RISK POSED BY THE H5N1 VIRUS CLADE 2.3.4.4B. GENOTYPE B3.13 CURRENTLY CIRCULATING IN THE US

SCIENTIFIC REPORT

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MANDATE AND TERMS OF REFERENCE

Scientific Report

- provide a summary of the virological information currently available on the **virus**, of the **outbreaks** in **dairy cattle** in the US, and the **measures** that have been recommended or applied by the US authorities
- describe the **potential pathways for entry** of the virus into the European continent via **trade** and via **migratory birds**, and timelines associated with the potential entry via migratory birds
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Scientific opinion

- assess the **potential impact** of the infection of dairy cows in the EU;
- describe possible **measures to prevent** the **introduction** of the virus into **dairy cows** and **poultry** in the EU as well as possible risk mitigating measures to prevent its **spread** in the EU;
- describe possible options for adaptations of the current EU **surveillance for HPAI** that would allow **detection** of an **introduction into the EU dairy cows** populations posing a significant animal or public health threat;
- in a hypothetical scenario that lactating dairy cows are found to be infected with this virus, assess, taking into account the application or not of risk mitigating measures described above, the **likelihood of bulk milk to be contaminated**;
- in a hypothetical scenario that bulk milk is found to be contaminated with this virus in the EU, (i) assess the levels of **viable virus** at the **point of consumption** in **raw milk**, **colostrum**, **dairy products** and **colostrum-based products** produced and consumed in the EU, (ii) estimate the **risk for humans** due to the exposure to those assessed levels of viable virus via the foodborne route, and (iii) critically review the **available measures to mitigate** the estimated risk.

INTERPRETATION OF TERM OF REFERENCE 1

Assessment question 1:

What virological information is currently available on the H5N1 B3.13 **virus**?

- Genomic characterization
- Transmission, incubation period, clinical signs, viremia onset and duration, shedding (how, onset, viral loads, duration), immunity
- Infectivity and pathogenicity for other hosts

Assessment question 2:

Describe the **outbreak** in US dairy cattle caused by the H5N1 B3.13 virus

- How many individuals and herds have been infected by location over time (absolute numbers and proportion of all affected and of all susceptible)?
- What are the age, sex, breed and production system of the infected animals?
- Which risk factors for introduction and spread have been identified?

Assessment question 3:

Which **measures** have been recommended or applied by the US authorities to control the outbreak in US dairy cattle caused by the H5N1 B3.13 virus?

- Which measures to prevent spread have been **recommended**, where and when?
- Which measures to prevent spread have been **applied**, where and when?

INTERPRETATION OF TERM OF REFERENCE 2

Assessment question A:

What are the potential pathways for entry of the H5N1 B3.13 virus into the European continent via **trade**?

- Which commodities can be contaminated with the H5N1 B3.13 virus?
- Which of these commodities are traded from the US to the EU?

Assessment question B:

What are the potential pathways for entry of the H5N1 B3.13 virus into the European continent via **migratory birds** and what are the associated timelines?

- What are the migratory bird species in the US that could carry the H5N1 B3.13 virus ?
- What are the direct flyways of these migratory birds from the US to the European continent and when does this migration occur?
- Through which indirect pathways (overlaps with other flyways) could the virus be carried by migratory birds to the European continent from the US?
- Where could the migratory bird species from the US potentially enter the European continent

DATA & METHODS

ToR 1:

Extensive review of online resources:

- official government websites
- structured media monitoring
- scientific literature

Review of draft text and provision of further information by US authorities

ToR 2A Trade:

- Identification of
  - potentially contaminated commodities
  - commodities that can be legally traded from the US to the EU
- Trade data from TRACES, EUROSTAT
  - commodity type
  - amount traded
  - 2023–2025

ToR 2B Migratory Birds:

Contractor:

- US migratory bird species
- direct flyways used by migratory birds from the US to the European continent
- indirect pathways (overlaps with other flyways)
- time of migration
- potential locations of entry

RESULTS TOR 1 : VIRUS, OUTBREAK, MEASURES

Virus:

- Mild clinical signs in cattle (-21 d)
- Reduced milk production (-45 d)
- High viral loads in milk
- Within-farm transmission milk, milking
- Incubation period 12-21 d (1-2 d experiments)
- Significant host range and zoonotic potential

Outbreaks:

