

Safety testing: from development to implementation and regulatory acceptance

TABST/LABST waiver... and more in veterinary vaccines



December 2-4 2025

Bangkok, Thailand

Animal testing replacement for vaccines. A One Health View: global outlook and future strategy.

Laure MARTINEZ




Health for Animals
global animal health association

Who is HealthforAnimals?



The voice of the animal health industry globally and an advocate for the fundamental role of healthy animals



Improving global wellbeing, sustainability and prosperity.

Manufacturers of



- veterinary pharmaceuticals
- veterinary vaccines
- other animal health products (incl. diagnostics)

28 national and regional **Associations** that represent companies at national and regional level in **40 Countries**



It represents **90%** of the global animal health sector.



10 Largest Animal Health Companies (**100+** Countries)

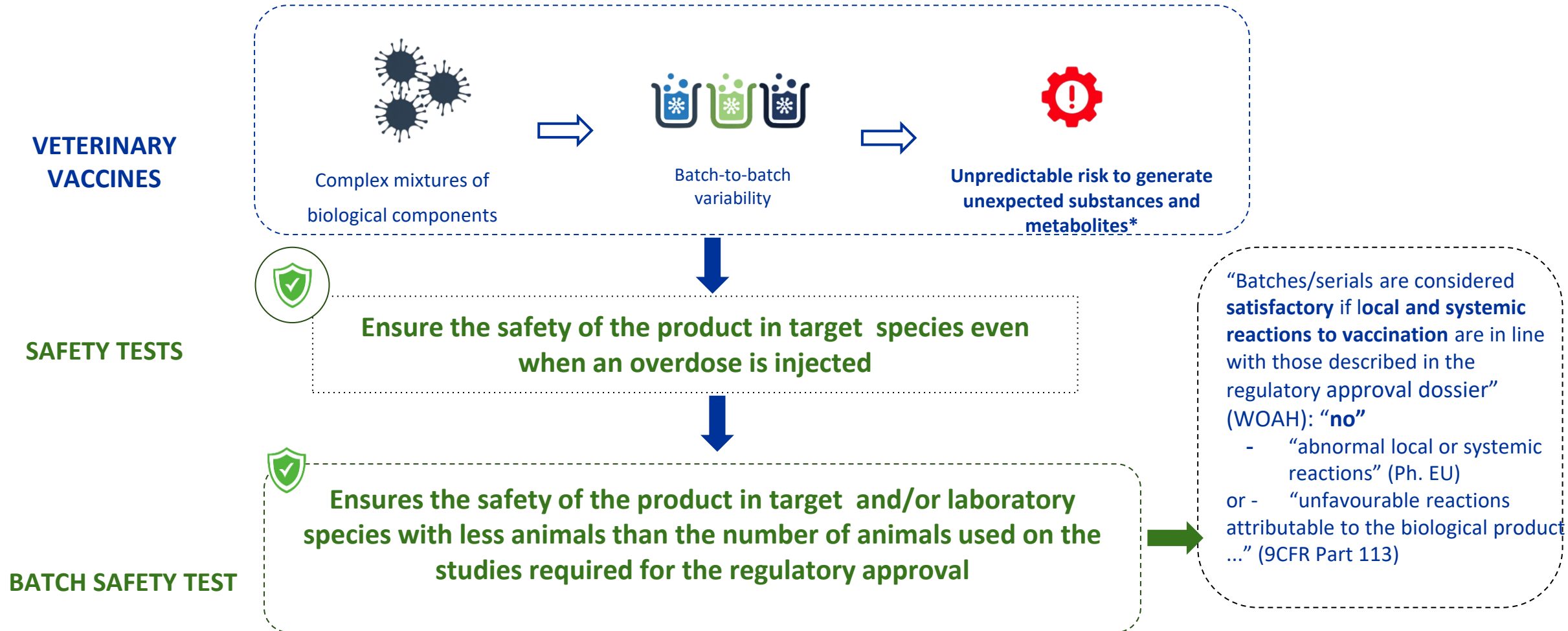


Agenda

- **Why do TABST/LABST exist?**
- **Examples of TABST/LABST in regulation**
- **The global momentum toward reduced animal experimentation**
- **Enabling factors for reduction**
- **International harmonization (VICH guidelines/WOAH chapters)**
- **Global status of TABST/LABST deletion**
- **Conclusion and future outlook**



Why do TABST¹/LABST² exist?



