

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 10<sup>th</sup> meeting of the Working Group on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Held on 24 06 2013, Parma**

**(Agreed on 26 06 2013)**

**Participants**

- **Working Group Experts:**
  - Anette Bøtner (Chair)
- **EFSA:**
  - AHAW Unit: Sandra Correia, Per Have, Sofie Dhollander

**1. Welcome and apologies for absence**

The Chair welcomed the participants. No apologies were received.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the expert invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

#### **4. Scientific topic for discussion**

##### **4.1 Topic n°1 ([EFSA-Q-2012-00912](#))**

The latest draft opinion was sent to the AHAW Panel and to the EC on the 18 June. The comments received from the AHAW Panel were considered. During this meeting all pending issues were addressed and amendments were made in the draft opinion.

The document was prepared to be presented at the following Panel meeting (25-26 June).

- **Next meetings**

No further meetings are foreseen.

AHAW UNIT

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 9<sup>th</sup> meeting of the Working Group on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**TELE-conference, 11 06 2013**

**(Agreed on 20 06 2013)**

**Participants**

- **Working Group Experts:**
  - Anette Bøtner (Chair)
  - Christine Fourichon
  - Maurice Pensaert
  - Kristien Van Reeth
  - Ian Brown
  - Marco De Nardi
  - Olga Munoz
- **EFSA:**
  - AHAW Unit: Sandra Correia, Per Have
- **ECDC:**
  - Eeva Broberg

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Maria Pitman, Marina Marini (DG SANCO), Celine Gossner (ECDC), Sophie Dhollander (AHAW)

**2. Adoption of agenda**

The agenda was adopted without changes.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Scientific topic for discussion

#### 4.1 Topic n°1 ([EFSA-Q-2012-00912](#))

The revised draft was carefully revised mainly focusing on the pending issues from the last comments and suggestions received from the experts and the EC. It was explained that the AHAW scientific coordinators talked with the EC representatives and that some suggestions were received in relation to the references made to the current legislation and the legal context of the two scenarios developed for the risk assessment.

The structure of some specific chapters of the draft opinion were finally agreed (on the cross immunity to North American H3N2 swine influenza viruses in Europe). Some adjustments were made concerning the risk assessment results. Some issues related to the nomenclature used were also agreed. Some pending tasks were assigned to the experts to be solved in the following days.

The scientific opinion will be revised and prepared to be circulated to the AHAW Panel for discussion and possible adoption at its plenary in June (25, 26).

- **Next meetings**

10<sup>th</sup> WG meeting – 24 June (afternoon), preparatory meeting with the Chair.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

AHAW UNIT

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 8<sup>th</sup> meeting of the Working Group on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**TELE-conference, 07 05 2013**

**(Agreed on 13 05 2013)**

**Participants**

- **Working Group Experts:**
  - Anette Bøtner (Chair)
  - Maurice Pensaert
  - Kristien Van Reeth
  - Ian Brown
  - Marco De Nardi
  - Olga Munoz
- **European Commission:**
  - Maria Pitman, Marina Marini (DG SANCO)
- **EFSA:**
  - AHAW Unit: Sandra Correia, Sophie Dhollander, Per Have

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Christine Fourichon.

**2. Adoption of agenda**

The agenda was adopted without changes.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Scientific topic for discussion

#### 4.1 Topic n°1 ([EFSA-Q-2012-00912](#))

The structure for the reply to the mandate was discussed and agreed. The background for all ToRs will be kept separated at the beginning and the reply to each ToR will be done in specific chapters where the conclusions and recommendations will be included.

The current draft conclusions included in the latter chapters were thoroughly discussed and amended. A few specific tasks were assigned to some of the experts. Some definitions will be added in the glossary.

In relation to the reply to ToR2 (risk of introduction of H3N2v in EU), the assumptions made for the risk assessment were discussed and agreed with the EC. The risk flow pathway was further improved as well the description of the procedure. Some further changes will be introduced in order to reflect the legislation in terms of "residency period" of the animals at the holding destination. Two scenarios will be developed: with and without separation of the imported animals from the other pigs at the farm of destination. The conclusions in relation to ToR3 on the implications and consequences of the possible evolution of this strain in the EU pig population, will be revised taking into consideration the last part of the risk flow pathway (after introduction of the virus strain in the first farm and spread to the other farms after the above mentioned "residency period"). The reply to ToR5 (risk factors for emergency of pandemic strain from H3N2v), in relation to chapter 9, will be further revised and simplified.

