Vietnam – Japan Food Trade Development Seminar
~Food Allergen Regulations~

Nov. 20th 2026

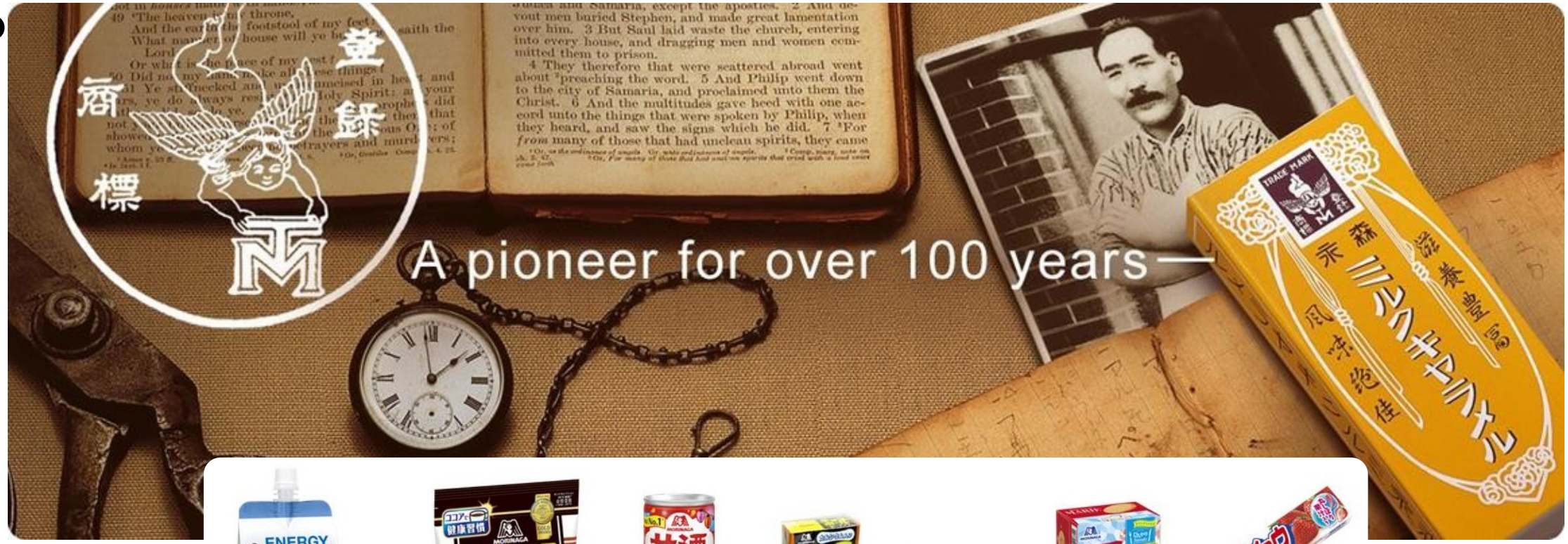
Morinaga BioScience, Inc.
&
Yamaguchi Vietnam Industrial J SC

Today's agenda

- Introduction to Morinaga / Yamaguchi Vietnam
- Food Allergen Regulations in global
- Japanese Food Allergen Regulations
- Morinaga Products
- Q&A session

Introduction to Morinaga

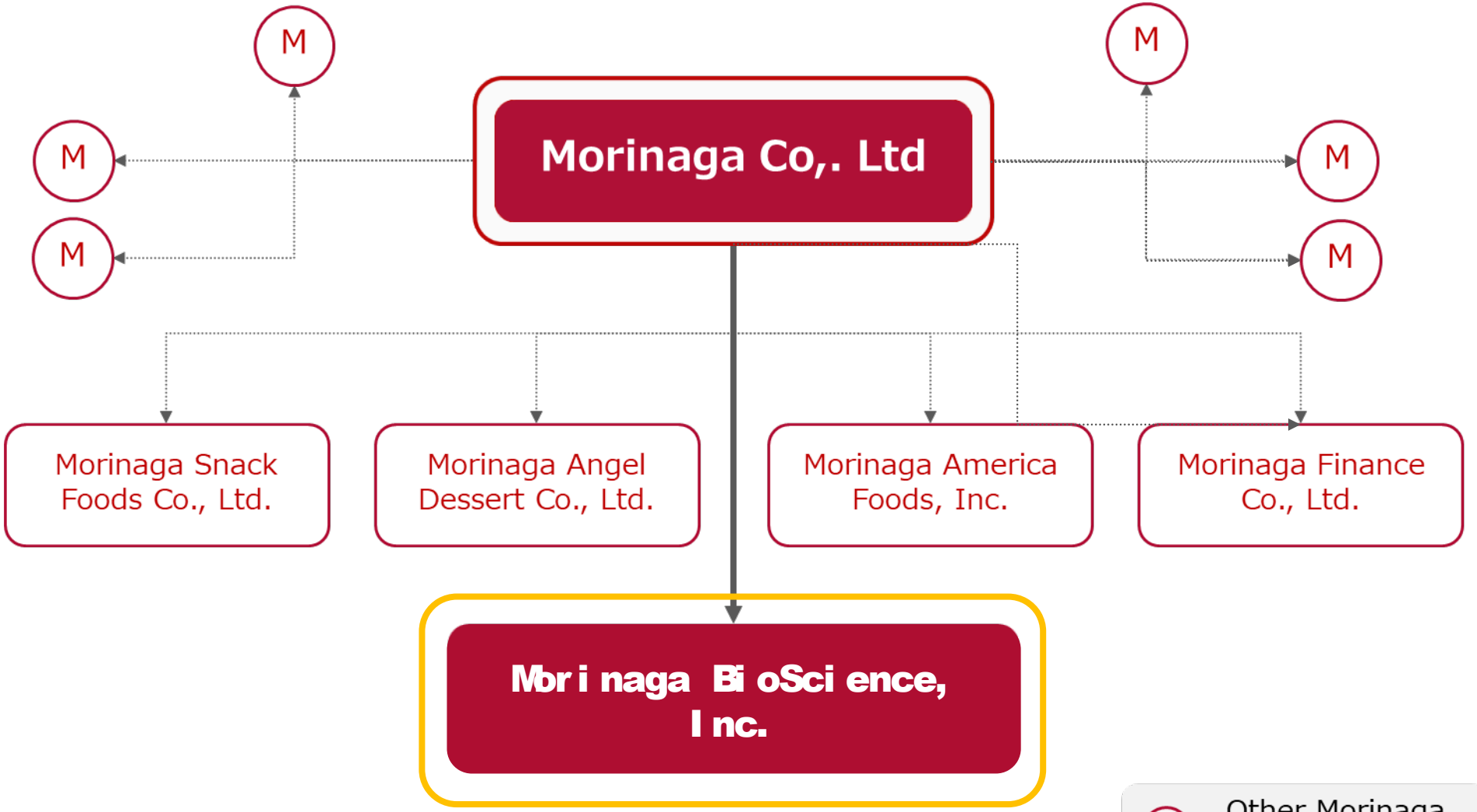
Who is Morinaga Co





One of the largest food manufacturers in Japan

What is Morinaga BioScience, Inc.?



Who is Morinaga BioScience, Inc.?







Our company was established in 1973 as the biochemical laboratory of the Morinaga & Co., Ltd. Research Institute.

