Emerging Global Environmental Materials Regulations for MedTech

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Johnson&Johnson
MedTech

Global Regulatory Policy

Agenda

1. Introduction
2. Intersecting Worlds of Regulation
3. Timeline / Landscape View
4. Chemicals Targeted for Restrictions and Bans
5. Common Issues we see in supplier declarations
6. Call to Action

Parynaz Mehta

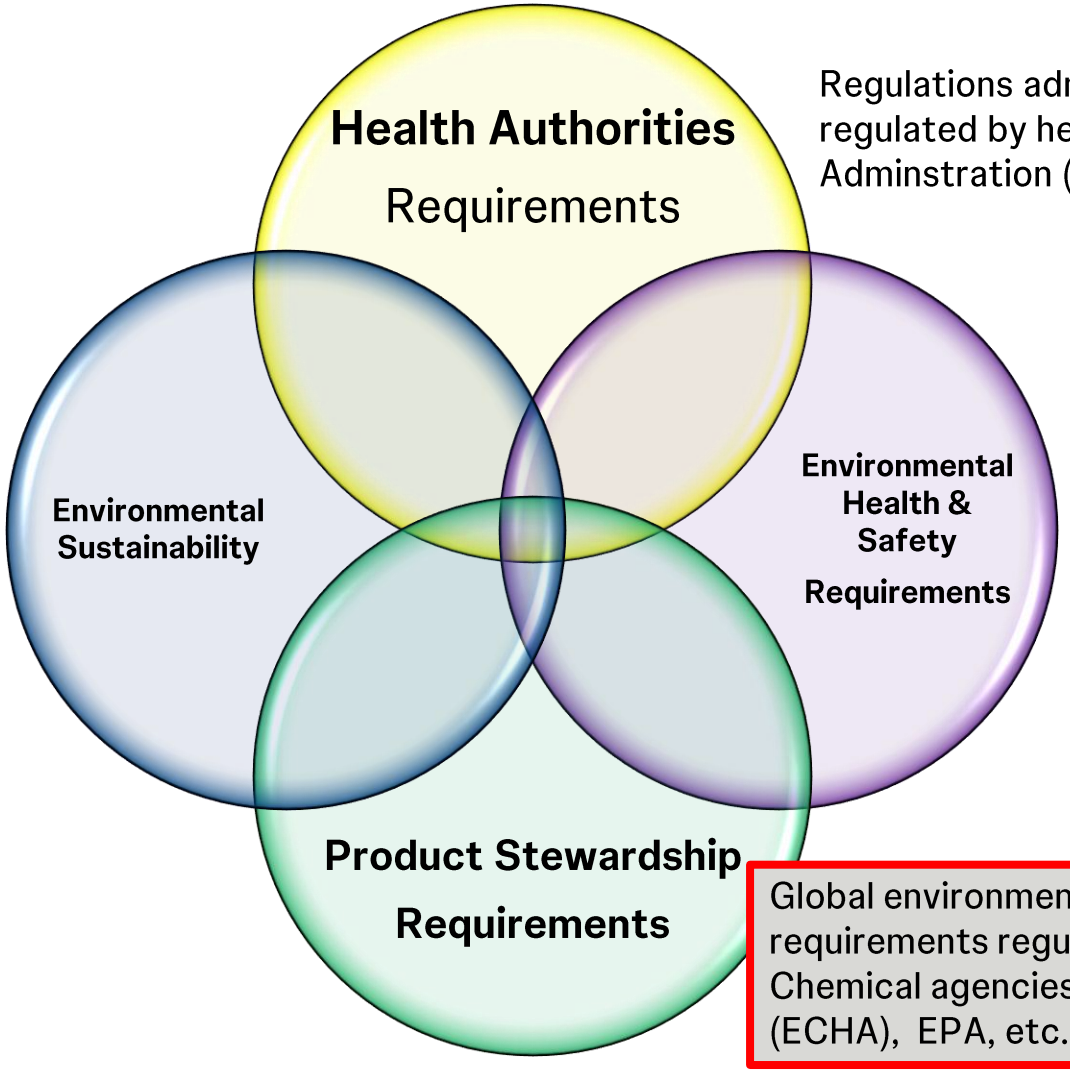
Parynaz is the Global Director of MedTech Product Stewardship since 2016. She has been with J&J for 17 years in various capacities – first in the Environmental Health and Safety (EHS) organization and now in MedTech Global Regulatory Affairs.

