

**EXPLANATORY MEMORANDUM TO THE
GENERAL PRODUCT SAFETY REGULATIONS 2005**

2005 No. 1803

- 1.1 This explanatory memorandum has been prepared by the Department of Trade and Industry and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and the House of Lords Select Committee on the Merits of Statutory Instruments.

2 Description

- 2.1 The Order is made by the Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs, Gerry Sutcliffe, under the powers conferred on him by section 2(2) of the European Communities Act 1972, and transposes Directive 2001/95/EC on general product safety into UK law.
- 2.2 These Regulations replace the General Product Safety Regulations 1994 (1994/2328) and further strengthen the legislative framework covering consumer product safety. They do this by clarifying, as well as adding to, existing obligations on producers and distributors to place only safe consumer products on the market, and strengthening the powers available to enforcement authorities to police this 'general safety requirement'. Nevertheless voluntary action by producers and distributors is encouraged in preference to formal enforcement action.

3. Matters of special interest to the Joint Committee on Statutory Instruments / House of Lords Select Committee on the Merits of Statutory Instruments

- 3.1 None.

4. Legislative Background

- 4.1 The new Regulations implement Directive 2001/95/EC on general product safety and replace the existing General Product Safety Regulations 1994. A Transposition Note is attached as Annex A
- 4.2 Unlike the 2004 Regulations, the 2005 Regulations include the necessary enforcement provisions and do not rely on those in the Consumer Protection Act 1987 (CPA). We have extended the scope of the Regulations beyond the Directive to include the supply of antiques other than for sale (currently covered by the CPA). This allows us to repeal section 10 of the CPA. The existing product safety regime is therefore clarified and simplified by the introduction of these Regulations.
- 4.3 Most of the changes introduced by the Directive (compared with the previous Directive - 92/59/EEC) are minor in nature or close loopholes and have presented few

difficulties for implementation. However, there have been a number of definitional issues and the requirement for enforcement authorities to have a ‘last resort’ power to order the recall of a dangerous product from consumers was a new departure for the UK. This was seen to cause concern within the business and the enforcement communities during initial consultations. Businesses were concerned that inexperience would lead to over or misuse of this power by the enforcement authorities, and the latter were concerned that they would be exposed to an increasing number of compensation claims. Further consultations with both sides to find a way of implementing this power that satisfied their concerns is the principal reason why we are late in transposing the Directive. The outcome was a Recall Advisory Scheme operated by the Chartered Institute of Arbitrators to give a reasoned opinion on the case for recall where there are differences of opinion between business and the enforcement authorities as to the need for a measure.

5. Extent

- 5.1 This instrument applies to all of the United Kingdom. Although certain niche products that could fall within the scope of the Regulations are included in the exception to the reservation for product safety in the Scotland Act 1998, Scottish Ministers are content for the Regulations to cover Scotland.

6. European Convention on Human Rights

- 6.1 The Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs, Gerry Sutcliffe MP, has made the following statement regarding Human Rights:
- 6.2 “In my view the provisions of the General Product Safety Regulation 2005 are compatible with the Convention rights.”

7. Policy background

- 7.1 The Directive on general product safety should have been transposed into the laws of all member states by 15 January 2004. As noted above we are late, with the main reason being the difficulties raised by stakeholders in respect of the new last resort power to order the recall of products from consumers.
- 7.2 The underlying objective is to keep the UK as one of the safest places in Europe for consumers by ensuring that consumer products placed on the market are safe, and where they are not, that enforcement authorities have the necessary powers to protect consumers from risk. This will be achieved by transposing Directive 2001/95/EC on general product safety (GPSD) into UK law.
- 7.3 The Directive reaffirms that all consumer products placed on the market by producers and distributors must be safe in normal and reasonably foreseeable use. This ‘general safety requirement’ was introduced in the UK by the Consumer Protection Act 1987 (CPA), and in Europe by the 1992 Directive on general product safety (which the 1994 General Product Safety Regulations transposed into UK law). In effect, the 2001 GPSD is an incremental improvement over the 1992 Directive aimed at further harmonising practices and bringing them up to the best.

- 7.4 The GPSD covers the safety of all products used by consumers, including second-hand products and products covered by vertical (sectoral) Community legislation where that does not match the safety objectives or the measures available in the GPSD. In particular, the GPSD introduces new 'last resort' provisions for the mandatory recall of unsafe products where voluntary action taken by producers and distributors has not been sufficient or satisfactory and no other measure can remove the risk to consumers.
- 7.5 In order to make the safety regime as simple to follow as possible, we have included the necessary enforcement provisions in the Regulations. In consequence, the enforcement provisions of the CPA will no longer apply for general product safety purposes.
- 7.6 Bringing the legal requirements as to product safety together in one set of Regulations is in line with the Government's policy on regulatory simplification and provides for a more coherent and consistent product safety regime. To enable this to happen the Regulations have been extended to cover the safety of antiques that are supplied other than for sale, which were covered by the safety provisions of the CPA (though not by the GPSD). This will allow us to repeal section 10 of the CPA.
- 7.7 The prevailing view among enforcement authorities, consumer groups and business is that subjectively the UK does not have a product safety problem and the Commission is thought to regard the UK as one of the safest countries in the EU. However, one response to the consultation warned of "a threat to consumer safety posed by increasing numbers of imports from the Far East."
- 7.8 The consultation on the draft Regulations received around sixty substantive responses, including from businesses representatives, enforcement bodies, consumer groups and law firms. The general view expressed by all groups was that the draft Regulations had effectively addressed the main issues for transposition of the Directive, though a few concerns were raised and there were requests for clarification on particular issues. The Government's response was published on 16 June 2005. As a result of the Consultation the Regulations have been revised, mainly to provide some of the extra clarity requested. The Guidance Notes to accompany these Regulations will provide further help.
- 7.9 The most recent scrutiny history for this Directive saw the DTI submitting an Explanatory Memorandum (6214/01) on 8th March 2001 on an "Amended Proposal for a Directorate of the European Parliament and of the Council on General Product Safety". The Commons European Scrutiny Committee considered it not legally or politically important and cleared it (Report 9, 22143, Sess 00/01). The Lords Select Committee on the EU did not report on it (Progress of Scrutiny, 23/3/01, Sess 00/01). The DTI had previously submitted an EM (8585/00) on 20th June 2000 on a "Proposal for a Directive of the European Parliament and of the Council on General Product Safety". The Commons European Scrutiny Committee considered it politically important and cleared it (Report 30, 21297, Sess 99/00). The Lords Select Committee on the EU cleared it from scrutiny in Sub-Committee D (Progress of Scrutiny, 27/10/00, Sess 99/00).

8. Impact

- 8.1 The new Regulations will place negligible extra burden on UK businesses (estimated at an additional 1 – 3% of the existing compliance cost) as they are generally responsible in their actions towards consumers. And, under the existing 1994 Regulations (which will be repealed) business for the most part already complies with the general safety requirement. A Regulatory Impact Assessment is attached to this memorandum. In cases where business seeks referral of a proposed measure to the Recall Advisory Scheme there will be a cost to that business of around £5.5k.
- 8.2 The impact on the public sector will also be minimal. Any additional burdens on enforcement authorities resulting from the new power to recall will be offset by the benefits resulting from clearer legislation and the emphasis on producers/distributors taking voluntary action as an alternative to formal enforcement activity. The one-off cost of setting up the Recall Advisory Scheme (£3,500) will be met from existing DTI budgets.

9. Contact

- 9.1 Graham Bartlett at the Department of Trade and Industry (Tel: 020 7215 5496 or e-mail: graham.Bartlett@dti.gsi.gov.uk) can answer any queries regarding the instrument.

THE GENERAL PRODUCT SAFETY REGULATIONS 2005

Final Regulatory Impact Assessment

1. POLICY OBJECTIVE

- 1.1 The underlying objective is to keep the UK as one of the safest places in Europe for consumers¹ by ensuring that consumer products placed on the market are safe and, where they are not, that consumers are protected (including, where necessary, by providing that dangerous products can be recalled from consumers). This will be achieved by transposing the General Product Safety Directive 2001/95/EC (GPSD) into national legislation (which the Directive requires us to do) in an effective and proportionate manner.²
- 1.2 The Directive reaffirms that all consumer products placed on the market by producers and distributors must be safe. This '*general safety requirement*' was introduced in the UK by the Consumer Protection Act 1987 (CPA), and in Europe by the 1992 Directive on product safety³. In effect the 2001 GPSD is an incremental improvement over the 1992 Directive aimed at further harmonising practices and bringing them up to the best. With guaranteed free circulation of products in an enlarged European Union, common standards of safety are an important factor for consumer confidence and competition.
- 1.3 The GPSD covers the safety of all products used by consumers, including second-hand products and products covered by vertical (sectoral) Community legislation where that legislation does not cover the same aspects of safety or have safety provisions with the same objective as the Directive. In particular the GPSD introduces new last-resort provisions for the mandatory recall of unsafe products where the voluntary action taken by producers and distributors has not been satisfactory or sufficient and where no other measure can remove the risk to consumers.
- 1.4 In order to make the safety regime as simple to follow as possible, we have included separate enforcement provisions in the Regulations. In consequence the enforcement provisions of the CPA will no longer apply for general product safety purposes.
- 1.5 Bringing all product safety issues together under one set of Regulations is in line with the government's policy on regulatory simplification and provides for a more coherent and consistent product safety regime. We are, therefore, in part extending the implementing Regulations to cover the safety of antiques that are supplied other than for sale. As these products are currently covered by the CPA this does not represent an extension to the UK product safety regime, but taking this action will allow us to repeal Section 10 of the CPA, which will serve no further purpose. The proposal to do this has been welcomed by businesses and enforcement authorities.
- 1.6 The proposed legislation will place little additional burden on businesses (record keeping, notification and co-operation) as products placed on the market by producers and distributors are already required to be safe and for the most part comply with this general safety requirement. Where products do not meet this requirement (ie they are not a safe product⁴), and the degree of risk to consumers merits it, business will generally take steps voluntarily to recall the products. Nevertheless, the new Regulations set out clearly the obligations on producers and distributors, what they can expect if they avoid these obligations, and what steps may be taken by the competent authorities to enforce the protection of consumers.
- 1.7 What few additional requirements there are in the Regulations are more than compensated for by increased benefits to the consumer in terms of product safety and transparency, greater clarity for producers, distributors and enforcement authorities, and fairer competition.

