#### Food Business Root Cause Analysis

#### Report Form

|  |  |
| --- | --- |
| Introduction | For completion by the food business |

A root cause analysis (RCA) can be undertaken to determine the initial cause of a food safety incident. Details of the RCA should be recorded on this form in the event of a food incident, in particular where the Food Standards Scotland (FSS) has issued an Allergy or Food Alert or where FSS considers there is potential for lessons learned.

This report form allows RCA information to be recorded through a choice of two methods – the ‘5 Whys?’ or the ‘Fishbone / PEM PEM’.

More information on RCA can be found at: [www.foodstandards.gov.scot/root-cause-analysis](http://www.foodstandards.gov.scot/root-cause-analysis) or contact your competent authority for further advice.

This form should be completed by the investigating officer / representative and submitted to the Food Standards Scotland via the enforcement authority, as indicated in the sections below.

|  |  |
| --- | --- |
| Section A: | For completion by FSS |

FSS Reference (if available):

|  |  |
| --- | --- |
| Allergy Alert or Product Recall Information Notice (PRIN) reference: |  |
| CLIO Incident Number: |  |

|  |  |
| --- | --- |
| Section B: | For completion by the food business |

Food business details:

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |

Food business investigating officer / representative details:

|  |  |
| --- | --- |
| Contact details | Name:  Telephone:  Email: |

Product name(s):

|  |
| --- |
|  |

Description of product(s):

|  |
| --- |
|  |

Please record details of the completed root cause analysis using one of the following options:

|  |  |
| --- | --- |
| Root Cause Analysis – Option 1: | ‘5 Why’s?’ method |

|  |  |
| --- | --- |
| Step 1 | State the specific problem associated with the food incident in the box below |

|  |
| --- |
|  |

|  |  |
| --- | --- |
| Step 2 | Why did the problem happen? Write the answer in the box below |

|  |
| --- |
|  |

|  |  |
| --- | --- |
| Step 3 | If the above answer does not identify the root cause of the problem stated in the answer to Step 1, ask “Why?” again and write the answer in the box below |

|  |
| --- |
|  |

|  |  |
| --- | --- |
| Step 4 | Loop back to Step 3 and ask “Why?” again; until the team reaches agreement that the root cause of the problem has been identified.  This may require asking ‘Why?’ fewer or more than 5 times. |

|  |
| --- |
|  |

|  |  |
| --- | --- |
| Step 5 | Loop back to Step 3 and ask “Why?” again; until the team reaches agreement that the root cause of the problem has been identified.  This may require asking ‘Why?’ fewer or more than 5 times. |

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **Root Cause Analysis:** | **Outcome** |
| State the initial issue (the root cause) that led to the food incident occurring |  |
| State the corrective measures identified to prevent incident reoccurrence |  |

|  |  |
| --- | --- |
| Root Cause Analysis – Option 2: | Fishbone/PEM PEM method |

|  |  |  |  |
| --- | --- | --- | --- |
| Source(s) & Reason(s) for Error(s) | Select | Description | Root cause determined & corrective measures identified to prevent incident reoccurrence |
| **Source: People** | |  |  |
| Procedures not followed -one-off operator error or intentional (please indicate which) |  |
| Training – absent or incomplete |  |
| Understaffing / Sickness |  |
| Other |  |
| **Source: Environment** | |  |  |
| Inadequate lighting |  |
| Inadequate space / layout |  |
| Inadequate temperature control |  |
| Other |  |
| **Source: Method** | |  |  |
| Cleanliness – absent or inadequate |  |
| Specifications - absent or non-compliance |  |
| Work instructions - absent or inadequate |  |
| Other |  |
| **Source: Plant** | |  |  |
| Machinery failure |  |
| Machinery – incorrect use |  |
| Machinery damage |  |
| Routine maintenance – absent or inadequate  (e.g. inspection, testing, measurement or adjustment) |  |
| Servicing – absent or inadequate  (e.g. Annual Service Plan, recalibration or parts replacement) |  |
| Other |  |
| **Source: Equipment** | |  |  |
| Ancillary devices |  |
| Computer/IT issues |  |
| Printer/scanner issues e.g. barcodes |  |
| Weighing machine – inaccurate calibration |  |
| Other |  |
| **Source: Material** | |  |  |
| Composition – incorrect ingredients / substitution |  |
| Contaminated product |  |
| Food storage - inadequate or inappropriate |  |
| Labelling - absent / incomplete / incorrect |  |
| Packaging – defective / incorrect |  |
| Other |  |

