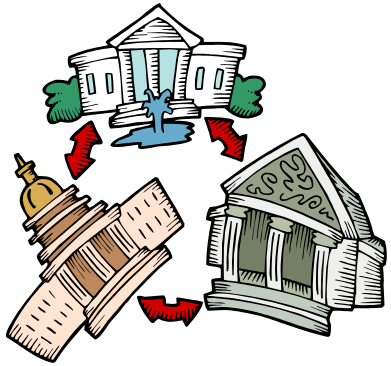
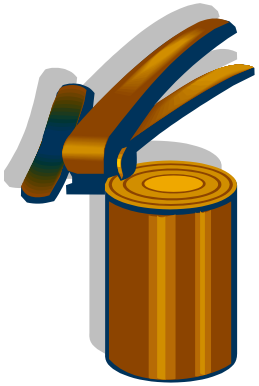
Agricultural Update Study

Feb 22, 2014





Background Training for the March Units: LWVUS Agricultural Consensus

→ Introduction to Risk Assessment

→ Summary Background (Pro and Cons) for the Consensus Questions:

III. Research and Development (New Technology)

IV. Food Safety

V. Food Labeling

Risk Assessment

The evaluation of newer technologies for safety faces the general difficulty of identification of small risks of new products in the population in general.

Many different factors that can influence if a risk factor will result in beneficial change or damage:

* genetic difference
* exposure to sunlight
* exposure to certain chemicals and other substances
* exposure to some viruses and bacteria
* exposure to certain hormones
* exposure to endocrine disruptors
* being overweight or underweight
* exposure to ionizing radiation
* tobacco use
* immune response
* family history
* exposure to pesticides
* alcohol use
* diet
* age
* physical activity

In fact identical twins (same genetic background) may respond differently to a factor as a result of difference in environmental exposures to other factors and acquired difference in the individual's microbial population on the skin or in the gut.

Risk assessment utilizes complex biostatistics to determine small effects from a perturbation. It attempts to quantitate the beneficial effect over any negative effects.

Risks to the public are measured by **direct observation studies** or by applying **mathematical models** and a series of assumptions to animal risk study results to infer potential risk to humans.

No matter how risks are defined or quantified, they are usually expressed as a **probability** of effects associated with a particular activity. Risk/probability is expressed as a fraction, without units, from 0 to 1.0. A probability of 1.0 indicates an absolute certainty that an event or outcome will occur. Scientific notation is generally used to present quantitative risk information.

Research and Development

The Research and Development questions are asking which approaches to research and development that the government should fund or accomplish.

It has the note that for the purpose of these questions and questions under food safety and food labeling the “developed using any new technology or new technologies refers to any of the many scientific processes for developing new crops or animals with genetic engineering, nanotechnology or other new techniques which are not the traditional breeding or hybridization techniques.

The Kickoff Event provided an introduction of Genetic Engineering, the background papers from LWVUS and other links have been added to the webpage. Please also refer to the various ILR articles regarding the new technology.

Research and development (R&D) uses science and engineering:
- to understand the processes and structures of organisms
- to create new products or processes for agriculture
- to determine health and safety of a product
- to determine the environmental impact of a product or process
- to develop conservation methods
- to improve efficiency

R&D utilizes scientific methods and statistical testing to achieve valid repeatable results.

Private corporations, universities, consulting organizations and laboratories, and government agencies perform agricultural R&D.

- Agricultural research by public universities began in 1862 when the Morrill Act established land grant universities across the United States
- Private R&D is generally more applied than basic and is motivated by the desire to produce a profitable product.
- Government agencies review this private research when regulatory approval for a product or process is required.
-Many government agencies conduct their own research.

Safety Concerns for GMO's

Genetic engineering is utilized in plants to induce characteristic that could: generate a higher yield for the crop; provide resistance to disease, insects or herbicides, enhance nutritional value, allow plants to thrive under unfavorable growing conditions (soil salinity), increase pharmaceutical value, or create a plant more effective for removing pollutants from soil or water.

