

## Current status of Data Transportability in Japan

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## Today's Topics

1. Overview of Environmental Risk Assessment (ERA) of GM crops in Japan  
-Process, Assessment Endpoint and Confined Field Trial (CFT)
2. Concept of Data Transportability of CFT and Application thereof in Japan
3. Consensus about Data Transportability Developed through Recent ILSI Japan's Activities

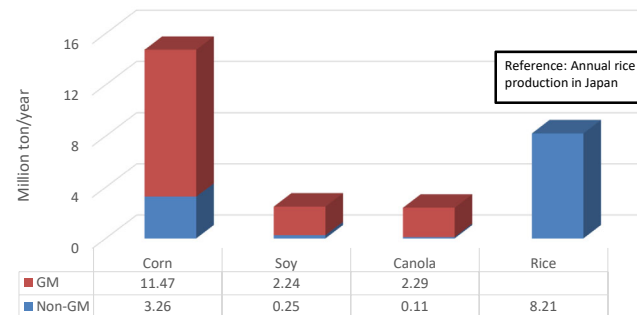
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1. Overview of Environmental Risk Assessment (ERA) of GM crops in Japan  
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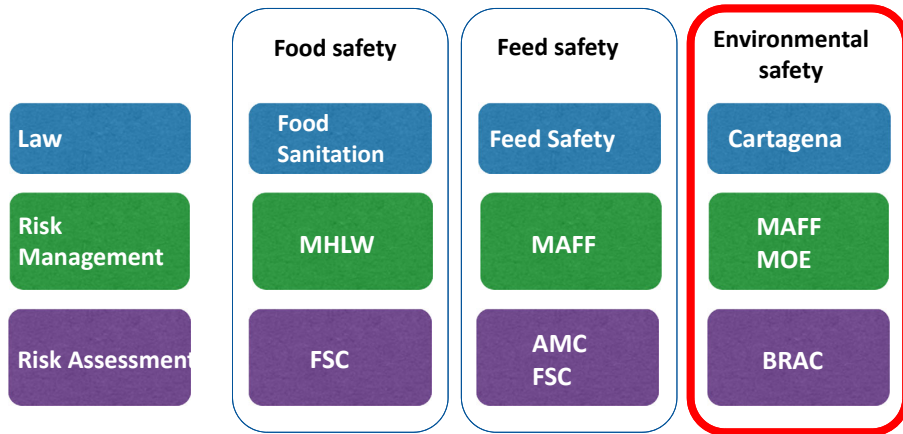
## Japan Grain Imports and Ratio of GM Crops

- GM crops are not cultivated, but imported 16 million tons/year
  - out of >30 million tons of crop per year
  - Twice as annual rice production in Japan



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## Overall GM Regulation in Japan

