Practical Guidance on the Application of Allergen Quantitative Risk Assessment

Neil Buck

Munich GERMANY 4-6 May 2022
IAFP'S EUROPEAN SYMPOSIUM ON FOOD SAFETY

ILSI Europe
International Life Sciences Institute

Contents

- Summary
- Project Conduct
- Project Output
- Next Steps

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Summary

Yesterday

- Binary Approach
- judgement on whether allergen is potentially present or not
- lack of industry alignment
- Inaccurate information passed along supply chains
- Proliferation of Inaccurate Precautionary Labelling

Today

- Growing expectation of more accurate cross-contact understanding
- Application of allergen reference doses, and QRA

But …

- Lack of harmonization in when allergen QRA is appropriate and how to perform

Tomorrow

- Consensus guidance on the application of allergen QRA

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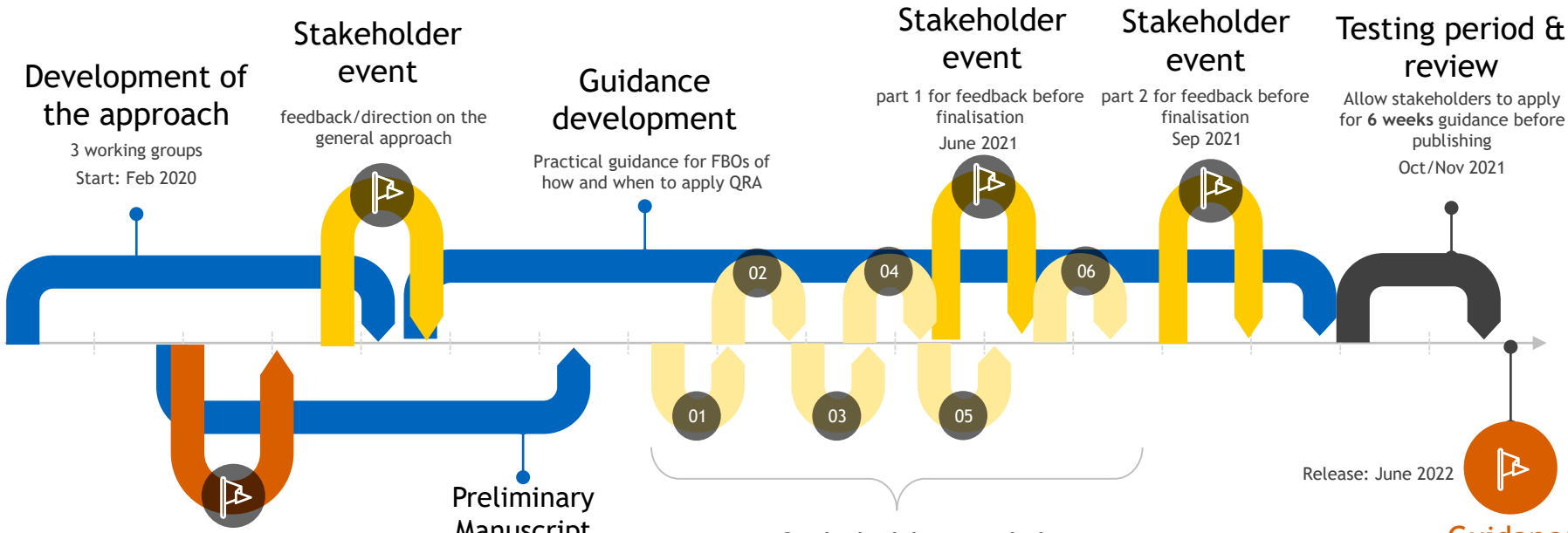
The Project Conduct



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The Project Conduct

Dev
th

Stakeholder

activity launch with the Stakeholder community

Stakeholder

the Guidance (Apr-Jul 2021)

Stakeholder
event

r feedback before
nalisation
Sep 2021

Testing period & review

Allow stakeholders to apply for **6 weeks** guidance before publishing

Oct/Nov 2021

Release: June 2022

Guidance published (open access)

Food Control 138 (2022) 108917

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

Check for updates

Allergen quantitative risk assessment within food operations: Concepts towards development of practical guidance based on an ILSI Europe workshop

Benjamin C. Remington [a], Joseph Baumert [a], W. Marty Blom [b], Luca Bucchini [c], Neil Buck [d], René Crevel [e], Fleur De Mooij [f], Simon Flanagan [g], James Hindley [h], Bushra Javed [i], Despoina Angeliki Stavropoulou [j,*], Myrthe W. van den Dungen [k], Marjan van Ravenhorst [l], Si Wang [m], Michael Walker [n], Participants in the ILSI Europe Virtual Workshop of 29th October 2020 [1]

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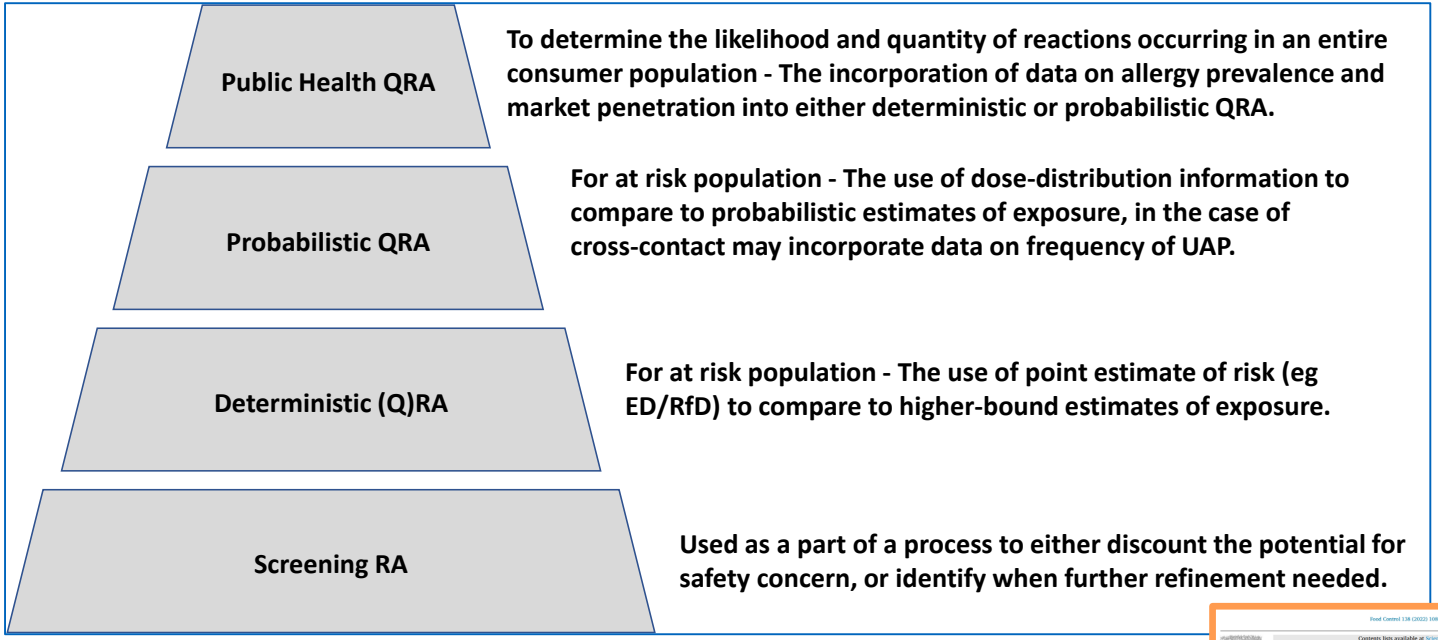
Different types of (Q)RA exist




Food Control

Allergen quantitative risk assessment within food operations: Concepts towards development of practical guidance based on an ILSI Europe workshop

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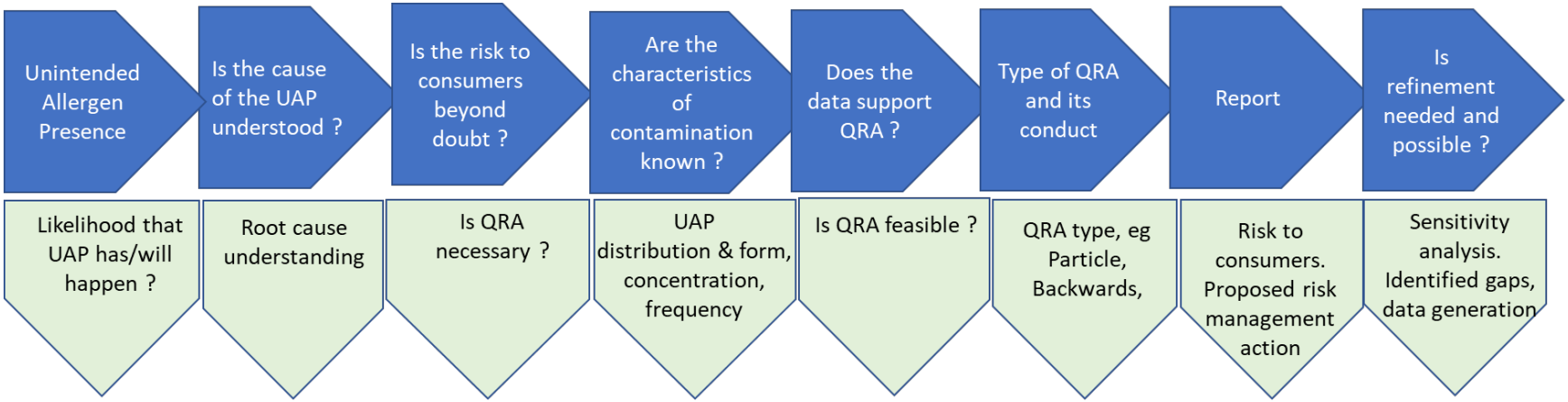
QRA isn't always necessary/appropriate or feasible

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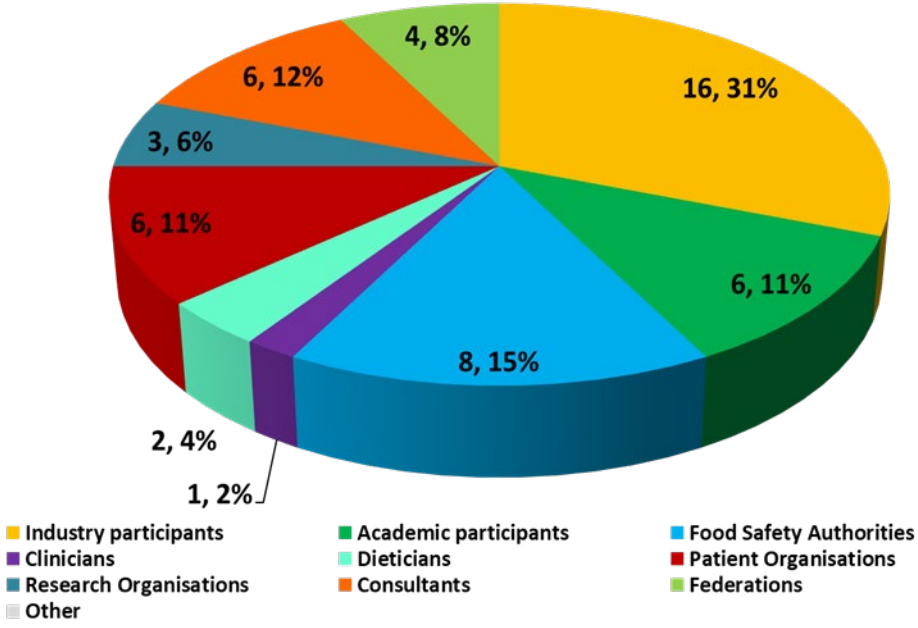
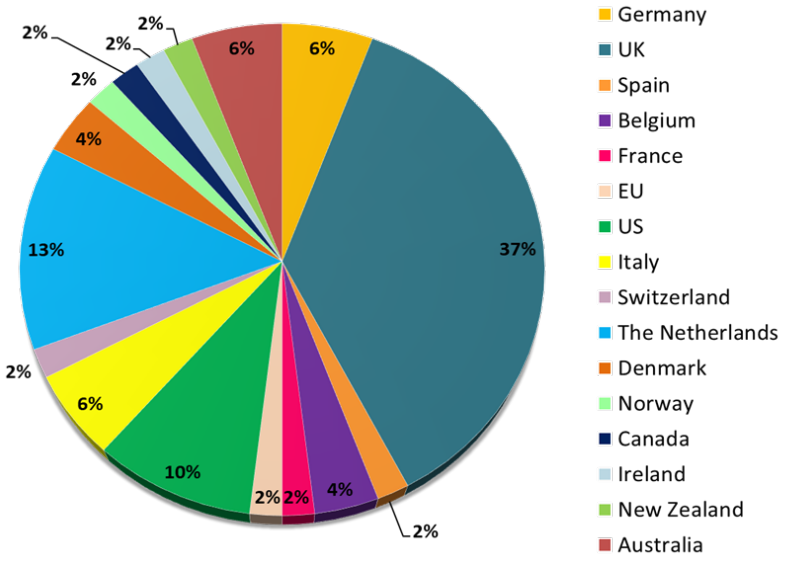
The Project Conduct: Participants





