

ICAR TECHNOLOGIES

VACCINES FOR LIVESTOCK AND POULTRY

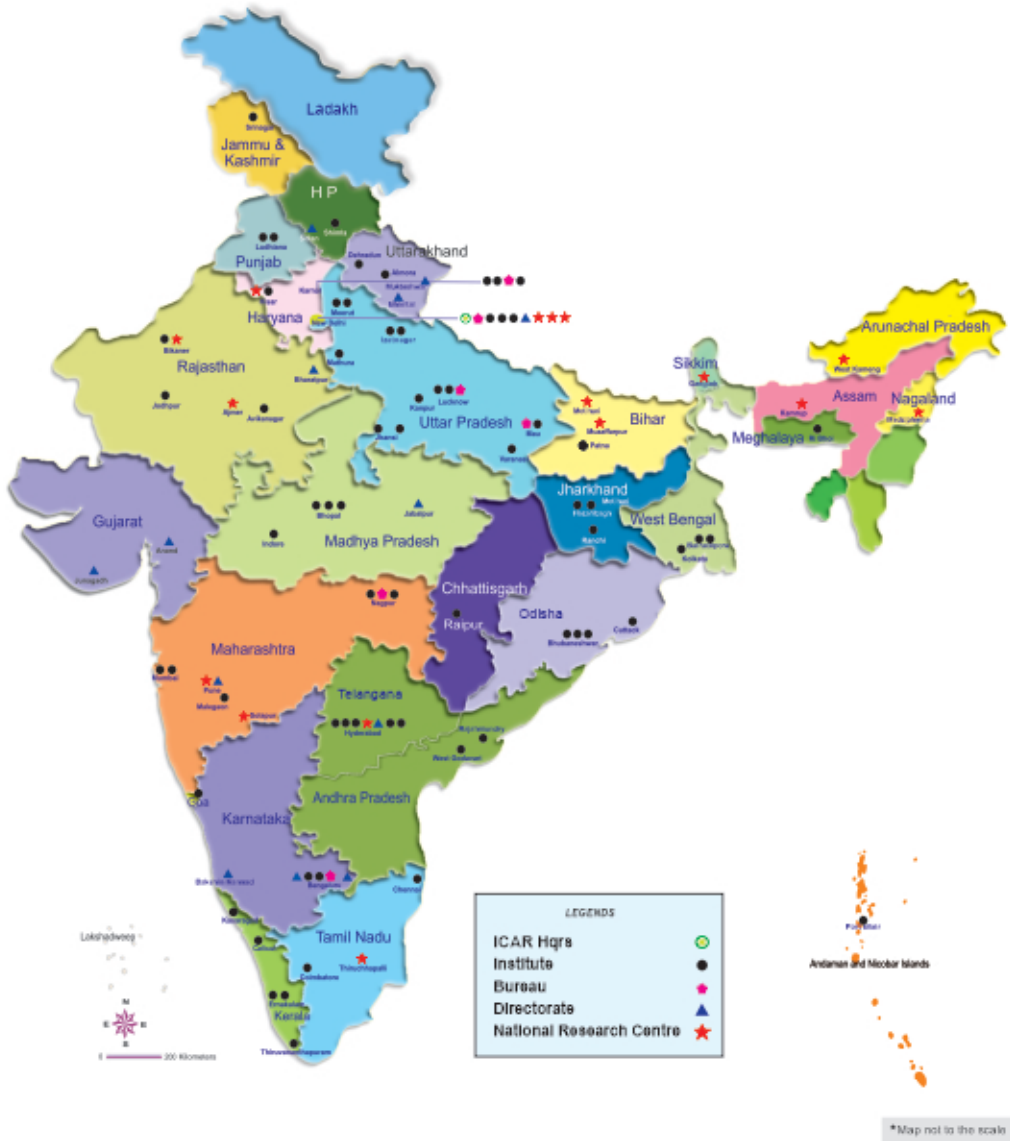


Indian Council of Agricultural Research
New Delhi



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ICAR TECHNOLOGIES

**VACCINES
FOR
LIVESTOCK AND POULTRY**



Indian Council of Agricultural Research
New Delhi

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Editing

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MESSAGE

Livestock sector is a key subsector of the Indian agriculture. It is an important livelihood source for farmers, supporting agriculture and contributing to the health and nutritional security of the household as well as supplementing incomes with employment opportunities. It is emerging as an important growth engine of the Indian economy and has registered a growth of 6.1% per annum.

The most effective way to increase livestock productivity and minimize losses from disease morbidity and mortality is by monitoring health, and diagnosis and control of diseases by using effective vaccines. The R & D work on veterinary biologicals in the country has led to successful eradication of three important diseases *viz*, rinderpest, African horse sickness and contagious bovine pleuropneumonia from the country.

Control of several bacterial and viral diseases of cattle and buffaloes (FMD, HS, BQ, anthrax), sheep and goats (PPR, sheeppox, goatpox, enterotoxaemia), pigs (classical swine fever) and poultry (Newcastle disease, infectious bursal disease, avian influenza, infectious bronchitis) is being done through the use of prophylactic vaccines developed by Animal Science Institutes of ICAR. Biologicals developed have been transferred to various commercial manufacturers and state biological production units to ensure adequate supply in the country.

The Animal Science Institutes of the Council are continuously toiling to develop better, apt and effective vaccines for livestock and poultry diseases and to improve and refine the current ones in the light of epidemiological findings and contemporary advancement in technology. This is evident from the list of vaccines compiled in this document that includes a sub-viral particle-based recombinant vaccine. Efforts are also going on for the development of DIVA-capable marker vaccines, combined vaccines and thermo-stable vaccines.

I am confident that this informative compilation of vaccine technologies developed by the ICAR will help all those engaged in animal health management and disease control in the country.



