

ISSUE 9, JANUARY 2026

Product & Consumer Protection

Annual Review 2025

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Welcome

Product & Consumer Protection Annual Review 2025

In the six months since the publication of our 2025 Mid-year Review, there have been several significant developments in the EU products and consumer protection law space. We review some of the key developments during the year and look ahead to future reform for 2026 and beyond.

In this Review, we will consider a number of key issues including:

- The recent publication of the guidelines on the General Product Safety Regulation
- The overhaul of toy safety regulation in the EU
- The doctrine of exhaustion in trade mark rights
- An update on sustainability for products regulation
- The EU ban on TPO, a substance commonly used in gel nail products

We hope you enjoy our Product & Consumer Protection Annual Review for 2025.

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Michaela is Head of the Products practice. She advises clients in the pharmaceutical, healthcare, medical device, digital health, cosmetic, video game, software and general consumer products sectors on various regulatory compliance matters. She has particular expertise in wearables and software medical devices.

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Anna is Of Counsel in our Product Regulatory team. She advises clients across a number of sectors on the regulatory frameworks applicable to their products and services throughout their life cycle. She specialises in the regulation of consumer products, food, cosmetics, medical devices, and pharmaceuticals.

She advises clients on all issues they may encounter when launching a product on the market including marketing, advertising, labelling and packaging requirements.

Her expertise lies in managing large-scale, multi-jurisdictional product launches for clients and providing specialist support on transactions linked to highly regulated products.

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New General Product Safety Regulation Guidelines



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The long-awaited guidelines on the EU General Product Safety Regulation were published by the European Commission in November 2025. These guidelines aim to provide clarity for economic operators when interpreting their obligations under the Regulation. Our Product Regulatory team examines the guidelines.



WHAT YOU NEED TO KNOW

- The guidelines provide clarity on aspects of the EU General Product Safety Regulation (GPSR) which may be difficult for businesses, particularly SMEs and microbusinesses to interpret.
- The guidelines contain helpful checklists for businesses regarding their responsibilities under the GPSR.
- The guidelines provide welcome guidance on the product recall and safety reporting process set out in the GPSR.

The European Commission published the eagerly anticipated guidelines¹ for businesses regarding compliance with the EU’s General Product Safety Regulation (GPSR) in November 2025. The guidelines include practical steps on the use of the Safety Business Gateway, the mandatory means of reporting dangerous products and accidents to the market surveillance authorities in Member States. The publication of these guidelines was a requirement under Article 17 of the GPSR.

SMEs, micro-businesses and online marketplaces will likely find these guidelines particularly helpful with the interpretation of the legislation and their obligations under the GPSR.

The guidelines clarify the new, direct obligations of EU and non-EU manufacturers, particularly regarding:

- Risk assessments
- Accountability, and
- The handling of recalls

Key takeaways from the guidelines include:

Risk assessment scope

The concept of “health” includes mental health risks. Assessments must consider the characteristics, effect and presentation of a product. The guidelines further set out that the categories of consumers using the product must be considered. The potential risks that products may pose to vulnerable consumers e.g. children, older people, and people with disabilities should be assessed. Characteristics including the gender of the user must also be considered. Businesses should update their risk analysis procedures to evaluate products for psychological risks and account for diverse user characteristics beyond basic physical safety.

Cybersecurity features

Cybersecurity features of a product also need to be considered to protect the product against external influences and evolving, learning and predictive functionalities.

¹European Commission - Commission Notice – Guidelines on the application of the EU general product safety legislative framework by businesses (C/2025/6233)

Meaning of substantial modification

An entity making a substantial modification is considered the manufacturer for the modified risk. Businesses should review supply chain contracts to confirm who assumes manufacturer liability in rebranding or modification scenarios and ensure technical files are updated accordingly.

Traceability and labelling

Warnings must be easily understandable for consumers. The guidelines provide clarity on what specific information should be included in a product’s technical documentation. It also details when the documentation needs to be drafted. The technical documentation needs to be maintained and be available for 10 years.