52 Stakeholders
Drafting by an ILSI Expert Group composed of 13 members

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The Project Conduct

Split into 3 Working Groups, across 2 distinct assessment categories

- Proactive assessments for food production under normal conditions (upstream and in-house)
- Reactive assessments as part of an allergen incident response

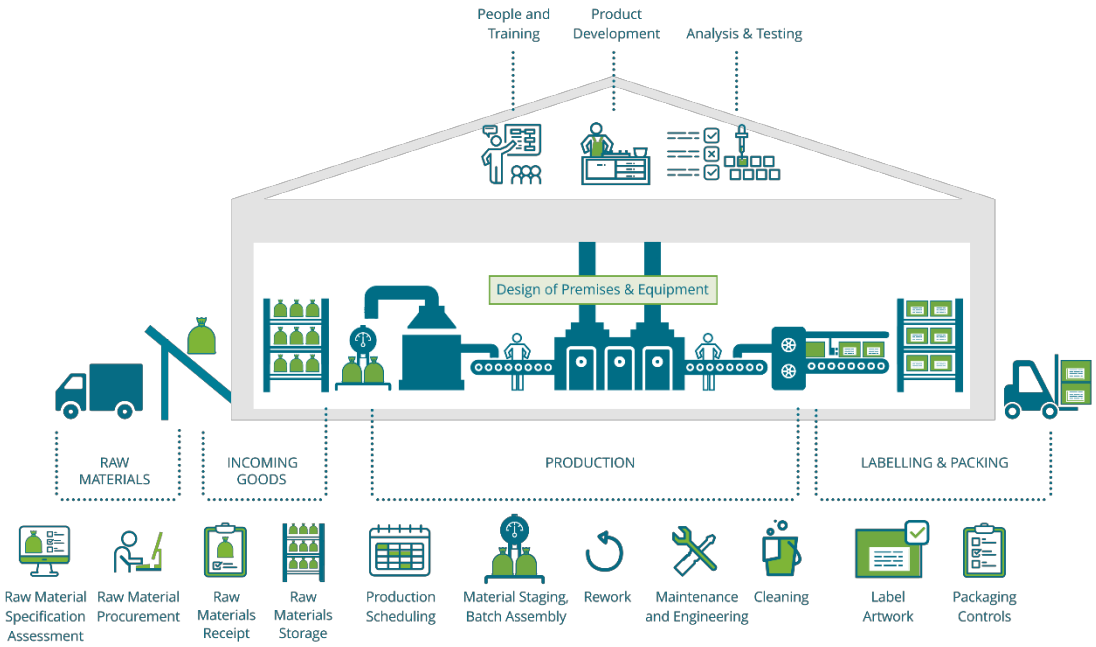

Diagram from the Allergen Bureau

The Project Conduct

WG 1: Supply Chain

- Up-steam communication with your supplier
- Establishing transparent flow of information

