PANORAMIC

PRODUCT RECALL

Greece

LEXOLOGY

Product Recall

Contributing Editor

Sarah-Jane Dobson

Ashurst

Generated on: October 8, 2024

Contents

Product Recall

IMPLICATIONS FOR PRODUCT LIABILITY CLAIMS

UPDATES AND TRENDS

Contributors

Greece

Bahas, Gramatidis & Partners

Dimitris Emvalomenos d.emvalomenos@bahagram.com

PRODUCT SAFETY LAWS

Product safety legislation

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 recently modified especially by Law No. 5019/2023 – 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 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GPSD is to be repealed as of 13 December 2024 by Regulation (EU) 2023/988 on 'general product safety', which was enacted in line with the New Consumer Agenda of 2020 and its basic aims are as follows:

1. to update GPSD ensuring a safety net for all products; and
2. to safeguard that the legal regime will provide greater consistency between EU-harmonised and non-harmonised products.

The General Secretariat of Commerce, including the General Directorate of Market and Consumer Protection and the Directorate of Consumer Protection, of the Ministry of Development (the Ministry) is the central competent authority regarding producers' compliance with the product safety rules (collectively, 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. Examples are listed below.

Appliances using gaseous fuels

Ministerial Decision 44027/DTVN 742/2018 (GGB 1506/B/2-5-2018) provides for additional measures necessary for the implementation of Regulation (EU) 2016/426/EU on appliances for the combustion of gaseous fuels. The competent authority is the General Secretariat of Industry of the Ministry (the Industry Secretariat).

Boilers

Presidential Decree 335/93 (GGB 143/A/2-9-1993), as amended by Presidential Decree 59/95 (GGB 46/A/27-2-1995) and Presidential Decree 32/2010 (GGB 70/A/14-5-2010). Relevant EU legislation also applies. The competent authority is the Industry Secretariat.

Chemicals (including industrial raw materials, industrial products and candles)

EC Regulations 1907/2006 and 1272/2008, as amended (up to 2024, by EU Regulation 197/2024), and various Ministerial Decisions issued subsequently to specify their provisions. Competent authorities are the National Organization for Medicines (EOF) and the State's General Chemical Laboratory, depending on the specific product.

Cosmetics

EC Regulation 1223/2009 on Cosmetics, as amended multiple times, among which by EU Regulation 2195/2022, and various Ministerial Decisions issued subsequently to specify its provisions. The competent authority is the EOF.

Liquid fuel storage facilities (non-Petroleum Products Trading Companies)

Presidential Decree 44/1987 (GGB 15/A/17-2-1987), as amended by Ministerial Decision 28.6/1991 (GGB 578/B/29-7-1991) on technical specifications for the design, construction and safe operation of the mechanical liquid fuel storage facilities of companies that are not Petroleum Products Trading Companies. The competent authority is the Industry Secretariat, along with the Fire Service.

Metal scaffoldings

Ministerial Decision 16440/F.10.4/445/1993 (GGB 756/B/28-9-1993) on production and placing on the market of assembled metal elements for the safe construction and use of metal scaffolding. The competent authority is the Industry Secretariat.

Plastic tubes

Ministerial Decision 14097/757/2012 (GGB 3346/B/14-12-2012), as amended by Ministerial Decision 114233/2019 (GGB 4878/B/25-11-2019), on the control of technical specifications for plastic pipes and fittings for the transport of drinking water, sewage and underfloor heating. The competent authority is the Industry Secretariat.

Steam boilers

Ministerial Decision 10735/651/2012 (GGB 2656/B/28-9-2012), as amended by Ministerial Decision 136860/1673/F15/2018 (GGB 6210/B/31-12-2018), on the installation, operation and control of steam boilers. The competent authority is the Industry Secretariat.

Toys

Joint Ministerial Decision 3669/194/2011 (Government Gazette Bulletin (GGB) 549/B/7-4-2011) 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 or supplemented various times, and most recently by Ministerial Decision 11297/4-2-2022 (GGB 535/B/09-2-2022), in compliance with the EU Directives 2020/2088, 2020/2089 and 2021/903. The competent authority is the Industry Secretariat.

