III

(Other acts)

EUROPEAN ECONOMIC AREA

EFTA SURVEILLANCE AUTHORITY DECISION

No 447/14/COL

of 5 November 2014

adopting guidelines for the management of the Rapid Information System 'RAPEX' as established under Articles 11 and 12 of Directive 2001/95/EC (the General Product Safety Directive) [2016/487]

THE EFTA SURVEILLANCE AUTHORITY

Having regard to Articles 5(3), 12(3), point 2 of Annex I and point 8 of Annex II to the Act referred to at point 3h of Chapter XIX of Annex II to the Agreement on the European Economic Area ('the EEA Agreement'), Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ([1]), as adapted to the EEA Agreement by Protocol 1 thereto,

Having regard to Article 5(2)(d) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice ('the SCA'), according to which the EFTA Surveillance Authority ('the Authority') shall carry out the functions which, through the application of Protocol 1 to the EEA Agreement, follow from the acts referred to in the Annexes to that Agreement, as specified in Protocol 1 to the SCA,

Having regard to Article 1(2) of Protocol 1 to the SCA, according to which the Authority shall carry out certain functions corresponding to the functions of the European Commission,

Having regard to College Decision No 198/10/COL empowering the College Member with special responsibility for general product safety to (1) submit draft Guidelines to the responsible EFTA Committee on Technical Regulations, Standards, Testing and Certification ('the Committee') ([2]) and to (2) adopt Guidelines concerning the management of the Rapid Information System 'RAPEX' after having consulted the Committee ([3]) on the matter ('the RAPEX Guidelines'),

Whereas:

In accordance with Article 12(3) and point 8 of Annex II to Directive 2001/95/EC, the European Commission shall prepare and regularly update the RAPEX Guidelines.

By Decision 2010/15/EU ([4]), the European Commission adopted amended RAPEX Guidelines thereby repealing those adopted by Commission Decision 2004/418/EC ([5]). By Decision 396/10/COL of 19 October 2010, the Authority thus adopted equivalent RAPEX Guidelines.

([1]) OJ L 11, 15.1.2002, p. 4.
([2]) The EFTA Committee on Technical Regulations, Standards, Testing and Certification, as designated by Decision No 4/2012/SC of the Standing Committee of the EFTA States of 26 October 2012.
([3]) Ibid.
([4]) Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System RAPEX established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) (OJ L 22, 26.1.2010, p. 1).
([5]) Commission Decision 2004/418/EC of 29 April 2004 laying down 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 (OJ L 151, 30.4.2004, p. 83).

Following a request from the EFTA States by intermediary of the EFTA Secretariat dated 14 April 2014, the Authority amended and prepared draft amended RAPEX Guidelines to reflect the new procedure and foreseen future validator tasks of the national RAPEX contact points of the EEA EFTA States, as outlined and described in greater detail in Appendix 6 to the draft amended RAPEX Guidelines.

In accordance with the written procedure provided for in Article 8 of its rules of procedure, the Committee was consulted on the draft amended RAPEX Guidelines ([1]).

The RAPEX Guidelines should be addressed to the national authorities of the EFTA States designated as contact points in the RAPEX system, and in charge of the notification procedures under Article 11 of Directive 2001/95/EC.

The Authority will use the RAPEX Guidelines as the reference document for managing RAPEX and the notification procedure under Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

1. After having consulted the EFTA Committee on Technical Regulations, Standards, Testing and Certification on the matter, the Authority hereby adopts amended guidelines to supplement the Act referred to at point 3h of Chapter XIX of Annex II to the Agreement on the European Economic Area for the management of the Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of the Act.

2. The Decision, including the amended guidelines set out in the Annex, shall be published in the EEA Section of, and the EEA Supplement to, *the Official Journal of the European Union*.

3. The Decision is authentic in the English language.

4. This Decision is addressed to the EFTA States.

Done at Brussels, 5 November 2014.

For the EFTA Surveillance Authority

Helga JÓNSDÓTTIR
College Member

Xavier LEWIS
Director

([1]) See letters of 8 July 2014 (Events No 714776, 714853, and 714857).

ANNEX

EFTA Surveillance Authority Guidelines for the management of the Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)

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PREFACE

The revised General Product Safety Directive, as adapted to the Agreement on European Economic Area by Protocol 1 thereto, entered into force in the EFTA States on 1 March 2004.

In accordance with Article 12(3) of the Directive and point 8 of Annex II to the Directive, the European Commission (hereafter referred to as 'the Commission' or 'the EC') shall prepare and regularly update guidelines concerning the management of the Community Rapid Information System (RAPEX). By Decision 2004/418/EC, the Commission adopted, for the first time, guidelines to supplement Directive 2001/95/EC for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of that Directive. By its Decision 2010/15/EU, the Commission adopted new guidelines, thereby repealing Decision 2004/418/EC.

According to Article 5(2)(d) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the EFTA Surveillance Authority (referred to also as 'ESA' or 'the Authority' in these guidelines) shall carry out the functions which, through the application of Protocol 1 to the EEA Agreement, follow from the acts referred to in the Annexes to that Agreement, as specified in Protocol 1 to the Surveillance and Court Agreement. Furthermore, pursuant to Article 1(2) of Protocol 1 to the Surveillance and Court Agreement, the EFTA Surveillance Authority shall carry out certain functions corresponding to the functions of the European Commission. The EFTA Surveillance Authority therefore considers it necessary to adopt and issue guidelines equivalent to, and serving a similar purpose as, the new Commission guidelines.

These guidelines are addressed to the national authorities in the EFTA States designated as contact points in the RAPEX and in charge of the notification procedure under Article 11 of Directive 2001/95/EC. The EFTA Surveillance Authority shall use these guidelines as the reference document in operating RAPEX and the Article 11 notification procedure.

It should be noted that in these guidelines, the term 'EFTA States' shall read 'EFTA States contracting parties to the EEA Agreement in respect of which the Agreement has entered into force'. Also, in the context of these guidelines, the term 'EEA States' shall mean all States which belong to the European Union and those EFTA States which are contracting parties to the EEA Agreement.

These guidelines may be amended or supplemented by the EFTA Surveillance Authority where necessary or to accord with the guidelines issued by the Commission.

These guidelines and future amendments and additions thereto will be published in the EEA Section of the *Official Journal of the European Union* and the EEA Supplement thereto in accordance with the Arrangement with regard to Publication of EEA Relevant Information, referred to in the Final Act of the EEA Agreement.

PART I

Status and addressees of the Guidelines

1. *STATUS, OBJECTIVES AND UPDATING OF THE GUIDELINES*

1.1. **Status**

The 'Guidelines for the management of the Rapid Information System "RAPEX" established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)' (the 'Guidelines') are adopted by the EFTA Surveillance Authority pursuant to Article 11(1) and Annex II, point 8, to the Act referred to at point 3h of Chapter XIX of Annex II to the Agreement on the European Economic Area, Directive 2001/95/EC, as adapted to the EEA Agreement by Protocol 1 thereto. In carrying out this task, the Authority is assisted by an advisory committee composed of the representatives of the EFTA States acting in accordance with the advisory procedure ([1]).

([1]) The EFTA Committee on Technical Regulations, Standards, Testing and Certification was designated by Decision No 4/2012/SC of the Standing Committee of the EFTA States of 26 October 2012, formerly referred to as the EFTA Consumer Product Safety Committee assisting the EFTA Surveillance Authority (designated by Decision No 12/94/SC of the Standing Committee of the EFTA States of 19 May 1994, as amended by Decision of the Standing Committee of the EFTA States No 3/2004/SC of 3 June 2004).

It follows from point 8 of Annex II to the GPSD that the EFTA Surveillance Authority shall prepare and regularly update, in accordance with the applicable advisory procedure, guidelines concerning the management of RAPEX by the EFTA Surveillance Authority and the EFTA States. Furthermore, Article 11(1) of the GPSD states that the guidelines drafted for the purpose of the RAPEX notification procedure should also regulate various aspects of the notification procedure established under Article 11 of the GPSD. Therefore, the Guidelines regulate the operation and management of the RAPEX notification procedure established under Article 12 of the GPSD, as well as the notification procedure established under Article 11 of the GPSD.

The Guidelines form a self-standing document that governs the RAPEX notification procedure established under Article 12 of the GPSD. This procedure applies to preventive and restrictive measures taken in relation to consumer products posing a serious risk to the health and safety of consumers. However, the structure and content of the Guidelines allow them to be adapted, if appropriate, to include provisions relating to the notification procedure established under Article 22 of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([1]).

EEA States, applicant countries, as well as third countries and international organisations which are granted access to RAPEX (on the conditions defined in Article 12(4) of the GPSD), participate in the system according to the rules provided for in the GPSD and the Guidelines.

1.2. **Objectives**

The GPSD provides for the establishment of guidelines to lay down simple and clear criteria and practical rules to facilitate the operation of the notification mechanisms established under Articles 11 and 12 of the GPSD. The objectives of the Guidelines are to:

— clarify the scope of the two notification mechanisms,

— set out the notification criteria for the two notification mechanisms,

— define the content of notifications and reactions sent under the two notification mechanisms, in particular what data are required and forms to be used,

— establish follow-up action to be taken by EFTA States upon receipt of a notification and the type of information to be provided,

— describe the handling of notifications and reactions by the EFTA Surveillance Authority,

— set deadlines for the various types of action taken under the two notification mechanisms,

— set out the practical and technical arrangements needed at the level of the EFTA Surveillance Authority and the EFTA States for the notification mechanisms to be employed effectively and efficiently,

— establish a risk assessment method and, in particular, criteria for identifying serious risks.

1.3. **Updating**

The Guidelines will be regularly updated by the EFTA Surveillance Authority in accordance with the updates adopted by the Commission in the light of experience and new developments in the product safety area and in accordance with the advisory procedure referred to in point 1.1.

2. *ADDRESSEES OF THE GUIDELINES*

The Guidelines are addressed to all the authorities of the EFTA States acting in the consumer product safety area and participating in the RAPEX network, including market surveillance authorities responsible for monitoring the compliance of consumer products with safety requirements, and authorities in charge of external border controls.

([1]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30) has not yet been incorporated into the EEA Agreement. Reference to the possibility for adaption of the Guidelines to include provisions relating to the notification procedure established under Article 22 of that act is, therefore, conditional upon the future incorporation of the act into the EEA Agreement.

The EFTA Surveillance Authority should use the Guidelines as a reference for managing, in cooperation with the Commission, the RAPEX system established under Article 12 of the GPSD and the notification procedure under Article 11 of the GPSD.

PART II

Rapid information system 'RAPEX' established under Article 12 of the General Product Safety Directive

1. *INTRODUCTION*

1.1. **Objectives of RAPEX**

Article 12 of the GPSD establishes a Rapid Information System ('*RAPEX*'). RAPEX was established in order to:

— provide a rapid information exchange mechanism between the EEA States, the Commission and the EFTA Surveillance Authority on preventive and restrictive measures taken in relation to consumer products posing a serious risk to the health and safety of consumers,

— inform the EEA States, the Commission and the EFTA Surveillance Authority of the conclusions of follow-up action taken by national authorities with regard to information exchanged through RAPEX.

RAPEX plays an important role in the area of product safety; it complements other action taken both at national and at European level to ensure a high level of consumer safety in the EEA.

RAPEX data help to:

— prevent and restrict the supply to consumers of dangerous products,

— monitor the effectiveness and consistency of market surveillance and enforcement activities carried out by EEA States' authorities,

— identify needs and provide a basis for action at EEA level,

— make for consistent enforcement of the EEA product safety requirements and thus the smooth functioning of the Internal Market.

1.2. **Components of RAPEX**

RAPEX consists of several complementary components, which are crucial for effective and efficient operation. The most important are:

— the legal framework, which regulates how the system operates (i.e. the GPSD and the Guidelines),

— the online application ('RAPEX application'), which allows EEA States, the Commission and the EFTA Surveillance Authority to exchange information rapidly via a web-based platform,

— the RAPEX contact points network, which consists of the single RAPEX contact points responsible for operating RAPEX in all the EEA States,

— the national RAPEX networks established in all EEA States, which include the RAPEX contact points and all the authorities involved in ensuring consumer product safety,

— the Commission RAPEX Team in the department responsible for the GPSD, which examines and validates documents submitted through RAPEX by EU Member States, and maintains and ensures correct operation of the RAPEX system with regard to these states,

— the EFTA Surveillance Authority's RAPEX Team which examines documents submitted by EFTA States, prior to the validation by the EFTA States thereof in the RAPEX database, in view of transmission to the Commission, and which maintains and ensures correct operation of the RAPEX system with regard to these States,

— the RAPEX website ([1]), which provides summaries of RAPEX notifications in application of Article 16(1) of the GPSD,

— RAPEX publications, such as RAPEX statistics, RAPEX annual reports and other promotional materials.

2. *RAPEX NOTIFICATION CRITERIA*

RAPEX, which is established under Article 12 of the GPSD, applies to measures which prevent, restrict or impose specific conditions on the marketing and use of consumer products posing a serious risk to the health and safety of consumers.

Under the GPSD, the participation of the EFTA States in RAPEX is mandatory, and thus the EFTA States have a legal obligation to notify the EFTA Surveillance Authority when the following four notification criteria are met:

— the product is a consumer product,

— the product is subject to measures that prevent, restrict or impose specific conditions on its possible marketing or use ('preventive and restrictive measures'),

— the product poses a serious risk to the health and safety of consumers,

— the serious risk has a cross-border effect.

2.1. **Consumer products**

2.1.1. *Products covered by RAPEX:*

Under Article 2(a) of the GPSD, consumer products for the purpose of RAPEX are:

— 'products intended for consumers' — products that are designed and manufactured for and made available to consumers,

— 'migrating products' — products that are designed and manufactured for professionals, which are likely, however, under reasonably foreseeable conditions, to be used by consumers. These are products manufactured for professionals that are made available to consumers, who can purchase and operate them without any special knowledge or training, e.g. a power drill, an angle grinder and a table saw designed and manufactured for professionals, but also supplied on the consumer market (i.e. consumers can readily purchase them in shops and operate them on their own without any special training).

Both products intended for consumers and migrating products can be given to consumers free of charge, can be purchased by consumers or can be provided to consumers in the context of a service. All three situations are covered by RAPEX.

Products provided to consumers in the context of a service include:

— products supplied to consumers that are taken away and used outside the premises of a service provider, such as cars and lawn-mowing machines rented or leased in rental salons, and tattoo inks and implants (that are not classified as medical devices) implanted beneath the skin of a consumer by a service provider,

— products used on the premises of a service provider, provided that consumers themselves actively operate a product (e.g. start the machine, have the option of stopping it, affect its operation by changing its position or intensity during use). Sun-beds used in tanning salons and fitness centres are examples of such products. Use of the products by consumers must be active, and involve a significant degree of control. Merely passive use, such as the use of shampoo by a person whose hair is washed by a hairdresser, or the use of a bus by its passengers, does not qualify as use by consumers.

([1]) www.ec.europa/rapex

By contrast, equipment used or operated by a service provider to supply a service is beyond the scope of RAPEX and therefore such products cannot be notified through the system, e.g. equipment on which consumers ride or travel which are operated by a service provider.

2.1.2. *Products which are not covered by RAPEX:*

RAPEX does not cover:

1. Products that are not covered by the definition of a 'product' laid down in Article 2(a) of the GPSD:

   — products that were designed and manufactured for and made available only to professionals and are not likely, under reasonably foreseeable conditions, to be used by consumers ('professional products'),

   — second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that a supplier clearly informs the person to whom he supplies the product to that effect.

2. Products that are covered by specific and equivalent notification mechanisms established by other EEA legislation:

   — food and feed covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council ([1]),

   — medicinal products covered by Directive 2001/83/EC of the European Parliament and of the Council ([2]), and Directive 2001/82/EC of the European Parliament and of the Council ([3]),

   — medical devices covered by Council Directive 93/42/EEC ([4]),

   — *in vitro* diagnostic medical devices covered by Directive 98/79/EC of the European Parliament and of the Council ([5]),

   — active implantable medical devices covered by Council Directive 90/385/EEC ([6]).

2.2. **Measures**

2.2.1. *Categories of measures*

All categories of preventive and restrictive measures taken in relation to the marketing and use of consumer products posing a serious risk to the health and safety of consumers are subject to the notification obligation under RAPEX. Article 8(1)(b) to (f) of the GPSD provides a list of the different categories of measures that are notifiable under RAPEX, including measures:

— marking a product with appropriate warnings on the risks it may present,

— making the marketing of a product subject to prior conditions,

— warning consumers of the risks that could be posed by a product for certain persons,

— temporary ban on the supply, offer to supply and display of a product,

([1]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Act referred to at point 13 of Chapter I of Annex 1 to the EEA Agreement.

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). Act referred to at point 15q of Chapter XIII of Annex II to the EEA Agreement.

([3]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1). Act referred to at point 15p of Chapter XIII of Annex II to the EEA Agreement.

([4]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Act referred to at point 1 of Chapter XXX of Annex II to the EEA Agreement.

([5]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1). Act referred to at point 2 of Chapter XXX of Annex II to the EEA Agreement.

([6]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17). Act referred to at point 7 of Chapter X of Annex II to the EEA Agreement.

— ban on the marketing of a product and any accompanying measures,

— withdrawal of a product from the market,

— recall of a product from consumers,

— destruction of a withdrawn or recalled product.

For the purpose of RAPEX, the term 'withdrawal' is used exclusively for measures aimed at preventing the distribution, display and offer of a dangerous product to consumers, while the term 'recall' is used only for measures aimed at achieving the return of a dangerous product that has already been made available to consumers by a producer or distributor.

2.2.2. *Type of measures*

Preventive and restrictive measures can be taken in relation to dangerous products either on the initiative of a producer or a distributor who placed and/or distributed it on the market ('voluntary measures') or as ordered by an authority of an EEA State competent to monitor the compliance of products with the safety requirements ('obligatory measures').

For the purpose of RAPEX, the obligatory measures and voluntary measures are defined as follows:

— Obligatory measures:

  Measures adopted or decided to be adopted by EFTA State authorities, often in the form of an administrative decision, which oblige a producer or a distributor to take preventive or restrictive action in relation to a specific product that they made available on the market.

— Voluntary measures:

  — Preventive and restrictive measures adopted on a voluntary basis by a producer or a distributor, i.e. without any intervention of an authority of an EFTA State. Products posing a serious risk and the related preventive or restrictive measures initiated by a producer or a distributor should be immediately notified to the competent authorities of EEA States under the notification mechanism provided for in Article 5(3) of the GPSD.

  — Recommendations and agreements with producers and distributors concluded by EFTA State authorities. This includes agreements which are not in written form and result in preventive or restrictive action taken by producers or distributors in relation to products posing a serious risk that they made available on the market.

Under Article 12(1) of the GPSD, both obligatory and voluntary measures are to be notified through RAPEX.