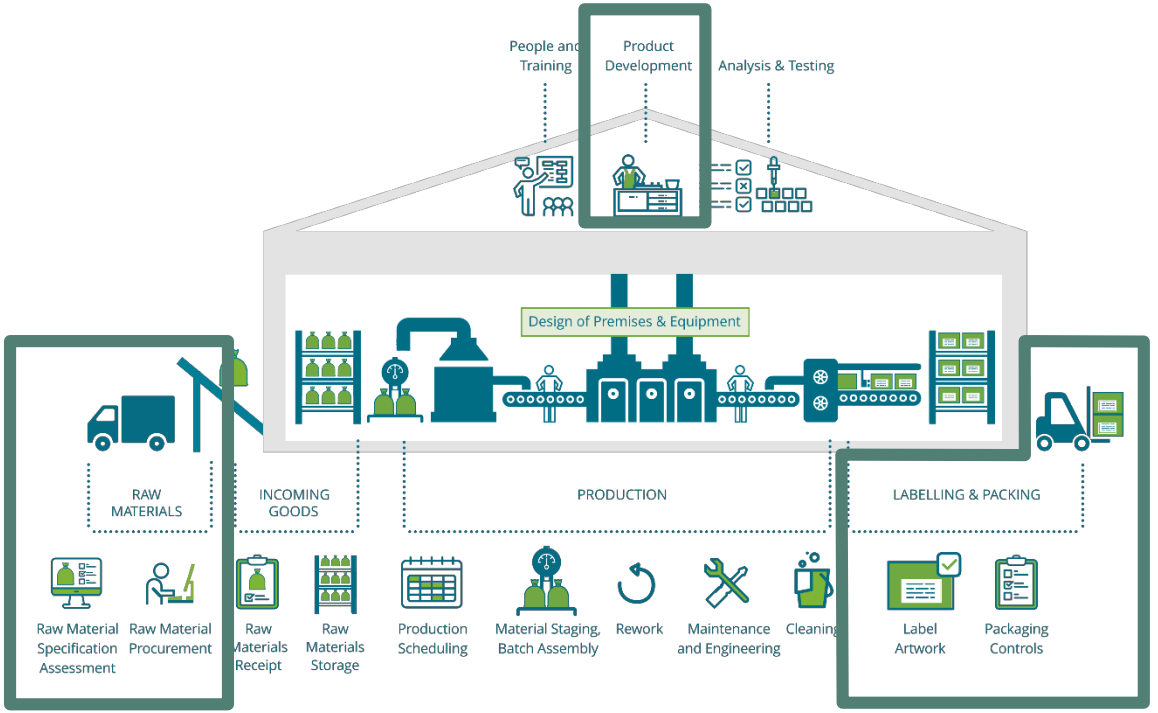

Diagram from the Allergen Bureau

The Project Conduct

WG 2: Cross-contact – PAL

- cross-contact risk assessment for operations

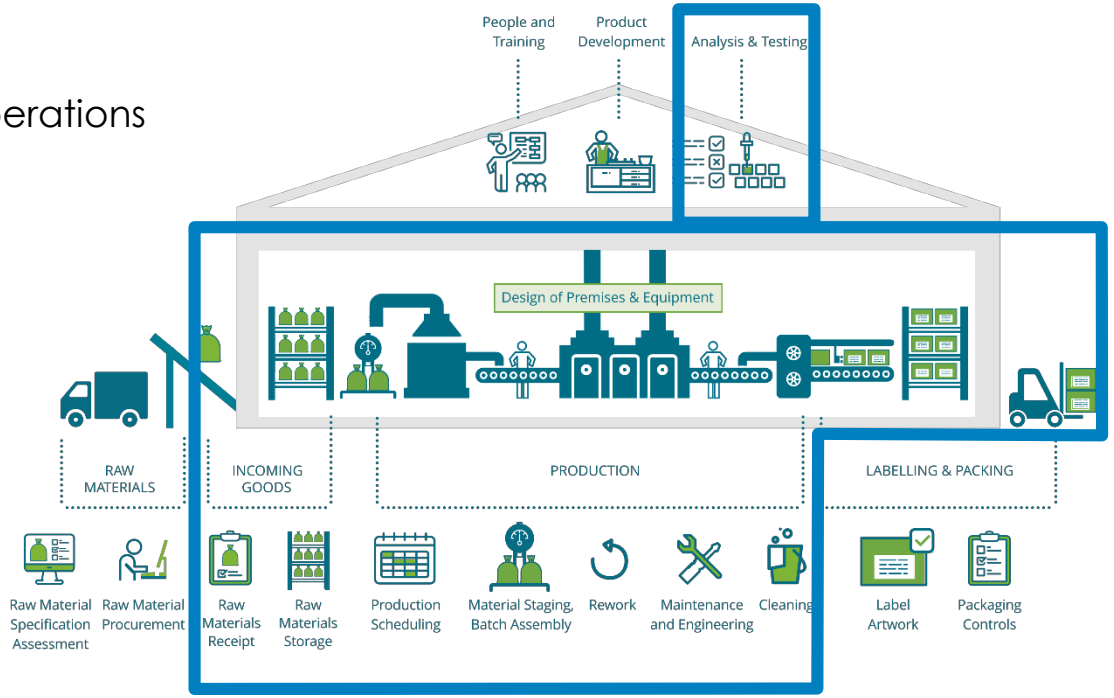

Diagram from the Allergen Bureau

The Project Conduct

WG 3: Incidents

- Unanticipated
- Errors outside of normal GMP or change management

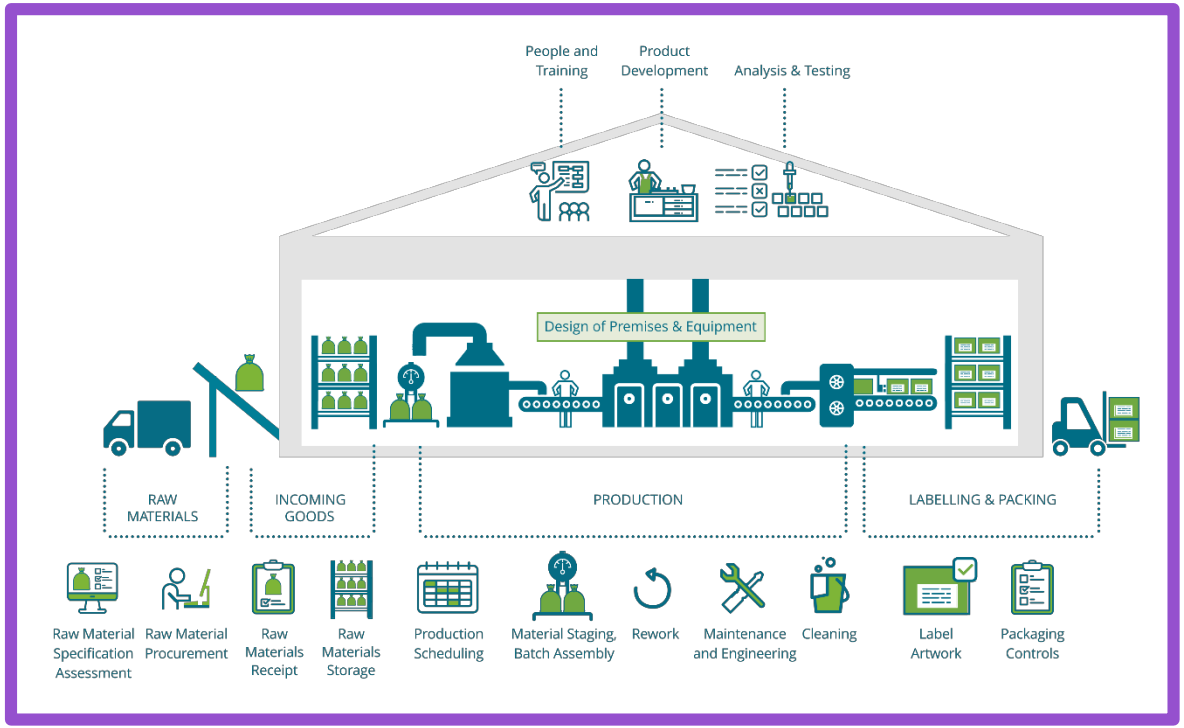

Diagram from the Allergen Bureau

The Project Conduct

WG 1:
Supply Chain

WG 2:
Cross-contamination - PAL

WG 3: Incidents

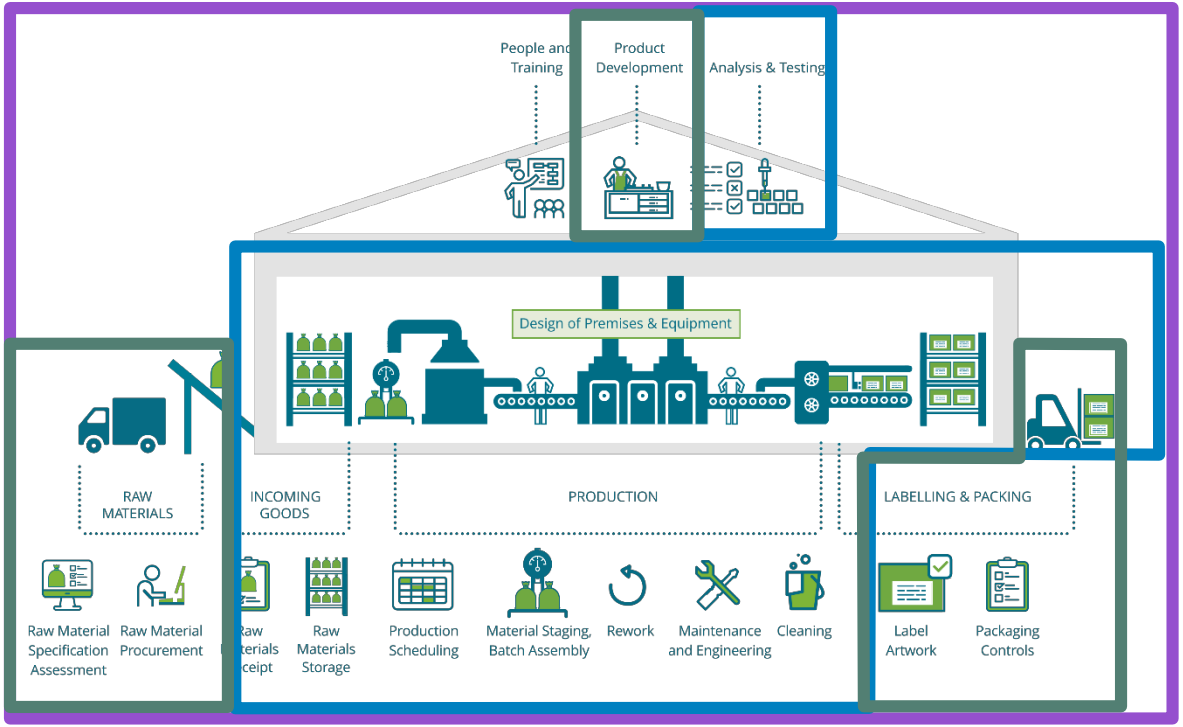

Diagram from the Allergen Bureau

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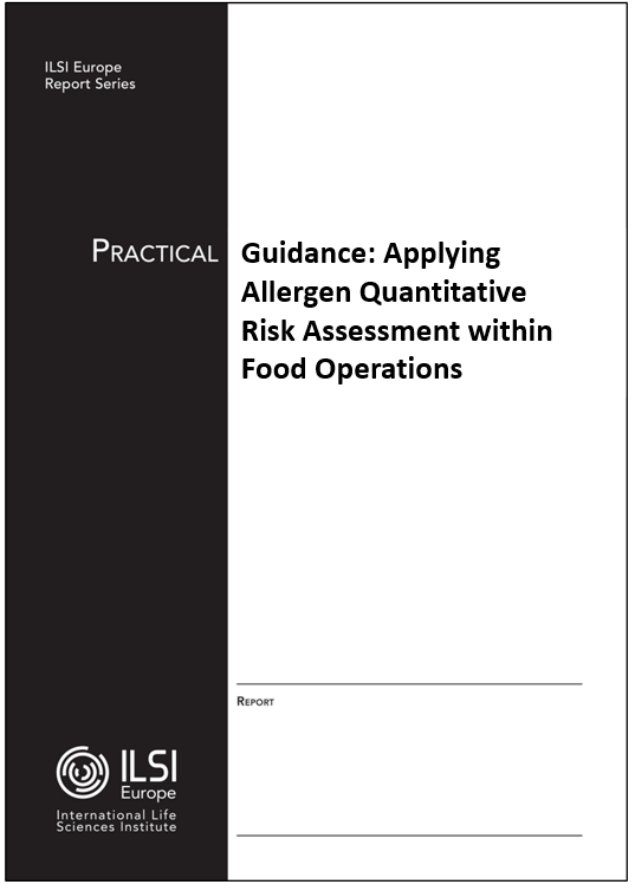


Introduction

- The place of QRA in allergen management

Communication Across the Supply Chain

- Global regulatory aspects
- Information requirements
- How to obtain the required information

Management of Operations

- QRA within allergen control programs
- Guide on QRA within site cross-contact
- Cleaning

Management of Incidents

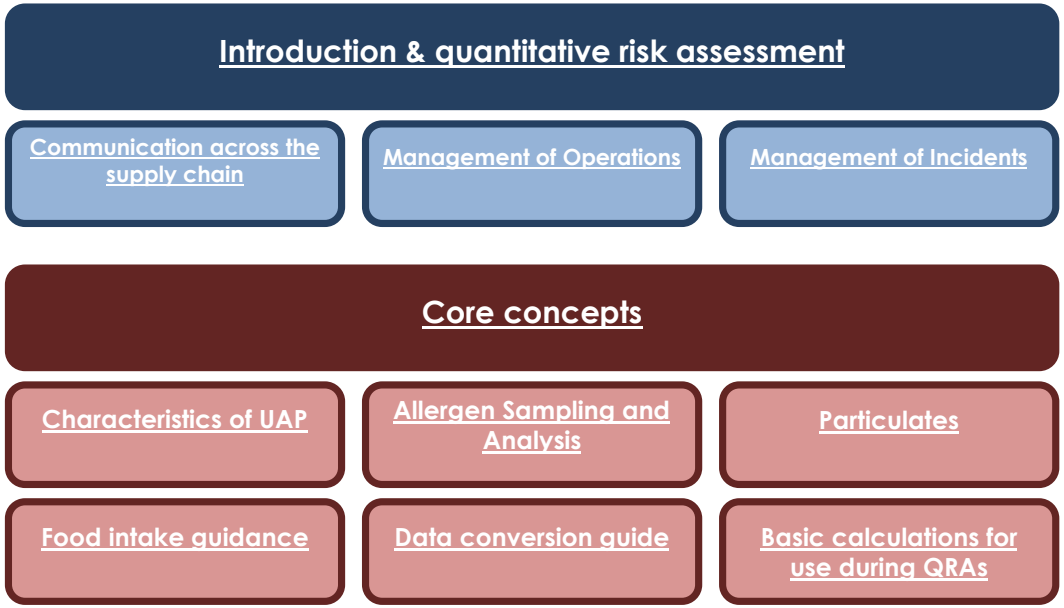
- Guidance on incident assessment

Core Concepts

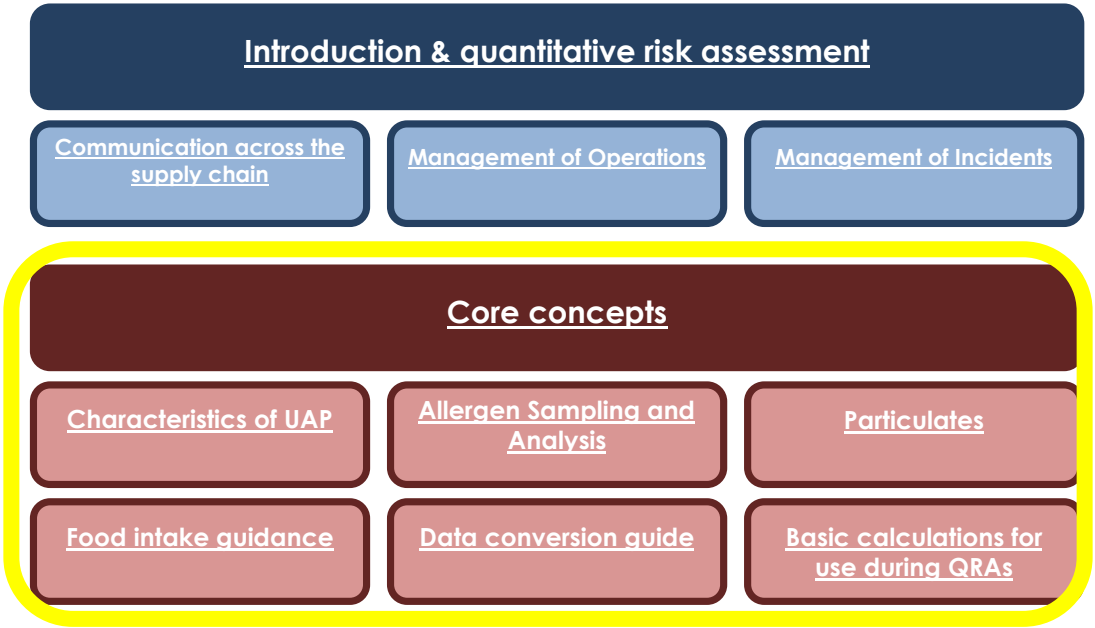
- UAP Scenarios an characteristics
- Amount of UAP in food
- Guidance on Food intake
- Basic calculations

