

COMMISSION

COMMISSION DECISION

of 14 December 2004

laying down guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors, in accordance with Article 5(3) of Directive 2001/95/EC of the European Parliament and of the Council

(notified under document number C(2004) 4772)

(Text with EEA relevance)

(2004/905/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⁽¹⁾, and in particular the second subparagraph of Article 5(3) thereof,

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

Whereas:

- (1) Directive 2001/95/EC establishes in Article 5(3) that producers and distributors are to inform the competent authorities if they know or ought to know, on the basis of the information in their possession and as professionals, that a product they have placed on the market is dangerous according to the definitions and criteria of the Directive.
- (2) Annex I(2) to Directive 2001/95/EC requires the Commission, assisted by a Committee of representatives of the Member States, to define the content and draw up the standard form for the notification concerning information on products that do not comply with the general safety requirements to be provided to the competent national authorities by producers and distributors, while ensuring the effectiveness and proper functioning of the notification system. In particular, the Commission has to

put forward, possibly in the form of a guide, simple and clear criteria for determining the special conditions, particularly those concerning isolated circumstances or products, for which notification is not relevant.

- (3) The obligation to inform the authorities about dangerous products is an important element for improved market surveillance as it enables the competent authorities to monitor whether the companies have taken appropriate measures to address the risks posed by a product already placed on the market and to order or take additional measures if necessary for avoiding risks.
- (4) In order to prevent a disproportionate burden on producers, distributors and the competent authorities and to facilitate the effective application of this obligation it is appropriate to establish, in addition to a standard form, operational guidelines concerning the most relevant notification criteria as well as practical aspects of notification, which are put forward in particular in order to assist producers and distributors in the implementation of the provisions laid down in Article 5(3) of Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

The Commission hereby adopts guidelines for the notification of dangerous consumer products by producers and distributors to the competent authorities of the Member States, in accordance with Article 5(3) of that Directive 2001/95/EC.

⁽¹⁾ OJ L 11, 15.1.2002, p. 4.

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

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 14 December 2004.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors in accordance with Article 5(3) of Directive 2001/95/EC

1. INTRODUCTION

1.1. *Background and objectives of the guidelines*

The General Product Safety Directive (GPSD) aims to ensure that non-food consumer products placed on the EU market are safe. It includes an obligation for producers and distributors to provide information on findings and measures concerning dangerous products to the competent authority.

The GPSD mandates the Commission, assisted by the GPSD Committee of Member States, to draw up a guide defining simple and clear criteria to facilitate the effective application of this obligation. In addition the guide is to simplify the work of economic operators and the competent authorities by defining the particular conditions, especially isolated circumstances or products, for which notification is not appropriate. The guide should also define the content and lay out of the standard form for notifications by producers and distributors to the authorities.

In particular the Commission is responsible for ensuring the effectiveness and proper functioning of the notification procedure.

The objectives of these guidelines are therefore to:

- (a) clarify from the operational point of view the scope of producers' and distributors' obligations in such a way that only the information relevant for risk management is notified and that any information overload is prevented;
- (b) make reference to relevant criteria for applying the concept of 'dangerous products';
- (c) provide criteria for identifying the 'isolated circumstances or products' for which notification is not relevant;
- (d) define the content of notifications, in particular the information and data required, and the form to be used;
- (e) identify to whom and how the notification should be submitted;
- (f) 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.

1.2. *Status and further developments of the guidelines**S t a t u s*

These are operational guidelines. These guidelines have been 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 notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors.

F u r t h e r d e v e l o p m e n t s

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 the guidelines are addressed*

These guidelines are addressed to the Member States. They should be used to guide producers and distributors of consumers' products as well as the national authorities designated as contact points to receive information from producers and distributors, in order to ensure the effective and consistent application of the notification requirement in question.

