

Vaccines are biological products and may be exposed to organic and inorganic products during their manufacture. Some people have faith, morality or safety-based concerns about the use of animal derived products, such as gelatin, calf serum, or human cells during the manufacture of vaccines.

Vaccine manufacture and composition is tightly regulated to maximise safety. The safety of individual components, and the vaccine itself, must be clearly demonstrated before a vaccine can be approved for use. Many of the products used during the manufacturing process, if still present in the finished vaccine, are only present in minute (trace) amounts.

This fact sheet summarises the animal derived products used during vaccine manufacture, identifies the New Zealand (NZ) National Immunisation Schedule vaccines involved and responds to some issues raised about the use of animal derived products.

Bovine and porcine products

Bacteria and cells to grow viruses for some vaccines need a growth medium to provide optimal nutrition and moisture conditions. Some growth mediums use bovine serum albumin or fetal calf serum from cow blood to provide the nutrition the bacteria and cells need. Some components in the following vaccines have been exposed to bovine-derived materials in growth medium or milk-derived materials, such as bovine serum albumin, fetal calf serum, or casein: Boostrix[®], Hiberix[®], Infanrix[®]-hexa, Infanrix[®]-IPV, IPOL[®], NeisVac-C[®], M-M-R[®] II, Priorix[®], Rotarix[®], Varilrix[®], Varivax[®] and Zostavax[®].

Gelatin, like the ingredient used to make jelly for a trifle or marshmallows, is used in some vaccines as a stabiliser. It may be bovine or porcine derived.

Bovine spongiform encephalopathy

Theoretical concerns have been raised about the possibility of bovine products in vaccines being contaminated with bovine spongiform encephalopathy (BSE) or 'mad cow disease' and whether they could cause variant Creutzfeldt-Jakob disease (vCJD) in humans. Variant Creutzfeldt-Jakob disease is a rare but fatal brain infection. There have been no cases of a human developing vCJD after receiving a vaccine anywhere in the world. Cases of humans developing vCJD after eating animal products infected with BSE are rare.

The World Health Organization, U.S. Federal Drug Administration (FDA) and the Australian Therapeutic Goods Administration have addressed the theoretical risk of infected bovine products being used in vaccines. They estimate an exceedingly small risk of contracting vCJD from a vaccine or blood derived medical product. Very strict controls have been placed on the standards that vaccine manufacturers must adhere to.

Manufacturers may only acquire bovine products from BSE free countries, must state the type of bovine tissue used, and must provide details of their manufacturing process. Since 2000 the Center for Biologics Evaluation and Research, within the FDA, has inspected vaccine manufacturers on a routine basis to determine whether sourcing and documentation are consistent with current recommendations.

Perspective of major religions

Bovine-derived material

Major religions have not expressed specific objections about the use of bovine products during vaccine manufacture.

Porcine-derived material

Islam

The transformation of the bones, skin and tendons of a judicially impure animal into gelatin with different characteristics, changes the substance that is prohibited into a substance that is judicially permissible.

Judaism

There are no problems with porcine or other animal derived ingredients in non-oral products. In non-oral products, the transformation of pork into gelatin makes them permissible. When there is no alternative available, immunisation for disease prevention and to preserve life is a necessity. Additionally, the minute quantities of trypsin residual or gelatin stabiliser in the final product become exceptions based on dilution.

Chicken embryos and embryonated eggs

Chicken embryo cells are used to grow measles and mumps vaccine viruses. The cells are removed from an egg, placed in a growth medium and infected with the weakened measles or mumps virus. As the cells multiply, so does the amount of measles or mumps virus that is available to be used in M-M-R II and Priorix.

The egg white (albumin) in embryonated chicken eggs provides a perfect food for influenza viruses to grow. Although the influenza virus is taken out of the egg white once there is enough to make a vaccine, small amounts of egg white could still be attached to some of the viruses. Influenza vaccines made using eggs, such as Afluria Quad Junior[®] and Afluria Quad[®], may contain small amounts of egg white protein in them.

Guinea pig embryos

Embryonic guinea pig cells are used to grow varicella viruses in Varivax and Zostavax.

Monkey kidney cells

The continuous Vero cell line started with monkey kidney cells in 1962. Descendants of the original cells are used to grow polio viruses for Infanrix-hexa, Infanrix-IPV, and IPOL and rotavirus for Rotarix. These kinds of cells never run out of energy to make more cells and the original cells are like the great, great, great, great ... grandparents of the cells being used to grow viruses for vaccines now.

