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JOINT CONFERENCE

May 6-7, 2025 | Washington, DC

WORKSHOP 2: Consumer and Product Compliance

May 7, 2025



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Consumer and Product Compliance

European Union

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EU legal framework

- EU has conferred legislative powers → it can only legislate to the extent that it has received an explicit mandate by the EU treaties; divergencies among sectors
- EU adopts legislation in the areas of, *e.g.*, products safety, environment protection & consumer rights
 - Products safety and sustainability rules are often implemented in regulations → reasonable level of harmonization among MS; products meeting EU rules can circulate freely in the EU
 - MS can in some circumstances adopt supplementing rules but subject to mutual recognition
 - Consumers protection is mostly enshrined in directives – obligatory as to a result to be achieved but possible divergencies at national level; rules adapt to national context
- EU must rely on MS for its enforcement and sanctioning
- EU litigation against or for the interpretation of EU acts; B2B & B2C litigation in national courts of MS
- National administrative and penal law applies

Products Safety & Compliance

- **General Product Safety Regulation (EU) 2023/988 (GPSR)**
 - Aims at ensuring safety of all consumer products placed on the EU market - safety net when no specific rules
 - Safety depends on different factors: intended use, presentation, use instructions, compliance with EU standards
 - Regulate products withdrawal & recalls; obligation to notify the authorities about potentially unsafe products
- **Specific regulations: chemicals, foods & food contact materials/packaging, toys, cosmetics, personal protective equipment, textiles, electronics, vehicles ...**
 - Chemicals safety assessment, classification and labelling – products legislation often building up on chemicals rules
 - Different approaches to ensure products safety in foods and various products legislation
 - Compositional requirements, positive or negative lists of substances and ingredients, *i.e.*, foods, cosmetics
 - External verification for some types of products, *i.e.*, personal protective equipment
 - Labelling requirements and obligation to provide instructions for use
 - Shift from products safety towards sustainability, rules on products eco-design, recycling targets, etc.

Consumers Protection & Claims

- **Consumer Rights Directive 2011/83/EU**
 - Harmonizes key aspects of MS legislation on B2C contracts, *i.e.*, information to provide to consumers
 - Essential feature: consumers can withdraw within 14 days from distance contracts without providing reasons & at no costs; if consumers not informed about it, period extended to 12 months; exemptions
- **Right to Repair Directive (EU) 2024/1799 (“R2RD”), ongoing MS transposition**
 - Obligation for traders to ensure the repair of some consumer products (i) when reparability requirements already exists in the EU (electronics, appliances, etc.) and (ii) which are not under warranty anymore
- **Product Liability Directive (EU) 2024/2853 (“PLD”)**
 - Sets principle of traders’ liability without fault for defective products that caused damage to consumers
 - National courts in MS can oblige traders to disclose information to facilitate consumers’ claims
- **EU Collective Redress Directive (EU) 2020/1828 (“CRD”)**
 - Enables qualified entities representing consumers’ interests (non-profit) to bring actions before courts or administrative authorities against violations of EU law that harm collective interests

False Claims & Greenwashing

- **Directive on Unfair Commercial Practices 2005/29/EC (“UCPD”)**
 - Regulates the unfair B2C practices in the EU; the misleading commercial practices (false claims by action or omission) & certain specific behaviors are considered unfair (*i.e.*, false approvals or time-limited offers)
- **Consumers Empowerment Directive (EU) 2024/825 (“CED”), in 2026**
 - Focus on green claims and sustainability advertising; *e.g.*, claims on future performance, recycled content, etc.
 - Regulates sustainability labels, logos & certification schemes
- **Green Claims Substantiation Directive), under discussion**
 - Forthcoming & expected significant impact, should be adopted in Q2 2025, then national transposition
 - Will establish minimum requirements on the substantiation and communication of explicit environmental claims made voluntarily by traders about consumer products

Consumer and Product Compliance

India

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Product Liability

Consumer Protection Act, 2019 (CP Act):

The primary legislation governing consumer protection in India.

- Consumer: Who buys goods or services for personal use—not for resale or commercial purposes.
- Manufacturers and Sellers liable for harm from defective products (injury, illness, property damage, emotional distress).
- Remedies include defect removal, replacement, refund, compensation, and bans on hazardous goods.

Food Safety and Standards Act, 2006 (FSSA):

- Regulates food safety at all supply chain stages. Food Business Operators (FBOs) must ensure compliance with prescribed standards.
- Violations can lead to fines or imprisonment.

