Introduction

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Bayer’s products and services are designed to improve the lives of humans, animals and plants. Bayer has three legal entities in the Philippines: Bayer Philippines, Inc., Bayer CropScience, Inc. and Bayer Business Services, Philippines, Inc.

Bayer Crop Science Commitment to Sustainable Agriculture

In line with our commitment to sustainable agriculture, we promote and improve corresponding farming practices. Moreover, we are steadily expanding our successful food chain partnerships. In these projects, Crop Science works with all participants in the food chain to sustainably safeguard and increase yields, and to satisfy the quality criteria in the food chain. With the Bayer Forward Farming initiative, we cooperate with farmers to develop and promote innovative solutions for the respective crops and facilitate sustainable agriculture. We plan to establish model operations known as “ForwardFarms” in all major agricultural markets by 2018.

Huang et al 2016, Nature Genetics Vol. 1, No. 2
What are the new technologies?
Recombinant DNA techniques (Stacks/combined events)
- Agrobacterium mediated
- Gene gun mediated
- A foreign DNA fragment is inserted into the host genome randomly

Plant Breeding Innovations
- Gene or genome editing
  - SDN1, 2, 3 – CRISPR, TALENs
  - ODM, etc.

Why do we need them
- Reduced pesticide use: use cut by 619 mil kg (-8.1%) from 1996 to 2015, equal to more than China’s total usage each year
- Saved virgin forests: farmers allowed to grow more without needing to use additional land
- Increased yields and farm income: yield +13.1% for IR corn, +15% for IR cotton, +9.6% IR soybeans from 1996 to 2015; net farm level economic benefit was $15.5 billion, equal to an average increase in income of $90/hectare in 2015 (48.7% have been earned by developing country farmers). In the Philippines, GM corn adoption increased household income by 50% (from $400 to $600/year)
- Direct environment benefit: reduced greenhouse gas emissions (26.7 billion kg of CO₂ equal to removing 11.9 million cars off the roads in 2015)
- Output traits – Golden rice, vit A enriched bananas.

Trade
- Asia-Pacific is mainly a region of commodity import and regulatory activities in most countries are to get import approvals – Food, Feed and processing.
- Asia-Pacific is important to businesses in Americas as it impacts on ability to launch products.
- Relatively young regulatory system (<25 years)
- Grappling with regulating some newer concepts – stacks, plant breeding innovation, asynchronous approvals

Countries of cultivation vs countries of import
- Products launched in production countries – US, Brazil, Argentina, Canada, Australia
- Main countries of import – EU, China, Korea, Japan
- Few cultivation countries for GM: Australia, India, Philippines

Launch Strategies
- Excellence through Stewardship (ETS)
  - Adopted by tech providers
  - Obtain approval in key import countries
Perspectives on New Technologies Development - Impact of Regulation on Food Crop Improvement & Trade

Regulatory Timelines

<table>
<thead>
<tr>
<th>Region</th>
<th>Time between submission and approval (currently)</th>
<th>Time between submission and approval (previous)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>5+ years</td>
<td>&lt; 2 years (2006)</td>
</tr>
<tr>
<td>China</td>
<td>3-5 years</td>
<td>~1 year (2009)</td>
</tr>
<tr>
<td>Japan</td>
<td>5+ years</td>
<td>~3 years</td>
</tr>
<tr>
<td>Korea</td>
<td>~4 years</td>
<td>~1 year</td>
</tr>
<tr>
<td>Australia</td>
<td>1-2 years</td>
<td>&lt;1 year</td>
</tr>
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<td>Philippines</td>
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</tbody>
</table>

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Regulatory Hurdles

Submission: Dossier/data

Assessment: Expert panel/committee review

Approval: Registration

Commercialization

Lack of harmonization leading to asynchronous approvals
Political motivations
Unpredictability

What if things go wrong

Event: MIR 162

Discovery:

- Cost: $17.6
- Number of responses: 5
- Late discovery: $13.4
- Total Cost: $31.0

Construct optimisation:

- Cost: $28.3
- Number of responses: 5

Commercial Event production & Selection:

- Cost: $13.6
- Number of responses: 6

Introgression Breeding & Wide Area Testing:

- Cost: $28.0
- Number of responses: 6

Regulatory Science:

- Cost: $17.9
- Number of responses: 6

Registration & Regulatory Affairs:

- Cost: $17.2
- Number of responses: 6

Total Cost: $136.0

McDougall study in 2014 reported a compound annual growth rate of 9.9% in seed and trait R&D since 2000 (responses from 15 leading companies in the seed and trait sector).
Continuing challenges

Thresholds – Low level presence (LLP)
Zero % threshold is unworkable in modern agriculture
LLP – event is approved in at least one country

Testing
Increasing sensitivity
Not possible to test everything
Look out for false positives or false negatives

Discontinued products
Unlike pesticides, biotech events can persist after stopping sales
Some countries have requirement "for renewals"

The future
- World population of about 10 billion by 2050 (FAO)
- Need to produce 50% more food, feed and biofuel
- Continuum of plant breeding innovations are important
- Science of innovation is advancing fast but regulatory approvals not keeping in pace
- Need for consistent approach when determining scope of regulatory oversight
The Options:

- Appropriate, predictable, science-based regulation
- Enhancing regulatory harmonization
- Sound LLP management
- Regulatory cooperation among governments via safety assessment sharing or joint assessments or mutual recognition of food safety assessments

Thank you!