Online marketplaces obligations

Products offered online must include clear manufacturer, responsible person and product identifiers on the listing. Non-compliant products are considered “illegal content” under the Digital Services Act. Businesses should ensure online sellers display all mandatory information including the responsible person’s contact details on their e-commerce listings to meet the stricter due diligence requirements. Businesses should also consult the Safety Business Gateway prior to listing any products.

Expanded definition of ‘health’

The guidelines set out that in line with the definition of ‘health’ established by the World Health Organisation, this definition also includes risks to mental health. The guidelines set out that the design and foreseeable use of a product should not create risks for consumers’ cognitive abilities or cause depression, anxiety or poor sleep quality. This is of potential relevance to digital products, particularly software.

Safety reporting

The guidelines provide useful guidance for using the Safety Business Gateway portal. This includes providing practical information regarding submitting notifications via the portal. The guidelines provide information relating to:

- The product information to be submitted
- The product risk or safety issue, and
- Information about the supply chain of the product

Comment

Whilst the guidelines themselves are not legally binding, they provide valuable guidance in assisting businesses, especially SMEs and micro-businesses to ensure practical compliance with their obligations under the GPSR. The checklists will be of particular assistance to those businesses.

The guidelines provide key clarifications on areas which may be difficult to navigate, including the level of detail required for risk assessments, particularly with regards to the scope of mental health/cybersecurity, and also provide useful information regarding responsibilities for online marketplaces.

The guidelines highlight that economic operators and online marketplace providers must ensure products are safe by design, supported by thorough risk assessments and detailed technical documentation. It highlights the use of European standards as a key means of demonstrating product safety.

All relevant stakeholders should consider these guidelines and review their compliance systems to ensure they meet the relevant legal requirements.



“The guidelines include practical steps on the use of the Safety Business Gateway, the mandatory means of reporting dangerous products and accidents to the market surveillance authorities in Member States.”

02

New Toy Safety Regulation Officially Adopted



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The Toy Safety Regulation (TSR) was adopted by the European Parliament in November 2025. The TSR will replace the previous legislation governing toys in the European Union, the Toy Safety Directive² (TSD). The TSR is awaiting publication in the Official Journal of the EU and will officially enter into force 20 days after publication.



WHAT YOU NEED TO KNOW

- The list of prohibited chemicals in toys has been extended to include endocrine disruptors and “forever chemicals” known as “PFAS”.
- The new rules will require toys to have a Digital Product Passport (DPP).
- The regulations introduce further requirements on economic operators, particularly where online sales of toys are concerned.

The TSR introduces new requirements for manufacturers placing toys on the EU market. These requirements include:

- Stricter requirements regarding the regulation of chemicals in toys
- New rules for online marketplaces, and
- Additional obligations placed on manufacturers to create digital product passports for all toys

The TSR provides for a four-and-a-half-year transitional period, to give time for the industry to adapt and implement the new rules efficiently. The TSD will remain applicable during the transition period, after which the TSR will apply.

Key takeaways from the Toy Safety Regulation

Chemicals ban – endocrine disruptors and PFAS

The TSD has an existing ban on the use of carcinogenic, mutagenic and reprotoxic (CMR) chemicals in toys. The TSR extends this ban to other categories of chemicals which could potentially be harmful to children.

The new prohibition targets chemicals falling under the additional hazard categories of the Classification, Labelling and Packaging (CLP) Regulations³. Endocrine disruptors and chemicals which are toxic to the skin and other organs will fall under this prohibition.

The TSR also bans the usage of per- and polyfluorinated alkyl substances (PFAS) in toys, components of toys or micro-structurally distinct parts of toys. The TSR also prohibits the use of certain bisphenols and specific fragrance allergens in toys for children under the age of three.

The prohibition on these chemicals aim to ensure fewer hazardous chemicals in toys which could potentially cause harmful effects for children using the toys.

² 2009/48/EC

³ Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Digital Product Passports

As set out in the TSR, the manufacturer will need to create a Digital Product Passport (DPP) for each toy product prior to placing the toy on the market. The DPP will contain a statement of compliance with the TSR requirements and other relevant data. The DPP must be available in all languages required by the EU Member State where the toy is being marketed.

The information contained in the DPP must be accurate. It is the manufacturer’s responsibility to ensure the DPP is updated where necessary.