Drugs and Cosmetics Act, 1940 (DC Act):

- Governs safety and quality of drugs, cosmetics, and medical devices. Holds entities accountable for harmful products.
- Consumers cannot claim compensation under FSSA and DC Act but can report violations to regulators. For personal claims, they must use the forum under the CP Act.

Product Safety Standards

Different laws govern product safety based on the specific products they regulate.

BIS Standards: The Bureau of Indian Standards Act, 2016 – sets products standards. Certain standards are voluntary, other mandatory. Over 688+ products require mandatory compliance.

Sector-specific laws:

- **Food** – Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 plus specific standards for certain specific food products, such as vegan food, infant food, alcoholic beverages, organic foods, health supplements, etc.
- **Drugs/Cosmetics** – Drugs and Cosmetics Act, 1940
- **Medical Devices** – Medical Devices Rules, 2018. The International Organization for Standardization (ISO) or the International Electrotechnical Commission (IEC) standards if BIS not available.
- **Automobiles** – Motor Vehicle Act, 1988 and Central Motor Vehicle Rules, 1989 prescribe emission norms, standards for build quality of vehicles and components.

Labelling Requirements (1/2)

- **General Labelling – Packaged Commodities Rules, 2011**

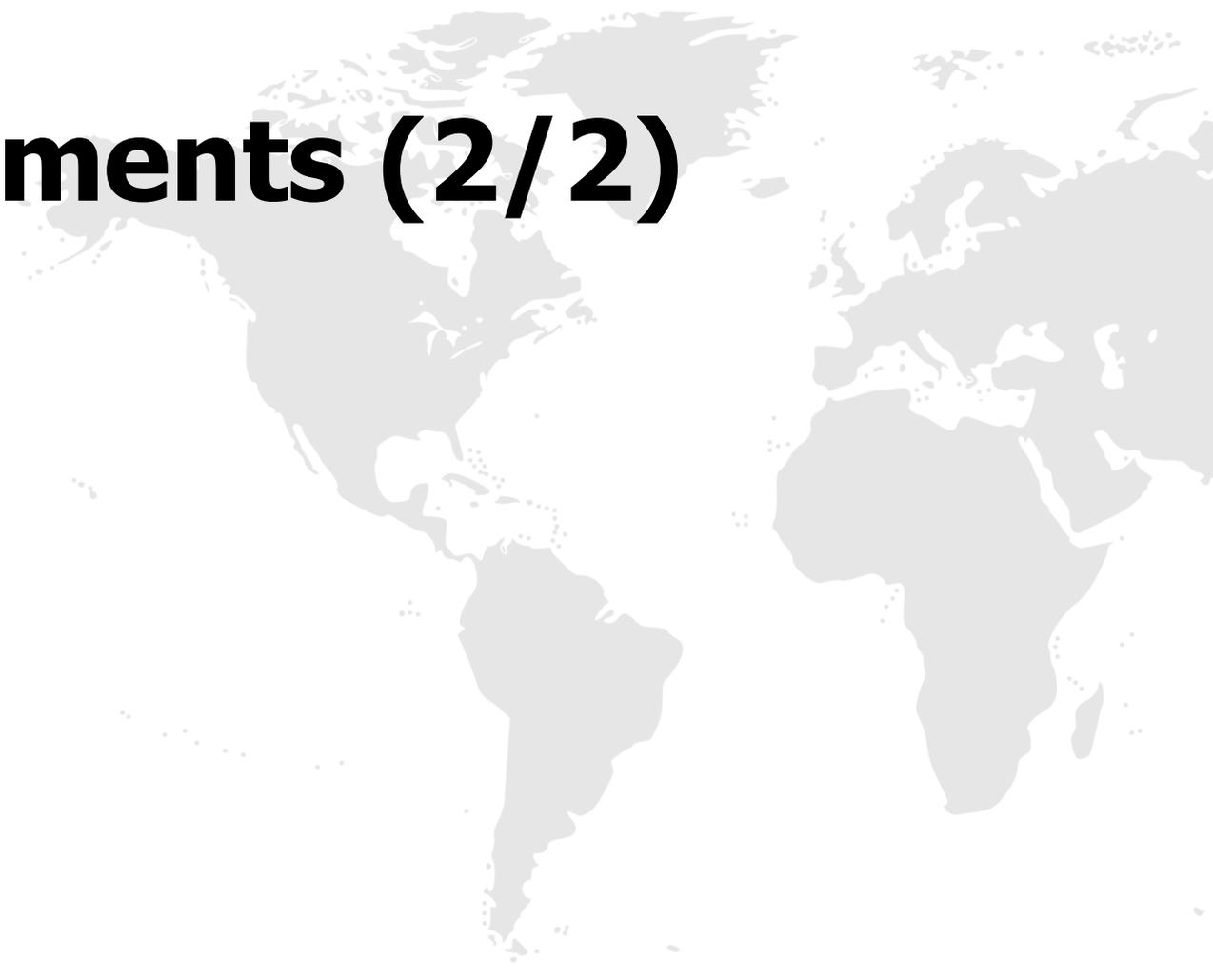
Applies to all pre-packaged goods in India. Must include:

