Global Landscape of Regulatory Policy: Perspectives from USDA

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Emerging Themes:

• Front of Pack Nutrition Labeling to address Non Communicable Diseases (NCDs)

• EU Pesticide Regulation
  – Registration of Glyphosate
  – EU “Hazard-Based” Criteria for Endocrine Disruptors in Pesticides

• Regulation of Gene Editing Technology
WHO NCD Agenda: sugary drink taxes, front of pack labeling

“In the view of the WHO Director-General, the widespread occurrence of obesity and diabetes throughout a population is not a failure of individual willpower to resist fats and sweets or exercise more.

It is a failure to make bold political choices that take on powerful economic operators, like the food and soda industries.

If governments understand this duty, the fight against obesity and diabetes can be won. The interests of the public must be prioritized over those of corporations.”

*Ten years in public health, 2007–2017: report by Dr. Margaret Chan, Director-General, World Health Organization*  [http://www.who.int/publications/10-year-review/en/]
16 different FOPL systems identified in 23 countries.

### Table 2. Systems Implemented in Total

<table>
<thead>
<tr>
<th>Interpretive</th>
<th>Informative (or Non-Interpretive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified by Member Countries</td>
<td>Identified by Observer Organizations</td>
</tr>
</tbody>
</table>

![FOPL systems images]
Chile implemented nutrition “Stop Sign” FOPL in 2016

- Concerns expressed in WTO TBT Committee by Brazil, Canada, EU, Mexico, U.S., others
Is Chile’s labeling threshold based upon an appropriate total diet study?

Are imported and **all** domestic foods treated the same?
EU reauthorized Glyphosate for 5 years in 11/2017

What impact if Member States ban?

Or if no more EU renewals?

EU Parliament Resolution on Glyphosate in 10/2017

Calls for phase out … glyphosate in the European Union no later than 15 December 2022 [goo.gl/fXhxh9](https://goo.gl/fXhxh9)

Despite EU reauthorization, French and Italian leaders said they would still ban glyphosate over the next three years.

[https://twitter.com/MollyMEP/status/935195921486417921](https://twitter.com/MollyMEP/status/935195921486417921)
Estimate of Affected Agriculture Trade Due to Hazard-Based Criteria in EU Pesticide Regulations:

€70 billion
(Bryant Christie Inc. for ECPA.EU)

Methodology:
58 active substances in pesticides identified under EU hazard based regulations.
Imports assumed to be impacted if MRL for the crop exists in exporting country.

European Union 2016 Covered Commodity Imports by Region, Value in Euros

Central & South America
€23.9B
34.3%

North America & Caribbean
€9.4B
13.5%

Europe (Non-E.U./EFTA)
€7.5B
10.8%

Southeast Asia
€5.9B
8.4%

North Africa & Middle East
€4.3B
6.2%

East & South Asia
€4.3B
6.2%

Sub-Saharan Africa
€11.1B
15.9%

Oceania
€1.9B
2.7%

Central Asia
€1.4B
2%

https://goo.gl/ui3SXJ
Many agricultural inputs and outputs are regulated for the safety of human, animals and the environment.

Promote innovation while addressing health & safety goals

Cost of regulation should be justified by the benefits of regulation
Depending on its characteristics, a product may be subject to review by one or more of these agencies.

A key principle of U.S. regulation: GE products will continue to be regulated according to their characteristics and unique features and not according to their method of production.
### Share of GE Crops in Total Production – 2016

Source: ISAAA Brief 52, 2016

<table>
<thead>
<tr>
<th>Country</th>
<th>Soy</th>
<th>Corn</th>
<th>Cotton</th>
<th>Sugar Beets</th>
<th>Canola (rape seed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>78 %</td>
<td>97 %</td>
<td>95 %</td>
<td>Na</td>
<td>Na</td>
</tr>
<tr>
<td>Brazil</td>
<td>96 %</td>
<td>88 %</td>
<td>78 %</td>
<td>Na</td>
<td>Na</td>
</tr>
<tr>
<td>Canada</td>
<td>94 %</td>
<td>92 %</td>
<td>Na</td>
<td>100 %</td>
<td>93 %</td>
</tr>
<tr>
<td>China</td>
<td>Na</td>
<td>Na</td>
<td>95 %</td>
<td>Na</td>
<td>Na</td>
</tr>
<tr>
<td>India</td>
<td>Na</td>
<td>Na</td>
<td>96 %</td>
<td>Na</td>
<td>Na</td>
</tr>
<tr>
<td>Paraguay</td>
<td>96 %</td>
<td>44 %</td>
<td>100 %</td>
<td>Na</td>
<td>Na</td>
</tr>
<tr>
<td>United States</td>
<td>94 %</td>
<td>92 %</td>
<td>93 %</td>
<td>100 %</td>
<td>90 %</td>
</tr>
</tbody>
</table>
How does GE help in the development context?