2. SUMMARY OF THE PROVISIONS IN THE GPSD ON NOTIFICATION BY PRODUCERS AND DISTRIBUTORS

2.1. *Obligation to inform competent authorities in the Member States*

Under the GPSD, producers and distributors must inform the competent authorities if they know or ought to know, on the basis of the information in their possession and as professionals, that a product they have placed on the market is dangerous (according to the definitions and criteria of the Directive).

'Isolated' circumstances or products are excluded from the obligation to notify.

Producers and distributors could give the authorities preliminary information about a potential product risk as soon as they are aware of it. With this information the authorities may be able to help producers and distributors to carry out their notification duty correctly. In addition, they are encouraged to contact their national authorities if they have a doubt as to whether a product risk exists.

2.2. Reason and objectives for the provision on notification

The obligation to inform the authorities about dangerous products is an important element for improved market surveillance and risk management.

Producers and distributors, within the limits of their respective activities, are responsible in the first instance for preventing risks from dangerous products. However, producers and distributors may not have taken (or may not be in a position to take) all the necessary measures. Moreover, other products of the same type may pose risks similar to those related to the products considered.

The purpose of the notification procedure is to enable the competent authorities to monitor whether the companies have taken appropriate measures to address the risks posed by a product already placed on the market and to order or take additional measures if necessary to prevent risks. The notification also allows the competent authorities to assess whether they should check other similar products on the market. Therefore, competent authorities must receive adequate information to enable them to assess whether an economic operator has taken adequate measures with regard to a dangerous product. In this respect it should be noted that the GPSD entitles the competent authorities to request additional information if they feel unable to assess whether a company has taken adequate measures with regard to a dangerous product.

3. NOTIFICATION CRITERIA

3.1. Scope

The first requirement for notification under the GPSD is that the product should be within the scope of this Directive and that the conditions of Article 5(3) are met.

It should be noted that separate requirements for the notification of dangerous food products are established by EU food law (Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽¹⁾).

If Community sectoral legislation on product safety establishes notification obligations with the same objectives that excludes the applicability of the GPSD obligation to the categories of products covered by the sectoral requirements. For further information on the relationship between the notification procedures and their purposes, please see the *Guidance Document on the Relationship between the GPSD and certain Sector Directives*⁽²⁾. This document will be further developed, in particular if in light of experience any overlapping or uncertainty appears concerning the application of Article 5(3) of the GPSD and relevant sectoral information or notification requirements in specific Community legislation.

In addition, it is worth noting that these guidelines are not relevant for, and do not interfere with the application of requirements concerning 'safeguard clauses' or other notification procedures established by vertical Community legislation on product safety.

Important criteria for notification are:

- the product is within the scope of Article 2(a) of the Directive: a product intended for or likely to be used by consumers (including in the context of providing a service and second-hand products);
- Article 5 of the Directive is applicable (that is, no specific similar obligation is established by other Community legislation, cf. Article 1(2)(b) GPSD);
- the product is on the market;
- the producer or distributor has evidence (from monitoring the safety of products on the market, from testing, from quality control or from other sources) that the product is dangerous as defined by the GPSD (it does not satisfy the general safety requirement, taking into account the safety criteria of the GPSD) or does not satisfy the safety requirements of the relevant Community sectoral legislation applicable to the product considered;

⁽¹⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

⁽²⁾ http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/reviseGPSD_en.htm

- the risks are therefore such that the product may not remain on the market and producers (and distributors) have the obligation to take appropriate preventive and corrective action (modifying the product, warnings, withdrawal, recalling, etc. depending on the specific circumstances).

3.2. General safety requirement and conformity criteria

Producers and distributors must inform the competent authorities of the Member States if a product they have placed on the market poses a risk to consumers 'that is incompatible with the general safety requirement'. Producers are obliged to place only 'safe' products on the market. Article 2(b) defines a safe product as one that *under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons taking into account the following points in particular:*

- (i) *the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;*
- (ii) *the effect on other products, where it is reasonably foreseeable that it will be used with other products;*
- (iii) *the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;*
- (iv) *the categories of consumers at risk when using the product, in particular children and the elderly.*

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'dangerous'.