Parynaz started her career at J&J as the NJ Environmental Lead for Cordis Corporation. She took on responsibility for Product Stewardship for Cordis and then MedTech in general and has built the J&J MedTech Product Stewardship program from ground up.

Before joining J&J, Parynaz was an ISO 14001 EHS Management Systems Lead Auditor and an environmental management systems consultant.

Parynaz graduated from Tufts University in Massachusetts with a Master of Science in Civil/Environmental Engineering and Policy. She also holds a Master of Science degree in Life-Sciences with a specialization in Macromolecular Biology from University of Mumbai, India.

The boundaries of Health, Patient Safety, Community, Environmental Compliance and Environmental Sustainability Requirements are converging...



Regulations administered by Health Authorities and regulated by health agencies like the US Food & Drug Adminstration (FDA).

Environmental Sustainability / Supply Chain requirements. Regulated by various environmental agencies and international organizations such as OECD, UN, etc.

Facility environmental and worker safety requirements.

Global environmental product and packaging requirements regulated by various Environmental and Chemical agencies such as European Chemicals Agency (ECHA), EPA, etc.

Global Environmental Product & Packaging Regulations applicable to MedTech Industry

JAN 2025:
PORTUGAL B2C: Jan 1, Labelling requirement becomes effective

EPR (UK): Jan 1, Updated fee modulation EiF

BASEL CONVENTION: Jan 1, amendments to Annexes on entries for e-waste.

D4/D5/D6 (CH): Jan 1, Restrictions EiF.

FEB 2025:
UV-328 (EU): Feb 26, EiF. Beginning of transition period and restriction.

UV-328 (SC, SG, JP): Feb 26, Import of products containing UV-328 are prohibited

UV-328 (NZ): Feb 26, EiF. Articles where UV-328 used and PoM are exempt.

PIC (SA): Regulation EiF.

APRIL 2025:
WEEE (CANADA): April 1, Alberta – Amendment for EEE/WEEE AR 94/2004.

ESPR (EU): Adoption of Working Program*

JUNE 2025:
MINAMATA (CANADA): Jun 19, Products Containing Mercury Regulations Amendment EiF.

JULY 2025:
UV-328 (AU) – July 1, import of products containing UV-328 are prohibited with limited exemptions.

PLASTIC WASTE MGMT (INDIA): July 1, Amendment EiF.

Q2 2025 (TBD):
OSOA (EU) – Adoption and entry into force of the legislation.

AUG 2025:
BATTERIES (DK, NO): Aug 18, Economic operator verification, Due Diligence requirements, symbol for separate collection of batteries/wheelie bin logo, management waste batteries.

BATTERIES (EU): Aug 18, Economic operator verification, symbol for separate collection of batteries/wheelie bin logo, management waste batteries.

SEP 2025:
CANADA PLASTICS REGISTRY: Reporting for all plastic packaging.

BPAF (EU): Up-classification of substance under Annex VI, triggering EU MDR implications under CLP.

OCT 2025:
EPR (DK): Oct 1, Proposed application of EPR for packaging, disposable plastic products.

DEC 2025:
EPR (CANADA): Dec 31, New Brunswick – EPR Amendment for batteries.

UV-328 (CH): Dec 1, Restriction EiF.

MINAMATA (EU): Dec 31, phase out date of Part A Annex II of Mercury Regulation.

JAN 2026:
ROHS (CN): Jan 1, Additional phthalate restriction enforcement.

IMINAMATA (ISRAEL): Jan 1, Regulations and Exemptions EiF

FEB 2026:
UV-328 (EU): Feb 4, Restriction takes effect for articles PoM unless derogated.

MAY 2026:
MICROPLASTICS (EU): May 31, ECHA annual reporting for those using SPM to manufacture plastics.