A new version of the scientific opinion, including the risk assessment, will be forwarded to all WG members for comments and agreement to be revised in the next week. After this, the draft opinion will be circulated to the AHAW Panel for presentation and discussion at its plenary in May (21, 22).

- **Next meetings**

9<sup>th</sup> WG meeting – 11 June (Teleconference - to be confirmed)

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

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AHAW UNIT

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 7<sup>th</sup> meeting of the Working Group (with tele-conference) on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Held on 23 04 2013**

**(Agreed on 25 04 2013)**

**Participants**

- **Working Group Experts:**
  - Anette Bøtner (Chair)
  - Maurice Pensaert
  - Kristien Van Reeth
  - Marco De Nardi
  - Christine Fourichon
  - Gaelle Simon
  - Olga Munoz
- **EFSA:**
  - AHAW Unit: Sandra Correia, Sophie Dhollander, Per Have
- **Others**
  - Patricia Foley (USDA/APHIS)

**1. Welcome and apologies for absence**

The Chair welcomed the participants. Maria Pittman (EC), Ian Brown and Eeva Broberg (ECDC) were invited to participate by teleconference but it was decided during the meeting (morning) to cancel it due to the changes in the Agenda. Apologies were received from Celine Gossner (ECDC), Angus Nicoll (ECDC), Manuela Mura (EMA), Susan Trock (CDC), Joseph Anelli (APHIS), John Korslund (APHIS) and Amy Vincent (ARS).

**2. Adoption of agenda**

The agenda was adopted with changes in the sequence of the points to be discussed: the risk assessment became the first. Point Due to the length of the discussions related to the

risk assessment model, there was no time to discuss the draft opinion thoroughly. Just a few specific points were addressed.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

### 4. Scientific topic for discussion

#### 4.1 Topic n°1 ([EFSA-Q-2012-00912](#))

It was decided to start the meeting by presenting and discussing the proposal for the risk assessment to reply to the 2<sup>nd</sup> ToR (risk of introduction of H3N2v in EU). The draft risk flow pathway and the questions to determine estimates of the likelihood of certain events were further improved. The experts present at the meeting, discussed about the likelihood of those listed events and agreed on the estimated values (qualitatively) and the associated uncertainty. Modifications were introduced in the text of the scientific opinion, in relation to the cross immunity, cross protection and the proposed reply to ToR 4.

An expert from USDA/APHIS was contacted to clarify about the vaccines currently licensed in US.

A new version of all parts of the RA, including the proposed estimated values, will be forwarded to all WG members for comments and agreement.

A new version of the draft opinion will be also distributed, after including some contributions. After two rounds of comments by the working group, an improved version of the scientific opinion will be circulated to the AHAW Panel for discussion at the plenary in May (21, 22).

### 5. Next meetings

8<sup>th</sup> WG meeting – 7 or 8 May (Teleconference - to be confirmed)

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



AHAW UNIT

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 6<sup>th</sup> meeting of the Working Group (with tele-conference) on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Held on 19 04 2013**

**(Agreed on 25 04 2013)**

**Participants**

- **Working Group Experts:**
  - Marco De Nardi
- **EFSA:**
  - AHAW Unit: Sandra Correia, Sophie Dhollander, Per Have

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Non apologies were received.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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#### **4. Scientific topic for discussion**

##### **4.1 Topic n°1 ([EFSA-Q-2012-00912](#))**

The proposal for the risk assessment to be developed to reply to the 2<sup>nd</sup> ToR was thoroughly discussed and improved. The draft risk flow pathway and the questions to determine estimates of the likelihood of certain events were improved and will be forwarded to all WG members for discussion and agreement at the next meeting, 23 April. This qualitative risk assessment will support the evaluation of the risk of introduction in EU of H3N2v.

