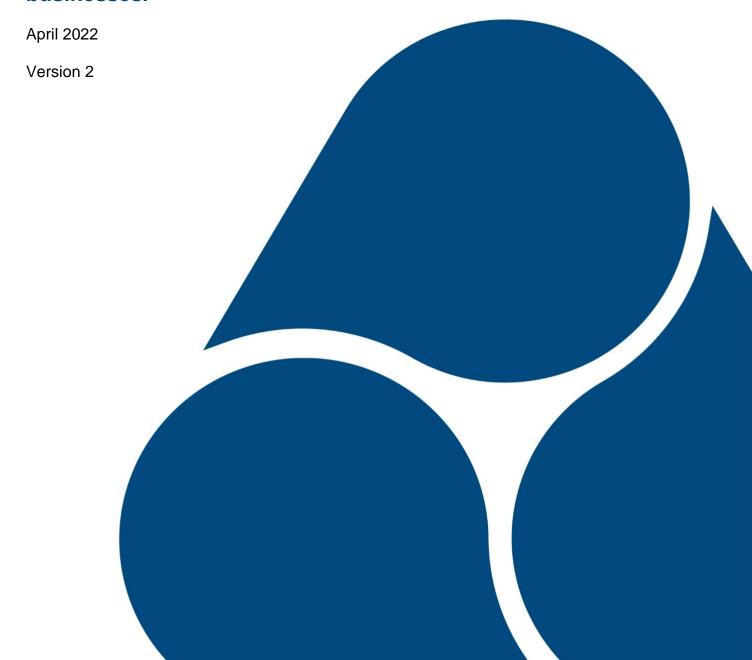


Product Safety and Noncompliance Notification Guidance

Guidance on product safety and noncompliance notifications for businesses.



Contents

1.	Introduction	3
2.	Notification Requirements – Businesses	
	General Product Safety Regulations 2005	4
	Sector-Specific Safety Legislation	4
	Northern Ireland	5
3.	Notifications – the role of MSAs and Enforcement Authorities	6
4.	Other Statutory Product Notifications to OPSS	7
	Legal Metrology	7
	Restriction of Hazardous Substances (RoHS)	8
	Serious Undesirable Effects (Cosmetics)	8
5.	Non-UK-based Businesses	10
An	nex A Summary of Notification Requirements and Relevant Authorities	11
	Product-Specific Legislation Notification Requirements	12
An	nex B – Suggested Notification Template	17

1. Introduction

- 1.1 The Office for Product Safety and Standards (OPSS) is part of the Department for Business, Energy and Industrial Strategy (BEIS) and exercises the powers of the Secretary of State in relation to a range of regulations:
 - We are the national regulator for product safety, providing scientific and technical capability, enforcing in relation to cases that are nationally significant, novel or contentious, and working with local authorities and border control authorities to keep consumers safe and ensure business compliance.
 - We are the national regulator for legal metrology, ensuring weighing and measuring instruments are accurate and reliable, and guiding the work of local authorities to give confidence to consumers and businesses in goods traded by quantity.
 - We enforce in relation to a range of goods-based and standards-based regulations.
 These include energy efficiency and environmental pollution requirements in product
 design and performance, standards and measurement in the energy supply
 infrastructure and due diligence in the trade of designated raw materials protecting
 consumers and the environment and helping to meet international commitments.
- 1.2 This guidance is for businesses supplying consumer and non-consumer products on the UK market and summarises the requirements to notify relevant authorities if products pose a risk to the health and safety of consumers or products are found to be noncompliant with the relevant legislation. This guidance includes requirements for businesses to notify relevant authorities, including OPSS, as part of product safety legislation, in addition to other regulations enforced by the OPSS.
- 1.3 This document sits alongside PAS 7100:2022 on Supporting better product recalls and provides guidance on meeting notification requirements and using Government channels to publicise recalls.
- 1.4 This guidance applies to businesses supplying goods on the Great Britain (GB) and Northern Ireland (NI) markets.
- 1.5 Notification requirements stem from legal obligations in the General Product Safety Regulations 2005 as they apply in GB and NI and product-specific legislation. Notifications should be made in a timely manner to the lead authority, which can be identified in Annex A.

