A new EC Directive on the Safety of Consumer Products

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The existing Directive

Directive 92/59/EEC on General Product Safety (GPS) came into effect on 29 June 1994. It places obligations on producers and distributors of consumer products, and surveillance obligations on member states and the European Commission. The main obligations on producers are:

1. To place only safe products on the market.[1]

2. To provide consumers with relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.[2]

3. To adopt measures commensurate with the characteristics of the products which they supply, enabling them to

(a) be informed of risks which these products might pose, and
(b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market [adequately and effectively warning consumers or recalls from consumers].[3]

Duties 1 and part of 2 apply in the pre-marketing situation. In the post-marketing situation, duties 2 and 3 effectively require a systematic procedure to be operated under which producers collect and evaluate information on the safety of their products in use, and then provide further relevant information to consumers. They must also be enabled to take action other than merely providing information, such as instituting a recall of products from the distribution chain (but not at present recalling a product once it has been sold to a consumer).

There is a considerable variation in the laws of Member States which transpose this Directive.[4] Broadly, some Member States have adopted previous legislation or had comprehensive previous vertical legislation on foodstuffs and consumer products which remained largely undisturbed, and others have created new legislation which uses largely identical wording to the Directive and might adopt a vertical approach to consumer products (e.g. Austria, Italy, Denmark, Ireland and Belgium). There are instances in which national legislation differs from the Directive, either by omitting parts of the Directive or by going beyond it. Some important divergencies are the exclusion of certain product sectors, exclusion of immovable property, variation in obligations imposed on producers and distributors, exclusion of a power of national authorities to withdraw products from the market, and other variations in enforcement powers. Notable instances where some national laws give a higher degree of protection to consumers than that granted by the Directive include the inclusion of services, the imposition of heavier obligations on distributors, the imposition of an obligation to inform the authorities of risk posed by products, and the power to prohibit exports of products or to require the refunding, repair or replacement of products.

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1 New Directive, article 3.1.

2 New Directive, article 5.1.

3 New Directive, article 5.1, which introduces the subdivision of this text into the two sub-paragraphs (a) and (b) recorded here, and also adds the wording in square brackets, which is discussed further below.

4 F Maniet "The transposition of the General Product Safety Directive 92/59/EC by the Member States of the European Union" [1999] CLJ 15-33.

Directive 92/59/EEC is now to be superseded by an updated and expanded Directive. After carrying out a review, the Commission concluded in 1999 that the Directive does not need major reshaping, but only reinforcement, clarification and improvement of particular aspects.[5] Discussions on the text of the replacement Directive took two years but were concluded in mid-2001. The European Parliament proposed a number of amendments, both on first and second reading, but both these, and some of the Commission's original proposals, were finally watered down. Negotiations on behalf of industry were led by UNICE.[6] The new Directive will be adopted in September 2001 and will come into force 2 years later. The following are the major amendments that will apply.

Consumer products

There has been some change to the scope of consumer products covered by the Directive. The new definition is as follows, with new wording in italics:

The Directive applies to any product - *including in the context of providing a service* - which is intended for consumers or likely, *under reasonably foreseeable conditions,* to be used by consumers *even if not intended for them*, and supplied *or made available*, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned. Not covered are second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.[7]

The scope of the Directive is, therefore, extended in a number of ways. First, it encompasses products which are made available to consumers, as well as supplied to them. This would include many products provided in beauty centres, theme parks or playgrounds or in connection with transport, sporting events or health treatments[8]. Enforcement action could be taken against unsafe products before they have been supplied. It is also mentioned that the Directive applies to products irrespective of selling techniques, including distance and electronic selling.[9] Secondly, it includes products supplied or made available in the context of providing a service. This would include repairs and after-sales service, maintenance and cleaning work, hotel and restaurant services, health treatment, provision of gas and electricity etc [10] or a tyre inflation gauge and compressed air pump at a garage. The retailer would usually have the less onerous obligations of a distributor, rather than a producer, for GPS purposes, but someone such as a garage owner who failed to keep a tyre inflation gauge in a condition such that it was inaccurate and therefore provided readings which made the inflation levels of tyres unsafe, would be a producer.

