

Drug Liability Rules in the European Union

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Agenda

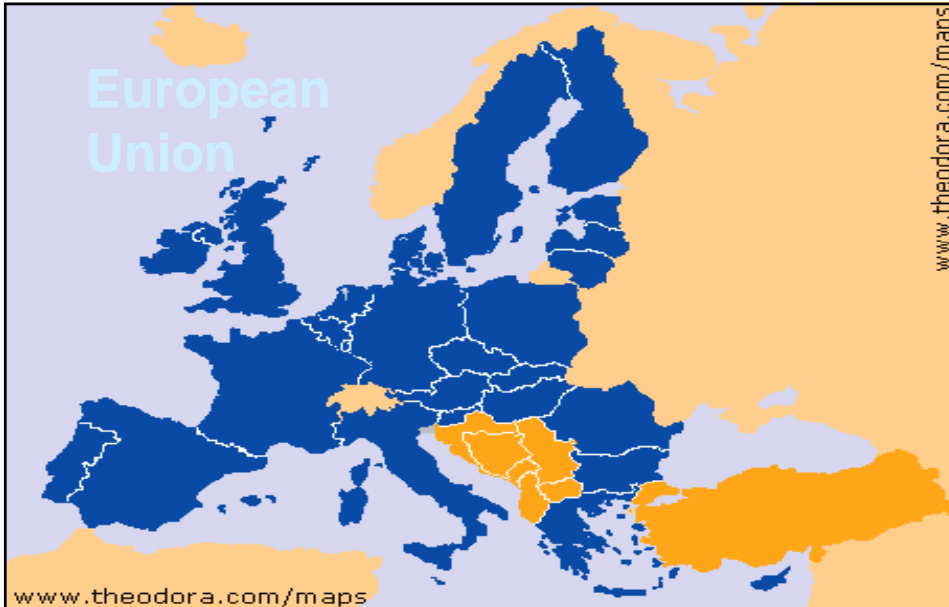
- Introduction to the European Union and its legal system
- Product liability within the European regulation
- Implementation of the Product Liability Directive in the Member States



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European
Union



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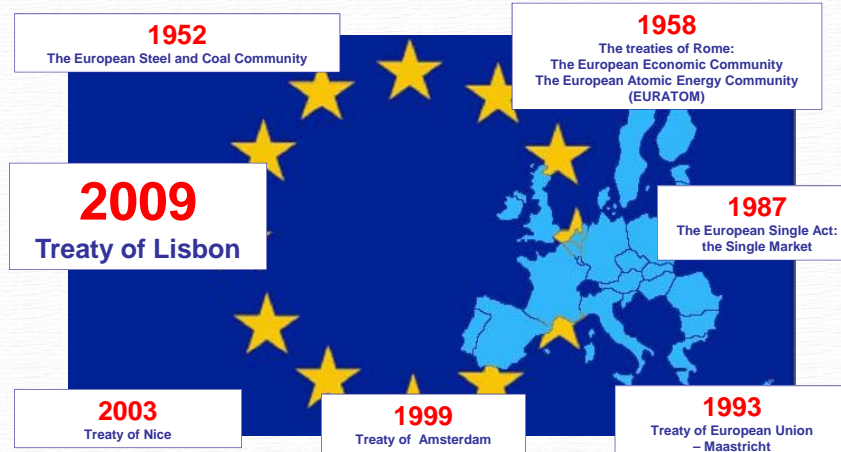


European Union

- What is NOT the European Union?
 - Federation
 - Organization for co-operation between the governments
- Independent sovereign countries
 - 6 -> 9 -> 10 -> 12 -> 15 -> 25 -> 27 -> to be continued



Treaties



The European Union According to the European Court of Justice

The European Economic Community constitutes a **NEW LEGAL ORDER OF INTERNATIONAL LAW** for the benefit of which the states have limited their sovereign rights, albeit within limited fields, and the subjects of which comprise not only the member states but also their nationals

61962J0026 Judgment of the Court of 5 February 1963. - NV Algemene Transport- en Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration. - Reference for a preliminary ruling: Tariefcommissie - Pays-Bas. - Case 26-62.



Three Key Players

The European Parliament - voice of the people

Jerzy Buzek, President of
of the European Parliament



The Council of Ministers - voice of the Member States

Herman Van Rompuy, President of the European Council



The European Commission - promoting the common interest

José Manuel Barroso, President
of the European Commission



How EU Laws Are Made

Citizens, interest groups, experts: discuss, consult

Commission: makes formal proposal

Parliament and Council of Ministers: decide jointly

National or local authorities: implement

Commission and Court of Justice: monitor implementation



EU Product Liability

- Council **Directive 85/374/EEC** of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products
- EU directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so



Product Liability Divergences

- Distort competition
- Affect the movement of goods within the common market
- Entail a differing degree of protection of the consumer



Main Elements of the Directive

- Product – all **movables** which have been industrially produced
- Liability **without fault** of the producer
- Burden of proof on the victim as regards the **damage**, the **defect** and the **causal relationship** between the two
- **Exemption** of producer from liability when he proves the existence of certain facts explicitly set out in the Directive

Implementation & Interpretation Product

- Electricity, energy, gas, natural forces
- Products incorporated into another movable or into an immovable
- Agricultural products
- Blood products
- Germany – excludes drugs (drug liability in the Drug Law)



Implementation & Interpretation Producer

- Many different wordings and interpretations
- Manufacturer of any component, raw material, EU importer are liable
- Pharmaceutical industry:
 - Marketing Authorization Holder (located in the EU)
 - Releasing manufacturer (QP release)



Implementation & Interpretation

Fault, damage, defect and causal relationship

- No need to prove the fault of the producer
- The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage



- Greece, Portugal – omitted the latter
- Germany - causal relationship is presumed



Implementation & Interpretation

Exemption of producers from liability

- Did not put the product into circulation
- The defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards
- Neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business



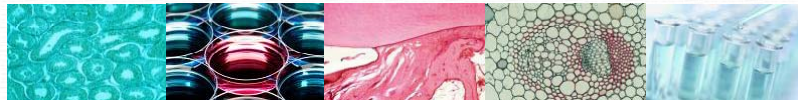
Implementation & Interpretation Exemption of producers from liability

- The defect is due to compliance of the product with mandatory regulations issued by the public authorities
- In the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product



Implementation & Interpretation Exemption of producers from liability State of the Art

- That the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the existence of the defect to be discovered



Implementation & Interpretation Exemption of producers from liability State of the Art

Development risk defence:

- Finland, Luxemburg – no for all products
- Spain – no for drugs, foodstuffs and food products intended for human consumption
- France – no for body parts/products, but conditional upon producer taking appropriate steps to prevent harmful consequences
- Some other countries in their Drug Law (for example Hungary)



Thank you!

Questions:

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