

The General Product Safety Regulations 2005
Notification guidance for producers and distributors

September 2005

CONTENTS

1. INTRODUCTION	3
2. SUMMARY OF THE PROVISIONS IN THE GENERAL PRODUCT SAFETY REGULATIONS 2005 ON NOTIFICATION BY PRODUCERS AND DISTRIBUTORS	4
2.1. Obligation to inform enforcement authorities	4
2.2. Why this provision has been introduced	4
3. NOTIFICATION CRITERIA	4
3.1. Application and Scope	4
3.2. General safety requirement and conformity criteria	5
4. NOTIFICATION PROCEDURE	9
4.1. Who must notify	9
4.2. To whom the notification should be presented	10
4.3. How to notify	11
5. CONTENTS OF NOTIFICATIONS	11
5.1. Background to notifications (obligation of post-marketing monitoring)	11
5.2. Notification form	12
6. FOLLOW-UP TO NOTIFICATIONS	13
ANNEX I - METHODOLOGICAL FRAMEWORK FOR FACILITATING CONSISTENT RISK ESTIMATION AND EVALUATION	14
ANNEX II - NOTIFICATION FORM FOR THE NOTIFICATION OF DANGEROUS PRODUCTS TO THE AUTHORITIES BY PRODUCERS OR DISTRIBUTORS	20
ANNEX III – ENFORCEMENT AUTHORITY CONTACT DETAILS	22

1. INTRODUCTION

The General Product Safety Regulations 2005 (“the Regulations”) implement Directive 2001/95/EC on general product safety (“the GPSD”) and came into force on 1st October 2005 (when they replaced the 1994 Regulations). They have the aim of ensuring that non-food consumer products placed on the market are safe.

One of the new duties placed on producers and distributors by the Regulations (Regulation 9) is to notify their local authorities (or other appropriate bodies – see section 4.2) when they become aware that a product they have placed on the market, or have supplied, “poses risks to the consumer that are incompatible with the general safety requirement” – see Regulation 5.

This guide has been produced by the DTI to help producers and distributors understand this requirement and how they should make notifications when necessary. Users of the guide might also find it helpful to read the general guidance on the Regulations¹ and the EC Guidelines on producer/distributor notifications².

In most areas the guidance applies to both producers and distributors, but where requirements are different the following definitions of *producer* and *distributor* should help readers decide what action is relevant to them.

The Regulations define a *producer* as:

- (a) The manufacturer of a product, when he is established in a Member State and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product;
- (b) When the manufacturer is not established in a Member State –
 - (i) If he has a representative established in a Member State, the representative,
 - (ii) In any other case the importer of the product from a state that is not a Member State into a Member State;
- (c) Other professionals in the supply chain, insofar as their activities may affect the safety properties of a product.

A *distributor* is defined as a professional in the supply chain whose activity does not affect the safety properties of a product. But a distributor or retailer is also a producer if it carries out any of the activities in (a) and (b) above.

¹ Available on the DTI website - <http://www.dti.gov.uk/ccp/topics1/safety.htm#gpsr>

² http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidelines_en.htm

2. SUMMARY OF THE PROVISIONS IN THE GENERAL PRODUCT SAFETY REGULATIONS 2005 ON NOTIFICATION BY PRODUCERS AND DISTRIBUTORS

2.1. Obligation to inform enforcement authorities

Producers and distributors are required to inform the enforcement 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 not a safe product (see section 3.2).

“Isolated” circumstances or products do not need to be notified.

Producers and distributors could give the enforcement authority preliminary information about a potential product risk as soon as they become aware of it. With this information the authorities may be able to help producers and distributors assess the risk and the appropriate response and to carry out their notification duty correctly. There is no requirement to give the enforcement authority preliminary information, but it is desirable.

2.2. Why this provision has been introduced

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/removing risks from consumer products. However, they may not have taken (or may not be in a position to take) all the measures necessary to do this. There is also the possibility that other products of the same type (made by other producers) may pose similar risks and may require similar measures to be taken.

The main purpose of the notification procedure is to enable the enforcement authority to monitor whether the company has taken appropriate action to address the risks posed by a product already on the market and to require (or take) additional action if necessary to prevent risks. When passed on by the DTI to the authorities in other Member States in which the product has been marketed, this information also allows those authorities to take appropriate action for their domestic markets.

