements) laid down in the directives. The safeguard-clause is, in this respect, the counterweight to the rule that Member States must presume that products declared to conform to the essential requirements set out in a directive, in principle comply. Under these circumstances, the safeguard-clause constitutes a mechanism to ensure a uniform position throughout the Community, since it aims at a Community approach to any Member State's decision that a given product does not conform.

This may lead either to the extension of the necessary restrictions to all Member States, thus ensuring an equivalent level of protection throughout the Community, or to the withdrawal of the national measures, thus ensuring the free movement of goods is restored. The Member State concerned must immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether the non-conformity is due to failure to meet the essential requirements referred to in the Directive, to incorrect application of the standards in question, or to shortcomings in the harmonised standards themselves. The Commission must enter into consultation with the parties concerned as soon as possible. After the consultation the Commission must indicate whether it considers the measure taken to be justified. The Commission position takes the form of an Opinion.

Where the Commission considers that the measure is justified, it must immediately inform the Member State concerned and the other Member States thereof.

9.3.3 ICSMS

ICSMS is a system with the main task to provide and exchange product information via the internet. 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, as well as voluntary industry recalls and postings made 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, RAPEX 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 un-authorised access.

Link of ICSMS: http://www.icsms.org/icsms/App/index.jsp

9.3.4 CIRCA Website

Another important IT tool is the Communication and Information Resource Centre Administrator (CIRCA). As the name implies it is a communication tool, it can be useful for all entities namely the enterprise, market surveillance authorities, consumers and customs. It is mainly a database administrated by the European Commission. There are also restricted areas within the database and can be accessed by authorised officials only. The two main important areas in the field of non-food product safety are the section of enterprise and the Health and Consumer Protection.

The link to the CIRCA website is the following: http://circa.europa.eu/

9.3.5 European Commission Website – Enterprise and Industry

Another very important database can be accessed from the European Commission Website, in the section of the 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 in this database.

The link to the European Commission website is the following

http://ec.europa.eu/enterprise/index_en.htm

9.3.6 Effective linkage with Media

The Media is an important tool to be used when a dangerous product is distributed within the market. Before making the statements on 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.

“Written, verbal, or visual statement containing information about risk, may or may not include advice about risk reduction behaviour, a formal risk message is a structured written, audio, or visual package developed with the express purpose of presenting information about risk”

9.3.7 Follow-up procedures on how to inform/update importers, producers and retailers

When a dangerous product is found on the market, the competent national authority is obliged to take the necessary actions. Some of the actions are withdrawal of the product from the market, recall from consumers, initiation of legal actions etc. When any of these actions are taken, the importers, producers and retailers should be informed in writing and to be kept informed regarding all actions taken.

9.3.8 Follow-up procedures on how and when to inform the public (importance of effective rapid communication in case of dangerous products)

The public should only be informed when one of the products encountered on the market poses a risk on 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 to withdraw the product from the market and to issue the public statements in order to protect the health of the consumers.

9.3.9 How to inform PRODUCERS and IMPORTERS of notification obligations

Article 5 of the General Product Safety Directive 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 by several methods for example, 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 etc.

9.3.10 How to inform CONSUMERS and MEDIA of dangerous products and instructions on how to react in order to avoid dangerous situations

When communicating through the media the following have to be in place:

- Clear Communications goals and key messages
- Information should be 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.

9.3.11 Notification to the COMMISSION on products that are prohibited or withdrawn from the market

Producers and distributors must inform the competent national authority where they know (or ought to know) that a product they have placed on the market (e.g. a toy or an electrical appliance) is dangerous. The competent national authorities are then obliged to in form the commission regarding any actions that were taken so that the information is disseminated between the EEA.

9.4 ADDITIONAL PRACTICAL WAYS OF EXCHANGING INFORMATION ON RISK / PRODUCT KNOW HOW

Utilising existing cross-border information systems

9.4.1 ADCO GROUPS

There are various Administrative Co-operation Groups (ADCO Groups) for the market surveillance for 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:

- the exchange of information between Member States' authorities concerning the national market surveillance mechanisms and the adopted solutions;
- the achievement 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;
- 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
- TCAM (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.

9.4.2 GPSD Committee and Network

The General Product Safety Directive (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.

9.4.3 PROSAFE –EMARS PROJECT

An extremely important development in the dissemination of information between the Member States is the creation of the Rapid Advice forum. This is a forum established by PROSAFE and the members are various experts in the field of the GPSD, Toys and PPE. Through this network the experts can give Public Officials from different Member States advice on the risks that are posed with particular products. This is envisaged to contribute to enhance harmonisation between member states and to eliminate possible existing gaps between decisions taken.