[T. Mohapatra]

Secretary, DARE & Director General, ICAR

FOREWORD

India has a vast resource of livestock and poultry, which plays a vital role in improving the socio-economic conditions of rural farmers. India possesses ~536 million livestock population, which includes 192.49 million cattle, 109.85 million buffaloes, 148.88 million goats, 74.26 million sheep and 9.06 million pigs, and poultry population of 851.5 million.

A significant obstacle in growth and production of livestock and poultry is the prevalence of diseases that cause huge economic losses in India. The livestock productivity is adversely affected by various animal diseases and many of them are zoonotic also. Animal health management is important to reduce productivity losses and overall production from the livestock sector. Foot-and-Mouth disease and haemorrhagic septicaemia inflict huge economic losses amounting to ~ Rs 14,000 and Rs 5,255 crores every year, respectively. In addition, many other infectious diseases of sheep, goats, pigs and poultry limit the true production potential of these livestock species and the economic return from their farming. ICAR has made significant contributions towards safeguarding the animal health in the country by developing several vaccines for use in livestock and poultry and their commercialization from time-to-time to meet the challenges of existing, emerging and re-emerging diseases.

The availability of vaccines has positively impacted growth of the livestock sector hugely. The mass scale use of PPR vaccine developed by ICAR-IVRI, Mukteshwar campus resulted in reduction of >75 per cent disease incidence. This vaccine has a very high impact on livelihood security of poor people, who depend on sheep and goat rearing. Similarly, FMD vaccine developed at ICAR-IVRI, Bengaluru campus helped to reduce incidence of this highly communicable disease and has ultimately impacted on livelihood security of poor farmers. The ICAR has also been contributing to nation-wide control programmes for several diseases such as FMD, HS, PPR, Brucellosis, etc, by playing a key role in developing trained human resource in the area of animal health and production of veterinary biologicals.

We strongly believe that this informative, concise compilation of veterinary vaccine technologies developed by the Animal Science Institutes of the ICAR will be a useful resource for all the stakeholders associated with the sector.



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PREFACE

Diseases of livestock and poultry cause heavy economic losses in terms of reduced productivity and production. Some of them have zoonotic potential and therefore pose serious public health risk. The most effective way of preventing diseases is through the use of vaccines. Vaccines not only protect the vaccinated animals, but also reduce disease among non-vaccinated ones through herd immunity. They also reduce antimicrobial usage and minimize the risk of antimicrobial resistance.

Animal Science Institutes of ICAR have made significant contributions in the development of effective and reliable vaccines against diseases of livestock and poultry. ICAR-IVRI, since its very inception, conducted research to develop potent biologicals against prevalent animal diseases. The institute produced useful products such as Anti-Anthrax Serum (1902), Polyvalent HS Vaccine (1908), Black Quarter Vaccine (1906-08), Goat Tissue Virus (GTV) Rinderpest Vaccine (1927), Ranikhet Disease Vaccine (1940), Tissue Culture Rinderpest Vaccine (TCRP vaccine) and Inactivated Foot-and-Mouth Disease (FMD) Vaccine (1946-52). In the post-independent era, IVRI developed African Horse Sickness Vaccine (1960-65), Irradiated Lungworm Vaccine (1973), Inactivated Goatpox Vaccine (1986), Live attenuated PPR Vaccine (2001), etc. In the fight against rinderpest, the potent vaccine developed and produced by IVRI helped eradication of the disease. The PPR vaccine developed by IVRI is now being used for PPR control in the country. There are number of other vaccines developed at IVRI and other ICAR institutes to help control diseases such as Sheeppox, Orf, Camelox, Buffalopox, Equine Influenza, Johne's disease, etc.

Truly, the ICAR has done humongous amount of work for development of these vaccines and has helped in eradication of some diseases and control of many others. On certain occasions, Dr Trilochan Mohapatra, Hon'ble Secy. DARE & DG, ICAR had expressed his desire for documenting such significant contributions of ICAR in the field of animal health and this impelled us to bring out this document on vaccine technologies developed at ICAR. In this effort, Dr J.K. Jena, DDG (Fisheries Science) and Dr B.N. Tripathi, DDG (Animal Science), encouraged and guided us throughout the process of conceptualization to actualization of this task. We gratefully acknowledge their contribution in this regard. We also wish to place on record our sincere thanks to the Directors and Scientists of the ICAR institutes who contributed to the development of these valuable technologies and their technical input for the preparation of this document.

We believe, this concise and informative account of vaccines for livestock and poultry developed by the Animal Science Institutes of ICAR will serve as a ready reference for all stakeholders including those involved in production and marketing of such products.

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INTRODUCTION

Livestock farming is an integral part of Indian agriculture. It is likely to be the instrument of future growth and development of this sector. The country currently hosts ~536 million livestock and is the world's largest producer of milk with 187.7 million tonnes per year with an annual growth of 6.5% (Annual Report 2018-19, NDDB). Significant increase in milk production popularly known as "White Revolution" has provided income security to the dairy farmers and ensured milk availability to a great majority of the population, thereby supplementing the efforts towards nutritional security in the country. A third dimension of livestock farming is supply of cow dung for enriching soil health, thereby enhancing and sustaining crop productivity. Proper management of the huge livestock resources the country has, is essential to derive the targeted benefits from them. In this direction ICAR has already identified and registered 199 livestock breeds, which are being conserved and further improved.

However, livestock productivity is adversely affected by various animal diseases, some of them being zoonotic in nature. Occurrence of diseases causes heavy economic loss in terms of livestock health vis-a-vis production and has serious impact on export of livestock products including germplasm. The outbreaks of Foot-and-Mouth disease and haemorrhagic septicaemia in cattle and buffaloes; PPR, goatpox, sheeppox, and orf in goats and sheep; classical swine fever in pigs; Newcastle disease, infectious bursal disease and highly pathogenic avian influenza in poultry have underlined the adverse impact of these diseases on livestock and poultry productivity.

The most effective way to overcome the loss from diseases and increase livestock productivity is through prevention of diseases using vaccines. The Animal Science institutes of ICAR have made significant contributions in control of major livestock and poultry diseases through development of several vaccines against them.

