



ENVIRONMENT POLICY DEVELOPMENT AND SCRUTINY PANEL

PRODUCT SAFETY INCIDENT MANAGEMENT PLAN

REPORT BY HEAD OF PLANNING, ECONOMIC DEVELOPMENT & REGENERATION

A. PURPOSE OF REPORT

The purpose of this report is to make the panel aware of the draft Product Safety Incident Management Plan that has been developed in line with guidance from the Office for Product Safety & Standards.

B. RECOMMENDATION

It is recommended that the panel notes and considers the draft Product Safety Incident Management Plan as detailed in Appendix 1 of this report which is intended to be presented to the Council Executive with the following recommendations:

1. Notes the content of the report and the Product Safety Incident Management Plan.
2. Approves the Product Safety Incident Management Plan.
3. Approves any future amendments to the plan being approved by the Environmental Health and Trading Standards Manager.

C. SUMMARY OF IMPLICATIONS

| | | |
|------------|--|--|
| I | Council Values | Being honest, open and accountable; making best use of our resources; working in partnership |
| II | Policy and Legal (including Strategic Environmental Assessment, Equality Issues, Health or Risk Assessment) | Development of the Product Safety Incident Management Plan demonstrates compliance with PAS 7100:2018 (Code of Practice on consumer product safety related recalls and other corrective actions). Trading Standards are a designated Market Surveillance Authority and have the enforcement responsibility for product safety legislation covered by the Product Safety Incident Management Plan. There are no equality issues identified. |
| III | Implications for Scheme of Delegations to Officers | None. |

| | | |
|-------------|---|---|
| IV | Impact on performance and performance Indicators | None identified at this stage. |
| V | Relevance to Single Outcome Agreement | We live longer, healthier lives and have reduced health inequalities. |
| VI | Resources - (Financial, Staffing and Property) | There are no new financial resources identified or required with the development or delivery of the Product Safety Incident Management Plan |
| VII | Consideration at PDSP | This is the first report to PDSP. |
| VIII | Other consultations | Chief Executive's Office - Emergency Planning |

D. TERMS OF REPORT

D1. Background

The Council's Trading Standards team are a designated Market Surveillance Authority for the purposes of consumer products safety. Fulfilling this enforcement responsibility helps protect consumers by ensuring the free circulation of safe and compliant products throughout the EU and by intervening where products are found to be unsafe or non-compliant. A key component of the UK's market surveillance approach is providing information, guidance and advice to business on product safety legislation in order to prevent and address non-compliance. Underpinning the market surveillance system is collaboration and co-operation between the Office for Product Safety & Standards, the national Market Surveillance Authorities and over 200 local authority regulators. The Office for Product Safety & Standards has stated the UK will continue to have a robust approach to market surveillance after exit from the EU.

Thankfully, to date there have been very few incidents of major non-compliance within West Lothian however it would be dangerous to become complacent. Recent interventions by Trading Standards have included advice and guidance provision to home-based cosmetic manufacturers, enforcement action after an item of jewellery was found to contain an excessive level of lead and the voluntary recall, and subsequent reworking, of four lines of children's clothing by a local producer. Using the product safety outcome model, adapted from a similar scheme used by the Department of Transport, the latter intervention is estimated to have saved the public purse almost £50,000 through preventative action.

D2. Code of Practice

Against a background of growing and widespread concern about the failure of manufacturers to respond to major product safety incidents, such as the recent controversy surrounding the Whirlpool tumble drier and washing machine recalls, the Office for Product Safety & Standards and the British Standards Institution (BSI) published '*PAS 7100:2018 – Code of Practice on consumer product safety related recalls and other corrective actions*' (the Code), to make sure that businesses understand what they need to do if product safety issues arise with an item which they have manufactured and/or are marketing or have sold.

The Code includes details on how a business can monitor the safety of products and plan for a recall, and how Market Surveillance Authorities can support businesses in their monitoring of incidents and their implementation of corrective action. The Code details how manufacturers, importers and distributors can plan for their response to product safety incidents. It also sets out guidance and advice that local authorities should make available to businesses to help them meet their legal responsibilities and take any action needed to protect consumers. The Code was created to ensure that businesses can react in a proactive rather than reactive manner when dealing with product safety issues. The emphasis is on businesses to plan for potential corrective action and not to wait until there is a product safety issue.

