

# SCOR Papers

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## Development Risk

### *Abstract*

*The concept of development risk is once again in the news. It is a risk that is unknown at the time a product is launched and that is discovered as a result of later advances in scientific and technical knowledge, proving the product to be harmful. Examples are found increasingly often, starting with the contaminated blood crisis and including BSE, diethylstilboestrol (DES), growth hormones and the Mediator diabetes drug scandal. The French legal system, which exempts product manufacturers from liability related to development risk, is only seemingly stable, heightening the insecurity that surrounds the debate on the risk's insurability.*

In France, the concept of development risk is closely related to changes in the legal liability of product manufacturers. It is a shortened manner of defining the risk run by the manufacturer with regard to the development of scientific knowledge and technological advances that enable a hitherto unknown defect to be discovered at a later date. In less legal terms, one could say that this risk appears for a product (or service) over time as its use may become harmful in the future, even though the product (or actions) which cause what will be deemed harmful in the future are not considered as such at the time of marketing. The risk is related to the (unforeseen) development of scientific knowledge or, more worryingly, the observation of statistical causality between the use of the product (or service) and physical harm or damages to property or the environment.

This issue not only covers simple causality, such as that for asbestos (recognised as causing cancer in workers using the material and people living in contact with it in certain buildings), but also causality in frequency (diethylstilboestrol (DES)) when epidemiological studies showed abnormal incidences of harmful illnesses in users (in the distant past) of certain substances, considered harmless when distributed, and even authorised by public authorities.

It is difficult to distinguish the concept of development risk from other risks facing manufacturers of foodstuffs, pharmaceutical products or construction materials. This is at present highlighted in France by the rapid emergence of environmental liability law, which extends the scope of damages for bodily injury to compensation for damages to “the environment” (water, soil, biodiversity), and naturally through the use of the precautionary principle in positive law.

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(1) Lamy Assurance 2147, p. 852. Article 138611 of the French Civil Code states that “The producer shall be [...] liable unless he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered”, (notion related to “latent defects”).

The question of scientific and technical knowledge is broadened with evidence that at the time of marketing, all efforts were made to determine the effects of the products. The contaminated blood “scandal” is a good example of the new and extremely difficult task facing judges of assessing the proper application of the precautionary principle. The Mediator diabetes drug issue which recently hit the news following the growth hormone scandal shows how the application of liability is becoming more subjective. Reputed experts have accepted the use of substances which are now deemed harmful. The general public is wondering how these eminent figures “could not have been aware” of the product’s harmfulness on time. Have they taken the necessary precautions, or have they even deliberately overlooked them? What did public authorities do at the time? Clearly, guilt is easily attributed with hindsight. Let us not forget that asbestos was considered to be a useful (and even necessary) fire-retardant by a society traumatised by fires in public places (the 5/7 dance hall, Pailleron lower secondary school).

Lastly, the European Commission Green Paper dated 28 July 1999 reviews the possibility of exemption from liability relating to the development risk open to Member States in 1985, used by France (not without debate), and considers its withdrawal. This is a recurring theme that is once again topical today.

## A vague notion

Even today, the notion itself is not clearly defined. The subject was likened to latent defects for a long time, for which car manufacturers have obtained insurance guarantees. The experience of the product, and not scientific or technical progress, revealed its defects: abnormal wear, frequent shortcomings, manufacturing defects that cannot be initially identified, etc. Although this was costly in terms of claims, this type of insurance hardly ever raised issues. Yet its very existence took part in polluting the debate: why insure against a manufacturing defect that becomes apparent over time, and not the harmful consequences of a product which will also become apparent in the future, generating the risk shifting from an immediate lack of knowledge to later discovery through improved knowledge?