AUGUST 2026:
PPWR (EU): Substances in Packaging (5.2a), DoC and technical documentation.

SEP 2026:
CANADA PLASTICS REGISTRY: Reporting for all plastic contained in EEE products.

Q3 2026:
ESPR (EU): Reporting of destruction of unsold consumer goods.

DEC 2026:
MINAMATA (EU): Additional mercury prohibitions EiF.

2026 (TBD):
CIRCULAR ECONOMY ACT (EU): Publication of proposal, including WEEE revision and harmonization of EPR.

2025

2026

JAN 2025:
PIC REGULATION (EU): Jan 1, Amendment to update Annex I/II.

CANADA PFAS REGISTRY: Jan 29, PFAS Reporting due for FY2023.

RoHS (EU): Pack 22 delegated draft acts for Pack 22 exemptions, EiF TBD.

MAR 2025:
OREGON PACKAGING REPORTING: Reporting quantities, types packaging/materials PoM deadline.

PIC (EU): Mar 1, Amendment to Annex I/II takes effect.

UV-328 (NZ): Mar 14, Restriction EiF.

MINAMATA (SA): Restriction EiF

MAY 2025:
PACKAGING (BR): May 31, Annual packaging reports due.

CRMA (EU): May 24, Implementing acts with list for recovery potential

BATTERIES (DK): May 21, Executive Order EiF that exceeds EU Battery regulation req'ts.

JULY 2025:
BATTERY WASTE MGMT RULES (INDIA): July 1, Amendment EiF

REACH (NO): July 4, REACH amendment EiF aligning with EU.

RoHS (CN): Draft combined standard published.

AUG 2025:
EPR (ECUADOR): Aug 1, Waste Management Plan submittal due.

UV-328 (EU): Aug 4, Restriction EiF, articles have 6-month deadline before ban.

OCT 2025:
MICROPLASTICS (EU): Oct 17, SPM deadline for labeling for product-level requirements. Reporting to ECHA regarding uses of SPM.
UV-328 (UK): Oct 1, Articles made prior to EiF of restriction are now banned.

PIC (SG): Oct 22, Amendment EiF.

Q4 2025:
ROADMAP TO PHASE OUT ANIMAL TESTING IN CHEMICAL SAFETY ASSESSMENTS (EU): Publication of roadmap with legal initiatives

REACH (EU): Revised legislation proposal expected.

RoHS (EU): Digitalization amendment finalized and published, 2-year transition period.

JAN 2026:
REACH (VIETNAM): Jan 1, Regulation EiF.

PFAS (US-MN): Jan 1, Reporting information regarding products containing intentionally added PFAS.

BATTERIES (LT): Jan 1, EiF of legislation.

