

Product Recall 2020

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Product Recall

2020

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Lexology Getting The Deal Through is delighted to publish the eleventh edition of *Product Recall*, which is available in print and online at www.lexology.com/gtdt.

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

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Ireland.

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

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Alison Newstead, Devin Ross and Scott Kaiser of Shook, Hardy & Bacon LLP, for their continued assistance with this volume.



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France

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GENERAL PRODUCT OBLIGATIONS

Basic laws

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

The basic French laws governing the safety requirements that products must meet are:

- Act No. 83-660 of 21 July 1983 (published in the Official Journal (JORF) of 22 July 1983, page 2,262);
- consolidated versions of the Decrees 2004-670 of 9 July 2004 and 2008-810 of 22 August 2008 (published in the Official Journal No. 0196 of 23 August 2008, page 13,238 text 13 and JORF No. 159 of 10 July 2004, page 12,520) implementing Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety (General Product Safety Directive) in France;
- consolidated versions of the Decrees 2016-301 of 14 March 2016 and 2016-351 of 25 March 2016
- Act No. 2017-203 of 21 February 2017, ratifying Decrees No. 2016-301 and 2016-351; and
- special acts in force that also govern specific fields; there are, for example, specific provisions within the Public Health Code (CSP), concerning safety requirements regarding drugs and public health, etc.

Decree No. 2004-670 of 9 July 2004 and 2016-301 of 14 March 2016 and Decree No. 2016-351 of 25 March 2016 are integrated into the Consumer Code under Title II, Book IV.

Article L421-3 of the Consumer Code creates a fundamental right to safety for consumers:

Products and services must, under normal conditions of use or under other circumstances that may reasonably be foreseen by the professional, offer the safety that can legitimately be expected, and must not be a danger to public health.

Article L421-1 et seq of the Consumer Code also define other obligations for professionals in connection with this general product safety obligation, including the obligation to provide information, the follow-up obligation and the obligation to notify.

The safety requirements apply to any professional, that is to say the 'producer' and the 'distributor' (article L421-1 of the Consumer Code):

- 'producer' means the manufacturer of the product, the manufacturer's representative and other professionals in the supply chain, as far as their activities may affect the safety properties of a product; and
- 'distributor' means any professional in the supply chain whose activity does not affect the safety properties of a product.

Traceability requirements

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

French law has set up requirements to ensure the traceability of products to facilitate recalls:

- article L423-2 of the Consumer Code introduces a follow-up obligation for the producer who accordingly has to take measures in order to control, follow up and be informed about risks that its products might present, for example, by organising their traceability (by indicating, on the product or its packaging, the producer's identity and address, as well as the product reference or the batch of products to which it belongs);
- article L412-1 of the Consumer Code insists on the requirement of taking measures to ensure the traceability of products and foods; and
- French case law requires the organisation of the traceability of products based on the precautionary principle (decision of the French Administrative Supreme Court of 29 December 1999).

Non-compliance penalties

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

The Consumer Code does not stipulate specific penalties for non-compliance with the obligations regarding the safety of products set forth in article L421-3 et seq (ie, the obligations to provide information, to follow up and to notify). However, the government does want the professionals to be aware of their responsibilities and also wants to promote collaboration between them and the authorities.

Nevertheless, there can be civil or criminal penalties if non-compliance with one of these provisions leads to harm to a consumer. In this case the professional may be held liable in both civil and criminal jurisdictions and may be sentenced by the civil courts to remedy the damage caused to the victim. Furthermore, a person who has misled or tried to mislead his or her contracting partner about the nature, origins or risks inherent in the use of the product (deception) is punishable by a fine of €300,000 and up to two years' imprisonment (articles L441-1 and L454-1 of the Consumer Code).

There are no administrative penalties in the case of non-compliance with these laws.

REPORTING REQUIREMENTS FOR DEFECTIVE PRODUCTS

Government notification

- 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?

The obligation to notify government authorities (or other bodies) of defects discovered in products, or known incidents or property damage, results from the General Product Safety Directive and was implemented in article L423-3 of the Consumer Code.

According to article L423-3 of the Consumer Code, the professional responsible for marketing a product has to inform the competent administrative authorities as soon as he or she notices that a product does not comply with the general product safety requirements provided by article L421-3.

Notification criteria and time limits

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

Criteria applied for determining when to notify a defect

According to article L423-3 of the Consumer Code, the professional has to notify government authorities (or other bodies) of defects in products, or incidents, as soon as he or she knows that the product he or she has put on the market does not comply with the requirements laid down in article L421-3 of the Consumer Code (general safety obligation).

