

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.



WHEN
TO TEST



TAKE
NOTE



WHAT
& HOW



RAW
MATERIAL



SURFACE
SWABS



RINSE
WATER



PURGE /
FLUSH



WORK IN
PROGRESS



NEXT
PRODUCT



HAND
SWABS



AIR
PLATES



FINAL
PRODUCT



DIRECT



INDIRECT



LATERAL FLOW
DEVICES



PROTEIN
SWABS

• 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.

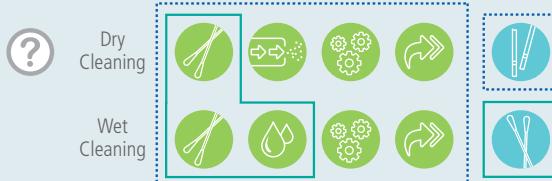


• Support allergen control verification - cleaning

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.



• 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.

