

**Corrigendum to 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**

*(Official Journal of the European Union L 151 of 30 April 2004)*

Decision 2004/418/EC should read as follows:

**COMMISSION DECISION**

**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**

*(notified under document number C(2004) 1676)*

**(Text with EEA relevance)**

(2004/418/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety<sup>(1)</sup>, and in particular the third subparagraph of paragraph 1 of Article 11 thereof,

After consulting the Committee set up by Article 15 of Directive 2001/95/EC,

Whereas:

(1) Directive 2001/95/EC establishes a Community Rapid Information System (RAPEX) for the rapid exchange of information between the Member States and the Commission on measures and actions relating to products posing a serious risk to the health and safety of consumers.

(2) The RAPEX helps to prevent the supply to consumers of products which pose a serious risk to their health and safety, facilitates the monitoring of the effectiveness and consistency of market surveillance and enforcement activities in the Member States, and provides a basis for identifying needs for action at Community level.

(3) The notification procedure under Article 11 of Directive 2001/95/EC provides for an exchange of information between the Member States and the Commission on measures and actions relating to dangerous products which do not present a serious risk to the health and safety of consumers.

(4) The effective operation of the notification procedures under Directive 2001/95/EC by the Commission and the competent authorities of the Member States requires consistent implementation of the relevant provisions of that Directive, in particular of the concept of serious risk and of risks the effects of which do not, or cannot, go beyond the territory of one Member State but which can be of interest for all Member States.

(5) In order to facilitate the operation of RAPEX and of the Article 11 notification procedure, the guidelines should include a standard notification form and criteria for the classification of notifications according to the degree of urgency. The guidelines should also define the operating arrangements including deadlines for the various steps of the notification procedures.

(6) The guidelines should be addressed to the national authorities designated as contact points in the RAPEX and in charge of the notification procedure under Article 11 of Directive 2001/95/EC. The Commission should use the guidelines as the reference document for managing RAPEX and the Article 11 notification procedure,

HAS ADOPTED THIS DECISION:

*Article 1*

The Commission hereby adopts 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.

The guidelines are set out in the Annex to this Decision.

<sup>(1)</sup> OJ L 11, 15.1.2002, p. 4.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 29 April 2004.

*For the Commission*

David BYRNE

*Member of the Commission*

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## ANNEX

**GUIDELINES**

**for the management of the Community Rapid Information System (RAPEX) and for notifications presented pursuant to Article 11 of Directive 2001/95/EC**

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## 1. INTRODUCTION

### 1.1. Background and objectives of the guidelines

Directive 2001/95/EC <sup>(1)</sup> on general product safety (GPSD) establishes a Community Rapid Information System (RAPEX) for the rapid exchange of information between the Member States and the Commission on measures and actions in relation to consumer products posing a serious risk for the health and safety of consumers in so far as there are no specific provisions in Community law with the same objective.

Furthermore, the notification procedure in Article 11 of the GPSD is intended for exchange of information between the Member States and the Commission on measures and actions in relation to consumer products that do not present a serious risk to the health and safety of consumers.

These procedures are part of the provisions of the GPSD aimed at ensuring an effective and consistent enforcement of the applicable safety requirements.

The objectives of the RAPEX system are:

- (a) to provide a rapid exchange of information between Member States and the Commission about measures and actions taken in relation to consumer products because of a serious risk to the health and safety of consumers;
- (b) to inform Member States and the Commission about the existence of a serious risk even before measures are adopted or actions taken;
- (c) to obtain and circulate to all Member States information on the follow-up given to the information exchanged by the Member States receiving it;

with the aim of:

- (a) preventing the supply to consumers of products which pose a serious risk to their health and safety, and where necessary withdrawing them from the market or recalling them from consumers;
- (b) facilitating the monitoring of the effectiveness and consistency of market surveillance and enforcement activities in the Member States;
- (c) identifying the need and providing a basis for action at Community level, where necessary;
- (d) contributing to the consistent enforcement of Community product safety requirements and to the proper functioning of the internal market.

The notification mechanism of Article 11 of the GPSD also facilitates prevention of the supply to consumers of dangerous products (not presenting a serious risk) and monitoring of market surveillance activities in the Member States.

The GPSD provides for the 'establishment of non-binding guidelines aimed at indicating simple and clear criteria and practical rules, which may change in order to be completed, improved or adapted in the light of the experience and new developments, to facilitate the effective operation of RAPEX by the Commission and the competent authorities of the Member States <sup>(2)</sup>', in other words these guidelines are intended to facilitate the effective and consistent application of the provisions of the GPSD related to notification procedures.

The objectives of these guidelines are:

- (a) to clarify the scope of RAPEX from the operational point of view, by
  - setting a conceptual framework for the provisions of the Directive related to products posing serious risks and in particular criteria for applying the concept of 'serious risk',
  - giving guidance on the types of measures, action and situations that need to be notified,
  - providing guidance on how to notify the Commission of measures taken by producers or distributors on a voluntary basis, in agreement with the authorities or when required by these authorities,
  - providing criteria for identifying 'local events' (cases where the effects of the risk in question do not, or cannot, go beyond the territory of one Member State) that could be of interest for all Member States, in which case they would have to be notified,
  - setting criteria for notifying information on dangerous products to the Commission before a Member State decides to adopt measures or take actions,
  - identifying the products covered by a specific equivalent exchange of information systems, therefore excluded from the scope of RAPEX,
  - classifying and indexing notifications according to the degree of urgency;

<sup>(1)</sup> OJ L 11, 15.1.2002, p. 4.

<sup>(2)</sup> In the context of this document the term 'Member States' means all States which belong to the European Union and also those States which are parties to the EEA Agreement.

- (b) to define the contents of the notifications, in particular the information and data required, and the forms to be used for the RAPEX system;
- (c) to define the follow-up action to be taken by the Member States receiving a notification and the information to be provided on such follow-up;
- (d) to describe the treatment of the notifications and of the follow-up information by the Commission;
- (e) to set the deadlines for the various steps of the RAPEX processes;
- (f) to define and document the practical arrangements at Commission and Member States level for the operation of RAPEX and all the relevant technical details.

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

#### 1.2. *Status and further developments of the guidelines*

##### Status:

These are operational guidelines. These guidelines are adopted by the Commission, after consultation of the Member States within the GPSD Committee acting in accordance with the advisory procedure.

They therefore represent the reference document for the application of the provisions of the GPSD concerning RAPEX as well as for notifications presented according to Article 11 of the GPSD.

