A vertical decorative bar on the left side of the page, containing five white stars arranged vertically on a dark background.

# Vaccines and substances of ruminant origin

## The EU viewpoint

Roland Dobbelaer, Dr. Sc.  
CPMP Biotechnology Working Party  
EMA - London

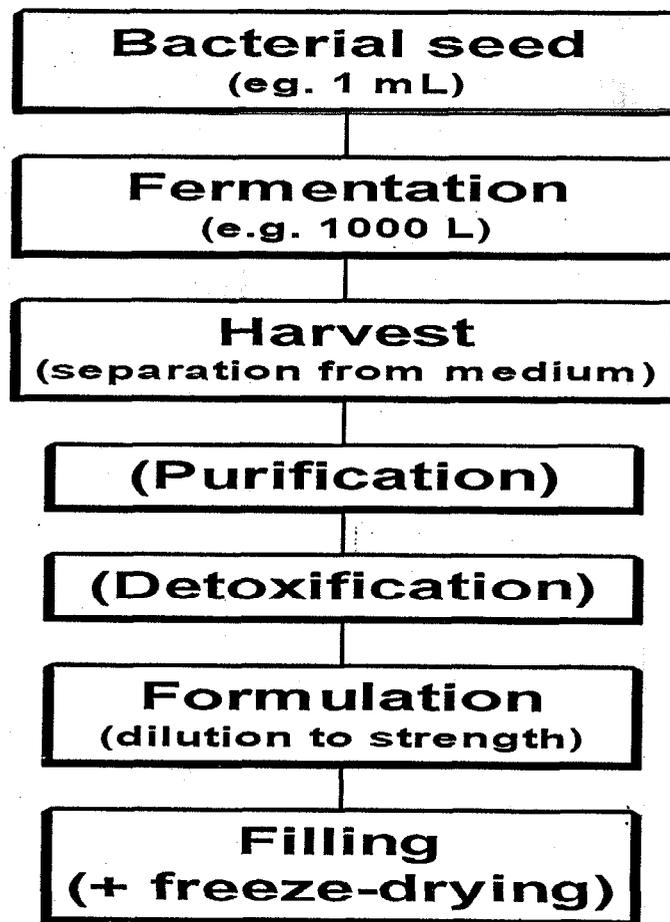


## Vaccines: examples

<i>Type of vaccine</i>	<i>Examples</i>
<i>Bacterial cells (live or inactivated)</i>	<ul style="list-style-type: none"><li>• Live Oral Typhoid vaccine</li><li>• Inactivated Whole Cell Pertussis vaccine</li></ul>
<i>Purified bacterial cell products</i>	<ul style="list-style-type: none"><li>• Diphtheria and Tetanus toxoids</li><li>• Acellular Pertussis Antigens</li><li>• rDNA Hepatitis B vaccine</li><li>• Haemophilus b vaccine</li></ul>
<i>Live and purified inactivated viral vaccines produced on mammalian cells</i>	<ul style="list-style-type: none"><li>• Live attenuated Measles, Mumps, Rubella vaccines</li><li>• Inactivated Poliomyelitis vaccine (IPV)</li></ul>



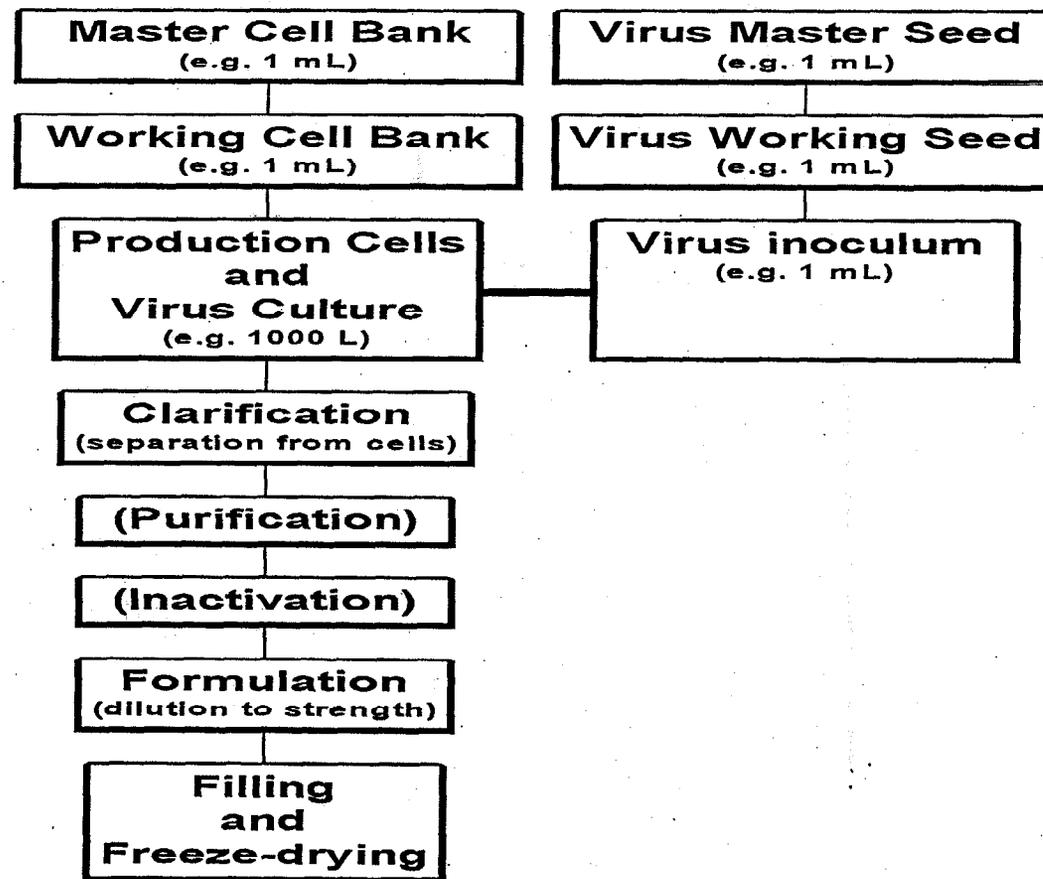
## Bacterial Vaccines: production process



