HUNGER AND ENVIRONMENTAL NUTRITION DPG

Webinar Series

Genetically Modified Organisms (GMO)

From Science to Policy

October 29, 2012

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Hunger and Environmental Nutrition (HEN) Dietetic Practice Group

HEN Vision
Optimize the nation’s health by promoting access to nutritious food and clean water from a secure and sustainable food system.

HEN Mission
Empower members to be leaders in sustainable and accessible food and water systems.

Sustainability
HEN defines sustainability as: "A sustainable and resilient food system [that] conserves and renews natural resources, advances social justice and animal welfare, builds community wealth, and fulfills the food and nutrition needs of all eaters now and in the future."

(Harmon A. & Tagtow A., 2008)
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Moderator

MELINDA HEMMELGARN, MS, RD.

Investigative Nutritionist
HEN External Relations Chair
foodsleuth@gmail.com
Critical Thinking Strategies
to Navigate Messages about GMOs

• Who owns the message?
• What information is included; what is left out?
• What are the unintended consequences of the technology?
• What persuasive techniques are used in the messages?
• Who stands to gain from this technology? Who stands to lose?
• How rigorous is the science?
Introduction Of Speakers

CHARLES BENBROOK, PH.D.
Research Professor, Washington State University

MICHAEL HANSEN PH.D.
Senior Staff Scientist, Consumers Union

JILL KRUEGER, JD.
Senior Attorney, The Network for Public Health Law
GMOS: From Science to Policy

Charles Benbrook, PhD

Center for Sustaining Agriculture and Natural Resources
Washington State University
Pullman, WA

HEN Webinar
October 29, 2012
NEW GOALS DRIVING THE SEED INDUSTRY

Genetically Engineer seeds to express proprietary pest management traits

Control the direction of plant breeding by controlling germplasm and breeding priorities, with help from patent law

Profit from multi-trait GE seeds sold at markedly higher prices, while limiting the supply of conventional seed
GE Crops

- Corn and sweet corn
- Soybeans
- Sugarbeets
- Cotton
- Alfalfa
- Canola

GE Traits –
- Herbicide tolerance (about $\frac{3}{4}$ of total GE acres)
- $Bt$-based insect resistance (corn and cotton only)
Percent of National Acres Planted to Herbicide-Tolerant (HT) and Bt Transgenic Crop Varieties, 1996-2011
GE Crop-Pesticide Use Simulation Model

Linked series of 15 tables in an Excel workbook

Widely accepted USDA data are available on:
• Acres planted to corn, soybeans, and cotton
• Percent crop acres planted and not planted to major GE traits
• Herbicide and glyphosate use rates per acre
• Use rates of insecticides displaced by Bt corn and cotton
By crop, major GE trait, and year, the model estimates:

- Herbicide use on acres planted to herbicide-tolerant and non-GE varieties, and hence differences in rates
- Insecticides per acre not applied as a result of the planting Bt corn or cotton
- Impacts of GE traits on pesticide use across all acres planted to GE crops by year, and from 1996 through 2011
From 1996-2011 in the U.S. --

Herbicide use on RR corn, soybeans, and cotton is 527 million pounds higher than it otherwise would be

Insecticide applications on Bt corn and cotton down 123 million pounds

Overall pesticide use has been increased 404 million pounds

Approximate 7% increase in overall pesticide use since 1996, but ~20% increase in 2011 and progressively larger differences likely in next several years
Key Results: 2011 Herbicide Rates

Each acre planted to a HT variety required substantially more herbicides than acres not planted to HT crops:

- 0.73 pounds per acre more in the case of soybeans
- 0.41 pound/acre corn
- 0.86 pound/acre cotton

## Changes in the Rate per Crop Year of Glyphosate (Roundup)

<table>
<thead>
<tr>
<th>Crop and Period</th>
<th>Glyphosate Rate in 1996 (pounds / acre)</th>
<th>Glyphosate Rate in 2010 (pounds / acre)</th>
<th>Total Increase (pounds / acre)</th>
<th>Percent Change</th>
<th>Average Annual Percent Change in Period Noted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn (1996-2010)</td>
<td>0.68</td>
<td>1.05</td>
<td>0.37</td>
<td>54%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Cotton (1996-2010)</td>
<td>0.63</td>
<td>1.93</td>
<td>1.3</td>
<td>206%</td>
<td>14.7%</td>
</tr>
<tr>
<td>Soybeans (1996-2006)</td>
<td>0.69</td>
<td>0.67</td>
<td></td>
<td>96.6%</td>
<td>9.8%</td>
</tr>
</tbody>
</table>

