Methods & Models for Conducting Risk Assessments Under the BRC Standard

George Howlett, CEO

What is risk ASSESSMENT?

Why is risk important in food safety?

What is Risk Assessment (RA)?

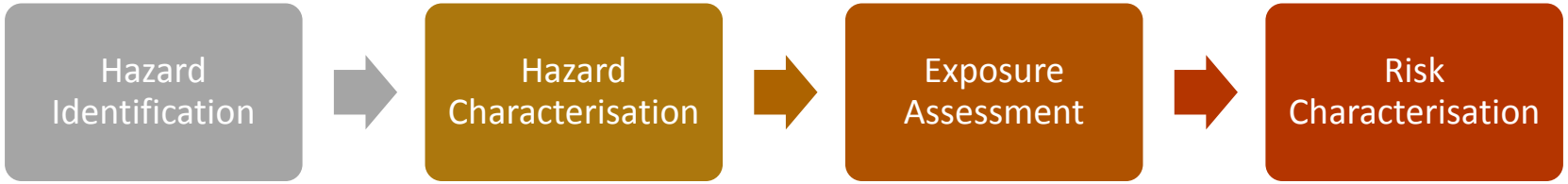
- Process or tool for identifying a hazard and estimating the risk presented by that hazard
- Widely used in the field of food safety
- It may be quantitative or qualitative
- Quantitative – “1 death per year in given population from hazard X in product Y”
- Qualitative – “High risk”

What is Risk Assessment (RA)?

- Quantitative preferred but seldom possible at site level
- More often characterised by what we don't know than what we do know
- Structured approach
- Supports decision making and resource allocation – risk management
- Contributes to better understanding of hazards and food safety
- Approach adopted internationally e.g. EU, WHO (Framework)

Risk Framework

Steps of Risk Assessment



Risk Assessments Used in Food Safety

- Proliferation of risk assessments in the food sector
- HACCP
- VA
- TACCP
- HARPC

What is Risk?

Probability x Severity = Risk

Risk assessment and the brc

How to address requirements under the BRC

Risk Assessment and the BRC

"The BRC likes risk assessment…"

Definitions in the BRC:

- Risk: The likelihood of occurrence of harm from a hazard.
- Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.
- Risk assessment: The identification, evaluation and estimation of the levels of risk involved in a process to determine an appropriate control process.

BRC Food Issue 7

- Referred to no fewer than 97 times in the Standard
- Required documented risk assessment - 14 times
- Implied document risk assessment - 20 times
- Most refer to PRP's and management processes

When does BRC Require Risk Assessment?

- Not always clear when and what is required
- Application of language and terminology not always consistent
- “The scope and frequency…shall be established in relation to the risks”
- “The frequency of these inspections shall be based on risk”
- “The company shall undertake a documented risk assessment”
- “…dependent on risk assessment”

When does BRC Requires a Risk Assessment?

- "…at a predetermined frequency, based on risk assessment"
- "eliminate potential risks to product safety"
- "prevent any risk of product contamination"
- "minimise the risk"
- "according to risk"
- "The site shall carry out an assessment"
- "on the basis of risk assessment"

Challenges

- When is risk assessment required?
- Should it be documented?
- Should it be structured?
- What is the difference between “The Company shall undertake a documented risk assessment” and “The site shall carry out an assessment”?
- What is the difference between “eliminate potential risks to product safety” and “prevent any risk of product contamination”
- Very little guidance on risk assessments

Required and Implied Risk Assessment in the BRC Standard

- Interpretation
- The standard operates on two levels
- Required or Implied
- Required - “The Company shall undertake a documented risk assessment”
- Implied – “…shall be based on risk”
- Semantics?