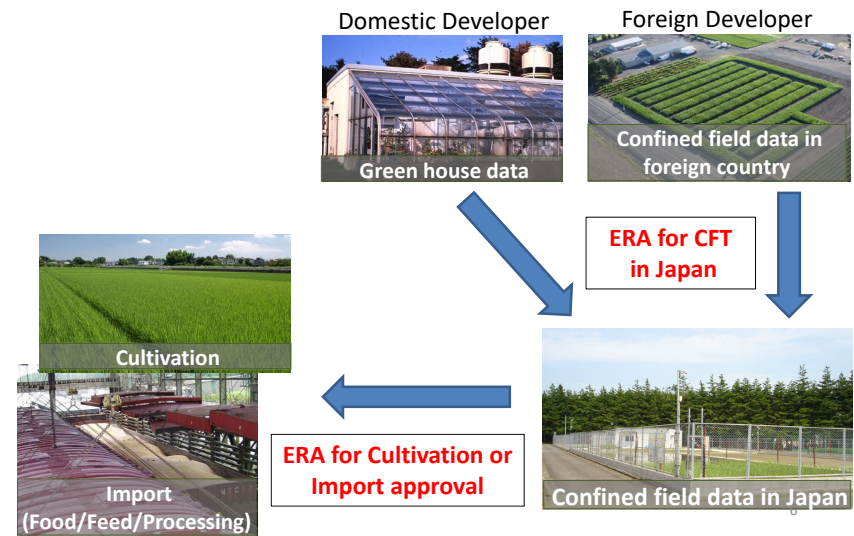


MHLW: Ministry of Health, Labour and Welfare  
 MAFF: Ministry of Agriculture, Forestry and Fisheries  
 MOE: Ministry of the Environment  
 FSC: Food Safety Commission  
 AMC: Agricultural Materials Council  
 BRAC: Bio-diversity Risk Assessment Committees

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## Process for Cultivation and Import Approval of GM Crops

- CFT in Japan is required for both Cultivation and Import approval
- CFT are not requested for stack products

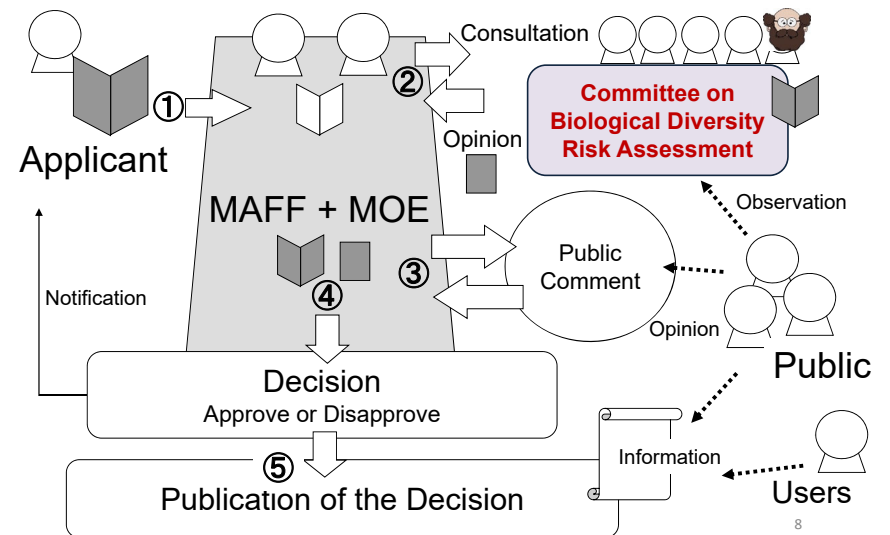


## Scope of Environmental Approval & Requirement for Local CFT in Japan

- Import or cultivation approval is required depending on host crop;
  - Import only: the host crop is not cultivated in Japan (Cotton)
  - Import & Cultivation: the host crop is cultivated in Japan (Corn, soybean etc.)
    - To cover the case of GM seeds contamination in Non-GM seeds for cultivation
- Conducting CFT is mandatory for ERA irrespective of import or cultivation approval
  - Considering the case of adventitious growth of GM crop due to spillage during transportation
- Purpose of CFT is to collect the information of GM crop pertaining to use in a similar environment to the one in which Type 1 Use is intended, and the characteristics of the GM crop grown under natural conditions in Japan shall be clarified.
  - Conventionally carried out at single site in single year

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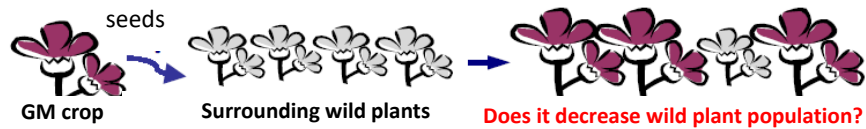
## ERA Process for GM Crops in Japan



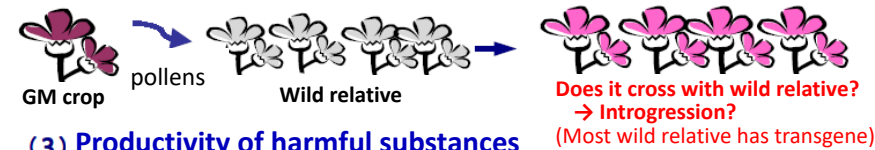
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# Assessments Endpoints for ERA of GM Crops

