Case Study III: potato

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Potato Tuber Moth (PTM)-Resistant Potato

- **Developer:** Michigan State University
- **Subject:** Potato containing a plant-incorporated protectant (PIP); *cry1Ia1* gene.

- **Contact:** ***no prior contact***

PTM-Resistant Potato – 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)**
  - *cry1Ia1* gene and resulting expression products
  - *nptII* gene and resulting expression products

Potato – Safety Assessment

- Known toxins or allergens in potato? **Yes.**
- Major source of any nutrient? **Yes.**
- Significant animal feed use? **Yes.**
- Substantial changes in composition?

  Case dependent.

Potato – Compositional Analysis

Proximate nutrients	Minerals & Vitamins	Amino Acids & Fatty Acids	2° Metabolites & Anti-nutrients	Glycoalkaloids
• Ash • Fat • Moisture • Fiber • Carbohydrates • Protein • Solids	• Calcium • Sodium • Copper • Zinc • Iron • Magnesium • Phosphorus • Potassium • Vit B1, B2, B3, B6 & B9 • Vit C	• …..	• trypsin inhibitor • lignin • lectin	• Total GA • α-chaconine • α-solanine

- Example compiled from previous potato consultations (BNFs) and published literature
- BNFs: Nos. 5 and 33 (Colorado potato beetle); 48 (CPB and potato leafroll virus); and 49 (CPB and potato virus Y)
- Comparators: transgenic to non-transgenic and literature

Potato – Discussion Points

- **Potato consultations: BNFs 5, 33, 48, & 49**
  - submitted to FDA between 1994 and 1997
  - approx. 14 years since last BNF consultation
    - changes to food/feed uses?
    - changes to relevant safety data/analytical methods?
- **Glycoalkaloids**
  - table* potatoes 200 mg/kg total GA
  - GA content in processed potato fractions that may be used for food/feed?

Potato – Discussion Points

- **Precedent can be a starting point…but food/feed uses change** (example)
  - traditional: canola oil (human) and canola meal (animal)
  - new: canola protein isolates (human)
  - new consideration to include meal components in food
- **Statistical analysis can be complex**
  - trend in analyzing greater number of components means more false positives
  - trend in more field trial " treatments/conditions" means more complex statistical analysis

Potato – Discussion Points

What if the genetic modification wasn't a PIP?

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

- **Toxic & allergenic potential of expression products**
- **Assessment of potential for toxicity**
  - history of dietary exposure
  - identity, function, & sequence homologies
  - information on ADME and oral toxicity

Primary Sequence Databases

- **A cloned gene/cDNA sequence and its predicted protein sequence is first deposited in one of the three primary databases. They are inter-connected; so the sequence can be retrieved by accessing any one of the three databases.**

- **Secondary/Specialized databases are built by harnessing sequences of interest from these primary databases.**

- **These three primary databases can be accessed through the web**

    1. **NCBI/GenBank in U.S.A.**
    2. **EBI/EMBL in U.K.**
    3. **DDBJ in Japan**

Clue:
NCBI = **N**ational **C**enter for **B**iotechnology **I**nformation
EBI/EMBL = **E**uropean **B**ioinformatics **I**nstitute/**E**uropean **M**olecular **B**iology **L**aboratory
DDBJ = **D**NA **D**ata **B**ank of **J**apan

Thank you.

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