##### Further developments:

These guidelines will need to be adapted in the light of experience and of new developments. The Commission will update or amend them as necessary in consultation with the Committee referred to in Article 15 GPSD.

#### 1.3. *To whom are the guidelines addressed*

These guidelines are addressed to the Member States' national authorities designated to participate in the RAPEX network as contact points and in charge of the notification procedure under Article 11 of the Directive. The Commission will use these guidelines as the reference document for managing RAPEX and the notification procedure under Article 11 of the Directive.

## 2. **GENERAL SCOPE OF RAPEX**

#### 2.1. *Definition of the products covered by the GPSD and criteria for applying this definition for the aims of RAPEX*

The provisions of the GPSD, and in particular the RAPEX procedure, apply to consumer products that pose a serious risk to consumers in so far as there are no specific provisions in Community law with the same objective. Examples of products covered by RAPEX are toys, domestic electrical appliances, lighters, childcare articles, cars and tyres, etc.

The products covered by the GPSD are defined in its Article 2(a):

“product’ shall mean any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.’

The following elements are particularly relevant:

- products must be intended for and supplied or made available to consumers, or
- likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for consumers. Products ‘migrating’ from professional use to the consumer market should also be covered. In other words, products that had been originally developed for professional use and allowed on the market as intended for professionals, which have subsequently also been marketed to consumers,

- products provided in the context of a service: the GPSD also covers products supplied or made available to consumers in the course of a service provided to them. Consumer products are often made available in connection with certain services (for example renting of machines). The equipment used by the service provider to supply a service is beyond the scope of the GPSD, in particular, equipment on which consumers ride or travel operated by a service provider.

## 2.2. *Products excluded from RAPEX because covered by specific and equivalent requirements for the rapid exchange of information*

The following products are excluded from RAPEX because they are covered by equivalent notification mechanisms established by Community legislation:

- pharmaceuticals covered by Directives 75/319/EEC <sup>(1)</sup> and 81/851/EEC <sup>(2)</sup>,
- active implantable medical devices covered by Directive 90/385/EEC <sup>(3)</sup>, medical devices covered by Directive 93/42/EEC <sup>(4)</sup>, and in vitro diagnostic medical devices covered by Directive 98/79/EC <sup>(5)</sup>,
- food and feed covered by Regulation (EC) No 178/2002 <sup>(6)</sup>.

Further information on the relationship between the different notification procedures established by Community law can be found in chapter 9.1 and in the separate 'Guidance Document on the Relationship between the GPSD and Certain Sector Directives' <sup>(7)</sup>.

## 2.3. *Measures, decisions and actions to be notified under RAPEX*

An indicative list of the different types of measures and actions of the competent authorities of the Member States that should be notified under RAPEX, can be found in Article 8 GPSD. These measures and actions are aimed at:

- imposing conditions prior to the marketing of a product,
- requiring that a product be marked with warnings concerning any risks,
- alerting consumers about a risk related to a product,
- banning temporarily or definitively the supply, the offer to supply or the display of a product,
- organising the withdrawal or the recall of a product,
- ordering producers and distributors to withdraw a product, recall it from consumers, and destroy it.

Other measures and actions that authorities can adopt or take and should notify are:

- agreements with producers and distributors to take actions necessary to avoid the risks posed by products,
- agreements with producers and distributors to organise jointly the withdrawal, the recall of products from consumers and their destruction or any other relevant action,
- agreements with producers and distributors to coordinate the recall of a product from consumers and its destruction.

Member States should notify all such measures even if an appeal against them is likely or they are under appeal at national level or subject to publication requirements. Member States should indicate in the notification whether the measure is of a definitive nature (because it has not been contested by the manufacturer or importer, or because it has been finally confirmed) or if it is still likely to be, or is currently, under appeal. In any case, any subsequent change in the status of the measure should be communicated to the Commission.

<sup>(1)</sup> OJ L 147, 9.6.1975, p. 13. Directive as last amended by Directive 2000/38/EC (OJ L 139, 10.6.2000, p. 28).

<sup>(2)</sup> OJ L 317, 6.11.1981, p. 1. Directive as last amended by Directive 2000/37/EC (OJ L 139, 10.6.2000, p. 25).

<sup>(3)</sup> OJ L 189, 20.7.1990, p.17.

<sup>(4)</sup> OJ L 169, 12.7.1993, p.1; Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>(5)</sup> OJ L 331, 7.12.1998, p.1; Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>(6)</sup> OJ L 031, 01.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

<sup>(7)</sup> [http://europa.eu.int/comm/consumers/cons\\_safe/prod\\_safe/gpsd/revisedGPSD\\_en.htm](http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm)

Under Article 5 producers and distributors are obliged to inform the national authorities of voluntary actions or measures taken to prevent risk to the consumer. The authorities must notify these voluntary measures to the Commission when the product poses a serious risk (see chapter 4.3).

#### 2.4. *Other information on serious risks that may be exchanged under RAPEX*

Member States may inform the Commission of:

- any information regarding the existence of a serious risk at the stage before deciding to adopt measures or to take action (Article 12.1, third subparagraph). In such cases RAPEX contact points should also inform the Commission about the final decision,
- measures on a specific production batch which has been withdrawn from the market by a Member State due a serious risk and when all items in this batch have been withdrawn from the market by the Member State,
- customs authority decisions to block or to reject products at the EU borders if the consumer product blocked or rejected presents a serious risk. Contact points should circulate this information to their customs authorities (see details in chapter 8.3).

The Commission may receive information relating to products that present a serious risk to the health of the consumer from Third Countries or through equivalent information systems established by other organisations including non-EU countries. The Commission will evaluate the information and may transmit it to the Member States.

These types of additional information on serious risks that may be exchanged under RAPEX do not require a formal reaction from the rest of Member States and the use of a standard form is not required.

#### 2.5. *Criteria for notifying measures related to risks not going beyond the territory of a Member State*

Measures and actions related to risks where the effects do not or cannot go beyond the territory of a Member State are excluded from the scope of RAPEX.

However, in certain cases such measures and actions are likely to interest the enforcement authorities of the other Member States. In order to assess whether a measure dealing with a risk of local effect involves information on product safety likely to be of interest for the other Member States, the authority should take into account for example whether the measure is taken in response to a new type of risk which has not yet been reported in other notifications, or whether it is related to a new risk arising from a combination of products or whether it is a new type or category of product that is dangerous.

