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Product Recall

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

General regulations

European Community Law

- Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products;
- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Directive 2001/95); and
- 2004/905/EC: Commission Decision of 14 December 2004 laying down guidelines for the notification of dangerous consumer products to the competent authorities of the member states by producers and distributors, in accordance with article 5(3) of Directive 2001/95/EC of the European Parliament and of the Council (Commission Decision 2004/905).

National Law

- Act No. 30/1992, of 26 November, on the legal status of the public administration and the common administrative procedure;
- Act No. 14/1986, of 25 April, on the general health system (Act 14/1986);
- Act No. 21/1992, of 26 June, on Industry;
- Royal Decree-Law No. 1/2007, of 16 November, which approves the consolidated general law on the defence and protection of consumers and users (Consumers General Act); and
- Royal Decree No. 1801/2003, of 26 December, on general product safety, which transposes Directive 2001/95/EC (RD 1801/2003).

Main specific regulations (among others)

Food products

- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs;
- Royal Decree No. 709/2002, of 19 July, which lays down the legal Statute of the Food Safety Spanish Agency (RD 709/2002); and
- Royal Decree No. 640/2006, of 26 May, which regulates certain conditions from the European regulations on hygiene in the production and commercialisation of foodstuffs.

Medicines and sanitary products

- Regulation (EC) No. 726/2004, of the European Parliament and of the Council, of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- Act No. 29/2006 of 26 July, on Medicine (Act 29/2006); and
- Royal Decree No. 1591/2009, of 16 October, on Sanitary Products.

Cosmetics

Royal Decree No. 1599/1997, of 17 October, on Cosmetic Products.

Toys

- Directive No. 2009/48/EC of the European Parliament and of the Council, of 18 June 2009, on the safety of toys; and
- Royal Decree No. 880/1990, of 29 June, on Toys.

Machinery

- Directive No. 2006/42/EC, of 17 May, on machinery, and amending Directive 95/16/EC;
- Royal Decree No. 1435/1992, of 27 November, which transposes the Directive No. 2006/42/EC, on Machinery; and
- Royal Decree No. 1644/2008, of 10 October, which lays down the regulation for commercialisation and implementation of machinery.

2 What requirements exist for the traceability of products to facilitate recalls?

There is no specific regulation for traceability purposes. However, there are references in the general and specific regulations for products and regulations on how a lack of traceability in products may be penalised.

RD 1801/2003 is the general regulation on product safety, and its applicability is subsidiary. If there is a specific regulation (as in the areas of medicines, food, etc) to ensure the traceability of a certain product, this specific regulation will apply in the first place and all the issues that are not foreseen will fall under RD 1801/2003.

RD 1801/2003 uses very general terms, and gives the administration high levels of discretion to ensure that traceability is guaranteed. Therefore, the requirements of traceability may vary depending on the product.

Regarding the manufacturers, they must indicate on the product or its container the name of the company, the reference of the product and if appropriate they must also mention the manufacturing batch number. This information, irrespective of the product, ought to be retained for three years.

As an exception to the rule of three years' retention, RD 1801/2003 foresees a term of only one year of preservation of the

information if the products are perishable, namely products that have a recommended consumption deadline or expiration date.

As for distributors, they must maintain and provide to the authorities, if requested, all the necessary documentation to ascertain the origin of the products, especially the identity of the suppliers; moreover, if they are not retailers, they must keep information about the destination of the product. This information must be kept for three years from the date the product leaves the distributor.

Both producers and distributors must cooperate within their areas of competence with the administration to prevent hazards that products may cause.

Regarding toys and machinery, it is notable that the manufacturer guarantees the conformity of products with the EC legislation by means of the 'CE' mark; therefore it or its representative must retain the documents and information concerning the procedure of manufacture and its conformity with the EC legislation, as well as the copies of it when filing before the competent administration, the address and place of manufacture and storage.

Under articles 87 and 15.4 of Act 29/2006, among other information regarding the use and components of the medicine the packaging of all medicines must contain information regarding the medicine's national code, batch, and unit that allows its mechanical, electronic or computer identification.

3 What penalties may be imposed for non-compliance with these laws?

The general regulation, namely RD 1801/2003, refers to the penalties established in the Consumers General Act or Act 14/1986, depending on the nature of the non-compliance.

