



# **USDA-APHIS Deregulation Case Study: 'HoneySweet' Plum**

December 2011

Riverdale, MD

# Petition Process for Nonregulated Status

**Petition Received (9/9/04)**

**Petition reviewed (request for clarifications/ more information sent 2/5/05)**

**Revised petition received 11/17/05**

**Petition deemed complete 4/7/06**

**Draft risk assessment and environmental documents published for comment 5/16/06 (1725 comments received)**

**Comments analyzed-- Decision and Final documents published (7/13/07)**



# Background for 'HoneySweet' (C5) Plum



- Developed by USDA-ARS
- *Agrobacterium tumefaciens* transformation
- Engineered with
  - *Cauliflower mosaic* 35S promoter
  - *PPV-cp* gene
  - GUS gene from *E. coli*
  - NPT II gene from *E. coli*
- Similar construct to that used in GE papaya granted non-regulated status in 1996 (Cornell University and U of Hawaii)



# Background for 'HoneySweet' Plum



Provides high level of resistance to plum  
pox virus

# Background for 'HoneySweet' plum



## Regulatory timeline

- Field tested from 1995 -- 2007 under APHIS permits/notifications
  - Also field tested in Poland, Spain, Romania
- Petition for non-regulated status submitted September 2004
- APHIS granted non-regulated status on July 13, 2007
- Completed food/feed safety consultation with FDA January 16, 2009
- Issued "Conditional Registration" by US EPA May 7, 2010



# Risk Assessment for 'HoneySweet' Plum



## **APHIS Assessment:**

Plant Pest Risk Assessment – Relates directly to our decision making regulatory authority. We assess whether the engineered plant poses risks to plants or plant products.

National Environmental Policy Act (NEPA) Assessment – NEPA requires that a government agency examine the environmental impact of its decisions compared with reasonable alternatives. It encompasses a broader range of environmental parameters than does the APHIS plant pest risk assessments.

# Plant Pest Risk Assessment



BRS asks if the organism could:

- Exhibit plant pathogenic properties
- Become a weed
- Increase the weediness of sexually compatible plants
- Harm non-target organisms (beneficial, endangered)
- Transmit the genes to organism with which it does not normally interbreed (horizontal gene transfer)



# Plant Pest Risk Assessment



## Does the GE plant exhibit plant pathogenic characteristics?

- Data indicated no differences to other plum pests/diseases observed in the field.
- The genes inserted into 'HoneySweet' would not be expected to cause disease.

**Conclusion: 'HoneySweet' plum does not exhibit plant pathogenic characteristics and its use will not lead to new plant pests or to the dissemination of plant pests**



# Plant Pest Risk Assessment



## Will 'HoneySweet' plum become a weed?

- Plum is not a weed in the U.S. and does not have weedy characteristics.
- The genes inserted into 'HoneySweet' do not impart characteristics that would increase the weediness of plum
- Data from field trials showed no differences in a range of horticultural phenotypic characteristics.

**Conclusion: 'HoneySweet' plum will not become a weed**



# Plant Pest Risk Assessment



## Will 'HoneySweet' increase the weediness of sexually compatible plants?

- *Prunus domestica* is not native to the US
  - Hexaploid/ allopolyploid ( $2n=6x=48$ )
  - *P. spinosa* and/or *P. cerasifera* parents
- >25 *Prunus* species are native to the US
  - Most are diploid
  - Most will not hybridize easily with *P. domestica*
  - If hybrids can be produced, they are often very weak and/or sterile
  - No indications that inclusion of PPV resistance would increase fitness of any resulting hybrid progeny

**Conclusion: Use of 'HoneySweet' will not cause sexually compatible relatives to become weeds**



# Plant Pest Risk Assessment



## Will 'HoneySweet' plum impact non-target organisms (including beneficial organisms)?

- Except for the PPV cp, genes inserted (NPT II, GUS) are similar to those in other GE crops
  - Hawaii GE papayas, altered oil canola
  - These crops have been grown cumulatively on millions of acres for well over 10 years
  - Analyses have demonstrated compositional equivalence to non-GE plum
  - No reports of pathogenic or toxic effects
  - Reviews by FDA, EPA have reached same conclusion

**Conclusion: 'HoneySweet' plum will not impact non-target organisms**



# Plant Pest Risk Assessment



**Will genes from 'HoneySweet' move to organisms with which it does not typically interbreed (horizontal gene transfer)?**

- Though horizontal gene flow has been demonstrated in vitro under highly artificial conditions, recent reviews indicate that it is highly unlikely in nature
- Even if the highly unlikely event occurred, the genes are driven by plant specific promoters which would not be active in microbes

**Conclusion: Horizontal gene transfer from 'HoneySweet' is highly unlikely and is an extremely low risk**



# NEPA Environmental Assessment



## The following issues were identified as important to the scope of the analysis:

- Gene introgression and weediness
- Impacts on Non-target Organisms: Beneficials, threatened and endangered species
- Biodiversity
- Viral interactions/ development of new viruses
- Commercial use: Organic production, other agricultural commodities



# NEPA Assessment



## Alternatives explored in the NEPA Assessment.

- A. No action
- B. Grant non-regulated status, in whole
- C. Grant non-regulated status, in part

**Alternative B (grant non-regulated status, in whole)** was ultimately chosen because the plant pest risk assessment indicated it was not a plant pest.



# APHIS Determination of Non-regulated Status



**'HoneySweet' plum was given non-regulated status by USDA/APHIS on June 27,2007 based on:**

- **Completion of Environmental Assessment and Finding of No Significant Impact**
- **Risk Assessment showing it does not pose a plant pest risk.**