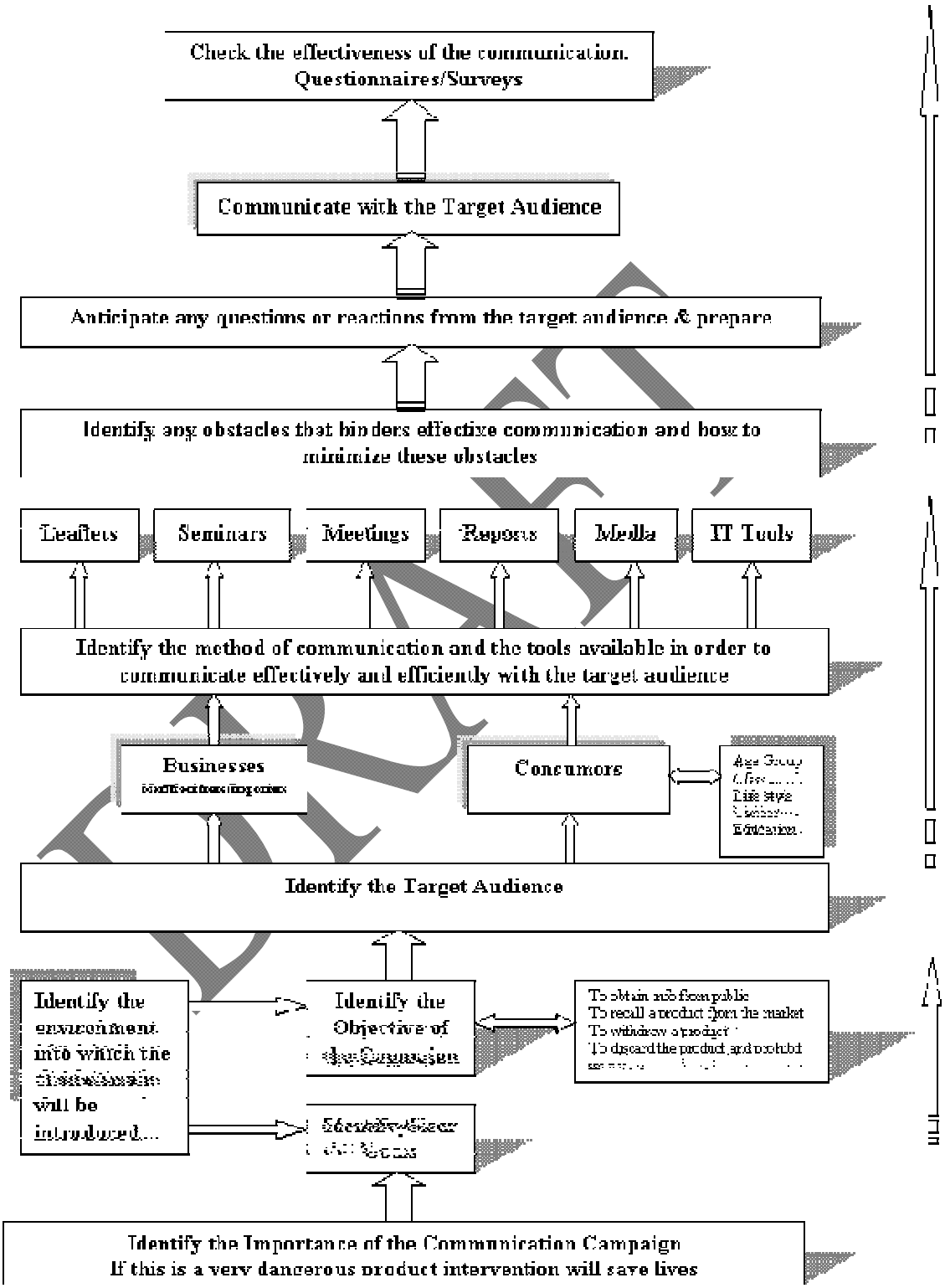
9.4.4 EDUCATION AND AWARENESS CAMPAIGNS

Effective Awareness Campaigns for Consumers and Businesses

If we work together in order to create the best market surveillance institutions with the best market surveillance officers having a brilliant and full proof 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.

The table in the following page shows the strategy and methodology of a risk communication procedure. Reaching the target audience in the shorter possible time with clear objectives and instructions can save LIVES.

The first thing to tackle is to determine the importance of the information campaign, 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.


Check the effectiveness of the communication.
Questionnaires/Surveys
Communicate with the Target Audience
Anticipate any questions or reactions from the target audience & prepare
Identify any obstacles that binders effective communication and how to minimize these obstacles
Leaflets
Seminars
Meetings
Reports
Media
IT Tools
Identify the method of communication and the tools available in order to communicate effectively and efficiently with the target audience
Businesses
Consumers
Identify the Target Audience
Identify the environment into which the
will be introduced...
Identify the Objective of
To obtain info from public
To recall a product from the market
To withdraw a product
Identify the Importance of the Communication Campaign
If this is a very dangerous product intervention will save lives

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 in further segments (age group, class, life-style, gender or education) as shown in table above.

Following the identification of the target audience, one has to determine the most feasible and viable tool to communicate (please refer to table 1 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 obstacles that may hinder the effectiveness of the communication. One has to 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 queries from the target audience.

When all the above mentioned steps 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.

PART C
COMMUNITY & CROSS-BORDER MARKET SURVEILLANCE ACTIVITIES

10 THE MAIN EUROPEAN / INTERNATIONAL STAKEHOLDERS WITHIN MARKET SURVEILLANCE

Beside national legislators, national policy makers, producers, distributors and individual consumers who e.g. complain about specific products, stakeholders organisations can have a very important influence on the market surveillance policy in several ways.

In this chapter the main International and European stakeholders organisations in the area of consumer product safety market surveillance are very briefly addressed. The given hyperlink to the website of the stakeholder organisation in question provides more detailed information.

10.1 International / European Agreements and Treaties

International agreements on World trade (and especially the technical barriers to trade) and the European Treaty of the EU have a major impact on the national legislation and policy in the area of consumer product safety. The WTO and the European Commission act as "guardian" of the agreements and treaties and both organisations promote the developments and elaboration of the substance of the agreements and treaties.

10.1.1 WTO (World Trade Organisation)

The hyperlink to the website of the WTO is: www.wto.org. Of especial 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*

10.1.2 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 (*http://ec.europa.eu/consumers/index_en.htm*) has the task of keeping 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.
- 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 are, inter alia,: 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.

10.1.3 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 stakeholders in standardisation (including hyperlinks to websites) are:

- ISO (International Organization for Standardization): *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/*

10.2 General International and European Stakeholders organisations

10.2.1 ICPSC (International Consumer Product Safety Cocus)

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 are amongst others: Asia (NITE, AQSIQ, KATS), Australia (Australian Competition & Consumer Commission), North America (CPSC and Health Canada), Europe (European Commission, DG SANCO and PROSAFE)

10.2.2 ICPHSO (International Consumer Product Health and Safety Organisation)

The International Consumer Product Health and Safety Organisation was founded in 1993. ICPHSO is an organization 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* /

10.2.3 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/*

10.3 Business representatives

10.3.1 Business Europe

BusinessEurope, the confederation of European Business represent small, medium and large companies. BusinessEurope's members are 39 central industrial and employers' federations from 33 countries, working together to achieve growth and competitiveness in Europe. The hyperlink to the website of BusinessEurope is: *http://www.businesseurope.eu*

10.3.2 Orgalime

Orgalime is the European federation representing the interests at the level of the EU institutions of the European mechanical, electrical, electronic and metal articles industries as a whole. The hyperlink to the website of Orgalime is: http://www.orgalime.org

10.3.3 CECED

CECED represents the European Industry of household appliances, which employs 200.000 people directly. It represents a yearly turnover of about 40 billion Euro. CECED member companies produce the following products:

- large household appliances (including refrigerators &freezes, dishwashers, washing machines, clothes dryers, ranges & ovens, hoods);
- small household appliances (covering a wide range of products from shavers to vacuum cleaners);
- heating, ventilation, and air conditioning equipment, mainly for residential use.