2. Notification Requirements – Businesses

- 2.1 The product safety legal framework requires businesses supplying goods on the UK market to notify the relevant authority where they become aware that a product they have placed on the market, supplied or distributed is unsafe and poses a risk to the user, or is noncompliant with the relevant legislation.
- 2.2 Product safety notifications support:
 - The safety of people and the environment, by ensuring that corrective actions and steps are taken to reduce the risks to consumers and users;
 - Business, by allowing regulators to provide advice and support to address issues, minimising the likelihood of future noncompliance; and
 - Regulators, by recording and sharing information to permit authorities to focus activities on issues and products identified as presenting the greatest safety risks.

General Product Safety Regulations 2005

- 2.3 The General Product Safety Regulations 2005 (GPSR) require all products to be safe in their normal and reasonably foreseeable usage and enforcement authorities have powers to take appropriate action when this obligation isn't met.
- 2.4 Regulation 9 GPSR requires producers or distributors, where they know that a product they have placed on the market or supplied to a consumer does not meet the general safety requirement, to notify an enforcement authority of that information and the action they have taken to prevent risk to the consumer. ¹
- 2.5 A suggested notification template for notifications to relevant authorities can be found in Annex B.

Sector-Specific Safety Legislation

- 2.6 Sector-specific safety legislation, such as the Toys (Safety) Regulations 2011, also contain specific requirements for business to notify the relevant authority where they have reason to believe they have placed a product which does not meet the safety requirement on the market or distributed a product that does not meet the safety requirement.
- 2.7 A list of sector-specific safety legislation and references to the legal provisions for notification can be found in Annex A, including the relevant authority for each regulation and circumstance.

-

¹ This requirement does not apply:

⁽a) In the case of a second-hand product supplied as an antique or as a product to be repaired or reconditioned prior to being used, provided the supplier clearly informed the person to whom he supplied the product to that effect,

⁽b) In conditions concerning isolated circumstances or products.

Northern Ireland

- 2.8 If a product sold on the Northern Ireland market is found to be unsafe, this must be reported to the relevant authority who will share this information with OPSS via the Product Safety Database.
- 2.9 Individual EU Member States may have specific arrangements in place for notifications where a product that does not meet the safety requirement has been supplied on their markets. You should seek confirmation within each Member State you supply products to regarding product safety notifications and may wish to make use of the EU Product Safety Business Alert Gateway system (https://webgate.ec.europa.eu/gpsd/).

3. Notifications – the role of Market Surveillance Authorities and Enforcement Authorities

- 3.1 Market surveillance authorities and enforcement authorities will review information received as part of product safety notifications to ensure that people and the environment are being protected; ensure adequate steps are taken to address the noncompliance and its effects; and minimise the likelihood of future noncompliance.
- 3.2 Authorities operate under the Regulators' Code, which provides a clear, flexible and principles-based framework for how regulators should engage with those that they regulate. For further information on the Regulators' Code, please access the following link: https://www.gov.uk/government/publications/regulators-code.
- 3.3 The authority receiving the notification may also be required under law to take a number of actions, including reporting notifications received on the UK Product Safety Database.²
- 3.4 If a notification concerns a recall or serious safety issue, the authority receiving the notification will also be able to provide advice on raising awareness of the recall or safety issue through centralised channels, including the Product Safety Alerts, Reports and Recalls site and the OECD Global Recall Portal.
- 3.5 The authority will also be able to advise on the undertaking of a recall, as set out in PAS 7100:2022 'Supporting better recalls': https://shop.bsigroup.com/products/product-recall-and-other-corrective-actions-code-of-practice/standard
- 3.6 For further information on the role of authorities in product safety notifications, please access the following guidance: https://www.gov.uk/guidance/notification-of-unsafe-and-noncompliant-products

The Product Safety Database is a database used by regulators to submit notifications relating to unsafe and/or noncompliant products and the outcomes of market surveillance activities. It is owned by OPSS and used by over 200 local authorities and 9 other national regulators.

4. Other Statutory Product Notifications to OPSS

- 4.1 OPSS is responsible for:
 - policy, market surveillance, and coordination of local authorities in relation to legal metrology;
 - cosmetics policy and the administration of notifications of Serious Undesirable
 Effects related to cosmetic products; and
 - the enforcement of the Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment Regulations on behalf of Defra.
- 4.2 The following section details requirements to notify OPSS of safety or compliance issues required by law in the above areas.