3. NOTIFICATION CRITERIA

3.1. Application and Scope

For the notification obligation to apply the following criteria must be satisfied:

- the product is within the scope of regulation 2 – i.e. it is a product intended for or likely to be used by consumers (including in the context of providing a service and second-hand products);

- the product is on the market;
- the producer or distributor has evidence (from monitoring activities, testing, quality control or from other sources) that the product is dangerous as defined by the Regulations, or that it does not satisfy the safety requirements of the relevant sectoral legislation;
- the nature and level of risk requires preventative and corrective action, including removing the products from the market, recalling the product from consumers, modifying the product, issuing warnings etc., depending on the specific circumstances.

Where consumer products are subject to sector-specific legislation dealing with aspects of their safety, and where that legislation does not have similar notification obligations, the notification requirements of the Regulations apply. Examples of such products include (but are not limited to):

- Toys
- Electrical equipment
- Cosmetics
- Personal protective equipment
- Construction products
- Machinery
- Motor vehicles

The notification requirements of the Regulations do not however extend to consumer products falling under sector specific legislation with separate notification obligations (e.g. medical devices, medicinal products etc).

3.2. General safety requirement and conformity criteria

Producers and distributors are obliged to supply or to place on the market only products that are safe. Regulation 2 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. In determining the foregoing, the following shall be taken into account in particular:

(a) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, instructions for installation and maintenance,

(b) the effect of the product on other products, where it is reasonably foreseeable that it will be used with other products,

(c) 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, and

(d) the categories of consumers at risk when using the product, in particular children and the elderly.”

Any product that does not meet this definition is regarded as dangerous.

Regulation 6 describes how conformity with this requirement is assessed with reference to national legislation, European standards and other reference material. Where suitable European standards do not exist the Regulations allow other elements to be taken into account in assessing the safety of a product - e.g. national standards, codes of good practice, etc.

In addition to the above, the Regulations also refer to serious risk, which is defined in regulation 2 as *“a serious risk, including one the effects of which are not immediate, requiring rapid intervention.”*

Nevertheless, the Regulations recognise that the feasibility of obtaining higher levels of safety, or the availability of other products presenting a lesser degree of risk, do not on their own constitute grounds for considering a product to be “dangerous”. It should also be borne in mind that non-compliance with a relevant standard (where compliance was not made mandatory by legislation) would not necessarily mean that a product was unsafe.

The level of risk could depend on a number of factors, e.g. 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. The level of risk which is characteristic of the product and regarded as acceptable by consumers also has to be taken into account. Society accepts higher risks in some circumstances (e.g. such as motoring), than in others (e.g. such as children’s toys). A knife has to be sharp in order to be able to cut and therefore presents a risk, but the product is not regarded as dangerous because the risk is an obvious one and a characteristic of the product that consumers accept.

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 corrective action or notification needs to be undertaken.

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 European Commission’s guidance on risk assessment at Annex I is one approach to risk assessment that producers and distributors can use 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 across the EU and does not take account of all possible factors, but should facilitate consistent, reasoned professional judgements on the risks posed by specific consumer products. Some industry sectors have proven risk assessment procedures to assist producers to come to a conclusion; but they should always be used only as an indicator of appropriate action. In all cases, the producer must take responsibility for the decision. 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 damage to human health and safety. 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 damage to human health and safety resulting from an exposure corresponding to the intended or reasonably expected use of the product has also to be considered as well as the probability of the product being or becoming dangerous in normal or reasonably foreseeable use including duration.
- 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, however, be taken into account when deciding on the type of action to be taken to solve the problem, and the data concerned is essential to conduct a risk assessment.
- 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.

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.

It follows therefore that any risk assessment should take into account the type of person likely to use a product and if the product is likely to be used by vulnerable people (such as children, the elderly) the level of acceptable risk be set at a lower level.

Producers and distributors are encouraged to contact the enforcement authority if they are in any doubt as to whether evidence of a potential problem in their possession should be notified. The enforcement authority is responsible for assisting and helping them to correctly fulfil their notification obligation.

3.3. Criteria for non-notification

Subject to the final sub paragraph of 3.2 above, there are certain circumstances where a notification is specifically not required.

The objective is to prevent a burden to business and a 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 these Regulations:

- products that are not within the scope of regulation 3 or the definition of “product” in Regulation 2, or products that are covered by regulation 4;
- products that are covered by specific notification procedures under sector-specific legislation (e.g. medical devices and medicinal products);
- 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;
- when the producer/distributor knows that the authorities have already been informed and have all the required elements of information.

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 – but they should not duplicate notifications.