The asbestos and contaminated blood cases have influenced the way this risk is assessed and described. In both cases, the risk is the result of major social changes rather than scientific advances. The priority given to fire protection via asbestos gives way to the protection of persons (whatever their situation) exposed to the material. Yet the harmful properties of asbestos had long been recognized by the French Social Security Code for miners (occupational diseases). As regards blood, the transmission of AIDS through blood transfusions was assessed extremely rapidly once the epidemic became known. The “contaminated blood” is an unfortunate defect in the processing of a medical product, just like other serious medical accidents. It has more in common with the disputes launched on the adverse effects of drug substances than with development risk. In an effort to clarify the difference, Mediator may well be the first real application of development risk.

Issues regarding the environment and liability resulting from damage to water, land and biodiversity are even closer to development risk. In a legal context still undergoing change, the development of the environmental liability concept (and not only liability arising from damages to the environment) paves the way for myriad claims under development risk. Today we talk about “approval liability”. It is the same as stating that what is approved today, and authorised by public authorities, may lead to liability claims tomorrow. Again, this has probably not as much to do with science as with society’s changing tolerance, as what is licit today may no longer be tomorrow, while claims are authorised against those who relied on the license granted by the authorities.

Clearly, the “precautionary principle” which is now constitutional, introduces extreme legal uncertainty in the development risk debate. Who, other than the judge, will say that sufficient precautions were taken before a product was distributed, and according to which type of evidence? Especially as expert appraisals and the various administrative authorisations no longer protect, or will no longer protect, manufacturers from liability claims.

Lastly, scientific research also brings about a development in the use of statistical correlations. Chains of causation become more probable. In future, it is likely that the comparison and correlation between the use of a product (chemical, pharmaceutical or foodstuff) and the abnormal incidence (or above-average incidence) of a disease will constitute damages entitled to compensation. This is without considering contraception drugs, obesity and the possible (but probable) correlation with certain practices or eating habits (polyunsaturated fatty acids and sugar) that could in future cause considerable financial difficulties for major companies in the out-of-home food market ...

### Apparent and misleading legal stability

For the moment, the legal situation in Europe, and therefore in France, is relatively secure. The Directive dated 25 July 1985 on product safety (defective products) was incorporated into French law by the Act dated 19 May 1998, thirteen years later. This timeframe demonstrates the passionate debate on the issues of defective products, latent defects, development risk and the aggressive attitude of consumers’ organisations. It is true that the contaminated blood “crisis”, and the later BSE scandal significantly left their mark at this time. These provisions are also found in the 2001 Directive on product safety, incorporated by the French edict dated 6 July 2004. All these texts provide for the exemption of manufacturer liability on the condition that he can prove (reversal of the burden of proof) “that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered”. However, the French law dated 9 December 2004 provides that the exemption of liability related to scientific development does not apply to body parts or bodily fluids (blood, organs, and probably growth hormones). The Directives provide for a possibility for Member States to use this liability exemption. After much debate, France used this provision, but that can be reversed.



In fact, this does not mean that the legal situation is as stable and guaranteed as the European and French laws may lead to believe. First of all, liability can be claimed due to scientific advances for some care and treatment products. Contaminated blood leads to liability under the development risk. We must consider what was known in 1984/85 about blood, retroviruses in humans, and the transmission of hepatitis C. For the animal-to-human contamination of retroviruses, medical literature often mentioned the impassable nature of the “species barrier”. Then, avian flu, bovine spongiform encephalopathy and swine flu (influenza A or H1N1) came along and cancelled out this reassuring information. We also remember the theory of “healthy HIV carriers” who became HIV positive. Science is far from being the bed of roses that can be described in hindsight.

There is also real ambiguity in the notions of detectable defect and latent defect which underpin these consumerist-inspired regulations. In simple terms, it is as if we use notions related to consumer durables (cars, toys, “white” or “brown” appliances) which are frequently recalled for changes, when dealing with products ingested by people, with consequences that are harmful in a far more serious way.

This is where case law comes in and makes full use of this ambiguity in definitions and the difficulties with regard to negative evidence against the manufacturer. The manufacturer should prove, not that there is a latent defect or a defect the manufacturer could have identified, but that the state of scientific knowledge at the time the product was marketed did not allow the harmful effects or side effects to be identified. It must also be acknowledged that case law on unfair terms in insurance policies and in particular that which aims to limit compensation in the event of damages, creates possibilities for judges who consider that their duty is to protect (compensate) the victims of damages, and bodily injuries in particular.

