

Product Recall

In 22 jurisdictions worldwide

Contributing editors

Alison M Newstead and Harley V Ratliff



2015

GETTING THE
DEAL THROUGH 

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Product Recall 2015

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CONTENTS

Global Overview	5	Greece	60
Alison M Newstead and Harley V Ratliff Shook, Hardy & Bacon International LLP		Dimitris Emvalomenos Bahas, Gramatidis & Partners	
European Overview	7	Ireland	65
Alison M Newstead Shook, Hardy & Bacon International LLP		Ronan Geary Ronan Daly Jermyn	
Argentina	11	Italy	69
Gastón Dell’Oca and Luis Eduardo Sprovieri Forino Sprovieri Dell’Oca Aiolo Abogados		Federica Cinquetti and Salvatore Gaudiello Gianni, Origoni, Grippo, Cappelli & Partners	
Australia	14	Japan	74
Colin Loveday and Ross McInnes Clayton Utz		Kei Akagawa and Yasuhiro Kawabata Anderson Mōri & Tomotsune	
Austria	20	New Zealand	78
Andreas Eustacchio and Maximilian Moser Eustacchio & Schaar Rechtsanwälte		Mark Gavin and Lucy Archer Hudson Gavin Martin	
Belgium	24	Poland	83
Eric Montens and Emmanuel Plasschaert Crowell & Moring		Andrzej Tomaszek Drzewiecki, Tomaszek & Partners	
Brazil	29	Russia	88
Paulo Rogério Brandão Couto and Eliane Leve Brandão Couto, Wigderowitz & Pessoa Advogados		Ekaterina Kalinina and Thomas Mundry Noerr	
Canada	34	South Africa	92
Sara Zborovski and Kelly Friedman Davis LLP		Evert van Eeden and Louis van Wyk Van Eeden Rabie Inc and Spoor & Fisher	
China	39	Spain	97
Ellen Wang and Yu Du MMLC Group		Sönke Lund and Ramon Romeu Monereo Meyer Marinel-lo Abogados	
Denmark	47	United Kingdom	102
Søren Stæhr and Christian Holm Madsen Gorissen Federspiel		Alison M Newstead Shook, Hardy & Bacon International LLP	
France	51	United States	107
Florian Endrös and Muriel Mazaud EBA – Endrös-Baum Associés		Harley V Ratliff and Devin K Ross Shook, Hardy & Bacon LLP	
Germany	56	Venezuela	112
Martin Alexander and Joachim Krane BLD Bach Langheid Dallmayr Rechtsanwälte Partnerschaftsgesellschaft		Pedro Ignacio Sosa Mendoza, Pedro Luis Planchart and Rodrigo Moncho Stefani Araquereyna	

Greece

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General product obligations

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

The basic legislative documents that set out the Greek legal framework on product safety are Ministerial Decision Z3/2810/14 of December 2004 (MD), which implemented EU Directive 2001/95/EC on General Product Safety (GPSD) and Law 2251/1994 on Consumers' Protection (usually referred to as the Consumers' Law, as in force today – Law 2251), which, inter alia, implemented EU Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products (as amended by EU Directive 99/34/EC, the PL Directive). The above legal framework is supplemented by Regulation (EC) No. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, in force as of 1 January 2010.

The General Consumer's Secretariat of the Ministry of Development and Competitiveness is the central competent authority regarding producers' compliance with the products safety rules (the General Secretariat).

The above-mentioned basic legislative documents supplement the provisions of the legislation on various specific product categories, where the latter does not cover certain matters, such as the description of the powers of the competent authorities on safety issues.

A product is safe if, under normal or foreseeable conditions of use, including its expected lifespan, it does not present any risk, or it presents only a minimum risk that is considered acceptable and compatible with a high level of protection for consumer safety and health (article 2b of the GPSD and the MD and article 7, paragraph 3, Law 2251).

There are various provisions for specific product categories, including the following.

Toys

Common Ministerial Decision 3669/194/2011 (Government Gazette Bulletin (GGB) 549/B/2011), implemented EU Directive 2009/48/EC on the Safety of Toys. The competent authority is the First Directorate of Industrial Policy, of the General Secretariat of Industry, of the Ministry of Development and Competitiveness (the Industry Secretariat).

