Office for Product Safety & Standards

Product Safety and Noncompliance Notification Guidance

Guidance on product safety and noncompliance notifications for UK market surveillance authorities and enforcement authorities

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Contents

1. Introduction

1.1 This guidance is for market surveillance and enforcement authorities responsible for regulating product safety and legal metrology in the UK and outlines the requirement to notify the Secretary of State if products pose a risk to the health and safety of consumers or products are found to be noncompliant with the relevant product safety legislation.

1.2 This guidance applies to authorities operating in respect of both Great Britain and Northern Ireland markets, and outlines the notification requirements placed on them through legal obligations in:

- Great Britain (GB), the General Product Safety Regulations 2005 (as applicable in GB) and the Regulation on Accreditation and Market Surveillance (retained and amended in GB).
- Northern Ireland (NI), the General Product Safety Regulations 2005 (as applicable in NI) and the Regulation on Market Surveillance and Compliance of Products 2019/1020 (“MSC”) (directly applicable in NI).
- and relevant product specific legislation as they apply in NI and GB.

1.3 Notifications should be made using the Product Safety Database (PSD) and this guidance should be read alongside the PSD user guidance.

1.4 This guidance outlines legally required functions and actions OPSS will take following notification on the PSD, including validation and publication of alerts where required; updating of recall sites; and international reporting.

1.5 It also outlines OPSS’ surveillance function and details any referrals you may receive from OPSS, in addition to support OPSS may be able to provide in coordination with international partners and overseas regulators.

It should be noted that the Government is seeking to find a new balance in the Protocol in order to place it on a more sustainable footing. These proposals, set out in the Government's July 2021 Command Paper (Northern Ireland Protocol: the way forward), include the arrangements covering trade in goods and the institutional framework. This includes a dual regulatory regime in Northern Ireland that would allow goods made to either UK or EU rules to circulate within Northern Ireland, reducing burdens on businesses trying to put goods from Great Britain on the market.

2 Legal requirements to notify product safety risk and noncompliance

The General Product Safety Regulations 2005[1] ("GPSR") and Regulation on Accreditation and Market Surveillance ("RAMS")[2] establish the notification requirements for products found to pose a risk to the health and safety of consumers and/or products that have been found to be noncompliant with the relevant legislation.

General Product Safety Regulations 2005

2.1 Products subject to the GPSR include a product "intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them and which is supplied or made available, whether for consideration or not, in the course of a commercial activity and whether it is new, used or reconditioned." GPSR also "includes a product that is supplied or made available to consumers for their own use in the context of providing a service. "Product" does not include equipment used by service providers themselves to supply a service to consumers, in particular equipment on which consumers ride or travel which is operated by a service provider".

2.2 Regulation 33 (Duty to notify Secretary of State) of GPSR requires that enforcement authorities notify the Secretary of State (BEIS) using the PSD in the following circumstances. When:

- an enforcement authority receives a **notification from a business** regarding an unsafe product they have placed on the market or supplied which poses risks to the consumer that are incompatible with the general product safety requirement; or
- an enforcement authority **takes a measure which restricts the placing on the market of a product**, or requires its withdrawal or recall; or
- an enforcement authority adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, a measure or action to prevent, restrict or impose specific conditions on the possible marketing or use of a product by reason of a **serious risk**.

2.3 In practice, this covers most corrective measures for unsafe and/or noncompliant products.

Regulation on Accreditation and Market Surveillance (Great Britain)

2.4 The Regulation on Accreditation and Market Surveillance (RAMS) as amended by Schedule 33 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 applies in England, Scotland and Wales (GB).

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1 The General Product Safety Regulations as they apply in GB are amended by Schedule 9 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and as they apply in NI are amended by Schedule 3 to the Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020.

2 RAMS applies unamended in NI. RAMS as it applies in GB is amended by Schedule 33 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019. At the time of writing The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 are subject to Parliamentary approval but if approved, they will amend Schedule 33 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, which in turn amends RAMS as it applies in GB.

2.5 Products subject to the market surveillance provisions of RAMS are “a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction”.

2.6 RAMS requires market surveillance authorities to:

- Ensure that products which present a **serious risk** requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Secretary of State for GB is informed without delay.
- Ensure that any decision regarding whether a product represents a serious risk is based on an appropriate **risk assessment** which takes account of the nature of the hazard and the likelihood of its occurrence.
- Where a market surveillance authority or enforcement authority for GB takes or intends to take a measure in accordance with Article 20 it must **immediately notify the Secretary of State** of that measure.

2.7 If a product presenting a serious risk has been made available on the GB market, market surveillance authorities in GB must notify the Secretary of State of any measures taken and communicated by an economic operator.

2.8 For GB and in respect of Articles 20 and 22, measures taken against products presenting a serious risk must be notified to the Secretary of State by the relevant MSA and this obligation is fulfilled by a notification on the PSD.

2.9 Additionally, measures taken against unsafe and noncompliant products at the border, such as those detailed in Article 29, should also be notified on the PSD. This does not replace any additional reporting requirements under grant funding arrangements.

EU Regulation on Market Surveillance and Compliance (MSC) of Products (Northern Ireland)

2.10 From 16 July 2021, the EU Regulation on Market Surveillance and Compliance of Products (MSC) applies in Northern Ireland.

2.11 These regulations change the scope of notifications and reporting required in respect of Northern Ireland. As under RAMS, there are requirements to notify in the case of a serious risk which must be assessed based on an appropriate risk assessment (Articles 19 and 20 MSC). Measures taken in respect of dangerous and noncompliant products at the border (under Article 28 MSC) must also be notified.

2.12 In addition to the requirements outlined above, MSC also requires under Article 34 that MSAs must report all relevant information (including results of testing, identification of risks) and measures taken where an in-depth compliance check has taken place, including where the product is judged to be compliant.

