Outline

• Why define risk management objectives?
• Considerations
• Scope
• Applicability
• Statement of risk management objectives
• Conclusions
Why define risk management objectives? (1)

• Allergic reactions to foods occur when an allergic person comes into contact with the responsible allergen in an amount above their threshold
  – This can occur in a variety of ways (misunderstanding, mislabelled allergenic ingredient, cross-contact, etc)

• Allergic reactions to foods have a range of potential outcomes from the barely perceptible to the life-threatening

• Risk = f(hazard, exposure)
  – Zero risk is therefore not possible without zero exposure
Why define risk management objectives? (2)

• There are different ways of managing the risk from different types of possible encounter with allergens
• There is (obviously) a different tolerance to the different possible outcomes (types of reaction)
• So before we can assess that risk, we need to define:
  – the risk scenario (ingredient, cross-contact, etc)
  – the risk endpoint that we are trying to mitigate
Why define risk management objectives?(3)

• Potential risk mitigation measures can often have unintended consequences, e.g.
  – Current use of precautionary labelling for allergens: risk-taking by allergic persons
  – Labelling some types of allergenic derivatives: wrong conclusions drawn by allergic persons about their condition

• Defining the risk management objectives enables a holistic view to be taken of the risk management problem and apply appropriate solutions
Defining the Risk Management Objectives: Considerations

• Risk management measures need to be technically feasible within operational constraints
  – Can they be implemented with current technologies?
  – Can they be implemented while maintaining operational viability?
  – Is the technology available to verify that the measures are achieving their intended effect?
    • e.g. are analytical techniques sufficiently robust and reliable to detect allergens at the action levels?
Defining the Risk Management Objectives: Considerations

• Need to balance several potentially conflicting requirements
  – Potential effects on other safety parameters (microbiological, chemical)
  – Potential adverse environmental effects
Defining the Risk Management Objectives: Considerations

• Need to ensure that risk management objective actually delivers what it intends
  • Potential unintended consequences opposite to the desired effect
  • e.g. Excessive use of precautionary labelling resulting in
    – Decreased food choices and quality of life for people with food allergies
    – Loss of credibility leading to risk-taking
Defining the Risk Management Objectives: Considerations

• Potential unintended consequences well-illustrated in the consideration by the US FDA of a regulatory threshold for gluten
  – Hazard assessment estimated tolerable daily intakes of 0.4 mg gluten/day for adverse morphological effects and 0.015 mg gluten/day for adverse clinical effects to protect the most sensitive (0.01ppm – 0.6ppm in food)
  – However “At the current time, FDA is not aware of any analytical methods that have been validated to reliably and consistently detect gluten below 20ppm”.
  – “We believe that we should set a gluten threshold level for “gluten free” labeling that best assists most individuals with celiac disease in adhering life-long to a “gluten-free” diet without causing adverse health consequences”.
  – “moving to a definition of “gluten-free” that adopts a criterion that is much lower than < 20 ppm gluten could have an adverse impact on the health of Americans with celiac disease”.

Food Allergy: From Thresholds to Action Levels, 13-14 September 2012, Reading
Scope of risk management objectives

• Primary concern is risk from *presence of unintended allergen* in products as a result of cross-contamination at some point in the supply chain
  – Allergens used as ingredients are generally out of scope
    • But exceptions could be considered
  – Allergens which are undeclared for other reasons (e.g. incorrect labelling, packaging, etc are out of scope)

• Same principles of risk assessment could be used by regulators to exempt certain allergens or their derivatives when present in demonstrably trivial amounts
Applicability

- Risk assessment approaches described apply at the population level
  - Cannot predict the risk for any one specific allergic person
  - No different from other types of public health risk assessment e.g. microbiological or chemical
  - Can nevertheless help the individual allergic person through increased transparency by
    - Setting the boundaries within which the risk assessment was conducted, including assumptions and level of protection
    - Providing a reference point to which s/he can relate her/his own condition
• What is our risk management objective?
  – It is not to make life easier for the food industry, although it will
  – It is not the scientific challenge, although it has been exciting to pursue it (and continues to be)
  – It is assuring the safety of people with food allergies
The aim of managing food allergens is:

To ensure that food-allergic consumers can make safe choices by having both

– The right allergen information about foods (credible, trustworthy, accurate)

– Access to food products which are safe
  and

– the right information about their condition
  (e.g. severity, which foods to avoid)
What does it mean in practice?

- What does assuring the safety of people with food allergies really mean?
  - Recapitulation
    - Zero risk is not possible in practice
      - Food allergens cannot be excluded from the food supply
    - Precautionary labelling is a potentially valuable mitigating measure but has severe limitations
      - Credibility in inverse proportion to extent of use
      - Therefore need to find a balance that maximises its protective value
    - So, no reactions at all is not an achievable goal
Precautionary labelling use and effectiveness
What does it mean in practice?

• How do we assure the safety of people with food allergies in practice?
  – Build a risk management framework based on
    • Identifying the range of allergen doses over which precautionary labelling minimises the overall number of reactions,
    • Choosing realistic, achievable reference doses, providing a high degree of protection and resulting in
      » No severe reactions and few mild, self-limiting reactions
    • Defining how it is applied
    • Communicating these conditions to people with food allergies and those who look after them.
Subsidiary objectives

• Better Quality of Life among people with food allergy
• Improved understanding of allergen labelling
• Consistent approach to allergen management across industry, based on a common understanding
  – Harmonised application of precautionary labelling; i.e. “may contain” means the same on any product
• Improved trust in allergen labelling
Conclusions

• Clear definition of risk management objectives is a prerequisite to successfully achieving them and avoiding unintended (and undesirable) consequences

• The nature of food allergens precludes their exclusion, or even minimising their presence in the food supply, making zero risk unachievable

• Minimising the number of reactions from the unintended presence of allergens is proposed as the overall risk management objective, based on
  – Highly protective reference doses as the threshold for precautionary labelling
  – Excellent communication of risk management framework and its implications to all stakeholders
Thank you for your attention