Required Risk Assessment – 14 areas

NO	REQUIREMENT		RISK ASSESSMENT REQUIREMENTS
2	THE FOOD SAFETY PLAN – HACCP*		
2.7	LIST ALL POTENTIAL HAZARDS ASSOCIATED WITH EACH PROCESS STEP, CONDUCT A HAZARD ANALYSIS AND CONSIDER ANY MEASURES TO CONTROL IDENTIFIED HAZARDS – CODEX ALIMENTARIUS STEP 6, PRINCIPLE 1		Documented RA required
2.7.1	The HACCP food safety team shall conduct a hazard analysis to identify hazards which need to be prevented, eliminated or reduced to acceptable levels.		Documented RA required
3.4	INTERNAL AUDITS*		
3.4.1	The scope and frequency of the audits shall be established in relation to the risks		Documented RA required
3.4.4	The frequency of these inspections shall be based on risk (hygiene and fabrication)		Documented RA required
3.5.1	MANAGEMENT OF SUPPLIERS OF RAW MATERIALS AND PACKAGING		
3.5.1.1	The company shall undertake a documented risk assessment of each raw material or group of raw materials including packaging to identify potential risks to product safety, legality and quality.		Documented RA required
3.5.1.2	The approval and monitoring procedure shall be based on risk		Documented RA require
3.5.2.1	The company shall have a documented procedure for the acceptance of raw materials and packaging on receipt based upon the risk assessment (clause 3.5.1.1).		Documented RA required

Required Risk Assessment – 14 areas

NO	REQUIREMENT		RISK ASSESSMENT REQUIREMENTS
3.5.4	MANAGEMENT OF OUTSOURCED PROCESSING AND PACKING		
3.5.4.4	The company shall establish inspection and test procedures for products where part of the processing or packing have been outsourced, including visual, chemical and/or microbiological testing, dependent on risk assessment.		Documented RA required
4.2	SECURITY		
4.2.1	The company shall undertake a documented assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements to reduce risks shall be implemented and reviewed at least annually.		Documented RA required
4.10	FOREIGN-BODY DETECTION AND REMOVAL EQUIPMENT		
4.10.1.1	A documented assessment in association with the HACCP study shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination.		Documented RA required
4.10.2	FILTERS AND SIEVES		
4.10.2.2	Filters and sieves shall be regularly inspected or tested for damage on a documented frequency based on risk.		Documented RA required
4.10.3	METAL DETECTORS AND X-RAY EQUIPMENT		
4.10.3.1	Metal detection equipment shall be in place unless risk assessment demonstrates that this does not improve the protection of final products from metal contamination. Where metal detectors are not used justification shall be documented. The absence of metal detection would only normally be based on the use of an alternative, more effective method of protection (e.g. use of X-ray, fine sieves or filtration of products).		Documented RA required

Required Risk Assessment – 14 areas

NO	REQUIREMENT		RISK ASSESSMENT REQUIREMENTS
4.14	PEST CONTROL		
4.14.2	The frequency of inspections shall be determined by risk assessment and shall be documented.		Documented RA required
5.3	MANAGEMENT OF ALLERGENS		
5.3.3	A documented risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross-contamination is avoided.		Documented RA required
5.4	PRODUCT AUTHENTICITY, CLAIMS AND CHAIN OF CUSTODY		
5.4.2	A documented vulnerability assessment shall be carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution.		Documented RA required

Implied Risk Assessments – 20 areas

NO	REQUIREMENT		RISK ASSESSMENT REQUIREMENTS
1.1	SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT*		
1.1.6	The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews … new risks to authenticity of raw materials		Documented RA implied
2.14	REVIEW THE HACCP PLAN		
	The HACCP food safety team shall review the HACCP plan and prerequisite programmes at least annually and prior to any changes which may affect product safety …. emergence of a new risk (e.g. known adulteration of an ingredient)		Documented RA implied
3.7	CORRECTIVE AND PREVENTIVE ACTIONS		
3.7.2	Where a non-conformity places the safety, legality or quality of products at risk this shall be investigated and recorded including … assessment of consequences by a suitably competent and authorised person		Documented RA implied
3.11	MANAGEMENT OF INCIDENTS, PRODUCT WITHDRAWAL AND PRODUCT RECAL		
3.11.2	The company shall have a documented product withdrawal and recall procedure. This shall include …. guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained		Documented RA implied
4.4	BUILDING FABRIC, RAW MATERIAL HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS		
	High-risk areas shall be supplied with sufficient changes of filtered air. The filter specification used and frequency of air changes shall be documented. This shall be based on a risk assessment, taking into account the source of the air and the requirement to maintain a positive air pressure relative to the surrounding areas		Documented RA implied
4.5	UTILITIES – WATER, ICE, AIR AND OTHER GASES		
4.5.1	The microbiological and chemical quality of water shall be analysed at least annually. The sampling points, scope of the test and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.		Documented RA implied

