Sharing Experience : Data Transportability for assessment of GM plants (maize, cotton, soybean) in Japan.

HLPDAB WS
Moving Forward on Agricultural Biotechnology through Continuing Efforts on Regulatory Cooperation in APEC
August 14, 2024

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Outline

1. Evaluation of GM plants in Japan

- Regulatory framework
- ERA for GM plants
- Confined Field Trials

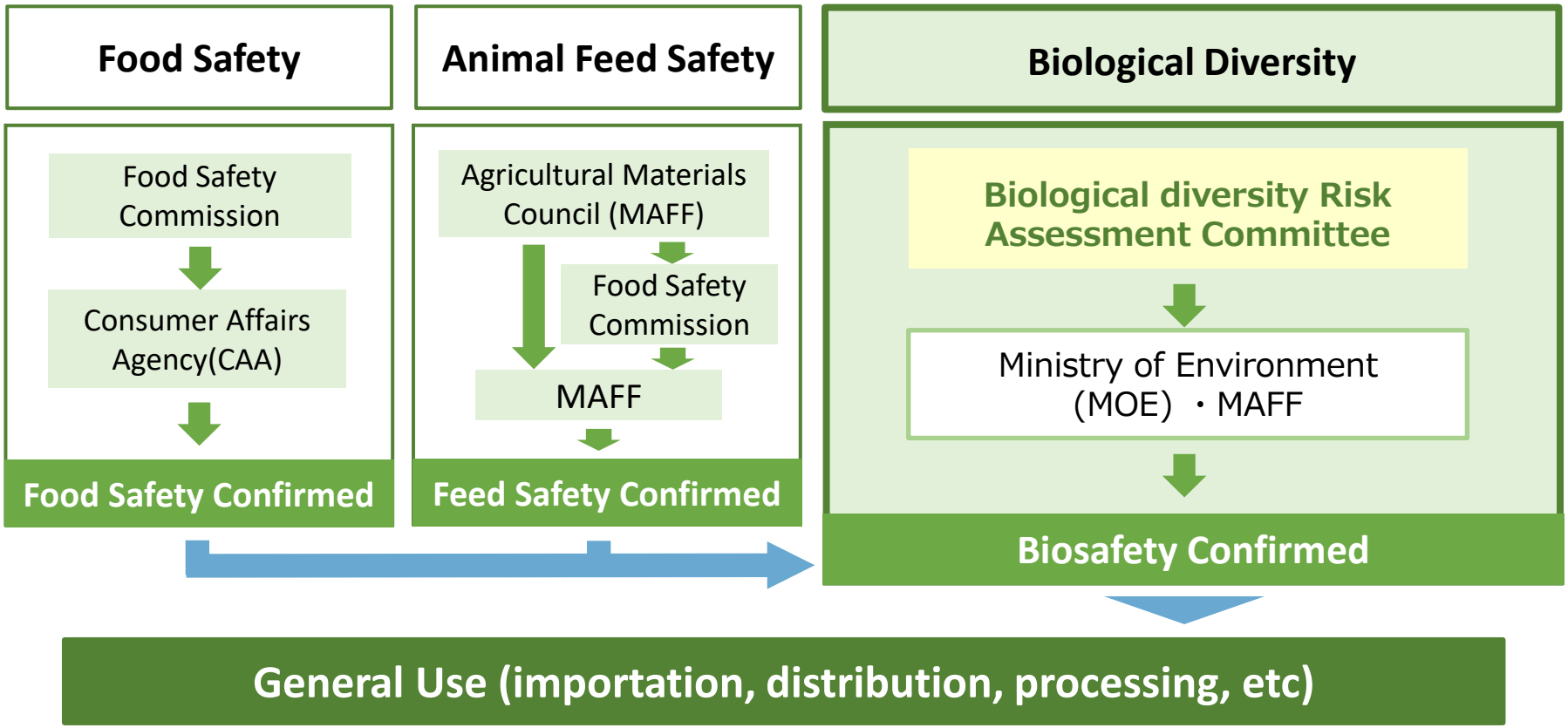
2. Data transportability (DT) for ERA of GM plants in Japan

- Definition, benefit and requirements for DT
- Case (maize, cotton, soybean)

1. Evaluation of GM plants in Japan

Regulatory framework for ensuring the safety of GM (Genetically Modified) plants in Japan

GM plants are approved for general use only when no adverse effect is confirmed on Food Safety / Animal Feed Safety / Biological Diversity.