The Animal Science institutes of ICAR, particularly, ICAR-Indian Veterinary Research Institute (ICAR-IVRI) played a pivotal role in eradication of the dreaded disease, Rinderpest, from the country with the development of vaccine against it. However, other diseases leading to major economic losses, such as Foot-and-Mouth Disease (FMD), demand their effective control and the ultimate target is their eradication. ICAR-IVRI has developed and commercialized several vaccines from time-to-time to meet the challenges of existing, emerging and re-emerging diseases of livestock and poultry. There is a constant endeavor to develop and enhance vaccines for different infectious diseases of livestock and poultry.

Besides ensuring optimal livestock productivity, protecting human health from zoonotic diseases entails prevention, control and eradication of animal diseases through use of cost-effective and efficacious vaccines. The Animal Science institutes of ICAR have worked hard to meet this requirement. The biologicals including vaccines developed by ICAR-IVRI were supplied throughout the geographical area of the then British India as well as whole of the independent India (Fig 1).

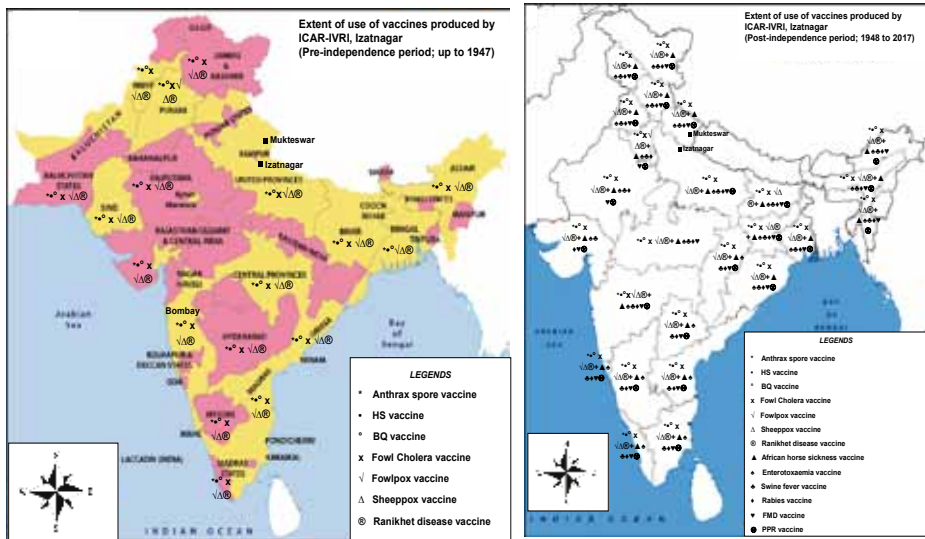


Fig 1. Vaccine use: Pre and post-independence.

Besides developing vaccines against many important animal diseases for control of various diseases, the Animal Science institutes of ICAR are also contributing indirectly in disease control by playing key central role in developing trained human resource in the area of animal health by teaching and training veterinarians on various aspects of vaccines/diagnostics production and quality control through different P.G./Diploma programmes. Further, they are also entrusted with the job of supplying various vaccine seed cultures and challenge strains to the manufacturers including state biological production units to ensure quality of biologicals and harmonize the vaccines being produced and used in the country.

ICAR-Indian Veterinary Research Institute, Izatnagar (ICAR-IVRI, Izatnagar) has been a pioneer in the world and produced the first veterinary biological *viz*, anti-rinderpest serum way back in 1899 and supplied it to the Middle East and other Asian countries apart from supplying to whole of the then India. After this first biological, ICAR-IVRI, Izatnagar played a major role in developing a series of other biologicals in the country including anti-anthrax serum in 1902, polyvalent HS vaccine in 1908, black quarter vaccine in 1906-08, goat tissue virus (GTV) vaccine in 1927; Ranikhet disease vaccine in 1940, tissue culture Rinderpest Vaccine (TCRP Vaccine) technology, inactivated Foot-and-Mouth Disease (FMD) vaccine in 1946-52; inactivated African horse Sickness vaccine in 1960-65; irradiated lungworm vaccine in 1973; inactivated goatpox vaccine in 1986, live attenuated PPR vaccine in 2001; low volume (2.0 ml) saponified haemorrhagic septicaemia vaccine in 2004. Live attenuated Vero cell-based vaccines for goatpox, high passage goatpox vaccine, sheeppox, orf, camelpox, buffalopox, combined conventional goatpox and PPR vaccine for goats, double combination sheeppox and PPR vaccine for sheep, triple combination (HGPV+PPR+Orf) vaccine for goats were developed during 2005-2008. On the same line, other Animal Science Institutes such as ICAR-National Research Centre on Equines, Hisar (ICAR-NRCE, Hisar) developed Equine Herpesvirus-1 vaccine and Equine Influenza vaccine (Updated) and ICAR-Central Institute for Research on Goats, Makhdoom (ICAR-CIRG, Makhdoom) developed Johnes Disease Vaccine (Inactivated).

Out of the above vaccines developed till date by ICAR, 16 have been commercialized or transferred to various State veterinary biological production units and are currently in production by them. Seven newly developed vaccines have been taken up for commercialization.

A concise information of vaccines for livestock and poultry that have contributed to the animal health management in the country and disease control is presented in this compilation.



VACCINES FOR CATTLE AND BUFFALOES



1

ANTHRAX SPORE VACCINE



- Anthrax is a zoonotic disease caused by the spore forming bacterium *Bacillus anthracis*.
- Anthrax is most common in wild and domestic herbivores.
- In herbivores, anthrax commonly appears as an acute septicaemia with a high fatality rate.
- In livestock, anthrax can be controlled largely by annual vaccination of all grazing animals in the endemic area.
- At present, live anthrax spore vaccine prepared from *B. anthracis* Sterne strain suspended in glycerine is available in India. ICAR-IVRI, Izatnagar adopted this vaccine technology in 1951.
- First vaccine is given at the age of 6 months in anthrax enzootic area and then it is repeated annually before monsoon with not less than 10 million spores/dose.
- The production of anthrax spore vaccine started in 1956-57 at ICAR-IVRI, Izatnagar, which gradually increased and with highest production recorded in 1964-65, when more than 6.6 lakh doses were manufactured and supplied. Gradually the technology was transferred to various State biological products units.
- The vaccination led to remarkable decrease in disease outbreaks in the country.



