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Product Recall

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Contributing editor
Alison M Newstead and
Harley V Ratliff
Shook, Hardy & Bacon International LLP

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Gideon Roberton

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Marketing manager (subscriptions)
Rachel Nurse
subscriptions@gettingthedealthrough.com

Head of editorial production
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Jonathan Cowie

Subeditor
Davet Hyland

Director
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Managing director
Richard Davey

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Fax: +44 20 7229 6910

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Law Business Research

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Russia

Alexandra Lysova*

Egorov Puginsky Afanasiev & Partners

General product obligations

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

The primary law that defines the framework for the establishment and application of mandatory and discretionary safety requirements for products and processes related to products in the Russian Federation is Federal Law No. 184-FZ 'On Technical Regulation' of 2002 (the Technical Regulation Act or the TRA).

The adoption of the TRA in 2002 laid the foundation for restructuring, systematising and updating a vast volume of legislative acts and by-laws containing requirements regarding the quality and safety of products and processes. Under the TRA, the mandatory requirements regarding the quality and safety of specific types of products and processes are established by Technical Regulations.

A Technical Regulation is a document – in the form of an international agreement, federal law, presidential act or an act of government or a federal governmental authority – that sets mandatory requirements for products or products and processes related to products (such as research, development, production, use, storage and transportation) to ensure product safety. Work on the formulation and adoption of Technical Regulations is now in progress at two levels: at the level of the Customs Union (the member states are Belarus, Kazakhstan and Russia) and at the national level of the Russian Federation.

At the level of the Russian Federation, Technical Regulations currently in force are adopted by the federal laws as well as the government of Russia. These regulations establish mandatory requirements for products sold and processes performed within the territory of Russia and remain in force until replaced by international regulations.

Between 1996 and 2000 an integration process between Belarus, Kazakhstan, Kyrgyz Republic and Russia led to the signing of two main treaties creating a Customs Union (Treaty on Customs Union and United Economic Area of 1999) and Eurasian Economic Community – EurAsEC (Treaty on the establishment of the Eurasian Economic Community of 2000). In developing these agreements a number of treaties have been signed between the members of EurAsEC and the Customs Union aimed at the harmonisation of requirements to products and product-related processes. Within the general line of harmonisation of legislation of members of the Eurasian Economic Community (EurAsEC) and the creation of a common economic area between members of the Customs Union, the Customs Union Commission and its member states (Belarus, Kazakhstan and Russia) are working on unified Technical Regulations for products and product-related processes that will be directly enforceable within the territory of the Customs Union.

The TRA provides two procedures for confirming the compliance of products for sale within the territory of the Russian Federation with the requirements of the Technical Regulations: declaring conformity or certification. The applicability of such declaration or certification procedure depends on the type of product. The government of the Russian Federation adopts not only a list of products, whose compliance with the Technical Regulations shall be declared, but also a list of products for which certification is necessary. The main difference between the procedures is that the declaration of the product's compliance with the Technical Regulation is performed by the manufacturer or the seller based on the evidence they have obtained themselves or with the assistance of a certification agency (an entity or a sole proprietor accredited by the government agency), or an accredited laboratory, whereas the certification is performed by a certification agency based on the results of an examination (test), with procedures and measurements performed by an accredited laboratory.

A number of government agencies, depending on the types of products, are charged with the oversight of compliance with Technical Regulations and often several governmental agencies have overlapping authority in respect of a particular type of product.

Apart from mandatory requirements, the TRA sets a framework for discretionary safety requirements, which can be established by international, national, corporate and other standards. A manufacturer or a seller can apply to a certification agency for the certification of compliance of products or product-related processes with a particular standard or a set of standards.

The Federal Law No. 52-FZ 'On Public Sanitary and Epidemiological Welfare' of 1999 (the Public Sanitary and Epidemiological Welfare Act or PSEWA) sets the regulations aimed to ensure the safety of products, materials and processes in relation to public health and the environment.

In accordance with the PSEWA, the specific mandatory requirements ensuring safety and security for public health and the environment for products, equipment, materials and processes are established by the Sanitary Rules and Regulations and Hygienic Regulations. Currently there are over 200 such regulations, and, depending on the type of product, the product itself and the processes related to it may fall under the requirements of several Sanitary Rules and Regulations and Hygienic Regulations.

