

# Legislative initiatives with impact on veterinary medicines

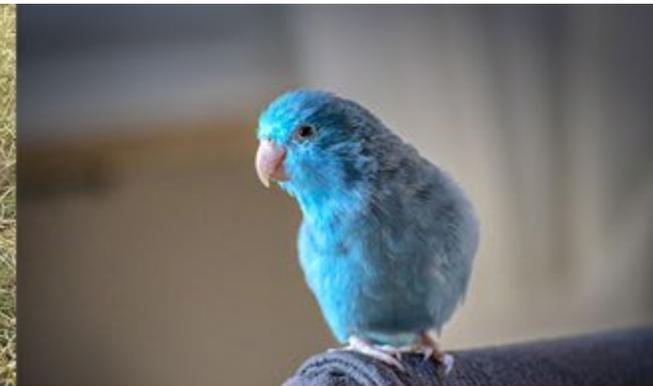
## Biotech Act & Horizontal Legislation

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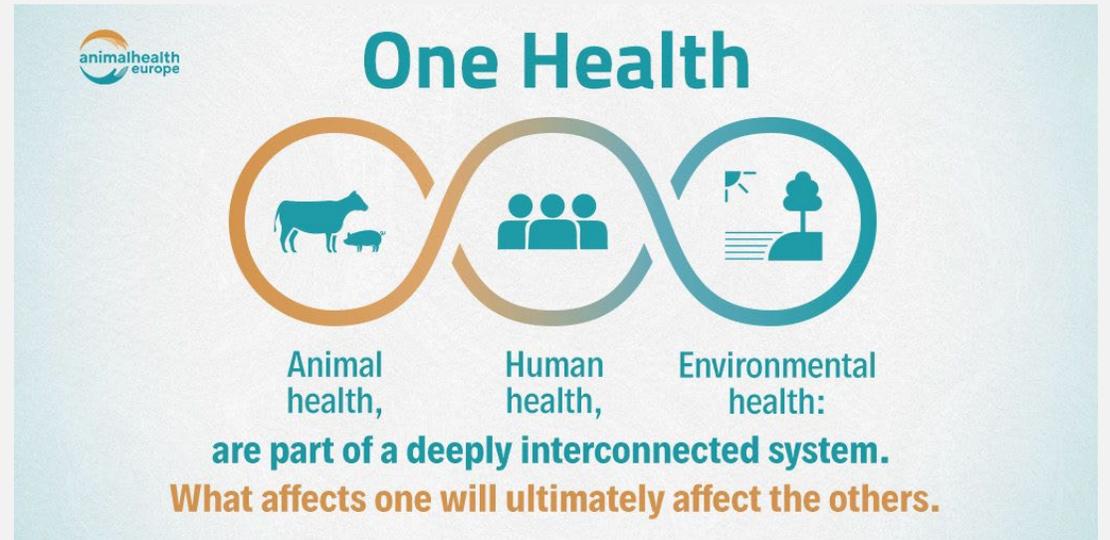
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## Our Mission

Our sector contributes to

- Animal health through the development of medicines used to keep animals healthy.
- One Health by safeguarding food supply, reducing zoonotic risks, and supporting sustainable livestock systems.

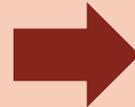


# Our Regulatory Framework

REGULATIONS 2019/6 & 2019/4



HORIZONTAL LEGISLATION



Animal  
health  
industry



HORIZONTAL LEGISLATION

PFAS restrictions - REACH - CLP - One Substance, One Assessment - PPWR - EPR - TiO<sub>2</sub> - Talc - Siloxanes ...

## ...& the Biotech Act

## Biotech Act opportunities

**Animal health is already a biotech sector** : Veterinary recombinant vaccines, biotherapeutics, advanced diagnostics, digital and AI tools.

The Biotech Act initiative represents a strategic opportunity for animal health :

- to accelerate innovation and support regulatory simplification,
- to strengthen EU competitiveness and resilience,
- and support One Health objectives,

provided that animal health specificities are fully integrated and taken into account.

It is, today, the most concrete regulatory initiative impacting our sector, in the absence of other omnibus approaches.



# Animal health industry perspectives on the draft Biotech Act

# GMOs - Opportunities Created

**GMO legislation does not apply to animals treated by GMO products**

**GMO parallel assessment no longer applies to veterinary medicinal products**

- Removal of parallel assessment by GMO Competent Authorities is a clear improvement and significantly reduces admin burden for the regulatory submission and assessment of the product.
- Uncertainty on clinical trials: "the competent authorities *may consult with the bodies set up by the Union or Member States in accordance with under Directive 2001/18/EC*, in particular in case of novel questions or first-in-class veterinary medicinal products".

