

The truth about using animals in vaccines



The Alliance for Cruelty Free Science

Many current vaccine pipelines (both for human and veterinary use) still rely on animal-derived components or animal testing, but there is rapid progress toward animal-free alternatives due to scientific advancements, regulatory shifts (e.g., the FDA's 2025 roadmap to phase out or reduce animal testing for biologics including vaccines), and ethical pressures. These include in vitro methods, organ-on-chip technologies, AI/computational modeling, synthetic media, and cell-based systems that avoid animal use.

Vaccines Commonly Using Animal-Derived Components in Production

Here are some examples of vaccines that still commonly involve animal-derived elements, alongside visuals of typical production processes (showing traditional vs. modern approaches): These illustrate cell culture in vaccine production (often historically using animal sera) and a modern cell-based influenza vaccine facility.

Alternatives like recombinant or synthetic stabilizers, chemically defined media, and cell-free systems exist or are in development.

These often involve animal products like:

a) *gelatin (porcine or bovine, used as stabilizers)*

Live virus vaccines stabilized with porcine gelatin (e.g., some MMR, nasal flu/Fluenz, and varicella/chickenpox vaccines like Varivax) — Gelatin prevents temperature damage during storage.

Alternatives: Gelatin-free versions exist for some (e.g., Priorix MMR, Varilrix varicella), and synthetic stabilizers are feasible.

b) *fetal bovine serum (FBS) (for cell growth media)*

Rabies vaccines (e.g., Imovax) — Some versions use human fetal cells (not animal, but ethically debated) or involve animal testing for potency; traditional production may include animal-derived media. In vitro potency tests and recombinant approaches are advancing.

Hepatitis A vaccines (e.g., Havrix, VAQTA) — Grown in human fetal cells but often with animal-derived media components like FBS historically. Chemically defined, animal-free media are increasingly adopted.

Other examples — Many viral vaccines (e.g., older inactivated types) use FBS or other bovine-derived reagents in cell culture.

Regulatory bodies (FDA, EMA, WHO) now push for animal-origin-free solutions to improve safety and scalability.

c) *egg proteins (for influenza), or growth in animal-derived cells*

Influenza vaccines (many egg-based) — Grown in chicken eggs, introducing egg proteins.

Alternatives: Cell-based (e.g., MDCK cells) or mRNA alternatives are already available and more scalable, reducing animal reliance.

Vaccines Requiring Animal Testing in Development/Quality Control

1. Preclinical safety, potency, and neurovirulence testing often uses animals (e.g., mice, monkeys, ferrets for flu).

Alternatives: Projects like VAC2VAC aim to replace these with in vitro consistency testing.

2. Traditional potency tests (e.g., for DTaP, rabies, meningitis vaccines) — Animal-based challenge tests.

Alternatives: In vitro alternatives (e.g., MAT for pyrogens) are being validated.

3. Rabies potency testing — Often involves animal models; human-relevant in vitro methods are progressing.

4. Influenza and emerging vaccines — Ferret or mouse models for immunogenicity; cell-based or AI-driven alternatives are reducing this.

Pipelines That Could Be (and Are Becoming) Animal-Free

Many pipelines are transitioning:

1. mRNA vaccines (e.g., COVID-19 platforms, potential for rabies/influenza)

FULLY REPLACED - Fully synthetic, no animal cells or testing required in production.

2. Cell-based vaccines (e.g., Vero or MDCK cells for Japanese encephalitis, flu)

FULLY REPLACED - Shifted from mouse-brain or egg-based, with synthetic media replacing FBS.

3. Virus-like particles (VLPs) (e.g., HPV Gardasil)

FULLY REPLACED - In vitro potency assays already replace animal tests.

4. Recombinant/subunit vaccines

FULLY REPLACED - Avoid live viruses and animal growth entirely.

5. AI, organoids, and organ-on-chip — Emerging for preclinical testing, supported by FDA's phase-out plan (initially for monoclonal antibodies but expanding to vaccines).

The shift is accelerating: Regulatory changes (FDA roadmap, 2025 initiatives), projects (VAC2VAC, 3Rs efforts), and technologies make fully animal-free pipelines realistic for most vaccines within the next few years, especially new ones.

Older established vaccines are slower to change due to regulatory validation needs. Nothing to do with the availability of science only the will to change.