Any product that does not meet this definition is regarded as dangerous (Article 2(c)). In other words, a product is 'dangerous' when it does not satisfy the general safety requirement (products on the market must be safe).

Article 3 GPSD describes how conformity is assessed with reference to national legislation, European standards and other reference material. Where suitable European standards do not exist, the GPSD allows other elements to be taken into account in assessing the safety of a product: national standards, codes of good practice, etc.

In addition to the above, the Directive also refers to serious risk, which is defined in Article 2(d) as 'any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities'.

Nevertheless, the Directive recognises that the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk do not constitute grounds for considering a product to be 'dangerous'.

The level of risk could depend on a number of factors such as for example the type and vulnerability of the user and the extent to which the producer had taken precautions to guard against the hazard and warn the user. It is considered that these factors should also be taken into account in determining the level of risk that is regarded as dangerous and requires producers to notify the competent authorities.

A risk could be the result of a manufacturing or production error or it could result from the design of, or the materials used in, the product. A risk could also arise from a product's contents, construction, finish, packaging, warnings or instructions.

In determining whether a product is dangerous under the terms of the GPSD several issues should be analysed: the utility of the product, the nature of the risk, the population groups exposed, previous experience with similar products, etc. A safe product must have no risk or only present the minimum risk compatible with the product's use and needed in order to ensure useful operation of the product.

Producers are expected to undertake a risk assessment of their products before they are marketed. This will form both the basis of their conclusion that the product satisfies the general safety obligation and can be marketed, and also provide a reference for subsequent reassessment of further risk information and whether the product continues to satisfy the definition of 'safe product' or notification needs to be made.

If producers or distributors become aware of information or new evidence showing that a product may be dangerous they should determine whether such information leads to the conclusion that a product is actually dangerous.

The guidance referred to in this document was developed for the *Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC*⁽¹⁾. It is presented here in order to assist producers or distributors to decide if a specific situation caused by a consumer product justifies a notification to the competent authorities. It represents a methodological framework intended to promote consistency and does not take account of all possible factors, but should facilitate consistent, reasoned, professional judgements on the risks posed by specific consumer products. However, if producers or distributors consider that they have clear evidence based on different considerations of the need for notification they must carry out the notification.

Producers or distributors should analyse the information collected and decide whether a particular hazardous situation should be notified to the authorities taking into account:

- the gravity of the outcome of a hazard, depending on the severity and probability of the possible health/safety damage. Combining the severity and probability gives an assessment of the gravity of the risk. The accuracy of this assessment will depend upon the quality of the information available to the producer or distributor.

The severity of health/safety damage for a given hazard should be that for which there is reasonable evidence that the health/safety damage attributable to the product could occur under foreseeable use. This could be the worst case from health/safety damages that have occurred with similar products.

The probability of health/safety damage for a normal user who has an exposure corresponding to the intended or reasonably expected use of the defective product has also to be considered as well as the probability of the product being or becoming defective.

The decision to notify should not be influenced by the number of products on the market or by the number of people who could be affected by a dangerous product. These factors may be taken into account in deciding on the type of action to be taken to solve the problem.

- the factors which affect the level of the risk such as the type of user and, for non-vulnerable adults, whether the product has adequate warnings and safeguards and whether the hazard is sufficiently obvious.

Society accepts higher risks in some circumstances (e.g. such as motoring), than in others (e.g. such as children's toys). It is considered that among the important factors affecting the level of risk are the vulnerability of the type of person affected and, for non-vulnerable adults, the knowledge of the risk and the possibility of taking precautions against it.

The type of person using a product should be taken into account. If the product is likely to be used by vulnerable people (such as children, the elderly) the level of risk which should be notified should be set at a lower level.