Ht Crops have a gene for glyphosate resistant enzyme that permit spraying with weed killers to reduce weeds
- Can result in fields of super weeds which are resistant to herbicide resulting in increase use of herbicides

Bt Crops have been engineered to be resistant to insect predation
- Can result in rootworm resistant to the Bt

Research on environmental impacts have focused on effects on beneficial insects and animals (bees and bats) have found some potential problems, but others have not. Further studies are necessary

Concerns about exposure to GE pollen contamination of non GE crops
- the possible unintended genetic modification may result in loss of income because the farmer can not sale contaminated crops in their target market at the higher prices offered for non-GE products
- the possibility that a manufacturer could sue a farmer whose crop was unintentionally contaminated. This has been resolved with Monsanto pledging not to prosecute unintended contamination

Regulations of GMOs is based on the concept of substantial equivalences, wherein products are evaluated in a manner that compares them to conventional (non-GM) produces or processes does not require extensive safety testing.
The evaluation of substantial equivalence includes consideration of the transgene and its likely effects within the host as well as measurements of protein, fat, and starch content, amino acid composition, vitamin and mineral equivalency along with levels of known allergens and other potentially toxic components.

FDA reports the completed 98 reviews of GE crops or traits for commercialization's. Farmers have rapidly adopted GE crops and expanded their production.

Majority of GE literature concluded that the majority of peer reviewed papers do not indicate a health risk for animals or humans consuming GE products or provide evidence of environmental hazards.

Risk assessments studies are still very early, and not detailed enough to assess the risk from complex exposures that include GE foods, animal antibiotics and hormones, pesticide residues, nanomaterial's and novel food processing materials. Lack of labeling of GE foods also make risk assessment difficult.

Nanotechnology and other emerging new Technologies

There is agreement that new technologies such as Nanotechnology may be important in the future; however with the rapid expansion of research and development of new uses, questions as to safety and potential toxicity from these products need to addressed as soon as possible.

Those that favor government funding of basic research say:

* Governmental support of basic research is critical since commercial and private groups are not willing to fund the basic research
* Government Support of basic research develops better understanding of new technology, and its long term effects.
* Basic research also provides and develops (better paying) jobs
* Basic Research can help to provide data for risk assessment of new technology and products

Those that oppose say:

* Budget deficits do not permit the luxury of funding basic research
* Basic Research could result in the development of products that can be harmful
* Government needs to focus on food safety and product labeling rather than funding basic research.
* EPA and FDA are already underfunded and unable to perform the necessary inspections and oversight to provide for safe food.

7. *Which of the following approaches to research and development (R&D) should government fund or accomplish?*

Note: For the purpose of these questions and some questions below, ***"developed using any new technology"*** *or* ***"new technologies"*** *refer to any of many scientific processes for developing new crops or animals with genetic engineering, nanotechnology or other new techniques, which are not the traditional breeding or hybridization techniques.*

a) Basic research (Yes, No, No Consensus)

b) Independent third-party (such as an academic institution) risk assessment of products *developed using any new technology* (Yes, No, No Consensus)

c) Research to assess the impacts of *new technologies* on human health and the environment, prior to their widespread adoption (Yes, No, No Consensus)

d) Research that advances the continuation of diversified and sustainable agricultural systems (Yes, No, No Consensus)

e) Seed banking, research, and other means that promote and preserve genetic diversity (Yes, No, No Consensus)

f) Both transparency in the reporting of research studies related to approval of new products **and** respect for intellectual property rights of private enterprises engaged in research (Yes, No, No Consensus)

g) Research on long-term effects of new crops, products and processes (Yes, No, No Consensus)

h) Development of new practices and technologies to promote conservation for all types of farms (Yes, No, No Consensus)

Comments:

Food Safety and Labelling

are two very important aspects
of the federal role in food safety and agriculture.

This update was done in response to the increasing use of newer technologies.

The globalization of the world market have also increased the concerns over the inspection of food, and food labeling.

The increase identification of food poisoning from bacterial contamination (ground beef, spinach, cantaloupe , and milk products (cheese and yogurt) and spread of viruses in food have also brought to the public attention the need for better inspection and regulation.

Food Safety

Responsibility for food safety is shared by a number of federal, state and local agencies.

Among the key issues of interest concerning food safety programs in the U.S. are
(1) the current division of responsibilities among agencies
(2) agency differences in approaches to inspection and enforcement
(3) the adequacy of funding for the different food safety missions.

Over the years there has been a great deal of discussion about reforming the structure and organization of the food safety system and whether consolidation of monitoring responsibilities into a single agency would improve performance; the two recommended readings present different points of view on how to reform the system.

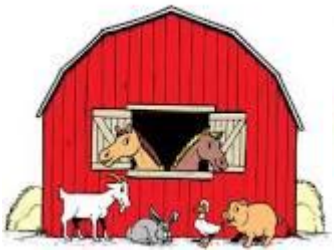
The United States has a complex food system.