The hyperlink to the website of CECED is: *http://www.ceced.eu/*

10.3.4 CELMA

CELMA is a Federation established for an unlimited period, representing 18 National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires. CELMA members' Associations are representing some 1200 companies in the Luminaires and Electrotechnical Components for Luminaires industries in 12 European countries.

The hyperlink to the website of CECED is: *http://www.celma.org/*

10.4 Distributors representatives

10.4.1 Eurocommerce

Established in 1993, EuroCommerce represents the retail, wholesale and international trade sectors in Europe. Its membership includes commerce federations in 29 countries, European and national associations representing specific commerce sectors and individual companies.

The hyperlink to the website of Eurocommerce is: *http://www.eurocommerce.be/*

10.5 Consumer representatives

10.5.1 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 a international consumer movement to help protect and empower consumers everywhere. The hyperlink to the website of Consumer International is: *http://www.consumersinternational.org/*

10.5.2 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*

10.5.3 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

10.5.4 ANEC

ANEC 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.

10.6 The hyperlink is: http://www.anec.org PROSAFE

Prosafe is the forum were European MarServ Authorities meet and inform each other about up coming risks, developments in the member states in relation with MarServ, exchange best practices and discuss about the future of Market Surveilllance.

The hyperlink to the website of PROSAFE (the Product Safety Enforcement Forum of Europe) is: http://www.prosafe.org/

10.7 EMARS

Emars is a project of Prosafe, funded by the European Commission. One of the aims is to improve MarServ in Europe by gathering and developing best practices in MarServ. 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

10.8 Sectorial Administrative Coorperation 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

11 CROSS-BORDER INFORMATION SYSTEMS

For effective pan-European market surveillance close cooperation between the market surveillance authorities in the member states is a necessity.

11.1 CIRCA

11.2 RAPEX

11.2.1 Safeguard Clause Procedures

All the New approach directives include a 'safeguard procedure'. In many of the Directives this procedure is described in article 7, but in a few directives, for example the Low Voltage Directive, the procedure is under another article.

Counterintuitive for market surveillance officers, this procedure is meant in the first place 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. Only as a second consideration it also allows to maintain the high level of consumer protection the new approach aims for.

The safeguard procedure also plays a role in the information exchange between the authorities about dangerous and non compliant products. Detailed information on the safeguard procedure can be found in the Guide to the implementation of directives based on the New Approach and the Global Approach. Here we will only discuss some aspects directly relevant to market surveillance authorities.

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 5. Both the exact meaning of the notions 'substantial hazard' and 'binding legal effect' are not directly obvious and have therefore been subject of discussion and varying interpretations.

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 an 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 such is the case, proportional measures should be taken and further trade should be stopped. If, however, the charges in the safeguard clause cannot be confirmed and the companies 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.

11.2.2 ICSMS

11.2.3 Information systems under EMARS

12 CROSS BORDERS MARKET SURVEILLANCE PLANS AND THE IMPORTANCE OF JOINT PROJECTS

12.1 Introduction.

Market surveillance programmes have to be effective and based on risks assessments, according to the General Product Safety Directive.

In the current situation, market surveillance programmes are planned and executed in all the member states of the E.U. and connected countries. However, programmes and projects are planned in each member state solely, almost without any proved connection or relation with the programmes in the other member states of the E.U.

Since the market for consumer products is a world market, market surveillance has to have a broader focus then only the 'own' member state. After all, in contrast with food or veterinary products non-food consumer products have no expire date and can be stored for years and years after production. Therefore non-food consumer products can be delivered all over the world and be sold over a long period of time.

It is imaginarily that products which are banned in one country are sold in ore moved to an other country by the producer or importer.

If market surveillance has the aim to protect citizens against unsafe products, MarServ Authorities must cooperate with each other to achieve an effective system of supervision and enforcement.

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5 See: Guide to the implementation of directives based on the new approach.

12.2 Ways to cooperate.

Several forms of cooperation in market surveillance are possible and can be used separate or next to each other at the same time. But remember that methods and structures of cooperation are only successful when participants are pro active and really willing to work together. The motivation of market surveillance officers and their natural behaviour to think cross border are the base for successful and optimal market surveillance system and optimal protection of citizens.

12.2.1 Cooperation in case of incidents (reactive).

Rapex.

When a dangerous and unsafe product is detected on the market, MarServ officers have to inform their colleagues in other countries where this product is sold or might be sold. Members of the EU, or countries connected to it, should use the RAPEX system of the European Commission (see elsewhere in this book).

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 (by letter, e-mail or phone).

The aim of this cooperation is to ban the dangerous or unsafe product from the market as soon as possible.

12.2.2 Cooperation in case of no safety related non conformities (reactive).

ICSMS.

When 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 regulation, action must be taken to have the producer or importer correct the product or the attached user manual or safety descriptions. In those cases, MarSurv authorities should inform each other bilaterally (by letter, e-mail or phone), or use the ICSMS system (see elsewhere in this book).

12.2.3 Cooperation in surveillance programmes (pro active).

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 big diversity of consumer products and the large scale of world wide producers, MarServ Authorities should tune their programmes with each with each other to achieve the right spreading across the range of products and producers to avoid inefficiency and waste of money.

12.2.4 Neighbouring cooperation.

'Neighbouring cooperation' is established by the Baltic Sea Initiative to adjust their import controls and is a good example of neighbouring cooperation in MarServ, as well as the agreement between Malta and the Netherlands to test samples taken by the Maltese Authority are tested in the Netherlands. Same neighbouring programmes exist in Europe, f.i. Latvia and Lithuania, Poland and the Czech Republic, etc.

12.2.5 Joint Action Programmes.

More formal and structural cooperation takes place in the 'Joint Action Programmes', funded by the European Commission (DG Sanco) and coordinated by the Adco's (extension cords, lighters, etc.). Every year each member state has the possibility to take the initiative to propose subjects or products for the Joint Action Programmes.

12.2.6 Prosafe Annual Plan Adjusting Programme.

Prosafe started recently the adjustment of all the annual plans of the member states and connected countries by inventory the annuals plans and discuss the overview in the Prosafe meetings and workshops. Countries should be transparent in the planning stage of their programmes to their colleagues and make contributions to an Annual Plan Adjusting Programme that Prosafe is developing.

12.2.7 Cooperation in development and improvement.

Risk assessment.