Vehicles and parts for vehicles

Various legislative documents. The competent authority is the Ministry.

Law stated - 23 July 2024

Basic pre-launch requirements

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

Greek laws are in line with 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 in question. Within that framework, the special coronavirus legislation introduced in March 2020 was in a constant state of flux as the pandemic developed and had to be taken into account.

Law stated - 23 July 2024

Guidance

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 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 in question. Within that framework, the special coronavirus legislation introduced in March 2020 was in a constant state of flux as the pandemic developed and had to be taken into account.

Law stated - 23 July 2024

ENFORCEMENT OF PRODUCT SAFETY LAWS

Regulators

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, including the General Directorate of Market and Consumer Protection and the Directorate of Consumer Protection, of the Ministry of Development (the Ministry) is the central competent authority for product safety (collectively, the General Secretariat). Various other authorities exist depending on the products in question.

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

Regarding sectoral authorities and indicatively, for food products, the competent authority is the Hellenic Food Authority (EFET), supervised by the Ministry of Rural Development and Food. For medicines, sanitary products and equipment, the competent authority is the 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 cooperation between public administrative bodies, provided that such cooperation serves a specified, legitimate cause and the case falls within their scope of competence. Greek regulators may also cooperate with analogous international regulators within the framework of existing international legislation (eg, the EU Rapid Alert System for unsafe consumer products (RAPEX)).

Law stated - 23 July 2024

Enforcement actions and penalties

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. They may also define the time frame within which these actions should be accomplished. If the obliged party fails to 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, the withdrawal or the disposal of the product, the destruction of the product and any other relevant topic are regulated by a decision of the Minister of Development or by a joint decision of it 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 established regulatory scheme. Further, Greek authorities' websites do not provide a facility for the public to post remarks or reports of incidents.

However, the European Commission's Business Gateway to report dangerous products to the member state authorities (formerly known as the GPSD Business Application) allows the producers or distributors of the notified product or their authorised representatives to submit notifications under the General Product Safety Directive (GPSD). It also allows 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 Rapid Alert System for unsafe consumer products (with the exception of food, pharmaceuticals and medical devices, which are covered by other mechanisms) established under article 12 of the GPSD. 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 here and here). Further, the EU Commission has issued guidelines for the management of RAPEX by its Implementing Decision (EU) 2019/417, as amended by its Implementing Decision (EU) 2023/975 of 15 May 2023.

Regarding penalties, they have been updated and expanded following the amendment of Law No. 2251 by Law No. 5019/2023 and are included in articles 13(a) to 13(i). In summary, 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 sanctions may be imposed by a decision of the competent organ of the Ministry of Development, acting either ex officio or after a complaint filed, namely:

1. a recommendation for compliance within a specified deadline as well as an order to stop the infringement and refrain from it in the future; and
2. a fine of between €5,000 and €1.5 million. The maximum amount of the fine may reach €3 million if, within the last five years, more than one decision imposing fines has been issued against the same infringer for breaches of Law No. 2251 (or of other laws referring to article 13(a) of Law No. 2251 for the imposition of a fine).

For the imposition of the above penalties, certain criteria are indicatively listed. This includes any sanctions imposed on the same infringer for the same breach in other EU member states regarding transboundary cases, if relevant information is available under the Regulation (EU) 2017/2394 'on cooperation between national authorities responsible for the enforcement of consumer protection laws', as in force.

Moreover, when the Greek authorities are to impose penalties under article 21 of Regulation 2017/2394 for 'widespread infringements' or 'widespread infringements with a Union dimension', the maximum fine may be up to 4 per cent of the infringer's annual turnover in the relevant EU member state and, in case there is no information on such turnover, the fine may reach €5 million.

By an amendment of 2022, an additional sanction of a temporary closure of the infringer's business for a period ranging from three months to one year, that could also be imposed in certain conditions, was abolished.

Further, a special set of sanctions may be imposed on infringers that do not provide requested documents, or that do not respond to consumers' complaints per the provided proceedings.

Broad authorities are given to the Directorate of Consumer Protection for Law No. 2251 enforcement regarding the access to, collection and even seizure of any relevant data and information.