2.13 This is wider than the previous RAMS requirement to report all information for products presenting a risk. While Articles 28 and 34 MSC relate to ICSMS rather than RAPEX, all information required for reports under MSC must be reported to the PSD and OPSS will forward the notification to the appropriate system.

2.14 For further information on notifications and reporting in respect of Northern Ireland, please view Annex B.

Sector-specific legislation

2.15 Where market surveillance authorities for GB are required to notify the Secretary of State of an unsafe or noncompliant product as required through provisions in sector-specific product safety legislation, they should do so using the PSD, as outlined in Regulation 33 of GPSR.

2.16 The above requirements outline the legal minimum for product safety notifications; OPSS encourages authorities to make full use of the PSD to support information sharing; enable the development of comprehensive data sets for product safety issues; and reduce duplication of effort across authorities. OPSS particularly encourages all product recalls to be notified and published, to allow greatest access to information on unsafe and recalled products for consumers.

3 Notifying the Secretary of State using the Product Safety Database (PSD) – the Role of the Market Surveillance Authority

3.1 Market surveillance authorities should use the Product Safety Database (PSD) to notify the Secretary of State of measures taken where a product presents a risk to the health and safety of consumers or is noncompliant, and any further modification to these measures.

3.2 The PSD is a database that enables market surveillance authorities to report and share information relating to unsafe and noncompliant products. The PSD is not an intelligence database; current procedures for the recording and dissemination of intelligence are not impacted by this guidance and continue to be in line with legislative requirements and national guidelines.

3.3 Notifications should be made on the PSD where:

- A notification to the Secretary of State is required in product safety legislation, as outlined in Section 2;
- There is an established risk across an entire product line and action is taken to mitigate against that risk;
- You are planning to undertake an investigation and/or commission testing, to be able to share your results and prevent duplication of effort. OPSS encourages MSAs to notify early and update cases as they progress, to ensure other authorities are aware that an issue is being investigated – however, cases should not be left open indefinitely.

3.4 Sharing of intelligence via an intelligence database such as IDB would be more appropriate where:

- You've been made aware of or have identified a potential issue relating to a business, individual or product and need to make the relevant authority aware;
- You've been made aware of an individual consumer incident and need to make the relevant Primary Authority or home authority aware.

3.5 You can add a 'case' to the PSD to notify an unsafe and/or noncompliant product to the Secretary of State – this will fulfil the legal requirements to notify outlined in Section 2.

3.6 **Notifications should provide all available details**[3], and at least the following information, as required in Article 22 RAMS and Regulation 33(1) and 34 GPSR in GB, or in Northern Ireland Article 20 MSC, once the corrective measure has been decided or undertaken:

- information enabling the **product** to be identified;

[3] If you are adding OPSS Incident Management to a case to request publication or international coordination, please ensure these details are present on the case before doing so. If these details are not available, please specify this when adding OPSS to the case and outline exemptions or timescales for anticipated provision of further information.

- a **description of the risk** involved, including a summary of the risk assessment, and the supporting evidence, such as results of any **test or analysis** and of their conclusions which are relevant to assessing the level of risk;
- the nature and duration of the **measures or action** taken or decided on; and
- information on **supply chains and distribution** of the product.

3.7 The new Product Safety Risk Assessment Methodology (PRISM) is for use by market surveillance authorities in Great Britain with responsibility for consumer product safety[4]. Authorities in GB should now be using the PRISM methodology by routine. Further information on PRISM, including a list of products and hazards deemed serious risk and some example risk assessments, can be found at the following link:

https://www.gov.uk/guidance/product-safety-risk-assessment-methodology-prism

3.8 Detailed and individual risk assessments are not always required where it falls within scope of 'Products and hazards deemed serious risk' listed on the PRISM page. This includes where:

- The notification is for a product presenting a chemical risk where the product contains a chemical substance that is either prohibited or at a level that exceeds a prescribed legal limit
- The notification is for a Category III PPE product is found to be noncompliant for any reason
- The notification is submitted for a product with hazards of a specific type that have been assessed by OPSS as presenting a serious risk, for example as part of a Product Safety Alert.

3.9 OPSS can provide support with product safety risk assessment in the form of a 'critical challenge' of your draft assessments. Please contact lau.opss@beis.gov.uk with details of your request and any applicable PSD case reference numbers and the relevant officer will get back to you. There may be instances in which not all requests can be fulfilled, and in these circumstances, support will be prioritised for the most complex/urgent cases.

Adding OPSS to cases and publishing alerts

3.10 If the product poses a **less than serious risk** and has not been recalled, you may close the case once the measures taken are complete and there is no further activity anticipated. Less than serious risk products can be included on the Product Recalls and Alerts website(section 4.10) upon the MSA's request; this can be requested by adding OPSS Incident Management to the case prior to closure and requesting its inclusion in the message box provided. OPSS encourages the use of this resource where a product safety matter warrants a public-facing alert, and particularly for business generated recalls.

[4] Authorities operating in Northern Ireland are required to continue to use the RAPEX Risk Assessment Methodology.

3.11 If the product has been **recalled**, it should be added to the Product Recalls and Alerts website and the OECD Global Recall Portal. You should add OPSS Incident Management Team to the case on the PSD requesting its addition in the message box provided and OPSS will complete this for you. The case can be closed when all measures and public facing alerts have been completed.

3.12 If the product poses a **serious or high risk** to the health and safety of consumers as determined by a risk assessment you must add OPSS Incident Management to the case, stating the notification is for a product presenting a serious/high risk and therefore requiring validation and publication on the Product Recalls and Alerts website.

3.13 OPSS monitors all new product safety notifications added to the PSD – if OPSS identifies a notification where a public-facing alert is recommended, or a product presents a serious risk or has been recalled and IMT have not been alerted to this, they may contact the MSA to follow up and request consent for publication.