Here is a compiled list of credible sources that support the key claims and information in the document we created together. These cover animal-derived components in vaccines (e.g., gelatin, FBS, egg-based production), ongoing transitions to animal-free alternatives, regulatory shifts (including the FDA's 2025 roadmap), projects like VAC2VAC, and examples of modern animal-free or reduced-animal pipelines.

Regulatory and Policy Shifts (FDA Roadmap 2025 and Animal Testing Reduction)

1. FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs (April 10, 2025) — Official FDA announcement on reducing/replacing animal testing, initially focused on monoclonal antibodies but part of broader efforts applicable to biologics including vaccines.

<https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs>

2. Roadmap to Reducing Animal Testing in Preclinical Safety Studies (FDA PDF, April 2025) — Details the FDA's strategy to reduce and replace animal testing in preclinical assessments.

https://www.fda.gov/files/newsroom/published/roadmap_to_reducing_animal_testing_in_preclinical_safety_studies.pdf

3. FDA Roadmap to Reducing Animal Testing: A New Regulatory Era (BiolVT Blog, July 2025) — Overview of the 3–5 year plan and implications for biologics.

<https://bioivt.com/blogs/fda-roadmap-to-reducing-animal-testing-a-new-regulatory-era>

Alternatives to Animal Testing in Vaccine Development (VAC2VAC and Related Efforts)

1. VAC2VAC Project (Innovative Health Initiative / IHI) — EU-funded project focused on developing and validating non-animal testing approaches for human and veterinary vaccines.

<https://www.ihieuropa.eu/projects-results/project-factsheets/vac2vac>

2. IMI Project Drives 'Historic' Decision to Drop Common Animal Test (IHI News, September 2024) — Discusses outcomes from VAC2VAC leading to replacement of certain animal tests.

<https://www.ihieuropa.eu/news-events/newsroom/imi-project-drives-historic-decision-drop-common-animal-test>

Animal-Derived Components in Vaccine Production

1. Gelatin (Porcine/Bovine) as Stabilizer:

Vaccine Ingredients: Gelatin (Children's Hospital of Philadelphia, updated 2022) — Explains porcine gelatin use in vaccines like MMR, varicella (e.g., Varivax), and alternatives.

<https://www.chop.edu/vaccine-education-center/vaccine-safety/vaccine-ingredients/gelatin>

2. Vaccines and Porcine Gelatine (UK Government / GOV.UK, December 2025) — Details porcine gelatin as a stabilizer in live virus vaccines.

<https://www.gov.uk/government/publications/vaccines-and-porcine-gelatine/vaccines-and-porcine-gelatine>

3. Fetal Bovine Serum (FBS) in Cell Culture:

Guide to Fetal Bovine Serum in Vaccine Production (Thermo Fisher Scientific) — Covers historical and ongoing use of FBS in viral vaccine production, including rabies and hepatitis A.

<https://www.thermofisher.com/us/en/home/references/gibco-cell-culture-basics/cell-culture-environment/fbs-basics/guide-to-fetal-bovine-serum-vaccine-production.html>

4. Egg-Based Influenza Vaccines and Alternatives:

Cell-Based Flu Vaccines (CDC, updated 2023) — Describes shift to cell-based (e.g., MDCK cells) influenza vaccines like Flucelvax as alternatives to egg-based production.

<https://www.cdc.gov/flu/vaccine-types/cell-based.html>

Quadrivalent Cell Culture Influenza Virus Vaccine: Comparison to Egg-Derived Vaccine (PMC article) — Analyzes advantages of cell-based over egg-based methods.

<https://pmc.ncbi.nlm.nih.gov/articles/PMC7482778/>

Animal-Free and Serum-Free Media/Production Advances

1. Serum-Free Vaccine Cell Culture Components (InVitria) — Discusses chemically defined, animal component-free media for Vero cells and virus production.

<https://invitria.com/application/vaccine-cell-culture-media>

2. A Complete Chemically Defined, Animal Component Free Medium for Vero Cells and Virus Production (Sartorius) — Examples of serum-free media supporting vaccine production.

<https://www.sartorius.com/download/1257886/a-complete-chemically-defined-poster-en-a0-b-sartorius-1-pdf-1--data.pdf>

These sources align with the document's points on current practices, ethical/regulatory pressures, and accelerating transitions (e.g., mRNA, recombinant, cell-based, and in vitro methods). For specific vaccines like MMR (Priorix as a gelatin-free option) or varicella (Varilrix), manufacturer package inserts or national immunization program factsheets (e.g., from NHS or CDC) often provide the latest details.