Note: All use data is from the USDA NASS surveys of pesticide use, and take into account both changes in the one-time rate of application and the average number of applications per crop year.
HT Technology has Dramatically Accelerated the Emergence and Spread of Resistant Weeds

Industry estimates suggest that 50-70 million acres in the U.S. are now infested with glyphosate-resistant weeds – more than one-third of the hectares now planted to HT crops annually.

- 23 weeds now resistant to glyphosate (International Survey of Herbicide-Resistant Weeds, www.weedscience.org)
- Some weeds have evolved glyphosate resistance via two or more mechanisms
No Major New Herbicide Mode of Action Commercialized in 20 Years *

“...It is very unlikely that new herbicides with new modes of action will be available within ten to 15 years.”


* Gerwick, “Thirty years of herbicide discovery: surveying the past and contemplating the future,” Agrow (Silver Jubilee Edition)
So... Industry Push to Market 2,4-D, Dicamba, and Paraquat HT Crops

High-risk gamble for farmers and public health – and the industry

Five weed scientists on second-generation HT crops:

“... we expect that synthetic auxin-resistant (2,4-D, dicamba) cultivars will be embraced by growers and planted on rapidly increasing areas in the US and worldwide over the next 5-10 years.”

Dramatic Increase Likely in 2,4-D Use If 2,4-D HT Corn Approved

• In 1971, 22% of corn acres were treated with 2,4-D at a 0.55 pound rate.

• Low point in 2,4-D use on corn in 2002 – 4% acres treated at ~0.35 pounds/acre.

• New label allows up to three 1.0 pound applications of 2,4-D on the new HT 2,4-D corn, up to point where corn is 48” high (mid to late July).

• Use likely to increase as much as 73-fold by 2019 compared to the low point in 2002.
## Bt Corn Cry Protein Quantities per Land Area: Major Events and Products

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Event</th>
<th>Cry Protein</th>
<th>Plant Stage</th>
<th>Plants/acre</th>
<th>Cry/acre $^g$ (lb/acre)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syngenta Agrisure® CB</td>
<td>BT 11</td>
<td>Cry1Ab</td>
<td>mature</td>
<td>26,500</td>
<td>0.252</td>
</tr>
<tr>
<td>Monsanto YieldGard® Corn Borer</td>
<td>MON 810</td>
<td>Cry1Ab</td>
<td>2 wk post-pollination</td>
<td>32,000</td>
<td>0.183</td>
</tr>
<tr>
<td>Monsanto YieldGard® Rootworm</td>
<td>MON 863</td>
<td>Cry3Bb1</td>
<td>forage, 90 DAP</td>
<td>32,000</td>
<td>1.732</td>
</tr>
<tr>
<td>Monsanto YieldGard VT™ Rootworm</td>
<td>MON 88017</td>
<td>Cry3Bb1</td>
<td>forage, R4-5</td>
<td>32,000</td>
<td>0.551</td>
</tr>
<tr>
<td>Monsanto Genuity™ VT Double PRO™</td>
<td>MON 89034</td>
<td>Cry1A.105, Cry2Ab2</td>
<td>forage, R4-5, forage, R4-5</td>
<td>32,000, 32,000</td>
<td>0.242, 0.355</td>
</tr>
<tr>
<td>DowAgrosciences Pioneer Hi-Bred Herculex® I</td>
<td>TC1507</td>
<td>Cry1F</td>
<td>forage, R4-5</td>
<td>32,000</td>
<td>0.097</td>
</tr>
<tr>
<td>Dow AgroSciences Pioneer Hi-Bred Herculex® RW</td>
<td>DAS 59122-7</td>
<td>Cry34Ab1, Cry35Ab1</td>
<td>forage, R4-5, forage, R4-5</td>
<td>32,000, 32,000</td>
<td>2.042, 0.45, 2.492</td>
</tr>
<tr>
<td>Monsanto Genuity™ SmartStax™, DowAgrosciences</td>
<td>MON 88017, MON 89034, TC 1507, DAS 59122-7</td>
<td>Cry3Bb1, Cry1A.105, Cry2Ab2, Cry1F, Cry34Ab1, Cry35Ab1</td>
<td>forage, R4-5, forage, R4-5, forage, R4-5, forage, R4-5, forage, R4-5</td>
<td>32,000, 32,000, 32,000, 32,000, 32,000</td>
<td>0.672, 0.256, 0.36, 0.112, 1.918, 0.412, 3.73</td>
</tr>
</tbody>
</table>
Bt Corn for ECB Endotoxin Production Compared to Insecticides Displaced