Also, appropriate injunctive measures, as a case may be, may be taken by the competent organs of the Ministry of Development.

A summary of any decision imposing a fine that exceeds €50,000 (or not, if it is imposed for a repeated infringement) is publicised by any appropriate means and it is uploaded at the website of the Ministry of Development within five working days from its issue.

Lastly, a general five-year prescription period was introduced for breaches falling within the enforcement authorities of the Directorate of Consumer Protection.

Law stated - 23 July 2024

Enforcement process and procedures

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 often take place as a more efficient and prompt procedure, especially in urgent cases. These include 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.

Law stated - 23 July 2024

Enforcement trends

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 to have a limited effect and practice, and there have not been any recent notable examples.

Law stated - 23 July 2024

Challenging enforcement actions

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 against those decisions is provided for within an exclusive period of 30 days as of the above service, whereas the minister must issue their 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 their decision being served on the interested party.

Law stated - 23 July 2024

NOTIFICATION REQUIREMENTS

Criteria for notification

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 immediately notify the General Secretariat and any other competent authority, depending on the type of product in question.

The notification is made in a form required by the competent authority and must include the following:

1. information to identify the product;
2. a complete description of the defect or the risk involved with the usage of the product;
3. information to locate the product in the market; and
4. 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, 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:

1. the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
2. the effect on other products, where it is reasonably foreseeable that it will be used with other products;
3. 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
4. the categories of consumers at risk when using the product, particularly 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 their own inspections and tests or based on initiatives from consumers, insurance companies, distributors or government bodies. In any case, it is necessary to notify the competent authority as soon as the producer establishes a 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:

1. the product is understood to be intended for, or likely to be used by, consumers (article 2(a) of the GPSD);
2. article 5 of the GPSD applies (unless there are specific provisions established by other EU legislation);
3. the product is on the market;
4. 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
5. the risks are such that the product may not remain on the market.

Law stated - 23 July 2024

Notification time limits

What are the time limits for notification?

The Guidelines (Annex, section 4.3) provide that 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 no 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.

Law stated - 23 July 2024

Competent authority for notification

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. The General Secretariat of Commerce, including the General Directorate of Market and Consumer Protection and the Directorate of Consumer Protection, of the Ministry of Development (the Ministry) is the central competent authority regarding producers' compliance with the product safety

rules (collectively, the General Secretariat). The authorities to which the notification should be made vary according to the product.

Below, we examine 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 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 Union 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 and for the Codex Alimentarius Commission (of the Food and Agriculture Organisation of the United Nations and the World Health Organization) and it is the local point of the European Food Safety Authority.

Medicines

For medicines and sanitary products and equipment, the National Organisation for Medicines (EOF) is the competent authority. The EOF was established in 1983 and is supervised by the Ministry of Health. The EOF's mission is to ensure public health and safety with regard to the following products marketed in Greece:

1. medicinal products for human and veterinary use;
2. medicated animal foods and food additives;
3. foodstuffs intended for particular nutritional uses and food supplements;
4. biocides;
5. medical devices; and
6. cosmetics.

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

1. evaluates and authorises new, safe and efficient health-related products;
2. monitors the post-marketing product's quality, safety and efficiency;
3. 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;
4. develops and promotes medical and pharmaceutical research; and
5. 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.

Law stated - 23 July 2024

Form and content of notification

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 guidelines of the EC Decision 2004/905/EC (the Guidelines, Annex, section 5), the notification must include at least the following:

1. details of the authorities and resellers or distributors notified;
2. details of the producer and distributors;
3. details of the contact person regarding the notification;
4. details of the product, including the category of the product, the product's brand or trade name, the product's model, barcode or the combined nomenclature (CN) tariff, the product's country of origin and a photograph or description of the product;
5. a description of the hazard and of the possible health or safety damages and conclusions of the risk estimation and evaluation carried out;
6. a record of accidents; and
7. 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.

Law stated - 23 July 2024

Obligations to provide updates after initial notification

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 must 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.

