Liability of Certification Agencies as Necessary Compensation for the Privatization of Product Safety Law – The PIP Case in French and German Courts

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Product safety law has been largely privatised with the then "New Approach" of EU law. The producer himself declares the compliance of his products with the relevant product safety laws by affixing the CE mark to his products. Once a product bears the CE mark, it can float freely in the internal market, whereas Member States are not allowed to exercise border controls. In the case of particularly risky products, their safety shall be guaranteed through a certification procedure, where a so-called notified body will certify the safety of the product design and control compliance with the certificate regularly.

The PIP case, however, demonstrated the vulnerability of that system. Poly Implant Prothèse (PIP), a producer of breast implants, systematically filled implants with cheap industrial silicone meant for use in mattresses rather than medical procedures. Only after years, the fraud was discovered by the French market supervision agency. About 300,000 women in 65 countries are believed to have received the now banned PIP implants.
Since PIP went bankrupt immediately after the fraud had come to light, the focus of the victims seeking reparation for their material and immaterial damage turned to the company that had certified the breast implants and that had controlled compliance with the certified design for years without noticing anything: TÜV Rheinland. Law suits were brought in various German courts as well as in the Tribunal de commerce de Toulon, where PIP was situated; with opposite results.
The paper will demonstrate how the reasoning of the courts shows significant differences in their understanding of the role of certification in the regulation of product safety, and why tort liability of certification agencies is a necessary ingredient of product safety law in a privatised regulatory environment.