



Case study: Peanut engineered to have reduced levels of certain allergens

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Considerations

- FDA's focus is on food safety and food labeling.
 - FDA's authority over food doesn't give it the ability to make a risk/benefit-based decision.
 - Food must meet all applicable provisions of the Federal Food, Drug and Cosmetic Act.

Considerations

- We have not previously evaluated a genetically engineered peanut or a plant with this type of trait.
 - For unique crops and traits it can be very beneficial to consult with FDA very early in the development process.
 - Consultation can
 - 1. help ensure data collection is useful and efficient and
 - 2. make the regulatory process more predictable.

Views and considerations presented on these slides are intended for discussion purposes only and do not reflect formal agency opinion.

Considerations

- How is the product intended to be marketed?
 - There are several known allergens that naturally occur in peanuts.
 - Reduction in one or several allergens may not make this peanut safe for consumption by all who are allergic to peanuts.
 - You may wish to consider cross-contact with peanuts from other peanut varieties and any implications it may have for your marketing plan.

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Considerations

- Which proteins are being targeted?
 - Do they interact with other proteins in a metabolic pathway?
 - Does a change in the level of one or more storage proteins affect the levels of other storage proteins?
 - If so, are any of the other storage proteins known allergens?
 - If you plan immunologic studies, it may be useful to obtain input from FDA on study design.

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Considerations

- What nutrients are considered to be the key nutrients in peanuts?
- Are their toxicants or anti-nutrients in peanuts that would be important to consider?

Considerations

- Labeling
 - Food Allergen Labeling and Consumer Protection Act (FALCPA) requires peanuts (and peanut protein) to be disclosed on the food label (unless exempted).
 - Whether food from this peanut variety would require additional variety-specific labeling would be determined by the characteristics of the food.



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