The Code consists of two parts. The first part focuses on non-food consumer products and is for use by manufacturers, importers and distributors. It details:

- How businesses can plan for a recall, including determining methods to deal with any identified product safety issue.
- How to manage a possible safety related product recall or other corrective action.
- How to create methods to monitor the safety of products.
- How to investigate any potential product safety issue.
- Reviewing corrective action programmes to make sure that product safety responsibilities are met.

The second part is aimed at regulators, such as Trading Standards. It sets out how they can help businesses meet their responsibilities around consumer product safety issues by:

- Monitoring incidents and analysing data.
- Supporting businesses in the preparation of a Product Safety Incident Plan.
- Supporting business in their monitoring of incidents and the implementation of appropriate corrective action.
- Having their own Product Safety Incident Management Plan in place for response to serious product safety incidents.

D3. Product Safety Incident Management Plan

The draft Product Safety Incident Management Plan, which is attached as Appendix 1 to this report, provides guidance to officers which should be followed when dealing with a serious product safety incident reported to Trading Standards, either by the business itself, a consumer or via market surveillance. Trading Standards have a duty to inform the Office for Product Safety & Standards of any consumer product that presents a serious risk in need of urgent intervention or presents a non-serious risk requiring intervention.

The Product Safety Incident Management Plan ensures that officers respond in a manner proportionate to the seriousness of the risk and take due account of the precautionary principle. It is written using the template provided by the Office for Product Safety & Standards and, whenever possible, retains the same headings and format to ensure the documents cover all of the requirements and provide some uniformity and consistency with those used by other local authorities.

The Product Safety Incident Management Plan will be reviewed periodically or following any lessons learned after an incident and it is proposed that the Environmental Health & Trading Standards Manager will give approval for any amendments that are required.

E. CONCLUSION

The draft Product Safety Incident Management Plan seeks to ensure the Council has an effective mechanism in place to respond to consumer product safety incidents.

F. BACKGROUND REFERENCES

None.

Appendices/Attachments: One – Appendix 1. Draft Consumer Product Safety Incident Management Plan.

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11 February 2020

Product Safety Incident Management Plan

FOREWORD

This Product Safety Incident Management Plan (IMP) has been developed to demonstrate compliance with *PAS7100:2018 - Code of Practice on Consumer Product safety related recalls and other corrective actions* (the Code) and support businesses with managing the recall or required corrective actions of non-food products. This IMP supports Trading Standards in assisting a business to manage a product safety incident and to ensure that informed decisions are made and accurate information is collected by the council and its officers.

This IMP is not a standalone document and must be used and read in conjunction with PAS7100. Trading Standards have access to a free copy from BSI and Part II of the Code is for Regulators.

This IMP is not intended to instruct on how to undertake a full corrective action or to explain how to carry out a risk assessment, but is a template framework to guide officers through the process.

For Terms and Definitions see pages 1-3 of PAS7100

CONTENTS

| Page(s) | Title |
|---------|--------------------------------|
| 3 | Organisation's Key Contacts |
| 4 | Fact Finding & Risk Assessment |
| 5 | Risk Assessment Outcome |
| 6 | Decision Flow Chart |
| 7 | Monitor, Follow up & Review |
| 8-9 | Annex I – RAPEX Information |

REVIEW

| Date | Nature of update | Updated by | Version Number |
|------|------------------|------------|----------------|
| | | | |
| | | | |

This IMP will be reviewed annually or after it has been used for a product safety incident.

ORGANISATION'S KEY CONTACTS

| Fact Finding / Support | | |
|---|---|--|
| Job Title | Name / contact details | Stage to Involve |
| Lead Safety Officer ¹ | Nikki Fagan, Trading Standards Officer nicola.fagan@westlothian.gov.uk Michelle McNab, Trading Standards Officer michelle.mcnab@westlothian.gov.uk | Fact finding |
| Line Manager ¹ | Malcolm Craig, Senior Trading Standards Officer malcolm.craig@westlothian.gov.uk | Corrective action |
| Other Staff | Ed Machin, Trading Standards Manager Ed.machin@westlothian.gov.uk | Once corrective action agreed |
| OPSS ² | OPSS.enquiries@beis.gov.uk | |
| Reporting | | |
| Job Title | Name / contact details | Stage to Involve |
| EH&TS Manager | Craig Smith, EH&TS Manager Craig.smith@westlothian.gov.uk | Review |
| Head of Regulatory, Economic Development & Regeneration | Craig McCorriston Craig.mccorriston@westlothian.gov.uk | Large scale/ high risk to local residents |
| Internal Comms | Media@westlothian.gov.uk | Large scale/ high risk to local residents |
| RAPEX ³ | rapex.unit@beis.gov.uk | |
| Internal Emergency Planning/Resilience | Caroline Burton, Project officer Caroline.burton@westlothian.gov.uk | Large scale/ high risk to local residents |