Legal Metrology

- 4.3 Market surveillance and enforcement responsibilities under the Measuring Instrument Regulations 2016 are undertaken by
 - For Great Britain
 - In relation to regulated measuring instruments other than gas meters, active electrical energy meters, taximeters and exhaust gas analysers, the local weights and measures authorities (Trading Standards) and
 - In relation to all measuring instruments in scope of the Regulations, OPSS
 - For Northern Ireland
 - In relation to cold water meters, automatic weighing instruments, material measures and non-water liquid measuring systems, the Department for the Economy
 - o In relation to gas meters and active electrical energy meters, OPSS and
 - In relation to taximeters and exhaust gas analysers, the Department for Infrastructure.
- 4.4 The Measuring Instruments Regulations 2016 require businesses manufacturing (Regulation 13), importing (Regulations 18 and 23) and/or distributing (Regulation 31) measuring instruments in scope of the Regulations, to notify the relevant authority where the instrument they have made available has been identified as not in conformity with the essential requirements and is presenting a risk.
- 4.5 Market surveillance and enforcement responsibilities under the Non-Automatic Weighing Instruments Regulations 2016 are undertaken by
 - Local weights and measures authorities (Trading Standards) and OPSS for Great Britain and
 - The Department for the Economy for Northern Ireland.

- 4.6 The Non-Automatic Weighing Instruments Regulations 2016 require businesses manufacturing (Regulation 12), importing (Regulation 17 and 22) and/or distributing (Regulation 30) non-automatic measuring instruments in scope of the Regulations, to notify the relevant authority where the instrument they have made available has been identified as not in conformity with the essential requirements and is presenting a risk.
- 4.7 To fulfil these notification requirements, the notification form in Annex B should be completed and returned to opss.enquiries@beis.gov.uk for notifications to OPSS in respect of products made available on the GB market or metrology@economyni.gov.uk for notifications to the Department for the Economy Northern Ireland or info@infrastructure-ni.gov.uk for notifications to the Department for Infrastructure Northern Ireland in respect of products made available on the NI market. Further details are available in Annex A.

Restriction of Hazardous Substances (RoHS)

- 4.8 The Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (the RoHS Regulations) are enforced by OPSS.
- 4.9 The Regulations require businesses manufacturing (Regulation 20), importing (Regulation 26) and/or distributing (Regulation 30) products in scope of the Regulations to notify OPSS of any noncompliance with the RoHS Regulations that has been identified and of the corrective measures taken.
- 4.10 Notifications should be made by sending a completed notification form to rohs@beis.gov.uk. Further information on the RoHS Regulations can be found on Gov.uk at the following link: https://www.gov.uk/guidance/rohs-compliance-and-guidance

Serious Undesirable Effects (Cosmetics)

- 4.11 Regulation (EC) No 1223/2009 on Cosmetic Products, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, requires that Responsible Persons and distributors notify Serious Undesirable Effects to OPSS (Article 23) where the serious undesirable effect took place in GB.
- 4.12 A 'Serious Undesirable Effect' (SUE) is an undesirable effect (an adverse effect to human health that occurs following the normal or reasonably foreseeable use of a cosmetic product) which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death. Notification should take place without delay.
- 4.13 To notify OPSS, you should complete the SUE form for Responsible Persons and distributors and submit this to seriousundesirableeffects@beis.gov.uk. The SUE forms are available at the following link:

 https://www.gov.uk/government/publications/cosmetic-products-reporting-sues.

- 4.14 The requirement to notify the European Commission in respect of SUEs relating to the NI market remains unchanged. The notification form for SUEs in NI should be sent to OPSS at seriousundesirableeffects@beis.gov.uk, who will inform the European Commission and (where the notification has been submitted by a distributor) the Responsible Person. The European Commission guidance on SUEs can be found at the following link for reference: https://ec.europa.eu/growth/sectors/cosmetics/market-surveillance_en.
- 4.15 Broader guidance on making cosmetic products available on the GB market can be found at the following link: https://www.gov.uk/guidance/making-cosmetic-products-available-to-consumers-in-great-britain

5. Non-UK-based Businesses

- 5.1 In some instances, not all businesses will have a UK-based legal entity and therefore they may not possess a natural link with a local authority.
- 5.2 If a business supplies goods on the UK market and must submit a product safety notification to a UK authority, where a local authority cannot be identified and the issue does not fall within the regulatory remit of other national regulators as identified in Annex A, businesses should make this notification to OPSS.
- 5.3 OPSS will then identify the appropriate lead authority and will contact you to progress the notification, as outlined in Section 3.
- 5.4 Notifications should be sent to ukproductsafetycp@beis.gov.uk.