If notification policy (e.g. who should notify) has not already been agreed within the supply chain, it may be sensible for such a discussion to take place following a risk becoming known and before a notification is made. At this stage, the producer may inform the TSD. If the producer subsequently concludes that notification, on the basis of a risk assessment showing that the product is incompatible with the GSR, is required, he must do this within 10 calendar days. This gives an opportunity for discussion with the TSD on the corrective action it is undertaking or planning. It should also be understood that the duty to notify rests with the party first becoming aware of the risk, and it is they who must make the notification unless they can be sure that another party will notify within the original 10-day period. If retailers receive information on a dangerous product from their producer/distributor, they should not inform the authorities if they know that the producer or distributor has already informed the authorities.

Producers and distributors are encouraged to hold discussions with everyone involved in the supply of an individual product before the need for notification arises. The benefit will be that in the event of a notification becoming necessary the various operators will know what to do in advance and unnecessary double notifications will be avoided.

In general, when a notification does become necessary we expect the following procedures to be followed:

If it is the producer that first becomes aware that its product is incompatible with the general safety requirement it should inform the home authority³ and forward a copy of the information to its distributors stating the date of the notification, to whom it was made and the action to be taken in respect of the product (i.e. remove it from sale). A distributor receiving such information from a producer may reasonably assume that a notification has been made. If a distributor is uncertain whether a notification has been made it should clarify the situation with the producer before taking any further steps.

If it is a distributor that first becomes aware that a product is incompatible with the general safety requirement, it should as a first step withdraw the product from

³ The Local Authorities Coordinators of Regulatory Services (LACORS) promotes the “Home Authority” principle, under which the local authority for the area where the decision-making function of a business is located accepts the primary responsibility for offering advice and preventative guidance on safety to the business. Other local authorities should liaise with the relevant home authority on any safety matters arising from the products supplied by that business and before implementing any measures. Businesses are encouraged to make contact with, and seek advice on any particular matter from their home local authority.

sale and then inform the producer of its concerns. Where the producer is in the UK, it is expected that it will make the notification – this will prevent multiple and unnecessary distributor notifications. But if the distributor cannot be certain that a notification will be made by the producer or another distributor it should advise the relevant enforcement authority by completing as much of the notification form as it can within the 10-day deadline and copy this to the producer for further completion of any gaps in the information. The producer should then send the updated form to its home authority for onward submission to the DTI (the local authority will have consulted the home authority following the distributor's notification). Communication with the producer is important so as to be able to determine whether the event recorded is an isolated circumstance and whether and to the authorities of which other member states the notification needs to be promulgated and the nature and scope of any necessary corrective actions.

Producers may only become aware of hazard situations 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 hazard, to assess the risk to consumers, and to take the measures that appear to be necessary, including notification of the authorities.

A company should assign responsibility for notifications to someone sufficiently senior in the organisation who has decision-making powers.

4.2. To whom the notification should be presented

Producers and distributors are required by the Regulations to submit their notifications to the appropriate market surveillance/enforcement authority, which in most instances will be the local authority (or the home authority for producers), who will then pass this information on to the DTI for onward transmission to the Commission and other Member States as necessary. For new motor vehicles and automotive products, notifications should be made to the Vehicle and Operator Services Agency (VOSA). See Annex III for information on how to identify local/home authorities and for VOSA contact details.

When a local authority receives a notification from a producer or distributor it will assess the risk for itself and advise on the nature and scale of the corrective actions undertaken or proposed. If the risk is deemed to be non-“serious” and not requiring urgent intervention the notification will be passed on to the DTI for onward transmission to the Commission and other Member States in which the product has been marketed. If the risk is deemed to be serious the local authority will generate a serious risk notification under the Rapid Alert Notification System (RAPEX) for the DTI to formally submit to the European Commission. In both cases the producer or distributor will be notified by the DTI when this information is being submitted for European circulation.

If the enforcement authorities conclude or obtain evidence that a product placed on the market is dangerous and that the producer and/or distributor was aware of

this but had not made a notification, the authority may apply the sanctions that are provided for under the Regulations.

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 enforcement authority. 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 and submitted immediately (Sections 1 to 5) and the second part (Section 6) should be completed as the information becomes available (a timetable for providing the missing information should be provided). This will assist the rapid notification process in the event of a serious risk being identified.

The Regulations require that the appropriate 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 calendar days of it obtaining reportable information. When there is a serious risk companies are required to inform the authority immediately and in no case later than three calendar days after they have obtained notifiable information.

In an emergency situation, such as where immediate corrective action is taken by a company, the company should inform the local authority immediately and by the fastest means possible.

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 established by the Regulations in that respect (Regulations 7(3) and 8 in particular), such as providing information to consumers, post-marketing monitoring of product risks, withdrawing dangerous products, etc, have been mentioned elsewhere.