Human cell lines

Attitudes and practices around abortion were different in the 1960s, 70s and 80s compared with the present day, but even then, pregnancies were not terminated for the advancement of science. Pregnancies were terminated to support the well-being of women and their families. Cells were taken from what, at that time, was considered the by-product of an abortion.

Babies are not being aborted to produce vaccines. The cells used now are not the originally harvested cells, they are descendants of those cells.

Perpetual human cell lines are used to grow the hepatitis A, rubella, and varicella (chickenpox or shingles) viruses for vaccines. They are also used to grow the adenoviruses used to deliver the instructions our cells need to make the protein shapes that teach our immune system to recognise and protect us from the SARS-CoV-2 virus in some COVID-19 vaccines.

- » The WI-38 cell line is used to grow rubella virus in M-M-R II and varicella virus in Varivax and Zostavax. The original cells came from a fetus in 1961 after an abortion because the parents felt they had too many children.
- » The MRC-5 cell line is used to grow rubella virus in Priorix, varicella (chickenpox or shingles) virus in Varilrix, Varivax and Zostavax. and hepatitis A virus in Havrix[®] Junior and Havrix[®] vaccines. The original cells came from a fetus in 1966 after an abortion because the mother had psychiatric problems.
- » The original rubella virus used in the M-M-R II and Priorix vaccines came from a fetus in 1964 after an abortion because the mother had been infected with the rubella virus.
- » The original HEK-293 cells used to grow cells for the AstraZeneca COVID-19 vaccine came from a fetus in the early 1970s. It is not known whether the pregnancy ended though miscarriage or termination.

Continued...

Human cell lines continued

» The original PER.C6 cells used to grow adenoviruses for the Janssen COVID-19 vaccine came from fetus in 1985 after an abortion to support the mother's wellbeing.

Perspective of major religions

Catholicism

The Vatican published moral reflections on vaccines prepared from cells derived from an aborted human fetus in June 2005. They said that, where there is no alternative vaccine, the use of vaccines derived from an aborted human fetus should not be misinterpreted as approving their production, marketing and use. They considered use of the vaccine is passive material cooperation and morally justified to avoid a serious risk, not only for one's own children but for the health of the whole population, especially pregnant women. They deemed that use of the vaccine occurs in a context of moral coercion of parents who are forced to act against their conscience.

In December 2020, Pope Francis approved the statement from the Vatican's Congregation for the Doctrine of the Faith on the receipt of COVID-19 vaccines. They stated that "It is morally acceptable to receive Covid-19 vaccines that have used cell lines from aborted fetuses in their research and production process" and "all vaccinations recognized as clinically safe and effective can be used in good conscience with the certain knowledge that the use of such vaccines does not constitute formal cooperation with the abortion from which the cells used in production of the vaccines derive."

Human blood products

Human albumin

Human albumin, either engineered from yeast cells or derived from human blood, is used as a stabiliser in some vaccines.

Human albumin used in the M-M-R II vaccine is not derived from liver or blood products. It is engineered from yeast cells to imitate real human albumin.

Human albumin is no longer used in the Varilrix brand of varicella (chickenpox) vaccine.

Perspective of major religions

Jehovah's Witnesses

The Watch Tower Society advise that acceptance of a transfusion of whole blood or its primary components, red cells, white cells, platelets or plasma, is considered contrary to God's law. However, the acceptance of products derived/fractionated from the primary components, such as albumin, clotting factors, or immunoglobulins, or medicines that utilise fractions, such as some cancer treatments, is a matter of personal choice.

Residual DNA

Humans are in contact with external DNA daily, e.g., in the foods we eat, and microbes we breathe in or swallow. Vaccine manufacturing processes expose vaccine components to materials that contain DNA, e.g., culture cells or other animal derived ingredients.

Fragments of genetic material from the vaccine manufacturing process are expected to be found in minute amounts in the finished product. They are left over from materials used earlier in the manufacturing process and have been part of the vaccine formulation throughout all the vaccine safety trials and the time the vaccine has been used in communities around the world, and no safety concerns have been identified.

Porcine circovirus

In March 2010 fragments of porcine circovirus (PCV) DNA were found to have been in both Rotarix and RotaTeq rotavirus vaccines since they were developed. The World Health Organization (WHO), European Medicines Agency, and U.S. Food and Drug Administration (FDA) reviewed available information and concluded that both vaccines have been shown to be safe and effective in preventing severe diarrhoea and there was no evidence of PCV disease in children who had already received the vaccines. Porcine circoviruses are also found in pork food products. They have been detected in adult faeces without any evidence of having caused harm or illness in humans.