According to the above-mentioned acts, there may be three kinds of infringements against consumers' interests or health, depending on the level of risk to the health of the consumer, the position of infringer within the market, the amount of profit obtained, the grade of intentionality, the severity of the social alteration, the generalisation of the infraction and any recurrence of the infringement.

According to these criteria, the infringement and consequent penalties may be considered as follows:

- minor infringement: up to €3,005.06;
- serious infringement: between €3,005.06 and €15,025.31 (the fine imposed may exceed those quantities until it reaches five times the value of the products that were the object of the infringement); and
- major infringement: between €15,025.31 and €601,012.10 (the fine imposed may exceed those quantities until it reaches five times the value of the products that were the object of the infringement). In this case the authority could also close the factory for a maximum of five years.

As accessory penalties, the authority is entitled to confiscate the defective or hazardous products and to make public the penalty, factory's name and its general information, to be identified by consumers and users.

It is important to emphasise that the expenses arising from the confiscation of the product, its transportation, distribution and destruction will be the responsibility of the party that neglected to follow the law.

The differing criteria are established in Act 29/2006, regarding medicines. Taking this as a basis, there are three kinds of infringements (minor, serious and major) for which the penalties may be imposed in different degrees (from minimum to maximum). According to article 102 of the above-mentioned act, the fines may arise as follows:

- minor infringement:
  - minimum degree: up to €6,000;
  - medium degree: between €6,001 and €18,000; and
  - maximum degree: between €18,001 and €30,000;
- serious infringement:
  - minimum degree: between €30,001 and €60,000;
  - medium degree: between €60,001 and €78,000; and
  - maximum degree: between €78,001 and €90,000;
- major infringement:
  - minimum degree: between €90,001 and €300,000;
  - medium degree: between €300,001 and €600,000; and
  - maximum degree: between €600,001 and €1 million (the fine imposed may exceed those quantities until it reaches five times of the value of the products that were the object of the infringement).

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

According to RD 1801/2003, the general regulation foresees two kinds of notification to the competent authorities, depending on the seriousness of the risk found.

Article 6 of the above-mentioned regulation provides the ordinary procedure for notifying a defective product. In such a case, producers and distributors that have knowledge or should have had knowledge about a product incompatible with the general safety regulation must notify the competent administrative authority, as soon as they have such knowledge. The communication must contain at least the following:

- information to precisely identify the product or batch of products;
- complete description of the risk that the products represent;
- all useful information to locate the product; and
- a description of the actions taken to prevent risks to consumers.

The notification should be sent pursuant to the form established by the National Consumption Institute, the National Medicine Agency or the Food Safety Spanish Agency, depending on the product.

With the exception of food and medicines, there is also a fast notification procedure to the authorities (RAPEX) for all dangerous consumer products if there is a serious hazard to consumers. This system allows a fast transfer of information about dangerous products identified in EU member states. In such a case, besides the above-mentioned information, the person who notifies must justify the results of the analysis to evaluate the risk and the use of this procedure.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Pursuant to Directive 95/2001 and Commission Decision 2004/905, the European Commission defines these criteria:

- the product must be within the remit of Directive 95/2001, which means that the product must be directed to consumers or that it could be used by consumers within the frame of a commercial activity;
- the product is on the market;
- the manufacturer or distributor has evidence of the product being dangerous or lacking compliance with the legal requirements for safety; and
- the product should not remain on the market due to the risk (to determine whether a product is hazardous, the manufacturer or distributor should analyse the severity of damage, predictability of damage, type of consumer, and in the case of no vulnerable adults whether the product is accompanied by accurate warnings).

Consequently, there are some circumstances in which the law understands that society accepts more risks than others and, therefore, the notification duty is at a lower level. An example of a high level of risk would be toy regulation, since children would be considered a vulnerable subject.

6 To which authority should notification be sent? Does this vary according to the product in question?

The notification of any hazard or defective product should be sent to the competent authority within the affected autonomous community. This may vary in the case that the product has been already supplied to consumers in more than one autonomous community.

In general, according to RD 1801/2003, the notification should be made to the competent body equivalent to the National Institute of Consumption in each autonomous community. If the risk has taken place in more than one autonomous community, the manufacturer or distributor should notify the competent authority of the autonomous community where it has its general headquarters. The competent body will inform the National Institute of Consumption.

