



# System of National Assay

National Veterinary Assay Laboratory, MAFF

The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics

Article 43.1

**The Pharmaceuticals designated by the Minister shall be assayed**



**by the person designated by the Minister.**

**Biological products  
(Vaccines, sera and  
diagnostics for infectious  
disease important for  
animal disease)**

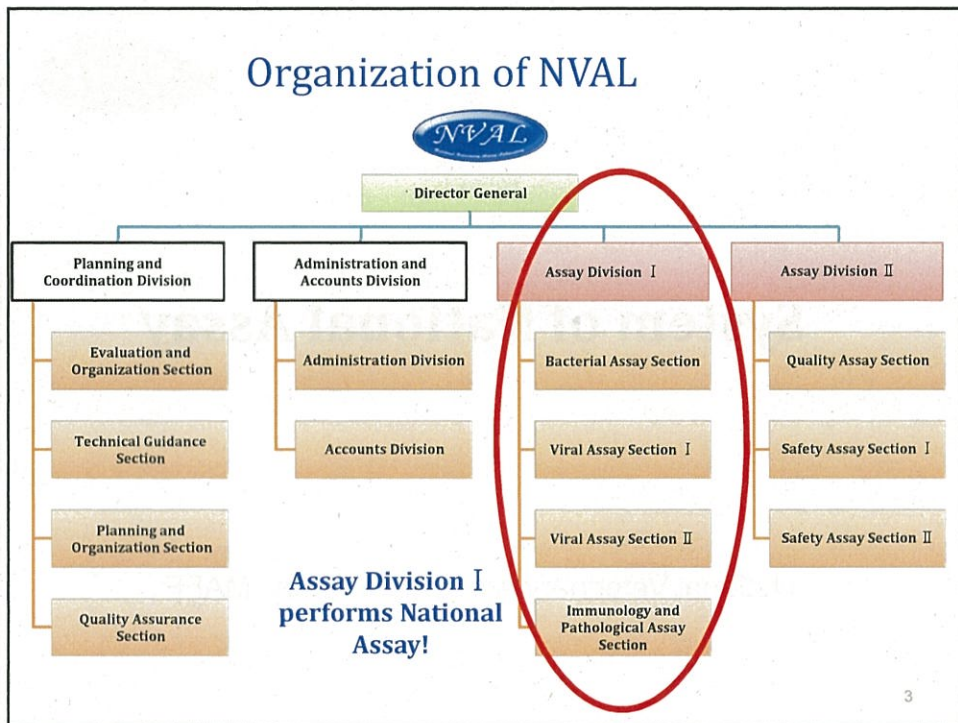


Ministerial ordinance (No. 107)

**That is to say.....**

**Veterinary biologics cannot distribute or sell unless pass the assay of NVAL.**

## Organization of NVAL



## National Assay of Veterinary Biological Products

**Target:** All kinds of vaccines except for a part of vaccines produced by seed-lot system

All kinds of sera

Diagnostics for infectious disease important for animal disease

**Charge:**

Assay fee (Notification of MAFF)



