Dr Vallat welcomed the group and thanked all the participants for their support to the OIE. He explained the terms of reference and emphasized the importance of the expected outcome of this group. The OIE gets many requests from countries to guide them in the implementation of vaccination programs against avian influenza (AI). OIE would like to be able to provide these countries with general guidelines and an overview of the available vaccines.

Dr Erasmus acted as chair and Dr Bouma acted as rapporteur. The Agenda and list of participants are presented as Appendices I and II, respectively.

Dr Erasmus proposed to move the point on trade implications up in the agenda. The group felt that the technical part should be discussed first and the agenda was left as it was proposed.

World Health Organization (WHO) will organize a meeting on human vaccine production in veterinary facilities and this point will be added at the end of the agenda. The use of combined vaccines will also be considered by the group. The group adopted the terms of reference.

The OIE and FAO explained their views on vaccination and the members of the group presented the vaccination policies in their countries.

1. World organisation for animal health (OIE)

Dr Bruschke explained the view of the OIE on vaccination against AI. The OIE recommends eradicating the disease at animal source to decrease the virus load in animals and environment and therewith to decrease the risk of human infection and the risk of a human pandemic. Classical eradication methods should be used primarily and vaccination can be used as additional tool. OIE receives many questions on the development and implementation of vaccination programs and would like to offer guidelines to the countries for this.

2. Food and Agriculture Organisation of the United Nations (FAO)

The view of FAO on vaccination is drawn up in the FAO recommendations on the prevention, control and eradication of highly pathogenic avian influenza (HPAI) in Asia (September 2004). According to Dr Domenech this document was still valid. He encouraged the group to take into account what already has been written and what we know now. He also mentioned that he would like to make the guidelines a living document that can be changed according to changing situation in the world.

3. Italy

Dr Marangon presented the vaccination strategy used in Italy in 2002

Monitoring showed that there were continuous introduction of low pathogenic virus strains. Italy asked European Union (EU) for permission to use the bivalent vaccine.
Summary:

- To control and eradicate LPAI.
- Targeted vaccination used (certain production types and some species),
- DIVA approach
- Emergency vaccination

Technology should be improved, since each bird should be vaccinated individually now.

Vaccination can be additional tool and does not have to be a sign of an inadequate managing an outbreak.

The HPAI outbreak in 1999 was controlled without vaccination. A LPAI H7 strain, however, re-emerged. After a long discussion, the DIVA approach was chosen and a targeted vaccination strategy was applied to turkeys, layers and breeders. The outbreak was successfully controlled. In 2002, a new LPAI strain was introduced, and eradicated by means of vaccination. In 2004 a bivalent vaccine (H5 and H7) was used to control an outbreak of LPAI. The outbreaks with LPAI of various H and N subtypes are assumed to originate from wild water fowl, which is endemically infected.

4. The Netherlands

Dr Bouma presented the situation in 2003 in the Netherlands on vaccination. In the 2003 outbreak no vaccines have been used and it has not been a point of discussion at that time. The virus spread so fast that it was not feasible to stop the epidemic with vaccination. After the outbreak of 2003 the discussion on vaccination was started. Beginning 2006 a plan was submitted to the EU to get permission to vaccinate zoo animals, pet birds and free range poultry. Free-range poultry should be sampled at the start, vaccinated twice and then 20 sentinels will be placed in cages in each flock. The sentinels will be sampled every 3 months. Vaccination is voluntary but if not, birds should be kept inside. For pet birds the same system applies. The animals are sampled, vaccinated twice and then 3 months later they are sampled again. All vaccinated animals can be kept outdoors after the vaccination procedure has been finished and this permission lasts for a year after the vaccination. It does not prevent the animals from getting culled when an outbreak would occur.

5. Peoples Republic of China

In China H5N2 was approved to use in chicken and was licensed to nine companies for production. One dose gave a protection of about 6 months.

The H5N1 gave much better immunity. Waterfowl play an important role in the spread of the virus in China. The vaccine was therefore tested in geese; they were fully protected after two doses. Antibody duration in ducks was much better than in geese.

Harbin also developed a recombinant vaccine H5N1 in fowlpox virus vector vaccine and a Newcastle Disease vector vaccine.

In China many outbreaks have been detected in 2005. All outbreaks occurred in the small scale free range backyard chicken and have been found in unvaccinated waterfowl. Also chicken vaccinated with unqualified vaccines have been found positive.

The major problems found in China are:

- Low vaccination ratio, less than 20%,
- Many back yard flocks
- Many wild waterfowl
- Use of not qualified vaccines

The possible solutions are:

- Government pays for the vaccines
- Improvement of the quality control of the vaccine production
6. **South Africa (SA)**

Dr Erasmus explained the situation in SA. Outbreaks of AI in ostriches in the Cape Province were detected in 1992. In 2001 an outbreak of H6N2 in chicken was diagnosed and permission was granted to vaccinate breeders and layers.

The bio-security in SA in poultry farms is not very high and farms are not wild bird proof. It is therefore not possible to separate the poultry completely from wild birds. The current policy is stamping out. There is no general compensation mechanism in place. The minister will decide in each individual outbreak. SA feels that prophylactic vaccination should be used as soon as possible. Ostrich industry is for more than 90% dependent on export. There are no experimental data available on the efficacy of vaccination in poultry.