01/03/2024-18/05 2025

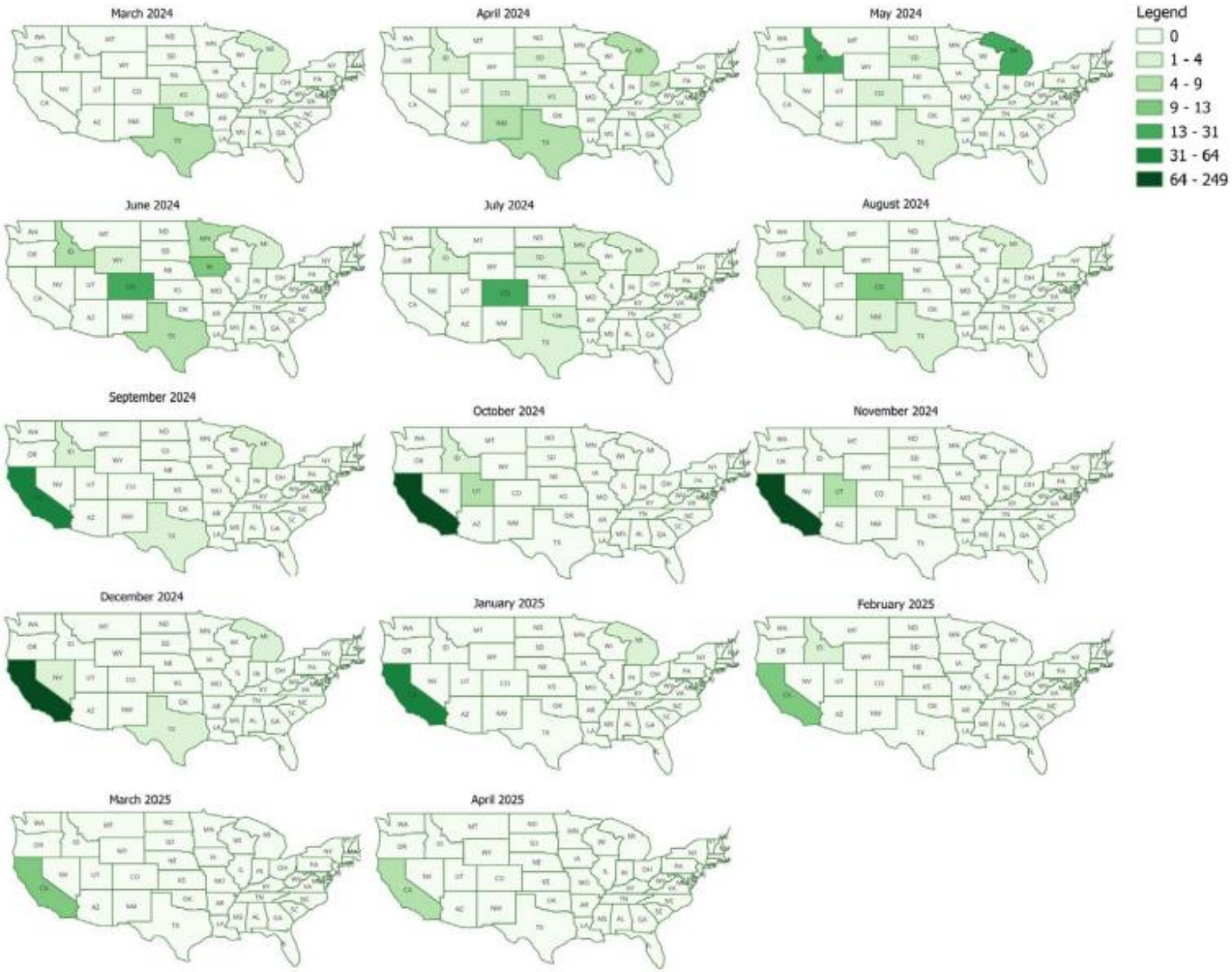
- 981 dairy herds in 16 US states (58% of national dairy cattle population)
- California 762 cases (69% Californian dairy farms)
- initially mild illness in cows, increasing reports of severe clinical manifestations, including respiratory, neurological and reproductive signs
- Farm-farm transmission: dairy cattle movements, shared farm resources

Measures:

- interstate movement restrictions
  - health certificates
  - pre-movement testing
  - quarantine
- mandatory reporting of dairy cattle for Influenza A virus
- National bulk milk testing scheme
- enhanced farm-level biosecurity recommended

