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The General Product Safety Regulations 2005

Notification guidance for local authorities

1. Introduction

These summary guidelines have been produced by the DTI to help enforcement officers determine when they need to inform the Department about unsafe consumer products in line with the various notification requirements set out in Directive 2001/95/EC on general product safety, and implemented by the General Product Safety Regulations 2005.

The guidelines are simplified ready reference desk notes intended as an aid to enforcement officers who already have some understanding of the notification process and should be read in conjunction with the Regulations guidance. They do not replace the notification references in the 2005 Regulations, nor the much more extensive European Commission Guidelines for notifying safety risks with consumer products, which may still need to be referred to from time to time. The Commission guidelines can be found at the following address:

http://europa.eu.int/comm/dgs/health_consumer/dyna/rapex/create_rapex.cfm

The notification procedures covered are those identified under the following Regulations in the General Product Safety Regulations 2005:

Regulation 9(1)-(3): the new procedure introduced to support the obligation on producers and distributors to notify problems with the products they supply, and to indicate what they have done to remove the risk to consumers;

Regulation 33(2): the exchange of information on products where action has been taken to restrict their supply, but which are not deemed to present a serious risk (see Annex I);

Regulation 33(4): the RAPEX procedure for notifying products that are found to present a serious risk to consumers and which require urgent action to be taken (see Annex I). This will include producer/distributor notifications received under Regulation 9 where these are considered to pose a serious risk.

The RAPEX requirements also apply to products covered by vertical directives which lack a similar notification requirement – **e.g. Toys, Low Voltage, Personal Protective Equipment, Cosmetics, Machinery, Motor Vehicles, Construction Products etc.**

Where a RAPEX notification obligation is seen to co-exist with the need to make a Safeguard notification, only the RAPEX notification needs to be made. This information will be passed on to the relevant Safeguard contact by the central RAPEX contact (indicated on the RAPEX notification form at Annex II). Otherwise, Safeguard notifications should be made directly to the Safeguard contact for the product in question. A list of Safeguard contacts will be made available on the DTI website.

With all notifications it is important that the correct forms are used and that the information is as complete as possible. The forms for Regulations 9 and 33 notifications are annexed to this guidance, as is a dual RAPEX/Safeguard form for use with toy products.

Additionally, the responsible enforcement authority should inform the home authority (where they are not one and the same). It would also be good practice to notify the TS Interlink mechanism.

The specific requirements of the each of the notification procedures are explained further in the following sections.

2. Regulation 33(4) (RAPEX) notifications

A RAPEX notification should be prepared and submitted to the DTI when it is learned that a product on the UK market (or elsewhere on the European market if the manufacturer is based in the UK) presents a serious risk to consumers and urgent action is required to remove that risk. RAPEX notifications have increased year-on-year. In 2004 there were 388 notifications across the European Union, in 2005 there were 847, and we expect there to be over 1000 in 2006. The number of RAPEX notifications initiated within the UK has also increased steadily. In 2004 there were 24, in 2005 there were 43 and in 2006 we expect there to be over 100.

Enforcement officers should try to assess the severity of the situation making some use of the Commission's risk assessment criteria set out in Annex I. Although this approach to risk assessment is not mandatory it is expected that the Commission's guidance will be used increasingly by enforcement authorities in other Member States as a basis for notifications (including RAPEX), which UK enforcement officers will need to reconcile with their own assessment of risk when the same product is found on the UK market. There is nothing to prevent parallel or exclusive use of one of the many other methodologies (e.g. nomograph) where this is seen to be more helpful.

The Commission's guidance also advises that a RAPEX notification may be made based on information relating to a serious risk before a decision on appropriate action has been taken (on the assumption that measures will be adopted). Since the formal legal notification requirements do not make such reference, if information contained in such a partial notification were made public by an authority and subsequent action were not taken promptly where it was justified under the Regulations publication might be held to be contrary to the judgement in the case of *R v Liverpool Council ex parte Baby Products Association* (the 'Babywalker Judgement'). Since the Secretary of State is duty bound to forward all notifications to the European Commission this does not constitute publication. However, enforcement authorities might, if they submit any such advance notifications, wish to make it clear that these are for information only and not for publication prior to a measure in the UK having been taken.

