

Target Animal Batch Safety Test (TABST)

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Definitions

What is it?

When is it used ?

TABST

Target Animal Batch Safety Test

Performed as a routine final product batch test on target species for all inactivated and/or live veterinary vaccines

LABST

Laboratory Animal Batch Safety Test

Performed as a routine final product batch test on lab. species for veterinary vaccines, in regions where it is required.

ATT

Abnormal Toxicity Test

Performed to ensure the safe and consistent production of serum products

Why is it a problem?

− Animal Batch Safety Test

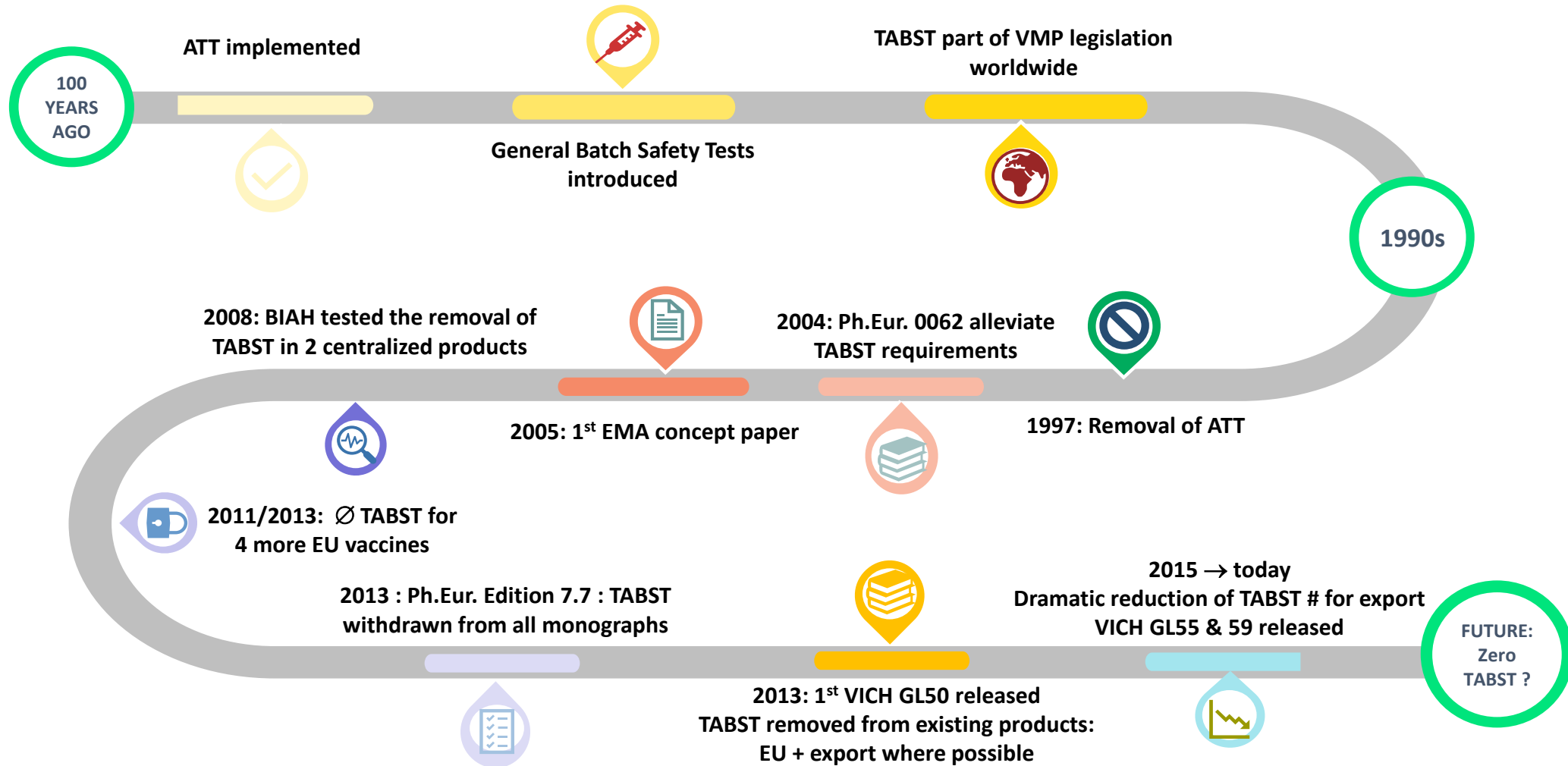
- Use lots of animals
- Scientific relevance ?
- Failed to detect problematic batches
- Lack of specificity
- Lack of reproducibility

