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

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prepared for

DG SANCO, European Commission

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EXECUTIVE SUMMARY

1. Background to the Study

The revised General Product Safety Directive (GPSD)[1] is aimed at ensuring that consumer products placed on the EU market are safe. It provides a generic definition of a 'safe' product and obliges producers to place only safe products on the market. Producers must take measures to be informed of the risks posed by their products and take appropriate measures to prevent the risks; consumers must also be informed of the risks associated with these products. The GPSD also obliges Member States to take the necessary measures to enforce its requirements on producers and distributors, to survey products on the market, and to inform the Commission about actions taken through either a safeguard clause procedure or the rapid information system for serious and immediate risks (RAPEX).

To promote the effective and consistent assessment of the risks posed by consumer products covered by the GPSD, the Commission contracted Risk & Policy Analysts (RPA) to establish a comparative inventory and assessment of current approaches, methods and practices used by surveillance and enforcement authorities, and conformity assessment bodies, in the Member States and in the European Economic Area (EEA) to assess the risks posed by certain categories of non-food consumer products. This should identify best practices and needs for further development or normalisation of risk assessment methods.

2. Approach to Study

A project start-up meeting was held with the Commission in December 2004 to clarify the study's aims and objectives and agree on an approach to the study.

Following this meeting, an initial literature review was carried out to identify the relevant regulatory and conformity assessment bodies for each country, amongst other things. Consultation was then undertaken to obtain detailed information from relevant stakeholders in each country on the approaches, methods and practices used for assessing the risks posed by the selected product groups.

The study was presented at the GPSD Committee Meeting held in Brussels in February 2005 and simple questionnaires were circulated to Member State Competent Authorities prior to and during the presentation. Responses were received from organisations in 25 out of the 28 EEA Member States. At the next GPSD Committee Meeting, held in Brussels in June 2005, a second questionnaire was circulated to the Competent Authorities requesting their contribution in selecting and providing information on specific products to be examined as case studies.

[1] Directive 2001/95/EC of the European Parliament and of the Council on General Product Safety, Brussels, Belgium, 3 December 2003.

Based on the feedback received (from organisations in 11 Member States), case studies were selected to test three of the formal risk assessment methodologies identified. The purpose of this testing was to illustrate the differences in the results derived from the use of different methods and to explore the reasons for such differences. The selected methods were:

- the **RAPEX methodology**, given its importance in the RAPEX system and its widespread use;
- the **Slovenian Nomograph**, which appears to be the most comprehensive of the other formal methodologies; and
- the **Belgian Risk Matrix**, which although still under development, offers some interesting features.

The study identifies and describes best practices in light of the findings of the comparative assessment and case studies. It also identifies areas where there is a need for further development of risk assessment methods. Based on the conclusions drawn, recommendations are made on how the study findings can inform the future development of the regulatory framework, and encourage the effective and consistent assessment of risks posed by consumer products covered by the GPSD.

3 Approach to Product Safety Across the EU and EEA Countries

The Main Report provides a detailed overview of the approach to identifying hazardous products and the risk assessment methods adopted by each EU and EEA country in determining the appropriate regulatory action to be taken. A distinction has been made between:

- a *formal risk assessment*: which often involves the use of a table or matrix and usually provides a quantified assessment of the risk; and
- an *informal risk assessment*: which is often less formalised and/or documented and provides an indicative or comparative assessment of the risk.

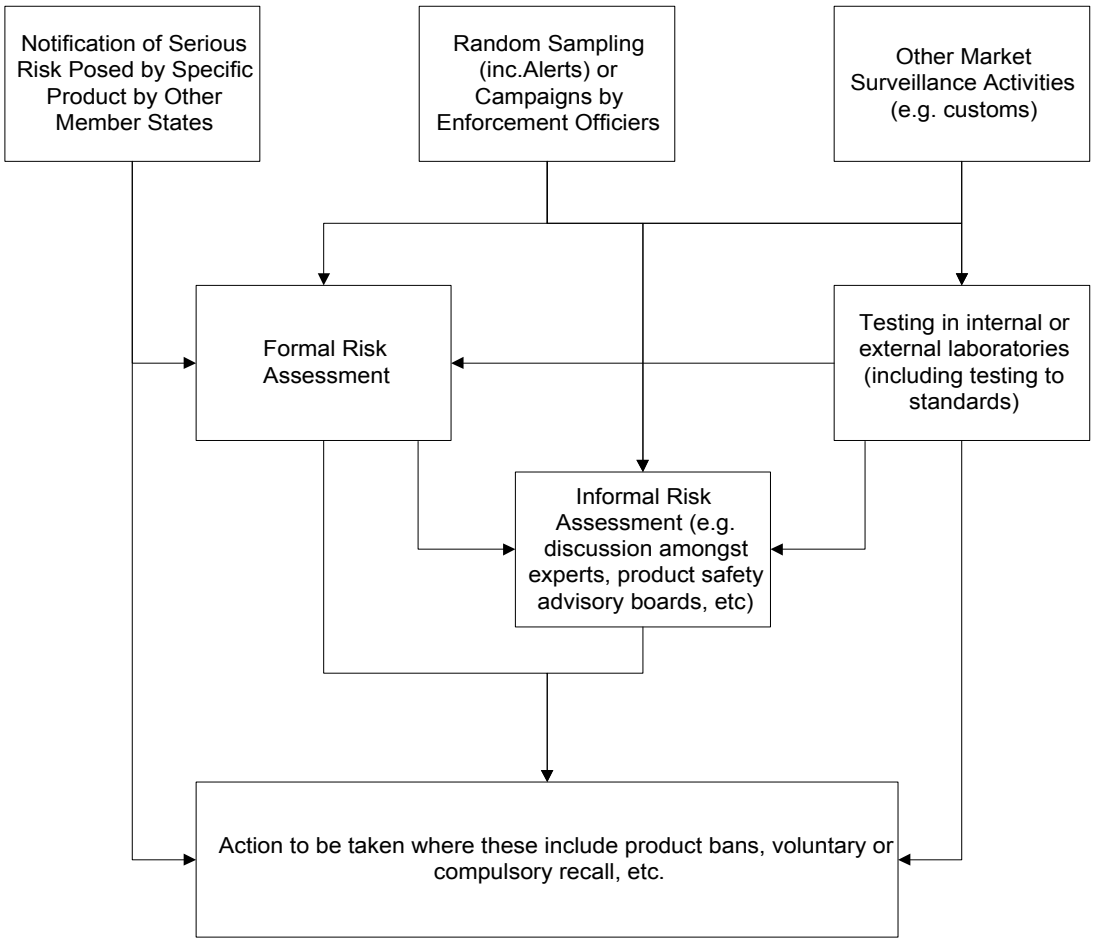
Table 1 below provides a summary of these formal and informal risk assessment methodologies. Figure 1 (opposite) highlights the role, position and relationship between formal risk assessment methodologies, informal approaches and product (or conformity assessment) testing. Consultation with Member States indicates that one or more of the routes described in the flow chart is used by all Member States to arrive at the appropriate action to be taken to ensure product safety.

Table 1: Overview of Approaches with Focus on Risk Assessment Methodologies

Country	**Outline of Risk Assessment Methodologies Employed**
Formal Risk Assessment Methodologies Used	
All EU-25	RAPEX
Belgium	Risk matrix at experimental stage
Czech Republic	National methodology in use
Denmark, Finland, Sweden, Norway	Nordic failure code list
Germany	National methodology may be in use
Slovenia	Risk assessment nomograph
United Kingdom	LACORS methodology for premises Risk assessment nomograph

Table 1: Overview of Approaches with Focus on Risk Assessment Methodologies	
Country	**Outline of Risk Assessment Methodologies Employed**
Expert Panel	
Austria	Product Safety Board and external experts
Denmark	Committee of market surveillance
Finland	Expert opinion
France	Consumer Safety Commission
Ireland	Product safety group
Italy	Conference of Services
Poland	Expert panel
Spain	Commission of Co-ordination
Other	
Austria	Testing laboratories
Belgium	Ranking method for specific campaigns
Greece	Reliance on test reports
Luxembourg	Reliance on product notifications by other Member States
Malta	Reliance on risk assessments by other Member States
Slovakia	Informal procedures
Norway	Reliance on manufacturers' obligations

Figure 1: Description of Overall Approach to Ensuring Product Safety in the EU



Differences and Divergences in Overall Approach to Ensuring Product Safety

Across the EU, there are key differences and divergences in the approaches, methods and actual practices used by surveillance and enforcement authorities, as well as conformity assessment bodies. Indeed, the role of risk assessment in the overall context of ensuring consumer safety in the EU varies from Member State to Member State.

The main differences in the overall process of ensuring consumer safety arise from:

- **The presence or absence of a legislative framework for the product(s) involved**. For products subject to sector-specific legislation, testing to ensure compliance with specified standards is the first step in ensuring product safety. Where a product is deemed to fail a specific test, action is generally required without need for a (formal) risk assessment; although in some cases, further discussion amongst experts or product safety committees (i.e. an informal risk assessment) may be used. The Nordic Failure Code for electrical products illustrates a more sophisticated approach to the use of test results.

  Where EU-wide legislation or harmonised standards are in place, these potentially provide a common basis for evaluating the risks associated with a product across the EU (although there are still difficulties and differences). Where legislation or standards are adopted at the national level, there is clearly potential for different approaches amongst Member States. This is even more the case where there are no relevant regulations or standards, as there will be no common basis against which producers and distributors can assess the safety of a product. In such cases, judgements on safety tend to be either subjective or based on risk assessment criteria read across from other related sectors or products. It is worth noting that three of the products most commonly notified through the RAPEX system are covered by vertical legislation: electrical products (LVD), toys and cosmetics.

- **Variations in organisational structure and method of enforcement in Member States**. The organisational structure in Member States also influences the approach and practice of risk assessment. In some countries, different authorities are responsible for assessing the safety of different products. In this case, it is likely that they will have an in-depth knowledge of potential risks and regulatory requirements associated with particular products and may have sufficient expertise to make use of informal approaches to risk assessment. In other Member States, the same authority is responsible for ensuring the safety of a wide range of products. It may be impossible for such authorities to understand the risks and regulatory frameworks for all products in depth; there may thus be a greater need for formal risk assessment approaches. On the other hand, such authorities may have a better grasp of overall product safety assessment from dealing with a wider variety of products. Some countries also have a cross-sectoral system of product safety surveillance where there may be two or three authorities responsible for the safety of one product, albeit covering different safety aspects.

- **Other factors**. These include the costs of undertaking product testing and the level of understanding and awareness of risk assessment. Product tests generally incur significant costs for enforcement and surveillance authorities, who often have limited funds. The result is that some Member States do not undertake significant product testing or risk assessment but rely mainly on enforcing notifications by other Member State (e.g. Luxembourg). Other Member States have the resources to focus on only a limited number of products at any particular time (e.g. Belgium). Similarly, some authorities have considerable expertise in risk assessment and have the ability to develop and apply reasonably sophisticated approaches. Others rely on approaches developed elsewhere and require a significant level of guidance to apply risk assessment methodologies effectively.

4. Conclusions and Recommendations

There is a general requirement under the GPSD for products placed on the EU/EEA market to be safe. However, there will always be associated hazards and/or risks to consumers, the extent of which will depend not only on the safety of the product itself but also upon the nature and behaviour of the consumer. Assessing the risks to consumers involves identifying the hazards, assessing the potential consequences and the probability that such consequences could arise.

There is a clear trade-off in the application of risk assessment methods between the consistency and level of detail of the outcome and the time and resources (particularly human and financial) required. Apparently simple methodologies may contain implicit weightings that may not be appropriate for every product being assessed. Judgement may be intuitive, based on implicit assumptions, especially in relation to the boundaries between categories. Taken together, these factors can result in a high degree of subjectivity in risk assessment, although this can be reduced by the extent of guidance provided to assist users to apply the various scales and ratings. In general, the greater the extent of subjectivity, the higher will be the potential for inconsistency in results.

The potential consequences of inconsistency in application of risk assessment methodologies are considerable. If the risk posed by a product is assessed to be higher than is actually the case, there may be significant economic consequences, in terms of lost sales for producers and distributors and lost access to products for consumers. There may also be impacts on enforcement authorities, if producers and distributors challenge the findings of the risk assessment in court. On the other hand, if the risks are assessed to be lower than they actually are, there could be impacts on consumer safety in the form of continuing injuries or even fatalities.

Having examined the various risk assessment methodologies (and possible revisions to them), it is evident that the selection of a 'best practice' methodology depends on the attitude of the product safety regulator to risk. Three different perspectives (which reflect the practice of consumer safety in EU Member States) have been considered and the following conclusions can be reached:

- the **RAPEX methodology** represents best practice under a 'risk averse' approach. In other words, in those Member States where the possible occurrence of (sometimes very) minor injuries, particularly amongst vulnerable people, would not be consistent with national/general approach towards risks, then the RAPEX methodology is the preferred approach. The development of the methodology could focus on greater differentiation between different risks to such groups;

- the **Risk Matrix** represents best practice where the inherent safety of the product is of prime concern. In other words, by taking no account of the consumer's behaviour and response (e.g. to hazard warnings and hazard recognition) and by focusing on the product rather than the consumer, the risk matrix provides for a 'worst case' approach; and

- the **Nomograph** represents best practice under the 'acceptable risk to the average consumer' approach. In other words, the actual risks of a product to (what is considered to be) the average (or typical) consumer would be somewhat lowered by the (perceived) effectiveness of warning labels and/or the degree of hazard recognition by the consumer.

Each of the methodologies has strengths and weaknesses, as well as implicit bias, which significantly affect the results obtained and the level of convergence possible. However, even a 'perfect' risk assessment methodology can neither be expected to assess all risks across all consumer products effectively (as methodologies often contain implicit weightings that may not be appropriate for every product being assessed) nor completely eliminate divergences (such as those due to differences in risk perceptions in the different Member States).

Potential areas for further development of risk assessment methodologies depend on the objectives of the Member States. For those wishing to pursue risk-based decision-making, there would be merit in further development of each of the three formal methodologies outlined above. While the adjustments to the methodologies would be expected to improve their results, the case studies also highlight areas where formal methodologies are inappropriate for ensuring the safety of products, these include:

- *assessing cumulative risks*: none of the methodologies provides an explicit basis for assessing cumulative risks. Instead, each hazard is assessed separately – it is possible that a number of low level hazards could, when combined, result in a relatively high risk;

- *interpreting accident data*: a key aspect of ensuring product safety and risk assessment is the 'number of incidents' or 'probability of occurrence'. But there are certain cases where the risk associated with the product does not change, but an increase in the population at risk (i.e. number of users) results in an increased number of accidents (i.e. increase in societal risk). Behavioural factors may also be a predominant risk factor; and

- *hazard identification*: the case studies showed that, in the absence of standards, risk assessment methodologies are not adept at identifying hazards.

It is thus equally important for regulators and authorities involved in risk assessment to accurately interpret the results derived using any particular methodology in the context of these limitations, as well as taking into consideration, their strengths, weaknesses and bias[2] (or implicit weightings).

For countries which rely on informal approaches to risk assessment, the use of standards, test reports and other technical documentation relating to the product reflect the 'acceptable risk to individual consumer' (or realistic 'worst case') approach. However, this approach encounters problems where there is no regulatory guidance (in the form of standards or legislation). These documents also tend to describe the product's characteristics and not the way products are used (or misused). Overall, the case studies show that standards make identification of risks, and enforcement of product safety, easier. While outside the remit of this study, the development of standards for more consumer products would be useful in ensuring the safety of products.

Compared with standards, **expert panels** may reflect a more rounded risk assessment, which takes into account behavioural attributes and may be of relevance in checking the robustness of risk assessment results. The case studies show that formal risk assessment methodologies (particularly the semi-quantitative ones) may give a false impression of accuracy/objectivity, which can be misleading. In the context of this study, best practice would involve ensuring that risk assessment results are discussed and agreed by an expert panel (minimum of two people). Where such expertise does not exist within an authority, it is recommended that outputs from risk assessment methodologies should clearly indicate that the risk assessment results have not been checked by an expert panel. This would be of benefit to other authorities wishing to use the results.

[2] As discussed earlier, the RAPEX methodology effectively treats any hazards to vulnerable consumers as being unacceptable; by contrast, the nomograph takes into account the fact that the consumer recognises the hazard prior to using the product whilst the risk matrix focuses on the risks relating to the product.

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1. INTRODUCTION

1.1 Background to the Study

The revised General Product Safety Directive (GPSD)[1] is aimed at ensuring that consumer products placed on the EU market are safe. The objectives of the Directive are to protect consumer health and safety, whilst ensuring the proper functioning of the internal market. The GPSD is intended to ensure a high level of product safety throughout the EU for consumer products not covered by sector-specific legislation. It also completes and complements the provisions of sector-specific legislation in terms of risks, producer obligations and the powers and tasks of authorities where the applicable legislation covers only certain aspects of product safety or categories of risk for the product concerned.

The GPSD applies to products intended for or likely to be used by consumers; it covers new, used and reconditioned products intended for consumers, or likely to be used by consumers, supplied in the course of commercial activity. It provides a generic definition of a 'safe' product and obliges producers to place only safe products on the market. Producers must take measures to be informed of the risks posed by their products and take appropriate measures to prevent the risks; consumers must also be informed of the risks associated with the products they supply. They must also be able to trace dangerous products. Under the GPSD, if a manufacturer identifies a safety risk in a product already on the market, he will need to inform its distributors and also immediately inform the relevant authority, both of the risks and the actions taken to protect consumers.

The GPSD obliges Member States to take the necessary measures to enforce its requirements on producers and distributors, to survey products on the market, and to inform the Commission about actions taken through either a safeguard clause procedure or the information system for serious and immediate risks (RAPEX). In particular, Member States must appoint the authorities in charge of market surveillance and enforcement. Article 10 of the GPSD provides for the establishment of a European network of surveillance and enforcement authorities that should, among other activities, facilitate the exchange of information on risk assessment, expertise and good practice on surveillance and enforcement. The Commission is requested to promote and take part in the operation of the network.

To promote the effective and consistent assessment of the risks posed by consumer products covered by the GPSD, the Commission has contracted Risk & Policy Analysts (RPA) to establish a comparative inventory and assessment of current approaches, methods and practices used by surveillance and enforcement authorities, and conformity assessment bodies, in the Member States and in the European Economic Area (EEA) to assess the risks posed by certain categories of non-food consumer products. This should identify best practices and needs for further development or normalisation of risk assessment methods.

[1] Directive 2001/95/EC of the European Parliament and of the Council on General Product Safety, Brussels, Belgium, 3 December 2003.

1.2 Objectives of the Study and Selected Product Groups

The objectives of the study are to:

- outline approaches, methods and practices used to assess the risks for consumer health and safety posed by the selected products (listed in Table 1.1 below);
- make a comparative assessment of the approaches, methods and practices;
- highlight cases where the methods currently used may lead to divergent risk assessment conclusions;
- identify and describe best practices; and
- identify needs for further development of risk assessment methods, where necessary.

The focus of the study is on six product groups, listed in Table 1.1.

Table 1.1: Product Groups Covered

Product Group	**Specific Products**
Childcare articles	Cots, high chairs, push chairs
Playground equipment	Climbing frames, swings, slides
Household products	Furniture, ladders, electrical appliances, gardening equipment
Sports equipment	Exercise machines, protective equipment, buoyancy and mobility aids
Toys	Dolls, ride-ons, battery powered toys, educational equipment
Clothing	Nightwear, children's clothing

A number of these product groups, particularly toys and electrical appliances (included within household products), are also the subject of sector-specific legislation. The relationship between the GPSD and this sector-specific legislation has been reviewed by the Commission and guidance has been given on how the two types of legislation interrelate (DG SANCO, 2003).

1.3 Approach to the Study

A project start-up meeting was held with the Commission in December 2004 to clarify the study's aims and objectives and agree on an approach to the study.

Following this meeting, an initial literature review was carried out to identify:

- the relevant regulatory and conformity assessment bodies for each country (contact details for Member State Competent Authorities were provided by the Commission);
- the relevant European and national legislation standards for each product group;
- current and most pressing issues (for each of the selected product groups) for regulatory authorities and conformity assessment bodies; and
- the most common types of accidents resulting from the selected product groups.

The information gathered from this literature review has informed, in particular, the assessment of specific products as case studies in Section 6.

Following the literature review, consultation was undertaken to obtain detailed information from relevant stakeholders in each country on the approaches, methods and practices used for assessing the risks posed by the selected product groups.

As a first step in the consultation process, the study was presented at the GPSD Committee Meeting held in Brussels in February 2005. Simple questionnaires were circulated to Member State Competent Authorities prior to and during the presentation; these were followed up by email and telephone contact, together with face-to-face meetings as appropriate (the questionnaire asked Competent Authorities to indicate the way in which they would prefer to be contacted). Responses to consultation have been received from organisations in 25 out of the 28 EEA Member States.

Based on the responses to the initial questionnaire and our literature review, we then followed up with specific and detailed questions aimed at gathering information on the:

- approaches in place for assessing the risks for consumers from the selected product groups and the regulatory framework in which these measures are applied;
- methods and practices used in risk assessments within the regulatory framework; and
- advantages and drawbacks of using the different approaches in practice.

At the next GPSD Committee Meeting, held in Brussels in June 2005, another questionnaire was circulated among the Competent Authorities requesting their contribution in selecting and providing information on specific products to be examined as case studies. The aim of the case studies is to demonstrate the implications of differences in risk assessment approaches, methods and practices for specific products. By describing specific products, and the particular assessment(s) undertaken, it is possible to provide a better picture of the significance of differences in risk assessment methodologies and to highlight cases where the methods currently used may lead to divergent risk assessment conclusions. It also enables account to be taken of the actual results achieved by different practices, which can otherwise be difficult to determine. Based on the feedback received (from organisations in 11 Member States), two case studies each have been selected for childcare articles, playground equipment and household products and one case study each for toys, sports equipment and clothing.

Consultation with conformity assessment bodies proved to be more complex because of the difficulties they face (in terms of resources and time) in providing the information required for this study. We sought the co-operation of the regulatory authorities in the relevant countries in contacting the conformity assessment bodies in their countries and informing them of the importance and need to provide information for this study. This had limited success; we therefore attempted to contact conformity assessment bodies directly. Questionnaires sent directly to conformity assessment bodies yielded minimal responses. One possible explanation for this is that some conformity assessment bodies are set up to address specific products and/or legislation; the broad scope of the study may thus not have encouraged them to reply. We tried to obtain more detailed information on the activities of conformity assessment bodies in the context of the case studies (for example, conformity assessment bodies dealing with toys were asked specifically about toys); however, only a marginally improved response rate was obtained.

The data obtained from consultation has been used to:

- provide a detailed overview of the approaches, methods and practices for risk assessment in various countries (Section 2);
- highlight areas where there are differences in risk assessment approaches, methods and practices (Section 5); and
- develop the case studies for the selected product groups (Section 6).

We have identified and described best practices in light of the findings of the comparative assessment (and case studies); these practices enable a high degree of consistency in their application that can provide a good level of consumer protection but are also cost-effective in terms of the time and resources required for their application.

Based on the above analysis, we have identified areas where there is a need for further development of risk assessment methods. These include areas where the existing methods are not sufficient or effective or important differences exist between the methods used. Based on the conclusions we have drawn, we have developed a series of recommendations on how the study findings can inform the future development of the regulatory framework, and encourage the effective and consistent assessment of risks posed by consumer products covered by the GPSD.

1.4 Organisation of the Report

The remainder of this Report has been organised as follows:

- Section 2 sets out the **methods, approaches and practices** adopted by the EU-25 and EEA Member States for assessing the risks posed by consumer products;
- Section 3 describes the **formal risk assessment methodologies** identified during this study;
- Section 4 describes the **informal risk assessment methodologies**;
- Section 5 provides a **comparative analysis of the risk assessment methodologies, approaches and practices** adopted across the EU-25 and EEA Member States;
- Section 6 assesses the implications of using different risk assessment methodologies in assessing the risks of specific products and, thus, the need for further development of risk assessment methods using a **case study approach**;
- Section 7 identifies **best practice** in the context of ensuring product safety and the case for further development of risk assessment methods;
- Section 8 sets out the **conclusions and recommendations** of the study; and
- Section 9 provides the list of **references**.

2. METHODS, APPROACHES AND PRACTICES FOR ASSESSING THE RISKS POSED BY CONSUMER PRODUCTS IN MEMBER STATES

2.1 Risk Assessment in the Context of Ensuring Product Safety

2.1.1 Introduction

From a regulatory viewpoint, the process of ensuring the safety of consumer products can be divided into three main steps:

- identifying potentially hazardous products and judging whether they are unsafe;
- assessing the risks posed by those products (i.e. risk assessment); and
- deciding on appropriate action.

2.1.2 Identifying Potentially Hazardous Products and Risk Assessment

In broad terms, the safety of products is determined by:

- the potential for products to be the cause of adverse effects amongst consumers; and
- the probability and severity of adverse effects occurring amongst consumers using such products.

These represent respectively the hazard and the risk associated with products and the procedure by which these issues are examined is a risk assessment. In a comprehensive report on these issues, DG SANCO (European Commission, 2000) has adopted the following definitions:

- ***Hazard*** – the potential of a risk source to cause an adverse effect(s)/event(s);
- ***Risk*** – the probability and severity of an adverse effect/event occurring to man or the environment following exposure, under defined conditions, to a risk source(s); and
- ***Risk Assessment*** – a process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s).

Clearly, such definitions are generic in nature and need to be adapted to the issues under consideration. For example, this study is not concerned with the potential impacts on the environment of products. More specifically, a distinction has been made in this study between:

- a *formal risk assessment*: which often involves the use of a table or matrix and would usually provide a quantified assessment of the risk; and
- an *informal risk assessment*: which is often less formalised and/or documented and provides an indicative or comparative assessment of the risk.

Risk assessment is an important part of the overall process of enforcement in the GPSD. When regulatory authorities become aware of potentially hazardous products (through market surveillance, accident reports and data, or through reporting by consumers, manufacturers or others), risk assessment enables them to focus their enforcement actions on the products posing the greatest risks. This not only benefits consumer safety by addressing the high risk products, it also means that the often limited resources available to regulatory authorities can be used in the most effective way. By identifying the nature and scale of the potential impact on consumers, risk assessment can also assist regulatory authorities to determine what type of action is needed[2]. In this way, unnecessary cost to producers and inconvenience to consumers can be minimised.

2.1.3 Appropriate Action

Where a risk assessment highlights a significant risk, regulatory authorities can take a number of actions (depending on the risk rating) ranging from discussions with the manufacturer or supplier, dissemination of warnings or precautions for use, product recalls with a view to replacement or alterations to implementing regulatory measures prohibiting the manufacture and supply of the offending products, and/or seizure and destruction of the offending products.

In practice, the approach to ensuring product safety does not rigidly follow the three steps as set out above; the approach to and method of identifying potentially hazardous products (i.e. market surveillance) varies greatly across Member States with resource availability being a major influencing factor. Also, although a formal risk assessment methodology has been adopted across the EU as part of the RAPEX system to respond to consumer products posing serious risks (European Commission, 2004a), other (additional) formal methodologies are employed at a national level. A number of Member States also adopt formal but undocumented, or informal procedures to assess the risks associated with consumer products (in addition to the formal methodologies). These include the use of in-house and outside experts (or safety boards), and reference to existing product safety standards and legislative requirements. Finally, in determining the appropriate action, some Member States prefer voluntary measures to regulatory or legal action and vice versa; all of these taken together influence product safety and constitute the *method, approach and practice* of ensuring consumer protection at a Member State level.

The Sections below provide an overview of the approach to identifying hazardous products, the risk assessment methods employed, and the actual practice adopted by each Member State in determining the appropriate action to be taken. This is based on information provided mainly from consultation with Member States, literature review (internet searches) and information available from the PROSAFE website[3].

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[2] A differentiation is sometimes made between risks to the individual (*individual risk*) and risks to consumers in general (*societal risk*). From the perspective of the regulator, it is useful to consider both individual and societal risks; this is because if the population at risk is very large, a low individual risk can result in a significant societal risk.

[3] PROSAFE (the Product Safety Enforcement Forum of Europe) is an organisation established entirely by enforcement officers and supported by DG SANCO, DG Enterprise, DG Internal Market and EFTA. Internet Address: www.prosafe.org

2.2 Approach to Ensuring Product Safety in Austria

In Austria, the task of ensuring consumer protection is undertaken by a number of ministries, which are responsible for specific products covered by sector-specific legislation (for instance, machinery falls under the Ministry of Economic Affairs while toys and cosmetics fall under the Federal Chancellery). The overall enforcement of the GPSD in Austria is the responsibility of the Federal Ministry of Social Security, Generations and Consumer Protection. Market surveillance is usually undertaken at the provincial level, although it is directed by the federal administration.

Austria generally adopts an informal procedure for assessing risks from consumer products, although it applies the RAPEX methodology where appropriate. This informal procedure includes the use of:

- a Product Safety Board, established under the Product Safety Act, consisting of around 18 representatives from various ministries, consumer associations, NGOs, etc. It has the competence to publish opinions on specific products and risks, although it acts more as an advisory board and its opinions are usually in the form of recommendations;

- opinions from accredited private laboratories or government institutes based on tests carried out on product samples. However, an underlying problem for the authorities with laboratories is that two different laboratories can arrive at two different scientific conclusions regarding the same product/risk (hence the need for the Product Safety Board); and

- views of external technicians (or expert witnesses) and discussions within the responsible unit within the Federal Ministry.