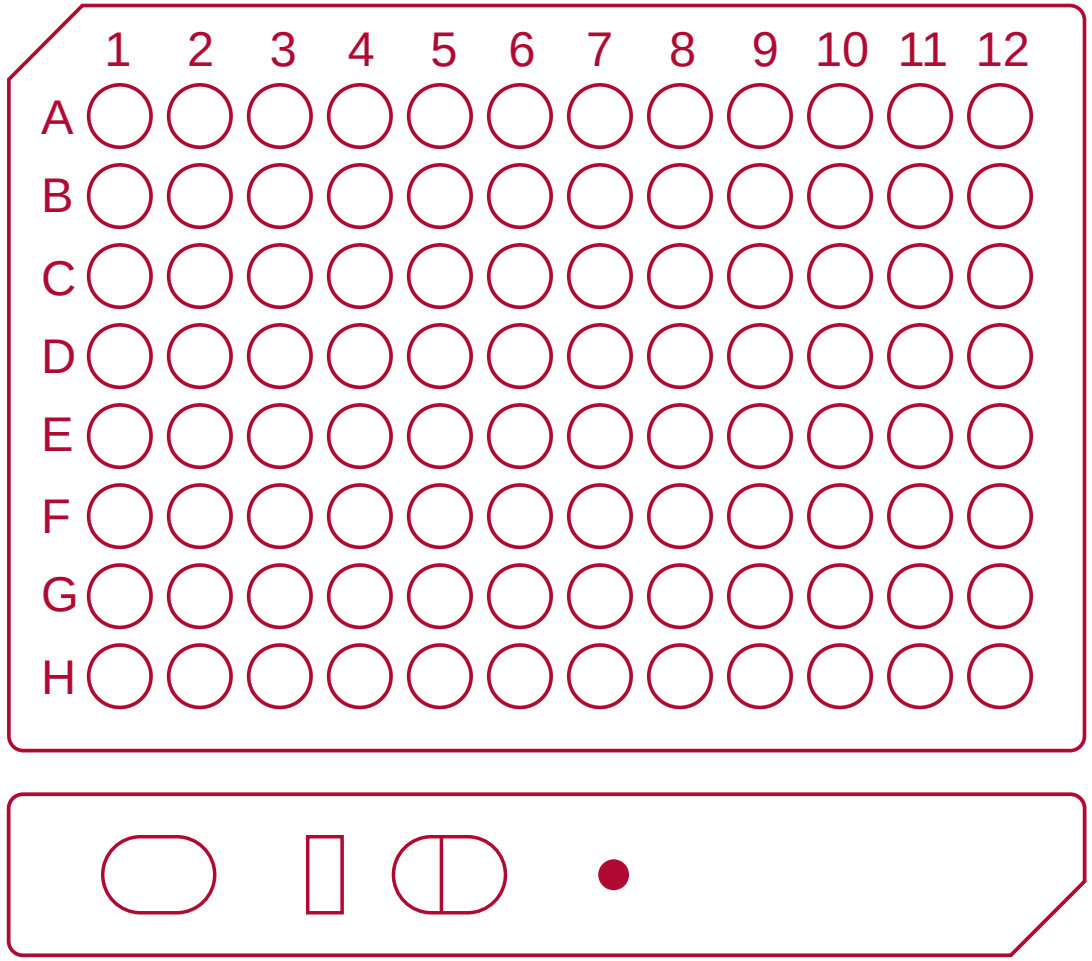
We became an independent entity, the Morinaga Institute of Biological Science, in October 1980, before rebranding to Morinaga BioScience, Inc. in 2024.

Morinaga & Co., Ltd. has been dedicated to food allergen management since well before official regulations (2002) were established in Japan.

Establishment	October 17, 1980
Major Business	Production and sale of immunoassay kits for food safety and drug discovery

©DESIGNALIKIE

The Core Business of Morinaga BioScience





- Morinaga BioScience focuses on manufacturing food safety analytical tools primarily based on antibody technology.
- Assay Formats: The company produces tools in two main formats: ELISA and lateral-flow devices (LFDs).
- Official Recognition: In Japan, the company's ELISA kits for food allergens are approved as the Japanese official method.

History of Morinaga Allergen Test Kit

Morinaga Co., Ltd.

1993: Produced a biscuit line entirely free of milk, egg, and soy.



*not selling now

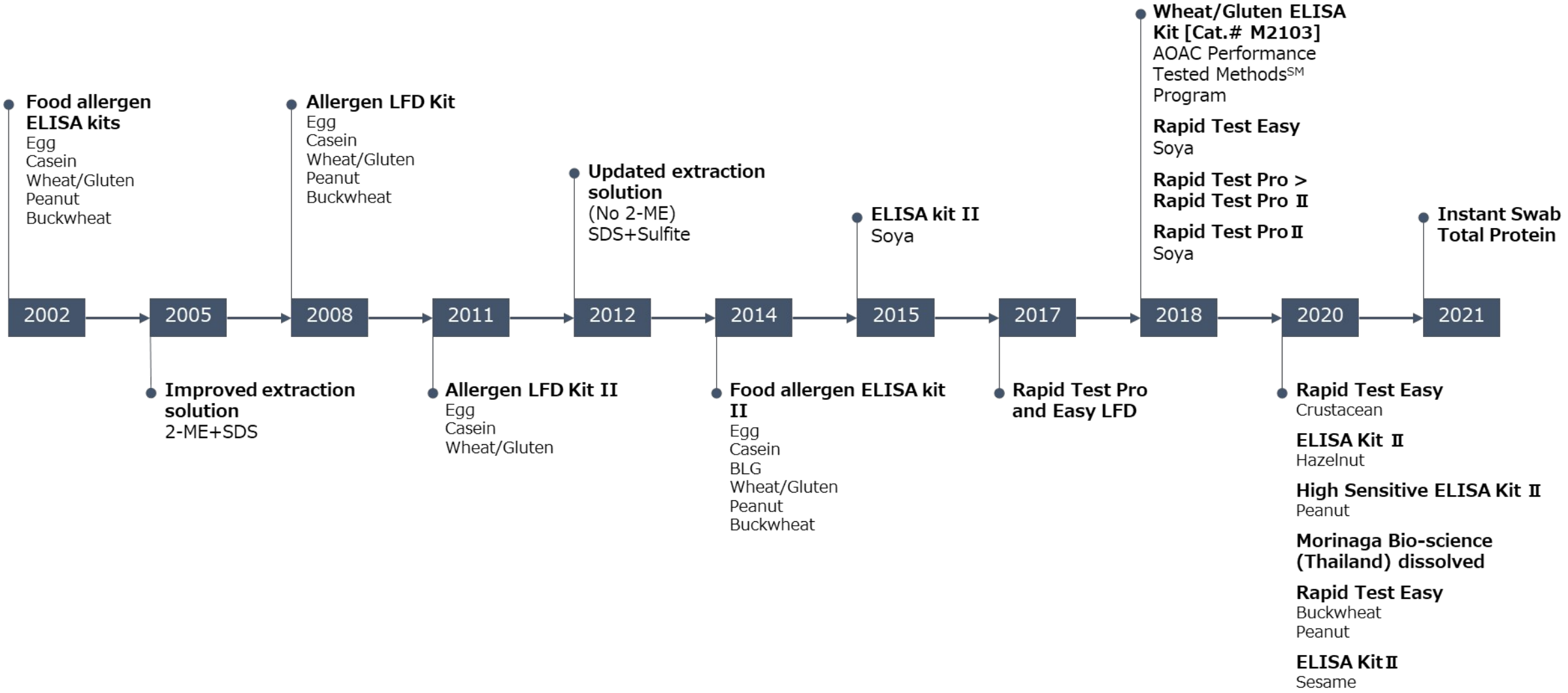
Morinaga Institute of Biological Sciences

From 1980: Started supplying antigens, antibodies, and immunoassay kits for development.

Food proteins + **Immunoassay (ELISA)**

1992: Began collaborations to monitor cross-contamination and ensure quality control by offering ELISA kits for detecting egg, milk, and soy proteins.

