LABELING OF GE FOODS IN THE US

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Overview

- History of GMO regulation in the US
- Regulations other than labeling in the US
- US labeling requirements for GM foods
- What's going on with State and local initiatives?
- What's on the horizon?

BACKGROUND & HISTORY

Overarching Philosophy of FDA

- GE or GMOs are defined as those in which the genetic material has been altered in such a way that it does not occur naturally
  - We'll use GE as it's more precise for our discussion
  - For example, one could lump traditional plant breeding into "genetic modification"
- This methodology is used to create (among other things) GE plants which are then used to grow GE food crops
  - We won't discuss animals, pharmaceuticals, supplements or other ingredients in this talk
- Food from GE plants must meet the same requirements, including safety requirements, as traditionally-bred plants
  - Nutritional quality, sensory characteristics, proximate analyses, allergenic proteins

A Key Event in GE Labeling

- The first GE food product on the US market was in 1994
  - Flavr Savr®
  - Bore a voluntary GE label
  - Also in-store information for customers about ripening characteristics
- FDA, when they approved the product in 1993, did NOT require any special labeling
  - Per the philosophy that we just mentioned

Many Food Ingredients are GE

- Source of the oft-quoted “70% of our food is GMO”
- Not completely true in that this references the number of food *ingredients* (sugar, corn starch, etc.) which may make up a lot or very little of the total food product
- However, it is true that growers have adopted many approved GE crops whose components make their way into our food supply (USDA-NASS, 2013)
  - 95% of sugar beets – sugar
  - 93% of soy – lecithin
  - 90% of cotton – cottonseed oil
  - 90% corn – many, many ingredients
- No labeling required on final food package that contain these ingredients, and very little consumer awareness

NON-LABELING GE REGS

General US Regulations for GMOs

- Genetic engineering started around 1973 with the laboratory manipulation of bacteria
- The scientific community was excited but understood this powerful new technology should be evaluated for risks
- NIH created (1976) an advisory panel (RAC) to establish strict guidelines for rDNA research in the lab. (Not in use anymore)
- FDA, USDA and EPA adopted these guidelines, thus ensuring that any federally funded research would be compliant
  - Generally focused on biosafety risk reduction and containment

Early 1980s Onwards

- The US took the approach of utilizing existing food regulations to govern the use of GE food products
- Have continued along this path
- Backed up by frequent reports by the NRC of the National Academies of Science that "…biotechnology presented no new risks…"
  - 1989, 2000, 2002, 2004
- The agencies have generally used their expertise in conventional technologies to cover/encompass GE organisms

Currently

- GE foods are regulated as part of a coordinated effort of agencies, which depending on the product and development stage, may include FDA, USDA and EPA

- For example, the ringspot virus-resistant Papaya line was evaluated, at various times, by all three agencies

- Let’s take a closer look at the process…

USDA

- Ensures agricultural and environmental safety of GE plant
- Through the Biotechnology Regulatory Service (BRS) office of APHIS, USDA regulates GE plants prior to their commercial release
- Each GE plant is considered a regulated article until deemed otherwise
- Goal for commercial release is to achieve non-regulated status

EPA

- EPA is mostly concerned with environmental and human health aspects of pesticides
- EPA regulates GE plants that have altered pesticide characteristics
  - Including “plant incorporated protectants” (PIPs)
- From the BNF file #00100
  - “Under EPA regulations, the *prsv-cp* gene in papaya line X17-2 and resulting expression products are considered pesticidal substances; and the *nptII* gene and resulting expression products are considered inert ingredients. EPA considers the recombinant DNA construct containing the *prsv-cp* and *nptII* genes to be part of the PIP in papaya line X17-2, and therefore EPA is reviewing the recombinant DNA construct and resulting expression products.”

