Carrie's ~~7~~ EIGHT Considerations:

Considerations 1 - 2

1. Consider reviewing a completed biotechnology consultation (BNF) with similarities to your new plant variety. Requests can be made in accordance with FOIA. See www.fda.gov .

2. Consider reviewing the scientific arguments laid out in a GRAS notice or two. See www.fda.gov . Food ingredient risk assessment follows a well-established paradigm, regardless of whether the ingredient is manufactured in….

a plant () or a plant ().

Considerations 3 - 4

3. Consider requesting a meeting with the FDA. We can arrange face-to-face, teleconference, and web-based communication.
   - Contact Dr. Bob Merker at Robert.Merker@fda.hhs.gov

4. Consider how each design option (crop variety, DNA donor, gene sequence, mechanism of transformation, comparators, etc) you choose early in the development process will impact your ultimate safety assessment.

Considerations 5 - 6

5. Consider whether the current scientific knowledge can be used to make a logical argument in answer to a safety question. “New” data are not always needed.

6. Consider favorable and unfavorable data and information and discuss how the information is or is not relevant to your safety conclusion. be explicit in your explanations, don’t assume the conclusion you come to is obvious.

Considerations 7 - 8

7. Consider getting expert assistance in areas where you are not an expert (e.g., statistics, food risk assessment, allergenicity).

8. Consider whether your document is well-written. Make sure that there are no spelling or grammar mistakes, and that your text is consistent with your data.

Thank you for your consideration....