+ Quality Control improvements

- Stricter control of starting materials
- Enhancement of Good Manufacturing Practice
- Improved post-marketing pharmacovigilance
- Introduction of more stringent quality control measures

Together, these advancements have led to calls for the **elimination of the TABST and LABST.**

Target Animal Batch Safety Test Removal : EU paved the path



3 related VICH guidelines

Harmonization of criteria to waive target animal batch safety testing for **inactivated vaccines** for veterinary use

- **VICH GL50**
- ✓ May 2013

Harmonization of criteria to waive target animal batch safety **testing for live vaccines** for veterinary use

- **VICH GL55**
- ✓ May 2017

Harmonization of criteria to waive **laboratory animal batch safety testing** for vaccines for veterinary use

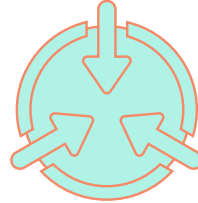
- **VICH GL59**
- ✓ Nov 2020

Overcoming regulatory barriers to a worldwide TABST removal



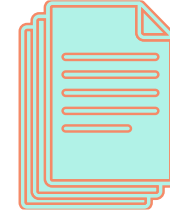
Pre-requisites

- Seed lot system
- Consistency of the production
- Quality GMP(-like) system
- Pharmacovigilance



Fair level playing for all stakeholders

- TABST now forbidden in some manufacturing countries although required in importing ones
- Issue recognition & lack of willingness
- Length of legislative update process & topics prioritisation



Administrative burden

- Compilation of data (min. 10 batches), cost & length of approval process
- Restricted scope (sometimes not all vaccines)

INTERNAL situation

<i>Species</i> →	DOG	CAT	HORSE	LIVESTOCK	AVIAN
% Reduction of TABST betw. 2015 and 2020 EU production site	-44%	-50%	-50%	-53%	-55%

Products manufactured worldwide, tests performed are all for export markets.

TABST run according to EU animal welfare standards

3/4 of the vaccines produced still have a TABST performed, on some batches only however.

Focus on Brazil – TABST/LABST Regulatory Waiver Timeline

Aug–Sep 2021: WC11 discussions (23 Aug – 02 Sep 2021)

- Sessions on the proposed removal of TABST/LABST
- Brazil intervention at WC11

Dec 2021 – Feb 2022: Public consultation (MAPA) (02 Dec 2021 – 01 Feb 2022)

- Consultation on draft Portaria exempting animals from safety tests (TABST/LABST)

07 April 2022: Regulatory adoption

- Signature of Portaria SDA No. 560 (final text)

08 April 2022: Official publication

- Publication in the DOU (Brazilian Official Journal)

02 May 2022: Entry into force

- Regulation becomes applicable (as referenced in communications)

Since May 2022: Operational implementation

- Waiver available upon request
- Conditions: 10 consecutive batches + PV report = MAPA approval

Sharing Brazilian experience

- Boehringer Ingelheim – 15 biological requested and 12 already approved
- Submission product by product: Certificates of analysis of ten consecutive batches with satisfactory results for animal safety tests and Pharmacovigilance report, attesting to the product's safety.

Reasons to recommend withdrawal to Brazilian companies:

- **Animal welfare :** Avoids the unnecessary use of animals in tests that no longer add scientific value and aligns Brazil with international practices for reducing animal experimentation.
- **Consolidated scientific basis :** There is consensus that the results of these tests do not provide additional relevant information and accumulated data and practical experience show that safety can be ensured without them.
- **Regulatory efficiency:** Reduces bureaucracy and time spent on activities with no real impact on risk assessment and allows MAPA to focus efforts on more meaningful analyses.
- **Industry competitiveness :** Lowers operational costs and speeds up registration processes and facilitates innovation and the introduction of new products to the market.
- **International harmonization:** Brings Brazil closer to standards already adopted by the European Union and other regions and strengthens the country's position in global forums on alternatives to animal use.

Conclusion

Today we have seen that TABST is not just a technical change, but a change in mindset. Fewer unnecessary tests, more relevant science, more respect for animals.

This journey requires scientific consensus, robust data, and state-of-the-art technical capacity. But every step we take brings us closer to a future where innovation goes hand in hand with responsibility.

Brazil has the opportunity to align with global best practices and to show that it is possible to move forward without giving up animal welfare. It is up to us to turn this commitment into reality.

Because, in the end, true science is not only about discovering — it is also about caring.