

# GM testing in supply chain & its quality control in the USA, including role of standards.

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Symposium Japan November 2019

# COI Disclosure Information

## Ray Shillito Ph.D.

I have the following financial and other relationships to disclose.

Employment: BASF Corporation

Leadership/committee positions:

Chair of ISO/TC 34/SC 16 – Molecular Biomarkers

Past President of AEIC ([www.aeicbiotech.org](http://www.aeicbiotech.org))

Chair of Cereals and Grains Association Biomarkers Committee

Member of CropLife Detection Methods Expert Team

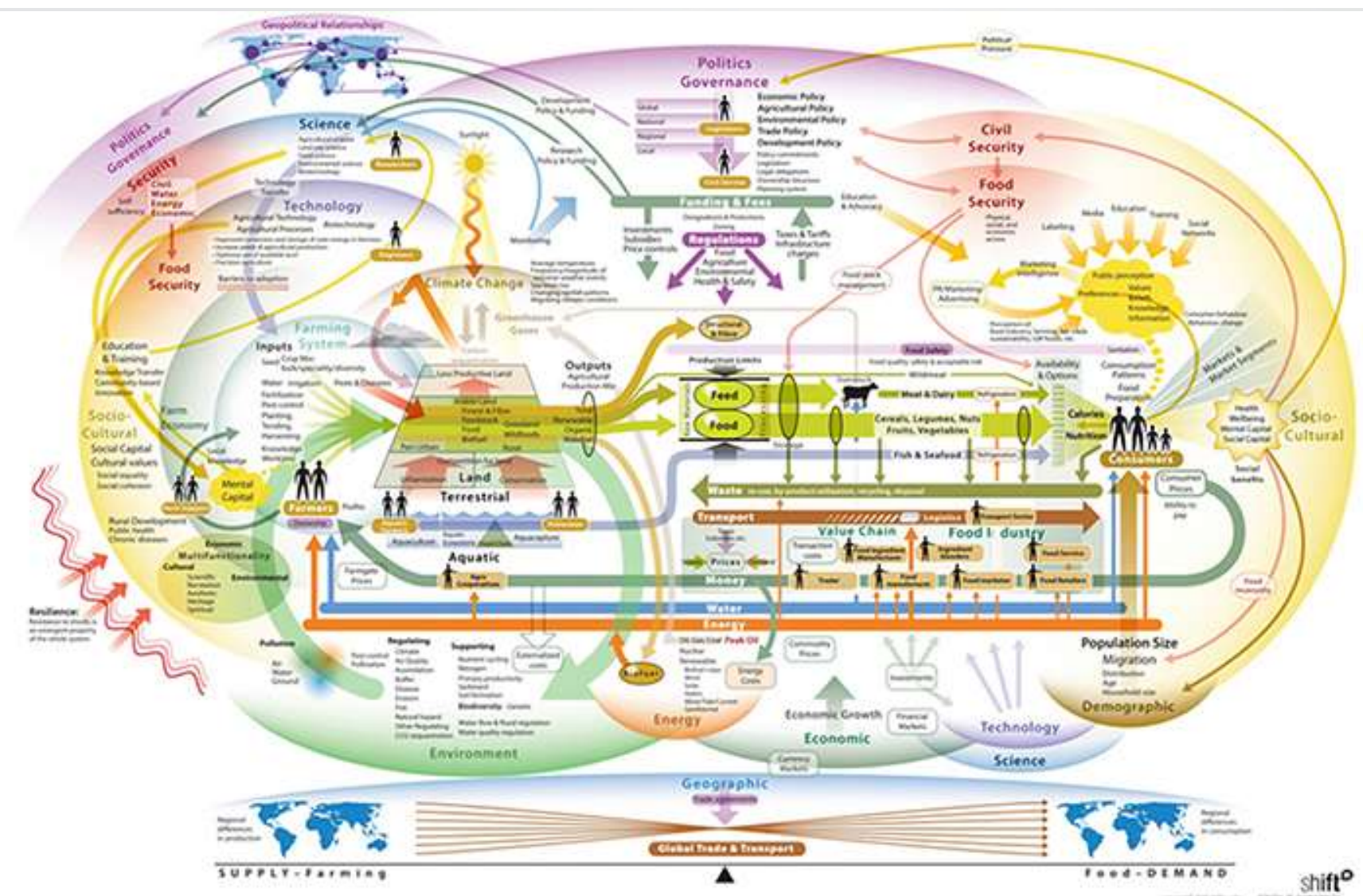
Global Industry Coalition representative to CBD

Member of ISTA, AOAC, AOCS, SCST, Cereals and Grains Assoc.

