



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 22 March 2023

Joint high-level hybrid Health Security Committee - Chief Veterinary Officers meeting

Audio meeting on Avian influenza A(H5N1)

22 March 2023 10:30-12:30

Summary report

Chair: DDG and Director B **John. F. Ryan** and G **Bernard van Goethem**, European Commission, DG SANTE

Audio participants: BE, BG, CZ, CY, DE, DK, EE, EL, ES, FI, FR, HU, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, NO, CH, DG SANTE, DG EMPL, HERA, ECDC, EFSA, EMA, EU-OSHA

Updated agenda points:

1. Openings speech – Director General SANTE Sandra Gallina
2. Avian influenza overview December 2022 – March 2023 (epidemiological situation from the animal health side) – presentation by EFSA
3. Measures for animals and humans – presentations by SANTE + ECDC + interventions by Member States on national and coordinated response
4. Workers protection from the exposure to biological agents, including avian influenza – presentation by DG EMPL and OSHA
5. Vaccines and antivirals – presentation by EMA and HERA
6. Meeting conclusions

Main messages:

1. Openings speech – Director General SANTE Sandra Gallina

DG Sandra Gallina referred to the scale of the current Highly Pathogenic Avian Influenza (HPAI) outbreaks in animals, the reports of human cases globally and the need to ensure a “one health” response. She highlighted the valuable work of European Food Safety Authority, European Centre for Disease Prevention and Control and the EU Reference laboratory regularly assessing and reporting about the epidemiological situation of avian influenza. She framed the meeting between the EU health security framework, with the new EU regulation on serious cross-border health threats and the EU eradication measures for HPAI in kept birds based on eradication and complemented by recently adopted harmonised rules for the use of vaccination in poultry. The purpose of the meeting is to strengthen prevention and preparedness, creating the synergies needed between the public health and the veterinary sectors to properly respond to the HPAI threat.

2. Avian influenza overview December 2022 – March 2023 (epidemiological situation from the animal health side) – presentation by EFSA

The **European Food Safety Authority (EFSA)** presented an overview of the recent epidemiological situation in animals in the EU focusing on the distribution of HPAI virus detections by virus type, affected poultry and wild bird categories and highlighting the temporal dynamics of the different virus genotypes. EFSA also presented the HPAI situation worldwide in birds, mammals and humans (including on the mutations recently identified) and some options for enhanced response: i) improving virological and serological surveillance in scavenger mammals, ii) increasing biosecurity at farms and iii) investigating events of mass mortality events associated with HPAI virus in mammals.

3. Measures for animals and humans – presentations by SANTE + ECDC + interventions by Member States on national and coordinated response

DG SANTE briefly elaborated on the recent epidemiological situation in poultry and wild birds in the EU highlighting that the epidemic peaks in poultry in the past detached from peaks in wild birds showed worrying spread between farms and that the ongoing epidemic shows reduced number of outbreaks in poultry but worrying recent trend in wild birds. SANTE presented the fully harmonised EU regulatory framework for prevention and control of HPAI in animals covering surveillance, notification, prevention, control, eradication and recovery. The Commission acts by applying regionalisation (via the Official Journal), produces legislation, monitoring implementation of the rules via audits and provide support to Member States (via EU Emergency Veterinary Team¹, EU co-financed emergency measures and vet programmes). Member States implement the measures and develop additional measures to address specificity of local conditions. Biosecurity and surveillance remain the main pillars of prevention. Vaccination is an additional option allowed by EU legislation under well-defined parameters. The affordability of large scale vaccination in poultry and the challenges related to the acceptability by certain trading partners remains an issue.

The **European Centre for Disease Prevention and Control (ECDC)** provided information about human cases: 27 human cases in 2022-23 (H5N1, H5N6) mainly in China, but also in other areas. For H5N6, case fatality ratio 40%. A risk factor is the proximity to nearby outbreaks in animals (often backyard poultry). Avian influenza infections in humans are still rare events. The current candidate human vaccine is promising and antivirals appear effective. The risk assessment has not changed: it is low for the general population and low to moderate for professionally exposed humans. Post exposure measures include both active and passive follow-up; a joint guidance for Member States has been produced. Avian Influenza infections need to be reported in Early Warning and Response System (EWRS) within 24H. Biosecurity measures for workers and for general population are recommended. There is an ongoing survey to Member States on measures applied in relation to Avian Influenza. While seasonal influenza vaccination is not protective for Avian Influenza, it reduces risk of co-infections.

