NAFTA 2.0 negotiations and the U.S. non-regulation of the new GMOs

Steve Suppan, ssuppan@iatp.org
Center for Human Rights, Mexico City
October 24, 2017
GE corn detected in 90% of tortillas despite Mexican GE corn planting ban

Los transgenes provienen de plantas transformadas en EU
90.4% DE TORTILLAS EN MÉXICO CONTIENE MAÍZ TRANSGÉNICO

Investigación encabezada por Elena Álvarez-Buylla y publicada en la revista Agroecology and Sustainable Food Systems
Patricia López, 18 de septiembre de 2017
Gene edited corn soon in the export pipeline

PUBLIC RELEASE: 9-OCT-2017

Genetically boosting the nutritional value of corn could benefit millions

Rutgers scientists discover way to reduce animal feed and food production costs by increasing a key nutrient in corn

RUTGERS UNIVERSITY
‘Harmonizing’ and exporting U.S. regulatory shortcuts in the NAFTA 2.0 negotiations

NAFTA 2.0: doing harm with ag biotech approval shortcuts

By Dr. Steve Suppan
September 29th, 2017

Trade
nafta
NAFTA: North American Free Trade Agreement
Lecture outline

• GMOs: no longer count on EU opposition against the U.S.
• Brief explanation of the new post-transgenic GMOs, their non-target effects and possible risks
• U.S. de facto non (self)-regulation of the new GMOs
• Conflict of interests and Confidential Business Information (CBI) in non (self)-regulation
• Exporting a crisis: U.S. farmer lawsuits vs. Syngenta and undefined Low Level Presence of GMOs in the TransPacific Partnership (TPP)
• NAFTA 2.0 refinements to the TPP: new GMOs accepted once, accepted everywhere
• Some proposals for a NAFTA 2.0 campaign
In April 2017, the European Commission refused the official European Network of GMO Laboratories (ENGL), in charge of GMO detection and identification, to undertake a specific study on the new techniques of genetic modification. A surprising position from the European risk manager who thus deprives itself from an important technical resource on a very political question.
Against the argument that the new GMOs are not subject to EU law

ENSSER Statement on New Genetic Modification Techniques:

Products of new genetic modification techniques should be strictly regulated as GMOs[1]
Classic technique of transgenic plant breeding
NAFTA 2.0 must comply with the definition of “modern biotechnology” in the Codex Alimentarius “Principles for Risk Analysis of Foods Derived from Modern Biotechnology and regulate GMOs accordingly, e.g.

8. The definitions below apply to these Principles:

“Modern Biotechnology” means the application of:

i) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

ii) Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection⁴.
Without transgenes: DNA ‘scissors’ and RNA ‘thread’ edit a genomic sequence

Figure 1: Nuclease (DNA-scissors): CRISPR-Cas9 – Clustered Regularly Interspaced Short Palindromic Repeats
U.S., Mexico and Canada, as Codex members, must conduct safety assessments for risks from the non-target effects of GE, regardless of technique, that may affect human health

SECTION 5 – OTHER CONSIDERATIONS

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.

Relevant risks from unintended mutations


- Increase in plant toxins
- Deficiency in proteins important for nutrition and plant disease defense
- Increase in allergens
- Disruption of genetic expression, which may “silence” a gene for generations with beneficial, neutral or harmful effects
- Increase in a plant’s invasive capacity
- Positional changes in genes that impact ecology without being evident in the GE derived product
Rewriting Life

GM Apples That Don’t Brown to Reach U.S. Shelves This Fall

Can genetic modification appeal to consumers? A new apple will test the market.

by Andrew Rosenblum  October 7, 2017
Some plants modified by new techniques without U.S. regulation

https://www.testbiotech.org/sites/default/files/Russian_Roulette_with_Biodiversity.pdf

<table>
<thead>
<tr>
<th>Crop</th>
<th>Trait</th>
<th>Developer</th>
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<tr>
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<td>Danforth Center</td>
<td>CRISPR-Cas9</td>
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<td>Potato</td>
<td>Reduced black spot (PP05 potato)</td>
<td>Simplot</td>
<td>TALEN / Agrobacterium</td>
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<td>Potato</td>
<td>Improved processing characteristics (PPO_KO potato)</td>
<td>Calyxt</td>
<td>TALEN</td>
<td>2016</td>
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<td>Waxy corn</td>
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<td>CRISPR-Cas</td>
<td>2016</td>
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<td>White button mushroom</td>
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<td>Penn State University</td>
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<td>Wheat</td>
<td>Resistance to powdery mildew</td>
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<td>Maize</td>
<td>Increased starch</td>
<td>Agrivida</td>
<td>Meganuclease, method: CBI</td>
<td>2015</td>
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<tr>
<td>Rice</td>
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<td>Iowa State University</td>
<td>TALEN</td>
<td>2015</td>
</tr>
</tbody>
</table>
Rewriting Life