As already mentioned, non-food consumer products are world wide goods and most of the time produced, distributed or sold by many different companies. Those companies work very often in different countries at the same time and therefore have contact with several market surveillance authorities. Because of the free market policy at one hand and the professional image of MarServ Authorities at the other hand, interpretation of test results or risk estimations have to be uniform and have to lead to the same outcome. That is why MarServ Authorities should cooperate in developing and use of risk assessment instruments (f.i. the GPSD-model).

When a new potentially risky product is detected or a new potentially risk is found, MarServ Authorities shall consult experts from other countries to check their own opinion and outcomes of their risk assessment process. It is recommended to use the Rapid Advise Forum of Prosafe in those cases.

12.2.8 Exchange of information.

In order to achieve a network of MarServ Authorities it is necessary to know each other and to exchange information. Prosafe is the forum were European MarServ Authorities meet and inform each other about up coming risks, developments in the member states in relation with MarServ, exchange best practices and discuss about the future of Market Surveilllance.

12.2.9 Developing of best practices.

Emars is a project of Prosafe, funded by the European Commission. One of the aims is to improve MarServ in Europe by gathering and developing best practices in MarServ. Most member states participate and make contributions.

12.2.10 World wide networks.

Every year MarServ Authorities from Europe, united in Prosafe, meet colleagues from USA and Canada (ICPSC / ICPHSO). Guided by a common agenda information exchanges and developments in production, products, politics etc. in relation with MarServ are shared.

12.2.11 Exchange of experts.

The ultimate form of cooperation is the exchange of MarServ officers. By sending people to other countries to help and to learn, MarServ 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) stimulate the exchange of experts by coordination and funding.

13 CUSTOMS CO-OPERATION IN CROSS-BORDER PROJECTS

The importance of co-operation between Customs and Market Surveillance authorities in cross-border activities.

This Chapter covers the cooperation between Member States on the check of products from Third Countries to be put in the free movement of goods in the Customs Area.

There is cooperation between Customs Authorities on fiscal activities and prevention of fraud and criminal activities. Within this cooperation there exists a notification system. This cooperation between Customs is outside the scope of this handbook

The cooperation between Member States on the check of products from Third Countries include the following important aspect:

- In many cases consignment on Customs transport (T1) are on transit to another Member States. As consequence the Customs declaration will be not be performed at the entry port, but are performed in this other Member State. Also the cooperation between the Customs and the Market Surveillance Authorities has to be fully available in this other Member State. In case of suspicion in the port of entry, the Member State who will perform the Customs declaration has to be notified. In the case of the water yoyo's, Customs and market surveillance authorities in the port of entry were aware that consignments of these products were on Customs transport (T1) to other Member States or to Third Countries in Europe. Customs and PROSAFE notified the receiving Member States or to Third Countries of the date and place of arrival of these consignments
- In some case these consignments will not enter the (EU) Custom Area and are on transit to another Third Country. The checks of the transit of these consignments is a primarily a task of the Customs and other Authorities when fraud or criminal activities are suspected.
- Exchange of risk profiles and coordination of establishing risk profiles has to be further enhanced.
- Relevant information included in RAPEX, Safeguard notifications and ICSMS has to be transferred to the Customs in two manners. Initially this information has to be transferred to check if no new consignments of similar products that are under RAPEX and/or safeguard notifications, will be declared to be put in the free movement of goods. Secondly categorical information included in the notifications needs to be taken into account when establishing risk profiles

Note Although there are other sectors within the book which talk about Customs, those are different topics. Refer to 3.1.6 – this is related to just the importance of having close links with Customs when building the initial infrastructure and 4.5.9 – this is related to level of practical participation of Customs needed in surveillance programmes and projects.

In the paragraph 4.1.7 a description is given of the cooperation in a Member State between the Customs and Market Surveillance Authorities on the check of products from Third Countries. In paragraph 5.5.9 the risk assessment to establish risk profiles is covered.

Hyperlink:

http://ec.europa.eu/taxation_customs/customs/procedural_aspects/imports/free_circulation/index_en.htm

Annex A - 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.1 Joint action on cigarette lighters – an overview

The action is 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 purposes 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 core 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 s in the financial scheme plus a number of authorit ies outside the financial scheme. It will comprise safety tests of some 150 lighters plus tests of the child-resistance of another 4 lighters. 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 markets 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 c ore group for lighters. Their meetings will be combined with project group meetings.

A.2 Best practice techniques applies in the action

The action is still very early in the implementation stage so the experiences from it are limited. Anyway, a number of best practices have been applied in the design of the project, which will be described below.

Once the action is up and running the participants will be encouraged to use the best practices described in the handbook and report back their experiences. Some of t his could go into the final update of the handbook.

The best practices that have been applied in the design of the action so far are:

- 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. then 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.

- 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 possible also to exchange test results and use them in the follow up in the different Member States.

It has turned out that those two issues meet legal obstacles. Some Member States are obliged to observe a 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.

- 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 core group for lighters.

- 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 European-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 is 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.

Annex B - THE LVD-ADCO Project s (Luminaires and extension cords)

Annex C - Additional Cross-Border Surveillance Projects (e.g. Playground equipment project, Christmas chains)

C.1 Playground Equipment Project

The polish authority OCCP (office of competition and consumer products) operates this project. Project start up meeting was held in Warsaw in October 2007. 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 was presented. This will be followed up by a closer coordination with chapters 4,5,6 and 7 in the book.

C.2 Baltic Sea project.

Electrical household products.

No relations made at this stage

C.3 Hungarian project.

Christmas lighting chains.

No relations made at this stage.

Annex D – 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

Risk management			
	Risk assessment		
		Risk analysis	
			Source[1] identification
			Risk estimation
		Risk evaluation	
	Risk treatment		
		Risk avoidance	
		Risk optimization	
		Risk transfer	
		Risk retention	
	Risk acceptance		
	Risk communication		

[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)

Risk analysis		
	Risk assessment	
		Hazard identification
		Hazard characterisation [2]
		Exposure assessment
		Risk characterisation
	Risk management [3]	
		Risk evaluation
		Emission and exposure control
		Risk monitoring
	Risk communication	
		Interactive exchange of information about risks

[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
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 characterization, exposure assessment, and risk characterization.

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 fort 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, behaviour of person and vulnerability of person.