|  |  |
| --- | --- |
| **Section C:** | **For completion by the enforcement authority** |

Enforcement authority submission details:

|  |  |
| --- | --- |
| Name of enforcement authority: |  |
| Enforcement Officer details | Name:  Job Title:  Telephone:  Email: |
| Date: |  |

|  |  |
| --- | --- |
| Enforcement authorities should submit the completed Food Business Root Cause Analysis Form to Food Standards Scotland: | |
| E-mail Address: | [incidents@fss.scot](mailto:incidents@fss.scot) |

|  |  |
| --- | --- |
| **Section** **D:** | **For completion completed by FSS** |

Description of food safety incident:

Please tick the appropriate ‘reported’ food safety incident problem(s) and type(s) from the selection below and provide a description of the food safety incident.

|  |  |  |  |
| --- | --- | --- | --- |
| Nature of problem | Type | Select | Brief description |
| Allergens | Labelling error |  |  |
| Undeclared |  |
| False claim |  |
| Other |  |
| Animal feed | Microbiological |  |  |
| Chemical |  |
| Labelling error |  |
| Other |  |
| Chemical | Pesticides |  |  |
| Biocides |  |
| Herbicides |  |
| Environmental contaminants |  |
| Process contaminants |  |
| Natural toxins (terrestrial) |  |
| Food contact materials |  |
| Histamine |  |
| Veterinary medicines |  |
| Emergency | Fire |  |  |
| Flood |  |
| Marine vessel incident |  |
| Radiological |  |
| Chemical incident |  |
| GMO / Novel Food | GMO |  |  |
| Novel food |  |
| Illegal activity | Illegal import / exports |  |  |
| Adulteration |  |
| Fraud incident |  |
| Malicious tampering |  |
| Other |  |
| Microbiological | Insufficient controls in vacuum packed product |  |  |
| Parasitic presence / infestation |  |
| Hygiene indicators |  |
| E. coli O157 |  |
| Non-O157 STEC |  |
| Listeria monocytogenes |  |
| Listeria spp. |  |
| Salmonella |  |
| C. botulinum |  |
| HEP A |  |
| Norovirus |  |
| Other contamination |  |
| On-farm | Lead |  |  |
| Copper |  |
| Chemical contaminant (other) |  |
| Botulism |  |
| Unapproved veterinary medicine residues |  |
| Other |  |
| Physical | Foreign body contamination – plastic |  |  |
| Foreign body contamination – glass |  |
| Foreign body contamination – metal |  |
| Foreign body contamination – string |  |
| Foreign body contamination – other |  |
| Production error | Labelling error (excluding allergens) |  |  |
| Other |  |
| Regulatory Breach | Unauthorised premises |  |  |
| Breach in hygiene regulations |  |
| Use of unauthorised ingredient |  |
| No validation of shelf-life or FSMS |  |
| Loss of traceability |  |
| Loss of temperature control |  |
| Breach of animal welfare |  |
| ABP breach |  |
| Breach of MPL |  |
| Other |  |
| Shellfish | Marine biotoxins |  |  |
| E. coli out with classification |  |
| Other | Inconclusive Investigation |  |  |
| No applicable operation type |  |

|  |  |  |
| --- | --- | --- |
| **Root Cause Analysis:** | **Outcome** | |
| Was the root cause of the food safety incident identified? | Yes |  |
| No |  |
| State the initial issue (the root cause) that led to the food incident occurring |  | |
| State the corrective measures identified to prevent incident reoccurrence |  | |