

Selective public support for different types of crop biotechnology

Are these good or bad reasons to genetically modify plants or animals?

	VERY GOOD	VERY BAD
→ To reduce the need to use pesticides on crops	43%	12%
To reduce the cost of fish, like salmon	21%	27%
→ To produce more affordable pharmaceutical drugs using plants	54%	8%
To produce more affordable pharmaceutical drugs using animals	23%	29%
→ To create peanuts that won't cause allergic reactions	42%	15%
→ To produce less expensive food to reduce hunger in world	52%	12%
To produce more affordable industrial compounds in plants	2%	17%
→ To create new types of grass that don't need to be mowed as often	39%	22%
To create fruits and vegetables that last longer on the store shelves	27%	30%
To produce beef with less fat	27%	32%
→ To expand our understanding of science and nature	46%	10%

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Regulation of GMO Crops in the USA

FS / BI 435 (H) / 535

Steve Strauss / 28 April 2009

Basic approach in the USA

- After lengthy debate researchers and government regulators concluded that risks of biotech crops and foods do differ in any substantial way from ordinary food and products of breeding
- Therefore, they should be regulated by the same standards applied to non-GM crops and foods
- Thus, use of established food and environmental laws to regulate
 - “Coordinated Framework” set up in 1986, still in effect today
 - USDA, FDA, EPA

Widely varying systems around the world create major problems

- Europe with special restrictive legislation
 - All GM produced products must be labeled even after regulatory approval, if any one component is 0.9% or more
 - Very difficult to comply with, monitor in practice – Thus a major impediment to use of biotech products
- EU states with their own rules, liability laws for contamination even with approved products – ongoing battles between EU and countries
 - US won World Trade Organization lawsuit against EU that GM regulations were a non-tariff barrier to trade
 - Outcome still pending

Widely varying systems around the world create major problems

- Canada: PNTs – plants with novel traits law, not just GM – but in practice effect similar to GM law
 - Also try to regulate conventional breeding, with a big fight each time
- Huge costs and challenges to food and ag companies to comply with regulatory approval and trade requirements that vary so dramatically
- Convention on Biological Diversity, Cartagena Protocol on Biodiversity, with special GM provisions, a further obstacle and variable
 - Recommended moratorium on an field research with GURTs, still in effect

The paradox of “product not process”

- Fundamental tenet in US is that the process is not more risky than other breeding methods
- Yes, under current rules all results of GM process are considered guilty until proven innocent, whereas all other forms of breeding are assumed safe until a problem occurs
 - Hard to do: Impossible to gather direct evidence from long term human feeding trials unless commercialized
 - Hard to do for environmental impacts, given that
 - All ag is environmentally damaging and intensification has both environmental benefits and impacts: Comparator?
 - Hard to do the environmental trials needed without environmental releases prior to regulatory approvals

Product not process?

- Due to process, GM in effect regulated similar to pesticides and food additives
 - Detailed toxicology and environmental data
- However, reviews at FDA are not mandatory – a major concern of critics
 - Power is to request the withdrawal of adulterated foods, not to certify safety of all new foods
 - But all companies consult with FDA to obtain their approval prior to marketing to avoid possible action later, once in food system
- Also, there are some gap in the Coordinated Framework: FDA the lead on GM salmon for open pen aquaculture, Glo-fish as pets

Concept of “substantial equivalence” (SE) is guiding international approach

- Compares foods (food ingredients) from genetically-modified crops to their conventional counterparts
 - Origin of genes
 - Agronomic parameters
 - Composition (key nutrients / anti-nutrients)
 - Consumption patterns
- Is it within range of conventional foods?

“Relative safety”

Possible SE outcomes

- Substantially equivalent to conventional counterpart: **No further testing**
- Substantially equivalent to conventional counterpart except for introduced trait(s) **Focus assessment on trait(s) / gene product(s)**
- Not substantially equivalent to accepted food or food component: **Combined nutritional / toxicological assessment**

FDA safety assessment for SE

- Safety and nutritional value of newly-introduced proteins
 - DNA is "GRAS"
 - But potential gene flow risk considered: Antibiotic resistance genes to human bacterial pathogens
- Identity, composition, and nutritional value of modified carbohydrates, fats, or oils
- Concentration and bioavailability of important nutrients for which a food crop is consumed
- Changes in toxins characteristic of host and donor plants
- The potential of food allergens to be transferred from one food source to another
 - Allergenic nature of source species
 - Amino acid homology to known allergens
 - Amount and speed/extent of digestibility in gastric acids
- General transcriptional and metabolic profiles can also be compared with current technology: -"omics" era
 - Hard to interpret, every plant genotype and environment unique

GM labeling in USA

FDA only requires labeling of rDNA technology-derived foods that differ significantly in composition, nutritional value, or safety from their conventional counterparts