Childcare products

Ministerial Decision Z3-818 (GGB 1395/B/2009). Competent authorities are the General Secretariat and the local prefectures.

Low-voltage products

Ministerial Decisions 470/85 (GGB 183/B/1985), B.64671/608/88 (GGB 214/B/1988) and 16717/5052/23.12.1994 (GGB 992/B/1994). The competent authority is the Fourth Directorate of the Industry Secretariat.

Power sockets and plugs

Ministerial Decision 529/28-1-2000 (GGB 67/B/2000), as amended by Ministerial Decisions 4822/17.3.2000 (GGB 352/B/17-3-2000) and 8991/14-5-2003 (GGB 643/B/2003). The competent authority is the Fourth Directorate of the Industry Secretariat.

Pressure products and systems

Ministerial Decisions B10451/929/88 (GGB 370/B/1988), 12479/F17/414/91 (GGB 431/B/1991), 14165/F17.4/373/93 (GGB 673/B/1993),

20769/6285/94 (GGB 977/B/1994), 14132/618/01 (GGB 1626/B/2001), 16289/330/99 (GGB 987/B/1999) and 12436/706/2011 (GGB 2039/B/2011). The competent authority is the Third Directorate of the Industry Secretariat.

Boilers

Presidential Decree 335/93 (GGB 143/A/1993) as amended by Presidential Decree 56/95 (GGB 46/A/1995) and Royal Decree 277/63 (GGB 65/A/1963). The competent authority is the Third Directorate of the Industry Secretariat.

Machines

Presidential Decree 57/2010 (GGB 97/A/2010), as amended by Presidential Decree 81/2011 (GGB 197/A/2011), which implemented EU Directive 2006/42/EC. The competent authority is the Third Directorate of the Industry Secretariat in collaboration with various other directorates.

Means of personal protection

Ministerial Decisions 4373/1205/93 (GGB 187/B/1993), 8881/94 (GGB 450/B/1994) and B.5261/190/97 (GGB 113/B/1997). The competent authority is the First Directorate of the Industry Secretariat.

Equipment for explosive works

Ministerial Decision B17081/2964/96 (GGB 157/B/1996). The competent authority is the Fourth Directorate of the Industry Secretariat.

Plastic tubes

Ministerial Decisions 14013/ 32/327/83 (GGB 597/B/1993) and 10347/32/176/93 (GGB 432/B/1993). The competent authority is the Second Directorate of the Industry Secretariat.

Structural construction products

Presidential Decree 334/94 (GGB 176/A/1994) and various Ministerial Decisions specifying the provisions of such PD. The competent authority is the Second Directorate of the Industry Secretariat.

Pleasure yachts

Ministerial Decision 4841/F7B/52/97 (GGB 111/B/1997). Competent authorities are the Third Directorate of the Industry Secretariat and the Ministry of Shipping.

Elevators

Ministerial Decisions 9.2/32803/1308/97 (GGB 815/B/1997) and 15085/593/03 (GGB 1186/B/03). Competent authorities are the following Directorates of the Industry Secretariat, namely the Third Directorate and the Supporting Directorate for Industry.

Bio-extinguishers

Presidential Decree 205/01 (GGB 160/A/2001). The competent authority is the National Organisation for Medicines (EOF).

Air fresheners

Ministerial Decision Y1/1880/01 (GGB 1018/B/2001). The competent authority is EOF.

Anti-smoking products

Ministerial Decision Y3d/515/94 (GGB 137/B/1994). The competent authority is EOF.

Cosmetics

Ministerial Decision 3a/132979 (GGB 352/B/2005), which implemented Cosmetics EU Directive 76/768/EEC, and various other Ministerial Decisions issued subsequently to specify its provisions. The competent authority is EOF.

Chemicals

Ministerial Decisions Y1b/7723/94 (GGB 961/B/1994), 378/94 (GGB 705/B/1994), which implemented EU Directive 67/548/EEC, and 265/02 (GGB 1214/B/2002), which implemented EU Directives 1999/45/EC and 2001/60/EC. Competent authorities are EOF and State's General Chemical Laboratory of the Ministry of Economy and Finance.

Vehicles and parts for vehicles

Various legislative documents. The competent authority is the Ministry of Development, Competitiveness, Infrastructure, Transportation and Networks.

