

Innovation and Market Access

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Global Representative for Plant Science



AFRICA/MIDDLE EAST

AFRICABIO
CROPLIFE AFRICA/
MIDDLE EAST

ASIA PACIFIC

CBI JAPAN
JAPAN CROP PROTECTION
ASSOCIATION
CROPLIFE ASIA

NORTH AMERICA

CROPLIFE CANADA
CROPLIFE AMERICA
BIOTECHNOLOGY INDUSTRY
ORGANIZATION (BIO)
AGROBIO MEXICO

EUROPE

EUROPABIO
EUROPEAN CROP
PROTECTION ASSOCIATION

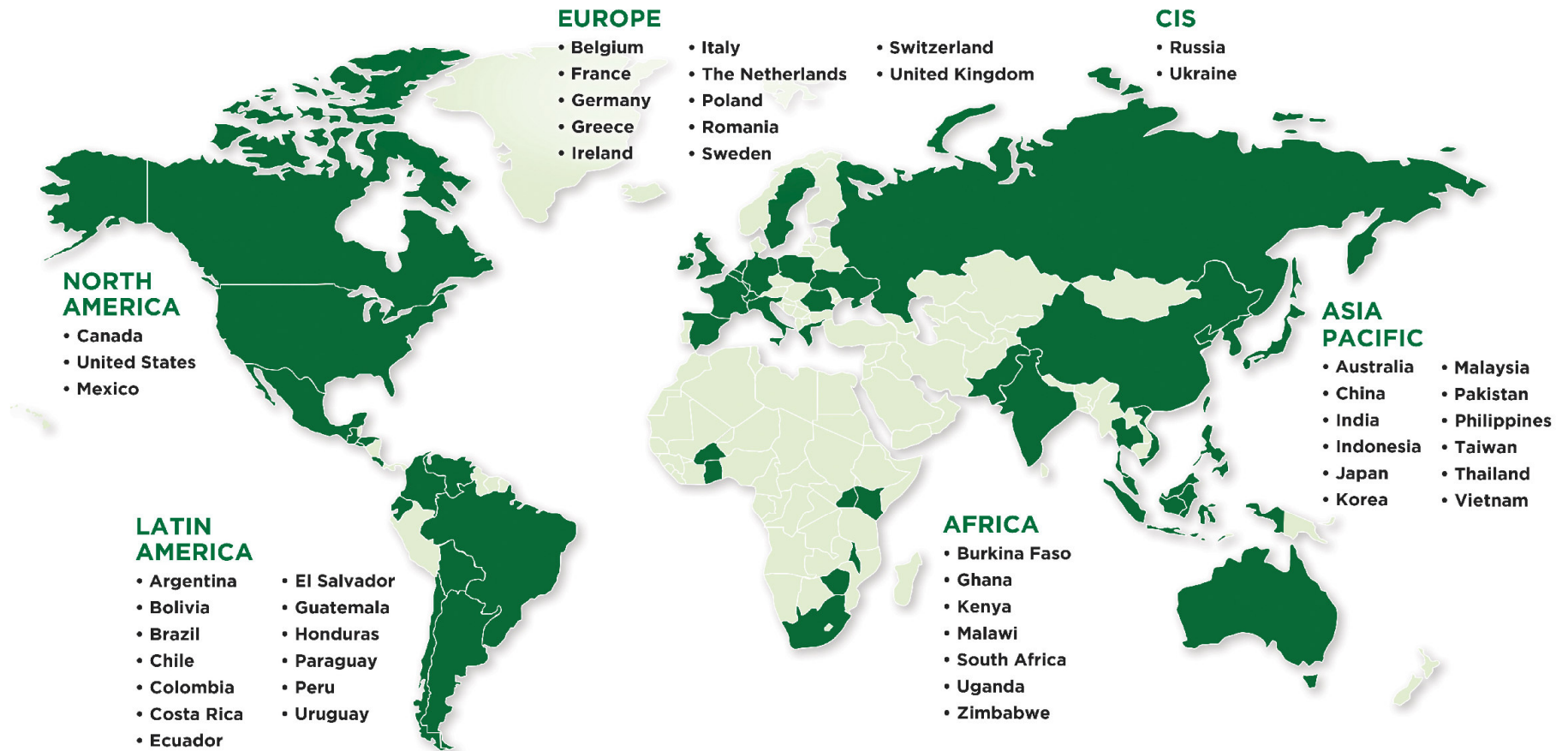
LATIN AMERICA

CROPLIFE LATIN AMERICA
AGROBIO BRAZIL
CIB BRAZIL
ARGENBIO

Corporate Members



Plant Biotechnology Global Network



Mission



SUSTAINABILITY

We work together around the world to help make the most of plant science's great potential to improve sustainable agriculture

