

GMO testing in Japan

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COI Disclosure Information

Kazunari Kondo
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I have no financial relationships to disclose

GMO testing in Japan

Topics

- ✓ Method for monitoring
- ✓ Method for labeling

GMO testing in Japan

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GMO testing for monitoring inspection

Food Sanitation Act :

Unauthorized GM foods must not be distributed
If detected, they have to be thrown away

MHLW tests imported GM foods based on monitoring plan
(papaya, rice, etc)

The method development principle:

Target – unauthorized GM foods

Method - qualitative real-time PCR

pLOD– it depends, mostly >50 copies

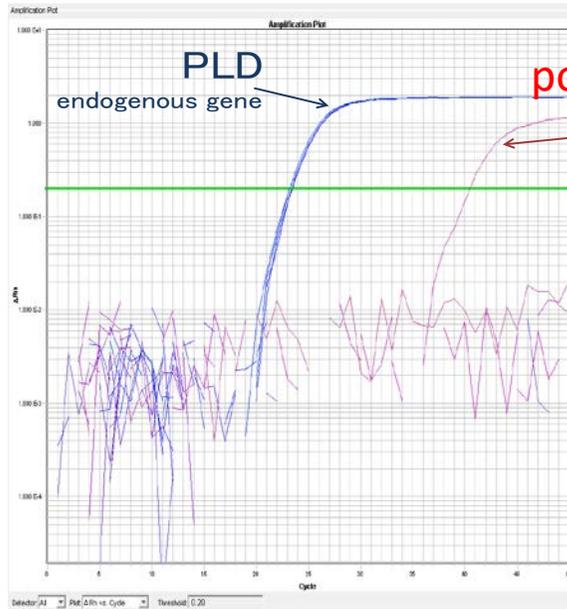
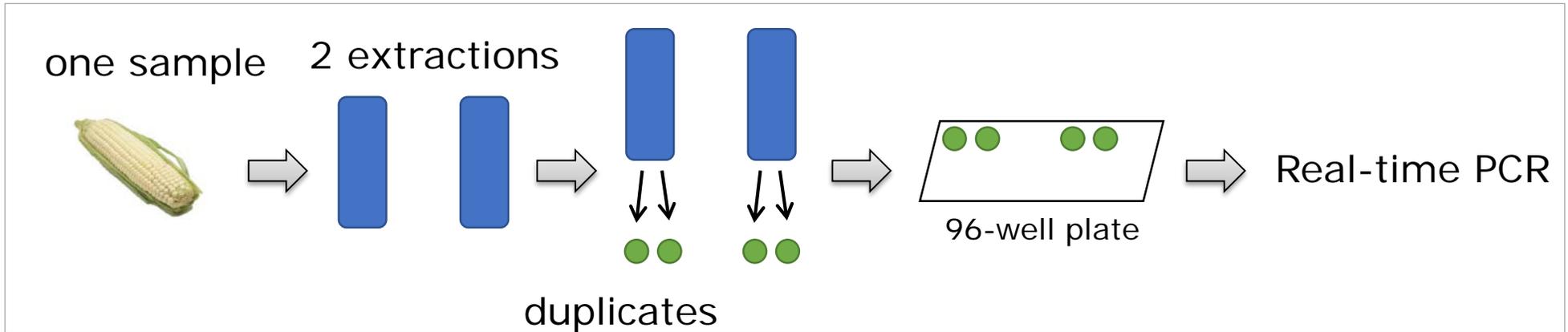
Ambiguous result - negative

Practical LOD is based on LOD decided by interlaboratory validation

LOD is the amount of analyte at which the analytical method detects the presence of the analyte at least 95% of the time (<5% false negative results) (codex CAC/GL74)

In case of ambiguous results, it is negative (ISO21569, 21570)

GMO inspection for rice – one example



positive
Cry1Ab
insect-resistant gene

When you have positive results from all four wells, Judge the sample as positive. Otherwise negative.

