

ALLERGEN MANAGEMENT FOR FOOD MANUFACTURERS

Training Course



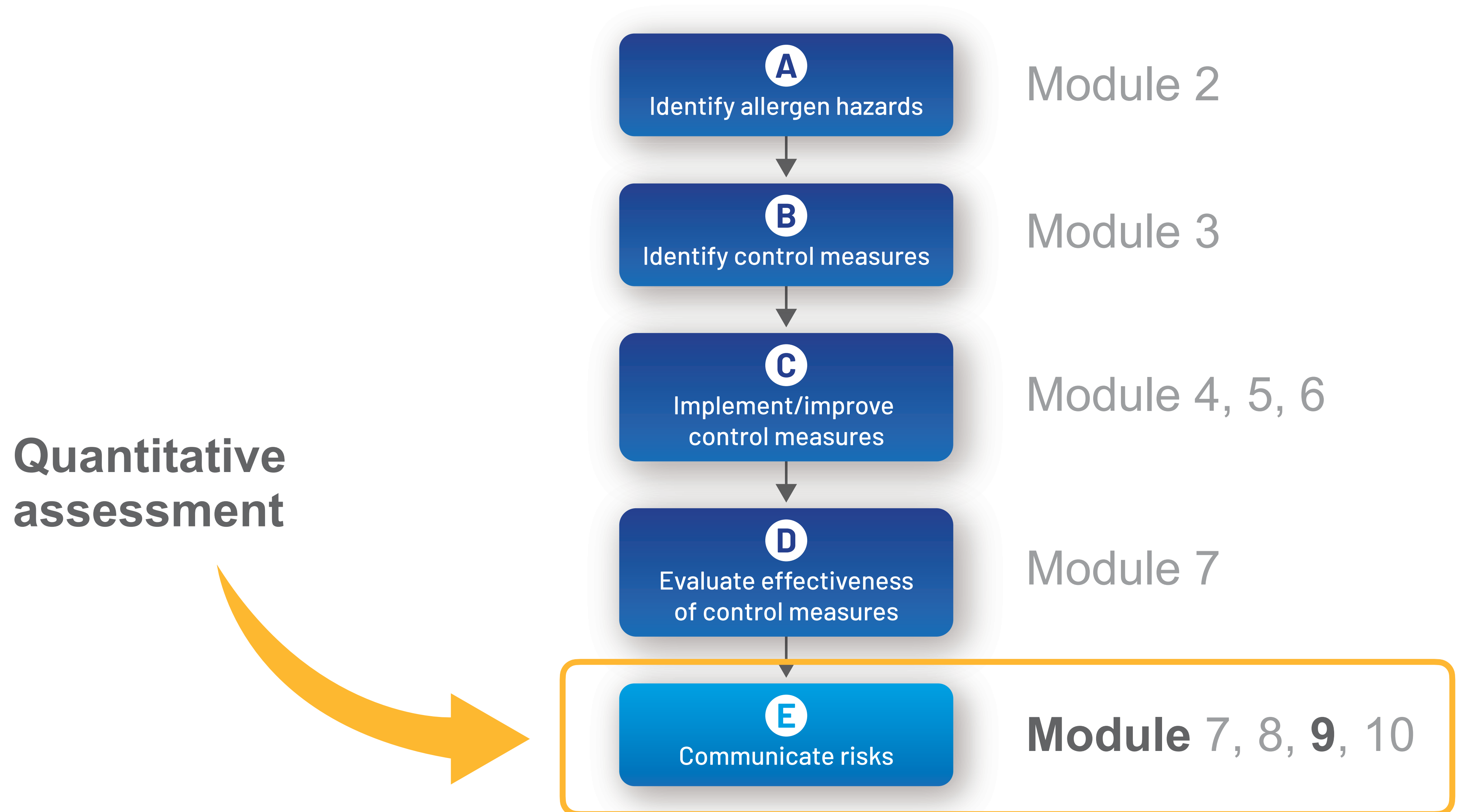
MODULE 9

Communicate risks

