EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants
Animal health

Highly Pathogenic Avian Influenza – Scenarios for the EU measures in animals other than birds, and food in the context of detections of HPAIV (H5N1 - B3.13 and others) in US dairy cows

Commission Working Document

Guidance Document

PAFF, 28-29 April 2025

Table of Contents

1. Scope 3

2. Background 3

3. Current EU measures and situations justifying EU measures in animals other than birds, and food 4

4. Ongoing EC prevention and preparedness actions 5

5. Possible regulatory reaction measures in animals and food 6

6. Disease notification and reporting 7

7. Conclusions 8

1. SCOPE

This document aims at providing an overview of already undertaken and ongoing actions by the European Commission, and those that the European Commission (EC) and Member States may envisage to take as a reaction to the recent unprecedented events of detection of highly pathogenic avian influenza (HPAI) virus with potential zoonotic impact in dairy cows. It aims to give guidance with practical indications for the actions to be taken by the Commission and the Member States as well as indication of the triggering factors for action to take place.

It reflects on possible EU proportionate preparedness and preventive actions, as well as reaction measures to protect EU animal health and public health from the spreading into EU animals of this particular HPAI virus, which has shown capacity to circulate among bovine animals, and represents a possible threat to humans, including through the consumption of milk and dairy products. The document describes the most plausible scenarios and indicates the range of possible measures to be taken depending on the option(s) chosen.

This document **does not describe** detailed measures that will be defined and implemented in accordance with EU rules and procedures. It addresses the potential zoonotic risks of this particular HPAI virus, but it does not intend to address the potential zoonotic risks of HPAI viruses in general. Moreover, actions targeting human health protection in *sensu stricto* such as medical countermeasures, including vaccines, are also not covered by this paper, as it is not meant to address the issue in general but to envisage a specific potential action pathway relevant to animal health control.

2. BACKGROUND

As from late March 2024, the United States of America (US) have been facing unprecedented events of detection of highly pathogenic avian influenza (HPAI) virus in dairy cows. The Department of Agriculture, Food and Drug Administration (USDA), Centers for Disease Control and Prevention (CDC), and state veterinary and public health officials have been investigating the occurrence of infection of dairy cows with HPAI H5N1 virus. The disease has spread among herds by animal movements especially by lactating cows, while the most reported spreading is within herds. Milk from infected animals has been demonstrated to be contaminated with the virus. Although the cows rarely show respiratory clinical signs, they suffer with mastitis and there is a decrease in the production and an abnormal appearance of the milk.

In addition, this virus, which is also occurring in wild birds and poultry, has demonstrated its transmissibility to other mammals, such as cats and pigs, as well as humans: as of 14 March 2025, out of 70 human cases of avian influenza A(H5), 41 have been reported in individuals exposed to dairy cows that were infected or presumed to be infected([1]). There has been to date no evidence of human-to-human transmission.

The US authorities, chiefly USDA-APHIS services, have taken several measures (regulatory, such as pre-movement testing scheme for interstate movements of dairy cows, advisory to operators and financial) to limit the spread of disease. The disease spread to 17 States and is still circulating([2]). The US federal authorities are also requiring compulsory pasteurisation of milk of affected or at-risk herds as a risk mitigating measure (beyond the 'pasteurisation act' demanding pasteurisation for interstate trade of milk), and have started a National Milk Testing Strategy, to collect

([1]) Majority with mild clinical symptoms, mainly conjunctivitis

([2]) https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-detections/hpai-confirmed-cases-livestock

unpasteurised milk samples to better assess where H5N1 is present, with the goal to better inform biosecurity and containment measures, as well as to inform state-led efforts to reduce risk to farm workers who may be in contact with animals infected with H5N1. In parallel, USDA has approved several vaccine field safety studies for vaccine candidates designed to protect dairy cows from H5N1 ([3]).

