Product Law bulletin

July 2022

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New guidance published for market safety and product recalls PAS 7050 and 7100

With the support of the OPSS, the British Standards Institution (BSI) have recently published PAS 7050: 2022 and 7100: 2022 which came into force on 31 March 2022.

The aim of PAS 7050 is to ensure businesses bring products to the market safely. PAS 7050 is split into two parts: Part I sets out guidance for businesses. The primary recommendation of the guidance is for all businesses to have a Product Safety Management Plan ('PSMP') with some of the most important elements to this plan being as follows

- There should be commitment from management to only bring safe products to market;
- Any measures should enable the business to respond to any changes which could affect its ability to comply with safety regulations;
- It should set out who is responsible for ensuring continued product safety across the entirety of the supply chain;
- Measures to ensure product safety should be considered throughout manufacturing process (i.e. specification for individuals parts/components/materials);
- Business should develop a Product Safety Incident Plan ('PSIP');
- Measures should be taken to ensure product safety through entire life cycle (i.e. ensure products can be safely repaired, recycled or discarded); and
- Review process should take into account any legislative of regulatory changes to ensure ongoing compliance with product safety.

Part II of PAS 7050 sets out guidance to Regulators to ensure they are providing sufficient support to businesses in the development of their PSMP and subsequent improvements to the same.

PAS 7100: 2022 supersedes its predecessor, PAS 7100: 2018 and is to be read in conjunction with PAS 7050: 2022. The amendments to PAS 7100 incorporate the changes regarding the UK following Brexit, deal with the addition of online marketplaces and brings the guidance into alignment with the recommendations set out in PAS 7050.

PAS 7100: 2022 sets out practical guidance for product recall and other corrective actions. The main focus of the guidance relates to businesses incorporating a PSIP within their PSMP with an importance placed on monitoring safety and traceability. The purposes of the PSIP is to ensure that businesses can act efficiently and quickly when an issue with product safety arises. The guidance suggests that a PSIP should include the following:

- Product and customer traceability plan, not just related to the tracking of products but also identifying who is responsible for ensuring customer contact information is systematically captured and stored, with their consent;
- Product safety monitoring plan to establish mechanisms to carry out effective risk-based monitoring of products;
- Legal notification plan with an emphasis placed on the early sharing of information when issues come to light;
- Risk assessment plan that sets out how incidents of product safety will be investigated and how risk assessments should be carried out;
- Corrective action decision plan that sets out how decisions are made, by whom and within what timescales whilst ensuring any action is proportionate to the level of risk posed by an unsafe product;
- Communications plan listing the organisations and individuals to be contacted during corrective action; and
- Training plan making management and all employees aware of the PSIP and those who are required to take action if an issue of product safety arises.

It also sets out that the requirement to test the PSIP periodically by way of review and/or simulated recalls or corrective action exercises to ensure it operates effectively.

The guidance further assists Regulators to support businesses developing their PSIP along and sets out how they should monitor any incidents of product safety and the effectiveness of any PSIPs

Back to contents>

Government introduces plans to ease UKCA marking transition

We previously wrote that the deadline for products being placed on the UK market to be UKCA marked (alongside or instead of EU CE marking) had been extended until 1 January 2023. In light of this approaching deadline, the Government has introduced a range of measures to ease the transition:

1. Legislation to allow manufacturers to apply the UKCA mark to products that have been conformity assessed by EU bodies prior to the end of 2022, with a separate UK test not being required until the product's certificate expires or 31 December 2027 (whichever is sooner);
2. Some CE-marked products imported into the UK before the end of 2022 will not require retesting or recertification for UKCA requirements;
3. Spare parts will be accepted onto the GB market where they adhere to the requirements that were in place at the time the original product entered the market;
4. Existing labelling easements will be extended until 31 December 2025 to continue to allow UKCA markings (and any other relevant information) to be added by sticky labels and/or accompanying documentation; and
5. Manufacturers of certain construction products that have been tested by an EU notified body before 1 January 2023 will be able to obtain a UKCA mark without the need for retesting.

The full guidance is published here.

Back to contents>

OPSS publish their Final Report on their Study on the Impact of Artificial Intelligence on Product Safety

The OPSS has published its final report following the study of the impact of artificial intelligence ('AI') carried out between January and June 2021. The objective of the study was to examine the current and predicted impact of AI in consumer products, what this could mean for product safety and any potential changes needed to the law. The full report can be found here.

The study identifies that the use of AI offers opportunities for the improvement of product safety through:

- The provision of more efficient and effective products generally;
- The ability to perform complex analytical tasks in real time (e.g. identifying patterns and processing data) and enhancement of the data collection processes during industrial assembly (expected to reduced the need for mass recalls);
- The use of predictive maintenance (not only improving product safety, but also reducing maintenance costs and downtime);
- Potential customisation and personalisation; and
- Potential use to protect against cyber attacks

Conversely, the report also recognises that there are challenges and risks involved in the use of AI, for example, through AI systems not acting as intended; incorrect data-inputting affecting the algorithm and outputs; and vulnerability to cyber attacks. The report identifies that such weaknesses could lead to both indirect and direct harm taking place.