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

There is no specific regulation for traceability purposes. Only general provisions exist, giving the authorities broad discretion to ensure that traceability is guaranteed.

In general, each product has to be duly labelled and identified and must therefore include information about its producer, namely, the name of an individual or the business name of a legal enterprise, and the address of the registered office. Accordingly, each product has to bear the specification of the product type or category, and, if applicable, its series or batch number. The product must further be labelled, which means that it must bear the information enabling the evaluation of risks connected with its use, or any other information relating to product safety. Such data must be stated directly on the product, on an attached leaflet or even on the packaging, in a visible and legible manner. The information must be stated at least in the Greek language. This enables a consumer to duly identify the product, its series and its producer.

Distributors must participate in the procedure of monitoring the safety of products they put in the market and to this end cooperate with the producers and the competent authorities, mostly conveying information regarding the dangers of the products and providing the necessary documents that can establish the products' origin.

For certain categories of products their producers must be able to identify the products' distributors if it is necessary to determine a group of consumers who might have obtained the defective product.

As far as food and medical products are concerned, lot numbers, manufacturer's serial number and respective date of production must be included on packaging.

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

According to article 13a of Law 2251 (as amended by Law 4177/2013), subject to the stipulations of the Criminal Code, the Rules Regulating the Market of Products and the Provision of Services and other special laws, the following civil and administrative sanctions may be imposed by a decision of the minister of development and competition, acting either ex officio or after a complaint filed, namely:

- recommendation for compliance within a specified deadline as well as an order to stop the infringement and refrain from it in the future;
- a fine of between €1,500 and €1 million. The maximum amount of the fine may be doubled if more than three fines are imposed on a distributor; or
- if more than three fines are imposed on a distributor, the minister of development and competition may order the temporary closure of the distributor's business for a period ranging from three months to one year.

Imposed sanctions may be generally readjusted by a joint decision of the Minister of Economy and Finance and the Minister of Development and Competition.

Further, the minister of development and competition has the authority, considering the nature and graveness of the violation, as well as its general repercussions on the consuming public, to publicise, through the press or any other means available, the sanctions imposed and the restraining measures taken with regard to the circulation of a product in the market.

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?

Should producers or distributors become aware that any of their products presents dangers to consumers, they must notify immediately and without delay the General Secretariat, and any other competent authority depending on the type of the products at issue, for the prevention of any danger and hazard to consumers.

The notification is made in a form provided by the competent authority and has to include information to identify the product, complete description of the defect or the risk involved with the usage of the product, information to locate the product in the market, description of the actions taken by the producer or distributor and actions that shall be taken by consumers to prevent any further risk.

If the product has been marketed outside Greece as well, the procedure under the RAPEX notification system may be followed. The system allows the fast, almost simultaneous, transfer of information on dangerous products within the EU. Respective procedures apply especially to food and medicines.

The notified authorities may request additional information, the submission of relative documents or measures to be taken by the producer or distributor.

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

The safety of the product in question determines any notification needs (see also question 1).

The following criteria are monitored from the point of view of risks to consumers' safety and health protection (article 7, paragraph 3, Law 2251 implementing the GPSD), namely:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; and
- the categories of consumers at risk when using the product, in particular children and the elderly.

The producer may be informed about the danger of a product by any appropriate means. The producer may find out that the product is not safe due to his own inspections and tests or on the basis of initiatives from consumers, insurance companies, distributors or governmental bodies. In any case, it is necessary to notify the competent authority as soon as the producer establishes such risk.

EC Decision 2004/905/EC sets out guidelines for the notification by producers and distributors of dangerous consumer products to the competent authorities of the member states (the Guidelines) in accordance with article 5, paragraph 3 of the GPSD.

The Guidelines (Annex, section 3) set out the notification criteria, which are as follows:

- the product is understood to be intended for, or likely to be used by, consumers (article 2a of GPSD);
- article 5 of GPSD applies (unless there are specific provisions established by other EU legislation);
- the product is on the market;
- the professional has evidence that the product is dangerous according to the GPSD, or that it does not satisfy the safety requirements of the relevant Community sectoral legislation applicable to the product considered; and
- the risks are such that the product may not remain on the market.