Scheme of inspection method development for Unauthorized GM foods

Based on information given, design primers/probe specific to the sequence of the junction region, develop methods

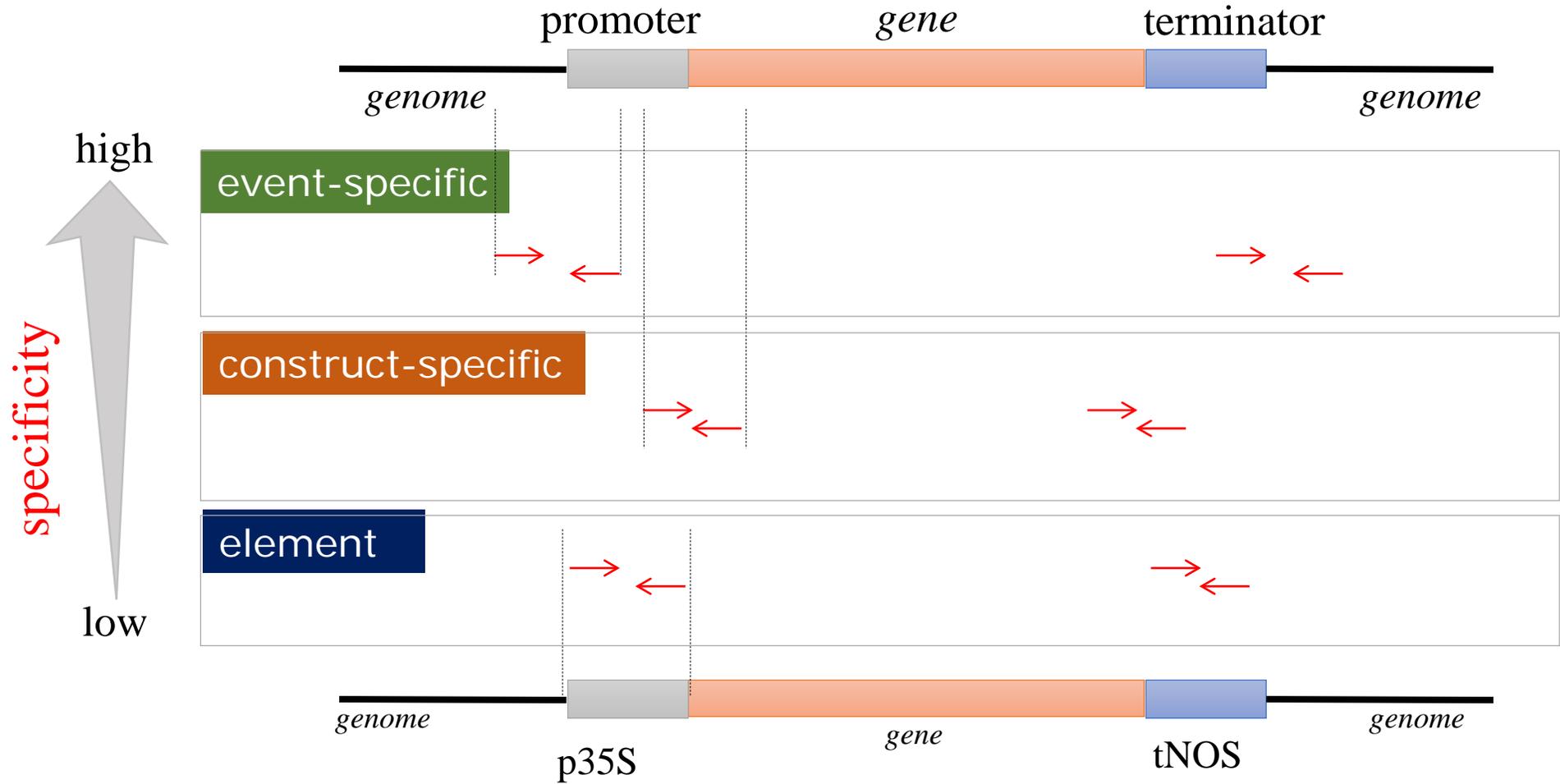


Validate the methods with multiple institutions/labs
(12 or more institutes)