Annexes

The Project Output

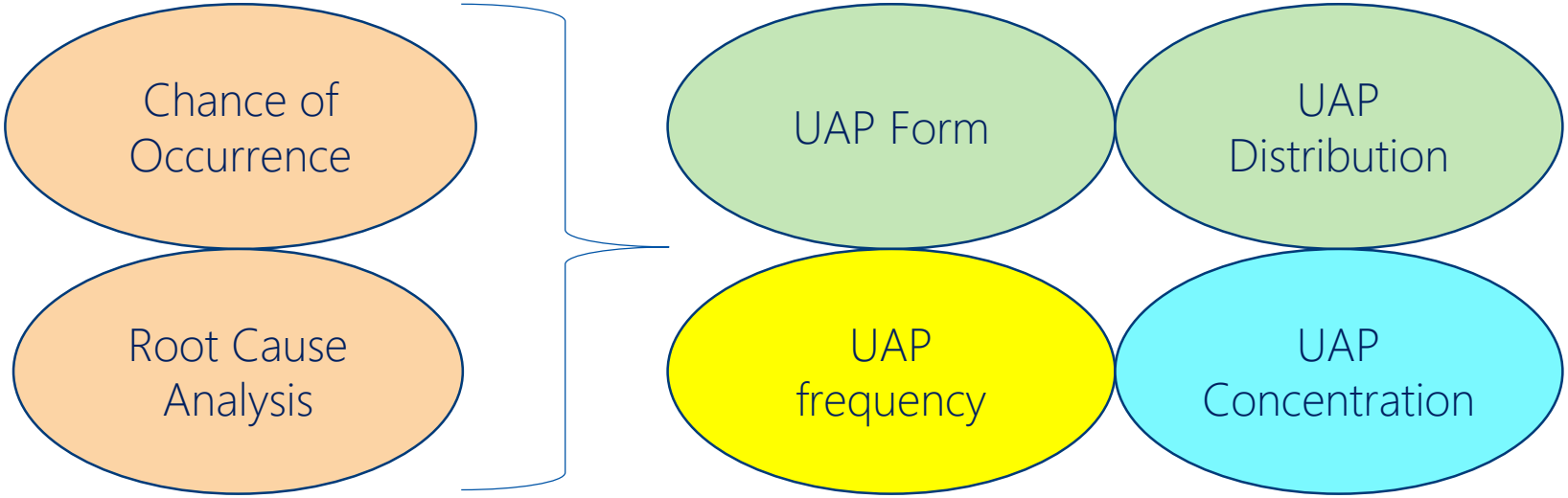


The Project Output



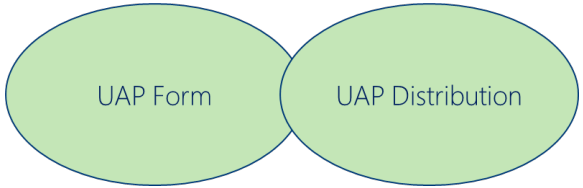
The Project Output: Core Concepts

Characteristics of UAP



The Project Output: Core Concepts

Example of how cross-contamination is characterized

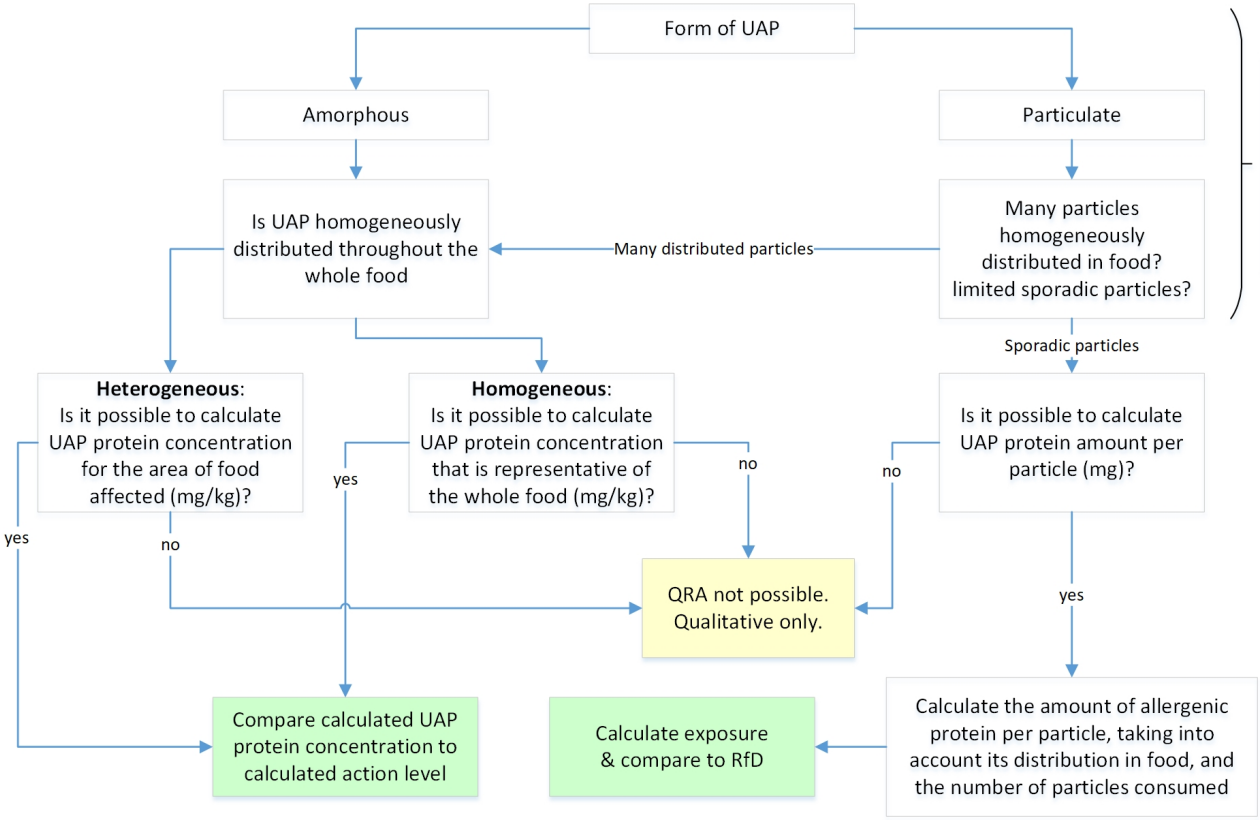


	Amorphous	Particulate
Homogeneous	UAP does not have a discrete structure, and is uniformly distributed within the sensitive product.	UAP has a discrete structure, those discrete structures are uniformly distributed within the sensitive product at a particular density per unit volume.
Heterogeneous	UAP does not have a discrete structure, but is clumped in one or more regions of the sensitive product.	UAP has a discrete structure, those discrete structures are not uniformly distributed within the sensitive product.

Form & Distribution: quality of evidence	Description
High uncertainty	There is insufficient information to describe the form and/or distribution of UAP in the sensitive product.
Med uncertainty	The form and/or distribution of UAP in the sensitive product can be inferred based on knowledge of materials and process, but has not been confirmed.
Acceptable uncertainty	The form and/or distribution of UAP in the sensitive product has been confirmed (observation and/or measurement).

The Project Output: Core Concepts

The influence of UAP Characteristics on the calculation method



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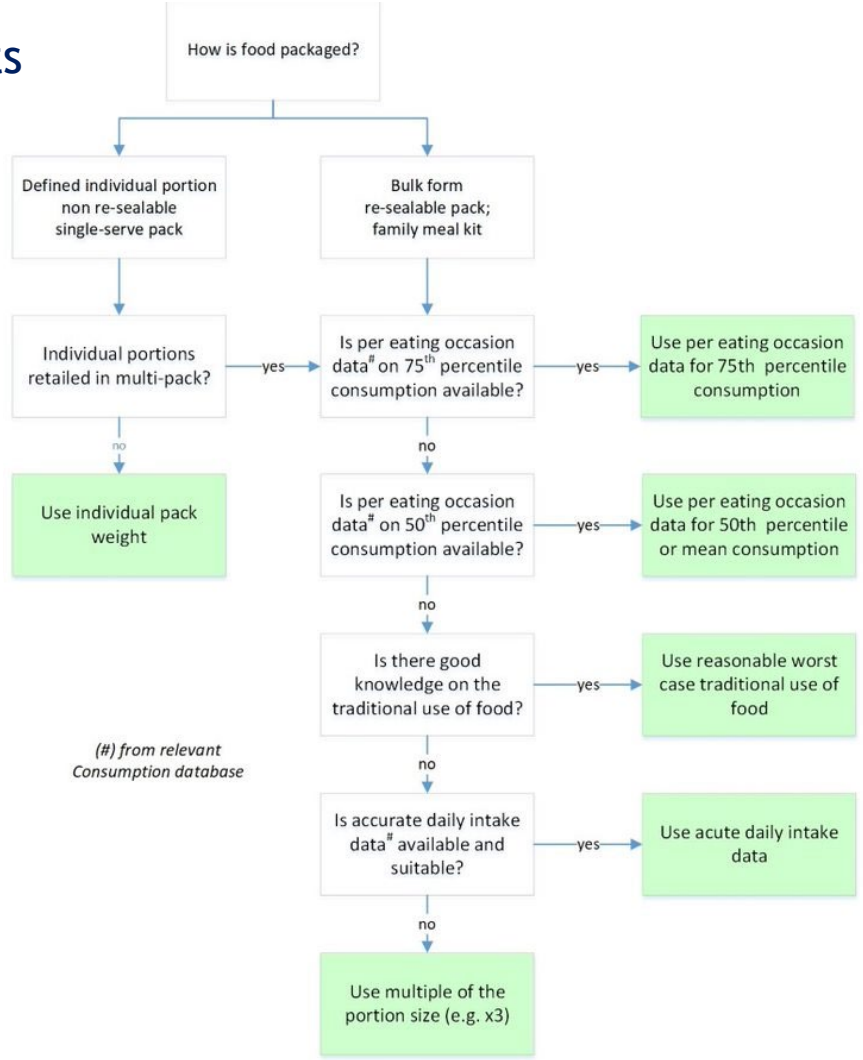
The Project Output: Core Concepts
Estimating consumption



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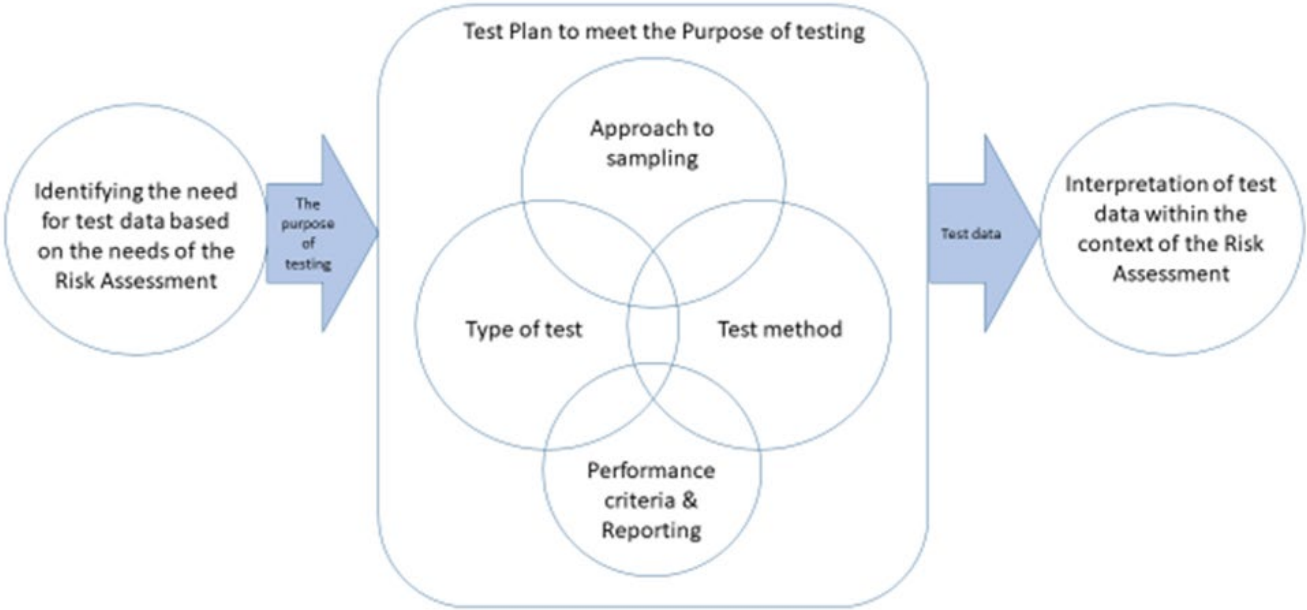
The Project Output: Core Concepts
Sampling & analysis



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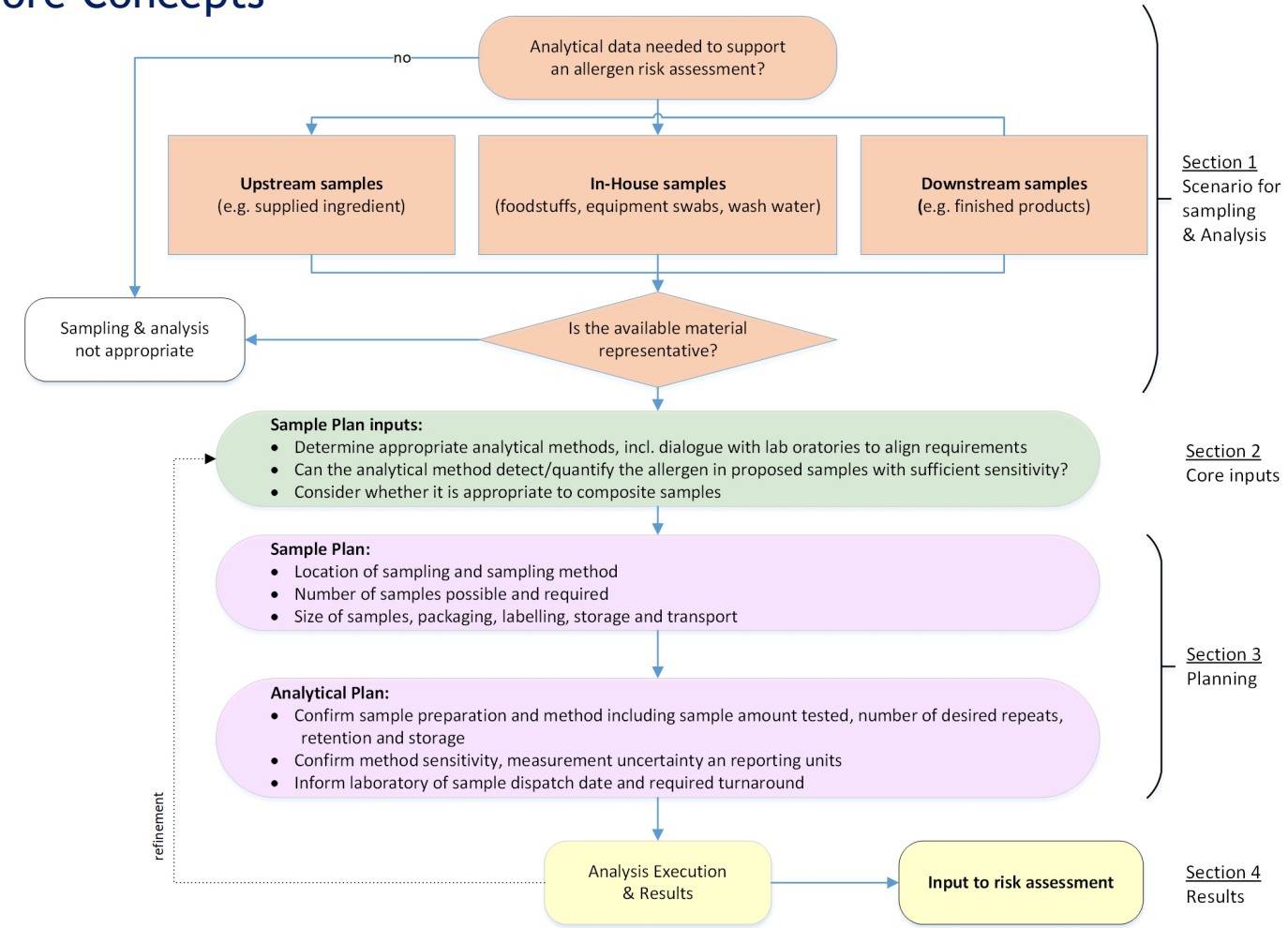
The Project Output: Core Concepts