- Quantitative assessment



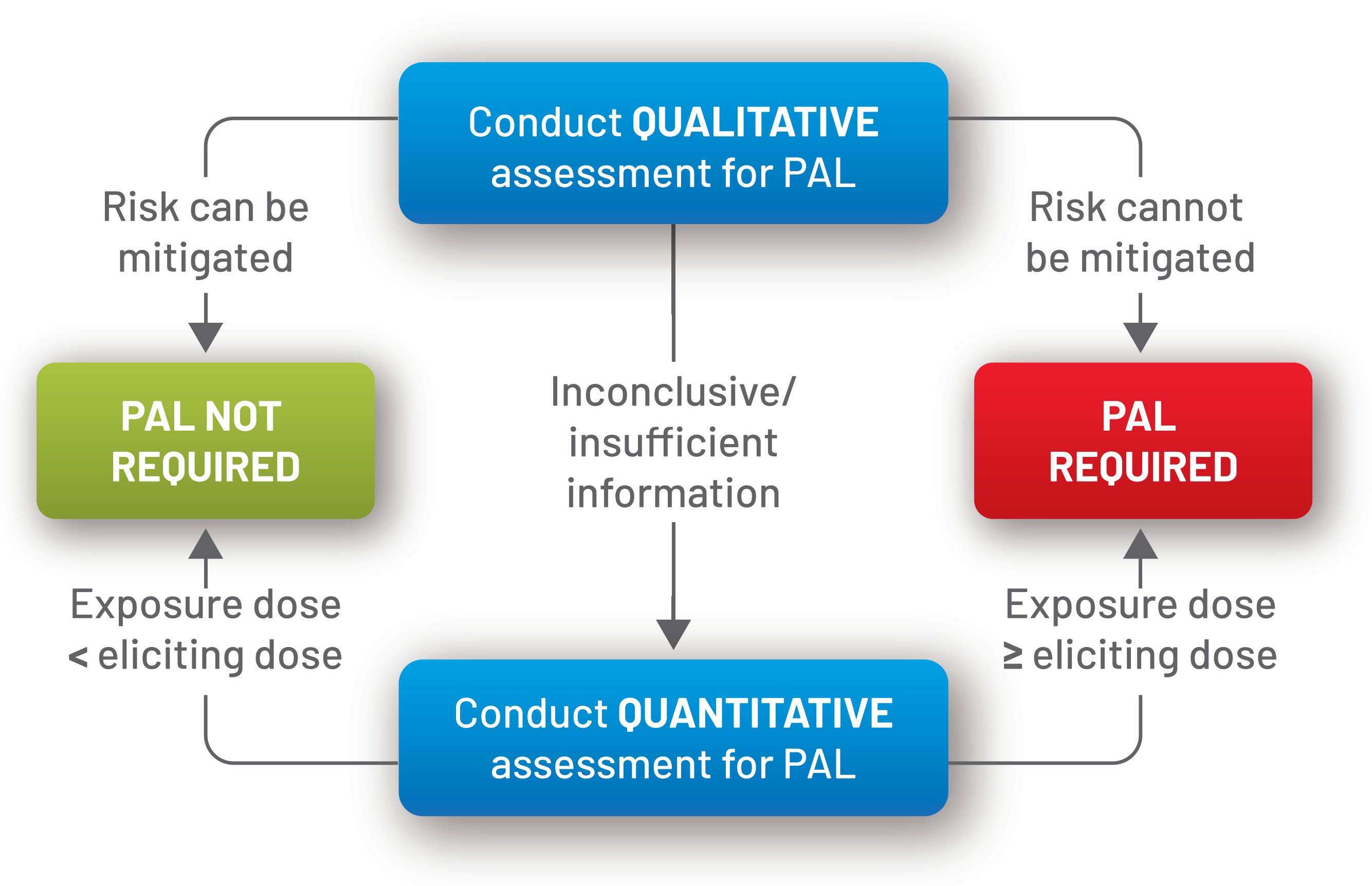
DEVELOPMENT OF AN ACP



QUANTITATIVE RISK ASSESSMENT

