France

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Producers and distributors of products in France must comply with stringent French product liability laws.

The French product liability system essentially grew from a system based on the contractual liability of distributors, extending to capture producers and manufacturers even where the claimant has no direct contractual relationship with the producer.

The system is one of strict liability: claimants need only prove lack of safety, not gross negligence or any intentional act.

Therefore it would be strongly in the interests of any producer or distributor on becoming aware of a safety risk relating to a product on the market, to implement a recall campaign or to withdraw it from the market.

However, even if a product recall campaign is executed, the producer or distributor will not escape liability if a consumer is injured by the product (despite the recall operation).

Directive 2001/95/EC[1] defines 'recall' as "any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor" (Article 2(g)).

This European definition applies directly in French law despite the French Consumer Act, which refers to 'recall' as one of the appropriate measures possible when handling risks due to unsafe products. Under that act, producers or distributors must:

- alert the public or issue appropriate and efficient warnings;
- withdraw the product from the market; and
- recall the product directly from the consumer (Article 221(1)2 II b of the Consumer Code).

1. Product safety regulation

1.1 Regulatory framework

Articles L212(1) and L221(1) of the Consumer Code refer to:

- a duty to verify if products comply with statutory safety requirements prior to their release on the market; and
- a duty to ensure levels of safety that can legitimately be expected.

1 Of the European Parliament and of the Council of December 3 2001.

These are 'self-regulatory' duties: the company must create its own safety standards including collection of statutory information and safety control procedures at all stages in production. Those procedures must be regularly tested and updated.[2]

Failures in the self-regulatory system will lead to penal liability of the firm.[3]

1.2 Safety standards

In general, and for most products, the safety rules in France are based on European standards, such as those contained in the European directives for machinery, toys, medical devices, pharmaceutical products, food and genetically modified products.

The conformity of a product with industrial standards and norms constitutes a simple presumption – that is, the product can conform to the standards and still be unsafe in fact; or it might not conform and be safe nevertheless. This will be a question of proof in practice.

Where a producer, manufacturer or other party that is subject to the product liability regime considers that a safety standard is not relevant to a product, a request for derogation can be made to the French Association for Standardisation (AFNOR), which will assess the safety of the relevant product for consumers (Article 18 of Decree 84-74 of January 26 1984).

A product cannot be considered as defective just because a more advanced product has subsequently been placed on the market (Article 1386(4), Civil Code; law of May 21 1998 (98-389)[4]).

In applying that law, AFNOR must consider all criteria relevant to the legitimate expectation of the public concerning the safety of the product, such as:

- any intrinsic risk or danger in the product;
- degree of care taken by the producer to inform the public about how to properly use the product; and
- measures taken by the producer to ensure that the product is safe.

2. Obligations of producers and distributors

2.1 Sources of duties

(a) Statute

In France, the product safety requirements are in particular regulated by Statute 83-660 of July 21 1983[5] and Decrees 2004-670 and 2008-810, passed on July 9 2004 and August 22 2008 respectively,[6] implementing the General Product Safety Directive (2001/95/EC). These pieces of legislation are also incorporated into the Consumer Code (Book II, Title II).

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2 Sylvie PUGNET, *La réglementation de la sécurité des produits, Contrats concurrence consommation* October 10 2009, study 10.
3 (*Cass Crim* October 30 1990, 89 (83.827).
4 Transposing EU Directive 85/374/EEC.
5 *Official Journal of the French Republic* (JORF), July 22 1983, p 2262.
6 JORF 0196, p 13238 and JORF 159, p 12520.

More specific provisions applicable to particular safety issues, such as certain specific provisions of the French Code on Public Health pertaining to drug safety.

(b) Tort

The fact that a product is considered dangerous cannot by itself trigger a manufacturer/producer's liability. Producers have several obligations in relation to safety. They must:

- bring to the market only products which are safe for their normal use and their foreseeable (not abnormal) misuse;
- provide consumers with adequate information about products;[7]
- comply with advertising rules (for tobacco or alcoholic beverages); and
- in general, take adequate precautions at all times in relation to safety.[8]

Failure to observe any of these obligations could lead to action by the administrative authority Article L 221(7), Consumer Code), eg, serving a caution on the producer.

(c) Contract

Where there is a contract, the victim or injured party can claim indemnification on the basis of the contractual legal guarantee against hidden defects (Article 1641, French Civil Code) or on the basis of contractual non–fulfilment (Article 1147, French Civil Code).

2.2 Pre-market obligations

According to Decree 2004(670 of July 9 2004 and Ruling 2008-810 of August 22 2008, a product will be considered to satisfy the general duty of safety (as defined by Article L221(1)) when it complies with any specific regulation which has as its purpose the protection of health or consumer security (Article L222(1), Consumer Code).

