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This Sampling and Analysis 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 form see: [here.](https://ilsi.eu/publication/practical-guidance-on-the-application-of-food-allergen-quantitative-risk-assessment-qra/)

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|  |
| --- |
| General Information & Summary |
| Sampling & Analysis Team |  |
| Sampling & Analysis to Support which Allergen Risk Assessment ? |  |
| Sample description |  |
| Date of sample(s) taken and date of analysis performed |  |
| Sample reference no.s |  |
| Type of samples  | [ ]  Upstream[ ]  In-house [ ]  Down-stream | Description of sample type:E.g., no. samples from batch of compound food |
| Sample preparation | e.g., individual samples, composite of 3 finished products, test portion and aliquot |
| Sample retention |  |
| Result(s) and Interpretation |  |
| Quality of sampling evidence | Acceptable, medium or low quality of evidence |

Sampling & Analysis Matrix

|  |
| --- |
| Section 1: Immediate Action |
| Why is analytical data needed to support the risk assessment ? | e.g. data needed to verify carry-over calculation |
| Availability of material to sample | e.g. a production lot (volume) is available for sampling, or a single product returned from market is available |
| Representativeness of Material |
| A - Representativeness | Notes |
| 3 [ ]  High  | Describe how the available material to sample is representative of the material for which the risk assessment is being conducted, e.g. material from the batch with potential UAP via carry-over (high). Finished product for which claim is being made (high). The same finished product associated with an on-market incident, but not the same lot (medium). Ingredient from one supplier being tested as representative of all suppliers (low). |
| 2 [ ]  Medium |
| 1 [ ]  Low or unknown |

|  |
| --- |
| Section 2: Core Inputs |
| Suitability of the analytical method (food matrix and sensitivity) | Can the analytical method detect / quantify the allergen in proposed samples at a sufficient sensitivity to facilitate risk assessment ? |
| Based on the sensitivity required for the risk assessment, and analytical capability, are single samples or composites appropriate and possible ? |  |
| Section 3: Planning |
| Sampling Plan |
| Form of sample(s) | e.g., liquid ingredient, swabs, finished product |
| Location of sampling and sampling method. |  |
| Number of samples possible and required. | See guidance on Error! Reference source not found. |
| Size of samples, packaging, labelling, storage and transport. |  |
| Analytical Plan |
| Sample preparation and method including sample weight tested, number of desired repeats/replicates. |  |
| Sample retention and storage. |  |
| Sampling & Analysis: Quality of Evidence(To a large extent this is a subjective judgement based on the adequacy of sampling, the numbers of samples, and the analytical data, but always act in a precautionary manner (e.g. with a spread of results such as <LoQ, <LoQ, 2.1, 7.9 25.8 mg/kg as allergen protein, proceed on the basis of the highest). |
| B - Likelihood of sampling an UAP that is present. | 3 [ ]  High 2 [ ]  Medium1 [ ]  Low or unknown |
| Method sensitivity and uncertainty. |  |
| Section 4: Results |
| Data (± uncertainty) |  |
| Overall scoreYou may want to use this simple scoring system as an aid to decision making however be aware that this is not a rigid approach and individual circumstances must over-ride this. |
| Overall sampling quality (sum of A + B) | 5-6 [ ]  Acceptable quality of evidence4 [ ]  Medium quality of evidence2-3 [ ]  Low quality of evidence |
| Number of individual samples taken |  |
| Laboratory used |  |
| Signed/dated |  |