Situación de los cultivos MG en Brasil

Flavio Finardi Filho
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Structure of the Brazilian regulation for GMOs

- **Risk assessment**
- **Biosafety maintenance**
- **National interest and socio economic issues on decision**
- **Registration and inspection agencies on specific areas**

**CIBio**
Internal Biosafety Commissions

**CTNBio**
National Technical Commission on Biosafety

**MAPA**
IBAMA
ANVISA

**CNBS**
National Biosafety Council
Each institution:

- Company, university, or research center must create an Internal Biosafety Commission
- Is regulated by law, has a certificate and registered members
- There are almost three hundred institutions in the country
- CIBio is responsible for the control of inner actions on biotechnology
- Must present an annual report the activities to CTNBio
- Must report immediately any accident occurred
Brazilian regulation

CTNBio
National Technical Commission on Biosafety

Risk assessment

54 members

27 incumbent
- 12 experts nominated by MCT
- 9 representatives from ministries
- 6 experts nominated by the ministries

27 substitute
- 12 experts nominated by MCT
- 9 representatives from ministries
- 6 experts nominated by the ministries

6/25/2014

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CNBS is a higher assistance agency of the President for formulating and implementing the National Biosafety Policy

- **Responsible for:**
  - Establishing principles and guidelines for federal agencies and entities
  - Analysing the socio economic convenience and national interest for clearing the commercial use of GMOs and their by-products
  - Deciding in the last and final prosecution stages the commercial release of GMOs and their by-products

National interest and socio economic issues on decision
Brazilian regulation

- Agriculture – MAPA
- Environmental – IBAMA
- Health – ANVISA
  - Fiscalize of field trials and products released
  - Enforce the law and rules
  - Receive the registers specific areas

Registration and inspection agencies on specific areas
Approval process

CIBio: Internal Biotechnology Committee
CTNBio: National Technical Commission on Biosafety
CNBS: Biosafety National Committee
MAPA: Ministry of Agriculture, Livestock and Supplies
IBAMA: Brazilian Institute of Environment and renewable natural resources
ANVISA: Brazilian Health Surveillance Agency

Product passes through the registration process to be produced and commercialized

CNBS might have the final decision based on social-economic factors
Comparative analysis

*case-by-case*

• Safety of species envolved
  – History of safe use, reports of anti-nutrient, toxic and/or allergenic compounds
  – Composition analysis
    • Comparative with regular conventional and parental seeds
  – Significative changes or doubts may lead the petition under investigative actions
    • Additional documents required
    • Demands for new data
Comparative analysis

*case-by-case*

- Analysis of the transgene
  - Maps of the construction
  - Sequence(s) of the gene(s)
  - Number of copies inserted
  - Molecular characteristics
    - Expression
    - Detection methods

- Data portability
Regular procedure

• Initial petition
  – Full description dossie
  – Field trials
  – Import of seeds

• Reports of the field trials
  – Agronomic parameters
  – Environmental impacts

• Final petition → Commercial approval
Restrictions imposed

• Cotton seed case
  – *Gossypium hirsutum* GM
  – *G. barbadense*, *G. mustelinum* (wild) and “moco”
  – First approval (2005) imposed exclusion areas:
    • Northeast
    • Amazonia
    • Tocantins State
  – Normative revision (2013)
    • Inclusion of Tocantins
# Evaluation parameters

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<th>Country</th>
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# Labeling

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* Brazil 2013
Commercial approvals of GM plants

- **Soybeans**: 5 events (1998 – 2010)
- **Cotton**: 12 events (2005 – 2012)
- **Maize**: 19 events (2007 – 2013)
- **Common Beans**: 1 event (2011)
Commercial approvals of non-plant GMOs

- **Vaccine**: 19 (1998 – 2014)
- **Yeast**: 3 (2010 – 2012)
- **Algae**: 1 (2013)
- **Mosquito**: 1 (2014)
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<tr>
<th>Produto</th>
<th>Nome Comercial</th>
<th>Identificador Género</th>
<th>Eventos</th>
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<th>Característica</th>
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**Maize**

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**Cotton**

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Última atualização: 07/04/2014
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### Products released

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</tr>
<tr>
<td>Common Bean</td>
<td>1</td>
</tr>
<tr>
<td>Yeast</td>
<td>2</td>
</tr>
<tr>
<td>Microalgae</td>
<td>1</td>
</tr>
<tr>
<td>Vaccines</td>
<td>19</td>
</tr>
</tbody>
</table>
Adoption of GMOs (millions ha)
## Economic impact of GMOs

<table>
<thead>
<tr>
<th>GM IR maize</th>
<th>Year</th>
<th>Cost savings ($/ha)</th>
<th>Net increase in gross margin ($/ha)</th>
<th>Impact on farm income at national level (million $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>2008</td>
<td>41.08</td>
<td>66.36</td>
<td>96.22</td>
</tr>
<tr>
<td></td>
<td>2009</td>
<td>44.12</td>
<td>30.37</td>
<td>144.54</td>
</tr>
<tr>
<td></td>
<td>2010</td>
<td>48.6</td>
<td>55.74</td>
<td>414.74</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>23.13</td>
<td>131.48</td>
<td>1141.4</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td>13.35</td>
<td>88.12</td>
<td>964.79</td>
</tr>
</tbody>
</table>
GM crops: global socio-economic and environmental impacts 1996-2012

“GM traits have contributed to a significant reduction in the environmental impact associated with insecticide and herbicide use on the areas devoted to GM crops. Since 1996, the use of pesticides on the GM crop area was reduced by 503 million kg of active ingredient (8.8% reduction), and the environmental impact associated with herbicide and insecticide use on these crops, as measured by the EIQ* indicator, fell by 18.7%.”