(a) CE marking

It is always the producer/manufacturer who should mark a product with the CE sign, if appropriate. The CE mark is the producer's guarantee that the product conforms to European standards, having been evaluated for this purpose. The European directives determine whether this evaluation must be made by a specific body or by the producer itself.

(b) Traceability, record keeping

The Consumer Code provides for product traceability requirements to facilitate recalls.

Producers are obliged to take measures to ensure traceability of their products as a means to control and monitor potential risks, including adding – either on the

7 Article L 221-1-2, Consumer Code; and *Cass 2e civ*, December 9 1975: JCP G 1977, II, 18588 – *Cass 1re civ*, June 10 1980: Gaz Pal 1980, 2, somm 569.)

8 Article L221(1)1 of the Consumer Code

product itself or on its packaging – information about the identity and address of the producer, as well as a product reference number and batch number (Article L221(1)2 II of the Consumer Code).

French case law has established a 'precautionary principle', which applies to product traceability cases (French Supreme Administrative Court decision of December 29 1999).

(c) Sector-specific obligations

Foods and novel foods: The Decree of April 15 1912 sets food safety requirements, such as a prohibition on the use of chemicals products.

Safe temperatures for the storage and transportation of products with animal origins or food containing products with animal origins are set by a ministerial decree of September 21 2009 (annexes). For example, fresh milk cannot be transported over 4°C.

'Novel foods' are defined as including "foods and food ingredients with a new or intentionally modified primary molecular structure" or "foods and food ingredients containing or consisting of genetically modified organisms" (Article R1323(1) of the Public Health Code and Article 1 of EU Resolution 58/97). Producers may neither produce novel foods that present risks to consumers nor produce novel foods that differ from the foods they are intended to replace in such a way that their consumption would be nutritionally detrimental or hazardous to the consumer; and producers may not attempt to mislead consumers (Article 3 of EU Regulation 258/97). In addition, the Consumer Code (Article 1323(2)) establishes a food safety enforcement agency, to which manufacturers and regulatory authorities must declare any problems or risks.

The placing on the market of genetically modified foods must be pre-approved by a competent administrative authority, depending on whether the product is a genetically modified organism for use in medicinal products, foods, or other uses (Article L533(5) of the Environment Code).

In cases of breach of this provision, the Ministry for the Environment can impose penalties on a sliding scale: first giving the company notice that it must meet the requirements in a set time period (Article L535(5) of the Environment Code). Where there is continued breach beyond that time limit, the authority can enforce compliance or suspend the approval (Article L535(5) of the Environment Code). If those remedies also fail, the company will face a penalty of up to two years' imprisonment and a fine of up to €150,000 (Article L536(5) of the Environment Code).

Food contact materials: According to Article 3 of EU Regulation 1935/2004:

> *Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof ….*

'Active materials and articles' is defined in an EU guidance note[9] as:

… materials and articles that are intended to extend the shelf life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food …

'Intelligent materials and articles' is defined in the same note as:

… materials and articles which monitor the condition of packaged food or the environment surrounding the food….

Medicines Regulations 1971: The preparation, import, export and distribution of medicines must meet good practice rules set by the *Agence Nationale de sécurité du medicament et des produits de santé* (ANSM – the National Agency for Security of Medicaments and Health Products (former AFSSAPS) (Article L 5121(5) of the Public Health Code). Non-compliance is punishable by a fine of €3,750 (Article L 5421(1) of the Public Health Code).

An industrially produced medicine must be approved by the ANSM before being put on the market (Article L5121(8) of the Public Health Code). If the medicine is put on the market without such approval, the company will incur a penalty of up to two years' imprisonment and/or a fine of up to €30,000 (Article L5421(2) of the Public Health Code).

Motor vehicles (Decree 2011-368 of April 4 2011): Motor vehicles must not produce smoke, toxic, corrosive or odorous gas in volumes that may disturb the population or compromise public health or security. Vehicle manufacturers can be punished by a fine of the fourth class (maximum €750; Article R318(1) of the Road Code). Motor vehicles must be produced and marketed in such a way that they ensure the safety of all road users (Article L311(1) of the Road Code). Vehicles can be taken off the road if it is shown that these requirements have not been fulfilled (Article R311(3) of the Road Code).

Electrical equipment ((Safety) Decree 2009-1139 of September 22 2009): Electrical equipment must not contain lead, mercury, cadmium, chromium hexavalent, prolybromobiphenyl or polybromodiphenylether (Article R543(175) of the Environment Code). Companies which fail to observe these restrictions may incur a fine of the fifth class (€1,500 maximum; Article R543(206) of the Environment Code).