Patents with: BASF Corporation

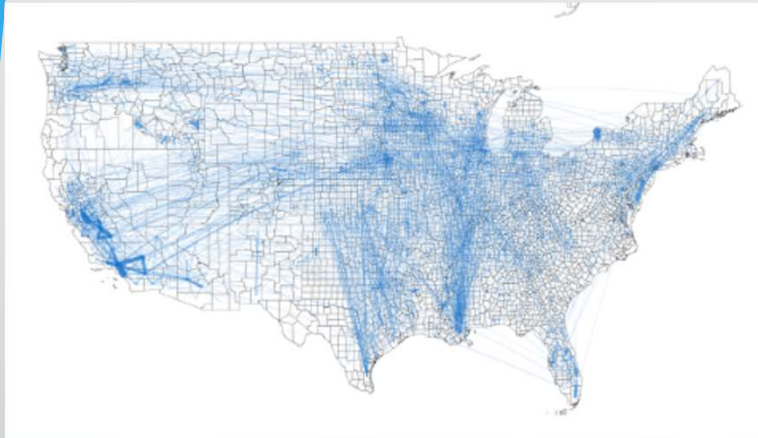
Hotel costs: ILSI

Opinions expressed are my personal opinions and not necessarily that of my employer.



2019 Cereal Foods World super theme: Global Food System. Source: shiftN

# US Domestic food flows

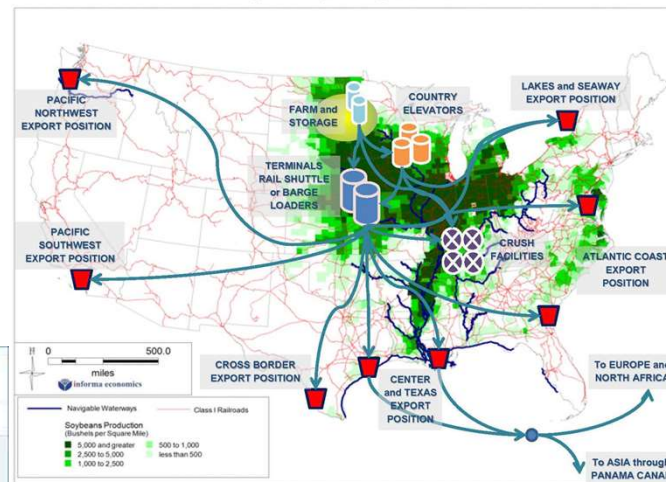


Lin et al. Environ. Res. Lett. 14 (2019)  
<https://doi.org/10.1088/1748-9326/ab29ae>