¹ A 2001 report produced by the European Consumer Safety Association (ECOSA) on Priorities for Consumer Safety in the European Union found that the UK had the lowest annual rate of home and leisure fatalities in the EU.

² Regulations made under Section 2.2 of the European Communities Act 1972

³ Directive 92/59/EEC

⁴ Safe product is defined in Article 2(b) of the GPSD and in Regulation 2 of the Regulations.

1.8 The principal enforcement authorities for product safety are local authority trading standards departments in England, Scotland and Wales and District Council Environmental Health Officers in Northern Ireland.

2. DEVOLUTION

2.1 The Regulations will apply to England, Wales, Scotland and Northern Ireland.

3. BACKGROUND

3.1 The revised text of the GPSD was negotiated in 2000-2001 and was adopted by the European Parliament and Council in December 2001. It builds on the previous Directive⁵ with the aim of improving the already high level of safety protection afforded consumers in respect of products placed on the market.

3.2 Most of the changes under the revised GPSD focus on scope and on tackling product safety problems that come to light after products are placed on the market.

3.3 Specifically, the implementing Regulations will introduce new provisions in the following areas:

- Extended coverage to include:

Products used by consumers in the course of a service;

Products intended for professionals but which migrate to the consumer market; and

In respect of products for which there are specific safety requirements imposed by vertical Community legislation, those aspects of safety and measures covered by the GPSD but not covered by the vertical legislation. For example the GPSD provides the possibility to order the recall of dangerous toys, the safety of which is otherwise covered by the Toy Safety Directive.

- Assessment of whether a product is safe

In considering whether a product is safe, that assessment will consider the normal or reasonably foreseeable conditions of use of the product and, where applicable, take into account the putting into service or installation of a product and its maintenance needs. While The Regulations do not apply to the safety of services, the safety of some products (eg certain machinery and gas appliances etc) is dependent on their putting into service, installation and maintenance and as such is an essential part of the contract to supply the product. Such activities will be taken into account when judging whether the product is a safe product.

- Voluntary European standards

The Directive introduces a new class of European standard. Products complying with such standards will be deemed to have satisfied the general safety requirement with respect to the safety aspects covered by the standard, unless there is evidence that despite such conformity the product is nevertheless dangerous.

- Product recall

⁵ The first General Product Safety Directive (GPSD) (92/59/EEC) was adopted in 1992, and was transposed in the UK through the General Product Safety Regulations 1994 (SI 1994 No. 2328) (the GPSR 1994). The GPSD introduced a framework for consumer product safety regulation in EU Member States by requiring that all consumer products placed on the market must be safe (the “general safety requirement”). It also placed certain obligations on the producers and distributors of consumer products, and provided for powers to be placed on the enforcement authorities to support and enforce the requirements. As the GPSD broadly mirrored the scope of the CPA, the GPSR 1994 simply ‘plugged’ into the enforcement provisions of the CPA.

The Regulations introduce the explicit obligation for producers to act to resolve the risks to consumers posed by their products. They may take these measures voluntarily or, if they fail to do so, they can be ordered to undertake a recall. Enforcement authorities will also acquire powers to coordinate or organise a product recall when necessary.

- Retention of documentation

Distributors will be required to keep and provide documentation to help trace the origin of products in the event of a safety problem and producers will be required to keep a register of safety complaints, where necessary.

- Notification of unsafe products placed on the market

Producers and distributors will be required to notify the enforcement authorities where they discover that they have put an unsafe product on the market, and also notify the action taken to counter the risk to consumers.

- Co-operation to reduce risks to consumers

Producers and distributors will also be required to co-operate with the enforcement authorities on action to prevent risk to consumers.

- Banning of exportation of dangerous goods

The export from the Community of dangerous products, which have been the subject of an Emergency Decision at Community level, will be banned – unless the Decision provides otherwise.

- 3.4 The following assessments are a general overview of the implications of the draft Regulations and take account of the responses to the public consultation. The risks, costs and benefits of specific changes will be addressed within the sections dealing with those changes.

4. RISKS ADDRESSED

- 4.1 The prevailing view among enforcement authorities, consumer groups and business is that subjectively the UK does not have a product safety problem and, anecdotally, the European Commission regards the UK as one of the safest countries in the EU. Consultation responses nevertheless warned of the threat to consumer safety posed by increasing numbers of imports from the Far East.
- 4.2 The UK's reputation for safe consumer products was forged due to the initial effectiveness of the Consumer Protection Act 1987 and the UK's implementation of the 1992 GPSD, which introduced an effective framework for product safety in Europe. However, the range of vertical European safety legislation introduced piece-meal over several years has led to differences in the level of protection that consumers might expect from product to product and variations in the available measures to enforce product safety. This has resulted in some uncertainty and a lack of clarity, a view that was echoed in consultation responses. The revised Directive fills these gaps creating a coherent safety regime for all consumer products.
- 4.3 Since the new Directive goes further than existing UK legislation, doing nothing is not an option. Moreover, the Directive requires that its provisions are transposed into the national legislation of all member states. Failure to transpose invites infraction proceedings before the ECJ.

- 4.4 A study undertaken by Nottingham University funded by the DTI showed that in 1999 product fault was involved in 2.8% of fatalities in the UK, 1.4% of serious injuries and 1.3% of non-serious injuries. However, in most cases the product fault was due to the article not having been serviced or maintained incorrectly. By comparison, behaviour was involved in 25.1% of fatalities, 35.1% of serious injuries and 44.8% of non-serious injuries. Home and Leisure Accident Surveillance System Statistics for the same period show that there were 5.9m accidents requiring a hospital visit and that 3974 people died as a result of an accident in the home.
- 4.5 Around 1 million producers and distributors of consumer products in the UK will be affected by the Regulations (as they currently are by the 1994 Regulations) of which over 90% are SMEs who employ around 35% of the total workforce for the sectors concerned.
- 4.6 DTI Reports on Consumer Safety record that in the period from 3 October 1994, when the 1994 Regulations came into effect and 31 March 1998⁶ there were 124 prosecutions made under the Regulations while in the period from 1 April 1998 to 31 March 2003⁷ there were 105 prosecutions. However, data in later years is known to be unreliable as there were many gaps in returns received from Trading Standards Departments. But importantly not all enforcement action results in prosecutions, and under the National Performance Framework for Trading Standards Departments launched in 2002 there has been increased emphasis on education to ensure a fair and safe trading environment which is reflected by the GPSD.

5. BENEFITS

- 5.1 The encouragement of voluntary action, as an alternative to formal enforcement activity, is a welcome feature of the Directive that fits with the general policy approach adopted by the National Performance Framework for Trading Standards Departments. When enforcement is considered necessary lesser Requirements to Warn or Mark will be available to the authorities alongside the power to suspend a product temporarily from the market while safety checks are undertaken and greater powers to order the permanent withdrawal of a product and, potentially its recall from consumers, where there is evidence that the product is dangerous.

6. COSTS

- 6.1 Businesses that already adopt good practice and trade in a responsible manner will face no significant mandatory new costs under the Regulations. Where compliance costs are met these will mostly serve the purpose of also addressing non-compliance with other legal requirements (e.g. the current General Product Safety Regulations 1994, Inland Revenue information requirements etc). As if to support this view, one consultation response suggested that variable levels of enforcement activity had resulted in significant non-compliance with the 1994 Regulations and that more rigorous enforcement under the new Regulations could lead to some businesses incurring catch-up costs, though we felt that this comment over-stated the level of non-compliance. The additional cost to business of compliance as a direct result of implementation of the 2001 Directive is therefore negligible, other than in relation to the extra precautions that producers of professional products might want to take where their use by ordinary consumers is foreseeable.
- 6.2 The GPSD's main impact on costs will be seen when an unsafe product is placed on the market (and will be little different from the situation that exists under the current 1994 Regulations). Assuming that the producer does not hide from his responsibility these costs will largely exist whether or not enforcement action has been taken and will result from increased reporting requirements and taking whatever action is necessary to remove the risk from the consumer. In some cases a product redesign could also be necessary in order to resolve the safety problem or regain market acceptance; inevitably an unsafe product is at risk of losing sales, generating negative publicity and damaging consumer confidence. But these are consequential commercial costs. It is against the background of limiting such damage that many producers act early and voluntarily to protect brand image. We guesstimate that the additional cost to business of compliance where unsafe products are placed on the market resulting from implementation of the Directive will be minimal and no more than an additional 1

⁶ DTI Report on Consumer Safety 1 April 1994 to 31 March 1998

⁷ DTI Report on Consumer Safety 1 April 1998 to 31 March 2003

- 3% of the current compliance cost. Nothing in the consultation responses has caused us to reconsider this assumption. The UK has been found to be one of the safest places in Europe for consumers and this suggests that compliance with safety legislation is already high. Underpinning that is the requirement that all products supplied or placed on the market must be safe. This general safety requirement and its enforcement significantly pre-dates any European safety legislation.