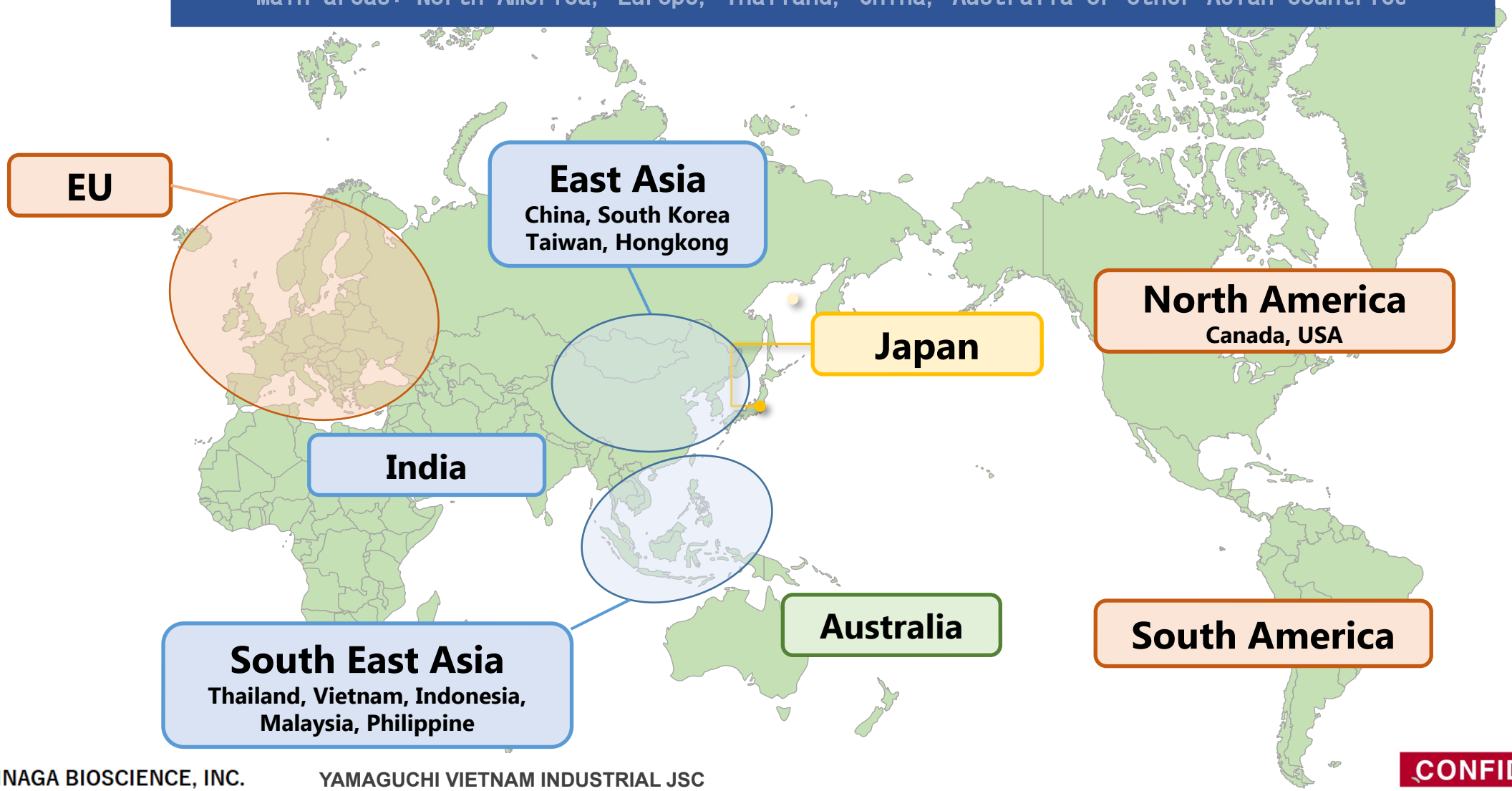
History of Morinaga food allergen test kits



The Worldwide Activity of Morinaga BioScience

Our ELISA Kits and LF are widely used around the world

Main areas: North America, Europe, Thailand, China, Australia or other Asian countries



Food Allergen Regulations

What are allergens, and why are they important to be managed?:

- Cause immune reaction in some people where the immune system mistakenly thinks a food protein is dangerous.
- Allergies cannot be treated
- Allergic reaction can lead to death within an hour
- Allergic consumers must avoid consuming the allergen
- Labelling is the only way to inform allergic consumers what is in the food

Food Allergen Management

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

E-mail: codex@fao.org - www.codexalimentarius.org

CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS

CXC 80-2020

Adopted in 2020.

- cereals containing gluten (i.e. wheat, rye, barley, oats[2], spelt or their hybridized strains)
- crustaceans;
- eggs;
- fish;
- milk;
- peanuts;
- soybeans; and
- tree nuts

https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC_080e.pdf

Updated: Remove soybeans and add sesame, specify tree nuts species

1) FAO/WHO RISK ASSESSMENT OF FOOD ALLERGENS, PART 1: REVIEW AND VALIDATION OF CODEX ALIMENTARIUS PRIORITY ALLERGEN LIST THROUGH RISK ASSESSMENT

Reference ： CODEX STAN 1-1985
4.2.1.4

Food Allergen Labeling Regulation: Current Situation

UNIVERSITY of NEBRASKA–LINCOLN

MORINAGA

Current information: 13 Aug. 2024

Food Allergens	Crustacean Shellfish	Egg	Fish	Milk	Peanut	Soy	Tree Nuts	Sesame	Wheat	Cereals w/ Gluten	Sulfites	Buckwheat	Celery	Lupin	Molluscan Shellfish	Mustard	Bee Pollen/ Propolis	Beef	Chicken	Latex (Natural Rubber)	Mango	Peach	Pork	Royal Jelly	Tomato
USA	X	X	X	X	X	X	X	X	X		X														
Canada	X	X	X	X	X	X	X	X	X	X	X				X	X									
EU[1]	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X									
Australia/NZ	X	X	X	X	X	X	X	X	X	X	X			X	X		X							X	
Argentina	X	X	X	X	X	X	X			X	X														
Bangladesh	X	X	X	X	X	X	X	X		X	X		X			X									
Belarus	X	X	X	X	X	X	X	X		X	X		X	X	X	X									
Bolivia	X	X	X	X	X	X	X		X	X	X														
Botswana	X	X	X	X	X	X	X			X	X														
Brazil	X	X	X	X	X	X	X		X	X	X									X					
Caricom Std.[4]	X	X	X	X	X	X	X		X	X	X														
Central America[5]	X	X	X	X	X	X	X		X	X	X														
Chile	X	X	X	X	X	X	X			X	X														
China	X	X	X	X	X	X	X		X	X															

Food Allergen Labeling Regulation: Current Situation

Current information: 13 Aug. 2024

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Colombia	X	X	X	X	X	X	X		X	X	X														
Cuba	X	X	X	X	X	X	X		X	X	X														
Egypt	X	X	X	X	X	X	X		X	X	X														
Fiji	X	X	X	X	X	X	X			X	X														
GSO[3]	X	X	X	X	X	X	X	X		X	X		X	X	X	X									
Hong Kong	X	X	X	X	X	X	X			X	X														
India	X	X	X	X	X	X	X			X	X														
Indonesia	X	X	X	X	X	X	X			X	X														
Israel (Pending)																									
Japan[2]	X	X		X	X		X		X			X													
Kazakhstan	X	X	X	X	X	X	X	X		X	X		X	X	X	X									
Malawi	X	X	X	X	X	X	X			X	X														
Malaysia	X	X	X	X	X	X	X			X	X														
Mexico	X	X	X	X	X	X	X			X	X														

Reference: https://farrp.unl.edu/IRChart

Food Allergen Labeling Regulation: Current Situation

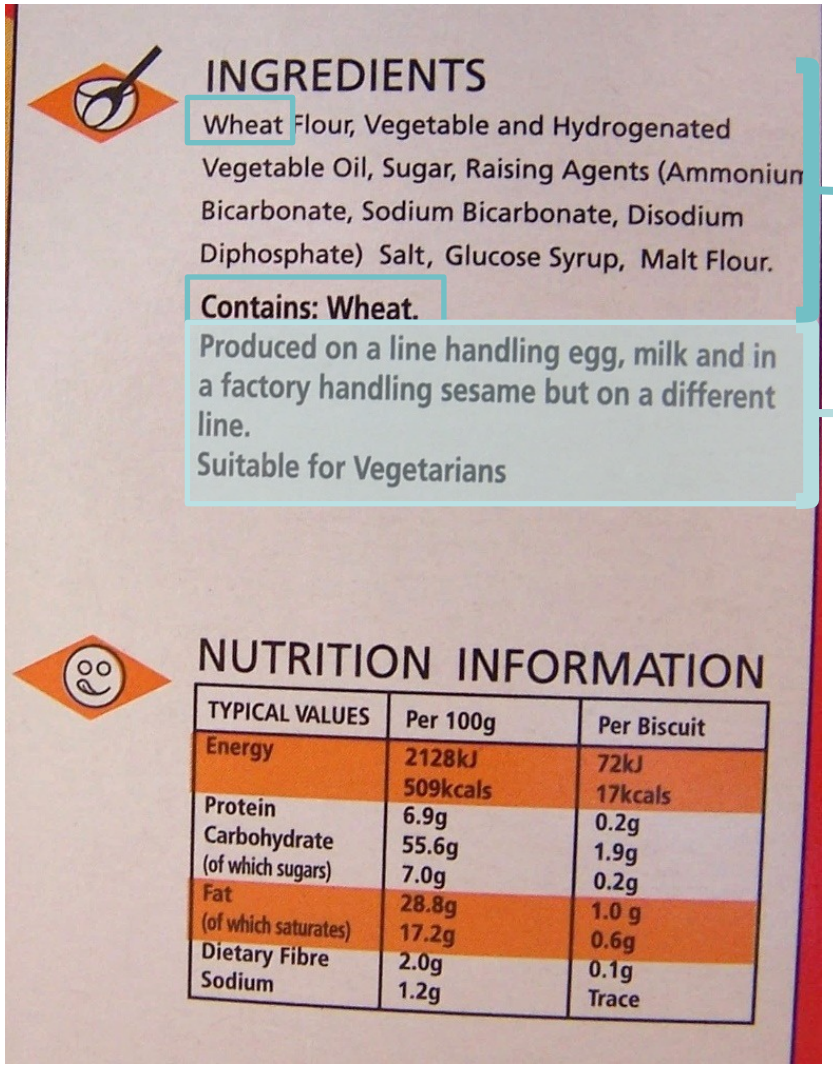
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UNIVERSITY of NEBRASKA–LINCOLN

