Appendix 1

Comhairle Ceantair
Lár Uladh
Mid Ulster
District Council

Product Safety

Incident Management Plan

Foreword

Officers with Consumer Protection duties within Mid Ulster District Council's Environmental Health Department, deal with non-food product recalls and corrective actions with businesses. An incident management plan (IMP) has been developed to demonstrate compliance with PAS (Publicly Available Specification) 7100:2018, which is a Code of Practice on Consumer Product safety related recalls and other corrective actions).

This IMP is to support the Environmental Health Department in assisting a business to manage a product safety incident and ensure informed decisions are made and accurate information is collected.

This plan is not a standalone document and must be used and read in conjunction with a copy of the PAS 7100 (Included as a supplementary document at the end of this IMP). Part II of the Code is aimed specifically for Regulators.

PAS 7100 covers non-food consumer products, it is not intended to conflict with existing sector specific schemes (e.g. automotive, medicines, medical devices) which should be referred to in respect of the product categories covered.

This document is not intended to instruct on how to undertake a full corrective action or to explain how to carry out a risk assessment. It is a template framework to guide Environmental Health Officers through the process.

For terms and definitions please see pages 1-3 of PAS7100.

Contents

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.

Organisations Key Contacts

Fact Finding / Support		
Job Title	Name / contact details	Stage to Involve
Safety & Standards	OPSS.enquiries@beis.gov.uk	*
Reporting		
Job Title	Name / contact details	Stage to Involve
Service Lead (or suitable senior position)	Fiona McClements, Head of Environmental Health	
RAPEX	rapex.unit@beis.gov.uk	**

*A local authority should notify the Office for Product Safety and Standards 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.

****Usually only required for serious risk products sold outside of the UK to EU/EEA Countries.**

Fact Finding

The questions below will help to ensure enough information is available to make an informed decision and also to determine at which point the goods are within the supply chain. This information will assist in deciding as to whether a product recall or other corrective action is required. This section supports the information provided in **Annex D** of PAS 7100:2018.

a) Name of person reporting
b) Business details, including
    a. Legal name
    b. Address
    c. Contact phone / email
c) Details of product, including:
    a. Nature of problem
    b. Quantity affected
    c. Location of product(s)
        i. Retailed in UK only or also in Europe?
        ii. No. under business control
        iii. No. in retail
        iv. Estimated no. with end user
        v. Sold online?
    d. Any reported incidents?
        i. Have any injuries been reported?
        ii. Age group of people being injured and/or target market?
    e. How problem was identified?
        i. Traceability of products i.e. batch coding
    f. Any identified solutions?
    g. Has a risk assessment been carried out?

SEE ANNEX I for Printout version of the above questions to record the details obtained

Risk Assessment

In order to inform Mid Ulster District Council as to the severity of the risk, a risk assessment must be carried out by Environmental Health. **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 Risk Assessment tool (RAG) available at: https://ec.europa.eu/consumers/consumer-safety/rag/#/screen/home

If it is identified that the business has not carried out a risk assessment, the above link will be sent to the business for them to complete (or risk assess ascertained by other methods).

Risk Assessment Outcome

Information required from a business will vary depending upon the type of business it is, (e.g) their relationship with the Local Authority (is there a Primary Authority agreement in place for business concerned; does the District Council act as Home Authority for the business; is the business known to the District Council?) Mid Ulster District Council will be mindful of the limitations of the information provided and may use other sources if confidence is low in the data received – e.g. OPS&S, CPSC, online reviews.