Measures and actions related to risks where the effects cannot go beyond the UK are excluded from the scope of RAPEX (though may still require some Safeguard action).

However, notifications can still be made on a 'for information only' basis in such cases where the local authority feels that the information could be of value to the Commission and other Member States.

Content of RAPEX Notifications

RAPEX notification should be made using the form at Annex II.

The Commission expects that the information provided by Member States Competent Authorities to be as complete as possible and should be **submitted electronically** to the DTI's (electronic forms are available alongside this guidance, on the TS Interlink and on the DTI website www.dti.gov.uk/consumers/Safety/products/unsafe-notification/index.html) RAPEX unit - rapex.unit@dti.gsi.gov.uk . Gaps in available information should not prevent a notification being made, but it should be indicated when the missing information is expected to be available, or the reason why the information will not be forthcoming. In effect we would like to see no blank boxes on the form. A good example of the form can be found at Annex V in this guidance.

The following is a step-by-step guide to completing the notification form:

Having read the information contained in this guidance it should be clear what type of notification you will be completing – Article 11, Article 12 or requiring emergency action. Please place an **X** next to the appropriate description.

General Information

Notifying Country: Always the UK

Date: This is the date that you **email** the completed form to the DTI's RAPEX Unit.

Product

Category of Product: Best description of the product i.e. can it be grouped as a power-tool, or toy, or electrical appliance, or lighting, or clothing etc.

Customs Code: All products that are either produced within the EU or enter the EU are given a customs code to help identify a product for purposes like tariffs. This is numerical and can be found at <http://mkaccdb.eu.int> By entering a short description of the product in the Tariffs database search engine you will be able to establish the first 4-6 digits of the Custom Code.

Product Name: This should be the main descriptor of the product.

Brand: Does the manufacturer have a name that encapsulates all it's products.

Price: If known this should be in Pounds and/or Euros.

Country of Origin: Where the product was manufactured. Please try and find out where the product was manufactured so the Commission can follow up with any further action.

Type/number of model/bar code/batch code: This is specific to each product and will be either numerical and /or alphabetical.

Description of product and packaging: Describe the product i.e. it's shape, colour, size. And the packaging is it boxed, clear and does it display warnings, instructions etc.

Photograph: Attach the photograph in a separate JPG, PDF or Word format. Ensure that the photograph(s) show both the product and the packaging.

Standards/Regulations: Depending on the product this will either be GPSD or be more specialised i.e. Machinery Directive, Low Voltage Directive etc.

Proof of Conformity: Does the product exhibit the British Standard (BSI) or European (CE) marking or other equivalent?

Producer/Exporter/Importer

Manufacturer/or Representative: As full as contact details you can – name, address, country, telephone, fax, email and web address

Exporter: This can be the same as 14 or if different then again - name, address, country, telephone, fax, email and web address

Importer: Who took possession at first point of entry into the EU? - name, address, country, telephone, fax, email and web address

Distributor/Retailer

Distributor/Representative: This may be the same as 16, if different - name, address, country, telephone, fax, email and web address

Supplier/Country of destination: How do consumers get hold of the product – a shop, by mail order, on the Internet? Is the product for the UK market only or will it go further a field in the EU? Again provide the details - name, address, country, telephone, fax, email and web address

Type of risk to consumer: The main risk to consumer for ex. Burns, poisoning, metals transfer, facial injuries, broken bones?

Summary of Test Report: A short paragraph to summarise what is in the report. The test report itself should be attached as a separate PDF or Word document.

Accidents: How many consumers have had an accident and what were their injuries?

Measures Adopted

Voluntary measures: Description of what measures the manufacturer and/or sellers imposed themselves. Include an attachment of any notices that were issued. State the date of the measure and how long this is to last.