* Risks to food safety can occur during the development of new plant and animal hybrids, during the growing of foods, during the harvest and processing of foods and during shipment and storage.

* Additional risk may accompany imported foods.

* Risk includes contamination with chemicals used in production, contamination with bacteria, fungi or viruses from multiple sources, nutrient loss due to processing or production techniques, introduction of allergens or other cross contamination.

Please refer to the numerous LWVUS Background Papers for additional information.



The USDA Food Safety Inspections have the primary responsibility for the safety of meat, poultry and egg products.

- oversees inspection of meat processing facilities
- fruits and vegetable program
- safety of imported food is under the purview of the USDA Animal and Plant Health Inspection Service

FDA is to provide food safety protection and education.

-FDA regulates domestically produces and imported human animal drugs, biologics, medical devise, food and animal feed, cosmetics and products that emit radiation.
- Food groups under FDA include dairy (milk, cheese butter), plant products (vegetables, fruits, nuts juice, spices), dietary supplements, seafood, grain based (bread, cereals, flour), bottled water and veterinary food and medicine
- The safety of genetically engineered food and food labeling is primarily the responsibility of the FDA

To increase food safety, federal agencies have developed a variety of standards, and guidelines. Testing to meet these standards is performed by private groups and governmental agencies.

Different approaches to inspection are illustrated by comparing USDA and FDA

	USDA	FDA
Inspections	has statutory authority to conduct continuous inspections No authority for on farm inspections	has authority for periodic inspections Has authority for on-farm inspections
Responsibilities	a limited number of similar food products (which would be expected to facilitate inspections)	A very diverse array of food and non-food products (which would complicate inspections and demand a greater range of expertise)
Budget and personnel	has 7800 inspectors for 6800 facilities	FDA has 2000 inspectors for more than 130,000 facilities Drug Staff is 3 x greater than Food Staff

Over time, there seems to be a general trend toward fewer facility inspections.

Actual food safety budgets and personnel do not always appear to be well calibrated with responsibilities.

Food Safety

Those that support government's role in food safety say

* To increase food safety, federal agencies have developed a variety of standards, and guidelines. Testing to meet these standards is performed by private groups and governmental agencies.

*Congressional action will most likely be required to ban non-therapeutic use of antibiotics in animals because several agencies control drug use and would need to coordinate (USDA, CDC, HHA, FDA).

* developers of new products should be required to provide data and other materials to independent third-parties (such as academic institutions) for pre- and post-market safety assessment as appropriate

*The complex food system requires federal government regulation and oversight to insure food safety

Those that oppose government's role in food safety say

*EPA, USDA and FDA are already underfunded and unable to perform the necessary inspections and oversight to provide for safe food.

*Antibiotic use in animals does not need government regulation; and would be costly to agriculture

* Budget control and less government oversight is required in the current economic times

* Corporations and Private agencies can provide sufficient testing . Government required testing is expensive. Corporation and Private agencies can provide sufficient testing for food safety. Additional rules and regulation only add to the cost of food.

8. *Which of the following approaches to food safety should government perform or fund?*

a) Clarify and enforce pre-market testing requirements for new foods and food additives *developed using any new technology* (see note below question 7) (Yes, No, No Consensus)

b) Require developers to monitor all food products *developed using any new technology* after releasing to the market (Yes, No, No Consensus)

c) Withdraw marketing approval if products are shown to be unsafe (Yes, No, No Consensus)

d) Require post-market monitoring of approved pharmaceutical applications in animal production for human health and environmental impacts (Yes, No, No Consensus)

e) Require developers of new products to provide data and other materials to independent third-parties (such as academic institutions) for pre- and post-market safety assessment as appropriate (Yes, No, No Consensus)

f) Limit use of antibiotics in animal production to treat and control disease (Yes, No, No Consensus)

g) Fund independent third-party (such as academic institutions) risk assessment of long-term and multiple exposures from foods on human health and the environment (Yes, No, No Consensus)

h) Promote crop management practices that decrease dependency on added chemicals (pesticides, herbicides, and synthetic fertilizers) (Yes, No, No Consensus)

i) Fund, train and add personnel for assessment and compliance functions of regulatory agencies (Yes, No, No Consensus)
Comments:

Food Labelling

Food labeling, primarily as a means of consumer protection, is a topic of interest that has evolved from the need to address dynamic challenges stemming from the food industry.

In recent years, attention focused on food labeling has exploded with concerns related to nutrition, genetic modification, pesticide and/or additive use, identification of known allergens, product origin disclosure, tracking of products relative to recalls, and more.

