Product Risk Radar
Guidance for product recalls

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OPSS guidance

In April 2022, the Office for Product Safety and Standards ("**OPSS**") published new guidance containing practical advice for businesses on notifying the authorities about product safety issues/recalls and/or product regulatory noncompliance. Annex A outlines some of the key product legislation, which includes notification requirements and contains guidance on which authority to notify. Annex B provides a template for businesses to complete when making a notification to the relevant regulator. The guidance sits alongside PAS 710:2022 discussed below on supporting better product recalls.

OPSS also published new guidance for market surveillance authorities in December 2022. This guidance contains a useful reminder of the factors that market surveillance and enforcement authorities will consider in relation to product safety issues. It also refers to the new Product Safety Risk Assessment Methodology ("**PRISM**"), which market surveillance authorities must now use in Great Britain with respect to general non-food consumer products. Further information on PRISM, including a list of products and hazards deemed a serious risk, example risk assessments, and notes on the key differences between PRISM and the former RAPEX model can be found on the government website here. The government website also provides a list of all the products with product safety alerts, reports, and recalls accessible here. The guidance also discusses the role of OPSS, and Annex D contains a useful flowchart for UK market surveillance authorities.

Both guidance notes distinguish between the approach for Northern Ireland and the rest of the UK. For example, authorities operating in Northern Ireland are still required to use the RAPEX Risk Assessment Methodology. The treatment of Northern Ireland could change depending on developments concerning the Northern Ireland protocol.

The BSI Codes of Practice

In March 2022, BSI published the following Codes of Practice, which were sponsored by OPSS, and are available to download for free on the BSI website:

a) **A revised version of the Code of Practice for Supporting Better Product Recalls (PAS 7100:2022)**

- The revision updates guidance for product recalls and other corrective actions. PAS 7100:2022 is designed to help anyone placing products on the consumer market to comply with product safety legislation: Part I (businesses); and Part II (regulators). The key changes made to the guidance since PAS 7100:2018 include:

  - changes to ensure the code is aligned with the UK's exit from the EU;

  - the taking of a more pragmatic approach to the point at which a recall or corrective action can be closed, moving away from a requirement for 100% success to a requirement for "reasonable endeavours";

  - new sections for online marketplaces, in particular, guidance is provided for online market operators who should have a Product Safety Incident Plan ("**PSIP**") in place;

  - new sections for businesses that repair and refurbish products also have a role to play to facilitate and act with due care in supporting the sale of safe products and should have a PSIP in place; and

  - alignment with PAS 7050:2022.

b) **The Code of Practice for Bringing Safe Products to the Market (PAS 7050:2022)**

This is a new Code introduced to support businesses and regulators in complying with their regulatory duties, with a particular focus on the preparation of a product safety management plan. PAS 710:2022 is split into two parts: Part I is intended for businesses whereas Part II is intended for regulators that support businesses and the implementation of the PSIP. It is intended to be read in conjunction with PAS 7100:2022. We set out below a high-level overview of the code's most pertinent points.

The code:

- applies to all new and second-hand consumer products, including products for hire and loan. The legislation includes duties to: (i) place only safe products on the market, supported by information on their correct use; (ii) warn consumers about potential product-related risks; (iii) monitor the safety of products; (iv) inform the relevant regulator if a safety issue is identified (where appropriate); and (v) take effective corrective action where necessary.

- provides recommendations, and a checklist, for ensuring **optimal management of internal systems and supply chains** in order to ensure that products placed on the market are safe.

- states that all businesses involved in the supply of consumer products, including online marketplace operators, should have a **product safety management plan** in place ("PSMP"). The code goes on to provide guidance on how a PSMP should be put together, and crucially the key aspects that should be incorporated, including:

  I.   evidence of management's commitment to safe products;

  II.   measures to foster a product safety management culture and the provision of training;

  III.   processes to monitor the regulatory environment and market conditions to allow for adaption to any changes;

IV.   clarity of supply chain responsibilities;

V.   details on how to best assess and manage (i) supplier risks; and (ii) product risks (including at the design stage);

VI.   measures to ensure consideration of product liability during the manufacturing processes;

VII.   product traceability measures including, in particular, measures to ensure markings remain legible and can withstand general wear and tear;

VIII.   processes to monitor the safety of products supplied;

IX.   a PSIP;

X.   measures put in place to ensure a product remains safe throughout the product lifecycle; and

XI.   provision for reviewing (at least on an annual basis) product safety practices (including the PSMP) to ensure they conform to the latest requirements.

- emphasises the need for regulators to take a collaborative approach and work with businesses to support businesses in achieving (and maintaining) compliance with the code. However, the code also indicates that regulators must be prepared to implement "effective" **enforcement actions** where required (although no light is shed on what such enforcement actions may include).

The Codes of Practice overlap to some extent. However, the key difference between them is that:

(I)   PAS 7050:2022 focuses on what businesses should do when bringing products to market; and

(II)   PAS 7100:2022 focuses on what businesses should do to prepare for and address problems with products that are already on the market.

Why businesses need to be aware of these developments

While there is some overlap between the content of the two Codes of Practice, they each have separate focuses and therefore businesses should ensure they are familiar with, and have considered, both. The Codes of Practice apply to all sectors that are not otherwise covered by alternative sector-specific national guidance (such as medicines, medical devices, and vehicles). They are intended for use by all business sizes, from small companies to large multinationals.

The Codes of Practice are not legally binding, but they are supported by OPSS, and the authorities are likely to refer to the recommendations in the Codes of Practice when considering product safety issues.

Where to seek further help

Baker McKenzie has extensive experience with advising clients in respect of their product safety and incident policies and procedures. To discuss how your business can best position itself in respect of product safety and liability issues, please get in touch with one of our team today.

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