Helping
Farmers
Grow

We increase awareness and understanding of the benefits of plant science so that it becomes increasingly accepted and supported by our stakeholders

EDUCATION

We promote the responsible development and sustainable use of plant science technologies

STEWARDSHIP

CropLife Engagement

- Intergovernmental policy
 - Food security, sustainability, climate change
- Education, market acceptance, communication
- Regulatory frameworks
- International trade
 - Import market approvals
 - Asynchronous approvals
 - Low level presence (LLP)
 - TradeStatus database
- Stewardship
 - Launch Stewardship Guideline
- Intellectual property

Agriculture & Innovation

Why Do We Need Innovation?

Population Growth → More Agricultural Demand

1960 Food
Production



Farmers have doubled global
food production over the last 50
years

Present Day



Plant science technologies have helped farmers increase production to
keep up with the world's growing demand for food

Present Day



Food production must increase
by 70% to meet rising demand

2050 Food
Demand



Future production requires **greater adoption of
innovative technologies like plant biotechnology**

Source: UN Food and Agriculture Organization (FAO), 2009

Transformational Agricultural Innovations

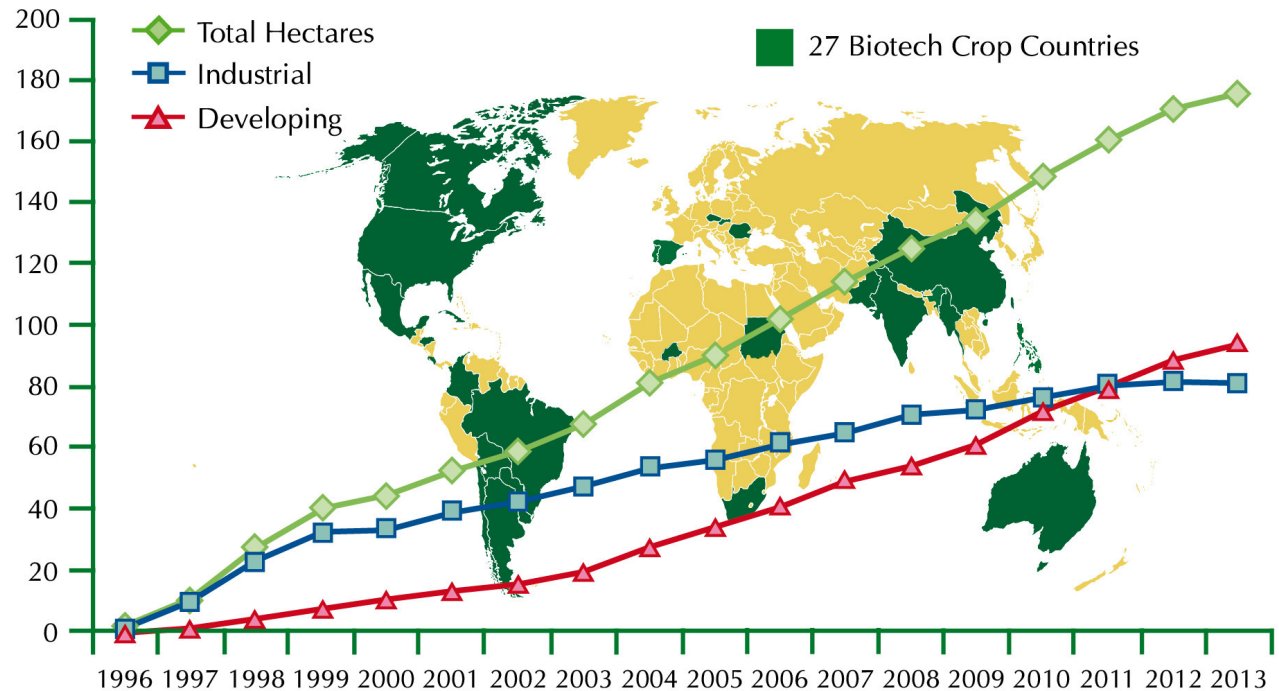


- Mechanization 1868 (tractor)
- Synthetic fertilizers 1908 (ammonia)
- Hybrid seeds 1924 (corn, Wallace)
- Crop protection chemicals 1939 (insecticides)
- Biotechnology 1996 (HT soybean)