2.2.3. *Obligatory measures initiated by authorities in charge of external border controls*

Measures adopted by the authorities in charge of external border controls that prevent the marketing in the EEA of a consumer product posing a serious risk to the health and safety of consumers (e.g. decisions to stop the import at the national border) should be notified to the EFTA Surveillance Authority through RAPEX in the same manner as measures adopted by market surveillance authorities that restrict the marketing or use of a product.

2.2.4. *Exclusion of generally applicable obligatory measures*

Generally applicable acts adopted at national level and aimed at preventing or restricting the marketing and use of (a) generally described category(ies) of consumer products due to the serious risk they pose to the health and safety of consumers should not be notified to the EFTA Surveillance Authority through the RAPEX system. All such national measures that apply to only generally defined categories of products, such as all products in general or all products serving the same purpose — and not to (categories of) products specifically identified by their brand, specific look, producer, trader, model name or number, etc. — are notified to the EFTA Surveillance Authority under Directive 98/34/EC of the European Parliament and of the Council [1].

[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998), as last referred to at point 1 of Chapter XIX of Annex II to the EEA Agreement.

2.2.5. *Timing of the notification*

Article 12(1) of the GPSD requires EFTA States immediately to notify the EFTA Surveillance Authority through RAPEX of preventive and restrictive measures. This provision applies to both obligatory and voluntary measures, although the timing of the notification is different.

— Obligatory measures

These measures are notified through RAPEX immediately after being adopted or the decision to adopt them, even if an appeal against them at national level is likely, they are already under appeal or subject to publication requirements.

This approach is consistent with the objective of RAPEX, i.e. to ensure the rapid exchange of information between EEA States, the EFTA Surveillance Authority and the Commission in order to prevent the supply and use of products that pose a serious health or safety risk to consumers.

— Voluntary measures

Under Article 5(3) of the GPSD, producers and distributors are obliged to notify the competent EFTA State authorities of voluntary action and measures taken to prevent risks to consumers posed by products they have made available on the market ('business notification'). The authority of an EFTA State receiving this kind of business notification uses this information as the basis for a RAPEX notification (when all the RAPEX notification criteria provided for in Article 12(1) are met) and sends it immediately after receipt of the business notification.

Where voluntary measures are adopted in the form of an agreement between a producer or a distributor and an authority of an EFTA State or on the basis of a recommendation from an authority to a producer or distributor, a RAPEX notification is submitted immediately after the conclusion of such an agreement or the adoption of such a recommendation.

To ensure common application of the RAPEX notification obligation, Appendix 3 to the Guidelines lays down specific deadlines for submitting notifications to the EFTA Surveillance Authority via RAPEX [1].

2.2.6. *Notifying authorities*

Both obligatory and voluntary measures are notified through RAPEX by the national RAPEX contact point, which is responsible for all information transmitted through the system by its country [2].

2.2.7. *RAPEX notification concerning business notifications*

Article 5(3) of the GPSD requires producers and distributors to notify information concerning a dangerous product (at the same time) to the competent authorities in all EEA States where the dangerous product was made available. The conditions and details for this notification are laid down in Annex I to the GPSD.

In these situations, the RAPEX notification obligation applies to all EEA States that received a business notification. However, in order to simplify the practical application of Article 12(1) of the GPSD and to avoid unnecessary duplication of RAPEX notifications, it has been agreed with the EEA States that a RAPEX notification should be submitted only by the EEA State where the notifying producer/distributor is established ('main EEA State'). Once a RAPEX notification has been validated and distributed through the system by the EFTA Surveillance Authority, the EFTA States and the Commission, other EEA States (especially the ones that also received the same business notification) should submit reactions to this RAPEX notification.

Where a main EFTA State does not submit a RAPEX notification by the deadline specified in Appendix 3 to the Guidelines and does not inform the EFTA Surveillance Authority of the reasons for the delay, any other EEA State that received the same business notification can submit a notification through RAPEX.

[1] For more information about deadlines, see Chapter 3.10. of the Guidelines.
[2] For more information about the RAPEX contact points and their obligations, see Chapter 5.1 of the Guidelines.

2.3. **Serious risk**

2.3.1. *Serious risk*

Before an authority of an EFTA State decides to submit a RAPEX notification, it always performs the appropriate risk assessment in order to assess whether a product to be notified poses a serious risk to the health and safety of consumers and thus whether one of the RAPEX notification criteria is met.

As RAPEX is not intended for the exchange of information on products posing non-serious risks, notifications on measures taken with regard to such products cannot be sent through RAPEX under Article 12 of the GPSD.

2.3.2. *Risk assessment method*

Appendix 5 to the Guidelines sets out the risk assessment method to be used by EFTA State authorities to assess the level of risks posed by consumer products to the health and safety of consumers and to decide whether a RAPEX notification is necessary.

2.3.3. *Assessing authority*

The risk assessment is always performed by an authority of an EFTA State that either carried out the investigation and took appropriate measures or monitored voluntary action taken with regard to a dangerous product by a producer or a distributor.

Before a RAPEX notification is sent to the EFTA Surveillance Authority, the risk assessment performed by an authority of an EFTA State (to be included in the notification) is always verified by the RAPEX contact point. Any unclear issues are resolved by the contact point with the authority responsible before a notification is transmitted through RAPEX.

2.3.4. *Risk assessment in business notifications*

Notifications on dangerous consumer products submitted by producers and distributors under Article 5(3) of the GPSD to the competent authorities of EFTA States should include a detailed description of the risk. National authorities receiving such notifications examine their content and analyse the risk assessments provided. If, on the basis of the information provided and an independent risk assessment, an authority of an EFTA State decides that the notified product poses a serious risk to the health and safety of consumers, a RAPEX notification concerning this product is immediately transmitted to the EFTA Surveillance Authority (the fourth subparagraph of Article 12(1)of the GPSD).

Risk assessments carried out by producers and distributors are not binding on EFTA State authorities. It is therefore possible for an authority of an EFTA State to come to a different conclusion regarding the risk assessment from a conclusion drawn in a business notification.

2.4. **Cross-border effects**

2.4.1. *International event*

Under Article 12 of the GPSD, an EFTA State submits a RAPEX notification only if it considers that the effects of the risks posed by a dangerous product go or can go beyond its territory ('cross-border effects' or 'international event').

In the light of the free movement of products in the Internal Market, and the fact that products are imported into the EEA through different distribution channels and that consumers buy products during stays abroad and via the internet, national authorities are encouraged to interpret the cross-border effects criterion in a fairly broad sense. A RAPEX notification, therefore, is submitted where:

— it cannot be excluded that a dangerous product has been sold to consumers in more than one EEA State, or

— it cannot be excluded that a dangerous product has been sold to consumers via the internet, or

— the product originates from a third country and is likely to have been imported into the EEA through multiple distribution channels.

2.4.2. *Local event*

Measures adopted in relation to a product posing a serious risk that can only have local effects ('local event') are not notified through RAPEX. This applies to situations where an authority of an EFTA State has reason to believe that a product has not been and will not be made available (by any means) to consumers in other EEA States, e.g. measures taken with regard to a local product manufactured and distributed only in one EEA State.

A notification involving a local event should still be submitted to the EFTA Surveillance Authority but under Article 11 of the GPSD and only where it involves information on product safety likely to be of interest to other EEA States, especially information on measures adopted in response to a new type of risk which has not yet been notified, a new type of risk arising from a combination of products or a new type or category of dangerous products (the second subparagraph of Article 12(1) of the GPSD).

3. *NOTIFICATIONS*

3.1. **Types of notifications**

3.1.1. *RAPEX notifications*

There are two types of RAPEX notifications, namely 'Article 12 notification' and 'Article 12 notification requiring emergency action'.

— Where all the RAPEX notification criteria laid down in Article 12 of the GPSD (see Chapter 2 of Part II of the Guidelines) are met, an EFTA State prepares and submits to the EFTA Surveillance Authority a RAPEX notification classified in the RAPEX application as 'Article 12 notification'.

— Where all the RAPEX notification criteria are met and, in addition, a product poses a life-threatening risk and/or there have been fatal accidents and in other cases where a RAPEX notification requires emergency action by all EEA States, the notifying EFTA State prepares and submits to the EFTA Surveillance Authority a RAPEX notification classified in the RAPEX application as 'Article 12 notification requiring emergency action'.

Before sending a RAPEX notification to the EFTA Surveillance Authority, the RAPEX contact point of the notifying EFTA State checks that all RAPEX notification criteria are met and that it should be sent through the RAPEX application as an 'Article 12 notification' or an 'Article 12 notification requiring emergency action'.

3.1.2. *Notifications for information*

If a notification cannot be sent through the system as a RAPEX notification, the contact point may choose to use the RAPEX application to send the information concerned for information. Such notifications are classified in the RAPEX application as 'Notifications for information' and they may be sent in the following situations:

(a) Where all the RAPEX notification criteria laid down in Article 12 of the GPSD are met but a notification does not contain all the information (mainly on product identification and distribution channels) necessary for other EEA States to ensure follow-up ([1]) to such a notification. A notification where the product name, brand and picture are missing and thus the notified product cannot be correctly identified and it cannot be distinguished from other products of the same category or type that are available on the market, is an example of a notification that can be distributed through the RAPEX application as 'Notification for information'. Assessment as to whether a notification contains sufficient information for other EEA States to ensure follow-up is always on a case-by-case basis.

(b) Where an EFTA State is aware of the fact that a consumer product that is available on the EEA market poses a serious risk to the health and safety of consumers, but preventive and restrictive measures have not yet been taken by the producer or distributor or adopted or decided to be adopted by an authority of an EEA State (the fourth subparagraph of Article 12(1) of the GPSD). If information on such a product is distributed through the RAPEX application before measures are taken, the notifying EFTA State subsequently informs the EFTA Surveillance Authority (as soon as possible and not later than the deadlines specified in Appendix 3 to the Guidelines) of the final decision taken with regard to the notified product (mainly, what type of preventive or restrictive measures were taken or why such measures were not taken).

([1]) For more information on follow-up actions, see Chapter 3.7.

(c) Where an EFTA State decides to notify preventive and restrictive measures taken in relation to a consumer product posing a serious risk to the health and safety of consumers which has only local effects ('local event'). If, however, as explained in Chapter 2.4.2, a notification by 'local event' involves information on product safety likely to be of interest for other EEA States, it should be sent under Article 11 of the GPSD.

(d) Where a notification concerns a consumer product whose safety aspects (especially the level of risk posed to the health and safety of consumers) are subject to discussion at EEA level to ensure a common approach between EEA States to risk assessment and/or enforcement action ([1]).

(e) Where a decision cannot be taken with certainty that one or more of the RAPEX notification criteria are met but a notification involves information on product safety likely to be of interest for other EEA States. A notification on a product that cannot be indisputably classified as a consumer product, which however provides information on a new type of risk to the health and safety of consumers, is an example of a notification that can be distributed through the RAPEX application as a 'Notification for information'.

When sending a 'Notification for information', the RAPEX contact point clearly states the reasons for doing so.

3.2. **Content of notifications**

3.2.1. *Completeness of data*

Notifications should be as complete as possible. The standard notification form is provided in Appendix 1 to the Guidelines. All fields of the notification form should be completed with the required data. Where the required information is not available when a notification is submitted, this is clearly indicated and explained on the form by the notifying EFTA State. Once the missing information becomes available, the notifying EFTA State updates its notification. The updated notification is examined by the EFTA Surveillance Authority before being transmitted to the Commission for validation and distribution through the system.

RAPEX contact points provide all national authorities that participate in the RAPEX network with instructions on the scope of data required to complete the standard notification form. This helps to ensure that the information provided by these authorities to the RAPEX contact point is correct and complete.

EFTA States should observe the established deadlines and not delay a RAPEX notification on a product posing a very serious or life-threatening risk to the health and safety of consumers because part of the information required by the Guidelines is not yet available.

Before submitting a notification, the contact point checks (to avoid any unnecessary duplication) that the product concerned has not already been notified through the application by another EEA State. If the product has already been notified, rather than creating a new notification, the contact point submits a reaction to the existing notification and provides any additional information that may be relevant for authorities in other EEA States, such as additional vehicle identification numbers, a detailed list of importers and distributors, additional test reports, etc.

3.2.2. *Scope of data*

Notifications sent to the EFTA Surveillance Authority for uploading and distribution in RAPEX include the following types of data:

— Information enabling the notified product to be identified, i.e. product category, product name, brand, model and/or type number, barcode, batch or serial number, customs code, description of the product and its packaging accompanied by pictures showing the product, its packaging and labels. Detailed and accurate product identification is a key element for market surveillance and enforcement, as it allows national authorities to identify the notified product, to distinguish it from other products of the same or similar type or category that are available on the market and to find it on the market and take or agree on appropriate measures.

([1]) For more information on notifications on safety aspects subject to discussions at EEA level, see Chapters 3.5.2 and 3.8.1.

— Information establishing the product's origin, i.e. country of origin, name, address and contact details, such as telephone number and email address, of a manufacturer and exporters. In particular, EFTA States provide all available information on manufacturers and exporters located in third countries that cooperate closely with the EU/EEA on product safety. The EFTA Surveillance Authority and the Commission thus regularly inform the RAPEX contact points of recent developments in this area. The following documents also are to be attached to the form where available: copies of orders, sales contracts, invoices, shipping documents, customs declarations, etc. Detailed information on third country producers allows the Commission to promote more effective enforcement in those countries and helps to reduce the number of dangerous consumer products exported into the EEA.

— Information on the safety requirements applicable to the notified product, including the reference number and name of the applicable legislation and standards.

— A risk description of the notified product, including a description of the results of laboratory or visual tests, test reports and certificates proving non-compliance of the notified product with the safety requirements, a complete risk assessment with conclusions and information on known accidents or incidents.

— Information on the supply chains of the notified product in the EEA States, and, in particular, information on the countries of destination, plus information on importers, and also, if available, on distributors of the notified product.

— Information on measures taken, in particular, the type (obligatory or voluntary), category (e.g. withdrawal from the market, recall from consumers), scope (e.g. country-wide, local), date of entry into force and duration (e.g. unlimited, temporary).

— Indication of whether a notification, part of it and/or attachment(s) are covered by confidentiality. Requests for confidentiality are always accompanied by a justification clearly stating the reasons for such a request.

EFTA States are encouraged to obtain and provide information on the supply chains of the notified product in non-EEA countries that cooperate closely with the EEA on product safety.

3.2.3. *Updating of data*

The notifying EFTA State informs the EFTA Surveillance Authority (as soon as possible and not later than by the deadlines specified in Appendix 3 to the Guidelines) of any developments that require changes to a notification transmitted through the RAPEX application. In particular, EFTA States inform the EFTA Surveillance Authority of any changes (e.g. following a ruling by a court during an appeal procedure) to the status of the notified measures, to the risk assessment and to new decisions regarding confidentiality.

The EFTA Surveillance Authority examines the information provided by the notifying EFTA State, which shall be forwarded to the Commission in view of updating the information concerned in the RAPEX application and on the RAPEX website, where necessary.

3.2.4. *Responsibility for the information transmitted*

Point 10 of Annex II to the GPSD states that 'Responsibility for the information provided lies with the notifying Member State'.

The RAPEX contact point of the notifying EFTA State and the national authority responsible ensure that the data provided through RAPEX, especially product and risk descriptions, are accurate so as to avoid any confusion with similar products of the same category or type that are available on the EEA market.

The RAPEX contact point and the authority involved in the notification procedure (e.g. by performing the risk assessment of the notified product or by providing information on distribution channels) take responsibility for the information provided through RAPEX. The RAPEX contact point checks and validates all notifications received from the authorities responsible before transmitting them to the EFTA Surveillance Authority.

Any action taken by the EFTA Surveillance Authority or the Commission, such as examining notifications, validating and distributing them through the RAPEX application and publishing them on the RAPEX website, does not imply any assumption of responsibility for the information transmitted, which remains with the notifying EFTA State.

3.3. **Confidentiality**

3.3.1. *Disclosure of information as a general rule*

Under Article 16(1) of the GPSD, the public has the right to be informed about dangerous products posing a risk to their health and safety. To meet this obligation, the Commission publishes overviews on the RAPEX website of new RAPEX notifications (i.e. 'Article 12 notifications' and 'Article 12 notifications requiring emergency action'). EFTA States do the same and provide the public with information in the national languages on products posing a serious risk to consumers and on measures taken to address this risk. Such information can be distributed via the internet, on paper and by electronic media, etc.

The information made available to the public is a summary of a RAPEX notification and includes only the details specified in Article 16 of the GPSD, i.e. product identification and information about the risks and measures taken to prevent or restrict those risks. The EFTA Surveillance Authority, the Commission and the EEA States do not disclose whole notifications to the public, especially not detailed risk descriptions with test reports and certificates or detailed lists of distribution channels, as some of this information, due to its nature, is confidential (professional secrets) and needs to be protected.

3.3.2. *Exceptions to the general rule*

Paragraph 1 of Article 16(1) of the GPSD states that the information should be disclosed to the public 'without prejudice to the restrictions required for monitoring and investigation activities' while paragraph 2 stipulates that the Commission and the EEA Member States should not 'disclose information […] which, by its nature, is covered by professional secrecy in duly justified cases, except for information relating to the safety properties of products which must be made public if circumstances so require, in order to protect the health and safety of consumers'.

In the light of these provisions, the EFTA States and the EFTA Surveillance Authority should not disclose to the public any information about a dangerous product notified through the RAPEX application if such disclosure undermines the protection of court proceedings, monitoring and investigation activities or professional secrecy, except for information relating to the safety properties of products which must be made public if circumstances so require to protect the health and safety of consumers.

3.3.3. *Request for confidentiality*

A notifying EFTA State may request confidentiality in a notification. Such a request clearly indicates the part(s) of the notification that should be kept confidential.

Furthermore, each request for confidentiality is accompanied by a justification clearly stating the reasons, as provided for in Article 16(1) and (2) of the GPSD.

Requests for confidentiality are subject to examination by the EFTA Surveillance Authority. The EFTA Surveillance Authority checks that the request is complete (i.e. that it states which parts of the form are covered by confidentiality and that it contains a justification) and justified (i.e. that it is in line with the provisions of the GPSD and the Guidelines). A decision as to the validity of the request is taken by the EFTA Surveillance Authority after consulting the respective RAPEX contact point and in cooperation with the Commission.

3.3.4. *Handling of notifications covered by confidentiality*

Article 16(2) of the GPSD states that 'Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant for ensuring the effectiveness of market monitoring and surveillance activities'. Notifications covered partially or fully by confidentiality are examined by the EFTA Surveillance Authority and, after being validated and distributed through the RAPEX application, they are subject to the usual follow-up by the EEA States. The confidentiality of a notification or parts of it does not prevent it from being handled and distributed through RAPEX to the competent national authorities.