Measures related to second-hand products sold by private individuals and custom-made products that present a serious risk are excluded from the scope of RAPEX if the Member State which took the measure can conclude from the existing information that the product could not be found in another Member State.

Taking into account the free circulation of products at European level, the openness of the European economy and the fact that consumers buy products not only in their home market but also during holidays abroad or by Internet, contact points are encouraged to report actions taken when there is uncertainty whether the risk could be relevant or of interest for another Member States.

### 3. **CRITERIA FOR IDENTIFYING SERIOUS RISKS**

#### 3.1. *Definition of serious risk in the GPSD and objectives of the guidance on serious risks*

Serious risk is defined in Article 2(d) of the GPSD as follows: 'serious risk shall mean any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities'.

This definition of serious risk is characterised by two key elements. First, it includes all types of serious risk to consumers created by a product (immediate threats as well as possible long-term risks); second, the risks considered are those requiring a rapid intervention.

The following subchapters give general guidance to assist the authorities in assessing the level of seriousness of the risk and deciding whether a rapid intervention is necessary. The objective is to help the authorities in identifying the cases to which the concept of serious risk under the GPSD applies. The guidelines in this chapter are not exhaustive and do not try take account of all possible factors. The national authorities should judge each individual case on its merits taking into account the criteria set out in these guidelines as well as their own experience and practice, other relevant considerations and appropriate methods.



### 3.2. Criteria on the level of gravity of risks

A consumer product may present one or more intrinsic hazard. The hazard may be of various types (chemical, mechanical, electrical, heat, radiation etc.). The hazard represents the intrinsic potential of the product to damage the health and safety of users under certain conditions.

The severity of each type of hazard may be given a rating, based on qualitative and sometimes quantitative criteria related to the type of damage that they are liable to produce.

It may happen that not all individual products present the hazard in question, but only some of the items placed on the market. The hazard may in particular be related to a defect that appears only in some of the products of a certain type (brand, model...) placed on the market. In such cases the probability of the defect/hazard being present in the product should be considered.

The potential of a hazard to materialise as an actual negative effect on the health/safety will depend on the degree to which the consumer is exposed to it when using the product as intended or as could reasonably be expected during its lifetime. In addition the exposure to certain hazards may in some cases involve more than one person at a time. Finally when determining the level of the risk presented by a product by combining the severity of the hazard with the exposure, consideration should be given also to the ability of the exposed consumer to prevent or react to the hazardous situation. This will depend on the evidence of the hazard, the warnings given and the vulnerability of the consumer who may be exposed.

Taking into account the above considerations, the following conceptual approach may assist enforcement officers to decide whether a specific hazardous situation caused by a consumer product constitutes a serious risk under the GPSD.

The officer should:

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

Table B indicates the gravity of the outcome from Table A for which a serious risk situation exists and for which rapid action is to be adopted by the enforcement authorities.

Table A:

#### **Risk estimation: severity and probability of health/safety damage**

In Table A the two main factors affecting the risk estimation, namely the severity and the probability of health/safety damage, are combined. The following definitions of severity and probability have been drawn up to assist the selection of appropriate values.

#### *Severity*

The assessment of severity is based on consideration of the potential health/safety consequences of the hazards presented by the product considered. A grading should be established specifically for each type of hazard <sup>(1)</sup>.

<sup>(1)</sup> As an example, for certain mechanical risks the following definitions of the severity classifications may be proposed, with their typical injuries:

| Slight   | Serious   | Very Serious                             |
|--|---|--|
| <2 % incapacity<br>usually reversible and not requiring<br>hospital treatment. | 2 – 15 % incapacity<br>usually irreversible requiring hospital<br>treatment | >15 % incapacity<br>usually irreversible |
| Minor cuts   | Serious cuts  | Serious injury to internal organs        |
| Minor fractures  | Loss of finger or toe   | Loss of limbs                            |
|  | Damage to sight   | Loss of sight                            |
|  | Damage to hearing   | Loss of hearing                          |

The assessment of severity should also take into account the number of people who could be affected by a dangerous product. This means that the risk from a product which could pose a risk to more than one person at a time (e.g. fire or gas poisoning from a gas appliance) should be classified as more severe than a hazard which can only affect one person.

The initial risk estimation should refer to the risk to any person exposed to the product and should not be influenced by the size of the population at risk. However, it may be legitimate for the authorities to take account of the total number of people exposed to a product in deciding on the action to be taken.

For many hazards it is possible to envisage unlikely circumstances which could lead to very serious effects, e.g. tripping over cable, falling and banging head leading to death, although a less serious outcome is more likely. The assessment of the severity of the hazard should be based on reasonable evidence that the effects selected for characterizing the hazard could occur during foreseeable use. This could be worst case experience involving similar products.

#### *Overall probability*

This refers to the probability of negative health/safety effects to a person exposed to the hazard. It does not take into account the total number of people at risk. Where the guide refers to the probability of a product being defective, this should not be applied if it is possible to identify each one of the defective samples. In this situation, the users of the defective products are exposed to the full risk and the users of the other products to no risk.

The overall probability is the combination of all the contributing probabilities such as:

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

These two probabilities are combined in the following table to give an overall probability which is entered into table A.

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

Combining the severity and overall probability in Table A gives an estimation of the gravity of the risk. The accuracy of this assessment will depend upon the quality of the information available to the enforcement officer. However, this assessment needs to be modified to take account of the society's perception of the acceptability of the risk. Society accepts much higher risks in some circumstances such as motoring, than in others, such as children's toys. Table B is used to input this factor.

*Table B*

#### **Grading of risk: type of person, knowledge of the risk and precautions**

Society accepts higher risks in some circumstances than in others. It is considered that the main factors affecting the level of risk that is considered to be serious are the vulnerability of the type of person affected and for normal adults, the knowledge of the risk and the possibility of taking precautions against it.