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

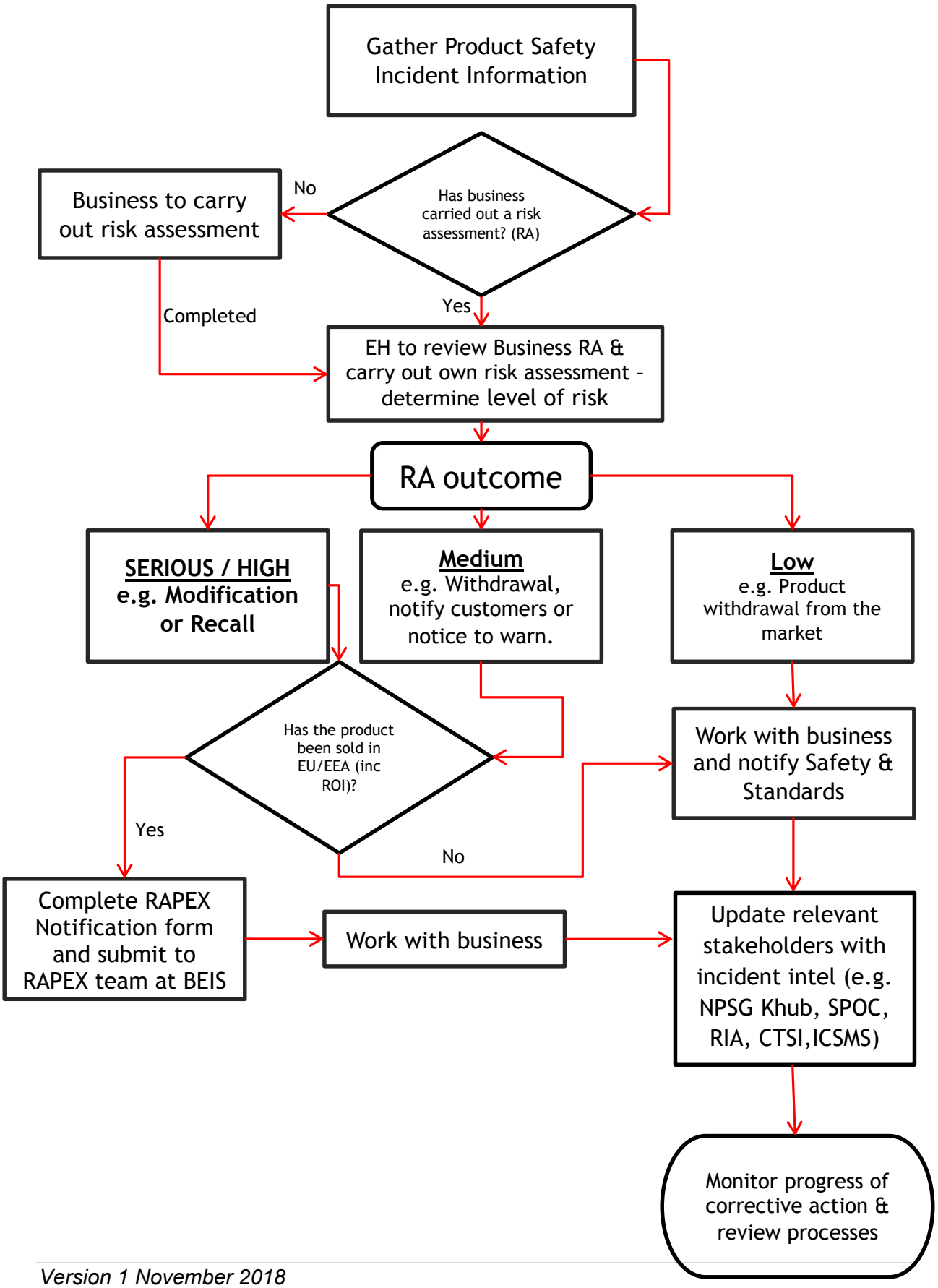
The business will be advised of the outcome of the risk assessment and of the appropriate action to take.

If the incident requires an informative notice to consumers, there are template examples within **Annex G** of PAS 7100:2018.The business will be advised 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.

Mid Ulster District Council will notify the Office of Product Safety & Standards about the incident, including sufficient information to identify the producer / UK distributor and the product affected along with details of the action being taken to prevent risk to the consumer.

Mid Ulster District Council 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). The latest guidance from BEIS Rapex Team for Rapex Notifications is attached in **Annex II** (of this IMP).

1. Decision Flow Chart



Monitor, Follow up & Review

Monitor

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

During the process of the recall (or corrective action), Mid Ulster District Council will monitor the progress to ensure the maximum effectiveness of the actions agreed, this will include:-

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

Review

On conclusion of the corrective action, the process will be reviewed and the IMP updated as necessary. The business will be advised to update their PSIP.

Local Government Sign Off

Position	Name	Signed	Date
Head of Environmental Health	Fiona McClements		

Annex I
Fact Finding Questions[a]

a) Name of person reporting	
b) Business details, including:	
a. Legal name	
b. Address	
c. Contact phone / email	
c) Details of product, including:	
a. Nature of problem	
b. Quantity affected	
c. Location of product(s)	
d. Location of product(s)	
i. Retailed in UK only or also in Europe?	
ii. No. under business control	
iii. No. in retail	
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v. Sold online?	
e. Any reported incidents?	
i. Have any injuries been reported?	
ii. Age group of people being injured and/or target market?	
f. How problem was identified?	
i. Traceability of products i.e. batch coding	
g. Any identified solutions?	
h. Has a risk assessment been carried out?	

[a] To be used in conjunction with page 4.

Annex II

RAPEX information and latest guidance 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 The Office for Product Safety and Standards: 0121 345 1201 Email: rapex.unit@beis.gov.uk Rapex Unit, Office for Product Safety & Standards, Department for Business, Energy & Industrial Strategy, 1 Victoria Square House, Victoria Square, Birmingham B2 4AJ.

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.