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Technology transferred to:

1. State biological production units.

2

BLACK QUARTER (BQ) VACCINE



- Black Quarter (BQ) is a generalized infection of cattle, buffalo and sheep caused by bacterium *Clostridium chauvoei*.
- It is characterized by emphysematous swelling of the muscles especially those of gluteal region.
- Black Quarter vaccine is available in India as a formalin-inactivated *C. chauvoei* culture, adjuvanted with aluminium hydroxide gel or alum precipitated vaccine. ICAR-IVRI, Izatnagar adopted this vaccine technology in 1906.
- First vaccination is done at the age of 6 months and is then repeated annually.

- Black quarter vaccine production started at ICAR-IVRI, Izatnagar in 1922-23 and was supplied to the then United Provinces, Punjab, Bengal, Assam, Bihar & Orissa, Central Province, Bombay, Madras, Sind & Rajasthan and Mysore. Gradually vaccine production increased



and during 1954-60 more than 10.0 lakh doses/year and in 1959-60 approximately 17.0 lakh doses were manufactured at ICAR-IVRI, Izatnagar to cover the large animal population.

- Vaccination has led to decrease in disease outbreaks in the country.

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3

HAEMORRHAGIC SEPTICAEMIA (HS) VACCINE



- Haemorrhagic Septicaemia (HS) is mainly caused by the bacterium *Pasteurella multocida* type B:2 and affects cattle and buffalo.
- HS vaccine is available in India as formaldehyde inactivated culture of *P. multocida* with aluminium hydroxide gel adjuvant or oil adjuvant or alum precipitated vaccine.
- First vaccination is done at 4-6 months of age and then repeated annually at least 15-20 days prior monsoon.
- The production of HS vaccine was started in 1923-24 at ICAR-IVRI, Izatnagar and supplied to the then United Provinces, Punjab, Bengal, Assam, Bihar & Orissa, Central Province, Bombay, Madras, Sind & Rajasthan and Mysore.
- Between 1942-46, about 64.0 lakh doses of vaccine were produced and supplied to almost all parts of country and military organizations. In 1956, HS adjuvanted vaccine also started to be manufactured and in the year 1962-63 approximately 9.7 lakh doses of adjuvanted HS vaccine and 6.3 lakh doses of plain HS vaccine were produced.
- Subsequently, after the transfer of technology and training imparted by ICAR-IVRI, Izatnagar to State biological products units, they became self sufficient.
- Vaccination has led to decrease in disease outbreaks in the country.



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1. State biological production units.

4

BRUCELLA ABORTUS VACCINE (S-19 STRAIN)



- Brucellosis remains one of the most common bacterial zoonosis, with over 5,00,000 human cases reported globally every year.
- *Brucella spp.* is highly pathogenic bacteria that affect several livestock species including cattle, buffalo, sheep, goat, camel, pig, yak, dog and horse. It also affects various wild animal species viz, wild boar, deer, birds, antelopes, African buffalo and reindeer.
- Most species of *Brucella* can infect animals other than their preferred hosts.
- Vaccination has been successfully used as one of the most effective measures to reduce the prevalence of bovine brucellosis.



- The most effective vaccine against brucellosis is the live *Brucella abortus* strain 19 vaccine. ICAR-IVRI, Izatnagar adopted it in 1956.
- Female calves between 4-8 months of age are vaccinated once in life time with not less than 4×10^{10} viable organisms subcutaneously.
- The production of *Brucella* S-19 vaccine at ICAR-IVRI, Izatnagar started in the year 1962-63 and continued till 2012-13.
- Vaccination of animals using this vaccine has led to decrease in disease outbreaks in the country.



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Technology transferred to:
1. Vivimed Labs.

5

FOOT-AND-MOUTH DISEASE (FMD) VACCINE (INACTIVATED)



- Foot-and-Mouth Disease (FMD) is one of the most contagious transboundary animal diseases in the world, caused by FMD virus.
- FMD causes huge economic loss in India and vaccination with inactivated trivalent vaccine twice in a year is followed to control the disease.
- A polyvalent aqueous aluminium hydroxide and saponin adjuvanted vaccine comprising of serotypes O, A22, C and Asia 1 was developed at Bengaluru campus of ICAR-IVRI.
- The virus antigen, grown in BHK-21 suspension cells is inactivated with formaldehyde, adsorbed on aluminum hydroxide and adjuvanted with saponin.
- Large-scale production of FMD vaccine for field use was started in 1976 at Bengaluru campus of ICAR-IVRI.
- During 1980 to 2010, a total of about 175 million doses of FMD vaccine were produced. The vaccine was supplied throughout the country.
- The vaccine has contributed significantly in reducing the incidence of FMD in the country.
- Following the implementation of FMD control program, ICAR and DAHD, Govt. of India harmonized the strains used for FMD vaccine production. Since October 2003, ICAR-DFMD provides appropriate vaccine strains based on antigen matching studies to the FMD vaccine manufacturers in the country.