- ~0.12 pound insecticides applied per acre for ECB control in 2010
- MON 810 produces 0.18 pound of endotoxin per acre
- Bt 11 produces 0.25 pound of endotoxin per acre
- Dow/Pioneer Herculex TC1507 produces 0.097 pound per acre
- MON 89034, Cry1A.105 plus Cry2Ab2 produces 0.6 pound of two endotoxins per acre (5-X insecticides displaced)
Bt Corn for Rootworm Control
Endotoxin Production Compared to Insecticides Displaced

• ~0.19 pound insecticides applied per acre in 2010

• MON 88017, Cry3Bb1 produces 1.7 pounds endotoxin per acre

• Dow/Pioneer DAS 59122-7, Cry34Ab1 plus Cry35Ab1 produces 2.5 pounds per acre (13-X insecticides displaced)
Monsanto-Dow AgroSciences
SmartStax Corn

- Each plant expresses six different Bt Cry proteins, three for ECB/Lepidoptera, and three for corn rootworm (CRW)/Coleoptera control

- Total expression of Bt proteins is 3.73 pounds per acre: 12-times more than the insecticides displaced (0.31 pounds active ingredients >> [0.12 ECB + 0.19 CRW pounds])
What About Bt Endotoxin Production Compared to Natural Levels of Bt in the Soil?

<table>
<thead>
<tr>
<th>Natural Bt Soil Microorganisms</th>
<th>Bt Cotton</th>
<th>Bt Corn</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.25 g/ha</td>
<td>400 – 1,000 g/ha</td>
<td>2,800 – 4,200 g/ha</td>
</tr>
</tbody>
</table>

Bt cotton produces up to 4,000 times more Bt than soil microorganisms, while Bt corn produces up to 16,800 times more.

Clear evidence that Bt resistance is emerging in multiple Cornbelt corn rootworm populations

Why? Bt corn for rootworm control produces only a moderate dose….and over 41% of corn farmers did not comply with mandatory Bt corn resistance-management provisions in 2010


“Insufficient planting of refuges and non-recessive inheritance of resistance may have contributed to resistance. These results suggest that improvements in resistance management and a more integrated approach to the use of Bt crops may be necessary.”

CONSEQUENCES FOR FARMERS

3-X to 5-X increase in seed expenditures/acre

50% to 100% increase in herbicide expenditures to deal with resistant weeds

Few non-GE varieties now offered for sale, and non-GE seed supply is limited to <10% planted acres
RESPONDING TO RESISTANT WEEDS

Farmers must diversify the tactics embedded in their weed management systems – integrate “many little hammers”
Ominous Trends in Plant Health

Declining plant health triggered by changes in genetics, planting densities, and crop management during the GE crop era

2010 – 11% corn was treated with fungicide (USDA-NASS data)

✓ Less than 1% of corn acres were treated with fungicides in all previous NASS surveys
Lessons From the U.S. Experience with First-Generation GE Crops

Expecting too much from GE technology is asking for trouble

The impacts of GE technology will be determined by the overall health of the agricultural system in which it is deployed
GMOs: Inadequate Regulations and Unanswered Safety Questions

Michael Hansen, Ph.D.
Senior Scientist
Consumers Union
GMO: From Science to Policy Webinar
October 29, 2012
Outline

• Basics of Biotechnology
• FDA GMO policy
• New science raises safety questions
• Summary
The basic structure and functions of genes and chromosomes
Plant transformation with *Agrobacterium* (Ti plasmid) and gene gun
Major GE crops on the market

