

# Building a framework to help define tolerable risk in food allergy

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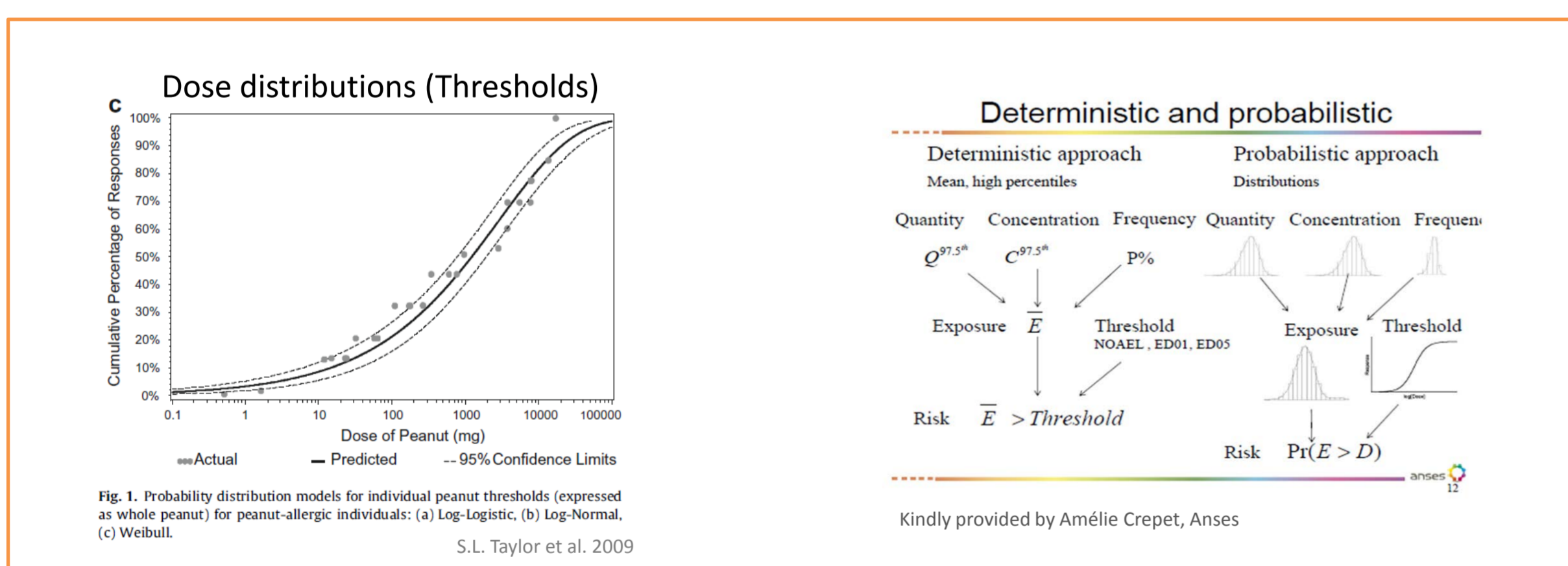
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## KEY MESSAGES

- Unintended allergen presence in foods poses a risk to people with food allergies
- The rationale and values underlying decisions about what risk is tolerable in food allergy are not clear
- This lack of clarity has hindered definition of appropriate risk benchmarks for food allergens, leaving people with food allergies frustrated and not knowing when to trust that foods are safe for them
- The ILSI-Europe Food Allergy Task Force has assembled an Expert Group to develop a framework to help multiple stakeholders reach consensus on tolerable risk with transparency