Two Member States shared their experiences:

France: The control of the disease is based on preventive and control measures, as well as financial support. Recommendations to mitigate human risks are provided for; the zoonotic infection potential is

¹ https://food.ec.europa.eu/animals/animal-diseases/veterinary-emergency-team_en

monitored. France is considering vaccination of poultry to reduce virus spread and the risk of mutations. Vaccination would be accompanied by a strict surveillance system. Poultry trade needs to be preserved; to do so trading partners need to be convinced prior to moving towards vaccination. France also presented their passive surveillance system for Avian Influenza in humans focused on workers. A new protocol for the systematic testing of workers will be implemented in high-risk areas. France is reviewing their generic pandemic response plan. This year the vaccine is free of charge for exposed workers and farm owners. Vaccine stockpiles have been reviewed. Given the delays in availability of Avian Influenza pandemic vaccines, could there be a discussion to have an EU wide action.

The **Netherlands** have biosafety measures for poultry (no farm-to-farm transmission); vaccine trials in poultry are ongoing. Biosafety measures for humans (in line with ECDC guidelines), hygiene protocols, timely removal of dead animals, vaccination of workers and farmers for seasonal influenza, active surveillance (PCR to be confirmed by serology), active monitoring of wild fauna (both birds and carnivores); pig farms could be a risk area: this is currently assessed whether specific measures would be needed.

During the discussion session:

ES confirmed that the human poultry farm workers in Spain were false positive (negative to serology tests) which was linked to environmental contaminations.

PT asked about the possible interaction with environmental and nature institutions/authorities to better address surveillance of wild animals (birds and mammals).

The **NL** supported France as regards concerns on availability of poultry vaccines that will benefit not only animals, but also human health. The NL asked about epidemiological peaks (why now no peak in farms despite peak in wildlife?); the role of farmed mammals in emerging zoonotic avian influenza. Should we have an EFSA opinion on surveillance in farmed mammals and possible risk mitigation measures.

BE updated on their preparedness (surveillance in poultry and wild birds); underlined the benefit of vaccinating poultry for the human risks.

ES described their control measures, including active testing of exposed workers in affected farms or working with infected wild animals and expressed the need to include primary health care and not just hospitals in any avian influenza surveillance system. Possible trade restrictions on commodities from vaccinated animals should be taken into account or controlled if moving to poultry vaccination strategies (see the huge potential economic impact).

SANTE clarified that there is a working group on poultry vaccination simultaneously to this meeting, it will address trading issues, affordability. There is a communication action towards trading partners to explain the EU approach.

EFSA elaborated as regards possible surveillance in mammal, in particular on pigs indicating that the EFSA quarterly report already provides recommendations on surveillance. There is however a lack of data for

circulation of avian influenza in pigs highlighting that there are no data on China poultry outbreaks. EFSA uses a predictive model that needs good data.

4. Workers protection from exposure to biological agents, including avian influenza – presentation by DG EMPL and OSHA

DG EMPL presented the EU legal framework on occupational health and safety (based on Art 153 TFEU), which covers all sectors of activity, both public and private, and all risks, both physical and psychosocial. With this legal basis, it is possible to adopt minimum requirements under EU Directives to protect workers' health and safety. The existing EU directive on Biological Agents (2000/54/EC) is in particular relevant for the current avian influenza situation, aiming to protect workers against risks to their health and safety that arise or are likely to arise from exposure to biological agents at work. Biological agents are classified into four risk groups, according to their level of risk of infection. HPAI H5 viruses are classified as risk group 3 viruses (can cause severe human disease and present a serious hazard to workers; may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available). DG EMPL highlighted that the employer must reduce risks to the lowest possible level for workers and must take appropriate measures. DG EMPL also shared several links to support and guidance reports for employers.