#### **5. Next meetings**

7<sup>th</sup> WG meeting – 23 April 2013

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 5<sup>th</sup> meeting of the Working Group (with tele-conference) on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**TELE-conference, 18 04 2013**

**(Agreed on 25 04 2013)**

**Participants**

- **Working Group Experts:**
  - Anette Bøtner (Chair)
- **EFSA:**
  - AHAW Unit: Sandra Correia, Sophie Dhollander, Per Have

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Non apologies were received.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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#### **4. Scientific topic for discussion**

##### **4.1 Topic n°1 ([EFSA-Q-2012-00912](#))**

A proposal for the risk assessment to be developed to reply to the 2<sup>nd</sup> ToR was discussed and improved. The changes and refinements made in the proposal will be further developed in the following day as a preparatory work for the next overall WG meeting next week, 23 April. A qualitative risk assessment is being developed to assess the risk of introduction in EU of H3N2v. The risk flow pathway and the questions to determine estimates of the likelihood of certain events were improved.

#### **5. Next meetings**

6th WG meeting - 19 of April 2013

7<sup>th</sup> WG meeting – 23 April 2013

**AHAW UNIT**

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 4<sup>th</sup> meeting of the Working Group (with tele-conference) on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Held on 12 03 2013, Parma**

**(Agreed on 12 04 2013)**

**Participants**

- **Working Group Experts:**

- Anette Bøtner (Chair)
- Maurice Pensaert
- Kristien Van Reeth
- Marco De Nardi
- Christine Fourichon has participated via teleconference
- Ian Brown has participated via teleconference
- Gaelle Simon has participated via teleconference
- Olga Munoz has participated via teleconference
- Celine Gossner ECDC has participated via teleconference

- **Hearing Experts:**

Sue Trock (CDC), Joseph Anelli (APHIS), John Korlund (APHIS) and Amy Vincent (ARS) have participated via teleconference

- **EFSA:**

- AHAW Unit: Per Have

## **1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Sandra Correia, Angus Nicoll, Eeva Broberg (ECDC), Manuela Mura (EMA) and by the EC officials.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

## **4. Scientific topic for discussion**

### **4.1 Topic n°1 ([EFSA-Q-2012-00912](#))**

The overall structure of the document was discussed in detail and proposals for changes/restructuring made. It was agreed to present all necessary information and evidence in the initial chapters and to maintain the chapters responding to the ToRs short and concise.

Each of the ToRs were discussed in detail. The approach for ToR 2 will be a qualitative assessment and it was agreed that the assessment should be limited to live pigs. The risk pathway(s) and questions will be adapted accordingly and presented at the next WG meeting.

Information was provided by USDA on the current situation in USA, concerning the impact of this strain in the pigs' population and on their vaccination.

For ToR 5 it was acknowledged that there is very limited information about the adaptation of swine influenza strains to humans. The work that has been undertaken in the Flurisk project will be used as a basis for the reply to this ToR. The previous opinion on pandemic H1N1 and risk of emergence of pandemic viruses from animal influenza should also be considered.

## **5. Next meetings**

5th WG meeting - 23 of April 2013

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

**SCIENTIFIC PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 3<sup>rd</sup> meeting of the Working Group on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Tele-conference, 18 02 2013**

**(Agreed on 07 03 2013)**

**Participants**

- **Working Group Experts:**
  - Anette Bøtner (Chair)
  - Christine Fourichon
  - Marco De Nardi
- **EFSA:**
  - AHAW Unit: Sandra Correia, Per Have

**1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Celine Gossner (ECDC).

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

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#### **4. Scientific topic for discussion**

##### **4.1 Topic n°1 ([EFSA-Q-2012-00912](#))**

A proposal for the development of the risk of introduction assessment was presented and discussed. This will support the reply to ToR2 and ToR3. For ToR2, a risk of introduction assessment of this influenza virus strain in EU with all possible pathways is going to be included (release/ exposure part). For ToR3, a description of the clinical manifestations and transmission of the virus between pigs (in herds and between herds), taking also into consideration the possible evolution of the infection in the pig population (transmission, pig health), based on the consequences part of the risk of introduction assessment, is going to be developed. A qualitative approach is going to be taken. Different risk pathways will be produced for free range and for limited biosecurity holdings. Gaps in knowledge will be identified. If required, data will be compiled through an expert elicitation. The uncertainty associated with the data and information used for the risk assessment will be included. The model used for the previous ASF EFSA scientific opinion will be used as a basis.