6.3 The presumption before the final public consultation had been that the resource implication for local authorities would be broadly neutral in overall terms. We had taken the view that in many cases increased activity aimed at education and encouragement of voluntary action (which is already happening under the National Framework) would be offset by a consequent reduction in formal enforcement activity. We also felt that recourse to the new recall power would not be an every-day occurrence. We still largely hold to these views, but we have had to reflect on feedback received from both the Trading Standards Institute (TSI) and the Local Authorities Coordinators of Regulatory Services (LACORS).

6.4 In responding to the first consultation TSI estimated that enforcement authorities collectively would incur implementation costs in respect of training and preparation for legislative change in the region of £60k. In contrast, a more recent LACORS estimate indicated possible enforcement costs for a single 'worst-case' recall of £60k, and £1.7m for network training.

6.5 We believe that the TSI estimate is about right and appears to see training being absorbed fairly seamlessly into existing training provisions. The LACORS estimate, on the other hand, incorporates some exceptional costings that suggest that every Trading Standards Officer would need three days training on the new Regulations (which are not radically different from the 1994 version) and gives no consideration of the economies of scale that would derive from regional specialisation and shared training. Also, it is not understood why LACORS feel that eight hundred enforcement officers should each incur a further £5k in costs advising new businesses (in accordance with the Home Authority Principle). The existing advisory role they undertake should embrace a wide range of legal requirements and advising on the obligations that business have under the GPSD and the implementing regulations should not be seen as an additional task.

6.6 With regard to LACORS' estimate of costs for a "worst case" recall that a TSD may have to undertake itself, we agree that there are cost implications. But where a recall notice is served and the person on whom it is served refuses to act, the TSD may recover its costs from that person through the courts. Consequently the "worst case" scenario (where there is no producer or distributor on whom to serve a notice and the TSD has to stand the costs itself) is likely to exist only rarely, and then a range of options as to how to give effect to the recall are available that could help mitigate the cost implications of having to act.

6.7 Many responding to the consultation felt there would be additional burdens on enforcement authorities and stressed the importance of ensuring they were adequately resourced. We felt, however, that these views focussed only on enforcement without also taking into account the balancing impact that clearer legislation, the emphasis on voluntary action, and local awareness raising would have on reducing the non-compliance that leads to formal enforcement.

7. OPTIONS FOR TRANSPOSING THE NEW PRODUCT RECALL PROVISION

7.1 As the revised GPSD requires its transposition into national law we have no option other than to implement the changes it introduces and to do so through legislation.

- 7.2 Producers are obliged by the Directive to take measures enabling them to be informed of the risks posed by their products and to take appropriate action to avoid those risks (including recalling a product from consumers). The Department fully recognises that where recall is appropriate producers are generally swift to remove the product from consumers. Nevertheless, the introduction of this power has been the most controversial part of the transposition process, with business concerned that enforcement authorities lack experience in recall and that there could be over or misuse of the power.
- 7.3 We believe, however, that these concerns are largely unfounded. The Directive does after all require enforcement authorities to seek a resolution to the safety problem through voluntary action by the producer in the first instance. Even so, we presented four options for implementation in the proposals, which in different ways sought to allay business fears and provide a safeguard.

Risks Addressed

- 7.4 Research undertaken on behalf of the DTI in 2000 found that during the period 1990 to 1996 there were an average of 42 consumer product recalls per annum in respect of unsafe products (excluding food, pharmaceutical and automotive goods). Nearly half the items concerned were electrical goods (47%) followed by non-electrical toys (17%), childcare items (7%) and clothing (7%).
- 7.5 The main cause of recalls (46%) was a potential electrical fault including overheating, fire or electric shock. Choking by children (15%) was the next largest risk category. 59% of the recalls resulted from poor design and 32% from manufacturing process problems. 66% of recalls were initiated by the manufacturer/importer and 71% by consumer complaints. 35% were triggered by accidents to consumers, half of which involved just one single accident. The average cost of the recalls studied was found to be £39k. Despite these findings, one response to the consultation suggested that the cost of advertising alone for a recall could theoretically reach £100k. We felt, however, that this estimate probably reflected a very unlikely scenario involving an unrepresentatively large range of media.
- 7.6 Another response indicated that recall press notices had doubled in the last ten years. This reflects consumer expectations and the lengths that producers are prepared to go to protect brand image. Many of these voluntary recalls are in response to defects rather than safety problems such as would warrant a recall under the Regulations. There is no reason to believe that the business will not continue as now to voluntarily recall products to protect brand image. There is every reason to believe that the possibility of mandatory recall will increase further the spread of voluntary action.
- 7.7 Additional research among trading standards officers and organisations such as the Royal Society for the Prevention of Accidents (RoSPA) and Institute of Trading Standards Associations (ITSA - now TSI) undertaken at the time of the DTI study suggested that on average 35 products were placed on the market each year which were unsafe to the extent that a recall would have been appropriate. These represented 1.5million individual products that reached consumers, less than 0.1% of a total 2-2.5 billion similar products that were safe. The best estimate was that these unsafe products could be responsible for 94 serious fires, 7 fatal injuries and 121 serious injuries. On the basis of the figures in the study, the cost of recalling these products could result in additional costs to business of £1.4m a year spread across all consumer products and all producers and distributors.
- 7.8 Since there is no suggestion that responsible producers or distributors are shirking their responsibilities to consumers the introduction of the new power will focus attention where recall should have occurred but has not. The very fact that new powers to order recall are being introduced and enforcement authorities will be encouraging voluntary action should have the effect of reducing the cases where recall doesn't happen as a matter of course. Consequently there should be few occasions where it will be necessary for an enforcement authority to actually order a recall. Nevertheless, the last resort power is important to fill in

where action taken by the producer or distributor is insufficient or unsatisfactory and to ensure that action is taken where a producer or distributor is absent, is unable or remains unwilling to act. To transpose this new requirement there is no alternative other than to provide for recall in the Regulations.

- 7.9 Currently, enforcement authorities are empowered to require producers to suspend or remove dangerous products from the distribution chain and prosecute for placing unsafe products on the market. However, they cannot require producers to recall dangerous products that have already been supplied to consumers. The new power to order, coordinate or organise recall when necessary will act as an incentive to businesses who might duck their responsibility to consumers to recall voluntarily and, in a small number of remaining cases enhance enforcement authorities ability to protect consumer safety.

Options Considered Benefits and Costs

- 7.10 Our goal was to identify an option for transposing the recall requirement that left the power to recall responsive to need, that was proportionate to the risks perceived but which also addressed business concerns. The following four options were considered.

Option 1: Make no special provisions (let TSOs decide);

Option 2: Create a national decision-making body;

Option 3: Establish an advisory process;

Option 4: Make recall subject to an application to Court for an Order.

Option 1:

- 7.11 Given local authorities' statutory duty to act to protect the interests of the persons in their area, this would be the most straightforward option. The main benefit would be the speed with which a recall notice could be issued and acted upon, and consumer safety restored. It would avoid many of the delays one might face using a mechanism that involved third parties. But leaving this level of power in the hands of enforcement authorities would do nothing to allay business fears which, if well founded, would inevitably result in appeals to the courts entailing significant additional financial burden to businesses and to the enforcement authorities alike and significant delays.
- 7.12 This option would mean that the cost to the enforcement authority would be subsumed within the general costs of enforcing product safety to which Central Government makes a contribution, and place no additional burden on businesses (separate from the cost of undertaking the recall and making any appeal).
- 7.13 Only one consultation respondent gave this option any support, feeling that leaving decisions to the enforcement authorities would result in low costs and would still allow appeals to go to court. This is LACORS preferred option too.

Option 2:

- 7.14 Creating a national decision-making body could provide for consistent and binding decisions and address business concerns over the possible misuse of recall powers. But setting up and maintaining what would be an executive agency established by statute with its own staff and budgets would weigh heavy on the public purse, and on this point alone would be hard to justify given the likely infrequent need for recall action even though there would be some offsetting savings in local authority enforcement budgets. Appeal would remain through the courts so would take time and be costly for both sides. Moreover, in view of the Hampton recommendation of reducing the no of enforcement authorities from 31 to 7, setting up a new one appears now to be an even less viable option
- 7.15 The option of setting up a Tribunal was also considered and rejected on policy grounds. Tribunals are principally geared to settling disputes between individuals and the state as an alternative to a formal court process. As a consequence the Department of Constitutional Affairs were unconvinced that a Tribunal was appropriate to these circumstances and advised

that this option would not in any case be responsive to the needs of individual product safety cases where a relatively quick view needs to be taken whether to recall or not.