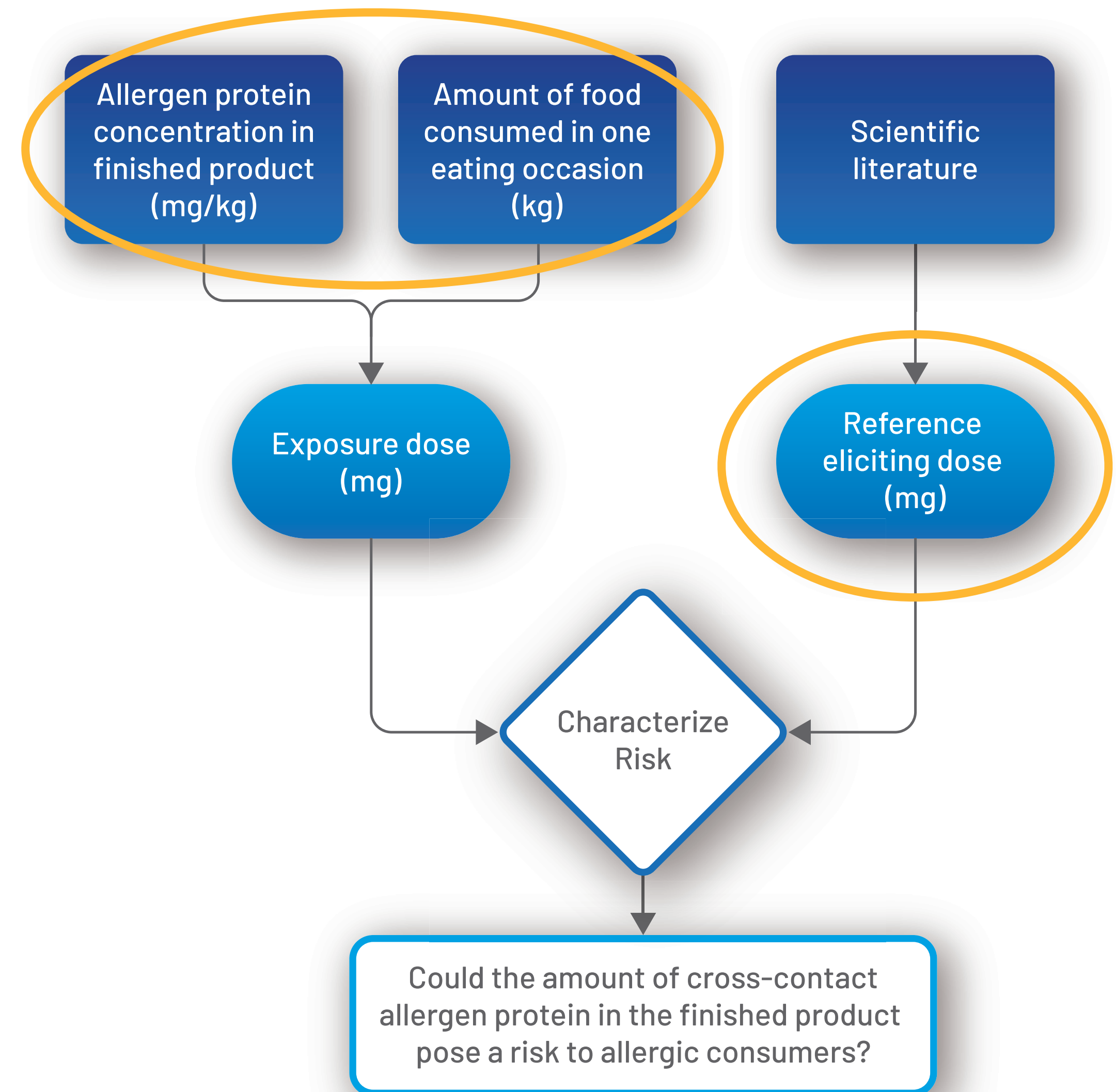
- When qualitative assessment is inconclusive
- Numerical input data
- Worst-case scenario

