

# Product Law Bulletin

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## New regulations on batteries

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## Developments in e-scooter and e-bike battery safety discussion

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## EU CE marking recognition extended indefinitely

On 1 August 2023, the Department for Business and Trade announced an indefinite extension to the use of CE marking for businesses. This decision supersedes previous plans to replace the mark with the UK Conformity Assessed ('UKCA') marking system and follows several extensions to the UKCA marking implementation period.

The Government says that this is part of a wider package of smarter regulations intended to ease business burdens and help grow the economy. Kevin Hollinrake, Business Minister, has said of the indefinite extension, "The Government is tackling red tape, cutting burdens for business, and creating certainty for firms – we have listened to industry, and we are taking action to deliver", and "By extending CE marking use across the UK, firms can focus their time and money on creating jobs and growing the economy."

Whilst this extension has been met positively by some of the industry, for example, Stephen Phipson, CEO of Make UK (the manufacturers' organisation), who describes it as a "pragmatic and common sense decision that manufacturers will very much welcome and support", it remains to be seen if there will be any backlash against the decision, for example, by those businesses who have already incurred the expense of seeking advice on and implementing UKCA marking.

## Best Practice for food allergen labelling published by FSA

There are around 2 million people living in the UK with a diagnosed food allergy and these allergies are the most common cause of life-threatening anaphylaxis in the UK.

Recent figures released by the Medicines and Healthcare products Regulatory Agency found there were 25,721 admissions to England's hospitals for allergies and anaphylaxis in 2022/23, more than double the 12,361 admissions in 2002/03. Of these admissions there was a 154% increase for food-related anaphylaxis and other adverse reactions from 2002/03 to 2022/23.

In September 2023, the Food Standards Agency ("FSA") published best practice technical guidance to support food business with allergen labelling to ensure consumers are kept safe.

A Precautionary Allergen Label is voluntary statement that food businesses can choose to apply to food products where there is an unavoidable risk of allergen cross-contamination, i.e. "may contain nuts."

The FSA has recommended the following changes in relation to how food businesses should use the Precautionary Allergen Label (PAL):

- A PAL should only be used if there is an unavoidable risk of allergen cross contamination which cannot be sufficiently controlled by segregation and cleaning.
- Food Businesses should avoid generic statements about allergens by specifying which of the 14 major allergens are contained in the product, i.e. use "may contain peanuts" instead of "may contain nuts."
- Use PAL statements in combination with "vegan" labels where a risk of cross-contamination with an allergen has been identified.

Despite these recommendations to further improve the labelling of food allergens, Natasha Smith, Deputy Director of Policy at the FSA, said:

*"We continue to encourage consumers who have allergies and intolerances to check the label of food products at all times, to make sure the food does not contain ingredients they may be allergic to."*

The FSA are continuing to treat food hypersensitivity as a priority and given the significant increase in those treated for food related allergies over the past 20 years food businesses need to ensure they are doing everything they can to make consumers aware of the allergens contained in their products.

## Consultation on non-surgical cosmetic procedures

Following a substantial increase in the number of non-surgical procedures (such as Botox, dermal fillers and other such 'tweakments') being carried out, concerns continue to grow over the safety and regulation of such treatments. The current regulatory landscape is fragmented and inconsistent across the range of treatments available, with concerns that many of the providers are untrained or insufficiently knowledgeable.

As a result, the government has sought to regulate the area: the introduction of the Botulinum Toxin and Cosmetic Fillers (Children) Act 2021 introduced criminal offences in relation to administering Botox and cosmetic fillers to people under 18, and this has been followed by the Health and Care Act 2022.

The Health and Care Act 2022 gave the Health Secretary the power to introduce a licensing scheme. The government says, "The purpose of the scheme is to ensure that consumers who choose to undergo a non-surgical cosmetic procedure can be confident that the treatment they receive is safe and of a high standard".

In July 2022, the Health and Social Care Committee published its report (['The impact of body image on mental and physical health'](#)) setting out a range of recommendations for future regulation. As a result, the Government has recently published a consultation (found [here](#)) to seek the input of those in the industry and people who have undergone non-surgical cosmetic procedures to provide their insight into the proposed measures to regulate the industry. Specifically, it seeks their views on:

1. Restrictions on which practitioners should be permitted to perform certain procedures;
2. The procedure types that should fall within the scope of the scheme; and
3. Age restrictions for those undergoing such procedures.

In relation to the first two points for consideration, the government proposes a two-part process to restrict high-risk procedures:

1. Setting out in regulations that specified high-risk procedures are restricted to be carried out by qualified and regulated healthcare professionals only; and
2. Amendment of CQC regulations to include such procedures as regulated activities.

The further proposals include the categorisation of certain procedures as either 'green' for procedures with the lowest risk of complications, 'amber' for those with medium risks of complications, and 'red' for procedures with the highest risk of complications.