Law stated - 23 July 2024

Penalties for failure to notify

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

Regarding penalties, they have been updated and expanded following the amendment of Law No. 2251 by Law No. 5019/2023 and are included in articles 13(a) to 13(i). In summary, 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 sanctions may be imposed by a decision of the competent organ of the Ministry of Development and Investments, acting either ex officio or after a complaint filed, namely:

1. a recommendation for compliance within a specified deadline as well as an order to stop the infringement and refrain from it in the future;
2. a fine of between €5,000 and €1.5 million. The maximum amount of the fine may reach €3 million if, within the last five years, more than one decision imposing fines has been issued against the same infringer for breaches of Law No. 2251 (or of other laws referring to article 13(a) of Law No. 2251 for the imposition of a fine); or
3. both of the above.

For the imposition of the above penalties, certain criteria are indicatively listed, including any sanctions imposed on the same infringer for the same breach in other EU member states regarding transboundary cases, if relevant information is available under the Regulation (EU) 2017/2394 'on cooperation between national authorities responsible for the enforcement of consumer protection laws', as in force.

Moreover, when the Greek authorities are to impose penalties under article 21 of Regulation 2017/2394 for 'widespread infringements' or 'widespread infringements with a Union dimension', the maximum fine may be up to 4 per cent of the infringer's annual turnover in the relevant EU member state(s) and, if there is no information on such turnover, the fine may reach €5 million.

By an amendment of 2022, an additional sanction of a temporary closure of the infringer's business for a period ranging from three months to one year, that could also be imposed in certain conditions, was abolished.

Further, a special set of sanctions may be imposed on infringers that do not provide requested documents, or do not respond to consumers' complaints per the provided proceedings.

Broad authorities are given to the Directorate of Consumer Protection for Law No. 2251 enforcement regarding the access to, collection and even seizure of any relevant data and information.

Also, appropriate injunctive measures, as a case may be, may be taken by the competent organs of the Ministry of Development.

A summary of any decision imposing a fine that exceeds €50,000 (or not, if it is imposed for a repeated infringement) is publicised by any appropriate means and it is uploaded at the website of the Ministry of Development within five working days of its issue.

Lastly, a general five-year prescription period was introduced for breaches falling within the enforcement authorities of the Directorate of Consumer Protection.

Law stated - 23 July 2024

Public disclosure of notification information

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 related to the notified product and the risk from its usage, but they are prevented from disclosing information containing commercial or industrial secrets that 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.

Law stated - 23 July 2024

Use of information in prosecution

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.

Law stated - 23 July 2024

Information sharing between regulators

Is notification information shared with other regulators?

Notification information may be shared among the Greek regulators provided it falls within the scope of their competence and it serves a specified legitimate cause. The same applies to non-Greek regulators, as provided by relevant laws (eg, RAPEX).

Law stated - 23 July 2024

CORRECTIVE ACTIONS AND RECALLS

Criteria for corrective action

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 hazards from that product's use as soon as any defect comes to their 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 where no other measure would eliminate the danger. The recall may be initiated either 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 surveil lance authorities and dated 22 July 2021.

Law stated - 23 July 2024

Scope of corrective action

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 implementation 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.

Law stated - 23 July 2024

Traceability requirements

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

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

In general, each product must be duly labelled and identified and must, therefore, include information about its producer, including 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 with 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 on the packaging in a visible and legible manner. The information must be stated at least in Greek. This enables a consumer to 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 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.

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

Law stated - 23 July 2024

Consumer messaging

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 measures without delay 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. They must also define the measures to be taken.

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

Law stated - 23 July 2024

Content of recall notices

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

In accordance with the guidelines of the EC Decision 2004/905/EC (the Guidelines, Annex, section 5), a notification must include at least the following:

1. details of the authorities and resellers or distributors notified;
2. details of the producer and distributors;
3. details of the contact person regarding the notification;

4. details of the product, including the category of the product, product's brand or trade name, product's model, barcode or combined nomenclature (CN) tariff, product's country of origin and a photograph or description of the product;
5. a description of the hazard and of the possible health or safety damages and conclusions of the risk estimation and evaluation carried out;
6. a record of accidents; and
7. 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.

Law stated - 23 July 2024

Mode of communication

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.

Law stated - 23 July 2024

Time frame

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.

