European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

WG meeting of the Working Group on bluetongue

15-16 June 2016, Parma

Invited participants:

WG members:	CALISTRI Paolo, MIRANDA Miguel Angel, BOTTNER Anette (via teleconference), GUBBINS Simon, ZIENTARA Stephan, Thomas BALENGHIEN (phone)
EFSA:	Alessandro BROGLIA, Francesca BALDINELLI (ALPHA), GARCIA Ana, CORTINHAS Josè (AMU)
EC	Dimitrios DILAVERIS (available on the phone)

NOTES

DISCUSSION

The mandate was introduced by the Chair

The workplan for each of the subquestion of the first 3 ToRs was discussed as below.

TOR 1: VACCINATION, ERADICATION AND SURVEILLANCE

TOR 1.1 *Assess the most suitable duration of a BT vaccination campaign intended to achieve disease freedom in a country or region considering any relevant factors that may affect and influence disease spread, and persistence.*

The proposed approach is:

- Modified BT spread model developed by Pirbright
- Applied the model in some countries of example (FR, IT, ES, UK, BE), selected on the basis of data availability and to take on board the different eco-systems
- Key parameters and data inputs: vaccine coverage, vaccine effectiveness, vector seasonality data (VectorNet, MS), Temperature (25*25Km resolution), hosts demography at NUT3 level

TOR 1.2 *Assess the probability of BT recurrence in BT affected areas that have regained BT freedom, in particular due to BT virus becoming endemic with low level circulation in these*

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areas and reoccurring "spontaneously" (low-noise circulation in livestock or wildlife, maintenance in vectors or other possible mechanism to be considered).

Proposed approach

- Modified BT spread model developed by Pirbright to test the probability of "low level circulation" in domestic ruminants under different scenarios
- "Low-noise circulation" in wildlife or maintenance in vectors will not be quantitatively assessed due to lack of reliable data, but it will be addressed in a descriptive way.

TOR 1.3 *Revise and assess the suitability of the provisions on surveillance laid down in Regulation (EC) No 1266/2007 to ensure reliable and robust demonstration of absence of virus transmission in a Member State or epidemiologically relevant area, considering point 1.2 above.*

Proposed approach:

- Modified BT spread model developed by Pirbright to set the minimum design prevalence needed to make BT spread start again. Considering different surveillance schemes: as required by Regulation as minimum requirements, examples of what done by MS.
  - Output- minimum design prevalence linked to BT re-occurence; geographical size (radius of the spread) 20km kernel from the model
  - Data needed: Test sensitivity
- Previous opinion on surveillance and monitoring will be also considered.

TOR 2: OPTIONS FOR SAFE TRADE APPLICABLE TO MOVEMENTS OF LIVE ANIMALS FROM RESTRICTED ZONES

Presentation and agreement on assessment questions as defined in Prometheus protocol (see draft opinion). Data will be obtained by a procurement, to be ready by end of September.

TOR 3: PROTECTION FROM BTV VECTORS AND VECTOR-BASED PROVISIONS APPLICABLE TO MOVEMENTS OF LIVE ANIMALS FROM RESTRICTED ZONES

TOR 3.1 *Review and update previous opinions as regards vectors ecology, in order to have more accurate and applicable criteria for the determination of the seasonally vector-free period*

Proposed approach

- Vector free period (VFP): Attempt to correlate vector abundance with BTV circulation data or diagnostics in sentinel animals in selected areas of countries for which data is

available (case studies and data from ES, in areas where there is no incursion from N. Africa, and Italy). Parous female abundance to be matched with virus transmission.

- To look for synergies with Vectornet and VBD opinion for the seasonality of vectors, in particular data from FR, IT, Spain, UK ,(Portugal?)
- Update of the previous opinion in relation to criteria currently used by MS

TOR 3.2 *Review and update previous opinions as regards over- wintering mechanisms and the duration of the BT viraemia*

Proposed approach:

- Update the previous EFSA opinion with the new available literature, which is expected to be limited. Expert knowledge could be also considered.

In particular:

- Possible mechanisms for virus to overwinter (in host, in vectors, etc.)
- What covered in past opinions
- What new for which mechanisms
- Cross check Schmallenberg opinion, similar question

TOR 3.3 *Review and update previous opinions and provide a scientific assessment of the appropriateness of the use of insecticides and repellents against Culicoides as BT competent vectors, including an assessment of their efficacy and recommendations of adequate protocols for their uses, in particular as regards their suitability to protect animals against attacks by vectors performing at least equal to the protection provided by vector-proof establishments - without the need to keep animals in a vector protected facility*

Proposed approach

- Update the previous opinion with new evidence: literature as collected from VBD mandate, data from ECHA on active substances efficacy, products authorised by national authorities.