For non-vulnerable adults the level of risk which is high enough to require notification should depend on whether the hazard is obvious and necessary for the function of the product and whether the manufacturer has taken adequate care to provide safeguards and warnings, especially if the hazard is not obvious.

Annex II gives more details on the risk estimation and evaluation assessment method developed for the *Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC*. Other methods may be suitable and the choice of method may depend on the resources and information available.

Producers and distributors should be encouraged to contact the authorities if they have evidence of a potential problem in order to discuss whether a notification is appropriate. The authorities will be responsible for assisting and helping them to correctly fulfil their notification obligation.

⁽¹⁾ Commission Decision 2004/418/EC of 29 April 2004 (OJ L 151, 30.4.2004, p. 86).

3.3. *Criteria for non-notification*

The flow of information must be manageable for both sides: the economic operators and the authorities. The notification procedure should deal only with justified cases taking into account the criteria mentioned above and avoid overloading the system with non-relevant notifications.

In order to assess if a notification by producers or distributors to the competent authorities is justified, it is also relevant to know on what terms a notification is not required.

The objective is to prevent a possible proliferation of notifications of measures, actions or decisions related to 'isolated circumstances or products' which do not require any verification, monitoring or action by the authorities and do not provide information useful for risk assessment and consumer protection. This may happen when it is clear that the risk is related to a limited number of well-identified products (or batches) only, and the producer or distributor has solid evidence to conclude that the risk has been fully controlled and its cause is such that knowledge of the incident does not represent useful information for the authorities (such as the malfunctioning of a production line, errors in handling or packaging, etc.).

Producers and distributors do not need to notify under the GPSD:

- products that are not within the scope of Articles 1 and 2(a) GPSD such as: antiques, products not intended for use by consumers and not likely to be used by consumers, second-hand products supplied for repair;
- products that are not within the scope of Article 5(3) GPSD such as: those covered by specific notification procedures of other Community legislation;
- products for which the manufacturer has been able to take immediate corrective action for all the items concerned. The defect is limited to well identified items or batches of items and the producer has withdrawn the items in question;
- problems related to the functional quality of the product, not to its safety;
- problems related to non-compliance with applicable rules not affecting safety in such a way that the product could be considered 'dangerous';
- when the producer/distributor knows that the authorities have already been informed and have all the required elements of information. In particular, if retailers receive information on a dangerous product from their producer/distributor or from a professional organisation that diffuses the information provided by a producer/distributor, they should not inform the authorities if they know that the authorities have already been informed by the producer or distributor.

4. NOTIFICATION PROCEDURE

4.1. *Who must notify*

The obligation to notify applies to both producers and distributors, within the limits of their respective activities and in proportion to their responsibilities.

There may be doubts as to who should be the first to give information. Because of this it will be useful for everyone involved in the supply chain to discuss the practical arrangements related to the responsibility for notification before the need arises. Then if a notification becomes necessary, the various operators will know what to do and unnecessary double notifications will be avoided. In addition, direct contact between the authorities and business is highly important if businesses have doubts about the fulfilment of their notification obligation.

If it is the manufacturer or the importer of the product that first has evidence that a product is dangerous, they should inform the competent national authority and forward a copy of the information to retailers and distributors. A distributor or retailer receiving product hazard information from a manufacturer or importer must inform the authorities **unless** it knows that the national authority has already been adequately informed by the producer or by another authority.

If it is the retailers or distributors of a product that first have evidence that it is dangerous, they should inform the competent national authority and forward a copy of the information to the manufacturer or importer. A manufacturer or importer receiving product hazard information from a retailer or distributor must complete the information provided by them by passing to the authority(ies) all information they have concerning the dangerous product, in particular identification of other distributors or retailers of the product in order to ensure the product's traceability.

Distributors who have doubts about the safety of a product or whether a dangerous product represents an 'isolated case' must transmit to the producer the information they have. They can also contact the competent authorities for advice on how to proceed.

