

# ESSENTIAL ALLERGEN TESTING GUIDE

An allergen management resource designed by FACTS



## WHY?

### REASONS FOR ALLERGEN TESTING

- Support supplier & raw material risk assessments
- Allergen cross-contact risk assessment & profiling
- Support allergen control validation - cleaning
- Support allergen control verification - cleaning
- Assess the efficacy of handwashing
- Assess aerial cross-contact risk
- Investigate consumer & customer complaints
- Prove free-from claims & assess need for PAL



## WHAT?

### TYPES OF SAMPLES TO TEST



-  **Ingredients**  
“Are ingredients contaminated?”
-  **Surface Swabs**  
“Were allergen residues removed from surfaces?”
-  **Rinse Water**  
“Was enough water used to flush away residue?”
-  **Purge / Flush**  
“Was enough purge or flush material used?”
-  **Work in Progress**  
“Is there carryover into the next product?”
-  **Next Product**  
“Is there carryover into the next product?”
-  **Hand Swabs**  
“Is the handwashing protocol effective?”
-  **Air Plates**  
“Is aerial cross-contact a risk?”
-  **Final Product**  
“Is a free-from claim or PAL appropriate?”


## HOW & HOW MUCH?


### LABORATORY-BASED TESTING

-  **DIRECT**  
Target protein - uniquely shaped portions of a protein or unique protein peptides.
-  **INDIRECT**  
Targets unique region of DNA.

### RAPID ON-SITE TESTING

-  **LFD (lateral flow devices)**  
Target uniquely shaped portion of a protein.
-  **PROTEIN SWABS**  
Target protein in general.

-  **Particulate cross-contact**  
E.g. pieces of nuts, seeds, chunks, solid agglomerates etc., that remain intact and form allergen “hot-spots”. Assess risk by testing multiple, randomised product, purge or raw material samples.

-  **Homogenous cross-contact**  
I.e. when cross-contact is homogenously distributed in the product. Test representative product, purge or raw material samples.



**• Support supplier & raw material risk assessments**  
Ingredient testing forms part of the supplier quality-assurance programme

- Prior to supplier approval.
- Periodically thereafter, based on risk.
- Prior to ingredient positive release - to ensure that it is (e.g.) gluten-free.

**• Laboratory-based testing** - Choose most appropriate method & sample.

**• Rapid on-site testing** - Ensure that the LFD has been validated for the raw material/s you intend to test, or complete a matrix check.

**• Allergen cross-contact risk assessment & profiling**  
Assess the impact of cross-contact risk from shared equipment/utensils/facility

- After identifying the cross-contact risk.
- A combination of different types of samples should be analysed, if possible.
- Combination depends on equipment size & design.

**• Assess the efficacy of handwashing**  
Prove that a handwashing protocol is fit for purpose

- Earliest possible opportunity.
- When changes are made (soap, water temperature, etc.)
- Periodically, based on risk (e.g. once a year)

**• Swab hands pre- and post-handwashing.**

**• Ensure that hands are thoroughly swabbed.**

**• Support allergen control validation - cleaning**  
Prove cleaning protocol is fit for purpose

- Before implementation of cleaning protocol.
- Change control (new allergen/s, equipment, cleaning protocol)
- Pre-established intervals based on risk.

**• A combination of different types of samples should be analysed if possible.**

**• Combination depends on equipment size & design.**

**• ALWAYS consider testing next product sample.**

**• Test positive controls.**

**Dry Cleaning**

**Wet Cleaning**

**• Support allergen control verification - cleaning**  
Prove that the cleaning protocol was performed correctly  
Ensure cleaning protocol remains fit for purpose

- Ongoing
- After an allergen clean

**• Choose the most appropriate rapid on-site testing kit for your set of circumstances.**

**• When testing next product/WIP/purge, using LFD, ensure that it has been validated for the materials you intend to test, or complete a matrix check.**

**• Protein swabs can be used to test rinse water by using a special protocol.**

**Dry Cleaning**

**Wet Cleaning**

**• Assess aerial cross-contact risk**  
Assess cross-contact risk associated with:

- ingredient and product dust settlement
- aerosols, overspray and dust blowout

- After identifying an aerial cross-contact risk.
- If the profile of an existing risk changes.

**• The placement of the air plates is important.**

**• Select a 'worst case' location and leave the plate open for an appropriate amount of time.**

**• Investigate consumer & customer complaints**  
To detect contamination/cross-contact in ingredients and/or products  
Part of customer complaint root-cause analyses

- When a customer or consumer complaint is received.

**• Food Manufacturers** - If possible, test the exact product that the consumer ate or drank. Alternatively, test a sample from the same batch/lot with same time/date stamp.

**• Ingredient suppliers** - If possible, test a sample drawn at client facility; alternatively, test a sample from the same batch/lot.

**• Prove free-from claims & assess need for PAL**  
It is a regulatory requirement to prove the validity of an allergen free-from claim via product analyses

- Prior to the commercial launch of the product.
- When changes are made (new suppliers, ingredients, cross-contact risk, formulation, allergen controls, etc.).

**• Choose most appropriate method & sampling strategy.**