

Avian Influenza preparedness in the EU

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DG SANTE - G2 Animal health

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Contents

Avian influenza preparedness in the EU (as a reaction to the US situation in dairy cows)

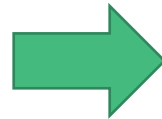
- Background, ongoing discussions and reflections
- Overview of ongoing actions
- Current regulatory measures and legal tools/possibilities
- Possible scenarios for the EU (as a reaction to the US situation in dairy cows)
- EC conclusions



Background: HPAI virus in bovine animals

Infection of US dairy cows with H5N1 virus

- Few clinical signs
- Spread within and between herds – lactating cows
- Milk contaminated with the virus; transmission in milking parlours
- Other animals and zoonotic ability



USDA-APHIS services have taken several measures,
Not very successful at halting the spread

Virus H5N1, Eurasian lineage goose/Guangdong
clade 2.3.4.4b. genotype B3.13 and D1.1, not
reported in EU

EURL, EFSA and ECDC are closely monitoring the
situation

Prudent to consider various potential options for
risk assessment of the situation with a view of
exploring possible action ahead of a possible
future introduction

Ask support from EFSA and get scientific advice
assessing animal health and food safety risks



EU Preparedness – ongoing work and discussions

- **EC internal reflections** on possible EU actions to address the specific events of HPAI in dairy cattle
 - CVO meeting on 5 March 2025 where EC presented a comprehensive overview of already **ongoing actions** and **scenarios for possible future measures** and available tools to react
- CVOs welcomed the information and requested the EC to develop a document / working paper / guidance document for MS to support their action for such events



EC reflection on measures in animals other than birds, and food

- It is **prudent to consider various potential options of action** in animals, notably in dairy cows, ahead of a potential introduction of this virus even if:
 - (i) the EU is not currently affected by this virus genotype(s),
 - (ii) some other circulating strains in the EU have proven capacity to infect other mammal species and
 - (iii) there are already measures in place to mitigate risks posed by HPAI in the EU,
- Consider possible **EU proportionate preventive, preparedness and response actions** to protect EU animal health and public health from the spreading into EU animals of this HPAI virus, which has shown capacity to circulate among bovine animals, and represents a possible threat to humans, exposed through direct contacts or through the consumption of milk (some of those actions already ongoing)
- EC developed a draft document addressing the above to support MSs action



Ongoing EU prevention and preparedness actions



Ongoing EU actions

- Reinforced monitoring of the situation by EFSA, EURL and ECDC, including requests for scientific advice
- Risk based structured surveillance of HPAI strains in the EU under the Union Surveillance Programme
- EC requested support from EFSA on HPAI in bovines
- Initiatives for awareness on biosecurity
- SIMEX exercise focussed on zoonotic HPAI (December 2024)
- Member States actions under EU4Health



EFSA mandate HPAI / bovines

- Scientific and technical assistance on the risk posed by the HPAI virus H5N1, Eurasian lineage goose/Guangdong clade 2.3.4.4b. genotype B3.13, currently circulating in the US
 - ✓ **summary of the virological information currently available on**
 - ✓ the virus
 - ✓ the outbreaks in dairy cows in the US
 - ✓ the measures recommended or applied by the US authorities
 - ✓ **potential pathways for entry of the virus into the European continent**
 - ✓ via trade
 - ✓ via migratory birds
 - ✓ timelines associated with the potential entry via migratory birds
- Deadline: **By 31/05/2025**



EFSA mandate HPAI / bovines

- Scientific opinion on risk analysis of the infection of dairy cows in the EU with the HPAI virus H5N1, Eurasian lineage goose/Guangdong clade 2.3.4.4b. genotype B3.13, currently circulating in the US
 - ✓ **potential impact of the infection of dairy cows in the EU**
 - ✓ **possible measures to prevent the introduction into the EU and possible risk mitigating measures to prevent its spread within the EU**
 - ✓ **possible options for adaptations of the current EU surveillance**
 - ✓ **considering the application or not of risk mitigating measures, likelihood of bulk milk to be contaminated**
 - ✓ levels of viable virus at the point of consumption
 - ✓ risk for humans due to the exposure to those assessed levels
 - ✓ available measures to mitigate the estimated risk
- Deadline: **by 30/11/2025**



Initiatives on awareness on biosecurity targeted to identified weaknesses

Led by EFSA :

- audience analysis
- detailed communication strategy for an awareness raising campaign

Together with stakeholders from poultry industry:

