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## **The Directive 85/374/EEC**

The Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, approved on 25 July 1985, has introduced new rulings for the regulation of the producer's liability, aiming to harmonise the different laws existing in the Member States.

The directive has introduced a common scheme of strict liability which does not require the proof of the producer's negligence but the existence of the defect in the product, the harm and the casual relationship between the damage and the defect.



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## **The Directive 85/374/Ce Definition of “product”**

According to article 2 of the Directive 85/374/ECC “ 'product' means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable. 'Primary agricultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. 'Product' includes electricity”.

The large economic losses following the impact of the BSE syndrome disease and the scandal concerning chicken-breeding in Belgium, has led the European Union to take a different attitude towards these kinds of products, also extending to primary agricultural products the product liability regime contained in the 85/374/EC directive with the approval of Directive 99/34/EC



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## The Directive 85/374/EEC

# The “state of art defence”

The Directive allows national legislation to introduce limitations and defences that practically dilute the economic impact of strict liability. Among them there is the “state of art defence”

### Article 7, e)

The producer shall not be liable as a result of this Directive if he proves:

e) 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



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## The Directive 85/374/EEC

# The “state of art defence”

According to article 15 of the Directive, art. 7 (e) is not a mandatory provision since the Member States may have maintained or provided the producer’s liability also for the development risks

Art. 15 Each Member State may: (...)

- b) by way of derogation from Article 7 (e), maintain or, subject to the procedure set out in paragraph 2 of this article, provide in this legislation that the producer shall be liable even if 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 a defect to be discovered.



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## State of art defence

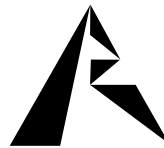
# The interpretation of the European Court of Justice

Case n. 300/1995

## Scientific and technical knowledge

*“Article 7(e) is not specifically directed at the practices and safety standards in use in the industrial sector in which the producer is operating, but, unreservedly, at the state of scientific and technical knowledge, including the **most advanced level of such knowledge**, at the time when the product in question was put into circulation”*

*“The clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been apprised, but the **objective state of scientific and technical knowledge of which the producer is presumed to have been informed**”.*



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## State of art defence

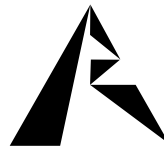
# The interpretation of the European Court of Justice

Case n. 300/1995

## The relevant time

*“The relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation.*

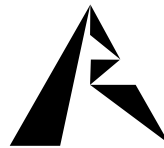
*It follows that, in order to have a defence under Article 7(e) of the Directive, the producer of a defective product must prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation was not such as to enable the existence of the defect to be discovered”*



## **The functioning of the “state of art defence in Member States”**

The functioning of the development risk clause in all Member States varies according to the type of product, and there have been cases where it was not applied either because it was not introduced in the national laws, or because even if introduced, it was not provided for some kinds of products. Thus, in relation to the application of the state of art defence, it is possible to distinguish three different models of implementation:

- 1) The state of art defence does not apply to any products;
- 2) The state of art defence applies to all products;
- 3) The state of art defence applies to some kind of products and in particular circumstances.



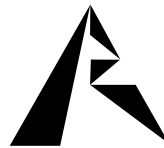
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## National regulatory regimes

Member State	Development risk	Products
Austria	NO	
Belgium	NO	
Denmark	NO	
Finland	YES	All (Art. 7, e) Directive 85/374/ce)
France	YES - partially	Human derivative
Germany	YES - partially	Pharmaceutical
Greece	NO	
Ireland	NO	
Italy	NO	
Luxembourg	YES	All (Art. 7, e) Directive 85/374/ce)
Netherland	NO	
Portugal	NO	
Sweden	NO	
Spain	YES - -partially	Pharmaceutical & foodstuff
United Kingdom	NO	Pharmaceutical

Study on the economic impact of development risk clause as provided by in Directive 85/374/EEC on Liability for defective products





## **The state of art defence does not apply**

Finland and Luxembourg have decided to exclude the application of the state of art defence for all products. That means that producers are liable also for development risks.

The exclusion of the clause has not been well accepted by associations of producers and professional corporations. In Luxembourg it was said that the exclusion of the above mentioned clause could have curbed the scientific and technical research and damage the imports of foreign products in Luxembourg. Producers, in fact, in order to export their goods in these two countries (where the development risks clause does not apply) will have to insure for the damages deriving from development risks, consequently their expenses will increase and this will have a negative effect on the final price of their products. There are no information on legal proceedings where the development risks clause could have been applied and was not applied because of the national law.



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## **The state of art defence applies to all products**

In most of the Member States the development risks defence has been introduced and it applies to all products with no exceptions, namely UK, Italy, Ireland, Sweden, Greece, Portugal, Austria, the Netherlands, Denmark and Belgium



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## Austria

National law implementing the Directive 85/374/ECC and directive 99/34/EC:  
Product Liability Act 1988/99 (BGBl 1988/99) as amended by BGBl 1993/99;  
BGBl 1999/185

**General rule:** The producer can escape liability by referring to the state of art defence; the producer **is not liable** for products defects that, at the time when the product was put into circulation, were not such as to enable the existence of the defect to be discovered

No exceptions



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## Belgium

National law implementing the Directive 85/374/ECC and directive 99/34/EC:

Law 25 February 1991 and law 12 December 2000

**General rule:** the producer can escape liability by referring to the state of art defence

**Peculiarities:** as concerns the meaning of “**mise en circulation**”, the Belgian law has introduced an original definition.. Art. 6 of the law of 25 February 1991 states that a product is put into circulation when the producer shows the intention to indicate to which use it is directed by transferring it to other people or using it for the advantage of third parties. In case of damages, it indicates both the moment the Courts will have to refer to in order to establish whether the product was defective, and, as it has already been said, the moment to take into consideration when looking at the scientific and technical knowledge for the application of the state of art defence.