3.14 Please ensure that whenever you add OPSS Incident Management to a PSD case, you add the requested action in the provided message box and ensure all required details are present to avoid unnecessary delays. For example, if you notify OPSS Incident Management team of a serious/high risk product or of a product recall for inclusion on the Product Recalls and Alerts website you can add “Please publish this on the Product Safety Report” in the message box.

3.15 For further information on how market surveillance authorities should use the Product Safety Database, please see the PSD user guidance at the following link:

https://www.product-safety-database.service.gov.uk/help/about.

3.16 If you have any questions relating to the PSD, notification requirements and the publication of alerts, please contact opss.enquiries@beis.gov.uk.

4 Post-Notification Actions and Requirements – The Role of OPSS

4.1 OPSS has taken responsibility for a number of functions and responsibilities following EU Exit to ensure market surveillance authorities are able to fulfil their legal requirements to:

- Make information relating to unsafe and recalled products available to the public; and
- Report unsafe and noncompliant products with a cross-border supply chain to other countries where required in international law, including the EU-UK Trade and Cooperation Agreement, Northern Ireland Protocol, Withdrawal Agreement and free trade and mutual recognition agreements with market surveillance information sharing provisions.

4.2 The UK Product Safety Contact Point (UKCP), part of the Incident Management Team, are responsible for monitoring the PSD and undertaking any actions required, as set out in the remainder of this section. The UKCP can also provide advice on reporting requirements, use of the PSD, and liaison with overseas regulators.

4.3 The procedures for market surveillance authorities acting in respect of Northern Ireland are detailed in Annex B.

4.4 OPSS may also use information notified on the PSD for monitoring and horizon scanning purposes.

Validation of Product Safety Notifications

4.5 OPSS has implemented a validation function which must be completed before alerts are published on the Product Recalls and Alerts website. The validation function consists of three interrelated elements, and primarily acts as a check to ensure notifications have been fully completed; sufficient evidence is available to support the product's notification; and that no commercially sensitive or otherwise sensitive information is disclosed when the notification is published.

4.6 The three elements of the validation are:

- Data validation: a quality assurance of information and data provided to ensure all notification components are present, as outlined in 3.6.
- Risk validation: a review of the risk model (sometimes referred to as steps to injury) and the supporting information provided (test reports or visual inspection statements). This element aims to ensure risk is being considered and applied consistently by market surveillance authorities and does not constitute an endorsement of the risk assessment.
- Incident validation: a consideration of whether the safety issues identified may fall under nationally significant, novel or contentious criteria, as outlined in the OPSS Incident Management Plan.

4.7 Market surveillance authorities may be asked for additional information or to clarify certain elements of the notification during this validation stage. To streamline the validation process, MSAs should ensure the four categories of information outlined in 3.7 are provided before the product is notified to OPSS Incident Management.

4.8 Once a product safety notification has been validated by OPSS Incident Management, this will be reflected on the 'Overview' tab of the PSD case page and the notifying authority will receive an auto-generated email notification.

Publication of Alerts

Product Recalls and Alerts website – Gov.uk

4.9 OPSS publishes information on unsafe products notified on the PSD where they have been identified as presenting a serious or high risk or have been recalled, where these have been notified to OPSS Incident Management on the PSD and validated.

4.10 Notifications for serious and high risk products or those that have been recalled, should be notified to OPSS Incident Management and published included by routine. Publication of products outside of these criteria but where publication of product safety information will be of benefit to the public is also encouraged i.e. where product identification information is detailed; where large unit numbers are affected by the safety risk; or where the corrective measure has been applied to a known brand.

4.11 A template outlining the PSD fields and equivalent categories on the Product Recalls and Alerts website. and hence those that are publishable can be found in Annex A. OPSS may edit the content of certain fields for clarity and accessibility to ensure greatest benefit to the public, but encourage MSAs to notify clear, concise and publication-ready content on the PSD notification.

4.12 The new Gov.uk Product safety alerts, reports and recalls page includes a subscription service. If you would like to receive notifications/alerts of Product Safety Reports, recalls and safety alerts, please click the "subscribe to feed" button on the right of this page https://www.gov.uk/product-safety-alerts-reports-recalls.

OECD Global Recall Portal

4.13 The OECD Global Recall Portal brings together information on product recalls issued around the world on a regular basis in this one OECD-held platform. The portal includes information on consumer product recalls issued by a governmental body and made publicly available.

4.14 The portal is used by regulators in taking corrective actions; consumers in checking for safety concerns around products they are intending to purchase; and businesses to track emerging hazards and risks around the world.

4.15 OPSS manages the UK's input into this resource, adding PSD notifications for recalls where information is publicly available and the case has been notified to IMT and/or UK recalls are identified through other routes, such as direct requests from businesses or trade associations.

International Reporting and Market Surveillance Data Exchange

4.16 Since the end of the Transition Period, requirements and procedures for reporting of unsafe and noncompliant products, and market surveillance outcomes, have changed.

4.17 In multiple pieces of international law, UK market surveillance authorities are required to report information relating to unsafe and noncompliant products to other countries, including the EU, on a reciprocal basis.

4.18 To operationalise these requirements in a consistent, streamlined and central format, and as reports relate to the same safety issues and market surveillance outcomes that should already be notified by MSAs on the PSD, OPSS will fulfil these reporting requirements through ongoing monitoring of new PSD cases. MSAs need take no action to ensure these requirements are met.

EU Information Exchange

4.19 There are multiple routes and mechanisms by which UK MSAs can, and in some cases must, share information relating to unsafe and noncompliant products with the European Commission and EU Member States.