Global Adoption of Biotech Crops

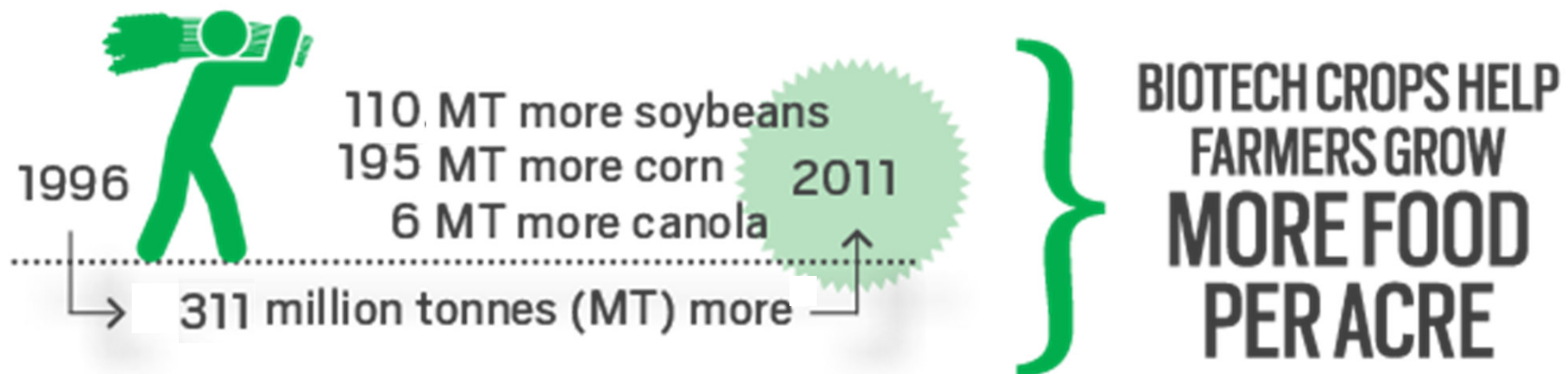
- 4 billion acres planted since 1996
- 2013:
433 million acres, +3%
18 million farmers
- 90% of growers are small, resource-poor farmers
- Repeat planting is 'virtually 100%'

GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996-2013)



Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2014

Biotech Crops Increase Food Production



Source: PG Economics, 2014

Benefits of Plant Biotech

Economic Growth



From 1996 to 2012, the **global economic benefit** at the farm level due to enhanced production and efficiency from the adoption of plant science technologies was **\$117.1 billion**

Significant economic benefits to **developing world farmers**

Source: PG Economics, 2014

Role of Plant Biotech

Economic Growth

- 90% of growers are small, resource poor farmers
- Over 50% of biotech crop acres are planted in the developing world
- Biotech has the potential to transform agricultural economies in developing countries
- Plant biotech traits enable greater productivity which promotes more trade

Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2014

Technology → Productivity



Impact in 2050 under climate change conditions

- Drought Tolerance
 - Can increase grain yields 15-20% during severe drought in the U.S., China & East Africa
- No-till Practices (enabled by Biotech)
 - Single most impactful technology for improving global maize & wheat production
 - 67% increase in irrigated maize yields & 57% increase in irrigated wheat yields
- Nitrogen-use efficiency
 - Could nearly double maize yields in Sub Saharan Africa and Latin America when combined with irrigation

Source: IFPRI, *Food Security in a World of Natural Resource Scarcity: The Role of Agricultural Technologies*, 2014

AgriTech Toolbox: <http://apps.harvestchoice.org/agritech-toolbox/>

Future of Plant Biotech



CropLife International Member Companies

- **Farmer & Processor Benefits**
 - New disease, insect and weed control (resistance control)
 - Drought tolerance & nitrogen-use efficiency
 - Next-generation yield, feed efficiency and ethanol traits
- **Consumer Benefits**
 - Healthy edible oils
 - No trans fat; low saturated fat soybean
 - Higher omega-3 levels (soybean)
 - Enhanced Nutrition
 - Rice: Higher beta-carotene
 - Biofortified Sorghum: Higher vitamin A, iron, & zinc