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6

BUFFALOPOX VACCINE (LIVE ATTENUATED; BPXV VIJ/96 STRAIN)



- Buffalopox is an infectious disease caused by buffalopox virus [BPXV], an orthropox virus of the family *Poxviridae*.
- It causes both localized and generalized infection of buffaloes, cattle and also humans as a zoonotic agent. It is enzootic in India and other buffalo rearing countries.
- Occurrence of the disease in animals is associated with productivity losses in terms of meat, milk and draught capacity of the animal.
- A live-attenuated vaccine has been developed by Mukteswar campus of ICAR-IVRI in 2009-10 using an indigenous isolate (BPXV Vij/96 strain).
- The vaccine was developed by attenuating the virus in Vero cells and has been tested for safety, efficacy and potency in buffalo calves.
- The recommended dose of the vaccine is 0.5 ml (containing a minimum of $3.0 \log_{10} \text{TCID}_{50}$) to be inoculated by intra-dermal on the abaxial surface of the tail. Animals older than 4 months of age can be vaccinated with this vaccine.
- The freeze dried buffalopox vaccine is stable and has a shelf-life of more than one year at 4°C.
- The vaccine has profound economic benefit in India and other neighboring countries, where the disease is endemic.
- The vaccine is ready for commercialization.



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7

JOHNE'S DISEASE VACCINE (INACTIVATED)



- Infection of *Mycobacterium avium* subspecies *paratuberculosis* (MAP) causes chronic incurable granulomatous enteritis called Johne's Disease (JD) in domestic livestock leading to reduction in productivity. MAP is transmitted from infected animals to healthy animals via contamination of soil, water and grazing area and also through milk and colostrum to the offsprings.
- Control of Johne's Disease (JD) is important in the context of economic viability of livestock industry as well as public health concerns.
- Currently available imported vaccine is less effective since it is based on different strains of pathogen.
- ICAR-CIRG, Makhdoom has developed an inactivated JD Vaccine for both large as well as small ruminants.

- The vaccine is available in two forms: 1. Johne's Disease vaccine, inactivated, mineral oil adjuvant and 2. Johne's Disease vaccine, inactivated, aluminum hydroxide adjuvant.



- Vaccination has been successful in limiting the disease spread and also helps in recovery of known MAP infected animals.

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Technology transferred to:

1. Biovet Pvt. Ltd.

B

VACCINES FOR SHEEP AND GOATS



1

SHEEPPOX VACCINE (LIVE ATTENUATED; RF-STRAIN)



- Sheepox is an infectious disease of sheep caused by sheeppox virus.
- The disease is characterized with a morbidity of 80-100% and mortality of more than 50%.
- The disease is endemic in India and causes substantial losses.
- ICAR-IVRI, Izatnagar has adopted this live attenuated sheeppox vaccine technology.
- It is a cell-culture (lamb testicle/Vero)-based live attenuated freeze dried vaccine prepared from Roumanian (RF) strain of sheeppox virus.
- The dose of vaccine is 0.1 ml for all age groups and is given intradermally in the caudal fold or tip of the ear.
- The vaccine confers immunity for more than one year.
- The technology for sheeppox vaccine has been transferred to various state veterinary biological units of the country.
- The vaccine is being used extensively for mass vaccinations in the field.
- Millions of animals are being vaccinated every year using this vaccine.
- Reduction of sheep mortality and overall development of sheep husbandry has been achieved in the country.



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Technology transferred to:

1. State biological production units.

2

SHEEPOX VACCINE (SRINAGAR STRAIN)



- Sheeppox, an infectious disease of sheep caused by sheeppox virus, is characterized by fever, muco-purulent nasal discharge, papules and nodules all over the body with a morbidity of 80-100% and mortality of >50%.
- The disease is enzootic in India and several sheep rearing countries and causes substantial losses to the sheep industry.
- Mukteswar campus of ICAR-IVRI developed a live attenuated vaccine in 2014 using 'Srinagar' isolate of sheeppox virus for preventive immunization of sheep against sheeppox.
- The vaccine is easy to administer, safe and potent in sheep.
- Production of small quantity (1 ml) of virus may yield ~10000 doses of vaccine.
- Scalability of the vaccine and downstream processing is simple and easy.
- It produces long lasting immunity with the protection up to 4 years.
- Disease affects the economy through lowering productivity, causing high mortality and increasing the treatment costs. Hence, vaccination of sheep population is expected to significantly contribute to enhanced sheep productivity in the country.



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Technology transferred to:

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3

ENTEROTOXAEMIA VACCINE



- Enterotoxaemia disease, also known as 'Pulpy kidney disease', is caused by *Clostridium perfringens* type D in sheep and goat.
- The classical enterotoxaemia of sheep is seen less frequently in goats and rarely in cattle. It has a worldwide distribution and affects animals of any age.
- The vaccine which is available in India was adopted by ICAR-IVRI, Izatnagar in 1956. It is formalin inactivated culture of *C. perfringens* type D and epsilon toxoid adjuvantated with aluminium hydroxide gel.
- In lambs, first vaccination is done at the age of 4 months if dam is vaccinated or at 1 week age, if dam is unvaccinated. After primary vaccination, vaccine should be repeated annually before monsoon.
- The production of enterotoxaemia vaccine started at ICAR-IVRI, Izatnagar in the year 1958-59.
- The vaccine has helped in control of the disease in the country.



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4

PPR VACCINE (LIVE ATTENUATED; PPRV/SUNGRI/ 96 STRAIN)



- *Peste-des-petits-ruminants* (PPR) is an important viral disease of sheep and goats, causing huge losses in India.
- Control of PPR is usually done by vaccination of animals with live attenuated vaccine at more than 3 months of age.
- The vaccine developed at ICAR-IVRI, Izatnagar in 2002 is a Vero cell based live-attenuated indigenous PPR vaccine (PPRV/Sungri/96 strain).
- The recommended dose of the vaccine is 1.0 ml (containing a minimum of $2.5 \log_{10} \text{TCID}_{50}$) to be inoculated by subcutaneous route in the neck region.
- The freeze dried PPR vaccine has a shelf-life of one year at 4°C and reconstituted (in 1M MgSO_4) vaccine should be used within 8 hours.
- Using economic surplus model, the change in total surplus as a result of mass vaccination of sheep and goats against PPR was found to be Rs. 8,253 crore per annum.
- There has been a reduction of more than 75% in disease outbreaks due to mass vaccination campaigns launched to control this disease during 2005-2016.
- 200 million doses of PPR vaccine have been produced by the companies after acquiring this technology from ICAR-IVRI, Izatnagar.
- A market of 100 million doses/annum for this vaccine exists in our country.



