



CENTER FOR
FOOD SAFETY

GMO Regulation, Contamination and Glyphosate

**USMCA Trade Dispute Webinar
April 23, 2024**

Bill Freese, Science Director
Center for Food Safety

Center for Food Safety

- Civil society organization founded 1997
- Mission: protect public health and environment from hazardous agricultural technologies; legal action when needed
- Experts on GMOs and pesticides & their regulation
- Freese W. & Schubert D. (2004). Safety testing and regulation of genetically engineered foods. *Biotechnology & Genetic Engineering Reviews* 21: 299-324.

What are GMOs?

- Plants genetically engineered to produce novel proteins derived from bacterial genes
 - Insect resistance: kills certain insect pests
 - Herbicide resistance: crop survives spraying to kill weeds
- GMOs do *not* have increased yield, better nutrition, etc.

Why is GMO Regulation Needed?

- GMOs pose potential risks that require careful evaluation, e.g. new toxins/allergens
- Government *should* serve as honest broker to assess those risks, restrict or prohibit use as needed

U.S. GMO “Regulation” Was Designed by Biotech Companies.....

- “The U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do.”
 - Henry Miller, formerly head of biotechnology at FDA
- As quoted in The New York Times: “Biotechnology Food: From the Lab to a Debacle”, January 25, 2001

To Promote Acceptance of GMOs, *not* Ensure Safety

“FDA's Voluntary Plant Biotechnology Consultation Program **Eases Pathway to Marketplace**”

By: Susan Mayne, Ph.D., Director, Center for Food Safety
and Applied Nutrition (CFSAN), and Dennis Keefe, Ph.D.,
Director, Office of Food Additive Safety, CFSAN

<https://www.fda.gov/news-events/fda-voices/fdas-voluntary-plant-biotechnology-consultation-program-eases-pathway-marketplace>



CFSAN Director, Susan Mayne, Ph.D.

FDA: Human Health Risks of GMOs

- **Novel (new) toxins or allergens**
- **Increased levels of native plant toxins**
- **Reduced nutritional content**
 - **Statement of Policy – Foods Derived from New Plant Varieties,**
 - **U.S. Food and Drug Administration, May 29, 1992**

U.S. GMO “Regulation” Is Not Compliant with USMCA

- USMCA, Article 28.1, defines regulation:
“regulation means a *measure of general application* adopted, issued, or maintained by a regulatory authority with which compliance is **mandatory**.”
- FDA's **Voluntary** Plant Biotechnology Consultation Program Eases Pathway to Marketplace

FDA “Regulation”

- Voluntary consultation, NOT mandatory
- No animal feeding trials with GE crop required
- Companies do their own testing, submit summary data to FDA if they choose
- FDA “does *not* conduct a comprehensive scientific review of data generated by the developer.” See <https://tinyurl.com/24e62849>
- Freese & Schubert (2004). Safety testing and regulation of genetically engineered foods. *Biotechnology & Genetic Engineering Reviews* 21: 299-324.

FDA Does Not Approve GMOs as Safe

“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 ... from corn currently on the market...”

“However ... ***it is Monsanto’s responsibility to ensure that foods marketed by the firm are safe...***”

FDA Letter to Monsanto, re: MON810 “Bt” corn, 9/25/96:
<https://tinyurl.com/ybm66bww>

Monsanto: FDA is Responsible

- "Monsanto should not have to vouchsafe the safety of biotech food," he said. "Our interest is in selling as much of it as possible. Assuring its safety is the F.D.A.'s job."
- Phil Angell, Monsanto's director of corporate communications, as quoted in Pollan, M. (1998). "Playing God in the Garden," NYT Magazine, Oct. 25, 1998

U.S. Dept. of Agriculture “Regulation”

- Most GMOs *exempted from any government oversight* – “regulatory relief”
- Companies can “self-determine” their GMOs are not regulated
- 79 GM plants, incl. 3 GM corn varieties, exempted over last 3 years
- “Wild West” for GMOs, no segregation

Enogen “Biofuels” GM Corn

- USDA approved GM corn “Enogen” for ethanol production in 2011.
- Contains high levels of enzyme (alpha-amylase) that degrades corn starch into sugar
- “It would only take one kernel of Enogen corn mixed with 10,000 kernels of food corn to ruin the food processing abilities of food corn, according to the North American Millers Association.”
 - Roseboro K (2017). GMO-ethanol corn contamination raises concerns about another “StarLink” disaster, The Organic & Non-GMO Report, Feb. 22, 2017. <http://tinyurl.com/5n7w9jch>

Enogen Contaminates White Corn

- Massive Enogen contamination of white corn in NE
- One farmer abandoned 25,000 bushels of white corn due to Enogen contamination
- “Nebraska is the number one producer of food grade white corn in the U.S. But many producers are concerned that the growing presence of Enogen corn may eventually force them to stop growing white corn...”

