Endogenous allergens:

considerations for GMO safety evaluation

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Endogenous allergens and GM crop safety

- Need to be clear about what risk is being assessed
  - Higher incidence of sensitisation to food because of higher dose (?of allergen with higher sensitizing potency)
  - Higher incidence of reactions to the food
- Basis of safety evaluation should be potential health impact
- What could this be:
  - *de novo* sensitisation because of higher dose
    - little evidence available to support this possibility: dose-response for sensitisation generally not well-defined and probably non-monotonic
  - Risk to those already allergic to crop
    - they should be avoiding the allergenic food as a part of their diet
    - Increase in endogenous allergens could require different management of the allergenic food to maintain same level of safety (thresholds for the food may alter)

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What should endogenous allergenicity assessment focus on?

- Allergens are defined by their IgE binding
- IgE binding is a necessary but not sufficient condition for allergenicity (ability to trigger an allergic reaction – the pathological process)
- Only allergens able to trigger reactions should be assessed (component resolved diagnosis can provide evidence for involvement)

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Approach to assessment of endogenous allergens

- Establish whether endogenous allergen(s) is/are within range of natural variation
- Only if outside (above) range, proceed with more detailed evaluation of potential health effects.

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