A H7N1 outbreak in ostriches in 1992 was controlled using an inactivated AI vaccine. In 2001, an outbreak with a H6 strain occurred, and breeders and layers in high risk areas were vaccinated using an inactivated dual vaccine against H6N2 and ND. In some areas the infection disappeared, in other areas sentinels seroconverted. The biosecurity measures in SA are not of a high standard.

7. **International Federation for Animal Health (IFAH)**

Dr Jones gave the opinion of the IFAH. Vaccination programs should not stand alone but should complement other measures. Preparedness policy is essential to make the capacity meet the demand and unexpected rise in demand can lead to a shortage of available vaccines. Inactivated vaccines for a wide range of strains are available for administration by injection. Sometimes the regulatory hurdles stand in the way of a fast availability.

To achieve a high efficacy all birds should be vaccinated. The majority of vaccinated birds do not shed and if they do, it is only for a short period and a limited amount of virus.

Vaccination programs have many implications; the monitoring requires preparation and resources, well organized response is necessary to handle an outbreak and issue of trade must be considered. From the regulatory point of view the different countries take different positions in relation to authorization of emergency vaccines and differentiate amongst full versus emergency registration. A balanced risk-benefit approach is essential.

Vaccine production is time consuming and should therefore be part of a contingency plan. The agreements with the pharmaceutical companies need to be put in place in peace time. Vaccine and antigen banks may assist availability.

The CVO’s, regulators, NGO’s and Industry need to work together in a structured dialogue.

The industry wants to be seen as partner in combating the disease not as vaccine sellers.

After the presentation of the different participants a list was made of points to be included in the guidelines. The group felt that the following points needed to be addressed: the conditions to decide whether to vaccinate or not, the choice of the product, the limitations and benefits, the implications and future needs. After some discussion it was decided to focus entirely on the veterinary situation and not take the public health situation into account as a point for discussion whether to vaccinate the animal population or not. The FAO position paper was taken into account. Thereafter all the points on the list were discussed by the group to proceed to the writing of the guidelines.

A good background document is pivotal according to the experts and the representatives from industry. It was decided that the introduction and background would be written jointly by OIE and FAO and will be a joint paper.

Dr Vallat mentioned that the OIE can use part of its Rinderpest fund for the procurement of vaccines for Africa. He would appreciate a good guidance on the vaccines to be used in Africa. He emphasized that fowlpox and Newcastle disease are endemic.

The guidelines are added as **Appendix IV** to the report.
Appendix I

MEETING OF THE
OIE AD HOC GROUP ON VACCINATION STRATEGIES FOR AVIAN INFLUENZA
Paris, 15 - 17 March 2006

Agenda

1. Finalisation of Agenda, Terms of Reference and working program

2. View of the OIE on vaccination for avian influenza (Dr Christianne Bruschke)

3. View of the FAO on vaccination for avian influenza (Dr Juan Lubroth)

4. Vaccine policies and experiences in selected countries (10 minutes each):
   a. Italy
   b. Netherlands
   c. Peoples Republic of China
   d. South Africa

5. Short overview by representatives of vaccine manufacturing companies on what vaccines are available and their applications

6. Framework for establishing guidelines on vaccination for Member Countries taking into consideration (list not exhaustive):
   a. Benefits and disadvantages of vaccination
   b. Consequences of vaccination
   c. Monitoring of vaccination
   d. The effect/role of compartmentalisation on vaccination strategies
   e. Additional precautionary measures that might be required
   f. Quality of vaccines (including transport, storage, application)
   g. National, regional and international vaccine banks
   h. Which vaccines to consider for national and regional strategic vaccines banks taking into consideration differences between developed and developing countries and regional differences
   i. Vaccines to be considered for the future
   j. Trade implications for the application of vaccination strategies


8. Finalisation of draft document on Guidelines for vaccination against avian influenza

9. Finalisation of report and recommendations of the Ad hoc Group
Appendix II

MEETING OF THE
OIE AD HOC GROUP ON VACCINATION STRATEGIES FOR AVIAN INFLUENZA
Paris, 15 - 17 March 2006

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Intervet vaccines
Vaccine availability: all Intervet vaccines are LPAI.
Mexico: Production H5N2, OIE compliant, QC in Netherlands
Spain: H5N2, H5N7m H7N1, H7N7, H9N2 OIE compliant
Combination: H5N2+ND, H9N2+ND, H5+H7.

Merial Vaccines
Inactivated products
- Gallimune Flu H5N9
- Bio Flu H7N1 + H5N9
- Bio Flu H7N1
- Fluvac H7N3
- Gallimune H7N3 + H9N2
- Bio Flu H6N2 + H9N2
- Bio Enflu H6N2 + H9N2 + HE + ND + \( R_{\text{anatipestifer}} \)
- Gallimune Flu H9N2
- Gallimune 208 ND + Flu H9N2
- Gallimune 308 ND, IBD + H9N2

Live Fowlpox Vector vaccines
- TROVAC AIV H5

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GUIDELINES ON AI VACCINATION
A joint OIE/FAO background introduction document
will be added to these guidelines