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Morocco	X	X	X	X	X	X	X			X	X														
Nigeria	X	X	X	X	X	X	X			X	X														
Philippines	X	X	X	X	X	X	X			X	X														
Russia	X	X	X	X	X	X	X	X		X	X		X	X	X	X									
Singapore	X	X	X	X	X	X	X			X	X				X										
South Africa	X	X	X	X	X	X	X		X						X										
South Korea	X	X	X	X	X	X	X		X		X	X			X			X	X			X	X		X
Taiwan[6]	X	X	X	X	X	X	X	X		X	X										X				
Thailand	X	X	X	X	X	X	X			X	X				X										
Tunisia	X	X	X	X	X	X	X			X	X														
Turkey	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X									
Ukraine	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X									
Venezuela	X	X	X	X	X	X	X		X	X	X														
Vietnam	X	X	X	X	X	X	X			X	X														

Reference: https://farrp.unl.edu/IRChart

Food Labeling Example (US/EU)



INGREDIENTS

Wheat Flour, Vegetable and Hydrogenated Vegetable Oil, Sugar, Raising Agents (Ammonium Bicarbonate, Sodium Bicarbonate, Disodium Diphosphate) Salt, Glucose Syrup, Malt Flour.

Contains: Wheat.

Produced on a line handling egg, milk and in a factory handling sesame but on a different line.
Suitable for Vegetarians

NUTRITION INFORMATION

TYPICAL VALUES	Per 100g	Per Biscuit
Energy	2128kJ 509kcals	72kJ 17kcals
Protein	6.9g	0.2g
Carbohydrate	55.6g	1.9g
(of which sugars)	7.0g	0.2g
Fat	28.8g	1.0 g
(of which saturates)	17.2g	0.6g
Dietary Fibre	2.0g	0.1g
Sodium	1.2g	Trace

Food allergen ingredients easy to identify:

- **US** – **"Contains"** statement after ingredient list
- **EU** – highlighted in the **ingredient list** (e.g. bold)

Precautionary labeling such as:

- **May contain**

Voluntary declarations such as

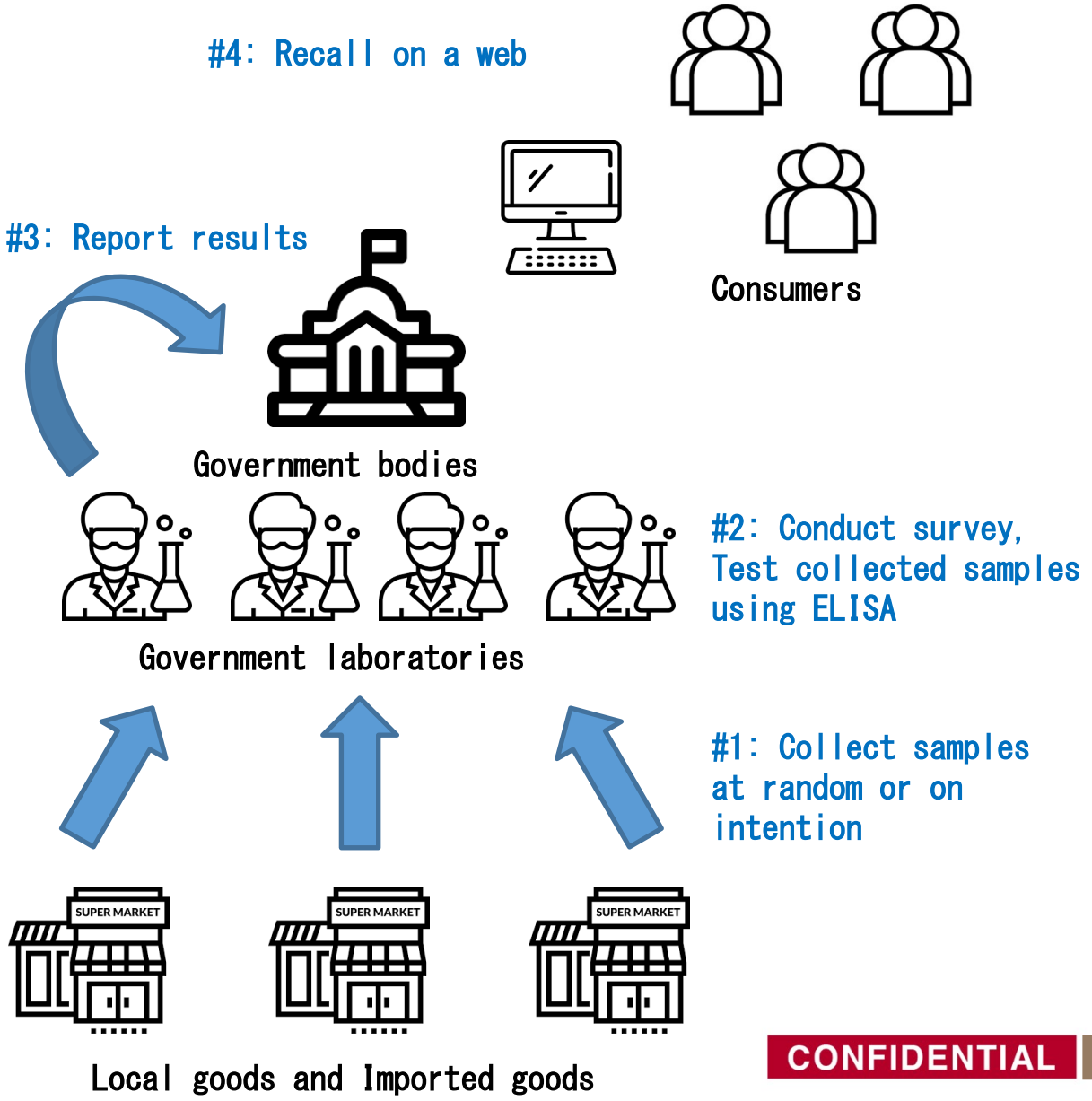
- Produced in a facility that also handles XXX allergen

…etc.

How government bodies execute allergen recalls?

US・Canada

- Government institutes conduct “survey” to check that a labeling of commercial food products is correct.
- They use a food allergen test kit, ELISA, to confirm a contamination level.
- Based on the contamination level (allergen concentration), they move into action.
- Although there is no threshold, they comprehensively decide its recall.



Managing and Controlling Food Allergens is Essential

Why it's essential?？
Because…

- Regulatory Compliance: Adhering to local and international food laws.
- Export Opportunities: Meeting the requirements of global markets.
- Certification Maintenance: Fulfilling the criteria for FSSC 22000, BRC, and HACCP.
- Customer & Client Demands: Responding to the safety expectations of your partners and consumers with correct food labeling.

