ALLERGEN MANAGEMENT FOR FOOD MANUFACTURERS

Training Course

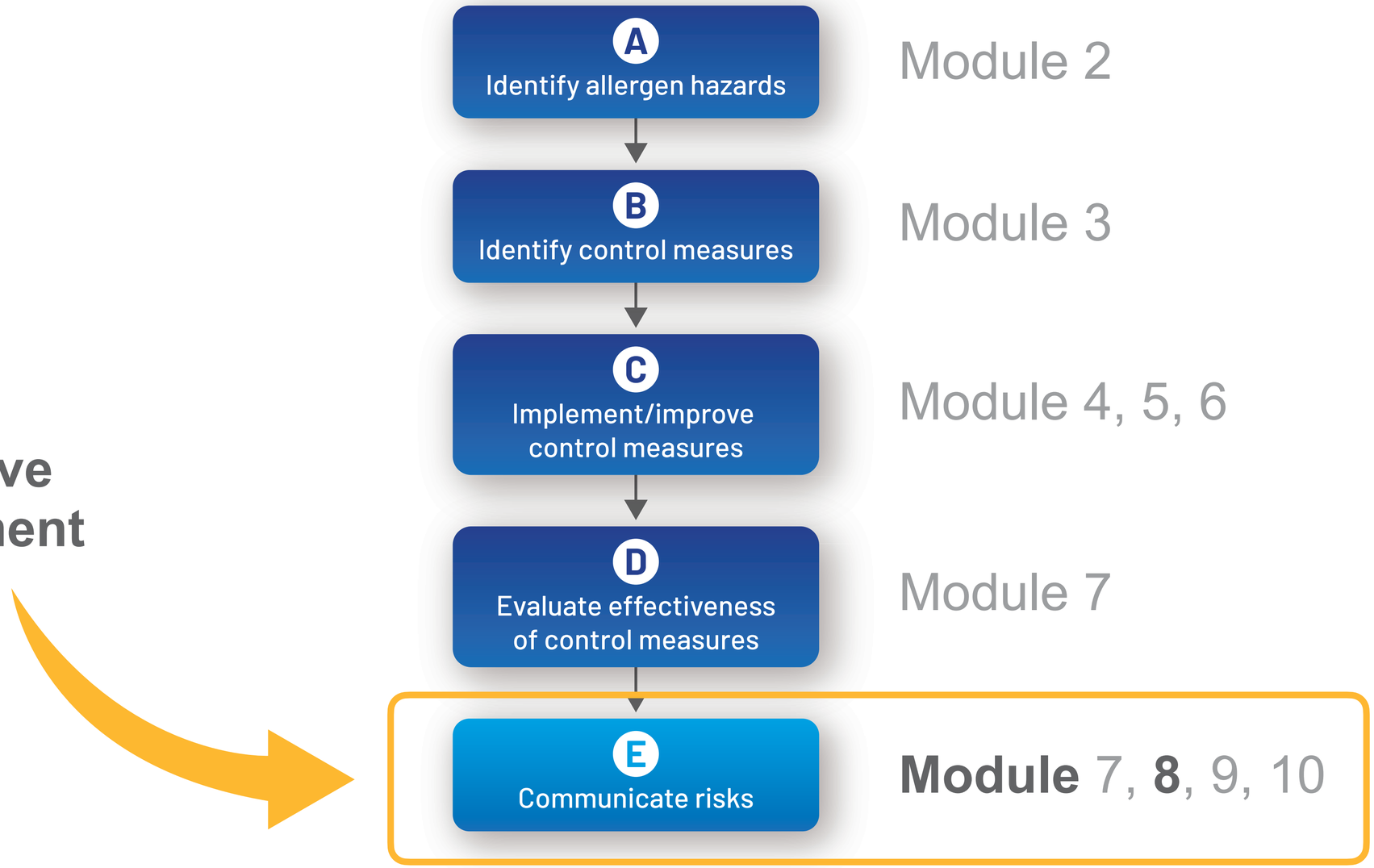
MODULE 8

Communicate risks

- Qualitative assessment

DEVELOPMENT OF AN ACP

Qualitative assessment



QUALITATIVE ASSESSMENT

Objective evidence

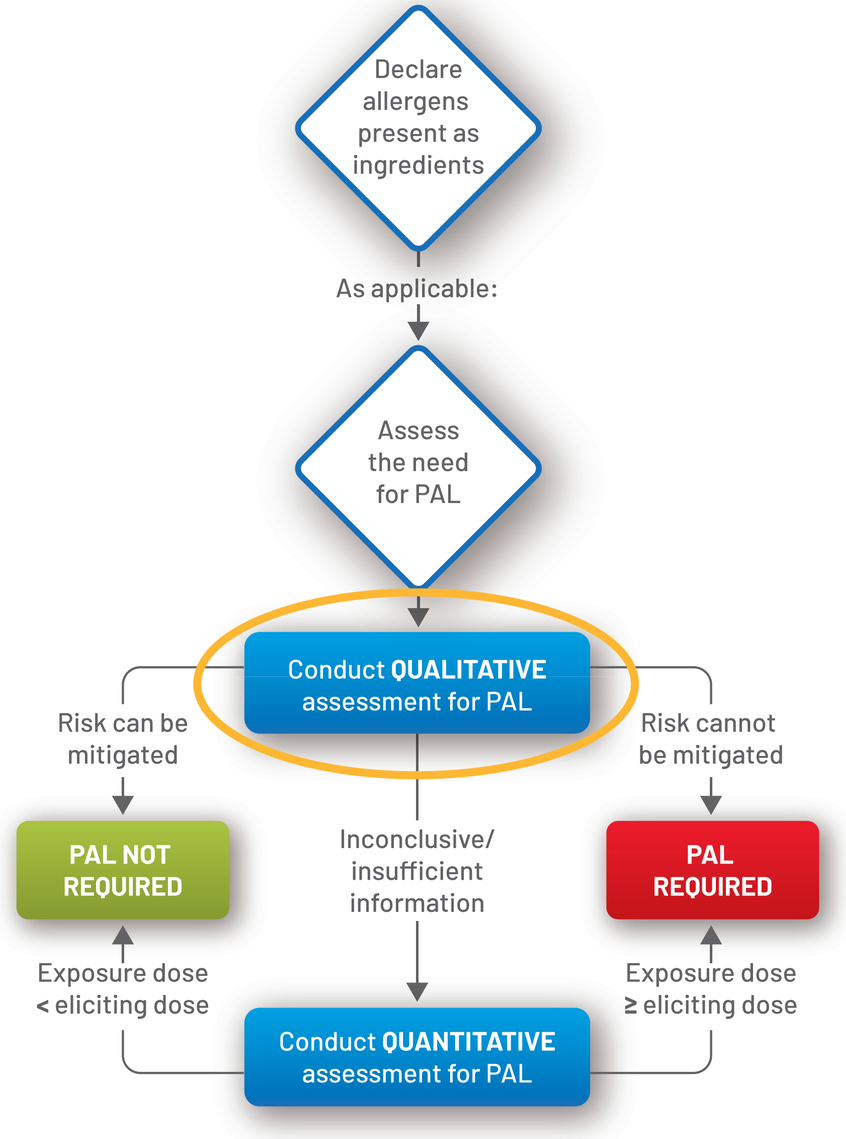
Entire manufacturing process

- Raw materials
- Reception & storage of raw materials
- Design of premises & equipment
- Production
- Cleaning

*Measures aiming to prevent **labelling errors** are critical. If deficiencies are noted, update practices before continuing the assessment*

WEIGHT OF EVIDENCE

- Some factors have a stronger effect than others on the occurrence of cross-contact of allergens
- Qualitative assessment likely influenced by the experience of the assessors
- Importance of multidisciplinary team



EXAMPLES

- Qualitative assessment for PAL
- Examples are simplified and must not be taken as conclusive recommendations

EXAMPLE 1: FOWL

Context

- If eggs are found inside the birds at the time of slaughter, they could spread to the surrounding carcasses. Can this be avoided?

Evidence

Conclusion

- Control measures cannot consistently prevent the occurrence of egg among adjacent carcasses. All fowl processed in this facility requires PAL for egg.

Production step	Control measures	Evidence	Weight
Raw materials	Supplier or FBO **cannot identify and segregate birds that carry eggs**	Introduction of egg in the facility cannot be prevented nor identified	Strong
Design of premises and equipment	Slaughter area and equipment **do not allow for sufficient space** to prevent spread of carcass contents. Modifications are not possible at the moment	Cross-contact during slaughter cannot be prevented	Strong
Production	Production cannot be scheduled such that birds with eggs are processed separately. Eggs: liquid, high protein content, likely to attach to poultry skin. Contaminated carcasses may have localized, high egg protein contamination. Contamination may spread during chilling	**Cross-contact is likely and could lead to highly contaminated products**	**Very strong**
Cleaning	Thorough cleaning after every production shift but it cannot control cross-contact during production	**N/A to this assessment**	

EXAMPLE 2: COOKIES

Context

- Cookie A containing milk is processed before cookie B that does not contain milk. Is milk transferred from A to B?

