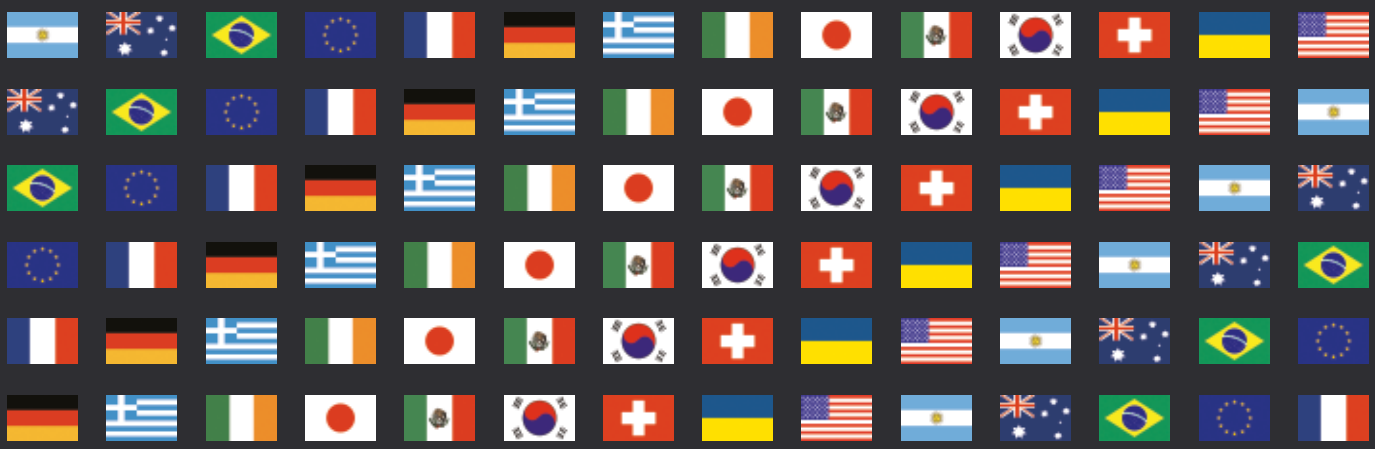
Product Recall 2022

Contributing editor
Sarah-Jane Dobson



LEXOLOGY
Getting The Deal Through

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Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Argentina, Brazil, Germany, the European Union, South Korea, Switzerland, Ukraine and the United Kingdom.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Sarah-Jane Dobson of Kennedys Law LLP, for her assistance with this volume.

LEXOLOGY®
Getting The Deal Through

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PRODUCT SAFETY LAWS

Product safety legislation

1 What basic laws govern the safety standards that products must meet in your jurisdiction?

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 amended many times and in force today after being codified in 2018 – Law No. 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 the latest Regulation (EC) No. 2019/1020 'on market surveillance and compliance of products', which came into force on 16 July 2021 (apart from its provisions on the new Union Product Compliance Network, in force as of 1 January 2021).

GPSD is to be repealed by a Regulation on general product safety and the currently proposed one is dated 30 June 2021; such proposal is in line with the New Consumer Agenda of 2020 and its basic aims are to a) update GPSD ensuring a safety net for all products and b) safeguard that the legal regime will provide greater consistency between EU harmonised and non-harmonised products.

The General Secretariat of Commerce and Consumer Protection of the Ministry of Development and Investments is the central competent authority regarding producers' compliance with the product 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 2(b) of the GPSD and the MD and article 7, paragraph 3, Law No. 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. Commission Regulation (EU) No 681/2013 also applies. The above Ministerial Decision has been amended and supplemented a number of times, and most recently by Ministerial Decision 61715/16.6.2020 (GGB 2537/B/24.6.2020), in compliance to EU Directives 2019/1922/EU and 2019/1929/EU. The competent authority is the General Secretariat of Industry, of the Ministry of Development and Investments (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

Common Ministerial Decision 51157/2016 (GGB 1425/B/2016), implemented EU Directive 2014/35/EU on the harmonisation of the laws of the member states relating to the making available on the market of electrical equipment designed for use within certain voltage limits. The competent authority is 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), 8991/14.5.2003 (GGB 643/B/2003) and 82373 (GGB 3245/B/4.8.2020). The competent authority is 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 12436/706/11 (GGB 2039/B/2011). The competent authority is 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). Relevant EU legislation also applies. The competent authority is 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 Industry Secretariat in collaboration with various other directorates.