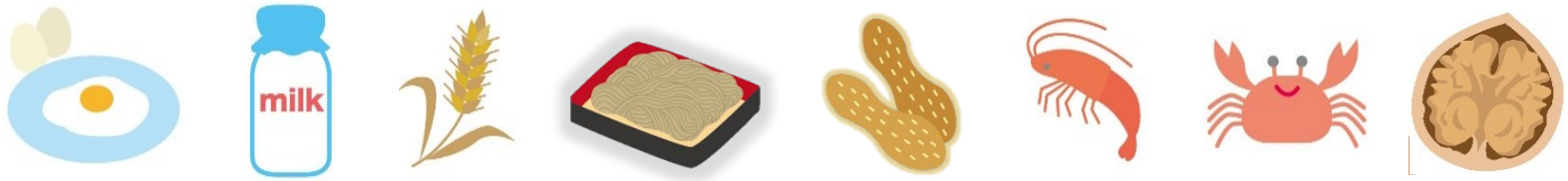
Key message to food manufacturers and exporters:

Accurate labeling is essential.

Therefore, verifying your procedures, operations, and management systems is essential.

Case study: Japanese food allergen regulations and its testing situation

Food Allergen Labeling Regulation in Japan



【Mandatory Labeling】

- Egg
- Milk
- Wheat
- Buckwheat
- Peanut
- Shrimp / Prawn
- Crab
- Walnut
- Cashew

【Recommendation Labeling】

- 20 commodities:
  almond, abalone, squid, salmon roe, orange, cashew, kiwifruit, beef, sesame, salmon, mackerel, soy, chicken, banana, pork, macadamia, peach, yam, apple and gelatin

Regulatory limit for mandatory labeling: 10 ppm [µg of proteins/g of food]

PAL is "not" allowed!

Food Labeling Example (JP)

名　　称　洋菓子
原材料名　小麦粉（国内製造）、砂糖、ショートニング、水あめ、植物油脂、鶏卵、ココアパウダー、加糖練乳、全粉乳、バター、乾燥卵黄、食塩、デキストリン／酒精、乳化剤（大豆由来）、膨脹剤、香料
内 容 量　6個
賞味期限　左側面に記載
保存方法　直射日光を避けて26℃以下で保存してください
製 造 者　森永製菓株式会社　〒105-8309　東京都港区芝浦1-13-16
製 造 所　森永製菓株式会社　小山工場　栃木県小山市大字出井1523-1

原材料に含まれるアレルギー物質（28品目中）	小麦・卵・乳・大豆	落花生を含む製品と共通の設備で製造しています。



Food allergen ingredients easy to identify:

- **Japan** - Must indicate all mandatory food allergens, such as egg, milk, wheat, buckwheat, peanut, shrimp, crab, walnut and cashew which contains over “few ppm”.

Voluntary declarations such as

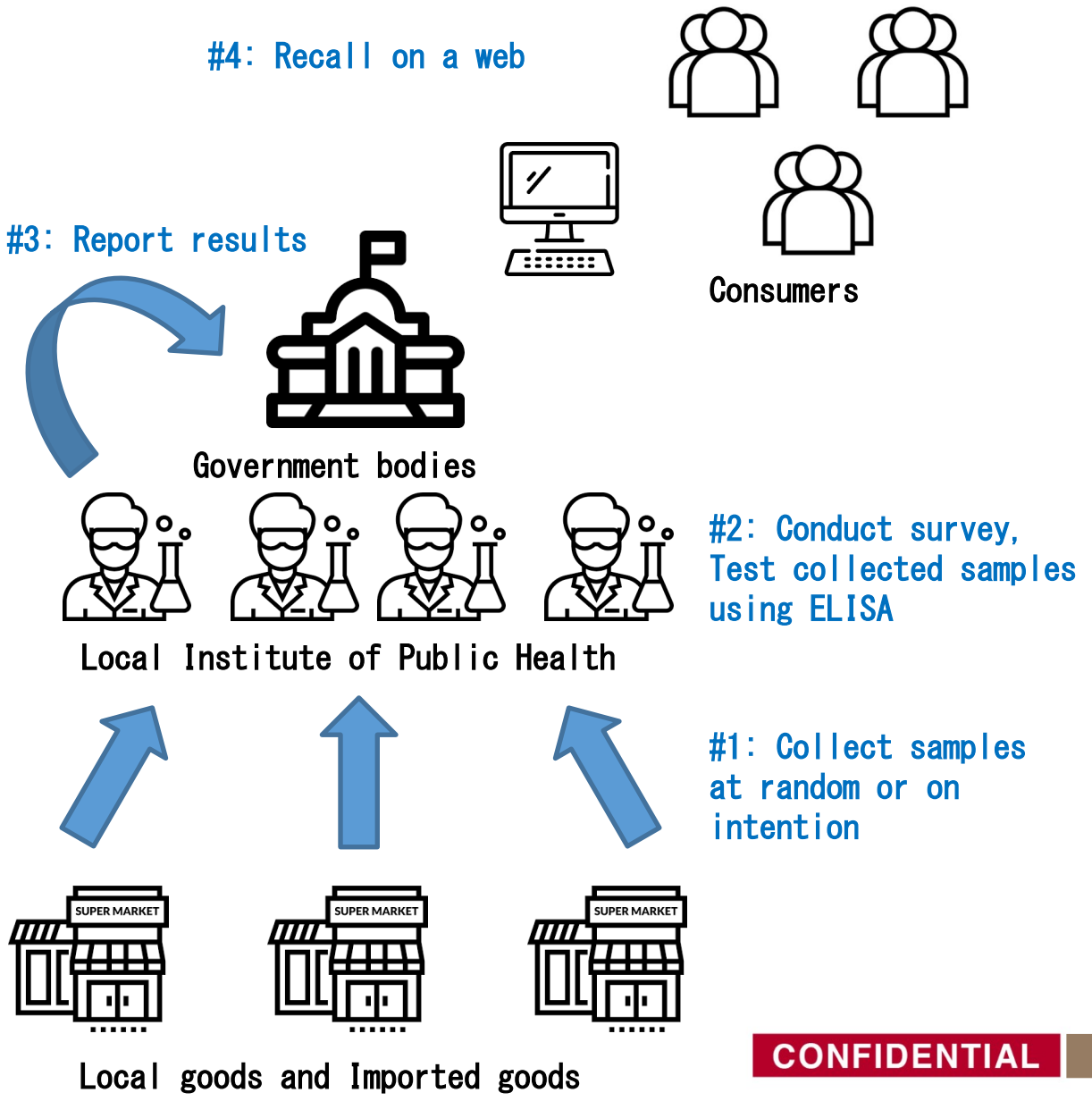
- Specific column for food allergens
- Produced in a facility that also handles XXX allergen

…etc.

How government bodies execute allergen recalls?

Japan

- Government institutes conduct “survey” to check that a labeling of commercial food products is correct.
- They use a food allergen test kit, ELISA, to confirm a contamination level.
- Because, the food allergen labeling regulation in Japan has **a threshold**, which is **10ppm.**
- When they found undeclared allergens with over 10ppm by the test result, the food producer will get penalty and recalled.



Food Allergen Testing Framework by Stage in Japan

In-Site / Self-Testing

- Hygiene & Rapid Monitoring
  -ATP
  -Total protein
- Specific Allergen Screening
  -Lateral Flow

Quantitation / Verification

- ELISA*

Confirmatory Testing

- PCR*
- Western blotting*
- LC-MS/MS*

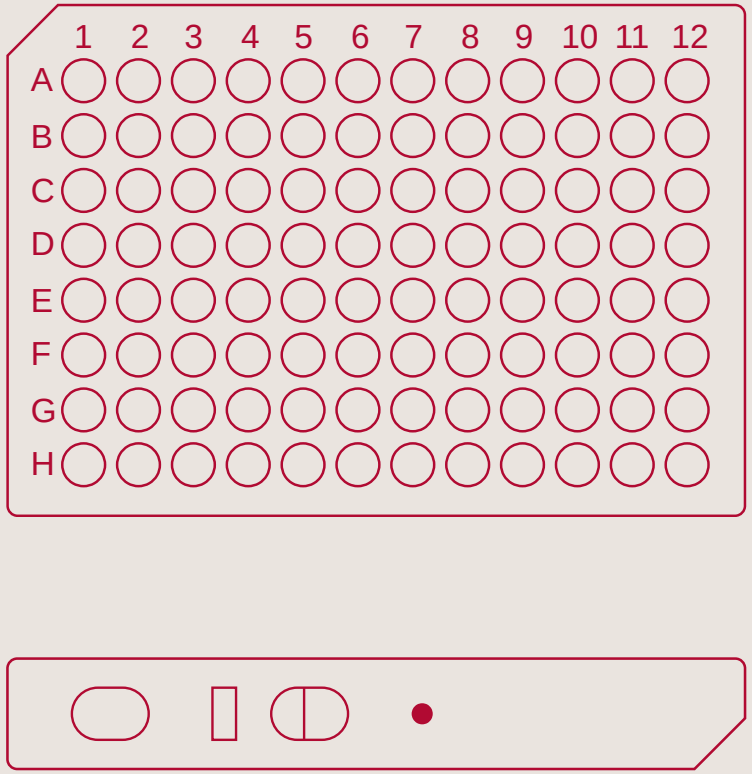
*Japanese official testing method,
But not mandate to public testing
laboratory and food industry.