The only significant difference in the handling and follow-up procedures is that the EFTA Surveillance Authority and the EFTA States should not disclose any parts of a notification that are confidential to the public. These parts have to remain confidential and thus they should not be published in any shape or form. EFTA State authorities that receive confidential information through RAPEX ensure that it is protected when performing their activities.

3.3.5. *Withdrawal of request for confidentiality*

The notifying EFTA State withdraws its request for confidentiality immediately after the authority in that State becomes aware that the justification for such a request is no longer valid. The EFTA Surveillance Authority shall notify the Commission thereof, which in turn, informs all EEA States of the withdrawal of confidentiality.

A RAPEX notification that is no longer covered by full or partial confidentiality is made available to the public in line with the 'general rules' applying to RAPEX notifications.

3.4. **Examination of notifications by the EFTA Surveillance Authority**

The EFTA Surveillance Authority checks all notifications received from EFTA States to be transmitted through the RAPEX application to ensure that they are correct and complete, before they are sent to the Commission. The Commission will, in turn, transmit the notifications to all EEA States.

3.4.1. *Correctness*

When assessing the correctness of a notification, the EFTA Surveillance Authority checks in particular that:

— a notification meets all the relevant requirements set out in the GPSD and in the Guidelines,

— the notified product has not already been notified (to avoid any unnecessary duplication),

— a notification made by the RAPEX contact point of the notifying EFTA State is classified in accordance with the criteria set out in Chapter 3.1 of the Guidelines,

— the information provided (in particular the risk description) is in line with the applicable product safety legislation and the relevant standards,

— the correct notification procedure has been used.

3.4.2. *Completeness*

Once a notification is confirmed as correct, the EFTA Surveillance Authority checks that it is complete. Chapters 3.2.1 and 3.2.2 of the Guidelines act as a point of reference. Special attention is given to the parts of a notification concerning product identification, risk description, measures, traceability and distribution channels.

As the EFTA Surveillance Authority is not empowered to perform a risk assessment of the notified product, checking only that the assessment is included in a notification submitted, the notifying EFTA State always provides an exhaustive risk description containing all the elements listed in Chapter 3.2.2 of the Guidelines.

3.4.3. *Requests for additional information*

Should, during examination, the EFTA Surveillance Authority have questions regarding a notification by one of the EFTA States, it may suspend validation of the notification and ask the notifying EFTA State for additional information or clarification. This additional information is provided by the notifying EFTA State by the deadline specified in the EFTA Surveillance Authority's request for information.

3.4.4. *Investigation*

Where necessary, the EFTA Surveillance Authority may carry out an investigation to assess the safety of a product notified by an EFTA State. This investigation may be conducted in particular where there are serious doubts as to the risks posed by the product notified via the RAPEX application. These doubts can either arise during the examination of a notification by the EFTA Surveillance Authority or be brought to the attention of the EFTA Surveillance Authority by an EEA State (e.g. through a reaction), by the Commission or by a third party (e.g. a producer).

As part of such investigations the EFTA Surveillance Authority may, in particular:

— ask any EFTA State to provide information or clarification,

— ask for an independent risk assessment and independent testing (laboratory or visual) of the product under investigation,

— inform the Commission about the investigation and invite the Commission to:

  — consult the Scientific Committees, the Joint Research Centre or any other institution specialising in the safety of consumer products,

  — convene the GPSD Committee, Consumer Safety Network and/or RAPEX contact points meetings, as well as consult the relevant working groups to discuss developments in an investigation.

Where an investigation concerns a product notified by an EFTA State through the RAPEX application, the EFTA Surveillance Authority may request the Commission to suspend validation of a notification or, where such a notification has already been validated and distributed through the RAPEX application, to temporarily remove the overview published on the RAPEX website. After an investigation, and depending on the outcome, the EFTA Surveillance Authority may ask the Commission (after consulting the notifying EFTA State, where necessary) in particular to validate and distribute through RAPEX the previously suspended notification, to uphold the validated notification in the RAPEX application (with any changes) or to permanently withdraw the notification from the RAPEX application.

The EFTA Surveillance Authority informs all EFTA States and the Commission of:

— its decision to launch an investigation, clearly stating the reasons for its decision,

— its decision to close an investigation, presenting its conclusions and changes to the investigated notification(s) (if any), and

— all the relevant developments during an investigation.

3.5. **Validation and distribution of notifications**

3.5.1. *Validation and distribution of notifications*

The EFTA Surveillance Authority examines the correctness and completeness of all notifications by EFTA States before they are transmitted to the Commission for validation and distribution in the RAPEX system ('validation'), by the deadlines specified in Appendix 4 to the Guidelines, and following the procedure outlined in Appendix 6 to the Guidelines.

Where, during an examination, a request for additional information or clarification was sent to the notifying EFTA State (followed by a reminder, if necessary), the EFTA Surveillance Authority may take the following decisions:

— where the additional information or clarification requested has been provided, the EFTA Surveillance Authority re-examines the notification and asks the Commission to validate it with the changed classification where necessary (e.g. from 'Notification for information' to 'Article 12 notification'),

— where the additional information or clarification requested has not been provided within a specified deadline or it is insufficient, the EFTA Surveillance Authority takes a decision on the basis of the information provided and, depending on the circumstances, asks the Commission either to validate the notification after changing the classification (e.g. from 'Article 12 notification' to 'Notification for information') or not to validate it.

3.5.2. *Validation of notifications on safety aspects subject to discussions at EEA level*

Once a common approach to risk assessment and/or enforcement has been agreed between the EEA States, depending on the circumstances and the views of the EEA States, the Commission may, in particular:

— keep the notifications concerned in the RAPEX application, or

— change the classification of the notifications stored in the RAPEX application, or

— withdraw notifications from the RAPEX application ([1]).

([1]) For more information on notifications on safety aspects subject to discussions at EU level, see Chapters 3.1.2.d and 3.8.1.

3.6. **Information on dangerous products sent by the Commission**

Point 9 of Annex II to the GPSD reads as follows: 'The Commission may inform the national contact points regarding products posing serious risks, imported into or exported from the Community and the European Economic Area'.

The Commission may transmit information to the EEA States about dangerous non-food consumer products of EEA and non-EEA origin that, according to the information available, are likely to be on the EEA market. This mainly concerns information that the Commission receives from third countries, international organisations, businesses or other rapid alert systems.

As far as possible, the Commission assesses the correctness and completeness of the data before transmission to the EEA States. However, the Commission can only carry out preliminary checks and cannot take legal responsibility for the validity of the information it transmits, as it cannot legally or technically perform a complete risk assessment or take enforcement action.

3.7. **Follow-up to notifications**

3.7.1. *Follow-up to the different types of notification*

EFTA States ensure appropriate follow-up to RAPEX notifications (i.e. 'Article 12 notifications' and 'Article 12 notifications requiring emergency action') and to information on dangerous products sent by the Commission (Chapter 3.6) as soon as possible and by the deadlines specified in Appendix 3 to the Guidelines at the latest.

Notifications for information do not require any specific follow-up. These notifications often do not contain the data needed for effective and efficient enforcement regarding the notified product (e.g. the notified product and/or measures are not sufficiently identified). However, EFTA States are encouraged to ensure follow-up to such notifications where the notified product is likely to have been made available to consumers on their market and product identification allows measures to be taken.

3.7.2. *Objectives of the follow-up*

On receipt of a notification, an EFTA State examines the information provided in the notification and takes appropriate action in order to:

— establish whether the product was marketed on its territory,

— assess what preventive or restrictive measures should be taken with regard to the notified product found on its market, taking into account the measures taken by the notifying EEA State and any special circumstances that could justify different types of measures or no action being taken,

— perform additional risk assessment and testing of the notified product, if necessary,

collect any additional information that may be relevant for other EEA States (e.g. information on distribution channels of the notified product in other EEA States).

3.7.3. *Follow-up techniques*

To ensure efficient and effective follow-up, best practice follow-up techniques should be employed by national authorities, including:

— Checks on the market

National authorities organise regular (planned and random) checks on the market in order to establish whether consumer products notified through the RAPEX application are made available to consumers.

— Cooperation with business associations

National authorities regularly provide business associations with overviews of the most recent notifications and enquire whether any of the notified products were produced or distributed by their members. National authorities provide businesses only with summaries of notifications, such as the weekly overviews published on the RAPEX website. Whole notifications should not be transmitted to third parties, as certain information (e.g. details of the risk description or information on distribution channels) is often confidential and should be protected.

— Publication of RAPEX data via the internet or electronic and paper media

National authorities regularly alert consumers and businesses about consumer products notified through RAPEX via their websites and/or other media. Information published in this way allows consumers to check whether they have and use dangerous products and often provides the authority with useful feedback.

National authorities should apply various follow-up techniques in parallel and should not limit their activities to only one of them.

Especially an EEA State in which a manufacturer, a representative or an importer of the notified product is established ('main EEA State') ensures appropriate follow-up to notifications distributed through the RAPEX application. The 'main EEA State' often has better legal and technical means of obtaining information on the notified case, which will help other EEA States to undertake effective follow-up.

3.8. **Permanent withdrawal of a notification by EEA States from the RAPEX application**

Notifications distributed through the RAPEX application are kept in the system for an unlimited period of time. The Commission may, however, in the situations presented in this Chapter, permanently withdraw a notification from the application.

3.8.1. *Situations where withdrawal is possible*

— There is proof that one or more of the RAPEX notification criteria ([1]) are not met and thus a RAPEX notification is not justified. This concerns cases in particular where it is established that the original risk assessment was performed incorrectly and that the notified product does not pose a serious risk to the health and safety of consumers. It also covers situations where the notified measures were successfully challenged in court or in other proceedings and they are no longer valid.

— No measures have been taken with regard to a product notified through the RAPEX application (for information) before it was decided to adopt measures or take action ([2]).

— After a discussion held at EEA level, EEA States agree that it is not useful to exchange information on certain safety aspects that have been notified through the RAPEX application ([3]).

— There is proof that products covered by a notification are no longer marketed and that all items that had been made available to consumers have already been withdrawn from the market and recalled from consumers in all EEA States.

Withdrawal of a notification cannot be requested on the basis of the fact that the notified product has been subject to changes needed for it to comply with all the applicable safety requirements, unless proof is provided that all the dangerous products (items) that had been made available to consumers have been withdrawn and recalled in all EEA States and that they are no longer marketed.

3.8.2. *Requesting EEA State*

The Commission may withdraw notifications from the RAPEX application only at the request of the notifying EEA State, as the latter takes full responsibility for the information transmitted through the system. A request for withdrawal by an EFTA State shall be addressed to the EFTA Surveillance Authority, which shall transmit the request to the Commission. Other EEA States are encouraged to inform the Commission or, in case of EFTA States, to inform the EFTA Surveillance Authority, of any facts that may justify withdrawal.

3.8.3. *Content of the request*

Every request for withdrawal is accompanied by justification stating the reasons and by all available documents supporting those reasons. The Commission examines each request and checks the justification and the supporting documents in particular. The Commission may request additional information, clarification or the opinion of the notifying EEA State and/or other EEA States before taking any decision.

([1]) For more information on the RAPEX notification criteria, see Chapter 2.
([2]) For more information on notifications sent through the RAPEX application before measures are taken, see Chapter 3.1.2.b.
([3]) For more information on notifications on safety aspects subject to discussions at EU level, see Chapters 3.1.2.d and 3.5.2.

3.8.4. *Decision to withdraw*

Should, on the basis of the justification provided, the Commission decide to withdraw a notification from the RAPEX application, it removes it from:

— the RAPEX application (or makes it otherwise invisible to all users of the system),

— the RAPEX website (if necessary).

The Commission informs all EEA States of the withdrawal of a notification by email or through other equally effective means and, if necessary, also the public by publishing a corrigendum on the RAPEX website.

3.9. **Temporary removal of a RAPEX notification from the RAPEX website**

3.9.1. *Situations where temporary removal is possible*

Where justified, the Commission may temporarily remove a RAPEX notification from the RAPEX website, especially where the notifying EEA State suspects that a risk assessment submitted in a notification has been performed incorrectly and thus the notified product may not pose a serious risk to the health and safety of consumers. A notification can be temporarily removed from the RAPEX website until the suspect risk assessment of the notified product has been clarified.

3.9.2. *Requesting EEA State*

The provisions of Chapter 3.8.2 apply.

3.9.3. *Content of the request*

The provisions of Chapter 3.8.3 apply.

3.9.4. *Decision to remove*

Should, on the basis of the justification provided, the Commission decide to remove a RAPEX notification from the RAPEX website, it informs all EEA States by email or by other equally effective means and, if necessary, also the public by publishing a corrigendum on the RAPEX website.

3.9.5. *Re-publishing of a notification*

The notifying EFTA State immediately informs the EFTA Surveillance Authority, which shall inform the Commission, when the reasons for the removal of a notification from the RAPEX website are no longer valid. In particular, it informs the Commission of the results of any new risk assessment to enable the Commission to determine whether to maintain a notification in the RAPEX application and to re-publish it on the RAPEX website or to withdraw it permanently from the RAPEX application (following a request from the notifying EFTA State).

The Commission may re-publish a RAPEX notification on the RAPEX website following a justified request from the notifying EFTA State submitted through the EFTA Surveillance Authority after the risk assessment has been clarified.

The Commission informs the other EEA States of the re-publishing of a RAPEX notification on the RAPEX website by email or by other equally effective means and also the public by replacing the corrigendum with a new one on the RAPEX website.

3.10. **Deadlines for submitting RAPEX notifications**

3.10.1. *Deadlines* [1]

EFTA States notify the EFTA Surveillance Authority of preventive and restrictive measures adopted in relation to consumer products posing a serious risk to the health and safety of consumers as soon as possible and by the deadlines specified in Appendix 3 to the Guidelines at the latest. Appropriate arrangements shall be in place at national level concerning the transmission of information between national authorities in charge of product safety and the RAPEX contact point to ensure that the deadlines are met.

[1] All deadlines mentioned in the Guidelines are expressed in calendar days.

The deadlines provided apply irrespective of any appeal procedure or official publication requirement.

3.10.2. *Emergency situations*

All 'Article 12 notifications requiring emergency action' by EFTA States are preceded by a telephone call by the RAPEX contact point to the EFTA Surveillance Authority RAPEX Team telephone number to ensure immediate validation and follow-up. This rule applies in particular to notifications transmitted at weekends or in holiday periods.

4. *REACTIONS*

4.1. **Communication of follow-up action**

EFTA States notify the EFTA Surveillance Authority of any follow-up regarding RAPEX notifications (i.e. 'Article 12 notifications' and 'Article 12 notifications requiring emergency action') and information on dangerous products sent by the Commission (Chapter 3.6).

EFTA States are encouraged to notify the EFTA Surveillance Authority of any follow-up regarding notifications distributed for information.

4.2. **Content of reactions**

4.2.1. *Data provided*

Results of follow-up activities by EFTA States are communicated to the EFTA Surveillance Authority in the form of reactions to notifications. To harmonise the type of information and to keep the work load to a minimum, EFTA States submit reactions in particular in the following situations:

— Product found

A reaction is sent when national authorities find the notified product on the market or at the external border. This reaction contains the full details of the product in question (e.g. name, brand, model number, bar code, batch number) plus information on the total number of items found. Furthermore, the following details of the measures taken are communicated: type (obligatory or voluntary), category (e.g. withdrawal from the market, recall from consumers), scope (e.g. country-wide, local), date of entry into force and duration (e.g. unlimited, temporary). If the notified product was found on the market but no measures were adopted, specific reasons justifying no measures being taken should be given in the reaction.

EFTA States do not inform the EFTA Surveillance Authority (unless the EFTA Surveillance Authority asks to be informed) of the conclusions of follow-up activities where the notified product was not found on the market.

— Different risk assessment

A reaction is sent when the conclusions of a risk assessment performed by an authority of the reacting EFTA State differ from the conclusions set out in a notification. This reaction contains a detailed risk description (including the results of tests, a risk assessment and information on known accidents and incidents) accompanied by supporting documents (test reports, certificates, etc.). Furthermore, the reacting EFTA State proves that the risk assessment submitted with a reaction was performed on the same product as the one notified, i.e. with the same brand, name, model number, production dates, origin, etc.

— Additional information

A reaction is sent when national authorities collect additional information (during follow-up activities) that may be useful for market surveillance and enforcement in other EEA States.

EFTA States are encouraged to collect additional information that may be relevant for authorities both in other EEA States and in third countries that cooperate closely with the EU on product safety. Details include product origin (e.g. information on the country of origin, manufacturer and/or exporters) and information on the supply chains (e.g. information on the countries of destination, importers and distributors). The reacting country attaches all available supporting documents to the reaction, such as copies of orders, sales contracts, invoices, customs declarations, etc.

The contact point of the reacting EFTA State together with the responsible authority ensure that all data provided in a reaction is accurate and complete and that there is no confusion with similar products of the same or similar category or type that are available on the EEA market.

4.2.2. *Completeness of reactions*

Information provided in reactions should be as complete as possible. The standard reaction form is provided in Appendix 2 to the Guidelines. Should certain relevant information not be available when a reaction is submitted, the reacting EFTA State indicates this on the reaction form. Once this information becomes available, the reacting EFTA State updates its reaction. The updated reaction is examined by the EFTA Surveillance Authority before it is transmitted to the Commission for validation and distribution through the system.

The RAPEX contact point provides all authorities in its own State that participate in the RAPEX network with instructions on the scope of the data required to complete the reaction form correctly. This will help to ensure that information provided by these authorities to the contact point is correct and complete.

4.2.3. *Updating of validated reactions*

The reacting EFTA State informs the EFTA Surveillance Authority (as soon as possible and by the deadlines specified in Appendix 3 to the Guidelines at the latest) of any developments that may require changes to a reaction distributed through the RAPEX application. In particular, EFTA States inform the EFTA Surveillance Authority of changes in the status of the measures taken and in the risk assessment submitted with a reaction.

The EFTA Surveillance Authority examines the information provided by the reacting EFTA State and if necessary updates the information concerned before it is transmitted to the Commission.

4.2.4. *Responsibility for reactions*

Point 10 of Annex II to the GPSD reads as follows: 'Responsibility for the information provided lies with the notifying Member State'.

The RAPEX contact point and the respective authority involved in the reaction procedure (e.g. by carrying out the risk assessment or by adopting restrictive measures) take responsibility for the information provided in reactions. The RAPEX contact point checks and validates all reactions prepared by the respective authorities before transmitting them to the EFTA Surveillance Authority.

Any action taken by the EFTA Surveillance Authority, such as examining and validating reactions, does not imply any assumption of responsibility for the information transmitted, which remains with the reacting EFTA State.

4.3. **Confidentiality**

A reacting EFTA State may request confidentiality in a reaction. Such requests clearly state which part(s) of a reaction should be kept confidential. Furthermore, all requests for confidentiality are accompanied by justification clearly stating the reasons.