For chemical substances, exposure is usually expressed as mg per kg body weight that is taken up by inhalation, dermal contact or ingestion; specific parameters include e.g. evaporation or diffusion.

For physical hazards, relevant parameters can be probability that a scenario will occur, energy transferred to a body part, etc.

Risk characterization

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.

References

References in the text are made with a number in brackets, e.g. [3].

The literature below is referenced in the handbook.

1. IPCS Risk Assessment Terminology published under the International Programme on Chemical Safety. Geneva, WHO Library Cataloguing -in-Publication Data, 2004.
2. Risk governance - Towards an integrative approach. Geneva, International Risk Governance Council (IRGC), January 2006.
3. ISO/IEC Guide 51 Safety aspects – Guidelines for their inclusion in standards. Geneva, ISO/IEC, 1999.
4. ISO/IEC Guide 73 Risk management – Vocabulary – Guidelines for use in standards. Geneva, ISO/IEC, 2002.
5. ”Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices”, report prepared for DG SANCO, European Commission by Risk & Policy Analysts Limited, UK, September 2005
6. Kaplan S and Garrick BJ. “On the quantitative definition of risk. Risk analysis”, 1981(1)1, 11-27
7. The RAPEX Guidelines (… 2008)
8. “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”, http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_guid_en.pdf

Annex E - Failure code list

(The codes are in use in Sweden, Finland, Denmark and Norway)

	1	2	3
Technical faults			
Accessible live part in normal use *Zugang zu stromführenden Teilen im Normalgebrauch möglich*			3
Accessible basic insulated parts on class II products *Zugang zu einfach isolierten Teilen bei Schutzklasse II Geräten möglich*		2	
Luminaries and domestic equipment of class 0 *Leuchten und Haushaltgeräte der Schutzklasse 0*	1		
The creepage and clearance distance is less than 10 % of the requirement in relevant standard *Die Kriech- und Luft (Abstands-) strecken betragen weniger als 10 % des in der jeweiligen Norm aufgeführten Wertes*			3
The creepage and clearance distance is more than 10 % and less than 50 % of the requirement in relevant standard / *Die Kriech- und Luft (Abstands-)strecken betragen zwischen 10 und 50 % des in der jeweiligen Norm aufgeführten Wertes*		2	
The creepage and clearance distance is more than 50 % of the requirement in relevant standard *Die Kriech- und Luft (Abstands-)strecken betragen mehr als 50 % des in der jeweiligen Norm aufgeführten Wertes1*	1		
Cord extension set with class 0 plug and class 1 outlet *Verlängerungskabel (Anschlusskabel) mit Schutzklasse 0 Stecker und Schutzklasse 1 Kupplung (Steckvorrichtung)*	1		
Cord extension set with class 1 plug and class 0 outlet *Verlängerungskabel (Anschlusskabel) mit Schutzklasse 1 Stecker und Schutzklasse 0 Kupplung (Steckvorrichtung)*			3
Cord extension set with class 2 plug and class 0 or 1 outlet *Verlängerungskabel (Anschlusskabel) mit Schutzklasse 2 Stecker und Schutzklasse 0 oder 1 Kupplung (Steckvorrichtung)*			3
Class 1 plug mounted on a supply cord without protective earth conductor, changing a class 1 appliance into a class 0 device. / *Schutzklasse 1 Stecker befestigt am Anschlusskabel ohne Erdungsschutz: Änderung von einem Schutzklasse 1 Gerät in Schutzklasse 0*			3
Phase and earth exchanged by mistake in earthed coupling *Phase und Erdung irrtümlich vertauscht bei geerdeter Kupplung*			3
The equipment lacks thermal cut-outs and/or current cut-outs. *Die Thermoschutzsicherung und/oder Überstromschutz fehlt*		2	(3)
The rated current in the equipment is one step too high *Die Nennstromaufnahme im Gerät ist zu hoch*	1		
The rated current in the equipment is more than one step too high *Die Nennstromaufnahme im Gerät ist wesentlich zu hoch*		2	
The rated current in the equipment is so high that it is a fire hazard *Die Nennstromaufnahme im Gerät ist so hoch, dass Brandgefahr besteht*			3
Marking is incomplete or missing *Kennzeichnung ist unvollständig oder fehlt*		2	(3)
CE-mark is missing *CE-Kennzeichnung fehlt*	1	(2)	
Incomplete and wrongful instructions for use and/or mounting which can cause danger *Unvollständige und fehlerhafte Bedienungs- bzw. Montageanleitung, die zu einer Gefahr führen kann*		(2)	3
National language operation instructions with necessary safety information is missing *Die Bedienungsanleitung in der Landessprache mit notwendigen Sicherheitshinweisen fehlt*		2	
The design diverges from standard or technical documentation /*Die Ausführung des Geräts weicht von der einschlägigen Norm oder der technischen Dokumentation ab*		2	(3)

Conductors not adequately attached *Die stromführenden Kabel sind nicht ordnungsgemäß angebracht*		2	(3)
Risk of mechanical damage to conductor *Gefahr der mechanische Zerstörung der stromführenden Kabel möglich*		2	(3)
Equipment with inadequate conductor (cross-section, insulation) *Querschnitt und/oder Isolation der stromführenden Kabel entsprechen nicht den einschlägigen Normen*		2	(3)
Cord anchorage is missing *Zugentlastung fehlt*		2	(3)
Ip-classification does not comply with the requirements *Schutzart (Ip-Klassifizierung) entspricht nicht den Anforderungen der einschlägigen Norm*		2	(3)
The design diverges from standard or technical documentation (great risk for electric chock/fire) *Die Ausführung des Geräts weicht von der einschlägigen Norm oder der technischen Dokumentation ab (großes Risiko eines elektrischen Schlags/Brandgefahr)*		2	(3)
Administrative procedures Verwaltungsverfahren/ **Formale Mängel**			
Declaration of conformity is missing *Konformitätserklärung fehlt*		2	
Errors in declaration of conformity *Fehlerhafte Konformitätserklärung*	1		
Technical documentation missing *Technische Dokumentation fehlt*		2	
Errors in technical documentation *Fehlerhafte technische Dokumentation*	1	(2)	
Modified product sold with the same type no. etc. as product where sales ban is issued. *Modifiziertes Gerät wird mit derselben Typnummer verkauft wie Produkte, die für den Verkauf nicht zugelassen sind.*	1		

Explanation of codes: (a parenthesis indicates that the code could be used in some cases)