Implied Risk Assessments – 20 areas

NO	REQUIREMENT		RISK ASSESSMENT REQUIREMENTS
4.8	STAFF FACILITIES		
4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).		Documented RA implied
4.10.3	METAL DETECTORS AND X-RAY EQUIPMENT		
	Metal detector checking procedures shall be based on good practice and shall as a minimum include the following: • Use of test pieces incorporating a sphere of metal of a known diameter selected on the basis of risk. The test pieces shall be marked with the size and type of test material contained.		Documented RA implied
4.10.6	CONTAINER CLEANLINESS – GLASS JARS, CANS AND OTHER RIGID CONTAINERS		
4.10.6.1	Based on risk assessment, procedures shall be implemented to minimise foreign-body contamination originating with the packaging container (e.g. jars, cans and other pre-formed rigid containers). This may include the use of covered conveyors, container inversion and foreign-body removal through rinsing with water or air jets.		Documented RA implied
4.11	HOUSEKEEPING AND HYGIENE		
	The frequency and methods of cleaning shall be based on risk.		Documented RA implied
4.14	PEST CONTROL		
4.14.9	An in-depth, documented pest control survey shall be undertaken at a frequency based on risk		Documented RA implied
4.15	STORAGE FACILITIES		
4.15.1	Documented procedures to maintain product safety and quality during storage shall be developed on the basis of risk assessment,		Documented RA implied
5.1	PRODUCT DESIGN/DEVELOPMENT		
5.1.2	All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or authorised HACCP committee member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment.		Documented RA implied

Implied Risk Assessments – 20 areas

NO	REQUIREMENT		RISK ASSESSMENT REQUIREMENTS
5.6.1	PRODUCT INSPECTION AND TESTING		
5.6.1.1	There shall be a scheduled programme of testing covering products and the processing environment, which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, frequency and specified limits shall be documented.		Documented RA implied
5.6.1.3	The site shall ensure that a system of ongoing shelf-life assessment is in place. This shall be based on risk and shall include sensory analysis and, as applicable, microbiological testing and relevant chemical factors such as pH and aw. Records and results from shelf-life tests shall verify the shelf-life period indicated on the product.		Documented RA implied
6.1	CONTROL OF OPERATIONS*		
6.1.4	Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores).		Documented RA implied
6.4	CALIBRATION AND CONTROL OF MEASURING AND MONITORING DEVICE		
6.4.2	All identified measuring devices, including new equipment, shall be checked and where necessary adjusted… at a predetermined frequency, based on risk assessment		Documented RA implied
7.4	PROTECTIVE CLOTHING: EMPLOYEES OR VISITORS TO PRODUCTION AREA		
7.4.4	Where protective clothing for high-care or high-risk areas is cleaned by a contracted or in-house laundry, this shall be audited either directly or by a third party. The frequency of these audits should be based on risk.		Documented RA implied
7.4.5	Protective clothing shall be changed at an appropriate frequency, based on risk. For high-risk and high-care areas the protective clothing shall be changed at least daily.		Documented RA implied
7.4.7	Where items of personal protective clothing that are not suitable for laundering are provided (such as chain mail, gloves and aprons), these shall be cleaned and sanitised at a frequency based on risk.		Documented RA implied

HACCP & Raw Materials

- Models well defined
- Use a simple matrix model based on probability and severity
- Focus of specific hazards – Biological, Chemical, Physical and Allergens
- Focus on specific processes, materials and products
- Based on Codex principles
- CCP's

Operational and General PRP's

- Traditional models breakdown or have limited value
- Risk assessment of PRP's don't focus on specific hazards
- Focus is on activities, tasks, programs
- Risk from hazards is "inherited"
- Can cause confusion for the risk assessor