1. Recommended to involve at an early stage.

2. A local authority should notify the Office for Product Safety and Standards (OPSS) when it becomes aware that:

- a producer has placed a product on the market, or
- where the producer is not based in the UK, a distributor has supplied a product that poses risks to the consumer that are incompatible with a safety requirement.

3. Usually only required for products which go outside of UK to EU/EEA Countries.

FACT FINDING

The questions below will ensure enough information is gathered to make an informed decision and also to confirm where the goods are within the supply chain. Ultimately, this will allow a decision to be made on whether a product recall or other corrective action is required. This is also to support the information provided in Annex D of PAS 7100:2018.

- Name of person reporting
- Business details, including; Legal name, Address, Contact phone / email
- Details of product, including; Nature of problem, Quantity affected
- Location of product(s);
Retailed in UK only or also in Europe?
Number of products under business control
Number of products in retail
Estimated number of products with end user
Has the product been sold online?
- Any reported incidents?
Have any injuries been reported?
Age group of people being injured and/or target market?
- How problem was identified?
Traceability of products i.e. batch coding
- Any identified solutions?
- Has a risk assessment been carried out?

RISK ASSESSMENT

In order to inform the authority as to the severity of the risk, a risk assessment must be carried out by Trading Standards. **Annex B** of PAS 7100:2018 explains the process including typical hazards and injury scenarios, severity of injuries and sensitivity analysis. There is also an online tool (RAG) available at: <https://ec.europa.eu/consumers/consumer-safety/rag/#/screen/home>

A peer review of the risk assessment internally or with another local authority Trading Standards Service may be useful to critically appraise the risk assessment. If it is identified that the business has not carried out a risk assessment, the above link should be sent to the business for them to complete (or Risk Assessment should be ascertained by other methods).

RISK ASSESSMENT OUTCOME

The information required from a business will vary depending upon the type of business and our relationship with it. We should be aware of the limitations of the information provided and may need to use other sources if confidence is low in the data received e.g. OPSS US Consumer Product Safety Commission (CPSC), online reviews.

The outcome of the risk assessment will be serious, high, medium or low risk. The rating will then help to inform as to whether the incident requires a recall or other corrective action.

We will advise the business of the outcome of the risk assessment and the appropriate action to take.