freeze-dried live vaccine

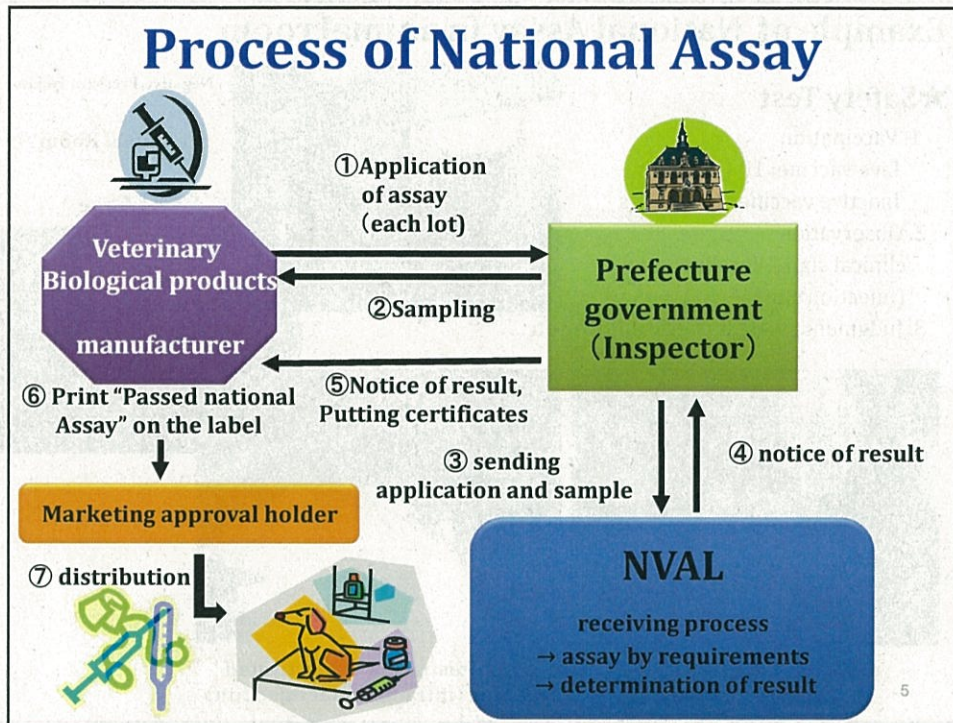


Liquid inactivated vaccine



Diagnostics

## Process of National Assay



## National Assay of Veterinary Biological Products

Method: Assay standards (Notification of MAFF)

Examples of test items for filling product;

- ND live vaccine
  - ① Mycoplasma test
  - ② Salmonella test
  - ③ Miscellaneous bacteria detection test
  - ④ Extraneous virus test
  - ⑤ Virus content test
  - ⑥ Marker test
  - ⑦ Safety test
- ND inactivated vaccine
  - ① Sterility test
  - ② Safety test
  - ③ Potency (protection) test



## Example of National Assay in animal room

### ★ Safety Test

1. Vaccination  
Live vaccine; 10 (5) doses  
Inactive vaccine; 1~2 doses
2. Observation  
clinical sign & local reaction  
(injection site)
3. Judgment ; weight check, autopsy etc...



← Negative Pressure Isolator

Animal Room

↓ Cage



Administration of live vaccine (eye drop)



Administration of inactivated vaccine (intramuscular injection)

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## Example of National Assay in Laboratory

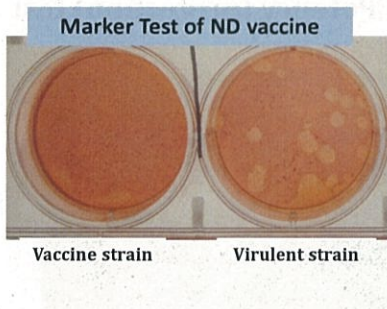
### ★ Extraneous Virus Test

CK cell culture (CPE, HAD)

### ★ Marker Test

Plaque formation of ND vaccine strain

Pock formation on CAM of ILT vaccine strain



Vaccine strain

Virulent strain

### ★ Potency Test (Serological Test)

Serum Neutralization (Eggs, Cells),

Haemagglutination Inhibition (HI) Test, ELISA etc



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## Result of National Assay of Veterinary Biological Products

Fiscal year*	2011	2012	2013	2014	2015
Number of sera (Rejected number)	1 (0)	1 (0)	4 (0)	0 (0)	1 (0)
Number of vaccines (Rejected number)	452 (4)	365 (1)	324 (2)	291 (0)	298 (2)
Number of diagnostics (Rejected number)	69 (0)	68 (0)	59 (0)	61 (0)	57 (0)
Total number (Rejected number)	522 (4)	434 (1)	384 (2)	352 (0)	356 (2)
Canceled number	1	1	0	1	0

\* ; The fiscal year begins on April 1 and ends on March 31 of the next year.

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### Question & Answer about national assay

In Japan, when a manufacturer submits a vaccine for inspection, do they need to provide their own examination methods and results for NVAL.

→ Marketing approval holder have to provide the results of their own examination for NVAL.

And, what is their reference for testing? Is it based on national inspecting standards or their own methods?

→ Marketing approval holder have to examine by the methods approved by MAFF. National assay standard established on the basis of their methods.

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What will you do if animal vaccines, general drugs and herbal medicine failed to pass from inspection in NVAL?

→ Veterinary biological products cannot distribute or sell unless pass the national assay. Biological products rejected by the assay are discarded under the observation of prefectural pharmaceutical inspector.

To ensure the quality of the veterinary medicinal products at the stages of manufacturing and distribution, sampling tests are conducted on biological products, general pharmaceuticals including herbal medicine and antibiotics that are not the target of national assay. Veterinary medicinal products rejected by the sampling test are recalled and discarded under the observation of prefectural pharmaceutical inspector.

**Thank you for your attention very much!**