It was originally proposed that the safety of services should also be regulated under the new Directive, but that issue proved to be difficult and contentious and it has been left for further consideration, although the Commission was pressed on the subject of services by the European Parliament, and has agreed to bring forward a report and proposals by the end of 2002.[11] For the present, new recital 9 provides that the safety of the equipment used by service providers themselves to supply a service to consumers does not come within the scope of this Directive since

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5 *Discussion Paper: Review and Revision of Directive 92/59/EEC (General Product Safety)* European Commission DGXXIV, June 1999.

6 The Union of European Confederations of Industry.

7 Article 2(a).

8 All of these were mentioned by Mr Erik Hansson of the Commission in his speech at the Product Recall Conference, Stockholm, Sweden, 25 and 26 June 2001.

9 Recital 7.

10 All mentioned by Mr Hansson, *supra.*

11 The Parliament forced inclusion of this point in article 20 and recital 1, during the conciliation procedure.

it has to be dealt with in conjunction with the safety of the service provided. In particular, equipment on which consumers ride or travel which is operated by a service provider is excluded from the scope of this Directive.

The addition of the provisos that products are included if they are likely *under reasonably foreseeable conditions* to be used by consumers *even if not intended for them*, are intended for clarification and should probably have little overall effect on the scope of products covered which are intended for consumers, but is subject to the following point. The existing Directive provided in recital 5 that production equipment, capital goods and other products used exclusively in the context of a trade or business are not covered. This provision has been omitted from the revised Directive but new recital 10 makes clear that, although business products are not included *per se*, the new Directive does include products which are designed exclusively for professional use but have subsequently migrated to the consumer market, as these can pose risks to consumer health and safety when used under reasonably foreseeable conditions. Laser pens are an example intended to be caught[12], as would be elevators in buildings, supermarket shopping trolleys, shampoo used by hairdressers, or medical devices used by healthcare professionals in the course of providing medical services.

Coverage of the Directive: Overlap with other Directives

There is considerable confusion under the existing Directive about exactly which, if any, of its provisions apply to products that are subject also to regulation under vertical, sectoral Directives. The theory of the existing Directive is that the provisions of the current Directive apply insofar as they are not covered by existing rules of Community law[13]: the GPS provisions are intended to "fill in the gaps" left by other Directives. In general, the GPS provisions which relate to post-marketing activities are not found, or included only to a lesser extent, in the vertical Directives which regulate specific product sectors. There has been enormous difficulty in working out which GPS provisions are ousted by vertical provisions, and which apply. This is exacerbated by differences in both the concepts and wording of the vertical and horizontal (GPS) provisions.

There has been no change in the policy that specific GPS provisions do apply to products regulated by other Directives. Some clarification of the demarcation on coverage provisions has been made in the new GPS Directive[14] but the position should be significantly clarified by guidance which the Commission has undertaken to issue on this tricky point. It is intended that this guidance will be made available before the date for implementation of the new Directive into national law, so that member states may specify in their national legislation precisely which GPS provisions do not apply to specific product types. For example, much or all producers' GPS duties should be disapplied in relation to pharmaceuticals and medical devices. But many other Directives do not contain significant post-marketing obligations on producers, or any obligations on distributors, or surveillance or enforcement obligations on member states: these do apply to consumer products covered by GPSD. It may be that vertical Directives will in due course be amended to provide for these aspects. Indeed, it would be preferable in many cases to have specific vertical, rather than general horizontal, provisions on these issues: trade associations should consider pressing for changes on these lines. It is intended that the Commission's guidance can in future be updated as and when vertical directives are amended (including further post-marketing obligations, or introduce obligations on distributors or member states), so as to remove the products concerned from the GPS regime.

Conformity assessment criteria: inclusion of harmonised standards

12 Speech by Mr Hansson, *supra*.
13 Directive 92/59/EEC, article 1.
14 Article 1.

In deciding whether a product is safe for the purposes of the current Directive, one is to consider a hierarchic order of national standards transposing European standards, Community technical specifications, national standards, codes of good practice, state of the art and technology, and the safety which consumers may reasonably expect.[15] This rather generalised approach gives rise to uncertainty. The Commission has recognised that "it will clearly not be possible to introduce in the Directive itself detailed safety requirements covering in a sufficient manner all the products falling into its wide scope"[16]. Neither could it include specific "essential requirements" for the various product categories and risks which are covered, as is the case in "new approach" Directives.

