SUMMARY OF OPINION

Opinion of the Scientific Panel on Animal Health and Welfare on a request from the Commission related with the vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds

(Question N° EFSA-Q-2006-309)

Adopted by the AHAW panel on 11 May 2007

Since the emergence of the HPAI strain of H5N1 in South East Asia and its westward spread, the prevention and control methods are under scrutiny in many parts of the world. Control measures are currently based on eradication of infected flocks, but increasingly more countries supplement these measures by the use of vaccination. As new scientific developments and vaccination data become available, vaccination is moving more and more to the forefront as a tool to control and prevent the propagation of the disease.

In order to support the Commission in the further developments of a vaccination policy, EFSA was required to provide a Scientific Opinion on the 1) most recent development of vaccines against AI of H5 and H7 subtypes, both for domestic poultry and other captive birds, and 2) on the evaluation of laboratory testing methods for surveillance of vaccinated poultry flocks, in particular discriminatory tests used in the context of a DIVA strategy.

At the Plenary Meeting of 26/27 October 2006, the AHAW Panel decided to entrust the Scientific Opinion to a WG under the Chairmanship of Dr. A. Osterhaus. The Scientific Opinion was adopted by written procedure on 11 May 2007.

On the most recent development on vaccines against AI of H5 and H7 subtypes it is concluded that current EU authorised AI vaccines for poultry such as chickens and ducks meet the relevant quality standards and are thus, safe and effective to be used. However, for other poultry and captive bird species the level of effectiveness of current AI vaccination is not sufficiently known and therefore additional data on the immunogenicity and effectiveness of current and future AI vaccines should be generated.

In general, the use of AI vaccines in poultry should be defined in advance dependant on the epidemiological situation, geographical area and overall risk perception as a preventive, emergency or in endemic situations. Vaccination may also reduce transmission of AI virus amongst captive and wild birds, having also major benefits for animal welfare as vaccination will prevent them from contracting the disease, death and

depending on the epidemiological situation from being culled during eradication measures.

Silent spread of AI viruses can occur after vaccination, and therefore serological monitoring with DIVA based strategies will be required to detect AI virus transmission after vaccination. New generation vaccines (including vectored and more updated vaccines) which deal with the limitations of the current ones (i.e. silent spread), may overcome the risks of sub-optimal AI vaccination. Mechanisms should be sought to fully exploit new scientific developments that leads to new generation AI vaccines.

Vaccination programmes using vaccines authorised by the competent authority may reduce the potential for human and other mammalian cases of HPAI, where the disease may become endemic. The use of EU authorised vaccines *per se i*s recommended because is safe and has no negative effect on poultry products for consumers.

On the evaluation of laboratory testing methods for surveillance of vaccinated flocks (in particular DIVA strategy), it is concluded that to date only conventional inactivated and recombinant live-vectored vaccines are available for use and can be coupled with a suitable companion diagnostic test.

An intrinsic problem of the DIVA principle is that infections with all AI subtypes (including non H5 and H7) may interfere. DIVA strategies should be based on selected vaccines and vaccination approaches in combination with tailored antibody and/or virus detection methods. More research and validation are required to optimise the DIVA strategy also with regard to different poultry species and types of holdings. The development of recombinant vaccines may, in particular, offer this opportunity.

Mechanisms should be introduced to enable assessment of vaccines intended for DIVA strategies in parallel with accompanying diagnostic tests. Ideally, registration of new AI vaccines and their tailored diagnostics assays for the implementation of the DIVA strategy should be combined.

Key words: Avian Influenza vaccines, H5 and H7 subtypes, vaccination, HPAI, LPAI, bio-security measures, surveillance, DIVA Strategy.