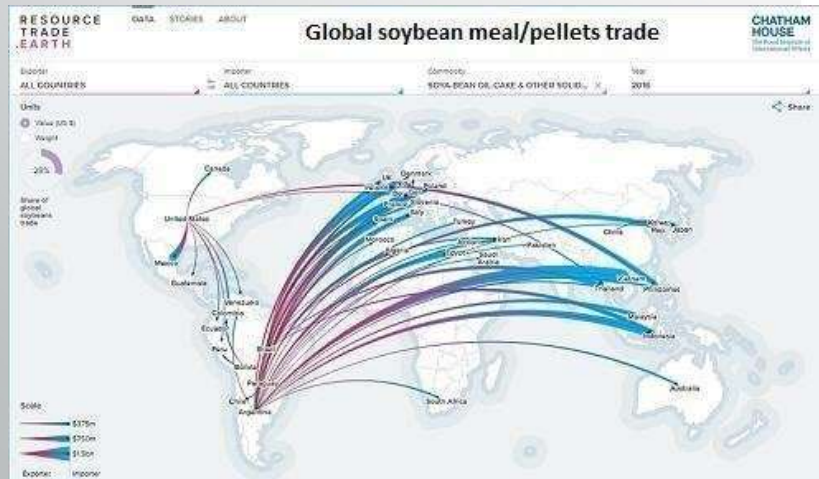
Farm to Market – A Soybean's Journey

August 2016

Figure 1: Soybean Logistics Flow



Soybean  
export  
flows

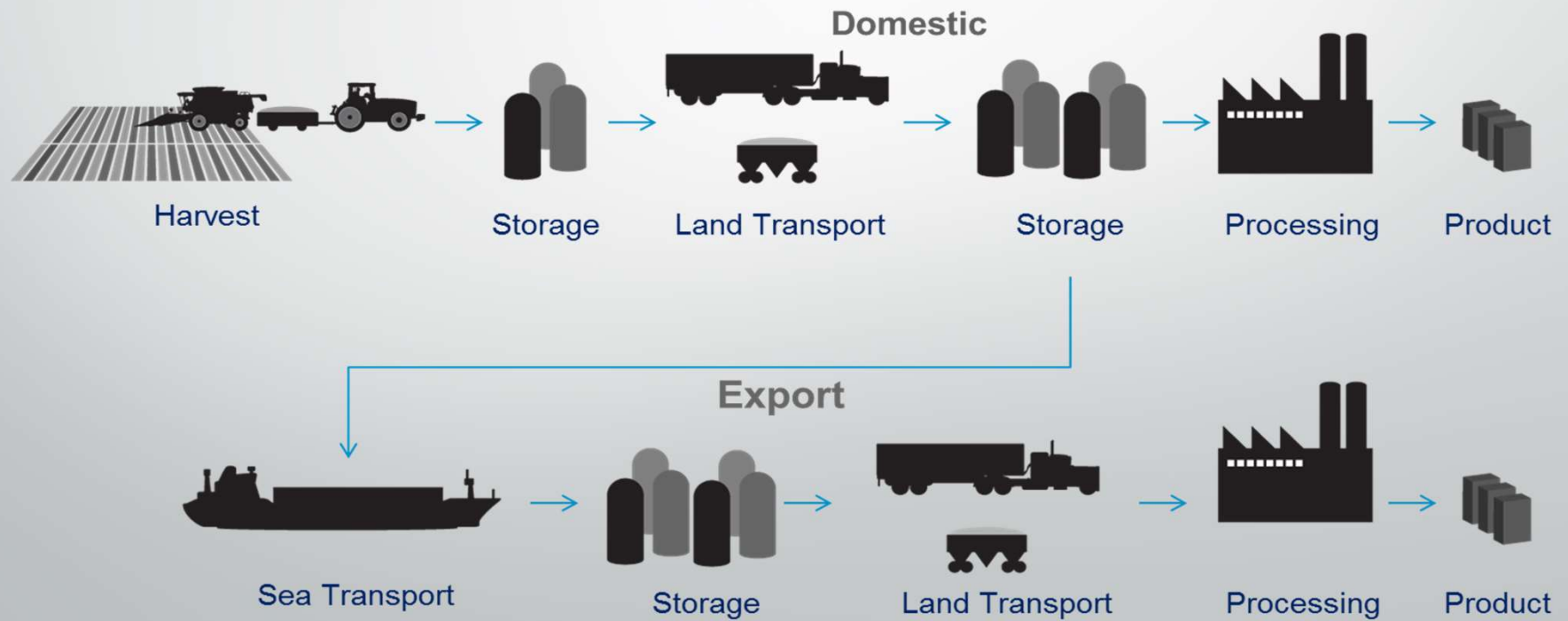


United Soybean Board

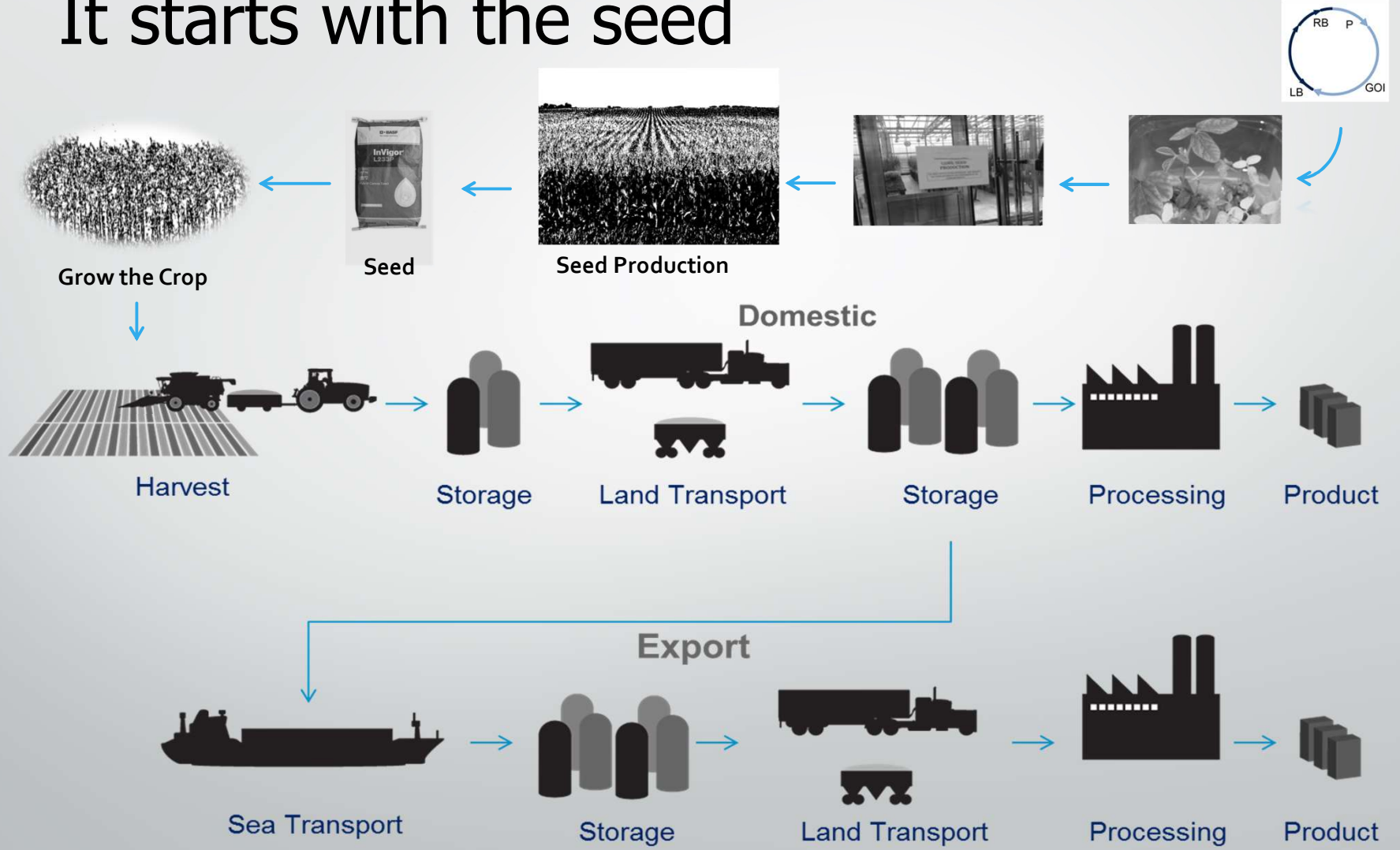
3



# Flow chart of grain to export



# It starts with the seed





# EXCELLENCE THROUGH STEWARDSHIP<sup>®</sup>

*Advancing Best Practices in Agricultural Biotechnology*



**Critical Control Points are Applied along the Product Development and Production Chain**

Figure 1a

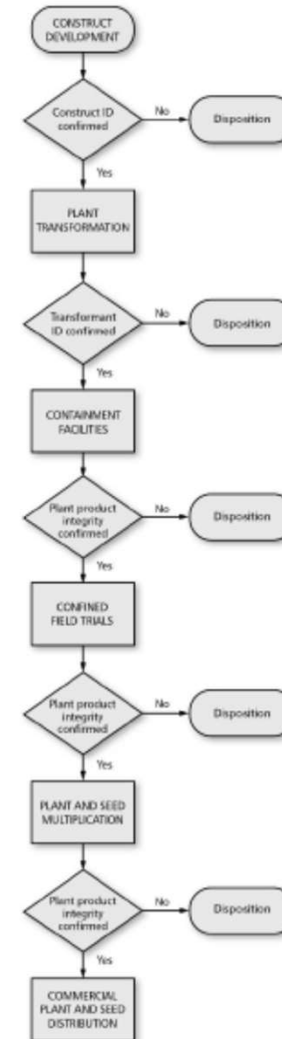


FIGURE 1. Work flow diagram indicating the key processes and decision points (Figure 1a) and Critical Control Points (Figure 1b) for addressing plant product integrity during the life cycle of biotechnology-derived plants as defined in the five modules of this Guide.