The report identifies that as these products develop and particularly for products which are more complex, there is potential for a number of legal issues to arise and it is not clear to what extent AI products would fall within the current legal framework and definitions, which in turn means there is a lack of legal certainty for both manufacturers and users.

This is a developing area which will need to be reviewed as and when the AI products expands further.

Back to contents>

Self-driving cars given the green light

The first self-driving cars are set to hit the roads later this year the Department for Transport has claimed. To allow for this, further changes must be made to the Highway Code. These new changes will be a 'major milestone in our safe introduction of self-driving vehicles' said Transport Minister, Trudy Harrison. It remains to be seen what specifically will be changed in the Highway Code, however, the provisions below have been confirmed by the Government.

- The code will allow people using self-driving cars to watch television on built-in screens but using mobile phone while driving is to remain illegal;
- The code will also permit hands-free driving in vehicles with lane-keeping technology on congested motorways would be allowed; and
- The above two points are to be on conditional on motorists being ready take control from an automated system when prompted.

The changes, which are expected to come into force this summer, were described by the Department for Transport as an interim measure to support the early adoption of the technology and a full regulatory framework is planned to be implemented by 2025, with research still ongoing (most recently, the Commission inviting views on remote driving issues here). Whether the measures are interim or not, the industry will no doubt welcome any guidance in this space as it has been limited to date.

The incoming changes show the Department for Transport's commitment to making UK roads safer, as driverless cars limit the scope for human error – which the Government says is a contributory factor in 88% of all recorded road collisions. Notwithstanding the introduction of new changes to the Highway Code clarifying the specifics around driverless cars, many issues around liability still remain.

We previously wrote about how the law is likely to apply under the Automated and Electric Vehicles Act 2018 here. However, the Law Commission published recommendations in January of this year on how the law should be updated in light of self-driving technology. The Commission recommended that human drivers should not be legally accountable for road safety in the era of autonomous cars. That framework provides certainty in a system where automated cars are fully automated. However, it appears that we are currently entering a period where self-driving cars are not fully autonomous and still rely on interaction between humans and machines. As we are approaching this grey area, manufacturers, insurers and drivers should all proceed with caution.

Back to contents>

Allergen updated: Natasha Trial to treat people living with food allergies

We previously wrote about The Food Information (Amendment)(England) Regulations 2019 ("Natasha's Law") which came into force on 1 October 2021 here and here. The Law was introduced following the death of Natasha Ednan-Laperouse following a severe allergic reaction in 2016. Following this, on 18 May 2022, it was announced that a new three-year oral immunotherapy (OIT) trial costing £2.2 million will be funded by the Natasha Allergy Research Foundation.

Researchers at Southampton University will lead the trial but will be partnering with Imperial College London, University Hospitals of Leicester NHS Trust, Newcastle University and Sheffield Children's Hospital to ensure participants include those from across the UK.

The purpose of the study is to show that the use of everyday foods containing trace amounts of peanut or milk – when taken carefully according to a standardised protocol under medical supervision – can be used as an alternative to pharmaceutical drugs to desensitise patients and manage food allergies.

The study will see 216 children and young adults with food allergies to cows' milk and peanuts undergo a 12-month desensitisation period before being monitored for a further two years to report on the longer term safety and cost effectiveness of this alternative treatment.

If successful it could reduce the reliance on expensive pharmaceuticals to treat allergies, with the NHS instead being able to use everyday foods for oral immunotherapy for patients most at risk of anaphylaxis. It could also allow individuals who suffer with persistent food allergies to safely enjoy foods that contain small amounts of allergens due to factory production lines or cross contact without the worry of any reaction.

It is hoped that this potential change in treatment alongside the new 2019 Regulations will contribute to reducing the number of claims brought by individuals who have suffered injury as a result of food allergens in the coming years.

Back to contents>

FSA issue a final call for CBD products to be added to the public list

In an attempt to regulate the CBD market following findings from the Committee on Toxicity, the FSA made the decision to classify CBD products as novel foods, as we previously wrote about here. Such classification means products must have a pre-market safety assessment and authorisation before they can be legally marketed within the UK. A deadline of 31 March 2021 was previously provided to companies, with a view to such products being fully authorised to be on the market in 2023.

On 31 March 2022, the FSA published its first list of CBD food products expected to be authorised for sale, in an early attempt to remove unregulated products from the market with the FSA advising "[We] have created the public list to help local authorities and retailers prioritise products to be removed from sale. If a product is not on the list, it should be removed from sale because it is not attached to a credible application to us for market authorisation". The FSA were also keen to emphasise that they were not endorsing the products on the list (nor guaranteeing they would be authorised prior to a full assessment for safety) but that it was published so "local authorities, retailers and consumers can make informed judgements".

However, the list faced significant backlash from a number of companies complaining that their products have been missed off or overlooked. The FSA responded advising that it was, "an unexpected development as this product information should have been provided to us much earlier in the process" and advising that they were making one final call for evidence from businesses to link their products to credible applications.

The deadline for further evidence to be submitted was 26 May 2022 with almost a further 6000 products being added during this interim period. The updated list can be found here.

Back to contents>