Compulsory measures: Description of the measure placed on the seller/manufacturer usually by the competent authority. Again, state the date and duration of measure and attach separately any notices issued.

Other Information

Additional information: This can be where you state what has happened to the product since 22 and 23 above. Has the product been reconfigured and made safe etc. Or anything else you would like the Commission to know which is not been made available in the form above.

Confidential: This is a Y/N answer. Y is usually requested if disclosure of information would undermine court proceedings, monitoring and investigation activities or professional secrecy, unless there were an overriding public interest in disclosure of information to protect the health and safety of consumers. Clearly state what part of the notification above you would like to be kept confidential. Majority of cases are N.

Justification: Why is 22 Y?

Any other information: This can be anything extra you think we would like to know in relation to the product, manufacturer etc. which is for DTI only and will not be forwarded to Commission.

Having completed the form to the best you can, you need to then **email** it with it's attachments to rapex.unit@dti.gsi.gov.uk ensuring you keep a copy for your records, you should also send a copy to LACORS Alison.Edwards@lacors.gov.uk for their information. Try to avoid sending RAPEX notifications in hard copy. **Electronic versions are easier to read, store and process.**

The Commission will be introducing a new RAPEX Application – Gras Platform – sometime in the first half of 2007, which will greatly enhance the way, notifications are processed. We will keep you informed of any changes to the notification forms and guidance.

Notification for Toys

There is a separate form for notifying the Commission via RAPEX about dangerous toys where there has been compulsory measures adopted by Member States (use general notification form where voluntary measures have been adopted). This can be found at Annex VI. The following link <http://www.dti.gov.uk/files/file11286.pdf> at the DTI website has produced Guidance notes on the UK Toys (Safety) Regulations 1995. Please read before completing the form. You will find that the form is slightly different to the normal Rapex notification in that part one concerns the Safeguard Clause Under Article 7 of **DIRECTIVE 88/378/EEC ON TOY SAFETY**.

Part One

Safeguard Procedure

Member States are required, within their own jurisdiction to:
remove from the market toys which do not satisfy the requirements as set out in the Regulations; or,
prevent non-complying toys from being placed on the market.

They must then notify the European Commission of the enforcement action when the non-compliance relates to safety and the toy bears the CE marking. Where the Commission is satisfied that the action is justified it is required to send details of the case to other member States so that they can consider taking similar action (this is the so-called 'safeguard procedure').

The DTI's Consumer Safety Unit is responsible for notifying the Commission of enforcement action taken in the UK based on information received from enforcement authorities. Traders against whom enforcement action has been taken should therefore ensure that the trading standards officers concerned have the fullest information including any statements they wish to make about the case. Such information dispatched from the UK is treated as commercially confidential and clearly marked as being for enforcement purposes only.

The safeguard procedure does not apply in the case of toys which do not bear the CE marking or toys which are second-hand.

Part Two of the form is completed the same as for a normal Rapex notification as listed above.

The information provided should be as complete as possible and should be submitted electronically to the DTI (electronic forms will be available alongside this guidance on TS Interlink and on the DTI website). Gaps in available information should not prevent a notification being made but it should be indicated when the missing information is expected to be available.

The following is an indicative list of the measures and actions which may require a RAPEX notification:

- Imposing conditions prior to the marketing of a product;
- Requiring a product to be marked with warnings concerning any risk;
- Alerting consumers about a risk related to a product;
- Banning temporarily or definitively the supply, offer to supply or the display of a product;
- Organising the withdrawal or the recall of a product;
- Ordering producers and distributors to withdraw a product, recall it from consumers, and destroy it, or agreeing with producers/distributors to do the same;
- Agreeing with producers and distributors to take actions to avoid the risks.

Enforcement authorities should notify all such measures, even if an appeal against them is likely.