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2. Indian Immunologicals Ltd.
3. Biomed Pvt. Ltd.
4. Brilliant Bio Pharma Pvt. Ltd.
5. Hester Biosciences Ltd.

5

GOATPOX VACCINE (UTTARKASHI STRAIN)



- Goatpox is a highly contagious viral disease of goats, which is listed in the notifiable diseases of the OIE.
- Mukteswar campus of ICAR-IVRI developed a live attenuated vaccine in 2006 using “Uttarkashi” isolate of goatpox virus in Vero cells.
- The vaccine is safe, potent and efficacious, providing immunity for at least 40 months and possibly life-long.
- The vaccine is stably attenuated and safe in goats.
- The vaccine does not interfere with immunogenicity of other vaccines such as PPR vaccine or vice versa. Vaccine can confer protection even at low dose of 10 TCID₅₀ per animal.
- Vaccine supplied in lyophilized condition can tolerate ambient temperate conditions without loss of titer.
- This disease affects the economy through lowering productivity, causing high mortality and increasing the treatment costs. Hence, vaccination of goat population is expected to significantly contribute to productivity of goats, a species largely owned by small and marginal farmers of the country.
- The vaccine has potential use in the endemic regions, not only in India but also in other affected regions including Southwest, Middle East, and Central Asia and Northern and Central Africa.



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2. Indian Immunologicals Ltd.
3. Hester Biosciences Ltd.

6

BLUETONGUE VACCINE (SEROTYPES 1, 2, 10, 16 AND 23)



- Bluetongue (BT) is a non-contagious arboviral (Culicoides transmitted) disease, caused by a double stranded RNA virus belonging to the genus Orbivirus and family *Reoviridae* affecting domestic (primarily sheep) and wild ruminants.
- Southern states like Tamil Nadu, Andhra Pradesh, Telangana and Karnataka are mostly affected by this disease.
- Under All India Network Project on Bluetongue, India's first multivalent inactivated pentavalent Bluetongue vaccine containing most prevalent serotypes 1, 2, 10, 16 and 23 was developed.
- Time of vaccination: 1st at the age of 4 months and booster after 28 days of first vaccination.
- Dose: 2 ml S/c (subcutaneously).



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Technology transferred to:

1. Indian Immunologicals Ltd.
2. Biovet Ltd.
3. Sanvita Biotechnologies Pvt. Ltd.
4. Brilliant Bio Pharma Pvt. Ltd.

7

ORF VACCINE (LIVE ATTENUATED; ORFV MUK 59/05 STRAIN)



- Orf is an infectious and highly contagious skin disease of sheep and goat caused by orf virus (ORFV), a parapoxvirus of the family *Poxviridae*.
- The disease is characterized by proliferative lesions including papules, vesicles leading to formation of scabs on the skin of lips, oral mucosa and around the nostrils of sheep and goat.
- The disease causes considerable morbidity both in sheep and goat with high mortality especially in young ones, complicated by secondary infections.
- A live-attenuated vaccine for orf infection has been developed by Mukteswar campus of ICAR-IVRI in 2013 using an indigenous isolate of Orf virus (Mukteswar 59/05 strain) by passaging the virus in primary lamb testes cells.
- The recommended dose of the vaccine is 0.20 ml (containing a minimum of $3.0 \log_{10}$ TCID₅₀ vaccine virus) to be inoculated by intra-dermal route with scarification on the inner aspect of thigh. Animals older than 4 months of age can be vaccinated.
- The freeze dried vaccine is stable and has a shelf-life of more than one year at 4°C.
- The vaccine will be useful for reduction of incidence of the disease in parts of the country where the disease is endemic.
- The vaccine technology is ready for commercialization.



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VACCINES FOR PIGS



1

CLASSICAL SWINE FEVER VACCINE (LIVE ATTENUATED, LAPINIZED)



- Classical swine fever (CSF) is a potentially fatal, highly contagious, viral disease of pigs.
- CSF is responsible for serious economic losses directly due to high mortality (up to 100%), growth and reproductive problems in affected pigs and indirectly by bringing restrictions on exports of pork and pork products.
- Current CSF control program in India is mainly dependent on prophylactic vaccination of domestic pigs using live attenuated lapinized vaccine.
- ICAR-IVRI, Izatnagar has been producing this live attenuated lapinized CSF vaccine since 1966.
- The vaccine consists of 10% spleen suspension of rabbits infected with a modified rabbit adapted classical swine fever virus strain.
- The suspension is made in a yolk-buffer base and is then freeze dried.
- Reconstituted vaccine (1 ml) is administered intramuscularly for active immunization of swine irrespective of age, breed and sex.
- Use of this vaccine resulted in reduction of morbidity and mortality in pigs in the country.



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Technology transferred to:

1. State biological production units.

2

CLASSICAL SWINE FEVER VACCINE (LAPINIZED, CELL CULTURE)



- Classical swine fever (CSF) is highly contagious devastating viral disease of pigs causing 100% mortality in affected pigs.
- In India, so far, lapinized CSF vaccine, produced in rabbits, is being used to control the disease by vaccination of piglets.
- From one rabbit, only 50 doses of vaccine can be produced, thus it is difficult to produce this lapinized CSF vaccine on a large scale.
- Realizing the problem, ICAR-IVRI, Izatnagar has developed a cell culture classical swine fever vaccine in 2007 by adapting lapinized CSF vaccine virus in PK-15 cell culture system.
- $10^{2.8} \text{TCID}_{50}$ cell culture virus contains 100PD_{50} (equivalent to one dose of vaccine) dose of the vaccine.
- As the vaccine virus grows to the titre of $10^{7.5} \text{TCID}_{50}$ per ml in PK-15 cells, around 5,000 doses of vaccine can be prepared from 1 ml cell culture virus.
- The technology is suitable for large-scale production of CSF vaccine. Further, this avoids use of rabbits for vaccine production.
- The vaccine technology has a potential to meet national demand of CSF-Control Program in the country.