National Immunisation Schedule vaccines and animal derived products

Table 1 on this page and the following page shows the vaccines on the National Immunisation Schedule that have had exposure to animal derived products during manufacture. Some finished vaccines that were exposed to animal derived products during manufacture have no residuals from animal derived products, others may have an amount so small it is presumed present but cannot be measured, and others an amount that can be measured perhaps as a trace, parts per million or parts per billion.

Vaccine purification at the end of the manufacturing process ensures that the final vaccine has no harmful components and a minimal amount of any ingredient that was part of the manufacturing process but is no longer needed for the vaccine to work.

Table 1. National Immunisation Schedule vaccines exposure to animal derived products during manufacture

Vaccine	Disease(s)	Exposure to animal derived products
Afluria Quad Junior Afluria Quad	Influenza	» Embryonated chicken eggs are used to propagate influenza viruses.
Boostrix	Tetanus/diphtheria/acellular pertussis	» Growth medium for tetanus bacteria is derived from bovine casein. » Growth medium for diphtheria bacteria contains bovine extracts.
Havrix Junior Havrix	Hepatitis A	» MRC-5 cell line derived from a fetus aborted in 1966 is used to propagate hepatitis A viruses.
Hiberix	<i>Haemophilus influenzae</i> type b (Hib)	» Growth medium for tetanus bacteria contains bovine extracts.
Infanrix-hexa	Diphtheria/tetanus/acellular pertussis/polio/hepatitis B/ <i>Haemophilus influenzae</i> type b (Hib)	» Growth medium for tetanus bacteria is derived from bovine casein. » Growth medium for diphtheria bacteria contains bovine extracts.
Infanrix-IPV	Diphtheria/tetanus/acellular pertussis/polio	» Vero cell line derived from monkey kidney cells in 1962 is used to propagate polio viruses.

Continued ..

Table 1. National Immunisation Schedule vaccines exposure to animal derived products during manufacture continued

Vaccine	Disease(s)	Exposure to animal derived products
Polio	Polio	<ul style="list-style-type: none"> » Vero cell line derived from monkey kidney cells in 1962 is used to propagate polio viruses. » Growth medium for Vero cells contains bovine extracts.
Menactra NeisVac-C	Meningococcal ACYW Meningococcal group C	<ul style="list-style-type: none"> » Growth media for bacteria contains bovine extracts, bovine casein or casamino acid.
M-M-R II Priorix	Measles, mumps and rubella	<ul style="list-style-type: none"> » Rubella virus derived from a fetus aborted in 1964. » Chicken embryo cells are used to propagate measles and mumps viruses. » MRC-5 cell line derived from a fetus aborted in 1966 is used to propagate rubella viruses in Priorix. » WI-38 cell line derived from a fetus aborted in 1961 is used to grow rubella viruses in M-M-R II. » Growth medium for cell lines contains bovine extracts. » Gelatin used as a vaccine stabiliser may be bovine or porcine derived.
Rotarix	Rotavirus	<ul style="list-style-type: none"> » Vero cell line derived from monkey kidney cells in 1962 is used to propagate the reassorted rotaviruses. » Growth medium for Vero cells contains bovine extracts. » Porcine circovirus DNA fragments.
Varilrix	Varicella (chickenpox)	<ul style="list-style-type: none"> » MRC-5 cell line derived from a fetus aborted in 1966 is used to propagate varicella viruses. » Growth medium for cell line contains bovine extracts.
Varivax Zostavax	Varicella (chickenpox) Herpes zoster (shingles)	<ul style="list-style-type: none"> » Embryonic guinea pig cells are used to propagate varicella viruses. » WI-38 cell line derived from a fetus aborted in 1961 is used to propagate varicella viruses. » MRC-5 cell line derived from a fetus aborted in 1966 is used to weaken/attenuate varicella viruses. » Growth medium for cell lines contains bovine extracts. » Porcine derived gelatin used as a vaccine stabiliser.