- Main traits—herbicide resistance (HR), insect resistance (~99.5% acreage), virus tolerant
- Main crops engineered:
  - Soybean (HR)—93%
  - Sugarbeets (HT)—95%
  - Corn (Bt and HR)—88%
  - Canola (HR)—93%
  - Cotton (Bt and HR)—94%
  - Papaya (virus tolerant)—80% (Hawaii)
  - zucchini (virus tolerant)—13% (2005)
FDA Policy on Genetically Engineered Plants

• Introduced at press conference at an industry gathering on May 27, 1992 by then Vice-President Dan Quayle as a deregulatory initiative

• Based on notion “that the new techniques [e.g. genetic engineering] are extensions at the molecular level of traditional methods and will be used to achieve the same goals as traditional plant breeding” (57 FR 22991, May 29, 1992)

• No requirement for human safety testing, only “voluntary safety consultations”; to date, some 93 voluntary safety consultations have been held
Key phrases in US Food and Drug Administration safety consultation letters

- MON 810 (Bt corn), dated Sept. 26, 1996
- “Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different in composition, safety, and other relevant parameters from corn currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA.”
  www.fda.gov/fFood/Biotechnology/Submissions/ucm161107.htm
- This sentence found in all 93 safety consultation letters
- FDA does not require premarket safety assessment and does not state its own opinion about the safety of the GE crop
Martineau, B. 2001. First Fruit: the Creation of the Flavr Savr tomato and the Birth of Biotech Foods

“Rather than personal opinion, the scientific community should give the public facts, hard facts; the results of studies that indicate these foods are safe to eat . . . simply proclaiming ‘that these foods are safe and there is no scientific evidence to the contrary’ is not the same as saying ‘extensive tests have been conducted and here are the results.’ In fact, without further elaboration, ‘no scientific evidence to the contrary’ could be construed as ‘no scientific evidence, period.’” (Martineau, 2001: 232-233)
Transformation—pleitropy, epistatis, unexpected effects

<table>
<thead>
<tr>
<th>Host plant</th>
<th>Trait / expression</th>
<th>Unintended effect</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canola</td>
<td>overexpression of phytoene-synthase</td>
<td>multiple metabolic changes (tocopherol, chlorophyll, fatty acids, phytoene)</td>
<td>Shawmaker et al. (1999)</td>
</tr>
<tr>
<td>Potato</td>
<td>expression of yeast invertase</td>
<td>reduced glycoalkaloid content (~37–48%)</td>
<td>Engel et al. (1998)</td>
</tr>
<tr>
<td>Potato</td>
<td>expression of soybean glycinin</td>
<td>increased glycoalkaloid content (+16–88%)</td>
<td>Hashimoto et al. (1999a); Hashimoto et al. (1999b)</td>
</tr>
<tr>
<td>Potato</td>
<td>expression of bacterial levansucrase</td>
<td>adverse tuber tissue perturbations; impaired carbohydrate transport in the phloem</td>
<td>Turk and Smekens (1999); Dueck et al. (1998)</td>
</tr>
<tr>
<td>Rice</td>
<td>expression of soybean glycinin</td>
<td>increased vitamin B6-content (+50%)</td>
<td>Momma et al. (1999)</td>
</tr>
<tr>
<td>Rice</td>
<td>expression of provitamin A</td>
<td>formation of unexpected carotenoid derivatives (beta-carotene, lutein, zeaxanthin)</td>
<td>Ye et al. (2000)</td>
</tr>
<tr>
<td>Soybean</td>
<td>expression of glyphosate (EPSPS) resistance</td>
<td>higher lignin content (20%) at normal soil temperatures (20°C); splitting stems and yield reduction (up to 40%) at high soil temperatures (45°C)</td>
<td>Gertz et al. (1999)</td>
</tr>
<tr>
<td>Wheat</td>
<td>expression of glucose oxidase</td>
<td>phytotoxicity</td>
<td>Murray et al. (1999)</td>
</tr>
<tr>
<td>Wheat</td>
<td>expression of phosphatidyl serine synthase</td>
<td>necrotic lesions</td>
<td>Delhalze et al. (1999)</td>
</tr>
</tbody>
</table>