The Guidelines provide that the notification shall be made without delay and specify the deadline for making notifications in terms of days. Accordingly, in case of serious risk companies are required to inform the authorities without delay and in no case later than three days after obtaining information; in any other case, within 10 days.

There are only minimal differences in the preconditions and time framework for notification for various specific product categories.

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

In general, notifications must be made to the competent authority as is stipulated in question 1. The authorities to which the notification shall be made vary according to the product.

Further to the authorities mentioned in question 1, we examine below two important categories of products.

Food

For food products, the competent authority is the Hellenic Food Authority (HFA), established in 1999. The HFA is supervised by the Ministry of Rural Development and Food.

The HFA's principal aims are to take all the necessary actions to ensure that food produced, distributed or marketed in Greece meets the standards of food safety and hygiene as described by the national and European legislation. The HFA also acts as the national contact point of the European Union regarding the management of the Rapid Alert System of Food (RASFF) and for the Codex Alimentarius Commission (of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO)) and it is the local point of the European Food Safety Authority (EFSA).

Medicines

For medicines and sanitary products and equipment, EOF (see also question 1) is the competent authority. EOF was established in 1983 and is supervised by the Ministry of Health and Social Solidarity. EOF's mission is to ensure public health and safety with regard to the following products, marketed in Greece:

- medicinal products for human and veterinary use;
- medicated animal foods and food additives;
- foodstuffs intended for particular nutritional uses and food supplements;
- biocides;
- medical devices; and
- cosmetics.

Within the framework of its mission, EOF, in cooperation with the European Union, performs the following tasks:

- evaluates and authorises new, safe and efficient health-related products;
- monitors the post-marketing product quality, safety and efficiency;
- monitors product manufacturing procedures, clinical studies and the marketing of products in order to ensure compliance with good manufacturing, laboratory and clinical practice, as well as with the existing legislation regarding the marketing, distribution, commercialisation and advertising of the products;
- develops and promotes medical and pharmaceutical research; and
- provides health scientists, competent authorities, and the general public with objective and useful information regarding medicines (for human or veterinary use) and other relevant products, in order to ensure their rational use and assess their cost-effectiveness.

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

In accordance with the provisions of the Guidelines (Annex, section 5), the notification must include at least the following:

- details of the authorities and resellers or distributors notified;
- details of the producer and distributors;
- details of the contact person regarding the notification;
- details of the product, including the category of the product, product's brand or trade name, product's model, barcode or CN tariff, product's country of origin and a photograph or description of the product;
- description of the hazard and of the possible health or safety damages and conclusions of the risk estimation and evaluation carried out;
- a record of accidents; and

- details of corrective actions taken, including the type, the scope and the duration of actions and precautions taken and the identification of the responsible company.

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

Greek legislation does not expressly regulate the obligation to provide authorities with updated information on risks. However, such obligation falls within the general scope of safety regulations that stipulate that all products on the market must be safe and if a product becomes unsafe, the producer or distributor has to take all appropriate measures to meet all possible risks.

Taking into consideration that a notification to the authorities is made according to an initial assessment of the product's hazard, the authorities will have to be kept informed of the results of any ongoing research in order to be updated and monitor the case.

Moreover, according to the provisions of Law 2251, the competent authority may request information from the producer or the distributor and can set a deadline, within which the information must be given to it.

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

See question 3.

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

In general, information containing commercial or industrial secrets shall not be disclosed to the public by the notified authorities.

The competent authorities shall make available to the public information in relation to the notified product and the risk from its usage but they shall prevent the disclosure of information containing commercial or industrial secrets, unless such disclosure is necessary to protect the public.

Moreover, any third party may request from the public prosecutor the issue of an order granting access to the files of the case kept by the competent authorities, including commercial or industrial secrets. Such a request may be granted if the applicant proves a lawful interest for this.

Thus, notified commercially sensitive information is not always protected against public disclosure.

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

There is no specific provision in Greek legislation. In general, information obtained by the authorities may be used in criminal proceedings.

Product recall requirements

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

There are no specific provisions regarding the criteria according to which a product recall or other corrective actions are determined. The producer or distributor of a defective product, must take any measure in order to eliminate possible hazard from that product's use, as soon as any defect comes into his knowledge. These measures may vary and can include warning notifications, retrospective instructions to consumers, invitations for servicing or updating of the product in order to become safe or notifications recalling the product.

