



Regulatory Challenges and Opportunities for Agricultural Biotechnology

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Asia BioBusiness and APEC

- **Food Security Policy in APEC (ongoing)**
 - Definitions, policies, interventions (analysis)
- **The Toolbox for the Commercialization of Agbiotech in APEC economies (HLPD - nearing completion)**
 - Knowledge sharing (South-South) to build capability in regulatory issues and risk communication



Challenges of Harmonization of Agricultural Biotechnology Regulatory Systems across APEC Economies

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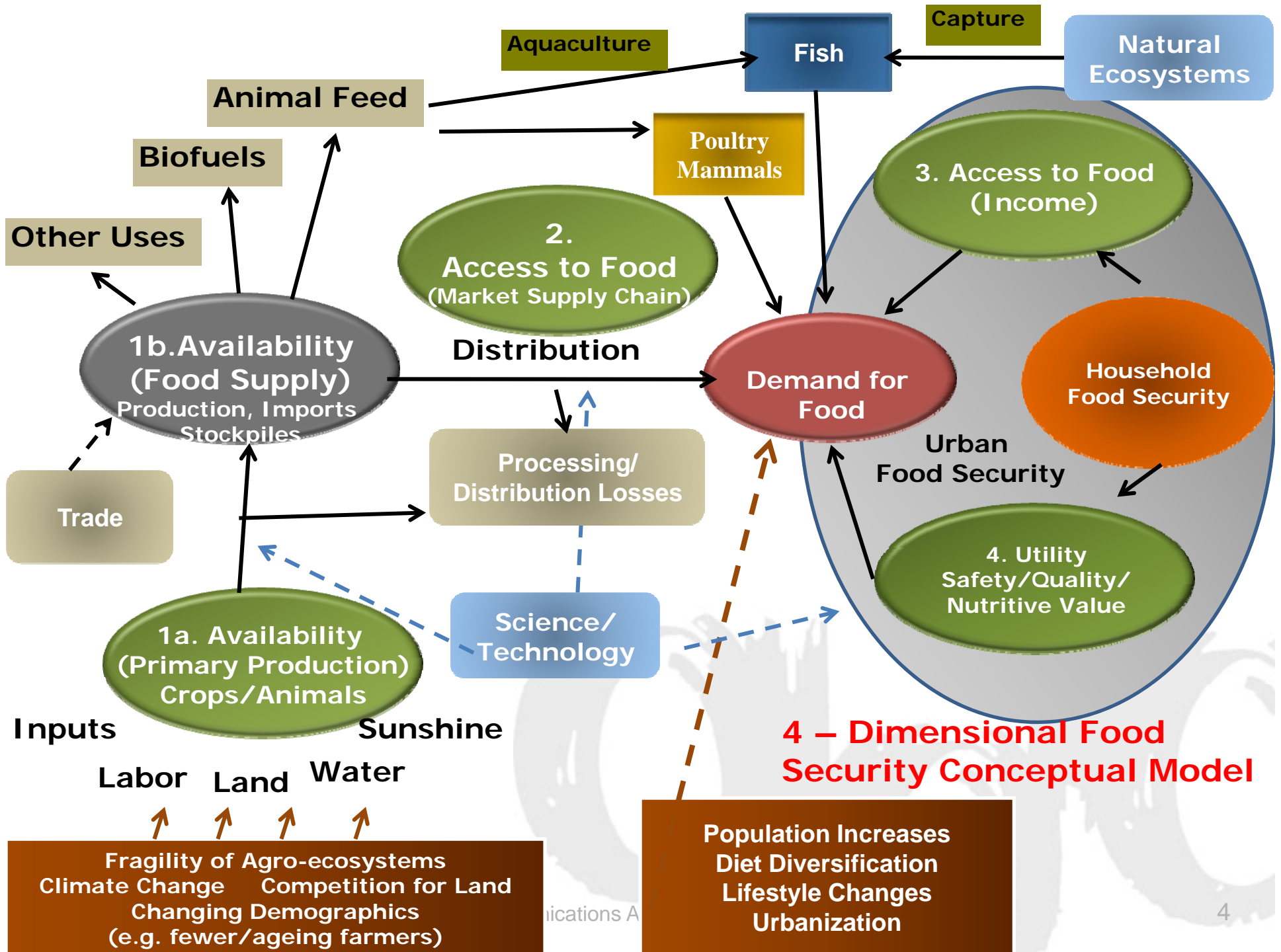
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Abstract

The Asia Pacific Economic Cooperation (APEC) consists of a mixed group of countries with a range of technical and technological capabilities vis à vis the regulation of Genetically Modified (GM) crops. Most have regulations or laws in place that enable the use of GM crops to some degree whether they cover only R&D activities or extend further to cover importation, field trials or release into the environment. Because experience with GM crops varies widely across the twenty-one economies, member countries are at different stages of development and implementation, have contrasting philosophies which are often reflected in national policies and have different regulatory capacities and resources. Such discord may be cause for concern particularly when many member countries face food security challenges. Delayed authorizations due to regulatory uncertainty and unpredictability can cause supply delivery problems, disrupt trade and create new market constraints that could increase the volatility of food prices. Unnecessary regulatory requirements can also result in additional costs making it difficult for any GM crop to make it market and into farmers' hands. Although the road towards alignment and harmonization of biosafety regulations across APEC economies is likely to be long, the current realities of a more fragile global food system and climate change may hasten this process.

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Biotech and GM in APEC

- Biotech including GM recognized as being important set of tools to raise agriculture productivity to feed growing population (2010 Ministerial meeting)
- R&D in almost all member economies
- Commercialization limited to 7 economies (but account for 53% of global area under cultivation)
- 9 other economies have GM crop approvals for import only
- Globally -
 - soybean 75% biotech in 2011
 - corn 32% biotech in 2011

Broad Regulatory Issues

Areas of divergence

- **Cartagena Protocol on Biosafety**
 - GM Producers, Non Parties (Affected in terms of trade flow)
 - Non-GM producers. Parties (Affected)
 - GM producers, Parties (Most affected)
 - Non-GM Producers, Non Parties (Not affected)
- **Number of GM crops authorized**
- **Type of regulatory process** (Product vs Process based)
- **Treatment of stacked traits**
- **Inclusion of non-safety related considerations**
- **Role of public participation**
- **Labeling regulations**
- **Policies on Low Level Presence**

Low Level Presence

- Biotech events that have been approved in the exporting country, but have not yet been approved in the importing country become mixed in with grain approved in both exporting and importing countries. (asynchronous approval).
- Biotech events that have been approved in the exporting country, but for which approval is not being sought in the importing country become mixed in with grain approved in both exporting and importing countries (asymmetric approval).

Storm Clouds

- Large pipeline of new events being developed - rice coming on board to add to corn, canola, soybean and cotton. Vegetables.
- Stacking of traits will exacerbate the issue
- More players from both public and private sector (44% of events will come from Asia)
- New GM crops in Asia will be locally or regionally focused so maybe unlikely to be submitted for approval in external markets
- Increased trade across the Pacific

Conclusion

At a time of increased food prices and a more fragile global food situation, the impact of any further increase in price and/or reduced agricultural production due to regulatory issues will only exacerbate the problem particularly for countries already suffering from food price inflation.