When a product posing risks is identified, the Austrian authorities prefer a voluntary approach in which they try to arrive at a suitable compromise with the manufacturer whose product(s) may pose a risk, rather than taking legal action. Thus, while formal methodologies provide guidance on the type of legal action to take when a dangerous product is found on the market, the preference for and success to date using a voluntary approach means that these guidelines are often not required.

The Austrian Product Safety Act also has a mutual recognition clause, whereby once a product is declared to pose unacceptable risks in another Member State, the risk assessment does not have to be repeated in Austria. This significantly reduces testing costs incurred by the Austrian authorities; the introduction of a similar mutual recognition clause for risk assessments may be a possible way forward across the EU.

2.3 Approach to Ensuring Product Safety in Belgium

The Ministry of Economic Affairs (FPS Economy) in Belgium is responsible for market surveillance for a number of New Approach Directives and the GPSD; hence it deals

with a range of products and legislation. As a result, experiences and expertise from the risk assessment of one product can be easily applied to other products, if required. For instance, the Belgian Risk Matrix was based on a methodology designed for use in machinery and installations, but has been recently applied to consumer products.

FPS Economy undertakes market surveillance in response to consumer complaints, presumption of danger, increase in accidents, notifications, etc. and also initiates specific campaigns on products known or suspected to pose a risk. For each campaign, a checklist is developed to guide inspectors, who may have limited experience of the product in question, in identifying hazardous products. The checklists:

- set out the key factors to be checked for safety, providing reference to relevant standards; and
- rank the importance of the factor for product safety on a scale from zero (zero risk) to three (immediate danger).

Campaigns focus on products where standards are in place. However, where there are no relevant standards, key factors are identified where possible from standards for similar products or different products with similar features.

Where a product is suspected of posing unacceptable risks, a number of different risk assessment methodologies are in use. Currently, the Belgian Risk Matrix (described in Section 3.3) is applied to products along with the RAPEX methodology, and the two results are compared. There is also a pre-evaluation procedure which is carried out side-by-side with the risk assessment; this is intended to ensure that the risk assessment is robust. Before proposing that a measure should be taken to address the risk, the opinions of one or two experts are also usually sought.

2.4 Approach to Ensuring Product Safety in Cyprus

The Competition and Consumer Protection Service under the Ministry of Commerce, Industry and Tourism is responsible for ensuring consumer protection in Cyprus. The Service is responsible for the enforcement of a range of legislation relating to consumer health and safety in addition to undertaking market surveillance activities aimed at identifying potentially hazardous products on the market. No further information was provided by the Cypriot authorities on their risk assessment approaches, methods and practices; although it is known that the authorities apply the RAPEX methodology.

2.5 Approach to Ensuring Product Safety in the Czech Republic

The Consumer Protection Department (under the Ministry of Industry and Trade) has overall responsibility for ensuring product safety and consumer protection in the Czech Republic while the Czech Trade Inspectorate is responsible for market surveillance of all non-food consumer products and the overall protection of consumers' economic interests.

The Czech authorities use two formal risk assessment methodologies for assessing product risks. One is a general guidance document for the Czech Trade Inspection Department (described in Section 3.5) which essentially provides a qualitative approach to risk assessment and management, while the second is the RAPEX methodology.

There are also a number of relevant non-governmental consumer organisations in the Czech Republic whose work focuses on providing advice and information through advice centres, publishing and education, the comparative testing of products and goods, and out-of-court settlement of disputes. A recent amendment to the Civil Court Procedure and the Consumer Protection Act has allowed consumer organisations to commence proceedings to seek an injunction for the protection of consumers' interests.

2.6 Approach to Ensuring Product Safety in Denmark

The Danish Safety Technology Authority (DSTA), part of the Ministry of Economic and Business Affairs, is responsible for the GPSD as well as other product areas, such as electrical safety and fireworks. It has a committee on market surveillance, which acts as an adviser on market surveillance in specific areas, including electrical and gas appliances, fireworks, toys and consumer products in general. The mandate of the committee also includes assisting in ensuring general support among stakeholders for market surveillance activities, evaluating product withdrawals and the use of sanctions.

The DSTA assesses the risks of consumer products using:

- the RAPEX methodology, which it believes provides a common 'language' for discussions between the authorities and manufacturers regarding product safety. However, the results are commonly open to varying interpretations and further dialogue with manufacturers is often required;

- a failure code list for electrical products (falling under the scope of LVD) which was developed through the Nordic safety co-operation (see Section 3.4). The failure code list is used by laboratories to classify the severity of various faults identified in electrical appliances during testing in order to enable the authorities to decide if a product is 'dangerous'. This methodology may be used in other fields provided the authorities can agree on a classification of typical product faults; and

- standards, wherever applicable, to define the safety level of a consumer product.

For electrical products, the Danish authorities find risk assessment very straight-forward as the standards (under the Low Voltage Directive) set out guidelines for designing and testing these products. However, where a risk is identified, the authorities use a simple grading system in deciding on the appropriate action to take, as follows:

- if the product poses an immediate risk to life; the authorities issue an immediate withdrawal from consumers;
- if the product is dangerous under reasonably foreseeable misuse, a sales ban at the retailers is issued;

- if the product is dangerous under a rather unlikely set of circumstances, a sales ban at the importers is issued; and
- if the product has a fault which does not pose any real risks, the importer will be required to correct the fault in future deliveries.

2.7 Approach to Ensuring Product Safety in Estonia

The Estonian Consumer Protection Board is responsible for formulating and implementing product safety legislation, as well as market surveillance of consumer products.

Product safety assessments are carried out under the (Estonian) Product Safety Act and different standards, as well as using the RAPEX methodology. With the RAPEX methodology, the Consumer Protection Board is of the opinion that there is no need for sector-specific or product-specific assessment methods and inspectors from different areas can easily use the same method to arrive at similar results. They, however, consider that the current RAPEX method should be supplemented with better guidance and made more specific. For example, ranges given in percentages should be more specific, also the category of vulnerable persons should be more clearly defined.

2.8 Approach to Ensuring Product Safety in Finland

The Finnish Consumer Agency has the main responsibility for ensuring consumer safety in Finland. It is responsible for undertaking and co-ordinating market surveillance of consumer products, the training of regional and local authorities, the handling of consumer reports and preparation of industry guidelines, and is the national contact point for RAPEX. It uses around 270 surveillance units in the municipalities and has five provincial offices which are responsible for the co-ordination of local authorities.

Other product safety surveillance authorities in Finland include the Safety Technology Authority, the Ministry of Social Affairs and Health, and the Customs Laboratory who are responsible for the surveillance of consumer products imported from non-EU countries. The Advisory Board for the Evaluation of Conformity covers all authorities carrying out market surveillance in Finland, coordinates and deals with problems encountered in market surveillance and promotes the use of best practices. In practice, Finland has a cross-sectoral system of product safety surveillance, for instance, there may be two or three authorities responsible for the safety of one product, albeit covering different safety aspects.

The Finnish Consumer Agency does not use formal and documented risk assessment methodologies for assessing the safety of consumer products. Instead, it makes use of experts (senior advisors, engineers, lawyers, etc.) who discuss the safety of dangerous products while maintaining close links with other market surveillance authorities and with the Customs Laboratory. The Product Safety extranet hosted by the Finnish Consumer Agency is also used to convey information to local product safety authorities (as well as other authorities).

2.9 Approach to Ensuring Product Safety in France

The Directorate-General for Competition, Consumer Affairs and the Suppression of Fraud (DGCCRF), under the Ministry of Economy, is responsible for ensuring consumer safety under the GPSD in France. It is the national contact point for RAPEX and has the main responsibility for co-ordination of market surveillance programmes for consumer products, overall quality control for various products and services, and the preparation of guidelines and training of regional and local authorities. DGCCRF has decentralised services throughout France, with 22 regional directorates in the capitals of each region and over 100 departmental directorates.

In addition to the DGCCRF, the Ministry of Industry has responsibility for ensuring that products for which there is sector-specific legislation (e.g. toys, cosmetic products, electrical appliances) meet the relevant requirements. An independent Consumer Safety Commission set up under the Consumer Safety Act also provides advice on measures to ensure consumer safety and enforcement of risk management programmes, in addition to collecting data on home and leisure accidents. The Directorate-General for Customs and Excise (DGDDI) is also responsible for monitoring the quality and safety of products imported from non-EU countries during customs clearance.

No further information was provided by the French authorities on the risk assessment approaches, methods and practices they use, although it is known that the authorities apply the RAPEX methodology and the Consumer Code, which sets out the powers of DGCCRF in the area of product safety, in particular to identify and ascertain infringements of safety legislation and apply penalties in the event of an infringement.

2.10 Approach to Ensuring Product Safety in Germany

In Germany, the federal ministries are responsible for policy matters relating to product safety; however, enforcement functions are undertaken by regional and local authorities with the involvement of health and safety authorities in cases where consumer safety is paramount. Besides the GPSD, there are over 15 regulations concerning the safety of various products; implementation of sector-specific legislation is overseen by various ministries and specialised agencies in some cases.

When a product posing risks is identified, the German authorities prefer a voluntary approach in which they try to arrive at a suitable compromise with the manufacturer whose product(s) may pose a risk. Further measures are taken only where voluntary measures fail to deliver the required result(s).

Information received from the Bundesanstalt für Arbeitsschutz und Arbeitsmedezin (Federal Institute for Occupational Safety and Health) indicates that it uses the RAPEX guidelines in assessing the risks posed by consumer products; different methodologies are not employed for different consumer products. One of the reasons is because the RAPEX guidelines are easily understood by field inspectors; also the RAPEX guidelines allow for greater consensus among inspectors (compared with a methodology which requires specific figures to be input).

The study carried out for the Commission by ITS Research and Testing Centre (2002) identified a semi-quantitative methodology from Germany which, effectively, provides a measure of societal risk using the formula:

$$\text{Risk} = (E+V) \times (A+S)$$

where E = probability of occurrence
V = market availability
A = extent of damage
S = affected groups

Each of these factors is scored to provide a numerical result of the risk. The first two factors relate to the probability of occurrence across the general population (by accounting for the product's availability) and the second two relate to the severity of the adverse effects (where these are adjusted using the 'S' factor if those affected are children or elderly). It was, however, not possible to confirm in which context this methodology is used and by which of the German authorities (whether regional or local).

2.11 Approach to Ensuring Product Safety in Greece

The Ministry of Development (General Secretariat for Consumer Affairs) is responsible for ensuring product safety under the GPSD and for market surveillance in Greece. Surveillance and enforcement work for products covered by sector-specific legislation are undertaken by ministries or departments designated under the relevant legislation; the Customs Authorities and the Consumer Protection and Trade Departments of the regional administrations also contribute to ensuring product safety.

In Greece, product safety assessments are usually based on the results of a report prepared by a testing laboratory; consumer products are regarded as being safe if they comply with the requirements of the tests. The RAPEX methodology is used mainly for administrative purposes (i.e. to ensure that products posing similar levels of risk receive comparatively similar (financial) penalties). The Greek authorities consider that for certain products (e.g. toys), two of the parameters in the RAPEX methodology for calculating risk are based on the user's subjective judgement; hence divergences in risk conclusions are bound to result.

2.12 Approach to Ensuring Product Safety in Hungary

The General Inspectorate for Consumer Protection under the Ministry of Economy and Transport is responsible for ensuring product safety under the GPSD in Hungary. Amongst other things, it develops and implements the market surveillance strategy, supervises the various consumer protection authorities and institutions, and ensures harmonisation of the regulations amongst various departments.

The Hungarian authorities use the RAPEX methodology in assessing product risks, especially for toys and childcare articles. While they do not have extensive experience in the use of this methodology, the authorities indicate that it often provides a finding of 'serious risk' (which they consider often overstates the actual risk) for products used by children under 3 years. They do not have sufficient resources to develop an alternative risk assessment methodology and do not have sufficient confidence in the results of the risk assessment to take appropriate action. They have suggested that information on best practice in other Member States would be helpful in this regard and/or further guidance from the Commission on how to adjust the risk derived using this methodology to reflect the actual risk.

2.13 Approach to Ensuring Product Safety in Ireland

The Office of the Director of Consumer Affairs (ODCA) in Ireland is responsible for the enforcement of a wide range of consumer protection laws. The enforcement unit of the ODCA ensures consumer protection legislation is complied with. Working in close co-operation with the Inspectorate, it conducts pro-active market surveillance of the country and investigates complaints by members of the public.

ODCA inspectors are authorised to investigate possible breaches of consumer legislation and carry out inspection visits, investigations and surveys. Inspectors in the field are aware of the RAPEX notifications or other information acquired over time relating to various products and/or risks which could present a danger for consumers. They also check to ensure that markings are properly affixed as appropriate for the particular product. If the inspectors feel that a product does not comply with the regulations, they take samples away for further examination.

On an inspector's return to the office, members of the product safety group examine the product and documentation obtained by the inspector (or sent in by a trader or consumer). Various aspects will be taken into account such as documentation provided, the number of products sold and the number and nature of the complaints. Vulnerable groups and intended use would also be taken into account. Ireland adopted the RAPEX methodology in 2003.

The authorities believe that their approach has served them reasonably well over the years bearing in mind that Ireland had no approved test laboratories and little or no information on sales figures of products, except from the local wholesaler. They are, however, also of the opinion that product(s) should not be assessed by one method only; rather a broad range of aspects should be taken into account in any assessment.

2.14 Approach to Ensuring Product Safety in Italy

The Ministry of Productive Activities (*Ministero delle Attivita' Produttive)* is the main authority responsible for ensuring consumer safety under the GPSD in Italy; in addition to its overall remit under the GPSD, it is also responsible for specific products covered by sector-specific legislation (e.g. toys).

Although the Italian authorities apply the RAPEX methodology for assessing the safety of consumer products where appropriate, they also adopt a step-by-step procedure to ensuring product safety as follows:

- market surveillance is undertaken by enforcement officers to ensure that products placed on the market are safe. Inspections are carried out at production and packaging plants, in warehouses or sales outlets, etc.;
- the authorities obtain the technical documentation for the relevant product from the manufacturer/supplier involved;
- product samples are taken for testing and analysis in laboratories in order to determine if they conform with legislative requirements;
- a report on the test findings is then sent to the administrative authorities; and
- the authorities decide on the most appropriate action to take, which could include conditions for placing product(s) on the market, appropriate warnings, bans or product withdrawals.

In addition to the Ministry of Productive Activities, other ministries, public departments and independent authorities are involved in ensuring consumer protection in Italy. For instance, the Ministry of Welfare is responsible for products used in the professional sector intended for consumers and the Ministry of Health is responsible where the product risks pertain to human health. Controls tend to be carried out by each Ministry through its own bodies and laboratories (except where it does not have a laboratory in which case, an outside laboratory may be used). Market surveillance and enforcement action tends to be undertaken at the local and regional level through over 100 Chambers of Commerce (*Camere di Commercio*) which can be found in the main town of each Italian province.

In Italy, the link between consumer policy and other policies is currently made under a number of general legal instruments which provide for coordination between the various authorities and bodies involved in the different sectors. Of particular note are the:

- Conference of the State and Regions (*Conferenza di Stato-Regioni*), which co-ordinates the activities of the central government and the regional bodies; and
- Conference of Services (*Conferenza di Servizi*) which co-ordinates the activities of the various Ministries and examines cases in which there may be conflicting interests or views. Consumer organisations can also send their comments to the central administration though the *Conferenza*.

2.15 Approach to Ensuring Product Safety in Latvia

The Consumer Rights Protection Centre (CRPC), under the Ministry of Economy, is responsible for ensuring consumer protection in Latvia. It co-ordinates and undertakes market surveillance of non-food consumer products and services, ensures co-operation between institutions involved in consumer safety and provides legal advice to consumers. The CRPC uses a variety of methods to ensure the safety of products, which include:

- the use of formal risk assessment methodologies which have been used in the original EU-15 countries and the RAPEX methodology, where appropriate;
- the views of experts;
- the results of product sampling and testing; and
- information on products and accidents obtained from databases such as RAPEX.

2.16 Approach to Ensuring Product Safety in Lithuania

The National Consumer Rights Protection Board, under the Ministry of Justice, is the main state institution in Lithuania responsible for formulating and implementing consumer safety policy. It co-ordinates the activities of other state institutions in the field of consumer protection, provides information on consumer products, is the national contact point for information exchange under RAPEX and works in collaboration with the representatives of the government and municipalities, counties, local authorities as well as subdivisions of state market surveillance offices to ensure consumer safety.

The State Non-Food Products Inspectorate, under the Ministry of Economy, is responsible for market surveillance and assessment of safety and quality of non-food consumer products and services. It uses the safety standards for various products, as well as the RAPEX methodology, in assessing the risks of consumer products. Information on the RAPEX website is also used to ensure that products on the market are safe.

2.17 Approach to Ensuring Product Safety in Luxembourg

The Ministry of Economic Affairs is the contact point for the Commission on the GPSD and is responsible for RAPEX notifications, as well as liaison with other Member States regarding product safety. It does not use any formal or informal procedures for risk assessment of consumer products.

As Luxembourg is a small country and has very little national production of consumer products, it depends mainly on product notifications from other countries. When such notifications are received, they are acted upon, although in many cases the products which are notified cannot be found in Luxembourg. No repeat tests are carried out on products for which notifications have been received.

While this system is indicated to be broadly effective in Luxembourg, there are on-going efforts to improve the overall enforcement and market surveillance of consumer products. Improved liaison with other Member State authorities is also an area of activity.

Products covered by sector-specific legislation (e.g. toys, electrical products, and cosmetics) are under the jurisdiction of other authorities. Most of these authorities have laboratories where they carry out the relevant tests; they may also carry out some form of risk assessment (possibly related to the existing European standards).

2.18 Approach to Ensuring Product Safety in Malta

In Malta, there are three authorities (all of which form part of the Ministry for Competitiveness and Communications) involved in ensuring product safety:

- the Market Surveillance Directorate (MSD), which is the main contact point at the European and international levels regarding product safety issues in Malta. It formulates the market surveillance *policy* and *coordinates and audits* the activities of the other authorities;

- the Consumer and Competition Division (CCD), which is the main government organisation undertaking market surveillance operations for consumer products and enforcement action or *risk management*; and

- the Malta Standards Authority (MSA), which is the government organisation responsible for *risk assessment* advice to the surveillance authorities.

In Malta, the vast majority of consumer products are imported from other EU Member States[4]. Due to the small size of the country and the limited resources available to the authorities, they rely on product risk assessments already undertaken by other Member States. Emphasis is placed on obtaining these risk assessment reports, analysing data from RAPEX and evaluating national and international data to identify products which may be causing problems. Information on these programmes is passed on to the market surveillance officers who undertake a preliminary risk assessment at the premises of the producer/supplier. Where there are still concerns, the product is passed to the MSA for further testing and/or risk assessment advice and where regulatory action is required, the CCD (working with the MSA) may apply a range of measures from voluntary withdrawal of the product to a complete ban.

The Maltese approach to ensuring product safety is particularly interesting because it takes into account the features which are unique to the country, such as the size of the country (which impacts on societal risk), product source (which impacts on product availability and risk management) and the resources available to enforcement officers (which ultimately influence the approach to risk management). In these circumstances, while a risk assessment methodology (such as the RAPEX methodology which is used in Malta) is important, communication with other Member States, the Commission and other relevant authorities is of equal (if not, greater) importance.

2.19 Approach to Ensuring Product Safety in the Netherlands

The Food and Consumer Product Safety Authority (VWA), an independent agency within the Ministry of Agriculture, Nature and Food Quality, is responsible for ensuring the safety of both food and consumer products at all stages of the production chain. It is

[4] Customs officers (in co-operation with the authorities) ensure the safety of products coming from non-EU countries.

involved in the development and implementation of policy relating to product safety, as well as informing various relevant (local and regional) authorities about risks to public health. The VWA consists of a central co-ordinating unit and two delivery units: the Inspectorate for Health Protection and Veterinary Public Health (KvW) and the National Inspection Service for Livestock and Meat (RVV).

The Inspectorate for Health Protection consists of five Regional Inspectorates which are responsible for all the enforcement activities in their region. Each Regional Inspectorate consists of an enforcement department and a laboratory where samples are tested. Each Regional Inspectorate has a specialised function or area of expertise; a General Inspectorate co-ordinates the activities of the Regional Inspectorates. Overall, inspectors organise their work according to the year plan and also react to incidents and accidents. The Dutch Consumer Safety Institute has also recently published a generic risk assessment methodology[5] (CSI, 2005) which draws, primarily, upon its work for the Netherlands' authorities.

2.20 Approach to Ensuring Product Safety in Poland

The Office for Competition and Consumer Protection (OCCP) is the contact point for RAPEX and for campaigns concerning product safety in Poland. It is also the authority in charge of market surveillance for the New Approach Directives and co-operates with other national authorities (such as Inspections and Customs) and international authorities.

Other than the RAPEX guidelines, the OCCP does not use any formal and documented risk assessment methodologies for assessing the safety of consumer products. Sometimes, an outside expert is asked for assistance.

The GPSD is seen as helpful for assessing the safety of consumer products. Where products are found to pose risks, the OCCP has a preference for voluntary measures prior to applying any measures. The producer is usually given a time limit to make the product compliant with the essential requirements or withdraw the product from the market.

2.21 Approach to Ensuring Product Safety in Portugal

The Consumer Institute (*Institudo do Consumidor*) is responsible for ensuring product and consumer safety in Portugal. It is involved in the market surveillance of products and services for consumers and develops policy measures which promote consumer safety. Product safety policy in Portugal is primarily a central government responsibility; safety inspection and enforcement work is largely carried out by inspectors working for the Ministry of Economy, both centrally and through regional delegations. There are also decentralised and regional bodies who carry out sampling and prosecution work.

The Portuguese authorities apply the RAPEX methodology, where appropriate.

[5] A preliminary review suggests that the 'core' of the methodology is essentially a simple two dimensional risk matrix (probability of occurrence vs severity of outcome).

2.22 Approach to Ensuring Product Safety in Slovakia

The Ministry of Economy (Consumer Protection Department) is responsible for ensuring product safety under the GPSD, as well as overall consumer protection. It co-ordinates and organises the activities of various state ministries, market surveillance authorities and certification bodies which are involved in ensuring product safety. It formulates and implements consumer safety legislation, co-ordinates national and international projects on consumer and health protection and is the central authority for implementation of RAPEX. It supervises and cooperates with experts who are members of working groups for the New Approach Directives (e.g. toys, low voltage electrical products, etc) in trying to solve problems under the GPSD as well as providing guidance for market surveillance authorities to apply in carrying out their work.

The Slovak Trade Inspectorate (STI) is the market surveillance authority in Slovakia. Inspectors normally undertake market inspections during which they collect samples of products, these are then passed to testing bodies (which are sometimes research institutes). The testing bodies usually test to existing European and international standards and legislative criteria and/or requirements. After testing, the STI informs the Ministry of Economy (and Ministry of Health) of the results and appropriate action is taken. The testing bodies also provide pre-market control for products from non-EU countries and provide information to the STI and Ministry of Economy regarding risks of products. If a product poses a serious risk, in accordance with the laws, the Ministry of Economy implements necessary remedial measures.

2.23 Approach to Ensuring Product Safety in Slovenia

The Ministry of Economy is responsible for formulating consumer safety policy in Slovenia. Two key bodies within the Ministry are the Consumer Protection Office and the Market Inspectorate.

The Consumer Protection Office is mainly involved in the policy and administrative aspects of consumer safety, e.g. undertaking comparative assessments of goods and services, dissemination of information and consumer education, and co-ordinating and monitoring national and international activities in the area of consumer safety.

The Market Inspectorate of the Republic of Slovenia is responsible for the implementation of regulations (including the New Approach Directives) relating to consumer protection in Slovenia. It operates from over 30 offices located across the country and uses two main formal risk assessment methodologies - the Nomograph and the RAPEX methodology (described in detail in Sections 3.2 and 3.8 respectively) - for assessing the risks from consumer products.

The Nomograph was used prior to the introduction of the RAPEX methodology; experience in using the Nomograph indicates that it is very useful as it provides a detailed and formal means of assessing safety, rather than a method based on personal judgement. A potential drawback is the need for a lot of statistical information relating to accidents (which is rarely available) in order to arrive at an accurate risk assessment.

The Slovenian authorities have also developed a methodology (based on the experience of TUKES (Finland) and summarised in Table 2.1 below) for assessing the safety of electrotechnical products. The methodology identifies the potential hazards of the product which are linked to number of irregularities (or non-compliances) and the potential consequence to determine the appropriate regulatory action to be taken. The authorities also use test reports of accredited laboratories (which form a basis for all product safety evaluations) as well as data from notifications of products under RAPEX.

Table 2.1: Summary of Risk Assessment Matrix for Electrotechnical Products in Slovenia

Potential Hazard	Potential Consequence	Recommended Measures
Immediate danger	Lethal	Notification of mass media, market withdrawal, product ban from market, legal action, fines, official warning
Irregularities endangering safety	Dangerous	Market withdrawal, product ban from market, legal action, fines, official warning
Irregularities, which might endanger safety	Dangerous	Market withdrawal, product ban from market, legal action, fines, official warning
Minor irregularities	Non-conforming, but not dangerous	Take appropriate decision, fines, official warning
Irregularities	Conditionally conforming	Official warning
Regular (No irregularities)	Conforming	Stop regulatory proceedings

2.24 Approach to Ensuring Product Safety in Spain

The central government authority responsible for co-ordinating consumer safety policy is the National Institute of Consumer Affairs (*Instituto Nacional de Consumo*) under the Ministry of Health and Consumer Affairs. The actual implementation and enforcement of product safety legislation is, however, undertaken at the regional level (*Comunidades Autonomous*). The 17 autonomous communities in Spain undertake their own product safety controls (including risk assessment) and municipalities also have an enforcement role at the local level, referring more serious matters to their respective regional authorities.

Regional authorities responsible for risk assessment do not use formal and documented risk assessment methodologies for assessing the risks from consumer products. However, where there are uncertainties regarding the safety of specific products and, consequently, risk assessment issues arise at the national level, the National Institute of Consumer Affairs uses EU methodologies or guidance (e.g. RAPEX guidelines) to resolve the issues.

Co-ordinating the work on product safety in Spain is difficult in view of the many different (and independent) government departments and regions involved in consumer safety. Two Commissions have thus been set up at the national level to help in co-ordinating consumer safety work:

- the *Commission for the Co-ordination of Administrative Inspections* covers matters relating to consumer goods and services. It co-ordinates market surveillance policy at the ministerial level, product testing/analysis and the enforcement of EU (product safety) regulations in Spain. The Commission, which is made up of representatives from the various Ministries and regional authorities, also meets twice a year to discuss risks regarding specific products and agree measures to be taken towards addressing these risks; and

- the *Commission of Co-ordination and Co-operation between Autonomous Communities and Central Administration in Consumer Matters* is concerned with developing a framework for co-operation between the various bodies that are involved in ensuring product safety throughout Spain. It organises national surveillance programmes and coordinates risk assessment activities between the national authority and the regional authorities. It also implements the measures recommended by the *Commission for the Co-ordination of Administrative Inspections* according to its established working groups (e.g. market control, surveillance, training, etc.).

2.25 Approach to Ensuring Product Safety in Sweden

The Swedish Consumer Agency has overall responsibility for ensuring product safety in Sweden, although there are a number of other authorities that deal with product safety in specific areas. The Swedish Consumer Agency does not have any local organisation for undertaking market surveillance across Sweden. However, it collaborates with the Consumer Advice Offices in the municipalities. There are local consumer advisors working in almost all of the 290 municipalities in Sweden; some municipalities also assist in inspections (mainly to check CE marking and information requirements and to send products to the Agency for testing). Market surveillance in Sweden is also coordinated by the Swedish Board for Accreditation and Conformity Assessment (SWEDAC).

The Consumer Advice officers visit shops without advance warning; officers would usually introduce themselves, explain the reason for the visit, purchase the product(s) to be tested and complete a questionnaire regarding the product(s) purchased which is signed by the seller. The questionnaire includes information on the date of delivery to the shop, the importer, the article number, name of the shop and organisation number, etc. The Consumer Advice officers submit the inspection forms and products to the Consumer Agency and the products are sent to an accredited laboratory for testing. The number of samples tested may vary, for instance, for toys, between one and three specimens are normally tested; it is normally sufficient for one failed toy to show that the toy does not satisfy the requirements.

The Swedish authorities do not have any national formal risk assessment methodology for assessing the risks of consumer products, although the failure code list for electrical products (see Section 3.4) which was developed through the Nordic safety co-operation and the RAPEX methodology (see Section 3.8) may be applicable.

If a product fails the safety requirements, legal proceedings may be initiated although, in general, the Consumer Agency prefers to negotiate with the manufacturer or importer of the product (and not the retailer), as safety measures taken by businesses at the manufacturing stage have a greater effect on the market (i.e. manufacturers have the ability to change the design of the product). In practice, most cases concerning product safety are resolved on a voluntary agreement basis. It is only where this is not possible that the Consumer Ombudsman can bring proceedings in a court. The Swedish Consumer Agency has also established safety standards, in the form of guidelines, which have been developed following discussions with industry.