*Vulnerable people*

The type of person using a product should be taken into account. If the product is likely to be used by vulnerable people, the level of risk which is serious should be set at a lower level. Two categories of vulnerable people are proposed below, with examples:

| Very vulnerable     | Vulnerable         |
|---------------------|--------------------|
| Blind               | Partially sighted  |
| Severely disabled   | Partially disabled |
| Very old            | Elderly            |
| Very young (<3 yrs) | Young (3 – 11 yrs) |

*Normal adults*

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

Table B — Grading of Risk

| Severity of Health/Safety Damage    |           | Vulnerable people |                                      | Normal adults |                            |     |     | Adequate warnings and safeguards? |     |
|-------------------------------------|-----------|-------------------|--------------------------------------|---------------|----------------------------|-----|-----|-----------------------------------|-----|
| Slight                              | Serious   | Very Serious      | Very vulnerable                      | Vulnerable    | No                         | Yes | No  | Yes                               | Yes |
| Probability of Health/Safety Damage | Very High | High              | SERIOUS RISK – RAPID ACTION REQUIRED |               | No                         | No  | Yes | Yes                               |     |
|                                     | High      | Medium            |                                      |               | No                         | No  | Yes | Yes                               |     |
|                                     | Medium    | Low               | Moderate risk Some action required   |               | Low risk — Action unlikely |     |     |                                   |     |
|                                     | Low       | Very Low          |                                      |               |                            |     |     |                                   |     |
|                                     | Very Low  |                   |                                      |               |                            |     |     |                                   |     |

Table A — Risk Estimation

| Severity of Health/Safety Damage    |           | Vulnerable people |                                      | Normal adults |                            |     |     | Adequate warnings and safeguards? |     |
|-------------------------------------|-----------|-------------------|--------------------------------------|---------------|----------------------------|-----|-----|-----------------------------------|-----|
| Slight                              | Serious   | Very Serious      | Very vulnerable                      | Vulnerable    | No                         | Yes | No  | Yes                               | Yes |
| Probability of Health/Safety Damage | Very High | High              | SERIOUS RISK – RAPID ACTION REQUIRED |               | No                         | No  | Yes | Yes                               |     |
|                                     | High      | Medium            |                                      |               | No                         | No  | Yes | Yes                               |     |
|                                     | Medium    | Low               | Moderate risk Some action required   |               | Low risk — Action unlikely |     |     |                                   |     |
|                                     | Low       | Very Low          |                                      |               |                            |     |     |                                   |     |
|                                     | Very Low  |                   |                                      |               |                            |     |     |                                   |     |

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

Table B is used to determine the rating of the gravity of risk depending on the type of user and, for normal adults, whether the product has adequate warnings and safeguards and whether the hazard is sufficiently obvious, and to decide whether a serious risk situation exists and rapid action is required

**Example (indicated by the arrows above)**  
A chain saw user has suffered a badly cut hand and it is found that the chain saw has an inadequately designed guard which allowed the user's hand to slip forward and touch the chain. The enforcement officer makes the following risk assessment.

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

Table B — The chain saw is for use by normal adults, has an obvious hazard but inadequate guards, so the risk rating would be Moderate.

The High gravity is therefore intolerable so a serious risk situation exists and rapid action is required.

#### 4. CONTENTS OF RAPEX NOTIFICATIONS

##### 4.1 *Information to be entered on the notification form*

Information should be as complete as possible: contact points should fill in all the fields in the notification form (Annex I of the Guidelines). If information is not available, this should be indicated and explained. A timetable for providing the missing information should be transmitted.

Responsibility for the information provided lies with the notifying Member State (GPSD Annex II.10).

In order to be useful to the authorities of the other Member States in their market surveillance activities, the notification must include all the data needed to identify the dangerous product, trace its origin, identify the marketing and distribution channels, determine the related risks, etc.

Confidentiality could be requested if disclosure of the information would undermine the protection of court proceedings, monitoring and investigation activities or professional secrecy, unless there were an overriding public interest in disclosure of the information to protect the health and safety of consumers.

The notifying Member State could also require confidentiality for annexes to the notification, such as legal proceedings, that do not contain information relevant for consumer protection and need to be protected.

According to the GPSD, the public must have access to information relating to the safety properties of products, the nature of the risk, product identification and the measure taken.

Contact points should pay special attention to checking that the following items of essential information appear in the notification:

- a detailed description of the product (including if possible the customs code of the product) together with a photograph in order to facilitate its identification by enforcement authorities. The identification and description of the product should be accurate in order to avoid any confusion with similar products in the same category that are safe,
- the risk assessment including, in particular, results of tests carried out by the authority,
- the scope and the nature of the measure taken in order to avoid the risk, its duration and the follow-up. The notifying Member State should inform the Commission of any amendment to the measure taken and of the final decision taken on the product in question. The Member State should indicate in the notification whether the measure has a definitive character (i.e. it has not been contested by the manufacturer or importer, or has been confirmed by an instance that does not admit appeal) or could be, or is currently, subject to appeal. In any case, any change in the status of the measure should be communicated to the Commission,
- the information needed to identify the product's distribution channels and its origin, in particular its producer, importer or exporter, as well as other information related to its traceability.

In the case of products imported from Third Countries, and in order to facilitate investigation by the authorities of the Third Country of origin of the product, the following documents and information should also be communicated (if available): copies of Sales Contract, Letter of Credit, date and port of export and batch number of the products.

##### 4.2 *Information to provide in relation to measures concerning use of chemicals*

When the measure notified pursuant to Article 11 or Article 12 seeks to limit the marketing or use of a chemical substance or preparation, the Member States must provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available.

They will also communicate the anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93 <sup>(1)</sup> in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC <sup>(2)</sup> in the case of a new substance.

<sup>(1)</sup> OJ L 84, 5.4.1993, p. 1.

<sup>(2)</sup> OJ 196, 16.8.1967, p. 1/67. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

#### 4.3 Notification of the voluntary measures taken by producers and distributors

Article 5(3) of the GPSD obliges producers and distributors to inform the national authorities of any voluntary action or measure taken to prevent risk to the consumer.

Article 12(1) fourth subparagraph requires Member States to notify the Commission of the voluntary measures taken by producers and distributors in the case of a serious risk.

When the authorities receive information from producers and distributors concerning a risk and the voluntary actions taken to avoid it, they should examine this information in order to assess whether a notification to the Commission is justified due to the involvement of a serious risk, taking into account the criteria outlined in chapter 3.

Such notification at Community level is required in the case of a serious risk the effects of which can go beyond the territory of a Member State (taking into account the criteria for notifying local events: see chapter 2.5).

The information transmitted to the Commission should include details of the voluntary action taken by the producers or distributors. All relevant information on the risk should also be notified. In particular:

- information to identify and trace the product or batch of products,
- description of the risk,
- identification of the producers and distributors participating in the application of the measure,
- description of the action taken by producers and distributors to avoid risks to consumers (scope, countries covered, monitoring),
- final destination of the dangerous product (destruction, recondition),
- follow-up actions that national authorities would take in order to monitor the effectiveness of the voluntary measures taken by producers and distributors,
- actions provided for in other Member States by the producers or distributors.