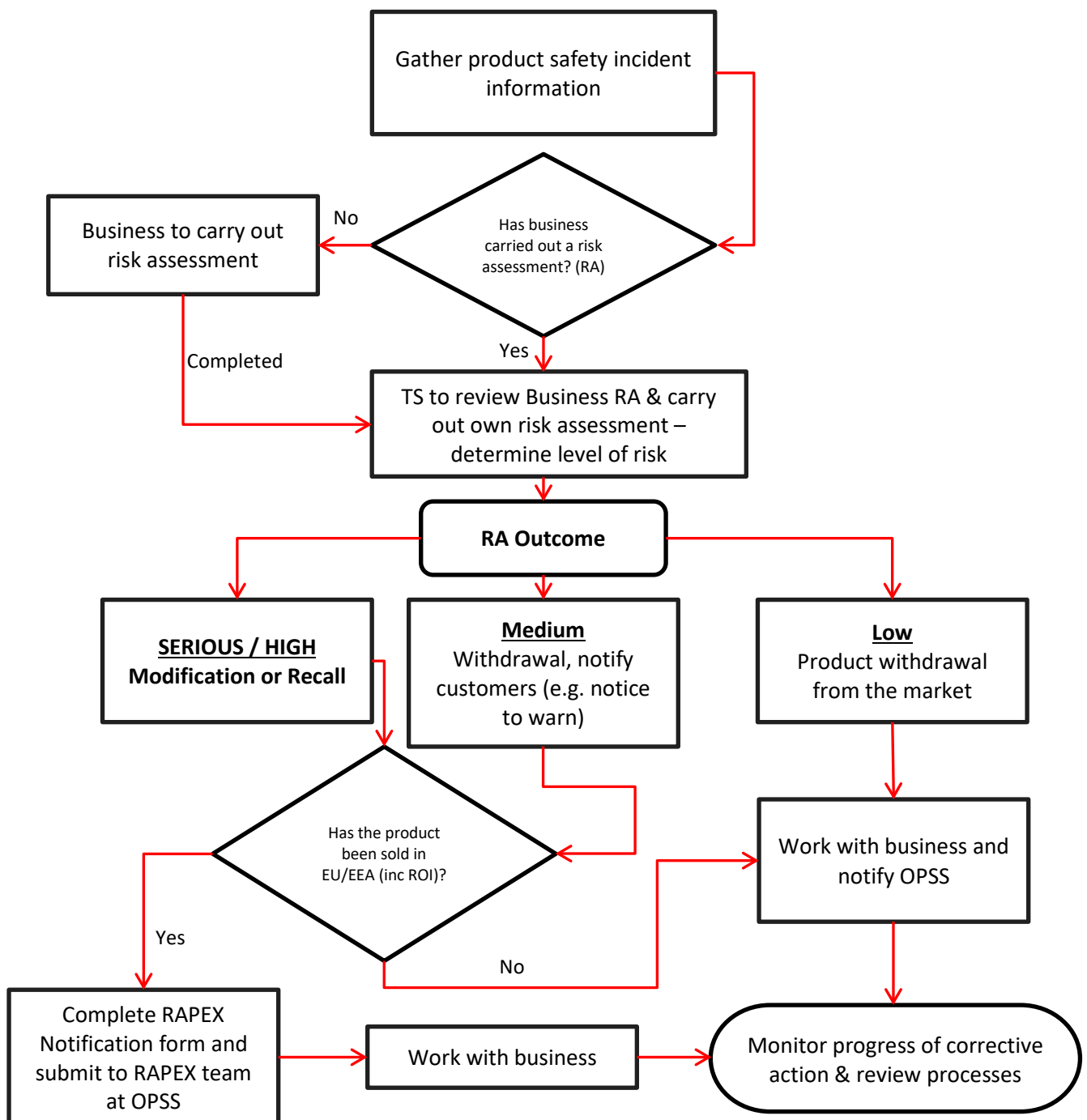
If the incident requires an informative notice to consumers, there are template examples within Annex G of PAS 7100:2018. We will advise the business of the best way to identify relevant consumers and consider the best way to provide the incident information to the target audience e.g. newspapers, business, website, social media, specialist publications.

We will notify OPSS of the consumer product safety risk identified and include sufficient information to identify the producer / UK distributor and the consumer product affected along with details of the actions being taken to prevent risk to consumers.

We will complete the RAPEX notification form where there is a serious risk and the business supplies the affected product outside of the UK. This includes the Republic of Ireland (ROI). Current guidance on the use of RAPEX can be found the OPSS web site.

In addition, we will place details of the incident on the TSS intelligence system Memex.

DECISION FLOW CHART



MONITOR

This section should be undertaken in conjunction with Annex E and F of PAS 7100.

During the process of the corrective action (or recall) it is important to monitor the progress to ensure the maximum effectiveness of the actions agreed, this would include:-

- Obtaining updates on the numbers of product that has been returned, modified or replaced
- Review the numbers of further complaint data
- Carry out additional risk assessments based upon new complaints data and amend corrective action if required
- Review the actions and consider whether further actions are needed, such as additional consumer contacts e.g. second letters, further publications of the notice in other relevant media sources and/or websites.

REVIEW

On conclusion of the corrective action we will review the process and update the IMP and ensure the business updates their Product Safety Incident Plan (PSIP) which should be in place in order to satisfy Part 1 of PAS 7100.

Annex I

RAPEX INFORMATION & LATEST FROM BEIS RAPEX TEAM

Rapid Alert System Users (RAPEX)

We continue to see a year-on-year increase in the number of notifications received through the Rapid Alert System.