Annex A Summary of Notification Requirements and Relevant Authorities

- 6.1 This section outlines some of the key product legislation which includes notification requirements and the lead authority to receive product safety and product noncompliance notifications, including their contact details.
- 6.2 Product safety and noncompliance notifications support:
 - The safety of people and the environment, by ensuring that corrective actions and steps are taken to reduce the risks to consumers;
 - Business, by enabling the provision of advice and support to address issues, minimising the likelihood of future noncompliance; and
 - Regulators, by recording and sharing information to permit authorities to focus activities on issues and products identified as presenting the greatest safety risks.
- 6.3 If the lead authority is stated to be a local weights and measures authority, this usually refers to the local authority service known as 'Trading Standards', or District Councils in Northern Ireland. If you have a Primary Authority Partnership in place, you may notify your Primary Authority to meet this requirement³.
- 6.4 Contact points within other national regulators are as follows:

United Kingdom:

Driver and Vehicle Standards Agency (DVSA) — https://www.gov.uk/government/publications/code-of-practice-on-vehicle-safety-defects-and-recalls

Ofcom – https://www.ofcom.org.uk/about-ofcom/contact-us

Office for Nuclear Regulation – https://www.onr.org.uk/notify-onr.htm

Great Britain only:

Health and Safety Executive – https://www.hse.gov.uk/contact/concerns.htm

Northern Ireland only:

Health and Safety Executive Northern Ireland – https://www.hseni.gov.uk/contact

Department for the Economy - metrology@economy-ni.gov.uk

Department for Infrastructure – info@infrastructure-ni.gov.uk

For further information on Primary Authority, please access the following website: https://www.gov.uk/government/publications/primary-authority-overview

Product-Specific Legislation Notification Requirements

Regulations	Requirements	Lead Authority
Cosmetic Products Enforcement Regulations 2013 ⁴	Responsible Person (manufacturer, importer, distributor, or other person designated as Responsible Person by written mandate) – Article 5	In Great Britain, the weights and measures authority or the Office for Product Safety and Standards In Northern Ireland, the district council or Office for Product Safety and Standards
Domilation	Distributors – Article 6	La Carat Britain a mainhta and managaria
Regulation 305/2011 on	Manufacturers – Articles 11(7) and 59B(2)(b)	In Great Britain, a weights and measures authority
Construction Products	Importers – Articles 13(2) and 13(7)	In Northern Ireland, a district council
	Distributors – Articles 14(2) and 14(4)	
Electrical Equipment (Safety) Regulations 2016	Manufacturers – Regulation 12 Importers – Regulations 17 and 29 Distributors – Regulations 27	Where electrical equipment is designed for use or operation in the workplace, in GB, the Health and Safety Executive (HSE), or in NI, the Health and Safety Executive Northern Ireland (HSENI)
	and 29	Where electrical equipment is designed for private use or consumption, in GB, a weights and measures authority, or in NI, a district council
		Where electrical equipment is intended exclusively or primarily for use on relevant nuclear sites, the Office for Nuclear Regulation
Electromagnetic Compatibility	Manufacturers – Regulation 15	In Great Britain, a weights and measures authority
Regulations	Importers – Regulations 19 and 23	In Northern Ireland, a district council
2016	Distributors – Regulations 28 and 30	
Equipment and Protective	Manufacturers – Regulation 15 Importers – Regulations 20 and	In Great Britain, the Health and Safety Executive (HSE)
Intended for Use in Potentially	25 Distributors – Regulations 31 and	Where intended exclusively or primarily for use on relevant nuclear sites, the Office for Nuclear Regulation
Regulation 2016/426 on	Manufacturers – Article 7.8	Appliances or fittings for private use or consumption:

⁴ The process for notifying Serious Undesirable Effects, as required. by Article 23, is described at 4.11.