7.16 There was virtually no comment on this option in consultation responses

Option 3:

- 7.17 An advice-based mechanism could be more easily and cheaply developed and administered than a national decision-making body, and could also (depending on the model) be more appropriate to the perceived infrequent need for action. Such a mechanism would not generate binding decisions, but would provide a lower-cost and less formal steer on the appropriateness of recall action.
- 7.18 The option of an advisory Non-Departmental Public Body (NDPB) was considered but it was felt that infrequent use would make it difficult to convene sufficiently quickly. It was considered unlikely that appointees would be able to drop everything at a moments notice and it was perceived that the infrequent need for meetings would lead to the appointees losing interest. These issues would lead to problems establishing a quorum. Thus there would be a frequent and on-going requirement to re-populate the body in accordance with the Guidance issued by the Office of the Commissioner for Public Appointments which would give rise to concerns about the consistency of advice offered and concerns about the administrative burden of maintaining an NDPB for this specific purpose. There would also be a small impact on the public purse in terms of the provision of secretariat and meeting facilities (estimated total cost £8k – 12k pa) and a much larger one in respect of the retainer fee for the Chairman of the body (estimated at £20k - £40k pa). The cumulative impact of these considerations led the Department to take the view that an NDPB was not an appropriate or cost-effective vehicle for taking a view on product recall cases, especially in the light of the alternative set out below. There were no substantive comments from the consultation, either supporting or disagreeing with this view.
- 7.19 Discussions with the Chartered Institute of Arbitrators (CI Arb) identified a strong case for developing a bespoke form of Early Neutral Evaluation (ENE) that would deliver a reasoned opinion by a former member of the judiciary on a recall case based on the evidence presented by the parties. The benefits were an independent if non-binding review of the facts, relative speed and simplicity (needing no more than 2-4 weeks per case) and the scheme's adaptability to ad hoc and infrequent need.
- 7.20 This approach would leave open the option of post-opinion negotiation between enforcement authority and producer and have the virtue of being available on demand rather than being a mandatory step. Overall, this approach would make for more solidly founded enforcement authority decisions, and would do more than any of the other options to encourage voluntary action, which underpins the Directive.
- 7.21 The scheme can be set up with a one-off public sector outlay of £3,500 + VAT to establish the scheme parameters and produce the detailed rules for its use, and will be cheap to use. The cost of the whole process once instigated is estimated to be a maximum of £5,500 in each case. This cost should, we believe, fall to the party seeking use of the advisory scheme to avoid its casual use. While the advice would be non-binding it would be taken into account by the enforcement authority because the outcome would inevitably have an influence on any subsequent appeal. This goes a long way toward meeting the business concern to prevent over or misuse of recall powers.
- 7.22 On the whole, businesses and enforcement authorities generally agreed with our assessment of this option, though there were a number of comments worth noting. For example, one industry association, in coming to the view that costs to producers using this system could run into five figures, mistakenly believed that other parties' experts (e.g. Evaluator's and enforcement authority's) would also have to be paid for. Another suggested that this option was weakened by not delivering a binding decision. A small number of responses expressed concern that the process might delay the taking of urgent action. While acknowledging that a small delay would be created by instigating this service, we nevertheless feel that the sixteen days or so it will take to complete the process strikes a sensible balance between taking knee-jerk action in the face of serious risk to consumers and being reasonably sure that the action proposed is proportionate to the risk.

7.23 One aspect of this option that attracted widespread comment was the instigating party paying for the cost of the evaluation regardless of which side was most favoured by the Evaluator's advice. We feel, however, that this is not unreasonable as the purpose of the process is to provide advice for those who ask for it; the Evaluator does not deliver a winner/loser decision.

7.24 There was a general call for clearer guidance on the process, which we will produce.

Option 4:

7.25 Making recalls subject to court order would have the benefit of being a decision-making process, and would offer business re-assurance on the proper and proportionate use of these powers. However, every case would have to go to court and there would be a delay as an application worked its way through the system (six months is not unheard of), and the court's decision could still be appealed. It is not inconceivable that different courts would come to different decisions on recall so in addition the risk of inconsistent application persists with this option.

7.26 However, given that seeking a court order is a serious step there would be a safeguard against speculative action.

7.27 Application for a court order would entail a cost for the enforcement authority on every occasion, and for both parties in some cases. Further costs would accrue (for either or both parties) from any appeal.

7.28 This option was favoured by some enforcement authorities, principally because it would produce binding decisions from the outset and because they so it avoiding the delay in taking urgent action that the advisory service might introduce. However, the latter view ignores the fact that these Regulations will provide the right to apply to have a recall notice set aside pending appeal, which is a right that is likely to be used more often if producers do not have recourse to the advisory service.

Stakeholder Impact

7.29 The new obligation to be in a position to recall a dangerous product may have a greater impact on small business producers than larger producers, in that the former are less likely to have significant reserves for contingency planning. However, the European Guide to Corrective Actions Including Recall, which was part funded by the DTI, is a useful resource document especially for small businesses. A copy of the Guide can be found in the Consumer & Competition Policy section on the DTI web site⁸.

7.30 Theoretically, it is possible to insure against the cost of undertaking a product recall and any loss of profits related to it, and in some cases this insurance may already be available under an existing business catastrophe or disaster policy. However, recall insurance is a niche product as the risk is considered quite remote and relatively small in financial terms, so neither business nor the insurance industry appears very interested in it. Nothing in the consultation responses substantively challenged this view.

7.31 Overall, the majority of responses to the public consultation tend to agree that the DTI's proposals would implement this obligation in a proportionate and workable way, would help to prevent frivolous cases being made and would minimise unnecessary new burdens on businesses, including small business.

Enforcement

7.32 Enforcement will be conducted in the main by local authority Trading Standards Officers in England, Scotland and Wales and Environmental Health Officers in Northern Ireland.

Recommendation

⁸ <http://www.dti.gov.uk/ccp/topics1/safety.htm#gpsr>

- 7.33 Option 1 offers the simplest solution but would not have offered business any safeguard against the issuing of inappropriate recall notices. The Option 2 national decision-making body was initially favoured by business, but an executive agency would be too costly to set up and maintain, particularly given that it would be called upon only very rarely. Few chose to comment on these two options in the consultation.
- 7.34 On balance, the Department and the stakeholders consulted preferred the flexibility and lower-cost of the Option 3 ad hoc advisory scheme operated by the CI Arb over the inflexibility and anticipated higher costs of court orders in Option 4.

8. OTHER CHANGES INTRODUCED BY THE GPSD

8.1 The other changes introduced by the GPSD (listed below) concern extension to the scope of the existing safety regime and the additional responsibilities it places upon suppliers and distributors. These changes do not lend themselves to the usual approach of assessing different ways of implementing each requirement. We have therefore sought only to highlight the risks, benefits and costs of each.

8.2 The changes analysed are:

- Changes to scope (section 9)
- Installation, Commissioning and Maintenance (section 10)
- Use of voluntary standards (section 11)
- Obligation on distributors to keep and provide documentation to help trace the origin of products in the event of a safety problem (section 12)
- Obligation on producers and distributors to notify dangerous products, and to co-operate with the authorities (section 13)
- Requirement to Mark and Requirement to Warn (section 14)
- Withdrawal Notices (Section 15)
- Community Decisions and the export ban (section 16)

9. CHANGES TO SCOPE

9.1 Certain changes in the revised GPSD effectively extend its scope over the original Directive, and these are described below. In addition to these changes, the new Regulations will also embrace a further extension by covering antiques that are supplied other than for sale. Although not covered in the GPSD, these products have until now been covered in the CPA because otherwise the lack of a clear definition of an antique would have made it all too easy for producers and distributors to inappropriately describe certain products as antiques and thereby sidestep safety legislation. By taking these products into the draft Regulations the safety regime is simplified, and without additional cost to business.

Link with Vertical Directives

9.2 The Directive introduces a clearer linkage with the sectoral directives so as to fill the gaps in their safety cover, thereby ensuring that all products are broadly subject to a consistent and coherent safety regime (the so-called “borderlines” issues).

Risks Addressed

9.3 At present there are gaps in the risks covered by the GPSD that affect the safety of consumer products. This means that the level of protection afforded a consumer in respect of one product may be different to the next. Accident and prosecution data does not differentiate between products covered by the vertical directives and the GPSD.

Options

9.4 The Directive states that the terms of the GPSD shall apply to a product covered by a vertical Directive where the safety cover afforded by that Directive is seen to be deficient in comparison with the GPSD. We do not view non-implementation with the attendant risk of infraction procedures as being a viable option.