Official method in Japan

GMO testing in Japan - 1



unauthorized GMO testing

Rice:	Bt63, NNBt, CpTI (China)
Wheat:	MON71800, MON71700 (Monsant)
Papaya:	PRSV-YK (Taiwan), PRSV-SC (Thailand) PRSV-HN (China)
Potato:	F10、 J3、 Y9、 X17 (Simplot)
Flax:	FP967
Maize:	for old event
Rapeseeds:	RT73 (Canada)
Salmon:	AquAdvantage

old	Rice:	Bt63, NNBt, CpTI (China)
new	Wheat:	MON71800, MON71700 (Monsant)
old	Papaya:	PRSV-YK (Taiwan), PRSV-SC (Thailand) PRSV-HN (China)
new	Potato:	F10、 J3、 Y9、 X17 (Simplot)
	Flax:	FP967
old	Maize:	for old event
	Rapeseeds:	RT73 (Canada)
new	Salmon:	AquAdvantage

event, construct-specific

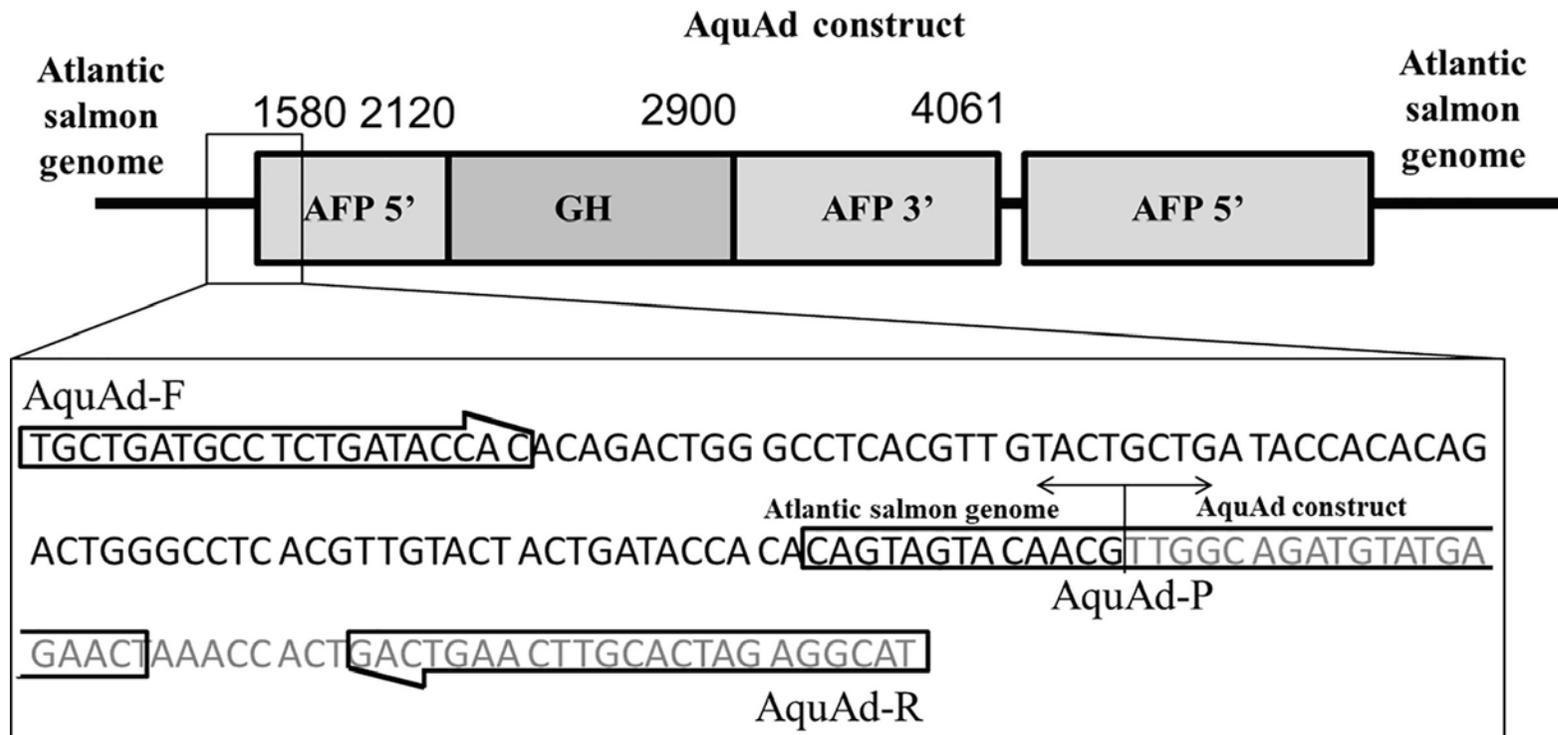
Criteria for method development

We do not adopt screening methods based on element specific sequences.

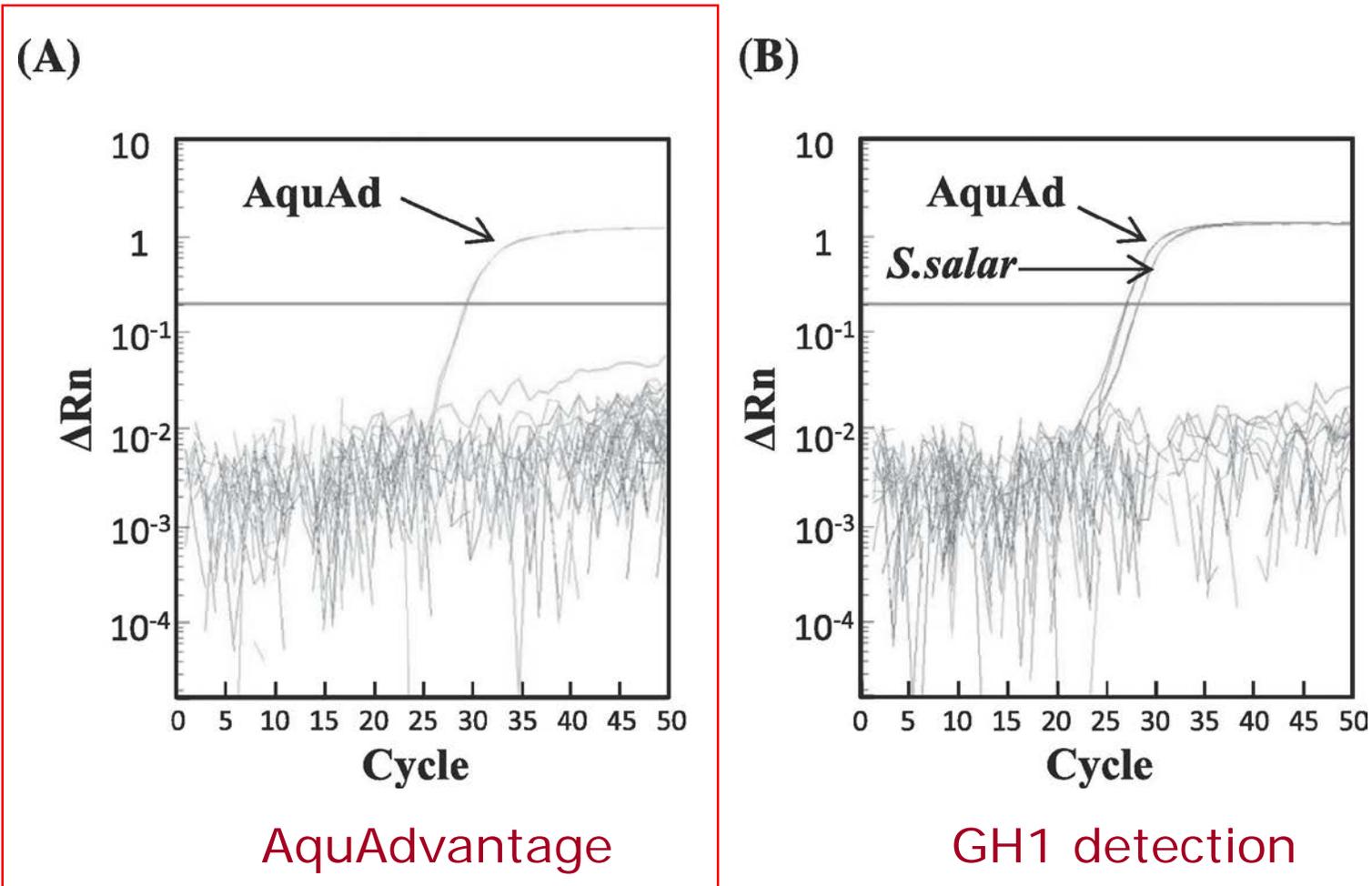
The object of inspection is an event that commercially cultivated in a certain country and that has not undergone safety assessment process in Japan.