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Technology transferred to:

1. Punjab Veterinary Vaccines Institute.
2. Indian Immunologicals Ltd.

3

CLASSICAL SWINE FEVER VACCINE (LIVE ATTENUATED CELL CULTURE)



- Classical swine fever (CSF) is a highly contagious viral disease of pigs with 100% mortality and has a great economic impact on pig farmers.
- ICAR-IVRI, Izatnagar has developed live attenuated cell culture vaccine for CSF using an Indian field isolate.
- This vaccine has a very high titre ($1 \times 10^{9.5}$ TCID₅₀/ml), so the cost of production will be very economical.
- The vaccine has been extensively tested for safety and potency and has been found to provide 100% protection.
- The vaccine has been found to induce protective immunity from day 14 of the vaccination till 18 months.
- This cell culture vaccine can replace the currently used lapinized vaccines which are being produced by using large number of rabbits for each batch.
- The cell culture vaccine can be produced on a large scale very easily.
- This vaccine will be of immense help to the CSF control programme already launched by DAHD (CSF-CP), Government of India.
- The vaccine is ready for commercialization.



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VACCINES FOR HORSES



1

EQUINE HERPESVIRUS- 1 VACCINE



- Infection due to equine herpesvirus-1 (EHV1) in horses is the main cause of abortion, and respiratory and neurological diseases, thereby leading to heavy economic losses to the equine industry.
- Inactivated vaccine is generally recommended for immunoprophylaxis against EHV1.
- The vaccination of horses against EHV1 infection is being practiced by Indian equine breeders for last several years with an imported inactivated vaccine.
- ICAR-National Research Centre on Equines, Hisar has developed inactivated equine herpesvirus1 (EHV1) vaccine for EHV1 infection.
- It is a formalin inactivated vaccine prepared from an indigenous EHV1 (strain Hisar-90-7), grown in Vero cells.
- This is an oil emulsion mannide monooleate (OEMM) EHV1 vaccine.
- The vaccine is intended for all equine species especially for pregnant mares.
- Dosage schedule: 2 ml intramuscular at 5 months of pregnancy followed by two boosters at 7th and 9th months of pregnancy.
- The technology is ready for transfer to drug and vaccines manufacturers, state veterinary biological production units, etc.



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2

EQUINE INFLUENZA VACCINE (UPDATED)



- Equine influenza, commonly known as 'Horse Flu,' is a viral disease of horses caused by Equine Influenza virus (EIV) subtype H3N8.
- The disease results in heavy morbidity leading to huge economic losses.
- An inactivated aluminum hydroxide adjuvant vaccine was developed by ICAR-NRCE, Hisar in 1987, which was further upgraded in 2016 by incorporating A/eq/Katra (Jammu)/06/08 (H3N8) EIV isolate prevalent in recent outbreaks.
- Vaccine is intended for immunization of horses, mules and donkeys.
- Dosage: 1 ml intramuscular.
- Vaccination schedule: First vaccination in animals above 6 months of age followed by a booster vaccine after 4-5 weeks and then repeated annually or after monitoring the titer.
- The technology is ready for transfer to the drug and vaccine manufacturers, State veterinary biological production units etc.
- This vaccine will help in controlling influenza in equines in the country.



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E

VACCINE FOR CAMEL



1

CAMELPOX VACCINE (LIVE ATTENUATED; CMLV 1/97 STRAIN)



- Camelox is a contagious and OIE notifiable viral disease, affecting specifically young camel calves caused by camelox virus (CMLV), an orthopox virus of the family Poxviridae.
- The disease is endemic in Asia including India, Middle East and, Africa and characterized by febrile papulopustular eruptions over the body and mucous membrane with high morbidity and moderate mortality.
- The disease mostly affects young ones aged 2-3 years and is also zoonotic in nature.
- The disease causes significant economic loss by incurring high morbidity in adults and mortality in young calves.
- A live Vero cell attenuated vaccine has been developed by Mukteswar campus of ICAR-IVRI using an indigenous isolate (CMLV 1/97 strain).
- The recommended dose of the vaccine is 0.5 ml (containing a minimum of 3.0 log₁₀ TCID₅₀ vaccine virus) to be inoculated intra-dermally on the ventral aspect of the caudal fold. Animals older than 4 months of age can be vaccinated.
- The freeze dried camelox vaccine has a shelf-life of more than one year at 4°C.
- The vaccine would be useful in reduction of the disease incidence in camel rearing belts in the country.
- It also possesses export potential to Middle East and other camel rearing countries.
- The vaccine technology is ready for commercialization.



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F

VACCINES FOR POULTRY



1

NEWCASTLE DISEASE/ RANIKHET DISEASE VACCINE



- Newcastle disease/Ranikhet disease (RD) is a highly contagious and most lethal viral disease of poultry.
- The disease is responsible for substantial economic losses to the poultry industry, which is controlled through vaccination using lentogenic (F) and mesogenic (R2B) vaccines.
- ICAR-IVRI, Izatnagar produced R2B strain vaccine since 1940 and F strain vaccine since 1953.
- These vaccines are freeze dried suspension of a modified live virus produced in embryonated chicken eggs.
- These freeze-dried vaccines can be stored at -15 to -20°C and transportation should be done at 2-6°C.
- RD F vaccine is a live vaccine and administered by intranasal, intraocular, drinking-water or spray administration in 1 to 5 days old chicks.
- RD R2B vaccine is an inactivated vaccine and is usually administered by injection under the skin inside the wing in 8-weeks-old adult birds.
- The immunity produced by RD F vaccine lasts for about 15 weeks. Chicks should be revaccinated with the RD R2B vaccine between 8-10 weeks after primary vaccination.
- Reduction of morbidity and mortality in poultry in the country was achieved by use of these vaccines.



