



Case Study I: plum

Specialty Crop
Regulatory Assistance Workshop
December 6-8, 2011

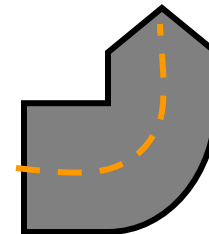
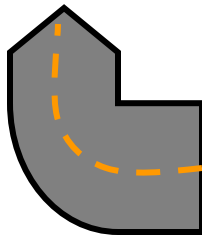
Carrie McMahon, Ph.D.
Consumer Safety Officer

FDA/Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review



When you come to a fork in the road, take it.

Lawrence Peter Berra



FDA Consultation on Virus-Resistant Plum (BNF 000101)

- **Developer:** individual/USDA scientist
- **Subject:** Plum containing a plant-incorporated protectant (PIP), *ppv-cp* gene

- **Initial contact:** February 2005
- **Final consultation:** January 2007
- **FDA response:** January 2009

Virus-Resistant Plum – Regulatory Authority

- Food or feed use? **Yes. (FDA)**
- New food additive? **No.**
 - FD&C Act, 201(s) defines the term food additive ... and excludes pesticide chemicals.
 - FD&C Act, 201(q) defines pesticide chemicals ... any substance that is a pesticide within the meaning of FIFRA, including “all active and inert ingredients of such pesticide.”
- PIP? **Yes. (EPA)**
 - *ppv-cp* gene and resulting expression products
 - *nptII* & *uidA* genes and resulting expression products

Virus-Resistant Plum - Safety Assessment

- Known toxins or allergens in plum? **No.**
- Major source of any nutrient? **No.**
- Significant animal feed use? **No.**
- Substantial changes in composition? **No.**
- **FDA's response: No further questions**
 - <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=biolisting&id=3>

Virus-Resistant Plum – Compositional Analysis

Proximate nutrients	Minerals	Carbohydrates	Secondary metabolites	Vitamins
<ul style="list-style-type: none"> • Ash • Fat • Moisture • Total dietary fiber • Carbohydrates • Protein 	<ul style="list-style-type: none"> • Calcium • Magnesium • Sodium • Potassium • Iron 	<ul style="list-style-type: none"> • Total sugar • Glucose • Sucrose • Lactose • Maltose • Fructose • Starch 	<ul style="list-style-type: none"> • Phenolics • Antioxidant capacity 	<ul style="list-style-type: none"> • Thiamine (B1) • Riboflavin (B2) • Niacin (B3)

- Transgenic line compared to 5 non-transgenic lines (including parent)
- Literature values reviewed
- Developer conclusion: No indication that plum differs from other plums

Virus-Resistant Plum – Discussion Points

- **Iterative Process**

- Safety and/or administrative questions
- Add'l info: April & June '07 and Sept '08

What if the genetic modification wasn't a PIP?

...then the gene(s) and expression products would be evaluated under FDA's authority for food and feed.

Virus-Resistant Plum – Discussion Points

- **Non-PIP traits fall to the food additive authority of FDA**
- **Risk (safety) analysis of food/feed ingredients**
 1. **risk assessment**
 - what is “it”? how much of “it” would be consumed?
how much is too much?
 - how does the EDI compare to the ADI ?
 2. *risk management*
 3. *risk communication*



Thank you.

Contact FDA :

Dr. Robert Merker

Robert.Merker@fda.hhs.gov

Dr. Carrie McMahon

Carrie.McMahon@fda.hhs.gov

Office of Food Additive Safety

premarkt@fda.hhs.gov