Evidence

Conclusion

- Control measures can consistently prevent the occurrence of milk in B.
  B does not require PAL for milk.

Production step	Control measures	Evidence	Weight
Raw materials	Ingredient: skim milk powder. Receiving procedures are in place and personnel are trained	Milk from this raw material is clearly identified, handled and stored upon receiving – but cross-contact **cannot be prevented at this step**	Weak
Design of premises and equipment	Equipment is recent and designed to allow for proper cleaning	Equipment design does not hinder cleaning but **does not directly prevent** cross-contact	Weak
Production	The presence of milk in A is addressed in changeover procedures. Training of personnel is adequate and is conducted at the required frequency	Cross-contact is addressed in changeover procedures, but they **do not ensure** absence of cross-contact	Medium
Cleaning	Cleaning objectively meets a visually clean standard. A validation study analytically demonstrated that milk proteins are not detected in B, when cleaning after production of A. The validation study is robust and recent. Cleaning is verified per SOP, targeting milk detection on surfaces. No deviations have been documented	Cleaning assures no visible residue and analytical tests report undetectable milk proteins in B	**Very strong**

EXAMPLE 3: DRY MIXES

Context

- Ingredient with PAL for mustard. Does the finished product require PAL for mustard?

Evidence

Conclusion

- Insufficient evidence. Quantitative assessment is required.

Production step	Control measures	Evidence	Weight
Raw materials	Ingredient: multi-component, dried flavour, not mustard-based. Presence of mustard is not evident. Approved supplier with strong history of compliance. PAL for mustard was only recently added to this ingredient; there is no history of testing. This change was communicated by the supplier before shipment of the first lot, per purchasing agreement. The supplier has not been audited since this change was implemented. A targeted supplier questionnaire indicates that cross-contact mustard may come from agricultural commingling, but no other information is available	Supplier control measures are robust but **cannot prevent occurrence of cross-contact mustard in the raw material.** The prevalence or concentration of mustard in this ingredient is unknown	Medium
Design of premises and equipment	Design of premises and equipment does not affect introduction of allergens from ingredients	N/A	N/A
Production	Production practices do not affect introduction of allergens from ingredients	N/A	N/A
Cleaning	Cleaning does not affect introduction of allergens from ingredients	N/A	N/A

EXAMPLE 4: BAGELS

Context

- Sesame seeds are sometimes found in certain equipment and production areas. Do all or some finished products require PAL for sesame?

Evidence

Conclusion

- Control measures cannot consistently prevent unintended sesame. All products made in this facility require PAL for sesame.

Production step	Control measures	Evidence	Weight
Raw materials	Approved supplier. Sesame seeds identified as allergens at receiving, and adequately stored, sealed and segregated	Sesame is clearly identified, handled and stored. **Cross-contact is unlikely** at this step	Weak
Design of premises and equipment	Ingredients staged in an area not physically separated from production. Old ovens, cannot be fully accessed during cleaning. Replacement or modifications are not possible at the moment	Design of premises and equipment **does not allow for adequate physical segregation and may hinder cleaning**	Strong
Production	Sesame bagels processed every day, 1st run, along with products not containing sesame. Staging employees adequately trained. Sesame seeds adequately handled, but they are sometimes found in scales and on the floor of the staging area. Bagels sprinkled with sesame seeds on the trays in which they are baked. Sesame seeds are found on the production floor. It is not possible to have only one oven dedicated to sesame bagels	**Cross-contact is likely and cannot be consistently prevented** with the control measures in place	**Very strong**
Cleaning	Facility cleaned every day at the end of production. Staging and production areas consistently meet visibly clean standards. Sesame seeds are sometimes found in these areas at the start of the next day's production. Oven cleaning does not consistently meet a visually clean standard. Sesame seeds are sometimes found in oven areas that cannot be accessed during cleaning.	**Visibly clean standards cannot be consistently met.** Sesame seeds are likely to spread, and are difficult to remove from environment and equipment in this facility	**Very strong**

SUMMARY

Procedure to conduct qualitative assessment for PAL

- Based on objective evidence on the effectiveness of control measures
- Evidence weighed
- May provide sufficient information for PAL

NEXT: MODULE 9

Step E:

Communicate risks

- Quantitative assessment