Examples of TABST/LABST in regulations



([version](#) adopted May 2022) → CHAPTER 1.1.8. PRINCIPLES OF VETERINARY VACCINE PRODUCTION → 2.2. Batch/serial safety test

“Some regulatory authorities still require safety tests for the release of each batch/serial and typical tests are described in CFR Title 9 part 113, in this Terrestrial manual and elsewhere”.

“Some authorities **do not permit batch/serial safety testing in laboratory animals**, requiring a test in one of the **target species** for the product”.

Ph. EU no longer requires a batch safety test in target animal species for vaccine release nor a general safety test in mice or guinea pigs



Title 9 CFR Part 113

D1

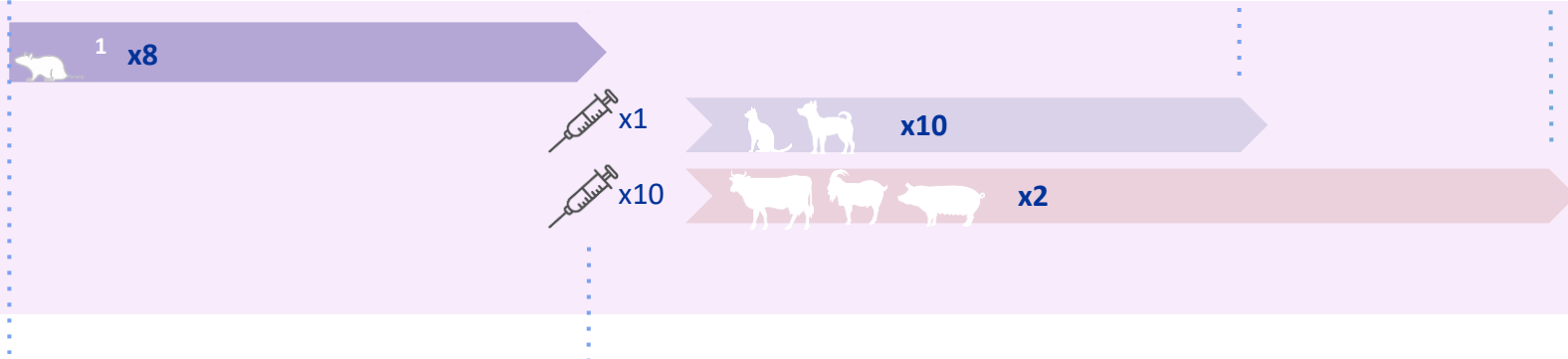
LABST

D7/T0

TABST

T14

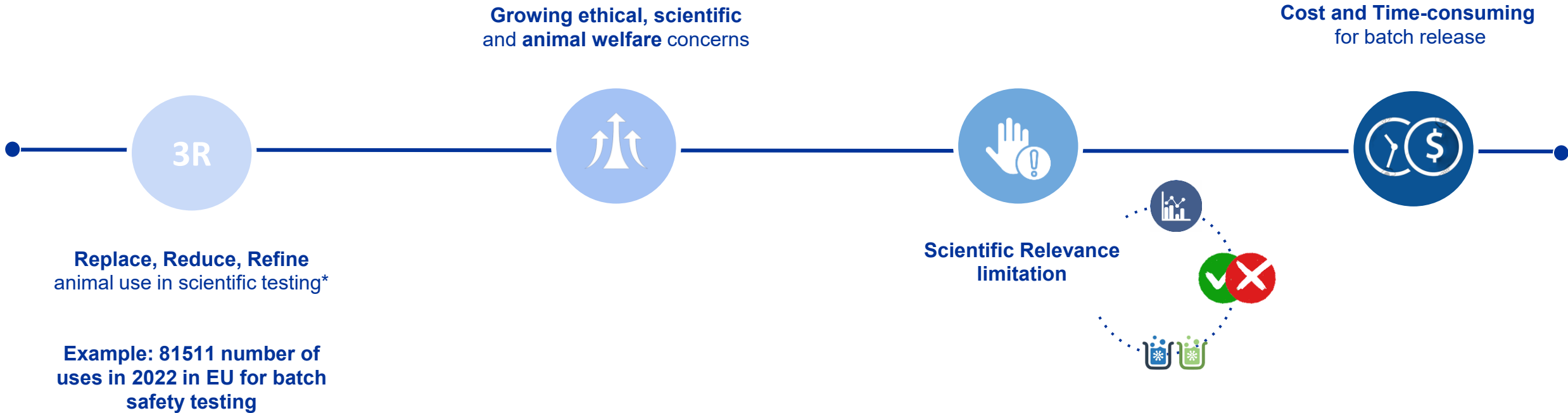
T21



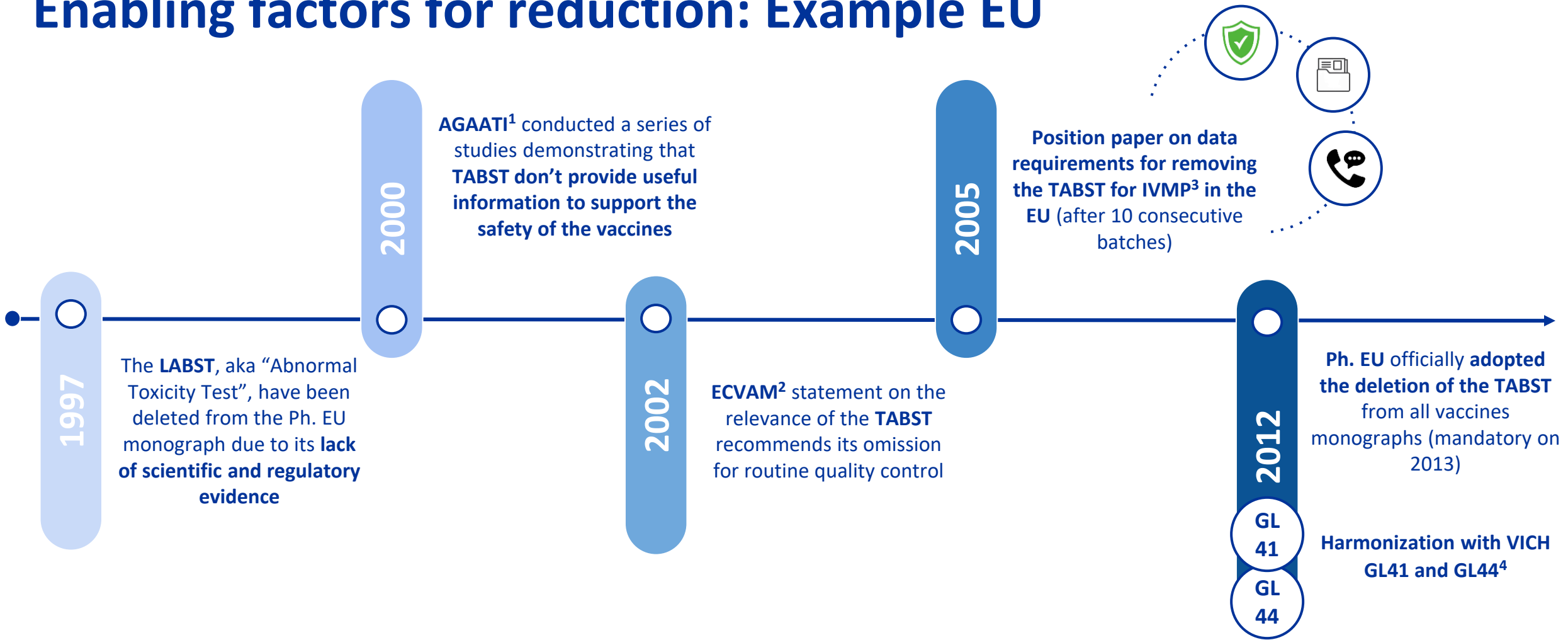
LIVE VIRAL VACCINE



The global momentum toward reduced animal experimentation