Sequence info needed to develop a method is available

Detection method for GM Atlantic Salmon (event-specific)



Detection method for GM Atlantic Salmon (event-specific)



GMO testing in Japan - 1

quarantine stations



○ Two quarantine offices monitoring of imported GM foods

In the future

If there is possibility of unknown,
hazardous GMO contaminations,
What should we do?



Short-reads + long reads



Rapid analysis of gene construct or genome edited

GMO testing in Japan

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Food labeling system



Law: Food labeling law (Consumer Affairs Agency)

Purpose: Right to consumer's choice of food

Enforcement: April 1st 2015

Labeling target:

- ◆ 8 kinds of agricultural products of soybean, corn, potato, rapeseed, cottonseed, alfalfa, sugar beet, The weight ranking in the total weight of raw materials is in the top 3, and the content is 5% or more
- ◆ 33 processed foods



Labeling not required for Highly refined products
DNA or protein are not detected

- Soy sauce
- Soybean oil
- Corn oil
- Sugar
- Japanese Vinegar



GMO testing for labeling

MHLW not test approved GM foods

Consumer Affairs Agency involved in labeling on GM foods

Authorized GM foods must be labeled

Unintentional contamination (<5%) is accepted as nonGM



Labeling as nonGMO will only be allowed
at a lower level (0.1%?) after 2023

320 events approved

crops	# Event
Soybean	28
Maize	206
Potato	9
Rape seeds	21
Cotton seed	47
Sugar beet	3
Alfalfa	5
Papaya	1