These Are Not Your Father’s GMOs

A new wave of gene-edited crops are dodging regulators, and they’re about to reach stores.

by Antonio Regalado  December 19, 2017
Rationales to not risk assess independently or regulate the new GMOs

- If a product derived from a new GE technique does not have the potential to develop “weediness,” it is not subject to regulation (USDA)
- Unnecessary use of government resources and unnecessary delay to commercialize GE products
- Product developer selects studies and data for government scientists to review
- WTO requirement that only final product, not the production process, may be risk assessed
- The scientists’ conflict of interest problem
- Food exports and non-regulatory policy as “soft power” diplomatic tools
Preparing for Future Products of Biotechnology

Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System

Board on Life Sciences
Board on Agriculture and Natural Resources
Board on Chemical Sciences and Technology
Division on Earth and Life Studies

A Report of
The National Academies of
SCIENCES • ENGINEERING • MEDICINE

THE NATIONAL ACADEMIES PRESS
Washington, DC
www.nap.edu
National Academies Revise Conflict of Interest Policy

The proposed changes follow revelations in recent years that committee members preparing reports for the Academies did not disclose industry relationships.

By Ashley P. Taylor | May 3, 2017
Conflicts of interest among scientists lead to “regulation” of GMOs by the industry
Confidential Business Information claims: making science unavailable for peer review
One consequence of not regulating GMO use:
>100 acres of glyphosate resistant weeds

*Des Moines Register 6/21/2014*

'Superweeds' choke farms

Donnelle Eller, deller@dmreg.com  Published 11:23 p.m. CT June 21, 2014 | Updated 10:09 a.m.

8 photos: The Palmer amaranth super-weed
At a Glance

Why We Did This Review

We conducted this review to assess the U.S. Environmental Protection Agency's (EPA's) management and oversight of resistance issues related to herbicide-resistant genetically engineered crops. We looked at EPA processes and practices, steps the EPA has taken to validate risk, and how the agency collects herbicide resistance data.

Approximately 90 percent of the U.S. soybean, corn and cotton crops are genetically modified to withstand herbicide applications on surrounding weeds. However, when weeds adapt and acquire the ability to withstand the effects of herbicides, this results in herbicide resistance. According to the EPA, the Federal

EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls

What We Found

The EPA's Office of Inspector General (OIG) found that the agency has taken few steps to address herbicide resistance. The EPA believes that a delay in herbicide resistance is in the "public good." Delaying resistance minimizes the amount and type of herbicides applied to combat weeds, reduces human and environmental exposure, and increases grower productivity. However, the EPA has several management and oversight challenges related to the agency effectively addressing herbicide resistance.

We found that the EPA uses the pesticide registration process to collect information on human health and environmental risks from pesticides used on herbicide-resistant weeds, but no information is collected regarding synergism. Synergy occurs when the effect of a mixture of chemicals is greater than the sum of the individual effects.

In addition, labels for products such as glyphosate currently do not require information about the chemical pathway that describes how a herbicide causes harm to a plant (i.e., the "mechanism of action"). Not requiring this information on labels can result in the improper use of pesticides to combat herbicide resistant
As part of bringing this consultation to closure, Monsanto submitted to FDA a summary of its safety and nutritional assessment of the genetically engineered corn, which FDA received on May 25, 2015. Monsanto submitted additional information, received by FDA on February 2, 2016. These communications informed FDA of the steps taken by Monsanto to ensure that this product complies with the legal and regulatory requirements that fall within FDA’s jurisdiction. Based on the safety and nutritional assessment Monsanto has conducted, it is our understanding that Monsanto has concluded that food and feed from MON 87419 corn are not materially different in composition, safety, and other relevant parameters from corn-derived food and feed currently on the market, and that genetically engineered MON 87419 corn does not raise issues that would require premarket review or approval by FDA.

It is Monsanto’s responsibility to obtain all appropriate clearances, including those from the Environmental Protection Agency and the United States Department of Agriculture, before marketing food or feed derived from MON 87419 corn.

