Providing safe products for the UK marketplace

Guidance for businesses on PAS 7050: *Bringing safe products to the market. Code of practice*

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INTRODUCTION
This document provides the background to PAS 7050

What is a PAS document?
A PAS document is similar to a British standard, although it has a different development model. It is generally voluntary and is a tool devised for the convenience of those who wish to use it. It is usually:

- developed in response to an identified need
- developed at the request of a sponsor
- a way of quickly introducing standardisation (PAS documents tend to have a quicker development time than a British standard)
- unrestricted in use, so it can be used for any marketplace, not just the UK
- considered for further development – for example, into a British standard
- reviewed after two years

A PAS document usually fits into the following types:

- **Specification**. Sets out detailed requirements to be satisfied by a product, material, process, service or system, and the procedures for checking conformity to these requirements
- **Guide**. Gives broad and general information about a subject, with background information where appropriate
- **Test method**. Sets out a detailed procedure for performing an activity (for example, measuring a quantity, testing a product, or determining a characteristic) and sets out a way of determining and presenting the results
- **Code of practice**. Gives

recommendations for accepted good practice, as followed by competent and conscientious practitioners, and brings together the results of practical experience and acquired knowledge for ease of access and use of the information

As well as these four, there are other types of PAS document, which include management systems, methods of specifying, vocabulary or classification. Refer to PAS 0: *Principles of PAS standardization* for further information.

PAS 7050
PAS 7050 is a code of practice; it therefore gives a set of recommendations, in this case about bringing safe products to market. It was developed in response to a need for greater clarity for economic operators* about the process of bringing safe products to the market, and was published in 2022.

[*'Economic operators' are manufacturers, authorised representatives, importers and distributors. There are differing levels of responsibility for each type of economic operator.]

Although most products on the market are considered to be safe, some are not, which can lead to significant injuries and even fatalities. This can be detrimental to economic operators. Most businesses do not plan to sell unsafe products and would welcome advice on how to reduce the probability of this happening.

The degree of market diversity for products made this PAS document a challenge to develop, but it also presented an opportunity to highlight key processes and plans that are relevant, regardless of the product under consideration. It is a document

intended for businesses that would like to verify their plans and processes or those that wish to develop and implement such plans and processes to manage risk in relation to product conformity and safety.

The PAS document was sponsored by the Office for Product Safety and Standards (OPSS), and facilitated by the British Standards Institution and a steering group, which included 29 organisations. It is structured in two parts: part I for businesses and part II for regulators that support businesses.

PAS 7050 should be read in conjunction with PAS 7100: *Product recall and other corrective actions. Code of practice*, which was first published in 2018 and updated in 2022. PAS 7050 focuses on the development of a 'product safety management plan' (PSMP) while PAS 7100 focuses on the 'product safety incident plan' (PSIP).

Why was PAS 7050 needed?
Under the General Product Safety Regulations 2005, and sector-specific product regulations, only safe products may be placed on the market. Even though these regulations and requirements have been in force for many years, unsafe products continue to be placed on the market, as demonstrated by OPSS's product recalls and alerts information on the GOV.UK website.

Most businesses want, and aim, to sell safe products, but for various reasons challenges occur that lead to mostly unintentional consequences. It is vital that all businesses involved in producing or selling products to consumers have a plan in place to mitigate the risk to consumers from unsafe products. This should be laid out in a plan similar to the PSIP noted in PAS 7100.

Not only should businesses have a plan in place for when an incident occurs (as highlighted in PAS 7100), they should also have plans and processes in place to prevent such incidents and to learn from incidents when they do occur. The aim of PAS 7050 is to provide suggestions and recommendations on what this proactive product safety management plan may look like.

PAS 7050 provides simple concise advice to businesses that want to bring safe products to the market and are prepared to put in place processes to ensure this. When PAS 7100 was first published, it was almost like the sequel to a then non-existent PAS 7050, focusing on a product safety incident and when a challenge arises. PAS 7050 provides a more proactive focus with the aim of preventing unsafe products from reaching the market in the first place.