TASK DISTRIBUTION

By next meeting on 19-20 July an update will be provided about the following tasks:

ToR	WHAT	WHO
1.1	Modelled scenario of disease introduction in one (or more than one, covering different situations) specific country + spread and behaviour of different duration of vaccination.	Simon G., Josè
1.2 BT	Check behaviour of the model and check ability to generate	Simon G., Josè

recurrence	persistence at low level	
	Explain in narrative why we do not show in the model the elements asked in the ToR (low-noise circulation in livestock or wildlife, maintenance in vectors or other possible mechanism to be considered)	Paolo
1.3	Model to set the minimum design prevalence needed to make BT spread start again	Josè
	Data from France needed	Stephan
2	Procurement launched, data model provided, critical appraisal for the studies	Alessandro, Ana, Anette
3.1	Seasonality of vectors: Vectornet: data from FR, IT, Spain, UK ,(Portugal) VFP: Relationship between vector abundance and BT outbreaks or diagnostics in sentinel animals	Miguel + Thomas
3.2	Draft short review from past opinions: possible mechanisms for virus to overwinter (in host, in vectors, etc.), what covered in past opinions, what new for which mechanisms, cross check Schmallenberg opinion for similar questions.	Miguel
	Look for data from US about overwintering and duration of viraemia	Alessandro
3.3	Review past opinion + news about recent products/recent studies lab and field level	Miguel + contribution from Simon Carpenter + Lara
	Cross check with EC the reason for compare repellents and vector proof facilities (to be applied in very different scenario)	Alessandro

TIMELINE, NEXT MEETINGS

- 19-20 July from lunch to lunch in Parma
- 13-14 September: update to the AHAW Panel
- 15 Sept whole day+ 16th September am in Parma
- 20th October : whole day in Parma

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

WG meeting of the Working Group on bluetongue

19-20 July 2016, Parma

Invited participants:

WG members: CALISTRI Paolo, MIRANDA Miguel Angel, GUBBINS Simon

EFSA: Alessandro BROGLIA, Francesca BALDINELLI (ALPHA)

NOTES

DISCUSSION

An update on the work plan for each of the sub-questions of the first 3 ToRs was presented and discussed as below.

TOR 1: VACCINATION, ERADICATION AND SURVEILLANCE

TOR 1.1 *Assess the most suitable duration of a BT vaccination campaign intended to achieve disease freedom in a country or region considering any relevant factors that may affect and influence disease spread, and persistence.*

The proposed approach is to use a modified BT spread model developed by Pirbright. An example was presented by Simon Gubbins.

The scenarios to be explored by the model are:

- two main geographical scenarios to be considered, according to the *C. obsoletus* group and *C. imicola* spatial distribution, thus one scenario related to FR+BE+southern UK and a second one for Italy +southern Spain.
- Data for bionomics of the vectors (mortality rate, biting rate, seasonal activity, etc.) will be derived from literature and, for *C. obsoletus* asking to Simon Carpenter.
- The main overwintering mechanism considered is the transplacental transmission in cattle and sheep . Different fixed parameter values (not a whole distribution) will be considered.
- Viraemia duration: in the example provided at WG meeting 21 days is used, this has to be cross checked with VBD opinion.

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- Demographic data: cattle, sheep, mixed population / lambing seasons (cross check with the work done on Schmallenberg).
- Mortality due to the disease: the values observed in Sardinia (or BTV1 in southern Spain) will be considered as worst case scenario, but also mortality rates registered in France during the BTV8 andBTV 1 epidemics will be taken on board.
- The start of epidemics is considered to take place in i) France close to Belgian borders, ii) southern UK, iii) southern Spain, in order to consider different climatic, demographic and vector conditions.
- Vaccination effectiveness: now it is considered equal to 100%. More realistic values will be derived from published field studies from Italy and Belgium.
- Dynamics of the simulations should include the following chronological phases: 1) Epidemics> 2) vaccination> 3) how many vaccination campaigns needed for the epidemics to fade out.
- A table of the parameter values will be circulated.

TOR 1.2 *Assess the probability of BT recurrence in BT affected areas that have regained BT freedom, in particular due to BT virus becoming endemic with low level circulation in these areas and reoccurring "spontaneously" (low-noise circulation in livestock or wildlife, maintenance in vectors or other possible mechanism to be considered).*

- It was discussed about to check the model ability to generate persistence at low level in domestic animals: the minimum no. of animals to maintain the infection.
- Role of wildlife: Paolo presented a section about the role of wildlife in BTV infection persistence at “low noise”. Possible conclusions: lack of data to prove the role of wildlife, contrasting evidence. In France, a possibility was the low level circulation of undetected BTV in domestic animals. A table summarising the results of surveys in European wild ruminants was provided by Paolo.
- It was proposed to try to mimic the BTV transmission dynamics in wildlife through the model: to check whether the infection can persist over years in one homogenous area (modelled as one single farm) with a certain number of wild animals, not vaccinated, considering the known values for wild ruminants in relation to viraemia duration and population demographic.