The new Directive therefore establishes a procedure[17] for granting standardisation mandates to the European standardisation bodies so as to produce harmonised standards which have the legal status of giving rise to a presumption of conformity with GPS obligations, in the same way as applies under many other product regulatory Directives. Such standards could then be available for voluntary application by producers and give greater certainty that GPS obligations had been complied with. It is recognised that such standards could not be prepared quickly and, as an interim solution, it has been proposed that certain Community technical specifications might be adopted.

Market surveillance: strengthening of member states' powers and improved collaboration on market surveillance and enforcement

The Commission believes that there are serious weaknesses in market surveillance under this Directive.[18] The Commission criticises the empowerment by Member States of competent authorities as being in some cases "weak, insufficient or ineffective"[19]. There is also an absence of formal requirements for arrangements for collaboration between market surveillance authorities, which should be structured and systematic. "The market is unified but the surveillance is fragmented"[20]. The Commission is seeking to establish comparable levels of performance and proceed on the basis of equivalent principles and approaches.

Some of the larger member states have had product safety regulation for some years or even decades prior to the Directive and therefore have well-established legal and practical mechanisms. On the other hand, other member states, particularly those of southern Europe, have very limited central or local structures, budgets or manpower for consumer product safety, surveillance and enforcement. By increasing the obligations on member states under this Directive, DG SANCO hopes to force governments to provide greater resources for this task.

Previous deficiencies in the co-ordination of the authorities' market surveillance and enforcement are primarily intended to be addressed through an obligation on the Commission to promote and take part in the operation of a European network of authorities of the member states.[21] This will further the development of the existing informal collaboration mechanism involving enforcement authorities, called PROSAFE.[22]

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15 Directive 92/59/EEC, article 4.

16 Proposal for a Directive of the European Parliament and of the Council on general product safety, COM(2000) 139 final/2, 15.6.2000, Explanatory Memorandum, p6.

17 Articles 3, 4.

18 *Commission report to the European Parliament and the Council on the experience acquired in the application of Directive 92/59/EEC on general product safety* COM (2000) 140 final.

19 Ibid, p19.

20 Proposal *supra*, Explanatory Memorandum, p11

21 Article 10.

22 It is presumed that PROSAFE will transform and develop itself into the formal Product Safety Network envisaged: some informal preparations were started during 2001 to this effect.

The new Directive provides that[23] this network operation shall develop in a coordinated manner with the other existing Community procedures, particularly RAPEX. Its objective shall be, in particular, to facilitate:

(a) the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;
(b) the establishment and execution of joint surveillance and testing projects;
(c) the exchange of expertise and best practices and cooperation in training activities;
(d) improved cooperation at Community level with regard to the tracing, withdrawal and recall of dangerous products.

The obligations and enforcement powers of Member States[24] have been expanded to include the following elements:-

(a) a detailed definition of the tasks, powers, working procedures and organisation of market surveillance competent authorities;
(b) establishment of sectoral surveillance programmes by categories of products or risks and the monitoring of surveillance activities, findings and results;
(c) the follow-up and updating of scientific and technical knowledge concerning the safety of products;
(d) periodic reviewing and assessments of the functioning of the central activities and, if necessary, revision of the surveillance approach and organisation;
(e) implementation of procedures to receive, consider, follow-up and answer complaints from consumers and others on product safety, surveillance or control activities;
(f) exchange of information between Member States on risk assessment, dangerous products, test methods and test results, recent scientific developments and other aspects relevant for control activities;
(g) joint surveillance and testing projects between surveillance authorities;
(h) appointment of market surveillance contact points.
(i) improved collaboration at Community level on tracing, withdrawal and recall of dangerous products.

It is also provided that member states have the responsibility of laying down the rules on penalties applicable to infringements and "shall take all measures necessary to ensure that they are implemented".[25] The penalties provided for shall be "effective, proportional and dissuasive"[26] The power of a member state to order or organise the issuance of warnings about, or recall of, dangerous products is clarified.