4.20 Article 43.1 of the Withdrawal Agreement commits the UK and the EU to exchanging relevant information on serious risk and noncompliant products where the product was placed on the market before 1 January 2021 and there is an EU-based economic operator in the supply chain (UK-based for EU reports). OPSS exchanges information on the UK's behalf through the monitoring of new PSD notifications and collation of reports which are exchanged on a weekly basis.

4.21 In circumstances where there are cross-border product safety issues out of scope of the above arrangement, it is possible to exchange or request information with individual Member States through national contact points. If you would like OPSS to support with this, please add OPSS Incident Management to the case outlining the issue in the message box or contact ukproductsafetycp@beis.gov.uk.

4.22 The EU-UK Trade and Cooperation Agreement made provision for a RAPEX-PSD data sharing agreement, which is currently in negotiation. This guidance will be updated with information relating to the operationalisation of this agreement once it has been finalised and implemented.

4.23 Market surveillance authorities operating in respect of Northern Ireland are also required to continue reporting to the European Commission on RAPEX and ICSMS under the Northern Ireland Protocol. As agreed with the EU, OPSS will do this on behalf of MSAs operating in NI. Further details on Northern Ireland procedures can be found in Annex B.

Non-EU Information Exchange

4.24 The requirement exists in some of the UK's trade agreements for the Government to report when market surveillance authorities take enforcement action against goods originating from the territory of specific trade partners. To fulfil these obligations to the extent required by the agreement, it is necessary that all enforcement action taken by UK market surveillance authorities is notified on the PSD.

4.25 OPSS will undertake this legal obligation on behalf of UK market surveillance authorities through the monitoring of PSD notifications. MSAs do not need to undertake any action to fulfil these requirements but must ensure all relevant information is added to the PSD, as outlined in Section 2.

5 Additional UK Product Safety Contact Point functions

5.1 The UK Product Safety Contact Point (UKCP) also undertakes a number of additional functions to support UK market surveillance authorities. This includes receiving statutory reports for unsafe products from other countries and triaging for UK impact; monitoring and operating a surveillance function for product safety and recall activity overseas; and facilitating engagement with overseas regulators on specific cases and issues.

5.2 Through these functions it may become apparent that there are risks associated with products identified on the UK market. In this instance, the matter will be referred to lead market surveillance authorities.

5.3 Market surveillance authorities should anticipate referrals from OPSS (and other MSAs) through the PSD. When referrals are made, an email notification will be received into the shared mailbox address you provided when you signed up to the database. If you do not know which email address was provided, please contact the PSD team administrator within your authority or email opss.enquiries@beis.gov.uk.

Overseas Liaison and Engagement

5.4 Where OPSS receives reports on unsafe and noncompliant products with a cross-border effect through arrangements outlined in Section 4, the UKCP will triage all reports to assess relevance to the UK market.

5.5 Where a UK-based producer, importer or distributor is identified in the product's supply chain, or if the product is identified as on sale in the UK via online market surveillance, the notification will be added to the PSD and referred to the relevant authority for follow up as they deem appropriate. The Primary Authority Register will be consulted to identify preferred method of contact for primary authorities, but a PSD case will also be created in parallel to ensure a complete record on the PSD.

5.6 If an unsafe product has been notified and measures have already been taken in the UK, the case will be added to the PSD by the UKCP and will not be referred, but relevant authorities may be made aware of the action taken for information purposes by adding them to the case.

International Monitoring

5.7 The Contact Point also operates an international monitoring function, identifying and triaging product safety alerts published by EU and non-EU countries and new recalls on the OECD Global Recall Portal.

5.8 Where the product is identified as available on the UK market or otherwise presents a risk to UK consumers and is believed on initial triage with available information to also be noncompliant with UK safety regulations, the Contact Point will ensure the relevant market surveillance authority is made aware and, if appropriate, make a referral via the PSD.

5.9 If a UK-based economic operator is identified in the product's supply chain or the product is identified as on sale in the UK via online surveillance, the case will be referred to the relevant authority for follow up as they deem appropriate. The Primary Authority Register will be consulted to identify preferred method of contact for primary authorities, but a PSD case will also be created in parallel to ensure a complete record on the PSD. OPSS does not set the case risk level as this function is intended to be in relation to the UK-assessed risk level for any UK measures taken.

5.10 If the product is available on the UK market but there is no UK-based economic operator in the supply chain, OPSS will follow up on the issue through direct liaison with overseas economic operators and liaison with national product safety regulators in other countries, as required.

5.11 Should the relevant authority follow up with the economic operator following a formal report from another country or international surveillance, OPSS request that the relevant PSD case is updated with findings to ensure other MSAs are aware of the action taken. This function acts as a national resource and service and any follow up investigation or enforcement activity undertaken subsequent to a UKCP referral is at their own discretion and as they deem appropriate. A referral made to an MSA does not indicate that it has been formally ascertained that a product does not comply with UK regulations as this is for the MSA to confirm with the economic operator following the referral.

Domestic Surveillance

5.12 OPSS also reviews domestic sources of information relating to unsafe and recalled products within the UK, including stakeholder websites such as the Electrical Safety First recall site.

5.13 If the product has not been notified on the PSD and is found to be present on the UK market and is produced, imported or distributed by a UK-based economic operator, the Contact Point will contact the relevant authority by email to ensure it is aware of the issue and request notification on the PSD, as outlined in the legal requirements applicable to market surveillance authorities in Section 2.

Annex A – Publication Template

The below template outlines the format of PSD notification alerts that are publishable on the Product Safety Alerts, Reports and Recalls site. The italicised text in the body of the alert outlines the PSD fields that are extracted to produce the reports.

The body of the alert may be supplemented and/or summarised for consistency and clarity but it is requested that authorities provide information to a publishable standard to reduce intervention.

Should an authority wish to provide a completed template, or review a drafted alert prior to publication, please contact ukproductsafetycp@beis.gov.uk.