Intrinsic vs Inherited Risk

- Traditional RA's and HACCP focus on a specific hazard at a specific process step
- Clear line between hazard analysis, characterisation, exposure and risk
- The risk is Intrinsic
- For PRP's the focus is on the potential failure of the activity based on the inherited risk identified in HACCP
- More akin to FMEA (Failure Mode Effect Analysis) – not a tool normally used by technical staff in food industry

Intrinsic Vs inherited risk

Example - Calibration

Cooking – cooked meat RTE (HACCP)

- Hazard – E.Coli O157
- Probability (Survival due to inadequate temp/time) – Medium Probability
- Severity – High Impact
- Risk Rating – High Risk
- Control – temperature and time, core product
- In this case there is a clear line between Hazard Identification, Risk Assessment and Management

Cooking – cooked meat RTE (PRP – Calibration)

- Device – temperature probe
- PRP – calibration
- Probability (of being out of calibration) – Medium
- Severity – High (Inherited from the HACCP risk assessment)
- Control – frequency and scope of calibration
- In this case the RA is based on the failure and effect model.
- The probability of failed calibration status combined with the inherent risk of exposure to the consumer

Risk assessment model

Risk Assessment for Non-HACCP requirements

Need for Clear RA Model for Non-HACCP Assessments

- Different models required for non-HACCP RA's
- Workbook provided for conducting RA's on Safefood 360 website
- Internal Auditing
- Calibration
- Cleaning
- Pest Control
- Metal Detection
- Packaging Materials
- Vulnerability Assessment

Construction of RA Models

- Step 1: Define the RA matrix
- Step 2: Define Probability criteria
- Step 3: Define Severity criteria
- Step 4: Define Outcome and Decisions Criteria
- Step 5: Define Special Points of Attention
- Step 6: List all identified points / activities / tasks / programs etc
- Step 7: Describe each point / activity
- Step 8: Describe the risk
- Step 9: Rate the probability and severity to produce risk rating
- Step 10: Define outcomes and decisions

Example RA for Internal Auditing Programs

- BRC Clause 3.4 Internal Audits “The scope and frequency of the audits shall be established in relation to the risks”
- Interpretation – a risk assessment of each audit program is required and the scope and frequency of audits shall be established based on this. Documented risk assessment to support audit of this requirement.

Example RA for Internal Auditing Programs

- Risk Assessment Model

Safefood 360°

RISK ASSESSMENT MODEL
Internal Auditing

Company: ABC Food Company Inc.
Date of Assesment: 11/12/2015

Assessment Conducted By: G Howlett, P Gillen

Scope: HACCP, PRP's, procedures and requirements of the BRC standard

Risk Assessment Model

Risk Assessment Matrix

		Probability		
		1	2	3
Severity	1	1	2	3
	2	2	4	6
	3	3	6	9

Notes: After rating each point the multiplication of the severity and potential rating determines wheather a point is high, medium or low in regard to significance.

Probability Criteria		Severity Criteria		Outcome Decision Critieria		Special Points of Attention	
3	Failure of the activity being audited is likely to happen, often, frequent	3	Failure of the activity being audited is likely to lead to an immediate / grave health impact, recall or regulatory issue	High	Audit the activity at a frequent level - minimum every 3 months	1	Scope to include HACCP programme, prerequisite programmes and procedures
2	Failure of the activity being audited can happen, but not frequent	2	Failure of the activity being audited is unlikely to pose an immediate / grave risk to the consumer but repeated failure over time may	Medium	Audit the activity at a reduced level - minimum every 6 months	2	All activities shall be audited at least annually regardless of risk
1	Failure of the activity being audited is unlikely to happen, rare, remote	1	Failure of the activity being audited is unlikely to pose an immediate / grave risk to the consumer.	Low	Audit the activity at a minimum level - minimum every 12 months	3	Fundamentals to be audited a minimum of 6 months