The Commission's decision of 14 December 2004 sets out guidelines for the notification of dangerous consumer products to the competent authorities of the member states by producers and distributors (the guidelines) in accordance with article 5(3) of the General Product Safety Directive. This is the reference document for the application of the provisions of the General Product Safety Directive concerning notification of dangerous consumer products to the French competent authorities by producers and distributors.

These guidelines set out the notification criteria that apply to France and read as follows:

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

Time limits for notification

According to article L423-3 of the Consumer Code, the professional has to notify the competent administrative authorities of the incident immediately. No precise time limit is defined within the national provisions.

The guidelines for the notification of dangerous consumer products in France (commission's decision of 14 December 2004) provide two time limits:

- a company must inform the competent authorities as soon as the relevant information has become available, and in any case within 10 days from when it has reportable information, even while investigations are continuing, indicating the existence of a dangerous product; or
- when there is a serious risk, companies are required to inform the authorities of the situation no later than three days after having obtained notifiable information.

Competent authority

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

According to the ministerial order of 9 September 2004 concerning the application of article L423-3 of the Consumer Code, notifications (pursuant to article L423-3) should be sent to one of the three authorities. Depending on the product in question, the competent authority is one of the following:

- the Directorate for Road Safety and Traffic: notification must be provided from car manufacturers and their distribution network when vehicles and equipment sold under the manufacturer's brand are concerned;
- the Directorate General for Food: notification must be provided when food products are concerned, which includes animal food, animal food products or human food. All notifications regarding food products that are not included in these categories (such as additives and aromas) are to be submitted to the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF); and
- the DGCCRF: the DGCCRF receives any other notifications that do not fall under the auspices of the Directorate for Road Safety and Traffic or Directorate General for Food referred to above.

Notification information

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

According to article 2 of the Ministerial Order of 9 September 2004, the following information should be provided in a notification to the competent authority:

- the date of notification;
- the name and address of the professional or company providing the notification, as well as those of its suppliers and the professionals who have been supplied with the product;
- the product's description (particularly its name, brand, batch number, volumes involved, etc);
- the description of the danger and the measures taken by the professional; and
- any other information that could be useful to the authorities.

Notification forms can be found on the DGCCRF's website: <https://www.economie.gouv.fr/dgccrf/Securite/Rappel-de-produits/Signalement-des-produits>.

Obligations to provide updates

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

There is no explicit obligation under French law (the Consumer Code) to provide authorities with updated information about risks. The professional's obligation to inform, as laid down in articles L423-1 and L423-2 of the Consumer Code, only concerns the obligation to provide the consumers with information that enables them to assess the risks inherent in a product.

However, French controlling officials, listed in article L511-3 of the Consumer Code, have investigatory powers, and the professionals must respond to their enquiries (article L512-8 et seq).

It should be emphasised that this new article (amending the old article L215-1) has significantly reduced the number of authorities that are entitled to investigate and note professionals' infractions: only the officers of competition law, consumption and fraud control have that power from now on.

Article L512-5 of the Consumer Code authorises those officials to enter business premises, and premises in which a service is being provided. Moreover, this new article gives them the power to exercise their mission on the public highway.

They can also require to be provided with all information allowing them to determine the specifications of the products or services or to estimate whether the product or the service is dangerous (article L512-8 et seq of the Consumer Code).

The Sanitary Surveillance Institute (IVS), created in 1998, and whose task is, in the case of a threat to public health, to inform the public authorities of the origin of the threat and to take appropriate measures to avert the danger, can also request that a person communicate any information in his or her possession relating to serious threats to human health (article L1413-5 of the CSP).

Penalties

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

See question 3.

Public disclosure

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

Article 11 of the Criminal Procedure Code specifies that the procedure during an inquiry is secret.

In accordance with this fundamental principle, the officials and employees of the competent authorities have to respect professional confidentiality. Despite the provisions of article 11 of the Criminal Procedure Code, article L512-22 of the Consumer Code does, however, allow the disclosure of confidential information where doing so would avert the risk of serious and immediate danger to the health and safety of consumers.

Therefore, commercially sensitive information that has been communicated to the competent authorities is not in all circumstances protected against public disclosure.

Use of information in prosecution

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

Information notified by professionals to the authorities can be completed by means of inquiries or hearings before the competent authorities that are in charge of the investigation and assessment of breach of the legal provisions regarding product safety (indeed, the professionals have to provide them with all information related to the product and its potential danger (see question 8)). For this reason, information notified by the professionals to the authorities and completed during the inquiries may be used in a criminal prosecution when a breach of the legal provisions regarding product safety has been noted.