If the Technical Regulation for a product is adopted, it usually includes requirements ensuring the safety and security of such product for public health and thus supersedes the relevant Sanitary Rules and Regulations and Hygienic Regulations with regard to such product.

Additional requirements for quality and safety of consumer products are provided by the Federal Law No. 2300-1 'On Protection of Consumers' Rights' of 1992 (the Consumers' Rights Protection Act or CRPA).

There are also a number of federal laws regulating specific spheres that set additional requirements for the quality and safety of products, including Federal Law No. 29-FZ 'On the Quality and Safety of Food Products' of 2000, Federal Law No. 3-FZ 'On Public Radiation Safety' of 1996, Federal Law No. 171-FZ 'On State Regulation of Production and Circulation of Ethanol, Alcoholic and Alcohol-Containing Products and on Limitation of

Consumption of Alcoholic Products' of 1995 and Federal Law No. 61-FZ 'On Circulation of Pharmaceuticals' of 2010 (the Circulation of Pharmaceuticals Act or CPA).

A number of the laws listed above require registration of new products, including registration of certain types of new food products, materials and goods under the Federal Law 'On the Quality and Safety of Food Products', registration under the PSEWA of new products and substances potentially dangerous for humans or certain products and substances imported for the first time to Russia, as well as registration of pharmaceutical products and medical devices under the CPA. The production of certain types of products or activities involving certain types of products, for example, the production and sale of pharmaceuticals, alcohol and alcoholic products, requires a licence.

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

There is no general requirement for traceability applicable to all types of products.

Consumer products, according to the CRPA, should be supplied with information identifying the manufacturer and importer, including their addresses and, for food products, information about the date and place of production and packaging. This information can be provided in accompanying technical documentation, by labels or in any other way that is customary for that type of product.

Sector-specific legislation and by-laws and Technical Regulations sometimes provide additional requirements that may assist in tracing the products.

For example, in respect of pharmaceutical products (pharmaceuticals) there are additional requirements for transport packages, which should display identifying information including the name and batch of the pharmaceuticals, the name and address of the manufacturer and, moreover, a barcode should be placed on any secondary consumer package of the pharmaceuticals; wholesale pharmaceuticals shall be accompanied with a covering document that contains information identifying the name and batch, manufacturer, seller and purchaser of the pharmaceuticals.

The Customs Union Technical Regulations for Food Products In Respect of Their Labelling (in force since 1 July 2013) requires that the transport packaging of the food products displays, together with other data, information identifying the name and batch of the product as well as its manufacturer.

Other than the packaging, the products could generally be traced through the company's records and with the means voluntarily applied by manufacturers (eg, barcodes).

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

Russian legislation provides for administrative and criminal penalties for non-compliance with the product quality and safety regulatory regime.

Depending on the type of offence, administrative penalties for non-compliance with product quality and safety requirements under the Code of Administrative Offences may include administrative fines, seizure and, in some cases, suspension of operations. For example, the administrative fine imposed on entities for non-compliance with Technical Regulations without aggravating circumstances is 100,000 to 300,000 roubles. The administrative fine for inaccurate (false) declaration of conformity is 100,000 to 300,000 roubles for legal entities. In the case of non-compliance resulting in the damage or threat of damage the to health or life of people or plants or animals, to property or the environment the administrative fine for legal entities is 300,000 to 600,00 roubles, along with the possibility of seizure of the products. Other penalties may also be applied, depending on the type of product and the particular requirements not complied with.