Law stated - 23 July 2024

Consumer remedies

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 as the manufacturer of a finished product or of any raw material or of any component, as is any other person who presents themself as a producer by putting their name, trademark or other distinguishing feature on the product. Moreover, any person who imports a product within the EU for sale, leasing, hire or any form of distribution will be responsible as a producer. Where the producer of the product cannot 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 them 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 their product. Damage includes the following:

1. damage owing to death or physical injury; and
2. 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 their personal use or consumption.

Damages for moral harm or mental distress may also be due based on the above regulation.

Further remedies may derive from the general law on sale of goods (articles 513 ff of the Greek Civil Code (GCC), as in force following the transposition of Directive (EU) 2019/771 'on certain aspects concerning contracts for the sale of goods' by Law No. 4967/2022 as of 9 September 2022. A seller is strictly (irrespective of fault) liable for the lack of conformity of the sold product with the sales contract at the time the risk passes to the buyer (any buyer not only a consumer), as such conformity is defined by the law, together with relevant conditions (especially articles 534-540 of the GCC); the buyer may request the following:

1. the repair or replacement of the defective product;
2. a reduction of the consideration;
3. rescission of the contract; or
4. compensation, under conditions (articles 542-547 of the GCC).

Additionally, according to the general provision on tortious liability, whoever acts unlawfully and by default causing damages to another party is obliged to compensate the injured party (article 914 of the GCC).

Moreover, both Law No. 2251 and the GCC regulate the provision by the seller of a product guarantee. Where such a guarantee was provided and the defect is detected and noticed within the guaranteed period, the consumer has the rights that were guaranteed notwithstanding their rights by law (especially articles 534 ff and 559 of the GCC). By a revision of 2022 (due to Law No. 4967/2022), Law No. 2251 was amended 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:

1. a mandatory, two-year free, statutory one; and
2. 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 their rights from a contract for the sale of goods (movables) for lack of conformity is two years and, in the case of continuous supply of digital elements, six months from the end of the contractual term. Further detailed regulation applies (articles 554–558 of the GCC).

Tort claims are subject to a five-year limitation period starting from the day the victim became aware of the damage and the person is liable to compensate them. The same action or omission may constitute a breach of a contract and tort under requirements. Last, the general limitation period for claims is 20 years and claims for unjust enrichment fall within this period (articles 249 and 937 of the GCC).

Law stated - 23 July 2024

Returned products

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 to 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.

Law stated - 23 July 2024

Penalties for failure to recall a product

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

Regarding penalties, they have been updated and expanded following the amendment of Law No. 2251 by Law No. 5019/2023 and are included in its articles 13(a) to 13(i). In summary, 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 sanctions may be imposed by a decision of the competent organ of the Ministry of Development and Investments, acting either ex officio or after a complaint filed, namely:

1. a recommendation for compliance within a specified deadline as well as an order to stop the infringement and refrain from it in the future; or
2. a fine of between €5,000 and €1.5 million. The maximum amount of the fine may reach €3 million if, within the last five years, more than one decision imposing fines has been issued against the same infringer for breaches of Law No. 2251 (or of other laws referring to article 13(a) of Law No. 2251 for the imposition of a fine).

For the imposition of the above penalties certain criteria are indicatively listed, including any sanctions imposed on the same infringer for the same breach in other EU member states regarding transboundary cases, if relevant information is available under the Regulation (EU) 2017/2394 'on cooperation between national authorities responsible for the enforcement of consumer protection laws', as in force.

Moreover, when the Greek authorities are to impose penalties under article 21 of Regulation 2017/2394 for 'widespread infringements' or 'widespread infringements with a Union dimension', the maximum fine may be up to 4 per cent of the infringer's annual turnover in the relevant EU member state and, if there is no information on such turnover, the fine may reach €5 million.

By an amendment of 2022 an additional sanction of a temporary closure of the infringer's business for a period ranging from three months to one year, that could also be imposed in certain conditions, was abolished.

Further, a special set of sanctions may be imposed on infringers that do not provide requested documents, or do not respond to consumers' complaints per the provided proceedings.