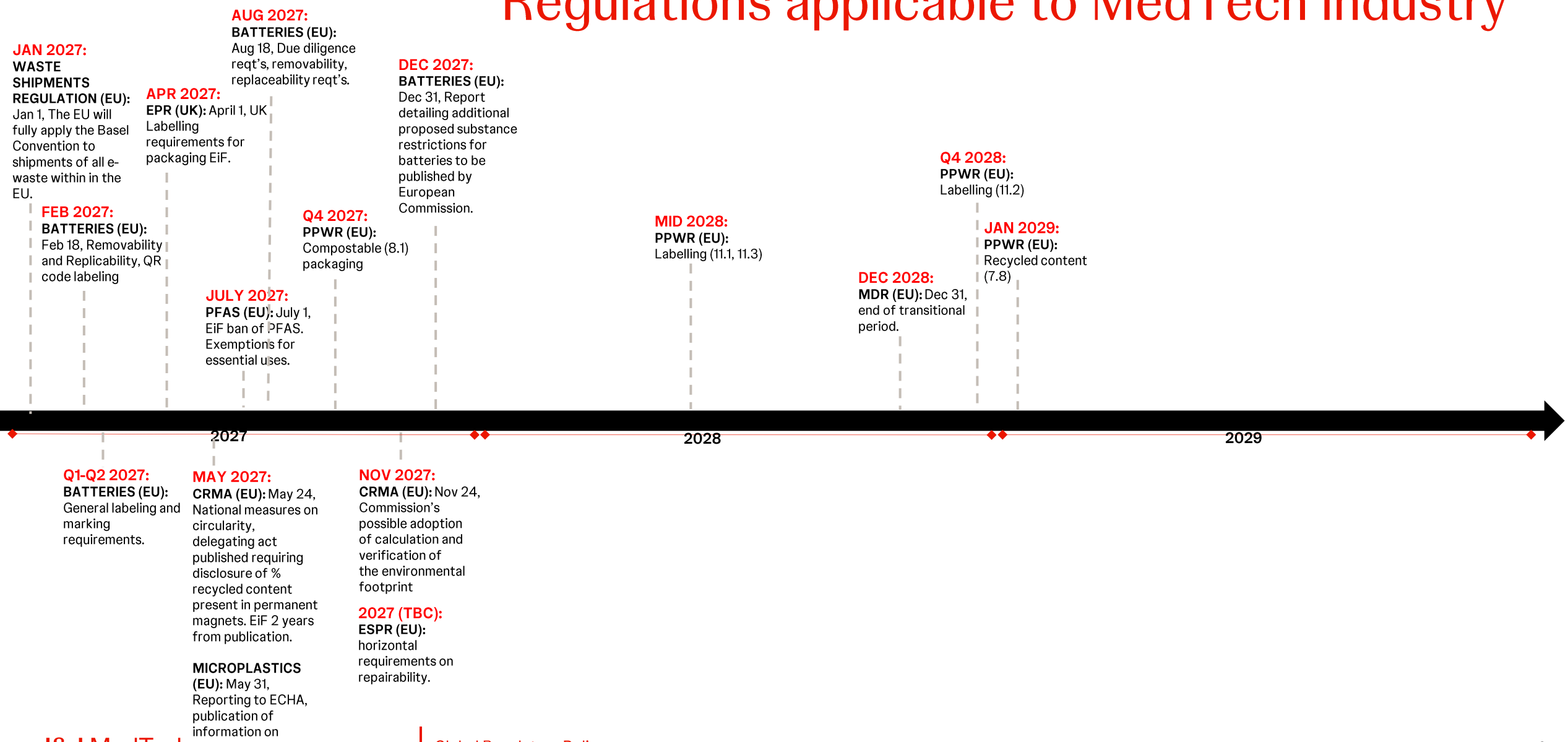
JUNE 2026:
D4/D5/D6 (EU): June 6, REACH Restriction EiF, non-derogated uses are restricted from being placed on market.

JULY 2026:
ESPR (EU): July 18, Ban of destruction unsold products.

NOV 2026:
CRMA (EU): Nov 24, Commission's report on prioritization for environmental footprint declaration for critical raw materials, labeling act published with a 2-year transition for labeling requirements.

Information current as of August 19, 2025

Global Environmental Product & Packaging Regulations applicable to MedTech Industry