An extended list of enforcement powers is included in the new Directive, which entitles the following measures to be taken, where appropriate:[27]

(a) for any product:

(i) to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;
(ii) to require all necessary information from the parties concerned;
(iii) to take samples of products and subject them to safety checks;

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23 Article 10.
24 Articles 6 to 10.
25 Article 7.
26 Article 7; and Case C-354/95.
27 Article 8.1.

(b) for any product that could pose risks in certain conditions:

(i) to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present;

(ii) to make its marketing subject to prior conditions so as to make it safe;

(c) for any product that could pose risks for certain persons:

to order that they be given warning of the risk in good time and in an appropriate form, including the production of special warnings;

(d) for any product that could be dangerous:

for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;

(e) for any dangerous product:

to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;

(f) for any dangerous product already on the market:

(i) to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;

(ii) to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions.

The precautionary principle

The Commission's first draft of the new Directive proposed that the precautionary principle should apply to the activities of producers and of member states. However, after it was pointed out that no definition of a precautionary principle was included and that its meaning and relevance in this context were unclear, the reference was removed, on the basis that the Commission published at that time its discussion paper on what is meant by the precautionary principle.[28] It was argued by industry that it is difficult to see how the precautionary principle is consistent in the pre-marketing assessment of safety with the Directive's requirement for "a high level of protection" of health and safety. According to the Commission's understanding of the precautionary principle set out in its discussion paper, the principle only comes into play where there is scientific uncertainty as to the level of risk.

Nevertheless, on both first and second readings, the European Parliament strongly requested the inclusion in the body of the Directive of a requirement for competent authorities to act in accordance with the precautionary principle. The Commission and member states, urged by industry, resisted this view. The Common Position merely included a reference to the precautionary principle in a recital and the compromise reached during the final conciliation procedure is to include the following substantive obligation on member states:

"When the competent authorities of the Member States take [enforcement] measures ... they shall act in accordance with the Treaty, and in particular Articles 28 and 30 thereof, in such a way as to

28 Communication from the Commission on the precautionary principle, COM (2000) 1.

implement the measures in a manner proportional to the seriousness of the risk, and taking due account of the precautionary principle."[29]

Public availability of information and confidentiality

The issue of how much information shall be available to consumers was the subject of strong debate between interested parties during discussion on the new Directive. The Directive adopts the general principle that information which is available to the authorities relating to consumer health and safety shall in general be available to the public, in accordance with the requirements of transparency.[30] In particular, the public shall have access to information on product identification, the nature of any risk and measures taken.

This provision will introduce a principle of availability of information which may have major consequences for business (see below). Restrictions on availability of information are recognised on monitoring and investigation activities.[31] However, information which is obtained by the authorities shall not be disclosed "which, by its nature, is covered by professional secrecy in duly justified cases".[32] This confidentiality provision was included at the request of industry since it would otherwise have severely impeded the operation of commercial markets through the disclosure of confidential proprietary information.

In practice, it will be necessary for economic operators to mark documents and communications with authorities as confidential, and to be prepared both to justify this and to fight for compliance by the authorities. Industry may wish to press for the adoption of guidance on disclosure, including a prior notification mechanism by the authorities and an opportunity for the document/information owners to object prior to disclosure.

Safeguard action

The "safeguard clause" procedure for taking action against unsafe products (Article 11, formerly 7) has been slightly simplified, so as to provide information on measures taken by a member state, as well as any modifications to them, to be more rapidly provided to the other member states, since there has previously been both a communication gap and heavy administrative burden on the Commission. The previous Article 7 procedure has been regarded as difficult to manage: for the period 1994/98 only 27% of notifications under Article 7 reached the last stage of the procedure.