Safe Bt protein: NO
 Safe new oil type: NO
 New allergen: YES
 Vitamins above normal range: YES



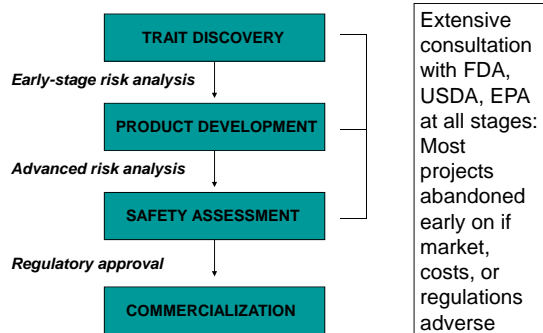
GM foods: Critics perspective

- Genetic engineers cannot control with precision where genetic material will be inserted into a host plant, and how it will interact with other genes: *SE concept unsatisfactory*
 - *Rationale for event-by-event regulation and its huge costs to food system and risks to companies*
- Scientists do not fully understand the impact that genetic changes can have on nutrition, toxicity, and other food properties
 - Still cannot say what is good, safe, unsafe for normal food: GRAS does not mean safe

Are GM foods safer than conventional foods?

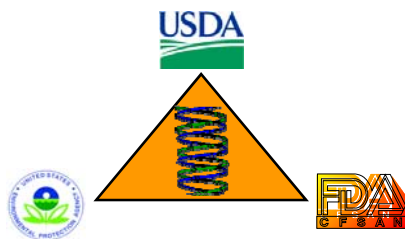
- No other foods in history have been tested and observed as diligently as those developed from modern biotechnology
 - No required testing for any other kinds of breeding modifications
- For more than two decades before approval for the consumer market, GM crops and their derivatives were laboratory- and field-tested to ensure safety for human and animal consumption
 - Vast literature, often in “grey literature” on safety
 - Not fully peer reviewed or consulted by scientists

The GMO food development process



The GMO regulatory triangle

Extensive web based resources and descriptions



EPA - Environmental Protection Agency

FDA - Food & Drug Administration

GM approval levels

- Lab/greenhouse research: Institutional biosafety review committees
 - Follows NIH “Health Guidelines for Research Involving Recombinant DNA Molecules”
- Field research
 - USDA APHIS does it all except for very large tests of PIP plants (then also EPA)
- Commercial uses – depends on the product what agency is the lead, and which are involved
 - FDA: Safety of consumed food or feed, animal environmental impacts
 - EPA: PIPs (“plant incorporated protectants,” pesticidal genes or growth regulating genes of any kind)
 - USDA: Harm to agriculture or trade, endangered species

Regulatory trait examples

Trait/Crop	Agency (ies)	Assessment
Insect resistant in a food crop	USDA FDA, EPA	Agricultural, food & environmental safety
Herbicide resistance in a food crop	USDA FDA EPA	Agricultural, food & environmental safety; herbicide use safety
Herbicide resistance in an ornamental crop	USDA EPA	Agricultural and environmental safety; new herbicide use
Modified vegetable oil	USDA FDA	Food, environment & agricultural safety
GM salmon	FDA, USDA	Agricultural, food, environmental safety

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

GEERTSON SEED FARMS, et al.,
Plaintiffs, No. C 06-01075 CRB
MEMORANDUM AND ORDER

v.
MIKE JOHANNIS, Secretary of the United
States Department of Agriculture, et al.,
Defendants.

Lawsuits: Major new regulatory force

In this lawsuit plaintiff alfalfa growers along with the Sierra Club and other farmer and consumer associations challenge the Department of Agriculture's decision to deregulate alfalfa genetically engineered to resist the herbicide glyphosate, the active ingredient in

"That is exactly the circumstances of this case." *Id.* Substantial questions are raised as to whether (1) the deregulation of Roundup Ready alfalfa without any geographic restrictions will lead to the transmission of the engineered gene to organic and conventional alfalfa; (2) the possible extent of such transmission; and (3) farmers' ability to protect their crops from acquiring the genetically engineered gene. Substantial questions are also raised as to the extent to which Roundup Ready alfalfa will contribute to the development of Roundup-resistant weeds, especially when considered in conjunction with the already deregulated and soon-to-be deregulated Roundup Ready crops, and as to how farmers will address such weeds. APHIS failed to answer these substantial questions, concluding instead

Regulatory decisions with GMO crops considered major federal environmental decisions – thus subject to NEPA

- Environmental Impact
Statements required: Take years to prepare and millions of dollars
- A process based law: Does not critique decision, only if process to reach it was adequate
- But given vagueness of environmental standards, clearly a much higher environmental and political hurdle for new types of GM crops