Regulatory & Legal Environment in Latin America

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CropLife Latin America

November 2010
1. Overview of Latin America

2. Regulatory & Legal Challenges

3. Overview of Brazil

4. Regulatory Pathways & Challenges
Latin America: Agricultural Potential

Evolution of agriculture global demand and supply drivers

- **Demand**
- **Yield**
- **Acreage**

<table>
<thead>
<tr>
<th>Crop</th>
<th>1960 Yield (ton/ha)</th>
<th>2008 Yield (ton/ha)</th>
<th>Change</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn</td>
<td>1.4</td>
<td>4.3 (~3x)</td>
<td>2.9</td>
<td>FAO, USDA, Goldman Sachs Commodities Research, FAPRI, Syngenta</td>
</tr>
<tr>
<td>Soybeans</td>
<td>1.1</td>
<td>2.8 (~2.5x)</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Wheat</td>
<td>1.1</td>
<td>2.7 (~2.5x)</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Rice</td>
<td>1.8</td>
<td>4.8 (~2.5x)</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>Sugarcane</td>
<td>49</td>
<td>80 (~1.3x)</td>
<td>31</td>
<td></td>
</tr>
</tbody>
</table>

**Global land available for agriculture expansion**

- **Tech improvement**
- **Area expansion**

**Latin American production as percentage of global agriculture (in tons)**

- **Corn**: 14% (1960), 15% (2008)
- **Soybeans**: 17% (1960), 19% (2008)
- **Wheat**: 11% (1960), 12% (2008)
- **Rice**: 21% (1960), 23% (2008)
- **Sugarcane**: 11% (1960), 80% (2008)

Source: FAO, USDA, Goldman Sachs Commodities Research, FAPRI, Syngenta
LatAm Agrochemical Sales 2009 = USD 11,255 mi

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>14,6%</td>
</tr>
<tr>
<td>Brazil</td>
<td>63,3%</td>
</tr>
<tr>
<td>Colombia</td>
<td>3,7%</td>
</tr>
<tr>
<td>Chile</td>
<td>2,6%</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>84,2%</strong></td>
</tr>
<tr>
<td>Others</td>
<td>15,8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Source: ANDEF
Latin America could be the right place at the right time…
However…

How will technology be transferred to support growth?
Latin America: Regulatory Data Requirements

- Potential improvement
- Current status
Latin America: Regulatory Data Requirements

- There have been upgrades from checklist for formulated agrochemicals to tiered, comprehensive requirements starting with a.i.’s

- More and more, the Ag, Health & Env triad gets involved in agrochemical evaluation, namely in larger markets

- In general, regulators in smaller markets struggle to abandon checklist practices
Prohibitions/restrictions in absence of risk assessments (and sometimes due process)
- Dominican Republic - SANCO/PVO Audits
- Panama
- 1A/1Bs

REI used as a marketing tool in absence of proper regulation in Colombia
Latin America: Risk assessment?

- Water quality issues in Colombia:
  - Ground water modeling tool developed with industry support, but
  - Ground water guidance values are used to assess residues in drinking water

- Generalized concern about EU remaining a.i. inventory & impact on MRLs
Objective decisions based on sound science
Balanced risk/benefit judgements made
Right of appeal is part of the process
Labels are clear, reflect conditions of approval and appropriate GHS elements are included
Limited political interference
Monitoring of compliance with registrations is in place
Illegal imports are controlled
Stewardship is valued
Appropriate management of adverse incidents
Potential improvement
Current status
Latin America: Approval Process/Post-Registration

- Increased E-NGO campaigns
  - Nicaragua + El Salvador: Kidney failure
  - Costa Rica: CI campaign against pineapple exports to EU

- Thorough evaluation for first-registrants vs. relaxation for follow-ons
Latin America: Approval Process/Post Registration

- Regulatory adaptation to industry dynamics: Minor change vs. notification
  - Chile
  - Brazil
- Anti-agribusiness policies in Argentina include restriction to technology
  - Taxation of agricultural output
  - Attempt to limit biotechnology
  - Attacks to a.i. using pseudo-science
Latin America: Approval Process/Post Registration

Pseudo-science says: “certified poison”
Scientist says: “Injecting glyphosate directly in the embryos is totally stupid, like drinking a shot of pesticide”... “that work helps to show students how scientific research should not be done”.