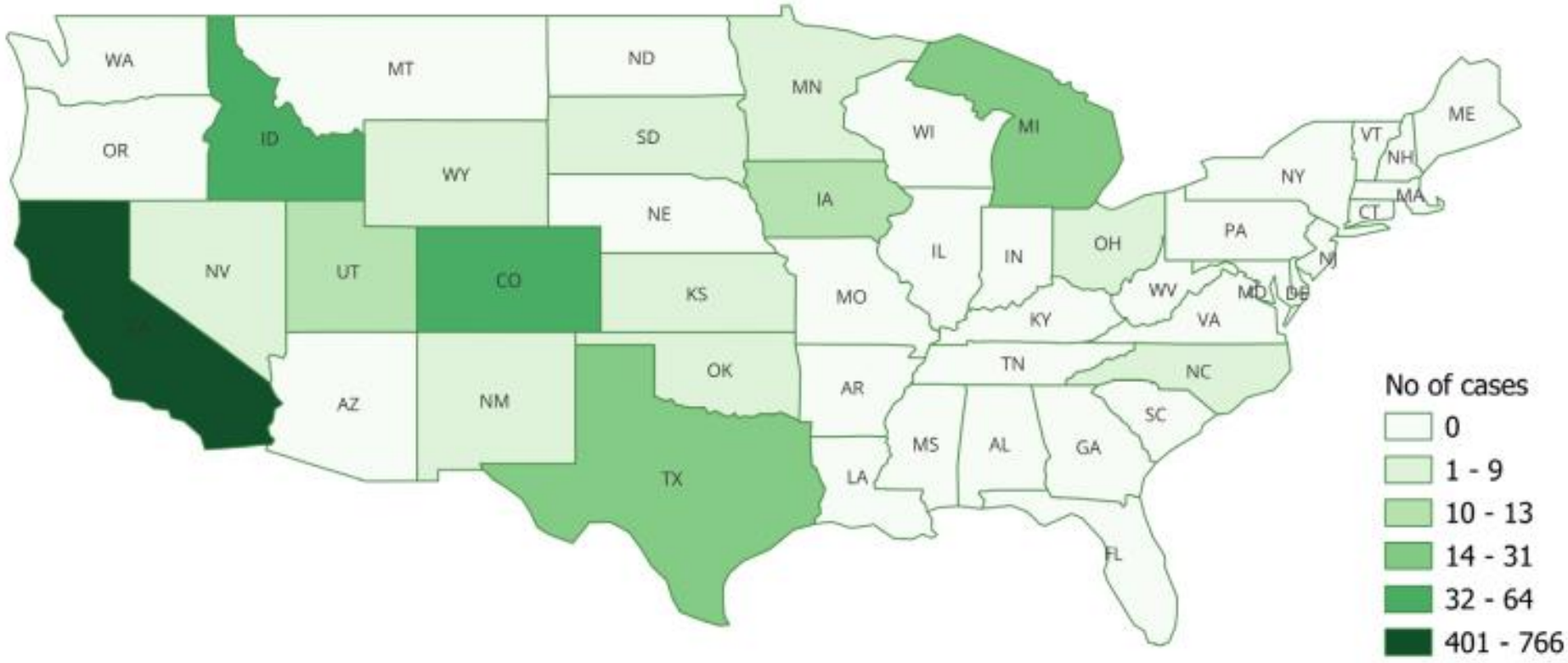
OUTBREAK IN US DAIRY CATTLE

Monthly number of HPAI H5N1 B3.13 reported cases in dairy farms per state (25/03/2024 – 30/04/2025)