Benefits

- 9.5 The benefits of the change cannot be quantified. Generally, we believe there is already a high degree of protection for consumers from unsafe products, especially in the UK where producers tend to act voluntarily to resolve problems when they materialise and without any involvement from the enforcement authorities. However, more clarity on the scope of the safety regime will inevitably result in more coherence, which should be to the general benefit of enforcers and consumers alike and thus result potentially in some long-term reduction in death and injury. There should also be some ongoing savings for all stakeholders arising from the clearer legal environment, and possibly some indirect benefits such as making life more difficult for rogue traders and increasing consumer confidence.
- 9.6 Business, consumers and enforcers generally welcome the revised Directive's linkages with the sectoral directives, but some stressed the need for clear guidance to reduce the level of confusion caused by the spread of vertical product safety legislation. The Commission has published generic guidance on this based on an analysis of four sectoral Directives and the GPSD. This document is publicly available on the DG Sanco website⁹. A second part to this guidance addressing interaction with a further five vertical Directives is currently being drafted and should be available before the end of the year.

Costs

- 9.7 It is impossible to make a quantitative assessment of the costs of these changes to the scope of the legislation. However, given that most products are already safe in normal or reasonably foreseeable use the resulting compliance costs will be negligible. It is important to recognise that the Regulations will only 'bite' significantly where products placed on the market are unsafe. Even if the Regulations only result in one less serious injury or death this will have a positive impact on the emergency and National Health Services.

Stakeholder Impact

- 9.8 There may be several grey areas that will have to be resolved as they occur before the European Commission complete its guidance on the relationship between the GPSD and all the sectoral directives. This will have an impact on all concerned. Generally however the outcome should be improved consumer protection where there is no general safety requirement or where the measures available under the GPSD are more expansive than under the vertical Directive. This could well result in some additional burden on business (depending on the product and the nature of the vertical legislation) but only where it has compromised the safety of its products.

Enforcement

- 9.9 Compliance with these provisions will be enforced, in the main, by local authority trading standards officers (TSOs) in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland.

Product Migration

- 9.10 Under the Directive safety cover extends specifically to professional products that migrate to the general consumer market.

Risk Addressed

- 9.11 There is no data on the migration of products to the consumer market intended for the professional market. However, anecdotally, this is increasing encouraged by DIY television shows and the availability of specialised equipment through tool hire shops.

Options

⁹ http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf

- 9.12 The GPSD requires that a consumer enjoys the same degree of safety when supplied with (for personal use) a product that was designed specifically for professional use as he would when being supplied with a product intended for the consumer market. Migration does not necessarily make a product unsafe and the Directive does not provide for migration to be proscribed. Importantly, the safety of such products may already be covered by a vertical directive (e.g., the Machinery Directive) and the GPSD only applies once it has migrated to the consumer market. The same product's professional use is not regulated by the GPSD. In practice this falls to Health and Safety at Work legislation. We do not view non-implementation with the attendant risk of infraction procedures as being a viable option.

Benefits

- 9.13 The new provisions covering products migrating from the professional market may result in better control being exercised over products intended solely for the professional market (and which would not be regarded as safe for use by ordinary consumers) by their suppliers. Increased use of labelling such as "for professional use only" and improved warnings and instructions about the safe use of such products where their use by an ordinary consumer is reasonably foreseeable are also likely. Such markings should provide an unambiguous guide for the enforcement authorities about whether a product is intended for professional use or consumer use, and whether the risks to consumers are sufficiently covered such that it might nevertheless be regarded as meeting the general safety requirement.

Costs

- 9.14 We asked business through the consultation to provide an estimate of the cost of implementing this new provision but received little or no information in return. Without such information it is impossible to make a quantitative assessment of the possible burden. . Business may have to bear extra costs exercising control over the products in the market place and the cost of additional warnings etc on the product and its packaging where consumer use is 'reasonably' foreseeable. A small number of consultation respondents suggested that this would be so. It is important to recognise that migration does not automatically mean that a product is unsafe. The Regulations will only 'bite' where the risk that the product poses to a consumer is such that the enforcement authorities deem that it cannot meet the general safety requirement. Even if the Regulations only result in one less serious injury or death this will have a positive impact on the emergency and National Health Services.

Stakeholder Impact

- 9.15 Although business feels that the market does not split neatly between consumers and professionals, there is broad support on all sides for measures that have the capability to restrict (where necessary) the supply to consumers of professional products that could be dangerous in non-professional hands (e.g. top handled chain saws).

Enforcement

- 9.16 Compliance with these provisions will be enforced, in the main, by local authority trading standards officers (TSOs) in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland.

Products Used in the Course of a Service

- 9.17 The revised legislation explicitly covers products supplied for consumers for their own use in the course of the delivery of a service, thus extending the protection available to consumers from unsafe products that they have not purchased or hired but which are nevertheless made available to them for personal use on a temporary basis (e.g. a hotel hair-dryer).

Risks Addressed

- 9.18 This provision addresses a gap in the safety afforded consumers by existing product safety legislation. However in the main we expect that the majority of products that are made available for the use of consumers in this way will also be generally available to them for sale and hence covered anyway. The additional risk is therefore likely to be marginal unless the product is specialised.

Options

- 9.19 The GPSD requires that the consumer is offered the same safety cover in respect of a product provided for his use in the course of supplying a service as he would if the product was supplied in any other conventional manner, eg for purchase or hire. We do not view non-implementation with the attendant risk of infraction procedures as being a viable option.

Benefits

- 9.20 Due to the marginal nature of the risk from products not already covered by existing legislation, the benefits of the change cannot be quantified. Generally, we believe there is already a high degree of protection for consumers from unsafe products in the UK, where producers tend to act voluntarily to resolve problems when they materialise and without any involvement from the enforcement authorities. However, broadening the safety regime in this way should inevitably result in more coherence, which should be to the general benefit of enforcers and consumers alike.

Costs

- 9.21 It is impossible to make a quantitative assessment of the costs of these marginal changes to the scope of the legislation. One consumer group did comment that many such products (particularly in hotels) are not made available to the consumer with accompanying instructions, which would entail some additional costs to put right. But the reality is that many such products are in fact every day items with which the consumer is totally familiar, and are already safe in normal or reasonably foreseeable use. In other instances it may be a specialised piece of equipment used in the delivery of a service where the consumer ordinarily obtains a detailed briefing on its proper and safe use. The need to make provision for additional instructions in these instances should not be over-stated and any resulting compliance costs will be small. It is important to recognise that the Regulations will only really 'bite' where products provided to consumers for their use are unsafe. Even if the Regulations only result in one less serious injury or death this will have a positive impact on the emergency and National Health Services.

Stakeholder impact

- 9.22 Stakeholders generally appreciate this extension to the scope of the safety legislation. The changes will impact most on producers and distributors who place unsafe products on the market and who then fail adequately to deal with the problems voluntarily.

Enforcement

- 9.23 Compliance with the Regulations will continue to be enforced, in the main, by local authority trading standards officers (TSOs) in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland. However, with regards to products made available for the use of consumers in the course of a service, we believe a new (but we expect, quite limited) enforcement responsibility, complementary to the powers they already have under the Health and Safety at Work Act 1974, should be available to Environmental Health Officers in England, Scotland and Wales. The consultation did not comment negatively on this proposal and the Chartered Institute of Environmental Health is content.

10. INSTALLATION, COMMISSIONING AND MAINTENANCE

- 10.1 The definition of a 'Safe product' has been extended to include *where applicable* putting into service, installation and maintenance requirements.

Risk Addressed

- 10.2 Services are not covered per se by general product safety legislation, Therefore we have interpreted this provision as meaning that where a product is designed in such a way that installation, commissioning and maintenance has to be by (or under the control of) the producer and this is integral to the safety of the product and is therefore an essential part of the contract to supply, these facets should be taken into account when considering the risk to

the consumer from the product in normal or reasonably foreseeable use. This is not a judgement as to the safety of the service but the safety of the product. However, given that such products are consumer products and were not excluded by the previous Directive, existing safety legislation already covers them.

Options

- 10.3 The GPSD identifies this as part of the definition of a safe product *where applicable*. We do not view non-implementation with the attendant risk of infraction procedures as being a viable option.

Benefits

- 10.4 The benefits, if there are any, of the introduction of this provision will only be realised through the practical application of the legislation. It seems clear that the provision can only apply to a quite limited range of consumer products the safety of which is already covered by the existing Directive. Expressly, the unsafe installation of an otherwise safe product is not covered by this change.

Costs

- 10.5 It is impossible to make a quantitative assessment of the costs of these changes to the scope of the legislation, and again nothing was offered from consultation responses to help with this assessment. However, where installation, commissioning and maintenance are judged to be an essential part of the contract to supply it may be expected that these costs are already being passed on to the consumer in the normal way. Such costs will be specific to the product and not susceptible to generalisation.

Stakeholder Impact

- 10.6 Business organisations have stressed that the distinction between products and services must be as clear as possible. Consumer bodies see the change as helpful.

Enforcement

- 10.7 Compliance with these provisions will continue to be enforced, in the main, by local authority trading standards officers (TSOs) in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland.

11. USE OF VOLUNTARY STANDARDS

- 11.1 At present, the conformity of a product with the general safety requirement established by the GPSD can be assessed by conformity with specific rules of national law of the Member State(s) in which the product is in circulation. In the absence of such national rules the safety of a product is assessed taking account of other factors, including voluntary standards. The revised GPSD extends the presumption of safety to products assessed to be in conformity with voluntary national standards that transpose a new class of European Standards introduced by the Directive, the references to which have been published in the Official Journal of the European Union and nationally.