There are, however, key challenges in ensuring product safety where there are no standards against which to test products conformance, for example in sports equipment and clothing. For sports equipment (such as PPE), the risk assessment has to take account of the fact that the product in itself is not inherently unsafe but that it might not live up to consumer expectations as regards safety, while for clothing, public acceptance of risk assessments undertaken by the Agency is an issue. Consumers may not always understand that clothing may be hazardous as regards flammability or that children might get stuck in their clothes (due to strings).

2.26 Approach to Ensuring Product Safety in the United Kingdom

The Department of Trade and Industry (DTI) is responsible for formulating consumer safety policy in the UK and is the central government contact for product safety matters. However, the main responsibility for enforcing consumer protection legislation in the UK rests with local authorities, through over 200 local Trading Standards Authorities (TSA).

These local authorities are responsible for enforcing a wide range of statutory provisions in relation to consumer protection and for bringing criminal prosecutions where necessary.

Each local authority is responsible for its service and decides its priorities (based on its resources), although a degree of co-ordination is maintained between the DTI and the TSAs. Also, each TSA is linked to a computer network known as TS LINK, operated by the Institute of Trading Standards Administration. The system conveys urgent messages by electronic mail and provides historical data and information on CD ROM; some TSAs also have their own web site which provides information to businesses and consumers.

In the UK, emphasis is placed on preventative methods to ensure product safety requirements are being observed. Local authorities tend to work closely with businesses operating within their area to ensure compliance with existing legislation, including issuing informative guidance notes to assist manufacturers and suppliers of goods. The UK has developed a risk assessment methodology (LACORS, see Section 3.6) which focuses on the risks associated with businesses, rather than a methodology which focuses on the risk associated with a particular product. This system is used by local enforcement officers to determine risk-based inspection frequencies (i.e. the higher the risk, the more frequently the business is inspected).

Typically, the approach to ensuring product safety in the UK is as follows:

- a trading standards (enforcement) officer will undertake some random sampling of a specific product or a range of products on the market. Sometimes, such sampling is undertaken in response to a consumer complaint or the results of the LACORS risk assessment;

- selected products are examined by the officers, followed by a test purchase of a product, which is sent to an external testing laboratory to be tested to the relevant standards and/or legislation;

- at the end of the tests, the laboratory will either indicate that the product has passed (in which case there is no problem) or failed the standards. Failures may result in suspension and forfeiture of the product or a formal caution may be issued to the business and, in certain circumstances, the business may be prosecuted in a Magistrates' Court. In the court, the testing body will be required to provide evidence showing that the product poses a risk; this would normally require the prosecuting team to present the results of a risk assessment. The Slovenian Nomograph (see Section 3.2) has been used by UK authorities (or testing bodies) in courts as proof of having undertaken a risk assessment; and

- where the manufacturer or supplier loses the court case, the products have to be taken off the market. Where formal action is taken and the products concerned are covered under the GPSD, the local authority informs the DTI of those products which present a serious and immediate danger for notification under the RAPEX system. DTI will then complete the relevant paper work and will notify other authorities under Article 11 or 12 (RAPEX) of the GPSD as relevant.

2.27 Approach to Ensuring Product Safety in Iceland

The Icelandic Consumer Agency is responsible for ensuring consumer protection in Iceland. It undertakes market surveillance of consumer goods and represents Iceland in international negotiations in the area of product safety. The Product Safety and Market Surveillance Authority (which is one of four departments under the Consumer Agency) is responsible for ensuring product safety under the GPSD (as well as for toys and personal protective equipment). Its main task involves ensuring that consumer products fulfil regulatory requirements and do not cause risks or damage to health or the environment. The Department of Electrical Safety (also under the Consumer Agency) is responsible for ensuring the safety of electrical products, as well as market surveillance and other policy aspects relating to electrical safety.

The Icelandic authorities declined to participate in this study; no further information was thus received relating to risk assessment approaches, methods and practices in Iceland.

2.28 Approach to Ensuring Product Safety in Liechtenstein

The Office of Economic Affairs is responsible for product safety in Liechtenstein. No further information was provided by the Liechtenstein authorities on their risk assessment approaches, methods and practices.

2.29 Approach to Ensuring Product Safety in Norway

In Norway, there are a number of Inspectorates and Ministries responsible for ensuring product safety within the non-food area. The Directorate for Civil Protection and Emergency Planning (DCPEP), a subordinate agency of the Rescue and Emergency Planning Department under the Ministry of Justice and Police, is responsible for product safety matters relating to the GPSD in Norway.

The work of the DCPEP encompasses a wide range of activities from national preparedness to fire protection, electrical safety and individual product safety. It implements the Norwegian *Act on the Control of Products and Consumer Services* and carries out market surveillance activities of manufacturers and suppliers of goods and services, and supervises other ministries, county governors and municipalities in the area of product safety. The Directorate also carries out extensive information activities and campaigns aimed at ensuring that the general public (and individuals) are better equipped to look after their own safety. The authorities have the power to restrict or ban the sale of products and to withdraw non-conforming products from the market; fines and other punishments can also be imposed for non-compliance with regulatory requirements.

The Norwegian authorities do not use any formal risk assessment methodology in assessing the risks of consumer products, although the failure code list for electrical products (see Section 3.4) which was developed through the Nordic safety co-operation may be applicable. Consumer policy in Norway emphasises the role of the manufacturer or supplier in ensuring the safety of products, including an obligation on the producer to identify and address the relevant risks (presumably using some risk assessment methodology). A key consideration in this approach may be the lack of (or limited) practical experience among the authorities of formal (and informal) risk assessment methodologies.

2.30 Summary of Member States Approaches to Ensuring Product Safety

Table 2.2 provides a summary of the approaches to risk assessment adopted by Member States. The formal risk assessment methodologies are described in detail in Section 3.

Table 2.2: Overview of Approaches with Focus on Risk Assessment Methodologies	
Country	**Outline of Risk Assessment Methodologies Employed**
Formal Risk Assessment Methodologies Used	
All EU-25	RAPEX (see Sections 3.7 - 3.9)
Belgium	Risk matrix at experimental stage (see Section 3.3)
Czech Republic	National methodology in use (see Section 3.5)
Denmark, Finland, Sweden, Norway	Nordic failure code list (see Section 3.6)
Germany	National methodology may be in use (see Section 2.10)
Slovenia	Risk assessment nomograph (see Section 3.2)
United Kingdom	LACORS methodology for premises (see Section 3.4) Risk assessment nomograph (see Section 3.2)
Expert Panel	
Austria	Product Safety Board and external experts (see Section 2.2)
Denmark	Committee of market surveillance (see Section 2.6)
Finland	Expert opinion (see Section 2.8)
France	Consumer Safety Commission (see Section 2.9)
Ireland	Product safety group (see Section 2.13)
Italy	Conference of Services (see Section 2.14)
Poland	Expert panel (see Section 2.20)
Spain	Commission of Co-ordination (see Section 2.24)
Other	
Austria	Testing laboratories
Belgium	Ranking method for specific campaigns (see Section 2.3)
Greece	Reliance on test reports (see Section 2.11)
Luxembourg	Reliance on product notifications by other Member States (see Section 2.17)
Malta	Reliance on risk assessments by other Member States (see Section 2.18)
Slovakia	Informal procedures (see Section 2.22)
Norway	Reliance on manufacturers' obligations (See Section 2.29)

3. FORMAL RISK ASSESSMENT METHODOLOGIES

3.1 Types of Formal Risk Assessment Methodology

3.1.1 Introduction

This Section describes in detail the formal risk assessment methodologies used by regulatory authorities across the EU. These formal risk assessment methodologies come in a number of forms, as described briefly below.

3.1.2 Qualitative Methods

At its simplest, if the purpose is to provide a preliminary screening of risks, then the use of a qualitative 'risk matrix' is likely to be sufficient. In a risk matrix, the two components of risk - probability and severity of consequences - are measured on a simple qualitative scale.

Qualitative methods are quick and apparently simple to apply. However, they are highly subjective and this may result in inconsistent application, especially where limited guidance is given on how the qualitative scale is applied (e.g. what is the boundary between a high and a medium probability of occurrence?). Considerable experience may therefore be required to apply qualitative methods consistently.

3.1.3 Semi-Quantitative Methods

In many cases, the use of a simple risk matrix is insufficient to differentiate amongst a number of different risks. The most prevalent means of evaluating the risks is through the use of multi-attribute techniques in which each attribute (component of overall risk) is individually scored against a set of pre-defined descriptors (on, for example, a 1 to 5 scale). The scores for each attribute are then combined, perhaps with the use of weighting factors to reflect the relative significance of each attribute. The total weighted score then provides a 'risk rating' to enable the overall risks associated with particular events (or activities or locations) to be compared and contrasted.

Semi-quantitative methods offer the advantage of speed and ease of use, but retain an element of subjectivity.

3.1.4 Quantitative Risk Assessment

Quantified risk assessment[6] (QRA) techniques were originally developed in the 1960s and 1970s to assess the risks associated with 'high hazard' facilities - notably in the nuclear and chemical industries. In recent years, QRA techniques have been applied more widely in terms of both the nature of the hazard and the range of consequences (for example, in assessing risks to the environment).

[6] Other terms in use include 'probabilistic risk assessment' (PRA) and 'probabilistic safety assessment' (PSA, particularly in the nuclear industry).

Within each step of the assessment, many specialised techniques have been developed to assist with the analysis of particular risks. Many of the techniques are now computerised. Furthermore, where many assessments used to be deterministic, using single values for each of the parameters, it is now possible to explicitly account for uncertainty in the analysis through the use of probabilistic distributions to generate probabilistic results using such techniques as Monte Carlo analysis.

Quantitative methods have a lower degree of subjectivity and the process by which risks are assessed is transparent. They also allow for a range of risks to be assessed and compared. The drawback with such methods is that they are less simple to apply than qualitative or semi-quantitative methods and may require access to specific software.

The Sections below discuss the various formal risk assessment methodologies used by regulatory authorities in various EU Member States.

3.2 Slovenian Nomograph

3.2.1 Overview

A risk assessment nomograph was prepared for the Ministry of Consumer Affairs in New Zealand (Benis, 1990). In 2002, this nomograph was adopted by the Market Inspectorate of the Slovenian Ministry of Economy to assist in the assessment of product safety and is henceforth referred to as the Slovenian Nomograph. This is a semi-quantitative approach to risk assessment based on four parameters. These are:

- maximum potential injury;
- probability of hazard occurrence;
- hazard recognition; and
- availability.

The nomograph is a graphical means to represent the estimate of risk which is based on the generalised equation:

$$\text{Risk} = f(\text{maximum injury}) \times f(\text{probability of occurrence}) \times f(\text{hazard recognition}) \times f(\text{availability})$$

3.2.2 Maximum Potential Injury

This consists of scaling the injury, based on indicators such as a specific product complaint, nature of an ensuing injury and type of defect. The scale is divided into six levels of injury:

- minor;
- moderate;
- serious;
- severe;
- critical; and
- death.

Examples are provided of the most common types of injuries categorised under each severity rating. Consideration should be given to disadvantaged groups (children 0 to 4 years old, the elderly and disabled). There is also the potential to make a double risk assessment if the severity of the potential injury to the disadvantaged is likely to be greater than to the average consumer. Definition of what constitutes 'greater' is not provided, however, and is left to the decision of the investigating officer.

3.2.3 Probability of Hazard Occurrence

This can be based on available failure rate data, but these must be reliable. However, the nomograph notes that failure rate data are not generally available; testing by a qualified body should then be sought. The parameter is scaled linearly in six levels:

- almost inevitable;
- highly probable;
- probable;
- possible;
- unlikely; and
- remote.

3.2.4 Hazard Recognition

This relates to the capability of an average adult to recognise defects and potential misuse and is scaled in five levels:

- almost inevitable;
- probable;
- possible;
- improbable; and
- highly improbable.

In other words, where potential hazards are recognised, the average adult is assumed to take corrective action.

3.2.5 Availability

This refers to the availability of the product on the market. It is scaled in four levels:

- very high;
- general;
- limited; and
- rare.

However, this factor can be bypassed if information is not readily available. As more information becomes available, the original assessment should be reviewed and updated.

3.2.6 Final Risk Assessment

The appropriate ratings for each of the four parameters described above are linked by a series of lines (on the nomograph) to determine the final risk assessment. This is scaled into 10 different ratings, as follows:

- extremely high risk, with an associated score of 90;
- very high, with a score of 80;
- high, with a score of 70;
- significant, with a score of 60;
- moderate, with a score of 50;
- low, with a score of 40;
- very low, with a score of 30;
- extremely low, with a score of 20;
- remote, with a score of 10; and
- 0, virtually non-existent risk.

3.2.7 Use of the Nomograph in Slovenia and the UK

As well as being used by the Slovenian market surveillance authorities, it is understood that the nomograph is also used by some UK market surveillance authorities.

3.3 Belgian Risk Matrix (Under Development)

3.3.1 Overview

An experimental formal risk assessment methodology was presented to the consultants by the Belgian authority responsible for risk assessment of consumer products under the GPSD (Ministry of Economic Affairs, Product Safety Service). This method is still under development and has not yet been shared with other authorities.

This methodology, referred to in this report as the 'Belgian Risk Matrix', is currently being developed and is applied in parallel with the RAPEX guidelines. The Belgian risk matrix was adapted from a system designed for use in machinery and installations, drawing on experience in the risk assessment of products.

The Belgian Risk Matrix involves the following:

- estimation of the seriousness (ernst, E) of the consequences (seven categories ranging from first aid only to catastrophic, where the latter implies death of all users and bystanders);
- determination of the probability (waarschijnlijkheid, W) of occurrence (eight categories ranging from impossible to almost certain); and
- estimation of the degree of exposure (blootstelling, B) (seven categories ranging from never to constant).

The resultant risk (risico, R) is then the product of the scores for each of the above factors, i.e:

$$R = E \times W \times B.$$

The calculated risk is associated with the typical use of a single product (individual risk) and no account is taken of the number of such products on the market.

3.3.2 Scoring System

The scores for each of the factors are summarised in Table 3.1.

Table 3.1: Factor Scores and Associated Descriptions for the Belgian Risk Matrix

Seriousness of Consequences, E		Probability of Occurrence, W		Exposure, B	
100	Catastrophic (all users and bystanders killed)	10	Almost certain	10	Constant
80	Major calamity (all users killed)	6	Very possible	6	Frequent (daily)
40	Calamity (several deaths)	3	Unlikely	3	Occasional (weekly)
15	Very serious (one death)	1	Improbable	2	Sometimes (monthly)
7	Serious (permanent injuries)	0.5	Conceivable	1	Seldom (few times per year)
3	Cuts, etc. (equivalent to a lost-time accident)	0.2	Near impossible	0.5	Very seldom (less than once a year)
1	Minor (first aid may be required)	0.1	Impossible unless aided	0	Never
		0	Impossible		

The resulting level of risk and required action, based on R = E x W x B, are categorised as shown in Table 3.2.

Table 3.2: Belgian Risk Scores & Actions Required

Risk Score = E x W x B	Risk Level	Action Required
>320	Very high	Stop activity
160-320	High	Immediate measures
70-160	Substantial	Reduction required
20-70	Possible	Attention
<20	Slight	Perhaps acceptable

3.3.3 Worked Examples

The following two examples have been developed by the consultants:

- an extension ladder for domestic use; and
- a domestic iron.

An illustration on the application of the Belgian methodology to these examples is shown in Table 3.3.

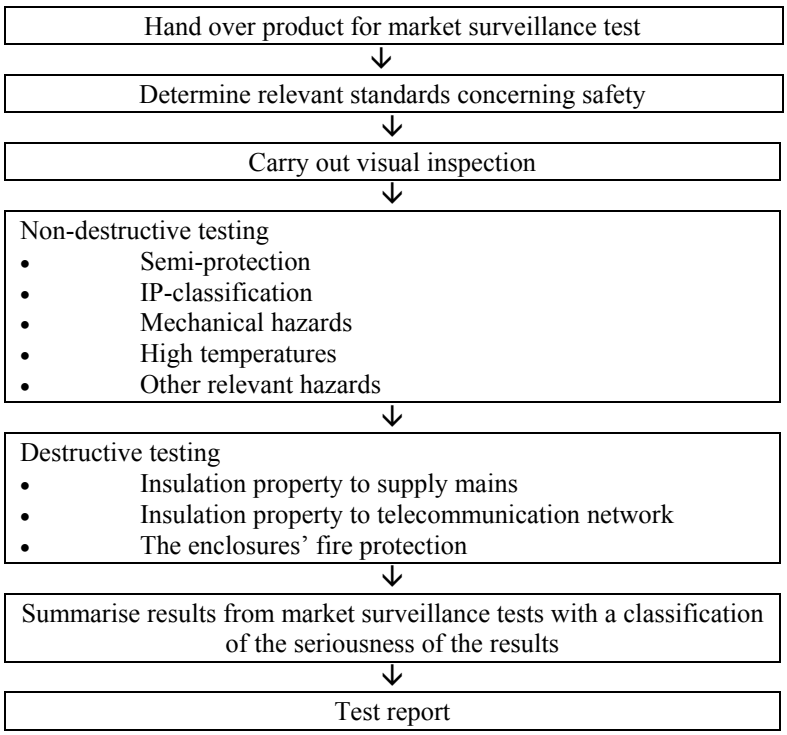
Table 3.3: Illustrative Examples of Application of Belgian Risk Matrix		
Parameter	**Extension Ladder (Domestic)**	**Domestic Iron**
Seriousness of Consequences	Very serious (one death)	Burns
Score (E)	15	3
Probability of Occurrence	Conceivable	Unlikely
Score (W)	0.5	3
Exposure	Monthly	Occasional
Score (B)	2	3
Risk = E x W x B	**15 (slight)**	**27 (possible)**
Action required	Perhaps Acceptable	Attention

3.4 Nordic Failure Code List

3.4.1 Overview

Although the RAPEX methodology is used by the Danish authorities (Danish Safety Technology Authority), use is also made of a formal methodology developed by the Nordic authorities (which also include Finland, Norway and Sweden) for electrical products covered by the Low Voltage Directive. The overall process of market surveillance for these products in the Nordic countries is set out in Figure 3.1.

Figure 3.1: Outline diagram Swedish National Electrical Safety Board Market Surveillance test



To assist in preparing the test report, a list of common product deficiencies is provided. This is shown in Table 3.4. Each deficiency is allocated a code, from 1-3, representing its seriousness. The codes are: (1) Remark (2) Criticism and (3) Serious Criticism.

This classification of failures assists the Competent Authority to evaluate the scale of risk posed by the product and thus to decide on appropriate action. This may be:

- no action;
- corrections to be made by the supplier; or
- banning sale of the product and notification to the European Commission and other Competent Authorities.

Table 3.4: Market Surveillance Codes for Common Deficiencies in Electrical Products (in use in Sweden, Finland, Denmark and Norway)

Technical Deficiencies	**Codes**		
Accessible live part in normal use			3
Accessible basic insulated parts on class II products		2	
Luminaries and domestic equipment of class 0	1		
The insulation distance is less than 10% of the requirement in relevant standard			3
The insulation distance is more than 10% and less than 50% of the requirement in relevant standard		2	
The insulation distance is more than 50% of the requirement in relevant standard	1		
Cord extension set with class 0 plug and class 1 outlet	1		
Cord extension set with class 1 plug and class 0 outlet			3
Cord extension set with class 2 plug and class 0 or 1 outlet			3
Class 1 plug on 2-conductor cable to class 0-device			3
Phase and earth mixed up in earthed coupling			3
The equipment is lacking thermal cut-outs and/or current cut-outs.		2	(3)
The fuse in the equipment is too highly fused, one step	1		
The fuse in the equipment is too highly fused, more than one step		2	
The equipment is too highly fused, which can cause fire hazard			3
The mark is incomplete or missing		2	(3)
CE-mark is missing	1	(2)	
Operation instruction is misguiding, which can cause danger		(2)	3
National language operation instructions with necessary safety information is missing		2	
The design diverges from standard or measuring blade (?)		2	(3)
Incorrect or defective assembled connectors		2	(3)
Risk for mechanical damage to conductor		2	(3)
Equipment with deficient conductor (area, insulation)		2	(3)
Cord anchorage is missing		2	(3)
IP-classification diverges from requirements in standard		2	(3)
The performance diverges from standard or measuring blade great risk for electric chock/fire		2	(3)
Administrative deficiencies			
Declaration of conformity is missing		2	
Errors in declaration of conformity	1		
Technical documentation is missing		2	
Errors in technical documentation	1	(2)	
Inadequate classification/labelling	1		

1. Remark
2. Criticism
3. Serious criticism

3.5 Czech Risk Guidance

3.5.1 Overview

A general guidance document for the Czech Trade Inspection Department (Pražák & Langšádl, 2004) provides, essentially, a qualitative approach to risk assessment and management. A matrix is provided where the axes represent the scale of injury and the probability that such injuries could occur.

3.5.2 Scale of Injury

There are three levels of injury as outlined below:

- serious: internal injury, poisoning, cancer, serious burns, compounded fracture(s), loss of a limb(s), loss of sight, loss of hearing, death;
- damaging: skin infection, serious stab or piercing through, serious cut, loss of a finger, medium burns, more serious uncompounded fracture, concussion, asthma, damage to sight, damage to hearing, etc.; and
- insignificant: irritation, grazes, scratches, sting, cut, slight burn, sprain, light fracture, etc.

3.5.3 Probability of Occurrence

As for 'scale of injury', there are three levels of probability:

- probable: at least one eye witness account is available about the damage occurrence;
- possible: only intermediate information is available that it could actually occur; and
- improbable: one can imagine that damage could happen, but there is not even intermediate information that it could actually occur.

3.5.4 Risk Matrix

The resultant 'risk matrix' (which is based on the BS 8800 standard: 1996) which presents risk levels ranging from 'negligible' to 'intolerable' is shown in Table 3.5.

Table 3.5: Czech Risk Matrix

		Level of Risk		
Scale of Injury	*Serious*	**Small**	**Serious**	**Intolerable**
	Damaging	**Minimal**	**Small**	**Serious**
	Insignificant	**Negligible**	**Minimal**	**Small**
		Improbable	*Possible*	*Probable*
		Probability of Occurrence		

Note: All definitions of injury, probability and risk are based on an informal translation of the original Czech document. In case of doubt, reference should be made to the original document.

The resulting actions to be taken by the enforcement officers on a particular product depend on the associated level of risk. As would be expected for negligible risk, no action is required whilst at the other end of the spectrum, an 'intolerable' risk must be immediately reduced. For minimal risks, increased surveillance should be provided whilst steps should be found to reduce small and serious risks.

3.6 UK LACORS Trading Standards Risk Assessment Scheme

3.6.1 Overview

Unlike the other methodologies presented in this section, which focus on the risk associated with a particular product, the UK system focuses on the risks associated with businesses. This system is used by local enforcement officers to determine risk-based inspection frequencies (i.e. the higher the risk, the more frequently the business is inspected). It has been included as it provides an interesting perspective on how authorities tackle consumer risks more generally.

The scheme, which has recently been updated (LACORS, 2004), comprises a national element that is scored on a national basis and a local element that is particular to the individual business and determined by local authorities.

3.6.2 The National Element

The national element of the scheme deals with the *potential risk*. Scores are provided for a lengthy list of broad-based business categories. However, if a business cannot be included in any of the existing categories then local authorities can assess its national score based on four questions as shown in Table 3.6.

3.6.3 The Local Element

The local element of the scheme deals with the *particular business systems of risk management*. Individual local authorities can determine this by assessing compliance levels, complaints received and systems of management control used in the particular business. The associated scoring system is reproduced in Table 3.7.

3.6.4 Overall Scores

The resultant risk score is the sum of the scores assigned to each question, giving up to 100 points for the national elements and 30 points for the local elements. The scheme categorises businesses into high, medium, low and zero risk which, in turn, provides a guide to the frequency of activities by local enforcement officers. These categorisations are shown in Table 3.8.

The local element will only change an overall business risk rating by up to one national risk rating, e.g. from Medium to High. A business could revert to the original lower risk rating once risk management practices had improved sufficiently, following enforcement activity. A business can never be in a category lower than the national score – this is to ensure consistency across Local Authorities.

Table 3.6: LACORS System – Description of Scoring System for the National Element		
Question	**Scope**	**Score and Description of Scoring System**
Q.1 – What is the maximum potential risk to the public posed by the business?	This question is intended to provide an indication of the risks posed, to consumers and competitors, of the business failing to comply with the trading standards laws that apply to it. This will be dependent on the type of goods or services that the business trades in. In answering this question consideration should be given to the maximum cost to consumers in terms of their safety or in financial terms. Consideration will also need to be given to the potential to cause economic harm to competitors.	**5** **Minimal Detriment –** retail handling of low risk and unregulated goods only e.g. selling pre-packed foods, clothing, low value goods. **10** **Minor Detriment –** business that can cause some financial harm to consumers and unfair competition with other traders. Weighing and measuring of goods. Applying descriptions to low and medium value goods and services. Credit on medium value items. **20** **Significant Detriment –** businesses that trade in foods subject to critical dates. Applying descriptions to high value items such as vehicles and property. Credit for high value items. Safety of products not subject to specific safety regulations. Underage sales of products. **30** **Major Harm –** businesses manufacturing foods. Safety of products subject to specific safety regulations. Firework importation.
Q. 2 – To what extent do the activities of the business affect the hazard?	This question is intended to take account of what influence the business has on the actual risk. This will be dependent on the business' position in the supply chain and also the level of determination they undertake. For example, a manufacturer of toys will influence the design and labelling of the product whereas a retailer of the same product will not be able to influence these factors.	**5** **Minimal –** retailers who undertake no determination. Retail bakers selling pre-packed bread. **10** **Low –** retailers who do limited determination such as weighing or measuring of goods on an in-store business. Retail bakers selling only from own premises. Locally based service providers. **20** **Medium –** food retailers who label loose goods, undertake some pre-packing. Business undertaking some pre-packing and distributing locally. Responsibility for the preparation of goods prior to sale. Marketing of goods/services in a particular way. **30** **High –** Average quantity packers distributing on a regional or national basis. Food manufacturers/processors. Large retailers with range of non-prepacked counters. Manufacturers/importers of goods subject to safety regulations. Plant bakers.
Q. 3 – What volume and complexity of legislation does the business have to comply with?	This question is intended to take into consideration the volume and complexity of trading standards legislation that the business has control over and has to ensure compliance with. It will take into account the number of subject areas such as metrology, safety, etc. that the business has to comply with and also the complexity of the legislation, e.g. complex safety standards.	**5** **Low –** price marking. Business Names. Underage sales. **10** **Medium –** pricing offers, applying descriptions (food and non-food), use of basic weighing and measuring equipment. Credit broking. **15** **High –** retailer with large product range, use of complex weighing and measuring equipment, manufacturers/suppliers of regulated products. Devising non-complex credit adverts. **20** **Very High –** manufacturers with wide range of products, complex product requirements, large average quantity manufacturers. Nationally based home authority companies. Credit providers devising complex advertisements.
Q. 4 – How many consumers are likely to be affected by the business failing to comply?	This question is intended to provide a measure of the number of consumers who are likely to be put at risk by the business failing to comply with the trading standards legislation.	**0** **Very few –** very small customer base, business to business. **5** **Few –** supplying local trade, local high street retailer. **10** **Intermediate –** larger businesses whose trade extends to a regional basis beyond the local area. **20** **Substantial –** national and international client base. Head Office premises.

Table 3.7: LACORS System –Description of Scoring System for the Local Element		
Question	**Scope**	**Score and Description of Scoring System**
Q. 5 – What confidence do you have in the business' control systems based on levels of previous and current compliance and knowledge of management's systems of control?	This question is to be answered locally and is determined by an assessment of individual business' risk management processes. This should be based on the outcomes from previous enforcement actions, complaint levels, and quality systems in place in individual businesses including use of internal and external audits. Consideration should also be given to the status of any 'Home Authority' relationships. Local priorities determined from consultation with stakeholders will also form part of the score for this question.	**0** **High level of confidence –** high standard of compliance with statutory obligations and industry codes of recommended practice, very good record of compliance, use of approved quality systems, minimum number of significant complaints, good communication with Home Authority or evidence of good communication with legal advisors, evidence of documented management procedures. **5** **Medium level of confidence –** high standard of compliance with statutory obligations and industry codes of recommended practice, evidence of quality systems and internal auditing, some significant complaints, communication with Home Authority or legal advisors, evidence of documented procedures and systems. Little or no public concern about the business. **10** **Some level of confidence –** some non-compliance with statutory obligations and industry codes of recommended practice, satisfactory record of compliance, staff demonstrate awareness of relevant legislation/necessary controls, evidence of a number of significant complaints, minimal documented procedures and systems. Some level of public concern about the business. **20** **Little confidence -** some major non-compliance with statutory obligations, varying record of compliance, poor appreciation of relevant legislation and controls, large number of significant complaints, no procedures or systems in place. Public concern about the business. **30** **No confidence –** general failure to comply with statutory obligations, poor track record of compliance, little or no awareness of statutory obligations, large number of significant complaints, previous prosecutions against the business, no evidence of communication with Home Authority or legal advisors, no evidence of systems or procedures. High level of public concern about the business.