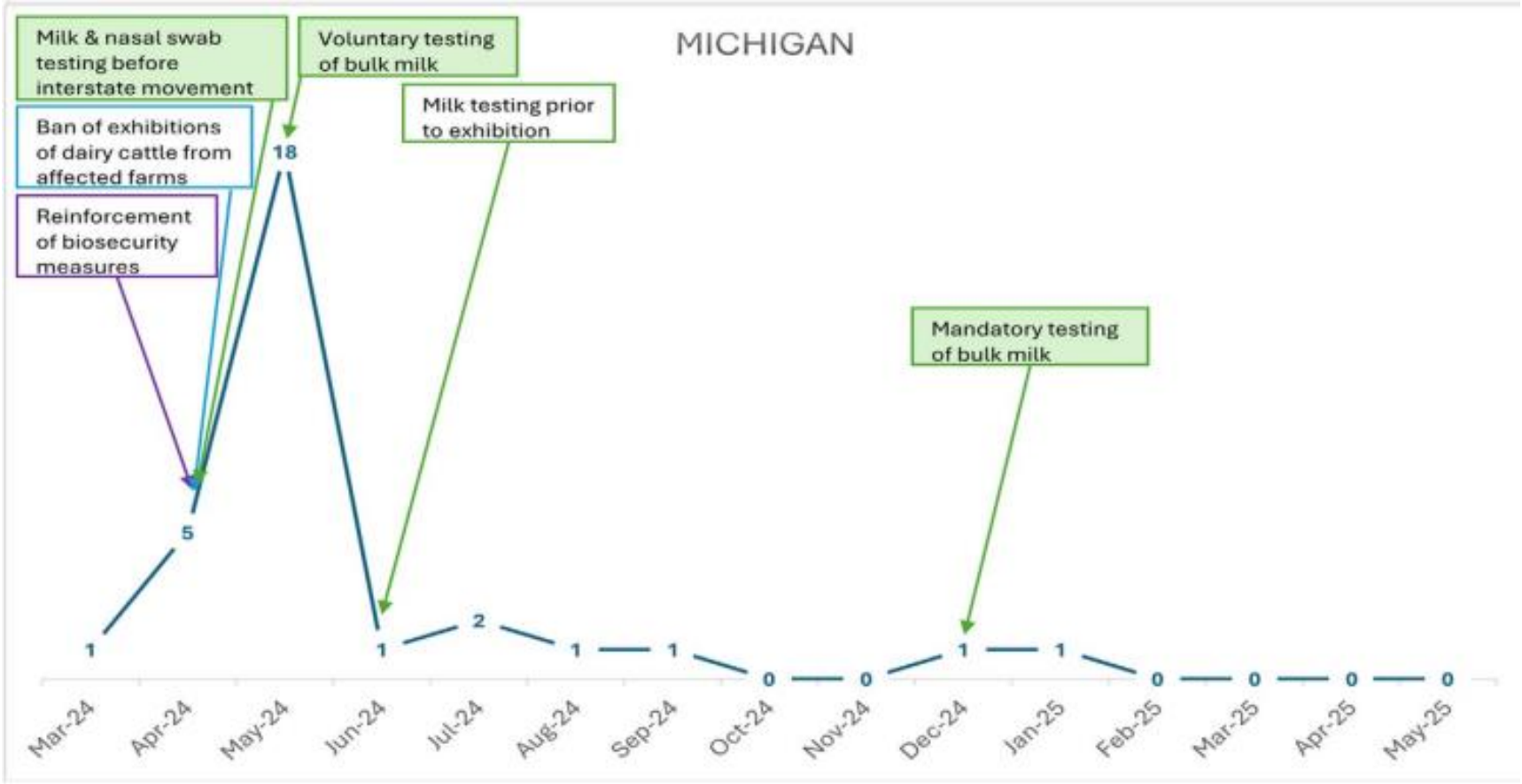
OUTBREAK IN US DAIRY CATTLE

Cumulative number of HPAI H5N1 B3.13 reported cases in dairy farms per state in US (25/03/2024 – 30/04/2025)



MEASURES IN US DAIRY CATTLE

Monthly outbreak distribution of cases in dairy cattle by state and
timeline of control measures implemented



RESULTS TOR 2A QUESTION 1: TRADE

Possible pathways:

- Milk and milk products, specifically raw or insufficiently treated milk and dairy products, with uncertainty around the efficacy of non-thermal treatments and product labelling
- Live bovine and bovine meat, but limited virus detection in muscle tissue