Future of Plant Biotech

Other Developers

- Triple-stack rice (*Arcadia Biosciences*)
 - Salt-tolerant, water-efficient & nitrogen-use efficient
- Pink Pineapple (*Del Monte*)
 - Higher lycopene levels
- Arctic Apples (*Okanagan Specialty Fruits*)
 - Prevent browning after slicing
- Innate Potatoes (*J.R. Simplot*)
 - Prevent bruising and browning

Future of Plant Biotech

Public Sector

- **EMBRAPA** (Brazil)
 - Herbicide & disease tolerant soybeans
- **CSIRO** (Australia)
 - Salt-Tolerant & nutrient enhanced wheat, insect-resistant cotton
- **Kenyan Agricultural Research Institute**
 - Nitrogen-use efficient & drought-tolerant maize
- **African Agricultural Technology Foundation**
 - Pest control and drought tolerance in maize, cowpea, rice & bananas
- **Rothamsted Research Institute** (UK)
 - Aphid-resistant wheat
- **China Public Pipeline**
 - Sweet pepper, tomato, papaya, soybeans, maize, rice, potatoes
- **India Public Pipeline**
 - Brinjal, tomato, cabbage, cauliflower, okra, mustard, wheat, chili, peanuts, maize, cotton, rice, potatoes

How Will This Impact Trade?



- More differentiated crop production
 - Challenges
 - Grain segregation; Asynchronous approvals; LLP
 - Stewardship
 - Communication
 - Business Opportunities
 - Manage the challenges

INNOVATION → PRODUCTIVITY → TRADE

Innovation and Market Access



- Innovation, stewardship and market access must work together
- Barriers to market access impede innovation
- Stewardship is key to keep innovation and market access moving smoothly

What is the greatest barrier to market access for biotech innovations?

Regulatory Environments That Impede Innovation and Trade

- Unpredictable regulatory frameworks
 - Authorization timelines and processes
 - Lack of low level presence (LLP) policy
 - Asynchronous approvals
- Political decisions
 - Protectionism
 - Ideology
 - Anti technology
 - Anti MNC

Low Level Presence (LLP)

LLP incidents increasing

- 198 LLP incidents reported 2002-2012
 - 138 or 70% were in 2009-2012
- Rice, linseed and maize exports had most LLP incidents
 - Bt rice from China
- Lack of LLP policy hinders industry compliance
 - 54% of UN countries surveyed reported having no threshold levels for LLP

Source: UNFAO 2014

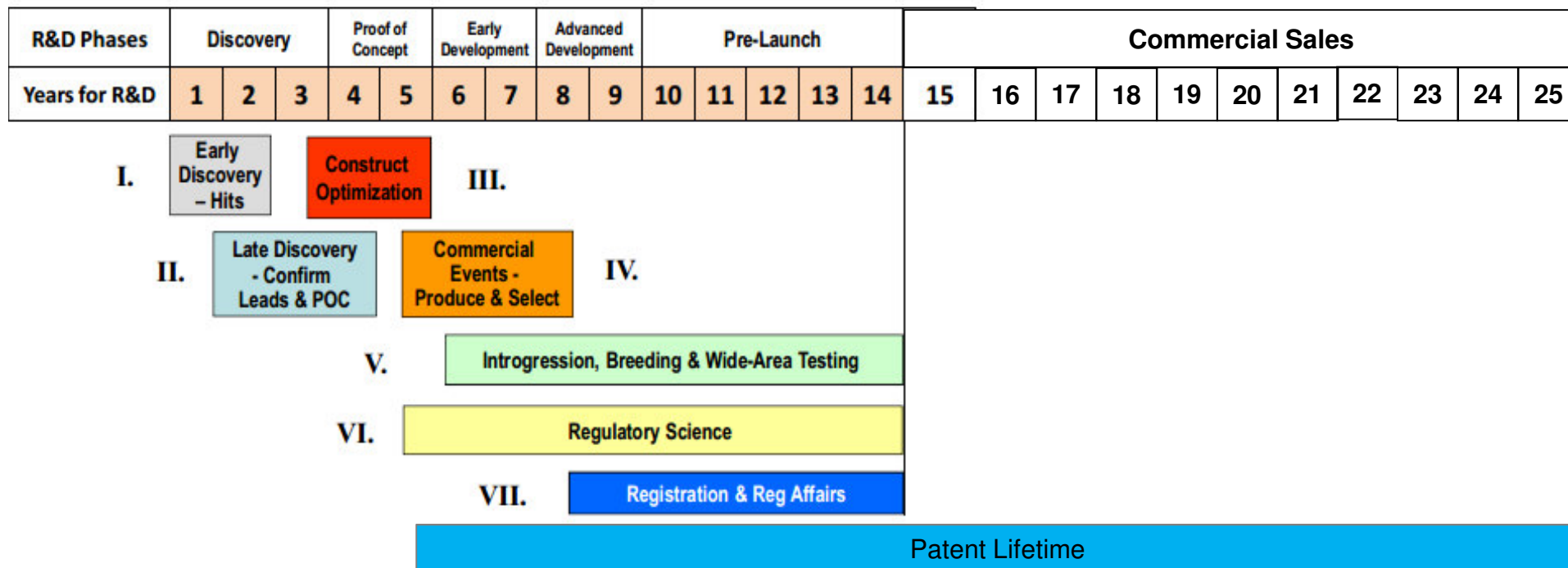
What is required to bring a new biotech trait to market?