Japanese official ELISA kit supplier

To harmonize and establish a consistent result, CAA (Consumer Affairs Agency) informed "Local Institutes of Public Health" to conduct survey or investigation using the following two different test kits.
This is not mandate to general testing laboratories and food manufacturers.

Item	Morinaga	NH Foods	Prima Meat Packers	Shimadzu Diagnostics
Egg	○	○	○	N.A.
Milk	○	○	○	N.A.
Wheat	○	○	○	N.A.
Buckwheat	○	○	○	N.A.
Peanut	○	○	○	N.A.
Crustacean	○	N.A.	N.A.	○
Walnut	○	○	N.A.	○
Cashew	○	○	N.A.	○

Only Morinaga available all food allergens.



Morinaga Products

Strength of Morinaga



Government Collaborations: Morinaga BioScience maintains strong connections with international government laboratories, including the US-FDA, CFIA (Canada), CVUA-MEL (Germany), and the Japanese National Institutes of Health.



Minimizing False Negatives: A core focus of the "Morinaga ELISA" and "Rapid Test Pro II" is a unique approach to allergen testing designed specifically to minimize "false negative" results. In addition to this, our gluten ELISA kit (M2103) has the AOAC PTM approval.



Alignment with Global Standards: In response to trends in FSSC, ISO, and BRC, we provide the "Rapid Test Easy" line for more practical and straightforward testing.

Morinaga Unique Approach

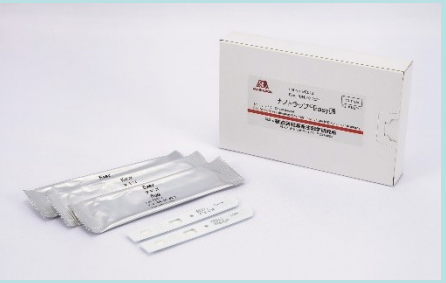
Native and Denatured Protein Detection, patented technology
Morinaga ELISA and Rapid Test Pro II

- The "Morinaga ELISA" and "Rapid Test Pro II" utilize a patented extraction method and original antibodies to solubilize and detect both native and denatured proteins, which is critical for reducing false negative reactions..

Environmental Monitoring
Rapid Test Easy

- The "Rapid Test Easy" concept is built for reliable, quick surface testing. It targets "solubilized" or "free-proteins" on manufacturing line surfaces or in rinse water to prevent cross-contact.

Morinaga Food Allergen Test Kits Series

	Food Allergen ELISA Kit Ⅱ	Rapid Test ProⅡ	Rapid Test Easy
Product			
Format	ELISA	Lateral flow	Lateral flow
Category	Quantitative	Qualitative	Qualitative
Target sample	Foods and swab	Foods, rinse water, and swab	Rinse water and swab solution
Sample Extraction	Overnight extraction/ 10min boiling extraction	10min boiling extraction (with the ready-to-use extraction buffer)	No need
Assay time	1 hour 50 min	15 min	10 min
Necessary equipment	Plate reader… etc.	Boiling water bath for sample extraction… etc.	None
Handling	By trained personnel	Easier	The easiest

High accuracy

Easy handling

Morinaga Food Allergen ELISA Ⅱ

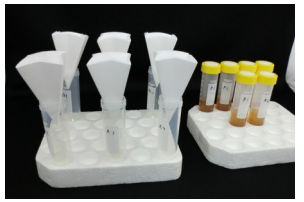
- Egg, M2111
- Beta-lactoglobulin, M2112
- Casein, M2113
- Wheat/Gluten, M2114
- Buckwheat, M2115
- Peanut, M2116
- Soya, M2117
- Crustacean, M2118
- Hazelnut, M2119
- High Sensitive Peanut, M2120
- Sesame, M2121
- Total Milk, M2122
- Almond, M2123
- Walnut, M2124
- Cashew New
- Mustard coming in 2027



**Same extraction buffer,
Same extraction procedure,
and Simply reliable.**

Overview

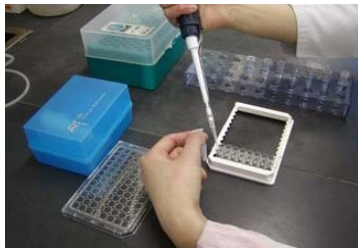


◆Sample – Extract Preparation (Grind, Extract, Centrifuge, Filtrate)

◆Dilution examples for Calibration Curve

Add diluted standard solution or sample (100µL/well)

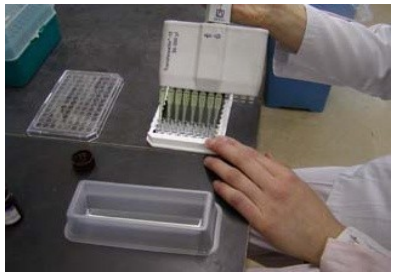


Reaction for 1h

Wash



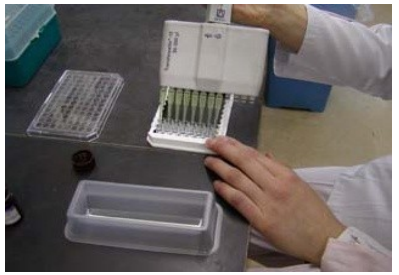
Add enzyme conjugated antibody (100µL/well)



Reaction for 30 min

Wash



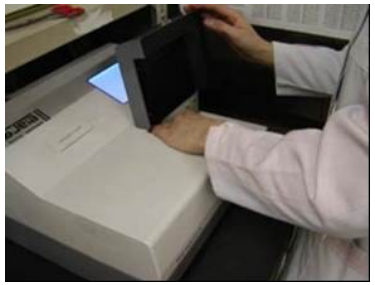


Add chromogenic substrate (100µL/well) and react for 20 min



Solution to stop the reaction (100µL/well)





Read the optical densities at 450nm/600-650nm

Morinaga LFDs:

Rapid Test Easy: Test for swab and rinse water

Rapid Test ProⅡ: Test for food samples *(can test swab & rinse water)



Rapid Test Easy



Rapid Test ProⅡ

Principle of Morinaga LFDs

Test Solution → 10 ~ 15 min → Result

Positive

Negative



Interpretation

Test window

- Red or black line indicates **POSITIVE** sample.
- No line indicates **NEGATIVE** sample.

Confirmation window

- Color window: **VALID** test
- No color: **INVALID** test (Repeat the test with a new stick).

Morinaga LFDs: Rapid Test Pro Ⅱ

Limit of detection	5 ppm (μg protein/g of food) 1 ppm highly sensitive method is available for egg, milk, wheat.
Sample preparation time	Approx. 30 min.
Assay time	15 min.
Expiration date *from the date manufactured*	24 months
Storage temperature	2-8 ℃ （35-46℉）
Other features （Extraction buffer）	・ Same composition as one of our ELISA KitⅡ ・ Patented EP 2224239 (AT, BE, DE, ES, FR, GB, IT, NL, CH)

Can test food, rinse water, and swab sample
Easier handling and lower cost than ELISA



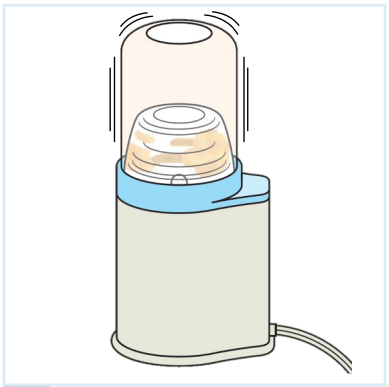


Item line up

- Egg (Cat.# M2261)
- Total Milk (Cat.# M2269)
- Gluten (Cat.# M2263)
- Buckwheat (Cat.# M2264)
- Peanut (Cat.# M2265)
- Soya (Cat.# M2266)
- Crustacean (Cat.# M2267)
- Walnut (Cat.# M2268)
- Shellfish (Cat.# M2270)
- Cashew (Cat.# M2260) Available.