OPSS will ensure that all alerts are consistent and no information that is sensitive and protected under GDPR will be disclosed.

Brand/Product Name/Model	
Aspect	**Details**
Images	*Product Image*
Alert Number	*PSD Case Number*
Product Type	*Product Category – Product Subcategory*
Product Identifiers	*Product Brand, Barcode Number, Batch Number, Other Product Identifiers*
Product Description	*Product Description*
Country of Origin	*Country of Origin*
Counterfeit	*Product Authenticity*
Risk Level	*Case Risk Level*
Risk Type	*Hazard*
Hazard	*Test Results/Description of Hazard/Legislation*
Corrective measures	*Type of Action*
Online Marketplace	*Online Marketplace Name / Delisting Information*
Notifier	*Notifying Authority*

Annex B – Northern Ireland Market Surveillance Authorities

The above notification requirements, processes and procedures apply to all UK market surveillance authorities, including those acting in respect of the Northern Ireland market.

Market surveillance authorities with responsibility for the Northern Ireland market are also subject to additional requirements, primarily those relating to the scope of product safety and compliance notifications that must be reported, and use of EU market surveillance IT systems, which are outlined in this section.

It should be noted that the Government is seeking to find a new balance in the Protocol in order to place it on a more sustainable footing. These proposals, set out in the Government's July 2021 Command Paper (Northern Ireland Protocol: the way forward), include the arrangements covering trade in goods and the institutional framework. This includes a dual regulatory regime in Northern Ireland that would allow goods made to either UK or EU rules to circulate within Northern Ireland, reducing burdens on businesses trying to put goods from Great Britain on the market. This would mean that the proposed rules as set out in this annex would apply only if manufacturers wished to make goods to EU rules to access the EU as well as the NI market.

Scope of required notifications

The EU Regulation on Market Surveillance and Compliance of Products (2019/1020) comes into effect in the EU on 16 July 2021. For as long as the NI Protocol is in place, these rules will also apply in NI.

The Regulation has expanded the scope of product safety and compliance matters that must be reported. In addition to the requirements outlined in Section 2, it also requires under Article 34 that MSAs must report all relevant information (including results of testing, identification of risks) and measures taken where an in-depth compliance check has taken place, including where the product is judged to be compliant. This is wider than the previous RAMS requirement to report all information for products presenting a risk. While Article 34 relates to ICSMS rather than RAPEX, all information required for reports under the new Regulation must be reported to the PSD.

Procedure for notifications

To avoid the need for Northern Ireland market surveillance authorities to notify on multiple systems, OPSS has agreed with the European Commission that NI MSAs will notify products to OPSS on the PSD, with OPSS undertaking any subsequent required notification to the EU.

To ensure cases are finalised before they are notified, NI MSAs should add OPSS Incident Management to the PSD case once the measure has been taken, noting that the notification relates to Northern Ireland in the message box provided. This is usually interpreted where either the market surveillance authority enforcing the measure or undertaking the market surveillance project is located in Northern Ireland, or if the economic operator is based within Northern Ireland.

OPSS will then report the product on RAPEX (for serious risk products) or ICSMS (for less than serious risk, noncompliant or safe and compliant products).

Access to EU information

OPSS and NI MSAs do not have access to RAPEX notifications by default, but non-public information relating to a serious risk notification can be requested from the European Commission by exception. Should an MSA require non-public information relating to a RAPEX notification in relation to their responsibility for the NI market, the request should be sent to ukproductsafetycp@beis.gov.uk, who will request this information from the European Commission in their capacity as UK RAPEX Contact Point.

OPSS, NI MSAs and certain officers in national regulators with responsibility for the NI market have been provided with partial access to ICSMS. Authorities can access ICSMS to search for information relating to notified products and communicate with other market surveillance authorities.

Cooperation with EU Member States and their Market Surveillance Authorities

MSC also outlines the way in which the European Commission, EU Member States and their authorities should communicate, collaborate and exchange information with each other in relation to market surveillance. NI MSAs should anticipate requests for information, mutual assistance or enforcement by EU MSAs through automated ICSMS alerts; these should be received into the shared team mailbox supplied when being onboarded to the system in December 2020.

If you require any support or advice relating to liaison with EU MSAs and reporting in respect of Northern Ireland, please contact the Single Liaison Office at OPSS-SLO@beis.gov.uk.

Annex C – PSD and Notifications Frequently Asked Questions

The below questions and answers document has been produced following the five Product Safety Database and notifications training sessions held in February/March 2021, in addition to other queries received by OPSS. If you have further questions relating to the Product Safety Database or notifications, please email ukproductsafetycp@beis.gov.uk.

Product Safety Database

Q. If the local authority PSD administrator is unavailable, can someone else undertake the admin functions and grant permissions for new staff?
A. Please email opss.enquiries@beis.gov.uk in this instance and OPSS can either set up a new admin or undertake any required admin functions.

Q. How do notifications and referrals reach the user? Are they sent by email or does the user need to be logged on and receive a notification on-system?
A. To help teams manage their investigations, cases can be owned by the whole team, or a specific individual within the team. Users can also choose to add a shared mailbox to their team. If there's a shared mailbox added to the team, notifications will be sent there. If there isn't a shared mailbox in place, some notifications will be sent to the whole team, even if the case is owned by an individual. In either case, users do not need to be logged in to PSD to receive notifications.

Q. Is there an easy way to export cases and attachments?
A. You can download individual attachments where these are visible to you when using the service, but should seek permission when using attachments from the notifying authority beforehand. If individuals in your authority would benefit from seeing full case information, we would encourage you to onboard them to the service where possible. Please ensure you store and use attachments in line with relevant data protection policies.