- Manufacturer/Importer details, Country of Origin
- Product Name, Net Quantity
- Manufacture Date, Best Before/Use By Date
- Maximum Retail Price (MRP), Size/Dimensions
- Consumer Complaint Address, Unit Price

Sector-specific labelling requirement:

- **Food** – General guidelines under the Food Products (FSSAI Labelling & Display Regulations, 2020) **plus** food specific label requirements for specific foods, such as vegan, organic, fortified, infant foods.

Labelling Requirements (2/2)



Sector-specific labelling requirement:

Drugs (Drugs and Cosmetics Rules, 1946):

- Brand & Generic Name, Active Ingredients, Dosage
- Mfg. & Expiry Date, Batch No., Storage Conditions
- Schedule Drug Warning

Cosmetics (Drugs and Cosmetics Rules, 1946):

- Product Name, Manufacturer Details
- Batch No., Expiry Date, Directions for Use
- Ingredient, and Warnings

Medical Devices (Medical Devices Rules, 2017):

- Device Name, Intended Use
- Manufacturer Info, Import License No.
- Mfg./Exp. Date, Batch No., UDI for Traceability

False Claims and Advertising

- The Consumer Protection Act, 2019 (**CP Act**): Prohibits misleading advertisements and deceptive claims (**false guarantees, conceals important facts, false and misleading descriptions and claims**).
- Guidelines of 2022 by the Central Consumer Protection Authority under the CP Act: Ads must be **truthful, verifiable, and non-deceptive**.
- Penalties under CP Act: Up to INR 5 million and 5 years' jail.
- **Advertising and Standards Council of India Code** is mandatory for **TV ads**.
- Specific regulations regarding false claims on foods, drugs and cosmetics.

Consumer and Product Compliance

United States of America

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General US Framework



- **Statutory and Common Law Schemes**
- **Federal Law**
 - U.S. Consumer Product Safety Commission
 - Federal Trade Commission
- **State Law**
 - Uniform Commercial Code
 - State Attorneys' General

Restaurant and Food Service Industry



- **U.S. Food and Drug Administration**
- **Local Health and Safety Boards**
- **Plaintiff's Attorneys**
- **Restaurant Associations**
- **Third-Party Vendors/Licensing**

Restaurant and Food Service Industry

- **Food safety/health and sanitation**
- **Liquor license laws, liquor liability, and dram shop laws**
- **Packaging**
- **Nutrition, additives and fat content information**
- **Food traceability**

Medical, Health and Wellness Industry

- **State corporate practice of medicine laws and regulations**
- **Telehealth and prescribing laws and regulations**
- **Data privacy laws such as HIPAA**
- **Anti-kickback, fee-splitting, and physician self-referral laws and regulations**
- **Physician and provider licensing and registration laws**

Medical, Health and Wellness Industry

- **R+Regulations pertaining to medical devices and healthcare equipment**
- **Rules and regulations promulgated by esthetician boards, nursing boards, pharmacy boards and medical boards**
- **Laws governing marketing claims and commercial speech**
- **Employment laws related to wage and hour requirements**
- **Laws related to workplace safety such as those promulgated by the Occupational Safety and Health Administration**

Federal and State False Claims Acts

- **Federal False Claims Act**

- protects the federal government from being overcharged or sold deficient goods or services.
- The FCA provides that any person who knowingly submits, or causes to submit, false claims to the federal government is liable for three times the government's damages plus a penalty.
- FCA allows private citizens to file suits on behalf of the government (so-called "qui tam" suits)

- **State False Claim Acts**

Thank you for your attention!

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