Broad authorities are given to the Directorate of Consumer Protection for Law No. 2251 enforcement regarding the access to, collection and even seizure of any relevant data and information.

Also, appropriate injunctive measures, as a case may be, may be taken by the competent organs of the Ministry of Development.

A summary of any decision imposing a fine that exceeds €50,000 (or not, if it is imposed for a repeated infringement) is publicised by any appropriate means and it is uploaded at the website of the Ministry of Development within five working days of its issue.

Lastly, a general five-year prescription period was introduced for breaches falling within the enforcement authorities of the Directorate of Consumer Protection.

Law stated - 23 July 2024

AUTHORITIES' RECALL AND CORRECTIVE POWERS

Corrective actions

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, the withdrawal or disposal under terms or destruction and any other relevant

topic are regulated by a decision of the Minister of Development or by a joint decision with them and by any other competent minister.

Law stated - 23 July 2024

Government recalls

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

Government authorities may organise a product recall where a producer or other responsible party has not already done so.

Law stated - 23 July 2024

Voluntary versus mandatory recalls

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 to promptly act by the parties obliged to it.

Law stated - 23 July 2024

Publication of warnings, corrective actions and recalls

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 established regulatory scheme. Further, Greek authorities' websites do not provide a facility for the public to post remarks or reports of incidents.

However, the European Commission's Business Gateway to report dangerous products to the member states authorities (formerly known as the GPSD Business Application) allows the producers or distributors of the notified product or their authorised representatives to submit notifications under the General Product Safety Directive (GPSD). It also 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 Rapid Alert System for unsafe consumer products (with the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms) established under article 12 of the GPSD. 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 hereand here). Further, the EU Commission has issued guidelines for the management of RAPEX by its Implementing

Decision (EU) 2019/417, as amended by its Implementing Decision (EU) 2023/975 of 15 May 2023.

Law stated - 23 July 2024

Costs

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?

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.

Law stated - 23 July 2024

Challenging decisions

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 against those decisions is provided for within an exclusive period of 30 days as of the above service, whereas the minister must issue their 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 their decision being served on the interested party.

Law stated - 23 July 2024

IMPLICATIONS FOR PRODUCT LIABILITY CLAIMS

Repercussions for liability in court proceedings

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) must only 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.

Law stated - 23 July 2024

Disclosure of information

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 their 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 their possession relevant to support the claim. These must be clearly specified by the claimant. Thus, communications, internal reports and the like may be disclosed in product liability actions. In practice, however, owing to the strict prerequisites imposed by case law on the claimant regarding the specification by them of the requested documents, the success of such a 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.

Law stated - 23 July 2024

UPDATES AND TRENDS

Key developments of the past year

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

Regarding the use of 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 recent notifications:

1. 2024 (January-July): three;
2. 2023: nine;
3. 2022: eight; and
4. 2021: two.

Consumer awareness is rather low. Very few consumer organisations are actively focusing on challenging abusive general terms and conditions. However, the new collective redress landscape introduced by Law No. 5019/2023 (see below) may trigger claims for product recall among other consumer claims.

Consumers' reports and complaints are filed with the General Secretariat, in person or through an authorised representative, via phone (basically, No. 1520), email (1520@mindev.gov.gr), internet (at https://kataggelies.mindev.gov.gr) or post to its postal address (Kaniggos Square, Athens 10181).

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

Further, the fines imposed by the General Secretariat for unsafe products in 2024, 2023, 2022 and 2021 are approximately as follows (they are extracted from its website as they are not published in a consolidated form, so they are not official):

1. 2024 (January-June): €0.450 million;
2. 2023: €0.900 million
3. 2022: €0.500 million; and
4. 2021: €0.825 million.

Law No. 2251 has been amended several times and its most recent amendments were enacted by Laws No. 4933/2022, 4967/2022, 5019/2023, 5039/2023 and 5111/2024. Law No. 5019/2023 transposed Directive (EU) 2020/1828 'on representative actions' with effect from 26 June 2023 and related to product recalls, the basic modification of Law No. 2251 concerned the general sanctions regime (new articles 13(a) to 13(i) of Law No. 2251).

Law stated - 23 July 2024