PAS 7050, with the support of PAS 7100, aims to provide a proactive way of approaching product safety, thus protecting consumers, preventing injuries and potentially saving lives.

Some businesses will have never encountered a product safety incident, but is important that they make themselves aware of both PAS 7050 and PAS 7100. If an incident does occur, the PAS documents may be referred to by, for example, a Trading Standards officer.

HOW PAS 7050 HELPS BUSINESSES

How your business could prevent, and if necessary deal with, a product safety-related incident

Supporting businesses

PAS 7050 supports businesses in bringing safe products to market, which is imperative for any business, especially those that want to have a safe product and satisfied customers. Improving product safety and quality can be key in preventing product returns, injuries and - even worse - fatalities. This in turn is not only the right thing to do, but can save businesses money and support them in complying with legal obligations.

Product safety management plan

A 'product safety management plan' (PSMP) is a plan that identifies the key processes, documents and contacts in relation to the production and supply chain for any product, which will help ensure that it is safe. It will vary from organisation to organisation and may have a different naming convention; however, any PSMP should consider the following:

- **management commitment**. Demonstration and commitment from management to product safety, allocating the necessary resources
- **product safety management culture and training**. An evident product safety culture; training should be provided where appropriate
- **monitoring the regulatory environment and market condition**s. Processes in place to monitor changes in product safety legislation, standardisation and what constitutes compliance
- **clarity of supply chain responsibilities**. Agreements with supply chain partners on product safety-related responsibilities
- **supplier risk assessment and management**. Processes in place for risk assessment of suppliers and how to manage identified risks
- **product risk assessment and management**. Processes in place for completing product risk assessments, identifying product compliance, testing and reviewing labelling
- **manufacturing**. Assessment and risk of variation throughout manufacturing, including the identification of critical control points and production processes to ensure that they remain in control and products are safe
- **product traceability.** Arrangements in place to allow for product identification if an issue arises
- **monitoring product safety performance in the marketplace**. A review of how products perform in the market. This could include how consumers are interacting with the product (consumer reviews / complaints) and identification of any potential product safety issues and how these may be addressed
- **product safety incident plan**. A plan on how to deal with an incident, should one occur (PSIPs are covered in detail in PAS 7100)
- **safety throughout the product life cycle**. Products should remain safe throughout their expected product life cycle and use
- **review process**. A review of the PSMP should take place to ensure that the plan and all related documents and processes are fit for purpose, particularly after any product safety incident

Most organisations will have their own processes for managing product risk, which may be similar to the above. Some may be more detailed than others, but the key is to have a plan in place that is useful and understood by all relevant members of staff, and that the processes and documents that

support it are integrated and well-established throughout the business. This may be new for some businesses and more common for others, but it should be a plan that is part of the culture of the business and not something that is there to 'tick a box'.

Product safety incident plan

A 'product safety incident plan' (PSIP) identifies the key processes, documents and contacts in relation to a product safety incident. (As mentioned above, the PSIP is the focus of PAS 7100, which should be read alongside PAS 7050.) It forms part of the PSMP and covers similar topics. These plans will vary in each organisation and may have a different naming convention; however, any PSIP should consider the following:

- **management commitment.** This is similar to the PSMP noted above
- **product and customer traceability plan**. As noted above for the PSMP under 'product traceability', arrangements should be in place to allow for product identification in the event of a product safety issue. Records of customer contact details should also be maintained (where practical and proportionate). Product traceability provides the means of distinguishing products that are, or may be, unsafe from those that can be confidently assumed to be safe. It also identifies where such products have been supplied to or are being stored, so that they can be isolated, reworked, withdrawn from the market or recalled from consumers. Additionally, good traceability allows quality and conformity assessment documents to be easily associated with products that are placed on

the market, which provides an opportunity for regulators, such as Trading Standards officers, to verify that a product batch is safe

