

How PAS 7050 helps businesses

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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 with 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.

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 and training should be provided where relevant.

Monitoring the regulatory environment and market conditions. 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 labelling review.

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.

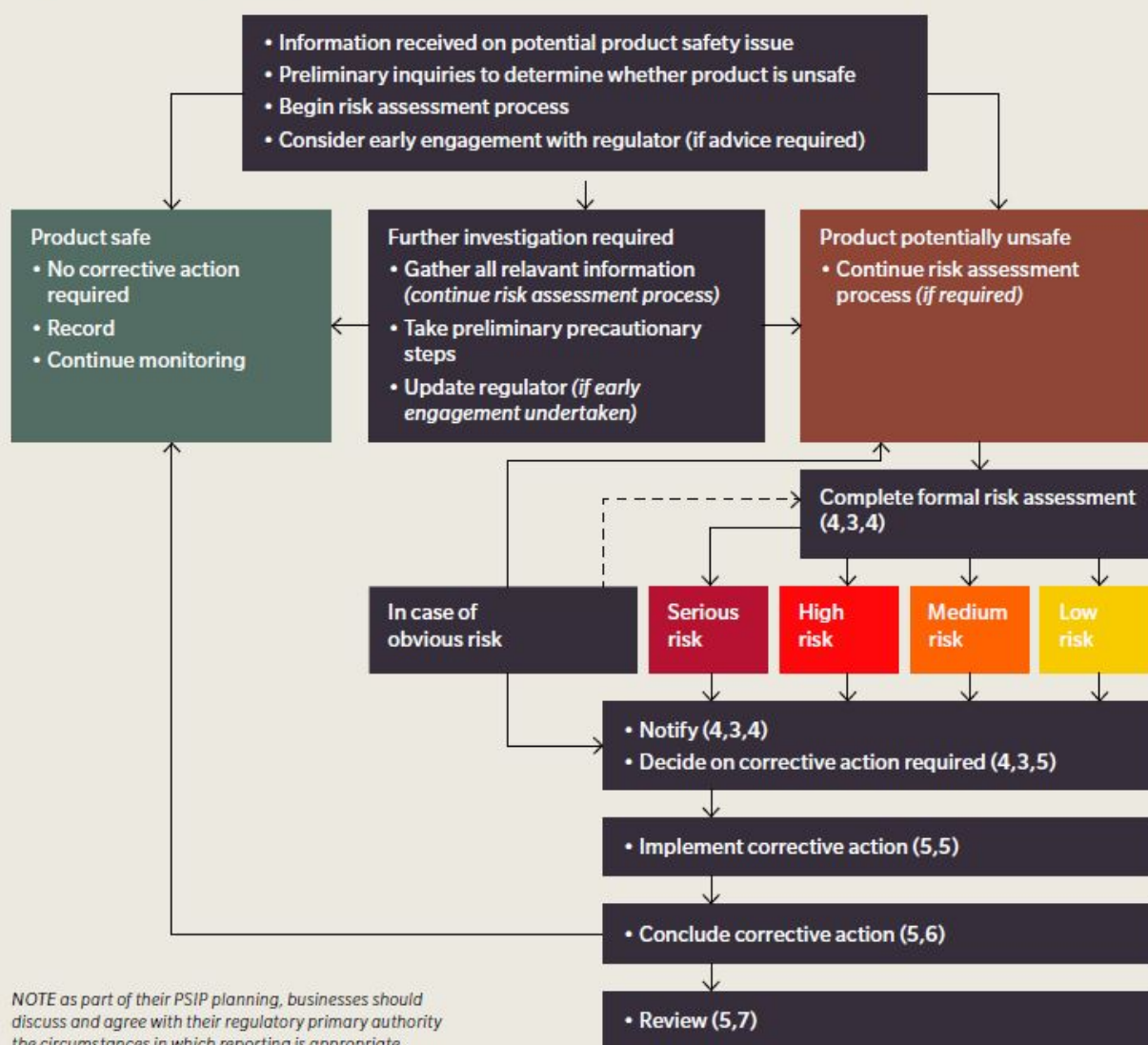
Testing plan. The PSIP should be tested with a simulated recall and other corrective action exercises.

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).

Figure 2

Typical corrective action sequence



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 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.

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