Risks Addressed

- 11.2 The vaguer the criteria underpinning the presumption of conformity the more difficult it is for producers through due diligence to ensure that safety is built into a product at the design stage, and this gives rise to potential difficulties for enforcement authorities. The revised GPSD helps address this by allowing conformity with a new class of European standards (published in the Official Journal) to equate to a presumption of conformity with the general safety requirement, unless there is evidence that despite such conformity the product is nevertheless dangerous.

Benefits

- 11.3 Standards are already important in providing benchmarks for product safety, and are widely used by producers. Whether or not they already use standards, producers should find that this new means of assessing the safety of their products offers them a benefit in terms of greater certainty. Since the standards are voluntary, they will only be used if they offer producers some additional benefit when compared with the other means of assessing product safety. Business responses to the previous consultation indicate that they welcome this new mechanism.
- 11.4 If producers adopt the new mechanism on a large scale, enforcement authorities should also find that this offers some advantages in terms of resource savings, since the process of assessing the conformity of products should become generally simpler.
- 11.5 One side effect should be a greater incentive to use standards, which should in turn provide greater impetus for the development of new standards for a wide range of products as producer, supplier and consumer demand grows.

Costs

- 11.6 Testing against the new standards is voluntary. But in practice most producers ensure that their products conform (Directive or not) where standards exist. Large retailers are increasingly insisting on compliance before they will buy or sell products, and producers themselves see compliance as being worthwhile. Indeed the fact that business itself is involved in the process of standard setting for its own sector demonstrates the value of standards, as does the fact that business is prepared to devote time, money and resources to their development. The impact of the Directive in this area should not therefore go significantly beyond what is already happening. Standards compliance is now increasingly being factored into product development costs alongside safety. As a consequence of the drift towards the setting and use of standards the net cost of compliance resulting from the Directive and the implementing Regulations should be very low.
- 11.7 Indeed, one might expect that there could be overall cost benefits associated with the use of voluntary standards since they would not be adopted by business if there was no general advantage in doing so. In respect of standards, it is expected there will be no new requirements for compliance labelling but producers and distributors ordinarily advertise the fact that their products meet a specific standard.
- 11.8 Only two consultation respondents saw this change imposing additional costs on businesses, though one of these clearly did not understand that compliance with standards under the GPSD is voluntary. The other believed that investigation into standards-compliance claims of counterfeit goods would carry additional costs but such investigation is outside of the scope of the Regulations; the need for testing will relate to a suspicion that the product is unsafe, whether counterfeit or otherwise.

Stakeholder impact

- 11.9 The impact of what must be seen as additional encouragement to use voluntary standards will inevitably be greatest on those producers who do not currently do so.

Enforcement

- 11.10 Conformity with standards is voluntary so direct enforcement of their use under the Regulations is not an issue. But there should be advantages for the enforcement authorities when considering whether a product complies with the general safety requirement.

12. OBLIGATION ON DISTRIBUTORS TO KEEP AND PROVIDE DOCUMENTATION TO ENABLE TRACEABILITY OF UNSAFE PRODUCTS

- 12.1 These changes are aimed at improving the traceability of products released on to the market. To ensure compliance with the terms of the Directive, the only viable option is to transpose via suitable legislative provisions to ensure that distributors clearly understand their obligations to keep and provide the documentation necessary to trace the origin of products, and to co-operate in enforcement if needed.

Risks Addressed

- 12.2 The premise behind the provision is that tracing the source of an unsafe product would be made easier if distributors were to keep records that helped to identify their source. For the most part producers mark their products (and their production batch) to ease traceability but there may be issues with very small products, lower value volume products and products where it is impracticable for them to be marked or simply where the producer is not obvious. In these instances distributor's records can be used to trace an unsafe product back to its source and allow enforcement authorities to take action where appropriate against the producer.

Benefits

- 12.3 It is already acknowledged as good practice for distributors to be able to cooperate in tracing products in case a voluntary recall becomes necessary. Where, however, the keeping of records is not systematic there will be benefits in terms of reduced levels of harm caused by unsafe consumer products remaining on the market.

Costs

- 12.4 There are already various requirements to maintain paper trails of transactions for VAT and Inland Revenue purposes. For the most part we expect these records, which must be kept for six years, to suffice to identify from whom the products were purchased and to whom they were sold (if not for retail). This was a view shared by most of the businesses responding to the consultation.
- 12.5 When it is not possible for a distributor to immediately identify the producer, e.g. when products are bought from a middleman, we believe that so long as records are kept throughout the supply chain there should be adequate traceability. As a result any additional costs or burdens to business should be minimised.
- 12.6 A small number of consultation respondents saw an additional burden (mostly un-quantified) in respect of the traceability and record-keeping obligations, though we felt that these opinions failed to take into account qualifications like "where it is reasonable to do so". One industry association suggested that the overall cost implication for its small business members would be approximately 2% of a sector-wide turnover of £400m, but this was unsubstantiated and no other organisation even hinted at costs of this scale. It was the view of one enforcement authority that additional record keeping would be needed if the full intent of these obligations were to be met, but this was not elaborated upon.

Stakeholder impact

- 12.7 As indicated under costs, any additional burden on businesses (including small businesses) resulting from this obligation is expected to be minimal. While producers and some larger distributors often maintain technical files on the products they produce/sell it would be unreasonable to insist that every distributor, especially small ones did so. Moreover it would be unreasonable to expect a small business who bought through a middle man to necessarily be able to identify the producer with any certainty. We would however expect them to be able to identify from whom they purchased the products and, if not for retail, to whom they were sold. This information is generally recorded on invoices. In consequence for the most part the obligation is already being met through current business practice and by meeting existing VAT and Inland Revenue requirements. Records for these purposes are required to be kept for a minimum of 6 years. In many cases this may coincide with the useful life of the product. Where that is not the case and the product life cycle is usually, or often, longer it will be a simple task to keep the records for as long as is necessary. During the negotiation of the revised GPSD, MEPs and others expressed concern that this change could have a disproportionate impact on the charity sector as charity shops would be unable to fulfil the obligation in respect of donated goods. Recital 19 to the revised GPSD makes it clear that the obligation must apply "in proportion to [distributors'] respective responsibilities", and specifically refers to charity shops in this context. However if and when charity shops obtain goods commercially for supply to consumers we can see no reasonable argument why they should not be responsible for maintaining the necessary records and producing them on demand like any other business.

Enforcement

12.8 Compliance with these provisions will be enforced, in the main, by local authority trading standards officers (TSOs) in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland.

13. OBLIGATION ON PRODUCERS AND DISTRIBUTORS TO NOTIFY DANGEROUS PRODUCTS, AND TO CO-OPERATE WITH THE AUTHORITIES

13.1 To ensure that the notification requirements in the Directive are followed, and that their obligations here are clearly understood by producers and distributors, the only viable option is to transpose via suitable legislative provisions.

Risks Addressed

13.2 This change addresses the risk that a producer or distributor who identifies, or is otherwise alerted to the fact that a product is dangerous, may do nothing about it or may not take action that is proportionate to the risk, leaving consumers exposed to the danger unless the problem is picked up by the enforcement authorities. It also means that in future a clearer picture of the extent of product safety failures will be built up.

Benefits

13.3 The likely scale of benefits arising from this change is impossible to estimate. As with the change imposing an obligation to recall dangerous products, the scale of the risk, and hence of the likely benefits, depends on current observance of good practice. In the main we believe observance to be high in the UK because of the potential damaging brand impact that leaving an unsafe product on the market can have, though we accept that there may be a small number of less scrupulous traders for which this 'brand image effect' is not a sufficient deterrent. These same traders may be less likely to volunteer notification to the authorities of the problem and the action taken without the encouragement of penalties for failure to do so. An additional benefit is the sharing of information about risks between EC Member States where the same products are available.

Costs

13.4 The simple obligation to notify seems unlikely to impose any significant implementation or policy costs, even on those few producers and distributors who may be prepared to avoid their obligations to consumers. The main costs relate to having to do something about an unsafe product, which will now be harder to ignore or hide from. This is an equitable proposition. There will be some additional but unquantifiable cost on the authorities where, having been informed of a problem, they will want to make sure that the producer's response is appropriate, and where it is not, to consider enforcement action. Of course, encouraging dialogue and voluntary action is already part of the modernisation of enforcement heralded by the National Performance Framework for Trading Standards Departments.

13.5 While the Directive refers to producers notifying other member states when they become aware of dangers posed by their product, this in practice will be done by the DTI acting as the central notification point for unsafe products in the UK. This new notification requirement will carry with it additional costs for the public sector (DTI), estimated at around £8 - £9k (i.e. assuming half of one admin officer's time).

Stakeholder impact

13.6 As noted above, the impact of the change will fall mainly on those producers and distributors who currently fail to do anything about the dangerous products they put on the market. There was general support in the consultation for the DTI's offer to notify other Member States (in which the dangerous product has also been marketed) on behalf of UK businesses, leaving them only needing to notify their local enforcement authority.

Enforcement

- 13.7 Enforcement will be conducted in the main by local authority Trading Standards Departments in England, Scotland and Wales and Environmental Health Officers in Northern Ireland.