A product recall is an action taken in the event that no other measure would eliminate the danger. The recall may be either initiated by the producer or distributor of the product or ordered by the competent authority.

A guide containing information on determining when a recall or another corrective action is required according to the Guidelines is provided by the EU at http://ec.europa.eu/consumers/cons_safe/action_guide_en.pdf.

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?

Producers and distributors are obliged to market only safe products. If they fail to do so, they are obliged to take any appropriate measure without delay

Update and trends

Greek authorities are especially active in using the RAPEX procedure. Based on the official data from the past six years, the General Consumer's Secretariat annually made an average of approximately 109 notifications (2013: 61, 2012: 82, 2011: 69, 2010: 159, 2009: 153, 2008: 129). There are currently no available data for 2014.

Consumer awareness must be considered low. Very few consumer organisations are active, focusing on challenging abusive general terms and conditions.

Consumers' reports and complaints are filed with the General Consumer's Secretariat. A total of 13,173 complaints were filed in 2013. Since October 2013, complaints may be filed at any time through the new General Consumer's Secretariat web page, at www.1520.gov.gr. Besides the online filing, the General Consumer Secretariat operates a call centre, which responded to approximately 17,412 consumers' phone calls in 2013. There are currently no available data for 2014.

Further, during the most recent years, competent authorities have intensified market controls regarding unsafe products. So, in 2013 fines of a total amount of €4,874,568 were imposed by the General Consumer's Secretariat. There are currently no available data for 2014.

Lastly, Law 2251 continues to be amended from time to time. After extensive and significant amendments were introduced to it in 2007, Law 2251 was modified again in 2012 and in 2013. The latest amendments (by Law 4177/2013) basically concern the financing of consumer organisations, the sanctions that may be imposed for non-compliance with Law 2251's provisions and a categorisation of the complaints filed by consumers and consumer organisations (amended articles 10, 12 and 13a and new article 13b of Law 2251).

and as soon as possible in order to prevent any hazard to consumers. Both the producer and the distributor have this obligation.

It is the producer and the distributor of a product who must determine whether it is defective, thus whether the authorities need to be notified thereon accordingly. The above persons have to define the measures to be taken.

The competent authorities retain their powers to impose additional measures ensuring the safety of users.

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

See question 7.

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

Greek legislation does not provide for specific media to be used for the warnings or recalls. Any type of publicity that can accomplish the scope of the elimination of the danger may be used. The competent authority may request more extensive publication than the publication used by the producer or distributor, depending on each case.

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

Greek legislation does not provide for such targets or periods.

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

Article 6 paragraphs 2 to 4 of Law 2251 provide (in conformity with the PL Directive) that a producer responsible for the defect, is regarded the manufacturer of a finished product or of any raw material or of any component, as is any other person who presents himself as a producer by putting his name, trademark or other distinguishing feature on the product. Moreover, any person who imports a product within the EU for sale, leasing or hire or any form of distribution shall be responsible as a producer. Where the producer of the product may not be identified, each supplier of the product shall be treated as its producer unless he provides the injured person with information on the identity of the producer or of the person who supplied him with the product. The same applies to the supplier of imported products when the importer's identity is unknown, even if the producer's identity is known.

According to Law 2251 (article 6, paragraphs 1, 6 and 7), the producer must compensate the consumer for any damage incurred to the latter due to defects of his product. Damage includes the following: damage due to death or physical injury, damage or destruction, due to the defective product, of every asset of the consumer, apart from the defective product itself, including the right to use environmental goods, on condition that the loss from such damage or destruction exceeds €500, and on the condition that by nature they were destined to be and were actually used by the injured person for his personal use or consumption. Damages for moral harm or mental distress may also be due based on the above regulation.

Further, and by virtue of article 540 of the Greek Civil Code, the buyer (in general and not only a consumer) is entitled either to demand the repair of the defective goods he purchased or their substitution (on the condition that such substitution or repair does not imply excessive and unreasonable

cost for the seller), or to require a price reduction or to rescind the contract for sale of goods, unless the defect or the lack of conformity of the goods sold with any agreed qualities is minor. Additionally, according to the general provision of article 914 of the Greek Civil Code, whoever acts unlawfully and by default causes damages to another party is obliged to compensate the injured party.