To help guide you on completing a notification we'd like to provide the following summary of what constitutes a 'RAPEX' notification and how to make one. This will ensure that the platform is used effectively and that our limited resources (both at BEIS, Trading Standards & other UK authorities) are focused on processing serious risk notifications.

Before making a notification, please:

- Check the European Commission's Rapid Alert System website [RAPEX search](#) to see if the product has already been notified. If it has, then a UK reaction form should be submitted instead if measures are taken on the UK market (reactions are not required for UK notifications). Reactions can also be submitted when there is a divergence in the risk assessment of UK supplied products notified by other EU/EEA Member States.
- When identifying whether a RAPEX is appropriate, attention should be paid to the following:
- The product must pose a **Serious Risk** to the consumer under **Article 12 of the GPSD**. Complete a [risk assessment](#) to show the level of risk. This must be saved and sent as a PDF attachment with each notification.
- Since 2010, and as a result of the entry into force of Regulation (EC) No 765/2008, measures taken against professional/industrial products and products posing risks other than those to consumer health and safety also need to be notified on RAPEX.
- It must be found (or is very likely to be found) in **more than one Member State** and indicate where possible which ones it is sold in.
- Voluntary or compulsory measures must have been taken (i.e. product recall, withdrawal etc.) where possible attach details of the measure taken.
- There should be a short description of the product and packaging, including the type of materials from which it is made etc. Provide clear photos of the product, packaging and labelling, these should be in jpg, jpeg or png format, no more than 2MB in file size, not have the date taken printed on the photo, or the officer's hands or market surveillance markings/documents visible in the background (i.e. crop and reduce size of photos using Microsoft Office Picture Manager or Paint option to edit if available). The photos should be separate and not simply be part of a test report.
- There should be as much information regarding the brand, model/batch/barcode numbers (**also provide clear photos showing these**), manufacturer, exporter, importer and distributor as possible. The lack of branding and traceability could

invalidate a notification. Where possible always attach documents such as invoices showing full details of the economic operator(s).

- If the product is by a UK manufacturer, please provide details of the European distributors in a separate word or excel document.
- The test failure report should be summarised on the form to describe how the technical defect leads to the risk (if there is no test report please summarise the issue with the product and risk to user). This text is used for the Rapid Alert web publication, please use similar text to describe the risk as in the [Weekly reports](#) e.g. "The eyes of the toy can easily detach. A child could put them in the mouth and choke on them".
- A notification should include the separate copies of a test report, risk assessment, photos of the product and packaging, a copy of the measure, where available a list of European distributors/retailers. **Please ensure the maximum size limit of each attachment is 2MB or less.**

We are unable to process notifications for products where there is no branding or other markings that will distinguish it from similar products on the market. (We regularly receive notifications for generic products such as adapters, chargers or lighting chains which we are unable to action). If in doubt please speak to the BEIS RAPEX unit before drawing up a notification.

We propose to no longer notify products on RAPEX that are submitted under **Article 11 of the GPSD (Non-serious risk)** and **"For Information"** as these can dilute the primary purpose of notifying serious risk notifications. These should be placed on ICSMS. The UK's National Administrator is HSE, to access ICSMS contact: safety.unit@hse.gov.uk

To summarise:

Check the Commission's web-page by using the Search tool to see if the product has already been notified [RAPEX search](#)

Product must pose a serious risk (only notified under Article 12).

Notifications will not be submitted for products which other member state market surveillance authorities would be unable to distinguish from similar products placed on the market.

The Rapid Alert System by its nature is a rapid information electronic platform to identify and remove unsafe products that pose a serious risk. Therefore, if the measures taken are more than 6 months previous to the notification it will not qualify.

Where products do not meet the above criteria, we suggest placing the information on ICSMS which can be accessed by other Member States' authorities as well as those in the UK.

If in doubt contact Nick James: 020 7215 2349 Email: rapex.unit@beis.gov.uk Rapex Unit/Office for Product Safety & Standards, Department for Business, Energy & Industrial Strategy, 1 Victoria Street, London SW1H 0ET.

Please contact the above for the RAPEX notification and Reaction forms or for access to the RAPEX system in order to input notifications directly; you will first need to create an [EU LOGIN account](#).

Alternatively a RAPEX notification can be generated from ICSMS if users have the RAPEX creator credential as part of their user profile.