



SAWICKI LAW

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&  
KOLLEGEN RECHTSANWÄLTE

# Produkthaftung und („CE“-) Zertifizierung deutscher Unternehmen in den USA

# American Product Liability Law

- Implied and Explicit Warranties  
Source: Uniform Commercial Code (UCC)
- State Law Codifications of the UCC  
E.g. Texas Business & Commerce Code § 2.301, et seq.
- Why you care?  
Merely selling a product creates these warranties!

# Implied and Express Warranties

- Implied Warranties
  - Made simply by selling a product, making a transaction
  - IMPORTANT: Presumed unless disclaimed.
  - Examples:
    - Tex. Bus. & Com. Code § 2.314 – Warranty of Merchantability
    - Tex. Bus. & Com. Code § 2.315 – Fitness for a Particular Purpose

- Express Warranties
  - Promises or guarantees made in a sales document
  - No Magic Words to Create
  - BUT, can disclaim using “As Is” or “With All Faults” (Magic Words)
- IMPORANT: It’s not just Texas. Most US States have enacted Article 2 of the UCC.
- Example:
  - Tex. Bus. & Com. Code § 2.313
- Does not include opinions...(wait for it...)

# Is this true in products liability?

- **A Product Seller in the US can still be held liable for problems with their products!**
  - State Negligence
  - Federal Law & Regulations
  - State Deceptive Trade Practices Acts

- **Negligence – Strict Liability**
  - Failure to Warn / Marketing Defect
  - Design Defect
  - Manufacturing Defect

- **Failure to Warn / Marketing Defect**

“[A] marketing defect occurs when a defendant knows or should have known of a **potential risk of harm** presented by the product but markets it **without adequately warning** of the danger or providing instructions for safe use.”

Harrison v. Medtronic, Inc., No. 3:20-CV-1407-S, 2021 WL 4267511, at \*3  
(N.D. Tex. Sept. 20, 2021)



- **Design Defect**

To recover for a products liability claim alleging a design defect, a plaintiff must prove that

- (1) the product was defectively designed so as to render it unreasonably dangerous;
- (2) a safer alternative design existed; and
- (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery.

A product is unreasonably dangerous when its risk outweighs its utility.

Genie Indus., Inc. v. Matak, 462 S.W.3d 1, 6 (Tex. 2015)

- **Manufacturing Defect**

[A] manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.

Casey v. Toyota Motor Eng'g & Mfg. N. Am., Inc., 770 F.3d 322, 326 (5th Cir. 2014)

- **Many US States have Deceptive Trade Practices Acts**
  - Texas Deceptive Trade Practices Act
  - Also known as “The Laundry List.”

- **Tex. Bus. & Com. Code § 17.46**
  - 34 Different “Deceptive” Trade Practices
    - Passing off goods or services as those of another
    - Causing confusion as to the source, approval, or certification of goods or services
    - Representing that goods or services are of a particular standard and are not.

- **Federal Law may supersede State Law**
  - “Federal Preemption”
  
- **Other laws end liability by a certain time**
  - “Statue of Repose”

- **Remember State Law UCC and Negligence?**
- **Federal Law can “preempt” State law and lawsuit.**
- **What is “preemption?”**
  - US Constitution is supreme “Law of the Land”
  - Federal Law that differs with State Law on the same topic supersedes a State Law.
  - Include Federal Regulations
  - “Preemption” can be “express” or “implied.”

- Example - *Lamere v. St. Jude Medical, Inc. (Minn. 2013)*
  - Medical Device Act 1976
    - US FDA Premarket Approval Process
- Express Preemption Clause
- State Law requiring more than FDA did not apply.
- Compliance with Federal Regulations “preempted” the State lawsuit.

- **Remember State Law UCC and Negligence?**
- **Statute of Repose**
  - General Aviation Revitalization Act, 49 U.S.C. § 40101, et seq.
- Ends all claims for injury or damages against the manufacture of an aircraft or aircraft parts 18 years from the date of first delivery of the aircraft to a buyer or a party who sells aircraft.



- U.S. Government leaves product regulation largely to private sector.
- U.S. Government promulgates regulations with which private sector must comply.
- Leaves it to common tort law or regulatory proceedings to ensure compliance.
- U.S. Government Agencies that regulate products include:
  - Consumer Product Safety Commission
  - Food and Drug Administration
  - Bureau of Alcohol, Tobacco, & Firearms
  - Federal Communications Commission

- **Individual U.S. States also have laws and agencies regulating products**
  - California Proposition 65
  - Consumer Protection Division, Texas Attorney General's Office
  - New York State, Department of State, Division on Consumer Protection

## **CE-ZERTIFIZIERUNG IN EU: GILT DIESE AUCH FÜR USA?**

U.S. Consumer Product Safety Commission (CPSC)

RECHTLICHE GRUNDLAGEN DES US PRODUKTSICHERHEITSRECHTS UND  
PRODUKTHAFTUNGSRECHTS

**In Bezug auf die Produkthaftung in den USA ist die Gesetzgebung nicht einheitlich**

Welche Behörde ist zuständig? Reguliertes Produkt?

## REGULIERTE PRODUKTE IN DEN USA SIND

- Gesundheit/Körper (Alkohol, Lebensmittel, Kosmetik und Tabak)
- Fahrzeuge/fahrzeugbezogene Produkte (Flugzeuge, Boote, Autos usw.)
- Sicherheit/Feuerwaffen (Munition, Industrieprodukte, radioaktive Stoffe usw.)
- Viele andere Produkte

## **NICHT REGULIERTE PRODUKTE IN DEN USA**

- Produkt steht nicht auf der Liste der regulierten Produkte? Wahrscheinlich kein reguliertes Produkt.
- Nicht regulierte Produkte unterliegen grundsätzlich keinerlei Normen oder Verboten (bans).
- Meldung erforderlich, wenn ein nicht reguliertes Produkt defekt oder gefährlich ist.

## MARKTZUGANG FÜR MASCHINEN IN DEN USA

In Bezug auf die Produkthaftung in den USA ist die Gesetzgebung nicht einheitlich. Marktzugang wird nur für Maschinen mit Zulassung gewährt

### Voraussetzungen für den Marktzugang

Maschinen können nur durch von der Occupational Safety and Health Administration (kurz: OSHA) akkreditierten Prüf- und Zertifizierungsinstituten ([Nationally Recognized Testing Laboratories](#)) geprüft und zertifiziert werden.

## Zulassungsbestimmungen sind nicht landeseinheitlich

Die endgültige Entscheidung über die Inbetriebnahme obliegt der lokalen Kontrollstelle zur Einhaltung von lokalen Sicherheitsanforderungen (Authority Having Jurisdiction - AHJ).

Ausländische Importeure lassen sich von Zollagenten vertreten.  
„Nonresident Importer“-Status, Identifikationsnummer

## Warenanmeldung als elektronischer Prozess

Maschinen sind 15 Tage nach ihrer Ankunft der Zollbehörde zu melden und die Eingangsdokumente einzureichen.

„Automated Commercial Environment“ (ACE), ein Datenbearbeitungssystem für die Bearbeitung von Einfuhranmeldungen (Department of Homeland Security)

Zahlreiche Maschinen können in die USA zollfrei eingeführt werden.





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