## 2018 LibertyLink® Soybean Stewardship and Quality Assurance – Commercial Seed Production Manual

- Licensed growers and Labs
- Crop Quality
  - Varietal purity
  - Trait Purity
  - Stewardship
- Labelling





# Varietal Purity (soybean) is ensured by....

- CROP ROTATION: Previous Year cannot have been soybeans
- ISOLATION:
  - Non-Approved or Regulated Events
    - Seed production: 30m OR 3m plus flags denoting field edges
    - Commercial soybean: 3m
  - Non-GM Seed or Commercially Approved Traits
    - Different varieties: 3m
    - Similar variety: 1m
- Equipment cleanout

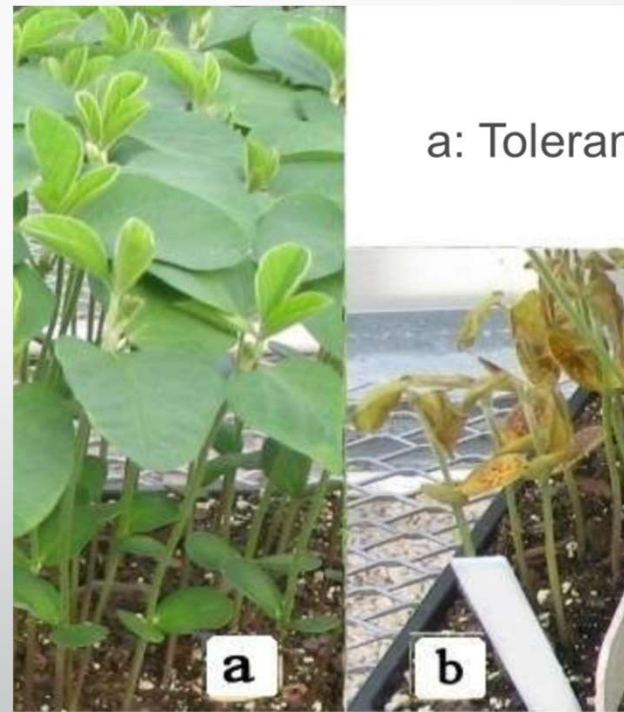
For Corn, Cotton and Canola these isolation distances are much larger