In reality, case law today is torn between the approach of compensating damages in which the notion of the manufacturer’s absolute obligation dominates the state of knowledge at the time of marketing and the admission of the development risk exemption in cases where damages are less serious (vaccinations, implosion of a television set).

To exaggerate this idea, it is tempting to say that in France, notwithstanding of the regulations, case law will refuse the exemption of product liability if a claim occurs involving many victims with serious bodily injuries. This was the attitude of the French public authorities during the BSE crisis, as soon as it was proved that the prion found in meat and bone meal used in animal feed crossed over the species barrier and is transmitted to humans, (possibly) causing cases of Creutzfeldt-Jakob disease. This is proof that no-one in France can really be protected from a liability claim due to the development of scientific knowledge.

### Is the development risk not insured de facto?

That being the case, and despite the existence of exclusion clauses in policies, it looks as if insurers cover development risk in the event of recurring serious bodily injury claims, without receiving a premium, and without a reserve system over time which allows them to deal with any possible claims. The conditions for cover over time are not set (as the risk is said to be not covered) and, with regard to risks of bodily injury, case law does not permit the value of coverage to be restricted. The contaminated blood scandal reminds us of the strength of these principles, and the ease with which the judge declares restrictive clauses in terms of value and timeframe legally null and void, not to mention coverage exclusions. While the general public (and politicians) increasingly tend to believe that damage to the environment and to water, soil and biodiversity in particular are as serious as bodily injuries, case law on the compensation of liability with regard to damage to the environment identified in the future is set to flourish for many a year, to the detriment of paying polluters and their insurers.

## Insurability of the development risk

Naturally, the Profession's official line justifies the exemption of the development risk due to its intrinsic uninsurability. We have heard the legal and sociological basis of these arguments time and again: manufacturers cannot legitimately be held liable for scientific advances; excessive protection of victims is an obstacle for research developments (argument also used against the precautionary principle in the past); France would be the only EU Member State to abandon the exemption made possible by the Directive (this is less true since the last decade, as some other Member States have accepted the precautionary principle); it is difficult to bring "negative" evidence against manufacturers on the status of science; and last but not least, it seems impossible to set a premium for occurrences for which insurers have no statistical experience.

The various, less empirical, considerations of courts of justice present numerous counter-arguments in favour of the risk insurability: manufacturers have a general absolute obligation with regard to product safety; victims cannot be left without compensation; the price of safety can be easily (at least according to the judge!) introduced in the product's price and therefore the insurance premium can be financed by the market; the very difficulty of providing evidence is a protection for the manufacturer's insurer against excessive victim claims.

These considerations, resulting from doctrine and case law, are clearly not sufficient to convince insurers. To ascertain the insurability of a risk, what better than to go back to the theory of insurance. It teaches that a risk is insurable under three conditions and three alone: the existence of unforeseeable factors (this is what differentiates insurance from subsidies), the lack or insufficient restriction of "moral hazard", and the existence of reinsurance capacities at acceptable prices. Does development risk satisfy these three points?

- There is no doubt that there is a risk; we can even consider that the risk is multiplied. Moreover, the fact that there is no statistical experience of the risk does not at all prevent insurers from setting a premium, as the specialists of spatial risk coverage or even the long term care risk in the 1980s/1990s or even the nuclear risk well know. The argument that a risk, for which an insurer has no experience, cannot be insured, is not admissible.