The **EU information agency for occupational safety and health (EU-OSHA)** presented several guidance and recommendations. EU-OSHA emphasised the importance of risk assessment. In case of a (suspected) outbreak, employers have to set specific measures (including self-isolation). Employers must keep a list of workers exposed to group 3 and 4 biological agents. Member States must establish rules for appropriate health surveillance. To avoid outbreaks and epidemics, synergies between Occupational health and safety and public health are needed.

5. Vaccines and antivirals – presentation by EMA and HERA

The **European medicines Agency (EMA)** provided an update on vaccines and antivirals against avian influenza A(H5N1) in both poultry and humans. Preliminary data has shown that the current composition (strain) of the [Aflunov](#) zoonotic influenza vaccines for humans is not cross-reactive against the current circulation strain. Discussions are ongoing on the strategy to change the composition to increase protection. EMA is in contact with the manufacturer. Other vaccines can currently only be used during a declared pandemic (Adjupanrix, pandemic influenza vaccine H5N1 Baxter AG, Foclivia, Pandemic influenza vaccine H5N1 AstraZeneca). There are several antivirals against pandemic influenza (Tamiflu, Ebilfumin, Dectova, Xofluz). There is currently one poultry vaccine (Nobilis) against HPAI viruses authorised for chickens. Based on preliminary data, it may not protect against disease and mortality from the currently circulating strain. EMA received two new poultry vaccine applications. There are several vaccines authorised outside the EU for poultry, but it is unlikely for those to be compliant with EU regulatory requirements for authorisation.

The **Health Emergency Preparedness and Response Authority (HERA)** gave a presentation on medical counter measures (MCM). Rapid sequencing and sharing of H5 HPAI viruses sequences from infected persons and animals is critical for rapid assessment and, where relevant, rapid adaptation of MCM, especially of pandemic vaccines. The HERA laboratory network (DURABLE) will contribute by enhancing rapid characterization of emerging pathogens, including avian influenza viruses, in a view of developing or adapting accordingly MCMs. The Commission is establishing Chemical Biological Radiological and Nuclear RescEU stockpiles containing personal protective equipment (FFP2 masks, gloves, full body protections, critical MCM like Tamiflu). A second call has been launched in February. HERA's current approach is to discuss Member States' domestic preparedness, to speed up development and access of

flu vaccines and therapeutics through the EU4Health 2023 work programme, to further support sequencing capacity, and to explore the monitoring of avian influenza under the Joint Action on wastewater surveillance.

6. Meeting conclusions

SANTE indicated that this is the starting point of future similar exchanges and presented the following conclusions:

1. The two major players (ECDC+EFSA) with support by the (EURL) for molecular epidemiology are performing very valuable work allowing timely provisions of key information for risk management on both the veterinary and human sides.
2. This also allows the undertaking of prevention and preparedness actions. On the animal health side, EU rules are well established and enable the most suitable approach for enhanced preventive and control measures in accordance with the risk, such as vaccination when appropriate along with other control measures to limit outbreaks and reduce risks of spill over, despite societal concerns and very high costs for public budgets and for industry.
3. An area of focus shall be on occupational risks for highly exposed individuals as they represent a constant interface between the animal and human health sides, possibly with a focus on farmers and cullers taking note of stocks of personal protective equipment and reinforcing their use. Refining guidelines for prophylaxis and vaccination measures were discussed for a more aligned approach by Member States.
4. Building upon the good collaboration between laboratories (veterinary and public health influenza labs) and working on genomic sequencing is also pivotal. Overall, a reinforced and more systematic cooperation of veterinary and public health competent authorities [and scientific bodies] must be ensured also at Member State, regional and local levels, enabling a swift response and activation of measures when needed on public health or veterinary side.
5. Assessments of current stock of medical countermeasures and the development of a strategy for joint procurement and stockpiling, including of human vaccines is under HERA responsibility.
6. A discussion with stakeholders will be organised by the Commission to discuss the avian influenza outbreak from the perspective of workers protection, involving representatives of the veterinary and public health communities.