The virus type affecting dairy cows in the US (H5N1, Eurasian lineage goose/Guangdong clade 2.3.4.4b. genotype B3.13 and D1.1) ([4]) is not present so far in the EU. The EURL, EFSA and ECDC are closely monitoring this situation. Even if the EU is not currently affected by this virus genotype, some other circulating strains in the EU have proven capacity to infect other mammal species and there are already measures in place to mitigate risks posed by HPAI in the EU, it is prudent to consider various potential options of action **in animals**, notably in dairy cows, ahead of a potential introduction of this virus.

3. CURRENT EU MEASURES AND SITUATIONS JUSTIFYING EU MEASURES IN ANIMALS OTHER THAN BIRDS, AND FOOD

The EU has a **well-developed current ongoing system with harmonised set of animal health rules for HPAI** with the focus on listed species, i.e. in case of HPAI, avian species. These rules based on Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') comprise the following main elements (not exhaustive):

- detailed rules for the control of HPAI in Delegated Regulation (EU) 2020/687 on disease control measures, mainly targeted to poultry and captive birds,
- rules for vaccination in Delegated Regulation (EU) 2023/361
- Avian Influenza Union Surveillance Programme according to Annex II of Delegated Regulation (EU) 2020/689 (N.B. in birds and in mammals)
- rules for entry into the Union in Delegated Regulation (EU) 2020/692 and Implementing Regulation (EU) 2021/404 (list of third countries, regionalisation)

The **factors triggering specific animal health and/or food safety measures** in the EU that would go **beyond the current ongoing system**, might be of various types, depending on the situation, incident or event identified.

1) The following would trigger **preparedness and initial prevention actions**:
   - **a)** indications that the spread of the US strain virus genotype B3.13 in dairy cows in the US is not controlled, or goes beyond USA to neighbouring countries posing increased risk for the EU;
   - **b)** indications from EFSA or other surveillance data that this virus is likely to spread towards Europe and to pose specific risks (such as the virus affecting EU bovine animals);
   - **c)** indication of new, riskier, transmission pathways of this virus among animals, beyond the movement of lactating cows;
   - **d)** indication of new, riskier, transmission pathways of this virus to humans, such as wide food-related transmission;
   - **e)** indications that there is human-to-human transmission.

2) The following would trigger **response actions**:

([3]) https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-livestock/testing

([4]) Which is different from the DI.1 genotype recently detected in Europe.

a) the detection in the EU, of occurrence of the infection with any HPAIV in dairy cows or of specific mutations of HPAIV circulating in the EU posing specific risk;

b) the detection in the EU of the US strain virus genotype B3.13 in any non-avian species, or in the environment or waste waters and attributable to a defined non-avian animal subpopulation;

c) the detection of an animal infected with this virus (B3.13), imported into the EU from the US or elsewhere;

d) the detection in the EU of an indigenous human case caused by the US strain virus genotype B3.13 (or others presenting the same features).

4. ONGOING EC PREVENTION AND PREPAREDNESS ACTIONS

Today, the EC, with the support of the EURL, EFSA and ECDC, as well as WOAH, is closely monitoring events related to HPAI H5N1 in dairy cows in the US and is in contact with the US authorities. The EU has so far not taken regulatory protective measures in reaction to the US events as no imminent risk to public health or animal health EU livestock or wildlife has been identified yet. However, several other prevention actions have taken place. A mandate was sent to EFSA to assess the specific risks posed by these events.

First EU ongoing actions include the following.