## 5. DEADLINES FOR SUBMISSION AND CIRCULATION OF RAPEX NOTIFICATIONS

### 5.1. Deadlines for submitting notifications to the Commission by the Member States

National contact points are required to notify the Commission as soon as possible and at the latest 10 days <sup>(1)</sup> after the competent authorities have taken the decision or have decided to adopt measures <sup>(2)</sup> relating to products presenting a serious risk.

Measures or action taken in agreement between authorities and producers and/or distributors should be notified to the Commission as soon as possible and at the latest 10 days after the agreement has been concluded.

Contact points are required to transmit information to the Commission on voluntary measures taken by producers and distributors which have been notified to the authorities by reason of a serious risk and which go beyond the territory of a Member State. This should be done as soon as possible and at the latest 10 days after the producer and/or distributor have informed the national authority.

In the case of notifications requiring emergency action from Member States (as defined in Chapter 7.1), the notifying national contact point is required to inform the Commission as soon as possible and at the latest three days after the measure has been adopted. This type of notification should always be preceded by a phone call to the Commission RAPEX mobile phone number (in particular during week-ends and holiday periods).

Information on serious risks to be exchanged under RAPEX as described in point 2.4 is to be transmitted to the Commission as soon as possible and at the latest 10 days after the contact point was informed.

National contact points are required to notify the Commission as soon as possible and at the latest 15 days after the competent authorities have taken the decision or have decided to adopt measures restricting the marketing or use of products by reason of a risk that is not serious.

<sup>(1)</sup> All deadlines mentioned in the text are expressed in calendar days.

<sup>(2)</sup> The measures, decisions and actions to be notified under RAPEX are described in point 2.3 of these guidelines.

These deadlines apply to the exchange of information between national contact points and the Commission. They do not take into account national deadlines applicable internally in the Member States (for instance between local and central authorities). Appropriate arrangements should be put in place at national level in order to ensure rapid transmission of the information between the different national authorities in charge of product safety.

These deadlines apply irrespective of any appeal procedure entered into by the producer or distributor or official publication requirements.

#### *5.2. Commission deadlines for the transmission of notifications to all the Member States*

The Commission will transmit the notification to the contact points only if the notifying Member State has provided the essential information described in chapter 4.1. Any follow-up by other Member States would not be feasible if such essential information were missing.

The Commission will treat the information received in accordance with the following degrees of urgency:

- notifications requiring emergency action from Member States will be treated as priority by the Commission and transmitted to Member States as soon as possible and at the latest three days after reception,
- alert notifications (Article 12 of the GPSD) will be transmitted to Member States within five days of reception. This category includes measures or action taken by authorities, agreements for action between authorities and producers and distributors, and voluntary measures taken by producers and distributors relating to products that present a serious risk,
- other information on serious risks to be exchanged under RAPEX will be transmitted within five days of reception,
- notifications presented in accordance with Article 11 of the GPSD will be sent by the Commission within 15 days of reception. These notifications relate to measures taken by the authorities which restrict the placing on the market or require the withdrawal or recall of products that do not create a serious risk.

#### *5.3. Deadlines for updating the information provided by the Member States*

Member States are required to notify the Commission of any modification or lifting of measures or actions at the latest five days after the competent authorities have taken the decision to modify or lift the measure.

Member States may provide information to the Commission at the stage preceding the decision on the measures to be taken, as provided for in GPSD Article 12(1) third subparagraph. The Member State will confirm or modify this information within 45 days of the first communication (GPSD Annex II.4).

## **6. FOLLOW-UP TO THE RAPEX NOTIFICATIONS**

#### *6.1. Action by the Member States to follow up the notifications*

Upon receipt of a notification Member States are required to examine all the information supplied in order to:

- find out whether the product has been marketed in their territory,
- enquire in order to collect any relevant information,
- perform any additional assessment of the risk (if needed),
- evaluate whether national measures should be adopted in the light of their own circumstances.

#### *6.2. Contents of the reaction to be communicated to the Commission*

Only notifications requiring emergency action from Member States and Alert notifications (Article 12) require a reaction from the Member States informing the Commission of their follow-up activities and conclusions. On the other hand, notifications presented according Article 11 and as 'Other information on serious risks that may be exchanged under RAPEX' do not require Member States to inform the Commission of the follow-up given to the information received.

After receiving a notification requiring emergency action from Member States or an Alert notification (Article 12) all Member States are required to inform the Commission, using the Reaction form in Annex II, of the conclusions of their market surveillance activities and in particular:

- whether or not the product has been found,
- any differing assessment of the risk notified,
- the measures taken or decided on and the reasons justifying a different measure,
- the special circumstances justifying lack of action or follow-up.

If the product is manufactured in the EU and the notifying Member State is not the country of origin of the product, the authorities of the Member State where the product is manufactured should inform the Commission about:

- any contacts with the manufacturer,
- the measures adopted to ensure that the manufacturer solves the problem at source, where appropriate,
- the distributors or retailers of the product in other Member States.

If the product is not manufactured in the EU and the notifying Member State is not the country where the product was first marketed in the EU, the authorities of this country should inform the Commission about:

- any contacts with the manufacturer's representative or with the importer of the product,
- the measures adopted by the manufacturer's representative or by the importer to ensure that the problem is solved at source,
- the distributors or clients of the product in other Member States.

#### *6.3. Circulation by the Commission to the Member States of the reactions received*

The Commission will circulate as a priority case-by-case reactions:

- to notifications requiring emergency follow-up from Member States,
- containing a different assessment of the risk,
- containing a different measure to deal with the risk.

The Commission will circulate in the form of weekly reports reactions received after the deadlines and reactions informing it:

- that the product has been found and similar actions taken,
- of a lack of action or of follow-up by Member States,
- that the product has not been found on the national market.

#### *6.4. Deadlines for submitting reactions to the Commission by the Member States*

Adequate follow-up by the Commission will not be possible if Member States do not fulfil their obligation to react to the notifications received.

Member States are required to react:

- as soon as possible and in any case not later than 20 days if the reaction relates to a notification requiring emergency action from Member States,
- as soon as possible and in any case not later than 45 days in the case of alert notifications on measures taken by authorities, actions agreed between authorities and producers and distributors, or voluntary actions notified at Community level concerning products presenting a serious risk.