GM plants Approval list

Since 2004, 200+ GM lines have been reviewed and approved.

Host	Plant lines approved for general use		Major properties
		Domestic cultivation	
Maize	98	96	・Insect resistance ・Herbicide tolerance
Cotton	38	—	・Insect resistance ・Herbicide tolerance
Soybean	30	23	・Insect resistance ・Herbicide tolerance ・High content of specific ingredients
Canola	20	18	・Herbicide tolerance
Mustard	1	1	・Herbicide tolerance ・Fertility resilience
Alfalfa	5	5	・Herbicide tolerance
Papaya	1	1	・Virus disease resistance
Sugar beet	1	1	・Herbicide tolerance
Carnation	8	8	・New flower color(blue)
Rose	2	2	・New flower color(blue)
Phalaenopsis	1	1	・New flower color(bluish-violet)
Total	205	156	

(as of July 2024)

ERA (Environmental Risk Assessment) for GM plants in Japan

- **Competitive superiority;**

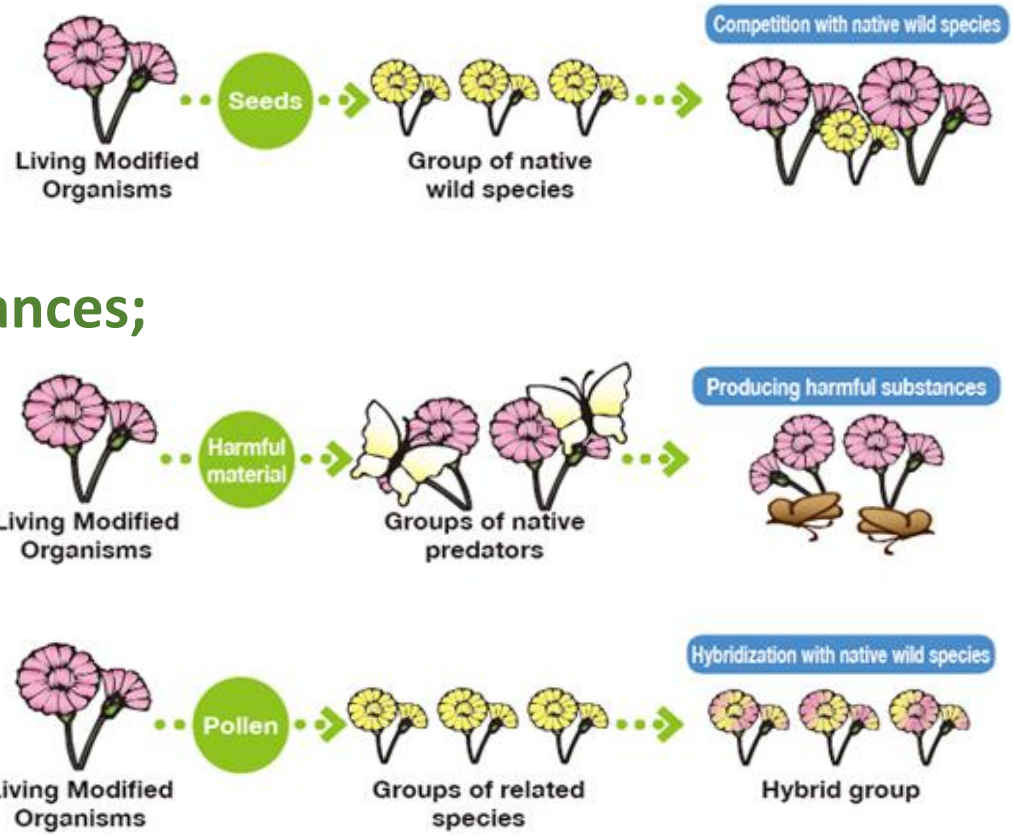
  Competition with native wild species for resources, including nutrient, sunlight and habitat etc.,