- **Risk-based structured surveillance of HPAI strains occurring in the EU**: this action is already ongoing, in birds as well as in mammals primarily through Avian Influenza Union Surveillance Programme. It is adapted to the risks, field findings, environmental surveillance, including from wastewaters as appropriate.
- Specific investigations, studies or additional specific risk assessment/analysis: **support from EFSA** has been already requested ([5]), **to analyse the situation in the US and obtain scientific advice assessing animal health and veterinary public health, including food safety**, risks linked with this particular HPAI strain, addressing in particular its likely evolution, its likelihood of spread to the EU or Europe in particular with the migratory wild birds and if likely, the estimated expected time for this spread, its potential impact on the EU and possible risk mitigation measures.
- Initiatives for **awareness on biosecurity**: a **mandate was sent to EFSA** to develop a communication strategy and awareness raising campaign. Together with **stakeholders from the poultry industry** the EC intends to support a **targeted communication with the poultry sector** to raise awareness and preparedness.
- **SIMEX exercise** took place in December 2024 focussed on zoonotic HPAI and explore how the One Health approach can be operationalised in practice during a zoonotic outbreak, rehearse the main procedures of cross-sectoral coordination and facilitate networking between EU/EEA representatives.

([5]) https://open.efsa.europa.eu/questions/EFSA-Q-2024 00715?foodDomains=Animal%20Health&type=Art%2029%20-%20Scientific%20opinion_Art%2031%20-%20Scientific%20and%20technical%20assistance

Beyond that, Member States alone are already be engaged in complementary specific actions such as those under EU4H One Health surveillance ([6]) or United4Surveilalnce ([7])

5. POSSIBLE REGULATORY REACTION MEASURES IN ANIMALS AND FOOD

1) Legal framework

Any regulatory measure to be set up is adopted based on the EU harmonised set of rules which are regulating animal health and food safety. The most relevant acts are the following:

- Regulation (EU) 2016/429 on transmissible animal diseases (Animal Health Law, AHL) and the relevant delegated and implementing acts adopted on its basis;
- Directive (EC) 2003/99 on monitoring of zoonoses;
- Regulation (EC) No 178/2002 – general food law (GFL);
- Regulation (EC) No 853/2004 – hygiene of products of animal origin;
- Regulation (EU) 2017/625 – Official Controls regulation (OCR).

2) Possible Member States measures

Member States take measures as they deem necessary in accordance with Article 257 (and/or Article 171) of the AHL and/or enhanced surveillance/increased priority of certain food in accordance with Article 4 of Directive 2003/99/EC.

Targeted population: Possibly only dairy cattle, targeted to lactating cows in affected herds and/or areas. If necessary, the measures are expanded to other mammal species (e.g. sheep, goats,) depending on the type of event.

Possible surveillance measures:

- Clinical and enhanced passive surveillance for virus detection and identification (genomic surveillance),
- specific surveillance based on the risk assessment and depending on the event (risk based and targeted surveillance).

Possible prevention and control measures:

- enhanced biosecurity (various levels, including isolation of animals, disinfection etc),
- movement restrictions of certain higher risk animals (e.g. lactating) or all herd,
- destruction and disposal or inactivation treatment of milk from affected animals or herds, other appropriate treatment of milk from establishments at risk.

3) Harmonised EU measures

The Commission adopts harmonised regulatory measures at EU level, such as movement restrictions, in addition to and beyond the existing control measures in case of outbreaks of HPAI in poultry, captive birds and wild birds in accordance with Delegated Regulation

([6]) https://ec.europa.eu/assets/sante/health/funding/wp2022_en.pdf

([7]) https://united4surveillance.eu/workshop-onehealth-surveillance-wp4/

(EU) 2020/687, with several options (the response intervention may be a combination of several measures):