Table 3.8: LACORS Risk Scores and Categories		
Number of Points	**Risk Category**	**Activity[1] Frequency**
0 - 14	No Risk	Not required
15 – 54	Low	Five-yearly
55 - 84	Medium	Two-yearly
85 - 130	High	Annually
Notes: *1) Activities could take the form of inspections, test purchasing, sampling, targeted enforcement projects, etc.*		

3.7 ITS Criteria for Serious Risk in the GPSD

3.7.1 Overview

The methodology developed by ITS (2002) formed the basis for the risk assessment methodology used in the RAPEX Guidelines (see Section 3.8). The ITS report reviewed risk assessment methodologies in different countries[7] and initially presented a quantitative methodology involving the following steps:

- determination of severity of potential adverse effects;
- determination of probability of occurrence of the 'defect'; and
- determination of the risk.

Following these steps, a series of other steps concerning risk management are presented. These aim to establish when intervention is required, based on the gravity of the outcome and the vulnerability of those at risk (young, old, disabled, etc.).

3.7.2 Determination of Severity

The numerical scale that is suggested for severity is based on the degree of disability or incapacity, as shown in Table 3.9. The report notes, though, that intermediate severity ratings could be defined if necessary.

Table 3.9: Severity of Potential Adverse Effects			
Severity (Qualitative)	**Slight**	**Serious**	**Very serious**
Numerical rating	1	10	100
Degree of disability %	<2	2 - 15	>15

[7] As part of the project, a number of other risk assessment methodologies were reviewed. These have not been included here, however, on the basis that further primary data have not been submitted by the relevant authorities during the course of consultation for this study.

3.7.3 Determination of Probability

The preferred definition is the overall annual probability of a person being injured by regular exposure to the product. However, the report notes, other criteria may be easier to use depending on the circumstances. These could include the:

- proportion of defective products;
- probability of being injured while exposed to hazardous products;
- total number of users or products; and
- the extent to which the hazard is caused by the product.

Table 3.10 provides the equivalent values of different probability criteria.

Table 3.10: Equivalent Values of Different Probability Criteria			
Probability (Qualitative)	**Low**	**Medium**	**High**
Numerical rating	1	10	100
Frequency per year of one user being injured	10^{-6}	10^{-5}	10^{-4}
	1/1,000,000	1/100,000	1/10,000
Frequency per year of 10 people being injured	10^{-7}	10^{-6}	10^{-5}
Frequency per 1,000,000 products or users per year	1	10	100
Frequency per 10^8 hours of people involved (based on 2000 hours/year)	0.05	0.5	5

These numerical definitions are provided for the benefit of users who have statistical data available and to enable quantitative comparisons to be made. Overall accident data may be used as a guide to the existence of a serious hazard, but analysis of the statistics needs to take into account a number of factors which may make them unreliable, such as:

- the total number of people affected by the product may be unknown;
- the differing levels of exposure of individuals within that population;
- the low level of reporting of non-serious injuries; and
- the low level of attribution of injuries to specific products.

3.7.4 Determination of Risk

The calculated risk is simply the product of the numerical ratings for severity and probability and could range from 1 to 10,000. The associated risk classification is shown in Table 3.11.

Table 3.11: ITS Classification of Risk					
Overall risk	**Very Low**	**Low**	**Moderate**	**High**	**Very High**
Severity x Probability	1	10	100	1,000	10,000

3. 8 RAPEX Guidelines

3.8.1 Overview

The GPSD established the Community Rapid Information System (RAPEX) for the rapid exchange of information between the Member States and the Commission on measures and actions in relation to consumer products posing a serious risk for the health and safety of consumers, in so far as there are no specific provisions in Community law with the same objective. Serious risk is defined in Article 2(d) of the GPSD as: "any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities".

In 2004, guidelines were issued on criteria to identify serious risks (European Commission, 2004a) to assist Member States in assessing the level of seriousness of the risk and deciding whether a rapid intervention is necessary[8]. This consists of the following:

- as a first step, determining the gravity of the outcome of a hazard, depending on both its severity and probability to materialise under the conditions of use considered, and of the possible health/safety effect related to the intrinsic hazardous characteristics of the product; and
- as a second step, assessing the gravity of the outcome depending on the type of consumer and, for normal adults, whether the product has adequate warnings and guards and whether the hazard is sufficiently obvious to make it possible to grade the risk level qualitatively.

A set of Tables, Table A and B respectively for each step, is also provided to aid the assessment. The RAPEX Guidelines draw directly from the ITS Report outlined above. As such, the methodology described below is sometimes referred to as the ITS/RAPEX Methodology.

3.8.2 Table A - Risk Estimation: Severity and Probability of Health/Safety Damage

There are two main factors affecting the gravity of the outcome, namely the severity and the probability of health/safety damage.

Severity

The assessment of severity is based on consideration of the potential health/safety consequences of the hazards presented by the product considered. A grading should be established specifically for each type of hazard. As an example, for certain mechanical risks, definitions of the severity classifications are suggested as shown in Table 3.12.

[8] These guidelines also provide guidance on the notification procedure of Article 11 of the GPSD by clarifying the scope of the procedure, detailing the contents of notifications and establishing arrangements for treatment and transmission of notifications.

Table 3.12: Assessing the Severity of Injury – Example for Mechanical Risks		
Slight	**Serious**	**Very Serious**
<2% incapacity usually reversible and not requiring hospital treatment	2 – 15% incapacity usually irreversible requiring hospital treatment	>15% incapacity usually irreversible
Minor cuts	Serious cuts	Serious injury to internal organs
Minor fractures	Loss of finger or toe	Loss of limbs
	Damage to sight	Loss of sight
	Damage to hearing	Loss of hearing

The assessment of severity also takes into account the number of people who could be affected by a dangerous product (that is, the hazard from a product which could pose a risk to more than one person at a time should be classified as more severe than one which can only affect one person).

Finally, the assessment of the severity of the hazard must be based on reasonable evidence that the effects selected for characterizing the hazard could occur during foreseeable use.

Overall Probability

This refers to the probability of negative health/safety effects to a person exposed to the hazard (individual risk). It does not take into account the total number of people at risk. The overall probability is the combination of all the contributing probabilities such as:

- the probability of the product being or becoming defective (if all products carry the defect then this probability would be 100%); and
- the probability of the negative effect materialising for a normal user who has an exposure corresponding to the intended or reasonably expected use of the defective product.

These two probabilities are combined in the following table (Table 3.13) to give an overall probability.

Table 3.13: Assessing the Gravity of Outcome for RAPEX				
Overall Probability of Health/Safety Damage		**Probability of hazardous product**		
		1%	**10%**	**100% (All)**
Probability of health/safety damage from regular exposure to hazardous product	Hazard is always present and health/safety damage is likely to occur in foreseeable use	Medium	High	Very High
	Hazard may occur under one improbable or two possible conditions	Low	Medium	High
	Hazard only occurs if several improbable conditions are met	Very Low	Low	Medium

Combining the severity and overall probability gives an estimation of the 'gravity of the outcome' (i.e. the risk), which is shown in Table A (see Figure 3.2 below). However, this assessment needs to be modified to take account of the society's perception of the acceptability of the risk, which is Step 2.

Table B - Grading of Risk: Type of Person, Knowledge of the Risk and Precautions

The main factors affecting the level of risk that is considered to be serious are:

- the vulnerability of the type of person affected; and
- for normal adults, the knowledge of the risk and the possibility of taking precautions against it.

Vulnerable People

The Guidance notes that if the product is likely to be used by vulnerable people, the level of risk which is serious should be set at a lower level. Categories of vulnerable people include blind people, severely disabled, the elderly and the very young.

Normal Adults

For normal adults, the level of risk which is serious depends on whether the hazard is obvious and whether the manufacturer has taken adequate care to make the product safe and to provide safeguards and warnings, especially if the hazard is not obvious. For example, if a product has adequate warnings and safeguards and the hazard is obvious, a high gravity of outcome may not be serious in terms of grading the risk (Table B), although some action may be needed to improve the safety of the product. Conversely, if the product does not have adequate safeguards and warnings, and the hazard is not obvious, a moderate gravity of outcome is serious in terms of grading the risk (Table B).

Figure 3.2 reproduces the RAPEX system for assessing products posing a serious risk.

Figure 3.2: Outline of ITS/RAPEX Risk Assessment Methodology

Risk Assessment of consumer products for the GPSD

This procedure is proposed to assist companies when deciding whether a specific hazardous situation caused by a consumer product requires notification to the authorities

Table A - Risk Estimation

Probability of Health/Safety Damage	Severity of Health/Safety Damage: Slight	Serious	Very Serious	Overall Gravity of Outcome
		Very High	High	Very High
	Very High	High	Medium	High
	High	Medium	Low	Moderate
	Medium	Low	Very Low	Low
	Low	Very Low		Very low

Table B – Grading of Risk

Vulnerable people		Non-vulnerable adults				
Very vulnerable	Vulnerable	No	Yes	No	Yes	Adequate warnings and safeguards?
		No	No	Yes	Yes	Obvious hazard?
SERIOUS RISK – Rapid action required						
Moderate risk – Some action required						
		Low risk – Action unlikely				

Table A is used to determine the gravity of the outcome of a hazard, depending on the severity and probability of the possible health/safety damage (see tables in notes)

Table B is used to determine the rating of the gravity of risk depending on the type of user and, for non-vulnerable adults, whether the product has adequate warnings and safeguards and whether the hazard is sufficiently obvious

Example (indicated by the arrows above)

A chain saw user has suffered a badly cut hand and it is found that the chain saw has an inadequately designed guard which allowed the user's hand to slip forward and touch the chain. The company's assessor makes the following risk assessment.

Table A - The assessment of probability is **High** because the hazard is present on all products and may occur under certain conditions. The assessment of severity is **Serious** so the overall gravity rating is **High.**

Table B – The chain saw is for use by non-vulnerable adults, presents an obvious hazard but with inadequate guards.

The **High** gravity is therefore intolerable so a **serious risk** exists.

3.9 Trial of the ITS/RAPEX Methodology

3.9.1 Summary

A trial of the ITS methodology and the RAPEX Guidelines in 2004 concluded that the method could give rise to significant discrepancies in the assessment of risks (Consumer Safety Institute, 2004). Competent authorities from 18 countries (17 Member States plus Iceland) provided assessments using the ITS/RAPEX methodology for 15 different products. Although most respondents were positive about the procedure, and felt that the resulting assessments were in line with their expectations, several respondents noted difficulties in assessing certain factors, for example:

- for childcare articles, a rapid action is normally required as children are vulnerable consumers so that, according to some respondents, there was no need to make the detailed assessment;
- there was considerable subjectivity in the evaluation of whether the injury is possible or probable;
- the severity of the injury was not always obvious (e.g. in the case of falling, the fracture could be more or less serious, sometimes leading to hospital admission);
- the gap between 10% and 100% probability of a hazardous product was found to be too great;
- in classifying severity, it was advisable to have a column of 'medium' severity between the column 'slight' and 'serious'; and
- the categories for the probability of hazardous products should be broader ranges, e.g. 1-5%; 10-30%; 50-100%; or instructions for rounding off the probabilities are, alternatively, needed.

The study concluded with a series of recommendations. Those concerning the content were:

- adding clear definitions for each factor: the current procedure does not contain clear definitions so that experts need to use secondary sources of information;
- adding guidelines on how to assess each factor, these could take the form of examples;
- preventing ambiguity between different categories, in particular, severity, probability factors and vulnerability; and
- investigating how factors can be defined so that experts can assess them independently.

3.9.2 Examples from CSI Report

A sample of results from the case studies provides some indication of the difficulties noted in the report.

Amongst the case study products are a BMX bicycle, a treadmill and a soft toy. The results for the categorisation of severity, probability that a hazardous product contains the hazard/defect and the probability of injury resulting from exposure for each of these three products are shown in Figure 3.3.

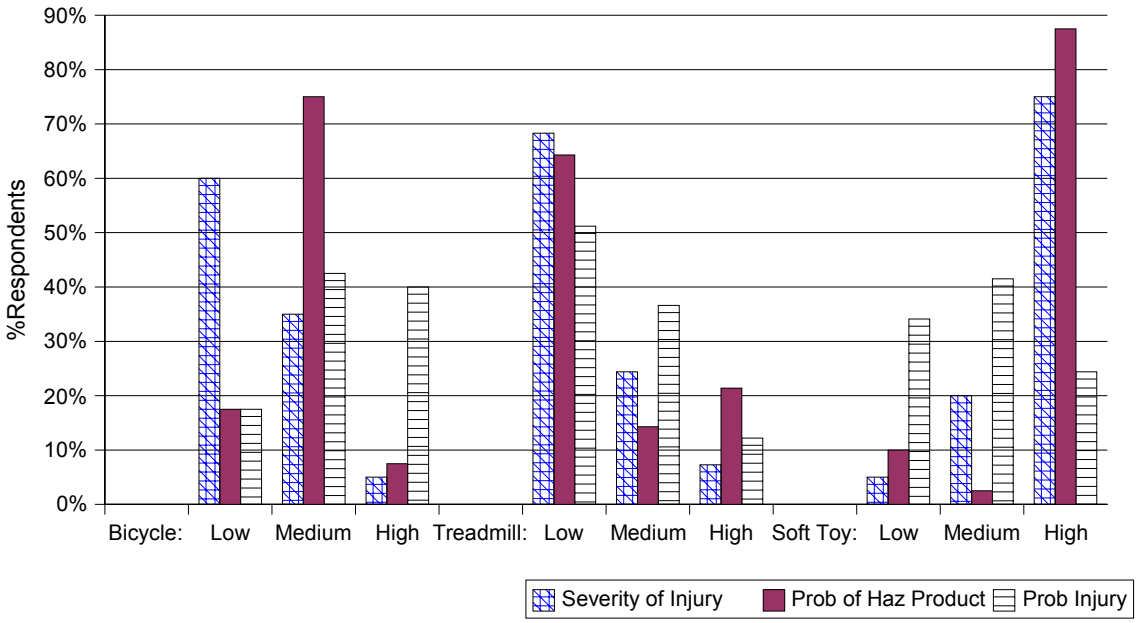


Figure 3.3: Sample Results from Three Case Studies presented in CSI, 2004

Figure 3.3 indicates that 60% or more of respondents categorised the severity of injury in the same manner (i.e. 'low' for the bicycle and the treadmill and 'high' for the soft toy). Similarly, more than 60% of respondents categorised the probability that the hazardous product contained the hazard/defect in the same manner (i.e. 'medium' for the bicycle, 'low' for the treadmill and 'high' for the soft toy).

However, assigning a category to the 'probability of health/safety damage from regular exposure to hazardous product' proved to be more subjective. Opinions were mainly divided between 'medium' and 'high' for the bicycle, and between 'low' and medium' for the treadmill. However, for the soft toys, the responses were about 35%, 40% and 25% for 'low', 'medium' and 'high' respectively.

In the ITS/RAPEX methodology, the 'gravity of outcome' depends on these three factors. Given the uncertainties in assigned scores to each factor, the resultant uncertainty in the 'gravity of outcome' would be expected to be greater and this is illustrated in Figure 3.4. Whilst the resultant categorisation of the associated risk (and need for further action) depends not only on the gravity of outcome but also on the vulnerability of the likely users and whether the hazards are obvious and/or mitigated against (as shown in Figure 3.2), there is less uncertainty associated with these factors.

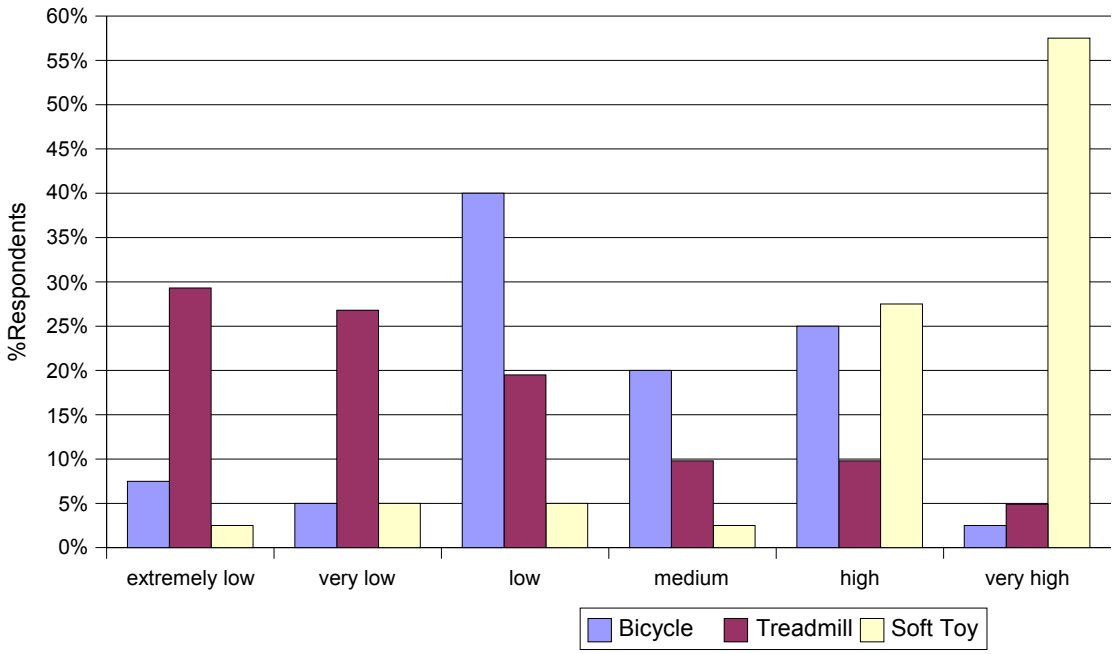


Figure 3.4: 'Gravity of Outcome' for Case Studies presented in CSI, 2004

As indicated in Figure 3.4, there is uncertainty in the predicted 'gravity of outcome' for the sample results presented. This raises the issue as to whether the use of the ITS/RAPEX methodology produces results that are more robust than those that would be generated by, for example, an expert panel.

4. INFORMAL RISK ASSESSMENT METHODOLOGIES

Informal risk assessment has been used in the context of this study to describe less formalised and/or documented procedures which provide an indicative or comparative assessment of risk. As described in Section 2, a number of Member States have adopted these informal risk assessment methodologies (in addition to the formal methodologies) to assess the risks associated with consumer products. These informal procedures include the use of internal and outside experts, or safety boards, and reference to existing product safety standards and legislative requirements.

The informal approaches to risk assessment identified in Section 2 can be broadly divided into two categories:

- *expert panels*: which refer to a group of knowledgeable people who are qualified to pass judgement on a particular product and/or risk; and

- *standards and technical documentation*: which refer to regulatory guidance which set out safety (and other) parameters which products are expected to comply with. These guidance are often used by testing laboratories, manufacturers and authorities.

Table 4.1 below provides a summary of the informal risk assessment methodologies used across the EU and EEA; these methodologies have been discussed in detail in Section 2 under the relevant countries. It should also be noted that the countries below are those which indicated a particular reliance on these informal approaches for regulatory guidance on action to take.

Table 4.1: Informal Risk Assessment Methodologies Across the EU and EEA	
Expert Panel	
Austria	Product Safety Board and external experts (see Section 2.2)
Denmark	Committee of market surveillance (see Section 2.6)
Finland	Expert opinion (see Section 2.8)
France	Consumer Safety Commission (see Section 2.9)
Ireland	Product safety group (see Section 2.13)
Italy	Conference of Services (see Section 2.14)
Poland	Expert panel (see Section 2.20)
Spain	Commission of Co-ordination (see Section 2.24)
Standards and Technical Documentation	
Austria	Testing laboratories
Belgium	Ranking method for specific campaigns (see Section 2.3)
Greece	Reliance on test reports (see Section 2.11)
Luxembourg	Reliance on product notifications by other Member States (see Section 2.17)
Malta	Reliance on risk assessments by other Member States (see Section 2.18)
Slovakia	Informal procedures (see Section 2.22)
Norway	Reliance on manufacturers' obligations See Section 2.29)

5. COMPARATIVE ASSESSMENT OF RISK ASSESSMENT METHODOLOGIES, APPROACHES AND PRACTICES

5.1 Introduction

The methods and approaches to risk assessment outlined in Sections 2 and 3 involve evaluation of a wide range of factors in order to assess the overall level of product safety. In all cases, there is recognition that risk involves consideration of the potential *severity of the consequences* of exposure to a hazardous product and the *probability (or likelihood) of such consequences occurring*. Some methods focus on individual risk (i.e. the risk to an individual consumer) whilst others take account of the extent of usage of a product, reflecting the societal risk to consumers in general.

This Section provides a comparative assessment of the formal risk assessment[9] methodologies identified in Section 3, followed by an assessment of the informal approaches and the overall framework (approach and practice) for ensuring product safety across Member States.

5.2 Comparative Assessment of Formal Risk Assessment Methodologies

5.2.1 Severity of Consequences

The majority of the formal risk assessment methodologies utilise a 'severity of consequences' factor based on consideration of the effects upon a single consumer (individual risk). The notable exception is the Belgian Risk Matrix, which includes extreme events where a product could result in many deaths (of both consumers and bystanders).

The focus of product risk assessment methodologies is primarily on those events which result in immediate acute effects (e.g. cuts and fractures). Clearly, some products may have the potential to cause adverse effects in the longer term due to exposure to, for example, harmful chemicals. The ability and relevance of risk assessment methodologies for consumer products (such as RAPEX) in addressing such hazards is clearly restricted.

Addressing longer-term hazards of products is also an issue in relation to product standards. Although in theory, standards should set out clear requirements concerning all types of product risk and specify methods by which compliance could be judged, this is not always the case in practice. Where there is no agreed method to measure the level of hazardous substance(s) within a product (for example, flame retardants in furniture, where the harmful effects of the chemical can arise many years after exposure), then the risk cannot be assessed and evaluation is based on hazard rather than risk.

[9] While consideration was given to the UK LACORS system in Section 3, this methodology does not lend itself to a product-based risk assessment and, as such, is not considered further in the context of this study.

5.2.2 Probability of Occurrence

Each of the formal risk assessment methodologies considered has a slightly different approach to the probability of occurrence.

The Czech Risk Matrix has a single factor: scale of injury (which is based on an actual event or occurrence, for instance, a 'probable' injury means that at least one eye witness account is available about the damage occurrence).

The Slovenian Nomograph utilises two factors: 'probability of occurrence' (based on available failure rate data or product testing) and 'hazard recognition' (in which the average adult is assumed to take corrective action where potential hazards are recognised). In other words, where hazards are obvious, it assumes that some action will be taken by the average adult consumer to avoid the risk. The Belgian Risk Matrix also has two factors: probability of occurrence (per exposure) and level of exposure (number of times used per unit time).

The ITS/RAPEX Methodology also uses two factors: probability of occurrence of a risk-causing defect (per product) and probability that a consumer will experience a risk under regular exposure to the product. It also factors in the provision of warning signs/safeguards to assist consumers in avoiding the risk and whether the hazard is obvious (in a similar way to the Slovenian Nomograph).

5.2.3 Resultant Risk

Consideration of Vulnerable Groups

Although not considered as a separate factor in the Slovenian Nomograph, the exposure of vulnerable groups (such as young children, elderly and disabled) to the product is considered in assigning a 'severity of consequence' score. In this case, there is the potential to make a double risk assessment if the severity of the potential injury to the disadvantaged (children 0 to 4 years old, the elderly and disabled) is likely to be greater than to the average consumer.

The exposure of vulnerable groups is explicitly considered in the ITS/RAPEX methodology. As illustrated in Figure 3.2, under the current RAPEX guidelines all products used by vulnerable people will at least be classified as having a 'moderate risk' (thus requiring at least some action) whatever the 'gravity of outcome'.

The Belgian and Czech approaches do not explicitly account for vulnerable groups in determining the risk. However, in the evaluation of the resultant risk, the Czech guidance specifically requires consideration as to whether the risk is to vulnerable groups.

Individual vs Societal Risk

The Belgian and Czech Risk Matrices do not account for product usage; nor does the ITS/RAPEX methodology. As such, these methods provide an estimate of the individual risk associated with the product.

The extent of product usage is explicitly addressed in the Slovenian Nomograph; the initial risk assessment is taken a step further by indicating the availability of the product on a scale (rare, limited, general, very high) to provide a final risk assessment result. As such, this method provides an estimate of the societal risk associated with the product.

5.2.4 Commentary

The above summary indicates that all the formal methodologies considered account for a range of risk factors and each is semi-quantitative, based on a multi-criteria analysis approach where the various factors are scored on a pre-defined scale and the scores combined to give an overall risk rating. The attraction of such an approach is that it can be developed by experts to reflect their collective expertise and yet be used by those with limited experience, to generate results which are expected to be consistent with those that would be generated by experts.

A methodology which explicitly accounts for a number of relevant contributory factors (such as the Slovenian Nomograph or the ITS/RAPEX methodology) might be expected to be more robust than a simple two dimensional matrix - such as the Czech Risk Matrix. However, as the review of the ITS/RAPEX methodology (CSI, 2004) illustrates, the subjective and uncertain rating of numerous factors can result in highly uncertain answers which may, in the end, be of no greater value than using a simple qualitative risk matrix or, indeed, the views of an expert panel (for instance, in Austria and Finland (see Section 2)).

5.3 Comparative Assessment of Informal Approaches

As discussed in Section 2, a number of Member States have adopted formal but undocumented, or informal procedures (in addition to the formal methodologies) to assess the risks associated with consumer products. These informal procedures include the use of internal and outside experts, or safety boards, and reference to existing product safety standards and legislative requirements.

In those countries where reliance is placed upon an expert panel, it is expected that the *severity of consequence* of exposure to a hazardous product and the *probability of occurrence* will be considered in any risk assessment process.

In considering the merits of expert panels, it should be borne in mind that formal risk methodologies rely significantly (albeit, to varying extents) on the users' subjective judgement, with the user assumed to be a fairly competent individual (although in most cases, users have limited expertise relating to the product or methodology). It could thus be suggested that there may not be a significant difference in terms of product safety

between the results of an expert panel consisting of highly knowledgeable people in the product or field concerned compared with those from a formal methodology.

The arguments in favour of informal approaches are that, compared with formal approaches, they:

- provide a pragmatic and safe solution to be arrived at where there are conflicting or diverging risk conclusions (arising sometimes from the formal methodologies);
- help to define an acceptable safety level of a consumer product (where the approach involves reliance on standards and legislation);
- allow authorities to ensure that the results of a formal risk assessment are robust, for instance, where the product involves vulnerable age groups;
- enable authorities to avoid direct legal action as a first recourse especially when such action can be complicated and expensive for authorities; and
- reflect more appropriately the administrative set up of the country (for instance, where there is an inter-departmental system of ensuring product safety or where emphasis is placed on preventative methods such as issuing guidance notes to manufacturers, etc.).

Drawbacks relating to informal approaches range from the lack of transparency relating to the risk results obtained, the potential lack of consistency relating to a case by case approach and the lack of a systematic use of statistical data.

In general, authorities with extensive risk assessment experience expressed the view that product risks should not be assessed using any single risk assessment method. Instead a range of methods should be used, which take a broad range of aspects for determining risk into account.

5.4 Comparative Assessment of Overall Approach to Product Safety

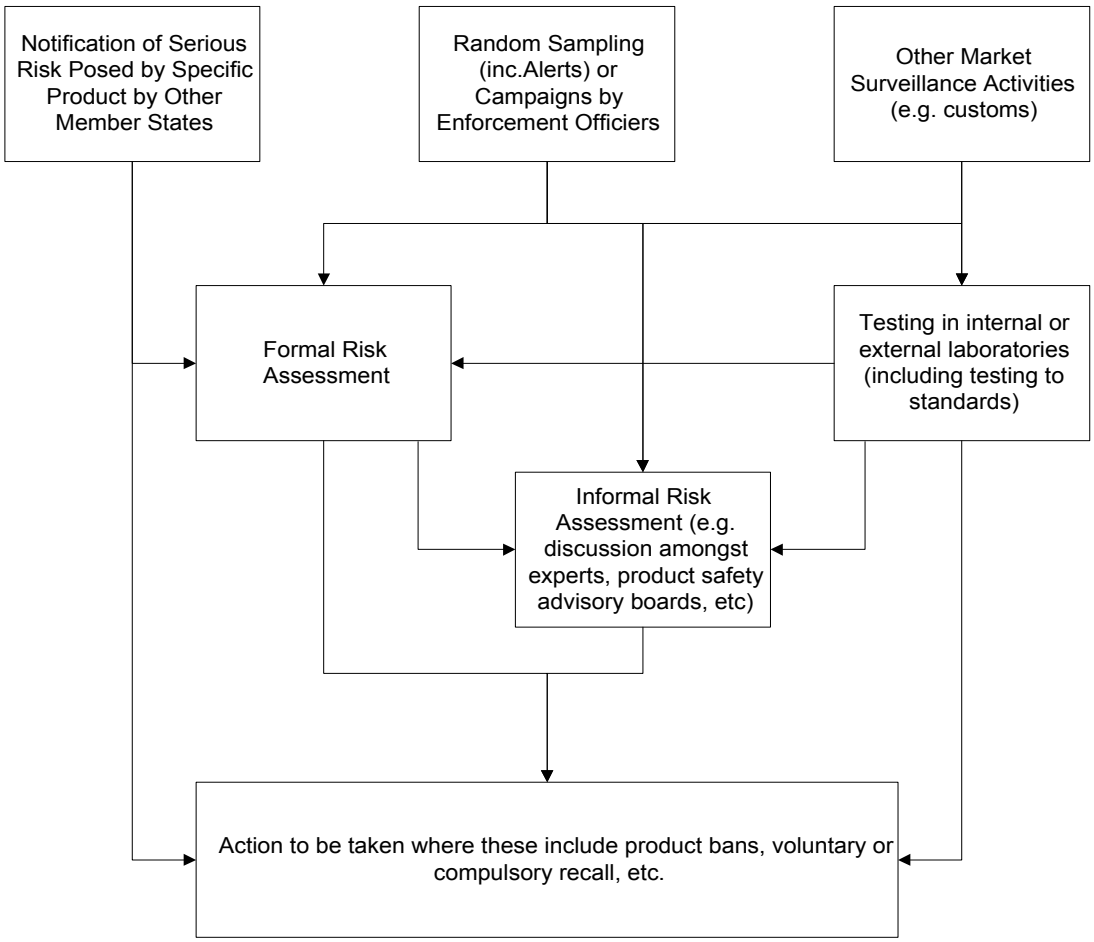
5.4.1 Overall Approach

Figure 5.1 provides an overview of the approaches, methods and practices for ensuring product safety employed across the EU. The figure highlights the role, position and relationship between formal risk assessment methodologies, informal approaches and product (or conformity assessment) testing. Consultation with Member States indicates that one or more of the routes described in the flow chart is used by all Member States to arrive at the appropriate action to be taken to ensure product safety.

