



JONES DAY
COMMENTARY

RISK ASSESSMENT UNDER FRENCH LAW: A BUSINESS REQUIREMENT

THE GROWING IMPORTANCE OF THE NOTION OF SAFETY

The increasing number of cases related to product safety and the abundant media coverage surrounding them reflect the ever-growing importance of the issue of safety and the increasing concern of Member States to ensure public health protection.

The attention to safety is paramount at all stages of a product's "life," not only at the product's manufacturing stage¹ but also further up the chain, *i.e.*, once the product has been introduced on the market and sold to a consumer. The producer/distributor is liable for the safety of the product he sells during the entire "life" of the product. Downstream, *i.e.*, once a damage has occurred as a result of a defective consumer good, a complete set of French legal civil and

criminal provisions can be enforced against the producer/distributor, whether a legal entity and/or an individual, and these sanctions can turn out to be very severe.

The importance of the safety issue described above explains the numerous European and national regulations concerning product safety. Both Council Directive² 85/374/EEC of July 25, 1985 (on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products) and Directive 2001/95/EC of December 3, 2001 (on general product safety) have been implemented in France. Consequently, French law is profoundly inspired by these European provisions.

1 The manufacturer must comply with the entirety of the standards that govern the manufacturing of a product, which must be performed in compliance with good engineering practices and existing standards.
 2 Directives are legislative acts of the European Union that require Member States to achieve a particular result without dictating the means of achieving that result. They can be distinguished from Regulations, which are self-executing and do not require any implementing measures.

HOW TO ASSESS THE RISK OF A PRODUCT

The risk associated with products can be assessed in different ways, and many methods to quantify risk exist.

The European Commission provides business with guidance on risk assessment in an appendix to a decision dated December 14, 2004. This decision lays down guidelines for the notification of dangerous consumer products to the appropriate authorities of the Member States by producers and distributors in accordance with article 5(3) of Directive 2001/95/EC.

New guidance has been published by the European Commission in an appendix to its decision dated December 16, 2009, laying down guidelines for the management of the Community Rapid Information System (“RAPEX”)³ established under Article 12, and of the notification procedure established under Article 11 of Directive 2001/95/EC. Although these last guidelines are addressed to the Member States, producers and distributors could use them since they are intended to represent “the best possible practice” for assessing product risks, setting out in a cogent way a nine-step methodology, and can be applied to identify serious risks.

WHAT SHOULD A PRODUCER/DISTRIBUTOR DO UNDER FRENCH LAW?

The producer’s/distributor’s obligations with respect to safety issues are essentially obligations to perform (“*obligation de faire*”). Such obligations must theoretically be initiated on a voluntary basis, but should the professional remain inactive or take insufficient action, the national authorities can also order⁴ certain actions (Articles L.221-3 to L.221-7 of the French Consumer Code).

The actions to be taken by the producer/distributor are listed under Articles L.221-1-2⁵ and L.221-1-3⁶ of the French Consumer Code and are the following:

- **Obligation to inform:** The producer/distributor must inform the consumer of the product’s risks and of the means to assess and avoid them by providing them with any “useful information,” and it has the obligation to “remain informed of risks that the products that it markets may present.”
- **Traceability:** The product and the producer/distributor must all be easily identifiable.
- **Necessary actions:** The producer/distributor may be required to withdraw the product from the market, recall it, and/or issue a warning to the consumers.
- **Notification:** “When a producer or a distributor knows that products intended for consumers which he has put onto the market do not meet the requirements of Article L. 221-1 [that is, *inter alia*, the requirement that products

3 RAPEX is the EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceuticals, and medical devices. It allows for the rapid exchange of information between member states via central contact points.

4 Public authorities can prohibit or restrict the manufacture, sale, and distribution of products (article L.221-3, 1° of the French Consumer Code); they can order their withdrawal or recall from the market (Article L.221-3, 3° of the French Consumer Code). Public authorities also have the ability to take temporary emergency measures such as temporary recall or withdrawal, should there be a serious or immediate risk for consumers (Article L.221-5 of the French Consumer Code).

5 “I. - The producer shall provide the consumer with sufficient information to enable him to evaluate the risks inherent in a product during its normal or reasonably foreseeable useful life and to guard against them, when such risks are not immediately apparent to the consumer without adequate forewarning [...].

II. - The producer shall adopt measures which, in view of the characteristics of the products he supplies, enable him to: a) Keep abreast of the risks which the products he markets may present; b) Implement the actions necessary to contain those risks, including withdrawal from the market, the issuing of adequate and effective warnings to consumers and recalling products sold from consumers.

Such measures may consist, *inter alia*, of sample testing or indication on the product or its packaging of instructions for use, the identity and address of the person responsible for marketing, and the product or batch reference. Such indications may be made compulsory by order of the Minister for Consumer Affairs and the other minister(s) concerned.”

6 “When a producer or a distributor knows that products intended for consumers which he has put onto the market do not meet the requirements of Article L. 221-1, he shall immediately inform the relevant administrative authorities thereof and indicate the actions he is implementing to guard against risks to consumers.

The informational requirements are stipulated by order of the Minister for Consumer Affairs and the other ministers concerned. The producer or the distributor cannot avoid his obligation by pleading ignorance of risks which he could not reasonably be unaware of.”

provide the safety that a person is entitled to expect], he shall immediately inform the relevant administrative authorities thereof and indicate the actions he is implementing to guard against risks to consumers.”

Producers/distributors that have marketed products that do not provide the safety to which consumers are entitled are to notify promptly/immediately the relevant public authority thereof⁷ and to indicate the measures that are initiated to prevent the risk.

Until recently, the French competent authority (the DDPP, “*Direction Départementale de la Protection des Populations*,” former DGCCRF)⁸ was to receive such notifications. Effective May 1, 2009, the reporting concerning non-food products must be done through the European IT application called “business application”⁹ made available by the General Directorate in charge of consumers of the European Commission. The notification filed by the producer/distributor will be entered into a database and then sent directly to the competent authorities of each Member State in which, according to the information provided by the producer/distributor, the product has been introduced.

When a national authority is aware of a safety risk posed by a product, depending on the extent of the risk incurred, that national authority may be compelled to pass the information to the European Commission through the “RAPEX” system.

Despite the clear duty to notify stated in the French Consumer Code, French law does not provide for any civil or criminal sanctions for the failure to comply with this duty. However, the failure to notify can be an aggravating circumstance in the event the producer’s liability is ultimately challenged.

LAWYER CONTACTS

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7 With respect to France, the competent authority is the DDPP, formerly DGCCRF, i.e., the “General Directorate for Competition Policy, Consumer Affairs and Fraud Control” as specified in a Recommendation to economic agents in JORF No. 159 of July 10, 2004, p. 12574.

8 As provided by Order of September 9, 2004 “*portant application de l’article L. 221-1-3 du code de la consommation*,” in JORF No. 224 of September 25, 2004, p. 16560.

9 This application form is available online at: <https://webgate.ec.europa.eu/gpsd-ba>.