

**OIE Regional Workshop on Risk Analysis for Import, Distribution and Handling of  
Animal Vaccine  
In Collaboration with Department of Veterinary Services, Malaysia  
Kuala Lumpur, Malaysia, 3 -5 November 2009**

**Conclusions and Recommendations**

Considering that

1. The OIE Regional Workshop on Risk Analysis for Import, Distribution and Handling of Animal Vaccines in collaboration with Department of Veterinary Services, Malaysia, was held in Kuala Lumpur, Malaysia, on 3-5 November 2009.
2. The main objectives of the Workshop were to provide national competent authorities with the information on registration of animal vaccinations and risk analysis of animal vaccines, especially for import, distribution and handling and to discuss the development of standards on risk analysis of animal vaccines in the Region.
3. A series of OIE meetings /workshops have been organized for harmonization of registration of veterinary medicinal products, and recently focusing on animal vaccines in the Region (ASEAN Member Countries and +3 including P.R. China, Japan and R.O. Korea) have been held. Those Meetings/Workshops have enabled Member countries to exchange information and share experiences in veterinary medicinal product registration, to familiarize with international cooperation on harmonization systems, and to provide the updated information on the quality control of vaccines. The previous Workshop held in Bandung, Indonesia discussed, in particular quality control of animal vaccines and Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).
4. The supply and effective usage of vaccines support the disease control and prevention and share the significant functions of animal disease prevention and control. Veterinary vaccines provide satisfactory results, when they are manufactured in compliance with internationally accepted standards and also properly used in the field.
5. OIE Risk Analysis for veterinary vaccines is founded on the principles of quality assurance including quality control, in the production of veterinary vaccines. Guidelines of Risk Analysis for animal vaccines are in place in the OIE Manual of

Diagnostic. Test and Vaccines for Terrestrial Animals, for reference of Veterinary Services.

6. Quality Assurance including quality control is considered as the best approach for securing high quality of animal vaccines, however, this may not absolutely guarantee the production of perfect quality products, thus Risk Analysis for animal vaccines is needed.
7. The current Workshop noted the progress of harmonizing registration of animal vaccines in the Region, while Risk Analysis on animal vaccines needs to be further strengthened.

The workshop recommends that

1. Risk Analysis models for animal vaccines should be developed (based on the OIE Standards) to support vaccine quality assurance in the Region.
2. A regional technical workshop should be considered to enhance understanding and identify gaps and develop such the models mentioned above.
3. International/Regional Organizations should be encouraged to support Regional activities on Risk Analysis for animal vaccines.
4. Other matters:
  - (1) The ASEAN Member States requested relevant lead countries to accommodate comments and inputs given at the Workshop in the following documents:
    - ASEAN Standards for Animal Vaccines: *Salmonella Gallinarum*, live and inactivated (Thailand)
    - ASEAN Standards for Animal Vaccines: Leptospira for pigs, inactivated (Indonesia)
    - ASEAN Standards for Animal Vaccines: Avian Influenza, inactivated (Indonesia)
    - ASEAN Register of Animal Vaccines (Indonesia)
    - ASEAN Standards for Good Manufacturing Practices (GMP) for Animal Vaccines (Indonesia)

- Protocol for Accreditation of ASEAN Animal Vaccine Testing Laboratories (Thailand)

(2) In view of the revision of the above documents, the ASEAN Member States agreed to the following schedules:

- Circulation of revised drafts by the lead countries to the National Focal Points by the end of November, 2009
- Provision of comments/inputs by the National Focal Points to the lead countries by the end of February 2010
- Circulate of final drafts by the lead countries to the National Focal Points by March 2010
- Finalization of the documents at the 12<sup>th</sup> Meeting of ASEAN National Focal Points on Animal Vaccines (AFPAV), scheduled in April/May 2010

(3) Regarding the Protocol for Accreditation of ASEAN Animal Vaccine Testing Laboratories, the ASEAN Member States requested Thailand to prepare and circulate a summary paper on pros and cons of accreditation by scopes (testing method) and by types of vaccines as a basis for individual countries consideration and internal consultation before deciding at the 12th Meeting of AFPAV.

(4) Each ASEAN Member State was requested to submit a list of assessors together with their CV (up to four assessors) to the AFPAV by the 12th Meeting of AFPAV. The assessors should have a) an academic degree in the field of veterinary medicines, veterinary science, veterinary microbiology (virology and bacteriology), biomedical sciences and other related disciplines, and b) at least three (3) years experience in testing animal vaccines or related work. Those with experience in ISO17025 or equivalent are preferable.

(5) The ASEAN Member States requested Indonesia as the secretariat of the ASEAN National Focal Points for Animal Vaccines with assistance of the ASEAN Secretariat to seek nomination of a Focal Point from countries which have yet to submit. The request was also made to Indonesia for the development of a draft Terms of Reference (TOR) of the ASEAN National Focal Points for Animal

Vaccines to facilitate future cooperation. This list of ASEAN National Focal Points for Animal Vaccines (including their contact information) and the draft TOR should be circulated to all Focal Points prior to the 12th Meeting of AFPV.

- (6) The ASEAN Member States requested Malaysia to report the outcome of the Workshop, including its conclusion and recommendations to the 12<sup>th</sup> Meeting of AFPV for consideration and support.