PRODUCT RECALL REQUIREMENTS

Recall criteria

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

According to article L412-1,II of the Consumer Code, a product recall can be ordered by decree of the French Administrative Supreme Court for modification or full or partial reimbursement or exchange if the products do not comply with the general safety obligations defined in article L421-3.

Under the provisions of article L521-17, a recall can also be ordered by ministerial order in cases of a 'grave or immediate danger' and if the products do not comply with the general safety obligations defined in article L421-3.

According to article R422-1 of the Consumer Code, these decrees and ministerial orders are made after consulting the National Agency for Safety of Medicine and Health Products (ANSM, formerly the AFSSAPS) and the Agency for Food, Environmental and Occupational Health & Safety (ANSES, formerly the AFSSA) in matters relating to their responsibilities.

Consumer warnings

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?

According to the provisions of the Consumer Code, two kinds of measures can be taken if products do not comply with the statutory safety requirements: permanent measures and temporary or urgent measures.

Permanent measures

Article L412-1 of the Consumer Code specifies that the government may order, by decree of the French Administrative Supreme Court, that products shall be recalled or withdrawn from the market for the purpose of modification or exchange if the products do not comply with the general safety obligation defined in article L421-3. This article also allows for determination of the different ways in which products or services are to be prohibited or regulated if they do not comply with the general safety obligation.

Temporary or urgent measures

Orders

In the case of serious or imminent danger in connection with the provision of a service, and if the products do not comply with the general safety obligation defined in article L421-3, the administrative authorities can take urgent measures and suspend the provision of a service for a period not exceeding three months (article L521-23 of the Consumer Code).

A recall can also be ordered pursuant to the provisions of article L521-17 by ministerial order (in case of serious or immediate danger in connection with the provision of a service and if the products do not comply with the general safety obligation defined in article L421-3). The representative may also order the destruction of the product or the suspension of the provision of a service as well as the publication of warnings.

Injunctions

Article L521-18 allows the competent ministries to issue two kinds of administrative injunctions (an injunction for the product to be adapted so as to be compliant with the safety provisions and an injunction for inspection by an authorised testing institute in order to rule out any danger).

Recall notices

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

There are no express requirements in French law for the content of recall notices. However, the decrees or orders must specify:

- the measure that has been taken;
- the duration of that particular measure (in the case of a temporary measure); and

- the conditions under which the costs incurred by the execution of this measure are borne by the professional.

Media

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

The communication of warnings or recalls to professionals and suppliers is made by decrees and orders.

The communication of warnings or recalls to users may be carried out by:

- information campaigns issued by the administrative authorities;
- publication of guidelines by the administrative authorities (for example, in the field of risk prevention for blood products and for pharmaceuticals obtained from blood, the Minister for Employment and Social Affairs published guidelines for patient information); and
- information on recalls in the press (for example, in the periodical *Que Choisir* managed by a consumer association), on television or on the internet.

Time frame

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

French law does not specify targets or a period after which a recall is deemed to be satisfactory.

Repair and replacement

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

The civil courts will sentence the producer or other suppliers to repair or replace recalled products or offer other compensation.

If the producer cannot prove that the end-user used the product despite being informed of the recall, he or she has to indemnify the victim.

Penalties

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

The penalties for failure to comply with decrees or ministerial orders ordering recalls or other corrective actions are as follows:

- a failure to comply with a decree taken in accordance with the provisions of article L412-1 of the Consumer Code is punishable by a fine defined in the decree; and
- a failure to comply with a ministerial order taken in accordance with the provisions of article L521-17 of the Consumer Code is punishable by a fine of €1,500 for an individual and of €7,500 for a corporate entity. The dangerous product can also be confiscated (article R532-1 and R452-4 of the Consumer Code).

There are also product-specific criminal consequences. For products whose intended use relates to health, there are special provisions in the CSP (article L5451-1 et seq).

These impose a criminal fine of €150,000 or a sentence of up to two years' imprisonment on a person who:

- continues trading despite a banning order;
- does not comply with any sales restrictions; or
- fails to withdraw the product from the market or to pass on warnings or the relevant instructions for use.

Similarly severe provisions apply to foodstuffs. In this regard, failure to comply with a withdrawal order may satisfy the definition of 'fraudulent

'misdescription' of goods for sale (falsification). The falsification occurs by creating the false impression that a product is marketed as complying with standards when it does not.