Timetable

A RAPEX notification must be communicated to DTI within 10 calendar days of the Local Authority decision to take measures to remove the risk (whether or not this is in agreement with the producer/distributor), or of appropriate voluntary action being taken in agreement with the Local Authority (whichever is sooner).

In the case of notification requiring emergency action from Member States the notification should be made as soon as possible and within 3 calendar days of the measure being adopted.

Other Actions

Enforcement authorities may also inform of the existence of serious risks before deciding to adopt measures or take action, and of serious risks relating to specific batches of products that have been withdrawn from the market or decisions by Customs Authorities to block the import of products presenting a serious risk at the EU border. Such notifications should be made as soon as possible and no later than 10 calendar days after the identification of the risk/event as appropriate.

Reactions

The General Product Safety Directive requires Member States to notify the Commission when they find products on their home market that have been the subject of RAPEX notifications submitted by other Member States. RAPEX notifications are posted on TS

Interlink in the UK (summarized RAPEX alert information is also to be found on the Commission's website - http://europa.eu.int/comm/dgs/health_consumer/dyna/rapex/create_rapex.cfm . On becoming aware of a RAPEX notification (particularly if it indicates that the product was marketed in the UK) local authorities are asked to investigate whether the product is on their local market, and to notify the central DTI contact if it is found. These 'reaction' notifications should be made using the Reaction form provided at Annex III, and should indicate whether the local authority agrees with the original risk assessment and what action it proposes to take to remove the risk.

The Commission requires Member States to submit 'reactions' as soon as possible and in any event no later than 20 calendar days after the RAPEX notification is communicated to the competent authorities (the local authorities) if this relates to a notification requiring emergency action from Member States, or no later than 45 days in respect of a serious risk. Local authorities should aim to comply with these deadlines whenever possible. Additionally, if the product is manufactured in the UK the Home Authority should contact the producer to ensure the problem is resolved at source and submit a reaction within 15 Calendar days.

3. Regulation 33(2) (Non-serious risk) notifications

Where measures are taken to restrict the placing on the market of products, or require their withdrawal or recall, but the risk is not considered to be serious, there is a requirement to notify the measures and the reasons for adopting them to DTI. These notifications should be made using the form provided at Annex II, and within 15 calendar days of taking a decision to adopt such measures.

If the enforcement authority considers that the effects of the risk do not, or cannot, go beyond the UK a notification need not be made, though an authority may still feel that some information on the case would be of value to the Commission and to other Member States. **Notifications made under Regulation 33(2) should be considered as additional to any Safeguard obligations.**

4. Regulation 9 (Producer/Distributor) notifications

This is a new obligation on producers and distributors to notify Local Authorities when they become aware that a product they have placed on the market is unsafe, and it is likely that initially many producers and distributors will be unaware of this obligation.

A separate guide for producers and distributors is being produced for this purpose and will be available on the DTI website at this address:

<http://www.dti.gov.uk/consumers/Safety/products/unsafe-notification/index.html>

Local Authorities are advised to also make this available on their websites.

Who should notify

Producers and distributors should be advised that they are both under an obligation to notify as soon as a safety issue has been identified. However to avoid a proliferation of duplicate notifications distributors should make their concerns known to producers. Where they are both in the UK, discussions should include who is to make the notification. Distributors should however be prepared to notify where they believe a problem exists even if the producer claims otherwise or does not make a notification himself.

In general, it is expected that the local authority first contacted will be the one to assist with and process the notification (ultimately forwarding this, and possibly also a RAPEX notification, on to the DTI central contact), though there will be times when it is sensible for another local authority to do this. In any event the Home Authority should always be informed when another local authority is approached in respect of a Regulation 9 notification (which is more likely to happen with distributors, particularly small retailers).

A notification must be made even if the problem is only thought to exist in another Member State. In such cases, the Local Authority must be informed if a distributor in the other country has also been instructed to make a notification there, and this must be made clear to the DTI when sending the notification on to the national contact point.