Many hazard situations are recognised by producers only as a result of an aggregated assessment of individual communications received from different retailers or distributors. The producer has the responsibility of assessing the information in order to determine the exact origin of the possible risk and to take the measures which appear to be necessary, including notification of the authorities.

A company should assign responsibility for the information to be notified to someone with sufficient knowledge of the product.

4.2. *To whom the notification should be presented*

Producers and distributors are required by the GPSD to submit their notifications to the market surveillance/enforcement authorities of all the Member States where the product has been marketed or otherwise supplied to consumers. Each Member State must designate the authority in charge of receiving such notifications. A list of the authorities designated to that effect is on the Commission's website.

Annex I of the GPSD states that the information specified in Article 5(3) must be submitted to the competent authorities in the Member States where the products in question are or have been marketed or otherwise supplied to consumers.

However, it is desirable to reduce the burden on producers and distributors by introducing arrangements simplifying the practical application of the requirements in question, while ensuring that all the interested authorities are informed. These arrangements will also contribute to prevent multiple notifications concerning the same fault.

Therefore, producers and distributors have the option of submitting the required information to the authority of the Member State in which they are established, if one of these two conditions is fulfilled:

- The risk is notified as being 'serious' or is considered 'serious' by the receiving authority and this authority decides to introduce a notification concerning the product in question under the RAPEX system. In such a case, the receiving authority should without delay inform the producer or distributor who has submitted the information of its decision to inform the other Member States' authorities through RAPEX.
- The risk is notified as not being 'serious' or is not considered serious by the receiving authority, but this authority has communicated to the producer or distributor who has submitted the information its intention to forward the information, through the Commission, to the authorities of the other Member States⁽¹⁾ where, according to the indications of the producer or distributor, the product is/has been placed on the market. In such a case, the receiving authority must inform the producer or distributor without delay.

The producer or distributor that only informs the authority of the country where it is located should always provide this authority with the available information about other countries where the product has been marketed.

If the national authorities conclude or obtain evidence that a product placed on the market is dangerous and they have not been informed by its producer or distributors, they must examine whether and when the relevant operators should have notified and decide appropriate action, including possible sanctions.

4.3. *How to notify*

A company should notify by filling in the form presented in Annex I and submitting it without delay to the relevant competent authority(ies). The operator notifying must provide the information required in the form. However, no company should delay a notification because part of the information is not yet available.

It may be helpful to divide the form into two parts. The first part should be filled in immediately (Sections 1 to 5) and the second part (Section 6) should be filled in when the information has been collected (a timetable for providing the missing information should be transmitted) and then when there is a serious risk situation or when the producer/distributor opts to submit the notification only to the authority of the Member State in which they are established. Notification should not be delayed when some of the fields in a section cannot be completed.

⁽¹⁾ The Product Safety Network of the GPSD provides the framework for the appropriate arrangements to facilitate such exchanges.

The GPSD requires that the competent authorities be informed immediately. A company must therefore inform them without delay, as soon as the relevant information has become available, and in any case within 10 days⁽¹⁾ since it has reportable information, even while investigations are continuing, indicating the existence of a dangerous product. When there is a serious risk companies are required to inform the authority(ies) immediately and in no case later than three days after they have obtained notifiable information.

In an emergency situation, such as when immediate action is taken by a company, the company should inform the authorities **immediately and by the fastest means**.

5. CONTENTS OF NOTIFICATIONS

5.1. *Background to notifications (obligation of post-marketing monitoring)*

In addition to the duty to comply with the general safety requirement for their products, producers and distributors have the obligation, as professionals and within the limits of their activities, to ensure an adequate follow-up of the safety of products they supply. The obligations for producers and distributors established by GPSD in that respect, such as information to consumers, post-marketing monitoring of product risks, withdrawing dangerous products, etc., have been mentioned above. The obligations on producers apply to manufacturers, but also to any other members of the supply chain who can affect the safety characteristics of a product.