Requests for confidentiality are examined by the EFTA Surveillance Authority to determine that they are justified (i.e. in line with the provisions of the GPSD and the Guidelines) and complete (i.e. it states which parts of the form that it covers and if it contains a justification). The final decision on confidentiality is taken by the EFTA Surveillance Authority after consultation of the responsible RAPEX contact point and in cooperation with the Commission.

The EFTA Surveillance Authority and the EFTA States treat reactions with requests for confidentiality in the same way as other reactions. The confidentiality of a reaction or parts of it does not prevent it from being distributed through the RAPEX system to the competent national authorities. However, neither the EFTA Surveillance Authority, the Commission nor the EFTA States should disclose any parts of a reaction that are confidential to the public. This information is confidential and therefore cannot be published in any shape or form.

The reacting EFTA State withdraws its confidentiality request immediately after that EFTA State's authority becomes aware that the reasons for such a request are no longer valid. The EFTA Surveillance Authority informs all EEA States through the Commission of the withdrawal of the confidentiality after the receipt of such a request from the reacting EFTA State.

4.4. **Examination of reactions from EFTA States by the EFTA Surveillance Authority**

4.4.1. *Correctness and completeness*

The EFTA Surveillance Authority checks all reactions from EFTA States received through the RAPEX application before they are transmitted to the Commission for validation and transmission to the EEA States. These checks focus on the correctness and completeness of the information provided.

The EFTA Surveillance Authority checks if a reaction received from an EFTA State meets all the relevant requirements set out in the GPSD and in the Guidelines and if the correct reaction procedure was applied. Once the correctness of a reaction is confirmed, the EFTA Surveillance Authority checks its completeness. Chapter 4.2.2 of the Guidelines is to be used as a point of reference for this examination.

The EFTA Surveillance Authority pays special attention to reactions with risk assessments. It verifies, in particular, that the risk description is complete, clearly presented and well documented, and that the risk assessment clearly relates to the product covered by a notification.

4.4.2. *Request for additional information*

Before validating a reaction, the EFTA Surveillance Authority or the Commission may request the reacting EFTA State to provide additional information or clarification within a given deadline. Validation of a reaction may be conditional on receipt of the data requested.

The EFTA Surveillance Authority may request the opinion of any EFTA State and, in particular, the notifying EFTA State on a validated reaction. The EFTA State submits its opinion to the EFTA Surveillance Authority within a deadline specified by the latter. Furthermore, the notifying EFTA State informs the EFTA Surveillance Authority whether any changes to the notification (e.g. to the risk assessment) or to its status (e.g. permanent withdrawal from the system) are necessary.

4.5. **Validation and distribution of reactions**

All reactions by EFTA States assessed as correct and complete by the EFTA Surveillance Authority are transmitted to the Commission for validation and distribution ('validation') by the deadlines specified in Appendix 4 to the Guidelines, and in accordance with the procedure specified in Appendix 6 to the Guidelines.

The Commission does not validate reactions with a risk assessment different from that of the notification they refer to, if the risk assessment is not complete, clearly presented and well documented or if it is not shown that the risk assessment was performed in relation to the product covered by a notification.

4.6. **Permanent withdrawal of a reaction from the RAPEX application**

Reactions distributed through the RAPEX application are kept in the system as long as the notification to which they are attached. The Commission may permanently withdraw a validated reaction from the RAPEX application if a notification to which this reaction is attached has been withdrawn from the RAPEX application (in accordance with Chapter 3.8 of the Guidelines). Furthermore, the Commission may withdraw a validated reaction where it clearly provides incorrect information, and in particular where:

— a product found on the market by the reacting EFTA State is different from a product covered by a notification,

— the measures adopted by the reacting EFTA State are successfully challenged in court or in other proceedings and subsequently withdrawn,

— the risk assessment performed by the reacting EFTA State is proven to be incorrect or to relate to a different product from the one covered by a notification.

The provisions of Chapters 3.8.2 and 3.8.3 apply.

Once the Commission decides to withdraw a reaction, it is removed from the RAPEX application (or otherwise made invisible to users of the system).

The Commission informs all EEA States of the withdrawal of a reaction by email or through other equally effective means.

4.7. **Deadlines for submitting reactions**

EFTA States submit reactions to the EFTA Surveillance Authority as soon as possible and by the deadlines specified in Appendix 3 to the Guidelines at the latest.

Appropriate arrangements are established at national level concerning the transmission of information between all competent authorities and the RAPEX contact point to ensure that the deadlines are met.

The deadlines apply irrespective of any appeal procedure or official publication requirement.

5. *OPERATION OF THE RAPEX NETWORKS*

5.1. **RAPEX contact points**

Every EFTA State establishes a single RAPEX contact point to operate the RAPEX system at national level. The national authorities decide within which national authority to set up the RAPEX contact point. Each EFTA State also organises its national RAPEX network to ensure the efficient flow of information between the RAPEX contact point and various authorities participating in RAPEX.

5.1.1. *Organisation*

Each EFTA State gives the RAPEX contact point the resources and information it needs to perform its tasks and in particular to operate the system with effective backup/business continuity.

The RAPEX contact point has a separate email account for participation in the RAPEX system, with access to all officials in that contact point (e.g. rapex@……). The RAPEX contact point also has direct phone and fax numbers through which it can be reached during and outside working hours.

5.1.2. *Tasks*

The main tasks of a RAPEX contact point are to:

— organise and steer the work of the national RAPEX network, in accordance with the rules set out in the Guidelines,

— train and assist all authorities in the network in the use of RAPEX,

— ensure that all RAPEX tasks stemming from the GPSD and the Guidelines are performed properly, and in particular that all required information (i.e. notifications, reactions, additional information, etc.) is provided to the Commission without delay,

— transmit information between the Commission and the national market surveillance authorities and authorities in charge of external border controls,

— check and validate the information received from all competent authorities before transmission to the EFTA Surveillance Authority for distribution through the RAPEX application,

— check before submitting a notification whether a product has already been notified or information relating to that product has been exchanged through the RAPEX application (to avoid any duplication),

— take responsibility (together with respective authority) for the information provided through the RAPEX application,

— participate in RAPEX contact points working group meetings and other events relating to the operation of RAPEX,

— suggest possible improvements to the operation of the system,

— inform the EFTA Surveillance Authority immediately of any technical problems in the functioning of the RAPEX application,

— coordinate all national activities and initiatives taken in relation to RAPEX, explain to stakeholders how the RAPEX system operates and what their obligations are under the GPSD, especially the business notification obligation set out in Article 5(3).

5.2. **RAPEX networks established at EEA and national levels**

5.2.1. *RAPEX contact points network*

The Commission organises and steers the work of the RAPEX contact points network. This network consists of all RAPEX contact points appointed in the EEA States.

The Commission regularly convenes RAPEX contact points network meetings in order to discuss the operation of the system (e.g. to communicate the latest developments concerning RAPEX, to exchange experience and 'know-how'), and to improve cooperation between contact points.

5.2.2. *RAPEX networks established at national level*

The RAPEX contact point organises and steers the work of its own 'RAPEX national network'. The network consists of:

— the RAPEX contact point,

— market surveillance authorities responsible for monitoring the safety of consumer products,

— authorities in charge of external border controls.

RAPEX contact points are encouraged to formally regulate the organisation and operation of the RAPEX national network so as to ensure that all authorities involved are aware of their roles and responsibilities in the operation of RAPEX. This may be binding or non-binding and should be consistent with the Guidelines.

The RAPEX contact point regularly holds meetings of the RAPEX national network in order to discuss with all the authorities involved how RAPEX is organised and operates and to give training courses. A RAPEX national network meeting can be linked with a RAPEX seminar where it is organised in that EEA State by the EFTA Surveillance Authority or the Commission.

5.3. **Means of communication, practical and technical arrangements for RAPEX**

5.3.1. *Languages*

The use of languages in notifications and reactions as well as communications between the RAPEX contact points, the EFTA Surveillance Authority and the Commission must take due account of the objectives of RAPEX and must ensure a rapid exchange of information between EEA States, the EFTA Surveillance Authority and the Commission on products posing serious risks to the health and safety of consumers.

5.3.2. *Online application for RAPEX*

The Commission establishes and maintains a web-based application for use as a communication tool for the purpose of RAPEX. The EFTA States and the EFTA Surveillance Authority use this application to submit notifications and reactions and additional information in relation thereto through RAPEX and the Commission uses it to validate the documents it receives.

The Commission provides access to the application to all RAPEX contact points, competent national authorities, the relevant Commission departments and the EFTA Surveillance Authority. The Commission creates as many users in the application as possible, taking into account needs and technical limitations. The Commission lays down the rules for granting access to the application.

Where the RAPEX application is temporarily not operational (for reasons other than regular and planned maintenance work), EFTA States should submit only RAPEX notifications to the EFTA Surveillance Authority (i.e. 'Article 12 notifications', 'Article 12 notifications requiring emergency action'). The submission of notifications for information and reactions is suspended until the RAPEX application is operational again. While the application is not operational, RAPEX notifications are sent to the EFTA Surveillance Authority by email to: rapex@eftasurv.int or to another email address communicated in advance. If email transmission is not possible, RAPEX notifications are sent to the EFTA Surveillance Authority by fax to the fax number communicated in advance. There is no need to send notifications via the Permanent Representation of an EFTA State to the EU/EFTA.

5.3.3. *Operation of RAPEX outside regular working hours*

The RAPEX system operates non-stop. The EFTA Surveillance Authority, the Commission and the RAPEX contact points ensure that officials responsible for operating RAPEX can always be contacted (by phone, email or other equally effective means) and that they can take whatever action is necessary, including in an emergency and outside regular working hours, such as weekends and holidays.

The EFTA Surveillance Authority provides the RAPEX contact points of the EFTA States with contact details of the EFTA Surveillance Authority RAPEX Team, including the names, email addresses and telephone and fax numbers of officials they can reach during and outside working hours.

The RAPEX contact points of the EFTA States provide the EFTA Surveillance Authority with their contact details, including the names of officials working within the contact point, the name and address of the authority where that contact point is established, and the email addresses, phone and fax numbers of officials who can be contacted during and outside working hours. Any changes to the contact details are immediately communicated to the EFTA Surveillance Authority by the RAPEX contact points of the EFTA States. The Commission publishes the contact details of the RAPEX contact points on the RAPEX website.

PART III

Notification procedure established under Article 11 of the General Product Safety Directive

1. *BACKGROUND AND OBJECTIVES*

Article 11 of the General Product Safety Directive establishes a notification procedure for the exchange of information between Member States and the Commission on measures taken in relation to consumer products posing a non-serious risk to the health and safety of consumers.

The Article 11 notification mechanism (despite similarities and links) should be treated as an independent procedure that is separate from the notification procedure established under Article 12 of the GPSD ('RAPEX').

The Article 11 notification procedure has two main objectives:

— To help the Internal Market to operate

The first objective of the Article 11 notification procedure is to ensure that the EFTA Surveillance Authority is informed about measures adopted by national authorities in EFTA States that restrict the marketing on the EEA market of products posing a non-serious risk to the health and safety of consumers.

This objective is similar to the objective of the safeguard clause procedure established under sectoral directives, which aims to ensure that the EFTA Surveillance Authority is kept informed of preventive and restrictive measures adopted by national authorities in EFTA States and can assess whether the restriction to the free movement of the notified product complies with EEA legislation and does not unduly infringe the free movement of goods. The Article 11 notification procedure complements the safeguard clause procedure and ensures that the EFTA Surveillance Authority is kept informed of preventive and restrictive measures adopted by national authorities that are not subject to the latter procedure.

— To prevent the marketing and use by consumers of dangerous products (not posing a serious risk)

The second objective of the Article 11 notification procedure is to ensure that EEA States can rapidly exchange information about products posing a non-serious risk to the health and safety of consumers and to prevent or restrict them from being marketed and used in the EEA. This is similar to the objective of RAPEX, although RAPEX only covers products posing a serious risk to the health and safety of consumers.

2. *NOTIFICATION CRITERIA*

The Article 11 notification procedure applies only to measures adopted by national authorities to restrict the placing on the market, to withdraw from the market or to recall from consumers products posing a non-serious risk to the health and safety of consumers. This excludes notifications of voluntary measures under this procedure.

Where the following five notification criteria are met, EFTA States have a legal obligation to notify the EFTA Surveillance Authority under Article 11 of the GPSD:

— the product concerned is a consumer product,

— it is subject to restrictive measures adopted by national authorities (obligatory measures),

— it poses a non-serious risk to the health and safety of consumers,

— the effects of the risk can or do go beyond the territory of one EEA State or do not or cannot go beyond its territory, but measures involve information likely to be of interest to other EEA States from a product safety standpoint,

— the measures adopted do not have to be notified under any other notification procedure established by EEA law (e.g. under RAPEX established under Article 12 of the GPSD or under the safeguard clause procedure established by sectoral directives).

The following Chapters in Part II of the Guidelines are relevant to the Article 11 notification procedure:

— Chapter 2.1 on consumer product (definition of consumer product),

— Chapter 2.2 on restrictive measures (categories of restrictive measures, definition of obligatory measures, timing of the notification and notifying authorities),

— Chapter 2.3 on risk assessment (risk assessment method, assessing authority),

— Chapter 2.4 on cross-border effects (international event, local event).

3. *NOTIFICATIONS*

Where all notification criteria are met, an EFTA State prepares a notification and sends it to the EFTA Surveillance Authority in accordance with the procedure outlined in Appendix 6 to the Guidelines, which will thereafter be transmitted to the Commission by using the RAPEX application. The standard notification form is provided in Appendix 1 to the Guidelines.

All notifications sent through the RAPEX application under Article 11 of the GPSD are classified in the system as 'Article 11 notifications'.

The RAPEX contact point of the notifying EFTA State ensures that all notifications meet all the notification requirements provided for in Article 11 of the GPSD.

The following Chapters in Part II of the Guidelines are relevant to the Article 11 notification procedure:

— Chapter 3.2 on the content of notifications (completeness, scope, updating of data, responsibility for the information transmitted),

— Chapter 3.3 on confidentiality (disclosure of information, exceptions to the general rule, requests for confidentiality, treatment of notifications covered by confidentiality and withdrawal of the confidentiality request),

— Chapter 3.4 on the examination of notifications by the EFTA Surveillance Authority (correctness, completeness, requests for additional information, investigation),

— Chapter 3.5 on the validation of notifications,

— Chapter 3.8 on the permanent withdrawal of a notification from the RAPEX application (withdrawal situations, requesting EEA State, content of the request, withdrawal decision).

EFTA States submit an 'Article 11 notification' as soon as possible and by the deadlines specified in Appendix 3 to the Guidelines at the latest. Chapter 3.10 of Part II of the Guidelines on deadlines applies.

4. *REACTIONS*

EFTA States are encouraged to ensure follow-up to 'Article 11 notifications' if product identification is likely to allow preventive and restrictive measures to be adopted. EFTA States are also encouraged to notify to the EFTA Surveillance Authority the conclusions of follow-up activities taken with regard to 'Article 11 notifications'.

The following Chapters in Part II of the Guidelines are relevant to the Article 11 notification procedure:

— Chapter 3.7 on follow-up activities (objectives, follow up action),

— Chapter 4.2 on the content of reactions (data provided, completeness, updating, responsibility for reactions),

— Chapter 4.3 on confidentiality,

— Chapter 4.4 on the examination of reactions by the EFTA Surveillance Authority (correctness and completeness, request for additional information),

— Chapter 4.5 on the validation of reactions,

— Chapter 4.6 on the permanent withdrawal of reactions from the RAPEX application.

5. *PRACTICAL AND TECHNICAL ARRANGEMENTS*

'Article 11 notifications' and reactions to them by EFTA States are prepared and sent to the EFTA Surveillance Authority by the RAPEX contact points. Chapters 5.1 to 5.3 in Part II of the Guidelines concerning the operation of RAPEX networks (established at EEA and national levels) and on practical and technical arrangements (languages, online application, and operation outside normal working hours) are relevant to the Article 11 notification procedure.

PART IV

Appendices [1]

1. *STANDARD NOTIFICATION FORM*

Notification form	
General information	
1.	☐ 'Article 12 notification requiring emergency action' ☐ 'Article 12 notification' ☐ 'Notification for information' ☐ 'Article 11 notification'

[1] For the purpose of these appendices, references to the Commission shall be read as references to the EFTA Surveillance Authority. References to the Member States shall be read as references to the EFTA States.

2.	Notification number
3.	Notification date
4.	Notifying country
5.	Contact details of the RAPEX contact point and person in charge of the notified case

Product identification

6.	Product category
7.	Product name
8.	Brand
9.	Type/number of model
10.	Batch number/Bar code
11.	Customs code
12.	Product and packaging description
13.	Photos (product, packaging and label)
14.	Total number of items covered by the notification

Regulations and standards applicable

15.	Legal provisions (directive, decision, regulation, etc.)
16.	Standards
17.	Proof of conformity
18.	Is the product counterfeit?