It should be made clear to the notifying producer/distributor that the DTI will on their behalf notify the enforcement authorities in all the Member States in which the product has been marketed they will not have to do this (which might seem to be indicated in the Directive). Businesses therefore only have to notify their Local Authority, or VOSA, MHRA etc where these are the most appropriate enforcement authorities for the product concerned.

What information is needed

Local Authorities will probably find that they often have to work with the business to ensure the form at Annex IV is properly completed, before submitting it to the DTI on the business's behalf. The producer/distributor should be strongly encouraged to prepare an electronic notification.

The information provided on the form should include details on the following:

- The enforcement authority receiving the notification;
- The producer/distributor;
- The product involved, including electronic photograph;
- The hazard presented by the product, including risk assessment and any reported accidents;
- The corrective action taken or planned;

- Other companies in the supply chain.

Commission guidance on producer/distributor notifications can be found at - http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidelines_en.htm
These guidelines should be used by enforcement authorities to guide producers and distributors through the notification process.

When an enforcement authority believes that a producer/distributor notification represents a serious risk and requires urgent action it should also submit a RAPEX notification to DTI along with the original producer/distributor notification.

Timetable

Whenever possible, businesses should be reminded that they must inform their local authority of a safety problem without delay. Notifications are required to be made to the national contact point within 10 calendar days of notifiable information becoming available. Sections 1 to 5 of the form should be filled in immediately and Section 6 submitted when the missing information has been collected. A timetable for collecting the missing information should be transmitted at the same time the first notification is made.

5. Notifications concerning chemicals

With a measure notified pursuant to regulation 33(2) or regulation 33(4) in respect of a chemical substance or preparation, the enforcement authority should provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available.

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

6. Decisions to Revoke, Vary or Amend the Measures Adopted

All such decisions must be notified to the national contact point within 5 calendar days.

7. Confidentiality

Confidentiality could be requested if disclosure of information would undermine court proceedings, monitoring and investigation activities or professional secrecy, unless there were an overriding public interest in disclosure of information to protect the health and safety of consumers. Confidentiality can also be required for annexes to the notification, such as legal proceedings, that do not contain information relevant for consumer protection and need to be protected.

8. Products excluded from RAPEX

Certain products are excluded from RAPEX because they are covered by equivalent notification mechanisms, for example pharmaceuticals (covered by Directives 75/319/EC and 81/851/EEC) and food and feed (Regulations EC No. 178/2002). Further information on the relationship between different notification procedures established by Community law can be found in the Commission's "Guidance document on the Relationship between the GPSD and Certain Sectoral Directives" which can be found at: http://europa.eu.int/comm/dgs/health_consumer/dyna/rapex/create_rapex.cfm

ANNEX I - 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 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 hazard¹.

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

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	

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 – RAPEX NOTIFICATION FORM

Regulation 33(2) notification (Article 11 of Directive 2001/95/EC)
Regulation 33(4) RAPEX notification (Article 12 of Directive 2001/95/EC)
Requiring emergency action from Member States

GENERAL INFORMATION

1. Notifying country:	United Kingdom
2. Date sent to DTI:	

PRODUCT

3. Category of product:	
4. Customs code:	
5. Product Name:	
6. Brand:	
7. Price:	
8. Country of origin:	
9. Type/number of model/ Bar Code/Batch Code:	
10. Description of product and packaging:	
11. Photograph of product (Please provide electronically as separate attachment – format. jpg, Max 2MB)	

12. Standards or regulations applicable:	
13. Proof of conformity:	

PRODUCER/EXPORTER/IMPORTER

(The Commission requires that these fields be completed as fully as possible. If at the time of notification you are unable to provide this information then state when you may have this information, or whether you will be unable to provide this information and why?)