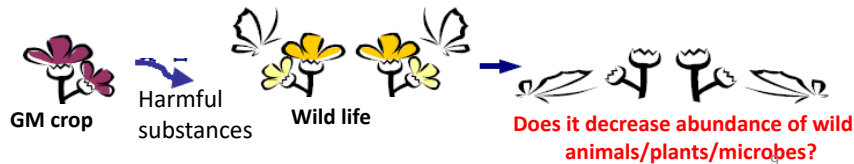
## (1) Competitiveness



## (2) Crossability

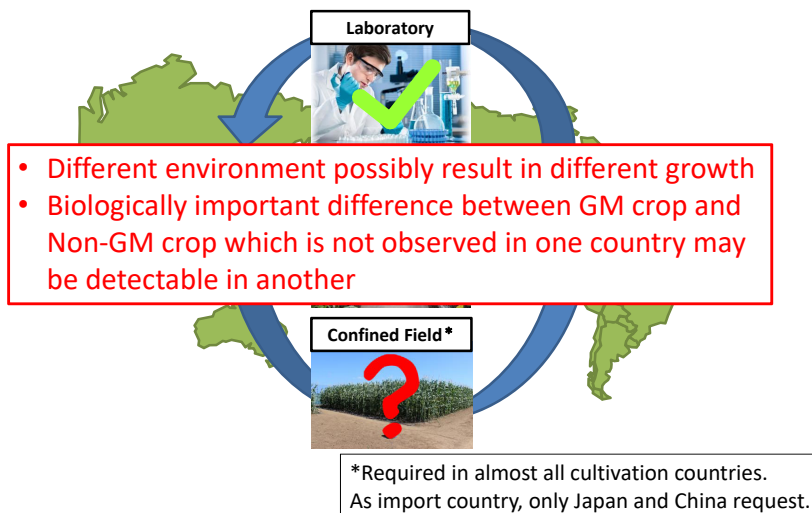


## (3) Productivity of harmful substances



## 2. Concept of Data Transportability of CFT and Application thereof in Japan

## Concept of Data Transportability of CFT



## Significance of Scientific Verification of Data Transportability of CFT

- Obtaining safety approvals of GM crop costs huge
  - Need to obtain Food/Feed/Environmental safety approvals in all cultivation & import countries
    - CFT needs to be conducted in each cultivation country
  - Obtaining global safety approvals of GM Crop costs ~5 billion per event, accounting for ~30% of total development cost; Prado et al. (2014)
- Consequently, just several developers globally can afford GM of major crops



- More scientific and effective way for safety assessment of GM crop allows more entries from public and private sector
  - **Data transportability of CFT is expected to be one of practical solutions if scientifically verified**

## Status of Data Transportability

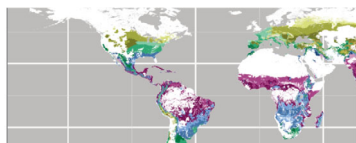
### 1. Applicable depending on the inserted gene and the host crop

- In Japan, data transportability is applicable when;
  - i) the inserted gene is same or equivalent to the gene which was reviewed in Japan in the past, and MOA of the gene must be well understood
  - ii) the host crop is maize

Event	Inserted Gene	Applicant
MON87419	mdmo, pat	日本モンサント
MZHG0JG	mepsps, pat	シンジェンタ・ジャパン
MZIR098	Ecry3.1Ab, mcry3A, pat	シンジェンタ・ジャパン

### 2. Applicable depending on the similarity of receiving environment

- Proposed by Monica Garcia *et al*, 2014



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## Data transportability is applicable to GM maize with following genes in Japan