**Enhanced food security**
- Higher yields
- More nutritious crops
- Reduced loss to insects and disease
- Adapt to changing weather conditions
- Addresses soil degradation and depleting water resources

**Economic impact – farmer incomes**
- Increase marketable yield
- Reduce input expenses – pesticides, fertilizers, irrigation, energy
What is the role of GE policy in supporting food security?

- Biosafety frameworks for regulation of GE crops
- Regional harmonization of biosafety standards
- Appropriate IPR regimes
- Support for innovative research
- Transparent food and trade policy
Because trade is global, regulation needs to be consistent internationally...
Asynchronous Approvals
> Limit producers ability to use new products

Low-level Presence
> Makes importers vulnerable to rejection

Inadequate Regulatory Systems
  Not science-based
  Not Predictable
  Not Practical
  Lack of transparency

Lack of approvals causes uncertainty in the marketplace

...to avoid trade disruptions
<table>
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<tr>
<th>Challenge</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Slow product authorizations</strong> (~7.5 years to approve)</td>
<td>• Slow authorizations limits producers ability to use new products.</td>
</tr>
<tr>
<td>• Scientific safety evaluations for GE crops from EFSA generally reach the same conclusions as those of US regulatory officials</td>
<td>• Lack of approvals causes uncertainty in the marketplace</td>
</tr>
<tr>
<td>• But authorizations influenced by politics</td>
<td>• Potential LLP makes importers vulnerable to shipment rejection</td>
</tr>
</tbody>
</table>
ECONOMIC IMPACTS OF GE REGULATION

• **Innovator** – is there a market? What is the return on R&D investment?

• **Producer** – what will make production most competitive, cost effective? Is there a market?

• **Exporter** – is there a market? What are the risks at port of entry?

• **Importer** – do I have a reliable supplier? What are the risks at port of entry?

• **Consumer** – is the product safe? Is the product available? Is the product affordable?
The Different Flavors of Biotechnology

Traditional Biotechnology:
• Uses Agrobacterium or gene guns to introduce DNA. Until recently, most commercially available biotech crops were created this way. These methods include transgenisis: When genes from one crop are incorporated into another crop.

Plant Breeding Innovations:
• Newer DNA modification techniques, such as genome editing, used to develop plant varieties
• Also called New Plant Breeding Techniques (NPBTs)
• Include genome editing techniques CRISPR-Cas9, TALEN, ZFN, etc.
• Genome editing techniques advantages
  - Increased precision
  - Greater efficiency
“Am I Regulated?” -- Genome Editing Examples excluded from USDA regulation

Soybean with higher oleic acid (May 2015)

TALEN - deletion to fatty acid desaturase 2 (fad2) gene

Anti-browning Mushroom (April 2016)

CRISPR Cas9 - deletion in polyphenyl oxidase (ppo) gene

Waxy Corn (April 2016)

CRISPR Cas9 – deletion in waxy (Wx1) gene
• Genome editing can potentially save years, or even decades, in bringing needed new varieties to farmers.

• The cost of technology like CRISPR-Cas9 are dramatically lower than the laboratory costs of traditional biotechnology.

• Lower costs can enable startup companies in developing countries to effectively compete with larger multinational companies.
Regulation of Gene Edited Products

• What cost will different levels of foreign regulation impose on the developers of gene edited products?

• Potential scenarios:

1. Grant a *blanket exemption* for certain techniques resulting in products similar to conventional breeding
2. Require a *case-by-case consultation* between tech developers and regulators to determine if product is regulated
3. Subject all products to *existing regulations* for transgenics

• *How do these scenarios affect the cost of innovation?*
• *What would be the costs to trade, in light of asynchronous approvals for biotech products and the need for fungibility of the grain trade?*
• *What is the opportunity cost of over-regulation?*
Regulations need Scientific Rationale

World Trade Organization – Sanitary and Phytosanitary (SPS) Agreement – Countries pledge to base regulations on science

“Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5 (provisional measures when scientific data lacking).
Key Points:

• **Agricultural Genome Editing** processes are accelerating agricultural innovation.

• International agricultural trade creates links between the national regulation of biotechnology.

• Regulators are at a crossroads with these new technologies.

• Over-regulation can inhibit global innovation and economic growth.
Thank You

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