- **product safety monitoring plan**. Processes in place to review how products perform in the marketplace, how consumers are interacting with the product (consumer reviews / complaints), and identification of any potential product safety issues and how these may be addressed
- **legal notification plan**. This should include details on who to contact and what information to provide. There is a legal duty to notify the relevant regulator
- **risk assessment plan**. Processes in place for completing product risk assessments
- **corrective action decision plan**. Clearly setting out how decisions on corrective actions should be made and who will make them. A 'corrective action' is something that is done to reduce the risk of harm from a product that has been found to be unsafe – for example, a product recall or a repair
- **communication plan**. Establishing mechanisms to ensure a comprehensive communication plan is in place, including content, responsibilities and communication channels
- **training plan**. Similar to the PSMP training, this should be provided where relevant
- **testing plan**. The PSIP should be tested with a simulated recall and other corrective action exercises
- **review plan**. Similar to the PSMP, the PSIP should be reviewed to ensure that the plan and all related documents and processes are fit for purpose, particularly after any product safety incident

PAS 7100 also includes details on managing a corrective action, which is summarised in figure 2 of the PAS document (reproduced below).

SPECIFIC ECONOMIC OPERATORS

Certain business types have been under scrutiny in recent years regarding product safety so specific sections of PAS 7050 were dedicated to them
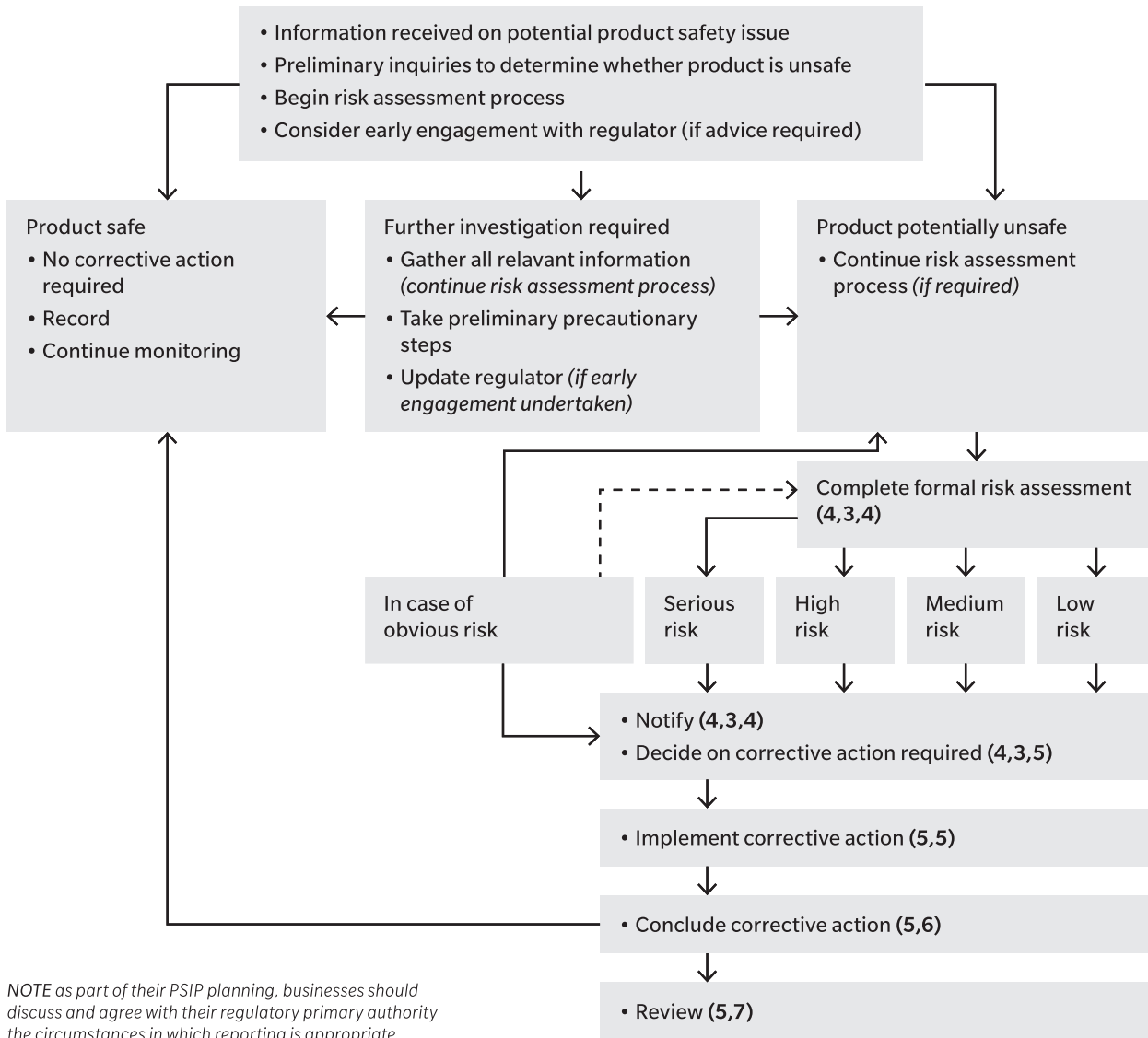
Online marketplaces