Risk Assessment

Point / Activity / Program	Description of Point	Risk Description	Probability	Severity	Value	Risk	Outcome of Risk Assessment / Decisions
1 SENIOR MANAGEMENT COMMITMENT	Activites and management processes designed to ensure the food safety systems are inplace, maintained and adequately resourced	These processes are high level and failure of the activites being audited do not pose an immediate	1	2	2	Low	Audit the activity at a minimum level - minimum every 12 months
2 THE FOOD SAFETY PLAN – HACCP*	Principles and practices of food safety risk assessment, management and control	This requirement is critical to the proper identification and control of hazards in the process and product. Failure of these requirements are liekly to lead to a serious food safety or compliance issue. It includes CCP's	3	3	9	High	Audit the activity at a frequent level - minimum every 3 months
4.11 HOUSEKEEPING AND HYGIENE	Covers housekeeping and cleaning systems to ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised. Requirements cover the high level prolicies and procedures and not the specific cleaning programs themselves.	Ensuring that cleaning and housekeeping systems are in place and effective is a major requirement for producing safe and legal food products. Individual hygiene failures may not lead to an immiedately impact on safety however over time the accumulated efffective may pose an issue.	2	2	4	Medium	Audit the activity at a reduced level - minimum every 6 months

Step 1 - Define the RA Matrix

Risk Assessment Matrix				
		Probability		
		1	2	3
Severity	1	1	2	3
	2	2	4	6
	3	3	6	9
Notes	After rating each point the multiplication of the severity and potential rating determines wheather a point is high, medium or low in regard to significance.			

Step 2 – Define Probability Criteria

Probability Criteria	
3	Failure of the activity being audited is likely to happen, often, frequent
2	Failure of the activity being audited can happen, but not frequent
1	Failure of the activity being audited is unlikely to happen, rare, remote

Step 3 - Define Severity Criteria

Severity Criteria	
3	Failure of the activity being audited is likely to lead to an immediate / grave health impact, recall or regulatory issue
2	Failure of the activity being audited is unlikely to pose an immediate / grave risk to the consumer but repeated failure over time may
1	Failure of the activity being audited is unlikely to pose an immediate / grave risk to the consumer.

Step 4: Define Outcome and Decisions Criteria

Outcome Decision Critieria	
High	Audit the activity at a frequent level - minimum every 3 months
Medium	Audit the activity at a reduced level - minimum every 6 months
Low	Audit the activity at a minimum level - minimum every 12 months

Step 5: Define Special Points of Attention

	Special Points of Attention
1	Scope to include HACCP programme, prerequisite programmes and procedures
2	All activities shall be audited at least annually regardless of risk
3	Fundamentals to be audited a minimum of 6 months

Step 6: List all identified points / activities / tasks / programs etc.

Point / Activity / Program
1 SENIOR MANAGEMENT COMMITMENT
2 THE FOOD SAFETY PLAN – HACCP*
4.11 HOUSEKEEPING AND HYGIENE

Step 7: Describe each activity / Step 8: Describe the risk / Step 9: Rating

Point / Activity / Program	Description of Point	Risk Description	Probability	Severity	Value	Risk
1 SENIOR MANAGEMENT COMMITMENT	Activites and management processes designed to ensure the food safety systems are inplace, maintained and adequately resourced	These processes are high level and failure of the activites being audited do not pose an immediate	1	2	2	Low
2 THE FOOD SAFETY PLAN – HACCP*	Principles and practices of food safety risk assessment, management and control	This requirement is critical to the proper identification and control of hazards in the process and product. Failure of these requirements are liekly to lead to a serious food safety or compliance issue. It includes CCP's	3	3	9	High
4.11 HOUSEKEEPING AND HYGIENE	Covers housekeeping and cleaning systems to ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised. Requirements cover the high level prolicies and procedures and not the specific cleaning programs themselves.	Ensuring that cleaning and housekeeping systems are in place and effective is a major requirement for producing safe and legal food products. Individual hygiene failures may not lead to an immiedately impact on safety however over time the accumulated efffective may pose an issue.	2	2	4	Medium

Step 10: Define Outcomes and decisions

Risk	Outcome of Risk Assessment / Decisions
Low	Audit the activity at a minimum level - minimum every 12 months
High	Audit the activity at a frequent level - minimum every 3 months
Medium	Audit the activity at a reduced level - minimum every 6 months