Means of personal protection

EU Regulation 2016/425 on Personal Protective Equipment (the PPE regulation) and various Ministerial Decisions specifying the provisions of the Regulation. The competent authority is the Industry Secretariat.

Equipment for explosive works

Presidential Decree 128/2016 (GGB 228/A/7.12.2016) implemented EU Directive 2014/28/EU and various Ministerial Decisions specifying the provisions of the Presidential Decree. The competent authority is the Industry Secretariat.

Plastic tubes
Ministerial Decision 14097/757/4.12.2012 (GGB 3346/B/14.12.2012) as amended by Ministerial Decision 114233/7.11.2019 (GGB 4878/B/25.11.2019). The competent authority is the Industry Secretariat.

Structural construction products
Presidential Decree 334/94 (GGB 176/A/1994) and various Ministerial Decisions specifying the provisions of the Presidential Decree, amongst which Ministerial Decision 6690/2012 (GGB 1914/B/15.6.2012). Relevant EU legislation also applies. The competent authority is the Industry Secretariat.

Pleasure yachts
Ministerial Decision 4841/F7B/52/97 (GGB 111/B/1997) as amended by Ministerial Decision 4113.183/01/2004 (GGB 1613/B/2004). Relevant EU legislation applies. Ministerial Decision 13926/2016 (GGB 273/B/11.2.2016) implemented EU Directive 2013/53/EU on Recreational Craft and Personal Watercraft. The competent authority is the Industry Secretariat, along with various other directorates.

Elevators
Ministerial Decision 28425/22.12.2008 (GGB 2604/B/2008) as amended by Ministerial Decision 68781/28.6.2019 (GGB 2760/B/3-7-2019). Relevant EU legislation applies. Ministerial Decision 39507/12.4.2016 (GGB 1047/B/13.4.2016) implemented EU Directive 2014/33/EU. The competent authority is the Industry Secretariat.

Bio-extinguishers
Presidential Decree 205/01 (GGB 160/A/2001). EU Regulation 528/2012 applies. 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
EC Regulation 1223/2009 on Cosmetics and various Ministerial Decisions issued subsequently to specify the provisions of the Regulation. The competent authority is EOF.

Chemicals (including industrial raw materials, industrial products and candles)
EC Regulations 1907/2006 and 1272/2008 and various Ministerial Decisions issued subsequently to specify their provisions. Competent authorities are EOF and the State's General Chemical Laboratory, depending on the specific product.

Vehicles and parts for vehicles
Various legislative documents. The competent authority is the Ministry of Development and Investments.

Basic pre-launch requirements

2 | What basic steps and safety requirements must be satisfied before a product can be marketed in your jurisdiction?

As a rule Greek laws are in line with the EU legislation covering the relevant legal field, subject to specific derogations to the extent they are allowed by the latter, which gives a basic comfort and certainty to the interested parties.

An important step is getting appropriate technical and legal advice on the general regulatory and legal framework as well as on the specific provisions covering the products at issue. Within that framework, the special coronavirus legislation introduced since March 2020, and being in a constant state of flux as the pandemic develops over time, must be taken into account.

Guidance

3 | Is there any guidance on the application of the product safety legal framework, or related commentary around its effectiveness?

As a rule Greek laws are in line with the EU legislation covering the relevant legal field, subject to specific derogations to the extent they are allowed by the latter, which gives a basic comfort and certainty to the interested parties.