Traceability

19.	Country of origin
20.	Countries of destination
21.	Contact details of the manufacturer or its representative
22.	Contact details of the exporter(s)
23.	Contact details of the importer(s)
24.	Contact details of the distributor(s)
25.	Contact details of the retailer(s)

Risk description

26.	Risk category

27.	Summary of test results (description of technical defects)
28.	Legal provisions and standards (with clauses) against which the product was tested and did not comply
29.	Risk assessment and conclusions
30.	Information on known incidents and accidents

Measures

31.	Type of measures
32.	Authority/economic operator taking notified measures
33.	Category of measures
34.	Date of entry into force
35.	Duration
36.	Scope

Confidentiality

37.	Is the notification confidential?
38.	Scope of confidentiality
39.	Justification

Other

40.	Additional information
41.	Justification for sending '*Notification for information*'

Annexes

42.	Test reports
43.	Certificates
44.	Photographs (product, packaging and label)
45.	Notification sent by a producer or a distributor under Article 5(3) of the GPSD
46.	Measures adopted

2. *REACTION FORM*

Reaction form	

General information

1.	Notification number
2.	Notifying country

3.	Notified product name
4.	Reaction date
5.	Reacting country
6.	Contact details of the RAPEX contact point and person in charge of the reaction
7.	Product name
8.	Brand
9.	Type/number of model
10.	Batch number/Bar code

Type of reaction

11.	☐ ***Product found*** ☐ **Measures adopted**	☐ **Different risk assessment**	☐ **Additional information**
12.	Total number of items found	Risk category	Complementary information on distribution channels and/or product's origin
13.	Type of measures adopted	Summary of the test results (description of technical defects)	Complementary information on the risk assessment
14.	Authority/economic operator adopting notified measures	Indication of legal provisions and standards (with clauses) against which the product was tested	Other complementary information
15.	Category of measures	Risk assessment and conclusions	—
16.	Date of entry into force	Information on known incidents and accidents	
17.	Duration	—	
18.	Scope		
19.	Justification, if no measures were adopted		

Confidentiality

20.	Is the reaction confidential?
21.	Scope of confidentiality
22.	Justification

Annexes

23.	Test reports
24.	Certificates

25.	Photos (product, packaging and label)
26.	Adopted measures

3. *DEADLINES FOR MEMBER STATES*

Notification procedure	Action			Deadline
Rapid Information System 'RAPEX' established under Article 12 of GPSD	Notifications	Send 'Article 12 notification requiring emergency action'		3 days after: — adoption or decision to adopt 'Obligatory measures' or — receipt of information on '*Voluntary measures*'.
		Send 'Article 12 notification'		10 days after: — adoption or decision to adopt 'Obligatory measures' or — receipt of information on 'Voluntary measures'.
		Confirm measures if the notification was sent before deciding to adopt measures		45 days after submission of the notification
		Update to a notification		5 days after receipt of the information on developments requiring changes to a notification
	Reactions	Ensure follow-up to:	'Article 12 notification requiring emergency action'	20 days after receipt of a notification
			'Article 12 notification' and to 'Notification sent by the European Commission'	45 days after receipt of a notification
		Send reaction to:	'Article 12 notification requiring emergency action'	3 days after: — the notified product was found on the market, or — the completion of a risk assessment with different results, or — receipt of additional information
			'Article 12 notification' and to 'Notification sent by the European Commission'	5 days after: — the notified product was found on the market, or — the completion of a risk assessment with different results, or — receipt of additional information
		Update to a reaction		5 days after receipt of information on developments requiring changes to a reaction

Notification procedure	Action		Deadline
Notification procedure established under Article 11 of GPSD	Notifications	Send 'Article 11 notification'	10 days after adoption of 'Obligatory measures'
		Update to the notification	5 days after receipt of information on developments requiring changes of the notification

4. *DEADLINES FOR THE COMMISSION*

Notification procedure	Action		Deadline
Rapid Information System 'RAPEX' established under Article 12 of GPSD	Notifications	Validate 'Article 12 notification requiring emergency action'	3 days after receipt of a notification
		Validate 'Article 12 notification'	5 days after receipt of a notification
		Validate 'Notification for information'	10 days after receipt of a notification
	Reactions	Validate reaction sent to 'Article 12 notification requiring emergency action'	3 days after receipt of a reaction
		Validate reaction sent to 'Article 12 notification' and to 'Notification sent by the European Commission'	5 days after receipt of a reaction
		Validate reaction sent to 'Notification for information'	10 days after receipt of a reaction
Notification procedure established under Article 11 of GPSD	Notifications	Validate 'Article 11 notification'	10 days after receipt of a notification
	Reactions	Validate reaction sent to 'Article 11 notification'	10 days after receipt of a reaction

5. *RISK ASSESSMENT GUIDELINES FOR CONSUMER PRODUCTS*

Table of contents

1. *INTRODUCTION*

Consumer products may cause harm when used, e.g. a hot flat-iron that can cause burns, scissors or knives that can cause cuts, or a household cleaner that can damage the skin. This kind of damage is not a usual occurrence because general knowledge or instructions teach how to use consumer products safely. Nevertheless, the risk of damage remains.

This risk can be assessed in different ways. A range of methods have been used to quantify risk for consumer products, such as a nomograph method ([1]), a matrix method ([2]), and the method previously recommended for the EU's RAPEX rapid alert system ([3]). While the general principles for risk assessment have always been agreed, how to quantify risks has been under permanent development. This has led to diverging results and ensuing discussions, as well as to consideration of what the best possible practice might be.

([1]) Benis HG (1990): A Product Risk Assessment Nomograph, report prepared for the New Zealand Ministry of Consumer Affairs, dated February 1990. Cited in: European Commission (2005) Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices. Report prepared by Risk & Policy Analysts (RPA), Loddon, Norfolk, UK.

([2]) Method used by the Belgian authorities. Cited in: European Commission (2005) Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices. Report prepared by Risk & Policy Analysts (RPA), Loddon, Norfolk, UK.

([3]) Decision 2004/418/EC.

The purpose of these risk assessment guidelines is therefore to improve the situation and, within the framework of the Directive on General Product Safety ([1]), to provide a transparent and practicable method for appropriate use by Member States' competent authorities when they assess the risks of non-food consumer products. These guidelines are based on a risk assessment method developed for other purposes ([2]), adapted to the specific requirements of non-food consumer products.

A certain amount of training will of course be needed before these guidelines can be put into practice, but expertise in risk assessment will greatly facilitate this task. This will be backed by exchanges of views between risk assessors, since expertise and experience accumulated through the years is invaluable.

In building up a risk assessment method in small, manageable steps, these guidelines help to focus on the relevant issues of a product, its user(s) and its use(s), and to identify possible divergences of views between risk assessors from the onset, thus avoiding time-consuming discussions. They should thus lead to consistent and robust risk assessment results based on evidence and science, and consequently to widely acceptable consensus on the risks that the many non-food consumer products may present.

A quick overview and a flow chart on how to prepare a risk assessment pursuant to these guidelines is provided in Section 5 — 'Consumer products' mean non-food consumer products throughout these guidelines.

These guidelines do not set out to replace other guidelines that may address very specific products or may be specifically provided for in legislation, such as in the area of chemicals, cosmetics, pharmaceuticals or medical devices. It is highly recommended to use this specific guidance, since it is tailor-made, but it will always be for the risk assessor to decide how best to assess the risks of a product.

Nor are these guidelines to be used by manufacturers 'just to avoid serious risks' when designing and manufacturing products. Consumer products have to be safe, and these guidelines aim at helping authorities to identify serious risks when, despite the best efforts of the manufacturer, a product is not safe.

2. *RISK ASSESSMENT — AN OVERVIEW*

2.1. **Risk — combination of hazard and probability**

Risk is generally understood as something that threatens the health or even the lives of people, or that may cause considerable material damage. Nevertheless, people take risks while being aware of the possible damage, because the damage does not always happen. For example:

— Climbing a ladder always includes the possibility of falling off and injuring oneself. 'Falling off' is therefore 'built into the ladder'; it is an intrinsic part of using a ladder and cannot be excluded. 'Falling off' is thus called the intrinsic hazard of a ladder.

  This hazard, however, does not always materialise, since many people climb ladders without falling off and injuring themselves. This suggests that there is a certain likelihood (or probability), but no certainty, of the intrinsic hazard materialising. Whereas the hazard always exists, the probability of it materialising can be minimised, for example by the person climbing the ladder being careful.

— Using a household cleaner with sodium hydroxide to free blocked sewage water pipes always entails the possibility of very severe damage to the skin, if the product comes into contact with skin, or even of permanent blindness if drops of the product get into the eye. This is because sodium hydroxide is very corrosive, meaning that the cleaner is intrinsically hazardous.

  Nevertheless, when the cleaner is handled properly, the hazard does not materialise. Proper handling may include wearing plastic gloves and protective glasses. Skin and eyes are then protected, and the probability of damage is much reduced.

([1]) Directive 2001/95/EC.
([2]) Kinney GF, Wiruth AD (1976) Practical risk analysis for safety management. China Lake, CA: NWC Technical Publication 5865, Naval Weapons Center, California, June 1976.

Risk is thus the combination of the severity of possible damage to the consumer and the probability that this damage should occur.

2.2. **A risk assessment in three steps**

It takes three steps to determine the risk:

1. Anticipate an injury scenario in which the intrinsic product hazard harms the consumer (see Table 1). Determine how severe the consumer's injury is.

   A yardstick for quantifying the intrinsic product hazard is the extent of the adverse effect that it can cause to the health of a consumer. The risk assessor therefore anticipates an 'injury scenario' that describes step by step how the hazard leads to the injury of a consumer (see Table 2). In short, the injury scenario describes the accident that the consumer has with the product in question, and the severity of the consumer's injury caused by that accident.

   An injury can vary in severity, depending on the hazard of the product, on the way the product is used by the consumer, on the type of consumer who uses the product, and much more (see Section 3). The more severe the injury, the more severe the hazard that caused it, and vice versa. The 'severity of the injury' is therefore a means of quantifying the hazard. These guidelines propose 4 levels of severity, from injuries that are normally completely reversible to very serious injuries that cause more than approximately 10 % of permanent disability or even death (see Table 3).

2. Determine the probability of the consumer being injured in practice by the intrinsic product hazard.

   While the injury scenario describes how the consumer is injured by the hazard, the scenario only happens with a certain probability. The probability can be expressed as a fraction, such as '> 50 %' or '> 1/1 000' (see left-hand side of Table 4).

3. Combine the hazard (in terms of severity of the injury) with the probability (in terms of a fraction) to obtain the risk.

   This combination can be made by looking up both values in the appropriate table (see Table 4); the table will provide the level of risk in terms of 'serious', 'high', 'medium' and 'low' risk.

Where different injury scenarios are foreseeable, the risk for each of those scenarios should be determined the highest risk being labelled as 'the risk' of the product. The highest risk is normally crucial because only action on the highest risk can effectively provide a high level of protection.

On the other hand, an identified risk may be lower than the highest risk, but require specific risk reduction action. It is then important also to take measures against that risk so that all risks are effectively reduced.

Once the above steps have been carried out, the risk assessment is basically complete.

A flow chart on building a risk assessment is at the end of Section 5.

2.3. **Some useful tips**

Seek information

As can be seen from the above examples, each of the above steps of a risk assessment requires anticipation of what might happen and how likely it is to happen, since the product under consideration will normally not have caused an accident, and thus the risk will not have materialised (yet). Previous experience with similar products will help in this exercise, as will any other information about the product, such as design, mechanical stability, chemical composition, operation, instructions for use, including possible risk management advice, type of consumers it is intended for (and those for which it is not), test reports, accident statistics, the EU Injury Database (IDB) [1], information about consumer complaints, about the behaviour of different consumers when they are using the product, and about product recalls. Product requirements laid down in legislation, in product standards or in checklists (such as in ISO 14121: Safety of machinery — Risk assessment) can also be useful sources of information.

[1] https://webgate.ec.europa.eu/idbpa/

Nevertheless, the products to be assessed may be quite specific and thus these sources may not contain the information required. The information collected may also be incomplete, inconsistent, or not fully plausible. This may be the case in particular for accident statistics, when only the product category is registered. The absence of an accident history, a small number of accidents or low severity of accidents should not be taken as a presumption of low risk. Product-specific statistics also have to be viewed with great care, since the product may have changed over time, be it in design or composition. The information must always be critically assessed.

Feedback from expert colleagues can be particularly useful, since they can draw from their real-life experience and provide suggestions that are not immediately obvious when assessing a product risk. They may also give advice when assessing the risk for different types of consumers, including vulnerable consumers such as children (see Table 1), since the latter may handle a product differently. They may also help to assess the risk for different injuries that a product may cause, and the way in which those injuries emerge through the use of the product. They can also judge whether an injury scenario is 'totally unperceived', too unlikely, and then guide the risk assessor towards more realistic assumptions.

Thus, feedback from experienced colleagues, although not an obligation, can be helpful in several aspects. A risk assessor from an authority could seek advice from colleagues in that same authority, in other authorities, in industry, in other countries, in scientific groupings, and elsewhere. Conversely, any risk assessor in industry could use his contacts with authorities and others when a new or improved product is to be assessed before it is placed on the market.

New information obtained should of course be used to update any existing risk assessment.

Make a sensitivity analysis of your risk assessment

If all information searches and queries to expert colleagues do not provide the required, very specific data, a so-called sensitivity analysis might help. In this analysis a lower and a higher value than previously chosen is assumed for each parameter of the risk assessment, and taken through the entire risk assessment procedure. The resulting risk levels will show how sensitive the risk level reacts to the input of lower and higher values. In this way the range in which the real risk of the product will be can be estimated.

If the most likely value of each parameter can be estimated, then those most likely values should be taken through the procedure, and the resulting risk level will be the most likely risk.

An example of a sensitivity analysis is illustrated in Section 6 below.

Let others check your risk assessment

Feedback from colleagues will also help when finalising the risk assessment. They will be able to provide advice on the assumptions and estimations made during the three steps above. They will feed in their experience and thus help to generate a more robust, more solid, more transparent and ultimately more acceptable risk assessment. It is therefore recommended that, ideally, advice be sought from expert colleagues, possibly in the form of a group discussion, before concluding a risk assessment. These groups, of perhaps 3 to 5 members, should include a combination of expertise appropriate to the product under assessment: engineers, chemists, (micro-)biologists, statisticians, product safety managers, and others. Group discussion will be particularly useful when a product is new on the market and has never been assessed before.

Risk assessments should be solid and realistic. However, since they require a number of assumptions, different risk assessors may come to different conclusions in view of the data and other evidence they have been able to find or because of their diverging experience. It is thus necessary for risk assessors to talk to one another in order to reach agreement or, at least, consensus. The step-by-step risk assessment described in these guidelines, however, should make such discussions more productive. Each step in a risk assessment must be clearly described in detail. Thus, any point of disagreement can be quickly identified, and consensus can more easily be reached. This will make risk assessments more acceptable.

Document your risk assessment

It is important to document your risk assessment, describing the product and all the parameters that you chose while developing it, such as test results, the type(s) of consumers you chose for your injury scenario(s), and the probabilities with the underlying data and assumptions. This will enable you to demonstrate unambiguously how you estimated the level of risk, and it will also help you to update your assessment while keeping track of all changes.

Several hazards, several injuries — but only one risk

When several hazards, several injury scenarios or differing severities of injuries or probabilities have been identified, each of those should be carried through the entire risk assessment procedure in order to determine the risk for each. As a result, the product may have several risk levels. The overall risk of the product is then the highest risk level identified, because action on the highest risk level is normally the most effective way of risk reduction. Only in special cases may a less-than-highest risk be considered particularly important, since it may require specific risk management measures.

As an example of several risks, a hammer may have a weak head and a weak grip, each of which may break when the hammer is used, and the consumer may be injured. If the relevant scenarios lead to different risk levels, the highest risk should be reported as 'the risk' of the hammer.

It could be argued that:

— the apparently most significant hazard should be decisive, since it would lead to the most severe injuries. In the above example of the hammer, this could be the hammer head breaking, since pieces of the broken head could fly into one's eye, possibly blinding the user. The hammer grip breaking, on the other hand, would never split into small pieces that could do as much damage to the eyes,

however, this would be a hazard assessment, not a risk assessment. A risk assessment also looks at the probability of an injury actually happening. Thus, the 'most significant hazard' might cause an injury that is much less likely than a lesser hazard, and therefore present a lower risk. Conversely, a scenario leading to a less severe injury may be much more likely than a scenario resulting in death, and the less severe injury may therefore present a higher risk,

— the highest probability for an injury scenario to happen should be the decisive factor for 'the risk' of the product. In the above example of the hammer, if the hammer grip is very weak, the most likely injury scenario would be from the grip breaking, and that should therefore be decisive,

however, this would not consider the seriousness of eye injuries that the hammer head breaking could cause. Looking at probability alone would not therefore give the whole picture.

In conclusion, risk is a balanced combination of both the hazard and the probability of the injury that the hazard can cause. Risk describes neither the hazard, nor the probability, but both at the same time. Taking the highest risk as 'the risk' of the product will ensure the most effective product safety (apart from specific risks requiring specific risk management, as mentioned above).

Can risks cumulate?

Several injury scenarios leading to several risks can be developed for virtually every product. For example, an angle grinder may present the risk of an electric shock, because electrical wires may be too exposed, and the risk of fire, because the machine may overheat and ignite during normal use. If both risks are considered to be 'high', do they add up to the grinder posing an overall 'serious risk'?

Where several risks are linked to the same product, one of them is obviously more likely to materialise and causes an injury. The overall likelihood of an injury is therefore greater. This does not mean that the overall risk is automatically higher, however:

— the overall probability is not calculated by simply adding up probabilities. More complex calculations are necessary, and these always result in a probability that is lower than the sum of all probabilities,

— there is difference of a factor of 10 between two succeeding probability levels (Table 4). This means that a lot of different scenarios of the same level would be needed to result in higher overall probability (and possibly risk),

— probability values are estimations which may not be totally accurate, as they often err on the 'safe' side in order to ensure a high level of protection. It is therefore more useful to look at a more accurate estimation of the probability of a scenario leading to the highest risk than to add up rough estimations of probabilities of all sorts of scenarios,

— with a little effort hundreds of injury scenarios could be developed. If risks were simply added together, the overall risk would depend on the number of injury scenarios generated and could increase 'endlessly'. This does not make sense.

Thus, risks are not simply cumulated. However, if more than one relevant risk exists, action to manage the risks may need to be taken more rapidly or may need to be more pronounced. For example, with two risks, a product may need to be immediately taken off the market and recalled, whereas, with a single risk, halting sales could be sufficient.

Risk management depends on many factors, not only on the number of risks that a product may present at one and the same time. Thus, consideration is given below to the link between risk and risk management (Section 4).

Compliance with limit values in legislation and standards

In market surveillance, consumer products are often tested against limit values or requirements laid down in legislation and in product safety standards. A product that complies with the limit value(s) or requirement(s) ([1]) is presumed to be safe in terms of the safety characteristics covered by those value(s) or requirement(s). This assumption can be made because the risks of a product from its intended and reasonably foreseeable use are taken into account when establishing the limit value(s) or requirement(s). Manufacturers thus need their products to comply with these values or requirements, because they then only have to look at risks with their products that are not be covered by those limit value(s) or requirement(s).

An example of a limit value in:

— legislation is the limit of 5 mg/kg benzene in toys which must not be exceeded, as per point 5 of Annex XVII, to the REACH Regulation ([2]), as amended by Commission Regulation (EC) No 552/2009 ([3]),

— a standard is the small parts cylinder: small parts of a toy for children under 36 months must not fit entirely into the cylinder described in the Toys Standard ([4]). If they do, they present a risk.

The product is presumed not to be safe where it fails to comply with established limit values. For limit values laid down in:

— legislation, such as on cosmetics or restrictions on marketing and use, the product must not be made available on the market,

— standards, the manufacturer may nevertheless try to provide evidence that his product is as safe as if it were compliant with the standard's limit value by way of a fully fledged risk assessment on his product. However, this may require more effort, and may be impossible in cases such as the small parts cylinder referred to above, than actually manufacturing the product in compliance with the standard's limit value.

Non-compliance with limit values does not automatically mean that the product presents a 'serious risk' (which is the highest risk level covered by these guidelines). Therefore, to ensure appropriate risk reduction measures, a risk assessment will be required for those parts of a product that do not comply with or are not covered by legislation or a standard.