Criminal penalties for the sale or production, storage and transportation of non-compliant products for the purpose of selling, as well as the unlawful issue or use of an official document falsely confirming the compliance of such products, include a fine of up to 300,000 roubles, the convicted person's income for up to two years, up to 360 hours of community service, or custodial restraint, compulsory labour or imprisonment for up to two years. Criminal liability applies only to natural persons and only for intentional or reckless crimes. In the case of legal entities, liability can extend to executive officers and other persons responsible for the actions that constitute a criminal offence. The same crime, if committed collusively by a group of persons, with respect to products or services intended for children under the age of six or if resulting in the reckless infliction of grave injury or death of a person, is punishable by a fine of 100,000 to 500,000 roubles, the convicted person's income for one to three years, compulsory labour for up to five years or imprisonment for up to six years, with the possibility of an additional fine of up to 500,000 roubles, or of the convicted person's income for up to three years. If the crime has resulted in the manslaughter of two or more persons, it is punishable by compulsory labour for up to five years or imprisonment for up to 10 years.

General provisions for civil liability for damages caused due to defects of products or services are set out by the Civil Code. If the product or service has been acquired for consumer use (ie, not for business purposes) the damages to life, health or property of people or to property of entities caused by the product or service should be compensated by the seller or the manufacturer irrespective of their fault (except for cases of force-majeure or incorrect use or storage of the product by the affected person) and of existence of contractual relations with the affected person. If the product or service has been acquired not for consumer use, general rules of the Civil Code for compensation of damages apply: either contractual violation or tort, if the manufacturer's or seller's fault is proven. The general rule is that both direct damages and a loss of profit should be compensated in full.

Reporting requirements for defective products

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

Under the TRA, if the manufacturer becomes aware that the products do not meet the requirements of the Technical Regulations, it must report such non-compliance to the authorised government authority within 10 days of being made aware of such non-compliance. If the seller or Russian representative of a foreign manufacturer receives information about non-compliance of a product with the Technical Regulations, it is also required to report such non-compliance to the authorised government authority and manufacturer within the same 10-day term.

If persons or entities that are not sellers, manufacturers or Russian representatives of foreign manufacturers become aware that the product does not meet the requirements of the Technical Regulations, they are entitled but not obliged to report such information to the government authority. If the government authority receives information about non-conformity from a person or entity that is not the seller, manufacturer or Russian representative of a foreign manufacturer, then it shall communicate such information to the manufacturer within five days of receipt.

The CRPA does not impose any obligation on the manufacturer, seller or other person or entity to notify government authorities or other bodies about the defects discovered in products or known incidents of personal injury or property damage or any other similar facts.

Sector-specific legislation may contain specific notification obligations, such as, for example, obligations established by

the CPA: all persons and entities engaged in the distribution of pharmaceuticals and medical devices must report to the authorised body any cases of side effects or adverse reactions not listed in the package leaflet, as well as the effects of specific interactions between pharmaceuticals and between medical devices and additional facts or circumstances that create a threat to the health and life of people, including medical workers, by use of medical devices.

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

In the case of notification in accordance with TRA requirements, notification must be sent if a manufacturer, seller or Russian representative of a foreign manufacturer receives information that the product does not comply with the requirements of the applicable Technical Regulation. The notification requirement is rather formal, for the TRA does not set any parameters for such non-compliance and there is no verification requirement for such claims of non-compliance before sending notification to a government authority. The time limit for notification is 10 days after becoming aware of non-compliance.

With regard to pharmaceuticals, the following criteria apply: notification about side effects, serious adverse reactions (death, hospitalisation or prolongation of hospitalisation, permanent or expressed incapacity or disability, congenital anomalies, tumour growth) about unexpected adverse events not listed in the leaflet, or specific interactions with other pharmaceuticals should be reported within 15 days after being made aware of such events. With regard to medical devices, notification about side effects not listed in the package leaflet, adverse reactions, serious and unexpected adverse events related to the product, the effects of specific interactions between medical devices or additional facts or circumstances creating a threat to the health and life of people, including medical workers, should be reported to an authorised agency within 20 business days.

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

The general rule is that notification under the TRA should be reported to the Federal Agency for Technical Regulating and Metrology (Rosstandard). Notice to other governmental agencies may also be necessary, depending on the type of product and safety requirements that are not met. For example, the Federal Service on Customers' Rights Protection and Public Welfare Supervision is an agency responsible for supervision of compliance with the Technical Regulation on Safety of Products for Children and Teenagers.