Most events are approved almost simultaneously or within a year

Current testing method

1. Screening methods – two option

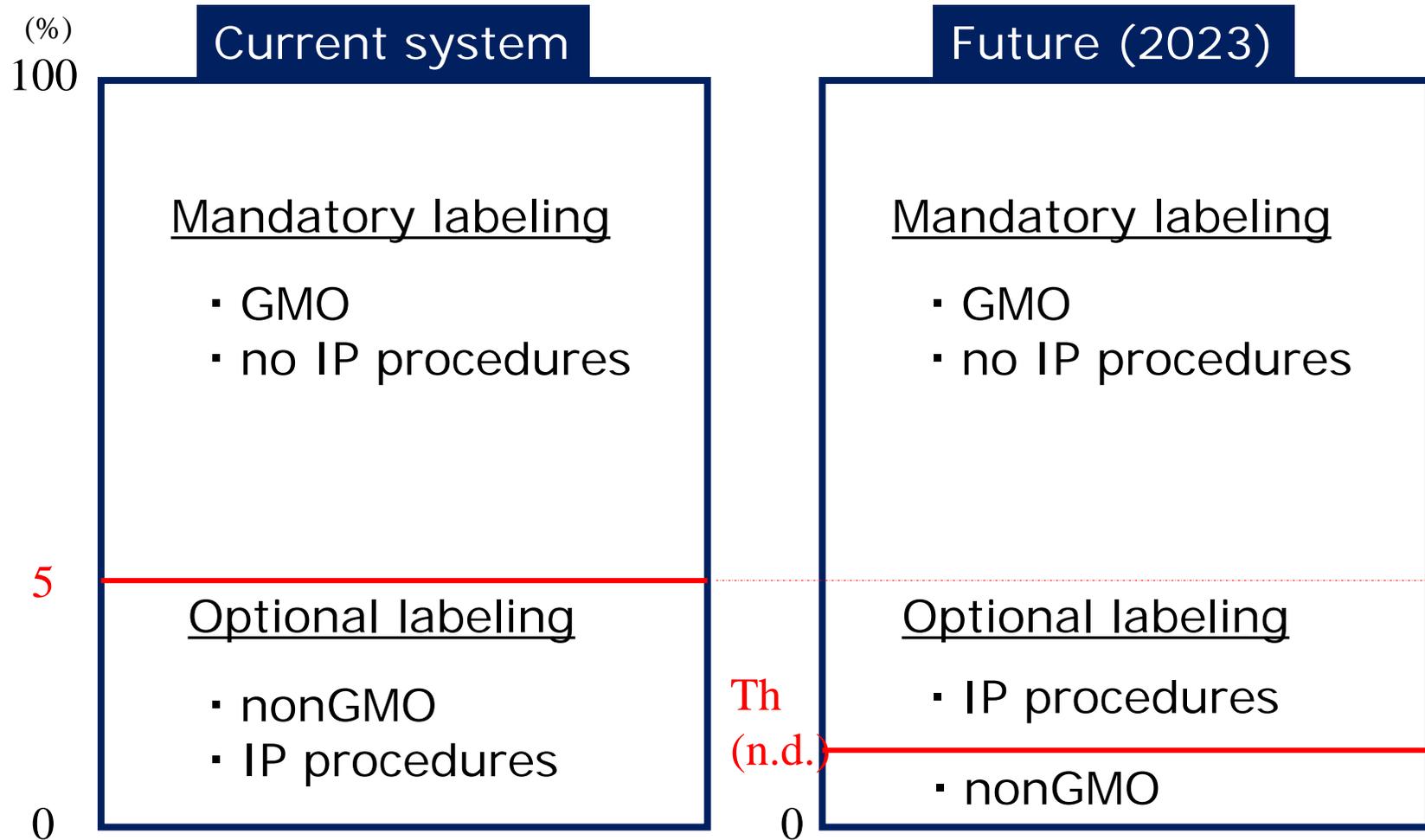
- If $>4.5\%$ (35S, MIRs (MIR162, 604)),
- if $\Delta\Delta Cq > 4\%$ (35S+tNOS),
go to the next