Merely offering for sale such fraudulently misdescribed foodstuffs or animal food constitutes fraudulent misdescription and carries the same sentence. If the misdescribed substance is harmful to human or animal health or if the offence is committed by an organised group, it is punishable by a criminal fine of €750,000 and a sentence of up to seven years' imprisonment (article L451-2 of the Consumer Code).

There are also general criminal law consequences. Three criminal offences may be committed in connection with a failure to withdraw unsafe products from the market or a failure to warn consumers of possible risks with those products:

- involuntary manslaughter;
- negligent bodily harm; and
- endangerment.

The elements of the offence of endangerment are satisfied if:

- the person concerned owes a duty to ensure the safety of the product;
- the violation of this duty creates the risk of death, mutilation or permanent disability;
- this risk is immediate;
- another person is exposed to this risk; and
- the breach of the duty to ensure safety was intentional (article 223-1 of the Penal Code).

AUTHORITIES' POWERS

Corrective actions

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?

In order to have manufacturers or others in the supply chain undertake a recall or take other corrective actions, the authorities may undertake investigations or take preventive measures:

- they may undertake investigations at workplaces between 8am and 8pm (article L512-5 of the Consumer Code);
- they may take test samples (article L512-23) or gather all kinds of information necessary in order to get to know the product's properties (article L512-8 et seq of the Consumer Code);
- they may request the transmission of different kinds of documents and information regarding the products (article L512-8 et seq of the Consumer Code); and
- they can even order the closing down of the entire firm or of parts of the firm manufacturing the product (article L521-5 of the Consumer Code).

The authorities can also take permanent or temporary measures (see question 13) and:

- order that products shall be recalled or withdrawn from the market (article L412-1 of the Consumer Code);
- order the destruction of the dangerous product (article L412-1 of the Consumer Code);
- suspend the fabrication, the importation, the exportation or the marketing authorisation of a product for a fixed time period, limited to a maximum of one year (article L521-17 of the Consumer Code); and
- order the publication of instructions for use and safety precautions (article L521-17 of the Consumer Code).

In the case of the manufacturers' non-compliance with these measures, the authorities may also apply specific penalties provided for by French law (fines, etc) (see question 18).

The authorities can also use the media (information campaigns, information on recalls in the press) in order to compel manufacturers to undertake a recall or other corrective actions (see question 15). The impact that the promulgation of such information has on consumers is very useful for the authorities with regard to obtaining the manufacturers' compliance with the ordered measures.

Government warnings

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

The ANSM must inform, if necessary, the public by any media, and notably by broadcasting health messages or recall notices on any product that represents a danger to human health (L5312-4 of the Public Health Code).

Finally, the IVS may warn the Minister for Health Affairs about any threat to public health.

The government authorities' websites also provide facilities for members of the public to post remarks and report incidents.

The website of the ANSM also provides a special form to report undesirable effects of a medicine.

Government recalls

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

Pursuant to the provisions of articles L412-1 and L521-17 of the Consumer Code, the government authority can organise a product recall where a producer or other responsible party has not already done so.

Costs

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?

The costs incurred by the government authorities in relation to product safety issues are recoverable from the producer or other responsible party.

This results from decisions of the Administrative Supreme Court as well as from the provisions of the Consumer Code. Article L412-1, II (2) regarding decrees of the Administrative Supreme Court and article L521-17 regarding ministerial orders stipulate that the decrees or ministerial orders indicate the conditions under which the costs associated with the safety measures pursuant to a decree or ministerial order are to be borne by the professional. However, the professionals often challenge the obligation to bear these costs.

Challenging decisions

23 | How may decisions of the authorities be challenged?

Decrees of the Administrative Supreme Court may be challenged before the administrative courts, setting aside an administrative decision on the grounds that such a decree is ultra vires; submitting that there were no safety regulations for the product in question or that the product complies with European safety provisions.

The banning or suspension order in the case of imminent danger issued by the prefect or by the competent minister is a unilateral administrative act that can also be challenged by claiming ultra vires.

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The opinions issued by the Consumer Safety Commission cannot be challenged before the administrative courts, because of their advisory nature and the fact that they are not regulatory decisions. The same applies for the opinions of the ANSES and the IVS.

IMPLICATIONS FOR PRODUCT LIABILITY CLAIMS

Repercussions for court proceedings

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?

The publication of a safety warning or a product recall is likely to be viewed by the French civil courts as an admission of liability for defective products, or at least as an indication that the product is defective.

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

In product liability actions, communications, internal reports or investigations into defects may be disclosed by the producers to claimants in order to prove that:

- their product is not defective (and that any damage is caused by the conditions of use of the product); or
- the defect results from a third-party product that has been supplied and incorporated into the end product.

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