#### **5. Next meetings**

4th WG meeting - 12 March 2013

5th WG meeting - 23 of April 2013



Parma, 11 February 2013

**PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 2<sup>nd</sup> meeting (with tele-conference) of the Working Group on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Parma, 30 January 2013**

**EFSA / AHAW Unit**

**(Agreed by the working group on 12 February 2013)**

**Participants**

WG Experts	Anette Bøtner (Chair), Marco De Nardi, Ian Brown (TC, pm), Kristien Van Reeth (TC, pm)
DG SANCO	Maria Pittman (TC, pm)
ECDC	Celine Gossner
EFSA	Sandra Correia, Per Have (AHAW)
Observer (CDC):	Susan Trock (TC, pm)

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Maurice Pensaert, Angus Nicoll, Eeva Broberg and Christine Fourichon.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Discussions**

AHAW scientific secretariat described the clarifications made by the EC in relation to the background and main purpose of this mandate. EMA will contribute to the response to ToR4. If support is needed in relation to the use of vaccines in humans, EMA will get involved. In

relation to ToR4 and ToR5, ECDC will get involved in particular for the expertise in human influenza and for the interface between human and animals. CDC will support on ToR 4 and 5. The EU Reference Laboratory will also participate in the work in relation to all ToR. In relation to ToR2, a risk of introduction assessment framework is going to be prepared for the working group. Parts of the work will be drafted in collaboration with FLURISK and ESNIP3 projects. USDA will be invited to collaborate. The work plan to be followed for each ToR was prepared by the working group. Tasks were assigned and deadlines defined.

## **5. Next meeting dates**

3<sup>rd</sup> WG meeting - February 2013, date to be confirmed, Tele-conference with some of the experts (risk assessment framework),

4<sup>th</sup> WG meeting - 12 March 2013

5<sup>th</sup> WG meeting - 23 of April 2013

Parma, 18 December 2012

**PANEL ON ANIMAL HEALTH AND WELFARE**

**Minutes of the 1<sup>st</sup> meeting (tele-meeting) of the Working Group on possible risks posed by the Influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health**

**Parma, 14 December 2012**

**EFSA / AHAW Unit**

**(Agreed by the working group on 19 December 2012)**

**Participants**

WG Experts	Anette Bøtner (Chair)
DG SANCO	Maria Pittman, Silvia Bellini
EMA	Kriz Nikolaus, Manuela Mura, Maurice Pensaert
ECDC	Celine Gossner, Angus Nicoll, Eeva Broberg
EFSA	Sandra Correia, Per Have (AHAW)
Observers	Ilaria Capua

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Christine Fourichon.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Discussions**

The EC explained the background and main purpose of this mandate. Human cases of infection with this variant (H3N2v) have been reported in the USA from 2011. It has been detected in several US States but has not yet been detected in EU, neither in pigs or humans. The EC is interested to know the significance for the health of pigs of the

occurrence of influenza A (H3N2v) virus in a naïve population (ToR1); the risk of a possible introduction of influenza A (H3N2v) virus in particular to EU pig herds and the diagnostic capabilities to early detect an incursion (ToR2); the implications and consequences of the possible evolution of the influenza A (H3N2v) virus on pig health such as clinical manifestation, transmission between pigs and specially the risk that animals from a herd which was infected with influenza A (H3N2v) virus spreads the virus after the last clinical signs of disease have been observed (ToR3); the possibility, efficacy and efficiency of vaccination in pigs, using the existing vaccines or newly developed vaccines against influenza A (H3N2v) virus, also in relation with the possible evolution of variants of influenza viruses posing a risk to public and animal health (ToR4) and which are the most important factors to be monitored that would suggest a risk for the emergence of a new pandemic influenza strain from the influenza A (H3N2v) virus (ToR5).

EMA will contribute to the response to ToR4. In relation to ToR4 and ToR5, ECDC will get involved in particular for the expertise in human influenza and for the interface between human and animals. The EU RL will also participate in the work.

Other experts, currently participating in two DG RTD projects (ESNIP3 and PIG FLU) and an EFSA art. 36 project (FLU RISK), will be included in the working group. CDC has also been invited.

## **5. Next meeting date**

January. Date to be decided.