If the hazard is related to food, the competent authority will be the equivalent to the Food Safety Agency in each autonomous community. If it is related to medicines, sanitary products or cosmetics, the competent authority will be equivalent to the National Medicine Agency.

7 What product information and other data should be provided in the notification to the competent authority?

For this purpose, the National Institute of Consumption sets forth specific forms to be completed by the producer or distributor according to the guidelines established by Commission Decision 2004/905. The further data (see question 4) that should be provided is:

- data of the addressee authority;
- data of the manufacturer or distributor;
- data on the product (brand, model, code, picture); and
- evaluation of the hazard.

The form may be downloaded from the National Institute of Consumption website, www.consumo-inc.es/Seguridad/notificacion.htm.

In the case of medicines, health-care professionals must notify, as soon as possible, the competent authorities in the drug supervision committee, which is a part of the National Medicine Agency.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Under RD 1801/2003, and in general, manufacturers and distributors have the obligation to cooperate with the authorities, providing all the information required, including information that is protected by industrial and commercial secrecy.

The manufacturers and distributors have five days to answer the enquiries of the administration. The authority is entitled to reduce this period due to the urgency of a specific case, however.

9 What are the penalties for failure to comply with reporting obligations?

RD 1801/2003 sets forth administrative measures without penalties to provide for warranties and restore the safety of the products.

Even though the previously mentioned Royal Decree has no penalties but just administrative measures, in addition to these measures Act 14/1986 and the Consumers General Act are applicable to apply the respective administrative punishment as stated in question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Information protected by commercial or industrial secrecy will not be used for any other purpose except the one that justifies its request.

In practice, although users and consumers are granted a right of access to the information on the defective product and should be informed by the administration in accordance with the specific case, the administrative body must implement the appropriate measures to prevent its employees from disclosing information protected by commercial or industrial secrecy that has been obtained for legal established purposes, under articles 6.4 and 17.3 of RD 1801/2003.

11 May information notified to the authorities be used in a criminal prosecution?

The administrative measures arising from notification of a defective product will not presume either criminal or administrative liability of the parties subject to those measures.

If the information provided shows that the actions of the manufacturer or distributor or any other agent may constitute an administrative or criminal infringement, the authorities are obliged to communicate this fact to the corresponding competent administrative or judicial authorities, to ensure that the neglectful party is guaranteed the appropriate legal protection during each procedure.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Article 8 of RD 1801/2003, in relation to the Consumers General Act, states the general principle according to which the applied corrective measures must be congruent with the causes that originated them, as well as proportionally related to the risk that is faced. Once these requirements are covered it is necessary to apply measures that are less restrictive of the free circulation of merchandise, liberty of enterprise and whatsoever affected right regarding these matters.

However, the administration is granted, in general, a high degree of discretion to take measures it may consider most appropriate to the current case.

Among the corrective actions likely to be applied, besides recall, there the possibility for sealing and preventing further movement of the product, recovery of the product from consumers, destruction of the product, and suspension of activities, selling and special offers.

Nevertheless, article 10 of RD 1801/2003 foresees special cases where specific measures should be taken:

- if there are signs of defects, the product supply should temporarily be suspended until, according to the respective evaluation, there is certainty of the safety of the product;
- if the risk of the product could be avoided by certain modifications and express warnings to consumers, before it is introduced in the market, the administrative request would specify what kind of warning should be added to the product and only then will it be able to circulate in the market; and
- regarding the recall: the regulation only states that when a product does not comply with the definition of 'safe product' and it has been introduced in the market, will it be subject to recall, recovery or destruction.

For the purpose of the previous points it is convenient to bear in mind that the definition of 'safe product' is, according to article 2 of RD 1801/2003, any product that in normal and rationally predictable conditions of use does not entail any risk to people's health and safety.

Moreover, in Spain a product will be deemed safe when it fulfils the requirements of health and safety as set out in specific regulations or, if it is not specifically regulated, it is at least supposed to be in

accordance with technical national rules that harmonise European rules, UNE rules (the Spanish quality and standardisation rules), good practice codes and the current status of technical knowledge.