2. Quantitative methods – two option

- single test testing
- group test

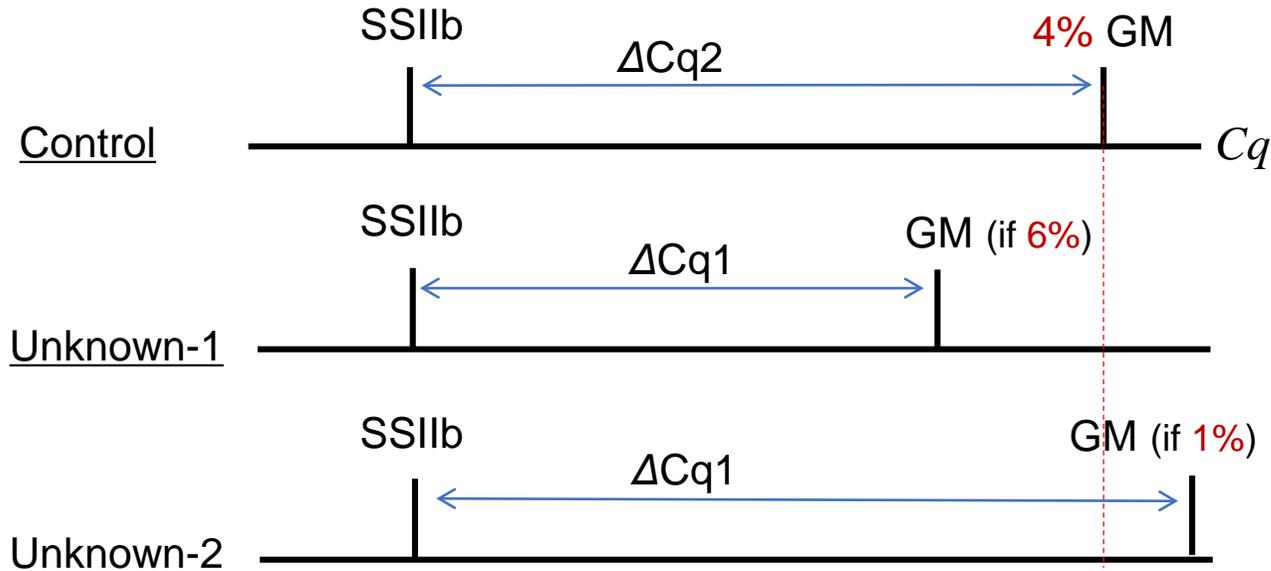
laborious

Labeling for GM foods



Current testing method for screening

- $\Delta\Delta Cq > 4\%$ (35S+tNOS)



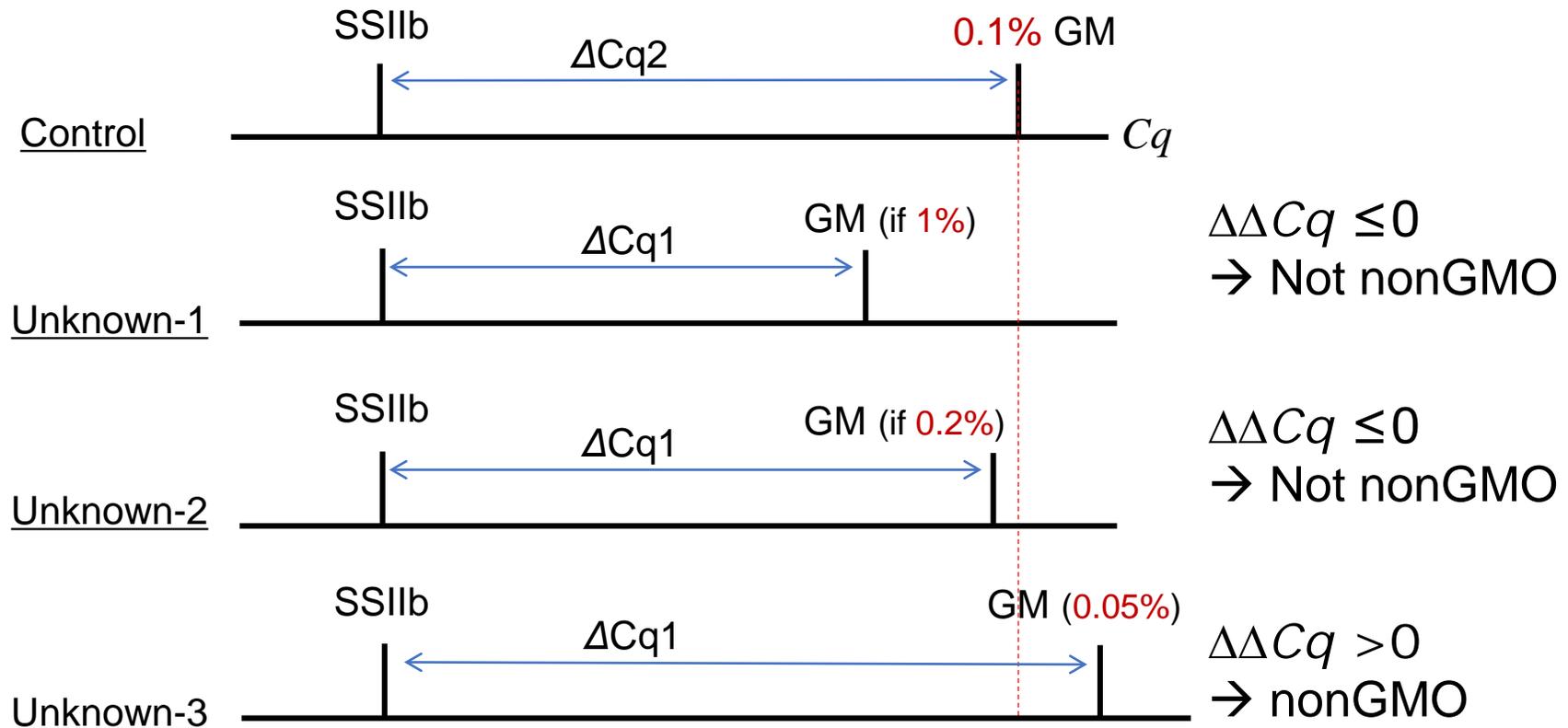
$$\Delta\Delta Cq = \Delta Cq_1 - \Delta Cq_2 \leq 0$$