References

- » Dubin G, Toussaint J-F, Cassart J-P, Howe B, Boyce D, Friedland L, et al. Investigation of a regulatory agency enquiry into potential porcine circovirus type 1 contamination of the human rotavirus vaccine, Rotarix. *Hum Vaccin Immunother*. 2013;9(11):2398-408.
- » European Medicines Agency. Questions and answers on the review of Rotarix (rotavirus vaccine, live). Outcome of a procedure under Article 20 of Regulation (EC) No 726/2004 [Internet]. London: European Medicines Agency; 2010 [cited 2021 August 16]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2010/07/WC500094832.pdf
- » Finn TM, Egan W. Vaccine additives and manufacturing residuals in vaccines licensed in the United States. In: Plotkin SOW, Offit P, Edwards K, editor. *Plotkin's Vaccines*. 7th ed. Philadelphia: Elsevier; 2018. p. 75-83.
- » Grabenstein J. What the world's religions teach, applied to vaccines and immune globulins. *Vaccine*. 2013;31(16):2011-23.
- » JW.ORG. The Watchtower – Study Edition | June 15, 2000. Questions from readers. Do Jehovah's Witnesses accept any medical products derived from blood? [Internet]. Pennsylvania: Watch Tower Bible and Tract Society of Pennsylvania; 2021 [cited 2021 August 16]. Available from: <https://www.jw.org/en/library/magazines/w20000615/Questions-From-Readers/>
- » Kelso JM. Update on vaccination guidelines for allergic children. *Expert Rev Vaccines*. 2009;8(11):1541-6.
- » Li L, Kapoor A, Slikas B, Bamidele OS, Wang C, Shaukat S, et al. Multiple diverse circoviruses infect farm animals and are commonly found in human and chimpanzee feces. *J Virol*. 2010;84(4):1674-82.
- » Medsafe. Data sheets for specified vaccines [Internet]. Wellington: New Zealand Medicines and Medical Devices Safety Authority; [various dates; cited 2021 August 16]. Available from: <http://www.medsafe.govt.nz/>
- » Nokleby H. Vaccination and anaphylaxis. *Curr Allergy Asthma Rep*. 2006;6(1):9-13.
- » Pontificia Academia Pro Vita. Moral reflections on vaccines prepared from cells derived from aborted human foetuses [Internet]. St Paul: Immunization Action Coalition; 2005 [cited 2021 August 16]. Available from: <http://www.immunize.org/concerns/vaticandocument.htm>
- » U.S. Food and Drug Administration. Bovine derived materials used in vaccine manufacturing questions and answers [Internet]. Silver Spring: U.S. Food and Drug Administration; 2009 [updated 2018 March 23; cited 2021 August 16]. Available from: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm143521.htm>
- » U.S. Food and Drug Administration. Package insert: Varivax (refrigerator) [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 1995 [updated 2020 March; cited 2021 August 16]. Available from: <https://www.fda.gov/media/76000/download>
- » U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee meeting minutes [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 2001. Available from: https://wayback.archive-it.org/7993/20170404095417/https://www.fda.gov/ohrms/dockets/ac/01/transcripts/3750t1_01.pdf
- » U.S. Food and Drug Administration. Vaccines and variant CJD (vCJD) questions and answers [Internet]. Silver Spring: U.S. Food and Drug Administration; 2009 [updated 2018 March 23; cited 2021 August 16]. Available from: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm143522.htm>
- » Vatican News. Vatican CDF says use of anti-Covid vaccines "morally acceptable" [Internet]. Vatican City: Vatican News; 2020 [cited 2021 August 23]. Available from: <https://www.vaticannews.va/en/vatican-city/news/2020-12/vatican-cdf-note-covid-vaccine-morality-abortion.html>
- » World Health Organization, Regional Office for the Eastern Mediterranean. 1995 decision by the Islamic Organization for Medical Sciences in English and Arabic [Internet]. Egypt: World Health Organization; 2001 [cited 2021 August 16]. Available from: <http://www.immunize.org/concerns/porcine.pdf>
- » World Health Organization. Questions and answers relating to finding of porcine circoviruses in rotavirus vaccines [Internet]. Geneva: World Health Organization; 2010 [cited 2021 August 16]. Available from: http://www.who.int/immunization_standards/vaccine_quality/PCV1_Q_and_As_rotavirus_vaccines_3Jun10.pdf
- » World Health Organization. WHO Guidelines on Transmissible Spongiform Encephalopathies in relation to Biological and Pharmaceutical Products [Internet]. Geneva: World Health Organization; 2003 [cited 2021 August 16]. Available from: <http://www.who.int/biologicals/publications/en/whotse2003.pdf>