Emergency enforcement action: RAPEX

The Rapid Alert System, RAPEX,[33] which is operated at EU level is also being improved. Member states are to inform the Commission immediately, which will in turn alert the other member states, if a product poses a serious risk. The trigger for the RAPEX emergency mechanism has been changed from "serious and immediate risk" to "serious risk", so as to include risks which may have a longer latency period. If necessary, emergency measures can be taken at EU level. The Commission believes that the system for exchange of information[34] has not worked well, with only 182 notifications received from member states in the first 4 years and reactions made by member states in only 50% of 47 notifications in 1998. Voluntary measures or agreements should in future be notified under the RAPEX system, which is to have improved follow-up procedures and more

29 Article 8.2.
30 Article 16.1.
31 Ibid.
32 Ibid.
33 Article 12, formerly 8.
34 old Article 8.

effective and efficient practical arrangements. Non-EEA member states may now also participate in the RAPEX system.

New obligations on producers and distributors: notification, collaboration and recall

A number of significant obligations are to be added to those referred to above that apply to producers.

4.[35] *Notification*

A duty immediately to inform the competent authorities if they know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement,[36] i.e. that it is dangerous. They shall also inform the authorities of action taken to prevent risks to consumers. These provisions also apply to distributors. Annex I specifies that the Commission will put forward a guide containing simple and clear criteria on notifications, together with the content and a standard form for notifications. In the event of serious risks, information shall include at least the following:

- information enabling a precise identification of the product or batch of products in question;
- a full description of the risk that the products in question present;
- all available information relevant for tracing the product;
- a description of the action undertaken to prevent risks to consumers.

These notification provisions constitute a major increase in regulation for producers and distributors. They are based on reporting requirements which apply in the United States,[37] and have arisen out of some frustration that member states and the Commission have not been informed about product withdrawals in Europe until US authorities inform them that the product has been withdrawn in the US market.

The notification provisions will require producers and distributors to put in place sophisticated procedures to capture and assess safety information. Deciding whether new information means that a product is no longer legally safe can be a major issue in practice and is best undertaken against the background of previous safety data and an assessment that the product's safety is acceptable. Companies' systems may need to provide for obtaining independent expert advice on these issues from scientists and lawyers. For certain products, at least, it will be necessary to undertake a documented risk analysis before a product is placed on the market, and subsequently to keep it up to date, so as to define the level of anticipated risks with a product's use, to determine that these are acceptable and that the general safety requirement is met, and to provide a background and baseline statement of acceptable risks against which any increase in risk may be assessed.

5. *Collaboration*

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35 This continues the numbering of producers' obligations adopted above.

36 Article 5.3.

37 The US requirements to notify the authorities of recalls of consumer products are in fact based on voluntary guidelines but compliance is widely observed in view of significant enforcement penalties which may be imposed in relation to offences such as of having marketed dangerous products which might not be so rigorously pursued if the guidelines on notification are observed. The GPS obligation therefore goes further than it's US model in requiring notification of the initial conclusion that a product is unsafe, after which the authorities can liaise further with the producer and intervene in how the issue is dealt with.

A duty to collaborate with the competent authorities, at the request of the latter, on action taken to avoid risks posed by products that they supply or have supplied.[38] The procedures for such cooperation, including procedures for dialogue with the producers and distributors concerned on issues related to product safety, shall be established by the competent authorities.[39]

6. *Warning system and recall*

A duty to have a system enabling them to adequately and effectively warn consumers of risks that they discover with products that have already been placed on the market, or to withdraw them from the market or recall them from consumers,[40] or to take other appropriate action. The current Directive includes an "appropriate action" duty that encompasses withdrawal from the market and providing a warning, whereas the new wording refers to "adequately and effectively warning consumers" and extends the recall obligation beyond the chain of distribution and up to the consumer/user of a product. A definition of "recall" is included in the new Directive as any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor.[41] Companies will therefore need to consider the extent and sophistication of their post-marketing systems that deal with product safety surveillance, and provision of information and recall as far down the chain as encompassing consumers.

Practical issues which may arise include the ability of a system adequately to contact users over safety issues, to measure the number and percentage of products returned in a recall, and decide what level of returns would be acceptable. The Directive does, however, specify that recall shall take place as a last resort, where other measures would not suffice to prevent the risks involved, in instances where the producers consider it necessary or where they are obliged to do so further to a measure taken by the competent authority.[42] It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist.[43] Accordingly, industry will wish to press for the agreement of such codes, on issues such as what level of uncertainty or risk would or would not trigger a recall, and how recall should be implemented.