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Technology transferred to:

1. State biological production units.

2

FOWLPOX DISEASE VACCINE



- Fowlpox is a disease of poultry and other birds caused by a dsDNA virus of the genus *Avipoxvirus* of the family *Poxviridae*.
- Its distribution is world-wide. The disease causes economic losses due to a transient drop in egg production and a reduced growth rate in young birds.
- The disease is characterized by the formation of wart-like proliferative lesions and scabs on the skin in dry form, and diphtheritic necrotic masses (cankers) in the upper parts of the digestive and respiratory tracts in wet form and conjunctivitis in oculo-nasal form.
- Vaccination at proper age with dependable vaccine is the most effective means of controlling fowlpox.
- Chickens are vaccinated with attenuated fowlpox virus-based vaccine at the age of 12–16 weeks, via the wing web method of injection.
- The production technology for the vaccine has been transferred to various state veterinary biological production units. The training on production of this vaccine has also been imparted through National Diploma Courses and different Capacity Building Programs.
- Reduction of morbidity and mortality in poultry in the country was achieved by use of this vaccine.



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Technology transferred to:

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3

INFECTIOUS BURSAL DISEASE VACCINE (SUBVIRAL PARTICLE-BASED)



- Infectious Bursal Disease (IBD) also known as Gumboro disease of poultry is caused by IBD virus.
- IBD virus infects the bursa of Fabricius, particularly the actively dividing and differentiating B lymphocytes in young chickens, resulting in morbidity, mortality and immunosuppression.
- Bursal damage and depletion of B cells enhances the susceptibility of chickens to other infections and interferes with vaccination against other diseases.
- ICAR-IVRI, Izatnagar developed the subviral particle (SVP)-based Infectious bursal disease vaccine in 2018.
- It comprises of subviral particles (SVPs) formed by yeast expressed IBDV major capsid protein VP2.
- This vaccine, in addition to its ability to stimulate antibody response, is highly effective in stimulating antigen specific cytotoxic T lymphocyte responses.
- The vaccine does not cause immunosuppression in birds.
- One single injection of 0.1 ml vaccine, equivalent to 400 µg of SVPs, is to be given per chick at day-old age by intramuscular route.
- A single shot of this vaccine in the hatchery can eliminate the costly and time consuming vaccination in the field.
- The vaccine is ready for commercialization.



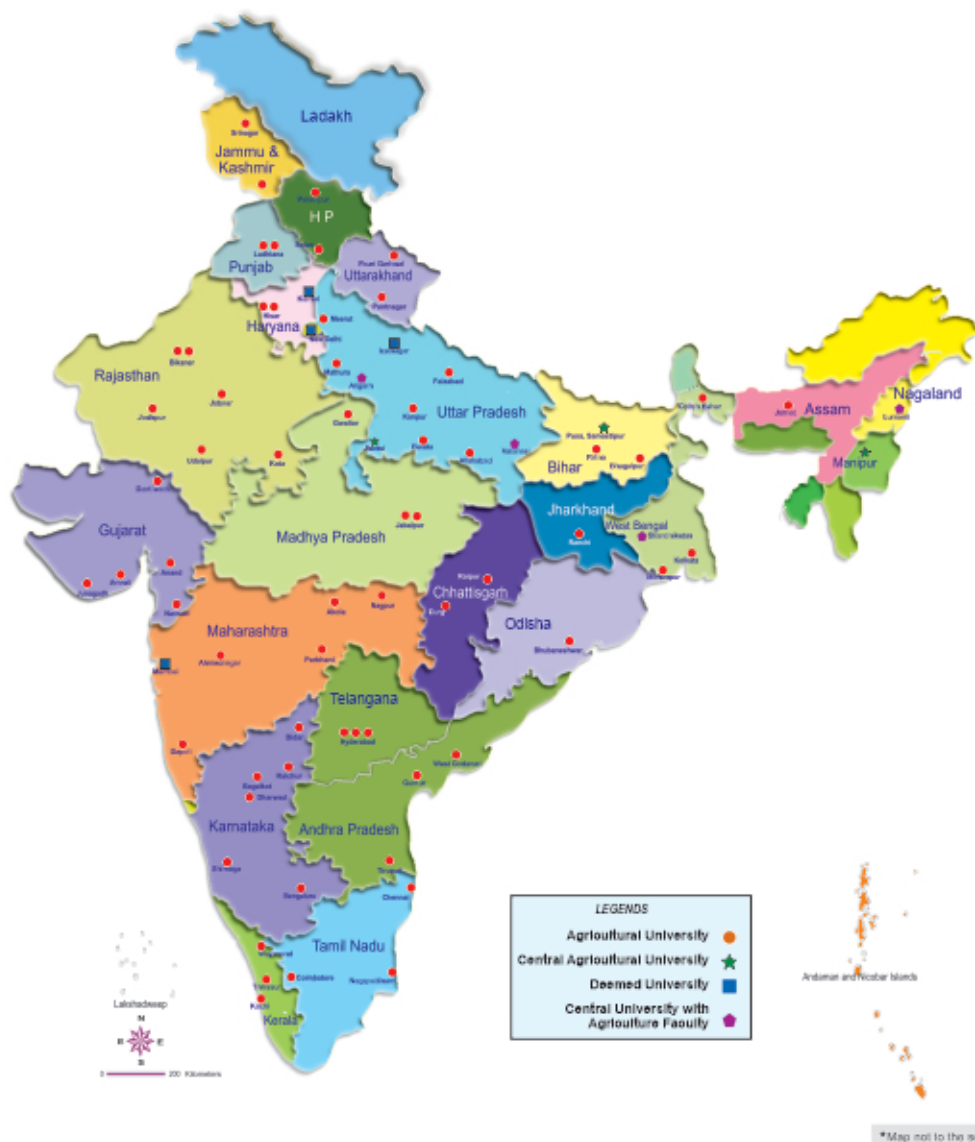
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