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**Latin America: Approval Process/Post Registration**

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**In the image:**

- **La Nación:** Coverage of a scientist's critical remarks on the use of glyphosate in embryonic research.
- **Headline:** Scientist says that injecting glyphosate directly into embryos is “totally stupid, like drinking a shot of pesticide”... “that work helps to show students how scientific research should not be done.”
- **Context:** The article discusses the approval process and post-registration of glyphosate in Latin America, highlighting concerns raised by scientists regarding its direct injection into embryos and the ethical implications of such research methods.
Latin America: Intellectual Property

- Respect for patents
- Applicants required to supply test reports
- Applicants required to supply letters of access to data not included in the submission, but needed for completion of the evaluation
- Confidential business information not accessible to third parties
- Data protection and compensation scheme in place
- Theoretical max
Access to technology/anti-MNC sentiment impacts intellectual property

- Ecuador: Compulsory licensing decree
- Venezuela: Confiscation includes trademarks, registrations
- US-Brazil WTO Cotton Dispute outcome to be influenced by US Farm Bill 2011
Latin America: Intellectual Property

Access to technology/anti-MNC sentiment impacts intellectual property

- Chile: Unenforceable data exclusivity & access to dossiers based on Transparency Act

- Paraguay: Data exclusivity mockery: 5 year of confidentiality protection if first approval is sought in Paraguay
Latin America: Opportunities Using Intellectual Property Rights?

- Bigger markets justify patenting, but
  - Backlogs in place
  - Patent term erosion given increase in regulatory clearance timelines
  - No business method or second use patents

  (Survey via AMCHAM network, ASIPI)

- Data protection for follow-on innovation?
  - Second uses discovered
  - Patenting not available in such cases
  - Regulatory data developed

- Free trade agreements bring data protection (10 year exclusivity) in Central America, Chile, Peru & Colombia
Brazil: The Opportunity, Yet a Challenge

Brazil takes off

The Brazilian generic pesticide market has gained ground in the past five years, according to a report by the Valor Economico news agency. The share of generic products has grown from 53.8% in 2004 to 62.5% in 2009. The 2009 generic market was valued at $3.20 billion, compared to $2 billion in 2004.

Increasing sales for herbicides have contributed to the sector's growth. The report notes that for Latin America, second only to Europe, an additional 174 applications for glyphosate were approved in 2009. Glyphosate accounts for 40% of the herbicide market in Brazil.

Generic agrochemical industry leader Fabio Yoshio Kagi says the 2009 high level of competition, mainly on the major pesticide, glyphosate, since been changed (Agrow 2009).
Brazil

- Area: 8.514.204,86 Km²
- Population: 194 million inhabitants
- Language: Portuguese
- Tropical Country

Brazil: Estimated Area (millions of ha)

<table>
<thead>
<tr>
<th>Type</th>
<th>Area (ha)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amazon Forest</td>
<td>350</td>
</tr>
<tr>
<td>Legal Reserves</td>
<td>55</td>
</tr>
<tr>
<td>Citys, Lakes, River and Swamp</td>
<td>20</td>
</tr>
<tr>
<td>Other uses</td>
<td>54</td>
</tr>
<tr>
<td>Reforestation</td>
<td>5</td>
</tr>
<tr>
<td>Sub-total</td>
<td>484</td>
</tr>
<tr>
<td>Pasture</td>
<td>215</td>
</tr>
<tr>
<td>Annual Crops</td>
<td>47</td>
</tr>
<tr>
<td>Permanent Crops</td>
<td>15</td>
</tr>
<tr>
<td>Available Agribusiness Area</td>
<td>90</td>
</tr>
<tr>
<td>Sub-total</td>
<td>367</td>
</tr>
<tr>
<td>Total</td>
<td>851</td>
</tr>
</tbody>
</table>

~14% of the world's water supply
Brazil: Potential Soil for Agriuse
(367 million hectares)

Source: J.L. Coelho, John Deere, 2001
## Agronegócio Brasileiro – Produção e Exportações