1 = Remark

2 = Criticism

3 = Serious criticism

Annex F - Bibliography & List of appropriate literature to consult/review

Chapter Eight of the "Blue Guide"
http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap08.pdf

COMMISSION OF THE EUROPEAN COMMUNITIES Brussels, 7.5.2003 COM(2003) 240 final COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT Enhancing the Implementation of the N ew Approach Directives
http://ec.europa.eu/cgi-bin/eur-lex/udl.pl?REQUEST=Service-Search&COLLECTION=com& SERVICE=all&LANGUAGE=en&GUILANGUAGE=en&DOCID=503PC0240

COMMISSION OF THE EUROPEAN COMMUNITIES Brussels, 14.02.2007 COM(2007) 35 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE The Internal Market for Goods: a cornerstone of Europe's competitiveness
http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0035en01.pdf

DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 December 2001 on general product safety
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002 :011:0004:0017:EN:PDF

Article on market surveillance and standards in health and safety in workplace field
http://hesa.etui-rehs.org/uk/newsletter/files/BTS012EN_35 -37.pdf

ECONOMIC COMMISSION FOR EUROPE COMMITTEE ON TRADE Working Party on Regulatory Cooperation and Standardization Policies Sixteenth session Geneva, 19 -21 June 2006 Item 9 of the provisional agenda MARKET SURVEILLANCE Concepts and definitions Note by the secretariat ECE/TRADE/C/WP.6/2006/11/Add.1
11 April 2006
http://www.unece.org/trade/ctied/wp6/documents/wp6_06/wp6_06_011a1e.pdf

Welmec Guide on market surveillance
http://www.welmec.org/publications/5 -2.pdf

Annex G Useful quotes

G.1 Source 2007 Communication 2007/35

….market surveillance activities are crucial to protect the consumers from unsafe or non-compliant products. The safety of the European market place depends to a great extent on the active and uniform enforcement of Community product safety requirements.

G.2 Source 2003 Communication

New Approach directives provide controls of products (depending on the subject and risk covered) for both pre-market (conformity assessment modules) and post-market (market surveillance). These controls should be considered as part of a spectrum whose common aim is to ensure a high level of safety of products on the market.

The appropriate balance between pre- and post-market controls varies from one sector to another – some items are relatively easy to check and trace once in use or in circulation (industrial machinery), others are not (toys, electrical appliances, etc.). In some sectors, experience shows that an adjustment of the balance may be required. This will need to be addressed in the context of individual revision of relevant directives.

Appropriate enforcement measures, including market surveillance, are essential to ensure that New Approach directives are correctly applied, allowing citizens to benefit from a high level of protection and enterprises to operate on a level playing field throughout the Internal Market.

G.3 GPSD 2001

Article 9
1. In order to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, which entails cooperation between their competent authorities, Member States shall ensure that approaches employing appropriate means and procedures are put in place, which may include in particular:
(a) establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks and the monitoring of surveillance activities, findings and results;
(b) follow-up and updating of scientific and technical knowledge concerning the safety of products;
(c) periodical 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.
2. Member States shall ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are followed up as appropriate. Member States shall actively inform consumers and other interested parties of the procedures established to that end.

G.4 Source Blue Guide

8.1. Principles of market surveillance

- Market surveillance is an essential tool for the e nforcement of New Approach directives.
- The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the Community. Citizens are entitled to an equivalent level of protection throughout the single mar ket, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.
- Member States must nominate or establish authorities to be responsible for mar ket surveillance. These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non -discriminatory way respectin g the principle of proportionality.
- Notified bodies should, basically, be excluded from the responsibility of market surveillance activities. This is to avoid conflicts of interest.

8.2 Market Surveillance Activities

- Market surveillance involves two main stages:
- national surveillance authorities shall monitor that products placed on the market comply with the provisions of the applicable national legislation transposing the New Approach directives;
- subsequently, when necessary, they shall take action to es tablish conformity.

Although market surveillance operations cannot take place during the design and product stages, efficient enforcement usually requires that surveillance authorities act in collaboration with manufacturers and suppliers in order to prevent the placing on the market of non-compliant products.

8.2.1. Monitoring of products placed on the market

- The objective of monitoring products placed on the market is to verify that they comply with applicable directives at the moment when placed on the market and, if relevant, when put into service.
- The EC declaration of conformity and the technical documentation provide the surveillance authority with necessary information about the product.

8.2.2. Corrective actions

- Before any action is taken, the par ty concerned must be notified and — unless the matter is urgent — given the possibility of being consulted.
- The corrective action depends on the level of noncompliance, which has to be established on a case by case basis, and it has to be in accordance wit h the principle of proportionality:
  - § first, the manufacturer, or the authorised representative, should be obliged to make the product comply with the provisions and to remedy the infringement;
  - § ultimately, where other measures have failed or they are not considered as sufficient, all appropriate measures shall be taken to restrict or prohibit the placing on the market and putting into service of the product in question, and to ensure that it is withdrawn from the market.

8.2.3. Complementary activities

- Efficient enforcement of directives usually requires that, in addition to market surveillance operations described in Sections 8.2.1 and 8.2.2, surveillance authorities should:
  - § act in collaboration with manufacturers and suppliers;

- § take appropriate action against the person who has affixed the CE marking to a non-compliant product, and against those who are responsible for the non-compliance of the product; and
- § have the possibility to warn persons who might be at risk, to destroy dangerous products and ban their export, to prohibit the use of such products, and to require the withdrawal of certificates.

8.3. Safeguard clause procedure

- New Approach directives include a form of safeguard clause, which obliges Member States to restrict or forbid the placing on the market and the putting into service of dangerous
  - o or, according to some directives, otherwise non-compliant – products, or to have them withdrawn from the market (156).
- As a general rule, this safeguard clause procedure is restricted to products which are:
  - § covered by New Approach directives;
  - § CE marked; and
  - § ascertained by the Member State to present a substantial hazard, even if the products are correctly constructed, installed and maintained, and used according to their intended purpose.
- This safeguard clause procedure shall be applied to national measures which:
  - § restrict or forbid the placing on the market of a product, or have a product withdrawn from the market;
  - § relate to all products belonging to the same batch or series; and
  - § have binding legal effects.
- The Member State must notify the Commission immediately after taking action that invokes the safeguard clause. The necessary information and evidence to justify the action must accompany the notification.
- If the Commission considers the national action to be justified, it informs the other Member States. They are required to take the necessary measures on their territory.