14. Name, address and contact information of the manufacturer or its representative:	
15. Name, address and contact information of the exporter:	
16. Name, address and contact information of the importer:	

DISTRIBUTOR AND RETAILER

17. Name, address and contact information of the distributors or their representatives:	
18. Supplier (shop, mail-order, or Internet) and countries of destination:	

DANGER

19. Type of risk:	
20. A Summary of the test results and conclusions are	

required by the Commission: In addition also <u>provide</u> an electronic copy of the test report.	
21. Description of accidents which have occurred:	

MEASURES ADOPTED

22. Voluntary measures: (scope, nature, date of entry into force and duration)	
23. Compulsory measures: (scope, nature, date of entry into force and duration). Please provide a copy of measure electronically if possible	

OTHER INFORMATION

24. Additional information:	
25. Is this information confidential?	
26. Justification of request:	
27. Any other information you may wish to provide in confidence to DTI: (will not be sent to European Commission)	

28. National contact point: (Email notification to): RAPEX.unit@dti.gsi.gov.uk	Miss Yeshim Halil General Product and Services Safety Consumer and Competition Policy Directorate Department of Trade and Industry 1 Victoria Street London SW1H 0ET
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<p>Email notification to LACORS - Alison.Edwards@lacors.gov.uk</p>	<p>Tel: 020 7215 0362 Fax: 020 7215 0357 Email: RAPEX.unit@dti.gsi.gov.uk</p> <p>Alternative contact if above is not available: Michael Porter Tel: 020 7215 6078 Fax: 020 7215 0357</p>
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The details below will not be included on notification sent to European Commission

<p>30. Details of Enforcement Authority:</p>	<p>Authority/Area office:</p> <p>Address:</p> <p>Name of contact:</p> <p>Tel:</p> <p>Fax:</p> <p>Email:</p>
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ANNEX III REACTION NOTIFICATION FORM

REACTION TO NOTIFICATION
(in application of Article 12 of Directive 2001/95/EC)

1. Reacting country:	United Kingdom
2. Date reaction sent to DTI: (Date will differ on Rapex system this will be date information entered by Commission)	
3. Notification number and country:	
4. Name of product:	
5. Product found:	YES/NO
6. Assessment of risk:	
7. Voluntary measures: (scope, nature, date of entry into force and duration)	
8. Compulsory measures: (scope, nature, date of entry into force and duration)	
9. Duration:	
10. Other information:	
11. Any other information you may wish to provide in confidence to DTI: (will not be sent to European Commission)	
12. National contact point: (Email notification to): RAPEX.unit@dti.gsi.gov.uk	Miss Yeshim Halil General Product and Services Safety Consumer and Competition Policy Directorate Department of Trade and Industry 1 Victoria Street London SW1H 0ET Tel: 020 7215 0362

<p>Email notification to LACORS – Alison.Edwards@lacors.gov.uk</p>	<p>Fax: 020 7215 0357 Email: RAPEX.unit@dti.gsi.gov.uk</p> <p>Alternative contact if above is not available: Michael Porter Tel: 020 7215 6078 Fax: 020 7215 0357</p>
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The details below will not be included on notification sent to Commission

<p>13. Details of Enforcement Authority:</p>	<p>Authority/Area office:</p> <p>Address:</p> <p>Name of contact:</p> <p>Tel:</p> <p>Fax:</p> <p>Email:</p>
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ANNEX IV

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 V


Example of how a form should be completed
ANNEX II – NOTIFICATION FORM

- Regulation 33(2) notification (Article 11 of Directive 2001/95/EC)
 X Regulation 33(4) RAPEX notification (Article 12 of Directive 2001/95/EC)
 Requiring emergency action from Member States

GENERAL INFORMATION

1. Notifying country:	United Kingdom
2. Date sent to DTI:	16 th October 2006

PRODUCT

3. Category of product:	Power Tools
4. Customs code:	8467219900
5. Product Name:	Rotary Hammer Drill 1050W
6. Brand:	Performance Power
7. Price:	£39.98/€64.98
8. Country of origin:	China
9. Type/number of model/ Bar Code/Batch Code:	05075294
10. Description of product and packaging:	Rotary Hammer Drill contained in a blow mould case with accessories
11. Photograph of product (Please provide electronically as separate attachment – format. jpg, Max 2MB)	 WFS785 Product Safety Notice.p...

