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This Incidents Form is prepared by ILSI Europe Food Allergy Expert Group on Allergen Quantitative Risk Assessment (QRA) as part of ""Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment"". For more information and guidance on how to use the incidents form see: [here](https://ilsi.eu/publication/practical-guidance-on-the-application-of-food-allergen-quantitative-risk-assessment-qra/).

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This Incident Form is prepared by ILSI Europe Food Allergy Expert Group on Allergen Quantitative Risk Assessment (QRA) as part of ""Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment". The following form may be adapted for use.

For more information and guidance on how to use the incident form see the section **4. Management of Incidents.**

**1 General Information & Assessment Summary**

|  |  |  |  |
| --- | --- | --- | --- |
| Assessment Team |  | | |
| Assessment Date |  | | |
| Incident Dates |  | | |
| Type of incident | Upstream  In-house  Downstream | Source of information | Point of cross-contact |
| Foodstuff and allergen(s): |  | | |
| Market(s): | Country, region, retailer etc. | | |
| Product disposition: | Number of consumer units on hold, in distribution, at market etc. | | |
| Risk to consumers: | * There is a risk to allergic consumers * Risk within agreed limits of acceptability * Not currently possible to determine | | |
| Quality of Evidence: | High, medium, or low | | |
| Scale of risk: | e.g., does identified risk relate to ingredient / labelling error, or concerns incorrect PAL statement, or concerns allergen presence in a product that claims absence?  What is the frequency of UAP?  Is there an excessive and clear risk to consumers? | | |
| Opportunity for refinement: | Next steps possible to improve the assessment | | |
| Regulatory situation: | Description of any non-compliance | | |
| Proposed mitigation & actions, next steps: | Proposed action plan, based on risk and quality of evidence, including recommendation to risk managers, contact with authorities or patient organisations etc. | | |

**2 Incident Flow Chart**

Diagram

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**3 Assessment Matrix**

|  |  |
| --- | --- |
| **Section 1: Immediate Action** | |
| Identity of foodstuff implicated |  |
| Allergen(s) implicated |  |
| Supporting information |  |
| Does labelling provide incident protection, or exacerbation ? | See explanation in 4.1.5 |
| Summary if relevant of consumer complaints | Including any trend in consumer complaints |
| **Chance of Occurrence of Cross-Contact** | |
| See ‘**Core concepts**’ Section **5.1.1** for a description of ‘Chance of Occurrence’ | |
| **Chance of Occurrence** | **Notes** |
| High or known to have happened |  |
| Medium |
| Low or unknown |
| **Track & Trace** | |
| Current status |  |
| Degree of success of T&T |  |
| Implicated batch no.s, production dates |  |
| No. Packs (consumer units) implicated |  |
| No. Packs Held |  |
| No. Packs in distribution |  |
| No. Packs at consumer market |  |
| Shelf-life remaining |  |
| Other supporting information |  |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 2: Data Capture** | | | |
| **Consumption** | | | |
| See ‘**Core concepts**’ section **0** for guidance on consumption estimates | | | |
| Pack size (consumer unit) (g) | Meal preparation | Portion size (g) | Quantity of implicated food eaten per consumption event (g) |
|  | How pack is used | See explanation in **Core concepts** section | possible range & description of uncertainties |
| **the ‘Tier of Refinement’** | | | |
| **Tier** | **Description** | | **Source of Data** |
| **Tier 1**  ‘Theoretical’ | Concern has been raised on UAP but there is no physical evidence of cross-contact at the product site or supply chain in question. | | No data available, only ‘reverse’ QRA possible (see **Core concepts**). |
| **Tier 2**  ‘Informed’ | Some physical evidence of UAP of the specific supply chain in question, high uncertainty in quantification. | | The data available for QRA is based on ‘reasonable worst case’ assumptions, e.g., hang-up estimation (see **5.2.3** carry-over guidance). |
| **Tier 3**  ‘Data-driven’ | Physical evidence of UAP at the production site or specific supply chain in question, with indirect quantification possible. | | The data available is from upstream in the supply chain, for example on a purchased ingredient. |
| **Tier 4**  ‘Verified’ | Physical evidence of UAP at the production site or specific supply chain in question, with direct quantification possible. | | data is available on finished product as presented to consumer, or in case of mis-labeling or ingredient error there is clarity on the allergen content of the food. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristics of UAP: Data & Uncertainty** | | | |
| See ‘**Core concepts**’ Section **5.1.2** for a description of UAP Characteristics and Uncertainty | | | |
| **Characteristics** | | **Uncertainty** | **Data & Notes** |
| A  Form of UAP | Amorphous | 1  High | -------------------------------------------------------------------  Note: If ‘unknown’, assessment should be based on both amorphous and particulate, until refined information is available. |
| Particulate | 2  Medium |
| Unknown  (please mark uncertainty as ‘high’) | 3  Acceptable |
| B  Distribution of UAP | Homogeneous | 1  High | -------------------------------------------------------------------  Note: If ‘unknown’, assessment should be based on both hetero’ and homogeneous, until refined information is available. |
| Heterogeneous | 2  Medium |
| Unknown  (uncertainty is always ‘high’) | 3  Acceptable |
| C  Frequency of UAP  (how often the cross-contact is happening) | Isolated | 1  High | ---------------------------------------------------------------------  Note: If ‘unknown’, assessment should assume UAP is ‘regular’. |
| Intermittent | 2  Medium |
| Regular | 3  Acceptable |
| unknown  (uncertainty is always ‘high’) |
| D  Concentration of UAP | 1  Unknown or Estimate (not analytical). Note: see carry-over guidance **5.2.3** | | Provide data:  Describe suitability of analytical 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.  In the case of mis-labeling or wrong ingredient used, where there is knowledge on amount of allergen present, mark as 3. | |
| Overall data uncertainty (sum of A-D) | | 4-7  High  8-10  Medium  >10  Acceptable | Notes |