8.4. Protection of CE marking

- Market surveillance authorities must check that the affixing and use of the CE marking is correct, and that the principles regarding additional markings and marks are respected.
- Where necessary, the authority has to take appropriate corrective action to protect the CE marking.
- A Member State must notify to the Commission and to the other Member States when it decides to restrict free movement due to incorrect affixing of the CE marking, or when it takes action against those who are responsible for a noncompliant product bearing the CE marking.

8.5. Information exchange systems

- A rapid information exchange system has been set up by the Directive on general product safety to handle emergency situations caused by consumer products that present a serious and immediate danger.
- A vigilance system applies for medical devices. This system requires that a national surveillance authority notifies to the Commission and to the other Member States serious performance defects, inadequate marking or instructions that can result in, or have resulted in, the death of patients or users, or a serious deterioration in their health.
- Information on injuries, particularly those resulting from home and leisure accidents, for example, caused by or involving products, is available in the Community injury data-collection and information-exchange system.

8.6. Administrative cooperation

- Administrative cooperation is an obligation of Member States. National surveillance authorities and the Commission must provide mutual assistance to ensure proper and uniform application of New Approach directives.
- Member States need to communicate to the Comm ission and the other Member States a list of surveillance authorities, which they have designated as contact points to coordinate administrative cooperation.
- National surveillance authorities should make information available spontaneously or on request, according to mutually agreed principles and mechanisms.
- National surveillance authorities should consider if coordination of national operations provides a means to increase the efficiency of market surveillance at Community level.
- The information exchanged in the framework of administrative cooperation has to be covered by the requirements of professional secrecy.
- Administrative cooperation regarding the enforcement of New Approach directives is organised in the standing committees established under the dir ectives, and in the horizontal group of Senior Officials for Standardisation and Conformity Assessment Policy.

8.7. Products imported from third countries

- A manufacturer established in a third country is responsible, in the same way as a manufacturer established in a Member State, for designing and manufacturing a product in accordance with all applicable New Approach directives and for carrying out the required conformity assessment procedure, where the product is intended to be placed or put into service on the Community market (183).
- The manufacturer may appoint an authorised representative established in the Community to act on his behalf (184).
- Where the manufacturer is not established in the Community and has no authorised representative in the Commun ity, the importer or person responsible for placing the product on the Community market may become responsible to some extent (185).
- Customs authorities shall, in the case of products imported from third countries, suspend the release of goods:
    - if they find products that display certain characteristics which would give rise to a serious concern as to the existence of a serious and immediate risk to health and safety; or
    - if they find products that are not accompanied by a document or marked in accordance with applicable rules on product safety.
- As regards products covered by New Approach directives, the attention of customs authorities must be drawn, in particular, to the CE marking of toys.
- Customs authorities and market surveillance authorities must keep e ach other informed, and take appropriate action based on the information received.

Annex H – FAQs: Frequently Asked Questions on Market Surveillance

1. What is Market Surveillance?

The term market surveillance relates to all the activities directed to products on the market, by a government entity, to ensure that such products:

- fulfill the legal requirements applicable to them;
- are marked and tested as prescribed;
- are accompanied by the required technical documentation.

The objectives of market surveillance include:

- ensuring that products on the market comply with the health and safety requirements that are prescribed in legislation;
- checking that the affixing and use of the CE marking is correct, and the principles regarding additional markings and marks are respected;
- countering unfair competition by ensuring that a manufacturer/ distributor/ importer/ retailer has complied with the requirements as stipulated in the legislation.

The purpose of Market Surveillance is to ensure that the provisions of applicable directives are complied with across the EU Community. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Furthermore, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

2. Does Market Surveillance cover counter fighting of products?

Market surveillance serves two purposes:

- It ensures that only safe products are placed on the market.
- It ensures an open and fair competition between producers.

The means for ensuring this are sampling of products, testing of compliance to safety requirements and checking of compliance to formal (and other) requirements.

Counterfeiting is a violation of a producer's intellectual property rights.

Depending upon the construction of the counterfeited product this may or may not imply that unsafe products are placed on the market. Often the counterfeited products have so poor quality that they are dangerous in which case the market surveillance authority should be involved. But it is not impossible that the counterfeited products have the same (or 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. Instead they will have to check the product's compliance to the formal procedures. If this is also OK, then the market surveillance authorities have no legal powers to take measures against the product.

Therefore, counterfeiting in itself is not an issue for market surveillance. In most Member States the issue is handled by units within the Customs authorities.

3. Who is responsible for Market Surveillance?

Market Surveillance is the responsibility of public authorities. This is, in particular, to guarantee the impartiality of market surveillance operations. Each Member State can decide upon the market surveillance infrastructure, as long as surveillance is efficient and covers the whole territory. These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel and act in an independent and non-discriminatory way respecting the principle of proportionality.

4. What does market surveillance involve?

Market surveillance involves:

- monitoring of products placed on the market so as to ensure that they comply with the provisions of the applicable national legislation transposing the New Approach directives
- checking the safety characteristics of products
- requiring all necessary information from parties involved like the technical documentation of the product
- acting in collaboration with manufacturers and suppliers
- responding to consumer complaints concerning the safety of products
- prohibiting temporarily the supply of a product if there are clear and consistent indications of its danger, and if time is needed for performing special tests
- taking appropriate action against the person who has affixed the CE marking to a non-compliant product and against those who are responsible for the non-compliance of the product
- warning persons who might be at risk, to destroy dangerous products and ban their export, to prohibit the use of such products and to require the withdrawal of products from the market.

5. What happens when a product on the market is found not to comply with the applicable directive?

Before any action is taken, the party concerned must be notified and - unless the matter is urgent- given the possibility of being consulted. The corrective action depends on the level of non-compliance, which has to be established on a case by case basis, and it has to be in accordance with the principle of proportionality:

- First the manufacturer, or the authorised representative, should be obliged to make the product comply with the provisions and to remedy the infringement.
- Ultimately, where other measures have failed or they are not considered as s ufficient, all appropriate measures shall be taken to restrict or prohibit the placing on the market and putting into service of the product in question, and to ensure that it is withdrawn from the market.

6. 5. Are manufacturers established in a third country obliged to follow the conformity assessment procedure?