- **Production of harmful substances;**

  Production of harmful substances interfering with surrounding environment including other plants or insects

- **Crossability;**

  Hybridization with the native wild species affect its populations

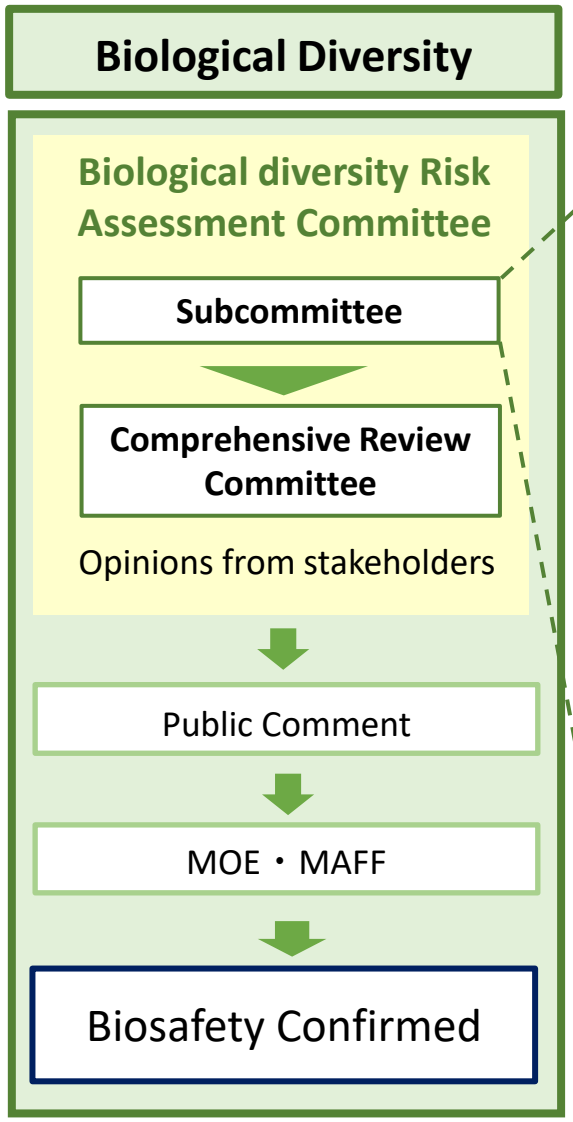


(figure: Ministry of Environment website)

Other properties;

Such as Predacity or parasitism(only for animal), and indirect effects on wildlife by changing the ecosystem etc.,

Opinions from experts in ERA



In the ERA, hearing opinions from experts on biological diversity effects.

Multiple Subcommittees based on host category.

- Crops Subcommittees
- Trees Subcommittees
- Insects Subcommittees
- Microorganisms Subcommittees
- Aquatic Organisms Subcommittees

< Example : Crops subcommittee Experts' fields >

- Conservation Biology
- Plant Pathology
- Horticultural Science
- Plant Physiology
- Weed Science
- Plant Thremmatology
- Environmental Biology
- Molecular Ecology
- Molecular Biology
- Molecular and Cellular Biology
- Theoretical Biology
- Evolutionary Ecology

etc.