If the product is manufactured in the EU and the notifying Member State is not the country of origin of the product, the authorities of the Member State where the product is manufactured should react to the notification within 15 days, providing information about the contacts with the manufacturer and the measures adopted to ensure that the manufacturer will solve the problem at source. The same deadline is applicable to the Member State where the manufacturer's representative or the importer of the product is established in cases where the product is not manufactured in the EU and the notifying Member State is not the country where the product was first marketed in the EU.



A reminder will be sent to the Member States that have not reacted to the notifications after 45 days from the date when the notification was sent. The GPSD Committee will also be informed about any missing reactions.

The Commission will circulate the reactions as follows:

- as soon as possible and in any case not later than three days if the reaction relates to a notification requiring emergency follow-up from Member States,
- as soon as possible and in any case not later than five days for other reactions to notifications on national measures, agreements between authorities and producers, or voluntary actions.

## 7. EXAMINATION BY THE COMMISSION OF NOTIFICATIONS

### 7.1. *Examination of the completeness and correctness of the notifications*

The Commission contact point checks all information received through the system before further transmission. The examination of the notifications by the Commission does not imply any assumption of responsibility for the information transmitted which remains with the notifying Member State.

Specific internal arrangements have been put in place in order to circulate information to the Commission services concerned.

The examination includes the following steps to check and complete the information, if necessary:

#### **Completeness check**

If the information is incomplete, additional details are requested from the contact point of origin.

If the product is manufactured in the EU and the notifying Member State is not the country of origin of the product and has not obtained the essential information for the notification, the Commission will contact the authorities of the Member State where the product is manufactured in order to complete the information on the distribution channels and destinations of the product. The authorities of the Member State of origin will be requested to obtain this information by contacting the producer or distributors.

If the product is not manufactured in the EU and the notifying Member State is not the country where the product was first marketed in the EU and has not obtained the essential information of the notification, the Commission will contact the authorities of the Member State where the product was first marketed in order to obtain information on the possible distribution of the product to other Member States.

To check the notifications received, the Commission will:

- verify in general whether the information received is in conformity with EU legislation and with the provisions applicable to the functioning of RAPEX as defined in these guidelines,
- contact the notifying country, if necessary, in order to obtain extra information.

#### **Classification**

Notifications will be classified according to the degree of urgency (GPSD Annex II. 11) in:

- (a) notifications requiring emergency action from Member States (serious risk, foreseeable need for measures to be agreed at Community level and/or likely political visibility of the issue and/or mass-media coverage);
- (b) alert notifications (Article 12 of the GPSD); measures or actions taken on products presenting a serious risk;
- (c) notifications under Article 11 of the GPSD; measures or actions taken by the competent authorities on products not posing a serious risk;
- (d) for Information Only: information on serious risks to be exchanged under RAPEX as described in chapter 2.4.

#### **Consultations**

When the product notified falls under the scope of specific sector legislation, the Commission contact point will ask for expert advice from other Commission services, if necessary. The Commission may, whenever it considers it to be necessary, carry out an investigation on its own initiative or ask for scientific advice.

### Database research

The Member States and the Commission should avoid any unnecessary duplication of notifications by checking previous notifications in the available database used by national authorities or by the Commission.

#### *7.2. Examination in relation to the scope of RAPEX*

The Commission will check whether the product notified is a consumer product falling under the scope of the GPSD as far as RAPEX provisions are concerned and whether it is covered by equivalent alert system.

The Commission will also verify that the notification complies with the GPSD and with the provisions applicable to the functioning of RAPEX.

The Commission will not make a risk assessment of the product. Therefore, Member States should include in all notifications a complete summary of their risk evaluation and the results of any tests or analyses carried out to assess the level of risk.

In the first instance, the Commission will base its conclusions on the classification of the notification on the information provided by the notifying Member State.

After examination the Commission will forward the notification to the other Member States or ask for clarification or additional information from the notifying Member State.

#### *7.3. Examination of the follow-up reactions*

On the basis of the examination of the information obtained from the notifications and reactions, the Commission will decide on the appropriate action, such as to:

- convene the GPSD Committee to discuss the information received and the results obtained and to evaluate the measures taken or to adopt,
- request an independent risk assessment,
- institute an investigation in cooperation with Member States,
- consult a Commission Scientific Committee,
- mandate the standardisation bodies to draft new standards or amend existing ones if clear and consistent safety specifications are not available for a category of products,
- inform Third countries,
- prepare proposals for new or modified legislation,
- launch the procedure for a Commission Decision based on Article 13 of the GPSD in urgent cases.

15 days after the date on which the reaction period has expired (45 days after the notification was sent), the Commission will send the national contact points a report with:

- the final conclusion on the notification taking into account the information received as reactions from Member States. If no further follow-up is required the file will be closed. If new developments concerning the notification occur later, the Commission will reopen the file,
- the follow-up actions to be taken by the Member States if any reactions are still outstanding or if there are different national approaches.

The GPSD Committee will be periodically informed of all the notifications received and of the follow-up.

## 8. NETWORK FOR THE EXCHANGES UNDER RAPEX

### *8.1 Setting up of two-way internal networks by the Member States to collect and to distribute the relevant information*

Member States should ensure that there are systems at national level so that their national, regional or local authorities are aware of their responsibilities and of the action they should take to inform other services if a problem comes to light in their area.

Member States should establish a two-level internal structure consisting of:

- a single contact point with the Commission. This contact point will send the Commission and receive from the Commission all information exchanged through RAPEX, and
- a national network involving all the authorities responsible for product safety. These authorities send to and receive from the contact point the notifications and reactions. The composition of the network should be communicated to the Commission.

8.2. *Designation of the authorities in charge of notifying the Commission and to whom the Commission communicates notifications*

The main tasks of the national contact points are:

(a) before sending a notification to the Commission

- to verify the information received from the national, regional or local authorities in order to decide whether use of the RAPEX system is required (based on the Directive, the guidelines and previous experience),
- to check if the product has already been notified or information related to it exchanged in order to avoid any unnecessary duplication,
- to check that the notification form and the information are complete,
- to classify the information into one of the predefined categories of notifications.

(b) after receiving information from the Commission

- to transmit the information to the national, regional or local authorities responsible for product safety at the various different levels,
- to ensure follow-up of the information,
- to inform the Commission of their conclusions.

National contact points should also:

- help explain the obligations and requirements created by Community and national legislation for producers and distributors concerning the notification of dangerous products,
- assist in the creation of a network culture among the different national authorities at the various different levels,
- assist these authorities in the use of RAPEX,
- ensure that the internal procedures for information exchange work properly.