Enabling factors for reduction: Example EU



Enabling factors for reduction: Example EU

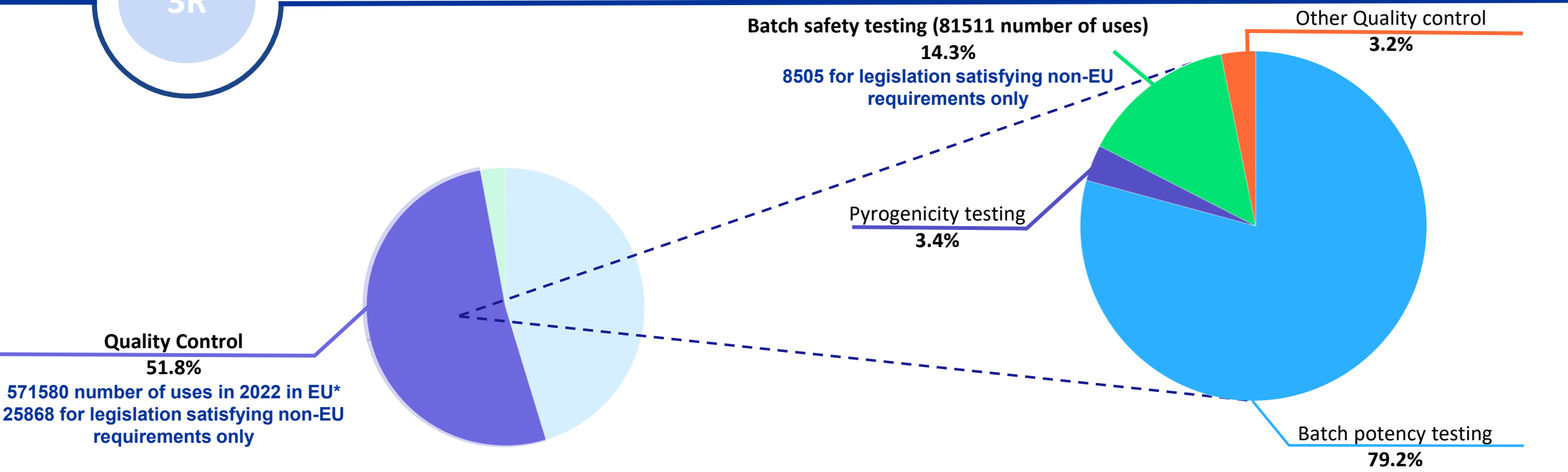
3R

1103612 number of regulatory uses in 2022 in EU*

2015

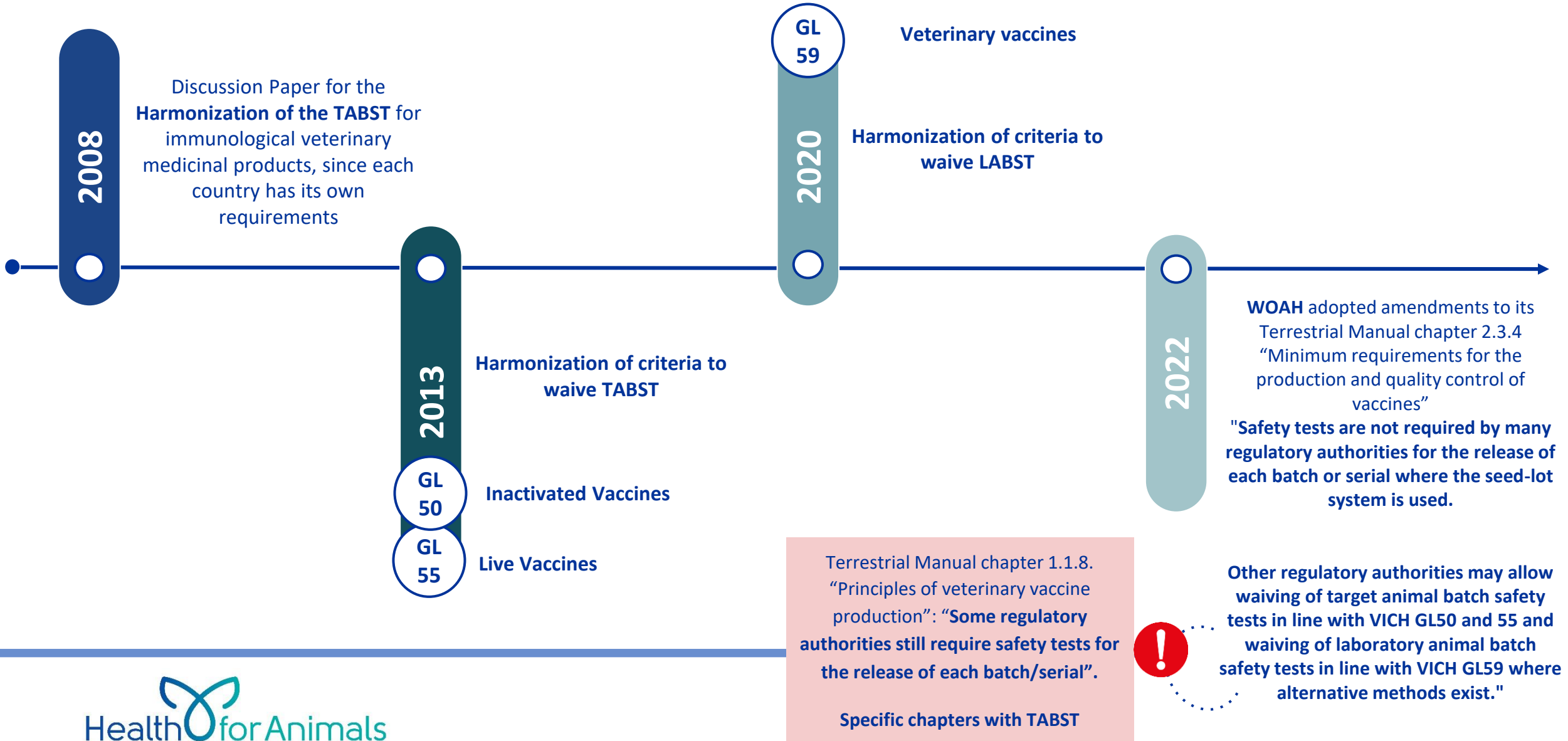
Regulatory uses: Quality control	Number of uses	Percentage
Batch potency testing	1032235	77.46%
Batch safety testing	228817	17.17%
Other quality controls	24931	1.87%
Pyrogenicity testing	46553	3.49%
Total	1332536	100,00%