Section 5 of PAS 7050 refers to online marketplaces, which are defined in PAS 7050 as a "provider of an intermediary service that allows third-party economic operators and buyers to conclude transactions for consumer products via online sales or service contracts, under which the third-party economic operator is the seller, utilising the online marketplace's website and services".

In recent years, the way consumers shop has changed; more products are purchased online, which can pose challenges in terms of product safety. In 2017 the European Commission issued a notice on the market surveillance of products sold online and in 2018 the product safety pledge was developed, which was agreed upon and signed by the main online marketplaces.

The pledge outlines the commitment to remove unsafe products from these marketplaces. These recent changes in consumer behaviour and in the product safety landscape made it vital to include these economic operators in PAS 7050. Like other economic operators, online marketplaces should have a PSMP in place, including all the relevant parts noted above. They should also have policies and

Figure 2 of the PAS document

Typical corrective action sequence

- Information received on potential product safety issue
- Preliminary inquiries to determine whether product is unsafe
- Begin risk assessment process
- Consider early engagement with regulator (if advice required)

Product safe
- No corrective action required
- Record
- Continue monitoring

Further investigation required
- Gather all relevant information *(continue risk assessment process)*
- Take preliminary precautionary steps
- Update regulator *(if early engagement undertaken)*

Product potentially unsafe
- Continue risk assessment process *(if required)*

Complete formal risk assessment (4,3,4)

In case of obvious risk

Serious risk

High risk

Medium risk

Low risk

- Notify (4,3,4)
- Decide on corrective action required (4,3,5)

- Implement corrective action (5,5)

- Conclude corrective action (5,6)

- Review (5,7)

NOTE as part of their PSIP planning, businesses should discuss and agree with their regulatory primary authority the circumstances in which reporting is appropriate.

processes in place to support sellers with product safety, including:
- confirming the identity of the seller
- providing training to sellers to help them sell safe products
- requiring sellers to sell compliant products
- monitoring the performance of sellers and removing products subject to a recall or uncompleted corrective action

- investigating product safety feedback from customers and promptly responding to information from regulatory authorities

Repairers and refurbishers

Section 6 of PAS 7050 is dedicated to repairers and refurbishers, which (in a similar way to online marketplaces) have featured heavily in the product safety landscape. It was vital to

include these economic operators in PAS 7050.

Repairers and refurbishers should have a PSMP in place and also ensure that the products or parts they supply:
- are safe and fit for purpose
- are accompanied by relevant labelling, instructions and warnings for their safe use
- have not been subject to recall or uncompleted corrective action

Second-hand products

Section 7 of PAS 7050 concentrates on distributors and importers of second-hand products. Just as online marketplaces and repairers / refurbishers have featured heavily in the product safety landscape, so have second-hand products. It was therefore essential that they were also included in the PAS document.