Graham Brookes & Peter Barfoot, May, 2014

* Environmental Impact Quotient
### Impact of changes in the use of herbicides and insecticides from growing GM crops globally 1996-2012

<table>
<thead>
<tr>
<th>Trait</th>
<th>Change in volume of active ingredient used (million kg)</th>
<th>Change in field EIQ impact (in terms of million field EIQ/ha units)</th>
<th>% change in ai use on GM crops</th>
<th>% change in environmental impact associated with herbicide &amp; insecticide use on GM crops</th>
<th>Area GM trait 2012 (million ha)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GM herbicide tolerant soybeans</td>
<td>-4.7</td>
<td>-6,654</td>
<td>-0.2</td>
<td>-15.0</td>
<td>79.1</td>
</tr>
<tr>
<td>GM herbicide tolerant maize</td>
<td>-203.2</td>
<td>-6,025</td>
<td>-9.8</td>
<td>-13.3</td>
<td>38.5</td>
</tr>
<tr>
<td>GM herbicide tolerant canola</td>
<td>-15.0</td>
<td>-509</td>
<td>-16.7</td>
<td>-26.6</td>
<td>8.6</td>
</tr>
<tr>
<td>GM herbicide tolerant cotton</td>
<td>-18.3</td>
<td>-460</td>
<td>-6.6</td>
<td>-9.0</td>
<td>4.4</td>
</tr>
<tr>
<td>GM insect resistant maize</td>
<td>-37.6</td>
<td>-2,215</td>
<td>-47.9</td>
<td>-45.1</td>
<td>42.3</td>
</tr>
<tr>
<td>GM insect resistant cotton</td>
<td>-205.4</td>
<td>-9,256</td>
<td>-25.6</td>
<td>-28.2</td>
<td>22.1</td>
</tr>
<tr>
<td>GM herbicide tolerant sugar beet</td>
<td>+1.3</td>
<td>-2</td>
<td>+29.3</td>
<td>-2.0</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>-503.1</strong></td>
<td><strong>-25,121</strong></td>
<td><strong>-8.8</strong></td>
<td><strong>-18.7</strong></td>
<td></td>
</tr>
</tbody>
</table>

Graham Brookes & Peter Barfoot, May, 2014
Market share in agrobiotechnology

- US: 40%
- Brazil: 23%
- Argentina: 14%
- India: 7%
- Canada: 7%
- China: 3%
- Others: 6%
Pipeline

Beans (*Phaseolus vulgaris*)

- EMBRAPA
- Initial process: 2010
- Commercial approval: 2011
- Modification
  - RNAi
- Resistant to golden mosaic virus
  - ≈100% of crop areas in NE
Rice (*Oryza sativa*)

- Bayer
- Initial process: 2013
- Commercial approval:
- Modifications
  - Herbicide tolerant
  - Insect resistant
- Previous event withdraw
Sugarcane (*Saccharum L.*)

- CTC – Sugarcane Technology Center
- Monsanto
- Bayer
- Initial process: 2013
- Commercial approval:
- Modifications:
  - Insect resistance
  - Herbicide tolerant
  - Sugar metabolism
Eucaliptus (*Eucalyptus globulus*)

- Fibria
- FuturaGene
- Initial process: 2007
- Commercial approval:
- Modifications:
  - Wood quality / volume
  - Cellulose / hemicellulose
Sorghum (*Sorghum bicolor* (L.) Moench ssp. saccharatum)

- Ceres
- Initial process: 2012
- Commercial approval:
- Modifications:
  - Carbohydrate metabolism
Orange (*Citrus sinensis*)

- Fundecitrus
- Embrapa
- Others
- Initial process: 2013
- Commercial approval:
- Modifications:
  - Resistant to greening
Lettuce (*Lactuca sativa*)

- EMBRAPA
- Initial process
  - 2013
- Modification
  - Production of folic acid
  - 15 time more than usual
  - 300 – 400 µg/g
Passion fruit
(*Passiflora edulis* and *Passiflora alata*)

- ESALQ – USP
- Initial process
  - 2013
- Modification
  - Resistance to cowpea aphid borrel mosaic virus – CABMV
  - Fruit hardness
**Mosquitoes (Aedes aegypti)**

- MOSCAMED and OXITEC
- Initial process
  - 2011
- Modification
  - “production” of sterile males
  - Control insect population
- Spread Dengue fever

**Fruit flies – several species (Ceratitis capitata)**

- MOSCAMED and OXITEC
- Initial process
  - 2013
- Modification
  - “production” of sterile males
  - Control insect population
- Fruit fly larvae
Seed and grain productivity


- Production (millions of tons)
- Planted area (millions of hectares)

O Estado de S. Paulo, 2013
Livestock production
millions of Tons

- Poultry (458%)
- Bovine (88%)
- Pork (238%)

O Estado de S. Paulo, 2013
Abstract

• CTNBio is the Brazilian technical committee responsible for the safety evaluation of GMOs based on scientific knowledge
• CTNBio’s meetings are open to the public following the governmental transparency policy
• Brazilian regulatory agencies perform an integrated work on the evaluation and control of the GMO development in the country
• The production of GM crops has a sustainable environmental basis
• GM crops released are as safe as their conventional counterpart
• CTNBio established coexistence rules for maize farmers
• 37 GM crops were approved in the country
• The biotechnology did not promoted a significant increase of agricultural areas
• The increase of farm productivity seams to be related to the advance of GM crops
• CTNBio also regulated organisms used on biofuel and chemical production, as well as animal and human health
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