([1]) NB: uncertainty always has to be taken into account when comparing a test result with a limit. See, for example,
— the 'Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation …' http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf
— the Summary report on the 'Preparation of a working document in support of the uniform interpretation of legislative standards and the laboratory quality standards prescribed under Directive 93/99/EEC'. http://ec.europa.eu/food/fs/scoop/9.1_sr_en.pdf.

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([3]) Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (OJ L 164, 26.6.2009, p. 7).

([4]) Standard EN 71-1:2005, Section 8.2 +A6:2008.

Furthermore, some products, such as cosmetics, require a risk assessment even when they are compliant with the limit values laid down in legislation. This risk assessment should provide evidence of the safety of the whole product ([1]).

In conclusion, compliance with limit values in legislation or in standards provides presumption of safety, but such compliance may not be sufficient.

Specific risk assessment guidelines in specific cases

For chemicals there are specific instructions on how to prepare a risk assessment ([2]) ([3]), and therefore they are not dealt with in detail in these guidelines. Nevertheless, they follow the same principles as for 'normal' consumer products:

— hazard identification and assessment — this is the same as determining the severity of the injury, as described above,

— exposure assessment — in this step, exposure is expressed as the likely dose of the chemical that the consumer may take up via oral, inhalation or dermal routes, separately or jointly, when using the product as anticipated in the injury scenario — this step is the same as determining the probability that the injury will indeed occur,

— risk characterisation — this step basically consists of comparing the dose of the chemical that the consumer is likely to take up (= exposure) with the derived no-effect level (DNEL) of that chemical. Should the exposure be sufficiently lower than the DNEL, in other words, should the risk characterisation ratio (RCR) be clearly below 1, risk is considered to be adequately controlled — this is the same as determining the risk level. Risk management measures may not be needed if the level of risk is sufficiently low.

Since a chemical may possess several hazards, risk is normally determined for the 'leading health effect', which is the health effect (or 'endpoint' such as acute toxicity, irritation, sensitisation, carcinogenicity, mutagenicity, toxicity for reproduction) considered to be the most important.

For cosmetics, there is also specific guidance ([4]), and there may be specific guidance for other products or purposes.

It is highly recommended to use such specific guidance, since it is tailored to the specific cases in question. Nevertheless, where the data required by the specific guidance do not exist or cannot be estimated the present guidelines may be used for a preliminary risk assessment. This risk assessment will have to be carried out with due care and attention in order to avoid any misinterpretation.

3. *BUILDING A RISK ASSESSMENT STEP BY STEP*

This section describes in detail what points have to be taken into account and what questions have to be asked when preparing a risk assessment.

3.1. **The product**

The product should be identified unambiguously. This includes the product name, the brand, the model name, the type number, a possible production lot number, any certificate that may come with the product, a child-resistant fastening if there is one, the identity of the person who placed it on the market, and the country of origin. A picture of the product, the packaging and the marking plate (if appropriate) and a test report(s) identifying the product hazard(s) can also be considered to be part of the product description.

In particular cases, the hazard may be limited to a distinct part of the product, which can be separate from it and also separately available to consumers. In such cases, it is sufficient only to assess the distinct part of the product. Rechargeable batteries of notebook computers which may overheat are an example of this.

([1]) Article 7a(1)(d) of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to (OJ L 262, 27.9.1976, p. 169).
([2]) Regulation (EC) No 1907/2006 (REACH Regulation) and guidance documents on REACH, see http://echa.europa.eu/
([3]) European Chemicals Agency (2008). The Guidance on Information Requirements and Chemical Safety Assessment. http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm
([4]) Scientific Committee on Consumer Products (SCCP), The SCCP's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 6th revision, 19 December 2006. http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_003.pdf

The description of the product includes any label that may be relevant for risk assessment, in particular warning labels. Instructions for use may also contain relevant information on the risk of the product and how to keep it as low as possible, for example by using personal protective equipment or by excluding children from using the product. An example of this is a chain saw.

Products may also need to be self-assembled by consumers before use, such as self-assembled furniture. Are the assembly instructions clear enough for the ready-to-use product to meet all the relevant safety requirements? Or could consumers make mistakes when putting the product together that could lead to unforeseen risks?

A risk assessment should always consider the entire life time of a product. This is particularly important when a new product has been developed and its risks are assessed. Will age and usage change the type or the extent of the hazard? Will new hazards appear with increasing product age or perhaps through reasonably foreseeable inappropriate use? How long is the 'time to product failure'? What is the product's lifetime, including shelf life? How long is the product used in practice by the consumer before it becomes waste?

Additional considerations may need to be taken into account when a product becomes unusable after a certain time period, even though it has never been used. Examples are electric blankets or heating pads. The electric cords in the products are usually thin and become fragile after ten years, even if the product has never been used. The heating cords can come into contact with each other, can cause a short-circuit and set the bedclothes on fire.

Finally, the packaging of the product should also be included in any risk assessment.

3.2. **The product hazard**

Hazard is the intrinsic property of the product that may cause an injury to the consumer who uses the product. It can appear in different forms:

— mechanical hazard, such as sharp edges that can cut fingers, or tight openings in which someone can trap their fingers,

— choking hazard, such as from small parts that come loose from a toy, which may be swallowed by a child and make the child choke,

— suffocation hazard, such as from the drawstrings of an anorak hood which may lead to strangulation,

— electrical hazard, such as from live electrical parts that can cause an electric shock,

— heat or fire hazard, such as a heater fan that overheats, catches fire and causes burns,

— thermal hazard, such as the hot outer surface of an oven that can cause a burn,

— chemical hazard, such as a toxic substance that can poison a consumer immediately upon ingestion, or a carcinogenic substance that can cause cancer in the long term. Some chemicals may damage the consumer only after repeated exposure,

— microbiological hazard, such as a bacteriological contamination of cosmetics which may cause a skin infection,

— noise hazard, such as ring tones from toy mobile phones that are much too loud and can damage children's hearing capacity,

— other hazards, such as explosion, implosion, sonic and ultrasonic pressure, fluid pressure, or radiation from laser sources.

For the purpose of these guidelines, hazards have been grouped, linked to the size, shape and surface of a product, to potential, kinetic or electric energy, to extreme temperatures, and others, as shown in Table 2. The table is for guidance only, and any risk assessor should adapt the scenario to the product under consideration. Of course not every type of hazard applies to every product.

Nevertheless, Table 2 should help risk assessors to look for and identify all possible hazards in consumer products that are being assessed. Where a product has several hazards, each hazard should be taken separately with its own risk assessment and the highest risk identified as 'the risk' of the product. Of course, risks requiring specific risk management measures should also be reported, to ensure that all risks can be reduced.

Note that a single hazard may lead to several injuries in the same scenario. For example, malfunctioning brakes on a motor cycle could cause an accident and result in damage to the driver's head, hands and legs, and could even cause burns if the petrol bursts into flames in the accident. In this case, all injuries would belong to the same injury scenario, and the severity of all injuries together would have to be estimated. Of course, these injuries together are very serious — several injuries in different scenarios should, however, not be added.

In the daily practice of market surveillance, it may be sufficient to assess the risk from even a single hazard. If the risk from that hazard provides for risk management action, that action can be taken without further ado. Nevertheless, the risk assessor should be sure that the risk identified is (one of) the highest risk(s), to ensure that the risk management action is sufficiently effective. This is always the case when the risk is serious, since this is the highest possible risk level proposed in these guidelines. In cases of less than serious risk, however, further risk assessments might be necessary and possibly specific risk management at a later stage. In conclusion, experience with risk assessment in market surveillance practice will limit the number of required risk assessments to a minimum.

Hazard identification by tests and standards

Hazards are often identified and quantified by tests. These tests and how to carry them out may be laid down in European or international product standards. Compliance of a product with a 'harmonised' European standard ('EN …'), of which the references have been published in the Official Journal, provides presumption of safety (albeit only for the safety characteristics covered by the value(s) or standard(s)). It can be presumed in such cases that the product presents only a minimum risk and a high level of protection with regard to the specific hazard tested.

Nevertheless, there may be instances where presumption of safety is not the case, and in such cases a particularly well-documented risk assessment will have to be prepared, including a call for amendment to the harmonised standard.

On the other hand, if a product fails the test, a risk can normally be assumed, unless the manufacturer can provide evidence that the product is safe.

Products may still present a risk even though they do not cause injuries

Products may not be hazardous but can nevertheless cause a risk, due to not being fit for their intended use. Examples of this can be observed in the area of personal protective equipment or life-saving equipment, such as reflective jackets that car drivers put on after an accident. These jackets are meant to get the attention of oncoming drivers and traffic participants to warn them of the accident, in particular at night. However, they might not be seen if the reflector stripes are too small or do not reflect sufficiently, and do not therefore protect users as they should. These jackets therefore pose a risk even though they are not hazardous in themselves. Another example is a sunscreen product which displays 'high protection' (sun protection factor of 30) on the label but provides only 'low protection' (factor of 6). This can lead to severe sunburn.

3.3. **The consumer**

The abilities and behaviour of the consumer using the product may greatly influence the level of risk. It is therefore of prime importance to have a clear idea of the type of consumer pictured in the injury scenario.

It may be necessary to generate injury scenarios with different types of consumers in order to identify the highest risk and thus 'the risk' of the product. It is not enough, for example, to consider only the most vulnerable consumers because the probability of their suffering adverse effects in the scenario may be so low that the risk is lower than in an injury scenario with a non-vulnerable consumer.

Consideration should also be given to people who are not actually using the product, but who may be in the vicinity of the user. For example, a chain saw may cause splinters to fly around and hit a bystander in the eye. Thus, although the risk from the chain saw may be effectively managed by the user him- or herself wearing protective equipment and complying with any other risk management measures specified by the manufacturer, bystanders may be under serious threat. Consequently, warnings should be given, for example in the chain saw instructions for use, about the risks to bystanders and how to minimise such risks.

Thus, when developing an injury scenario, the following aspects should be taken into account regarding the type of consumer and how they use the product. This is not a complete list, but it should encourage risk assessors to describe their injury scenarios with the necessary level of detail. It should be noted that 'consumer' also means people who are not actually using the product, but who may be affected by virtue of being nearby:

— Intended/non-intended user: The intended user of a product may use the product with ease because he goes by the instructions or because he is familiar with this kind of product, including its apparent and non-apparent hazard(s). The hazard of the product may not then materialise, and the product risk could be minor.

  The non-intended user may not be familiar with the product and may not recognise the hazard(s). He therefore runs the risk of injury, and the consumer risk is thus higher.

  Thus, the risk may be different for an intended and a non-intended user, depending on the product and the way it is used.

— Vulnerable consumers: Several categories of vulnerable and very vulnerable consumers can be distinguished: children (0 to 36 months, > 36 months to < 8 years, 8 to 14 years) and others such as the elderly (see Table 1). They all have less capacity to recognise a hazard, for example children who, when touching a hot surface, notice the heat only after some 8 seconds (and then are already burnt), whereas adults notice heat immediately.

  Vulnerable consumers may also have problems taking account of warning labels, or may have particular problems using a product they have never used before. They may also act in a way that makes them more exposed, for example young children crawling and mouthing. Children may also be attracted to products because of their appeal, which makes them a high risk in the hands of children. On the other hand, supervision by parents or other adults should normally prevent children from running straight into trouble.

  Furthermore, consumers who are not usually vulnerable may become vulnerable in specific situations, for example when the instructions or warnings on a product are in a foreign language that the consumer does not understand.

  Finally, in the particular case of chemicals, children may be more susceptible to the toxicity of chemicals than the average adult. Therefore, children should not be treated as if they were 'small adults'.

  In conclusion, a product that is normally safe for an average adult may not be safe for vulnerable consumers. This has to be taken into account when determining the severity and probability of an injury (see below) and thus the risk.

— Intended and reasonably foreseeable use: Consumers may use a product for other purposes than the one for which it is intended, although the instructions are clearly understandable, including any warnings. Therefore, as warnings may not be fully effective, other uses than the intended ones also have to be taken into account in a risk assessment. This aspect is particularly important for the manufacturer of a product, since he has to ensure that the product is safe under any reasonably foreseeable conditions of use.

  Reasonably foreseeable use may have to be based on experience, because there may be no information available in official accident statistics or other sources of information. It may then be difficult to draw the line between 'reasonably foreseeable' and 'totally unperceived' scenarios. Nevertheless, even 'totally unperceived' scenarios can be considered under these guidelines, even when they lead to very severe injuries, because such scenarios will always have very low probability. This possibly safeguards against such scenarios having too much of an influence in determining the overall risk of the product.

— Frequency and duration of use: Different consumers may use a product often or not so often, and for longer or shorter periods of time. This depends on the attractiveness of the product and the ease with which it can be used. Daily or long-term use could make a consumer entirely familiar with a product and its specifics, including its hazards, instructions and warning labels, thus making the risk minor. On the other hand, daily or long-term use may make the consumer too used to the product and lead to user fatigue where he recklessly ignores instructions and warnings, thus increasing the risk.

  Finally, daily or long-term use may also accelerate product ageing, and any parts that cannot withstand such frequent use may quickly fail and cause a hazard, and possibly an injury, which also increases the risk.

— Hazard recognition and protective behaviour and equipment: Some products are known for their hazards, such as scissors, knives, do-it-yourself drilling machines, chain saws, roller blades, bicycles, motor bikes and cars. In all these cases, the product hazard is clearly known or readily recognisable, or described in the instructions, which will include risk management measures. The consumer can then act carefully or use personal protective equipment such as gloves, helmets or seat-belts, thereby using the product in a way that minimises the risk.

  In other cases, the product hazard may not be so readily recognisable, such as a short-circuit within an electric iron, warning labels may be overlooked or misunderstood, and consumers will only rarely be able to take preventive measures.

— Consumer behaviour in the event of an incident: Where the hazard impinges on the consumer it may cause injury. It is thus important for a risk assessment to consider how the consumer may react. Will he put the product to one side calmly and take preventive action, such as combating a fire caused by the product, or will he throw it away in a panic? Vulnerable consumers, especially children, may after all not behave the same as other, non-vulnerable consumers.

— The consumer's cultural background and the way a product is used in his home country may influence the risk of a product. Manufacturers in particular have to take account of these cultural differences when launching a new product on a market. Manufacturers' experience in this area can thus be a valuable source of information for authorities preparing a risk assessment.

3.4. **Injury scenario: Steps leading to injury(ies)**

Most injury scenarios consist of the following three main steps:

(1) the product has a 'defect' or can lead to a 'dangerous situation' during its foreseeable lifetime;

(2) the 'defect' or 'dangerous situation' results in an accident;

(3) the accident results in an injury.

These three main steps can be divided into further steps to show how the product hazard can lead to injury and the like. Nevertheless, these 'steps to injury' have to be clear and concise, and not exaggerate the detail or the number of steps. With experience, it will be increasingly easier to identify the conditions for the occurrence of any given injury and the 'shortest path to injury' (or 'critical path to injury').

It is probably easiest to start with a scenario with the consumer for whom the product is intended where the consumer uses the product as per the instructions or, if there are none, according to normal handling and use. If this assessment produces the highest risk level, there is normally no need to carry out further assessments, and appropriate risk reduction measures can be taken. Similarly, where an incident is reported in a specific consumer complaint, a single injury scenario may be sufficient to conclude as to appropriate risk reduction measures.

Otherwise, further scenarios could be developed to include vulnerable consumers, in particular children (see Table 1), slight or more pronounced deviations from normal use, use under different climate conditions, such as very cold or very hot, unfavourable conditions of use, such as without proper daylight or illumination, use as suggested when the product was sold (for instance, a lamp sold in a toy shop should also be assessed for its risk when used by a child), use over the entire lifetime (including wear and tear), etc. Each scenario should be considered through the entire risk assessment procedure.

Where the product displays several hazards, injury and thus risk scenarios should be developed for each of them. Nevertheless, a plausibility check as to whether an injury scenario might lead to a risk requiring action can limit the number of injury scenarios.

From all the scenarios generated, the scenario providing the highest risk (= 'the risk' of the product) will normally be decisive for the risk reduction measures to be taken, because action on the highest risk reduces the risk most effectively. An exception to the rule might be a specific, less-than-highest risk stemming from a different hazard, which could be managed by specific measures and should, of course, also cover the highest risk.

As a rule of thumb, injury scenarios can lead to the highest risk level when:

— the injury(ies) considered are in the highest severity levels (levels 4 or 3),

— the overall probability of an injury scenario is quite high (at least > 1/100).

Table 4 provides further guidance in this respect. This might help to limit the number of scenarios.

Of course, the number of injury scenarios remains the responsibility of the risk assessor, and it depends on the number of factors that need to be taken into account when determining 'the risk' of the product. It is therefore impossible to give a specific number of injury scenarios that may be necessary in a specific case.

To help develop a suitable number of scenarios, these guidelines provide a table with typical injury scenarios (Table 2). These should be adapted to the specific product, consumer type and other circumstances.

3.5. **Severity of injury**

The injury that a hazard can cause to the consumer can have different degrees of severity. The severity of the injury thus reflects the effect the hazard has on the consumer under the conditions described in the injury scenario.

The severity of the injury can depend on:

— the type of hazard (see list of hazards above and in Table 2). A mechanical hazard, such as sharp edges, can cause cuts to the fingers; these are immediately noticed, and the consumer will take action to heal his injuries. On the other hand, a chemical hazard may cause cancer. This normally passes unnoticed, and the illness may appear only after many years, and is considered to be very severe since cancer is very difficult to cure, if at all,

— how powerful the hazard is. For example, a surface heated to 50 °C may cause slight burns, whereas a surface at 180 °C will cause severe burns,

— how long the hazard impinges on the consumer. A short contact time with an abrasion hazard may scratch the consumer's skin only superficially, whereas a longer time may take off large parts of the skin,

— what body part is injured. For example, penetration by a sharp point into the skin of the arm is painful, but penetration into an eye is a more serious and perhaps a life-affecting injury,

— what impact the hazard has on one or several body parts. An electrical hazard may cause an electric shock with unconsciousness and, subsequently, a fire which may damage the lungs when the unconscious person inhales the smoke,

— the type and behaviour of the consumer. A product labelled with a warning message can be used, without harm, by an adult consumer, because the consumer adjusts to using the product. On the other hand, a child or other vulnerable consumer (see Table 1) who cannot read or understand the warning label may be very seriously injured.

To quantify the severity of injury(ies), Table 3 in these guidelines shows how to classify injuries into four categories, depending on the reversibility of an injury, i.e. whether recovery from an injury is possible and to what extent. This categorisation is for guidance only, and a risk assessor should change the category if necessary, and report it in the risk assessment.

Where several injury scenarios are considered in the risk assessment, the severity of each injury should be classified separately, and considered throughout the entire risk assessment process.

An example: A consumer uses a hammer to knock a nail into a wall. The hammer head is too weak (due to incorrect material) and it breaks, one of the pieces flying into the eye of the consumer so hard that it causes blindness. The injury is thus an 'eye injury, foreign body in eye: permanent loss of sight (one eye)', which is a level 3 injury in Table 3.