|  |  |  |
| --- | --- | --- |
| **Section 3: Assessment** | | |
| **Assessment Decision** | | **Notes: rationale for selected option** |
| It is beyond doubt that there is an unacceptable risk, no further assessment required |  |  |
| Uncertainty is too large to enable an assessment, further information required |  |
| QRA is appropriate but not possible without further information, qualitative assessment only |  |
| QRA is appropriate and possible |  |
| **QRA Metrics (for ‘screening’ and ‘deterministic’ QRA)** | | |
| See ‘**Core concepts**’ section **5.4** for calculation guidance | | |
| Description of the exposure scenario |  | |
| In case an Action Level (ppm) was calculated to compare to concentration in food (ppm), what was is the Action Level ? | Action Level = | Conc in food = |
| In case exposure of allergic consumer was calculated (mg) to compare to RfD (mg), what was the exposure ? | Appropriate RfD[[1]](#footnote-1) = | Consumer exposure = |
| Description of the calculation |  | |
| In case of higher level calculations, eg probabilistic, population level, provide details |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 4: Assessment Outcome** | | | |
| **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 Presentation** | | | |
| Describe aspects of product presentation that may modify the risk | For example, partial risk mitigation due to existing PAL warning, or exacerbation due to use of a free-from claim.  Frequency of contamination as an indicator of scale of risk. | | |
| **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 cross-contact is occurring | Low or unknown  Medium  High or known to have happened |  | 1  2  3 |
| 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 |  | |
| **Opportunities for Refinement** | | | |
| If there is sufficient time available for refinement, describe data needed and next steps |  | | |
| **Root Cause Analysis & Corrective Action** | | | |
| Describe root cause, corrective action |  | | |

1. For more information and key references regarding the fundamentals of how allergen RfDs are derived from oral food challenge data and subsequen t dose-distribution models, as well as what might constitute an appropriate RfD see **Box Reference Doses** in the Guidance available [here](https://ilsi.eu/publication/practical-guidance-on-the-application-of-food-allergen-quantitative-risk-assessment-qra/). [↑](#footnote-ref-1)