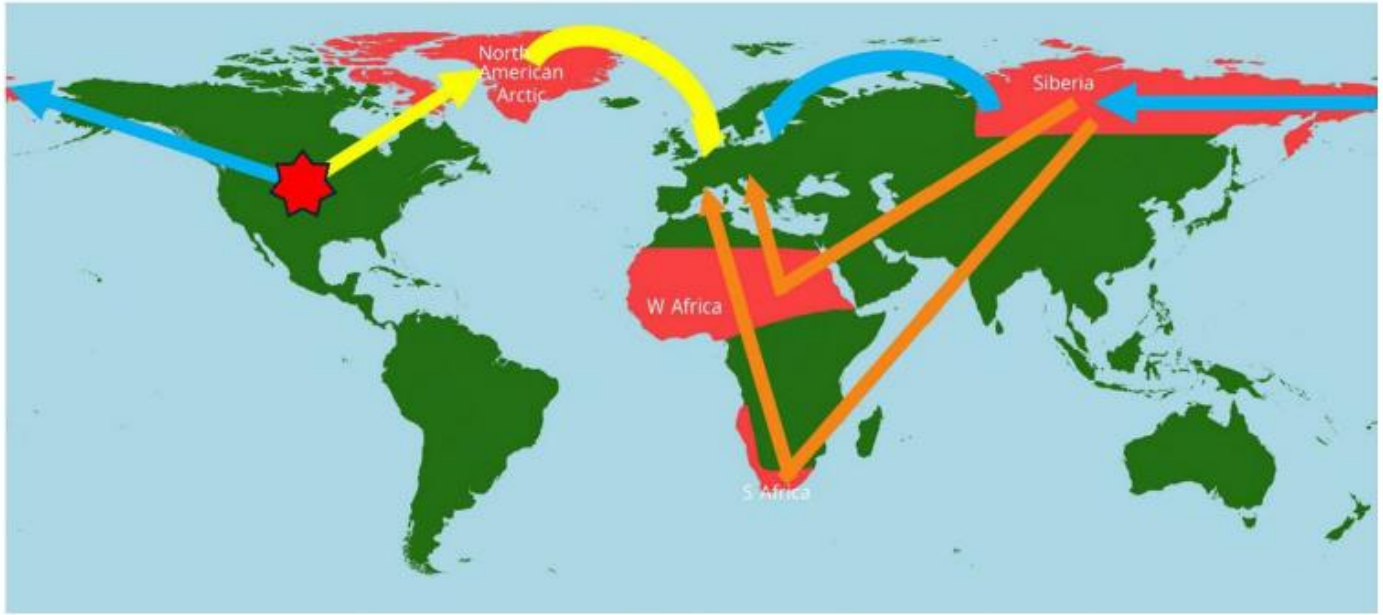
Lack of knowledge regarding pathway:

- No reports of investigations of bovine semen, embryos, oocytes or fetal calf serum

Overall: low quantities of commodities traded from the US to the EU

RESULTS TOR 2B QUESTION 2: MIGRATORY BIRDS

- Migratory waterbirds – especially gulls
- migration seasons (April–May) and non-breeding season (September–April)
- North American Arctic route most likely entry route
  - US migratory waterbirds may come into contact with European migratory birds
- Likely key entry points to EU:
  - Iceland, Ireland, western Scandinavia
  - large wetlands like the Wadden Sea



yellow arrows = intercontinental transmission via the North American Arctic
blue arrows = intercontinental transmission via Siberia
orange arrows = secondary transmission in West or South Africa

PUBLICATIONS

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SCIENTIFIC REPORT

efsa JOURNAL

Risk posed by the HPAI virus H5N1, Eurasian lineage goose/Guangdong clade 2.3.4.4b. genotype B3.13, currently circulating in the US

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract
The emergence of highly pathogenic avian influenza (HPAI) A(H5N1), clade 2.3.4.4b, genotype B3.13 in U.S. dairy cattle marks a significant shift in the virus' host range and epidemiological profile. Infected cattle typically exhibit mild clinical signs, such as reduced milk production, mastitis and fever, with morbidity generally below 20% and mortality averaging 2%. Transmission within farms is primarily driven by contaminated milk and milking procedures, while farm-to-farm spread is mainly linked to cattle movement and shared equipment. The virus demonstrates high replication in mammary glands, with infected cows shedding large quantities of virus in milk for up to 3 weeks, even in the absence of clinical signs. Shedding through other routes appears limited. Infected cattle develop virus-specific antibodies within 7–10 days, offering short-term protection, though the duration and robustness of immunity remain unclear. Between March 2024 and May 2025, the virus was confirmed in 981 dairy herds across 16 U.S. states, with California particularly affected. Risk factors identified for between-farm spread include cattle movement, shared equipment and contact with external personnel, while biosecurity measures, including waste management and wildlife deterrence, may re-

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Bird flu: EFSA analyses situation in US and tracks possible routes of spread

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The seasonal migration of wild birds and the importation of certain US products, such as those containing raw milk, could be potential routes for the introduction of the highly pathogenic avian influenza (HPAI) genotype currently affecting US dairy cows into Europe, a new report released by EFSA says. This virus type has not been reported so far in any country other than the USA.

OUTLOOK SCIENTIFIC OPINION

Assessment scope

- Impact of potential H5N1 B3.13 genotype virus introduction into EU dairy cows
- Measures that could prevent introduction into EU dairy and poultry
- Measures that could prevent spread in the EU
- Possible adaptations of the EU surveillance for HPAI to allow detection of an introduction into the EU dairy cow population
- Likelihood of bulk milk becoming contaminated if lactating dairy cows were infected with H5N1 B3.13 genotype virus
- Levels of viable virus in raw milk, colostrum, dairy products and colostrum-based products at the point of consumption if EU bulk milk is contaminated; foodborne infection risk for humans, measures to mitigate foodborne infection of humans

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