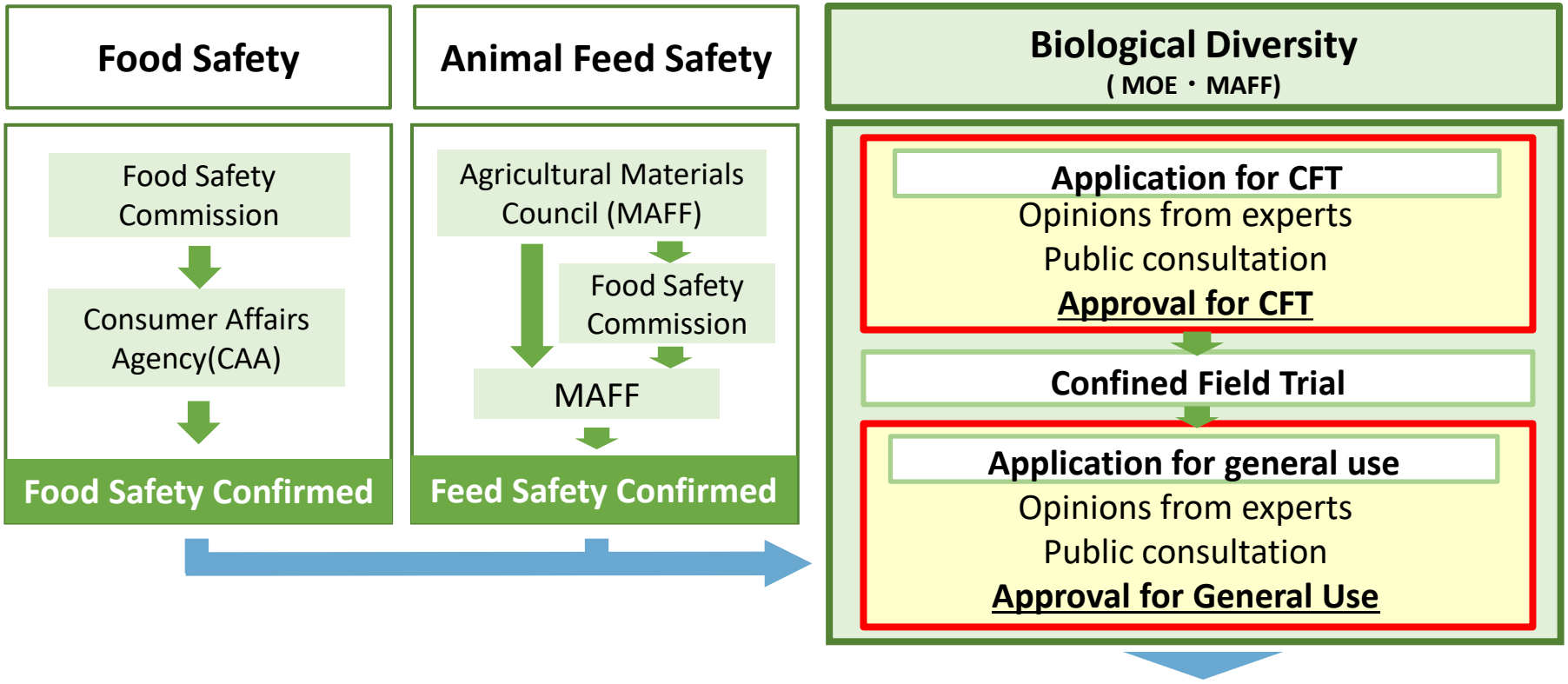
(as of July 2024)

Confined Field Trials (CFTs) in Japan

In the ERA, domestic CFT should be conducted when the growth of a GM plant in the natural environment in Japan is not scientifically clear.

Before the approval for general use, two sets of assessment/review are necessary

1) Assessment & Review for CFT application
2) Assessment & Review for general use application (Info from CFT considered)



2. Data Transportability for Confined Field Trials (CFTs)

What's Data Transportability ?

Data transportability (DT)

- To use field trials data in other economies for scientific examination of the growth of GM plants in the natural environment in Japan.