It should be borne in mind that, while there is an obligation for Member States to organise and carry out market surveillance under the GPSD, there is no single model for market surveillance and system of enforcement. As noted at the DG Sanco Conference on Market Surveillance (2005), the approaches, means, instruments and practices for

market surveillance and enforcement are in general very diverse, sometimes rooted in varying internal institutional and administrative systems which have developed over many years.

Figure 5.1: Description of Overall Approach to Ensuring Product Safety in the EU



5.4.2 Differences and Divergences

Across the EU, there are key differences and divergences in the approaches, methods and actual practices used by surveillance and enforcement authorities, as well as conformity assessment bodies, for the assessment of the safety of consumer goods. Indeed, the role of risk assessment in the overall context of ensuring consumer safety in the EU varies from Member State to Member State (as discussed in Section 2).

The main differences in the overall process of ensuring consumer safety arise from:

- **The presence or absence of a legislative framework for the product(s) involved**. For products which are the subject of sector-specific legislation, testing to ensure compliance with specified standards is the first step in ensuring product safety. One authority noted that sector-specific legislation and standards intrinsically provide a

strong indication of the level of safety expected from a product. Thus, where a product is deemed to fail a specific test, action is generally required without further need for a (formal) risk assessment; although in some cases, further discussion amongst experts or product safety committees (i.e. an informal risk assessment) may be used. The Nordic Failure Code for electrical products (see Section 3.4.4) illustrates a more sophisticated approach to the use of test results.

Where EU-wide legislation or harmonised standards are in place, these potentially provide a common basis for evaluating the risks associated with a product across the EU (although there are still difficulties and differences). Where legislation or standards are adopted at the national level, there is clearly potential for different approaches between Member States. This is even more the case where there are no relevant regulations or standards, as there will be no common basis against which producers and distributors can assess the safety of a product. In such cases, judgements on safety tend to be either subjective or based on risk assessment criteria read across from other related sectors or products. It is worth noting that three of the products most commonly notified through the RAPEX system are covered by vertical legislation: electrical products (LVD), toys and cosmetics.

- **Variations in organisational structure and method of enforcement in Member States**. The organisational structure in various Member States also influences the approach and practice of risk assessment. In some countries, different authorities are responsible for assessing the safety of different products. In this case, it is likely that they will have an in-depth knowledge of potential risks and regulatory requirements associated with particular products and may have sufficient expertise to make use of informal approaches to risk assessment. In other Member States, the same authority is responsible for ensuring the safety of a wide range of products. It will be impossible for such authorities to understand the risks and regulatory frameworks for all products in depth; there may thus be a greater need for formal risk assessment approaches. On the other hand, such authorities may have a better grasp of overall product safety assessment from dealing with a wider variety of products. Some countries also have a cross-sectoral system of product safety surveillance where there may be two or three authorities responsible for the safety of one product, albeit covering different safety aspects.

- **Other factors**. These include the costs of undertaking product testing and the level of understanding and awareness of risk assessment. Product tests generally incur significant costs for enforcement and surveillance authorities, who often have limited funds. The result is that some Member States do not undertake significant product testing or risk assessment but rely mainly on enforcing notifications by other Member State (e.g. Luxembourg). Other Member States have the resources to focus on only a limited number of products at any particular time (e.g. Belgium). Similarly, some authorities have considerable expertise in risk assessment and have the ability to develop and apply reasonably sophisticated approaches. Others rely on approaches developed elsewhere and require a significant level of guidance to apply risk assessment methodologies effectively.

6. ASSESSING THE NEED FOR FURTHER DEVELOPMENT OF RISK ASSESSMENT METHODS - A CASE STUDY APPROACH

6.1 Overview

6.1.1 Introduction to Case Studies

This Section is aimed at assessing the implications of the differences and divergences in risk assessment methodologies in the context of product safety and, thus, the need for further development of risk assessment methods. A case study approach has been adopted.

The aim of case studies is to demonstrate more specifically the implications of differences in risk assessment approaches, methods and practices for specific products. By describing specific products, and the particular assessment undertaken, it is possible to provide a better picture of the significance of differences in risk assessment methodologies and to highlight cases where the methods currently used may lead to divergent risk assessment conclusions. It also enables account to be taken of the actual results achieved by different practices and risk assessment methodologies, which can otherwise be difficult to determine and/or separate from other regulatory differences.

6.1.2 Selected Products

At the GPSD Committee Meeting held in Brussels in June 2005, a questionnaire was circulated among the Competent Authorities requesting their contribution in selecting and providing information on specific products to be examined as case studies. The case studies are intended to reflect product areas where:

- regulatory authorities and testing bodies have experienced difficulties or disagreements in testing and risk assessment methodologies;
- accidents are still occurring related to a specific product, which authorities are trying to address; and/or
- authorities feel there is a need for further guidance or development of risk assessment methods.

Based on the feedback received[10], the following products have been selected as case studies to be examined in this study:

- Case Study 1: Cots;
- Case Study 2: Push chairs;
- Case Study 3: Swings;
- Case Study 4: Climbing frames;
- Case Study 5: Foldable ladders;
- Case Study 6: Chainsaws;

[10] From 11 Member States.

- Case Study 7: Roller skates;
- Case Study 8: Dolls; and
- Case Study 9: Children's clothing with strings.

For each of these products, the case studies describe:

- the main **hazards** associated with the product which are of importance to its safety;
- **current regulatory requirements**, including EU/national legislation and standards, which influence how the product is regulated by the authorities;
- results and conclusions of **particular risk assessment or testing methodologies** undertaken for the product; and
- **implications of different approaches** and divergences in risk assessment conclusions in terms of ensuring consumer safety, as well as the need for further development of risk assessment methodologies.

6.1.3 Selected Risk Assessment Methods

The case studies have been used to test three of the formal risk assessment methodologies described in Section 3. The purpose of this testing is to illustrate the differences in the results derived from the use of different methods and to explore the reasons for such differences. This approach enables recommendations to be made as to the desirable characteristics of best practice in a product risk assessment. The selected methods are:

- the **RAPEX methodology**, given its importance in the RAPEX system and its widespread use;

- the **Slovenian Nomograph**, which appears to be the most comprehensive of the other formal methodologies. It is also the only methodology that explicitly accounts for the numbers of products on the market; however, the availability of the products on the market was (effectively) disregarded to facilitate comparison with the other two methods being assessed[11]; and

- the **Belgian Risk Matrix**. Although this method is still under development, it offers some interesting features. It is relatively simple, but offers a wider range of potential scores for each of its three factors compared with the other methodologies. This may reduce the level of subjectivity in the scoring and thus the relative uncertainty in the overall answer, providing there is clear guidance on the scoring system.

As noted earlier, the UK LACORS system does not lend itself to a product-based risk assessment and, as such, is not considered further. It was also considered that a methodology which explicitly accounts for a number of relevant contributory factors (such as the Slovenian Nomograph or the RAPEX methodology) would be more robust for the purposes of this study rather than a simple two dimensional matrix - such as the Czech Risk Matrix – which may be of practical use in the field for initial screening of risks.

[11] In the case studies, general availability of the product has been assumed which results in the same numerical value for the 'initial' and 'final' risk assessments.

6.2 Childcare Articles

6.2.1 Introduction

Background to Case Study

By their nature, childcare articles are targeted at a vulnerable group of the population, children. As a result, some EU Member States have adopted legislation and/or standards[12] relating to specific childcare articles. In the UK for example, the *Wheeled Child Conveyances (Safety) Regulations (1997)* govern the supply/sale of both new and second hand prams, push chairs and similar child conveyances. The regulations lay down specifications for the materials, construction and design of such products and are intended be used along with relevant standards, which provide specific guidance.

The responses of regulatory authorities to consultation identified two key factors as posing challenges in ensuring the safety of childcare articles. These were:

- lack of legislation on childcare articles; and
- overlap with other criteria, such as hygiene, which are subject to separate regulation.

In 2004, eight surveillance authorities undertook a joint exercise to assess the presence of dangerous cots on the EU market, amongst other objectives. A key finding of this study was that many cots on the market do not comply with the safety standards (EN 716). Over 900 children's cots were inspected and around 150 were selected for testing at a laboratory; around 50% of the tested cots did not meet the standards. Typical problems included lack of instructions, no recommendations on size of mattress, inappropriate distances between bedbase and ends, vertical bars breaking during inspection, etc.

According to ECOSA (2004), cot accidents usually involve or are a result of:

- corner posts, which pose a strangulation hazard as children's clothing or other items catch on them, especially if the child is trying to climb out; and

- cot design, which may cause a strangulation/suffocation hazard if it creates openings that can entrap a child.

Cots and **pushchairs** have been highlighted as products where accidents are still occurring, which authorities are trying to address; these two products will thus be examined as case studies under childcare articles. In this context, the case study aims to determine whether the risk assessment methods currently used lead to divergent conclusions and whether there is a need for further development of risk assessment methodologies for cots and pushchairs to ensure child safety.

[12] The relevant European standard for push chairs is EN1888 (*Child care articles - Wheeled child conveyances*) while that for cots is EN 716 (*Furniture - Children's cots and folding cots for domestic use*).

Case Study 1: Cots

Hazards Considered

For the comparative analysis of the three methodologies, three hazards for a hypothetical cot were selected:

1. vertical bars too far apart, permitting baby's head to become trapped (design fault);
2. wooden bars on the cot having splinters (quality control failure); and
3. small holes present in frame (for adjusting the height of opening side) which could harm fingers (design fault).

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.1, 6.2 and 6.3 respectively.

Table 6.1: RAPEX Assessment for Case Study 1 (Cots)			
Hazard	**1**	**2**	**3**
Severity (description)	**Head trapped**	**Splinter (in hand)**	**Finger trapped**
Severity (category)	*Slight*	*Slight*	*Slight*
Prob. of hazardous product	100%	10%	100%
Prob. of harm from exposure	likely to occur	likely to occur	likely to occur
Prob. of Harm	*Very high*	*High*	*Very high*
Gravity of Outcome	*High*	*Moderate*	*High*
Vulnerable people?	Yes – very	Yes – very	Yes – very
Adequate warnings?	n/a	n/a	n/a
Obvious hazard?	n/a	n/a	n/a
Risk Result	**Serious risk - rapid action required**		
n/a: not applicable			

Table 6.2: Nomograph Assessment for Case Study 1 (Cots) - see also Figure 6.1			
Hazard	**1**	**2**	**3**
Injury (description)	**Head trapped**	**Splinter (in hand)**	**Finger trapped**
Injury (category)	Moderate[1]	Minor	Minor
Prob. (occurrence)	Highly probable	Probable[2]	Highly probable
Hazard Recognition	Improbable	Probable	Possible
Initial Risk Assessment	**75**	**24**	**47**
Availability	General	General	General
Final Risk Assessment	**75**	**24**	**47**
Risk Category	**High/Very High**	**Extremely Low/ Very Low**	**Moderate**
Notes: *1) The 'moderate' injury category was selected due to potential bruising of the larynx.* *2) Since most cots do not have the hazard, the probability of occurrence for Hazard 2 is lower than for the other two hazards.*			

Table 6.3: Risk Matrix Assessment for Case Study 1 (Cots)			
Hazard	**1**	**2**	**3**
Consequences (description)	**Head trapped**	**Splinter (in hand)**	**Finger trapped**
Consequences (E)	3 (cuts, etc.)	1 (minor)	1 (minor)
Prob. of Occurrence (W)	10 (almost certain)	6 (very possible)	10 (almost certain)
Exposure (B)	6 (daily)	6 (daily)	6 (daily)
Risk = E x W x B	**180**	**36**	**60**
Risk Level	**High**	**Possible**	**Possible**
Action Required	**Immediate measures**	**Attention**	**Attention**

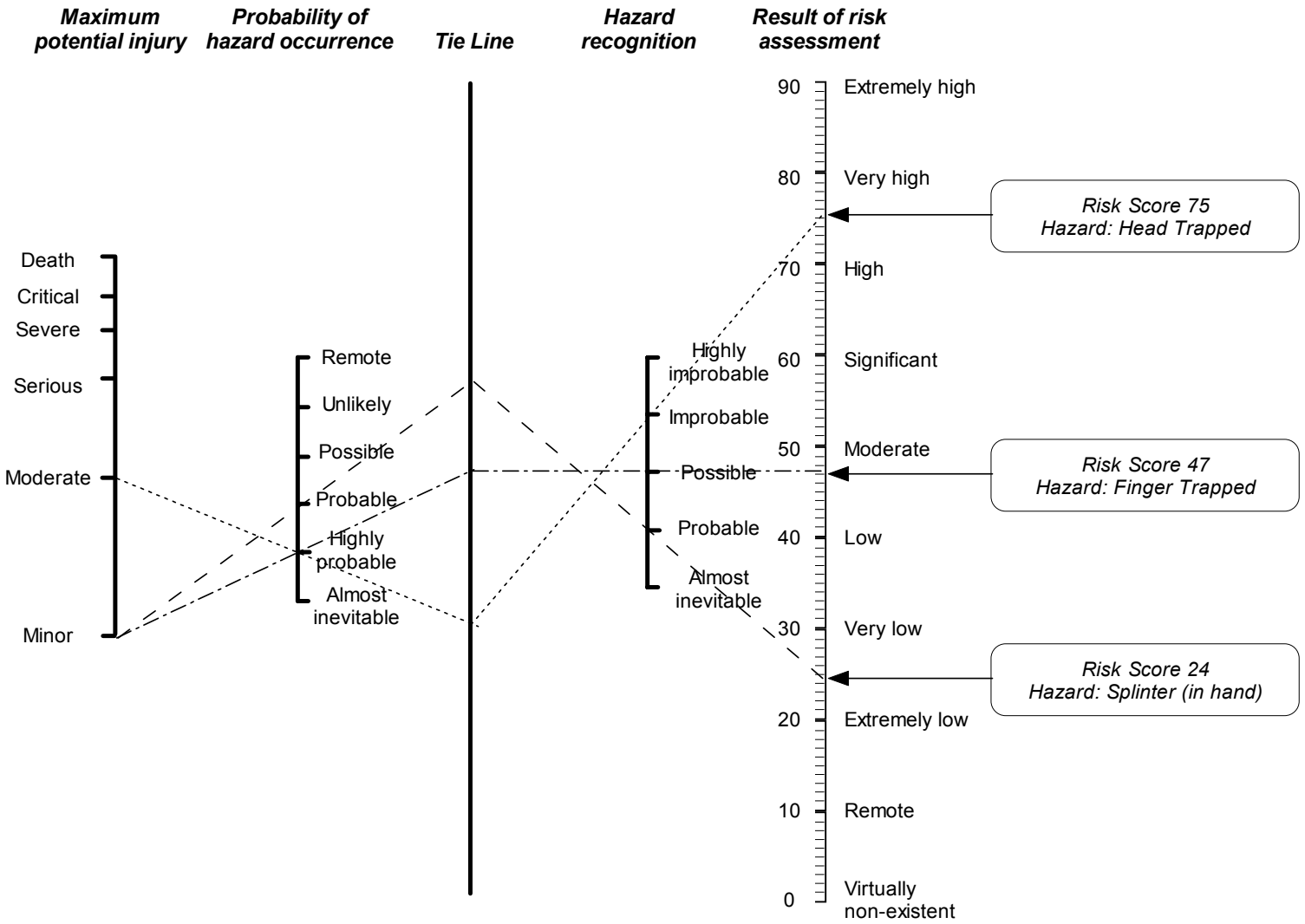


Figure 6.1: Example Application of Nomograph to Cots (Case Study 1)

Case Study 2: Push Chairs

Hazards Considered

A range of potential hazards are associated with push chairs. These are often compounded by the design requirement that a push chair can readily be folded up for easy storage. In a recent US example, over 500 reports of two stroller (push chairs) models collapsing unexpectedly have been recorded (US CPRC, 2005).

For the comparative analysis of the three methodologies, two hazards associated with design and/or construction for a hypothetical push chair were selected:

1. locking latches may not function, causing push chair to collapse leading to potential for bruising, cuts and, possibly, fractures;
2. loss of plastic covers may expose sharp edges, leading to cuts on fingers.

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.4, 6.5 and 6.6 respectively.

Table 6.4: RAPEX Assessment for Case Study 2 (Push Chairs)		
Hazard	**1**	**2**
Severity (description)	**Serious cut/fracture**	**Finger cut**
Severity (category)	*Serious*	*Slight*
Prob. of hazardous product	10%	10%
Prob. of harm from exposure	may occur	likely to occur
Prob. of Harm	*Medium*	*High*
Gravity of Outcome	*Moderate*	*Moderate*
Vulnerable people?	Yes – very	Yes – very
Adequate warnings?	n/a	n/a
Obvious hazard?	n/a	n/a
Risk Result	**Serious risk - rapid action required**	

Table 6.5: Nomograph Assessment for Case Study 2 (Push Chairs)		
Hazard	**1**	**2**
Injury (description)	**Serious cut/fracture**	**Finger cut**
Injury (category)	Moderate	Minor
Prob. (occurrence)	Possible	Probable
Hazard Recognition	Highly improbable	Possible
Initial Risk Assessment	**66**	**36**
Availability	General	General
Final Risk Assessment	**66**	**36**
Risk Category	**Significant/High**	**Very Low/Low**

Table 6.6: Risk Matrix Assessment for Case Study 2 (Push Chairs)		
Hazard	**1**	**2**
Consequences (description)	**Serious cut/fracture**	**Finger cut**
Consequences (E)	3 (cuts, etc.)	1 (minor)
Prob. of Occurrence (W)	3 (unlikely)	3 (unlikely)
Exposure (B)	6 (daily)	6 (daily)
Risk = E x W x B	**54**	**18**
Risk Level	**Possible**	**Slight**
Action Required	**Attention**	**Perhaps acceptable**

6.2.2 Analysis

Table 6.7 below summarises the results of the three risk assessment methodologies for the cots case study.

Table 6.7: Summary of Assessments for Case Study 1 (Cots)			
Hazard	**Bars too far apart**	**Splinters**	**Small holes in frame**
Present on all products?	Yes	No	Yes
Consequences	Head trapped	Splinter (in hand)	Finger trapped
Result of Risk Assessments			
RAPEX	Serious risk - rapid action required		
Nomograph	High/Very High Risk	Extremely Low/Very Low Risk	Moderate Risk
Risk Matrix	High risk - immediate measures required	Possible risk - attention required	

For each of the three hazards considered, the **RAPEX methodology** results in a conclusion of 'serious risk' requiring rapid action - primarily because there is a possibility of harm to a 'very vulnerable' consumer (i.e. a very young child). It should be noted that 'hazard recognition' is only explicitly accounted for in the RAPEX methodology when the consumer is a 'normal adult'.

In contrast, a key feature of the **nomograph** is the potential for the consumer to recognise the presence of the hazard. In this example, it is considered that parents are likely to appreciate the hazard potential of splinters (Hazard 2) and may appreciate the potential hazard of small holes into which their child may place a finger (Hazard 3) but are less likely to appreciate the potential for their child's head to become trapped between the bars (Hazard 1). The selection of the corresponding 'hazard recognition' categories has a direct and significant impact upon the result of the risk assessment.

Table 6.8 below summarises the results of the three risk assessment methodologies for the push chairs case study. For each of the two hazards considered, the **RAPEX methodology** results in a 'serious risk' requiring rapid action due, as before, to the possibility of harm to a very vulnerable consumer. Notably, the **nomograph** and **risk matrix** result in a very low or slight risk for Hazard 2 (*sharp edges exposed*). As with the cots case study, the potential for the consumer to recognise the presence of the hazard affects the risk result derived using the nomograph.

Table 6.8: Summary of Assessments for Case Study 2 (Push Chairs)		
Hazard	**Latches may fail**	**Sharp edges exposed**
Present on all products?	No	No
Consequences	Bruising, cuts and, possibly, fractures	Cut finger
Result of Risk Assessments		
RAPEX	Serious risk - rapid action required	
Nomograph	Significant/High Risk	Very Low/Low Risk
Risk Matrix	Possible risk - attention required	Slight risk - perhaps acceptable

The case studies on childcare articles highlight divergences in the conclusions of the three risk assessment methodologies used; these divergences are influenced significantly by the risk assessors' judgement regarding the consumers 'hazard perception', which could vary from assessor to assessor. The risk assessment methodologies also highlight a fundamental difference in risk acceptability. The RAPEX methodology effectively treats any risks to children as being unacceptable, whereas the nomograph assumes that parents have a significant influence on the actual risk posed by the product to their children.

The conclusion of the RAPEX methodology that 'rapid action' is required for a potential finger cut could be questioned. If the RAPEX methodology is excluded from the analysis, there is a significant similarity in the results of the risk matrix and the nomograph across the hazards considered.

In practice, it is likely that an initial assessment of the risk posed by the products would be undertaken by comparing the products with the requirements of the relevant standards (EN 716 and EN1888). In cases of non-compliance, the use of formal risk assessment methodologies (such as RAPEX) provides one option for deciding on the appropriate enforcement action to take. Where such an approach is adopted, the divergences in risk conclusions could either result in too little enforcement action, leading to residual risks to children (if RAPEX is right) or in unnecessarily stringent action against child-focused products (if the nomograph is right).

In both cases, though, the fact that a product did not meet the relevant standards would indicate that there was a risk and thus that some remedial action is necessary. Where standards are in place, these generally provide the basis for consensus amongst stakeholders. The divergence in conclusions between the risk assessment methodologies is likely to affect only the rate at which such action is taken, limiting the potential impact on safety of the product.

The hazards which have been examined in the context of this study all assume that the fault is related to the design of the childcare article. In practice, a number of accidents are related to the behaviour of the child in the product (for instance, children climbing out of cots). Whilst both standards and risk assessment methodologies aim to assess product safety in the context of foreseeable behaviour, they may not address all factors affecting the risk. For example, the strangulation hazard posed by children's clothing catching on corner posts or knobs as the child is trying to climb out can be increased by the nature of the clothing (e.g. the presence of strings). Assessing the cumulative risk of cots and children's clothing could result in an entirely different risk ranking. None of the methodologies identified provides an explicit basis for assessing such cumulative risks. Instead, each hazard is assessed separately.

The case studies on childcare articles, however, highlight the role of the GPSD as a safety net for products and risks not covered by sector-specific legislation. While the standards provide specific guidance to be complied with by manufacturers, the GPSD provides a framework for regulatory action in cases of infringement.

6.3 Playground Equipment

6.3.1 Introduction

Background to Case Study

Play equipment such as swings, slides and climbing frames, may be used either in consumers' homes and gardens (i.e. domestic use) or in a formal playground. The Toy Safety Directive (TSD) covers play equipment (swings, slides and similar activity toys) for indoor and outdoor domestic use; there is, however, no specific legislation covering other playground equipment.

There are two relevant harmonised standards for the safety of playground equipment, which came into force in January 1999. EN 1176 *Playground Equipment* covers the design, manufacture and installation of playground equipment and is published in seven parts. A further four parts are due to be introduced at some point in the future (RoSPA, nd). EN 1177 *Impact absorbing playground surfacing: Safety requirements and test methods,* specifies the requirements for surfacing in children's playgrounds and the methodology for its testing.

The Netherlands appears to be the only EU Member State to have a formal method of regulating the safety of playground equipment. The *Decree on the Safety of Fairground and Playground Equipment (1996)* prescribes design, operation and maintenance regimes. All equipment entering the Dutch market must obtain a certificate of type approval, and the Dutch Government has appointed a limited number of test houses entitled to issues these certificates. In the Netherlands, the European standards EN 1176 and EN 1177 are used to guide the approval process, but the final assessment is based on the requirements of the Decree.

In other Member States, more general national legislation may also cover the safety of playground equipment, although this is more likely to be associated with the provision of playground equipment as a service rather than a product. It is therefore limited to, for example, maintenance of the playground. In the UK, playgrounds are covered by the 1974 Health and Safety at Work Act, which covers visitors to premises, including the public and their children (Ball, 2002). Responsibility for safety therefore tends to fall upon the owner of the playground, which is often the local authority. Similar requirements are in place in Sweden, with the owner of the playground ultimately responsible for its safety, and for compliance with the Planning and Building Act. Reports from the UK (HSE, 2002) and Sweden (KO, 2002) suggest that market surveillance inspections of playgrounds are undertaken on a regular basis.

Number of Accidents

Data from the Health & Safety Executive (HSE) in the UK suggest that there is a significant number of accidents to children in playgrounds due to fixed play equipment (approximately 41,700 in 1998). There is one fatal accident every three to four years. Research in the UK (Ball, 2002) concluded that the risk of injury in UK playgrounds was

modest in comparison with the risks of other activities undertaken by children. The main risk factors were identified as behaviour, equipment height and body orientation in falls to the ground.

KO (2002) suggests that the safety of a playground is a complex interaction between many different factors, with the type of surface, the type of equipment and the height of the equipment being the most important. In Sweden, 15% of playground injuries were the result of poor design, unsuitable positioning or inadequate maintenance of equipment (excluding the ground surface) (KO, 2002). More specifically, Ball (2002) notes that a review of international studies of playground risk factors shows that equipment height, irrespective of other factors, is the most significant factor contributing to injuries; a height restriction of 1.5 metres is commonly suggested.

Types of Injuries

Deaths in playgrounds may result from strangulation (e.g. being caught in rope swings or clothing drawstrings), falls, collisions, asphyxiation, piercing wounds and maintenance activities (Ball, 2002). Such causes may not be directly related to the playground equipment. Fractures are generally regarded as the most serious of the commonly occurring injuries in playgrounds. However, Ball (2002) notes that skeletal fractures, which are very common in childhood, are not universally regarded as serious. This observation is supported by Swedish data, which note that more than half of the injuries are fracture, dislocation of joints or concussion. However, KO (2002) suggests that playground injuries are generally more serious than other accidents to children.

Equipment-related Accidents

Ball (2002) reports that, in the UK, the main locations where equipment-related playground accidents occur are public playgrounds, parks, schools, pubs (public houses) and (fast-food) restaurants. Similar observations are made in Sweden (KO, 2002). KO (2002) notes that over 75% of accidents occur when children are using swings, climbing frames or slides, and Ball (2002) suggests that accidents are fairly evenly distributed amongst these pieces of equipments. The most common cause in all cases is a fall, but behavioural factors are also important; most significantly in the case of swings, as well as being hit by the equipment in some way (although this is more common for seesaws, which are not considered here). Two case studies are examined under playground equipment, **swings** and **climbing frames,** with a focus on their domestic use.

Respondents to our consultation identified the main factors posing challenges for assessing the risks associated with playground equipment were the complexity of the legal framework in certain Member States and the fact that little testing was carried out. As noted earlier, the regulatory frameworks and associated standards for ensuring the safety of playground equipment used in the domestic situation vary significantly from that for the non-domestic situation, despite the fact that swings and slides are involved in accidents both in domestic gardens and in public parks.

Case Study 3: Swings

Hazards Considered

Although most accidents involving swings are not related to equipment failure, such failures are not unknown. In 2000, the US Consumer Product Safety Commission recalled 7,000 play sets following seven reports of chain swings breaking during use. For the comparative analysis of the three methodologies, two hazards associated with design and/or construction of a swing were selected:

1. supporting chain may break, causing a child to fall; and
2. use of a heavy seat may cause injury (when child gets hit by a moving swing).

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.9, 6.10 and 6.11 respectively.