An important step is getting appropriate technical and legal advice on the general regulatory and legal framework as well as on the specific provisions covering the products at issue. Within that framework, the special coronavirus legislation introduced since March 2020, and being in a constant state of flux as the pandemic develops over time, must be taken into account.

ENFORCEMENT OF PRODUCT SAFETY LAWS

Regulators

4 | Who enforces the product safety laws in your jurisdiction? If there are multiple regulators, how do their activities intersect and to what extent do they cooperate?

The General Secretariat of Commerce and Consumer Protection of the Ministry of Development and Investments is the central competent authority for product safety (the General Secretariat). Various other authorities exist depending on the products at issue.

For industrial products, a main authority is the General Secretariat of Industry of the Ministry of Development and Investments (the Industry Secretariat).

Regarding sectoral authorities and indicatively, due to the importance of the products for food products, the competent authority is the Hellenic Food Authority (EFET) supervised by the Ministry of Rural Development and Food and for medicines and sanitary products and equipment, the competent authority is National Organisation for Medicines (EOF) supervised by the Ministry of Health.

Product safety regulators are allowed to cooperate with other non-product safety regulators in the general frame of inter-relationship among the public administrative bodies provided a case falls within the subject matter of their competence and such cooperation serves a specified legitimate cause. Also, Greek regulators may cooperate with analogous international regulators within the framework of existing international legislation, for example, regarding the Rapid Exchange of Information System (RAPEX).

Enforcement actions and penalties

5 | What enforcement actions are available to the regulatory authorities? What penalties may they impose for non-compliance with product safety laws?

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

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 and Investments or by a joint decision of him or her and by any other competent minister.

Government authorities may also publish warnings or other information to users or suppliers and even organise a product recall where a producer or other responsible party has not already done so. 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, European Commission's 'Business Gateway to report dangerous products to the member state authorities' at https://webgate.ec.europa.eu/gpsd/ (formerly known as the GPSD Business Application), facilitating the producers or distributors of the notified product, or their authorised representatives to submit notifications under the GPSD, allows the Greek and other EU competent national authorities to use the information provided to submit a RAPEX notification if all criteria for this are met.

RAPEX is the EU's rapid alert system for unsafe consumer products and consumer protection. RAPEX does not encompass food and pharmaceutical products and drugs. RAPEX allows a quick exchange of information on measures such as repatriation or product recalls, whether carried out by national authorities or by voluntary action of manufacturers and distributors (more at https://joinup.ec.europa.eu/collection/rapex and https://ec.europa.eu/safety-gate/#/screen/home).

Regarding penalties, according to article 13(a) of Law No. 2251 (as amended by Law No. 4512/2018) and subject to the stipulations of the Criminal Code and the Rules Regulating the Market of Products and the Provision of Services (Law No. 4177/2013), the following civil and administrative sanctions may be imposed by a decision of the competent minister, acting either ex officio or after a complaint filed, namely:

- a 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 an infringer, the minister may order the temporary closure of his or her business for a period ranging from three months to one year.

Imposed sanctions may be generally readjusted by a joint ministerial decision.

A special set of sanctions may be imposed on infringers that do not respond to consumers' complaints per the provided proceedings.

Further, the Minister of Development and Investments has the authority, considering the nature and graveness of the violation, as well as its general repercussions on the consumer public, to publicise, through the press or any other means available, the sanctions imposed and the restraining measures taken by the appropriate administrative authorities or by the parties obliged to act with regard to the circulation of a product in the market.

Enforcement process and procedures

6 What is the typical process for enforcement actions and what procedures are involved? What rules govern enforcement actions?

Communications with the regulators are in writing, however informal oral contacts take place often in the frame of a more efficient and prompt procedure especially on urgent cases, including clarifications and unofficial guidance on the discussed actions. The authorities have extensive powers to take any measure considered appropriate in the circumstances to protect the health and security of the public.

Enforcement trends

7 How prevalent is enforcement action under the product safety laws? Have there been any notable recent examples of enforcement actions?