FDA

- The FDA is primarily concerned with threats to humans via food and to animals via feed
- Consultative system whereby pre-market review by FDA is obtained by the marketing entity
- Review of overall composition, as well as potential toxin, allergen and anti-nutritional factors
- While the system is criticized as being voluntary, in reality all GE foods and feeds have undergone this consultation

FDA – Example of Papaya Analyses to Compare to Other Transgenic Papaya and non-GE Papaya – no significant differences

- Proximate
  - Protein, lipid, carbohydrate, ash, moisture, total dietary fiber
- Minerals
  - Sodium, calcium, iron
- Carbohydrates
  - Total sugars
- Fats
  - SFAs, MFAs, PUFAs
- Secondary metabolites
  - Benzyl isothiocyanate
- Vitamins/precursors
  - Beta carotene, vitamin A, vitamin C

From: BNF #000100

US LABELING REGULATIONS

US Requirements

- GE foods and ingredients do not require special labeling if the food is not substantially different from the non-GE food product
- That is determined by assessing (in part):
  - If the GE food has a traditional counterpart that has a history of safe use? Is it substantially similar in composition?
  - Have any toxins or allergens been introduced?
  - Have levels of key nutrients changed?

- However, there is no prohibition against labeling foods as GMO-free if in fact that is true

How Does a Consumer Know if GMOs are Present?

- Voluntary labeling
  - Not governed by federal regulation
  - Similar to organic industry prior to USDA NOP

- USDA Organic
  - 100% organic cannot have GE ingredients

- PLU labels
  - 5 digits beginning with 8 indicates GE
  - 5 digits beginning with 9 indicates organic
  - 4 digits generally conventional
    - International Federation for Produce Standards
    - http://www.plucodes.com/docs/Users_Guide.pdf

IMPACT OF STATE LAWS

Briefly…

- At least 25 states have considered proposed legislation to require GE labeling
- Most of these have initiatives have had various levels of success in getting passed
- Only major mandatory labeling is in Alaska
  - has prohibited GE salmon for sale in the state, but that product has not been approved by FDA anyway
- The major bellwether event is the recent passage of mandatory GMO labeling on foods in Vermont (May 2014)
  - **UPDATE: Vermont Governor Signs GMO Labeling Bill**

    May 08, 2014

Reactions to the Vermont Legislation

- “I am proud that we’re leading the way in the United States to require labeling of genetically engineered food.”
  - Vermont Gov. Peter Shumlin

- “The constitutionality of the GMO labelling law (in Vermont) will undoubtedly be challenged”
  - Vermont Attorney General William Sorrell, noting he’s glad Vermont also will provide money to defend the new law

- The Grocery Manufacturers Association (GMA) lambasted the legislation:
  - “It sets the nation on a costly and misguided path toward a 50-state patchwork of GMO labeling policies that will do nothing to advance the safety of consumers.”

What's Next?

- Pushback on Vermont law on several fronts legally
  - Commerce Clause
    - US Constitution grants Congress the power to regulate interstate commerce and forbids individual states from unduly burdening interstate commerce
  - Supremacy Clause
    - Federal law prevails in any conflict with state law
  - The First Amendment Protection of Commercial Speech
- Probable action by additional states now that the Vermont legislation has proceeded successfully
- No clear resolution in sight

What's Next?

- **Grocery Manufacturers Association**

- "We encourage policymakers in Vermont and across the nation to support alternative legislation that would ensure that food labels are accurate and consistent for consumers. Bipartisan federal legislation, the Safe and Accurate Food Labeling Act, HR 4432, would require a label on foods containing GM ingredients if the FDA – our nation's foremost food safety authority – determines there is a health or safety risk. Any labeling of GM ingredients would therefore be based on science, not fear or the varying politics of the 50 states."

Resources to Stay Informed on Issue

- US FDA Website on GE Plants
  - http://www.fda.gov/food/foodscienceresearch/biotechnology/ucm346030.htm
- GMA Website on GE Legislation Impact on Food Industry
  - http://www.gmaonline.org/
  - Industry-funded
- CAST Report (2014)
  - https://www.cast-science.org/news/?to_label_or_not_to_label&show=news&newsID=18441
  - Available as a free .pdf
- International Food Information Council
  - http://www.foodinsight.org/
  - Industry funded; understanding consumer perceptions