Based on the information Monsanto has presented to FDA, we have no further questions concerning food and feed derived from MON 87419 corn at this time. However, as you are aware, it is Monsanto’s continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of
A lawsuit against the EPA permit for Dicamba forecasts the present crop damage
Another consequence of no regulation: damage to soy and other crops not GE resistant to dicamba

Iowa farmers make record number of pesticide misuse claims

Donnelle Eller, deller@dmreg.com  Published 6:39 p.m. CT Sept. 11, 2017 | Updated 11:24 a.m. CT Sept. 12, 2017

Dicamba drift is damaging soybean crops at an unprecedented rate, experts say. Zach Boyden-Holmes/The Register
Monsanto refused to allow a safety assessment of dicamba and EPA didn’t demand it.
Ineffective EPA response to the crisis: agreement with Dicamba manufacturers to develop voluntary labeling guidelines

EPA, herbicide makers agree to new limits for use of dicamba

By Michael Biesecker | AP  October 13

WASHINGTON — The Trump administration has reached a deal with three major agribusiness companies for new voluntary labeling requirements for a controversial herbicide blamed for damaging crops.
Upshot of the EPA and Dicamba manufacturer voluntary labeling agreement

• Farmer complaint: current labeling instructions are impossible to follow because of dicamba’s volatility, which turns a liquid into a gas
• Labeling guidelines, even if clarified, leave neighbors to litigate over crop damage: manufacturer are held harmless
• EPA fails to require Monsanto to prove its claim that it has developed a low volatility dicamba
• Farmers must buy dicamba resistant soy seed to protect that crop from dicamba drift
• Other crops and trees remain vulnerable to systematic damage from dicamba drift miles from the point of spraying
Goals: exporting the non-regulation of GMOs in NAFTA 2.0

• Minimum goal: codify in NAFTA 2.0 Article 2.29 of the TPP to expedite “Trade in Products of Modern Biotechnology”

• Ensure that bilateral NAFTA 2.0 agreements on Low Level Presence of GMOs unapproved in the importing country satisfy exporter demands

• Require CBI for regulatory data exchanged among governments

• Maximum goal: Mutual Recognition Agreements of standards and practices for not regulating GMOs
$1.5 billion: costs of exporting GMOs without a LLP agreement or simultaneous approval (Reuters)

Syngenta agrees to settle U.S. farmer lawsuits over GMO corn

Nate Raymond

3 MIN READ
Priorities of the Global Alliance for Agricultural Biotechnology Trade (GAABT)

• LLP agreements to allow import of GMOs unapproved in the importing country: overcome the trade barrier of non-simultaneous regulatory approvals
• LLPs must be “predictable, efficient and achievable by the industry and governments”
• LLPs must be “executable by government authorities”
• Quantitative LLP levels must be “realistic . . . based in the logistical practices of the international trade of grains and oilseeds”
Three achievements of the GAABT in the TPP

• An article that requires that risk assessment be based in “reasonably accessible” data and studies, i.e. in the information the product developers choose to provide per CBI claims

• An article that requires bilateral negotiations for quantitative LLPs to expedite trade in unregulated GMOs

• Agreement of Mexico and Canada with these articles, which would be imported into NAFTA 2.0
To be negotiated: quantitative LLPs and corresponding labeling requirements

J. Žel et al: *How to Reliably Test for GMOs* (2012)


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**Legislation on GMO Labeling and GMO Detection**

**Table 2** Labeling requirements in different countries adapted from Gruere and Rao (2007)

<table>
<thead>
<tr>
<th>Country</th>
<th>Mandatory Vs. Voluntary labeling</th>
<th>Product Vs. Process labeling</th>
<th>Threshold level (%)</th>
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<tbody>
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<tr>
<td>U.S.A.</td>
<td>Voluntary</td>
<td>Product</td>
<td>n/a</td>
</tr>
</tbody>
</table>
Agreement on methodologies for detecting and enforcing LLPs, e.g. EU (J. Žel et al)

Fig. 7 Scheme of GMO testing in EU official laboratories, simplified version (see text for detailed explanation). *If sample is feed it can be under LLP regulation (no. 5)
Negotiating LLPs according to the Codex Principles for two kinds of plants: grains/oilseeds and horticultural plants

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**ANNEX 3: FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD**

**SECTION 1 – PREAMBLE**

1. An increasing number of recombinant-DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances.

3. This Annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations:
U.S. Grain Inspection Service: too few compliance officers to enforce any LLP
NAFTA 2.0 goals of the U.S. Biotech Crops Alliance

- Chapter on trade of ag biotech products
- Mutual Recognition Agreements for GMO approvals, including approvals by non-NAFTA governments (!)
- Article to require bilateral negotiations of quantitative LLPs
A kind of conclusion:
Some proposals for a NAFTA 2.0 campaign

- A chapter to prevent agribusiness export dumping, including of GMO products
- A chapter to prevent anti-competitive business practices, including contraband export of GMOs
- Require risk assessment and regulation of the GE production system, not the isolated GE “event”
- Prohibition of CBI for risk assessment and regulation pertaining to the environmental, health and safety
- Prohibit importing GMOs in cases of safety assessment and risk management inconsistent with the Codex Principles