3.6. **Probability of injury**

The 'probability of injury' is the probability that injury scenario may indeed materialise during the expected lifetime of the product.

This probability is not easy to estimate; but when a scenario is described in distinct steps, each step can be given a certain probability, and multiplying these partial probabilities together gives the overall probability of the scenario. This stepwise approach should make it easier to estimate the overall probability. Of course, where several scenarios are developed, each scenario requires its own overall probability.

Where an injury scenario is nevertheless described in a single step, the probability of the scenario can also only be determined in a single overall step. This would only be a 'guesstimate', however, which could be severely criticised and thus call the entire risk assessment into question. A more transparent assignment of probabilities to a several-steps-scenario is therefore preferable, especially as the partial probabilities can be built on undisputable evidence.

These guidelines distinguish between 8 levels of probability to classify overall probability: from < 1/1 000 000 to > 50 % (see left-hand side of Table 4). The following example of a hammer head that breaks when the user knocks a nail into a wall should illustrate how to assign a probability to each step, and how to classify overall probability.

Step 1: The hammer head breaks when the user tries to knock a nail into a wall because the material of the hammer head is too weak. The weakness was determined in a test, and with the reported weakness the probability of the hammer head breaking during the otherwise expected lifetime of the hammer is put at 1/10.

Step 2: One of the pieces of the hammer hits the user when it breaks. The probability of this happening is put at 1/10, since the area of upper body exposed to the pieces flying off is considered to be 1/10 of the half-sphere in front of the wall. Of course, if the user were standing very close to the wall, his body would take a larger share of the half-sphere, and the probability would be higher.

Step 3: The piece hits the user on the head. The head is estimated to be about 1/3 of the upper body, and the probability is therefore 1/3.

Step 4: The piece hits the user in the eye. The eyes are considered to be about 1/20 of the area of the head, and therefore the probability is 1/20.

Multiplying the probabilities of the above steps together gives an overall probability for the scenario of 1/10 × 1/10 × 1/3 × 1/20 = 1/6 000. This translates into > 1/10 000 (see left-hand side of Table 4).

Once the overall probability has been calculated for an injury scenario, it should be checked for plausibility. This requires rather a lot of experience, thus suggesting that the assistance of persons experienced in risk assessment should be sought (see above in section 'Let others check your risk assessment'). As experience is gained with these guidelines estimating probability should become easier, and an increasing number of examples will become available to facilitate this task.

Assigning probabilities to different injury scenarios for the same product may lead to the following.

— When the product is used by more vulnerable consumers in a scenario, the probability may have to be raised in general because more vulnerable consumers can be injured more easily. This applies in particular to children, since children do not normally have the experience to take preventive action, on the contrary (see also 'Vulnerable consumers' in Section 3.3).

— When the risk is readily recognisable, including through warning labels, the probability may have to be lowered because the user will use the product more carefully in order to avoid injury as far as possible. This may not apply to an injury scenario with a (young) child or other vulnerable user (see Table 1) who cannot read.

— When accidents have been reported that fit into the injury scenario, the probability for that scenario could increase. In cases where accidents have only rarely been reported, or are not known at all, it may be useful to ask the manufacturer of the product whether he is aware of any accident or adverse effect caused by the product.

— When a fairly large number of conditions are needed for the injury to occur, the overall probability of the scenario would normally be lower.

— When the conditions needed for the injury to occur are easily met, this may increase the probability.

— When the test results of the product fail by a large margin to come within the limit values required (by the relevant standard or legislation), the probability of the injury (scenario) occurring may be higher than if the product performed close to the limit values.

The 'probability of injury' in this instance is the probability that the injury scenario may actually happen. Probability does not therefore describe the general exposure of the population to the product, calculated, for example, by considering the millions of product items sold on the market and then considering that a few of them might fail. Considerations of this kind do, however, play a role when determining the appropriate risk reduction measures (see Section 4).

Also, accident statistics, even if product-specific, have to be considered with care when used for to estimate probability. The circumstances of the accident may not be reported in sufficient detail, the product may have changed over time, or the manufacturer may be different, and so on. In addition, light accidents may not have been reported to those collecting the data for the statistics. Nonetheless, accident statistics can shed light on injury scenarios and their probability.

3.7. **Determination of risk**

Once the severity of the injury and the probability have been determined, if possible for several injury scenarios, the risk level then needs to be looked up in Table 4. Table 4 combines both the severity of the injury and the probability, and the highest risk is 'the risk' of the product. Risks requiring specific risk management measures should also be reported, to ensure that all risks are reduced to a minimum.

These guidelines distinguish between 4 levels of risk: serious, high, medium and low. The risk level between neighbouring severities of injury or probability normally changes by 1 level. This is consistent with the general experience that risk does not increase incrementally when input factors change gradually. However, where the severity of injury increases from level 1 to level 2 (on the right-hand side of Table 4), some risk levels increase by 2 levels, namely from medium to serious and from low to high. This is due to the fact that these guidelines include 4 graduations of severity of injury, whereas the original method (see Introduction) included 5. Nevertheless, 4 graduations are considered normal for consumer products, since they make for a sufficiently robust estimation of severity; 5 levels would be too sophisticated since neither the severity of the injury nor the probability can be determined with very high precision.

At the end of the risk assessment, be it for an individual injury scenario or for the overall risk of the product, the plausibility of the risk level and uncertainties in the estimates should be considered. This may mean verifying that the risk assessor has used the best information available to make his estimations and assumptions. Feedback from colleagues and other experts can also be helpful.

A sensitivity analysis can also be very valuable (see example in Section 6.3). How does the risk level change when the severity of injury or probability changes by 1 level up or down? If the risk level does not change at all, it is quite plausible that it has been estimated correctly. If it changes, however, the risk level may be borderline. It is then necessary to reconsider the injury scenarios and the assigned severity of injury(ies) and probability(ies). At the end of the sensitivity analysis the risk assessor should be confident that the risk level is sufficiently plausible and that he can document it and pass the information on.

4. *FROM RISK TO ACTION*

Once the risk assessment is complete it will normally be used to decide whether action needs to be taken to reduce the risk and thus prevent harm to a consumer's health. Although action is separate from risk assessment, some points are raised here to illustrate the possible follow-up of identified risks.

Within market surveillance, action will often be taken in contact between the authority and the manufacturer, importer or distributor. This can help the authority to determine the most effective and efficient way of managing the risk.

With a serious risk in a consumer product, measures to reduce the risk may include withdrawal from the market or recall. Lower levels of risk normally lead to less rigorous measures. It may then be sufficient to add warning labels on the product or to improve the instructions to make the product safe. Thus, whatever the level of risk, the authority should consider whether to take action, and if so, what action.

Nevertheless, there is no automatic link from risk to action. When a product shows several less-than-serious risks, and its overall risk is thus not serious, urgent action may be necessary since any of the risks may materialise quite quickly. The pattern of risks in the product may indicate a lack of quality control in production.

It is also important to take account of exposure of the population as a whole. Where there are a large number of products on the market and the product is therefore used by a large number of consumers, even a single less-than-serious risk may require quick action to avoid adverse effects to the health of consumers.

Less-than-serious risks may also require action when the product concerned could cause fatal accidents, even though such accidents may be extremely unlikely. This could be the case with a fastening on a beverage container, which could come loose and be swallowed by a child, causing the child to choke to death. A simple change of design to the lid could eliminate the risk, and no further action might be required. Even a selling-off period may be granted if the risk of a fatal accident were indeed extremely small.

Other risk-related aspects may be the public perception of risk and its likely consequences, cultural and political sensitivities and how it is portrayed in the media. These aspects may be especially relevant when the consumers concerned are vulnerable, in particular children. It will be up to the national market surveillance authority(ies) to determine what measures are required.

Taking action to counteract a risk may also depend on the product itself and the 'minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection' ([1]). This minimum risk will probably be much lower for toys, where children are involved, than for a chain-saw, which is known to be so high-risk that solid protective equipment is required to keep the risk at a manageable level.

Finally, even if there is no risk, action may be necessary, for example, when a product is non-compliant with the applicable regulation/legislation (e.g. incomplete markings).

In conclusion, there is no automatic link from risk to action. Surveillance authorities will take account of a range of factors such as those indicated above. The principle of proportionality always has to be considered, and action has to be effective.

5. *HOW TO PREPARE A RISK ASSESSMENT — IN BRIEF*

1. Describe the product and its hazard.

   Describe the product unambiguously. Does the hazard concern the entire product or only a (separable) part of the product?

   Is there only one hazard within the product? Are there several hazards? See Table 2 for guidance.

   Identify the standard(s) or legislation applicable to the product.

([1]) This is taken from the definition of 'safe product' in Article 2(b) of Directive 2001/95/EC.

2. Identify the type of consumer you want to include in your injury scenario with the hazardous product.

   Start with the intended user and the intended use of the product for your first injury scenario. Take other consumers (See Table 1) and uses for further scenarios.

3. Describe an injury scenario in which the product hazard(s) you have selected causes an injury(ies) or adverse health effect(s) to the consumer you selected.

   Describe the steps to the injury(ies) clearly and concisely, without exaggerating the details ('shortest path to injury', 'critical path to injury'). If there are several concurrent injuries in your scenario, include them all in that same scenario.

   When you describe the injury scenario, consider the frequency and duration of use, hazard recognition by the consumer, whether the consumer is vulnerable (in particular children), protective equipment, the consumer's behaviour in the case of an accident, the consumer's cultural background, and other factors that you consider important for the risk assessment.

   See Section 3.3 and Table 2 for guidance.

4. Determine the severity of the injury.

   Determine the level of severity (1 to 4) of the injury to the consumer. If the consumer suffers from several injuries in your injury scenario, estimate the severity of all those injuries together.

   See Table 3 for guidance.

5. Determine the probability of the injury scenario.

   Assign a probability to each step of your injury scenario. Multiply the probabilities to calculate the overall probability of your injury scenario.

   See left-hand side of Table 4 for guidance.

6. Determine the risk level.

   Combine the severity of the injury and the overall probability of the injury scenario and check the risk level in Table 4.

7. Check whether the risk level is plausible.

   If the risk level does not seem plausible, or if you are uncertain about the severity of injury(ies) or about the probability(ies), move them one level up and down and recalculate the risk. This 'sensitivity analysis' will show you whether the risk changes when your input changes.

   If the risk level remains the same, you can be quite confident of your risk assessment. If it changes easily, you may want to err on the safe side and take the higher risk level as 'the risk' of the consumer product.

   You could also discuss the plausibility of the risk level with experienced colleagues.

8. Develop several injury scenarios to identify the highest risk of the product.

   If your first injury scenario identifies a risk level below the highest risk level set out in these guidelines, and if you think that the product may pose a higher risk than the one identified,

   — select other consumers (including vulnerable consumers, in particular children),

   — identify other uses (including reasonably foreseeable uses),

   in order to determine which injury scenario puts the product at its highest risk.

The highest risk is normally 'the risk' of the product that allows the most effective risk management measures. In specific cases, a particular hazard may lead to a less-than-highest risk and require specific risk management measures. This has to be taken duly into account.

As a rule of thumb, injury scenarios may lead to the highest risk level set out in these guidelines where:

— the injury(ies) considered are at least at levels 3 or 4,

— the overall probability of an injury scenario is at least > 1/100.

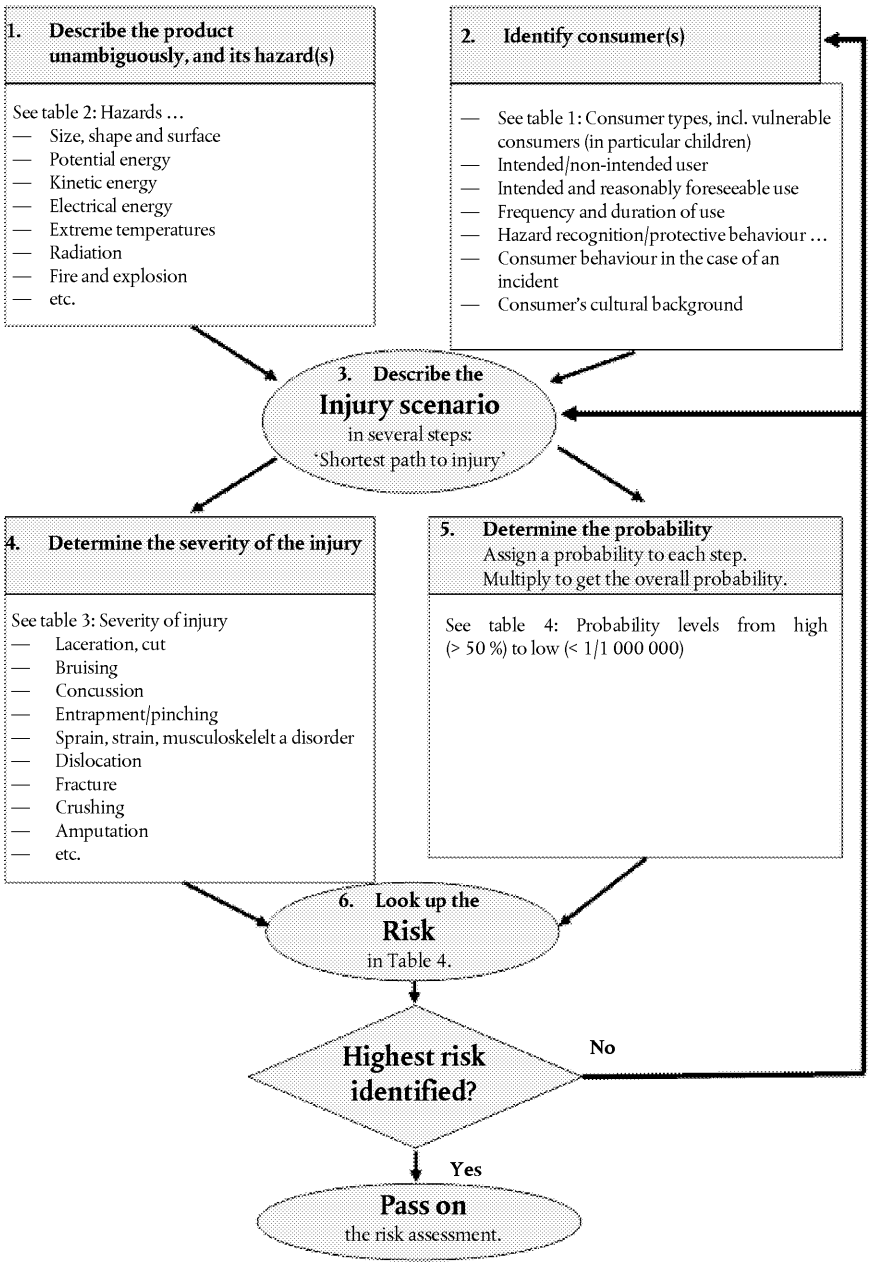
See Table 4 for guidance.

9. Document and pass on your risk assessment.

Be transparent and also set out all the uncertainties that you encountered when making your risk assessment.

Examples for reporting risk assessments are provided in section 6 of these guidelines.

Schematic flow of risk assessment



Examples

Folding chair

A folding chair has a folding mechanism constructed in such a way that the user's fingers can get trapped between the seat and the folding mechanism. This can lead to fractures or even loss of one or more fingers.

Determination of risk(s)

Injury scenario	Injury type and location	Severity of injury	Probability of injury		Overall probability	Risk
Person unfolds the chair, grips seat close to the back corner by mistake (Person inattentive/distracted), finger gets caught between seat and backrest	Minor pinching of finger	1	Unfolding the chair Gripping the seat at back corner while unfolding Finger gets caught Minor pinching	1 1/50 1/10 1	1/500 > 1/1 000	Low risk
Person unfolds the chair, grips seat at the side by mistake (Person inattentive/distracted), finger gets caught between seat and link	Minor pinching of finger	1	Unfolding the chair Gripping the seat at the side while unfolding Finger gets caught Minor pinching	1 1/50 1/10 1	1/500 > 1/1 000	Low risk
Person unfolds the chair, chair is clamped, person tries to push down the seat and grips seat close to the corner by mistake (Person inattentive/distracted), finger gets caught between seat and backrest	Fracture of finger	2	Unfolding the chair Chair clamps Gripping the seat at corners while unfolding Finger gets caught Fracture of finger	1 1/1 000 1/50 1/10 1	1/500 000 > 1/1 000 000	Low risk

Injury scenario	Injury type and location	Severity of injury	Probability of injury		Overall probability	Risk
Person unfolds the chair, chair is clamped, person tries to push down the seat and grips seat at the side by mistake (Person inattentive/distracted), finger gets caught between seat and link	Fracture of finger	2	Unfolding the chair Chair clamps Gripping the seat at the side while unfolding Finger gets caught Fracture of finger	1 1/1 000 1/50 1/10 1	1/500 000 > 1/1 000 000	Low risk
Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and backrest	Loss of digit	3	Sitting on chair Moves the chair while sitting Grips chair at rear part while moving Chair partially folds, creating a gap between the backrest and seat Finger is between backrest and seat Finger gets caught Loss of (part of) finger	1 1/2 ½ 1/3 1/5 1/10 1/10	1/6 000 > 1/10 000	High risk
Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and link	Loss of digit	3	Sitting on chair Moves the chair while sitting Grips chair at rear part while moving Chair partially folds, creating a gap between the backrest and seat Finger is between backrest and seat Finger gets caught Loss of (part of) finger	1 1/2 1/2 1/3 1/5 1/10 1/10	1/6 000 > 1/10 000	High risk

The overall risk of the folding chair is thus 'high risk'.

Socket protectors

This case deals with socket protectors. These are devices that users (parents) put into the electrical socket outlets to stop small children from accessing live parts by putting a long metal object into one of the holes in the outlet and getting a (fatal) electric shock.

The holes in this particular protector (where the pins of the plug go through) are so narrow that the pins can get stuck. This means that the user may pull the protector off the outlet when the plug is pulled out. The user may not notice this happening.

Determination of risk(s)

Injury scenario	Injury type and location	Severity of injury	Probability of injury		Overall probability	Risk
Protector is removed from the socket, which becomes unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing high voltage and is electrocuted.	Electrocution	4	Removal of protector Not noticing the removal of protector Child is playing with thin conductible object Child is unattended when playing Child inserts the object into the socket Access to voltage Electrocution due to voltage (without circuit interrupter)	9/10 1/10 1/10 1/2 3/10 1/2 ¼	27/160 000 > 1/10 000	Serious risk
Protector is removed from the socket, which becomes unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing high voltage and sustains shock.	Burns second degree	1	Removal of protector Not noticing the removal of protector Child is playing with thin conductible object Child inserts the object into the socket Access to voltage Child is unattended when playing Burn due to electric current (without circuit interrupter)	9/10 1/10 1/10 3/10 1/2 1/2 ¾	81/160 000 > 1/10 000	Low risk
Socket unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing high voltage and is electrocuted.	Electrocution	4	Child is playing with thin conductible object Child is unattended when playing Child inserts the object into the socket Access to voltage Electrocution due to voltage (without circuit interrupter)	1/10 1/100 3/10 1/2 ¼	3/80 000 > 1/100 000	High risk

The overall risk of the socket protectors is thus 'serious'.