- The "moral hazard" is related to unbalanced information between the insured person (who knows the risk) and the insurer. More generally, the insurance could authorise the insured person to take an excessive risk. If, in the notion of latent defects, the "moral hazard" can be fully applied (was the defect so well hidden that the customer was able to "sell" its absence to the insurer, banking on the fact that it would be impossible to demonstrate his knowledge of the risk at a later date), the same does not apply to the "development risk". We must remember that at the beginning of the AIDS epidemic, the scientific community hesitated about the malignant nature of the HIV infection, there was confusion over tests to detect the virus and highly respected scientists had theories concerning the "species barrier" and the transmission of retroviruses from some mammal species to humans. The insured person cannot mislead the insurer, as he himself cannot suspect the very existence of the risk in all fairness.

- With regard to reinsurance capacity, the economy has long taught us that its availability depends on the return expected by investors from the capital granted to reinsurers. The rapid reconstitution of underwriting capacity after 09/11 and the concentration of claims after hurricanes Katrina, Rita and Wilma over one quarter show that the problem can be dealt with, even though the solution may be costly.

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(2) For an excellent example of the uninsurability theory, see Lamy Assurance 2274 and the many bills in preparation of French Act dated 19 May 1998 transposing the EU Directive dated 25 July 1985.

(3) See Que Sais-je 3596 (remarkable) on the precautionary principle by François Ewald, Christian Gollier and Nicolas de Sadeleer (in French).

(4) Recent case law of the French Cour de cassation (highest court of appeal) (Cass 1ère Civ. (1st civil chamber) 19/12/90 -7 Orders-, Cass 1ère Civ. 6 February 1996, Cass 1ère Civ. 3 July 2001).

## The risk is insurable, but what about premiums?

The “development risk” in France is therefore legally excluded from third-party liability insurance policies but case law is at the very least ambiguous and leads us to think that in the event of recurring claims concerning a significant number of people and causing serious environmental damage, the courts of justice could overthrow the exemption and compensate the victims. The uninsurability brandished by the profession has hardly any technical justifications other than pricing difficulties (which can always be overcome, let us place our trust in the efficiency of actuarial science). Now, the real question is whether it is worth considering the insurance of this risk, defining the level of insurer involvement in financial terms, receiving premiums (and therefore launching work to explore the risk and set up a pricing system) and setting ceilings and time limits (the claims principle or limit for reporting the event causing the damage).

This attitude would allow us to find insurance solutions, either involving public intervention (the notion of “health disasters”) or securisation mechanisms such as “mortality bonds”. If such an approach is not adopted, the industry may well experience new third-party liability “crises”. As for all recurring claims involving bodily injury, the profession’s defensive position is rapidly demolished by civil society assisted by public authorities. Insurers and reinsurers are the deep pockets in which judges and victims feel they can delve because we are reputed to be rich. The recent medial liability situation is a good example of how difficult it can be to justify significant reserves for long tail claims, while civil society hunts out creditworthy people to blame and to tax for compensation of victims.

Should the risk become reality, the profession will probably be exposed, in particular if the State is without money, while nothing will have been organised to finance (premiums), define (what is development risk), limit (coverage time limits, ceilings and management of coverage limits), reinsure (mortality bonds), price the risk and manage the claims in liaison with judges and victims associations.

## Conclusion

The general message of this conclusion is twofold. The risk uninsurability argument is weak in a society with a growing aversion to risk. The barriers that it hopes to put up can always be overcome and the law always gives way to societal demands. It is Total that is paying for the Erika disaster, even though little responsibility can be charged on the cargo’s shipper, in an event at sea. Asbestos is recognised as an occupation disease by Social Security legislation but the criminal negligence of the employer circumvents the barrier around common law liability. We must reflect seriously on the the uninsurable risks which are insured de facto, and subsequently de jure, due to social pressure.

The second idea concerns society’s perfectly legitimate approach in favour of today’s victims with bodily injuries and tomorrow’s victim, the environment. It is pointless to deplore this situation or to attempt to obtain exemptions. To counter the idea of rich, taxable deep pocket insurers who can be called upon ruthlessly, we must lay down ideas about cost transparency, risk pooling and the acceptance of compensation conditions that must reflect pricing. The requirements of the solvency margin in the new SolvencyII regulations should back up the validity of this message.

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