Distributors and importers of second-hand products should have a PSMP in place. They should also ensure that the products or parts they supply:

- are safe
- are not damaged or defective in such a way that it has an effect on the product's safety
- are compliant with the relevant legal provisions
- are accompanied with instructions and warnings necessary for safe use
- have not been subject to recall or uncompleted corrective action
- have not been repaired or refurbished in a way that affects the product's safety
- if sold with software that is no longer supported, are sold with suitable guidance on continued safe use

Regulators

Part II of PAS 7050 provides recommendations to regulators that are supporting businesses with the development and implementation of a PSMP. In addition to responding proportionately where businesses fail to meet their legal obligations, regulators have an important role in supporting product safety and protecting consumers.

Although it is aimed at regulators, this part of the PAS document is also useful for businesses, helping them to understand the role that regulators play. Businesses can consult with the relevant regulator in the development of their PSMP or PSIP. This can be done through a Primary Authority, where applicable; see 'Primary Authority' for more information on this system.

Checklists

Annexes A to E include checklists for the various economic operators:

- annex A is for all businesses. The subsequent annexes should be used in addition to this one
- annex B is for manufacturers
- annex C is for online marketplaces
- annex D is for repairers and refurbishers
- annex E is for distributors and importers of second-hand products

These checklists are intended to support businesses and regulators when developing, implementing or reviewing a PSMP. These are provided as guidance only and can be adapted to fit the business they are referring to. They can be used as an aide memoire or perhaps an agenda list when discussing PSMPs. The annexes appear in PAS 7050 but annexes A-E are also attached above in Word for businesses to use as a template for their own PSMPs.

Annex F is an informative annex and includes information on technical and other documentation that supports compliance. This demonstrates the importance of technical documentation, also known as a technical file, which can vary depending on the product and the legal framework it sits under. This is a vital read for those who want to understand more about technical documentation, and the role both conformity assessment and the documentation itself play in ensuring that only safe products are brought to the market.

Annex G is another informative annex, this time on due diligence; in particular, it focuses on the 'due diligence defence', which is a key concept in product safety regulation. In the UK, many areas of the criminal law on consumer protection include the concept of 'strict liability', where it is irrelevant whether the accused did or did not intend to break the law in order for criminal liability to be established; someone who accidentally broke the law may be just as liable as someone who knew what they were doing. The due diligence defence is normally included in the legislation containing offences of strict liability.

To use this defence, a person establishes that they took "all reasonable steps and exercised all due diligence" to avoid an offence being committed. The defence includes broad principles, including the principle that sitting back and doing nothing is normally insufficient. Annex G also explores further broad principles that have been established regarding the due diligence defence. It is essential that those who want to understand more about due diligence read this annex.

Creating your own plans

In summary, any economic operator who works with products, whether it be a manufacturer, importer or distributor, should consider a PSMP and a PSIP.

Read the PAS 7050 and PAS 7100 documents, and if you then need help or support with the development of your plans, contact your local Trading Standards service.

Further information

The *Regulators' Code,* is "a framework for how regulators should engage with those they regulate".

The Office for Product Safety and Standards (OPSS) has produced a list of designated standards that businesses can use to show that they comply with legislative requirements.

OPSS has produced guidance on conformity assessment and accreditation, which includes information on the effects of leaving the European Union on the law in Great Britain.

OPSS has also produced an *Incident Management Plan,* which contains information on OPSS's framework for recognising and responding to product safety-related incidents.

OPSS's *Primary Authority Overview* explains the main features of the Primary Authority system, which allows businesses to enter into a relationship with a particular local authority (or authorities) to receive assured and tailored advice.

Product Safety Risk Assessment Methodology (PRISM). This is the new risk assessment methodology for use by those authorities in Great Britain that have responsibility for consumer product safety.

LEGISLATION
The laws featured in this guide

Trading Standards

For more information on the work of Trading Standards services - and the possible consequences of not abiding by the law - please see 'Trading Standards: powers, enforcement and penalties'.

Key legislation

- Consumer Protection Act 1987

- General Product Safety Regulations 2005

- Consumer Rights Act 2015

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Please note

This information is intended for guidance; only the courts can give an authoritative interpretation of the law.

The guide's 'Key legislation' links may only show the original version of the legislation, although some amending legislation is linked to separately where it is directly related to the content of a guide. Information on changes to legislation can be found by following the above links and clicking on the 'More Resources' tab.