Access to the DPP will need to be given free of charge to other economic operators, market surveillance authorities and consumers, if requested.

Marketplace duties

Any information referring to an offer of toys sold or promoted on online marketplaces which are not compliant with the TSR will be considered illegal content for the purposes of the EU Digital Services Act (DSA). Online marketplaces will have to comply with the requirements set out in the DSA, particularly regarding traceability of traders and the right to information.

Online marketplace providers should ensure their online marketplace clearly conveys their interface in a manner which allows sellers to display:

- The CE marking of their products
- The warnings to consumers, and
- The relevant data which allows consumers to access a toy’s DPP

Artificial intelligence

The TSR has evolved the toy safety legislative framework to account for toys which incorporate artificial intelligence (AI). The TSR mandates compliance with relevant legislation including the EU AI Act and the Cyber Resilience Act.

The TSR requires strict assessment for connected toys i.e. those which connect to the internet. Connected toys are those which connect to the internet. The TSR also addresses new risks, such as toys which may impact mental health or encourage dangerous behaviour.

Mental health risk assessment

The TSR mandates that manufacturers will need to conduct risk assessments regarding potential risks to children’s mental health and cognitive development. Safety evaluations must be conducted on the toys beyond the scope of a physical evaluation. Evaluations must also cover potential risks such as screen addiction or the display of inappropriate content.

This development is particularly relevant for digital and AI-powered toys. Holistic risk assessments must now cover all vulnerabilities, not just digital ones.

Comment

The TSR substantially revises the current toy safety framework. It imposes stricter controls on toys entering the EU market. Its aim is to ensure a higher level of child protection and reduce the number of unsafe toys on the EU market. It introduces new innovations to ensure a safer market for toys, with a particular focus on tightly regulating toys being purchased through online marketplaces.

Economic operators involved in the manufacturing and placing of toys on the market, including online marketplaces should familiarise themselves with the requirements of the TSR and begin to prepare for their new obligations, as the publication of the TSR in the Official Journal of the EU is duly awaited.

“

“The TSD has an existing ban on the use of carcinogenic, mutagenic and reprotoxic (CMR) chemicals in toys. The TSR extends this ban to other categories of chemicals which could potentially be harmful to children.”

03

Trade Marks in a Circular Economy

How brand owners can protect rights while meeting sustainability expectations



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We examine the application of the exhaustion of trade mark rights concerning second-hand goods sold in Ireland and throughout Europe, the doctrine’s limitations and instances where trade mark rights were not exhausted.



WHAT YOU NEED TO KNOW

- We examine consumer trends toward more sustainable purchases and how such practices may give rise to conflicts with the interests of trade mark owners.
- We consider the limitations of the doctrine of exhaustion of trade mark rights in Ireland and the EU.
- We examine instances where trade mark rights were found to have not been exhausted in cases of repair, refurbishment and upcycling of second-hand goods.

Consumers are increasingly seeking responsible production and sustainable materials, with a growing focus on repairing or repurposing of existing products. Cost-of-living pressures are reinforcing this trend, prompting more people to choose repair or reuse over buying new.

Recent legislative changes in Europe are also indicative of this shift. While consumer environmental and economic considerations are a positive, this activity sometimes conflicts with the interests of trade mark owners.

Exhaustion of trade mark rights

Under section 16 of the Trade Marks Act 1996 (TMA) and Article 15 of the EU Trade Mark Regulations 2017 (EUTMR), trade mark rightsholders cannot prohibit the resale of goods which have already been put on the market in the EU by them or with their consent. The trade mark rights related to these goods are said to have been “exhausted”. The purpose of these provisions is to facilitate the free movement of goods throughout the EU, upholding a key tenet of the single market.

However, the doctrine of exhaustion in the context of second-hand goods is not absolute and has some limitations. A trade mark proprietor may intervene where it can show “legitimate reasons” to oppose further dealings in second-hand goods, particularly where their condition has been changed or impaired after being put on the market in a way that could damage the reputation of the trade mark. Naturally, this has resulted in a conflict between the rights of trade mark owners and the rights of resellers to repair or repurpose goods in the EU.