# Ensuring trait purity for commercial seed is a multi-step process

Field



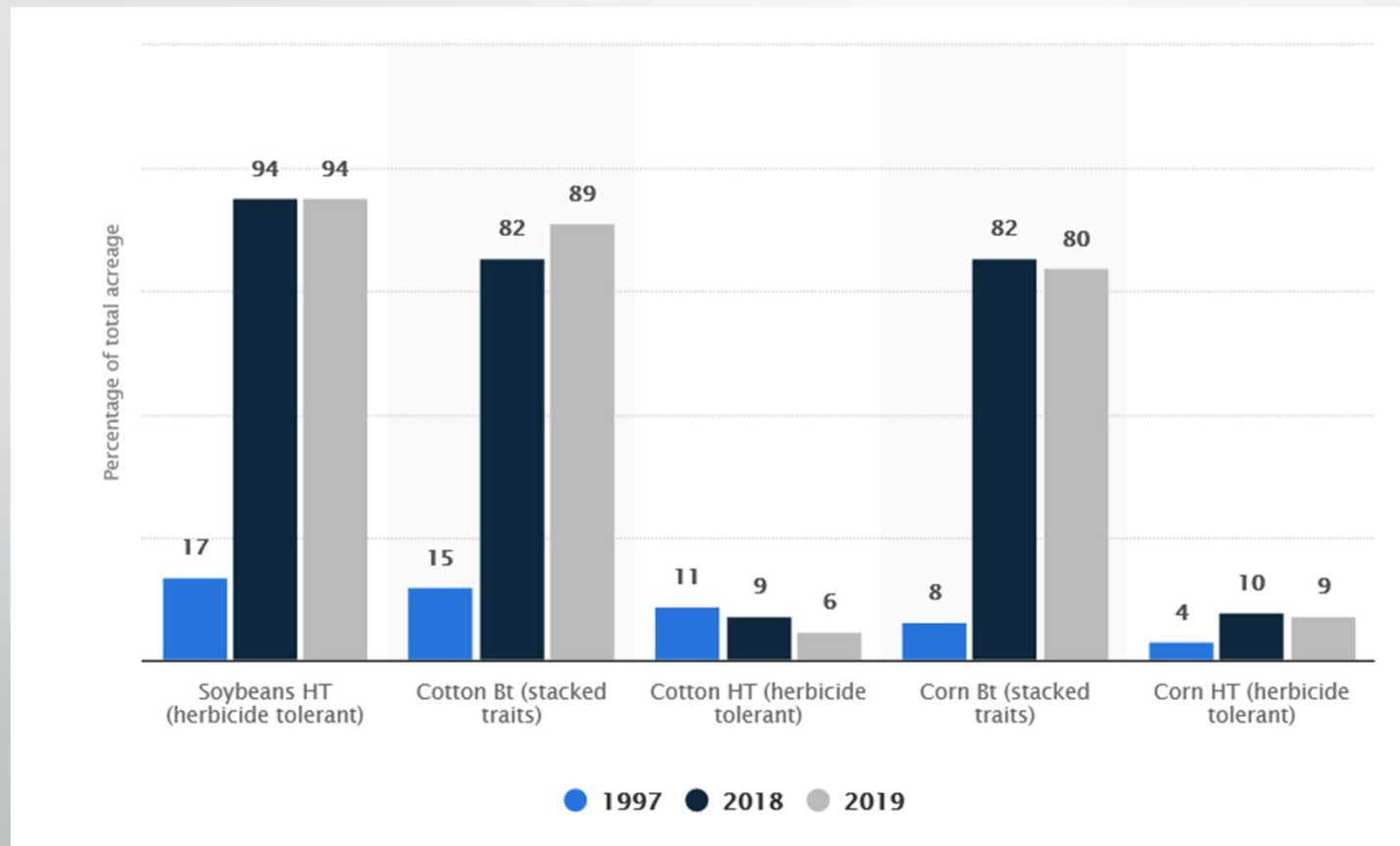
Laboratory



a: Tolerant control

b: Sensitive control

Three of the major row crops in USA, Maize, Cotton, Soybean are predominantly GMO.



# EU imported 15 Million Tons of Soybean in 2018

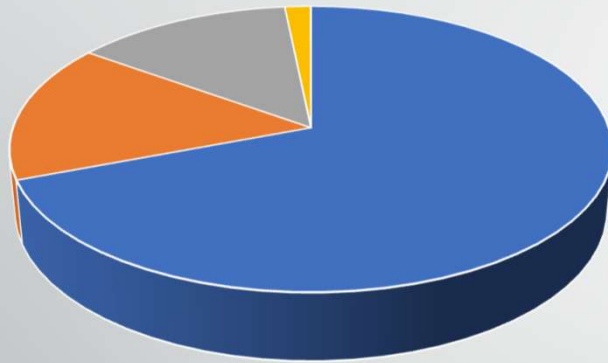


World total Soybean trade in 2018 was 150 Million Tons of which EU imported 15 MT and China imported 88 MT. Japan imported 3.3 MT.