14. REQUIREMENT TO MARK AND REQUIREMENT TO WARN

- 14.1 The Requirement to Mark and Requirement to Warn powers are now separately identified within the self-contained enforcement provisions of the new Regulations, having been previously rolled-up in the CPA power to serve Suspension Notices. This provides for a more tailored transposition of the revised GPSD, and beneficially to business provides the enforcement authorities with an opportunity to set notice requirements that fall short of product suspension.

Risks

- 14.2 These Requirements address the problem of inflexibility inherent in having to use the Suspension Notice mechanism to ensure that products are appropriately marked or that appropriate warnings are given especially to specific classes of persons who may be particularly at risk. While the new provisions do not prevent a Suspension Notice also being served they provide enforcement authorities with the freedom to exercise greater discretion on this point.

Benefits

- 14.3 Businesses should derive benefit from this change (through avoiding loss of sales) on occasions when enforcement authorities decide to use either Requirement as an alternative to serving a Suspension Notice.

Costs

- 14.4 The cost to business of continuing with the existing Suspension Notice approach to enforcement, or of introducing these new Requirements is impossible to specify as there are too many variables, none of which are themselves quantifiable. The cost impact in each case would depend on the type of product, the market, the length of suspension and whether or not suspension could be avoided in serving a Requirement to Mark or Warn instead. It is nevertheless reasonable to assume that introducing the more flexible approach would result overall in reduced costs and burdens on business. Consultation responses tended to support this view.

Stakeholder impact

- 14.5 Under the existing safety legislation producers are already required to suitably mark products that could pose risks in certain conditions or otherwise warn consumers of the risks their products pose. The new Requirements are remedies to adopt where producers or distributors have failed in their obligation to consumers. As such there will be limited impact and that impact will be reduced where a Suspension Notice would otherwise have been served.

Enforcement

- 14.6 Enforcement will be conducted in the main by local authority Trading Standards Departments in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland.

15. WITHDRAWAL NOTICES

- 15.1 The Regulations introduce the power for enforcement authorities to issue a Withdrawal Notice to permanently prevent a person from supplying a product believed to be dangerous. This is not a new power in the GPSD, but it will be new to these Regulations. We had previously chosen to meet this obligation in the 1994 Regulations by utilising the power vested in the Secretary of State to serve Prohibition Notices in the CPA. Introducing the power to issue Withdrawal Notices in these Regulations allows for a more accurate transposition of the

GPSD, but also provides for enforcement authorities themselves to bring product safety issues to a more satisfactory conclusion at the local level than is currently the case.

Risks addressed

- 15.2 The 1994 Regulations' use of CPA powers provides for permanent withdrawal of a product from the market through the serving of a Prohibition Notice by the Secretary of State. Given that we are not proposing that recall be solely in the purview of the Secretary of State it makes little sense for withdrawal (arguably a lesser action) to continue to be effected by means of a Prohibition Notice. The involvement of the Secretary of State raises the stakes and unnecessarily and unhelpfully takes control over this stage of corrective action away from local enforcement authorities.

Benefits

- 15.3 The ability to issue Withdrawal Notices locally will allow enforcement authorities to see corrective action through to a more satisfactory conclusion than at present. Withdrawal Notices will generally be issued subsequent to a determination following the issue of a Suspension Notice and subsequent testing that a product is believed to be dangerous and there is a concern that it will continue to be placed on the market without further action to prevent the risk. At present it is simply hoped that the product will not return to the market at the end of the Suspension Notice period.

Costs

- 15.4 When a Suspension Notice is issued this generally acts as a trigger for producers and distributors to deal with a product safety issue so that no further action is required by the enforcement authorities to protect consumers. The instances where the Withdrawal Notice power will mainly be used should therefore be where the producer has been reticent in resolving the matter or is less scrupulous than the majority of traders. Consequently there should be little extra cost to business, and only then where a product it has produced or distributed is unsafe, not enough has been done to convince the authorities that the problem has been corrected and that without further action, the dangerous product will find its way back on to the market. Again, consultation responses supported this view.

Stakeholder impact

- 15.5 It is expected that safety problems will in the main be dealt with without the need for recourse to a Withdrawal Notice however it will be a useful tool to keep unsafe products off the market permanently where the safety problems identified have not been addressed by the producer/distributor. It is only at this point that there should be any impact on stakeholders.

Enforcement

- 15.6 Enforcement will be conducted in the main by local authority Trading Standards Departments in England, Scotland and Wales, and Environmental Health Officers in Northern Ireland.

16. COMMUNITY DECISIONS AND THE EXPORT BAN

- 16.1 Where the Commission becomes aware of a serious risk from a product that is widely available in the Community just as under the previous Directive it may (after consulting with member states) take a decision aimed at ensuring consistency of enforcement activity across the Community. Under the revised GPSD such decisions are valid up to a maximum of 1 year, and extendable for further periods of up to 1 year at a time. The only exception being where the decision relates to one or more specific batches of products in which case the Decision will have no time limit. The revised Directive also now bans the export from the Community of products subject to such a decision unless the decision provides otherwise. The only viable means to transpose this requirement effectively is via a legislative provision.

Risks Addressed

- 16.2 The export ban prevents a producer whose product is the subject of a Commission decision from exporting the product (with its risk) to one or more third countries. The supply of unsafe products to third countries, especially where it can be shown that the producer/distributor was aware that they were unsafe, could do untold damage to the confidence of consumers in third countries towards Community products generally.

Benefits

- 16.3 The Commission has stated in its financial impact assessment of the revised GPSD that “there is no data on the type and number of dangerous products exported, or which might in future be exported to non-EU countries. The potential market lost by European producers, and the benefits deriving from the proposed prohibition of such exports, cannot be evaluated.”
- 16.4 While we do not necessarily believe the problem to be a large one, the change might be expected to produce benefits in terms of a reduction in the harm caused to consumers in third countries by the export of unsafe Community products, and the impact of any resultant product liability claims. The change will also provide an indirect benefit to European producers who export safe products to third countries in that they will not be at risk of being undercut by unscrupulous suppliers seeking to dump unsafe products that are the subject of enforcement action in the Community.
- 16.5 It should also further encourage producers only to put safe products on the market and to act rapidly to resolve the problems once they are identified.

Costs

- 16.6 As the Commission has noted (see under “Benefits” above), it is not possible to evaluate the loss of market likely to be suffered by European producers as a result of this provision. We received no comments on this issue from the consultation.

Stakeholder impact

- 16.7 Any additional burden arising from this provision would only have any impact where a producer or distributor, whose goods were unsafe and the subject of a Commission decision, chose to try to export the risk to a third country.

Enforcement

- 16.8 The new legislation will make it an offence to contravene a Commission decision banning the export of a dangerous product. This is enforceable by the Commissioners for Customs and Excise under their existing powers.

17. EQUITY AND FAIRNESS

- 17.1 The new provisions in the revised Regulations are in the interests of both consumers and business. They will reduce the risk faced by consumers in purchasing products that have the potential to be unsafe, while ensuring that producers who supply products that meet all safety requirements are not at a competitive disadvantage with those who choose to save costs at the expense of safety. Indeed the main impact of the Regulations falls (as it should) on those who have placed unsafe products on the market.

18. SMALL FIRMS IMPACT TEST

- 18.1 Feedback suggests that overall, the changes being introduced by these revised Regulations will entail only minimal additional burdens and cost for small business. As has been mentioned previously, additional cost will only fall to those producers or distributors who release unsafe products on to the market, or who do not adopt accepted good practice with record keeping (which is in any case required for other statutory purposes) and product marking.

- 18.2 Although the first consultation did not specifically target SMEs, small business views would have been represented within trade association responses. No significant issues for small businesses were identified in those responses.
- 18.3 As a precursor to the final consultation, over forty small businesses on the Small Business Service SME database were sent a short summary of the changes introduced by the revised GPSD and were asked to give their views on likely impact and cost. No substantive replies were received to that exercise. Very few comments referred to small businesses in the final consultation, and only one respondent suggested that the proposals would result in significant new burdens for them, but this view was not substantiated.

19. COMPETITION ASSESSMENT

- 19.1 We have applied the Competition filter test to the proposed new legislation and it is our view that it is unlikely to have a significant detrimental effect on competition. There is no disproportionate impact on any one sector. The revised legislation will apply to all sectors and to all size of business. What additional costs there are will be minimal and in most cases will only apply to those businesses that produce unsafe products or who do not already keep adequate records. Where they do apply, it is likely that smaller businesses will experience a slightly disproportionate burden, but the impact may be to raise standards and in doing so increase their competitiveness. The applicability of these provisions, and the instances where there is any additional cost will be equally applicable to both existing and new/potential businesses.
- 19.2 Overall, we anticipate these effects to enhance effective competition since the costs involved in implementing the proposed Regulations will fall primarily on traders who are not meeting the required safety standards at present. Moreover, if the Regulations serve to reduce the incidence of unsafe products being placed on the market there should be an increase in consumer confidence leading to greater prosperity and competitiveness. The fact that the directive will harmonise safety requirements across Europe will make it easier for firms to sell products in other member states. This should provide strong opportunities for UK firms who already meet many of the Directive's requirements to sell their products abroad and should increase competition across the EU providing consumers with greater choice.