Repairs and reuse

The use of non-original spare parts to repair second-hand goods is a key concern for trade mark rightsholders. The recent *Audi* judgment⁴, handed down by the Court of Justice of the European Union (CJEU) following a reference from the Regional Court of Warsaw, considered whether the use of a non-original radiator grille with a mounting device which took the shape of the Audi logo could be deemed to be infringing.

The Court found that the defendant’s sale of the grilles for repair purposes infringed Audi’s trade mark. The rationale for this decision was based on the view that their sale created a “material link” between the spare part and the trade mark, and that the mounting element was identical or similar to Audi’s trade mark. It was therefore determined that Audi had a legitimate reason to object their sale.

⁴Case C-334/22

It should also be noted that Directive (EU) 2024/1799, also known as the ‘Repair Directive’, recently came into force in the EU. Importantly, it establishes a “*right to repair*” for consumers. It is yet to be seen how this Directive may interact with trade mark rights, particularly where repairs are carried out by a third party. However, it is unlikely that the Audi case would have had a different outcome based purely on the Repair Directive. Ireland has until 31 July 2026 to transpose the Directive into national law.

Some second-hand goods may also be reconditioned and resold. The CJEU considered this use in *Soda-Club (CO2) SA and SodaStream International BV v MySoda Oy*⁵, following a reference for a preliminary ruling from the Finnish Court of Economic Affairs. The matter concerned the use by MySoda of SodaStream’s CO2 bottles which are designed to be refilled. The bottles in question are engraved on the neck with the trade marks SODA CLUB and SODA STREAM. While MySoda replaced the labels on the bottle with their own, the engravings were still visible to consumers.

The question before the CJEU was whether SodaStream had a legitimate reason to oppose the sale of the bottles on the basis that the consumers could be given a false impression that there is an economic link between the parties.

The CJEU accepted that a link like this could arise, but noted that each case must be assessed in light of the product’s labelling and presentation, distribution practices, and the likely level of consumer awareness.

Upcycling and refurbishment

Second-hand goods are often refurbished or may even be upcycled in some instances before resale. This was the case in the AGA UK⁶ matter whereby AGA cookers were refurbished and fitted with an electronic control system, known as the ‘eControl’ system. Save for the eControl system being installed, the cookers maintained their original look and the AGA badges and logos.

The Court acknowledged that customers would expect second-hand AGA cookers to include replacement parts, and that AGA did not object to the installation of the eControl system itself. However, the defendant marketed the cookers as “AGA cookers” and used pictures of AGA products. The Court found there was nothing to make it clear to a reasonably attentive customer that the defendants were not connected to AGA, and therefore infringement had occurred. AGA had a legitimate reason to object to the sale of the refurbished AGA cookers.

Comment

The principle of the exhaustion of trade mark rights is a clear doctrine aimed at protecting the free movement of goods throughout the EU. However, this approach has clear limits. The cases discussed show situations where “legitimate reasons” were accepted, but the threshold for objecting to second-hand dealings on trade mark grounds remains high.

What is clear is that the shifting trends in consumer buying habits together with legislative changes such as the Repair Directive will likely give rise to more disputes. Trade mark owners may increasingly object to second-hand dealings that either suggest an economic link with the brand owner or risk damaging the reputation of an established brand.



⁵Case C-197/21

⁶[2024] EWHC 1727 (IPEC)

04

Sustainability Requirements for Products



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WHAT YOU NEED TO KNOW

- Compliance with the EU Deforestation Regulation has been postponed to 31 December 2026 and simplified. Although it may be simplified further, applicable companies should continue to prepare for compliance.
- Compliance with due diligence obligations under the Batteries Regulation has been postponed to 18 August 2027, however other requirements are currently in force.
- Producers of electronics, textiles and other product groups should note new ecodesign requirements are being prepared under the Eco-Design for Sustainable Products Regulation.
- New rules for producers of packaging and packaging waste will apply under the Packaging and Packaging Waste Regulation from 12 August 2026.

New legal requirements for product sustainability are constantly emerging and changing. We review the current status of various laws and steps taken by the EU to simplify compliance. This is a helpful overview for companies of the current status of legislative developments.