A manufacturer established in a third country is responsible in the same way as a manufacturer established in a Member State, for designing and manufacturing a product in accordance with all applicable New Approach directives and for carrying out the required conformity assessment procedure, where the product is intended to be placed or put into service on the Community market. The manufacturer may appoint an authorised representative established in the Community to act on his behalf.

7. What does CE Marking mean?

The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer which are set out in the so called 'New Approach' Directives. The letters CE are an abbreviation of a French phrase "Conformite Européenne".

Without the CE marking, and thus without complying with the provisions of the directives, the product may not be placed on the market. Conversely, Member States are not allowed to restrict the placing on the market and putting into service of CE marked products, unless such measures can be justified on the basis of evidence of the non-compliance of the product.

8. Which products are to be CE marked?

Before a product is CE marked, the essential requirements of the applicable European Directive must be met. The CE marking applies to all products within the scope of directives providing for its affixing and which are intended for the community Market (e.g.: low voltage equipment, simple pressure vessels, toys, machinery, personal protective equipment, medical devices, recreational craft, refrigeration appliances etc,). The CE marking does not apply to cosmetics, chemicals, pharmaceuticals, and foodstuffs.

Directives may also exclude the applications of the CE marking on certain products even if the directive otherwise applies to the product. As a general rule, such products are subject to free circulation if:

- They are accompanied by a declaration of conformity (e.g. safety components referr ed to in the Directive on Machinery).
- They are accompanied by a declaration of compliance (e.g. products which play a minor part with respect to health and safety as listed in accordance with the Directive on Construction Products).
- A statement (e.g. custom-made medical devices as referred in the Directives on Active implantable medical devices) accompanies them.
- The product bears the manufacturer's name and indication of maximum capacity (e.g. instruments not subject to conformity assessment according t o the Directive relating to non-automatic weighing instruments).

- The product is manufactured in accordance with sound engineering practice (as in the case for certain vessels referred to in the Directive relating to simple pressure vessels and pressure equipment).

9. How is the CE marking acquired?

The manufacturer is responsible to check whether his product falls under the scope of any European Union legislation. If it falls under the scope of a New Approach directive, the CE marking is obligatory. Before affixing the CE marking, the manufacturer must:

- Determine if his product applies to any directive.
- Determine the essential requirements for design and manufacturing of the product.
- Choose the conformity assessment procedure indicated in the directives as applicable to the product
- Select the applicable product standards and test methods for the product.
- Prepare a declaration of conformity that indicates a list of the directives and standards, which the product conforms to, the product identification, and the manufacturer's name and details.

After these obligations are fulfilled, the CE marking is to be affixed to the product.

10. Who is entitled to affix the CE Marking?

The manufacturer, whether established inside or outside the Community is the person ultimately responsible for the conformity of the provisions of the directive and for the affixing of the CE marking. The manufacturer may appoint an authorised representative established in the Community to act on his behalf.

The CE marking may not in principle be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provision of the relevant directives. The CE mark must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents where the directive concerned provides for such documents.

If a notified body is involved in the design phase, the production phase or putting into service of the product (depending on the conformity assessment procedure applied), the CE marking shall be followed by the identification number of the notified body.

Sometimes several notified bodies are involved in the production phase, which is possible where more than one directive is possible. In these situations several identification numbers must follow the CE marking.

11. What if I don't bother with CE marking, who's going to stop me?

If you're a manufacturer from outside the EU, your product will probably not even get onto the market. Customs officials have a keen eye for products, which do not conform to the directives. Penalties for non-compliant products range from warnings and fines to a full market withdrawal. Ending up in court, being sued for damages caused by your defective product, is not something you wish for. But the most severe inspector of the conformity of your products is your customer. The bigger the customer, the more they know about current legislation. And losing a big customer and/or reputation is not a good business practice.

The obligation to affix the CE Marking extends to all products within the scope of the directive providing for its affixing and which are intended for the Community market. When products are subject to several directives which all provide for the affixing of the CE Marking, the

marking indicates that products are presumed to conform to the provisions of all these Directives.

12. What is a notified body?

Notified bodies are organisations, such as test laboratories, which provide information and the required conformity assessment services according to the product directives. They are free to offer their services to any economic operator established either inside or outside the Community. Notified Bodies employ the necessary personnel which has sufficient and relevant knowledge and experience to carry out conformity assessment in accordance with the directive in question. Notified bodies shall make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment. The European Commission publishes lists of notified bodies in the Official Journal of the European Community. Accreditation?

13. What is the difference between European standards and harmonised standards?

European standards are all standards, which are prepared and approved in conformity with the procedures of one of the European standards organizations (CEN, CENELEC and ETSI). Harmonised standards are only those European standards, which are directly related to New Approach directives and to GPSD. Their contents must match the essential requirements of the relevant directive. Harmonised standards are prepared following a mandate (formal request) by the European Commission. The application of harmonised standards provides a "presumption of conformity" with the corresponding essential requirements of the relevant directives. A standard is harmonized when published in the commissions Official Journal.

14. Why should harmonised standards be used if they are only voluntary?

Harmonised standards are technical specifications and their application is voluntary - under all circumstances. Under the New and the Global Approach, the application of harmonised standards provides a "presumption of conformity" with the corresponding essential requirements of the relevant directives, including GPSD. Consequently, their use may drastically simplify and speed up the procedure for conformity assessment. A manufacturer, whose product is in compliance with the relevant harmonised standards is not obliged to have his product type tested for conformity with the essential requirements of the related directive by a third party. He may issue his conformity declaration, affix the CE marking and market the product without any external intervention. Harmonised Standards are also the basic tool that will be used be MS authorities to verify the safety of a given product against the requirements of a given Directive as they define an adequate safety level.

15. CEN, CENELEC and ETSI

CEN is the European Committee for Standardization.
CENELEC is the European Committee for Electrotechnical Standardization.
ETSI is the European Telecommunications Standards Institute.

CENELEC, CEN and ETSI are the three European standardization bodies recognized as competent in the area of voluntary technical standardization. Together they prepare European Standards in specific sectors of activity and the three make up the 'European standardization system'.

Most standards are prepared at the request of industry. The European Commission can also request the standards bodies to prepare standards in order to implement European legislation. This standardization is 'mandated' by the Commission, through the Standing Committee of the Directive, in support of the legislation. If these standards are prepared within the framework of the "New Approach" directives, they are known as "harmonized standards".