Various types of evidence may become available to operators within the framework of their post-marketing responsibilities which may lead to a notification, such as and among others:

- reports or other information on accidents involving the company's products;
- safety-related complaints received from consumers, directly or through distributors or consumer associations;
- insurance claims or legal actions concerning dangerous products;
- safety-related non-compliance reported via the company's quality control procedures;
- any information relevant for identifying non-compliances with safety requirements that is brought to the company's attention by other organisations such as market surveillance authorities, consumer organisations or other companies;
- information on relevant scientific developments on product safety.

5.2. *Notification form*

The information required has been classified under the following sections:

1. Details of authority(ies)/company(ies) receiving the notification form: the person completing the form is requested to identify the authority(ies) and company(ies) that will receive the notification and the role that these companies have in the marketing of the product.
2. Details of the producer (as defined in the GPSD, Article 2(e))/distributor completing the notification form: the person filling in the form must enter complete details of their identity, that of the company and its role in the marketing of the product.
3. Details of the product involved: a precise identification of the product is required including its brand, model, etc., supported by photographs in order to avoid confusion.
4. Details of the hazard (type and nature) including accidents and health/safety effects and conclusions of the risk estimation and evaluation that has been carried out in accordance with Chapter 3 (Notification criteria) and in light of Annex II (Methodological framework).
5. Details of corrective actions that have been taken or are planned to reduce or eliminate the risk to consumers, e.g. recall or withdrawal, modification, informing consumers, etc. and of the company responsible for them.

⁽¹⁾ All deadlines mentioned in the text are expressed in calendar days.

6. Details of all company(ies) in the supply chain who hold affected products and reference to the approximate number of products in the hands of businesses as well as of consumers (this section applies in cases of serious risk or when the producer/distributor opts to submit the notification only to the authority of the Member State in which they are established) ⁽¹⁾.

In the event of serious risk, producers and distributors are required to include all the available information relevant for tracing the product. The information required for Section 6 of the notification form (see Annex I) may take longer to collect than the other sections, because it may be necessary to collect it from several organisations. Companies should complete and send Sections 1 to 5 as soon as possible and send Section 6 as soon as the information is available and in a situation of serious risk or when the producer/distributor opts to submit the notification only to the authority of the Member State in which they are established.

6. FOLLOW-UP TO NOTIFICATIONS

After a notification is sent, various developments are possible. In particular:

- the authority that has received the notification should, if appropriate, reply by asking for additional information or request the producer or distributor to take further action or measures;
- producers and distributors may have to provide additional information at their own initiative or on request from the authorities on any new developments or findings and/or success or problems with any action taken;
- the authority should decide where appropriate to take enforcement action and/or require producers and distributors to ensure cooperation on market surveillance or to inform the public about product identification, the nature of the risk and the measures taken, taking into account professional secrecy;
- if the requirements of a RAPEX notification are fulfilled (serious risk, product marketed in several Member States), the competent authority must send a RAPEX notification to the Commission which will then transmit it to all Member States.

⁽¹⁾ Even in case of a product marketed in just one Member State a list of the companies who hold affected products in that country is relevant in order to permit the competent authority(ies) to monitor the effectiveness of the action taken.