- Targeted communication
- Organising event(s), campaigns



Possibilities for a regulatory response actions and further measures



Current EU 'regular' measures to control HPAI

- Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') and the following key acts (not exhaustive):
 - disease control measures against HPAI in Delegated Regulation (EU) 2020/687 mainly targeted to poultry and captive birds
 - rules for vaccination in Delegated Regulation (EU) 2023/361
 - Avian Influenza Union Surveillance Programme (USP) - Delegated Regulation (EU) 2020/689 (in birds and in mammals)
 - entry into the Union in Delegated Regulation (EU) 2020/692 and Implementing Regulation (EU) 2021/404 (list of third countries, regionalisation)



Measures under the AHL for animal diseases other than listed diseases

Dedicated measures for emerging diseases (AHL Article 6)

- Defines what is considered as an emerging disease
- Sets the EU reaction on them – the COMM must take the measures

Emergency measures (AHL Articles 257, 258, 259, 260 and 261)

- Possibilities for MSs and the COMM

National measures for other and non-listed diseases (AHL Articles 170, 171 and 226)

- For MSs to take national measures



Further legislative tools for measures in animals other than birds, and food

- The EU has a well-developed harmonised set of rules which are regulating animal health and food safety. Any regulatory measure to be set up is adopted based on that legislation:
 - 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).



Further EU response actions to the US situation in dairy cows



Scenarios for measures in animals other than birds, and in food – when to react?

- The **factors triggering specific animal health and/or food safety measures** in the EU that would go **beyond the current ongoing**, might be of various types, depending on the situation, incident or event identified
 - indications that the spread in the US is not sufficiently controlled;
 - indications that this virus is likely to spread towards Europe;
 - indication of new, riskier, transmission pathways among animals, or to humans;
 - indications that there is human-to-human transmission;
 - detection in the EU of natural infection with any HPAIV in dairy cows;
 - detection in the EU of the US strain virus genotype B3.13 or similar in an animal or a human.



Possible response actions and the EU approach

- Member States actions, possibly as a first step:
 - **Member States take measures** as they deem necessary in accordance with Article 257 (and/or Article 171) of the AHL:
 - surveillance (enhanced passive for virus detection and identification + risk based targeted, ...)
 - biosecurity, movement restrictions, disposal or treatment of milk from affected animals / herds, ...
 - If insufficient, **EC adopts emergency measures** (short term and limited scope) on movements, placing on the market, additional surveillance, ...



Possible EU harmonised measures (1)

- EC adopts harmonised regulatory measures, in addition to and beyond the existing control measures, with **several options** (the response intervention may be a combination of several measures):
 - Short-term **emergency measures** (Article 259 of AHL)
 - The disease in bovines qualifies as an **emerging disease** (Article 6 of AHL) and
 - Measures of more robust and **sustained nature** (duration adapted to the risk and the evolution of the situation), based on Article 6 of the AHL and/or Directive (EC) 2003/99, which **could be comprehensive** and include :
 - **prevention and control**, including movement restrictions (animals at risk and milk)
 - possible structured Union **notification of occurrence**
 - **specific surveillance** enabling action, with **defined objectives** and follow-up actions



Possible EU harmonised measures (2)

- The measures may include **for animals** :
 - **prevention and control**, including **movement restrictions** of all animals at risk and their products, regionalisation, certification, biosecurity in transport and on farms, vaccination (if vaccine exists) with specific rules including surveillance, destruction of milk from **affected herds**, appropriate heat treatment of milk for **establishments at risk**, specific requirements and/or restrictions for **the entry** into the Union
 - **specific surveillance** enabling action, with **defined objectives** and follow-up actions, and **tailored** in terms of subpopulations, frequencies and sampling matrices
- Additional, **set of measures**, jointly with the above measures, may be based on Article 53 of the GFL on **milk treatment and other food safety risk mitigation measures** related to milk and dairy products
- **Member States** may always continue to adopt additional **disease prevention and control measures nationally**, provided that the measures do not hamper the Single Market



Other possible measures in animals other than birds, and food

- **Depending on the results of the risk assessment** further prevention and preparedness actions may include:
 - Amendment of rules for **updating specific surveillance**
 - Introduction of a **coordinated monitoring programme** for food (dairy) under Directive (EC) 2003/99
 - Measures on the **entry into the EU** for certain non-poultry animal species based on AHL, Article 261 (e.g. restrictions on specific animal populations)
 - Measures **for food** based on GFL, Article 53 (e.g. on import or treatment)



Conclusions

- 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
- Various options of actions 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
- Such measures can be swiftly adapted and modulated to take account of the evolution of the events
- Several actions are already ongoing
- 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.
- The Commission needs for its risk management actions a continuous risk assessment and support from EFSA and EURL



Thank you



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