There is also a presumption of defective products, which basically comprises a lack of administrative authorisations for the product and a lack of information with which to identify the producer, and where the product belongs to a group of products where one of them was deemed defective. In such cases, the product may be deemed defective, irrespective of its actual state, according to article 3 of RD 1801/2003.

In the case of medicines, the specific regulations are more restrictive, since article 99 of Act 29/2006 states that upon the suspicion of the existence of an imminent and serious risk to health, the competent authorities may take the following measures:

- quarantine, recall from the market and prohibition of use of the medicines and suspension of activities and advertising, as well as the closing of premises, which means the automatic blocking of the circulation of the products; and
- suspension of the manufacture, prescription, sale and supply of the medicines.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

The general requirements that producers or distributors should comply with to implement a measure to warn consumers and protect consumers from the defective product will be specified in the request made by the administrative authority for those who do not fully comply with the safety of products.

Such enquiry will include the time or deadline producers or distributors have to carry out the warning and a recommendation for corrective actions, but also grants freedom to the producer or distributor to act as it deems appropriate (unless it is expressly regulated in a specific case), according to article 9 of RD 1801/2003.

Moreover, to adopt the measures previously listed, it is necessary to carry out the administrative procedure referred in Act 30/1992. However, it will not be necessary to complete every single phase of the procedure, such as certain hearings and proof phases, as long as the hearing and evidence have been carried out before another administration of an autonomous community.

During the proceedings the technical commission for product safety (or similar autonomous institutions) has been required to issue a report and those have already provided the corresponding hearings, and their ruling does not substantially differ from that report.

It is important to remark that this procedure will be ended at any point if the affected individuals decide to implement the appropriate measures to prevent the risks, as long as the administrative authorities consider them sufficient. In this case they will issue a ruling to state the end of the proceedings.

The specific regulations for medicines state that the National Medicine Agency must be immediately informed about the measures taken by the administration. This agency will be in charge of, as soon as possible, providing all agents with this information.

14 Are there requirements or guidelines for the content of recall notices?

As stated in question 13, according to article 9 of RD 1801/2003 the enquiry from the administration will specify:

- the result intended from the request;
- a deadline for fulfilling the request;
- the monitoring of the procedure; and
- the administration may recommend measures to take to obtain the result, but the entity subject to such enquiry may take other measures that lead to the intended result.

If the petitioning party does not take the necessary measures or the measures taken are insufficient, the administration may implement the measures listed in article 10 of RD 1801/2003 (see question 12).

Moreover, there is a guideline document for manufacturers and distributors or suppliers provided by various European health ministries that offers information about how to proceed when they have knowledge of an imminent risk presented by a certain product. These guidelines may be found on the following websites:

- www.consum.cat/doc/doc_40488555_1.pdf;
- www.eurocommerce.be;
- www.businesseurope.eu/Content/Default.asp; and
- www.prosafe.org.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

In general, according to what has been stated, the petitioning party may choose which media it prefers to use to communicate the warning or recall to users and suppliers. Please note that if the administration considers that the measures taken are not sufficient, it may implement measures according to article 10 of RD 1801/2003.

However, regarding medicines, the specific regulation states that the National Medicine Agency will publish, by means of the appropriate media, the measures taken to let all the potentially affected persons know about these measures.

Concerning food products, the president of the Food Safety Spanish Agency will evaluate the risk to create crisis and emergency committees, which will carry out the due procedures according to articles 31 and 32 of RD 709/2002.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

As mentioned above, regarding the measures to be taken, the competent authority will be firstly the administration from the autonomous communities that have discretion – which must always be reasonable and justified – to take the measures for a reasonable period, always considering the right of free business and the interests at stake.

However, according to article 11.6 of RD 1801/2003, when the competent authority is the central administration, the measures taken must not exceed six months.

Act 29/2006, regarding defective or hazardous medicines, foresees that measures taken may be subject to further extensions if the nature of the risk justifies it.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The recall of products is an administrative measure to prevent further damage to consumers. Moreover, all regulations that establish recall measures foresee that those measures may be taken without prejudice to eventual civil or criminal actions.

This means that if, according to the General Consumers Act, the Civil or Commercial codes, the consumer or the purchaser of the affected goods can prove that he or she has suffered damage arising from the measure, such consumer or purchaser might be entitled to claim for the damages suffered.