Enforcement action under the product safety laws must be considered as having a limited effect and practice, whereas there have not been any recent notable examples thereof.

Challenging enforcement actions

8 What mechanisms are available to companies to challenge the imposition of enforcement actions?

The administrative decisions imposing sanctions on infringers must be served on the party affected thereby. A quasi-judicial proceeding before the Minister of Development and Investments against those decisions is provided for, within an exclusive period of 30 days as of the above service whereas the minister must issue his or her decision within an additional exclusive period of 60 days. Eventually, the minister's decision may be judicially challenged within a period of 60 days of his or her decision being served on the interested party.

NOTIFICATION REQUIREMENTS

Criteria for notification

9 What events or conditions trigger a requirement to notify the product safety authorities of issues discovered in products, or known incidents of personal injury or property damage?

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

The notification is made in a form required by the competent authority and must include information to identify the product, a complete description of the defect or the risk involved with the usage of the product, information to locate the product in the market, a description of the actions taken by the producer or distributor and actions that should 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 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.

Regarding any criteria for determining when a matter requires notification, the rule is that the safety of the product in question determines any notification needed.

The following criteria are monitored from the point of view of risks to consumers' safety and health protection (article 7, paragraph 3, Law No. 2251 implementing EU Directive 2001/95/EC on General Product Safety (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 because of his or her 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 of 14 December 2004 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 2(a) of the GPSD);
- article 5 of the 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.

Notification time limits

10 | What are the time limits for notification?

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

Competent authority for notification

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

In general, notifications must be made to competent authority. The General Secretariat of Commerce and Consumer Protection of the Ministry of Development and Investments is the central competent authority regarding producers' compliance with the product safety rules (the General Secretariat). The authorities to which the notification should be made vary according to the product. We examine below two important categories of products.

Food

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

EFET'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. EFET also acts as the national contact point of the European Union regarding the management of the Rapid Alert System for Food and Feed (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, the National Organisation for Medicines (EOF) is the competent authority. EOF was established in 1983 and is supervised by the Ministry of Health. 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's quality, safety and efficiency;
- monitors product manufacturing procedures, clinical studies and the marketing of products 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.

Form and content of notification

12 | What form should notification take? What product information and other data should be provided in the notification to the competent authority?

The notification is made in a form required by each competent authority and what matters are the contents of the same.

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.

Obligations to provide updates after initial notification

13 | What obligations are there to provide authorities with updated information about risks, or respond to their enquiries following an initial notification?

Greek legislation does not expressly regulate the obligation to provide authorities with updated information on risks. However, the 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 No. 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.

Penalties for failure to notify

14 | What are the penalties for failure to comply with notification obligations?

According to article 13(a) of Law No. 2251 (as amended by Law No. 4512/2018), subject to the stipulations of the Criminal Code and the Rules Regulating the Market of Products and the Provision of Services (Law No. 4177/2013), the following civil and administrative sanctions may be imposed by a decision of the competent minister, acting either ex officio or after a complaint filed, namely:

- a 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 an infringer, the minister may order the temporary closure of his or her business for a period ranging from three months to one year.

Imposed sanctions may be generally readjusted by a joint ministerial decision.

A special set of sanctions may be imposed on the infringers that do not respond to consumers' complaints per the provided proceedings.

Further, the Minister of Development and Investments has the authority, considering the nature and graveness of the violation, as well as its general repercussions on the consumer public, to publicise, through the press or any other means available, the sanctions imposed and the restraining measures taken by the appropriate administrative authorities or by the parties obliged to act with regard to the circulation of a product in the market.

Public disclosure of notification information

15 | Is the content of the notification publicly disclosed by the authorities? Is commercially sensitive information contained in the notification protected from public disclosure, or are the authorities otherwise bound by confidentiality?

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

The competent authorities may make available to the public information in relation to the notified product and the risk from its usage but they are prevented from disclosing information containing commercial or industrial secrets, which have been specified as such by the notifying party, unless such disclosure is necessary to protect the public.