Notifications under sector-specific legislation should be sent to the appropriate authorised agencies supervising the corresponding sector. For example, notifications on pharmaceutical side effects should be sent to the Federal Supervision Service for Healthcare.

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

There are no specific requirements as to data that should be provided in a notification under the TRA. Authorised agencies are entitled to establish forms of notification or lists of data that should be included in the notification, but there are currently no such requirements set. As mentioned in question 5, a manufacturer has to report information about the violation of Technical Regulations.

Requirements may be also established by sector-specific legislation. For notification about the side effects and specific reactions of pharmaceuticals and medical devices, forms have been adopted by the Ministry of Healthcare and Federal Supervision Service for Healthcare. The notification regarding pharmaceuticals should contain:

- information about the patient (name or initials, age and sex), a description of the adverse effect, including laboratory and other research data, and the outcome of the adverse events;
- information about the pharmaceutical product and details of the prescription thereof;
- information about the simultaneous use of any other pharmaceutical products and relevant medical history;
- measures taken to correct the adverse effect; and
- other details on the treating clinic and the treatment provided.

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

Under the TRA, if a manufacturer, seller or Russian representative of a foreign manufacturer receives information about a violation of any Technical Regulation, it should verify this information within 10 days of its initial receipt, unless a longer term is necessary due to the nature of the required verification procedures. The authorised government authority is entitled to request materials related to such verification. If information about the non-compliance of the product with Technical Regulations is confirmed, the manufacturer, seller or Russian representative of a foreign manufacturer must develop, and approve along with the authorised government authority, a programme of action for the prevention of damage within 10 days of verification of the non-compliance. The authorised government authority should initiate verification of a product's non-conformity with Technical Regulations requirements as soon as possible after being made aware of such non-compliance. During the verification process, a government authority is entitled to:

- request materials related to the verification of information performed by the manufacturer, seller or Russian representative of a foreign manufacturer;
- request additional information relating to the product and related processes, including the results of any examination (test) procedures and measurements performed within the procedure of confirmation of compliance of the product with Technical Regulations, from any person who may have such information;
- send information requests to other government authorities; and
- engage specialists for analysis of materials received.

A number of government authorities perform, supervise and monitor compliance with safety requirements in their respective fields. The CRPA and sector-specific legislation, as a general rule, establish an obligation on the manufacturer, seller and other persons as defined by respective acts to, upon request, provide the authorised government agency with any information, documents and other materials necessary for the performance of such supervision and monitoring. The scope of information that can be requested can vary, depending on the government agency and the product involved.

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

According to the Code of Administrative Offences, failure to submit products, information and materials necessary for governmental control and supervision of compliance with Technical Regulations and applicable standards may result in an administrative fine of 40,000 to 50,000 roubles for officers or 200,000 to 300,000 roubles for legal entities. In addition, in refusing to provide documents and information upon request of an authorised government agency, a manufacturer or other person specified by respective legislation may face the risk of losing their licence, permissions or registration necessary for manufacture or sale of that specific product.

The deliberate concealment or misstatement of information about events, facts or circumstances endangering the life, health or environment by a person obliged to report such information to public or governmental authorities is considered a criminal offence, which is punishable by a fine of up to 300,000 roubles, or of the

convicted person's income for up to two years, or compulsory labour or imprisonment for up to two years with the further possibility of deprivation of the right to hold a specific post or engage in certain activities for up to three years. If such concealment or misstatement has in fact resulted in damage to health or other grave consequences, the penalty is a fine of 100,000 to 500,000 roubles, the convicted person's income for one to three years, compulsory labour or imprisonment for up to five years, with the further possibility of deprivation of the right to hold a specific post or engage in certain activities for up to three years.

Civil liability is possible if the failure to comply with reporting obligations has caused damages to a person or an entity (see question 3).

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

As a general rule, government authorities are obliged to protect the confidential information they have obtained, unless otherwise provided by law.

Federal Law No. 98-FZ 'On Trade Secrets' of 2004 provides a list of information that cannot be considered confidential. Such information includes, in particular:

- information about environmental contamination, fire safety, sanitary-epidemiological and radiation safety, safety of food products and other factors that have a negative influence on the operational safety of production facilities, the safety of any individual and safety of the population as a whole;
- information about violations of legal requirements and about the penalties or liabilities imposed, if any.