45001 for legislation satisfying non-EU requirements only

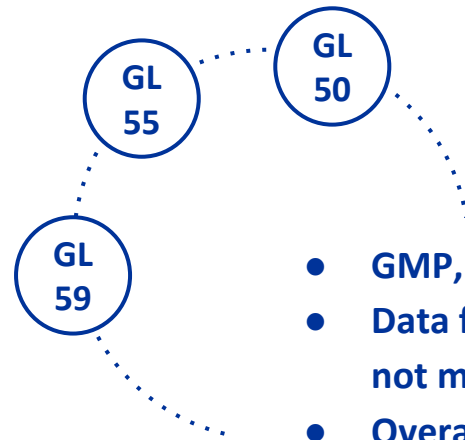


*Database EU ALURES

International harmonization (VICH guidelines/WOAH chapters)



International harmonization (VICH guidelines/WOAH chapters)



Key Requirements

- GMP, Seed lot system
- Data from 10 consecutive batches (or minimum 5 if 10 not manufactured in 3 years)
- Overall assessment of the product safety consistency
- Pharmacovigilance system and data



“In general, it is sufficient to evaluate existing information which is available from routine batch quality control and pharmacovigilance data, without the need for any additional supplementary studies”

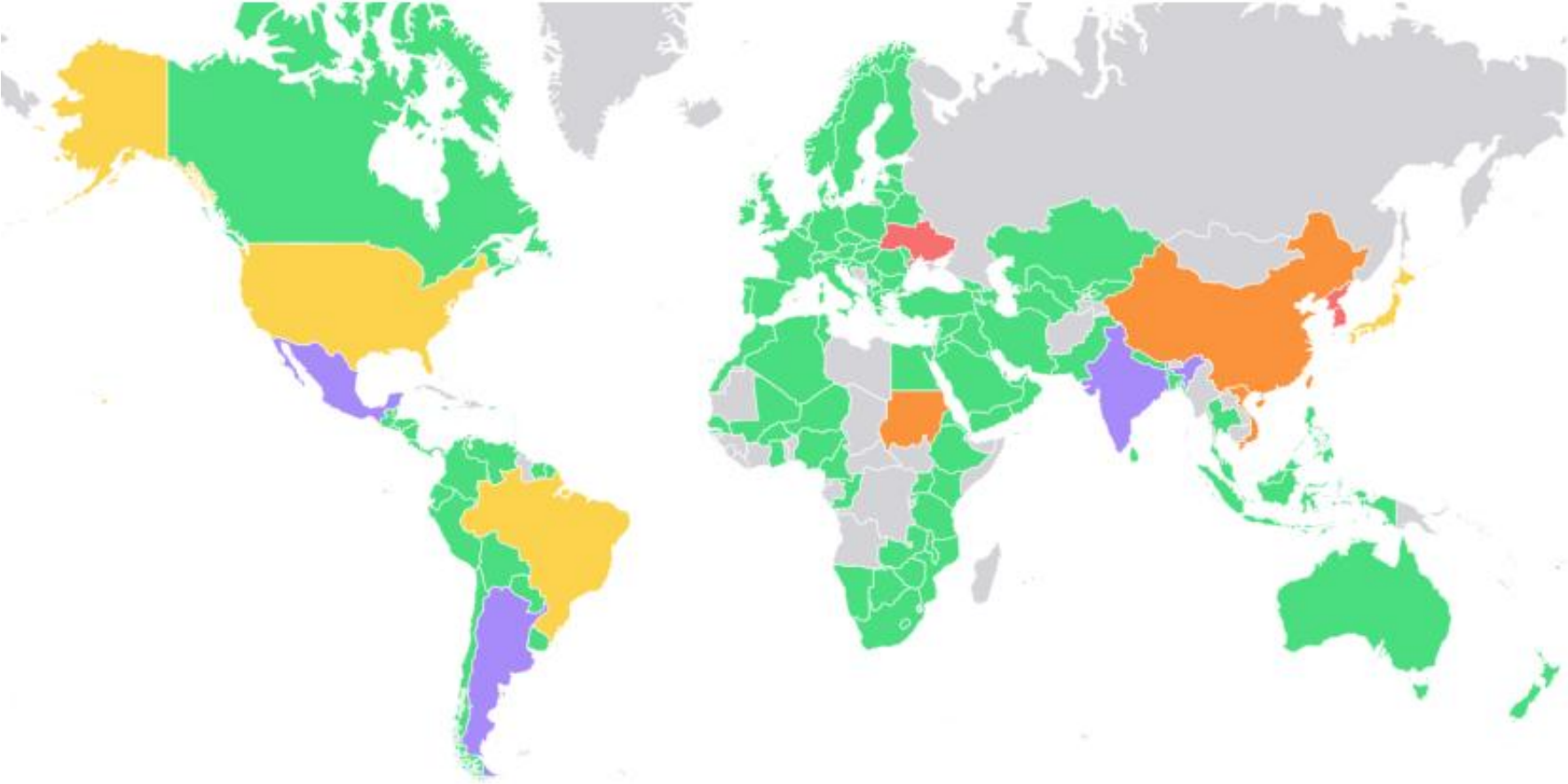
⇒ Challenges for old products:



OBSTACLE

Non-uniform regulatory environments ⇒ additional testing, costs and delays and administrative burden

Global status of TABST/LABST deletion (waiver registered/commercialized products)



Global status of TABST/LABST deletion (waiver registered/commercialized products)



Global status of TABST/LABST deletion



South Korea, Health Authority: APQA (Animal and Plant Quarantine Agency)



VICH GL 50, 55 and 59 not yet implemented in KR.

Routine Batch Testing: Release Tests

TABST and LABST are mandatory. APQA tests LABST only (manufacturer shall test TABST locally).

If a batch passes KR National Bios testing 10 consecutive times → exemption can be provided

TABST exemption will be discussed after 2027

LABST are exempted under the premise that TABST are performed

Product Approval – Dossier requirements

TABST are mandatory, while LABST are optional

If the applicant's dossier **doesn't have TABST or LABST data**, the KR affiliate may include both in the local clinical trial and submits those results as part of the local dossier

Live Vaccines will require TABST (using MS or WS¹)

LABST will be unnecessary

TODAY

SLS²

Global status of TABST/LABST deletion



Taiwan, Health Authority: APHIA (Animal and Plant Health Inspection Agency)



VICH GL 50, 55 and 59 not yet implemented in TW so no waiver possible. Authorities always perform TABST and/or LABST depending on the National Assay requirements.

Until now, all vaccines in National Standard Assays include at least LABST. Vaccines **could be submitted without TABST and or LABST with convincing document** (e.g. safety data, VICH, EU guidelines).