It proposes that 'green' procedures can be carried out by all practitioners where they meet the agreed standard; 'amber' procedures can be carried out by licensed non-healthcare professionals who have relevant oversight by a named regulated healthcare professional (who has gained the suitable accredited qualification) or by a qualified and regulated healthcare professional without oversight where they meet the agreed standards; and 'red' procedures should fall under QCQ-regulation (and therefore outside the scope of the licensing scheme) and be restricted to qualified and regulated healthcare professionals only (as set out in further detail above).

Full details of what procedures are proposed to fall under each category can be found within the consultation.

As to age limits, the proposals suggest prohibiting practitioners from performing procedures that fall within the scheme to people under 18 unless approved by a GMC registered doctor and carried out by a specified healthcare professional (in line with the Botulinum Toxin and Cosmetic Fillers (Children) Act 2021).

The consultation closed on midnight on 28 October 2023 and the Government says there will be a period of analysis and consideration to follow, including working with expert groups throughout 2024 and 2025, to inform future consultations with a view to finalising the regulations and implementing to the licensing scheme.

## UK Product Safety Review Consultation

Following a call for Evidence in March 2021 the Office for Product Safety and Standards ('OPSS') have now developed the following 5 proposals to develop a product safety regime that:

1. "Ensures business obligations are proportionate to the hazard presented by their products, exploring how to reduce compliance costs for lower risk products and make the conformity assessment process easier where possible.
2. Shifts the balance between regulations and industry-led standards to enable a more agile and responsive regulatory framework, allowing business greater scope to innovate when producing safe products.
3. Uses digital solutions, such as voluntary e-labelling, to reduce business costs and explore how digital options can be utilised to reduce burdens.
4. Addresses concerns regarding the ease with which unsafe products can be sold online, creating a fairer playing field so that shopping online is as safe as on the high street.
5. Enhances the leadership and coordination role of the Office for Product Safety and Standards alongside addressing identified enforcement gaps."

The consultation seeks views from those in the industry and other interested parties on its 13 core proposals (details of which can be found in the full consultation found [here](#)). It suggests that the proposals are beneficial for businesses and consumers alike as they would consolidate existing legislation making it easier to understand and follow; incentivise businesses to work with enforcement authorities; create an improved system for recalls (allowing for patterns and trends to be identified); and facilitate useful data sharing, and they would also improve sharing and coordination of information to allow quicker and more proactive responses, will provide wider authority to ensure only safe products are available on the market; will create an agile, adaptive enforcement regime that can respond to market changes; will simplify the process for recalls and notifications; and make it easier for consumers to seek redress.

Any new product safety regime will only be fit for purpose if it is agile enough to protect consumers from growing online marketplaces and the continued development of technology, including artificial intelligence. Business will likely be calling for a clear framework that enables them to continue to innovate products whilst complying with any safety requirements.

It is also likely that businesses will be concerned about the divergence of any new regime to EU Regulations. This could lead to businesses having difficulties placing products into certain markets if there is any confusion as to the relevant safety requirements that apply to that market.

The consultation closed on 24 October 2023, and it will be interesting to see how stakeholders responded to these proposals and how the product safety regime continues to develop in the UK against the backdrop of the EU's new Product Liability Directive which should come into force in 2024.

## EU Product Liability Directive

In September 2022, the European Commission published its proposal for a directive on liability of defective products with the aim of revising the existing Product Liability Directive ("PLD") that was adopted in 1985, nearly 40 years ago.

The aim of the PLD is to modernise the existing regime and make it fit for purpose in the world of online marketplaces and technology, which is developing at a rapid pace, with products becoming more complex and reliant on artificial intelligence and other technologies.

On 9 October 2023, the European Parliament's Internal Market and Consumer Protection Committee ("IMCO") and the Committee on Legal Affairs ("JURI") agreed a revised wording for the proposed PLD.

If adopted, the PLD will create significant change with some of the more notable issues considered below:

- The term "producer" will be replaced with "manufacturer" with the definition being expanded to include providers of software, digital services and online marketplaces which could increase the number of retailers that have to comply with the directives on product liability.
- The definition of "product" is expanded to include digital manufacturing files, software and digital services that affect how products work.
- The definition of "component" is widened to expressly include "embedded software" and liability of a manufacturer of a defective component where the defect is attributable to the product design (rather than the component design) and/or where the defect is attributable to directions given to the component manufacturer by the product manufacturer is excluded.
- The definition of "defectiveness" is proposed to be changed to a product being defective if fails to "provide the safety an average person is entitled to expect or is required under Union or national law". Further proposals to "defectiveness" include taking into account the product's expected lifespan, its ability to acquire new features or knowledge after being placed on the market and the removal of reference to "the specific expectations of the end-users for whom the product is intended".
- Whilst the 10-year longstop will remain in place there is a proposal for a 15-year longstop in relation to some latent personal injuries with the limitation period to be restarted if a product is substantially modified.
- It creates a rebuttable presumption of defectiveness where it would be too challenging for a Claimant to prove a products defectiveness or a causal link to their injury, where the nature of the product is too complex or technical, such as products involving AI.
- Introduction of strict product liability claims for defective products that cause "loss or corruption of data."