Commercializing New Innovations

- **\$136 million:** Cost to develop a biotech crop
- **13.1 years:** Time to develop a biotech crop
- Cost & time for cultivation and import regulatory approvals up 50% in past decade

Phillips McDougall 2012

Commercializing New Innovations

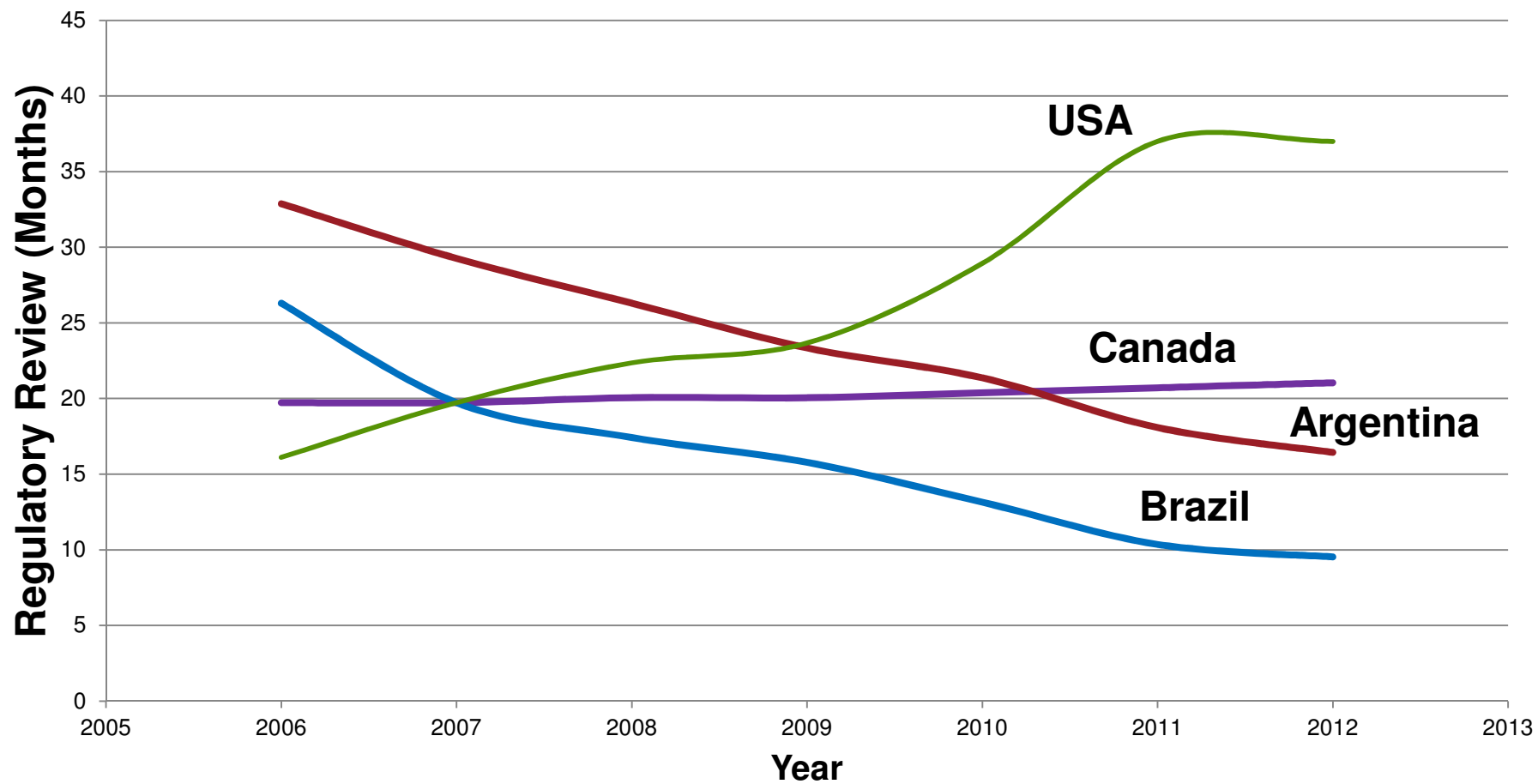


- Short window from commercial launch to patent exhaustion