The European Commission has been busy trying to reduce the regulatory burdens for sustainability of products allowed on the EU market. It has presented six simplification proposals, also referred to as ‘omnibus packages’, to the Council and the Parliament in 2025. These packages aim to:

- Simplify due diligence obligations
- Make sustainability reporting more accessible and easier to implement, and
- Reduce regulatory complexity for businesses

Some of the Regulations provided for in the omnibus packages include:

- EU Deforestation Regulation (EUDR)⁷
- Batteries Regulation⁸

The Commission has also set up the first working group to establish the first ecodesign requirements for products under the Eco-Design for Sustainable Products Regulation (ESPR)⁹. New rules for producers of packaging and packaging waste will apply under the Packaging and Packaging Waste Regulation (PPWR)¹⁰ from 12 August 2026.

⁷Regulation (EU) 2023/1115 of the European Parliament and of the Council of 31 May 2023 on the making available on the Union market and the export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010

⁸Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC

⁹Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC

¹⁰Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC

EUDR

Broadly, what does it require?

The EUDR requires certain products that contain one of seven prescribed commodities and sold in the EU or exported from the EU to be:

- Deforestation-free
- Produced in accordance with the relevant legislation of the country of production, and
- Covered by a due diligence statement

The products are primarily certain food & beverage, timber and rubber products. For further background, read [EU Deforestation Regulation – What you need to know](#)

What is the current status?

A revision of the EUDR came into force on 23 December 2025. It simplified the implementation of existing rules. It also postponed their application by one year, to:

- 31 December 2026 for large operators, and
- 30 June 2027 for micro and small operators

This is to allow operators, traders and authorities more time to properly prepare.

Under the revision, the obligation and responsibility to submit the required due diligence statement will fall exclusively on operators who first place relevant commodities and relevant products on the EU market. Only the first downstream operator in the EU supply chain will be responsible for collecting and retaining the reference number of the initial due diligence statement. This means the reference number will not have to be passed further down the supply chain.

Micro and small primary operators will only have to submit a one-time simplified declaration. They will receive a declaration identifier that will suffice for traceability purposes.

In an effort to further reduce administrative burden, the co-legislators also agreed to remove certain printed products such as certain printed media from the scope of the EUDR. The view is that these products are considered to have a reduced risk of being associated with deforestation.

What happens next?

The Commission must carry a simplification review by 30 April 2026. Based on that review, a report must be submitted to the Parliament and the Council. This may be accompanied by a legislative proposal.

Batteries Regulation

Broadly, what does it require?

The Batteries Regulation aims to ensure that batteries on the EU market are sourced, manufactured and recycled in a sustainable manner. The Regulation sets out rules on the sustainability, performance, safety, collection, recycling and second life of batteries. Specific obligations currently apply and vary according to an operator's role in the supply chain.

The Batteries Regulation also imposes stringent due diligence (DD) obligations on battery producers that place batteries, or put batteries into service, on the EU market. Producers are obliged to:

- Implement due diligence policies
- Have the policies verified and periodically audited by a third-party verification body, and
- Publicly report on their due diligence practices to prevent or reduce batteries' adverse impacts on the environment, including their waste management

Further information on the obligations can be found [here](#).





What is the current status?

The majority of the obligations are in force. Initially, the DD obligations were to apply to all operators having a turnover greater than €40 million. However, under the “Omnibus IV Package” that was agreed on 18 July 2025, the Commission increased this threshold limit to €150 million. This increase was to exempt “small mid cap” companies from the scope of these obligations.

The omnibus package also postponed the implementation of the obligations by two years, until 18 August 2027. This gives producers, manufacturers and exporters more time to comply with these DD obligations. It also provides more time to establish third-party verification bodies, as this process has previously encountered problems with the authorisation process.

What happens next?

The Commission is required to publish DD guidelines one year before the obligations take effect. This is to give timely guidance to businesses and to help ensure a smoother implementation of the new rules.

Businesses subject to the DD obligations should look out for the Commission’s guidance. Although the omnibus package gives businesses significantly more time to comply, the DD requirements can be onerous and preparation for compliance should start now.