The authority will set the National Standard Assays based on the submitted specification that will be mandatory for each release. TABST/LABST could be exempted **or performed by the Authorities (at least LABST)**

Ongoing discussion by Taiwan authorities → 3R strategy



Global status of TABST/LABST deletion



Vietnam, Health Authority: DAH (Department of Animal Health)



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VICH GL 50, 55 and 59 not yet implemented in VN

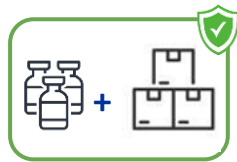


”

Testing on target animals aligns with WOAH guidance for evaluating vaccine safety and efficacy under a specific country's local conditions

Routine Batch Testing: Release Tests

- Local QC with TABST for each imported shipment



2 years

WAIVER

- Re-evaluation to be performed for this QC waiver after exemption letter expires

Product Approval - Dossier Requirements

Vaccines can be submitted without **TABST** or **LABST** in registration dossier.

- Local quality control test in lab conditions including safety and efficacy tests (TABST and/or LABST) conducted by the National Authority labs in VN.

Global status of TABST/LABST deletion



India, Health Authority: CDSCO (Central Drugs Standard Control Organisation)

○ 2024

VICH GL 50, 55 and 59 not implemented but Pharmacopoeia addendum 2024 introduced TABST waiving requirements

Routine Batch Testing: Release Tests

- **IP¹* Veterinary vaccines general requirements “Batch tests: safety”**
 - Safety test satisfactory on master seed lot
 - Consistency of manufacturing process
 - 10 consecutive batches comply
- **NO blanket waiver: decisions are made on a case-by-case basis**

Product Approval - Dossier Requirements

- Registration with TABST/LABST ⇒ impact on development (include in stability studies)

Global status of TABST/LABST deletion



Mexico, Argentina



?

VICH GL 50, 55 and 59 not yet implemented in MX

Routine Batch Testing: Release Tests

Latest experiences: follow VICH principles for waiving.

Product Approval - Dossier Requirements

- **3R is a basis and manufacturers do not seem to need to include additional safety tests.**
- Constataion test in MX is performed by national authorities before registration of a product and include safety tests but at the discretion of the authority.
 - **Argentina: waiting for a new decree.**

Global status of TABST/LABST deletion



Japan, Health Authority: JMAFF (Japanese Ministry of Agriculture, Forestry and Fisheries) NVAL (National Veterinary Assay Laboratory)

○ 2013-18-21

GL
50

GL
55

GL
59

Routine Batch Testing: Release Tests

Additional requirements to VICH

- Batch records with specifications JP and controls conform to JP



Limited scope

- “For certain types of vaccines related to vaccine-specific safety aspects, other tests using laboratory animals may exist”

Product Approval - Dossier Requirements

Registration with TABST/LABST ⇒ impact on development (include in stability studies)

Global status of TABST/LABST deletion



US, Health Authority: USDA (United States Department of Agriculture)

○ 2017-25

GL
50

GL
55

GL
59

Veterinary Services Memorandum (VSM) No. 800.116 (Target Animal Safety Testing Exemption) updated for incorporation of GL59 and released in 2025

Routine Batch Testing: Release Tests

Additional requirements to VICH

- Updates of outlines of production (maximum antigen content, inactivation kinetics and control,..)
- Requirement for batches from at least 3 consecutive antigen bulks for each antigen, sterility tests results,..
- Pivotal field study results summarized and published
- Administrative summary of product history
- Justify age ranges used in TABST

Product Approval - Dossier Requirements

- Registration with TABST/LABST following **Title 9 part 113 requirements**

Global status of TABST/LABST deletion



Brazil, Health Authority: MAPA (Ministry of Agriculture, Livestock and Food Supply)

○ 2022

GL
50

GL
55

GL
59

Ordinance SDA No. 560/2022 officially allowing the exemption of animal batch safety testing

Routine Batch Testing: Release Tests

Additional requirements to VICH

- During assessments: requirements of consecutive batches where the TABST/LABST are still performed

Product Approval - Dossier Requirements

- Brazilian law requires initial registration with TABST/LABST ⇒ impact on development (include in stability studies)

Conclusion and future outlook



Thank you for your attention!