Moreover, both Law 2251 and the Greek Civil Code regulate the provision by the seller of a product guarantee. In short, where such a guarantee was provided and the defect is detected and noticed within the guaranteed period, the producer or distributor is obliged either to repair or replace the product at issue.

Regarding prescription, Law 2251 provides that claims against the producer or the other persons liable for defective products are prescribed three years after the consumer became aware of the damage or should have been informed about the damage, the defect and the identity of the producer. Ten years after the product was put into the market the rights of the consumer are time-barred (article 6 paragraph 13, Law 2251).

The general limitation period within which a buyer, being a consumer or not, must exercise his rights from a contract for the sale of goods is two years. Tort claims are subject to a five-year limitation period starting from the day the victim became aware of the damage and the person liable to compensate him. The same action or omission may constitute breach of a contract and tort under requirements. Lastly, the general limitation period applying to claims is 20 years. Claims for unjust enrichment fall within this period.

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

See question 3.

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?

Authorities may request the producer, the distributor or any supplier to take specific preventive or corrective actions. To that extent, they may also define the time frame within which the scope of such actions shall have been accomplished. If the obliged party fails to comply with and satisfy such requests, the competent authority may impose fines (see question 3).

Products that present or may present serious dangers to the safety and health of consumers when used in conditions that are normal or predictable may be revoked or withdrawn, as a precaution, by the competent authority. The procedure, the terms and conditions for the revocation, withdrawal or disposal under terms, destruction and any other relevant topic, are regulated by a decision of the Minister of Development or by a joint decision of him and by any other competent minister.

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

Government authorities may publish warnings or other information to users or suppliers where a producer or other responsible party has not already done so. See question 19. There are no rules whereby the same authorities may issue informal information or notices outside the above-mentioned established regulatory scheme. Further, Greek authorities' websites do not provide a facility for the public to post remarks or reports

of incidents. However, since May 2009, the website of the European Commission (<https://webgate.ec.europa.eu/gpsd-ba/>) provides for the GPSD Business Application, which is an online application that businesses can use instead of traditional methods, such as e-mail or fax, to submit their notifications on dangerous products to national authorities; using this application, businesses can also notify all member states at the same time.

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

Yes, government authorities may organise a product recall where a producer or other responsible party has not already done so. See question 19.

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

Yes, if it is the authority that carries out the required product recall, it will be entitled to claim the relevant costs incurred by the responsible party that did not comply with its obligations. Apart from the product recall costs, other administrative costs are not recoverable.

23 How may decisions of the authorities be challenged?

The ministerial decisions mentioned in question 19 must be served on the interested party. Against those decisions a quasi-judicial proceeding before the minister is provided for, within an exclusive period of 30 days as of the above service. The minister has to issue his or her decision within an additional exclusive period of 60 days and such minister's decision may be challenged within a further period of 60 days as of the minister's decision being served on the interested party.

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?

Without prejudice to all necessary proceedings, including evidence production, which must take place before a court, the publication of a safety warning or a product recall is likely to be viewed by the civil courts as an admission of liability for defective products, or at least as an indication that the product is defective.

It is useful to note that, before a civil court, the consumer (claimant) has only to prove the defect of the product, the damage caused by it and the causal link, whereas proof of the absence of fault lies on the producer (defendant) under an adverse burden of proof rule established by case law to facilitate claimants.

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

A product liability action, being a private law dispute, is tried exclusively by civil courts. There is a general duty of truth but each litigant may only submit to the court the evidence being favourable to support his case.

The Greek Code of Civil Procedure does not provide for discovery within the meaning of the common law concept. However, a consumer (claimant) may request from the court – upon certain conditions – an order that the defendant (producer or distributor) files and discloses documents in his possession relevant to support the claim, which, however, must be clearly specified by the claimant. Thus, communications, internal reports and the like may be – at least in theory – disclosed in product liability actions. In practice, however, owing to the very strict prerequisites imposed by case law on the claimant regarding the specification by him of the requested documents, the success of such disclosure petition must be regarded as an exception.



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