

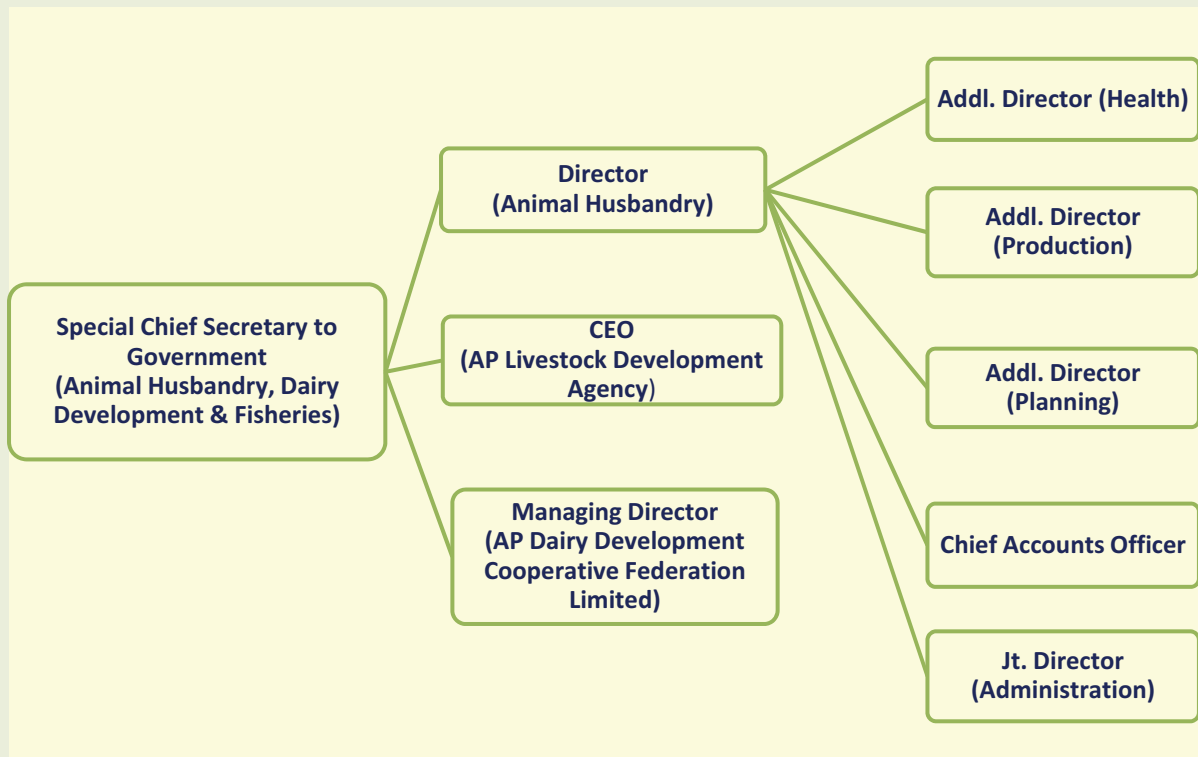
Chapter 3 - Animal Husbandry and Fisheries Department

3.1 Department profile

Animal Husbandry and Fisheries Department plays a major role in providing veterinary healthcare and improving the genetic production potentialities of livestock and poultry reared in the State. The main activities of the Department include, among others,

- ⇒ Utilisation of artificial insemination to improve the production potential of cattle;
- ⇒ Providing preventive and curative healthcare to livestock;
- ⇒ Augmenting fodder production to meet the nutritional requirements of livestock;
- ⇒ Providing relief measures to livestock during natural calamities;
- ⇒ Building awareness among farmers on profitable livestock production;
- ⇒ Increasing fish seed production and stocking, etc.

The organogram of the Department is given below.



As part of our audit, during the year 2010-11, we reviewed the production of animal vaccines at the Veterinary Biological Research Institutes (VBRI) at Hyderabad and

Samalkot in East Godavari district. Our audit revealed that animal vaccines were being produced in VBRI without valid licence and released for field distribution without complying with quality assurance standards prescribed by the Central Drug Control Authority. Detailed audit findings are discussed below.

3.2 Unauthorised production and distribution of animal vaccines

Animal vaccines are being produced at the VBRI at Hyderabad and Samalkot and tested at the quality control (QC) laboratory at Standardisation Division, Biological Products, Rajendranagar, Hyderabad (SDBP), before the vaccines are released for field distribution.

As per the norms prescribed in Schedule 'M' of the Drugs and Cosmetics Rules, 1945 (Rules), Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) are to be complied with by all the manufacturing units/testing laboratories. GoI made these norms mandatory with effect from July 2005. State Government accorded (August 2005) administrative sanction for modernisation of VBRI at Hyderabad and Samalkot and SDBP under the State scheme 'Modernisation of Animal Vaccine Production and Disease Diagnostic Units' to upgrade the laboratories to GMP and GLP standards including infrastructure development.

Modernisation works of the VBRI at Hyderabad and Samalkot were completed in January 2010 at a cost of ₹ 20.89 crore¹. Modernisation works of SDBP however, had not commenced even as of June 2011. State Government entrusted (February 2005) the works to APAGROS², but the agency backed out in March 2009 i.e., after four years of entrustment, expressing lack of technical competency to execute the work. Although the work was later entrusted (September 2009) to JNAFU³, Hyderabad, it has not commenced the work as yet. Lack of QC laboratory for testing the vaccines for compliance with GMP and GLP standards resulted in GoI denying (June 2011) renewal of licence to VBRI for production of vaccines.

Rules stipulate that quality control laboratories should be independent of production area but should be in the same premises to facilitate testing for strength, quality and purity of the drugs. Scrutiny of records of the Director of Animal Husbandry (Director) and Joint Director/Deputy Director of the VBRI revealed that, contrary to these Rules, though modernisation of SDBP was conceived along with the modernisation of VBRI, construction was taken up at the old premises, which is far away from VBRI, instead of constructing a new QC laboratory within the premises of VBRI. Delay in commissioning the work pushed up the initially estimated cost of construction/modernisation from ₹ 56.64 lakh to ₹ 5.75 crore as of December 2010.

As of June 2011, VBRI continued to produce vaccines in the modernised buildings without a valid licence and release them for field distribution without complying with quality assurance standards, thus ignoring the directive of Central Drug Control Authority (DCA).

¹ VBRI, Hyderabad: ₹ 12.84 crore; VBRI, Samalkot: ₹ 8.05 crore

² Andhra Pradesh State Agro Industries Development Corporation, Hyderabad

³ Jawaharlal Nehru Architecture and Fine Arts University

Government in its reply (September 2011), stated that farmers face huge economic losses if diseases are not controlled on prophylactic basis and timely supply of vaccines and controlling the diseases through vaccinations was the only way to stop the losses. The reply of the Government does not explain why the vaccines produced are not tested in a QC laboratory in conformity with GLP standards and why quality assurance standards are not being complied with. Failure to comply with regulatory provisions by Government agencies, especially in the domain of pharmaceutical production, would set a poor example and entail risk to the livestock health.