### Ranking - 2009

<table>
<thead>
<tr>
<th>Produtos</th>
<th>Produção</th>
<th>Exportação</th>
<th>N.de Marcados</th>
<th>Total Exportação US$ milhões</th>
</tr>
</thead>
<tbody>
<tr>
<td>Açúcar</td>
<td>1º</td>
<td>1º</td>
<td>113</td>
<td>6,167</td>
</tr>
<tr>
<td>Café</td>
<td>1º</td>
<td>1º</td>
<td>134</td>
<td>3,364</td>
</tr>
<tr>
<td>Suco Laranja</td>
<td>1º</td>
<td>1º</td>
<td>82</td>
<td>1,469</td>
</tr>
<tr>
<td>Soja</td>
<td>2º</td>
<td>1º</td>
<td>74</td>
<td>9,308</td>
</tr>
<tr>
<td>C. Bovina</td>
<td>2º</td>
<td>1º</td>
<td>144</td>
<td>3,923</td>
</tr>
<tr>
<td>Tobacco</td>
<td>2º</td>
<td>1º</td>
<td>114</td>
<td>1,752</td>
</tr>
<tr>
<td>Alcool</td>
<td>2º</td>
<td>1º</td>
<td>40</td>
<td>1,605</td>
</tr>
<tr>
<td>C. Aves</td>
<td>3º</td>
<td>1º</td>
<td>145</td>
<td>3,203</td>
</tr>
<tr>
<td>Milho</td>
<td>3º</td>
<td>4º</td>
<td>34</td>
<td>460</td>
</tr>
<tr>
<td>C. Suínos</td>
<td>4º</td>
<td>4º</td>
<td>72</td>
<td>1,036</td>
</tr>
</tbody>
</table>

Fontes: USDA, MAPA
Opportunities: Brazil’s Production Diversity

1998
- Soybean Complex: 22.0%
- Others: 11.2%
- Fruits Juices: 6.1%
- Cereals and Flour: 0.2%
- Tobacco: 7.2%
- Leather and Products: 8.8%
- Coffee: 12.1%
- Sugar and Ethanol: 9.2%
- Forest Products: 15.6%
- Meat: 7.5%

US$ 21.5 bi

2008
- Soybean Complex: 25.0%
- Others: 9.8%
- Fruits Juices: 3.0%
- Cereals and Flour: 3.1%
- Tobacco: 3.8%
- Leather and Products: 4.4%
- Coffee: 6.6%
- Sugar and Ethanol: 11.0%
- Forest Products: 13.0%
- Meat: 20.3%

US$ 71.8 bi
Opportunities: Brazil’s Agroexports Diversity

1998

- E.U - 27: 41,1%
- Mercosur: 8,6%
- Aladi (-Mercosur): 3,6%
- Africa (-Mid. East): 4,7%
- Eastern Europe: 3,2%
- Mid. East: 5,9%
- USA: 14,9%
- China: 2,7%
- Asia (-China, Mid. East): 11,2%
- Others: 4,1%

194 destinations
E.U + USA = 56%

2008

- E.U - 27: 33,1%
- Mercosur: 2,8%
- Aladi (-Mercosur): 6,0%
- Africa (-Mid. East): 6,7%
- Eastern Europe: 6,9%
- Mid. East: 7,1%
- USA: 8,7%
- China: 11,0%
- Asia (-China, Mid. East): 12,4%
- Others: 5,3%

211 destinations
E.U + USA = 42%
World Pesticide Consumption in 2008 – US$ bn

- Brazil: 7.1
- USA: 6.6
- Japan: 3.2
- France: 3.2
- China: 2.0
- Germany: 2.0
- Canada: 1.3
- Italy: 1.2
- Argentina: 1.2
- Spain: 0.9

Generics x Specialties Sales - 2008 - US$ 1,000

Specialties 3.267.566 (45.86%)
Generics 3.857.574 (54.14%)

Source: SINDAG, APRIL, 2009
Brazil: Share by Crop - 2009

- Soybean: US$ 3,121,225 (47.1%)
- Corn: US$ 754,341 (11.4%)
- Cane: US$ 541,294 (8.2%)
- Cotton: US$ 490,274 (7.4%)
- Coffee: US$ 251,903 (3.8%)
- Citrus: US$ 201,590 (3.0%)
- Others: US$ 1,264,983 (19.1%)