Moreover, any third party may request the issue of an order granting access to the files of the case kept by the competent authorities, including commercial or industrial secrets, from a competent public prosecutor. 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.

Use of information in prosecution

16 | 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.

Information sharing between regulators

17 | Is notification information shared with other regulators?

Yes, notification information may be shared among the Greek regulators provided it is the subject matter of their competence and it serves a specified legitimate cause. Same applies to non-Greek regulators, as provided by relevant laws, for example, RAPEX.

CORRECTIVE ACTIONS AND RECALLS

Criteria for corrective action

18 | What criteria are applied to determine when a matter requires a product recall or other corrective action?

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 to eliminate possible hazard from that product's use, as soon as any defect comes to his or her attention. 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 useful information on the recalls' legal framework and the process to be followed by the economic operators and the market surveillance authorities and assisting in the determination of when a recall or another corrective action is required and how to be best pursued, is provided by the European Commission, titled 'Recall process from A-Z: Guidance for economic operators and market surveillance authorities' and dated 22 July 2021 (https://ec.europa.eu/safety-gate/#/screen/pages/effectiveRecalls).

Scope of corrective action

19 What criteria are applied to determine the scope of a corrective action?

There are no specific provisions regarding such criteria but the general scope remains the prompt taking of any appropriate measures to eliminate or limit, to the extent possible, any hazard to the consumers caused by the use of the unsafe product.

A guide containing useful information on the recalls' legal framework and the process to be followed by the economic operators and the market surveillance authorities and assisting in the determination of when a recall or another corrective action is required and how to be best pursued, is provided by the European Commission, titled 'Recall process from A-Z: Guidance for economic operators and market surveillance authorities' and dated 22 July 2021 (https://ec.europa.eu/safety-gate/#/screen/pages/effectiveRecalls).

Traceability requirements

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

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 must 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 Greek. 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 on 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.

The producers of certain categories of products 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.

Consumer messaging

21 What are the legal requirements to publish consumer notices, warnings or other information to product users or to suppliers regarding product issues and associated hazards, or to notify consumers of recalls?

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

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

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

Content of recall notices

22 Are there any requirements or guidelines for the content of corrective action or recall notices?

In accordance with the provisions of the Guidelines (Annex, section 5), a 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.

Mode of communication

23 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 for the elimination of the danger, in the specific circumstances, may be used. The competent authority may request more extensive publication than the publication used by the producer or distributor, depending on each case.

Time frame

24 Do any laws, regulations or guidelines specify targets or a period after which a recall is deemed to be completed?

Greek legislation does not provide for such targets or periods and completion or not of a recall is a matter of fact per the circumstances of each case.

Consumer remedies

25 What remedies must be offered to consumers affected by a product corrective action or recall? Are there any requirements for how these remedies are offered to consumers?

Article 6, paragraphs 2 to 4 of Law No. 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 him or herself as a producer by putting his or her 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 will be responsible as a producer. Where the producer of the product may not be identified, each supplier of the product will be treated as its producer unless he or she provides the injured person with information on the identity of the producer or of the person who supplied him or her 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 No. 2251 (article 6, paragraphs 1, 6 and 7), the producer must compensate the consumer for any damage incurred to the latter because of defects of his or her product. Damage includes the following:

- damage owing to death or physical injury; and
- damage or destruction, because of 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 or her 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 or she 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 No. 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. By the revision of 2018, Law No. 2251 was redrafted as to the applicable guarantees in the sale of consumer goods (new articles 5 and 5(a), Law No. 2251). In short, Law No. 2251 categorises the guarantee of:

- a mandatory, two-year free, statutory one (which may be reduced up to one year for used products); and
- an additional, optional, commercial one provided against payment or, exceptionally, for free under detailed regulation.

Regarding prescription, Law No. 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 is put onto the market, the rights of the consumer are time-barred (article 6, paragraph 13, Law No. 2251).

The general limitation period within which a buyer, being a consumer or not, must exercise his or her 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 or her. 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 (articles 554-558 and 937 of the Greek Civil Code).