Sampling & analysis



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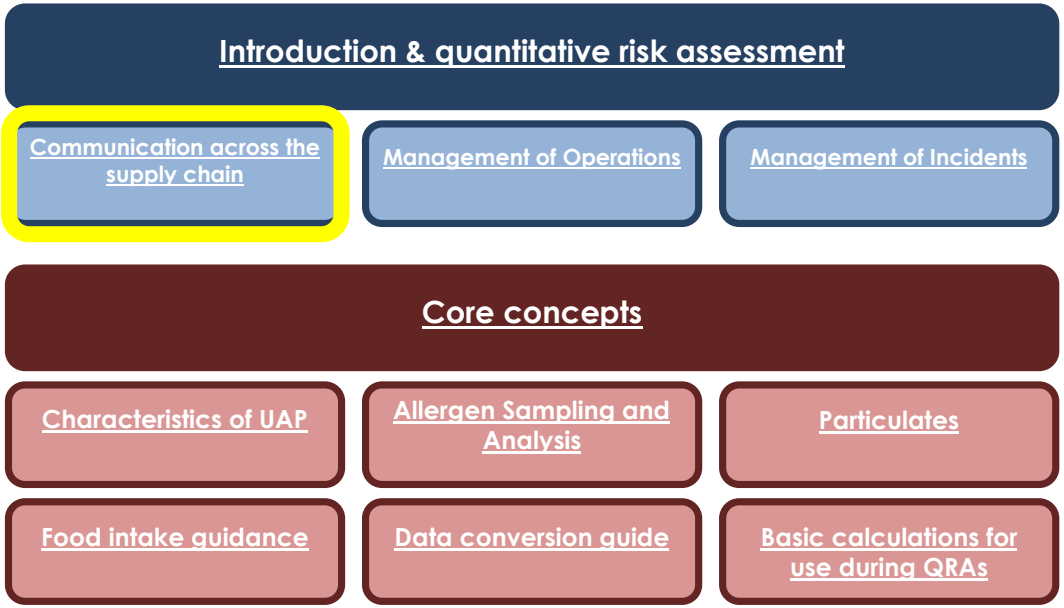
The Project Output: Core Concepts

Sampling

Supporting conditions to be considered	Regular frequency of allergen presence Low availability of material samples Homogeneous distribution of allergens Limited time & resource available	Homogeneous distribution of allergens Limited time & resource available Sufficient or abundant material available to sample from Urgent and more resources made available	Sufficient or abundant material available to sample from Urgent and more resources made available
Level of concern	**LOW** Routine verification of ingredients without claim	**MEDIUM** Routine verification of ingredients without claim	**HIGH** Quantification needed for risk assessment, claim validation or incident
Number of Samples recommended	**A single or small number of samples**	**Two up to six samples.** Particularly if allergen presence may be intermittent Sample size is also important	Allergen presence is regular and homogeneous: take **at least six samples** or two from every batch (risk based for claim validation). Allergen presence is NOT regular and/or NOT homogeneous: (i) consider the size of the batch and take "$\sqrt[3]{N}$" [or N^(1/3)] samples, where N is the number of units available; or (ii) consider incremental sampling (see main text).

The Project Output



The Project Output: Communication across the supply chain

Prioritization of ingredients

Geographic complexity	Ingredient / supplier complexity	Supplier technical capability
Low: Ingredients are being purchased from the same regulatory territory as the final product sales territory	**Low:** Homogeneous cross-contact risk 1. Low complexity environment 2. High complexity environment	**High:** Company with dedicated people and verified systems for allergen management
High: Ingredients come from a regulatory territory other than the final product sales territory	**High:** Heterogeneous cross-contact risk 1. Low complexity environment 2. High complexity environment	**Low:** Company with few to no people or systems dedicated to allergen management

Given your use of the ingredient, how likely is it that a cross-contact will present health risk at market ?
Role for 'backwards' QRA.

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The Project Output: Communication across the supply chain

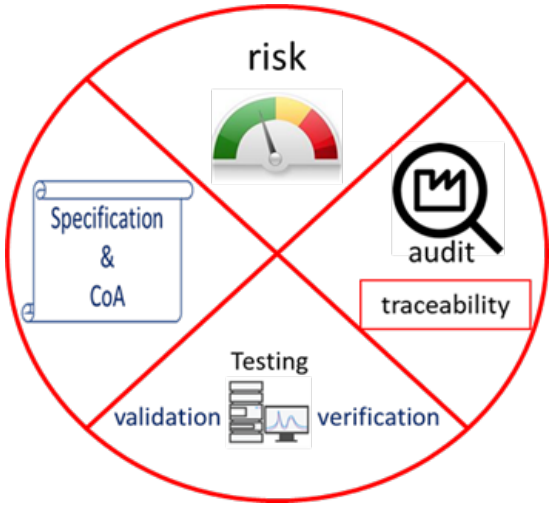
Example supplier questionnaire

1. Allergen information Regulation (EU) No 1169/2011 Annex II Including products thereof	**Recipe/ product formula = present** (added ingredients, additives, carriers, processing aids etc. derived from an allergenic source)						**Cross contamination = possibly present** (unintentional presence due to production on the same equipment, used utensils, personnel, airborne contact or by other means).					
	Used as ingredient?		Type of ingredient E.g. peanut oil, soy lecithin, wheat starch, celery seed	Com-position	Protein content from allergenic source (%) [1]	Exempt from allergen labelling? [2]	Used on same line?	Cross- contact possible?		Type of ingredient(s) which could cause cross contact. E.g. peanut oil, soy lecithin, wheat starch	Type of contamination Homogeneous: powder, liquid of paste. Inhomogeneous: particles. Provide detailed information of the contamination[4]	
	YES	**NO**		**%**	**%**		**YES**	**YES**	**NO**		**Homogeneous**	**Particle**
Cereals containing gluten												
Wheat	☐	☐	ingredient name	% recipe	protein %	☐	☐	☐	☐	yes->ingredient name	☐ ppm	☐ grams, protein %
Rye	☐	☐	ingredient name	% recipe	protein %	☐	☐	☐	☐	yes->ingredient name	☐ ppm	☐ grams, protein %
Barley	☐	☐	ingredient name	% recipe	protein %	☐	☐	☐	☐	yes->ingredient name	☐ ppm	☐ grams, protein %
Oats	☐	☐	ingredient name	% recipe	protein %	☐	☐	☐	☐	yes->ingredient name	☐ ppm	☐ grams, protein %
Spelt	☐	☐	ingredient name	% recipe	protein %	☐	☐	☐	☐	yes->ingredient name	☐ ppm	☐ grams, protein %

from Allergenen Consultancy B.V.

The Project Output: Communication across the supply chain

Supplier questionnaires and level of risk can be integrated with the other tools in your supplier-management arsenal



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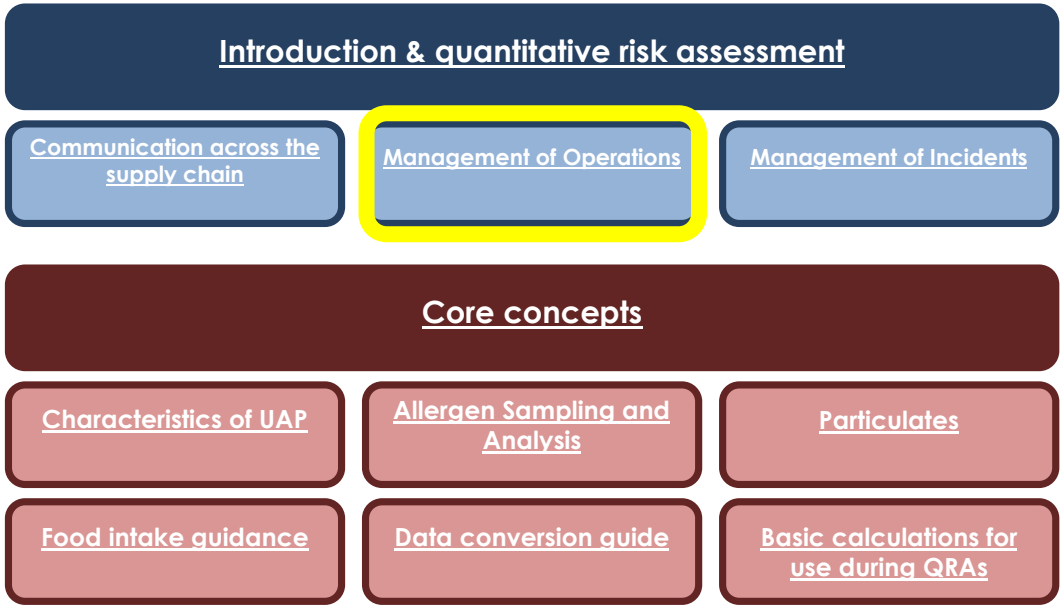
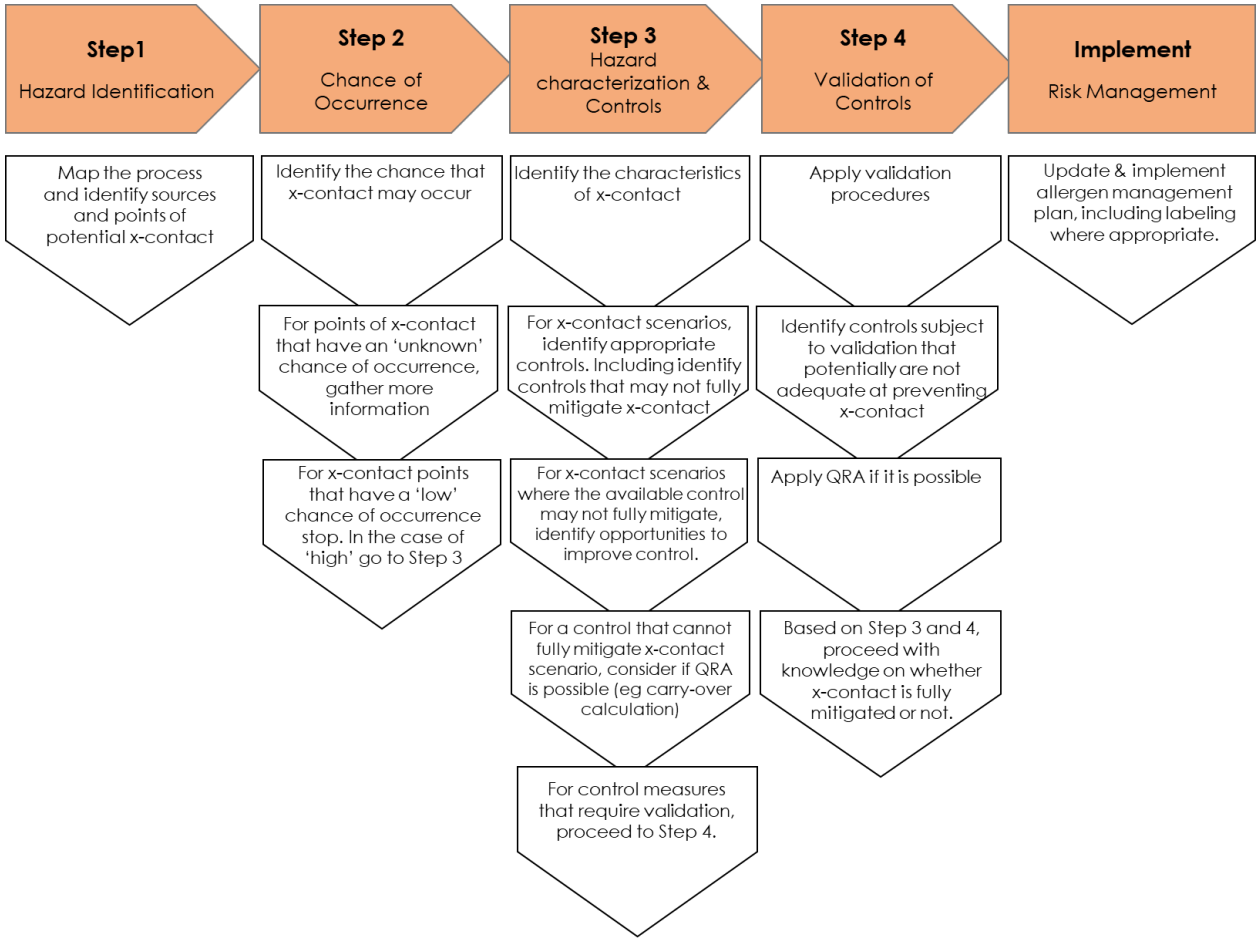
The Project Output