12. Standards or regulations applicable:	The Machinery Directive 98/37/EC The Low Voltage Directive 73/23EC The Electromagnetic Compatibility Directive 89/336/EEC The Waste Electrical and Electronic Equipment Directive 2002/96/EC
13. Proof of conformity:	CE marked

PRODUCER/EXPORTER/IMPORTER

(The Commission requires that these fields be completed as fully as possible. If at the time of notification you are unable to provide this information then state when you may have this information, or whether you will be unable to provide this information and why?)


14. Name, address and contact information of the manufacturer or its representative:	Kingfisher Asia Limited (Vendor GMC, Manufacturer – Jiangsu Golden Harbour Enterprise) 21 st Floor Cornwall House 979 Kings Road TaiKoo Place Quarry Bay Hong Kong Tel: 00 852 2378 1000 Fax: 00 852 2378 1099
15. Name, address and contact information of the exporter:	Kingfisher Asia Limited 21 st Floor Cornwall House 979 Kings Road TaiKoo Place Quarry Bay Hong Kong Tel: 00 852 2378 1000 Fax: 00 852 2378 1099
16. Name, address and contact information of the importer:	B&Q plc Portswood House, 1 Hampshire Corporate Park, Chandlers Ford, Eastleigh, Hampshire SO53 3YX Tel: 02380 256256 Fax: 02380 257480

DISTRIBUTOR AND RETAILER


17. Name, address and contact information of the distributors or their	B&Q plc, Portswood House, 1 Hampshire Corporate Park, Chandlers Ford, Eastleigh, Hampshire SO53 3YX Tel: 02380 256256
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representatives:	Fax: 02380 257480
18. Supplier (shop, mail-order, or Internet) and countries of destination:	B&Q plc Southern Ireland

DANGER

19. Type of risk:	Broken wrist, hand, fingers and/or facial injuries
20. A Summary of the test results and conclusions are required by the Commission: In addition also <u>provide</u> an electronic copy of the test report.	<p>The handle disengaged from the secure mounting on the drill body, rotating rapidly around it. A user would probably be gripping both this handle and the rear handle and would be at risk of injury as the two handles suddenly rotated with considerable force in relationship to each other.</p>  <p>hammer drill test report.pdf</p>
21. Description of accidents which have occurred:	9 recorded incidents on file. Various injuries from broken fingers to facial damage.

MEASURES ADOPTED

22. Voluntary measures: (scope, nature, date of entry into force and duration)	<p>Full product recall published in the national press (copy enclosed previously) with helpline support on 5th October. Featured for one day. All stores have also printed and displayed signs within the store to alert consumers to the recall. These signs will stay up as long as is deemed necessary by local authority.</p>  <p>Drill2.pdf</p>
23. Compulsory measures: (scope, nature, date of entry into force and duration). Please provide a copy of measure electronically if possible	<p>Recall notice is included within this notification. The advert was featured in the press on 5th October. Notices in store are an exact copy of the notice used in the press and are displayed behind the returns desk and service desk. These notices will be left in place for as long as is deemed necessary by the local authority.</p>

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OTHER INFORMATION

24. Additional information:	The product has already been reengineered and the old unit has been removed from the supply chain back in February 2006. The reengineered unit is now on sale with a new bar code allocated.
25. Is this information confidential?	No
26. Justification of request:	
27. Any other information you may wish to provide in confidence to DTI: (will not be sent to European Commission)	

28. National contact point: (Email notification to): RAPEX.unit@dti.gsi.gov.uk	Miss Yeshim Halil General Product and Services Safety Consumer and Competition Policy Directorate Department of Trade and Industry 1 Victoria Street London SW1H 0ET Tel: 020 7215 0362 Fax: 020 7215 0357 Email: RAPEX.unit@dti.gsi.gov.uk Alternative contact if above is not available: Michael Porter Tel: 020 7215 6078 Fax: 020 7215 0357
Email notification to LACORS- Alison.Edwards@lacors.gov.uk	

