

Bruxelles, le 5 mai 2022
(OR. fr)

8182/2/22
REV 2

AGRI 154
VETER 31

NOTE

Origine:	la présidence
Destinataire:	délégations
Objet:	Projet de Conclusions du Conseil : 'Influenza aviaire hautement pathogène (IAHP): une approche stratégique pour le développement de la vaccination en tant qu'outil complémentaire de prévention et de lutte'

En vue de la réunion du groupe "Animaux et questions vétérinaires" (Chefs des services vétérinaires) du 12 mai 2022, les délégations trouveront en annexe le projet révisé de Conclusions du Conseil intitulé 'Influenza aviaire hautement pathogène (IAHP): une approche stratégique pour le développement de la vaccination en tant qu'outil complémentaire de prévention et de lutte' prenant en compte le résultat des discussions du groupe des Conseillers/Attachés (Agri - Animaux et questions vétérinaires) du 4 mai 2022.

Les annexes sont présentées sous 2 versions:

- l'annexe I avec les changements par rapport à la REV 1 surlignés en jaunes;
- l'annexe II en version propre.

Highly pathogenic avian influenza (HPAI): a strategic approach for the development of vaccination as a complementary tool for prevention and control

THE COUNCIL OF THE EUROPEAN UNION

(1) STRESSES that highly pathogenic avian influenza (HPAI) is a transboundary animal disease with a capacity to spread very rapidly irrespective of national borders, causing severe **socio-economic** ~~and social~~ consequences, hampering agriculture and disrupting trade.

(1bis) (*former item 1 part 2*) RECALLS that, due to ~~the~~ its zoonotic capacity **of some HPAI strains**, it can also pose a ~~serious~~ risk to human health.

(2) NOTES with great concern that **in the last two years three major epidemic season occurred in the territory of the European Union and** the current HPAI epizootic ~~facced by Member States of the European Union~~ is the most severe in recent history.

(3) RECALLS the Council Conclusions of 2019¹ which **strongly emphasise the key role of biosecurity and** state **generally** that, ~~in order to minimise the negative consequences of transboundary animal diseases,~~ **every-all** efforts should be made to prevent their introduction into or spread within EU territory **of transboundary animal diseases in order to minimise their consequences** and ~~which strongly emphasise the key role of biosecurity in order to achieve those aims.~~

(4) NOTES that, **in addition to the application of strict biosecurity measures,** vaccination could ~~strengthen~~ **complement the existing** preventive and control measures against HPAI and **could contribute to reducing the** risk of further spread of the virus in the domestic bird population **and thus help also in reducing human exposure.**

¹ 'Council conclusions on biosecurity, an overall concept with a unitary approach for protecting animal health in the EU', adopted on 18 June 2019 (10368/1/19 REV 1).

- (5) In addition, CONSIDERS that vaccination could ultimately also help to reduce the preventive culling of large numbers of healthy birds in order to control HPAI **epizootics epidemics**, which **causes increasing concern** ~~has become increasingly unacceptable~~ to society and is difficult to accommodate with **the** goal of developing a European sustainable food system which has been endorsed by the Council as part of its conclusions on the Farm to Fork Strategy².
- (6) RECALLS that the international standards of the World Organisation for Animal Health (OIE) and ~~of~~ **the** EU legislation already render vaccination against HPAI possible, but for various ~~practical~~ reasons, such vaccination is not practiced on a large scale. Those reasons include in particular not only the lack of ~~any~~ effective and safe vaccines **approved within the EU** against HPAI, but also the fact that vaccination could constitute an obstacle to exports of poultry and poultry products as a number of third countries restrict imports of vaccinated animals and products thereof. **Moreover, there is also a need for further scientific knowledge, including updated risk assessments.**

In the light of the above,

- (7) REAFFIRMS that biosecurity and surveillance remain ~~the~~ **important** cornerstones of the fight against HPAI, but CONSIDERS that vaccination could become a relevant complementary tool
- (8) URGES the Commission and the **Member States** to step up their efforts in order to develop ~~and implement~~ vaccination **strategies** for the prevention and control of HPAI, **focusing on ‘at risk areas’² species and farming practices at risk**. NOTES that joint efforts are required in several fields in order **to** reach that goal, but STRONGLY BELIEVES that such efforts would be well rewarded.