PPWR

The PPWR came into force on 11 February 2025. It sets out new rules for sustainability of all types of packaging and packaging waste. They apply to the entire life cycle of packaging, from manufacture through to disposal.

Similar to the advisable approach in the context of the Batteries Regulation, businesses should identify their role in the supply chain and whether they are placing packaging or packaged products on the EU market. This is because the obligations vary accordingly. For example, EU manufacturers and importers are prohibited from placing packaging on the market which does not conform with the PPWR. EU importers must verify that manufacturers have complied with design and labelling obligations. Some key manufacturer obligations, subject to certain exemptions, include:

- Limiting harmful substances in packaging, particularly food packaging
- Recyclability and recycled content requirements
- Packaging minimisation
- Labelling, and
- Conformity assessments

Please see further information [here](#) for manufacturers and [here](#) for importers and distributors.

What is the current status?

The PPWR is long, detailed and complex. Its obligations apply from 12 August 2026. Obligations will come into effect on a phased basis from that date. This gives businesses

some time to comply with their obligations and make any necessary changes to their packaging and supply chains.

What happens next?

Manufacturers should take immediate steps to familiarise themselves and ensure appropriate procedures are put in place to comply with the PPWR. Importers and distributors should start getting their operations and supply chain ready for compliance now. Cooperation in the supply chain and comprehensive, accurate data collection will be critical to successfully achieving compliance.

ESPR

Broadly what does it require?

The ESPR entered into force on 18 July 2024. The ESPR is part of a package of measures that are central to achieving the aims of the EU’s 2020 Circular Economy Action Plan. It aims to significantly improve the sustainability of products placed on the EU market by improving their circularity, energy performance, recyclability and durability.

The ESPR does not prescribe rules for specific products. Rather, it is a framework for setting ecodesign requirements on specific product groups, covering virtually all physical products. There are only a few exceptions,

eg, food and medicinal products. Rules, known as ‘ecodesign requirements’ for specific product groups, will be established by the Commission on a phased basis.

Further information on the Regulation can be found [here](#).

What is the current status?

The Commission published its first ESPR working plan on 16 April 2025. The working plan covers the products for which new ecodesign requirements will be established during the first phase period 2025 – 2030. The product groups expected to be the primary focus of the first phase include:

- Information & communication technology (ICT) and other electronics
- Chemicals
- Energy-related products
- Iron and steel
- Aluminium
- Textiles
- Furniture
- Tyres

Some of these product groups, such as ICT and other electronics, are likely to be subject to “horizontal requirements” rather than product specific ecodesign

requirements. Horizontal requirements are a broader type of ecodesign requirement that apply to a wide range of products with similar characteristics.

What happens next?

The Commission recognises that the establishment of ecodesign requirements can impact international trade as all goods placed on the EU market, including imports, will have to meet the new requirements. For this reason, the Commission will carry out preparatory studies and impact assessments, aimed at ensuring a proportionate, systematic and high-quality assessment of international dimensions so that the impact on third country operators is understood.

Comment

Following the introduction of a large amount of sustainability rules, the EU has taken significant steps to simplify some of these rules. Although the EU aims to reduce regulatory complexity, the changes do make it difficult for businesses to stay abreast of legal developments.

Businesses should continue to identify the obligations they are subject to and prepare for compliance.

“

“The European Commission has been busy trying to reduce the regulatory burdens for sustainability of products allowed on the EU market. It has presented six simplification proposals, also referred to as ‘omnibus packages’.”

 **READ MORE**

New EU Packaging Regulation: Obligations for Importers and Distributors

05

TPO Ban in the EU

UV gel products in focus



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The European Commission has banned 22 cosmetic ingredients, including TPO, commonly used in gel nail products. Cosmetics containing TPO cannot be marketed or supplied in the EU from 1 September 2025.

The European Commission published the latest CMR¹¹ Omnibus Regulation¹² in May 2025. This legislation added 22 substances to the list of ingredients prohibited in the use of cosmetic products.

One of these ingredients was Trimethylbenzoyl diphenylphosphine oxide (TPO). TPO is commonly used in UV gels and other hybrid products which are hardened and cured under a UV light, to create a gel nail finish. TPO has now been classified as a CMR category 1B substance.

