

Categorisation of root causes associated with incidents notified

A draft categorisation system originating from the Efficacy of Recalls Project has been used to classify the root causes of incidents. The 'PEMPEM' model uses 6 commonly observed areas associated with food production: **P**rocess, **E**quipment, **M**aterial, **P**eople, **E**nvironment and **M**ethod; with associated sub-categories providing further descriptive information regarding the root cause type.

Root Cause Category	Sub-categories
P rocess	Contamination: Segregation failure
	Distribution Error
	Formulation / Assembly Error
	HACCP: Non-compliance / failure
	Labelling Verification Checks - absent / failure
	Packaging: Defective / incorrect
	Quality Control Checks: Absent / inadequate / incomplete
	Other (please specify)
E quipment	Machinery: Failure / incorrect use / damage
	Calibration: Absent / inaccurate
	Contamination: Cleaning absent / failure
	Computer / IT Issues
	Printing Issues e.g. Barcodes
	Routine Maintenance: Absent / inadequate / incorrect
	Other (please specify)
M aterial	Composition: Incorrect ingredients / substitution
	Ingredient Cross-contamination
	Ingredient Hygiene Controls: Absent / inadequate
	Ingredient Specification: Absent / incorrect / non-compliance
	Other (please specify)
P eople	Procedures Not Followed: One-off operator error / intentional
	Training: Absent / incomplete
	Understaffing / Sickness
	Other (please specify)
E nvironment	Access By Pests
	Design: Inadequate layout / space
	Ingredient / Product Storage Controls: Absent / inadequate / inappropriate
	Lighting: Inadequate
	Temperature Control: Absent / inadequate
	Other (please specify)
M ethod	Cleanliness or Sanitation: Absent / failure / inadequate
	Ingredient Specifications: Absent / non-compliance / incorrect
	Labelling Declaration: Absent / incomplete / incorrect
	Risk Analysis: Absent / inadequate
	Work Instructions: Absent / inadequate
	Other (please specify)

Classification of incidents by suspected or actual concern (Incident Type)

Incident notifications are classed according to the potential hazard that is under investigation or that is ultimately of concern. Therefore, even where no risk to the safety, quality or integrity of food and feed is identified, the incident will still be classified by the potential issue of concern.

The summarised RCA data refers to the following commonly observed Incident Types.

Incident Type	Examples
Allergens	Allergens incidents concern the undeclared presence of allergens, either as cross-contamination or undeclared ingredients. Includes all allergens incidents resulting from labelling issues and allergic reactions with unknown causes.
Foreign Bodies	Physical contamination incidents involving foods contaminated with e.g. Animal Origin (e.g. bone), Glass, Hair, Metal, Paper & Cardboard, Plastic, Pests (e.g. mites, rats, mice, etc.), Rubber, Stone, Wood & Other
Pathogenic Micro-organisms	Microbiological incidents relating to suspected, possible or actual contamination by harmful bacteria, viruses or fungi. They also include concerns about measures to control the risk from pathogenic micro-organisms.