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:

- reports or other information on accidents involving the company's products;
- safety-related complaints or other feedback received from consumers, directly or through distributors or consumer or other safety organisations;

- 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 organizations such as market surveillance authorities (including in other member states), consumer organisations or other companies including component or sub assembly suppliers;
- scientific reports or developments that have an impact on the assessment of risk of the product concerned.

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 regulation 2) / 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 or drawings 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 section 3 (Notification criteria) and in light of the risk assessment criteria at Annex I (or some other suitable assessment model).
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 where responsibility for these actions lays.
6. Details of companies in the supply chain who hold affected products (including approximate numbers of products in the hands of businesses and consumers). The amount of detail required should be discussed with the local/home authority. When identifying product availability in other Member States (needed only when the notifier has made the product available in those countries) only the main distribution point(s) in those countries needs to be indicated.

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.

6. FOLLOW-UP TO NOTIFICATIONS

After a notification is sent it is generally assumed that where the producer or distributor is already taking the action considered by the authority necessary to remove the risk to consumers it will not be necessary for the enforcement authorities to serve a safety notice. Voluntary action is specifically encouraged as an alternative to formal enforcement.

Having said that various developments are possible. In particular:

- the authority that has received the notification may, 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 local authority must send a RAPEX notification to the DTI for onward transmission to the Commission, which will then send this to all the Member States.
- The enforcement authority may have recourse to the various sanctions e.g. for placing an unsafe product on the market provided by the Regulations.

ANNEX I - METHODOLOGICAL FRAMEWORK FOR FACILITATING CONSISTENT RISK ESTIMATION AND EVALUATION

The following risk assessment procedures are currently being revised. They are included in this Guidance, but may be replaced in a future edition by a revised version. The DTI website should be checked regularly for updates on this. Attention is also drawn to the existence of more product-specific Risk Assessment procedures in some sectors.

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 is 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 hazard⁴.

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

⁴ 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	

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 characterizing 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.

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 (3-11 years)

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

Table B – Grading of Risk

Vulnerable people		Non-vulnerable adults				Adequate warnings and safeguards? Obvious hazard?
Very vulnerable	Vulnerable	No	Yes	No	Yes	
<div style="background-color: orange; padding: 5px;">SERIOUS RISK – Notification required</div>		No	Yes	No	Yes	<div style="background-color: yellow; padding: 5px;">Notification required</div>
		Yes	No	Yes	No	
<div style="background-color: yellow; padding: 5px;">Moderate risk</div>		<div style="background-color: green; padding: 5px;">Low risk Notification unlikely</div>				

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.

**ANNEX II - NOTIFICATION FORM FOR THE NOTIFICATION OF
DANGEROUS PRODUCTS TO THE AUTHORITIES BY PRODUCERS OR
DISTRIBUTORS**

Section 1: Details of AUTHORITY(IES)/COMPANY(IES) receiving the notification form	
Authority/Contact name/Address/Telephone/Fax/E-mail/Website	
Identification of the companies notified and their role in the marketing of the product	
Section 2: Details of PRODUCER/DISTRIBUTOR	
Producer or Producer 's representative/Distributor completing the form	
Contact name, responsibility, Address/Telephone/Fax/Email/Website	
Section 3: Details of PRODUCTS involved	
Category. Brand or trademark. Model name(s)or Bar code/CN Tariff. Country of origin	
Description/Photograph	
Section 4: Details of HAZARD	
Description of the hazard and possible health/safety damages and conclusions of the risk estimation and evaluation carried out	
Record of accident(s)	
Section 5: Details of corrective ACTIONS already taken	
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**

Section 6: Details of other COMPANY(IES) in the supply chain which hold affected products	
List of Manufacturers/ Importers or Authorised representatives by Member State: Name/Address/ Tel/Fax/E-mail/Website.	
List of Distributors/Retailers by Member State: Name/Address/ Tel/Fax/E-mail/Website	
Number of products (serial numbers or date codes) held by producer/importer/ distributor/retailer/consumers by Member State	

ANNEX III – ENFORCEMENT AUTHORITY CONTACT DETAILS

How to find local/home authorities:

Producers and distributors who do not already have this information can find the contact details for their local/home authority by visiting the Trading Standards Central website - <http://www.tradingstandards.gov.uk/>

Contact details for motor vehicle notifications:

Producers and distributors who need to make notifications concerning motor vehicle safety, or who want to discuss the possibility of doing this, should contact:

The Vehicle & Operator Services Agency
Vehicle Safety Branch
Room 101
Berkeley House
Croydon Street
Bristol
BS5 0DA

Tel: 0117 9543249

Email: Alison.martin@vosa.gsi.gov.uk

Consumer & Competition Policy Directorate
DTI
September 2005

URN 05/1457