It is anticipated that the PLD will come into force in the EU at some point in 2024 and given the integral nature of the relationship between the EU and UK, despite Brexit, it will be interesting to see whether the UK consider adopting any similar regulations as part of any updated product safety regime.

## New regulations on batteries

Earlier this year the UK Government issued a call for evidence on the scope of UK Battery Strategy with consultation ending on 28 September 2023, with a view to publishing a full UK Battery Strategy over the following months. The request follows what the government describes as the global demand for lithium-ion batteries seeing exponential growth and against a background of them taking action to tackle climate change and decarbonising the electricity system by 2035.

The government highlights within the Call for Evidence three strategic priorities:

1. "Design: Design and develop the batteries of the future that are smaller, lighter, and offer better capacity and value, building on UK world-leading research and innovation.
2. Build: Working in partnership with our domestic industry and international partners to secure a resilient UK battery manufacturing supply chain that supports our strong domestic growth and thriving export markets.
3. Sustain: Enable the development of a thriving and sustainable sector, supported by proportionate regulations that drive investment across the supply chain, from raw materials through to end of life and recycling".

They say that they intend to publish a clear, joined-up government/industry strategy to enable a battery ecosystem to encourage prosperity, whilst delivering on net zero ambitions.

The government's intentions mimic those regulating the European Union. The EU Batteries Regulation (Regulation 2023/1542) published on 28 July 2023 (and due to apply from 18 February 2024, subject to some later dates for compliance with certain issues) aim to increase sustainability, creating a more eco-conscious, circular, and safer battery industry. This regulation adopts a comprehensive life-cycle approach, addressing various facets of batteries from sourcing and manufacturing to use and recycling, all within a single, encompassing law. By addressing sustainability, circularity, and consumer empowerment, this Regulation is set to have a positive impact on both the environment and the battery industry as a whole.

In particular, the Batteries Regulation:

1. Takes a full life-cycle approach in which sourcing, manufacturing, use, and recycling are addressed and enshrined in a single law.
2. Introduces mandatory requirements on sustainability, such as carbon footprint rules, minimum recycled content, restricted amounts of harmful substances, performance, and CE labelling.
3. Defines mandatory requirements for all batteries placed on the EU market.
4. Requires battery manufacturers to provide information on the carbon footprint of their products.

Starting in 2027, consumers also will have the right to repair their batteries and will be able to replace individual cells instead of having to replace the entire battery, reducing the amount of post-consumer waste generated by batteries.

Companies in the battery industry will need to ensure that their products comply with the new requirements, with compliance being paramount to ensuring that products meet the stipulated sustainability standards. Additionally, companies should remain vigilant regarding any updates to the list of restricted substances, thereby safeguarding compliance with this evolving regulation.

While the outcome of the UK's call for evidence remains to be seen, the EU Batteries Regulation marks a significant milestone in the journey toward sustainable and safe batteries.

## Developments in e-scooter and e-bike battery safety discussion

In the fast-evolving landscape of personal transportation, e-bikes and e-scooters have captured the imagination of many in the UK. The battery-assisted devices provide an eco-friendly and convenient way to travel urban streets. However, the rising demand for e-bikes and e-scooters is accompanied by an emerging risk – the potential for battery-related fires.

The power behind most e-bikes and e-scooters lies in lithium-ion batteries. While they offer impressive energy density and longevity, they are not without their vulnerabilities. The batteries have been known to catch fire or even explode under specific circumstances, such as when damaged, overcharged, or used with incompatible chargers. The consequences of these incidents are dire, encompassing severe injuries, fatalities, and substantial property damage and potentially indicating a potential for an increase in related claims. For example, a Freedom of Information Act by Zurich revealed that in 2021, there were 167 fire incidents involving e-bikes and e-scooters in the UK, in contrast to 67 in 2020. These fires resulted in at least 190 injuries and multiple fatalities. Some victims found themselves trapped in their homes or flats, while others were caught in the midst of explosions while riding their devices. Similarly, the London Fire Brigade ('LFB') reports that in the first six months of 2023, they were called (on average) to a e-bike or e-scooter fire every two days (a 60% increase on the same period in 2022).

There is suggestion that such an increase is caused by the growth in popularity of such e-products (particularly for food-delivery services), and thought to be worsened by poor charging practices, consumers buying batteries (or chargers) from less or unregulated online marketplaces and/or DIY modifications being carried out.

In response to these developments, the LFB and, more recently, the OPSS and Fire England, have issued warnings and guidance to e-bike and e-scooter users. They both urge users to source their devices and batteries from reputable sources, strictly adhere to the manufacturer's charging instructions, and never leave these devices unattended while plugged in (along with further detailed guidance found [here](#), [here](#) and [here](#)).

Furthermore, the LFB is calling upon the government to implement stricter regulations and enforcement measures for e-scooters and e-bikes. It also advocates for greater public education on how to prevent and respond to battery fires. This is echoed by recent guidance published by Electrical Safety First ([here](#)), which sets out several recommendations to regulating the industry.