Q. Why are some cases restricted and not visible to MSAs?
A. The PSD has a 'restriction' function which ensures that case information is not viewable by other system users (including local authorities, OPSS and other national regulators). A circumstance where restricting a case would be appropriate would be where you are currently undertaking legal proceedings, and visibility may impinge upon these proceedings. However, this should be the minority of cases and we do encourage authorities to be as open as possible to make the service of as great a benefit as possible to other users.

Q. If you haven't created the case but another MSA has, can you add your own local reference number to the case for cross-referencing purposes?
A. It is not possible to add a secondary case reference number in the TS reference number field, but you may find it helpful to add your reference number as a comment on the Activity Tab.

Q. Does the PSD allow you to skip fields and return later to complete and save the data already entered?
A. Some fields, such as the initial product identification fields, must be completed when adding a case, but most of the others can be skipped and supplemented later. OPSS does, however, request that cases are not left with minimal information for long periods of time.

Q. Is there an option to find cases where an MSA has been added to a case?
A. Yes – a new feature has recently been implemented and you can filter by cases your authority has been added to using the filter on the left hand side of the PSD overview page.

Q. When searching for products and/or businesses that are currently or have been investigated, can you add an unsafe product notification to an existing business, or add an existing business to a notification?
A. Currently, when notifying a new business or product, this will create a new isolated incidence of both. OPSS are currently working on aligning the data so one business can be linked to multiple cases etc – you should see updates on-system in due course.

Q. Does the security pin received via SMS need to be input each time the service is accessed?
A. Once input, the SMS security code should not be required on the same device for seven days, unless the browser session is closed.

Q. Will PSD upload fields only accept PDFs?
A. No – the upload fields should accept most file types, including Zip files, Word documents, Excel files, various image types and emails. For documents, OPSS encourages PDFs to be uploaded rather than word documents so they cannot be altered.

Q. Is there a limit to the size of documents uploaded?
A. 100MB is the size limit for documents.

Q. Can you please advise who can access and download supporting documents (for examples test results or risk assessments)?
A. If a case is restricted, no individuals outside of your team can access any information. If a case is not restricted, individuals outside of the team can see test report and risk assessment attachments, but will not see other supporting information, such as if you added a piece of correspondence or a Declaration of Conformity as 'supporting information'. If you are added to a case, you can see all case information.

PSD Team Administrators

Q. How do I know if I am my team's PSD administrator?
A. Click on 'Your team' in the top right corner of the page. If you can see a green button stating, 'Invite a team member', you are an administrator.

Q. How do I give colleagues access to PSD?
A. Click on 'Your team' in the top right corner of the page. There will be a green button stating 'Invite a team member', which you can click and enter their email address. The individual will receive an invite to join via email.

Q. I am a PSD team administrator – how do I remove colleagues that no longer require access (i.e. those that have left)?
A. Please email opss.enquiries@beis.gov.uk requesting their removal and include details of the user requiring account deletion (email address, reason of access removal).

Notification Procedures and Requirements

Q. Does adding a case to the PSD effectively notify the Secretary of State?
A. Yes, although if a product presents a serious risk or the MSA wishes the alert to be published on the Product Safety Alerts, Reports and Recalls site, the MSA *must* add OPSS Incident Management to the case and outline the requested OPSS action to complete. The notification process is complete once this action has been taken.

Q. Should MSAs notify on the PSD before the receipt of test results to substantiate concerns?
A. Notification on the PSD is required in law where there is an established risk or noncompliance against an entire product line. However, OPSS encourages authorities to begin a notification on the PSD early so other authorities are aware that another authority is looking into an issue. As the investigation progresses, the case will remain open in the authority's name and can be

updated with information on test results, risk assessments and corrective measures when this becomes available. If you find the product to be safe and compliant, you can amend the safety and compliance information on the overview tab to reflect this finding.

Q. If a local authority identifies an issue and makes a referral to the Primary Authority, should the local authority notify on the PSD or should the Primary Authority do this once the risk is established and the measure taken?
A. Notifications should be submitted by the authority who is investigating the product and establishes the risk and/or enforces/monitors the corrective action decided or taken.

Q. When a local authority identifies a potential product safety issue with a product which has not yet been tested and needs referring to another local authority for intelligence purposes, should the PSD be used in this scenario or should this information be passed via email or through. Intelligence databases such as IDB?
A. Notification on the PSD is required where there is an established risk or noncompliance across a product line and a measure has been taken to mitigate this risk/correct the noncompliance. Where there is intelligence relating to a product suspected to be unsafe, this should be referred to the relevant authority through existing intelligence processes (e.g. IDB) or via email, ensuring relevant data protection policies and procedures are followed. If the matter relates to a Primary Authority, authorities may wish to check the Primary Authority Register in the first instance to check whether there are preferred/requested mechanisms in place for referrals.

Q. How do we determine if a measure is permanent or temporary?
A. The majority of measures will be permanent in nature e.g. a company is encouraged to honour a recall as long as there are affected products on the markets/in consumers' homes, or be withdrawn from the market on a permanent basis. Similarly, destruction at the border will be a permanent measure. Temporary measures may include measures where a suspension has been placed on the sale of products, or there is a specified time period in which a corrective measure will be undertaken.

Q. Who sets the case risk level for a notification?
A. Market surveillance authorities should set the case risk level for all notifications of unsafe products. The case risk level is usually determined by the MSA's consideration of risk level when determining the appropriate corrective action in the course of enforcement activities, as based on a risk assessment or risk model. However, the case risk level can also be set based on the business's risk assessment if the measure is voluntary and you agree with their risk conclusion. Authorities should set the case risk level for all PSD cases before closure or before adding OPSS Incident Management to a case. OPSS are only able to validate a case (a necessary step before publication) if the MSA sets the case risk level beforehand.