Food labels are prescribed in terms of what, where and how the information is presented. Contents of a food label must include name of product, ingredient list, nutritional information, net quantity, allergy information, and contact information (manufacture, packer, and/or distributor).

The US Food and Drug Administration (FDA):
The FDA is the agency tasked with ensuring the safety of domestically consumed foods, which are produced both domestically and internationally. Food safety and labeling requirements are regulated by the Federal Food, Drug and Cosmetic Act (FFDCA) and the Fair Packaging and Labeling Act, which require a standard nutrition labeling system for all foods other than meats and poultry, approximately 80 percent of food sold in the United States. The FDA does not pre-approve producers' food labels; they establish requirements and guidance for mandated food label attributes.

The US Department of Agriculture (USDA): The Food Safety and Inspection Service (FSIS), of the USDA, are responsible for the inspections and quality standards for meat and poultry consumables. Unlike the FDA, the FSIS mandates that all labels used for meat and poultry receive pre-approval before they can be used; this amounts to about 60,000 labels per year.

A driving force behind modern food labeling concerns has been the health industry.

As food science has progressed, food choices and consumption quantity have been recognized as key factors in public health. Obesity, heart disease, and diabetes are just a few of the diseases associated with modern eating habits. Health professionals have determined that educating the public on their choices and reducing confusion with regard to food labels is integral to stemming this threat to American's health and the American economy.

There is, however, substantial debate as to what information is appropriate and what method to communicate best serves the interests of stakeholders: consumers and producers.

From caloric counts to processing techniques, there are a number of variables in individual needs and desires when it comes to food labeling.

It is important to understand that the food system is very dynamic, as advances are made or new rules are contemplated, there are corresponding costs associated with education, development, implementation and enforcement.

Current concerns with Food Labeling include:

*Health and Ingredient claims cannot be substantiated and are used for marketing purposes are a problem because EPA lacks the authority to compel companies to provide substantiation information necessary to assess the health claims.

* Inaccurate image or sensory labeling in advertising by companies is also a problem.

Food Labeling Regulation

Those that Support Government involvement in Food Labels say:

* Provide nutrition facts, pesticide or additive use
*Provide allergen information
*Allow companies to make health and ingredient claims which can be substantiated
* Provide transparency regarding use of new technology (GE, nanotechnology) in the food development and/or where the food comes from.
*Allows tracking products relative to recalls

Those that oppose Government involvement in food labels say:

* As new rules are contemplated, there are corresponding costs associated with education, development, implementation and enforcement. These are costs to industry and to EPA and USDA.
* Labels are already too busy to assimilate the information.
* Labeling can unfairly stigmatize food (specifically as concerns new technologies).
* Labeling (new technologies) unfairly penalizes farmers, producers (especially small producers) and retailers who would incur a multitude of additional costs that they will have to pass on to consumers.

9. *How sufficient are the following regarding current food labeling?*

a) Nutrition Facts on food labels (Insufficient, Sufficient, Too much, No Consensus)

b) Nutrition Facts on food labels as a means of consumer education (Insufficient, Sufficient, Too much, No Consensus)

c) Common allergen labeling (Insufficient, Sufficient, Too much, No Consensus)

d) Health and ingredient claims that consumers can understand (Insufficient, Sufficient, Too much, No Consensus)

Comments:

10. *Which of the following should government achieve regarding marketing and ingredient claims on food labels?*

a) Define (and approve for use) health and safety marketing terms (e.g. immunity support, humane, pasture-raised, natural, etc.) (Yes, No, No Consensus)

b) Regulate the use of images or other sensory advertising (Yes, No, No Consensus)

c) Require that ingredient marketing claims accurately represent what is in the required ingredient list (Yes, No, No Consensus)

Comments:

11. *Recognizing that each food developed using any new technology can be unique, and assuming that required food labeling should be useful to consumers, should the following generalized information relating to how products or components are developed be presented on food labels?*

See note below question 7. All these questions also assume some percentage threshold of new technology ingredients, such as the 0.9% used in the European Union.

a) Contains ingredients developed using any new technology stating which technologies are involved (Not Recommended, Voluntary, Mandatory, No consensus)

b) Does **not** contain ingredients developed using any new technology (Not Recommended, Voluntary, Mandatory, No consensus)

c) If meat, fish, eggs, or dairy products are from animals that have consumed feed developed using any new technology stating which technologies are involved (Not Recommended, Voluntary, Mandatory, No consensus)

Comments