These measures are also foreseen in article 12.5 of RD 1801/2003, in general, and article 100 of Act 29/2006 for the medicines.

18 What are the penalties for failure to undertake a recall or other corrective actions?

When the public authorities deem that the entities that caused the infraction are not duly cooperating, they can proceed to perform the necessary actions themselves or with other entities' collaboration.

The fines that the administration may impose for a lack of collaboration with the measures taken (ie, the recall of the product or any other corrective measure) will be the ones stated in the

General Consumers Act, Act 14/1986 or Act 29/2006 depending on the nature of the infringement, in the terms set forth in question 3.

In general, this infringement will be considered as a minor infringement. However, depending on the nature of the risk and the interests at stake, the law allows the administration to deem the infringement serious or even major.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

As stated above, producers or distributors should be granted a determined period to correct the risk or defect of the product. Once this time has elapsed with no positive result, the administration may carry out either of the administrative measures that are stipulated in article 10 of RD 1801/2003 (see question 12), even the recall in the case of products that are already in circulation on the market.

The competent authority must ensure the full effectiveness of the corrective action to perform, which may be enforced or even directly performed by the authority itself.

20 Can the government authorities publish warnings or other information to users or suppliers?

According to article 17 of RD 1801/2003, considering the nature of the risk and interests at stake, the authorities will be entitled to inform users and consumers who are potentially endangered about the risks or irregularities in the products. This information may be displayed by the most appropriate means and will be related to the existing hazards and defects of the product, its identification, the adopted corrective measures that have been taken, as well as measures consumers must take to protect themselves.

Alternatively, citizens also have the right to access the general information that is in the possession of the authority as long as this information is not restricted due to control or investigation activity.

Similar measures are foreseen for medicines, under article 99 of Act 29/2006, which states that the National Medicine Agency will give notice of the measures taken through the most appropriate means.

Regarding food emergencies, apart from the RAPEX, which allows rapid information exchange between autonomous communities and, if applicable, member states, facing a food emergency, the Food Safety Spanish Agency may inform the population through its own Hazard Communication Office, which is entitled to choose among official notices, electronic means or the mass media, according to article 35 of RD 709/2002.

21 Can the government authority organise a product recall where a producer or other responsible party has not already done so?

As explained previously, if the neglectful party does not take the measures proposed by the administration or the competent authority deems that the producer or the distributor has not satisfactorily completed the proposed measure to prevent the hazard, it is entitled to enforce any corrective action including product recalls (see questions 13, 19 and 24).

22 Are any costs incurred by the government authority in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Under article 12.5 of RD 1801/2003 and article 99.5 of Act 29/2006, all the measures taken to prevent the hazards from affecting, or at least further affecting, consumers, even the ones that the administration takes by itself, will be at expense of the neglectful party.

23 How may decisions of the authorities be challenged?

However, according to article 99 of Act 26/2009, the measures of quarantine and suspension of medicines are foreseen as precautionary injunctions, and therefore the procedure to follow will be the equivalent of Act 30/1992, and not the ordinary administrative procedure.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

As stated above, administrative actions are always without prejudice to further civil or criminal actions. In this regard, it must be borne in mind that each procedure (civil, criminal and administrative) grants the defendant different kinds of guarantees and possibilities to allege.

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Therefore, the initiation of an administrative file, and the information about the product defects gathered may be used as evidence in other proceedings, or the publication of a safety warning will not be viewed automatically as an admission of liability.

If an affected consumer or purchaser of defective products has suffered damages that may entail civil or criminal liability, he or she will have to prove the damage and the liability of the defendant, according to the Civil or Criminal Procedure Laws.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

If those reports, investigations or communications evidenced that the actuation of the neglectful party entails criminal liability, the administrative procedure would be automatically suspended and brought before and dealt with by the competent judicial authority.

For medicines, article 100 of Act 29/2006 foresees that all the measures taken by the administration aimed at preserving the safety and health of the population may be maintained until the judge issues a ruling about their appropriateness.

Alternatively, the initiation of a civil procedure does not interrupt the administrative proceedings. If the claimant may have access to the reports, communications or investigations that had taken place within those proceedings, such claimant may use them as evidence to reinforce his or her arguments against the defendant.

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