Q. Is it just MSAs who can make notifications on the PSD or can companies refer unsafe products or make their own recall notifications?
A. The regulations require economic operators to notify the appropriate authority, which in most cases will be local enforcement authorities. Enforcement authorities are listed in legislation as being the body that must notify the SoS on the PSD. Only enforcement authorities have access to the PSD. Guidance for businesses on meeting their notification requirements has been produced and is available at the following link:
https://www.gov.uk/government/publications/business-notifications-of-unsafe-and-noncompliant-products

Q. Can we still submit a notification if we don't have all of the information listed in Article 20 RAMS (or in NI, Article 20 MSC) available?
A. Yes – OPSS acknowledge that in some cases, not all of the information will be available to you. These notifications should continue to be reported, but if there are significant gaps in information provided, OPSS may take the decision to not include on the Product Safety Alerts,

Reports and Recalls site (see 4.8-4.12 for further information on the Product Safety Alerts, Reports and Recalls site).

Q. Can you add more than one distributor/importer to each case?
A. Yes. Once a case is created, you can access the 'businesses' tab of the case and select 'add business'.

Q. If an MSA rejects a consignment at the border, is there a way of adding the whole brand of goods and including a packing list, or would each product need to be added individually?
A. OPSS requests all products are added individually, as this ensures that products and brands are searchable and allows accurate statistics to be generated to feed into the broader product safety intelligence picture. For example, if only a packing list covering multiple types and models of products was included, the search function would not be able to identify this and several consignments would appear to only evidence one market surveillance intervention.

Q. When should a case be closed?
A. A case should be closed when there is no further activity anticipated relating to the case and any required notification to OPSS Incident Management is completed. If you have requested an action from OPSS, please wait until that has been completed before closing the case.

Q. When would legal metrology instruments be added to the PSD?
A. The reporting requirements outlined in RAMS (or in NI, MSC) and GPSR can apply to measuring equipment; notification on the PSD would be required if a piece of measuring equipment presents a safety risk. The Office for Product Safety and Standards are the market surveillance authority in Great Britain and the Department for the Economy are the market surveillance authority in Northern Ireland, and this reporting requirement will likely be fulfilled by these authorities only.

Q. On ICSMS, there was the possibility of adding 'safe' products – for example, if you had a market surveillance testing project, you could add the 'positive' results for future searching/reference. The linear inputting of PSD doesn't seem to allow that. Is that correct? Is it an exclusively 'issues' database?
A. While notification of safe and compliant products is not required in legislation in respect of GB, we do encourage authorities to notify products they have found to be safe and compliant following inspection and/or testing so other authorities are aware that a product has been tested and found to be safe. When adding a new case to the PSD, there is an option to add a case as 'unsafe', 'noncompliant' or 'safe and compliant'- the latter would be the appropriate selection for this scenario.

Q. Is PSD only intended for practical testing of products, or also where administrative checks e.g. on Declarations of Conformity, are undertaken?
A. For GB authorities, notification on the PSD is measures based – if a measure has been taken following an identified safety issue or noncompliance identified by visual inspection or documentary checks, this would need notification as if the product had been formally tested at a test house. In respect of NI, any investigation including administrative checks should be recorded, as set out in Annex B.

OPSS Functions

Q. Is it preferable to use the PSD or email OPSS when requesting assistance?
A. All enquiries and requests for support from local trading standards authorities should be routed to the OPSS Local Authority Unit, who are contactable via lau.opss@beis.gov.uk and can coordinate required responses. Non-local authority users requiring PSD support specifically should contact ukproductsafetycp@beis.gov.uk. .

Q. Has OPSS provided information on products in scope of the serious risk rating, including examples?
A. Examples of products previously notified as serious risk can be found on the Product Safety Alerts, Reports and Recalls site and previous UK notifications on Safety Gate (https://ec.europa.eu/safety-gate-alerts/screen/webReport). All serious risk notifications should be supported by relevant evidence and a risk assessment, which will be considered on a case by case basis.

Q. When we set the risk level for a notification, is an individual risk assessment required for each product notified?
A. The product safety framework in the UK is risk-based, with appropriate corrective measures being determined and justified by the enforcement authority's consideration of risk presented to the consumer or user. However, we do recognise the practicalities surrounding this, so fuller risk models should be prioritised for those products presenting the greatest risk in the first instance. The risk level does not need to be set for products that are only noncompliant, but should always be set for product presenting a safety risk.

Q. When is it appropriate for the publication of a less than serious risk product to be included on the Product Safety Alerts, Reports and Recalls site?
A. It is at the market surveillance authority's discretion whether a product should be included on the Product Recalls and Alerts website but it is recommended particularly where (a) a product has been recalled; (b) a measure has been conducted voluntarily; (c) there is sufficient product identification information to be of benefit to the consumer; (d) there would be benefit to the consumer in having this information made available in a public facing forum; or (e) publication on the unsafe product report will promote greater regulatory outcomes, such as online marketplace delistings. OPSS are encouraging use of this resource on a more frequent basis by MSAs to cover a greater proportion of total notifications.

International Reporting and Coordination

Q. Have product details from ICSMS been carried over to the PSD?
A. It was not possible to transfer data from ICSMS to the PSD before the end of the Transition Period.

Q. Have all UK Market Surveillance Authorities had their access to ICSMS removed now the end of the Transition Period has passed?
A. Partial access to ICSMS has been provided to Market Surveillance Authorities based in Northern Ireland and to certain officers in national regulators to permit them to notify market surveillance activity in respect of Northern Ireland and access information relating to unsafe and noncompliant products as part of the Northern Ireland Protocol. This has involved the creation of a new country name on ICSMS, 'United Kingdom (Northern Ireland)' with all previous accounts deleted. Therefore, ICSMS users outside of new post-TP arrangements will have had their access rescinded and accounts deleted.