Returned products

26 Are there any requirements for proof of disposal of returned products subject to recall or corrective action? Are there any reasons why such products should be retained by the manufacturer responsible?

There are no such specific requirements, so the general provisions on the submission of evidence before a court apply. The same applies regarding any specific reasons why such products should be retained or not by the manufacturer responsible; evaluation of the appropriate actions will depend on the circumstances of each case.

Penalties for failure to recall a product

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

According to article 13(a) of Law No. 2251 (as amended by Law No. 4512/2018), subject to the stipulations of the Criminal Code and the Rules Regulating the Market of Products and the Provision of Services (Law No. 4177/2013), the following civil and administrative sanctions may be imposed by a decision of the competent minister, acting either ex officio or after a complaint filed, namely:

- a 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 an infringer, the minister may order the temporary closure of his or her business for a period ranging from three months to one year.

Imposed sanctions may be generally readjusted by a joint ministerial decision.

A special set of sanctions may be imposed on infringers that do not respond to consumers' complaints per the provided proceedings.

Further, the Minister of Development and Investments has the authority, considering the nature and graveness of the violation, as well as its general repercussions on the consumer public, to publicise, through the press or any other means available, the sanctions imposed and the restraining measures taken by the appropriate administrative authorities or by the parties obliged to act with regard to the circulation of a product in the market.

AUTHORITIES' RECALL AND CORRECTIVE POWERS

Corrective actions

28 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 that 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 these actions should have been accomplished. If the obliged party fails to comply with and satisfy these requests, the competent authority may impose fines.

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 and Investments or by a joint decision of him or her and by any other competent minister.

Government recalls

29 Can the government authorities organise a mandatory 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.

Voluntary versus mandatory recalls

30 | Are product recalls generally undertaken voluntarily or mandatorily in your jurisdiction?

Product recalls are generally undertaken voluntarily in Greece. A mandatory recall would presuppose negligence too promptly by the parties obliged to it.

Publication of warnings, corrective actions and recalls

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

Government authorities may also publish warnings or other information to users or suppliers and even organise a product recall where a producer or other responsible party has not already done so. 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, European Commission's 'Business Gateway to report dangerous products to the Member State authorities' at https://webgate.ec.europa.eu/gpsd/ (formerly known as the GPSD Business Application), facilitating the producers or distributors of the notified product, or their authorised representatives to submit notifications under the GPSD, allows the Greek and other EU competent national authorities to use the information provided to submit a RAPEX notification if all criteria for this are met.

RAPEX is the EU's rapid alert system for unsafe consumer products and consumer protection. RAPEX does not encompass food and pharmaceutical products and drugs. RAPEX allows a quick exchange of information on measures such as repatriation or product recalls, whether carried out by national authorities or by voluntary action of manufacturers and distributors (more at https://joinup.ec.europa.eu/collection/rapex and https://ec.europa.eu/safety-gate/#/screen/home).

Costs

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

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.

Challenging decisions

33 | How may decisions of the authorities in respect of corrective actions or product recalls be challenged?

The administrative decisions imposing sanctions on infringers must be served on the party affected thereby. A quasi-judicial proceeding before the Minister of Development and Investments against those decisions is provided for, within an exclusive period of 30 days as of the above service whereas the minister must issue his or her decision within an additional exclusive period of 60 days. Eventually, the minister's decision may be judicially challenged within a period of 60 days of his or her decision being served on the interested party.

IMPLICATIONS FOR PRODUCT LIABILITY CLAIMS

Repercussions for liability in court proceedings

34 | Are the civil courts in your jurisdiction likely to view a corrective action, recall or consumer warning 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 other corrective action, including 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.

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 even prior to the application of Law No. 2251.

Disclosure of information

35 | Can communications, internal reports, investigations into product issues or planned corrective actions be disclosed in product liability actions? Are there mechanisms to compel regulators to publish information regarding their handling of a corrective action, recall or notification?