Source: SINDAG 2010
Prospects – Pesticide Market - Brazil

Source: SINDAG, 2009

Growing Factor: 4.4%/Year

Based on export projection of: Soybean, corn, sugar cane (ethanol), coffee and cotton.
Prospects – Pesticide Market - Brazil

Growing Factor 4.1% / Year

Source: MAPA - Projections of the Agrobusiness 2018-2019
Based on export projection of: Soybean, corn, sugar cane (ethanol), coffee and cotton.
Brazil: Challenges

Regulatory challenges/Legal Environment

Credit crunch

Exchange rate valuation

Logistical and infrastructure deficit

Increase of agribusiness debts
Challenges: Regulatory Environment

- Highly regulated sector:
  - FEDERAL
  - STATE
  - MUNICIPAL

- Legislation:
  - Laws
  - Decrees Laws (issued by Executive)
  - Interministerial Rulings
  - Joint Normative instructions
  - Resolutions
• Lei nº 7802/89 – Lei Federal dos Agrotóxicos
• LAWS:
  – Lei nº 9279/96: Propriedade Industrial
  – Lei nº 9294/96: Propaganda
  – Lei nº 10603/2002: Proteção de informação submetida para aprovação da comercialização
• DECREE LAWS:
  – Dec. nº 3.179/99: Crimes Ambientais
  – Dec. nº 3.019/99: Regulamento ANVISA
• ORDERS:
  – Port. 45/90: Registro/Renovação
  – Port. 84/96: PPA – Potencial de Periculosidade Ambiental
  – Port. 86/2005: Segurança e Saúde no Trabalho
• NORMATIVE INSTRUCTIONS:
  – IN 49/2002: Registro de Produtos Equivalentes
  – IN 02/2006: Reavaliação Agronômica, Toxicológica ou Ambiental
  – IN 18/2007: Avaliação de Eficiência e Praticabilidade Agronômica
• RESOLUTIONS:
  – RES. 237/97: Licenciamento Ambiental
  – RES. 334/2003: Unidades de Recebimento de Embalagens Vazias
  – RES. RDC 216/2006: Estudos de Resíduos
- **Commerce & Trade:** Ministério do Desenvolvimento, Indústria e Comércio Exterior
- **Finance:** Ministério da Fazenda
- **Labor:** Ministério do Trabalho
Pesticide regulatory dossier submitted to 3 Ministries (Ag, Health, Env) simultaneously

- Tox Dossier
  - ANVISA Tox Assessment
  - Tox Report
  - Tox Report

- Agronomical Dossier
  - MAPA Agronomical Assessment
  - Final Label Approval

- Environmental Dossier
  - IBAMA Environmental Assessment
  - Environmental Report

REGISTRATION
Pathway: ANVISA

- Data Protocol
- Company

Tech Dept
GGTOX
starts process

Tech Requirements

Tech Queue

Tech Review

Review finalized

Tech Queue

Admin

DICOL Approves / DOU

Report/
Monograph*
issuance

* Registration for new a.i.’s

Check List

Document Validation

Label approval; Tox Report

MAPA

Company

Company

Public Consultation 40 days*

Report/
Pathways: IBAMA

Data Protocol

Company

Tech Dept
CGASQ
starts process

Check List

Queue

Tech Requirements

Tech Queue

Tech Review

Tech Requirements

Review finished; PPA issued

Label approved
PPA Report

Company

Admin

MAPA
Pathway: MAPA

CGA Publication DOU

Check List

Document validation

Protocol SDA

General protocol

Company

Tech Reaquirements

Compliance

Tech Queue

1º Awaits ANVISA/IBAMA

2º Label & container approval

REGISTRATION

Admin Certificate/DOU

General coordination for certificate

Diretor DFIA

Admin
Challenges: Exchange Rate
Challenges: Logistics
Logística pior tira US$ 3,9 bi do agronegócio

Perda no transporte terrestre e atrasos na operação nos portos sugam 7,8% da renda da exportação no ano, diz estudo
In sum, yes Brazil is not only...
It also is...

food  
feed  
fuel
Latin America has the potential to be a global efficient supplier of food, fiber, feed and renewable energies.

- Investment & enablement of technology
- Investment in human capital & infrastructure
- Business-oriented policies
Muchas Gracias!