The Project Output: Management of Operations



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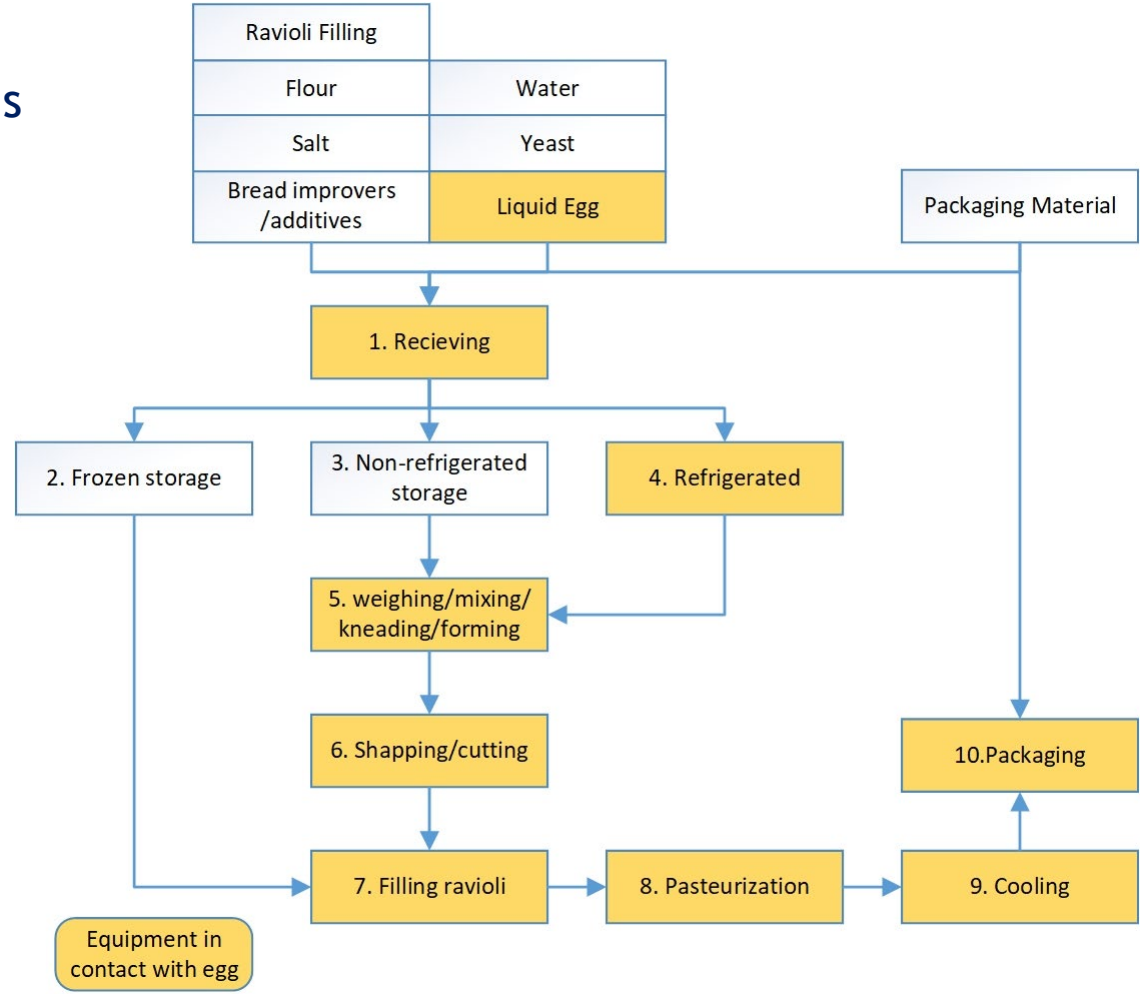
The Project Output: Management of Operations

Process mapping



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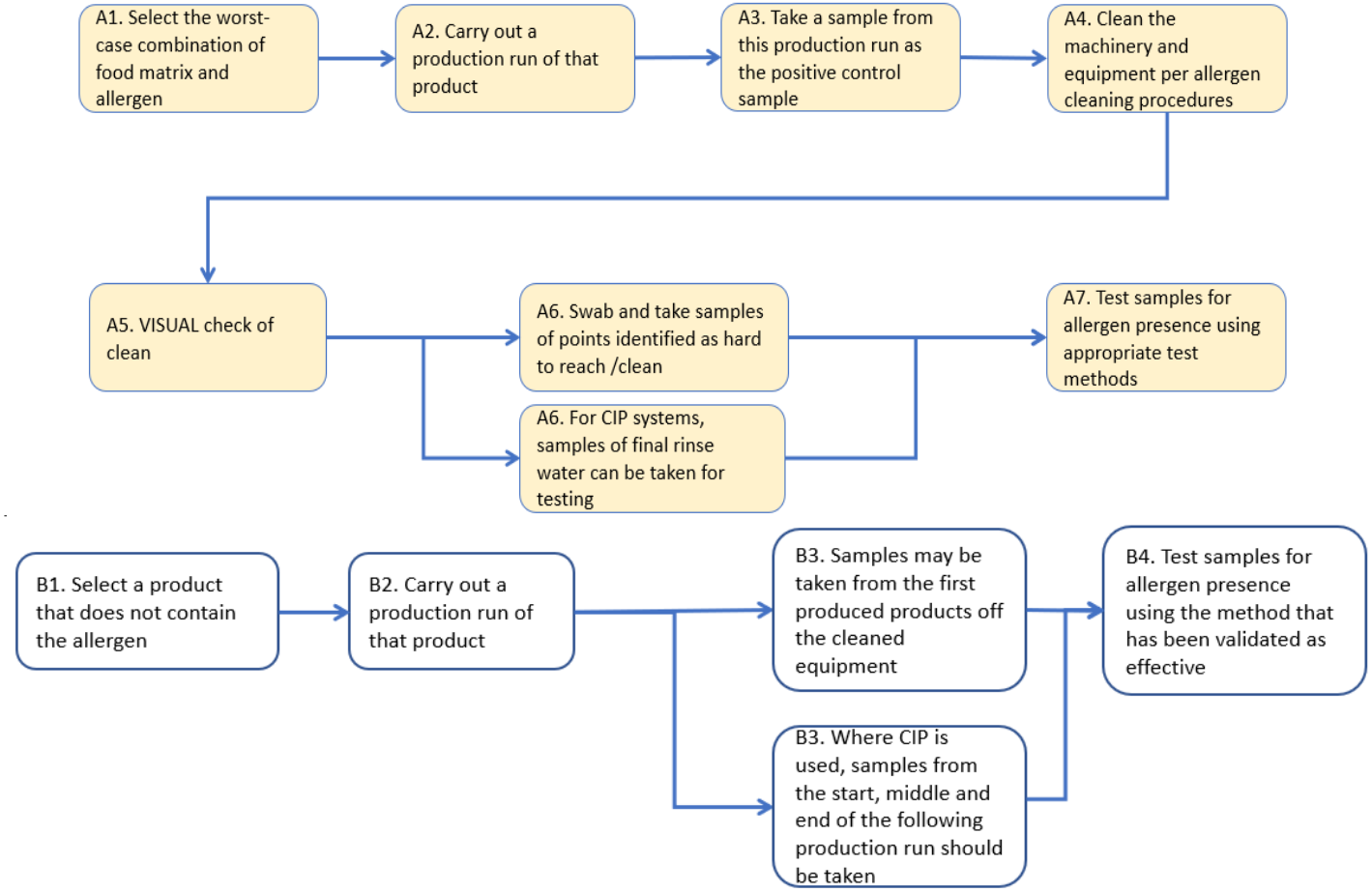
The Project Output: Management of Operations

Change over



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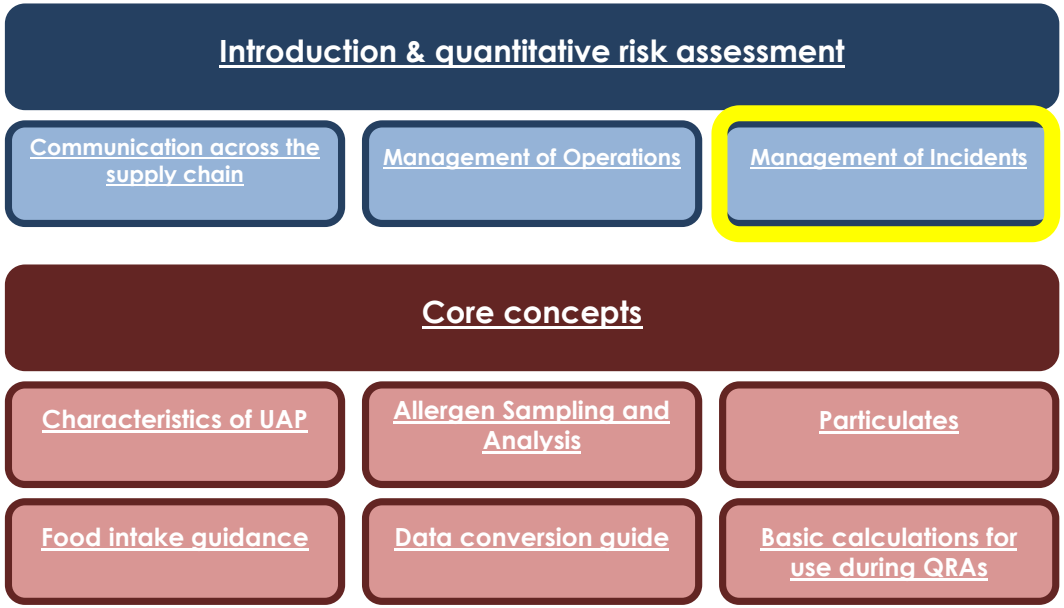
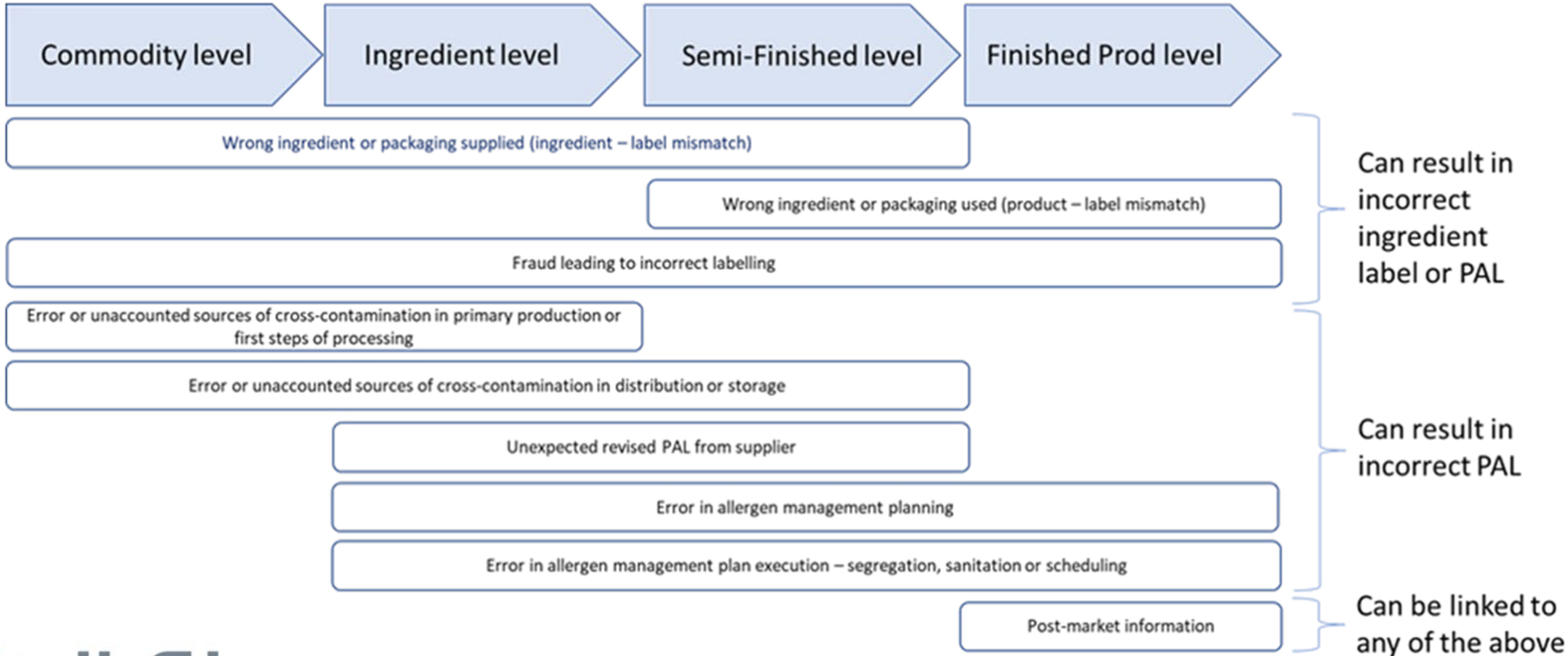
The Project Output