↳ Trigger concerns around criteria to consult or not and predictability of the timelines to launch clinical trials.

↳ How will this impact national transcription of the Directive 2001/18/EC and existing local provisions of the directive: CTA publication, ...

- Data requirements remain unchanged, and the ERA will still follow Directive 2001/18 in line with new guidelines.

# GMOs - Proposal for updated definition

To ensure consistency with the application of GMO requirements under Regulation (EU) 2019/6, we propose to incorporate the definition of “organism” directly into Regulation 2019/6

The **Definition** in Directive (EC) 2001/18/EC

- (1) ‘organism’ means any biological entity capable of replication or of transferring genetic material

should become in **Regulation (EC) 2019/6**

- Art. 4: ‘organism’ means any biological entity capable of replication and of transferring genetic material

⇒ GMO veterinary vaccine strains only pose a risk for the environment when they can replicate.

⇒ A clear definition in the Regulation will promote **alignment across all EU agencies.**

# GMOs - Proposal for Low-Risk GMOs

- The proposed amendment to Directive (EC) 2001/18/EC (COM(2025) 1031) introduces low risk Genetically Modified Microorganisms (GMMs) in articles 24e and 24f.
- Proposal to introduce a corresponding provision into Regulation (EU) 2019/6:
- *A GMO shall be considered a ‘low-risk GMO’ when it fulfils one of the following criteria:*
  - *Deletion mutant without the introduction of any new genes*
  - *A previously approved platform technology-based GMO*

# GMOs - Preventing regulatory inconsistencies

- **Annex II - Part IIIb.3D (5)** ERA requirements for VMPs containing GMOs : reference to Directive 2001/18/EC
  - **EMA/CVMP/074/95 Rev.1** on ERA for immunological vet products refers to Article 8(5) of Regulation (EU) 2019/6
  - **Article 8(5) - Regulation (EU) 2019/6**: refers to Directive 2001/18/EC and is proposed for deletion in the draft Biotech Act
- ↪ **Alignment and revision of the legislative texts and applicable EMA/CVMP guidelines are required to avoid validation issues and potential assessment divergence.**

## VNRAs - Opportunities Created

**Amendment of Art 61 on Variations that do not require assessment:**

- **Label-VNRAs Notified within 30 days after implementation**
- **One Year to Notify Non-Label VNRAs instead of 30 days**

The proposed amendment also removes the confirmatory step from the authorities (including the fees).

The provision applies to all products, which is beneficial and should be preserved during legislative negotiations.

- **Impact: Positive**

↳ **Releases resources to prioritise innovation over administrative burden.**

# Elements Requiring Further Clarification

## Scope of Articles 31(1) and 31(3) on the deployment and use of Artificial Intelligence

- Unclear whether the AI provisions apply to both human and veterinary medicines:
- Article 31(3) appears to focus only on medicinal products more broadly, without explicit inclusion of veterinary medicines.
- **Impact: Neutral/Negative** - risk of regulatory misalignment and uncertainty for VMPs using AI.

## Definition of NAMs (New Approach Methodologies)

- The definition is limited to *non-animal methods*, whereas the 3Rs concept is much broader (including “reduce”).
- The rationale for such an approach is unclear.
- Locking a narrow definition into legislation could constrain future regulatory flexibility with potential side-effects on other initiatives led by other institutions (e.g., EPAA)



# Provisions to be amended

## Regulatory Sandboxes (RS)

- The Regulatory Sandbox concept is designed to overcome innovation barriers caused by the current regulatory framework by providing a specific alternative regulatory pathway.
- For vet medicines, RS applies exclusively to products or technologies **not regulated** by the applicable regulation: "*not regulated under Union legislation*".

↪ Regulatory Sandboxes only cover products that **do not meet the definition of "veterinary medicinal product"** as per Regulation 2019/6.

# Provisions to be amended

## Regulatory Sandboxes (RS)

- All the other sectors in the Biotech Act have a broader scope (medical devices, SoHO, food law, ATMPs...): the RS applies to products or technologies **regulated** by the Regulation to be amended

**Proposal:** ~~which are not regulated under Union legislation~~ *that otherwise would not be possible or appropriate given the current legal framework'*

- **Impact: Positive if amended; Negative if unchanged** - unlikely to receive any real use: we work on products that are regulated.