Obligations on distributors

The introduction of notification provision referred to above applies equally to distributors and to producers, and will be a major change for distributors. Apart from this, the basic obligations on distributors have changed little, from the existing Directive, and are as follows, with new wording in italics:

"Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, *keeping and providing the documentation necessary for tracing the origin of products, and* cooperating in the action taken by producers and competent authorities to

38 Article 5.4.
39 Ibid.
40 Article 5.1.
41 Article 2(g).
42 Article 5.1.
43 Ibid.

avoid the risks. *Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently*."[44]

Ban on exports

There has been concern that dangerous products should not be dumped on foreign markets. Powers to prevent exports already exist in Austria, Belgium, France and Sweden, and under Directives 87/375/EEC (products which appear to be other than they are) and 92/52/EEC (infant formulae). The Commission has accepted that the safety of products intended for industrial or professional use may depend significantly on the context in which they are used, and that different countries may have a different approach to the acceptance of risk and cost-benefit analyses, but it asserts that it is difficult to see how a consumer product which is dangerous in the EU would be safe in a third country.

Accordingly, the new Directive includes a provision that when a product is subject to a Commission-initiative decision, after consulting the member states and whenever it proves necessary also a Community scientific committee, that requires member states to take measures in relation to a particular product that presents a serious risk, that product shall be prohibited from being exported from the Community, unless the decision provides otherwise.[45]

Aspects of the new Directive which require further attention

One issue which industry will need to address in future concerns the advantages of notifying and communicating with a single competent authority rather than a multiplicity of authorities, each of which may have its own ideas on the format or content of information which may be required or action that should be taken. The requirements of consistency, speed and efficiency all point towards having a unified system. One possible approach may be moves towards the development of a single European consumer products agency. An alternative approach, which can be developed incrementally out of the existing PROSAFE system, would be for enforcement authorities to agree an extension of the British "home authority" principle, under which a producer or distributor maintains liaison with its local authority, who in turn assumes responsibility for communicating with other authorities, and has primary responsibility for enforcement.

There is also scope for confusion, perhaps considerable confusion, over the fact that the obligation to notify the authorities of unsafe products applies both to producers and distributors. In other words, the same obligation applies to every operator in the chain of distribution of a product. This may lead to, for example, a producer being embarrassed if a distributor believes that it has to notify, particularly where there has been inadequate previous communication as to relevant safety information and its significance. Distributors may feel that they have to notify the authorities not later than contemporaneously with producers, if they are to avoid committing an offence. This would seem to point to the need for integrated communication channels along chains of distribution and common understandings as to standard operating procedures and risk assessments on individual products. There is a need for notification and enforcement protocols to be agreed with the authorities, which would include provision for primary notification points on both the enforcement and commercial sides, so as to avoid multiple and confusing communications.

Further work needs to be done on developing guidelines on risk assessments, notification requirements and recall procedures. Industry should also consider the development of the guidelines which will clarify the extent to which GPS provisions are excluded in relation to

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44 Article 5.2.

45 Article 13.3. A recital in a draft of the Directive, had indicated that where a foreign country has a prior consent system, it may be inappropriate for the Community to ban a product's export.

particular product sectors, and consider lobbying the Commission and member states so as to ensure first that the right conclusions are reached in these guidelines and, secondly, that member states enact these provisions into national law.

Member states are required to act in such a way as to implement measures which they take in a manner which is proportional to the seriousness of the risk. In this context, they shall encourage and promote voluntary action by producers and distributors. Recall is only a measure of last resort and may be effected within the framework of codes of good conduct.[46] This provision provides scope for particular product sectors to develop proportionate and appropriate codes in relation to post-marketing safety measures including recall.[47] Particular issues which might be included within such codes, and differ between different sectors, would relate to the scope or conclusions of any risk assessment, the level of safety which was regarded as being acceptable, and target percentage returns in a recall.

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46 Article 8.2. A good starting place is *Consumer Product Recall: A Good Practice Guide,* Department of Trade and Industry, 1999.

47 Such as *Guidance on Medical Device Recalls*, Medical Devices Agency, 2000.