Authorization Timelines Are Increasing Globally

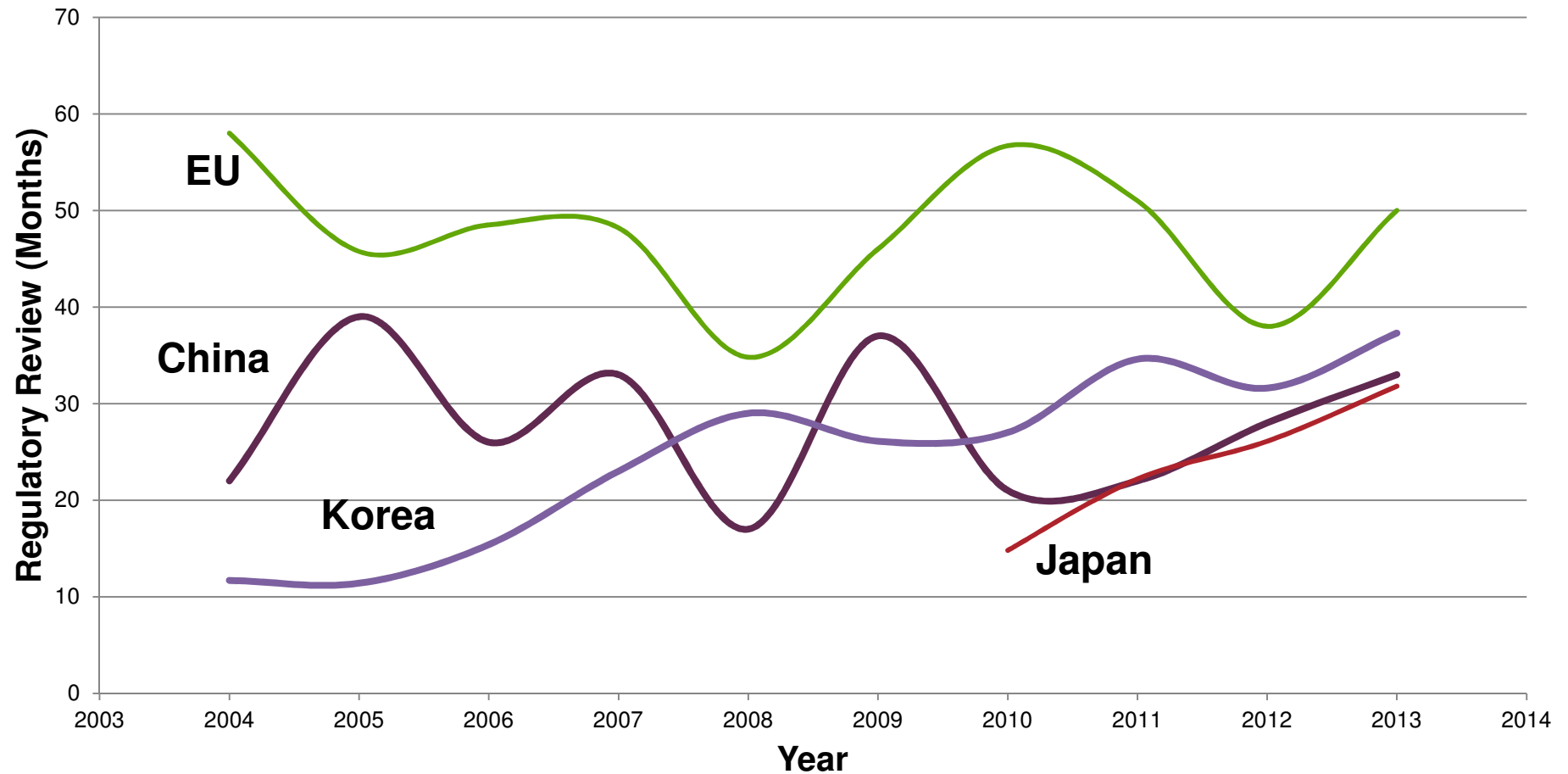
- Regulators are not adhering to authorization timelines (import and cultivation) in regulatory frameworks
- Backlogs of pending submissions are increasing
 - US: 14
 - EU: 74
 - China: 11
- Unpredictable and dysfunctional authorization processes cause trade disruptions and delay access to innovation