→ unknown-1 > 4%

$$\Delta\Delta Cq = \Delta Cq_1 - \Delta Cq_2 > 0$$

→ unknown-2 < 4%

Future method for nonGMO labeling



GMO testing in Japan

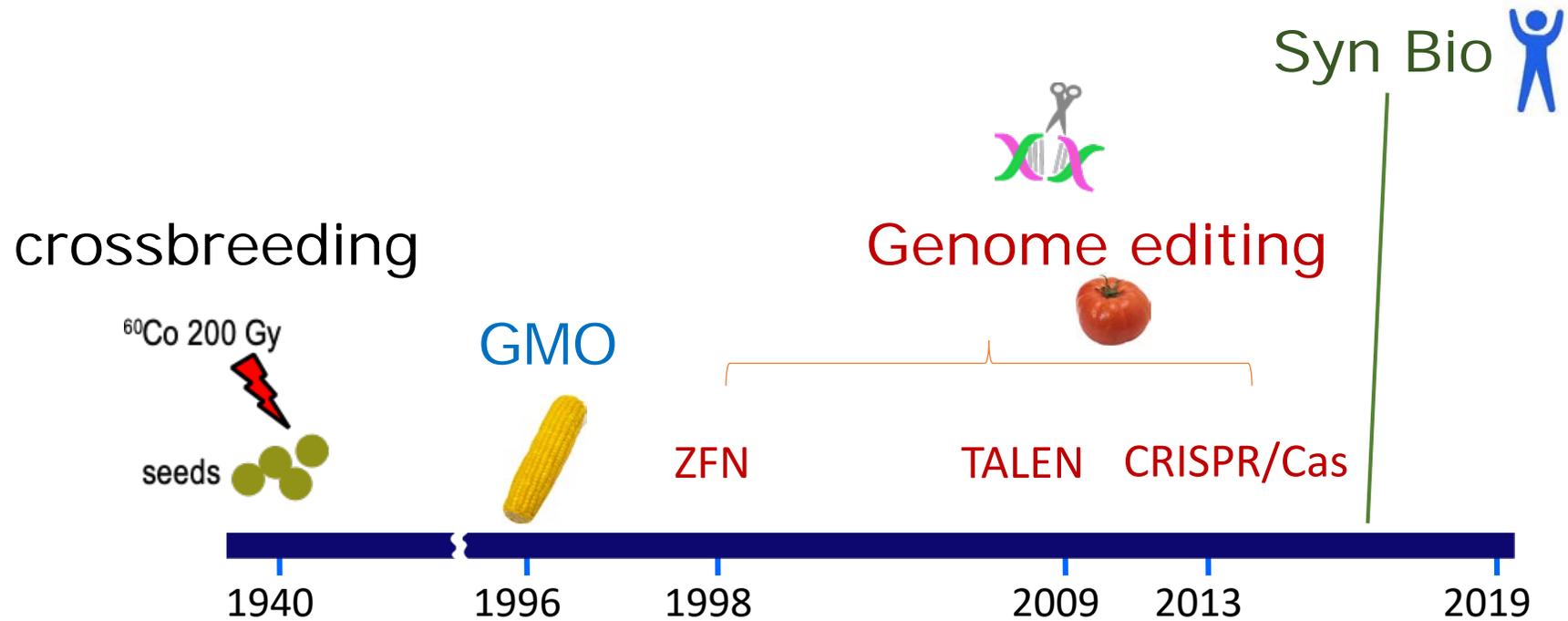
Topics

- ✓ Method for monitoring
- ✓ Method for labeling

extra

- ✓ Genome editing foods

Genome editing and beyond



Thank you for your attention

Validation by multilabs