Substances of ruminant origin may be used



# Viral Vaccines: production process



Substances of ruminant origin may be used



## Vaccines: residual quantities of substances of ruminant origin

- Bacterial vaccines:
  - <math><100\text{ ng}</math> (<math><0.1\mu\text{g}</math>)/single human dose when used in fermentation
- Viral vaccines:
  - <math><50\text{ ng}</math> (<math><0.05\mu\text{g}</math>)/single human dose from use in production cell culture
  - <math><0.01\text{ nL}</math> (<math><0.00001\mu\text{L}</math>)/single human dose from use in cell bank



## Vaccines and substances of ruminant origin

- *Milk and milk derivatives* (bacterial seeds and fermentation medium)
- *Blood and blood derivatives* (bacterial seeds and fermentation medium; calf serum in production of virus seed lots, cell banks, production cells)
- *Gelatin derivatives* (bacterial seeds)
- *Tallow derivatives* (glycerol as stabiliser in bacterial seeds and Tween 80 as emulsifier in viral vaccine production)
- *Meat and organ extracts* (bacterial fermentation)



# Vaccines and substances of ruminant origin

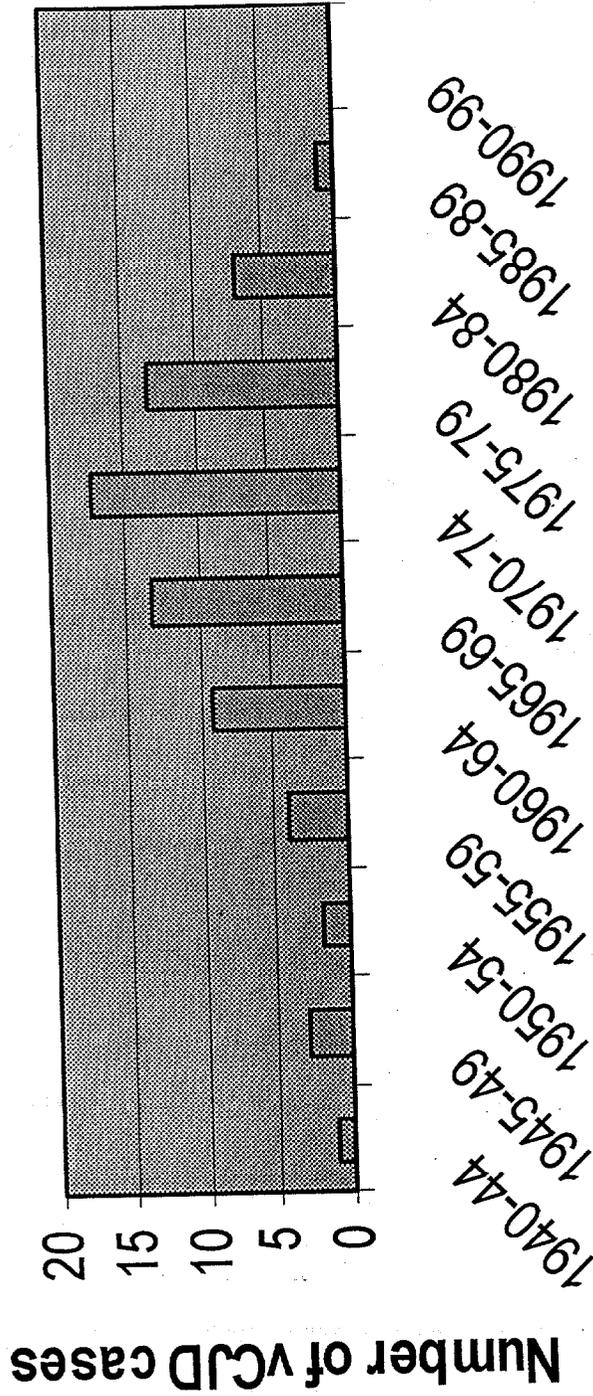
## Conclusions

- Substances of ruminant origin are used
- Vaccine safety ensured by the combination of
  - Control of origin (country/herd/animal)
  - Tissue of origin (no infectivity demonstrated)
  - Production stage at which used (generally initial stages)
  - Treatment (e.g. gelatin, Tween 80)



# Vaccines are not associated with vCJD

## vCJD by year of birth



Adapted from P D Minor, R G Will, D Salisbury 2000, Vaccine, in press