Standard EN 60204 establishes safety requirements for electrical equipment, such as making sure users are guarded against direct contact, protection against overload and earthing. All electrical equipment must be designed so that any batteries inserted can be easily extracted (Article R543(176) of the Environment Code). All electrical equipment placed on the market must be accompanied by instructions that indicate to users which type of battery is integrated and how to extract the batteries without any risk. Any item of electrical equipment placed on the market after August 13 2005

9 http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance_active_and_intelligent_scofcah_ 231111_en.pdf.

must be marked with information identifying its producer and confirming that it was put on the market after August 13 2005.

Toys (Decree 2010-166 of February 2010 on Toy Safety): Manufacturers must respect all security requirements set out in Annex 1 of Decree 2010-166. For example, toys must present no risk of asphyxia and must be physically robust enough to be able to resist the pressures to which they are likely to be exposed, without causing injury because of breakages or damage (Annex I of the decree). Before placing a toy on the market, the manufacturer must analyse any threats or potential exposure to dangers of a chemical, physical, mechanical or electrical nature, and any risks concerning flammability, radioactivity or hygiene presented by the toy (Article 7 of the decree). Manufacturers must also mark their toys with the CE safety compliance marking to indicate that the essential security requirements of Article 3 of the decree are satisfied (eg, to declare that the toy will not expose a child to strangulation risks and is not flammable (Article 7 of the decree)).

Cosmetics (Law 2011-12 of January 5 2011): Any enterprise engaged in manufacturing, preparing or importing cosmetics must be pre-approved by the AFSSAPS (Article L5131(2) of the Public Health Code); breach of this requirement may incur a fine of €30,000 and up to two years' imprisonment (Article L5431(2) of the Public Health Code). Cosmetics may be placed on the market only if the packaging bears the name and address of the manufacturer or distributor (Article L5131(6) of the Public Health Code). Article L5131(7) of the code requires manufacturers to convey information about the constituent ingredients used in the cosmetic to the relevant authority. EU Directive 76/769/EEC lists banned substances (eg, zoxazolamine, procainamide, its salts and derivatives, and benzidine).

Occupational health and safety: The EU Machinery Directive (2006/42/EC) aims to ensure the free movement of machines and their accessories, while imposing essential requirements regarding the health and safety of consumers. Before placing machinery on the market and/or putting it into service, manufacturers must ensure that it meets relevant essential health and safety requirements (set out in Annex I) and must provide essential information such as instructions. Manufacturers must also draw up the EC declaration of conformity and affix the CE mark, which creates a presumption of conformity with harmonised standards.

Liability attaches to manufacturers both when:

- the machine is used under conditions intended by the manufacturer; and
- it is used in foreseeable abnormal situations.

The French Supreme Court has held that an accident resulting from inadequate training of personnel in the use of the machine is a foreseeable abnormal situation (*Cass Crim*, December 6 2005). In another example, an employee using machinery in a manner that contradicted its instructions, and in spite of pictograms illustrating these instructions, was also considered to be a foreseeable abnormal situation (*Cass Crim* April 12 2005). The interpretation is very broad and onerous on the manufacturer.

To verify the safety of machinery and conformity with the directive, the relevant work inspection authority has the power to:

- enter company premises without notice;
- inspect machinery; and
- engage experts to evaluate the machinery.

Their report could lead to:

- written observations;
- formal notice to comply with the directive;
- fines; and
- a reference to the courts to deal with urgent matters to stop any high-risk activity.

Employers are responsible for appraising any risks presented to the health and security of workers (Article R4412(5) of the Labour Code).

2.3 Post-market safety obligations

(a) Corrective action

Parties responsible for marketing a product must immediately notify the competent administrative authorities if they notice that a product does not comply with the general product safety requirements provided by Article L221(1) of the Consumer Code.

Producers and manufacturers must take any necessary actions including withdrawal of the product from the market; giving adequate warnings to consumers; and recall of products already on the market (Article L 221(1)2 II of the Consumer Code).

Where products do not comply with statutory safety requirements, either permanent or temporary/urgent measures can be taken. See section 2.3.

2.4 Criminal liability

Article 223(1) of the Penal Code creates the offence of endangerment. The elements of this offence are satisfied when:

- a person owes a particular duty to ensure the safety of a product;
- violation of this duty creates the risk of death, serious injury or permanent disablement;
- the risk that this poses to third parties is immediate; and
- the breach of the duty to ensure safety was intentional.

Criminal prosecution may result from the following circumstances:

- negligent homicide – Article 221(6) of the Penal Code;
- negligent bodily injury – Article 222(19) of the Penal Code;
- threat to life of a third party – Article 223(2) of the Penal Code; and
- fraud (in relation to substantial properties of the product) – Article L213(1)[10] of the Consumer Code.

10 This article is not solely applicable to consumers.