↓ ↓
Safety margin



INPUT DATA

- If the estimated **exposure dose** is **higher** than the **eliciting dose**, the food product **may pose a risk to allergic consumers**



ALLERGEN PROTEIN CONCENTRATION

Estimated from in-process measurements

Consider:

- Cross-contact allergen matrix
- Processing
- Finished product



ALLERGEN PROTEIN CONCENTRATION

Analytical testing

- Only results that can be correlated with allergen concentration in finished product
- Sampling protocol, fit-for-purpose method

Attention to **how results are expressed**

- ppm = mg/kg
- Non-fat dry milk \neq total milk protein \neq casein
- Use protein-based units:

Total protein content of select allergenic foods	
Allergenic food	Protein content (%)
Hazelnut flour	16
Whole peanuts	25
Crushed sesame seeds	17
Raw or cooked wheat flour	10
Dried whole egg	46
Non-fat dry milk	36
Whole soybean	40
Whole cooked shrimp	23
Mustard seed	26

Total protein from the allergenic source =

commodity units of the
allergenic source

×

total protein fraction
in the allergen



Derivatives of the same allergenic food source may have different protein content and may be affected by food processing

FOOD CONSUMPTION

Amount of food consumed
in **one eating occasion**

- Not the same as portion size or daily intake
- **Worst case = maximum amount** consumed in one eating occasion

Data sources

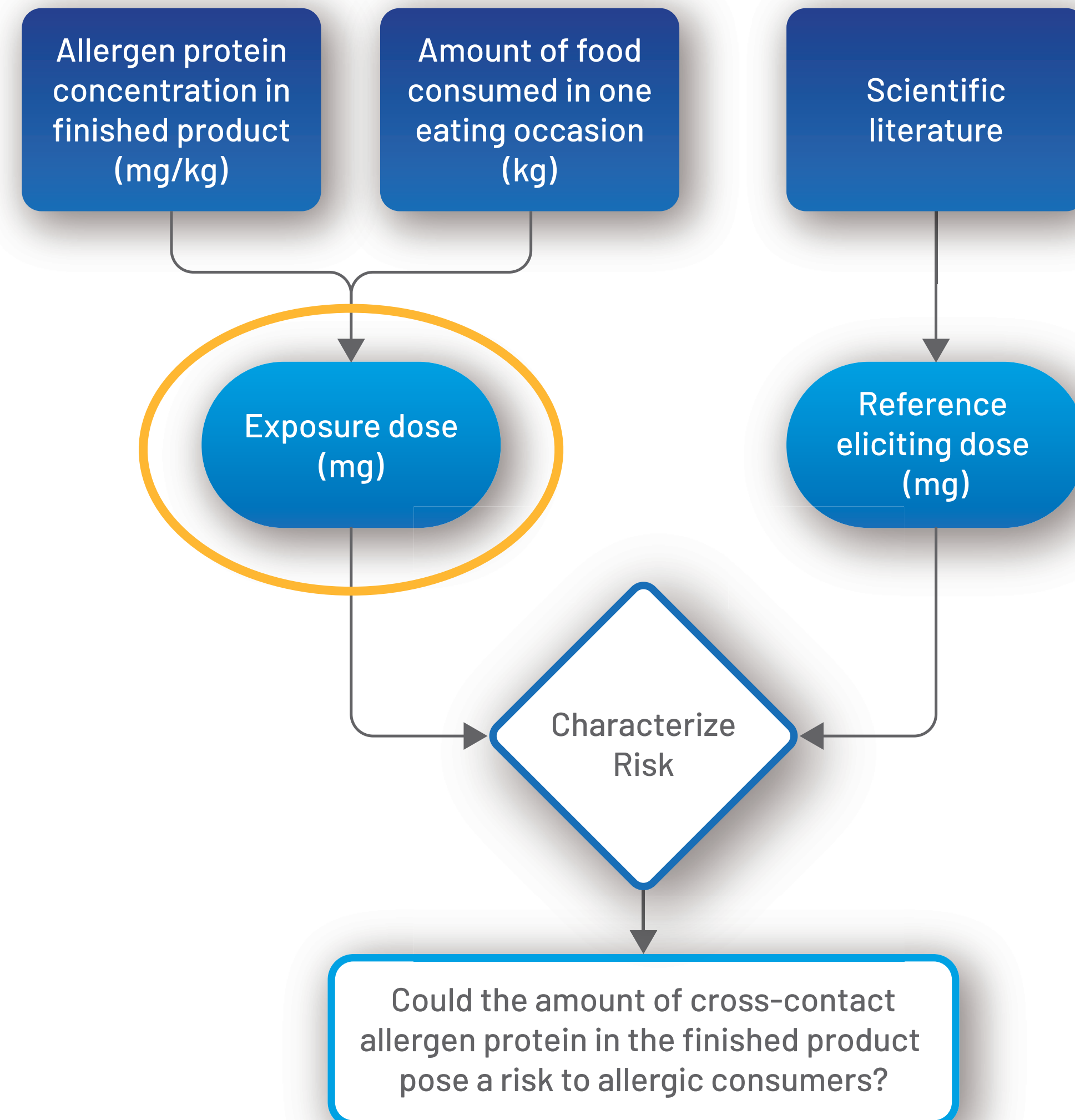
- Food consumption surveys
- Internal data
- Sometimes, portion size