20. GUIDANCE

- 20.1 National guidance covering the new legislation will be prepared to accompany its implementation. This will include guidance on the advisory service that is being set up to provide on-demand assistance where there is a dispute between a producer and the enforcement authority over the appropriateness of a recall action. Guidance on some aspects of the Directive and its operation has been prepared by the European Commission and is available on the DG Sanco website.

21. MONITORING AND REVIEW

- 21.1 The operation of the new legislation will be monitored over the first twelve months for reactions from producers, consumers and enforcement authorities, particularly in respect of costs and benefits. Face to face meetings will be held with the key interest groups. Amongst other things, we will be looking at how useful the ENE procedure is and will undertake to review this in detail after three years. We will also gauge reaction to our national guidance and consider whether any further explanation/revision is required, after twelve months. In addition, we will monitor the operation of the Commission's notification guidelines so that we may participate in any Brussels review of that based on experience of its operation in the UK.

22 CONSULTATION

Within Government

22.1 The following central Government departments/agencies were consulted on the proposals for implementation:

Department for Constitutional Affairs
Department for Environment, Food and Rural Affairs
Department for Transport
Food Standards Agency
Health and Safety Executive
Medicines and Healthcare Products Regulatory Agency
Northern Ireland Office
Scottish Executive
Small Business Service
Veterinary Medicines Directorate
Welsh assembly

22.2 In addition, the following organisations representing local government we consulted:

Local Authorities Coordinators of Regulatory Services (LACORS)
Local Government Association
Association of London Government

Public consultation

22.3 Approximately 700 non-governmental organisations were sent information on the public consultation, and sixty substantive responses were received. These broke down as follows: 28 business, 15 enforcement body (e.g. Trading Standards departments, or their representatives), 11 from legal services firms, 3 central Government and 3 consumer groups.

22.4 The responses overall were of a high quality and touched on almost every area of the proposals, ranging from detailed analysis of individual words and terms to a more general overview of the proposals and their impact on consumer safety and the business community.

22.5 The general view from all groups was that we had correctly identified the main issues for transposition. However, some concerns were raised but there were requests for further clarification on particular issues.

URN 05/1343

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs

Signed by the responsible Minister

Gerry Sutcliffe

The Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs, Department of Trade and Industry

Date 30th June 2005

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TRANSPOSITION NOTE

THE GENERAL PRODUCT SAFETY REGULATIONS 2005

The General Product Safety Regulations 2005 give effect to Council Directive 2001/95/EEC of 3 December 2001 of the European Parliament and of the Council on general product safety (the GPSD). The table below shows how the provisions of the Directive have been transposed into national law in the Regulations. These Regulations do more than is necessary to implement the Directive by extending their coverage to supplies of antiques other than for sale in order to clarify and simplify the product safety regime by repealing s10 of the Consumer Protection Act. In the context of the obligations on producers we have replaced the concept of what is appropriate (which is not defined in the Directive) with what is reasonable on grounds that this term is equivalent and is well understood by courts in the UK. We have also provided for compensation to be paid by the enforcement authorities in respect of any loss or damage that occurs as a result of their actions if there has been no contravention of any requirement under the Regulations. The Directive refers to the acts of placing on the market and supply in terms that suggest the former is something that producers do and the latter something that distributors do. However the Directive is not always consistent in this usage and as a consequence we have transposed the terms broadly as including preparatory acts which we consider meets the demands of the Directive. Finally, such were the stakeholder concerns about the introduction of the new recall powers that we have had to introduce a safeguard on their use involving making available an independent Recall Advisory Scheme operated by the Chartered Institute Of Arbitrators in cases where the need for recall is disputed.

Articles	Objective	Implementation	Responsibility
Chapter I: Objective, scope and definitions			
<u>Article 1</u>	<p>(a) Sets out the purpose of the Directive: to ensure that all products placed on the market are safe</p> <p>(b) Establishes the relationship between the application of the GPSD and safety requirements imposed by other Community legislation.</p>	<p>(a) Not transposed</p> <p>(b) Regulation 3</p>	

Article 2	Defines key terms in the Directive. For example: a product, a safe product, a dangerous product, a serious risk, a producer, a distributor, recall and withdrawal.	<p>Regulation 2. The definition of “product” in relation to products supplied in the context of a service incorporates for clarification part of recital 9 to the GPSD.</p> <p>The Directive excludes antiques and products for repair or reconditioning from the definition of a product. However supplies of antiques other than for sale have been included in the scope of the implementing regulations. Regulation 30 provides a defence where an antique is sold. The safety of antiques was previously regulated by section 10 of the Consumer Protection Act 1987 (the CPA). In consequence we can repeal section 10 so that the safety legislation for all consumer products will in future be found in one place only and be considerably simpler.</p>	
Chapter II: General Safety Requirement, conformity assessment criteria and European standards.			
<u>Article 3 (1)</u> <u>Article 3(2) – (4)</u>	<p>Requires that only safe products be placed on the market.</p> <p>Provides a presumption of conformity where products comply with certain safety standards whilst not preventing action where a product is dangerous.</p>	<p>Regulation 5 transposes this general safety requirement and also prohibits supply and acts preparatory to supply in order to give effect to the intention of the Directive to protect consumers from unsafe products.</p> <p>Regulation 6.</p>	
<u>Article 4</u>	Procedures for drawing up European Standards.	Does not require transposition	

<u>Article 6</u>	Requirement to ensure that producers and distributors comply with the GPSD and establish competent authorities to enforce the Directive.	Regulation 2 (definition of enforcement authority) and 10 (certain enforcement authorities under a duty to enforce the Regulations and necessary powers to do so).	
<u>Article 7</u>	Requirement to shall lay down the penalties for infringements	Regulation 20 provides penalties for breach of the general safety requirement and safety notices	Secretary of State
<u>Article 8(1)</u> <u>Article 8(2)</u>	Establishes the principal measures the competent authorities are to be able to take in respect of unsafe products: (a) safety checks and obtaining information and samples (b) marking the product with warnings (c) publication of warnings (d) temporary suspension of products from the market (d) and (e) a ban on marketing (f) product recall	Regulation 21-23 and 28 Regulation 12 Regulation 13 Regulation 11 Regulation 14 Regulation 15. In response to business	Secretary of State

	<p>Requirement for enforcement authorities to act in a way that is proportional and takes account of the precautionary principle and to encourage voluntary action by producers and distributors.</p> <p>The competent authorities may act with due despatch in cases where there is a serious risk.</p>	<p>concerns this regulation includes the possibility for the producer or distributor to require the enforcement authority to obtain advice from an independent person on whether the requirements for a product recall are met.</p> <p>In addition regulations 18 and 19 enable a court to order the forfeiture and destruction of dangerous products as an accompaniment to a withdrawal notice or recall notice.</p> <p>Regulation 10(5)</p> <p>Regulation 14(4), 15(5). and 16(1).</p>	
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<u>Article 9</u>	Market surveillance arrangements and complaints to the competent authorities.	Regulations 36 and 37.	
Article 10	Establishment of a European network for co-operation between competent authorities.	Does not require transposition	
Chapter V: Exchanges of information and rapid intervention situations			
<u>Article 11</u>	Obligation to inform the Commission where Member State takes action in respect of a product but the risk is not serious.	Regulations 33 and 34.	
<u>Article 12</u>	Obligation to inform the Commission where Member State takes action in respect of a product because of a serious risk.	Regulations 33 and 34.	

<u>Article 13</u>	Procedure for Commission to adopt decisions in relation to the safety of a product and enforcement by Member States' competent authorities including export bans.	Regulation 35.	<i>The type of product will determine which competent authority is to be directed to undertake enforcement. The export ban will be enforced by HM Revenue & Customs under the Authority provided by the Customs and Excise Management Act 1979 which contains its own offences and penalties.</i>
Chapter VI: Committee procedures			
Articles 14 and 15	These articles provide for the procedures for adopting European standards and for the Commission to make decisions under article 13 above.	Do not require transposition.	
Chapter VII: Final Provisions			
<u>Article 16</u>	Requires information on risks to public health and safety from products generally to be made available to the public. Paragraph 2 requires information covered by professional secrecy to be protected in duly justified cases.	Regulation 39(1). Regulation 39(2) and (3) and Part 9 of the Enterprise Act 2002	
<u>Article 17</u>	Provides that the Directive is without prejudice to 85/374/EEC (Council Directive on liability for defective products).	Transposition not required	
<u>Article 18</u>	Requires reasons to be given for decisions to restrict placing products on	Regulation 16(2)(b)	

	<p>the market, or to withdraw or recall them from the market;</p> <p>Allows the parties concerned to submit views before the decision is taken where feasible</p> <p>Requires notification be given to such parties of the decision taken and the remedies available and to ensure that measures can be challenged before a competent court</p> <p>Decisions taken under the Directive shall be without prejudice to assessment of the liability of the party concerned in the light of the criminal law applicable in the case in question.</p>	<p>Regulation 16(1)</p> <p>Regulation 16(2)(c) and regulation 17.</p> <p>Does not require transposition, any decision on criminal liability is a separate matter for the criminal court</p>	
<p><u>Articles 19-24</u></p>	<p>Review by Commission, coming into force, repeal of Directive 92/59/EEC on General Product Safety and final provisions.</p>	<p>Do not require transposition</p>	