If information about non-compliance of the product with the Technical Regulations is confirmed and immediate actions have to be taken to prevent damage to life and health, the authorised government authority is entitled to inform purchasers (including consumers) through mass media about the product's non-compliance with the Technical Regulations and about any danger the product presents to life and health. The manufacturer, seller, or Russian representative of a foreign manufacturer can challenge such actions of the government authority in court, and if the actions are considered unlawful, the claimant may be entitled to compensation of losses caused by the actions of the government authority.

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

Information obtained by authorities can be used in a criminal prosecution.

Moreover, if the authorised government agency, in performance of its oversight functions, discovers facts that may indicate a criminal offence, it shall report such facts to the proper investigating authority. Such report may constitute grounds for initiating criminal prosecution.

Product recall requirements

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

The general requirements are set forth in the TRA and the CRPA.

Under the CRPA, if, despite correct use, storage and transportation of the product by a consumer, the product causes or may cause damage to a consumer's life, health or property, or to the environment, the manufacturer (seller) of the product must immediately suspend its production (and sale) until the cause of the damage is eliminated, and, if necessary, take measures for removal of the product from the market and recall from consumers. If the cause of the damage is impossible to eliminate, the manufacturer must stop production of the product. If the manufacturer does not stop production, the authorised government agency shall take measures to recall the product from the market and from consumers.

Under the TRA, where non-compliance of the product with the Technical Regulations is verified, the manufacturer, seller or the Russian representative of the foreign manufacturer shall adopt a programme of action for damage prevention (see question 8).

The programme must include notification of purchasers (consumers) about the potential damage, the measures for prevention of such damage, and the terms in which those damage prevention measures will be performed. All expenses in connection with the implementation of the programme of action for damage prevention should be covered by the manufacturer, seller or Russian representative of the foreign manufacturer respectively. If the actions provided for in the programme cannot be performed or will not result in elimination of the risk of damage, the manufacturer, seller or Russian representative of the foreign manufacturer respectively must not only stop production and sale of the product but also recall the product. Sector-specific legislation and the Technical Regulations can establish additional criteria for determining when a product recall is required. For example, milk and milk products must be recalled if information on the packaging or in accompanying documents is false or does not conform with the identification parameters established by the Technical Regulations.

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

Certain legal requirements are established by the TRA and the CRPA (see question 12).

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

There are no specific requirements in this regard.

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

The general requirement is that the notice should be circulated to all product users (consumers) but, as this does not necessarily imply notification on an individual basis, mass media may be used. There are no specific requirements as to the form of media that shall be used.

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

The TRA and the CRPA provide that the product must be recalled from the market and from the purchasers (consumers). There are no other specific targets or time frames in this regard.

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

The manufacturer, seller or Russian representative of a foreign manufacturer must repair the product at its own expense. If the defects cannot be eliminated, the manufacturer, seller or Russian representative of a foreign manufacturer must offer compensation and pay other damages caused by the recall.

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

If the manufacturer, seller, or Russian representative of a foreign manufacturer does not take the necessary actions to prevent damage that can be caused by a product (see questions 8 and 12), the authorised government agency or any other person, who has become aware of responsible persons not taking preventive measures, can apply to court for mandatory recall of the product. If the court decides that recall is necessary, it shall require the defendant to undertake certain measures concerning recall of the product and to notify the purchasers (consumers) of the product about the court decision through mass media or by other means.

There is no specific penalty for failure to recall a product. Administrative penalties can vary depending on the grounds on which the product should have been but was not recalled. For details of possible sanctions, see question 3.

The administrative penalty for non-compliance with a court order is a fine of up to 100,000 roubles for legal entities. Fraudulent non-compliance with a court order constitutes a criminal offence punishable by a fine of up to 200,000 roubles, the convicted person's income for up to 18 months, or deprivation of the right to hold a specific post or engage in certain activities for up to five years, up to 480 hours of community service, administrative detention for up to six months, or compulsory labour or imprisonment for up to two years.