Q. Do Northern Ireland MSAs have to report on both ICSMS and the PSD?
A. Northern Ireland authorities continue to be required to report to the European Commission as required by the Northern Ireland Protocol. To ensure Northern Ireland authorities don't have to report the same product in two places, OPSS has agreed with the European Commission that OPSS will report on ICSMS on behalf of NI authorities once a case has been notified on the PSD and IMT have been added to the case.

Q. Will Northern Ireland authorities be passed batons from EU27?
A. Possibly, and in this instance your team mailbox will receive an email alert. It is likely that any baton will be passed to the UKCP in the first instance, however, and OPSS will be in contact with you directly.

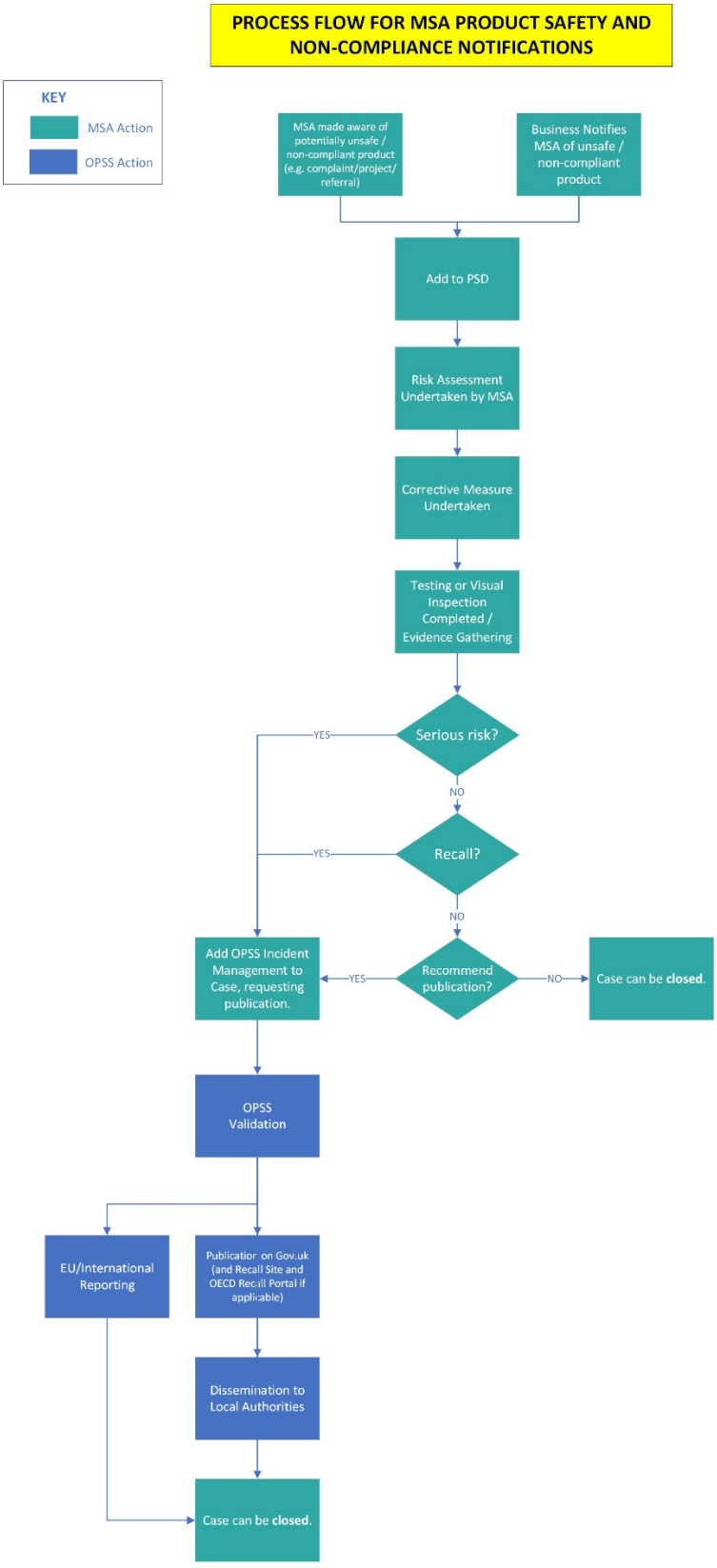
Miscellaneous

Q. Will OPSS be routinely cross-referencing product safety notifications with online marketplaces such as eBay and Amazon?
A. As part of the EU Product Safety Pledge, online marketplaces have committed to consulting information on recalled and dangerous products from various sources including the Gov.uk Product Recalls and Alerts website and OECD Global Recall Portal, and taking appropriate action in respect of products concerned, where they can be identified. Where MSAs submit notifications to OPSS Incident Management for validation and publication, OPSS will check to identify where the affected product remains on sale in the UK, including on online marketplaces, and make relevant referrals to online marketplaces, Primary Authorities or local authorities as required. However, notifications will not always be retrospectively checked post-validation and post-publication.

Q. Can you explain how to notify measures taken by online marketplaces on the PSD, and has OPSS published guidance on requiring overseas sellers to recall products before notifying a recall on the PSD?
A. Online marketplaces that have signed up to the EU Product Safety pledge regularly monitor RAPEX, the UK Product Recalls and Alerts website and the OECD recall portal, and where a product sold on their marketplace has been notified, they remove the listing and introduce a rule to ensure that this unsafe product cannot be relisted. Where a notifying authority has required a seller to recall in relation to the product and the risk posed it will prompt platforms to require their sellers to “recall from end users”. In some instances, they may also recall the product on behalf of their sellers if the sellers do not recall the products themselves.

If you have further questions relating to the PSD and product safety notifications, please contact ukproductsafetycp@beis.gov.uk. This guidance will be updated with further frequently asked questions.

Annex D – Notification Flow Chart for UK Market Surveillance Authorities



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