Cultivation Approvals



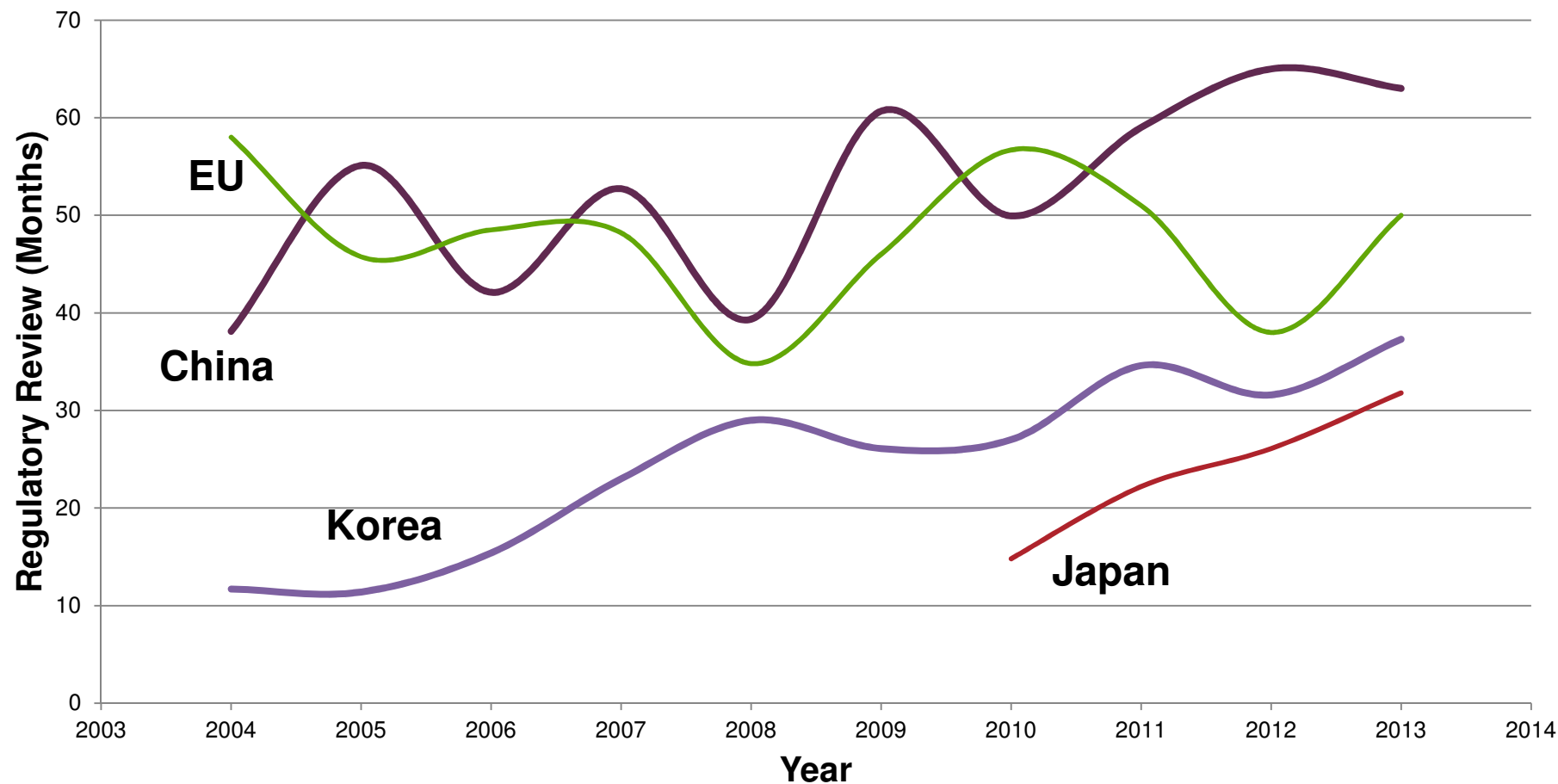
Import Approvals

Review time from date of submission



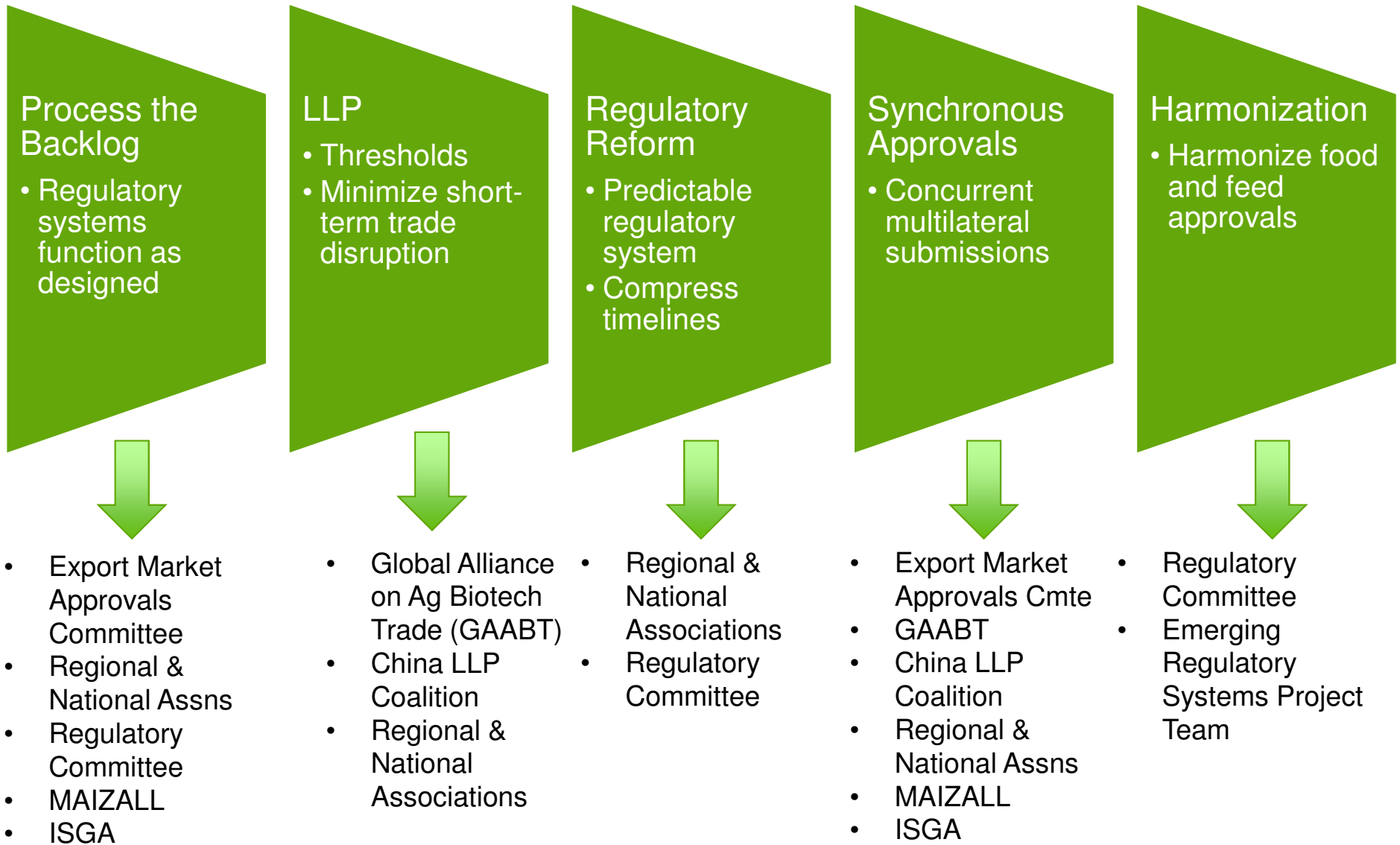
Import Approvals

Reality: China's approval process requires additional 2+ years since import dossiers cannot be submitted until cultivation is approved elsewhere



What is Being Done to Reduce Regulatory Barriers to Innovation and Trade?

CropLife & Coalition Engagement



Innovation and Market Access, Working Together



- Dialogue, collaboration and communication
- Focus on sustainable food security goals
- Address market access and trade barriers disguised as regulatory issues
- Roles & Responsibilities
 - Stewardship

THANK YOU!

Questions?