² ‘Council Conclusions on the Farm to Fork Strategy’, adopted on 19 October 2020 (12099/20).

- (9) CALLS FOR the **further** development of **and authorisation of effective and safe vaccines for different species of poultry** safe and efficient vaccines which provide sufficient immunity against the circulating HPAI virus strains. **Such vaccines should be**, which are easy to administer, **are and** compatible with farming practices in the EU. **In any case, it should be possible to** and which preferably allow for differentiating infected from vaccinated animals. INVITES the Commission and the Member States to collaborate with the pharmaceutical industry in order to achieve this objective.

9 bis (new item) **UNDERLINES the importance of continuously monitoring the evolution of the circulating virus strains and also any changes in the efficacy of vaccines in relation to any new virus strains.**

9 ter (former item 13) CONSIDERS it of key importance to identify and address gaps in risk assessments to support the development of vaccination strategies by the competent authorities **as relevant**, and therefore WARMLY WELCOMES the Commission's intention to mandate the European Food Safety Authority to update its opinion on vaccination against HPAI³. In addition, INVITES the Commission and the Member States to encourage and support the development of modelling tools to assess the impact of vaccination on the spread of the virus and to optimise vaccination strategies.

(10) *Sent to (14bis)*

- (11) INVITES the Commission to establish rules for appropriate and robust **tailor-made** surveillance to accompany vaccination against HPAI when it takes place, with a view to demonstrate HPAI free status taking into account the costs involved ,

- (12) ENCOURAGES the Commission and the Member States to carry out studies to assess the cost/benefit of vaccination at EU and local level respectively.

(12 bis)(former item 12 part 2) ENCOURAGES Member States to develop **risk based** strategies and solutions suitable for their local production types and circumstances;

³ EFSA Journal (2007) 489, Scientific Opinion on 'Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds' - EFSA-Q-2006-309, adopted on 11 May 2007.

- (13) Sent to (9ter)
- (14) ENCOURAGES Member States to carry out vaccination trials **and to share their results through scientific collaboration, as appropriate,** in compliance with the relevant legal framework **while** ~~and~~ taking appropriate preventive measures to protect animal and human health, as these trials are essential in order to gather scientific knowledge and support the definition of vaccination strategies;
- (14 bis) (*former item 10*) INVITES the Commission to explore the options for a block-purchasing or vaccine bank mechanisms in order to ensure a robust and reactive supply of vaccines;
- (14 ter) (*former item 16*) ENCOURAGES all relevant actors to communicate actively with stakeholders with the aim of raising awareness about the importance **of vaccination as well as its expected impacts** ~~and benefits of vaccination.~~
- (15) CALLS for joint efforts towards enhancing the acceptability of **the principle of** vaccination against HPAI in international trade. For this purpose, INVITES the Commission and the Member States:
- to jointly engage in a dialogue with the EU's trading partners ~~and~~
 - to promote discussions within the OIE at global and regional levels with the aim of further developing international standards to facilitate safe trade, also building on the concepts of regionalisation and compartmentalisation.
- Finally **To achieve these goals,** CALLS on the Commission and the Member States to swiftly develop an operational road map to support those dialogues and discussions;
- (16) *Sent to (14 ter)*
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Highly pathogenic avian influenza (HPAI): a strategic approach for the development of vaccination as a complementary tool for prevention and control

THE COUNCIL OF THE EUROPEAN UNION

- (1) STRESSES that highly pathogenic avian influenza (HPAI) is a transboundary animal disease with a capacity to spread very rapidly irrespective of national borders, causing severe socio-economic consequences, hampering agriculture and disrupting trade.
- (2) RECALLS that, due to the zoonotic capacity of some HPAI strains, it can also pose a risk to human health.
- (3) NOTES with great concern that in the last two years three major epidemic seasons occurred in the territory of the European Union and the current HPAI epizootic is the most severe in recent history.
- (4) RECALLS the Council Conclusions of 2019⁴ which strongly emphasise the key role of biosecurity and state generally that all efforts should be made to prevent the introduction into or spread within EU territory of transboundary animal diseases in order to minimise their consequences.
- (5) NOTES that, in addition to the application of strict biosecurity measures, vaccination could complement the existing preventive and control measures against HPAI and could contribute to reducing the risk of further spread of the virus in the domestic bird population and thus help also in reducing human exposure.