The details below will not be included on notification sent to European Commission

30. Details of Enforcement Authority:	Authority/Area office: Hampshire County Council. Trading Standards Service.
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	<p>Address: Sun Alliance House 47, Wote Street. Basingstoke. Hants. RG21 7NG.</p> <p>Name of contact: Richard Kerr.</p> <p>Tel:01256 776128.</p> <p>Fax:01256 817220.</p> <p>Email:richard.kerr@hants.gov.uk</p>

Annex VI

TOYS NOTIFICATION FORM

Notification under Article 12 of Directive 2001/95/EC) on General Product Safety and under Article 7 of Directive 88/378/EEC on Safety of Toys.

Notification under Article 12 of Directive 2001/95/EC) on General Product Safety requiring emergency action (from Member States) and under Article 7 of Directive 88/378/EEC on Safety of Toys.

PART 1: SAFEGUARD CLAUSE UNDER ARTICLE 7 OF DIRECTIVE 88/378/EEC ON TOY SAFETY	
Failure to meet essential requirements referred to in Article 3, if the toy does not meet the standards (Article 7 (1) (a):	
Reasons:	
Incorrect application of the standards (Article 7 (1) (b):	
Reasons:	
Shortcomings in the standards (Article 7 (1) (c):	
Reasons:	

PART 2: RAPEX NOTIFICATION

GENERAL INFORMATION

1. Notifying country:	United Kingdom
2. Date sent to DTI:	

PRODUCT

3. Category of product:	Toys
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4. Customs code:	
5. Product Name:	
6. Brand:	
7. Price:	
8. Country of origin:	
9. Type/number of model/ Bar Code/Batch Code:	
10. Description of product and packaging:	
11. Photograph of product (Please provide electronically as separate attachment – format. jpg, Max 2MB)	
12. Standards or regulations applicable:	
13. Proof of conformity:	

PRODUCER/EXPORTER/IMPORTER

(The Commission requires that these fields be completed as fully as possible. If at the time of notification you are unable to provide this information then state when you may have this information, or whether you will be unable to provide this information and why?)

14. Name, address and contact information of the manufacturer or its representative:	
15. Name address and contact information of the exporter:	
16. Name address and contact information of the importer:	

DISTRIBUTOR AND RETAILER

17. Name, address and contact information of the distributors or their representatives:	
18. Supplier (shop, mail-order or Internet) and countries of destination:	

DANGER

19. Type of risk:	
20. A Summary of the test results and conclusions are required by the Commission: In addition also <u>provide</u> an electronic copy of the test report.	
21. Description of accidents which have occurred:	

MEASURES ADOPTED

22. Compulsory measures: (scope, nature, date of entry into force and duration). Please provide a copy of measure electronically if possible	
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OTHER INFORMATION

23. Additional information:	
24. Is this information confidential?	
25. Justification of request:	

26. Any other information you may wish to provide in confidence to DTI: (will not be sent to European Commission)	
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<p>27. National contact point:</p> <p>(Email notification to): RAPEX.unit@dti.gsi.gov.uk</p> <p>Email notification to LACORS- Alison.Edwards@lacors.gov.uk</p>	<p>Miss Yeshim Halil General Product and Services Safety Consumer and Competition Policy Directorate Department of Trade and Industry 1 Victoria Street London SW1H 0ET Tel: 020 7215 0362 Fax: 020 7215 0357 Email: RAPEX.unit@dti.gsi.gov.uk</p> <p>Alternative contact if above is not available:</p> <p>Michael Porter Tel: 020 7215 6078 Fax: 020 7215 0357</p>
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The details below will not be included on notification sent to European Commission

29. Details of Enforcement Authority:	<p>Authority/Area office:</p> <p>Address:</p> <p>Name of contact:</p> <p>Tel:</p> <p>Fax:</p> <p>Email:</p>
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