1. EC reviews measures taken by Member States adopted as described in Point 2 and adopts short-term emergency measures based on Article 259 of the AHL – in dairy cows, bovine animals, restrictions including milk, regionalisation.
2. EC develops more comprehensive reaction to this situation. The disease in bovine animals qualifies as an emerging disease (as in the U.S.) based on Article 6 of the AHL as this is a listed disease occurring in a new host species, not affected so far and the:
    - EC adopts measures of more robust and sustained nature, based on Article 6 AHL, and/or Directive (EC) 2003/99; which could include disease prevention and control measures and specific surveillance; duration of measures can be adapted to risk and evolution of the situation. Focus of measures are on all animals considered at risk and to pose a risk, especially dairy cows:
        - specific surveillance enabling risk management action, with defined objectives and follow up actions, and tailored in terms of subpopulations, frequencies and sampling matrices; based on Article 6 AHL, and/or Directive (EC) 2003/99, an example of which could be illustrated by the one used in Commission Implementing Decision (EU) 2021/788 laying down rules for the monitoring and reporting of infections with SARS-CoV-2 in certain animal species;
        - special disease preventive and control measures: such as movement controls and restrictions, regionalisation, certification, biosecurity in transport and on farms, vaccination with specific rules including surveillance etc (if vaccine exists), destruction of milk from affected herds, appropriate heat treatment of milk for establishments at risk;
        - entry into the Union specific requirements and/or restrictions.
3. EC develops additional, separate set of measures, jointly with the above measures, based on Article 53 of the GFL on milk treatment and other food safety risk mitigation measures related to milk and dairy products, including maturation processes or channelization.
4. In the unlikely scenario, which cannot be currently excluded, that the risk stems from imported products or animals, the EC may adopt emergency measures based on Article 261 of the AHL and on Article 53 of the GFL, as regards the entry into the Union from the affected third countries of affected animal species and products thereof (e.g. dairy cows and milk).

Member States may always continue to adopt additional disease prevention and control measures nationally, provided that the measures do not hamper the Single Market or the rules for entry in the EU.

All measures (EU or MSs) may vary depending on the stage and on the magnitude of the event and can swiftly be adapted in accordance with the evolution of the epidemiological situation.

6. DISEASE NOTIFICATION AND REPORTING

Findings of Influenza A viruses of avian origin in mammals are ***NOT NOTIFIABLE*** in ADIS as „*HPAI(NON-P) in Wild Birds*“ nor in WAHIS as „*Influenza A viruses of high pathogenicity (Inf. with) (non-poultry including wild birds) – unusual host species*“ as they **do not match the relevant definitions of listed diseases / listed species** in both the AHL and WOAH Code context.

In the EU, MSs affected must notify the occurrence of the emerging disease to the EU (normally by letter and subsequent info note from EC) in accordance with Article 257(2)(a) of the AHL. In ADIS**:** obligation for Union reporting

- *currently,* MSs should report such findings as part of results of Union surveillance programmes (Article 6 of CIR (EU) 2020/2002), given **mammals** are **covered by the HPAI USP**
- *In future*: depending on epidemiological. situation, other kind of reporting or notification could be laid down under AHL (e.g. rules under Article 6 of the AHL as emerging disease, or in ADIS, by amending Implementing Regulation (EU) 2020/2002 or otherwise)

Member States must notify to **WOAH**.

- In WAHIS**: in bovines, notifiable as emerging disease** (NEW), SCAD assessed H5N1 in bovines in the USA as **emerging disease** (February 2025)
- However, members should inform WOAH by letter on findings in other mammals as "other important animal health information" (Article 1.1.5.1. of the Code, and NOT as "occurrence of a listed disease in an unusual host species" under Article 1.1.3.1.f).

7. CONCLUSIONS

1. The EU has a well-developed harmonised set of animal health and veterinary public health including food safety rules and procedures to manage a potential emerging risk due to epidemiological changes of the HPAI virus strain currently circulating in dairy cows in the USA.
2. Various options may be envisaged, depending on the level of risk and the amplitude of potential events, involving both the MSs and EC following a "toolbox" presented in the above points. Such measures can swiftly be adapted and modulated to take into account the evolution of the events.
3. Current surveillance in the EU enables the detection of such events, provides for genomic surveillance to inform public health reaction and may be adapted to the needs, as other rules can be adapted on short term basis. In that respect, the Commission may need for its risk management actions a continuous risk assessment and support from EFSA and EURL.