Morinaga LFDs: Rapid Test

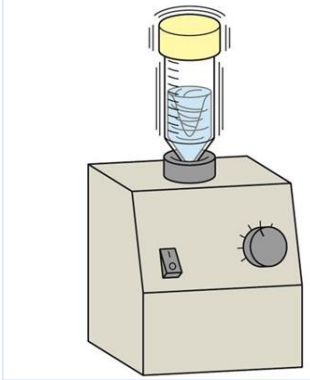
Pro II



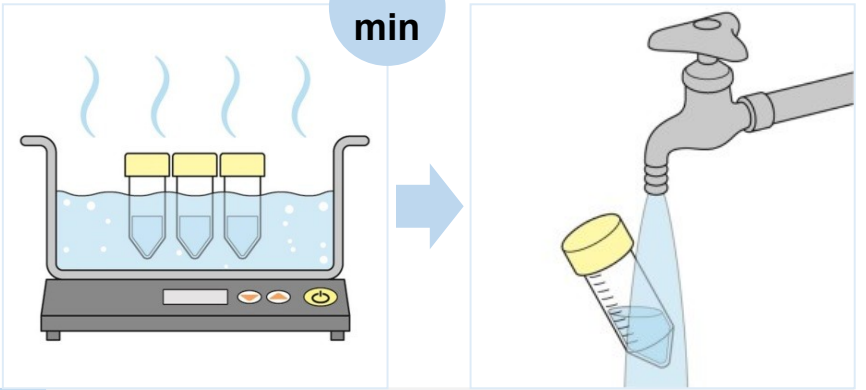
1 Sample Homogenization



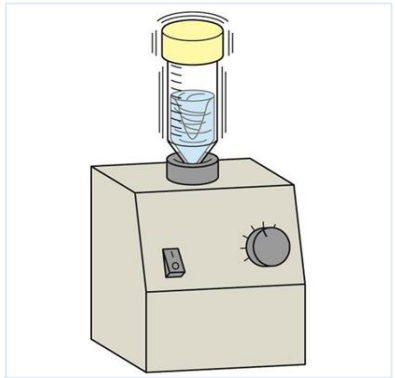
2 Sample Extraction Solution + 1g of sample. Mix



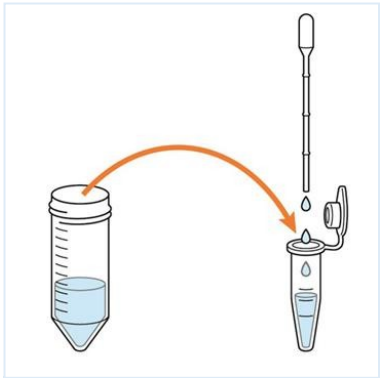
3 Vortex (30 sec.)



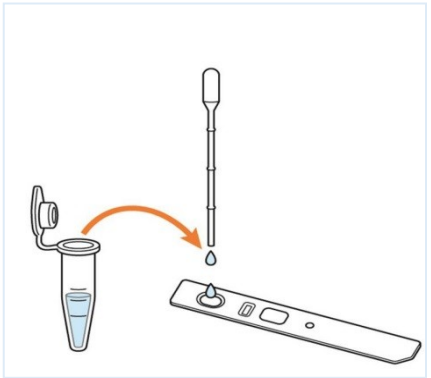
4 Incubate in a boiling water and cool it down (This step can be skipped in Simplified method)



5 Vortex (30 sec.)



6 Dilute 10-fold with Dilution buffer



7 Apply sample solution and Judge the result

Please watch procedure movies

Morinaga LFDs: Rapid Test Easy

Limit of detection	0.5 ppm (μg protein/mL of test solution)
Assay time	10 min.
Expiration date *from the date manufactured*	24 months
Storage temperature	2-30 ℃ （35-86℉）
Other features	・Easier handling and lower cost than ELISA ・Just 1 step procedure

Focus on swab and rinse water sample.

The easiest handling in our product line.





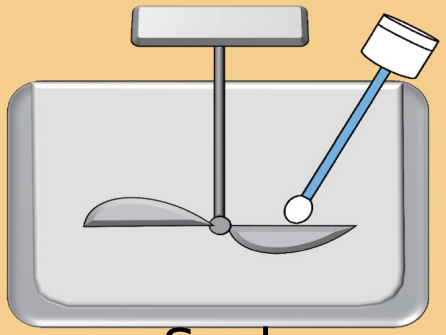
Item line up

- Egg (Cat.# M2241)
- Casein (Cat.# M2242)
- Gluten (Cat.# M2243)
- Buckwheat (Cat.# M2244)
- Peanut (Cat.# M2245)
- Soya (Cat.# M2246)
- Crustacean (Cat.# M2247)
- Sesame (Cat.# M2248)
- Mustard (Cat.# M2249)

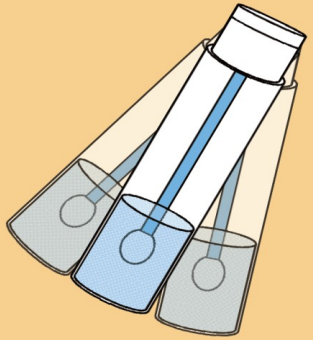
Rapid Test Easy: Test procedure

Please watch procedure movies

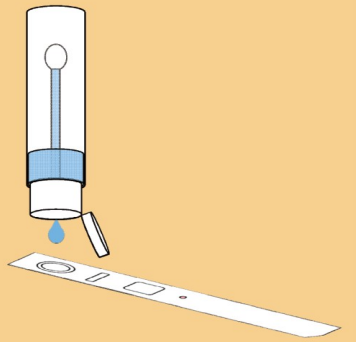
For Swab test sample



Swab the specified area

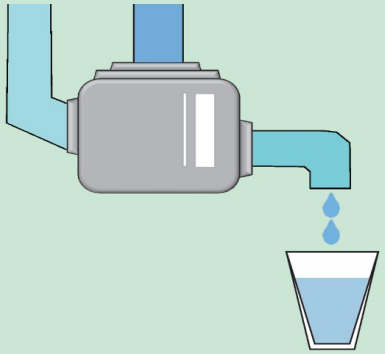


Shake

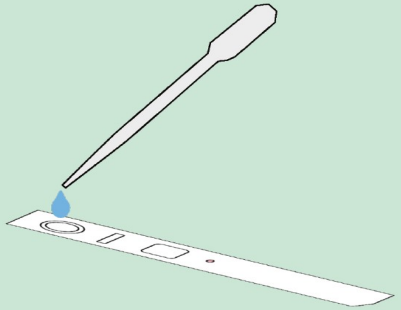


Add 200µL (4 drops) to test stick

For Rinse water sample



Collect rinse water

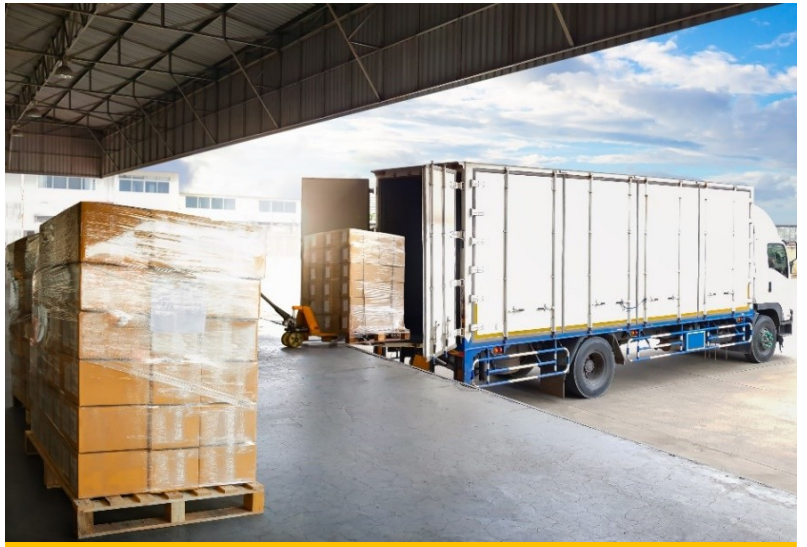


Add 200µL to test stick



Just 10 min.