⁴ 'Council conclusions on biosecurity, an overall concept with a unitary approach for protecting animal health in the EU', adopted on 18 June 2019 (10368/1/19 REV 1).

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- (6) In addition, CONSIDERS that vaccination could ultimately also help to reduce the preventive culling of large numbers of healthy birds in order to control HPAI epizootics, which causes increasing concern to society and is difficult to accommodate with the goal of developing a European sustainable food system which has been endorsed by the Council as part of its conclusions on the Farm to Fork Strategy⁵.
- (7) RECALLS that the international standards of the World Organisation for Animal Health (OIE) and the EU legislation already render vaccination against HPAI possible, but for various reasons, such vaccination is not practiced on a large scale. Those reasons include in particular not only the lack of effective and safe vaccines approved within the EU against HPAI, but also the fact that vaccination could constitute an obstacle to exports of poultry and poultry products as a number of third countries restrict imports of vaccinated animals and products thereof. Moreover, there is also a need for further scientific knowledge, including updated risk assessments.

In the light of the above,

- (8) REAFFIRMS that biosecurity and surveillance remain important cornerstones of the fight against HPAI, but CONSIDERS that vaccination could become a relevant complementary tool.
- (9) URGES the Commission and the Member States to step up their efforts in order to develop vaccination strategies for the prevention and control of HPAI, focusing on areas, species and farming practices at risk. NOTES that joint efforts are required in several fields in order to reach that goal, but STRONGLY BELIEVES that such efforts would be well rewarded.
- (10) CALLS FOR the further development and authorisation of effective and safe vaccines for different species of poultry which provide sufficient immunity against the circulating HPAI virus strains. Such vaccines should be easy to administer and compatible with farming practices in the EU. In any case, it should be possible to differentiate infected from vaccinated animals. INVITES the Commission and the Member States to collaborate with the pharmaceutical industry in order to achieve this objective.

- (11) UNDERLINES the importance of monitoring the evolution of the circulating virus strains and also any changes in the efficacy of vaccines in relation to any new virus strains.
- (12) CONSIDERS it of key importance to identify and address gaps in risk assessments to support the development of vaccination strategies by the competent authorities as relevant, and therefore WARMLY WELCOMES the Commission's intention to mandate the European Food Safety Authority to update its opinion on vaccination against HPAI⁶. In addition, INVITES the Commission and the Member States to encourage and support the development of modelling tools to assess the impact of vaccination on the spread of the virus and to optimise vaccination strategies.
- (13) INVITES the Commission to establish rules for appropriate and robust tailor-made surveillance to accompany vaccination against HPAI when it takes place, with a view to demonstrate HPAI free status taking into account the costs involved.
- (14) ENCOURAGES the Commission and the Member States to carry out studies to assess the cost/benefit of vaccination at EU and local level respectively.
- (15) ENCOURAGES Member States to develop risk based strategies and solutions suitable for their local production types and circumstances.
- (16) ENCOURAGES Member States to carry out vaccination trials and to share their results through scientific collaboration, as appropriate, in compliance with the relevant legal framework while taking appropriate preventive measures to protect animal and human health, as these trials are essential in order to gather scientific knowledge and support the definition of vaccination strategies.
- (17) INVITES the Commission to explore the options for a block-purchasing or vaccine bank mechanisms in order to ensure a robust and reactive supply of vaccines.
- (18) ENCOURAGES all relevant actors to communicate actively with stakeholders with the aim of raising awareness about the importance of vaccination as well as its expected impacts.

⁶ EFSA Journal (2007) 489, Scientific Opinion on 'Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds' - EFSA-Q-2006-309, adopted on 11 May 2007.

(19) CALLS for joint efforts towards enhancing the acceptability of the principle of vaccination against HPAI in international trade. For this purpose, INVITES the Commission and the Member States:

- to jointly engage in a dialogue with the EU's trading partners;
- to promote discussions within the OIE at global and regional levels with the aim of further developing international standards to facilitate safe trade, also building on the concepts of regionalisation and compartmentalisation.

To achieve these goals, CALLS on the Commission and the Member States to swiftly develop an operational road map to support those dialogues and discussions.