8.3. *Setting up of cooperation arrangements between the competent authorities, in particular with customs.*

Customs officials' decisions to block or to reject products at the EU borders for safety reasons are also of interest to market surveillance authorities and the Commission. The legal basis for such decisions is Council Regulation (EEC) No 339/93 of 8 February 1993 <sup>(1)</sup> on checks for conformity with the rules on product safety in the case of products imported from Third countries and Commission Decision 93/583/EEC of 28 July 1993 <sup>(2)</sup> drawing up a priority and non-exhaustive list of products as provided for in Article 8 of Regulation 339/93/EEC.

Contact points should inform the Commission about these decisions. This information is only pertinent if the consumer product blocked or rejected presents a serious risk. The Commission will transmit the information to the contact points and they should circulate this information to customs officials in their country in order to prevent the entry of these products within the European market.

The reasons for prohibiting entry into the EU should be mentioned in the documents accompanying the dangerous products.

Contact points should also inform their customs authorities of the measures and actions taken by market surveillance authorities relating to imported products presenting a serious risk in order to avoid further imports of the same product into the EU market.

<sup>(1)</sup> OJ L 40, 17.2.1993, p. 1; Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

<sup>(2)</sup> OJ L 279, 12.11.1993 p. 39.

#### 8.4 Means of communication, practical and technical arrangements applicable

##### Languages

The contact points in the Member States may issue the notification in their national language and/or in English. The notifications will be translated into English, French, German, Italian and Spanish by the Commission.

##### Transmission via Internet

The RAPEX system uses an Internet-based software application as a communication tool between the contact points linked to a database containing all the information from the notifications and reactions. This system, which is accessible via <https://reis.cec.eu.int/reis>, includes all the forms and a User's Guide.

If there are technical problems with this site, contact points may send notifications and reactions by e-mail (mail box: [Sanco-Reis@cec.eu.int](mailto:Sanco-Reis@cec.eu.int)) or by fax if (and only if) e-mail transmission is not possible (+32-2 29 64 323).

##### Out-of-hours service and permanent staffing during periods of closure

As emergencies may arise out of working hours, Member States should ensure that their national, regional or local authorities can be contacted in urgent cases such as for notifications requiring emergency action by Member States.

Changes at national contact point level are to be communicated immediately to the Commission, which will forward them to the other Member States.

The Commission will ensure the proper functioning of the RAPEX system during weekends, periods of closure and holidays.

##### Weekends

The contact points can reach the officials in charge of RAPEX operations by telephone (mobile phone) in case of an emergency. This will allow rapid organisation of an early warning.

##### Longer periods of closure

It should be noted that the Commission contact point ensures holiday coverage by using a mobile phone and a laptop computer that can be linked into the system via the Internet. In emergencies, before sending the notification to the Commission, national contact points should contact the Commission official in charge of the permanent staffing, using a mobile phone number which will be communicated to contact points before the holiday period starts.

Contact points are also requested to provide similar coverage during weekends, short periods of closure and holiday periods. A list of emergency phone numbers, e-mails and faxes for the RAPEX contact points is established by the Commission to ensure that RAPEX members can be reached without delay. Any subsequent change should be communicated to the Commission.

## 9. COORDINATION BETWEEN RAPEX AND OTHER NOTIFICATION MECHANISMS

### 9.1. Cases in which a measure notified under RAPEX must also be notified under another mechanism

Whenever a measure with binding legal effects relates to consumer products covered by specific community legislation such as toys, electrical appliances, etc., it should also be considered under the sector specific notification mechanism applicable (safeguard clause). The RAPEX system and the sector specific safeguard clauses involve separate legal obligations to notify because they serve different purposes.

For further information on the relationship between the notification procedures and their purposes, please see the separate 'Guidance Document on the Relationship between the GPSD and Certain Sector Directives (1)'.

(1) [http://europa.eu.int/comm/consumers/cons\\_safe/prod\\_safe/gpsd/revisedGPSD\\_en.htm](http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm)

## 9.2. *Arrangements for simplifying the submission of notifications due under different mechanisms*

When products are covered by other Community legislation with a notification procedure for national measures (safeguard clause), the Commission will, through its internal procedures, ensure that a single notification from national authorities fulfils the different obligations to inform the Commission under Community legislation.

A common notification form covering both the safeguard clause of Directive 88/378/EEC on Safety of Toys <sup>(1)</sup> and RAPEX is given in Annex III.

## 10. NOTIFICATIONS UNDER ARTICLE 11 OF THE GPSD

### 10.1 *Scope of these notifications*

The procedure in Article 11 of the GPSD covers the exchange of information between the Member States and the Commission for consumer products (as described in chapter 2.1) that do not present a serious risk to the health and safety of consumers (taking into account the criteria on serious risk outlined in chapter 3).

Measures that Member States adopt, such as those described in chapter 2.3, which restrict the placing on the market of products that do not pose a serious risk, have to be notified to the Commission specifying the reasons for adopting them.

The notifying Member State should inform the Commission of any amendment to the measure taken and of the final decision taken on the product in question.

If the Member State considers that the effects of the risk do not, or cannot, go beyond its territory, it should notify the measures concerned insofar as they involve information likely to be of interest to other Member States as defined in chapter 2.5.

### 10.2 *Contents of the notifications*

The notifying Member State has to include in the Notification Form (Annex I):

- a detailed description and photograph of the product in order to facilitate its identification by the enforcement authorities,
- the results of the risk assessment carried out by the authority that justify the measure adopted,
- the scope, nature, duration and follow-up of the measure taken in order to avoid the risk,
- information enabling the product's distribution channels and origin to be identified, and other information relating to its traceability.

If all the information is not available, this should be indicated and justified together with a timetable for providing the missing information.

### 10.3 *Processing and deadlines for circulation of Article 11 notifications*

National contact points are required to notify the Commission of the measures and actions taken as soon as possible and in any case not later than 15 days after the competent authorities have taken the decision restricting the marketing or use of products by reason of a risk.

This deadline is irrespective of any appeal procedure entered into by the producer or distributor and of official publication requirements.

The Commission will assess, on the basis of the information contained in the notification, whether it complies with Community law and with the guidelines. If necessary it will contact the notifying country to obtain additional information.

The Commission will circulate the notification to the other Member States within 15 days of its reception unless it concludes that the measure does not comply with the requirements. In this case the Commission will inform the Member State which initiated the action, explaining the reasons for its conclusion.