How to choose Morinaga Products

Incoming goods	Processing	Shipment
		
Detecting contamination in raw materials	Monitor the cleaning process and cross-contamination	Detecting contamination in finished products
Rapid Test Pro Ⅱ ELISA	Rapid Test Easy Rapid Test Pro Ⅱ ELISA	Rapid Test Pro Ⅱ ELISA

Support Items for Food Safety

Instant Swab Total Protein, Cat.# M2401

Limit of detection	10 µg (BSA base)
Assay time	In seconds
Expiration date *from the date manufactured*	2 years
Other features	・ 50 tests / pack ・ Storage 4－25˚C (39－77˚F)

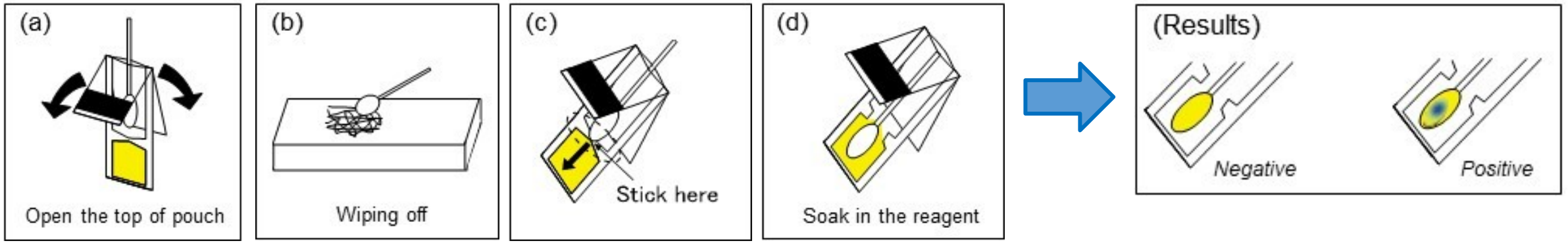


To confirm cleanliness on surface of food production lines.

Instant Swab Total Protein: Technical note

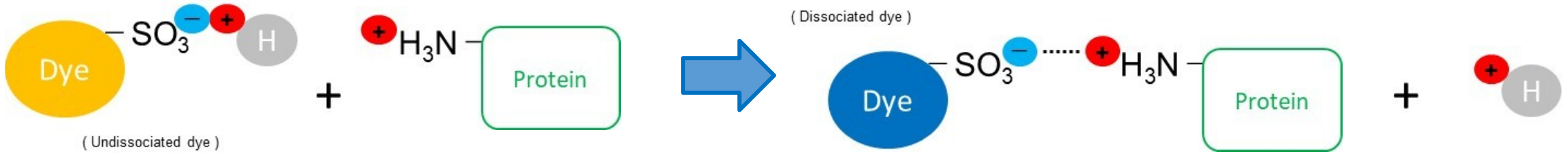
＜Test Procedure＞

Swab surface ⇒ Soak in the reagent ⇒ Immediately, interpret the result



＜Principle＞

Due to interaction between the dye and proteins,
the color change (yellow to blue-green) can be confirmed.



Sulfite Test Strip, upcoming in early 2027

Intended use	Quick detection of sulfite ion in rinse water or swab
Package	100 strips/bottle
Test procedure	Dip the test strip into the solution for 10sec, after that check a result immediately.
Test result	0 ppm 10 ppm
Expiration date *from the date manufactured*	2 years
Other features	Store in a cool, dry place away from direct sunlight.



To confirm sulfite residues on surface or in rinse water of food production lines.

Swab Kit, Cat.# M2402

Intended use	Sampling
Package	10 bottles/box (swab + 10 mL of PBS)
Expiration date *from the date manufactured*	3 years
Other features	Storage 2－30˚C (35－86˚F)



To confirm cleanliness on surface of food production lines.

Q&A session

CONTACT INFORMATION





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Hanoi, Vietnam

37 HT25 Str., Tan Thoi Hiep Ward,
Ho Chi Minh City, Vietnam

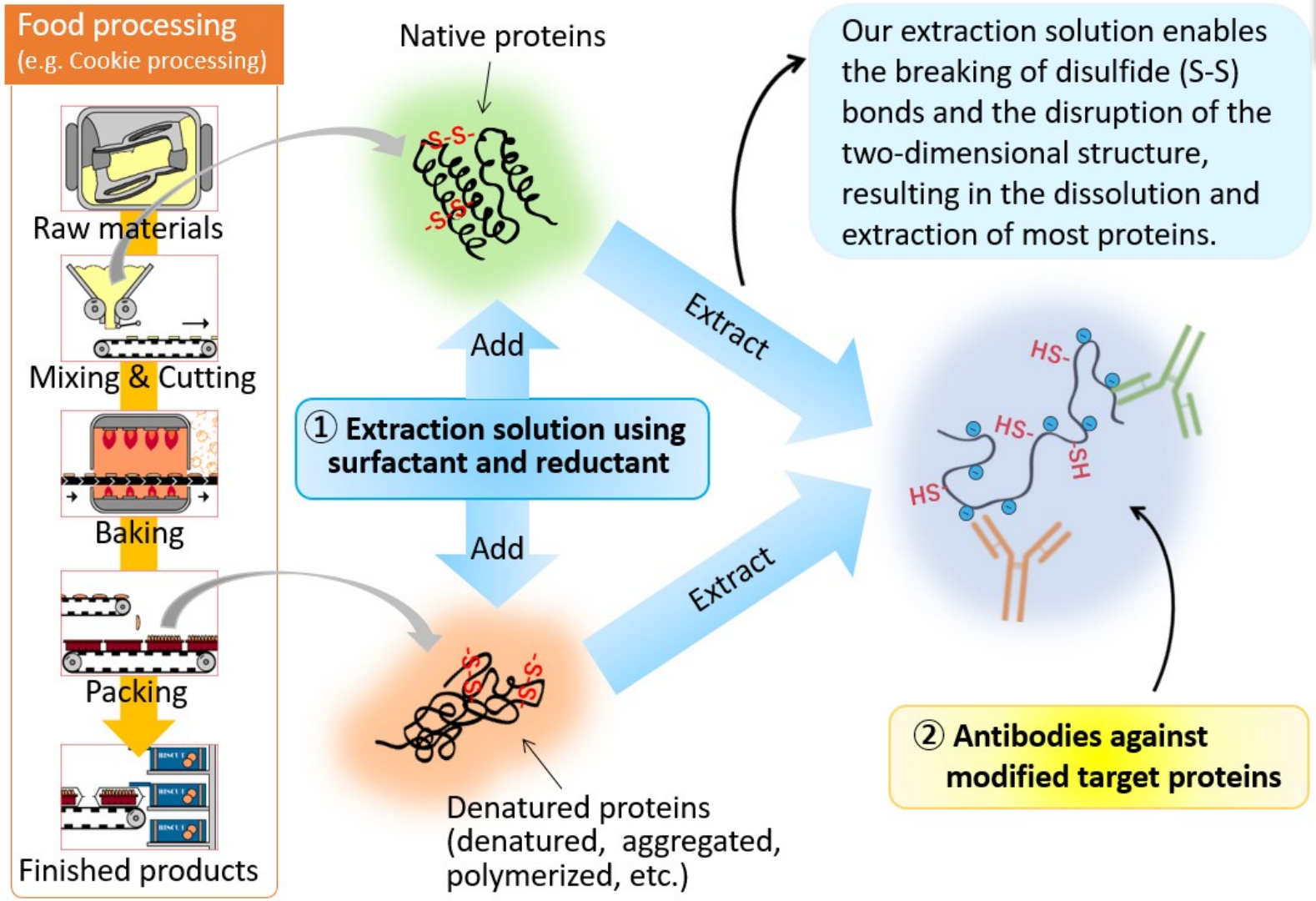
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https://yamaguchi.vn/

Fin.

Morinaga Unique Technology



Key Notes

- In general approach, most commercial test kits focus on either native or denatured proteins, rather than both protein types.
- Our extraction buffer, which contains both a surfactant and reducing agent, enables the solubilization of both native and denatured (or insoluble) proteins.
- In addition to the extraction buffer, our proprietary antibody is essential for the detection of solubilized proteins.
- The extraction buffer is protected under patent EU.PAT.2224239. US.PAT.8859212, AU.PAT.2008330507

Principle of Morinaga LFDs