Table 6.9: RAPEX Assessment for Case Study 3 (Swing)		
Hazard	**1**	**2**
Severity (description)	**Serious cut/fracture**	**Bruising**
Severity (category)	*Serious*	*Slight*
Prob. of hazardous product	(less than) 1%	100%
Prob. of harm from exposure	may occur	may occur
Prob. of Harm	*Low*	*High*
Gravity of Outcome	*Low*	*Moderate*
Vulnerable people?	Yes[1]	Yes
Adequate warnings?	n/a	n/a
Obvious hazard?	n/a	n/a
Risk Result	**Moderate risk - some action required**	**Serious risk - rapid action required**
Note *1) Young children (3-11) are classified as vulnerable, whereas younger children are classified as 'very vulnerable' - as in the previous examples.*		

Table 6.10: Nomograph Assessment for Case Study 3 (Swing)		
Hazard	**1**	**2**
Injury (description)	**Serious cut/fracture**	**Bruising**
Injury (category)	Moderate	Minor
Prob. (occurrence)	Unlikely	Possible
Hazard Recognition	Highly improbable	Possible
Initial Risk Assessment	**56**	**25**
Availability	General	General
Final Risk Assessment	**56**	**25**
Risk Category	**Moderate/Significant**	**Extremely Low/ Very Low**

Table 6.11: Risk Matrix Assessment for Case Study 3 (Swing)		
Hazard	**1**	**2**
Consequences (description)	**Serious cut/fracture**	**Bruising**
Consequences (E)	3 (cuts, etc.)	1 (minor)
Prob. of Occurrence (W)	1 (improbable)	3 (unlikely)
Exposure (B)	3 (weekly)	3 (weekly)
Risk = E x W x B	**9**	**9**
Risk Level	**Slight**	**Slight**
Action Required	**Perhaps acceptable**	**Perhaps acceptable**

Case Study 4: Climbing Frames

Hazards Considered

For the comparative analysis of the three methodologies, two hazards for a hypothetical climbing frame were selected:

1. lack of warning about sitting on hazard surfaces (design fault) increases risks associated with falls; and
2. sharp surfaces (on some products due to inadequate quality control) leads to potential for cuts.

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.12, 6.13 and 6.14 respectively.

Table 6.12: RAPEX Assessment for Case Study 4 (Climbing Frame)		
Hazard	**1**	**2**
Consequences (description)	**Fractures (requiring hospital treatment)**	**Cuts**
Severity (category)	*Serious*	*Slight*
Prob. of hazardous product	100%	10%
Prob. of harm from exposure	only occurs under several improbable conditions	may occur
Prob. of Harm	*Medium*	*High*
Gravity of Outcome	*Moderate*	*Moderate*
Vulnerable people?	Yes	Yes
Adequate warnings?	n/a	n/a
Obvious hazard?	n/a	n/a
Risk Result	**Serious risk - rapid action required**	

Table 6.13: Nomograph Assessment for Case Study 4 (Climbing Frame)		
Hazard	**1**	**2**
Consequences (description)	**Fractures (requiring hospital treatment)**	**Cuts**
Injury (category)	Serious	Minor
Prob. (occurrence)	Unlikely	Possible
Hazard Recognition	Probable	Probable
Initial Risk Assessment	**29**	**12**
Availability	General	General
Final Risk Assessment	**29**	**12**
Risk Category	**Very Low**	**Remote**

Table 6.14: Risk Matrix Assessment for Case Study 4 (Climbing Frame)		
Hazard	**1**	**2**
Consequences (description)	**Fractures (requiring hospital treatment)**	**Cuts**
Consequences (E)	7 (serious)	1 (minor)
Prob. of Occurrence (W)	1 (improbable)	3 (unlikely)
Exposure (B)	3 (weekly)	3 (weekly)
Risk = E x W x B	**21**	**9**
Risk Level	**Possible**	**Slight**
Action Required	**Attention required**	**Perhaps acceptable**

6.3.2 Analysis

Table 6.15 below summarises the results of the three risk assessment methodologies for the swings case study. For the first hazard (*swing chain may break*), the three methodologies provide relatively similar results; however, the second hazard (*heavy seat may cause injury*) results in distinctly varying results.

Table 6.15: Summary of Assessments for Case Study 3 (Swing)		
Hazard	**Swing chain may break**	**Heavy seat may cause injury**
Present on all products?	No	Yes
Consequences	Serious cut/fracture	Bruising
Result of Risk Assessments		
RAPEX	Moderate risk - some action required	Serious risk - rapid action required
Nomograph	Moderate/Significant Risk	Extremely Low/ Very Low Risk
Risk Matrix	Slight risk - perhaps acceptable	

A closer examination of the results of the analysis for the risk associated with the two swing hazards demonstrates the potential divergence between approaches to risk assessment. Although the risk matrix shows the two hazards to be comparable, the RAPEX methodology gives more weight to the seat risk while the nomograph gives greater weight to the swing chain risk.

Table 6.16 below summarises the results of the three risk assessment methodologies for the climbing frames case study.

Table 6.16: Summary of Assessments for Case Study 4 (Climbing Frame)		
Hazard	**No warning re: hard surfaces**	**Sharp edges**
Present on all products?	Yes	No
Consequences	Fractures (requiring hospital treatment)	Cuts
Result of Risk Assessments		
RAPEX	Serious risk - rapid action required	
Nomograph	Very Low Risk	Remote Risk
Risk Matrix	Possible risk - attention required	Slight risk - perhaps acceptable

For climbing frames, the nomograph and risk matrix provide similar risk rankings for the two hazards; the RAPEX methodology, however, results in a 'serious risk'. This finding correlates with the results of the case studies on childcare articles (Section 6.2) and supports comments from authorities that the RAPEX methodology results in a high risk for any product used by children (vulnerable groups).

The case studies on playground equipment highlight divergences in the conclusions of the risk assessment methodologies used. They also highlight the inherent bias in different risk assessment methodologies in risk weighting. For example, the RAPEX methodology effectively treats hazards to vulnerable consumers as being unacceptable.

As with childcare articles, there are also issues regarding hazard perception (by authorities and adults) and hazard acceptance (by adults and children) in the playground. In terms of hazard perception, an important influencing factor is the number of accidents. However, RPA (2004) notes that an increase over the last twenty years in the number of accidents involving garden-play equipment in the UK is likely to reflect the fact that these products (i.e. domestic climbing frames, swings, etc.) have steadily became available in much greater numbers and at lower prices than before.[13] Research in the UK found that the risk of injury in UK playgrounds was modest in comparison with the risks of other activities that children are encouraged to participate in (Ball, 2002).

The hazards which have been examined in this case study arise from faults in the design of the product. In practice, however, the most common cause of injuries involving playground equipment is a fall linked to the behaviour of the child (especially for swings). KO (2002) notes that the safety of a playground is a complex interaction between many different factors, with the type of surface, the type of equipment and the height of the equipment being the most important.

As with the previous case-study, some standards exist against which the safety of products can be assessed and the role of risk assessment may therefore be focused on the nature of enforcement action, rather than the need for remediation of faults. As before, the RAPEX methodology assumes that risks to vulnerable groups (in this case, children) are unacceptable and require rapid action.

6.4 Household Products

6.4.1 Introduction

Background to Case Study

There is no specific European legislation governing 'household products' as a group; however, there is legislation relevant to specific products and/or risks.

Respondents to our initial consultation indicated that the main issues in regulating the safety of household products arose from:

- the wide range of products, with rapid innovation;
- the varying risks associated with different products; and
- the absence of relevant standards.

Ladders and electrical equipment have been highlighted by regulatory authorities as products involved in a number of domestic accidents; two specific products - **foldable ladders** and **chainsaws** - were selected as case studies.

[13] RPA (2004) reports that accidents in the UK involving garden-play equipment (i.e. domestic climbing frames, swings, etc.) have shown a steady increase throughout a 20 year period (1980-1999).

Ladders

Ladders have been an enduring consumer safety concern, with significant numbers of deaths, hospitalisations and serious injuries attributable to their use. A study commissioned by the UK Health and Safety Executive (HSE) on stepladders notes that, in accident statistics, stepladders are commonly amongst some of the most injurious products within both the domestic and industrial environments, more than other patently dangerous tools, such as grinders, power saws, etc. (Navarro T *et al*, 2002). Approximately 30,000 people in the UK attend an accident and emergency (A&E) department of a hospital each year following a fall from a stepladder and between 5,000 and 6,000 leisure-use ladder accidents occur in Sweden per year (Navarro T *et al,* 2002).

HSE (2002) notes that continuing trends in the accident statistics suggest that user demands, especially for stability, are not being met. Moreover, current standards do not contain a dynamic testing element. Static deformation is clearly an essential part of an effective testing regime, but may not be sufficient on its own to ensure adequate safety in a product which may be in use for many years and which may have a finite fatigue life (HSE, 2002).

Ladders manufacture is controlled through the application of voluntary European Standards (EN 131-1 and 2, for terms, types and functional sizes and testing, marking, 15/02/1993). Standards are also available at Member State level although the UK differs somewhat from other European countries in offering a standard specific to stepladders intended for domestic use (BS 2037: 1994) whereas the European Standard (BS EN131: 1993) does not discriminate between 'domestic' and 'light trades' use.

Chainsaws

Overall, the risk of injury from electrical products has increased in recent years because of the larger number and variety of electrical products available to the consumer, as well as, more general trends towards DIY. In the UK, for instance, there was an increase in electrical injuries in the home involving fixed appliances, particularly portable equipment, between 1990 and 1998 (RoSPA, 2003).

A number of different Directives could apply to a single electrical product at the same time. For instance, electrical equipment may be covered by the Electromagnetic Compatibility Directive (to minimise electrical interference) and the Low Voltage Directive (for electrical safety). Electrically powered tools (including chainsaws) are also covered by the Machinery Directive - although, it is possible, if the hazards are primarily electrical in nature then the LVD would prevail.

It is of note that EC declarations of conformity for electric chainsaws (according to a major manufacturer) refer to the Machinery Directive rather than the LVD. In relation to the Machinery Directive, there is a requirement to undertake a risk assessment using a risk matrix approach, as set out in the European Standard EN 1050:1997 *Safety of Machinery - Principles of Risk Assessment*. There is also national legislation in Sweden (*National Board of Occupational Safety & Health: Use of Chainsaws and Brush Saws AFS 2000:2*) which specifies minimum safety requirements for the design and use of chainsaws.

Case Study 5: Foldable Ladders

Hazards Considered

For the comparative analysis of the three methodologies, two hazards for a hypothetical folding ladder were selected:

1. ladder collapses under use (design fault evident on few ladders); and
2. sharp surfaces (on some ladders due to inadequate quality control) lead to potential for cuts.

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.17, 6.18 and 6.19 respectively.

Table 6.17: RAPEX Assessment for Case Study 5 (Foldable Ladder)		
Hazard	**1**	**2**
Severity (description)	**Falls from height could lead to serious injuries, even death**	**Cuts**
Severity (category)	*Very serious*	*Slight*
Prob. of hazardous product	1%	10%
Prob. of harm from exposure	may occur	may occur
Prob. of Harm	*Low*	*Medium*
Gravity of Outcome	*Moderate*	*Low*
Vulnerable people?	No	No
Adequate warnings?	No	No
Obvious hazard?	No	Yes
Risk Result	**Serious risk - rapid action required**	**Moderate risk - some action required**

Table 6.18: Nomograph Assessment for Case Study 5 (Foldable Ladder)		
Hazard	**1**	**2**
Injury (description)	**Falls from height could lead to serious injuries, even death**	**Cuts**
Injury (category)	Death	Minor
Prob. (occurrence)	Remote	Possible
Hazard Recognition	Improbable	Probable
Initial Risk Assessment	**58**	**12**
Availability	General	General
Final Risk Assessment	**58**	**12**
Risk Category	**Significant**	**Remote**

Table 6.19: Risk Matrix Assessment for Case Study 5 (Foldable Ladder)		
Hazard	**1**	**2**
Consequences (description)	**Falls from height could lead to serious injuries, even death**	**Cuts**
Consequences (E)	15 (very serious)	1 (minor)
Prob. of Occurrence (W)	0.5 (conceivable)	3 (unlikely)
Exposure (B)	2 (monthly)	2 (monthly)
Risk = E x W x B	**15**	**6**
Risk Level	**Slight**	
Action Required	**Perhaps acceptable**	

Case Study 6: Chainsaws

Hazards Considered

Chainsaws are clearly hazardous pieces of equipment if not correctly designed, constructed and operated. For the comparative analysis of the three methodologies, two hazards (both of which have been the cause of product recalls) for a hypothetical electric chainsaw were selected:

1. chain brake not reliable (design fault evident on some chainsaws); and
2. possible exposure of power wires (on few chainsaws due to inadequate quality control).

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.20, 6.21 and 6.22 respectively.

Table 6.20: RAPEX Assessment for Case Study 6 (Electric Chainsaw)		
Hazard	**1**	**2**
Severity (description)	**Potential for very serious injuries**	**Potential for electrocution**
Severity (category)	*Very serious*	*Very serious*
Prob. of hazardous product	10%	1%
Prob. of harm from exposure	may occur	always present
Prob. of Harm	*Medium*	*Medium*
Gravity of Outcome	*High*	*High*
Vulnerable people?	No	No
Adequate warnings?	No	No
Obvious hazard?	No	Yes
Risk Result	**Serious risk - rapid action required**	

Table 6.21: Nomograph Assessment for Case Study 6 (Electric Chainsaw)		
Hazard	**1**	**2**
Injury (description)	**Potential for very serious injuries**	**Potential for electrocution**
Injury (category)	Severe	Death
Prob. (occurrence)	Unlikely	Remote
Hazard Recognition	Improbable	Possible
Initial Risk Assessment	**60**	**43**
Availability	General	General
Final Risk Assessment	**60**	**43**
Risk Category	**Significant**	**Low**

Table 6.22: Risk Matrix Assessment for Case Study 6 (Electric Chainsaw)		
Hazard	**1**	**2**
Consequences (description)	**Potential for very serious injuries**	**Potential for electrocution**
Consequences (E)	7 (serious)	15 (very serious)
Prob. of Occurrence (W)	3 (unlikely)	1 (improbable)
Exposure (B)	1 (few times/year)	1 (few times/year)
Risk = E x W x B	**21**	**15**
Risk Level	**Possible**	**Slight**
Action Required	**Attention required**	**Perhaps acceptable**

6.4.2 Analysis

Tables 6.23 and 6.24 below summarise the results of the three risk assessment methodologies for the case studies on foldable ladders and chainsaws.

Table 6.23: Summary of Assessments for Case Study 5 (Foldable Ladder)		
Hazard	**Ladder Collapse**	**Sharp edges**
Present on all products?	No	No
Consequences	Falls from height could lead to serious injuries, even death	Cuts
Result of Risk Assessments		
RAPEX	Serious risk - rapid action required	Moderate risk - some action required
Nomograph	Significant Risk	Remote Risk
Risk Matrix	Slight risk - perhaps acceptable	

Table 6.24: Summary of Assessments for Case Study 6 (Electric Chainsaw)		
Hazard	**Chain brake not reliable**	**Power wires may be exposed**
Present on all products?	No	No
Consequences	Potential for very serious injuries	Potential for electrocution
Result of Risk Assessments		
RAPEX	Serious risk - rapid action required	
Nomograph	Significant Risk	Low Risk
Risk Matrix	Possible risk - attention required	Slight risk - perhaps acceptable

The case studies on household products highlight divergences in the conclusions of the three risk assessment methodologies used. For the foldable ladders case study, there are divergences in the risk assessment results across all three methodologies for Hazard 1 (*ladder collapse*) but some similarity in the results for Hazard 2 (*sharp edges on ladder*). For the electric chainsaw, there is a similarity in the results of the risk matrix and the nomograph for Hazard 2 (*power wires may be exposed*) and across the three risk assessments for Hazard 1 (*chain brake not reliable*).

Both case studies highlight the difficulty in risk assessments when considering unlikely events with severe consequences. This applies particularly to the results from the risk matrix, in which potentially lethal faults emerge as having a 'slight risk' which is 'perhaps acceptable'. This appears inconsistent with the general aim of GPSD, to prevent dangerous products reaching the market. In the chainsaw case study, the low risk rating from the risk matrix and nomograph for Hazard 2 are the result of the 'exposure' and 'hazard recognition' factors respectively (i.e. the chainsaw is used only a few times a year and it is possible that the hazard posed by the exposed wires is obvious). Similarly, the low risk rating for foldable ladders (Hazard 1) reflects the low 'exposure' and 'probability of occurrence' (due to adequate market surveillance and/or enforcement of standards by manufacturers).

The results of the case studies are clearly problematic and this potentially indicates a need for further development or refinement of the risk assessment methodologies.

The hazards which have been examined in the context of this study all assume that the fault is related to the design of the ladder. In practice, however, a number of accidents are related to the inappropriate use of ladder, for example where a consumer does not follow the safety guidance for use of a ladder, which results in a fall from the ladder.

6.5 Sports Equipment

6.5.1 Introduction

Background to Case Study

Over 70% of regulatory authorities responding to the questionnaire for this study suggested rollers skates as a suitable sports equipment product to be examined as a case study. Roller skates account for a significant number of injuries in the EU, with injuries ranging from bruises to cuts and fractures when users fall over.

Roller skates are of particular interest because:

- they are used by both children (under the age of 14) and adults, but while roller skates used by children are covered by the Toy Safety Directive, those used by adults are not;
- legislation, industry practice and/or published standards usually distinguish between models for children and adults (e.g. by a size measurement), but this does not necessarily correspond to the body size of 14-year olds and many of these products bought for and used by children have been designed for adults[14]; and
- the risk characterisation for these products is influenced by diverse issues such as cultural differences, individuals' perception of risk, acceptance of inherent risk and economic (or trend) issues.

The case study addresses the inherent hazards associated with roller skates and also the hazards associated with the failure of protective equipment, helmets, etc. designed to protect users against these inherent hazards.

[14] This does not necessarily put children at greater hazard and is part of the increasing use children make of adult products as they grow up (particularly sports and IT equipment).

Case Study 7: Roller Skates

Hazards Considered

For the comparative analysis of the three methodologies, consideration was given to a hazards associated with failure of a hypothetical adult's helmet and the inherent risks associated with normal skating. The two hazards selected are thus:

1. helmet fails impact test (inadequate design/material) increases potential for head injuries; and
2. falls during normal skating (likely to result in cuts and bruises).

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.25, 6.26 and 6.27 respectively.

Table 6.25: RAPEX Assessment for Case Study 7 (Roller Skates)		
Hazard	**1**	**2**
Severity (description)	**Potential for irreversible head injuries**	**Potential for serious cuts and bruising**
Severity (category)	*Very serious*	*Serious*
Prob. of hazardous product	100%	100%
Prob. of harm from exposure	Only under several improbable conditions	Always present
Prob. of Harm	*Medium*	*Medium*
Gravity of Outcome	*High*	*Very High*
Vulnerable people?	No	No
Adequate warnings?	No	Yes
Obvious hazard?	Yes	Yes
Risk Result	**Serious risk - rapid action required**	

Table 6.26: Nomograph Assessment for Case Study 7 (Roller Skates)		
Hazard	**1**	**2**
Injury (description)	**Potential for irreversible head injuries**	**Potential for serious cuts and bruising**
Injury (category)	Critical	Moderate
Prob. (occurrence)	Remote	Almost inevitable
Hazard Recognition	Highly improbable	Almost inevitable
Initial Risk Assessment	**65**	**35**
Availability	General	General
Final Risk Assessment	**65**	**35**
Risk Category	**Significant/High**	**Very Low/Low**

Table 6.27: Risk Matrix Assessment for Case Study 7 (Roller Skates)		
Hazard	**1**	**1**
Consequences (description)	**Potential for irreversible head injuries**	**Potential for serious cuts and bruising**
Consequences (E)	15 (very serious)	3 (cuts, etc.)
Prob. of Occurrence (W)	1 (improbable)	10 (almost certain)
Exposure (B)	3 (weekly)	3 (weekly)
Risk = E x W x B	**45**	**90**
Risk Level	**Possible**	**Substantial**
Action Required	**Attention required**	**Reduction required**

6.5.2 Analysis

Table 6.28 summarises the results of the three risk assessment methodologies.

Table 6.28: Summary of Assessments for Case Study 7 (Roller Skates)		
Hazard	**Helmet fails impact test**	**Normal skating**
Present on all products?	Yes	Yes
Consequences	Potential for irreversible head injuries	Potential for serious cuts and bruising
Result of Risk Assessments		
RAPEX	Serious risk - rapid action required	
Nomograph	Significant/High Risk	Very Low/Low Risk
Risk Matrix	Possible risk - attention required	Substantial risk - reduction required

This example again illustrates the potential divergence in results using different methodologies. However, unlike the earlier case studies, the divergence does not necessarily relate to users' judgement, but to the inherent bias or focus of each methodology.

The 'very low/low risk' associated with normal skating using the **nomograph** is strongly influenced by the classification of hazard recognition as 'almost inevitable'. In practice, however, this may have little influence on skater behaviour. On the other hand, the **RAPEX methodology** results in a 'serious risk' requiring rapid action for *normal* skating; a conclusion which appears problematic. The **risk matrix**, which focuses on the products' characteristics, results in a 'substantial risk' which needs reduction.

There is similarity in the results of the three risk assessments for Hazard 1; all three methodologies recognise that the failure of the helmet to pass the impact test results in a risk which needs addressing. It should be borne in mind that this Hazard refers to an abnormal situation (unlike the 'normal' skating scenario). Thus, while normal skating is inherently risky (regardless of whether the skater recognises and/or accepts the hazards), a normal helmet should not be inherently risky. This is an important point in interpreting the results derived using a risk assessment methodology.

As in the other cases, RAPEX effectively treats any hazards to vulnerable consumers as being unacceptable; by contrast, the nomograph takes into account the fact that the skater (or guardian) recognises and accepts that there is a fall hazard prior to using the product whilst the risk matrix focuses on the risks relating to the product (without considering any extraneous factors e.g. hazard acceptance, use of protective equipment, etc).

In practice, the ability of manufacturers and/or regulators to identify and address the hazards from roller skates (for instance, by assuming that roller skates are sold along with proper helmets) cannot be expected to eliminate accidents. Most accidents involving roller skates and, indeed, skateboards are associated with skater behaviour. Whilst the wearing of protective equipment reduces the consequences of falls etc. under *normal* conditions, it may encourage the skater to attempt faster speeds or more extreme manoeuvres.

The roller skates market is also particularly prone to generational fashions and short-lived crazes, and this may affect accident statistics. An analysis of accident data presented in RPA (2004) highlighted the effects of these social variations, for instance, in the UK:

- there was an initial peak in skateboard accidents when they first hit the market around 1978 followed by another peak (reflecting another craze) in 1988-89; and

- roller-skate accidents peaked around 1994 and more strongly around 1997-98, when new designs and (particularly in-line skates) made a long-established children's toy suddenly fashionable.

Numbers of injuries can increase substantially when new products appear on the market or sales of existing products increase rapidly. Such an increase in accidents could trigger regulatory action in some Member States. In this case, however, it is not the risk associated with roller skates that changed, rather the population exposed through an increase in the number of users. It may also be the case that it is not the hazard posed by the roller skate itself, but behavioural factors, that are the predominant risk factor. In such cases, where regulatory action is triggered by an increase in accidents, the reasons for the increase need to be adequately reviewed (prior to regulatory action). This aspect is not readily addressed by formal risk methodologies.

In cases like those of roller skates, informal approaches to risk assessment may provide some advantages when combined with formal risk assessment methodologies. A pre-evaluation procedure (in which extraneous factors relevant to the product are taken into account to ensure a robust risk assessment, as practiced in Belgium) or expert panels may be of benefit in addressing issues relating to hazard acceptance, behavioural risks and generational crazes and trends. Standards are useful in ensuring that product design complies with safety standards, however, they are limited in terms of addressing the way these products are used.

6.6 Toys

6.6.1 Introduction

Background to Case Study

The safety of toys in the EU is ensured primarily by the Toy Safety Directive (TSD) (Council Directive 88/378/EEC) which lays down safety criteria and essential requirements which toys must meet before being placed on the EU market. In addition, certain obligations of the manufacturer and certain procedures under the GPSD apply to the toys sector, as the existing Directive does not contain comparable post-sale safety obligations.

Case Study 8: Dolls

Hazards Considered

For the comparative analysis of the three methodologies, three hazards (design faults) for a hypothetical doll were selected:

1. small parts (buttons) can be easily detached and placed in mouth (choking hazard);
2. doll contains excessive levels of phthalates (toxic hazard); and
3. plastic bag not perforated (suffocation hazard).

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.29, 6.30 and 6.31 respectively.

Table 6.29: RAPEX Assessment for Case Study 8 (Dolls)			
Hazard	**1**	**2**	**3**
Severity (description)	**Potential choking**	**Toxic effects**	**Suffocation**
Severity (category)	*Very serious*	*Serious*	*Very serious*
Prob. of hazardous product	100%	100%	100%
Prob. of harm from exposure	may occur	occurs under several improbable conditions	occurs under several improbable conditions
Prob. of Harm	*High*	*Medium*	*Medium*
Gravity of Outcome	*Very high*	*Moderate*	*High*
Vulnerable people?	Yes – very	Yes – very	Yes – very
Adequate warnings?	n/a	n/a	n/a
Obvious hazard?	n/a	n/a	n/a
Risk Result	**Serious risk - rapid action required**		

Table 6.30: Nomograph Assessment for Case Study 8 (Dolls)			
Hazard	**1**	**2**	**3**
Injury (description)	**Potential choking**	**Toxic effects**	**Suffocation**
Injury (category)	Critical	Serious	Critical
Prob. (occurrence)	Possible	Remote	Unlikely
Hazard Recognition	Probable	Highly improbable	Possible
Initial Risk Assessment	**48**	**56**	**50**
Availability	General	General	General
Final Risk Assessment	**48**	**56**	**50**
Risk Category	**Moderate**	**Moderate/ Significant**	**Moderate**

Table 6.31: Risk Matrix Assessment for Case Study 8 (Dolls)			
Hazard	**1**	**2**	**3**
Consequences (description)	**Potential choking**	**Toxic effects**	**Suffocation**
Consequences (E)	15 (very serious)	7 (serious)	15 (very serious)
Prob. of Occurrence (W)	3 (unlikely)	0.2 (near impossible)	1 (improbable)
Exposure (B)	6 (daily)	6 (daily)	6 (daily)
Risk = E x W x B	**270**	**8.4**	**90**
Risk Level	**High**	**Slight**	**Substantial**
Action Required	**Immediate measures**	**Perhaps acceptable**	**Reduction**

Toys are, by definition, used by a particularly vulnerable group (children) and constituted the category of products most often notified through the RAPEX system in 2003 (ECOSA, 2004). Respondents to our initial questionnaire also indicated that toys were the products most widely tested by regulatory authorities, but that a lack of clear guidelines on product classification, use and test methodologies posed challenges for assessing and regulating the risks. Respondents also felt that some toys declared as only suitable for children over three years might actually be used by younger children, posing additional difficulties for risk assessment.

Risks related to dolls are most significant for children under three, with accidents resulting mainly from ingestion of small parts such as eyes, buttons or pieces of stuffing. Although there are specific safety requirements under the TSD for soft toys in the EU, there appear to still be a significant number of such toys that do not meet the standards. In the UK, for example, dolls accounted for around 1,700 accidents per year between 2000 and 2002 (RPA, 2004).

6.6.2 Analysis

Table 6.32 summarises the results of the three risk assessment methodologies. For each of the three hazards considered, the **RAPEX** methodology results in a 'serious risk' requiring rapid action while the nomograph and risk matrix provide varying results. As in previous case studies, the RAPEX methodology effectively treats hazards to children as being unacceptable

Table 6.32: Summary of Assessments for Case Study 8 (Dolls)

Hazard	**Detachable buttons**	**Phthalates**	**Plastic bag**
Present on all products?	Yes	Yes	Yes
Consequences	Potential choking	Toxic effects	Suffocation
Result of Risk Assessments			
RAPEX	Serious risk - rapid action required		
Nomograph	Moderate Risk	Moderate/Significant Risk	Moderate Risk
Risk Matrix	High risk - immediate measures required	Slight risk - perhaps acceptable	Substantial risk - reduction required

As noted in earlier case studies, a key feature of the **nomograph** is the potential for the consumer to recognise the hazard. In this example, it is considered that parents are likely to appreciate the hazard potential for buttons to pose a choking hazard (Hazard 1) and may appreciate the potential suffocation hazard of the plastic bag (Hazard 3) but are far less likely to appreciate the toxic potential of the doll's construction material (Hazard 2).

The **risk matrix** provides a distinct differentiation amongst the different risks (unlike the nomograph) with the consequence (or severity of harm) a clear influencing factor.

Informal approaches to risk assessment may offer an alternative solution in addressing the risks from dolls, especially for chemical risks. Although, in theory, standards should set out clear requirements and specify methods by which compliance could be judged,

this is not always the case in practice. This is a particular problem for chronic hazards, such as those posed by chemicals, where harmful effects can arise many years after exposure. Where there is no agreed method to measure the level of hazardous substance within a product (for example, phthalates), then the risk cannot be assessed and evaluation is based on hazard rather than risk.

Nevertheless, within the context of the three hazards selected, it is uncertain that the (actual) risks from phthalates are greater than those associated with plastic bags and detachable buttons. This, in turn, casts some doubt on the nomograph results.

6.7 Clothing

6.7.1 Introduction

Background to Case Study

The safety of clothes placed on the EU market is not covered explicitly by any product-specific legislation. Some Member States have, however, adopted national regulations on clothing safety. For instance, in the UK, the *Children's Clothing (Hood Cords) Regulations 1976* specify that the hoods of children's outer garments must not be designed to be secured by means of a cord drawn through the material. There are also regulations in Ireland dating from 1976 (similar to those in the UK) and other less formal approaches to ensuring the safety of children's clothing.