**To be clarified:**

**Status of the Marketing Authorisation authorised through a RS ?** Temporary pending other data (e.g., no lab model, biomarkers unknown) or full MA ?

**International impact and opportunities for coordination with non-EU regulatory authorities?**

# Provisions to be amended

## One-Year Patent Extension

- The extension is theoretically positive, but the definition is so narrow (only for biotech products against zoonosis, unique mode of action, partial EU manufacturing, etc.) that it is practically inapplicable.

## Proposals

- **Enlarge the scope:** products that support the fight against AMR or TADs, contribute to food security... even if mechanism already known.
- **Extend the period:** 1 year is insufficient: long return on investment, uncertainties for outbreaks
- **Impact: Positive if amended; Neutral if unchanged :** no product in the animal health pipeline fits the criteria.

## Conclusion

The initiative reflects good intentions.

**GMO provisions and VNRA notification timelines are clearly positive and should be kept.**

In its current form, it may not be enough to address innovation barriers.

The NAMs definition needs alignment with EU stakeholders.

Revision of the scope of the regulatory sandboxes & patent extension is necessary.

⇒ Suggest to support innovation on new antibiotics, unmet needs, limited market, exceptional circumstances...

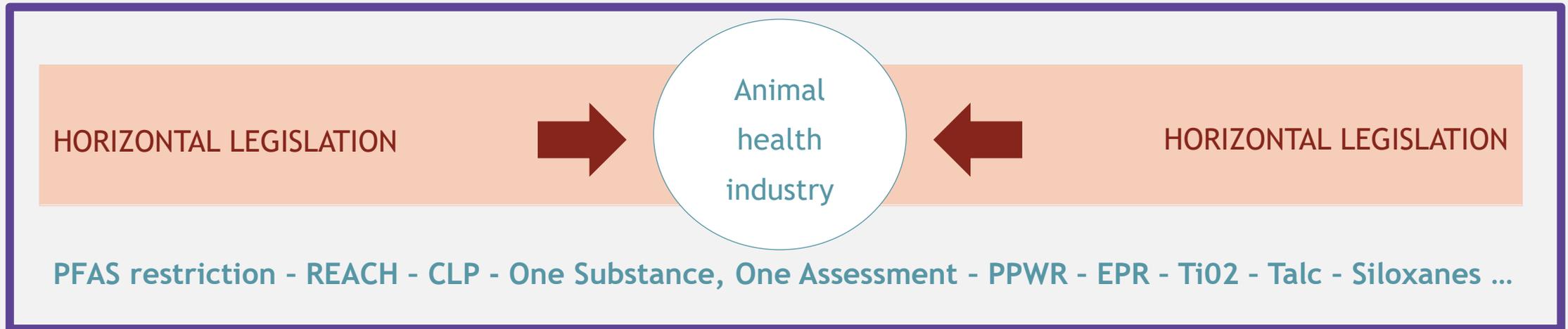
⇒ Suggest to reintroduce a temporary authorisation mechanism: Art. 25 & 110 not sufficient, unclear if Regulatory Sandboxes would cover all cases.



# Animal Health Industry & Horizontal legislation

# Our Regulatory Framework

REGULATIONS 2019/6 & 2019/4



...& the Biotech Act

## Our key asks

- **Prioritise a benefit-risk approach** over a risk-only approach
- **Veterinary medicines are an essential public good** ; supply chains must not be disrupted
- **Limit reporting to a strict minimum, with interoperable databases.**

### Examples:

- **PFAS:** permanent exemption for APIs; derogations for manufacturing and packaging where no alternatives exist, until viable solutions are agreed and qualified.
- **PPWR:**
  - reporting starts in Aug 2026, but guidance is missing and requirements are not fit for VMPs : a transitional, sector-specific approach is needed.
  - Existing derogations for veterinary medicines are temporary, raising concerns about long-term feasibility and medicine availability once these exemptions lapse.

↪ Stop here but many other examples ...

## Conclusion

**Horizontal legislations** raise concerns today:

It could somewhere foster innovation (e.g. substitution requirements)...

But indiscriminate application often hampers investment and affects veterinary medicines availability.

**The Biotech Act** is intended to drive innovation :

It requires some changes to fully deliver on its objective for the animal health sector.

But the animal health industry broadly supports the initiative, even more when the targeted adjustments will be made.

↪ **Keeping regulation science-based and proportionate is essential to preserve the animal health**