## Background

- Food allergy is the daily reality for at least 20 million Europeans (more if including their families, colleagues, etc)
- People with food allergy are a well-defined group who need accurate information on food contents to keep themselves safe
- The law protects them well against exposure to allergenic **ingredients**, but not to **unintended** allergen presence (UAP)
- Precautionary allergen labelling (PAL) aims to mitigate the risk from UAP, however there are no clear rules on whether and when to use PAL
- There is therefore no general, agreed risk level that triggers use of PAL and people with food allergies are left **FRUSTRATED, CONFUSED** and are potentially placed **AT RISK**
- Healthcare practitioners are **UNCLEAR** about what advice to give about which foods are safe and which aren't
- Additionally food businesses face unnecessary **UNCERTAINTY**
- Methods now exist which permit the effective derivation of transparent, risk-based benchmarks, all founded on human data



- However, they cannot be effectively implemented without a decision on **what risk is tolerable** (can be tolerated/accepted)

## Why a Framework to Define Tolerable Risk?

- Tolerable risk is the critical link between risk assessment and risk management
- Tolerable risk defines whether risk management objectives are attained
- Defining tolerable risk requires multiple stakeholders to reach valid and equitable conclusions, balancing the interests of all
- Tolerable risk works best when it is transparently defined

## Who, What and How?

- **WHO** needs to be involved?
  - Decision makers e.g. regulators, food business operators (FBOs)
  - Those bearing the consequences of the decision(s) e.g. people with food allergies, care givers, food businesses
- **WHAT** must the framework ensure?
  - All relevant factors are considered; data inputs are accurate and accessible
  - Concrete, practicable and theoretically justified information is used and conclusions are reached on what types of action to take (or not)
  - Transparent value judgements and methods are applied
  - Description of the societal distribution of the risks
- **HOW** should the framework operate?
  - The main criterion is transparency and inclusion of all relevant views

## Understanding the Current Landscape: Outcomes from a Workshop Session with Stakeholders on Tolerable Risk and Food Allergy

Can we compare food allergy risk to other accepted food related risks?

- Yes, an appropriate, well-matched benchmark is critical
- Need to reflect that risk only applies to a subpopulation

Acceptable risk and cost versus suffering

- Difficult to define costs
- Costs may not increase if PAL is harmonized
- Cost increases may threaten economic viability for some FBOs
- If PAL will be regulated then cost of suffering for allergic consumers will be reduced: the perception is yes but there is no evidence for that...

Scientific uncertainty and acceptable risk

- Different elements of risk assessment have distinct uncertainties:
  - Dose distribution (numbers, frequency and dose in models)
  - Translation from clinical trials (challenge) to community exposures
  - Factors included in the risk assessment models (severity?)
  - Learn by doing: e.g. establish temporary reference doses with one or more well-evaluated allergens

Is a risk acceptable when the general public say it is acceptable?

- Biases make this approach difficult to use
- Approach is dependent on knowledge
- Difficult to factor population versus individual risk
- How stable is a conclusion over time?

What is holding back the definition of tolerable risk for food allergies?

- Lack of consensus among stakeholders
- Lack of understanding of risk factors/uncertainties
- Lack of motivation/ no incentive to change
- Perception of increased risk (compared to current situation)

## References

- Madsen CB, Crevel RWR, Chan C-H et al. Food allergy: stakeholder perspectives on acceptable risk. Regul Toxicol Pharmacol 2010; 57: 256–65.
- Madsen CB, Hattersley S, Allen KJ et al. Can we define a tolerable level of risk in food allergy? Report from a EuroPreval/UK Food Standards Agency workshop. Clinical & Experimental Allergy, 2012 (42) 30–37.
- Murphy C, Gardoni P. The Acceptability and the Tolerability of Societal Risks: A Capabilities-based Approach. Sci Eng Ethics (2008) 14:77–92
- Taylor SL, Crevel RWR, Sheffield D, Kaborek J, Baumer J. Threshold dose for peanut: risk characterization based upon published results from challenges of peanut-allergic individuals. Food Chem Toxicol 2009;47:1198e204.
- WHO, 2001. In: Fewtrell, L., Bartram, J. (Eds.), Acceptable Risk in Water Quality: Guidelines, Standards and Health: Assessment of Risk and Risk Management for Water Related Infectious Disease. IWA Publishing, London (Chapter 10).