MINISTÈRE
DE L'AGRICULTURE
ET DE LA SOUVERAINETÉ
ALIMENTAIRE
Liberté
Égalité
Fraternité

General Directorate for Food

OFFICIAL VACCINATION PLAN

HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

FACT SHEET 2 – IMPLEMENTATION OF ON-FARM VACCINATION TRIALS ON MULARD DUCKS

In May 2022, France started trials to test vaccines on Mulard ducks for protection against Highly Pathogenic Avian Influenza (HPAI). The purpose of the trials was to obtain scientific evidence as to the efficacy and relevance of vaccination when dealing with the HPAI virus.

The trials were conducted under the terms of an agreement signed between the Ministry of Agriculture, ANSES (French Agency for Food, Environmental and Occupational Health & Safety), ENVT (the national veterinary school in Toulouse), CIFOG (the interbranch committee for the duck and goose foie gras sector), and the pharmaceutical firms supplying the two candidate vaccines (Boehringer Ingelheim Animal Health and Ceva Santé Animale), in addition to the French regional government administrations contributing to the funding of the programme: Brittany, Nouvelle-Aquitaine, Occitanie and Pays de la Loire.

These actions were entirely separate from the applications for authorisation the pharmaceutical firms will need to develop and file with the French Agency for Veterinary Medicinal Products (ANMV).

DESCRIPTION OF THE TRIALS

a. The candidate vaccines

The two candidate vaccines[1] selected for the trials were:

- Volvac B.E.S.T. AI+ND® from Boehringer Ingelheim animal health
- Duck H5-SRV vaccine® from Ceva Santé Animale

Selection of the candidate vaccines was based on their antigenic composition and pre-existing experimental data suggestive of efficacy against clade 2.3.4.4b in ducks.

[1] A single vaccine will be used in the vaccination programme to be conducted from 1 October 2023. See fact sheet 4.

b. Organisation of the trials

The purpose of the trials was to obtain data on Mulard ducks with regard to induced immune response, ability to reduce viral excretion and ability to slow viral transmission.

The study was conducted in two phases, each comprising a series of trials in field conditions on trial farms and a series of studies in experimental conditions in animal housing facilities with the aim of generating data for Mulard ducks relating to:

- For the first phase, the ability of the vaccines studied to provide clinical protection and reduce viral excretion.
- For the second phase, the ability of the vaccines studied to slow transmission of the 2.3.4.4b clade HPAI virus in a population of vaccinated ducks.

The farms selected for the series of trials under field conditions were located in four different French territorial *départements*. The ducks at these locations were vaccinated, and unvaccinated control birds were retained. In each group, virological and serological sampling was carried out to detect potential circulation of influenza virus and measure the immune response of the vaccinated birds. In the case of each of the vaccines studied, one of the trial sites was monitored up to the end of force-feeding (*gavage*) in order to obtain certainty as to the persistence of levels of immunity up to the end of the production process. Following this, one site presenting a typical post-vaccination response was selected for each vaccine from which birds (vaccinated and controls) were transferred to the A3 containment animal facilities of the national reference laboratory (LNR).

Following an adaptation period, the birds transferred to the LNR were subjected to viral challenge by administering clade 2.3.4.4b H5HP virus. The purpose of the viral challenges in the first phase of the study was to assess the level of replication and the duration of excretion of the challenge virus in previously vaccinated subjects. The purpose of the viral challenges in the second phase of the study was to evaluate the spread of the challenge virus in a population of previously vaccinated subjects.

It should be noted that the vaccinated birds and the "control" birds were euthanised at the end of rearing and none of their products entered the food chain.

RESULTS OF THE TRIALS

The results show satisfactory efficacy for the vaccines tested on Mulard ducks.

An initial interim report presents in summary form the results of the trials conducted in field conditions and, in greater detail, the trials focused on excretion reduction. The results in this first report show that both vaccines tested demonstrated their ability to significantly reduce the levels and durations of excretion of the challenge virus via the respiratory and digestive tracts of the vaccinated subjects.

A second report presents the results of the assessment of reduction in on-farm viral transmission in Mulard ducks vaccinated and subsequently challenged at the age of seven weeks. The results of this trial showed control of direct transmission of HPAI in vaccinated birds ($R0<1$) for both vaccines tested and absence of transmission by indirect contact (airborne transmission).

These favourable results provide sufficient guarantees for the launch of a vaccination campaign from autumn 2023.

For more information:

Reports and summaries available in English can be obtained via the following link:
https://agriculture.gouv.fr/experimentation-de-vaccination-des-canards-mulards-en-elevage-contre-un-virus-iahp-rapport

July 2023