Authorities' powers

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

Under the TRA, if non-compliance of a product with Technical Regulations is confirmed, the authorised government agency shall within 10 days issue instructions for the manufacturer, seller or Russian representative of a foreign manufacturer to develop and adopt a programme of actions for damage prevention (see questions 8 and 12). The agency shall approve the programme as well as assist in fulfilment of the programme. The government agency oversees fulfilment of the programme and meeting the time frames set out in the programme, and it is also entitled to request documents confirming that the actions provided for in the programme were undertaken. If the manufacturer, seller or Russian representative of a foreign manufacturer does not perform the programme of action for damage prevention, the government agency can apply to court for mandatory recall of the product.

If the information about non-compliance of the product with Technical Regulations is confirmed and immediate actions have to be taken to prevent damage to life and health, the authorised government authority is entitled to issue instructions for suspension of sale of the product as well as inform purchasers (consumers) through mass media about non-compliance of the product with the Technical Regulations and about the dangers the product presents to life and health.

Sector-specific legislation and the Technical Regulations can provide authorities with additional powers. For example, the Federal Service for Oversight of Consumers Protection and Welfare is entitled to issue mandatory instructions for the suspension of the production and sale of milk products that do not meet safety requirements as well as other mandatory instructions for corrective actions that must be performed within reasonable time frames set by such instructions.

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

The TRA provides that such notice can be issued if a product's non-compliance with Technical Regulations is confirmed and immediate action has to be taken to prevent damage to life and health. There are no specific requirements as to the content of such notice or the form of media through which it should be published.

Sector-specific legislation can contain additional provisions in respect of publication of information by governmental authorities. For example, under the CPA, in the case of serious adverse events the Ministry of Health can suspend the use of such pharmaceutical products in the territory of the Russian Federation, and information about any suspension or resumption of use of the pharmaceutical may be posted on the official website of the Ministry of Health.

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

Government agencies have no direct authority to initiate a recall. However, they can file a court claim for initiation of a mandatory recall (see question 18).

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

All the costs in relation to product safety compliance or product recalls are borne by the manufacturer or other responsible party. Under the current legislation, governmental authorities cannot bear any expenses related to product safety apart from those which are incurred as a part of the performance of their functions, and those expenses cannot be compensated by the manufacturer or other responsible party. If a governmental authority files a court claim for mandatory recall, and the court decides the recall is necessary, the court can also allocate the court costs to the defendant.

23 How may decisions of the authorities be challenged?

A decision of a government agency imposing administrative sanctions can be challenged in court or by appeal to a superior government authority. All other decisions may be challenged in a state court.

A claim to a superior authority must be filed within three days after the decision was rendered. The period for lodging an appeal in court is up to three months from the date on which the decision was rendered.

Implications for product liability claims

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

In our opinion, the current legislation does not allow for a safety warning or a product recall to be considered as an admission of liability for defective products. The fact that the product is defective and the causal link between the defect and incurred damages have to be proven. A safety warning or a product recall notice is one (although very persuasive) of the possible types of evidence that may be used to show the fact that a product is defective or to demonstrate the nature of the defect.

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

The current procedural legislation allows trial participants to review all case materials, which includes all evidence provided by the parties or ordered by the court. However, the court has the discretion to exclude from the case materials any documents and materials that are not relevant to the case.

The court is also entitled, upon the request of one of the trial participants, to order the production of evidence, including communications, internal reports and documents related to the investigations into the defects and planned corrective action, and to include these in the case materials.

** Original article of 2012 was written in co-authorship with Trina Sen.*

Update and trends

Product recall litigation is rare in Russia; recalls are mostly initiated voluntarily by the manufacturers or within administrative procedures. The main trend for Russian product quality control legislation remains the unification of product quality requirements within the Customs Union and enactment of new Technical Regulations at the level of the Customs Union.

LAW OFFICES | EGOROV PUGINSKY AFANASIEV & PARTNERS

Alexandra Lysova **alexandra_lysova@epam.ru**

24 Nevsky pr, Suite 132
191186, St Petersburg
Russia

Tel: +7 812 322 96 81
Fax: +7 812 322 96 82
www.epam.ru

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