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 or her 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 or her 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 or her of the requested documents, the success of such disclosure petition must be regarded as an exception.

A party establishing legal interest may request documents or information from a regulator regarding a specific file or case subject to data considered confidential such as commercial secrets; upon refusal by a regulator to share the data requested and not covered by confidentiality, the party may apply to a competent public prosecutor for a respective order. However, procedural or time constraints may render the relevant proceedings impractical in the circumstances of a specific case.

UPDATE AND TRENDS

Key developments of the past year

36 | Are there any emerging trends or hot topics in product recall and associated litigation in your jurisdiction?

Regarding the use of the RAPEX, based on data derived from the General Secretariat's website (which are not published in a consolidated form, thus they are not official ones), it made the following notifications since 2010: 2021 (January – July): 2, 2020: 24, 2019: 7, 2018: 23, 2017: 18, 2016: 50, 2015: 14; 2014: 63; 2013: 70; 2012: 82; 2011: 69; 2010: 159.

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

Consumers' reports and complaints are filed with the General Secretariat either its website (hyperlink): https://protocol.mindev.gov.gr/home or at the following link (with a name or anonymously):

http://www.mindev.gov.gr/%CE%BA%CE%B1%CF%84%CE%B1%CE%B3%CE%B3%CE%B5%CE%BB%CE%AF%CE%B5%CF%82-%CF%80%CE%BF%CE%BB%CE%B9%CF%84%CF%8E%CE%BD/.

Besides the online filing, the General Secretariat operates a call centre.

Further, the fines imposed by the General Secretariat for unsafe products in recent years are approximately as follows (they are extracted from its website as they are not published in a consolidated form, so they are not official):

- 2021 (January-July): €0.544 million;
- 2020: €0.518 million;
- 2019: €0.428 million;
- 2018: €0.405 million;
- 2017: €1.105 million;
- 2016: €1.940 million; and
- 2015: €2.230 million.

Law No. 2251 has been amended several times. The most significant changes introduced in the past regarding product liability, safety and product recall issues were enacted by Law No. 3587/2007 and Law No. 4177/2013. In 2018, Law No. 2251 was extensively amended by Law No. 4512/2018 (articles 100–111 and 126) and, by virtue of the same, ministerial decision No. 5338 of 17 January 2018 was issued codifying Law No. 2251 with effect as of 18 March 2018. Topics related to product recall that were affected by the latest revision of Law No. 2251 are:

- a narrower definition of 'consumer' (see below);
- the regulatory authorities and their enforcement duties;
- the funding of consumers' associations; and
- the administrative proceedings and sanctions that may be imposed (articles 1a.1, 7, 10, 13a and 13b, Law No. 2251).

The definition of 'consumer', before the above 2018 revision of Law No. 2251, was extremely broad, including any natural or legal person or entity without legal personality that was the end recipient and user of products or services, as well as any guarantor in favour of a consumer (but not for a business activity) (previous article 1, paragraph 4a, Law No. 2251). Moreover, the definition had been further expanded by case law to cover persons that used the products or services not only for private use but also for business use. As of 18 March 2018, this extended definition was narrowed and a consumer is only considered a natural person acting for purposes not falling within a commercial, business, handcraft or freelance activity (new article 1a, paragraph 1, Law No. 2251).

Also, an emergency legislation body was introduced in Greece following the occurrence of covid-19 around mid-March 2020. Such urgent and exceptional legislation necessarily follows the development of the numerous effects that the pandemic has had on our way of life, thus it is of a temporary nature and it is being modified periodically, adjusted to the needs of any specific time as they are medically monitored by the competent bodies and specialists. The pandemic legislation basically regards not the products and services themselves but the ways in which they are sold, offered, disposed of and consumed, imposing protective measures against the pandemic's expansion. Therefore, the best practice for a producer or supplier is to check the special rules applicable for the product or service at issue when it is to be circulated and, of course, for currently offered products, to monitor the law developments on a periodic basis.

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