*Data from publicly available reports.*

- Proteomics is the study of expressed proteins. This is good way to detect unintended effects associated with GE, particularly the disruptive effects due to the random insertion of transgene
- Superior study design: GE maize (MON810) and near isolate grown side-by-side in growth chamber, to control for environmental effects

- Results: “43 proteins resulted up- or down-regulated in transgenic seeds with respect to their controls (T06 vs WT06), which could be specifically related to the insertion of a single gene into a maize genome by particle bombardment.” (pg. 1850). Of these 43 proteins, 14 were down-regulated, 13 up-regulated, 9 shut off and 7 newly expressed.

- “Interestingly, a newly expressed spot (SSP 6711) corresponding to 50 kDa gamma zein, a well-known allergenic protein, has been detected. Moreover, as a major concern, a number of seed storage proteins (such as globulins and vicilin-like embryo storage proteins) exhibited truncated forms having molecular masses significantly lower than the native ones.” (pg. 1855)

- Well designed study: MON810 and near isoleine grown simultaneously in neighboring fields in Landriano, Italy, to control for environmental effects

- “This study evaluated the gut and peripheral immune response to genetically modified (GM) maize in mice in vulnerable conditions. Weaning and old mice were fed a diet containing MON810 or its parental control maize . . . for 30 and 90 days. . . As compared to control maize, MON810 maize induced alterations in the percentage of T and B cells and of CD4+, CD8+, γδT, and RT subpopulations of weaning and old mice fed for 30 or 90 days, respectively, at the gut and peripheral sites. An increase of serum IL-6, IL-13, IL-12p70, and MIP-1 [cytokines involved in allergenic and inflammatory response] after MON810 feeding was also found. These results suggest the importance of the gut and peripheral immune response to GM crop ingestion as well as the age of the consumer in the GMO safety evaluation.”
Velirimov et al. 2008. Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice.

• Carefully designed Austrian study: GE corn and a near isogenic line grown in adjacent fields in Canada in the same year (2005, 2007).
• Large sample sizes were used to detect more subtle adverse effects.
• Major result: statistically significant adverse reproductive effects shown in the reproductive assessment by continuous breeding (RACB) study. RACB is a feeding study whereby a pair of mice are fed GM maize for 140 days, during which time the female is bred so that she delivers 4 litters. RACB puts mice under stress making it easier to detect adverse effects.
Velirimov et al. 2008. Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice.

• 24 pairs of mice. In the non-GE group all 24 females delivered 4 litters. In the GE group the number of deliveries declined with time. In the 4th litter only 20 deliveries occurred (p=0.055). The average number of pups born was always lower in the GM group.

• More pups born in the non-GE than in the GE group (1035 versus 844). Furthermore females of the GE group always had smaller litters (n=8) as compared to females of the ISO group.”
Study involved 30 pregnant, 39 nonpregnant women in Quebec, Canada.

Blood taken from women and from fetal cord blood and tested for 3 pesticides associated with GM: glyphosate, glufosinate, Cry1Ab

Results: detected metabolite of glufosinate (3-MPPA) and Cry1Ab in maternal, fetal and nonpregnant women’s blood

- “Cry1Ab toxin was detected in 93% and 80% of maternal and fetal blood samples, respectively and in 69% of tested blood samples from nonpregnant women”
- Conclusion: “To our knowledge, this is the first study to highlight the presence of pesticides-associated genetically modified foods in maternal, fetal and nonpregnant women’s blood. 3-MPPA and Cry1Ab toxin are clearly detectable and appear to cross the placenta to the fetus. Given the potential toxicity of these environmental pollutants and the fragility of the fetus, more studies are needed, particularly those using the placental transfer approach.”