- <https://brownfieldagnews.com/rural-issues/enogen-vs-food-grade-coexistence-issue-nebraska/>

■ ”

Enogen Ruins Masa Products

- Masa flour sold by Amapola Market in Los Angeles likely contaminated with Enogen
- Customers made tamales for Christmas that were “gooey, fell apart, and even made people sick.”
- 120,000 lbs. of white corn contaminated
 - <https://www.latimes.com/local/lanow/la-me-ln-bad-tamales-20161226-story.html>

Bad Tamales



Bad Tamales from contaminated white corn. Los Angeles Times, 12/26/16.
<https://www.latimes.com/local/lanow/la-me-ln-bad-tamales-20161226-story.html>.



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Insect-Resistant GM Corn & Allergies

- GM corn produces multiple toxins derived from the bacterium *Bacillus thuringiensis* – “Bt corn”
- Some Bt toxins have properties of proteins that cause food allergies: resistance to digestion, heat stability, structural similarity to known allergens
- “...Bt proteins could act as antigenic and allergenic sources.”

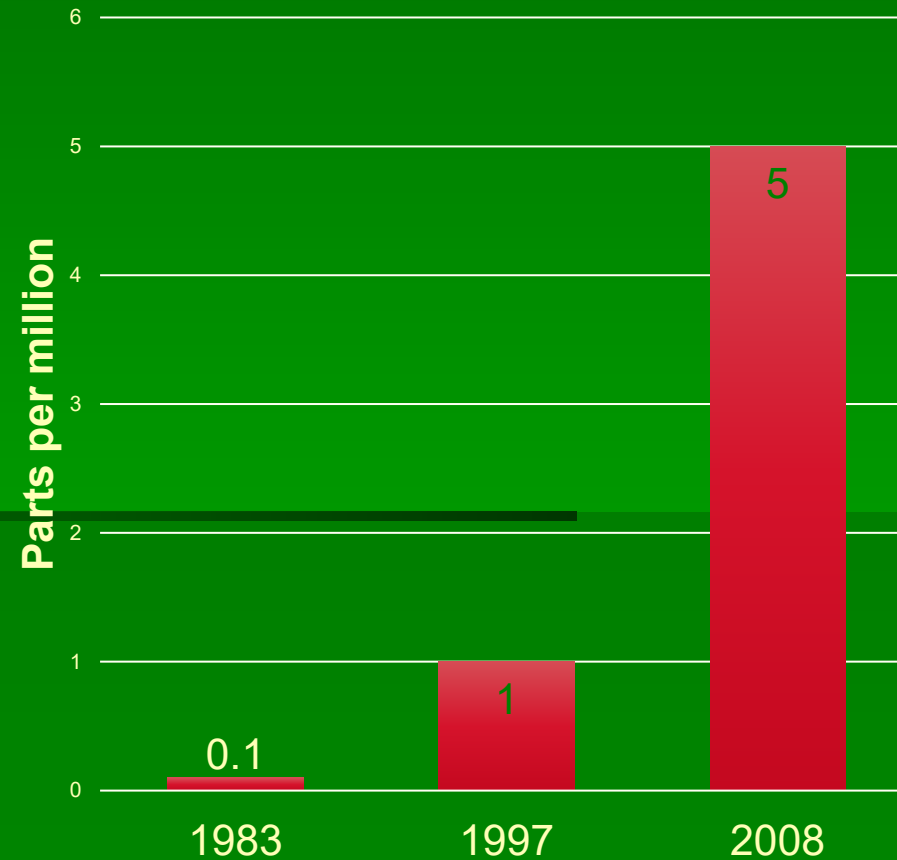
EPA Scientific Advisory Panel, Report No. 2000-07, 3/12/01, p. 76,
<https://archive.epa.gov/scipoly/sap/meetings/web/pdf/octoberfinal.pdf>

Herbicide-Resistant GM Crops

- Crop survives direct spraying of glyphosate (Roundup) and other herbicides that would otherwise kill it
- Roundup Ready soybeans, corn, cotton, canola, sugar beets and alfalfa
- Dramatically increased glyphosate use

Maximum Glyphosate Residues Increased

Corn Grain
Glyphosate Tolerance



Glyphosate and Health Harms

- Glyphosate “probably carcinogenic to humans” – linked to non-Hodgkin’s lymphoma (NHL) by WHO’s IARC
- Roundup users w/ NHL have won many lawsuits against Monsanto/Bayer
- Federal court struck down EPA’s human health assessment of glyphosate in lawsuit brought by CFS – EPA denied glyphosate causes cancer, but said it might cause NHL

Glyphosate and Liver, Kidney

- EPA once conceded glyphosate had adverse effects on liver (fatty liver) and kidney (damage to tubules) at low doses
- Now denies these harms, and has raised the “safe” human exposure level by 20 times: from 0.05 to 1.0 mg/kg bw/day

Conclusions

- U.S. “regulation” of GMOs is not compliant with USMCA: voluntary, not mandatory
- GMO contamination of white maize ruins masa corn products like tamales, makes people sick
- Insect-resistant Bt corn toxins might cause food allergies
- Glyphosate linked to cancer, liver and kidney disease
- Mexico cannot rely on U.S. government assurances re: safety of GMOs and glyphosate



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