### Example

#### (1) Insect Resistance

- ① Lepidopteran Resistance  
BT protein : *cry1Ab, cry1F, cry1A.105, cry2Ab2, cry1Ac, vip3A*
- ② Coleopteran Resistance  
BT protein : *cry3Bb1, cry3Aa2, ecry3.1Ab, cry34Ab1/cry35Ab1*  
RNAi : *DvSnf7*

#### (2) Herbicide Tolerance

- ① Glyphosate Tolerance : *cp4 epsps, mEPSPS*
- ② Glufosinate Tolerance : *pat, bar*
- ③ Aryloxyalkanoate Tolerance : *aad-1*
- ④ Dicamba Tolerance : *dmo*

#### (3) その他

- ① Thermostable Alpha-Amylase : *amy797E*
- ② High Lysin : *cordapA*
- ③ Drought Tolerance : *cspB*

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### 3. Consensus about Data Transportability Developed through Recent ILSI Japan's Activities

## Activities Undertaken by ILSI Japan for Data Transportability

- Science- base discussion considering the purpose of CFT, the characteristics of host crop and the way of ERA in other countries
  - **May, 2016 ILSI ERA workshop**
    - Comparison of the assessment endpoint and the data in ERA among JP, AUS and US.
  - **Nov. 2016 ILSI ERA study meeting**
    - Characteristics of weed
  - **Jun. 2017 ISB-GMO(Mexico)**
    - Oral presentation regarding data transportability



ILSI ERA workshop  
May, 2016






ISB-GMO in Mexico  
June, 2017

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## Comparison of Protection Goals and Assessment Endpoints in ERA

	 Japan	 Australia	 America	
<b>Regulation</b>	Act on The Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Law)	The Gene Technology Act 2000	The Federal Insecticide Fungicide and Rodenticide Act (FIFRA)	The Plant Protection Act (PPA) The National Environment Policy Act (NEPA)
<b>Agency</b>	MAFF, MOE	OGTR	EPA	USDA/APHIS
<b>Protection Goal</b>	Biological Diversity	Health and Safety of People, Environment	Man or the Environment	PPA: Health, Safety, Environment and Agriculture
<b>Assessment Endpoints</b>	<b>Competitiveness (Weediness potential) is the common assessment endpoint among JP, AUS and US</b>			
	substances	of desired vegetation • Reduced product quality, biodiversity or damage to physical infrastructure • Prevents movement of people, animals, vehicles, machinery and/or water • Toxic to people, stock and/or native animals • Reduced environmental health	Protectant*. - Humans (through environmental exposure) - Threatened and endangered species - Other valued or ecologically important species	• Noxious weeds  NEPA • Plant to survive and persist • Gene flow • Impact on organisms, especially threatened and endangered species

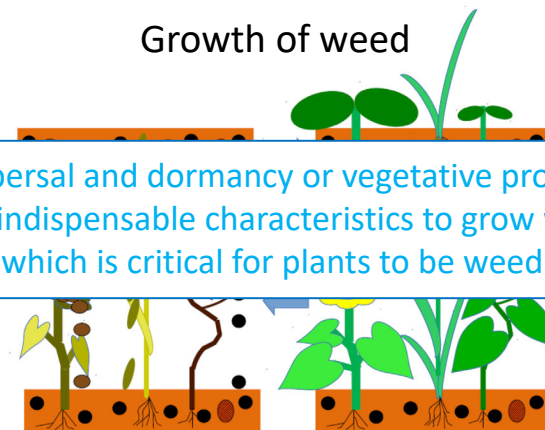
(Prepared by ILSI Japan based upon presentations of the speakers)

## What is necessary for domesticated crop to become invasive weed ?

- Need to grow wild prior to becoming invasive weed

Growth of weed

Seed dispersal and dormancy or vegetative propagation are indispensable characteristics to grow wild which is critical for plants to be weed



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## COI Disclosure Information Ryo Ohsawa

I have the following financial relationships to disclose.

Lecture fee from ILSI Japan