The Member State which initiated the action may resubmit the notification taking into account the comments from the Commission.

Under this procedure the other Member States receiving a new Article 11 notification are not required to inform the Commission about the follow-up given to the notification.

<sup>(1)</sup> OJ L 187, 16.7.1988 p. 1.

10.4. *Practical arrangements for the transmission of Article 11 notifications*

Contact points and the Commission will use the Internet site <https://reis.cec.eu.int/reis> for the transmission of Article 11 notifications. The standard form for Article 11 notifications and the User's Guide for the Internet application are available on this site.

If there are technical problems with this site, contact points may send notifications by e-mail (mail box: [Sanco-Reis@cec.eu.int](mailto:Sanco-Reis@cec.eu.int)) or by fax if (and only if) e-mail transmission is not possible (+32-2 29 64 323).

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*Annex I***NOTIFICATION FORM**

- ☐ **in application of Article 11 of Directive 2001/95/EC**
- ☐ **in application of Article 12 of Directive 2001/95/EC**
- ☐ **requiring emergency action from Member States**

**GENERAL INFORMATION**

- 01. Notifying country and contact person:
- 02. Date of notification:

**PRODUCT**

- 03. Category of products and customs code:
- 04. Product name, brand, price and country of origin:
- 05. Type/number of model/bar code/batch code:
- 06. Description/photograph (format .jpg) of the product and its packaging:
- 07. Standards or regulations applicable:
- 08. Proof of conformity:

**PRODUCER**

- 09. Name, address and contact information for the manufacturer or its representative:
- 10. Name, address and contact information of the exporter/importer:

**DISTRIBUTOR and RETAILER**

- 11. Name, address and contact information for the distributors or their representatives:
- 12. Supplier (shop, supermarket, by mail, Internet) and countries of destination:

**DANGER**

- 13. Type of risk:
- 14. Summary of the results of tests/analyses and conclusions:
- 15. Description of accidents which have occurred:

**MEASURES ADOPTED**

- 16. Voluntary measures (scope, nature and duration):
- 17. Compulsory measures (scope, nature and duration):

**OTHER INFORMATION**

- 18. Additional information:
-

## ANNEX II

**Reaction to notification in application of Article 12 of Directive 2001/95/EC**

01. **Reacting country and contact person:**
  02. **Date of reaction:**
  03. **Notification number, notifying country and product name:**
  04. **Product found:** yes/no
  05. **Assessment of the risk:**
  06. **Voluntary measures** (scope, nature, duration and justification):
  07. **Compulsory measures** (scope, nature, duration and justification):
  08. **Duration:**
  09. **Other information:**
-



## ANNEX III

## NOTIFICATION FORM FOR TOYS

Please tick the appropriate box below:

|  |  |
|--|--|
| <input type="checkbox"/> Notification under Article 7 of Directive 88/378/EEC of 3 May 1988 on Safety of Toys – Safeguard clause                                       | Use <b>Parts 1 and 2</b> of the form.<br><br>To be sent via the Permanent Representation to the EU to the Secretary General of the Commission with electronic copy to Entr-Textile-Leather-Toys@cec.eu.int   |
| <input type="checkbox"/> Notification under Article 12 of Directive 2001/95/EC on General Product Safety and under Article 7 of Directive 88/378/EEC on Safety of Toys | Use <b>Parts 1 and 2</b> of the form<br><br>To be sent via <a href="https://reis.cec.eu.int/reis">https://reis.cec.eu.int/reis</a> and to ENTR-Textile-Leather-Toys@cec.eu.int<br><br>As the notification is a safeguard clause it must also be sent via the Permanent Representation to the Secretary-General of the Commission |

## PART 1

## Safeguard clause pursuant to article 7 of directive 88/378/eeec on toy safety

Please tick the appropriate box below, and state the reasons for:

|                                       | Non-compliance is a result of:   | Reasons |
|---------------------------------------|--|---------|
|                                       | <input type="checkbox"/> Failure to meet the essential requirements referred to in Article 3, if the toy does not meet the standards (Article 7(1)(a)) |         |
|                                       | <input type="checkbox"/> Incorrect application of the standards (Article 7(1)(b))  |         |
|                                       | <input type="checkbox"/> Shortcomings in the standards (Article 7(1)(c))   |         |
| <b>ADDITIONAL INFORMATION ANNEXED</b> |  |         |
|                                       | Copy of the test reports, certificates, examinations, etc.   |         |
|                                       | Copy of the national measure   |         |

## PART 2

- ☐ **in application of Article 12 of Directive 2001/95/EC**
- ☐ **requiring emergency action from Member States**

**GENERAL INFORMATION**

Notifying country and contact person:

Date of notification:

**PRODUCT**

Category of products and customs code:

Product name, brand, price and country of origin:

Type/n Number of model/bar code/batch code:

Description/photograph (format .jpg) of the product and its packaging:

Standards or regulations applicable

Proof of conformity:

**PRODUCER**

Name, address and contact information for the manufacturer or its representative:

Name, address and contact information of the exporter/importer:

**DISTRIBUTOR and RETAILER**

Name, address and contact information for the distributors or their representatives:

Supplier (shop, supermarket, by mail, Internet) and countries of destination

**DANGER**

Type of risk:

Summary of the results of tests/analyses and conclusions:

Description of accidents which have occurred:

**MEASURES ADOPTED**

Compulsory measures (scope, nature and duration):

**OTHER INFORMATION**

Additional information:

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## ANNEX IV

**Deadlines for national contact points**

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

## ANNEX V

**Deadlines for the Commission contact point**

| Action  | Deadline<br>(from reception of the information by the Commission) |
|---|---|
| Send notifications relating to emergency situations to national contact points  | ASAP or maximum three days  |
| Notify national contact points of decisions and actions taken by the authorities, of measures and actions agreed between authorities and producers and distributors, of voluntary measures by producers and distributors  | ASAP or maximum five days   |
| Send information on serious risks liable to be exchanged under RAPEX to the national contact points   | ASAP or maximum five days   |
| Send the national contact points notifications presented under Article 11 of the GPSD   | ASAP or maximum 15 days   |
| Send reactions to notifications requiring emergency follow-up by the national contact points  | ASAP or maximum three days  |
| Send reactions to notifications of decisions and actions taken by the authorities, of measures and actions agreed between authorities and producers and distributors, of voluntary measures by producers and distributors | ASAP or maximum five days   |
| Send a reminder to national contact points that have not reacted to a notification  | 45 days after the original notification was sent                  |