Sensitivity analysis

The factors used to calculate the risk of an injury scenario, namely the severity of the injury and the probability, often have to be estimated. This creates uncertainty. Probability in particular can be difficult to estimate, since the behaviour of consumers, for example, can be difficult to predict. Does a person perform a certain action often or only occasionally?

It is therefore important to consider the level of uncertainty of the two factors and to make a sensitivity analysis. The purpose of this analysis is to establish how much the risk level varies when the estimated factors vary. The example below only shows the variation of probability, since the severity of the injury is usually predicted with more certainty.

A practical way of performing the sensitivity analysis is to repeat the risk assessment for a certain scenario, but to use a different probability for one or more steps in the scenario. For example, a candle containing seeds could cause a fire, because the seeds can catch fire and generate high flames. Furniture or curtains can catch fire and persons not in the room could inhale toxic fumes and suffer fatal poisoning:

Injury scenario	Injury type and location	Severity of injury	Probability of injury	Resulting probability	Risk
Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are not in room, but inhale toxic fumes.	Fatal poisoning	4	— Seeds or beans catch fire: 90 % (0,9). — People not in the room for some time: 30 % (0,3). — Furniture or curtains catch fire: 50 % (0,5) (depends on surface on which candle is placed) — Persons inhale toxic fumes: 5 % (0,05).	0,00675 > 1/1 000	Serious

The probability levels for the steps in the scenario were estimated as shown in the table.

The overall probability is 0,00675, which corresponds to > 1/1 000 in Table 4. This leads to the conclusion of 'serious risk'. Note that the exact probability is closer to 1/100 than to 1/1 000, which already gives some confidence in the risk level because it is a little deeper in the serious risk area of Table 4 than the > 1/1 000 row suggests.

Suppose we are uncertain about the 5 % probability that persons inhale the toxic fumes. We could put it at a much lower 0,1 % (0,001 = 1 in a thousand). If we recalculate with that assumption, the overall probability is 0,000135, which translates into > 1/10 000. Nevertheless, the risk is still serious. Even if for some reason the probability were to be a factor of 10 lower, the risk would still be high. Therefore, although the probability may vary 10- or 100-fold, we still find a serious or high risk (the latter being quite close to 'serious'). Thus, this sensitivity analysis lets us confidently assess the risk as serious.

In general, however, risk assessment should be based on 'reasonable worst cases': not too pessimistic on every factor, but certainly not too optimistic.

Table 1

Consumers

Consumers	Description
Very vulnerable consumers	Very young children: 0 to 36 months Others: Persons with extensive and complex disabilities

Consumers	Description
Vulnerable consumers	Young children: Children older than 36 months and younger than 8 years Older children: Children 8 to 14 years Others: Persons with reduced physical, sensory or mental capabilities (e.g. partially disabled, elderly, including those over 65, with some reduction in their physical and mental capabilities), or lack of experience and knowledge
Other consumers	Consumers other than very vulnerable or vulnerable consumers

Table 2

Hazards, typical injury scenarios and typical injuries

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Size, shape and surface	Product is obstacle	Person trips over product and falls; or person bumps into product	Bruising; fracture, concussion
	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child), or covers internal airway	Suffocation
	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
	Possible to bite off small part from product	Person (child) swallows small part; the part gets stuck in the digestive tract	Digestive tract obstruction
	Sharp corner or point	Person bumps into sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture; blinding, foreign body in eye; hearing, foreign body in ear
	Sharp edge	Person touches sharp edge; this lacerates the skin or cuts through tissues	Laceration, cut; amputation
	Slippery surface	Person walks on surface, slips and falls	Bruising; fracture, concussion
	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
	Gap or opening between parts	Person puts a limb or body in opening and finger, arm, neck, head, body or clothing is trapped; injury occurs due to gravity or movement	Crushing, fracture, amputation, strangulation
Potential energy	Low mechanical stability	Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; sprain; fracture, concussion; crushing; electric shock; burns
	Low mechanical strength	Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; fracture, concussion; crushing; electric shock; burns

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
	High position of user	Person at high position on the product loses balance, has no support to hold on to and falls from height	Bruising; dislocation; fracture, concussion; crushing
	Elastic element or spring	Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product	Bruising; dislocation; fracture, concussion; crushing
	Pressurised liquid or gas, or vacuum	Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects	Dislocation; fracture, concussion; crushing; cuts (see also under fire and explosion)
Kinetic energy	Moving product	Person in the line of movement of the product is hit by the product or run over	Bruising; sprain; fracture, concussion; crushing
	Parts moving against one another	Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed)	Bruising; dislocation; fracture; crushing
	Parts moving past one another	Person puts a body part between the moving parts while they move close by (scissor movement); the body part gets trapped between the moving parts and put under pressure (shearing)	Laceration, cut; amputation
	Rotating parts	A body part, hair or clothing of a person is entangled by the rotating part; this causes a pulling force	Bruising; fracture; laceration (skin of the head); strangulation
	Rotating parts close to one another	A body part, hair or clothing of a person is drawn in by the rotating parts; this causes a pulling force and pressure on the body part	Crushing, fracture, amputation, strangulation
	Acceleration	Person on the accelerating product loses balance, has no support to hold on to and falls with some speed	Dislocation; fracture, concussion; crushing
	Flying objects	Person is hit by the flying object and depending on the energy sustains injuries	Bruising; dislocation; fracture, concussion; crushing
	Vibration	Person holding the product loses balance and falls; or prolonged contact with vibrating product causes neurological disorders, osteo-articular disorder, trauma of the spine, vascular disorder	Bruising; dislocation; fracture; crushing
	Noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Hearing injury
Electrical energy	High/low voltage	Person touches part of the product that is at high voltage; the person receives an electric shock and may be electrocuted	Electric shock

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
	Heat production	Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam, etc., that hits a person	Burn, scald
	Live parts too close	Electric arc or sparks occur between the live parts. This may cause a fire and intense radiation	Eye injury; burn, scald
Extreme temperatures	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire	Burn, scald
	Hot surfaces	Person does not recognise the hot surface and touches it; the person sustains burns	Burn
	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds	Scald
	Hot gases	Person breathes in the hot gases emitted from a product; this causes lung burn; or prolonged exposure to hot air causes dehydration	Burn
	Cold surfaces	Person does not recognise the cold surface and touches it; the person sustains frostbite	Burn
Radiation	Ultraviolet radiation, laser	Skin or eyes of a person are exposed to radiation emitted by the product	Burn, scald; neurological disorders; eye injury; skin cancer, mutation
	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)	Person is close to the electromagnetic field (EMF) source, body (central nervous system) is exposed	Neurological (brain) damage, leukaemia (children)
Fire and explosion	Flammable substances	Person is near the flammable substance; an ignition source sets the substance on fire; this causes injuries to the person	Burn
	Explosive mixtures	Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
	Ignition sources	The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire	Burn; poisoning
	Overheating	Product overheats; fire, explosion	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Toxicity	Toxic solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets on skin Person breathes in solid or fluid, for example vomited material (pulmonary aspiration)	Acute poisoning; irritation, dermatitis Acute poisoning in lungs (aspiration pneumonia); infection
	Toxic gas, vapour or dust	Person inhales substance from product; and/or substance gets on skin	Acute poisoning in lungs; irritation, dermatitis
	Sensitising substance	Person ingests substance from product, e.g. by putting it in mouth; and/or substance gets on skin; and/or person inhales gas, vapour or dust	Sensitisation; allergic reaction
	Irritating or corrosive solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets on skin or in eyes	Irritation, dermatitis; skin burn; eye injury, foreign body in eye
	Irritating or corrosive gas or vapour	Person inhales substance from product, and/or substance gets on skin or in eyes	Irritation, dermatitis; skin burn; acute poisoning or corrosive effect in lungs or in eyes
	CMR substance	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets onto skin; and/or person inhales substance as gas, vapour or dust	Cancer, mutation, reproductive toxicity
Microbiological contamination	Microbiological contamination	Person gets into contact with contaminated product by ingestion, inhalation or skin contact	Infection, local or systemic
Product operating hazards	Unhealthy posture	Design causes unhealthy posture of person when operating the product	Strain; musculoskeletal disorder
	Overexertion	Design requires use of considerable force when operating the product	Sprain or strain; musculoskeletal disorder
	Anatomical unsuitability	Design is not adapted to human anatomy, which makes it difficult or impossible to operate	Sprain or strain
	Ignoring personal protection	Design makes it difficult for a person wearing protection to handle or operate the product	Various injuries
	Inadvertent (de)activation	Person can easily (de)activate product, which leads to unwanted operation	Various injuries
	Operational inadequacy	Design provokes faulty operation by a person; or product with a protective function does not provide expected protection	Various injuries
	Failure to stop	Person wants to stop the product, but it continues to operate in situation where this is unwanted	Various injuries
	Unexpected start	Product shuts down during a power failure, but resumes operation in a hazardous way	Various injuries
	Inability to stop	In an emergency situation, person is not able to stop operation of the product	Various injuries

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
	Inadequately fitting parts	Person tries to fit a part, needs too much force to fit, product breaks; or part is too loosely fitted and becomes loose during use	Sprain or strain; laceration, cut; bruising; entrapment
	Missing or incorrectly fitted protection	Hazardous parts are reachable for a person	Various injuries
	Insufficient warning instructions, signs and symbols	User does not notice warning instructions signs and/or does not understand symbols	Various injuries
	Insufficient warning signals	User does not see or hear warning signal (optical or audio), causing dangerous operation	Various injuries

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See Section 3.2.

Table 3

Severity of injury

Introduction

These risk assessment guidelines distinguish between four levels of injury severity. It is important to realise that severity should be assessed completely objectively. The aim is to compare the severity of different scenarios and to set priorities, not to judge the acceptability of a single injury at this stage. Any injury that could easily have been avoided will be difficult to accept for a consumer. However, authorities can justifiably invest more effort into avoiding irreversible consequences than into preventing temporary discomfort.

In order to assess the severity of the consequences (acute injury or other damage to health), objective criteria can be found, on the one hand, in the level of medical intervention, and, on the other hand, in the consequences to the further functioning of the victim. Both could be expressed as cost, but the costs of consequences of health damage may be difficult to quantify.

Combining these criteria, the four levels may be defined as follows.

1 Injury or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.

2 Injury or consequence for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete.

3 Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.

4 Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.

The following table, which should be considered as a guide rather than prescriptive or complete, provides **examples** of injuries at all four levels. National differences may exist, either cultural or caused by different systems of health care and financial arrangements. However, deviating from the proposed classification in the table will affect uniform assessment of risks in the EU; this should be clearly stated and explained in the risk assessment report, and reasons should be given.

Type of injury	**Severity of injury**			
	1	**2**	**3**	**4**
Laceration, cut	Superficial	External (deep) (> 10 cm long on body) (> 5 cm long on face) requiring stitches Tendon or into joint White of eye or cornea	Optic nerve Neck artery Trachea Internal organs	Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/dysfunction)
Bruising (abrasion/contusion, swelling, oedema)	Superficial ≤ 25 cm^2 on face ≤ 50 cm^2 on body	Major > 25 cm^2 on face > 50 cm^2 on body	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Brain stem Spinal cord causing paralysis
Concussion	—	Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma
Entrapment/pinching	Minor pinching	—	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable.)	(Same outcome as for suffocation/strangulation.)
Sprain, strain, musculoskeletal disorder	Extremities Joints Spine (no dislocation or fracture)	Knee ligaments strain	Ligament or tendon rupture/tear Muscle tear Whiplash	—
Dislocation	—	Extremities (finger, toe, hand, foot) Elbow Jaw Loosening of tooth	Ankle Wrist Shoulder Hip Knee Spine	Spinal column

Type of injury	Severity of injury			
	1	2	3	4
Fracture	—	Extremities (finger, toe, hand, foot) Wrist Arm Rib Sternum Nose Tooth Jaw Bones around eye	Ankle Leg (femur and lower leg) Hip Thigh Skull Spine (minor compression fracture) Jaw (severe) Larynx Multiple rib fractures Blood or air in chest	Neck Spinal column
Crushing	—	—	Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist Forearm Leg Shoulder Trachea Larynx Pelvis	Spinal cord Mid-low neck Chest (massive crushing) Brain stem
Amputation	—	—	Finger(s) Toe(s) Hand Foot (Part of) Arm Leg Eye	Both extremities
Piercing, puncturing	Limited depth, only skin involved	Deeper than skin Abdominal wall (no organ involvement)	Eye Internal organs Chest wall	Aorta Heart Bronchial tube Deep injuries in organs (liver, kidney, bowel, etc.)
Ingestion	—	—	Internal organ injury (Refer also to internal airway obstruction where the ingested object gets stuck high in the oesophagus.)	Permanent damage to internal organ
Internal airway obstruction	—	—	Oxygen flow to brain blocked without permanent consequences	Oxygen flow to brain blocked with permanent consequences

Type of injury	Severity of injury			
	1	2	3	4
Suffocation/Strangulation	—	—	Oxygen flow to brain blocked without permanent consequences	Fatal suffocation/strangulation
Submersion/ Drowning	—	—	—	Fatal drowning
Burn/Scald (by heat, cold, or chemical substance)	1°, up to 100 % of body surface 2°, < 6 % of body surface	2°, 6-15 % of body surface	2°, 16-35 % of body surface, or 3°, up to 35 % of body surface Inhalation burn	2° or 3°, > 35 % of body surface Inhalation burn requiring respiratory assistance
Electric shock	(See also under burns as electric current can cause burns.)	Local effects (temporary cramp or muscle paralysis)	—	Electrocution
Neurological disorders	—	—	Triggered epileptic seizure	—
Eye injury, foreign body in eye	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight Permanent loss of sight (one eye)	Permanent loss of sight (both eyes)
Hearing injury, foreign body in ear	Temporary pain in ear without need for treatment	Temporary impairment of hearing	Partial loss of hearing Complete loss of hearing (one ear)	Complete loss of hearing (both ears)
Poisoning from substances (ingestion, inhalation, dermal)	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system	Irreversible damage to nerve system Fatality
Irritation, dermatitis, inflammation or corrosive effect of substances (inhalation, dermal)	Local slight irritation	Reversible eye damage Reversible systemic effects Inflammatory effects	Lungs, respiratory insufficiency, chemical pneumonia Irreversible systemic effects Partial loss of sight Corrosive effects	Lungs, requiring respiratory assistance Asphyxia
Allergic reaction or sensitisation	Mild or local allergic reaction	Allergic reaction, widespread allergic contact dermatitis	Strong sensitisation, provoking allergies to multiple substances	Anaphylactic reaction, shock Fatality

Type of injury	Severity of injury			
	1	2	3	4
Long-term damage from contact with substances or from exposure to radiation	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Damage to nervous system, e.g. Organic Psycho Syndrome (OPS; also called Chronic Toxic Encephalopathy, also known as 'painters' disease'). Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nervous system	Cancer (leukaemia) Effects on reproduction Effects on offspring CNS depression
Microbiological infection		Reversible damage	Irreversible effects	Infection requiring prolonged hospitalisation, antibiotics-resistant organisms Fatality

Table 4

Risk level from the combination of the severity of injury and probability

Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		1	2	3	4
High	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S —	Serious risk
H —	High risk
M —	Medium risk
L —	Low risk

Glossary of terms

Hazard: Source of danger involving the chance of being injured or harmed. A means of quantifying the hazard in a risk assessment is the severity of the possible injury or harm.

Product hazard: Hazard created by the properties of a product.

Risk: Balanced combination of a hazard and the probability that damage will occur. Risk describes neither the hazard, nor the probability, but both at the same time.

Risk assessment: Procedure for identifying and assessing hazards, consisting of three steps:

— identification of the seriousness of a hazard,

— determination of the probability that a consumer will be injured by that hazard,

— combination of the hazard with the probability.

Risk level: Degree of risk, which may be 'serious', 'high', 'medium' and 'low'. When the (highest) level of risk has been identified, the risk assessment is complete.

Risk management: Follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk.

6. *TASKS AND ROLE OF THE NATIONAL RAPEX CONTACT POINTS OF THE EFTA STATES*

Tasks and role of the national RAPEX contact points of EFTA States

The role and tasks of the national RAPEX contact points of the EFTA States are equivalent to the tasks and role of the national RAPEX contact points of the EU Member States.

Their role and tasks are outlined in Guidelines for RAPEX, Decision 2010/15/EU.

National validation tasks — EFTA States

The national validation process is the responsibility of the national RAPEX contact points of the EFTA States.

During the validation process the national RAPEX contact points of the EEA EFTA States shall notify the ESA RAPEX contact point that a notification or reaction is pending by sending an email to the ESA RAPEX contact point's functional mailbox: rapex@eftasurv.int. The EFTA Surveillance Authority, via the ESA RAPEX contact point, is the competent body to review notifications and reactions from the EFTA States pursuant to Articles 11(2)-12(2) of Directive 2001/95/EC, in accordance with the adaptations that follow from Protocol 1 to the EEA Agreement.

If no response nor proposal for amendment of a notification or reaction is received from the ESA RAPEX contact point within 24 hours, following an email notification submitted by the national RAPEX contact points of the EFTA States to the ESA RAPEX contact point thereof on a working day within working hours [1], the notification may be validated and sent to the European Commission via the GRAS RAPEX system, by the national RAPEX contact points of the EFTA States.

In cases of urgency, the national RAPEX contact points of the EFTA States shall make direct contact with the ESA RAPEX contact point as quickly as possible to ensure that it has no concerns or objections to the notification or reaction being uploaded onto the GRAS RAPEX system, prior to validation and sending to the European Commission.

The national RAPEX contact points of the EFTA States shall not under any circumstances validate and send a notification or reaction to the EC without having duly notified the ESA RAPEX contact point thereof, and checked that it has no concerns or objections regarding the notification or reaction.

[1] The term 'working days' is to be understood as Monday through Friday except for those days published in the *Official Journal of the European Union* as the Authority's public holidays, whereas the term 'working hours' is to be understood as the time between 0700 and 1630 GMT+1. If the notification is received by the ESA RAPEX contact point at a point in time which is not on a working day within working hours, for example on a public holiday, on a Saturday or Sunday, or on a Friday at 1700 GMT+1, the 24 hours response deadline for the ESA RAPEX contact point will start running from the next working hour of the next working day, following the actual receipt of the notification.

Additional commitments

Every effort will be made to ensure the smooth and efficient management of the RAPEX system by ESA and the EFTA States contact points.