Why was the ban deemed necessary?

Under Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (as amended) (CLP Regulations)¹³, substances deemed carcinogenic, mutagenic, or reprotoxic (CMR) are classified into three categories based on the strength of evidence for their hazardous effects.

Under the CLP Regulation, TPO has now been classified as belonging to CMR Category 1B. This category is for substances for which CMR effects are possible “*but there is a need for further research to confirm the full effects*”. The TPO prohibition followed animal studies which linked TPO to long-term fertility issues. These studies also linked TPO products to causing skin irritation.

Article 15(2) of Regulation (EC) 1223/2009 on cosmetics products (Cosmetics Regulation), prohibits the use of any Category 1B CMR substances in cosmetics products. The list of prohibited substances can be found in Annex II of the Cosmetics Regulation. This list now includes TPO.

It is acknowledged that there is a tension between CLP and the Cosmetics Regulation. The European Commission announced a proposal in July 2025 to update the Cosmetics Regulation and reduce the administration and compliance burdens for cosmetics businesses.

The proposal includes clarification and simplification of Article 15(2) of the Cosmetics Regulation noting that the existing derogation procedure from the generic prohibition on the use of CMR substances will “*be set out in more detail considering the experience gained over more than 10 years*”, with the intention of preventing any unintentional bans on ingredients that are safely used in cosmetics products but are prohibited under CLP.

However, we do not expect updates to the Cosmetics Regulations to be made until at least the end of 2026.

¹¹Carcinogen, mutagen and reprotoxic
¹²Commission Regulation (EU) 2025/877
¹³Regulation (EC) No 1272/2008

What should stakeholders do now?

It is important to note that there is no ‘sell-through’ or ‘use-up’ period for cosmetic products containing TPO. It is prohibited to place any cosmetics on the EU market that contain TPO or to make them available from 1 September 2025.

This means that:

- Any new product that contains TPO cannot be placed on the market from 1 September 2025
- Any cosmetic product that has been placed on the market prior to 1 September 2025 cannot now be supplied, transferred or made available
- Professional users, e.g. nail technicians, must not use affected products on clients, and
- Affected stock should now be withdrawn from the EU market

Manufacturers are required to reformulate products without TPO. EU Responsible Persons will also need to ensure the products for which they are responsible comply with the prohibition on TPO.

What are other markets doing?

The UK is considering imposing a ban in late-2026. However, until then, cosmetics products containing TPO are still permitted on the market.

The US is yet to legislate on TPO, with products containing TPO still readily available on the market.

Conclusion

Businesses that are manufacturing or supplying cosmetic products containing TPO should ensure compliance with the prohibition.

Cosmetics businesses and other interested parties should ensure they keep up to date with any further announcements from the European Commission on anticipated updates to the Cosmetics Regulations and consider contributing to any further public consultations.

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“Businesses that are manufacturing or supplying cosmetic products containing TPO should ensure compliance with the prohibition.”

Recent MHC events, articles and publications

Events and webinars

CPD on Demand: Commercial Contracts: What’s Market 2025?	Link
CPD on Demand: Product Liability in Life Sciences - Recent Reforms	Link
CPD on Demand: In-House Counsel Masterclass - Recent Developments in IP	Link
CPD on Demand: Staying Ahead of Cyber Threats for 2025	Link
CPD on Demand: Mastering Product Claims in the EU	Link

Publications

Product & Consumer Protection Mid-year Review 2025	Link
Product & Consumer Protection Annual Review 2024	Link
Copyright and Design Rights in Furniture	Link
Vouchers and Discounts for Medicinal Products	Link
The Product Supplier as a “Producer” Under the EU Product Liability Directive	Link

ABOUT US

Mason Hayes & Curran is a business law firm with 124 partners and offices in Dublin, London, New York and San Francisco.

Our legal services are grounded in deep expertise and informed by practical experience. We tailor our advice to our clients' business and strategic objectives, giving them clear recommendations.

This allows clients to make good, informed decisions and to anticipate and successfully navigate even the most complex matters.

Our service is award-winning and innovative.

This approach is how we make a valuable and practical contribution to each client's objectives.

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