Table 1 Review of the longest chronic or subchronic toxicity studies in mammals fed with commercialized GM soybean and maize representing more than 80% of edible GMOs (2010)

<table>
<thead>
<tr>
<th>References</th>
<th>Plant</th>
<th>Pesticide contained</th>
<th>Name of event</th>
<th>Species</th>
<th>Duration</th>
<th>Main observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>[17,38,39,19,15]</td>
<td>Soybean</td>
<td>Roundup herbicide</td>
<td>mCP4 EPSPS</td>
<td>Mouse</td>
<td>240 days</td>
<td>Ultrastructural histochemistry disturbed</td>
</tr>
<tr>
<td>[14]</td>
<td>Soybean</td>
<td>Roundup herbicide</td>
<td>mCP4 EPSPS</td>
<td>Rat</td>
<td>91 days</td>
<td>Weight problems</td>
</tr>
</tbody>
</table>
| [40] | Soybean | Roundup herbicide | Optimum GAT DP-356043-5 | Rat | 93 days | Statistical differences
| [41] | Soybean | Roundup herbicide | Not precise | Rat | 104 weeks | Statistical differences
| [42] | Maize | Roundup herbicide | Optimum GAT DP-098140-6 | Rat | 91 days | Statistical differences
| [43,5] | Maize | Roundup herbicide | NK603 | Rat | 90 days | Controversial results |
| [44,5] | Maize | mCry1Ab insecticide | MON810 | Rat | 90 days | Controversial results |
| [25,2,4,5] | Maize | mCry3Bb1 insecticide | MON863 | Rat | 90 days | Controversial results |
| [16] | Maize | mBt insecticide | not indicated | Rat | Multi-generational (F3) | Histopathological, biochemical, organ weights alterations |
| [45] | Maize | mCry1F insecticide - glufosinate ammonium-based herbicide | DAS-Ø15Ø7-1 | Rat | 91 days | Statistical differences
| [46,47] | Maize | mCry34Ab1, mCry35Ab1 insecticides - glufosinate ammonium-based herbicide | DAS-59122-7 | Rat | 90 days | Statistical differences
| [48] | Maize | mCry1F, mCry34Ab1, mCry35Ab1 insecticides - glufosinate ammonium-based herbicide | DAS-Ø15Ø7-1 x DAS-59122-7 | Rat | 92 days | Statistical differences

*Statistical differences are not biologically meaningful for the authors; however, this can be debated. Oilseed rape and cotton have been excluded because they are not directly edible and not primarily grown for feed. This table includes authorized events for food and feed at least in the European Union and America.

Table 2 Meta-analysis of statistical differences with appropriate controls in feeding trials

<table>
<thead>
<tr>
<th>All parameters measured in vivo in GMO toxicity studies</th>
<th>Measured by organ (%)/Total (694-698)</th>
<th>Disturbed in each organ (%)/Total disrupted parameters (approximately 9%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Females</td>
<td>Males</td>
</tr>
<tr>
<td>Liver</td>
<td>22.9</td>
<td>22.9</td>
</tr>
<tr>
<td>Kidney</td>
<td>23.7</td>
<td>23.7</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>29.5</td>
<td>29.5</td>
</tr>
<tr>
<td>Total for 3 tissues</td>
<td>76.1</td>
<td>76.1</td>
</tr>
</tbody>
</table>

Commercialized soybean and maize GMOs were fed to rats and their blood analyses were obtained. The different parameters are classified according to the tissue [2] to which they are related (e.g., liver, kidney, bone marrow). Of the total parameters measured 76.1% are related to these three organs. The percentages of significantly different parameters to the controls are called “disrupted parameters.” There are in total 9% of disrupted parameters and, for instance, 43.5% of these are concentrated in kidneys in males. The bold values are significantly over the parameters measured per organ.
Summary

• US policy on GE plants inadequate
  – safety assessments not required
  – labeling not required

• Unanswered health questions persist for GE plants
Regulation of Genetically Modified Organisms

Presented October 29, 2012

Genetically Modified Organisms (GMO) from Science to Policy
Hunger and Environmental Nutrition Practice Group Webinar
Government Oversight of GMOs

» Federal Oversight—Coordinated Framework for Regulation of Biotechnology (1986)—apply existing laws to new research and products.