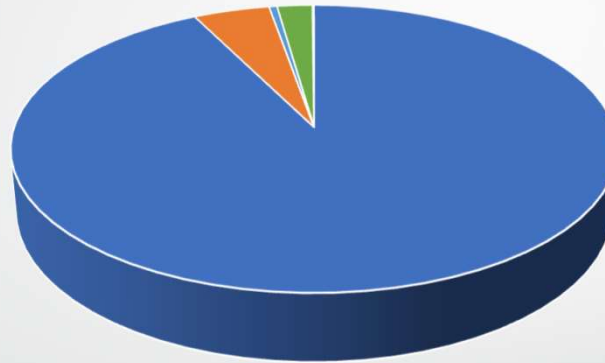


# Japanese Soy, Maize and Wheat Imports in 2018

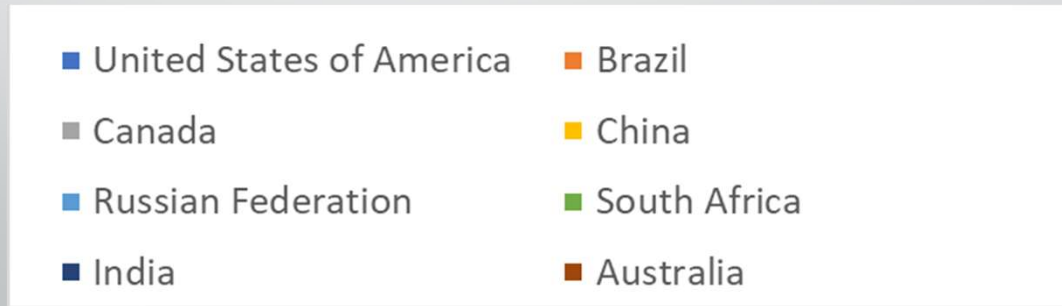
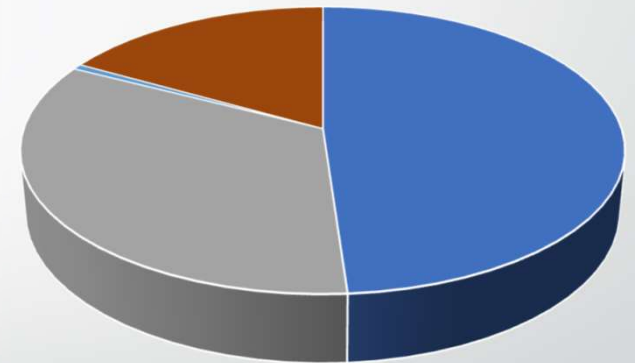
Soybeans



Maize

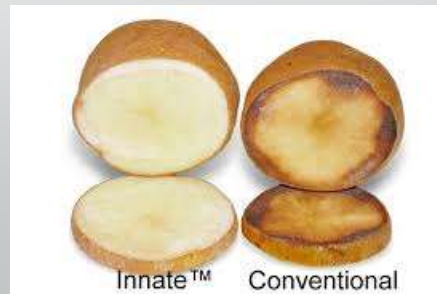


Wheat



# It is difficult to keep materials separate

- Most grain used for food, feed or for processing is shipped by bulk handling systems
- Systems are designed based on maximum economy, not ability to keep materials completely separate
- Different grains may move through the same infrastructure
- While biotechnology has traditionally been applied to large volume row crops, it is now being used to improve many other crops



# Seed Producers, Grain Channel, Exporters, Importers and Regulators Test the Product

- Protein-based tests (lateral flow strips)
- DNA-based tests:  
Polymerase Chain Reaction, Isothermal DNA



**Testing is performed to make sure processes worked, not as the first measure**

## *Not detected is not necessarily Zero*

- If a test gives a result of  $<0.01\%$ , there can still be a significant number of GE beans in a lot.
- To test to zero you would have to test every bean in the ship

<b>Unit (metric ton) 1 MT = 36.7 bushels</b>	<b>Number of trucks</b>	<b>Number of bushels</b>	<b>Number of soybeans (0.15g/bean)</b>	<b>0.01% GM</b>
<b>Bushel (27kg)</b>		<b>1</b>	<b>181,333</b>	<b>18 beans</b>
<b>Truck (25 Tons)</b>	<b>1</b>	<b>918</b>	<b>166.4 M</b>	<b>16,640</b>
<b>Vessel (50,000 tons)</b>	<b>2000</b>	<b>1.84 M</b>	<b>330 Trillion</b>	<b>33 M</b>



Grain for markets that accept low level or no GM grain is produced and handled in specialized facilities.



Grain is handled in separate trucks, elevators, trains or barges, and loaded into ships via separate elevators.



Photo: Russel Marine

# How do I contract for low GMO grain

- Long term planning and contracting required
- Typically 18 months ahead
  - Seed production
  - Production in an isolated location
  - Dedicated transport facilities
- These measures impose a significant cost on the process which are passed on the end-user.