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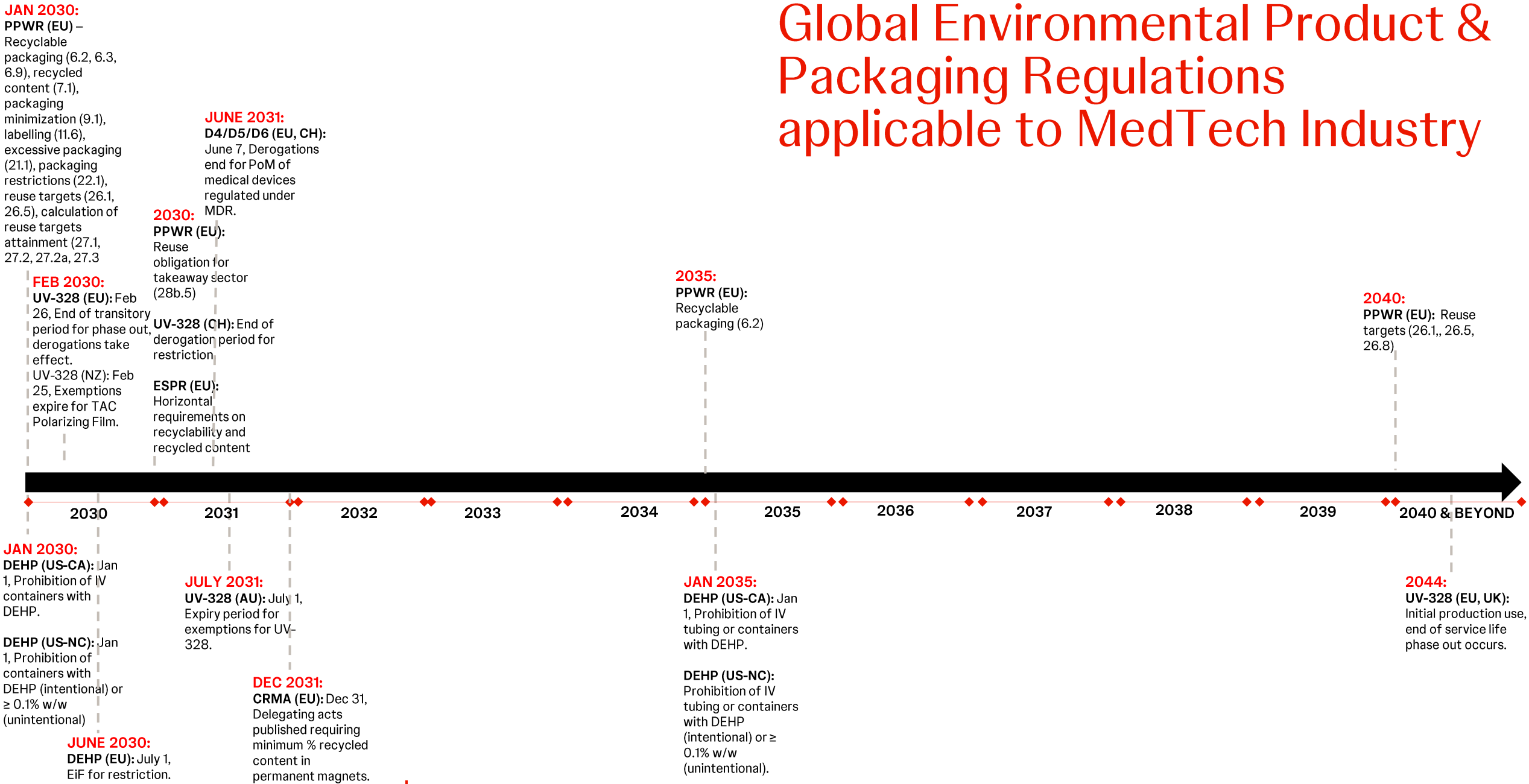

Information current as of August 19, 2025

Chemicals Targeted for Global Restrictions and Bans Potentially Impacting MedTech Industry

Legislation has been passed or proposed in certain regions **restricting or banning use** of these chemicals in MT products.

Restrictions and/or bans *have potential to cause* supply chain disruption

UV-328

- UV-328 is a phenolic benzotriazole used as a UV absorber to protect surfaces against discoloration and degradation in UV/sunlight
- Commonly used in Paints/Coatings Liquid crystal displays, Sealants, Plastics
- Global ban through the UN Stockholm Convention on Persistent Organic Pollutants (POPs) ratified by 186 countries. 36 have proposed or have already implemented a local ban, including the EU, UK, and Singapore.
- Inconsistency in how each country implements the ban

DEHP and Other Ortho-Phthalates

- DEHP and ortho-phthalates are plasticizers commonly found in rigid plastics to impart flexibility and processability. DEHP is commonly found in PVC.
- Commonly found in rigid plastics, printing inks, wires, cables, adhesives and sealants
- 14 ortho-phthalates are subject to ban under EU REACH Authorization
- 4 ortho-phthalates (incl. DEHP) restricted under EU RoHS
- Listed as EU REACH Substance of Very High Concern (SVHC)
- US – No federal restrictions on MT products
- US – Some US States (NC, NY, MA, CA, PA) have proposed restrictions on specific uses