For example, in Germany, several parties involved in the production, import and marketing of children's clothing have a written agreement not to use tear-proof tunnelled cords in the neck area of children's clothing and not to sell products that do not comply with these requirements (Access Guide, 2005a). In the UK, a British Standard Institution (BSI) Code of Practice (BS 7907:1997) gives recommendations for materials, design and manufacturing to promote the safety of children's clothing. A European harmonised standard dealing specifically with cords and drawstrings on children's clothing is also being developed (prEN 14682 which is currently 'under approval').

Case Study 9: Children's Clothing with Strings

Hazards Considered

From a safety perspective, the main risks posed by children's clothing with strings relate to suffocation or strangulation. Children are at risk of strangulation when a string, cord, or necklace attached to an item of clothing gets caught on an external object or, alternatively, becomes tightly wrapped or twisted around a child's neck. Over two-thirds of the deaths and non-fatal incidents involving hood/neck drawstrings are on upper body outer clothing and the majority of these cases involved strings catching on playground slides (ECOSA, 2004).

For the comparative analysis of the three methodologies, one hazard for a hypothetical child's hooded jacket was selected:

1. drawstring presents strangulation hazard.

Risk Assessment Results

The results of the RAPEX methodology, the Slovenian Nomograph and the Belgian Risk Matrix are presented in Tables 6.33, 6.34 and 6.35 respectively.

Table 6.33: RAPEX Assessment for Case Study 9 (Child's Jacket)	
Hazard	**1**
Severity (description)	**Potential for strangulation**
Severity (category)	*Very serious*
Prob. of hazardous product	100%
Prob. of harm from exposure	Only under several improbable conditions
Prob. of Harm	*Medium*
Gravity of Outcome	*High*
Vulnerable people?	Yes
Adequate warnings?	n/a
Obvious hazard?	n/a
Risk Result	**Serious risk - rapid action required**

Table 6.34: Nomograph Assessment for Case Study 9 (Child's Jacket)	
Hazard	**1**
Injury (description)	**Potential for strangulation**
Injury (category)	Death
Prob. (occurrence)	Remote
Hazard Recognition	Highly improbable
Initial Risk Assessment	**68**
Availability	General
Final Risk Assessment	**68**
Risk Category	**High**

Table 6.35: Risk Matrix Assessment for Case Study 9 (Child's Jacket)	
Hazard	**1**
Consequences (description)	**Potential for strangulation**
Consequences (E)	15 (very serious)
Prob. of Occurrence (W)	1 (improbable)
Exposure (B)	3 (weekly)
Risk = E x W x B	45
Risk Level	**Possible**
Action Required	**Attention required**

6.7.2 Analysis

Table 6.36 summarises the results of the three risk assessment methodologies.

Table 6.36: Summary of Assessments for Case Study 9 (Child's Jacket)	
Hazard	**Hooded jacket drawstring**
Present on all products?	Yes
Consequences	Potential for strangulation
Result of Risk Assessments	
RAPEX	Serious risk - rapid action required
Nomograph	High Risk
Risk Matrix	Possible risk - attention required

Although there is some divergence, all three assessments identify a substantial risk requiring attention. To some extent, the high risk associated with the **nomograph** results from an (assumed) lack of awareness of the hazard.

Even though there is a deviation in the result of the risk matrix, all three methodologies indicate that there is a risk to be addressed from these products. The approach adopted by Member States to address these concerns is of greater significance, considering the current lack of harmonised legislation, standards or clear guidance/best practice regarding these products. For instance, while some Member States have banned such products, others have adopted a voluntary approach. This could lead to confusion (as well as enforcement difficulties[15]) among authorities and consumers.

In the absence of standards, it may also be more difficult to demonstrate a risk and therefore to arrive at a consensus on what constitutes 'safe' clothing with strings. This finding correlates with responses from regulatory authorities which showed that a number of authorities lack the expertise to evaluate the risks from clothing, particularly in the absence of standards or legislation.

[15] One survey in Ireland in 1999 reported that less than 25% of outerwear garments for children inspected in department stores complied with recommended drawstring requirements suggesting a lack of enforcement.

7. IDENTIFICATION OF BEST PRACTICES AND NEED FOR FURTHER DEVELOPMENT OF RISK ASSESSMENT METHODOLOGIES

7.1 Introduction

The two final objectives of this study are:

- to identify and describe best practices in light of the findings of the comparative assessment, taking also into account the results achieved with the application of the approaches, methods and practices considered; and

- to identify needs for further development of risk assessment methods where the existing methods are not sufficiently developed or effective or important differences exist between the methods used, which may lead to divergent risk assessment conclusions.

In other words, the findings should set out which method(s) and/or approach(es) to risk assessment are particularly suitable for assessing whether products (covered by the GPSD) placed on the market are safe. These findings should also take into account the need (or not) for further development of risk assessment methods – and should increase the level of convergence in risk assessment results among authorities.

Best practice, in the context of this study, refers to the best possible way of assessing the risks of consumer products based on the existing approaches, methodologies, results and experiences of regulatory authorities in the various Member States. To some extent, the development of best practice depends on how regulatory authorities view and implement consumer safety policy and, in practice, this varies from Member State to Member State. It is thus important that any suggested best practice can be easily applied across Member States using their existing regulatory framework, and takes into account the administrative and regulatory differences which apply amongst Member States. Considering that a significant aspect of undertaking a risk assessment may be considered 'intuitive' or 'subjective' and the actual *implementation* of consumer safety policy across Member States often reflects 'subjective' aspects and attitudes to risk and risk management, it is important that possible differences arising from such aspects are kept to a minimum within any best practice.

Following from the above, it is considered that best practice would include:

- providing guidance to ensure that risk assessors actually understand the basis (i.e. the strengths and weaknesses as well as bias), process (i.e. applying the various scales and ratings) and results of any risk assessment methodology applied;
- creating a clear link between the output of the risk assessment methodologies and the enforcement action to be taken to ensure product safety; and
- using more than one risk assessment methodology, where possible and ensuring that all risk assessment results are discussed and agreed by an expert panel.

7.2 Selecting and Understanding Risk Assessment Methodologies and Implications for Best Practice

7.2.1 Introduction

Currently, there are three formal risk assessment methodologies in use within the EU which have been considered in detail in previous sections. These can be characterised as follows:

- a methodology which focuses on (ensuring) a very high level of safety (or 'risk averse' approach) for products used by vulnerable consumers such as children (the RAPEX methodology);
- a methodology which focuses on the inherent safety of the product, irrespective of the consumer's (or, indeed, regulator's) behaviour (the Belgian Risk Matrix); and
- a methodology which focuses on the overall safety of consumers. This is a combination of the products' inherent risks and consumer behaviour (the Slovenian Nomograph).

It is worth noting that the GPSD does not provide a specific definition and/or guidance on acceptable levels of safety which invariably leads to Member State discretion in interpretation and enforcement of safety requirements as well as adopting different approaches to assessing product safety. Whilst none of the above methodologies can meet the requirements of a single standardised risk assessment approach for all consumer products, each can be presented as an example of best practice (with some modifications) within the context of their characteristics and the prevailing regulatory situation, concern or focus.

In this section, consideration is given to the strengths (and weaknesses) of each of the three formal methodologies under consideration and their potential for application in different regulatory situations. Suggestions for possible improvements to each of the methodologies are also provided.

7.2.2 The RAPEX Methodology

Strengths and Weaknesses

In the case studies, the application of the RAPEX methodology resulted in a 'serious risk' for all the listed hazards - except in two cases involving the swing (*chain may break causing child to fall*) and foldable ladder (*sharp edges on ladder*) - where a 'moderate risk' (some action is required) was derived. As discussed earlier, the RAPEX methodology has a very low threshold for concern, particularly when considering vulnerable people and as such, does not provide a means to differentiate readily amongst a range of risks since, as in the case studies, most emerge as a 'serious risk'.

A second concern over the RAPEX methodology is that in some of the case studies, there were risks to vulnerable people (i.e. children) associated with 'obvious hazards'. As the methodology stands, whether or not a hazard is obvious has no impact on the risks to

vulnerable people. In practice, particularly for very young children (i.e. 'very vulnerable people'), the average parent is likely to check cots for splinters, dolls for loose buttons, etc. and take appropriate risk reduction measures if there is an obvious hazard.

Discussion

As indicated above, in most cases involving vulnerable consumers, the assessment of risks using the RAPEX methodology resulted in a 'serious risk' requiring 'rapid action' - even where the consequences were minor. Whilst many would support the view that consumer products (particularly those used by children) should not cause undue harm in normal use, the immediate conclusion that such hazards pose a 'serious risk' is questionable.

To illustrate this point, consider a school book for use by children in the age range 3-11. Nearly all books present a 'paper cut' hazard. Such 'paper cuts' 'may occur under one improbable or two possible conditions'. The resultant 'probability of harm' using the RAPEX methodology is 'high'. Should the hazard be realised, the consequences (a paper cut) will be 'minor'. The 'overall gravity of outcome' is thus 'moderate' which for 'vulnerable people' (including children aged 3-11) presents a 'serious risk' requiring 'rapid action'.

For those Member States where consumer safety policy is based on a 'risk averse' approach, the RAPEX methodology may be considered as best practice as it ensures that the possible occurrence of (sometimes very) minor injuries, particularly amongst vulnerable people, is identified as unacceptable (and, as such, is inconsistent with the national attitude towards consumer safety). It is, however, important to stress that the application of the RAPEX methodology to a wide range of products (especially for vulnerable groups) will result in a wide-ranging requirement for risk reduction measures[16]. This could lead to significant problems both in terms of product design and cost (as well as the possible substitution of one hazard with another).

Potential for Further Development of the RAPEX Methodology

The potential for further development of the RAPEX methodology depends on the approach adopted towards the acceptability of risk. In those Member States where consumer safety policy is based on a risk averse approach, there may be little potential (or need) for development, other than to make clear to users of the methodology that this is the case.

The RAPEX methodology could be slightly revised to increase the threshold for concern and, for vulnerable people, to differentiate between those hazards which are 'obvious' and those that are not. This would allow for more specific gradations of risk, linked to a differentiation amongst different groups. A suggested revised version of the RAPEX methodology (together with the original version for comparison) is presented in Figure

[16] Using the earlier example of books, this might require replacement of paper pages with rag pages in all books intended for children.

7.1. It should be noted that no change to the risk estimation (Table A) is proposed. The results of the application of the suggested revised RAPEX methodology are summarised in Table 7.1.

With reference to Table 7.1, it can be seen that the revised methodology leads to a differentiation of risks largely based on age. As such, those risks which can affect very vulnerable consumers (with particular regard to very young children) are still rated as 'serious'.

Table 7.1: Revised Results for RAPEX Methodology (with Modified Table B: Grading of Risk)

Product	**Hazard**	**Original Results**	**Revised Results**
Cot	Vertical bars too far apart permitting baby's head to become trapped	Serious risk	Serious risk
Cot	Wooden bars have splinters		
Cot	Small holes present in frame (for adjusting height of opening side)		
Push Chair	Latches may not function causing pushchair to collapse		
Push Chair	Loss of plastic covers may expose sharp edges		
Electric Chainsaw	Chain brake not reliable (design fault)		
Doll	Small parts (buttons) can be easily detached and placed in mouth		
Doll	Doll contains excessive levels of phthalates		
Doll	Plastic bag not perforated (suffocation hazard)		
Hooded Child's Top	Drawstring presents strangulation hazard		
Swing	Use of heavy seat may cause injury		Moderate risk
Climbing Frame	Lack of warning about siting on hard surfaces		
Climbing Frame	Sharp edges present (possibly leading to cut fingers)		
Foldable Ladder	Ladder collapses under use (design fault evident on few ladders)		
Electric Chainsaw	Possible exposure of power wires (inadequate quality control)		
Roller Skates	Helmet fails impact test (inadequate design/ material)		
Roller Skates	Normal skating		
Swing	Chain may break causing child to fall	Moderate risk	
Foldable Ladder	Sharp edges on ladder		Low risk

Figure 7.1: Possible Revisions to RAPEX Methodology

Original RAPEX Methodology

Table A: Risk Estimation

Probability of Health/Safety Damage	Severity of Health/Safety Damage: Slight	Severity of Health/Safety Damage: Serious	Severity of Health/Safety Damage: V. Serious	Overall gravity of Outcome
		V. high	High	V. high
	V. high	High	Medium	High
	High	Medium	Low	Moderate
	Medium	Low	V. low	Low
	Low	V. low		V. low

Table B: Grading of Risk

Vulnerable people		Non-vulnerable adults				Risk Mitigation
Very vulnerable	Vulnerable	No	Yes	No	Yes	Adequate warnings/ safeguards?
		No	No	Yes	Yes	Obvious hazard?
SERIOUS RISK – Rapid action required						
	Moderate Risk – Some action required					
		Low Risk – Action unlikely				

Suggested Revised RAPEX Methodology

Table A: Risk Estimation

Probability of Health/Safety Damage	Severity of Health/Safety Damage: Slight	Severity of Health/Safety Damage: Serious	Severity of Health/Safety Damage: V. Serious	Overall gravity of Outcome
		V. high	High	V. high
	V. high	High	Medium	High
	High	Medium	Low	Moderate
	Medium	Low	V. low	Low
	Low	V. low		V. low

Table B: Grading of Risk

Vulnerable people			Non-vulnerable adults			Risk Mitigation
Very vulnerable	Vulnerable		No	Yes (one only)	Yes	Adequate warnings/ safeguards?
	No	Yes	No		Yes	Obvious hazard?
SERIOUS RISK – Rapid action required						
	Moderate Risk - Some action required					
		Low Risk – Action unlikely				

7.2.3 The Risk Matrix

Strengths and Weaknesses

Although, the results from the case studies are dependent on the precise scoring of each of the parameters (in this case: consequence, probability of occurrence and exposure), the ranking of the results obtained provides some useful indicators as to the potential advantages and drawbacks of the Risk Matrix.

The application of the risk matrix in the case studies produced what appears intuitively to be a reasonable ranking of risks (see Table 7.2 below). In two cases, however, (the foldable ladder and electric chainsaw), remote events which could produce fatalities resulted in a 'slight risk'.

Table 7.2: Ranking of Risk Results using the Risk Matrix

Product	**Hazard**	**Results**	
Doll	Small parts (buttons) can be easily detached and placed in mouth	270	High
Cot	Vertical bars too far apart permitting baby's head to become trapped	180	High
Doll	Plastic bag not perforated (suffocation hazard)	90	Substantial
Roller Skates	Normal skating	90	Substantial
Cot	Small holes present in frame (for adjusting height of opening side)	60	Possible
Push Chair	Latches may not function causing push chair to collapse	54	Possible
Roller Skates	Helmet fails impact test (inadequate design/ material)	45	Possible
Hooded Child's Top	Drawstring presents strangulation hazard	45	Possible
Cot	Wooden bars have splinters	36	Possible
Climbing Frame	Lack of warning about sitting on hard surfaces	21	Possible
Electric Chainsaw	Chain brake not reliable (design fault)	21	Possible
Push Chair	Loss of plastic covers may expose sharp edges	18	Slight
Foldable Ladder	Ladder collapses under use (design fault evident on few ladders)	15	Slight
Electric Chainsaw	Possible exposure of power wires (inadequate quality control)	15	Slight
Climbing Frame	Sharp edges present (possibly leading to cut fingers)	9	Slight
Swing	Use of heavy seat may cause injury	9	Slight
Swing	Chain may break causing child to fall	9	Slight
Doll	Doll contains excessive levels of phthalates	8.4	Slight
Foldable Ladder	Sharp edges on ladder	6	Slight

Discussion

If a product is placed on the market, it will be used by a consumer who may or may not act in a safety conscious manner. One means to address this is to focus on the potential hazards to the consumer taking no account of the presence of hazard warnings or hazard recognition. Behavioural attributes, foreseen or unforeseen product misuses, consumer intelligence and other similar attributes are of limited relevance in this approach. In other words, the focus is on the product rather than on the consumer.

Of the three methodologies considered, hazard warnings and hazard recognition are accounted for in the RAPEX methodology and hazard recognition is accounted for in the nomograph; the risk matrix, however, takes no account of consumer behaviour and as such, provides for a relatively 'worst case' approach. Thus, in those Member States where the focus of regulatory concern is on the inherent safety of the product then the Belgian Risk Matrix constitutes best practice.

Potential for Further Development of the Risk Matrix

The low risk allocated to hazards with potentially fatal consequences suggests that the methodology could benefit from a revision to the scoring for seriousness of consequences in which a higher score should be awarded to the more serious potential consequences. Currently, the methodology contains score categories for extremely catastrophic consequences, which are unlikely to be relevant for the vast majority of consumer products. With these points in mind, an illustrative example of how the scores could be modified to provide a wider range of scores for the consequences more likely to arise from consumer products is presented in Table 7.3.

Table 7.3: Risk Matrix Scores for Seriousness of Consequences, E

Description	Existing	Suggested
Catastrophic (all users and bystanders killed)	100	removed
Major calamity (all users killed)	80	
Calamity (several deaths)	40	80
Very serious (one death)	15	30
Serious (permanent injuries)	7	15
Cuts etc. (equivalent to a lost-time accident)	3	3
Minor (first aid may be required)	1	1

The results of the revised scale are presented in Table 7.4 .

As would be expected, placing greater emphasis on those hazards with a serious consequence produces increased risks for those hazards (such as those associated with the chainsaw). However, as can be seen from Table 7.4, the revised methodology produces a ranking which is only slightly different from that from using the 'original' methodology.

Table 7.4: Revised Results for Risk Matrix (with Modified Consequence Scale)					
Product	**Hazard**	**Original Results**		**Revised Results**	
Doll	Small parts (buttons) can be easily detached and placed in mouth	270	High	540	Very high
Doll	Plastic bag not perforated (suffocation hazard)	90	Substantial	180	High
Cot	Vertical bars too far apart permitting baby's head to become trapped	180	High	180	High
Roller Skates	Helmet fails impact test (inadequate design/material)	45	Possible	90	Substantial
Roller Skates	Normal skating	90	Substantial	90	Substantial
Hooded Child's Top	Drawstring presents strangulation hazard	45	Possible	90	Substantial
Cot	Small holes present in frame (for adjusting height of opening side)	60	Possible	60	Possible
Push Chair	Latches may not function causing pushchair to collapse	54	Possible	54	Possible
Climbing Frame	Lack of warning about sitting on hard surfaces	21	Possible	45	Possible
Electric Chainsaw	Chain brake not reliable (design fault)	21	Possible	45	Possible
Cot	Wooden bars have splinters	36	Possible	36	Possible
Electric Chainsaw	Possible exposure of power wires (inadequate quality control)	15	Slight	30	Possible
Foldable Ladder	Ladder collapses under use (design fault evident on few ladders)	15	Slight	30	Possible
Push Chair	Loss of plastic covers may expose sharp edges	18	Slight	18	Slight
Doll	Doll contains excessive levels of phthalates	8.4	Slight	18	Slight
Swing	Use of heavy seat may cause injury	9	Slight	9	Slight
Climbing Frame	Sharp edges present (possibly leading to cut fingers)	9	Slight	9	Slight
Swing	Chain may break causing child to fall	9	Slight	9	Slight
Foldable Ladder	Sharp edges on ladder	6	Slight	6	Slight

Overall, the Belgian Risk Matrix has been shown to provide a means to assess the risks associated with a product - with the emphasis on the safety of the product (rather than on the behaviour of the average consumer). It is considered that the proposed modification to the scoring of the consequences provides for a more robust risk assessment methodology.

The risk matrix provides an example of best practice where the potential risk from the product is of prime concern. Minor adjustments to the scoring of the potential consequences will improve its applicability in determining gradations of risks to consumers.

7.2.4 The Nomograph

Strengths and Weaknesses

As for the risk matrix, a ranking of the results of the application of the risk nomograph to each of the hazards considered was undertaken (see Table 7.5 below). The overall ranking appears reasonable, with what one might perceive to be some of the highest risks near the top of the table and some of those with the lowest risks near the bottom of the table. Of particular interest, however, are three results which seem out of place:

- the possible exposure of power wires for the electric chainsaw leads to a 'low risk'. Although the consequences (electrocution) are serious, the likelihood of occurrence is remote (since most consumers rarely use their chainsaws and the hazard is not present on all chainsaws);
- the broken swing chain ranks much higher using the nomograph than using the RAPEX methodology; and
- the nomograph produces surprisingly similar results for each of the doll hazards.

Table 7.5: Ranking of Risk Results using the Nomograph

Product	Hazard	Results	
Cot	Vertical bars too far apart permitting baby's head to become trapped	75	High/Very High
Hooded Child's Top	Drawstring presents strangulation hazard	68	High
Push Chair	Latches may not function causing push chair to collapse	66	Significant/High
Roller Skates	Helmet fails impact test (inadequate design/ material)	65	Significant/High
Electric Chainsaw	Chain brake not reliable (design fault)	60	Significant
Foldable Ladder	Ladder collapses under use (design fault evident on few ladders)	58	Significant
Swing	Chain may break causing child to fall	56	Moderate/Significant
Doll	Doll contains excessive levels of phthalates	56	Moderate/Significant
Doll	Plastic bag not perforated (suffocation hazard)	50	Moderate
Doll	Small parts (buttons) can be easily detached and placed in mouth	48	Moderate
Cot	Small holes present in frame (for adjusting height of opening side)	47	Moderate
Electric Chainsaw	Possible exposure of power wires (inadequate quality control)	43	Low
Push Chair	Loss of plastic covers may expose sharp edges	36	Very Low/Low
Roller Skates	Normal skating	35	Very Low/Low
Climbing Frame	Lack of warning about sitting on hard surfaces	29	Very low
Swing	Use of heavy seat may cause injury	25	Extremely Low/Very Low
Cot	Wooden bars have splinters	24	Extremely Low/Very Low
Foldable Ladder	Sharp edges on ladder	12	Remote
Climbing Frame	Sharp edges present (possibly leading to cut fingers)	12	Remote

Discussion

If a product is placed on the market, it will be used by a range of consumers - some of whom will act in a safety conscious manner and some will not. As discussed for the risk matrix, the risks to the individual consumer can be derived without consideration of warning labels and/or hazard recognition - and, as such, is considered as a 'worst case'. However, in practice, the risks to the average (or typical) consumer would be somewhat lower depending on the (perceived) effectiveness of warning labels and/or the degree of hazard recognition.

Although hazard warnings and hazard recognition are accounted for in the RAPEX methodology (albeit only for adult consumers), hazard recognition is an important factor in the nomograph. It is thus considered that for assessing the risks for the 'average' consumer, perhaps the most suitable formal methodology is the nomograph.

Potential for Further Development of the Nomograph

The nomograph provides a five-point scale against which to judge 'hazard recognition'. As with all hazard rating schemes, the selection of the point on the scale (or associated score) for a particular factor is a matter of judgement. This enables the assessor to judge whether it is likely that the hazard has been recognised (and, by implication, appropriate action taken) irrespective of the consumer using the product. Thus, in relation to cots, for example, the risk was assessed on the basis that it was 'probable' that the parent(s) - rather than the child using the cot - would recognise that splinters present a hazard (and take appropriate action) (see Table 6.2).

However, the dolls case study (see Section 6.6) suggests that the importance of hazard recognition may be overstated in that three diverse risks (with different hazard recognition scores) ended up with very similar scores. One means to rectify this would be simply to reduce the range of the 'hazard recognition' scale on the nomograph (as shown in Figure 7.2). This revised nomograph was applied to the case studies considered in Section 6 and the results are presented in Table 7.6.

Table 7.6: Revised Results for Modified Slovenian Nomograph

Product	**Hazard**	**Original Results**		**Revised Results**	
Cot	Vertical bars too far apart permitting baby's head to become trapped	75	High/Very High	70	High
Hooded Child's Top	Drawstring presents strangulation hazard	68	High	59	Significant
Push Chair	Latches may not function causing pushchair to collapse	66	Significant /High	58	Significant
Electric Chainsaw	Chain brake not reliable (design fault)	60	Significant	55	Moderate/ Significant
Roller Skates	Helmet fails impact test (inadequate design/material)	65	Significant /High	55	Moderate/ Significant
Doll	Small parts (buttons) can be easily detached and placed in mouth	48	Moderate	54	Moderate/ Significant
Foldable Ladder	Ladder collapses under use (design fault evident on few ladders)	58	Significant	52	Moderate

Table 7.6: Revised Results for Modified Slovenian Nomograph					
Product	**Hazard**	**Original Results**		**Revised Results**	
Doll	Plastic bag not perforated (suffocation hazard)	50	Moderate	51	Moderate
Doll	Doll contains excessive levels of phthalates	56	Moderate/ Significant	48	Moderate
Swing	Chain may break causing child to fall	56	Moderate/ Significant	48	Moderate
Electric Chainsaw	Possible exposure of power wires (inadequate quality control)	43	Low	45	Low/ Moderate
Roller Skates	Normal skating	35	Very Low/Low	44	Low/ Moderate
Cot	Small holes present in frame (for adjusting height of opening side)	37	Low	39	Low
Push Chair	Loss of plastic covers may expose sharp edges	36	Very Low/Low	39	Low
Climbing Frame	Lack of warning about siting on hard surfaces	29	Very low	37	Very Low/ Low
Cot	Wooden bars have splinters	24	Extremely Low/Very Low	32	Very Low
Swing	Use of heavy seat may cause injury	25	Extremely Low/Very Low	28	Very Low
Foldable Ladder	Sharp edges on ladder	12	Remote	21	Extremely Low
Climbing Frame	Sharp edges present (possibly leading to cut fingers)	12	Remote	21	Extremely Low

The impact of the suggested revision is to compress the range of the risk results. In other words, high risk scores reduce and low risk scores increase with only slight changes to the overall ranking of the risk results. The most notable change is the reversal of the ranking of the doll risks (albeit with only slight variations in the risk 'scores') which reflects the concerns over the 'original' nomograph scores.

Overall, the Slovenian nomograph provides a means to assess the risks associated with a product - with the emphasis on the safety of the average consumer using the product (rather than on the safety of the product itself). It is considered that the proposed modification to the hazard recognition scale provides for a more robust risk assessment methodology.

In summary, where the (potential) risk to the average consumer is of prime concern, use of the nomograph would constitute best practice, subject to some minor adjustments to the 'hazard recognition' scale.

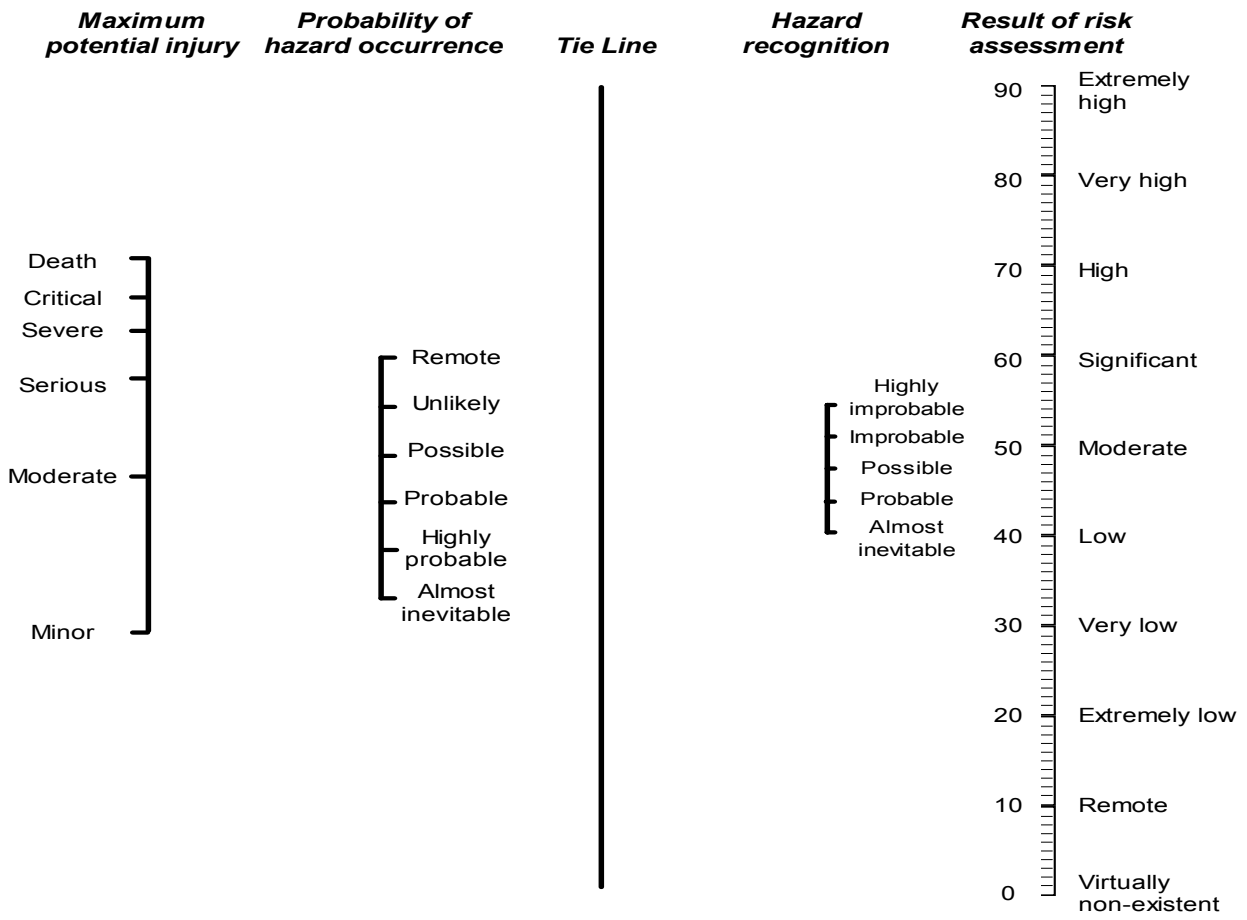


Figure 7.2: Revised Nomograph with Compressed Hazard Recognition Scale
(Compare with original Nomograph in Figure 6.1)

7.2.5 Summary

Having examined the various risk assessment methodologies (and possible revisions to them), it is evident that the selection of a 'best practice' methodology depends on the attitude of the product safety regulator to risk. Three different perspectives (which reflect the practice of consumer safety in EU Member States) have been considered and the following conclusions can be reached:

- the **RAPEX methodology** represents best practice under a 'risk averse' approach. In other words, in those Member States where the possible occurrence of (sometimes very) minor injuries, particularly amongst vulnerable people, would not be consistent with national/general approach towards risks, then the RAPEX methodology is the preferred approach. The development of the methodology could focus on greater differentiation between different risks to such groups;

- the **Risk Matrix** represents best practice where the inherent safety of the product is of prime concern. In other words, by taking no account of the consumer's behaviour and response (e.g. to hazard warnings and hazard recognition) and by focusing on the product rather than the consumer, the risk matrix provides for a 'worst case' approach; and

- the **Nomograph** represents best practice under the 'acceptable risk to the average consumer' approach. In other words, the actual risks of a product to (what is considered to be) the average (or typical) consumer would be somewhat lowered by the (perceived) effectiveness of warning labels and/or the degree of hazard recognition by the consumer.