Case Study – Cleaning Programs

Case Study

Case Study

- Objective: Case Study RA Cleaning Programs
- To conduct a risk assessment on all cleaning programs to determine which pose the greatest risk should failure occur in the activity. Use the outputs of the risk assessment to direct cleaning resources and verification activities to the high risk activities

BRC Requirement - Cleaning

- 4.11 “The frequency and methods of cleaning shall be based on risk”
- Implied requirement to conduct a documented risk assessment on all cleaning programs.
- Undertook a full Risk Assessment based on new model

HFG risk assessment model deployed

- Used a simple 3 by 3 matrix

Risk Assessment Matrix				
		Probability		
		1	2	3
Severity	1	1	2	3
	2	2	4	6
	3	3	6	9
Notes	After rating each point the multiplication of the severity and potential rating determines wheather a point is high, medium or low in regard to significance.			

Defined probability and severity requirements

- For each rating the character of the rating was defined

Probability Criteria		Severity Criteria	
3	Failure of the cleaning activity is likely to happen, often, frequent	3	Failure of the cleaning activity is likely to lead to an immediate / grave health impact, recall or regulatory issue
2	Failure of the cleaning activity being can happen, but not frequent	2	Failure of the cleaning activity may impact on consumer perception or lead to product rejection
1	Failure of the cleaning activity is unlikely to happen, rare, remote	1	Failure of the cleaning activity is unlikely to pose an immediate / grave risk to the consumer.

Defined the frequency and scope of verification required for High, Medium and Low ratings

Outcome Decision Critieria		Special Points of Attention	
High	Clean at a frequent level - between products with full verification (visual, ATP, photo, micro and chemical)	1	Special attention to food contact surfaces and environmental cleaning in open food handling areas
Medium	Clean at a reduced level - minimum daily with appropriate verification (Visual and environmental swabs)	2	The frequency and methods of cleaning shall be based on risk.
Low	Clean at a minimum level - as appropriate with visual verification	3	Appropriate verification depending on the risk. Risk to include food safety, business risk and potenital for customer recall due to legality

Measurable Risk Reduction (Allergens)

Ineffective Control Measures

3 (probability) x 3 (Severity) = 9 Unacceptable

RISK

1(probability) x 3(Severity) = 3 Acceptable

Effective Control Measures

Measurable Risk Reduction (Species Cross Contamination)

Ineffective Control Measures

3 (probability) x 3 (Severity) = 6 Unacceptable

RISK

1(probability) x 2(Severity) = 2 Acceptable

Effective Control Measures

Defined all programs, risks and ratings

- Listed all cleaning programs and described each and the associated risks
- Rated each program
- Probability of failure to conduct cleaning correctly
- Severity of impact if failure occurred
- Measure the Risk reduction of control implementation

Defined all programs, risks, ratings and set outcomes

Point / Activity / Program	P	S	V	Risk	Outcome of Risk Assessment / Decisions
Sausage Work In Progress Chill	2	1	2	Low	Clean at a minimum level - clean weekly
Species change-over Sausage Lines	3	2	6	High	Line change over (Allergen and species hazards) to be clean at a frequent level - between products with full verification (visual, ATP, photo, micro and chemical)
Allergen Change Over Sausage Lines	3	3	9	High	Line change over (Allergen and species hazards) to be clean at a frequent level - between products with full verification (visual, ATP, photo, micro and chemical)

Summary of RA

- RA identified that cleaning programs between allergens and species posed the greatest risk
- In particular cleaning programs on lines and contact surfaces between allergen and species change overs
- Criteria was established for high risk programs to include…
- Clear and detailed cleaning procedures for line change over between species
- Automatic notification of completed cleaning to supervisors
- Visual validation of specific contact surfaces
- ATP positive release
- New requirement to take a high resolution photo of cleaned and visually verified item
- Clear re-clean criteria and automatic alerting of same to management
- Employed IT solution to support the above

Outcome

- Structured approach to risk assessment
- Cleaning activities and programs based on RA
- Significant reduction in failures and re-cleans
- Digital recording and management of the process