ANNEX I

Notification form for the notification of dangerous products to the authorities by producers or distributors

| <i>Section 1: Details of authority(ies)/company(ies) receiving the notification form</i> | |
|--|--|
| Authority/contact name/address/telephone/fax/e-mail/website | |
| Identification of the companies notified and their role in the marketing of the product | |
| <i>Section 2: Details of producer/distributor</i> | |
| Producer or producer's representative/distributor completing the form | |
| Contact name/responsibility/address/telephone/fax/e-mail/website | |
| <i>Section 3: Details of products involved</i> | |
| Category. Brand or trademark. Model name(s) or bar code/CN tariff. Country of origin | |
| Description/photograph | |
| <i>Section 4: Details of hazard</i> | |
| Description of the hazard and possible health/safety damages and conclusions of the risk estimation and evaluation carried out | |
| Record of accident(s) | |
| <i>Section 5: Details of corrective actions already taken</i> | |
| Types/scope/duration of action(s) and precautions taken and identification of the company responsible | |
| Companies should complete and send Section 6 in case of a serious risk or when the producer/distributor opts to submit the notification only to the authority of the Member State in which they are established | |
| <i>Section 6: Details of other company(ies) in the supply chain which hold affected products</i> | |
| List of manufacturers, importers or authorised representatives by Member State (name/address/telephone/fax/e-mail/website) | |
| List of distributors or retailers by Member State (name/address/telephone/fax/e-mail/website) | |
| Number of products (serial numbers or date codes) held by producer/importer/distributor/retailer/consumers by Member State | |

ANNEX II

Methodological framework for facilitating consistent risk estimation and evaluation

The following text is based on the framework developed for the RAPEX Guidelines and is presented here in order to assist companies in assessing the level of a risk and deciding whether a notification to the authorities is necessary. The guidelines in this Annex II are not exhaustive and do not attempt to take into account all possible factors. The companies 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.

A consumer product may present one or more intrinsic hazards. 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 it is 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, etc.) 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 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 to it.

Taking into account the above considerations, the following conceptual approach may assist businesses when deciding whether a specific hazardous situation caused by a consumer product requires a notification to the competent authorities.

It is recommended that assessments be carried out by a small team who have knowledge and experience of the product and its hazards. Assessors may have to make subjective judgements if objective data are not available and it is hoped this procedure will help them to make consistent and reasoned judgements about actual or potential risks.

The assessor should analyse the information collected and use the risk assessment table as follows:

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

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 probability of health/safety damage, are combined. The following definitions of severity and probability have been drawn up to assist in the selection of appropriate values.

Severity of injury

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⁽¹⁾.

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 companies to take account of the total number of people exposed to a product in deciding on the type of action to be taken.

For many hazards it is possible to envisage unlikely circumstances that could lead to very serious injury, e.g. tripping over a cable, falling and banging one's 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 characterising the hazard could occur during foreseeable use. This could be the 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.

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

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

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 company. However, this assessment needs to be modified to take account of 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 are the vulnerability of the type of person affected and for non-vulnerable 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 should be notified 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 years) | Young (3-11years) |

Normal adults

The adjustment of the seriousness of risk for non-vulnerable adults should only apply if the hazard is obvious and necessary for the function of the product. For non-vulnerable adults, the level of risk 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).

Risk Assessment of consumer products for the GPSD

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

Table A — Risk Estimation

| | | | |
|-------------------------------------|----------------------------------|----------|--------------|
| | Severity of Health/Safety Damage | | |
| | Slight | Serious | Very Serious |
| Probability of Health/Safety Damage | Very High | High | Medium |
| | High | Medium | Low |
| | Medium | Low | Very Low |
| | Low | Very Low | |

Table B — Grading of Risk

| | | | | |
|--------------------------------------|------------|-----------------------------------|-----|--|
| Vulnerable people | | Non-vulnerable adults | | Adequate warnings and safeguards? Obvious hazard? |
| Very vulnerable | Vulnerable | Yes | No | |
| Serious Risk — Notification required | | No | No | Yes |
| | | No | Yes | Yes |
| Moderate risk | | Notification required | | |
| Low risk | | Low risk Notification unlikely | | |

| |
|----------------------------|
| Overall Gravity of Outcome |
| Very High |
| High |
| Moderate |
| 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 non-vulnerable adults, whether the product has adequate warnings and safeguards and whether the hazard is sufficiently obvious

Example (indicated by the arrows above)

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

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

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

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