	T	
appliances burning	Importers – Article 9.2 Distributors – Article 10.2	-In Great Britain, a weights and measures authority
gaseous fuel	Distributors - Article 10.2	-In Northern Ireland, a district council
		Appliances or fittings for use in the workplace or where accessible to persons outside of private use:
		-In Great Britain, the Health and Safety Executive
		-In Northern Ireland, the Health and Safety Executive for Northern Ireland
		Appliances or fittings intended exclusively or primarily for use on relevant nuclear sites
		-The Office for Nuclear Regulation
Lifts	Installers – Regulation 12	In Great Britain:
Regulations 2016	Manufacturers – Regulation 22	-In relation to lifts for use in the
	Importers – Regulations 27 and 32	workplace or safety components for such lifts, the Health and Safety Executive
	Distributors – Regulations 38 and 40	-In relation to lifts for private use and consumption of safety components for such lifts, the Office for Product Safety and Standards
		In Northern Ireland:
		-The Department for the Economy
Measuring	Manufacturers – Regulation 13	In Great Britain:
Instruments Regulations 2016	Importers – Regulations 18 ⁵ and 23 Distributors – Regulation 31	-In relation to regulated measuring instruments other than gas meters, active electrical energy meters, taximeters and exhaust gas analysers, a local weights and measures authority
		-In relation to all measuring instruments in scope of the Regulations, the Office for Product Safety and Standards
		In Northern Ireland:
		-In relation to cold water meters, automatic weighing instruments, material measures and non-water liquid measuring systems, the Department for the Economy
		-In relation to gas meters and active electrical energy meters, the Office for Product Safety and Standards

To note, notifications by importers in respect of Regulation 18 of the Measuring Instruments Regulations 2016 must be made to the Office for Product Safety and Standards.

Non-Automatic Weighing	Manufacturers – Regulation 12 Importers – Regulations 17 ⁶ and	-In relation to taximeters and exhaust gas analysers, the Department for Infrastructure In Great Britain, a local weights and measures authority or the Office for
Instruments Regulations 2016	22) Distributors – Regulation 30	Product Safety and Standards In Northern Ireland, the Department for the Economy
Regulation 2016/425 on Personal Protective Equipment	Manufacturers – Article 8.9 Importers – Article 10.2 Distributors – Article 11.2	In the case of PPE for private use or consumption: -In Great Britain, a weights and measures authority
		-In Northern Ireland, a district council
		In the case of PPE for use or operation by persons at work or in non-domestic premises available to persons:
		-In Great Britain, the Health and Safety Executive
		-In Northern Ireland, the Health and Safety Executive for Northern Ireland
		Insofar as the Regulations apply to PPE intended exclusively or primarily for use on relevant nuclear sites, the Office for Nuclear Regulation
Pressure Equipment	Manufacturers – Regulation 17 Importers – Regulations 22 and	In the case of pressure equipment and assemblies for use in the workplace:
(Safety) Regulations 2016	27 Distributors – Regulations 33 and 34	-In Great Britain, the Health and Safety Executive
		-In Northern Ireland, the Health and Safety Executive for Northern Ireland
		In the case of pressure equipment and assemblies for private use or consumption:
		-In Great Britain, a weights and measures authority
		-In Northern Ireland, a district council
		Insofar as the Regulations apply to pressure equipment or assemblies intended exclusively or primarily for use on relevant nuclear sites, the Office for Nuclear Regulation.
	Manufacturers – Regulation 22	In Great Britain:
·		

To note, notifications by importers in respect of Regulation 17 of the Non-Automatic Weighing Instruments Regulations 2016 must be made to the Office for Product Safety and Standards.