The Project Output: management of Incidents

Type of Incident



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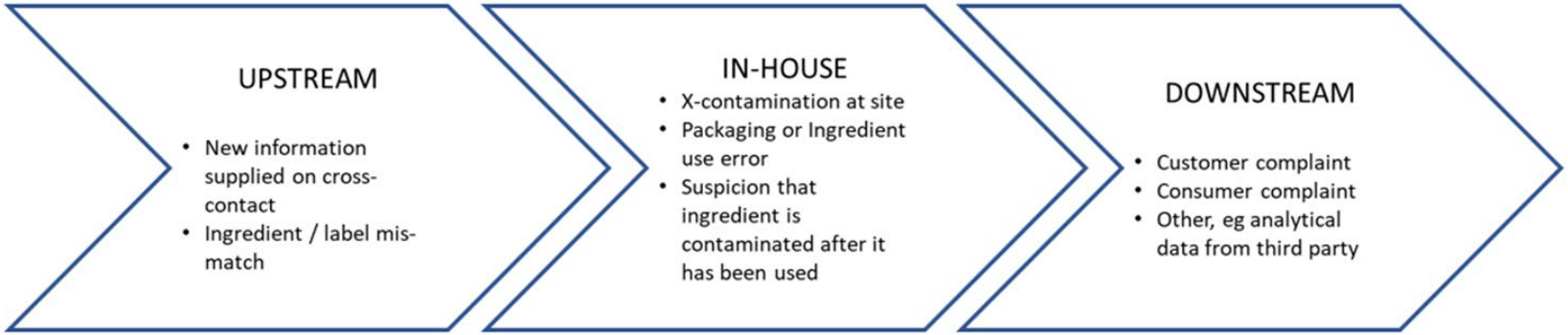
The Project Output: management of Incidents



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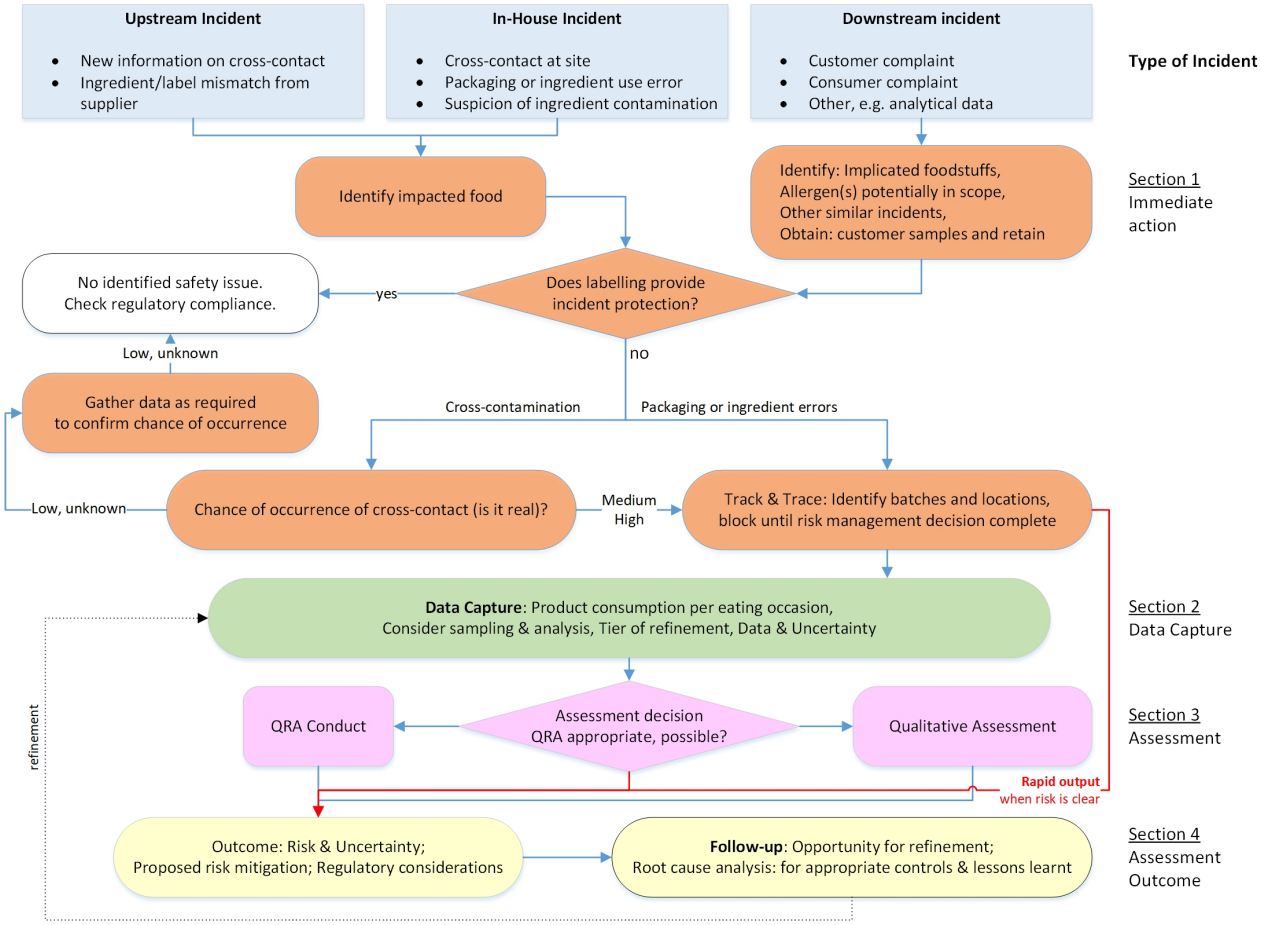

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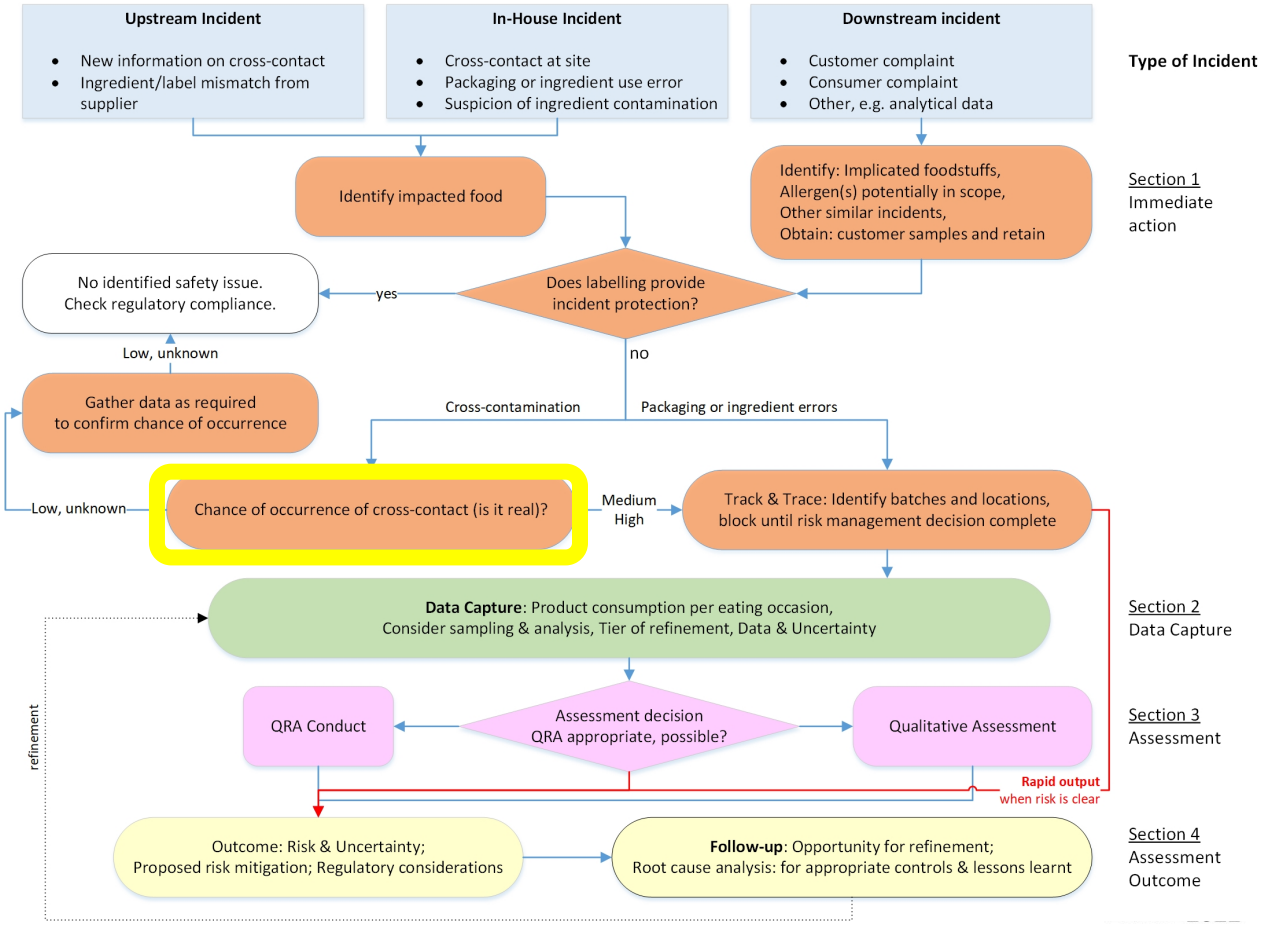
The Project Output: management of Incidents