Food and Drug Administration
Environmental Protection Agency
U.S. Department of Agriculture

» State Oversight of GMOs

California Proposition 37—pending
State statutes and common law
Food and Drug Administration

» **Enforces the Food Drug and Cosmetic Act**
  - Ensure safety of commercial food and food additives, except meat and poultry products
  - Take action against adulterated or misbranded food
  - Labels must use common name and reveal material facts—FDA position is that use of GMOs is not material

» **Statement of Policy on Foods Derived from New Plant Varieties, 57 Federal Register 22984 (May 29, 1992).**
  - Authority to require pre-market safety tests for food additives (unless Generally Recognized as Safe (GRAS)).
Environmental Protection Agency

> Enforces the Federal Insecticide Fungicide and Rodenticide Act (FIFRA)

- Regulates pesticides including “plant-incorporated protectants”
- Approves registration for manufacturers before commercial release of seeds that have been genetically modified to produce a pesticide.
- Sets tolerances (and exemptions) for pesticide residues in food
U.S. Department of Agriculture
Animal and Plant Health Inspection Service (APHIS)

» Enforces the Plant Protection Act and Toxic Substances Control Act

Reviews results of field trials
Goal is to prevent commercial sale of plant pests.
Focus on potential for direct or indirect injury, spread of disease, or damage to any plant

» 2008 Farm Bill required improved management and oversight (7 U.S. Code section 7701 note).
U.S. Department of Agriculture

National Organic Program (NOP)

» Enforces the Organic Foods Production Act

Regulations classify genetic modification as an “excluded method.” 7 C.F.R. sections 205.2 and 205.105(e).

» USDA Organic does not necessarily mean “GMO Free”

Problem of unintended application (i.e. drift)
“Process standard”
State Oversight of GMOs

**Common Provisions include:**

- Voluntary labeling of dairy products produced from herds not treated with growth hormones
- Procedures to be followed by manufacturers before inspecting fields or sampling crops
- Financial support for biotechnology research
- Sales, use, and excise tax exemptions for biotechnology manufacturers
- Damages for destruction/ classified as terrorism
- Preemption of seed labeling regulation by local governments
State Common Law

» In addition to statutes and regulations, indirect regulation may take place through private cases in the court system.

» So far, however, very few cases have addressed claims involving GMOs based on theories such as trespass or nuisance.
California’s Proposition 37

» California Right to Know Genetically Engineered Food Act (pending ballot initiative)

Requires labeling of food sold to consumers made from plants or animals with genetic material changed in specified ways. Prohibits marketing such food, or other processed food, as “natural.” Provides exemptions.

Official Voter Information Guide, California Secretary of State
Additional Resources


Contact Me

Jill Krueger
The Network for Public Health Law
St. Paul, Minnesota
651-695-7624
jkrueger@networkforphl.org
The Network for Public Health Law

Contact the Network to:

• Get practical legal assistance on a variety of public health topics
• Find helpful resources from webinars and trainings to fact sheets and legal briefs
• Connect with a community of experts and users of public health law

Support is available at no cost! Visit www.networkforphl.org for more information.
Tools & Resources

- [www.HENdpg.org](www.HENdpg.org)
  - Organic Talking Points (revision due 2013)
  - GMO resource list
  - Benbrook Point Counterpoint
  - Sustainable Food Systems Primer: Action Items for RDs
  - In The Works
    » Science of Sustainable and Resilient Food and Water Systems
    » An Educators Resource (Teaching Food Systems and Sustainability in Nutrition Education and Dietetic Training)
Hunger and Environmental Nutrition
Webinar Series
GMO: From Science to Policy

Charles Benbrook, Ph.D.
Research Professor
Washington State University
cbenbrook@wsu.edu

Michael Hansen Ph.D.
Senior Staff Scientist
Consumers Union
hansmi@consumer.org

Q & A

Jill Krueger, JD.
Senior Attorney
The Network for Public Health Law
jkrueger@networkforphl.org

Melinda Hemmelgarn, MS, RD.
Investigative Nutritionist
Food Sleuth Radio
foodsleuth@gmail.com
Hunger and Environmental Nutrition (HEN) Dietetic Practice Group

Member Benefits

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• Strategic Network relationships,...
Upcoming Webinars

Nourishing A Hungry Nation On A Budget

November 13, 2012
1:00 – 2:00 P.M. EST

Moderator: Hannah Miller, RD.
Speaker: Dawn Undurrga, MS, RD.
Speaker: Michelle Marshall, MS, RD, LDN.