Benefit of DT for GM risk management

- DT will enhance maintaining the quality of ERA by allocating more human and physical resources to the review of GM plants that require sophisticated and precise investigations. (e.g. new traits, new crops)

Requirements for DT (exemption of CFT)

- Mechanism of action of introduced gene(s) is well studied.
- Effect of introduced trait(s) is not exceeding the scope of previously reviewed traits.

CASE: GM maize and GM cotton (assessment)

Scientific findings from GM maize and GM cotton studies

- There exists no wild relative species that can hybridize with maize or cotton in Japan.
  [crossability]

- Maize and Cotton cannot survive and self-sustain without human cultivation in Japan.
  [competitive superiority]

- If no significant difference is found in field trials overseas between GMO & non-GMO, no significant difference is recognized in CFT in Japan.
  [competitive superiority & production of harmful substances]

CASE: GM maize and GM cotton (revision of risk assessment policy)

Considering the findings, the risk assessment policy revised,

Domestic CFTs are not necessary for GM maize and GM cotton (= DT is adopted) **as long as following requirements are met**.
(GM maize: from Dec. 2014, GM cotton: from Mar. 2019)

[Requirements]

1. *Mechanism of action of introduced gene(s) is clear. (ex. Peer reviewed article, consensus among experts)*
2. *Biological diversity effect of introduced trait(s) is not exceeding the scope of previously reviewed traits.*

Example of DT case (GM maize)

- Morphological and growth characteristics, Seed production, Pod shattering habit
  - Test Facilities: 8 fields in 5 states in the US
  - Materials: 1 GM, 1 control non-GM, 4 references (commercial varieties)

- Low-temperature tolerance in early growth stage, Harmful substances productivity
  - Test Facility: 1 facility in the US
  - Materials: 1 GM, 1 control non-GM, and 4 or 6 references (commercial varieties)

- Overwintering ability of adult plant, Pollen fertility and size, Seed dormancy and germination rate
  - Test Facility: 1 field in the US
  - Materials: 1 GM, 1 control non-GM , and 1 references (commercial varieties, without overwintering)

Evaluation using overseas field data instead of domestic CFTs data

CASE: GM maize (assessment with DT)

Since the introduction of DT acceptance for maize, **8 out of 15 events** were assessed with DT (without domestic CFTs).

Event	Introduced trait (gene)	Evaluated genes used as reference for decision making
Tolerance to Dicamba and Glufosinate Maize (MON87419)	Herbicide tolerant (modified *dmo*, *pat*)	Herbicide tolerant gene (*dmo*, *pat*)
Tolerance to Glyphosate and Glufosinate Maize (MZHG0JG)	Herbicide tolerant (*mepsps, pat*)	Herbicide tolerant gene(*mepsps*, *pat*)
Resistance to Coleoptera, Tolerance to Glufosinate Maize (MZIR098)	Insect resistance (*ecry3.1Ab, mcry3A*)	Insect resistance gene (*cry3.1Ab, mcry3A*)
	Herbicide tolerant (*pat*)	Herbicide tolerant gene (*pat*)
Resistance to Lepidoptera Maize (MON95379)	Insect resistance (*cry1B.868*, modified *cry1Da*)	Insect resistance gene (*cry1* type gene)
Resistance to Lepidoptera, Tolerance to Dicamba Maize	Insect resistance (*cry1Da2*)	Insect resistance gene (*cry1* type gene)
	Herbicide tolerant (*dgt-28 epsps*)	Herbicide tolerant gene (*cp4 epsps* type gene)
Resistance to Lepidoptera, Tolerance to Glufosinate Maize	Insect resistance (*cry1B.34*)	Insect resistance gene (*cry1* type gene)
	Herbicide tolerant (*pat*)	Herbicide tolerant gene (*pat*)
Resistance to Coleoptera, Tolerance to Glufosinate Maize	Insect resistance (*ipd072Aa*)	Insect resistance gene (*ipd072Aa*)
	Herbicide tolerant (*pat*)	Herbicide tolerant gene (*pat*)
Resistance to Lepidoptera, Tolerance to Glufosinate Maize	Insect resistance (C-terminal region deletion type *cry1Da*)	Insect resistance gene (*cry1Da*)
	Herbicide tolerant (modified *bar*)	Herbicide tolerant gene (*bar*)

