Providing safe products (PAS 7050, PAS 7100 and PRISM)

Guidance for businesses on PAS 7050: Bringing safe products to the market. Code of practice, PAS 7100: Product recall and other corrective actions. Code of practice and PRISM (Product Safety Risk Assessment Methodology)

This guidance is for England, Scotland and Wales

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INTRODUCTION

The background to PAS 7050, PAS 7100 and PRISM

In this guide, the words 'must' or 'must not' are used where there is a legal requirement to do (or not do) something. The word 'should' is used where there is established legal guidance or best practice that is likely to help you avoid breaking the law.

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 with 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: Bringing safe products to the market. Code of practice is, as the name suggests, 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 7100

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 were PAS 7050 and PAS 7100 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 PSMP 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.

PRISM

The Product Safety Risk Assessment Methodology (PRISM) was launched by OPSS in 2022, after extensive engagement with local authorities and national regulators. It has resulted in risk assessments becoming more robust and informed.

PRISM is designed to be used by the market surveillance authorities and enforcing authorities in Great Britain with responsibility for consumer product safety. It is similar to the EU Safety Gate approach, but has additional parts and reflects the same risk-level matrix. Even though PRISM has been designed for market surveillance and enforcement authorities, it can also be used by businesses or individuals who want to complete a risk assessment on their product.

HOW PAS 7050, PAS 7100 AND PRISM HELP BUSINESSES

How your business can bring safe products to market and could prevent, and if necessary deal with, a product safety-related incident

Supporting businesses

PAS 7050 supports businesses in bringing safe products to market; PAS 7100 supports businesses with corrective actions and recalls; and PRISM can help with the development of a risk assessment to provide support with a corrective action, recall or general decision-making (risk management). 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.

This 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 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 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), as well as 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 commitmen**t. This is similar to the PSMP noted above
- **product and customer traceability plan**. As noted above for the PSMP (in the 'product traceability' bullet point), 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
- **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

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

PAS 7050's annexes A to E include checklists for the various economic operators.

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 to E are also attached above in Word for businesses to use as a template for their own PSMPs:

- 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

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 roles that 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.

PRISM

The PRISM methodology is intended for non-food consumer products. A guide and toolkit are available on the GOV.UK website, which also has examples of completed risk assessments for six products:

- non-compliant cords and drawstrings identified in clothing intended for children (less than serious risk)
- non-compliant portable juice blender (less than serious risk and covers multiple hazards)
- non-compliant toy with a detachable part (less than serious risk)
- non-compliant car seat
- non-compliant room / space heater
- non-compliant remote control for lighting chain

The PRISM toolkit is an Excel spreadsheet that you can use to calculate your risk probabilities and the steps you are going to take. This should be supported by a rationale document (as shown with the six examples above) to explain your justification for each probability.

OPSS also provides some open-source data (again, see link above) to support risk assessment, which can be used to help with probability estimation and the development of injury scenarios.

How do PAS 7050 and PRISM relate?

PAS 7050 focuses on pre-market processes and PRISM is a post-market risk assessment methodology. PRISM is similar to the EU method, which is governed by Regulation

(EU) 2024/3173 with regard to rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk. Until 26 March 2025, Decision (EU) 2019/417 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' also applied in the EU; it is still a useful additional tool. Please note that, post-Brexit, neither of these are GB law. See below for a visual explanation of how PAS 7050 and PRISM relate.

Further information

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

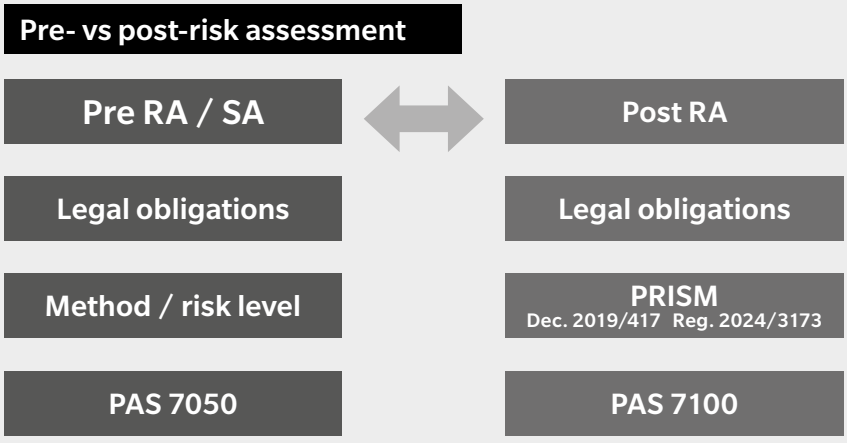
The Office for Product Safety and Standards (OPSS) has produced a list of Designated Standards that businesses can use to show that they comply with legislative requirements.

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 link provides information from OPSS on the risk assessment methodology for use by those authorities in Great Britain that have responsibility for consumer product safety.



Pre-market risk assessment

When post-risk assessment is discussed, people often ask about pre-market risk assessment. There is no specific template for pre-market risk assessment. However, for electrical goods, there is CENELEC Guide 32 (CENELEC is the European Committee for Electrotechnical Standardisation). The purpose of these assessments is to manage the risk before placing the product on the market and Standards are a good place to start.

LEGISLATION ETC

The laws featured in this guide / update information

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'.

In this update

Information about PRISM has been added. Last reviewed / updated: April 2025

Key legislation

- Consumer Protection Act 1987
- General Product Safety Regulations 2005
- Consumer Rights Act 2015
- Decision (EU) 2019/417 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX'
- Regulation (EU) 2024/3173 with regard to rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk

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.