	T .	
Pyrotechnic Articles (Safety)	Importers – Regulations 16 and 22	the weights and measures authority for Category F1, F2 and F3 fireworks.
Regulations 2015 ⁷	Distributors – Regulations 26 and 27	the Health and Safety Executive for Category F4 fireworks, Categories T1 and T2 theatrical pyrotechnic articles and category P1 and P2 other pyrotechnic articles.
		In Northern Ireland:
		the district council for Category F1, F2 and F3 fireworks.
		The Secretary of State for Category F4 fireworks, categories T1 and T2 theatrical pyrotechnic articles and category P1 and P2 other pyrotechnic articles.
Radio	Manufacturers – Regulation 15	In Great Britain, a weights and measures
Equipment Regulations	Importers – Regulations 22 and	authority
2017	27 Distributors – Regulations 32 and 34	In Northern Ireland, a district council
Recreational	Manufacturers – Regulation 16	In Great Britain, a weights and measures
Craft Regulations 2017	Importers – Regulations 20 and 24	authority In Northern Ireland, a district council
2017	Distributors – Regulations 28 and 31	
The Restriction on the Use of	Manufacturers – Regulation 20	The Office for Product Safety and Standards (rohs@beis.gov.uk)
Certain	Importers – Regulation 26	Standards (10113 @ Bets.gov.dk)
Hazardous	Distributors – Regulation 30	
Substances in Electrical and		
Electronic		
Equipment Regulations		
2012 ('RoHS')	Manufacturers Desided at 40	In Coast Britain
Simple Pressure Vessels (Safety)	Manufacturers – Regulation 13	In Great Britain:
Regulations 2016	Importers – Regulations 19 and 25	-A weights and measures authority for vessels for private use or consumption
	Distributors – Regulations 30 and 33	-The Health and Safety Executive in relation to vessels for use in the workplace

Regulation 20(2)(b) also requires manufacturers or importers placing pyrotechnic articles on the market after 16th October 2016 to transfer the traceability records referred to in Regulation 20(2)(a) to the Secretary of State should they cease to trade within the 10-year period in which traceability records must be maintained. Notifications in this respect should be made to opss.enquiries@beis.gov.uk, after which an officer will contact you to facilitate the transfer.

		In Northern Ireland: -A district council in relation to vessels for private use or consumption -The Health and Safety Executive for Northern Ireland in relation to vessels for use in the workplace
		Insofar as the Regulations apply to vessels intended exclusively or primarily for use on relevant nuclear sites, the Office for Nuclear Regulation
Toys (Safety) Regulations 2011	Manufacturers – Regulation 24 Importers – Regulation 30 Distributors – Regulation 35	In Great Britain, a weights and measures authority In Northern Ireland, a district council

Annex B – Suggested Notification Template

Business Information	
Business Name	
Business Address	
Business Contact (name, contact details and position)	
Company Registration Number	
Business type (manufacturer/ importer/ distributor/ retailer/other)	
Product Identification Inform	ation
Product Category (e.g. Toys, Cosmetics)	
Product Type (e.g. wooden toy, lipstick)	
Brand	
Product Name	
Model/Type	
Barcode	
Batch Number(s)	
Number of Units Affected by Issue	
Product Description	
Country of Origin (where was the product manufactured?)	
Was the product placed on the GB market before 1 January 2021?	
Has the product been placed on the GB market, the NI market, or both?	
Customs Code for Notified Product (https://www.gov.uk/trade- tariff)	

Photograph(s) (product/packaging/ labelling)		
Risk assessment of the notifi	er	
Risk Description/Description of Noncompliance		
Details of any testing undertaken		
Legal provision/s and designated standard/s against which the product was tested and did not comply		
Were there any accidents or incidents related to the product's noncompliance or safety risk? Please provide details		
Duration of noncompliance		
How was the noncompliance identified?		
Have you risk assessed the product? If yes, what was the outcome?		
Corrective actions already ta	ken or planned to take	
Action		
Scope of the actions		
Duration of the actions		
Results of the actions		
Company taking action		
Link to Recall/Measures website		
Are all the products traceable? Have you notified each end-user of the issue?		
Economic operators in the supply chain with affected products		
Names and addresses of relevant companies in the supply chain (manufacturer/ exporter/ importer/ distributor/other)		

Additional Information	
Additional Information of Relevance to Notification	

© Crown copyright 2022

Office for Product Safety and Standards

Department for Business, Energy and Industrial Strategy
4th Floor Cannon House, 18 The Priory Queensway, Birmingham B4 6BS
www.gov.uk/government/organisations/office-for-product-safety-and-standards

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3

Where we have identified any third-party copyright information you will need to obtain permission from the copyright holders concerned.

Alternative format versions of this report are available on request from enquiries@beis.gov.uk