(Reference)
Examples of transgene regarding the requirements for DT

【for Maize】

1. Pest resistance

Resistance to Lepidoptera
- BT protein type：*cry1Ab, cry1Ac, cry1A.105, cry1.B868, cry1Da, cry1F, cry2Ab2, vip3A*

Resistance to Coleoptera
- BT protein type：*cry3Aa2, cry3Bb1, ecry3.1Ab, mcry3A, cry34Ab1/cry35Ab1, ipd072Aa*
- RNA interference type：*DvSnf7, DvSSJ1*

2. Herbicide tolerance

Tolerance to Glyphosate：*cp4 epsps, mEPSPS, mepsps*
Tolerance to Glufosinate：*bar, pat*
Tolerance to Allyloxyalkanoate：*aad-1, ft_t*
Tolerance to Dicamba：*dmo*

3. Others

Thermostable α-amylase production：*amy797E*
Drought tolerance：*cspB*
High ear at silking stage：*ATHB17*
High-lysine production：*cordapA*
Yield increase：*zmm28*

(final update: Mar. 2023)

(Reference)
Examples of transgene regarding the requirements for DT

【for Cotton】

1. Insect resistance

Resistance to Lepidoptera

- BT protein type ：*cry1Ab, cry1Ac, cry1F, cry2Ab(cry2Ab2), cry2Ae, vip3A*

Resistance to Coleoptera, Hemiptera and Thysanoptera

- BT protein type ：*cry51Aa2*

2. Herbicide tolerance

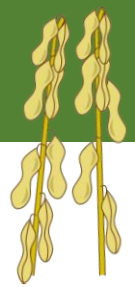
Tolerance to Glyphosate ：*cp4 epsps, 2mepsps*
Tolerance to Glufosinate：*bar, pat*
Tolerance to allyloxyalkanoate：*aad-12*
Tolerance to Dicamba：*dmo*
Tolerance to 4-Hydroxyphenylpyruvate Dioxygenase (4-HPPD)： *hppdPfW336-1Pa*

(final update: Mar. 2023)

Note

- The list is not exhaustive and periodically updated.
- Prior consultation with MAFF & MOE is necessary to confirm the acceptance of DT (= exemption from domestic CFT) for each application.

CASE: Soybean (in progress)



Scientific findings from GM soybean studies

- Potential GM-wild hybridization is extremely rare in the natural environment in Japan.
- In the rare case of hybridization, introduced gene(s) of GM soybean is unlikely to invade into wild soybeans.

[crossability]

- Soybeans cannot survive and self-sustain without human cultivation in Japan.

[competitive superiority]

- If no significant difference is found in field trials overseas between GMO & non-GMO, no significant difference is recognized in CFT in Japan

[competitive superiority & production of harmful substances]

Revision of risk assessment policy is proposed for incorporating **soybean** as a potential host for DT

Current Status

Maize, cotton and soybean accounts for **80%** of the GM lines ever approved.

Host	Plant lines approved for general use	Domestic cultivation	Major properties
Maize	98	96	・Insect resistance ・Herbicide tolerant
Cotton	38	—	・Insect resistance ・Herbicide tolerant
Soybean	30	23	・Insect resistance ・Herbicide tolerant ・High content of specific ingredients
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Summary

- DT has been introduced for **optimal use of resources**, thereby, contributing to appropriate management of GM plants.
- **Accumulated scientific knowledge and experience** enabled DT for maize and cotton when conditions are met. **Soybean** is proposed as a new host for DT.
- So far, **8 GM maize events have been assessed and approved using DT**.
- The three hosts account for 80% of the total number of approved lines.

Thank you for your attention!

MAFF
Ministry of Agriculture,
Forestry and Fisheries