

Legal impact of ISO 9001 certification

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Legal impact of ISO 9001 certification

- What is ISO 9001 (from a legal point of view?)
 - Voluntary
 - No sanction will apply if a company is not ISO 9001-certified, since it is not obligatory
 - Chain: **government authorities** (ex: UK: Secretary of State for innovation, universities and skills; BEL: Federal public service economy) -> **private accreditation bodies** (ex: BEL: BELAC; FRA: COFRAC; UK: UKAS; ITA: SICERT) – link: multilateral international agreements --> **accredited certification bodies** (ex: AFNOR, BSI, Bureau Veritas, Lloyds quality assurance...)
 - **ISO 9001 certified Manufacturer**

Legal impact of ISO 9001 certification

- **What is ISO 9001 (from a legal point of view?)**
 - relationship between government authorities and private accreditation bodies: the latter must follow the authorities' regulations (frequency of inspections; objects of testing, etc)
 - relationship between accredited certification bodies and manufacturer is contractual
 - What if, within the framework of a product liability case, the ISO 9001 manufacturer argues he should be exonerated due to his being certified by an accredited certification body, itself accredited by an accreditation body which followed government authorities' regulations?

Legal impact of ISO 9001 certification

- **Current EU and MS legislation + case law on product liability involving accreditation: legal framework**
 - Legislation on defective products (Dir : 85/374 CEE as modified by Dir. 99/34) strict liability on producer OR if unknown, each supplier (distributor/importer) will be treated as the producer
 - MS legislation on product liability
 - Environmental liability: same dialectic
 - Contractual liability
 - Case law

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■ Current EU and MS legislation on product liability

- Legislation on defective products (Dir : 85/374 CEE as modified by Dir. 99/34) only “producer” can be held liable
- Transposed in each EU MS – ex: French law: Art. 1386.10 Civ. code: “*The manufacturer can be held liable for the defect of the product even when the product has been manufactured by respecting the rules relating to the state of art or the **existing standards** or when it has been **approved by an administrative authority**”.*”

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■ Current EU and MS legislation on product liability

- French case law on the basis of Art. 1386.10 Civ.code:
 - Manufacturer (ISO 9001 certified) cannot be exonerated even if its products comply with the state of art or with standard
 - C. Cass 04/06/76: manufacturer is liable even if its products comply with AFNOR’s standards
 - Manufacturer (ISO 9001 certified) cannot be exonerated even if its product was approved by an administrative authority
 - Court of Appeal 27/01/98: the fact that the machine got a visa from a technical exam does not exonerate manufacturer from any liability (cf old case law on pharma. Products (risk of development exonerates manufacturer)

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■ Current EU and MS legislation on product liability

■ Can the final user or manufacturer directly sue the accredited certification body?

- In principle: yes
- In practice: he/she must prove that the control was not done appropriately...very difficult
- Accredited certification body will argue that its task consisted only in ensuring that the manufacturer fulfilled the necessary skills for producing goods of good quality
- However: what, in case of repetitive defects of a product, if final user proves that accredited certification body has committed a fault by not withdrawing the certification?
- In all cases: it will be easier for final user to sue the manufacturer.

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■ Is there a contractual relationship between the final user and the accredited certification body?

■ France: C. Cass – 2/10/07

- Grundig tv : 3025 FF (+/- 488 Euros) + 5 year guarantee – breaks down after 2 ½ years
- Mr. X sues AFNOR on the basis of a virtual insurance contract: requests new tv + 5 year guarantee + 5,000 FF damages
- French Tribunal: condemns AFNOR to pay 495,46 euros damages + 200 euros for moral prejudice on the basis of Art. 1142 civ.c.

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- Case law
 - France: C. Cass – 2/10/07
 - C. Cass: overrules tribunal
 - Grounds: Art. 1134 c.civ: “*contracts only bind those who have signed them*”
 - AFNOR cannot be held liable for the tv breakdown since no insurance contract between AFNOR and Mr. X

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- Nowhere, in the EU and MS legislation, is the ISO 9001 certified manufacturer expressly exonerated from its liability
- However:

Article 7 Directive 85/374 CEE: *“The producer shall not be liable as a result of this Directive if he proves:*

...

*(b) that, **having regard to the circumstances**, it is probable that 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; or*

...

*(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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- Possible interpretation of Art. 7 (b) and (e): exoneration of the producer's liability if he was granted quality certification? – What influence would this argument have on a judge who would have to assess the manufacturer's liability for its defective products?
- Developments in the US: USSC Medtronic – 20/02/08 – **catherer's rupture** "*common-law causes of action for negligence and strict liability at issue in that case impose "requirements" that were pre-empted by federal requirements specific to a medical device*"

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