

Vaccine manufacture and composition is tightly regulated to ensure safety. The safety of both the individual components and of the whole vaccine is carefully checked and tested before a vaccine can be licensed.

Vaccines are biological products and both organic (sometimes including animal products) and inorganic materials are used in their manufacture.

The statement of products used in vaccine manufacture (e.g. listed in the product information leaflet in the pack) is often very comprehensive. It is important to remember that many of the listed products are used during the manufacturing process, and if still present in the finished product, would only be in minute or undetectable amounts.

Some people are concerned about the use of animal derived products in the manufacture of vaccines. This may be for religious or faith based reasons or concerns about the possibility of contamination with animal diseases. This fact sheet summarises the animal derived products (including human) involved in vaccine manufacture, which vaccines are involved and issues arising from this.

### Porcine (pork)

Some vaccines use products derived from pork. In New Zealand the measles, mumps and rubella vaccine (MMR<sup>®</sup>II) may contain gelatine derived from pork as a stabiliser. This may be of concern to some religious groups. Approval by world religious leaders of use of vaccines containing porcine gelatin are referenced at the end of this fact sheet.

- **Observant Muslims:** The transformation of pork products into gelatin alters them sufficiently to make it permissible for observant Muslims to receive vaccines containing pork gelatin.
- **Observant Jews:** According to Jewish laws there are no problems with porcine or other animal derived ingredients in non oral products. This includes vaccines.

### Bovine (calf)

Bovine serum albumin or fetal calf serum is used during the production of some vaccines (MMR<sup>®</sup>II, RotaTeq<sup>®</sup>, Varivax<sup>®</sup> and Zostavax<sup>®</sup> <1ppm). There were theoretical concerns raised about the possibility of contamination with variant Creutzfeldt-Jakob disease (vCJD). This stemmed from rare, documented cases in the United Kingdom of vCJD in humans following ingestion of products from animals infected with bovine spongiform encephalopathy (BSE) or 'mad cow disease'. This has been closely addressed by a range of agencies including the WHO, the United States CDC and the Australian Therapeutic Goods Administration.

There are very strict controls on the standards that manufacturers must adhere to and they must provide detailed information on the source of all materials used in the vaccine process – including the source of the bovine product. The requirements include the country of origin (BSE free), the type of tissue used and details of the manufacturing process. Estimates of the risk of contracting vCJD from a vaccine are miniscule and are summarised by the FDA and CDC.

### Human tissue

Some people are concerned about the use of aborted fetal material in the manufacture of some vaccines, but what are the facts? What is the reason for using these cells?

1. Mature human tissue is made up of cells that are only capable of dividing a few times before dying, whereas fetal cells are effectively immortal.
2. Rubella is a human disease and requires human cells to replicate.

Early attempts to use animal cell lines were unsuccessful.

The only vaccine in the current New Zealand schedule in which fetal material is used during vaccine development is the rubella component of the MMR vaccine. It is important to understand that the vaccine strain of rubella virus was derived from a fetus infected with rubella in 1965. Viruses cannot multiply outside live cells so the rubella virus must be grown in suitable cell cultures. The cell cultures now used were also originally derived from fetal tissue. Despite laboratory attempts this virus can't be grown in other culture media as with some other vaccines. The fetal cells derived all those years ago have since been maintained in the laboratory for use in today's vaccines, so there has been no further (new) fetal tissue used in the production of rubella vaccine since it's original development in the 1960s.

Babies are not being aborted in order to produce vaccines.

### Human blood products

Jehovah's Witnesses do not accept transfusions of whole blood or it's primary components, but the use of immunoglobulins and albumin (albumin is used as a stabiliser in MMR vaccine) is a matter of personal conscience. This is their governing body's position as stated in "Watchtower" of June 1990, pages 30-31.

### Summary

Use of animal-derived materials raises concerns relating to the potential presence of contaminants. Regulations require that cultures remain free of extraneous organisms. All cell lines must be tested for the presence of microbial contamination. Manufacturers must provide evidence that their materials are safe.

### Additional web-based information:

Johns Hopkins

<http://www.vaccinesafety.edu/Porcine-vaccine-approval.htm>

WHO Letter from Muslim Leaders

<http://www.immunize.org/concerns/porcine.pdf>

List of vaccines containing porcine gelatine

<http://www.vaccinesafety.edu/components-Allergens.htm>

FDA and risk of vCJD

[www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Blood-Safety/ucm095062.htm](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Blood-Safety/ucm095062.htm)