EXPOSURE DOSE

Amount of allergen protein (**mg**) expected to be in an amount of finished product representing **an eating occasion**

Exposure dose =	
<i>total protein concentration from the allergenic source in food</i>	\times <i>amount of food consumed in one eating occasion</i>



REFERENCE ELICITING DOSE

Total dose of protein (**mg**) from an allergenic source predicted to produce a response in a % of the allergic population

- Example:
ED01 = 1% of allergic population would react
- No universal “safe” doses or “zero risk” thresholds
- Severity of reaction depends on individual
- Subject to review / update

Allergen	Recommended reference dose (mg total protein from the allergenic source)		
	VITAL scientific expert panel (2019)		FAO/WHO expert consultation (21/22)*
	ED01	ED05	ED05
Almond	—	—	1.0**
Cashew (and pistachio)	0.05	0.8	1.0
Celery	0.05	1.3	—
Egg	0.2	2.3	2.0
Fish	1.3	12.1***	5.0
Hazelnut	0.1	3.5	3.0
Lupin	2.6	15.3	—
Milk	0.2	2.4	2.0
Mustard	0.05	0.4	—
Peanut	0.2	2.1	2.0
Sesame	0.1	2.7	2.0
Shrimp	25	280.0	200.0
Soy	0.5	10.0	—
Walnut (and pecan)	0.03	0.8	1.0
Wheat	0.7	6.1	5.0