PVC

- PVC is a rigid thermoplastic
- Used in tubing and other hard plastic components such as pipes, cables, packaging, home siding, windows and flooring
- A restriction of PVC is being considered in Europe, timing TBD. Previously, the restrictions and bans had focused on the additives in PVC (lead stabilizers, DEHP, organotin catalysts, MCCPs).
- US – NY has proposed a ban of PVC in specific applications.
- Commonly flagged on Environmentally Preferred Purchasing (EPP) programs and tenders

Heavy Metals

- Variety of different metals or metal elements typically having high densities that can be toxic at certain concentrations
- Typically used in packaging, paints, pigments, electronics, catalysts, colorants, automobiles, plating inks
- CONEG Restriction – Model Toxics in Packaging
- EU REACH Bans/Restrictions
- EU RoHS and RoHS-Like
- Minamata Convention (global)
- EU PPWD and EU PPWR

*Registration, Evaluation, Authorization and Restriction of Chemicals (EU REACH)

Information current as of August 19, 2025

Chemicals Targeted for Global Restrictions and Bans Potentially Impacting MedTech Industry

Closely watched chemical developments – legislation is being passed or in proposal and/or comment periods.

Restrictions and/or bans on these chemicals ***might result in*** supply chain disruptions

Microplastics / Synthetic Polymer Microparticles (SPMs)

- Microplastics are small fragments (e.g, particles, fibers, mircobeads) of synthetic polymers
- Typically found in pellets/nurdles (used to manufacture plastic objects). Microbeads are typically found in face washes, shampoos, etc. Also used as additives in paints, adhesives.
- EU REACH restriction in force since 2023 - MT products are subject to reporting and disclosure (includes labeling)
- US – RI: Proposal to ban broad group of products containing microplastics with no exemptions or exclusions

Bisphenols

- Bisphenols, such as the well-known Bisphenol A (BPA) and related compounds like Bisphenol S (BPS) and Bisphenol F (BPF), are a group of chemicals primarily used in the production of polycarbonate plastics and epoxy resins.
- Typically found in polycarbonates, inks, paints, epoxy resins and thermal paper
- Restriction under consideration in EU REACH – proposed in 2023 and subsequently revoked. Timing TBD
- Classified as hazardous substance in Canada
- On CA Prop 65 list in US

D4/D5/D6

- D4/D5/D6 are silicone-based chemicals called cyclic siloxanes. They are widely used because they are smooth and slippery, evaporate without residue and have water-repelling properties.
- Typically used in silicone, polymers, coatings, sealants, anti-foaming agents, adhesives and lubricants
- EU Restriction of specific uses already in effect since May 2024. Broad EU ban proposed – timing TBD
- Ban on placing D4,D5,D6 ≥ 0.1 % (w/w) on the market in substances, mixtures and articles (From 6 June 2026)
- Global restriction under consideration under UN Stockholm Convention on POPs
- SVHC Status under EU REACH and UK REACH

Medium Chain Chlorinated Paraffins (MCCPs)

- MCCPs are chlorinated alkanes with chain lengths from 14-17 carbons
- Commonly found in metalworking fluids (e.g., fluids used during cutting, polishing and tapping operations), as well as plastics (e.g., as plasticizers or flame retardants)
- MCCPs are banned globally under the UN Stockholm Convention, which has been ratified by 186 countries

Common Issues we see with Supplier Declarations

- Incomplete data (100% materials composition has not been provided)
- Significantly out of date declarations; not referencing latest legislations
- Presence of a specific chemical (example, SVHC) is flagged but there is no indication which codes that chemical is present in, so either we have to assume that the entire portfolio has that problematic chemical or we have to reach back out to you again
- EU RoHS exemptions are flagged but no specificity on which products or codes are using those exemptions
- Missing thresholds or intentionality
- Memo stating awareness of legislation but no indication of compliance to that legislation
- Hesitation in providing inputs on ***proposed*** legislation

Call to Action to our Suppliers

- Maintain a process to engage with your suppliers as part of due diligence to verify accuracy of the declarations you provide to us.

- As part of our partnership – we value your sharing of information about potential supply chain and regulatory developments.