*Case study:*

*For two areas (Japan, Europe) and two commodities (maize, soybeans) annual cost of Identity Preservation: \$100 Million (2015 figures)*

Increased Coordination and Control

12 to 18 month versus 3 to 6 month advance planning

Re-engineered food chain

Protection from bulk commodities requires segregation in planting, harvesting, transportation, storage from farm to vessel

Additional risks and liabilities

Potential for breakdown, commingling at every stage

To be successful, **end-users** who perceive a benefit from the program must be willing to **pay the full costs**

# The Lower the Threshold for Labeling, the Higher the Cost of Grain (2009 prices)

IPC, 2005

<b>Threshold Level</b>	<b>0.9% (EU)</b>	<b>5% (Japan)</b>
<b>Soybeans</b>	\$US 14.9 per ton in additional costs	\$US 8.3 per ton in additional costs
<b>Maize</b>	\$US 8.3 per ton in additional costs	\$US 2.9 per ton per ton in additional costs



# Stacked Events

- DNA-based methods can identify each component in the stack separately.
- A single PCR methodology cannot be designed to specifically establish multiple events as components of a stack.
- Not possible to determine the presence of a stacked seed or grain in a bulk sample and distinguish from the presence of the two component events
- Stacks can only be determined if single seeds/grains or small bulks are examined (e.g. 20-seed bulks)

# International Trade Needs Standardized Sampling and Detection Methods

- Importer and Exporter will be testing grain and food
- Exporter will test to lower than actual threshold (e.g. 0.5% versus 0.9%)
- Detection methods include
  - Detection of the Protein (Immunoassay, LFD)
  - Detection of the DNA sequence (gel PCR, RTQPCR, Isothermal methods, Digital PCR)
- Ideally Exporter and Importer use the same methods -> International Standards are Important

# Standards range from International and Regional to National

- Codex Alimentarius Commission
  - often adopted as national standards
- International Standards Organization – ISO
  - coordinate with Codex on methods
- Regional – PASC, NASCF, CEN
- National – ANSI, ICONTEC, SAC, and Governments
- Scientific – Cereals and Grains Association (AACCI), AOAC, AOCS, ICC