RISK CHARACTERIZATION

Exposure dose \geq ED

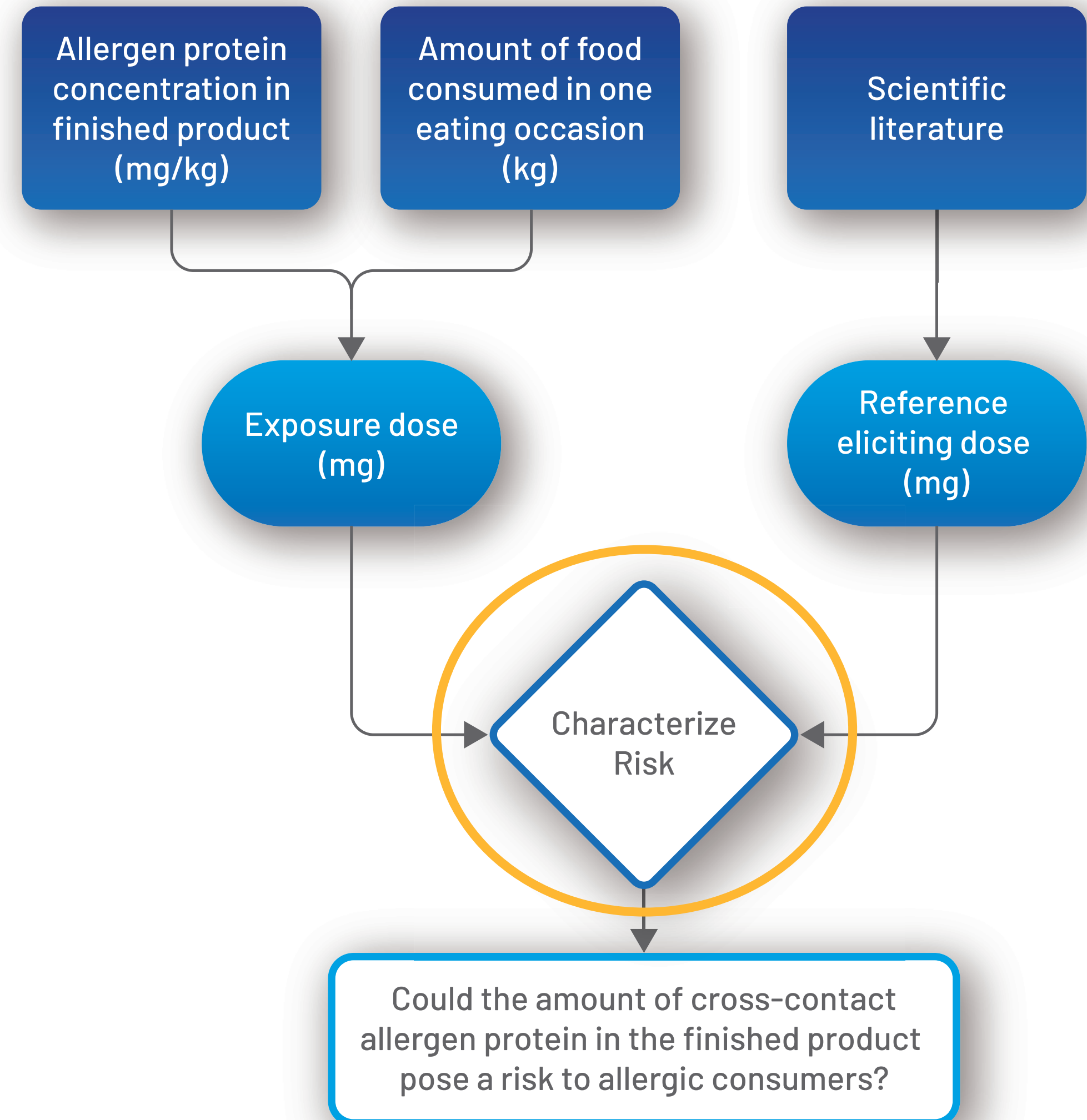


PAL strongly recommended

Exposure dose $<$ ED



PAL may not be needed



SUMMARY

- Quantitative assessment
 - ✓ Structure
 - ✓ Data needs and data sources
 - ✓ Risk characterization
- Standardized process to guide PAL decisions and better inform allergic consumers



NEXT: MODULE 10

Step E:

Communicate risks

- Examples of quantitative assessment