The key factor to bear in mind is that it has not been possible to recommend a single 'best practice' risk assessment methodology. Rather, each of the methodologies may be considered to represent an example of best practice within the context of different national attitudes towards consumer safety. Each methodology considered has strengths and weaknesses, as well as implicit bias, which significantly affect the results obtained and the level of convergence possible.

7.3 Creating a Link between Risk Assessment Outputs and Enforcement Actions

7.3.1 Introduction

The aim of risk assessment methodologies is to assist enforcement authorities to identify products that pose risks to consumers and to take appropriate action to address those risks. In order to be effective, therefore, the outputs of the methodologies need to be linked to the actions that enforcement authorities will take.

In practice, the greater divergences are related to the types of enforcement action taken by Member States in response to risk assessment results. As highlighted in Section 2, some Member States prefer a voluntary approach to a litigious approach and vice versa. More generally, there is a relative disparity between the level of default required to trigger a certain regulatory action. The methodologies need to provide a means for users to distinguish between different categories of action required (e.g. between risks requiring rapid, stringent action and those where some or no action is required and a longer time scale for action may be acceptable).

The three methodologies tested resulted in quite different risk conclusions for some of the case study products - even after incorporating the suggested revisions to each of the methodologies, as Table 7.7 shows. This has potentially significant consequences for the types of enforcement action that would result from their use. In the context of this study, 'best practice' should allow for an improvement in the level of convergence in risk assessment results.

Table 7.7: Summary of Risk Results using the Revised Formal Methodologies

Product	Hazard	RAPEX	Risk Matrix	Nomograph
Doll	Small parts (buttons) can be easily detached and placed in mouth	**Serious**	**Very high**	**Moderate/ Significant**
Cot	Vertical bars too far apart permitting baby's head to become trapped	**Serious**	**High**	**High**
Doll	Plastic bag not perforated (suffocation hazard)	**Serious**	**High**	Moderate
Hooded Child's Top	Drawstring presents strangulation hazard	**Serious**	Substantial	**Significant**
Roller Skates	Helmet fails impact test (inadequate design/material)	**Moderate**	**Substantial**	**Moderate/ Significant**
Roller Skates	Normal skating	**Moderate**	**Substantial**	**Low/ Moderate**
Cot	Small holes present in frame (for adjusting height of opening side)	Serious	**Possible**	**Low**
Push Chair	Latches may not function causing pushchair to collapse	Serious	Possible	Significant
Electric Chainsaw	Chain brake not reliable (design fault)	Serious	**Possible**	**Moderate/ Significant**
Climbing Frame	Lack of warning about siting on hard surfaces	**Moderate**	**Possible**	**Very Low/Low**
Cot	Wooden bars have splinters	Serious	Possible	Very Low
Foldable Ladder	Ladder collapses under use (design fault evident on few ladders)	**Moderate**	**Possible**	**Moderate**
Electric Chainsaw	Possible exposure of power wires (inadequate quality control)	**Moderate**	**Possible**	**Low/ Moderate**
Doll	Doll contains excessive levels of phthalates	Serious	Slight	Moderate
Push Chair	Loss of plastic covers may expose sharp edges	Serious	Slight	Low
Swing	Chain may break causing child to fall	**Moderate**	Slight	**Moderate**
Swing	Use of heavy seat may cause injury	Moderate	**Slight**	**Very Low**
Climbing Frame	Sharp edges present (possibly leading to cut fingers)	Moderate	**Slight**	**Extremely Low**
Foldable Ladder	Sharp edges on ladder	**Low**	**Slight**	**Extremely Low**

The possible results from the three risk assessment methodologies could be grouped, to reflect levels of risk requiring similar regulatory action, as follows:

- serious (RAPEX); very high and high (risk matrix); high and significant (Nomograph);
- moderate (RAPEX); substantial and possible (risk matrix); moderate and low (Nomograph); and
- low (RAPEX); slight (risk matrix); very low and extremely low (Nomograph).

Following from the grouping, if the revised results of the three methodologies were placed side by side (as shown in Table 7.7), it is notable that the three methodologies produce completely divergent results for only four (out of 19) hazard scenarios (21%); fully comparable results are obtained for eight of the hazard scenarios (42%) and the remaining seven hazard scenarios (37%) produce similar results for two risk assessments. Notably, the RAPEX methodology was singularly responsible for the largest divergence in results; this may, however, reflect the lower number of risk levels (three) compared with the other two methodologies. In simple terms, a single point variation in risk scoring leads to a different risk category and the implications of moving between 'serious' and 'moderate' risks on a three scale rating are more significant than moving from 'very low' to 'low' on, say, an eight scale rating (see Nomograph).

In terms of best practice, therefore, it would appear that in order to ensure more accurate and justifiable risk assessment results, as well as to achieve a higher level of convergence with other Member States, authorities should use more than one risk assessment methodology for assessing the safety of products. Where there is significant agreement using the two methodologies, there is sufficient scope to proceed with regulatory action. On the other hand, where there are divergences, it would be important to seek expert opinion in understanding the reasons for the divergence (although the strengths and weaknesses, as well as implicit bias of the methodologies are often the cause) and the appropriate regulatory action to be taken. Finally, a key advantage of using more than one methodology is that a number of different aspects of risk and safety criteria will be taken into account.

7.3.2 The RAPEX Methodology

Application of the RAPEX methodology resulted in only two types of risk conclusion; a 'serious risk' for 17 (90%) of the listed hazards and a 'moderate risk' in only two cases (10%), involving the swing (*chain may break causing child to fall*) and foldable ladder (*sharp edges on ladder*). With the suggested revisions (see Section 7.2.2), the application of the revised RAPEX methodology resulted in a 'serious risk' for 10 (53%) of the listed hazards and a 'moderate risk' for eight (42%). For one hazard involving the foldable ladder (*sharp edges on ladder*), the resultant risk was low.

Since the (original) RAPEX methodology is intended to be used in cases where potentially serious risks have been identified, it is perhaps not surprising that in most cases involving vulnerable consumers (for whom exposure is generally deemed unacceptable), the conclusion is that there is a serious risk requiring rapid action. However, the limited numbers of action categories under the RAPEX methodology does constrain the scope for users to match the risk level to the appropriate action to be taken.

7.3.3 The Risk Matrix

The matrix identifies five levels of risk: very high, high, substantial, possible and slight. The boundaries between the categories are fixed, meaning that a single point variation in scoring can lead to a different risk category.

Using the original risk matrix methodology, two hazards (11%) were categorised as having 'high' risks, two (11%) as having 'substantial' risks, seven (37%) as having 'possible' risks and eight (42%) as having 'slight' risks. The results of using the revised methodology (see Section 7.2.3) led to one of the doll hazards (detachable small parts) being categorised as having a 'very high' risk. Two hazards (11%) were categorised as having 'high' risks, three (16%) as having 'substantial' risks, seven (37%) as having 'possible' risks and six (32%) as having 'slight' risks.

Clearly, this differentiation of risk severity enables the degree of enforcement to be proportional to the level of risk.

7.3.4 The Nomograph

The nomograph allows for no fewer than eight possible risk conclusions, enabling a range of different actions to be taken depending on the risk conclusion. Using the original nomograph across the19 hazards considered in Section 6, resulted in four (21%) high risks (ranging from 'significant/high' to 'high/very high'), seven (37%) moderate to significant risks and eight (42%) lesser risks.

Using the revised nomograph (see Section 7.2.4) resulted in a narrower range of results (see Table 7.7) with just one high risk, nine (47%) moderate to significant risks and nine (47%) lesser risks.

It is worth noting that, in practice, many of the scores fell on the boundaries between categories (e.g. 'moderate/significant'; 'very low/low'). The existence of such overlaps does mean that the boundaries between categories are less sharp. For example, a single point difference between scores, which is well within the margin of error of the scoring process, does not necessarily move a product from one risk category to another. However, it is not clear whether the resulting large number of categories is really helpful to users in deciding the action to be taken once the assessment is complete.

7.3.5 Product Availability and the Actual Risk to Consumers in General

In theory, the overall risks to consumers (which could be referred to as the societal risk) in general associated with a particular product may be represented as follows:

Overall (societal) risk = N (consumers) x Average Risk/Consumer

In many cases, consumers would only own one item of a particular product, so that:

Overall (societal) risk = N (products) x Average Risk/Consumer

Such calculations are essential when reviewing accident data associated with particular products. For example, if there were five serious injuries reported last year associated with a particular child's toy of which 3,500 were in circulation, then the risk of a serious injury associated with that toy would be one chance in 700 per year.

However, for this study, the focus is on preventing risks and as such the risks should be assessed before large numbers of products were in circulation with the potential for associated casualties. It is of course accepted that, in practice, unsafe products are placed on the market and reliance is placed on surveillance systems to provide early warnings of potentially dangerous products (hence the development of the RAPEX methodology).

With these points in mind, although the nomograph does have the facility to incorporate an 'availability' factor to provide an indication of societal risk, this is not considered to be particularly helpful in relation to product safety.

In particular, it is very unlikely that it would be deemed acceptable to place a product on the market with limited availability which was significantly less safe than a very similar product which was widely available. By way of example, limited editions of cars are no less safe than the 'standard' models.

Also, as highlighted in the roller skates case study, it may be the case that the risk has not increased, but simply the population at risk.

7.4 Informal Approaches and Risk Assessment

7.4.1 Introduction

As described in Section 4, *informal risk assessment* has been used in the context of this study to describe less formalised and/or documented procedures which provide an indicative or comparative assessment of risk. The informal approaches to risk assessment identified in this study can be broadly divided into two categories:

- *expert panels*: which refer to a group of knowledgeable people who are qualified to pass judgement on a particular product and/or risk; and
- *standards and technical documentation*: which refer to regulatory guidance which set out safety (and other) parameters which products are expected to comply with. These guidance are often used by testing laboratories, manufacturers and authorities.

7.4.2 Standards – Strengths and Weaknesses

The presence of standards and other technical documentation provide a basis for assessing the safety of a product; basically, standards set the parameters for what is considered safe. In comparison to formal risk methods, they also provide sufficient basis for consensus on the appropriate action to be taken in any disputed cases by setting out detailed guidelines which are clear to manufacturers, testing bodies and surveillance authorities.

For instance, in the cots case study, the hazard 'vertical bars being too far apart' would constitute a failure to comply with the EN 716 standard. The fact that a product (or cot) did not meet the relevant standards would indicate that there was a risk and thus that some remedial action was necessary. In this case, a formal risk assessment is not necessarily required to prove fault and the presence of standards would provide the basis for consensus on regulatory action between the manufacturer/supplier and regulator. In this example, compared with the divergence in conclusions between the formal risk assessment methodologies, the use of standards is likely to affect only the rate at which regulatory action is taken, limiting the potential impact on safety of the product.

Standards do not, however, remove the need for risk assessment, for a number of reasons:

- compliance with a standard does not remove the general obligation under the GPSD to ensure that products are safe. It is possible for a product to comply with the relevant standard(s) and still be unsafe (for instance, where the fault relates to quality control, lack of warnings, etc.). Also, standards, by definition, relate to past problems and are slow to adapt to new risks;

- many products covered by the GPSD do not have harmonised standards and, where they do, these tend to be performance rather than safety-oriented (e.g. textiles, where only the flammability standards are truly safety-focused). Consumer products are also generally very difficult to develop standards for, because of the variability between products within a particular category and the development of new standards is a slow process which can take a number of years;

- although in theory, standards should set out clear requirements, and specify methods by which compliance could be judged, this is not always the case in practice. This is a particular problematic for chronic hazards, such as those posed by chemicals, where harmful effects can arise many years after exposure. Where there is no agreed method to measure the level of hazardous substance within a product (for example, flame retardants in furniture) then the risk cannot be assessed and evaluation is based on hazard rather than risk; and

- the presence of a standard does not address the problems of risk interpretation. For instance, in the cots case study, there is no objective way of differentiating the appropriate regulatory action for each of the hazards discussed. In summary, where a product does not comply with the standards, risk assessment methodologies may help to decide on how it is to be addressed.

7.4.3 Expert Panels – Strengths and Weaknesses

Where there are no standards or formal risk assessment methodologies, judgement of the safety of a product will be more subjective by nature and expert panels tend to be of greatest benefit in this regard. They are often used to address products and/or new risks which are complicated for enforcement officers due to technical reasons as well as economic, political and social sensitivities.

Expert panels are also of benefit in addressing issues relating to hazard perception (which invariably arises in issues relating to children) as well as in addressing behavioural risks and possibly changes in technology, fashion and other trends, which they are better placed to react to faster (compared with standards). This is of importance because the hazards which are normally addressed by standards (and those which have been examined in the context of this study) all assume that the fault is related to the design of the product. However, in practice, a common cause of injuries among children is linked to the behaviour of the child; this is particularly highlighted in the case studies on playground equipment and roller skates.

The most common cause of injuries involving playground equipment is a fall linked to the behaviour of the child (especially for swings) in the playground. As one surveillance authority noted, it is not possible for regulations and standards to cover all aspects of playground equipment and related services, especially as this is a diverse and permanently evolving sector.

The roller skates case study, however, highlights the need for a more rounded (common sense) approach to risk assessment which takes into account a number of variables when interpreting risk assessment results. In the case of roller skates, it is often the case that the product itself does not fail or develop faults, but behavioural factors are the predominant risk factor. The 'almost inevitable' hazard recognition cannot be ignored and where regulatory action is triggered by an increase in accidents, the reasons for the increase need to be adequately reviewed (prior to regulatory action).

A single and crucial drawback for expert panels is that they cannot operate in isolation (without standards, accident data or some sort of formal risk assessment methodology, albeit a simple one which looks at 'severity of consequence' and 'probability of occurrence').

7.4.4 Potential for Further Development of Informal Approaches

Some conclusions can also be drawn on the need for further development of informal approaches to risk assessment:

- the presence of standards facilitates both the identification of risks (whether using formal or informal approaches) and the enforcement of product safety. While outside the remit of this study, the development of standards for more products would be useful in ensuring the safety of products; and

- expert panels are of relevance in checking the robustness of risk assessment results. The case studies clearly show that formal risk assessment methodologies (particularly the semi-quantitative ones) may give a spurious impression of exactitude/objectivity, which can be misleading. In the context of this study, best practice would involve ensuring that risk assessment results are discussed and agreed by an expert panel (minimum of two people). Where such expertise does not exist within an authority, it is recommended that outputs from risk assessment methodologies should clearly indicate that the risk assessment results have not been checked by an expert panel. This would be of benefit to other authorities wishing to use the results.

8. CONCLUSIONS AND RECOMMENDATIONS

There is a general requirement under the GPSD for products placed on the EU/EEA market to be safe. However, there will always be associated hazards and/or risks to consumers, the extent of which will depend not only on the safety of the product itself but also upon the nature and behaviour of the consumer. Risks to consumers associated with products arise from two main causes:

- use of products which are inherently hazardous, through inappropriate design or faulty workmanship. For example, an electrical appliance may have a fault which results in a fire or an electric shock to the user; and
- inappropriate use of products, for example where a consumer does not follow the safety guidance for use of a ladder, which results in a fall from the ladder.

Assessing the risks to consumers involves identifying the hazards, assessing the potential consequences and the probability that such consequences could arise.

There is, however, a clear trade-off in the application of risk assessment methods between the consistency and level of detail of the outcome and the time and resources (particularly human and financial) required. Apparently simple methodologies may contain implicit weightings that may not be appropriate for every product being assessed (for instance, electrical products pose hazards of electrocution and fire that are not found in other products). Judgement of the 'probability of occurrence' or the gravity of the outcome may be intuitive, based on implicit assumptions, especially in relation to the boundaries between categories (e.g. between high and low). There are also differences in terms of the vulnerability of users and their ability to understand warnings and instructions, particularly where products are targeted at children.

Taken together, these differences can result in a high degree of subjectivity in risk assessment, although this can be reduced by the extent of guidance provided to assist users to apply the various scales and ratings. In general, the greater the extent of subjectivity, the higher will be the potential for inconsistency in results.

The potential consequences of inconsistency in application of risk assessment methodologies to product safety are considerable. If the risk posed by a product is assessed to be higher than is actually the case, there may be significant economic consequences, in terms of lost sales for producers and distributors and lost access to products for consumers. There may also be impacts on enforcement authorities, if producers and distributors challenge the findings of the risk assessment in court. On the other hand, if the risks are assessed to be lower than they actually are, there could be impacts on consumer safety in the form of continuing injuries or even fatalities.

Having examined the various risk assessment methodologies (and possible revisions to them), it is evident that the selection of a 'best practice' methodology depends on the attitude of the product safety regulator to risk. Three different perspectives (which reflect the practice of consumer safety in EU Member States) have been considered and the following conclusions can be reached:

- the **RAPEX methodology** represents best practice under a 'risk averse' approach. In other words, in those Member States where the possible occurrence of (sometimes very) minor injuries, particularly amongst vulnerable people, would not be consistent with national/general approach towards risks, then the RAPEX methodology is the preferred approach. The development of the methodology could focus on greater differentiation between different risks to such groups;

- the **Risk Matrix** represents best practice where the inherent safety of the product is of prime concern. In other words, by taking no account of the consumer's behaviour and response (e.g. to hazard warnings and hazard recognition) and by focusing on the product rather than the consumer, the risk matrix provides for a 'worst case' approach; and

- the **Nomograph** represents best practice under the 'acceptable risk to the average consumer' approach. In other words, the actual risks of a product to (what is considered to be) the average (or typical) consumer would be somewhat lowered by the (perceived) effectiveness of warning labels and/or the degree of hazard recognition by the consumer.

Potential areas for further development of risk assessment methodologies depend, to some extent, on the objectives of the Member States. For those wishing to pursue risk-based decision-making, there would be merit in further development of each of the three formal methodologies as discussed in Section 7. It is, however, important to note that a 'perfect' risk assessment methodology can neither be expected to assess all risks across all consumer products effectively (as methodologies often contain implicit weightings that may not be appropriate for every product being assessed) nor completely eliminate divergences (such as those due to differences in risk perceptions).

Also, while the adjustments to the methodologies would be expected to improve the results of the methodologies identified, the case studies also highlight areas where formal methodologies are inappropriate for ensuring the safety of products, these include:

- *assessing cumulative risks*: none of the methodologies identified provides an explicit basis for assessing cumulative risks, such as those from 'children wearing clothes with strings that are using playground equipment'. Instead, each hazard is assessed separately – it is possible that a number of low level hazards could, when combined, result in a relatively high risk;

- *interpreting accident data*: a key aspect of ensuring product safety and risk assessment is the 'number of incidents' or 'probability of occurrence'. As shown in the roller skates case study, there are certain cases where the risk associated with the product does not change, but an increase in the population at risk (i.e. number of users) results in an increased number of accidents (i.e. increase in societal risk). In this case, it was also shown that behavioural factors are a predominant risk factor; and

- *hazard identification*: the case studies showed that, in the absence of standards, risk assessment methodologies are not adept at identifying hazards.

It is thus equally important for regulators and authorities involved in risk assessment to accurately interpret the results derived using any particular methodology in the context of these limitations, as well as taking into consideration, their strengths, weaknesses and bias[17] (or implicit weightings) as discussed in Section 7.2.

For countries which rely on informal approaches to risk assessment, the use of **standards, test reports and other technical documentation** relating to the product reflect the 'acceptable risk to individual consumer' (or realistic 'worst case') approach. However, this approach encounters problems where there is no regulatory guidance (in the form of standards or legislation), as shown in the case study on children's clothing with strings. These documents also tend to describe the product's characteristics and not the way products are used (or misused). Overall, the case studies clearly show that standards make identification of risks, and enforcement of product safety, easier. While outside the remit of this study, the development of standards for more consumer products would be useful in ensuring the safety of products.

Compared with standards, **expert panels** may reflect a more rounded risk assessment which takes into account behavioural attributes and may be of relevance in checking the robustness of risk assessment results. The case studies clearly show that formal risk assessment methodologies (particularly the semi-quantitative ones) may give a false impression of accuracy/objectivity, which can be misleading. In the context of this study, best practice would involve ensuring that risk assessment results are discussed and agreed by an expert panel (minimum of two people). Where such expertise does not exist within an authority, it is recommended that outputs from risk assessment methodologies should clearly indicate that the risk assessment results have not been checked by an expert panel. This would be of benefit to other authorities wishing to use the results.

[17] As discussed earlier, the RAPEX methodology effectively treats any hazards to vulnerable consumers as being unacceptable; by contrast, the nomograph takes into account the fact that the consumer recognises the hazard prior to using the product whilst the risk matrix focuses on the risks relating to the product.

9. REFERENCES

Access Guide (2005a): **Germany Legislation: Safety of Children's Clothing**, Information available from Access Guide Website: www.cbi.nl/accessguide.

Ball DJ (2002): **Playgrounds – Risks, Benefits and Choices**, Contract Research Report 426/2002, prepared for the Health & Safety Executive, Information available from www.hse.gov.uk.

Benis H (1990): **A Product Risk Assessment Nomograph**, report prepared for the New Zealand Ministry of Consumer Affairs, dated February 1990.

Björnstig and Johnsson (1992): **Ladder Injuries: Mechanisms, Injuries and Consequences**, J. of Safety Research, 23: 9 -18.

Buszard (2001): **Developments in European Standardisation and Regulation,** FRCA, San Francisco, March, 2001.

Consumer Safety Institute (2004): **Risk Assessment in the Context of the General Product Safety Directive**, report prepared by the Dutch Consumer Safety Institute for DG SANCO, dated October 2004.

Consumer Safety Institute (2005): **Manual for Risk Assessment**, report prepared by the Dutch Consumer Safety Institute dated February 2005

DG SANCO (2003): **Guidance Document on the Relationship between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety**, dated November 2003.

DG SANCO (2005): **Presentation at the European Market Surveillance Programming Conference**, Brussels, 10 – 11 March, 2005.

ECOSA (2004): **Consumer Rights for Child Safety Products**, Final Report, European Child Safety Alliance and European Consumer Safety Association, dated September 2004.

European Commission (2000): **First Report on the Harmonisation of Risk Assessment Procedures**, DG Health & Consumer Protection.

European Commission (2004a): **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**, Brussels, Belgium, Commission Decision 2004/418/EC of 29 April 2004.

European Commission (2004b): **Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities in Accordance with Article 5/3 of Directive 2001/95/EC**, Brussels, Belgium, European Commission

HSE (2002): **Safety in Children's Playgrounds**, Local Authority Circular 79/2, dated February 2002, Information available from www.hse.gov.uk.

ITS Research and Testing Centre (2002): **Criteria for Serious Risk in the GPSD**, Final Report for DG SANCO, dated June 2002.

KO (2002): **Product Related Accidents in Playgrounds and School Grounds in Sweden**, Report 2002:7.

LACORS (2004): **Trading Standards Risk Assessment Scheme**, guidance published by the UK Local Authorities Coordinators of Regulatory Services, dated February 2004.

Navarro T *et al* (2002): **Ergonomics Evaluation into the Safety of Stepladders,** Literature and standards review, Phase 1, Prepared by Loughborough University for the Health and Safety Executive.

Pražák M & Langšádl T (2004): **Všeobecné Zásady Managementu Rizika** (General Principles of Risk Management), Prague, COI (Czech Risk Matrix).

Research Institute for Consumer Ergonomics (2002): **Ergonomics Evaluation into the Safety of Stepladders,** Literature and standards review Phase 1, a study for HSE (2002).

ROSPA (2003): **Domestic Electrical Safety**, Royal Society for the Protection of Accidents, Bristol, Information available from www.rospa.com

RoSPA (nd): **EN1176 Playground Equipment Standard**, Play Safety: Information Sheets: No 10.

RPA (2004): **Study on the Impact of Revisions to Directive 88/378/EEC on the Safety of Toys**, Final Report, prepared by Risk & Policy Analysts, dated October 2004.

US CPRC (2005): **Product Recall of Graco strollers by the US Consumer Product Safety Commission**, dated 27 July 2005.

Annex 1

Technical Specifications

SPECIFICATIONS ATTACHED TO THE INVITATION TO TENDER

General invitation to tender SANCO/2004/B3/012 concerning technical assistance for establishing a comparative inventory of approaches and methods used by surveillance and enforcement authorities and conformity assessment bodies for the assessment of the safety of consumer products covered by Directive 2001/95/EC on general product safety (GPSD), and identification of best practices in this area.

1. Introduction - Context of the contract

The technical assistance required under this contract is related to the application of the General Product Safety Directive (GPSD). Article 10 of the GPSD provides for the establishment of a European network of surveillance and enforcement authorities, with the aim to promote administrative co-operation among such authorities. The Commission is requested to promote and take part in the operation of the network. Article 10 states that the network should, among other things, facilitate the exchange of information on risk assessment and the exchange of expertise and good practices on relevant surveillance and enforcement activities.

With a view to promote effective and consistent assessment of risks posed by consumer products covered by the GPSD, the Commission wishes to establish a comparative inventory and assessment of current approaches, methods and practices used by the surveillance and enforcement authorities and conformity assessment bodies in the Member States of the European Union (EU) and the States of the European Economic Area (EEA) to assess the risks posed by certain categories of non-food consumer products, and to identify best practices and needs for further development or normalisation of risk assessment methods.

2. Purpose of the contract

The purpose of the contract is to provide a comparative inventory and assessment of the approaches, methods and practices used by the surveillance and enforcement authorities and conformity assessment bodies in the EU and EEA Member States for assessing the risks posed by the products belonging to the categories listed below, in order to verify their compliance with the safety requirements applicable to them, and to identify best practices and needs for further development or harmonisation of risk assessment methods.

The inventory and assessment will focus on the approaches, methods and practices which are codified or otherwise formally documented or at least are well identifiable and confirmed practices[7].

The scope of the work shall include consideration of the general way of dealing with risk assessment in relation to the product categories mentioned below, the structured quantitative or qualitative risk assessment methodologies and the relevant practices applied by the surveillance and enforcement authorities and conformity assessment bodies of the EU and EEA Member States.

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[7] A methodological framework for facilitating consistent estimation and evaluation of serious risks by the authorities and the Commission was developed for 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", Commission Decision 2004/418/EC of 29 April 2004. OJ L 151, 30.4.2004.

The **product categories** to be covered are the following:

- Childcare articles (i.e. cots, high and push chairs);
- Playground equipment (i.e. climbing frames, swings, slides);
- Household products (i.e. furniture, ladders, electrical appliances, gardening equipment);
- Sport equipment (i.e. exercise machines, protective equipment, buoyancy and mobility aids);
- Toys (i.e. dolls, ride-on toys, battery powered toys, educational equipment);
- Clothing.

The contractor is required:

- to identify and describe the approaches, methods and practices used by the surveillance and enforcement authorities and conformity assessment (testing and certification) bodies in the EU and EEA Member States for assessing the risks for consumer health and safety posed by the products mentioned above;

- to make a comparative assessment of the approaches, methods and practices identified, highlighting in particular any significant differences and their implications for the results of risk assessment;

- to highlight cases where the methods currently used may lead to divergent risk assessment conclusions;

- to identify and describe best practices in light of the findings of the comparative assessment, taking also into account the results achieved in practice with the application of the approaches, methods and practices considered;

- to identify needs for further development of risk assessment methods where the existing methods are not sufficiently developed or effective or important differences exist between the methods used, which may lead to divergent risk assessment conclusions.