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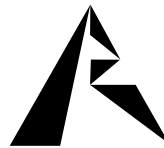
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## Denmark

National law implementing directive 85/374/ECC and directive 99/34/EC: Product Liability Act n. 371/1989; Lov 4/12/2000

**General rule:** the producer can escape liability by referring to the state of art defence

No exceptions



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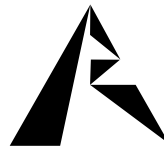
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## Greece

**National law** implementing directive 85/374/ECC and directive 99/34/EC: Joint Ministerial Decision n. B 7535/1077 of 31/3/1988 replaced by Law n. 1961/1991, ratified by Law n. 2000/1991; Law n. 2251/1994; Ministerial Decision n. Z1 659/2002

**General rule:** the producer can escape liability by referring to the state of art defence. Not only the “generally accessible knowledge” shall be included in the notion of “scientific and technical knowledge”. So it has been found that the producer would not be able to use the “state of art defense” in the case of a publication in a Japanese scientific magazine of a medical study in the Japanese language, which highlights suspicions of cancer in pharmaceuticals or chemical products .

No exceptions



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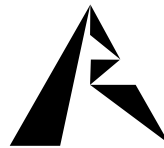
## Ireland

National law implementing directive 85/374/ECC and directive 99/34/EC: Consumer Protection Act 1987 and several orders (2000-2001)

**General rule:** the producer can escape liability by referring to the state of art defence

**Peculiarities:** The Irish Government in 1996 established a Judicial Tribunal to deal with compensation claims by women who contracted Hepatitis C from infected blood products supplied by the Government Agency – the Blood Transfusion Service Board. No actions were taken under the 1991 by these women mainly because of the ‘development risks’ defence – a reliable test for Hepatitis C was only perfected in 1991, long after many of these women were infected by the virus, therefore the Blood Transfusion Services Board would have been able to avail of the “development risks” defence as a means of avoiding liability for this tragedy.

No exceptions



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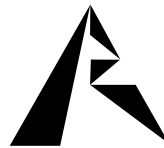
## Italy

National law implementing directive 85/374/ECC and directive 99/34/EC: Presidential Decree 224/88 and Legislative Decree 25/2001

**General rule:** the producer can escape liability by referring to the state of art defence

No exceptions





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## Netherlands

National law implementing directive 85/374/ECC and directive 99/34/EC: Law n. 487/1990 (which has introduced the articles n. 1407a-1407i of the old Civil Code and

**General rule:** the producer can escape liability by referring to the state of art defence

No exceptions



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## Portugal

National law implementing directive 85/374/ECC and directive 99/34/EC: Decree law 383/98; Decree law 131/2001

**General rule:** the producer can escape liability by referring to the state of art defence

No exceptions



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## Sweden

National law implementing directive 85/374/ECC and directive 99/34/EC: PAL 1/1/1993

**General rule:**the producer can escape liability by referring to the state of art defence

No exceptions



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## United Kingdom

National law implementing directive 85/374/ECC and directive 99/34/EC: Consumer Protection Act 1987 and several orders (2000-2001)

**General rule:** the producer can escape liability by referring to the state of art defence

**Peculiarities:** Art. 4 Consumer Protection Act: *“the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control”*.

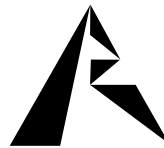
No exceptions



## **The state of art defence does not apply for particular products and in particular circumstances**

In Spain, France and Germany, the state of art defence has been implemented, however it does not apply in particular cases provided for by the national laws.

One exception that is common to the 3 countries - and that is the most relevant - is the one concerning blood derivatives. In fact both Spain, France and Germany consider the producer to be liable even for development risks when the blood of the blood derivatives he has supplied have caused damages to the consumers.

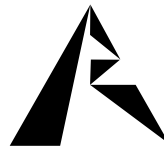


## France

National law implementing the Directive: Law 98-389 of 19th may 1998 (amending the civil code)

**General rule:** the producer can escape liability by referring to the state of art defence

**The defence does not apply:** 1) in case of damages caused by both human body products and derivative human products; 2) if during the period of 10 years after the product has been placed on the market its defects were discovered and the producer did not adopt all the necessary measures to avoid the damage.



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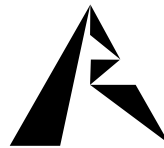
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## Germany

National law implementing directive 85/374/ECC and directive 99/34/EC: Product Liability Act 1989; Law n. 48, 7/11/2000

**General rule:** the producer can escape liability by referring to the state of art defence

**The state of art defence does not apply to:** Pharmaceuticals (German Drug Law)



## Spain

National law implementing directive 85/374/ECC: Law n.22 of 1994

**General rule:** the producer can escape liability by referring to the state of art defence

**The state of art defence does not apply to** (§ 6.3, L. n.22/1994): pharmaceuticals; blood derivatives; food; foodstuff.