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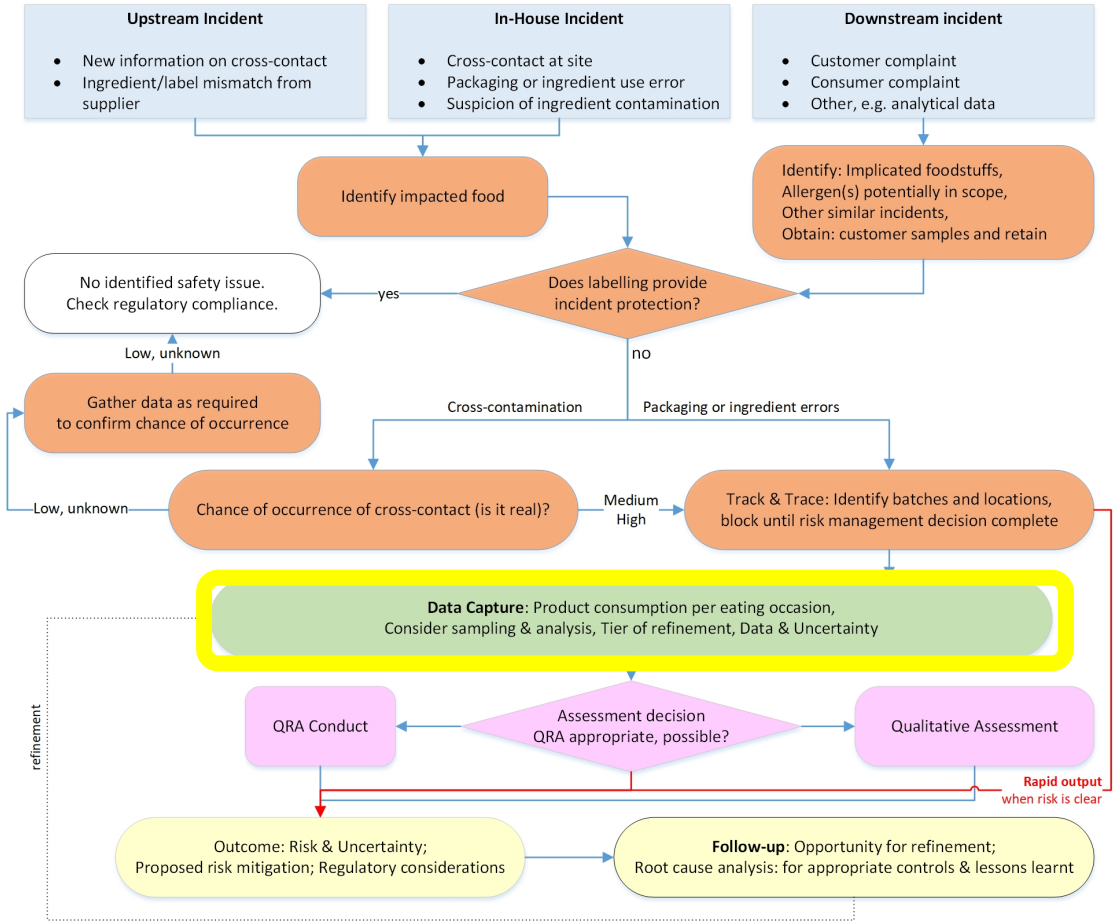
The Project Output: management of Incidents

Chance of occurrence of contamination (is it real) ?

Chance of Occurrence	Description	Recommended Action
High	It is more likely than not that UAP has occurred: The factors that cause contamination are known, and there is acceptable uncertainty that those factors have happened.	Proceed with the assessment (next step Track & Trace).
Medium	It is possible that UAP has occurred, but also likely it has not: The factors that may cause contamination are known, and there is significant uncertainty on whether those factors have happened.	Gather data to decrease uncertainty on whether the incident has occurred. or If due to level of concern or time constraints proceed with the assessment, when/ if data becomes available repeat assessment of chance of occurrence.
Low or unknown	There is circumstantial evidence only that UAP has occurred: Whether the contamination occurs or not cannot be estimated with acceptable level of certainty.	Gather data to decrease uncertainty before progressing with an assessment.

The Project Output: management of Incidents



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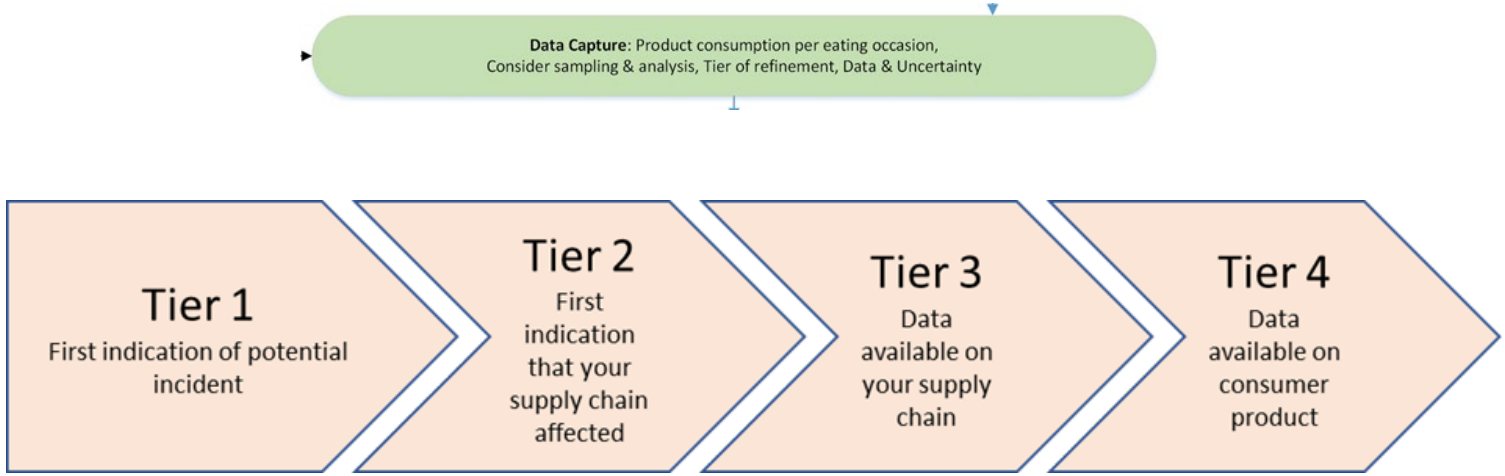
The Project Output: management of Incidents



The Project Output: management of Incidents

Data Capture: Product consumption per eating occasion,
Consider sampling & analysis, Tier of refinement, Data & Uncertainty

Data & Uncertainty			
Characteristics		**Uncertainty**	**Data & Notes**
A Form of contamination	☐ Amorphous	1 ☐ High	
	☐ Particulate	2 ☐ Medium	
	☐ Unknown (uncertainty is always 'high')	3 ☐ Acceptable	---------- Note: If 'unknown', assessment should be based on both amorphous and particulate, until refined information is available.
B Distribution of contamination	☐ Homogeneous	1 ☐ High	
	☐ Heterogeneous	2 ☐ Medium	
	☐ Unknown (uncertainty is always 'high')	3 ☐ Acceptable	---------- Note: If 'unknown', assessment should be based on both hetero' and homogeneous, until refined information is available.
C Frequency of contamination	☐ Isolated	1 ☐ High	
	☐ Intermittent	2 ☐ Medium	
	☐ Regular	3 ☐ Acceptable	
	☐ unknown (uncertainty is always 'high')		---------- Note: If 'unknown', assessment should assume contamination is 'regular'.
D Quantity of Contamination	1 ☐ Estimate – not analytical		Provide data: ---------- Note: If 'unknown', assessment can only be qualitative. More information is needed before QRA can be performed.
	2 ☐ Analytical, point data		
	3 ☐ Analytical, data range. Or understanding of quantity available in case of mis-labeling or wrong ingredient used.		
	1 ☐ Unknown		
Overall data uncertainty (sum of A-D)		4-7 ☐ High 8-10 ☐ Medium >10 ☐ Acceptable	Notes

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The Project Output: management of Incidents

Tier of Refinement	Overall Data Uncertainty		
	High	**Medium**	**Acceptable**
1*	Uncertainty too large, more data required	Uncertainty too large, more data required	Uncertainty too large, more data required
2*	Uncertainty too large, more data required	Qualitative assessment only	Qualitative or Quantitative assessment
3	Qualitative or Quantitative assessment	Quantitative assessment	Quantitative assessment
4	Quantitative assessment	Quantitative assessment	Quantitative assessment

**A 'reverse' QRA may be useful to understand the amount of UAP that would present concern, to enable evaluation of whether that amount is feasible given the UAP scenario.*

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The Project Output: management of Incidents

Outcome: Risk & Uncertainty;
Proposed risk mitigation; Regulatory considerations

Key Output	Evidence	
Risk Assessment Outcome	There is a risk to allergic consumers Risk within agreed limits of acceptability Not currently possible to determine	☐ ☐ ☐
Proposed risk mitigation (in case of risk to allergic consumers)		
Need to contact external agencies	Eg authority, patient org ?	
Method of assessment	Qualitative Quantitative (QRA) Not currently possible to assess	☐ ☐ ☐
Regulatory implications		
Product Presenta		
Describe aspects of product presentation that may modify the risk	For example, partial ri exacerbation due to u	

Quality of Evidence Framework			score
Tier of refinement	Tier 1 – theoretical Tier 2 – informed Tier 3 – data-driven Tier 4 – verified	☐ ☐ ☐ ☐	1 2 3 4
Chance that contamination is occurring	High or known to have happened Medium Low or unknown	☐ ☐ ☐	3 2 1
Overall data uncertainty	High uncertainty Medium uncertainty Acceptable uncertainty	☐ ☐ ☐	1 2 3
Quality of Evidence	9 – 10 : high quality evidence 6 – 8 : medium quality evidence 5 and below : low quality evidence	☐ ☐ ☐	

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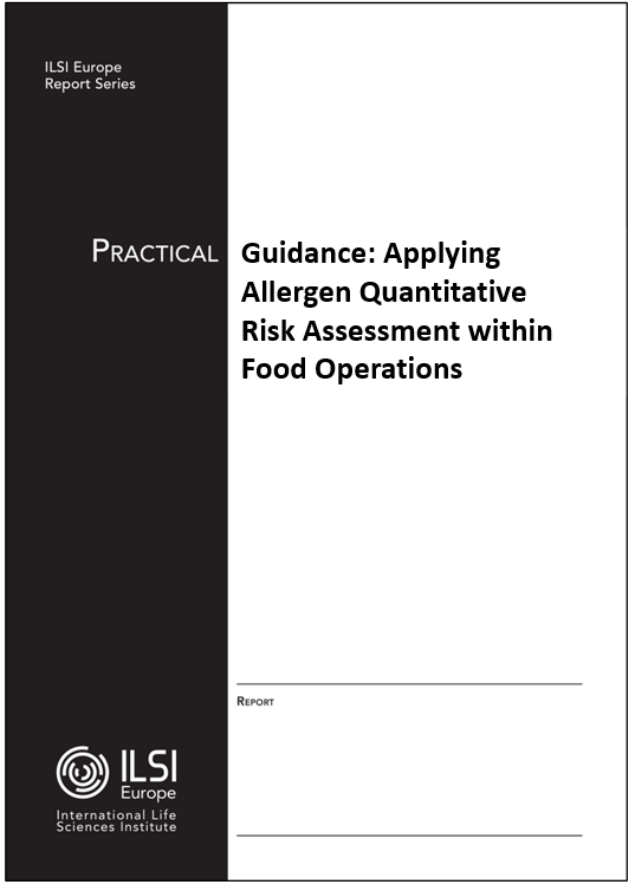
The Project Output



Introduction

- The place of QRA in allergen management

Communication Across the Supply Chain

- Global regulatory aspects
- Information requirements
- How to obtain the required information

Management of Operations

- QRA within allergen control programs
- Guide on QRA within site cross-contact
- Cleaning

Management of Incidents

- Guidance on incident assessment

Core Concepts

- UAP Scenarios an characteristics
- Amount of UAP in food
- Guidance on Food intake
- Basic calculations

Annexes

Key points

- Improving PAL requires implementation of allergen QRA

but …

- The benefit to consumers of allergen QRA will only come if there is consistent application

- There is a growing expectation that allergen QRA will be applied

but …

- Application is only relevant in specific situations to support established practices
- Misapplication will mislead

Bonus:

- QRA cannot be implemented without an improved understanding of cross-contamination within supply chains

So:

- A wide stakeholder group has developed consensus guidance

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Next steps

- Launch webinar for the Guidance document
- Release of training sessions

- Collection of further inputs, learnings and periodic update of the guidance

Summary

Yesterday

- Binary Approach
- judgement on whether allergen is potentially present or not
- lack of industry alignment
- Inaccurate information passed along supply chains
- Proliferation of Inaccurate Precautionary Labelling

Today

- Growing expectation of more accurate cross-contact understanding
- Application of allergen reference doses, and QRA

But …

- Lack of harmonization in when allergen QRA is appropriate and how to perform

Tomorrow

- Consensus guidance on the application of allergen QRA

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Thank you for your attention

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