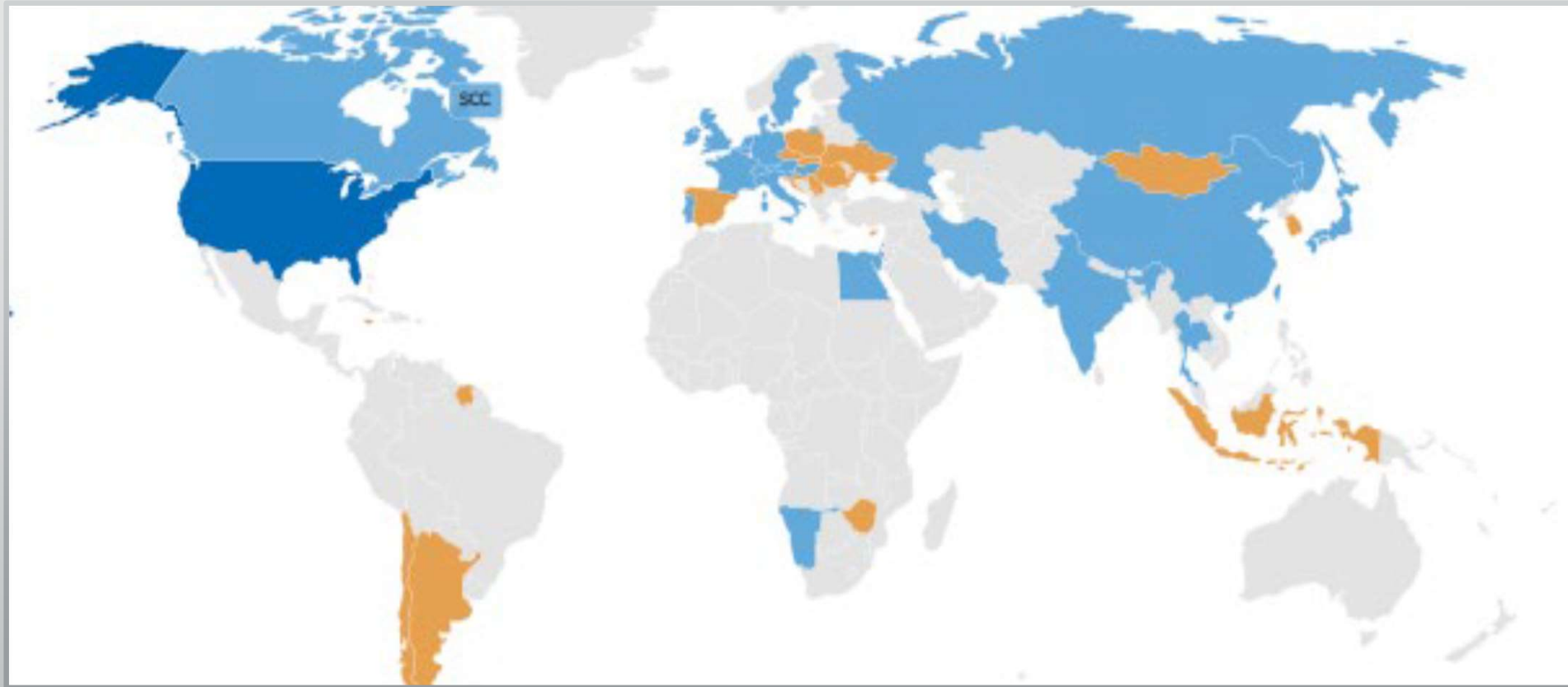


# ISO:

## International Standards Organization



- Established in 1947
- ISO standards make trade between countries easier and fairer.
- ISO standards safeguard consumers - as well as making their lives simpler.
- ISO is a non-governmental organization (NGO) led by standards institutes in each country
- Example: Country name codes
  - ISO 3166-1:1997 provides a unique two-letter code for each country.



Technical Committee 34/ Subcommittee 16  
Horizontal methods for molecular biomarker analysis

Participating Countries(25)    Observing Countries (19)



# Technical Committee 34/ Subcommittee 16

## Horizontal methods for molecular biomarker analysis



Participating Countries (25)		Observing Countries (19)
Austria (ASI)	Israel (SII)	Argentina (IRAM)
Belgium (NBN)	Italy (UNI)	Chile (INN)
Canada (SCC)	Japan (JISC)	Croatia (HZN)
China (SAC)	Namibia (NSI)	Cyprus (CYS)
Denmark (DS)	Netherlands (NEN)	Czech Republic (UNMZ)
Egypt (EOS)	Portugal (IPOQ)	Hong Kong (ITCHK SAR)
France (AFNOR)	Russian Federation (GOST R)	Indonesia (BSN)
Germany (DIN)	Slovenia (SIST)	Jamaica (BSJ)
Hungary (MSZT)	Sweden (SIS)	Korea, Republic of (KATS)
India (BIS)	Switzerland (SNV)	Mongolia (MASM)
Iran, Islamic Republic of (ISIRI)	Thailand (TISI)	Poland (PKN)
Ireland (NSAI)	United Kingdom (BSI)	Romania (ASRO)
	United States (ANSI) - secretariat	Serbia (ISS)
		Slovakia (SOSMT)
		Spain (AENOR)
		Suriname (SSB)
		Uganda (UNBS)
		Ukraine (DSTU)
		Zimbabwe (SAZ)



The 9<sup>th</sup> Plenary meeting of ISO/TC 34/SC 16 took place in Saitama, Japan on November 21-23<sup>rd</sup>, 2019.

# Scope of TC34/SC16

- Standardization of biomolecular testing methods applied to foods, feeds, seeds and other propagules of food and feed crops including:
- Methods that analyze nucleic acids [e.g., polymerase chain reaction (PCR), genotypic analysis and sequencing], proteins [e.g. enzyme linked immunosorbent assay (ELISA)], and other suitable methods. Variety identification and detection of plant pathogens.

\*The scope does not include food microbiological methods (TC34/SC9).

# Working Groups

- ISO/TC 34/SC 16/WG 8 Meat speciation (Japan and China lead)
  - ISO 20813:2019 — Molecular biomarker analysis — Methods of analysis for the detection and identification of animal species in foods and food products (nucleic acid-based methods) — General requirements and definitions
  - ISO 20224 series specific to species, plus other proposals
- ISO/TC 34/SC 16/WG 9 Subsampling of seeds and grains (Japan)
  - ISO/AWI 22753 — Molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms — Semi-quantitative method for the statistical evaluation of weight/weight GMO content in seeds and grains
- ISO/TC 34/SC 16/WG 10 Rapid nucleic acid amplification methods (USA)
  - ISO/NP 22942-1 — Molecular biomarker analysis in foodstuffs — Nucleic acid isothermal nucleic acid amplification based methods — Part 1: General requirements

# TC34/SC16 standards relevant to trade

- ISO 24276:2006 — General requirements and definitions
- ISO 21571:2005 — Nucleic acid extraction
- ISO 21570:2005 — Quantitative nucleic acid based methods
- ISO 21569:2005 — Qualitative nucleic acid based methods
- ISO 16578:2013 — General definitions and requirements for microarray detection of specific nucleic acid sequences
- ISO 16577:2016 — Terms and definitions
- ISO/TS 16393:2019 — Determination of the performance characteristics of qualitative measurement methods and validation of methods
- ISO 21572:2019 —Immunochemical methods for the detection and quantification of proteins



# Summary

- Major row crops in export countries contain Biotechnology, and other crops are being added
- Massive global trade in seeds and grain
- Labelling and other regulations must be met
- Control of content in trade starts with the seed
- Number of events and stacks are increasing -> increasing costs
- International standards can help harmonise testing