TOR 1.3 *Revise and assess the suitability of the provisions on surveillance laid down in Regulation (EC) No 1266/2007 to ensure reliable and robust demonstration of absence of virus transmission in a Member State or epidemiologically relevant area, considering point 1.2 above.*

Proposed approach:

- Modified BT spread model developed by Pirbright to set the minimum design prevalence needed to make BT spread start again. Considering different surveillance schemes: as required by Regulation as minimum requirements, examples of what done by MS.

- Output- minimum design prevalence linked to BT re-occurence; geographical size (radius of the spread) 20km kernel from the model
- Data needed: Test sensitivity

- Previous opinion on surveillance and monitoring will be also considered.

TOR 2: OPTIONS FOR SAFE TRADE APPLICABLE TO MOVEMENTS OF LIVE ANIMALS FROM RESTRICTED ZONES

An update was given on the work related to ToR 2: The procurement has been launched, data model have been provided for the collection of the relevant information. EFSA staff in in touch with the contractor. Data will be ready by end of September.

TOR 3: PROTECTION FROM BTV VECTORS AND VECTOR-BASED PROVISIONS APPLICABLE TO MOVEMENTS OF LIVE ANIMALS FROM RESTRICTED ZONES

TOR 3.1 *Review and update previous opinions as regards vectors ecology, in order to have more accurate and applicable criteria for the determination of the seasonally vector-free period*

Proposed approach:

- Vector free period (VFP): Attempt to correlate vector abundance with BTV circulation data or diagnostics in sentinel animals in selected areas of countries for which data is available (case studies and data from ES, in areas where there is no incursion from N. Africa, and Italy). Parous female abundance to be matched with virus transmission.
- To look for synergies with Vectornet and VBD opinion for the seasonality of vectors, in particular data from IT, Spain.
- Update of the previous opinion in relation to criteria currently used by MS.

Spain:

- no data on geo-referenced sentinel farms are actually available.
- 6 farms per provinces.
- Farms where presence of both vectors belonging to Obsoletus group and *C. imicola*.
- Farms to be selected for availability of data on vector surveillance and seroconversion in sentinel animals (or other evidence of virus circulation).

Italy:

- Extract seroconversion data in the last 3-4 years
- Select case/locations of seroconversion observed out of the typical vector season and extract entomological data for the same period (considering the incubation period and frequency of control) in or close to the farm.
- Data provided by Paolo about seroconverted sentinels and PCR positive animals in 2013-2015 for each month and province.

- Entomological data have to be analysed considering climatic areas, rather than countries. Ideally the entomological data needed would allow to differentiate nulliparous from parous insects. However, the current visual methods used in the laboratories for such differentiation (observing the level of pigmentation of abdomen) has been proven not solid. Evidence of pigmented nulliparous has been reported. Therefore, as a first glance, the total no. of *Culicoides* will be used. This could lead to an overestimation of the abundance of vectors, but it could be corrected, in case, taking into account what known about the gonotrophic cycle of these insects. In any case, this approach will lead to more conservative definitions of VBF criteria.
- Concerning the indoor activity of *Culicoides* compared to outdoor – to be updated with literature data

Assumptions:

- reliance on trapping system to check VFP
- >3 months without vector trapping=VFP

TOR 3.2 *Review and update previous opinions as regards over-wintering mechanisms and the duration of the BT viraemia*

Proposed approach:

- Update the previous EFSA opinion with the new available literature, which is expected to be limited. Expert knowledge could be also considered.

In particular:

- Possible mechanisms for virus to overwinter (in host, in vectors, etc.)
- What covered in past opinions
- What new for which mechanisms
- Cross check Schmallenberg opinion, similar question

To be done:

- To cross check studies provided by Jim (overwintering of parous *Culicoides* in California).
- To share the parameter table with Simon C. to be filled with bionomics data (in particular the overwintering parameters).
- To check the review by Simon Carpenter and Karin Darpel

Possible questions:

- How likely is vertical transmission (only for the 24 serotypes, the classical ones) of the pathogen in the host leading to overwintering? (cross check with Anette, VBD data).

- How likely is survival of an infected vector during the adverse season (e.g. winter)?
- How likely is vertical transmission of the pathogen in the vector? No evidence to date.
- How likely is overwintering of the pathogen via other mechanisms (blood/serum, germoplasts, persistence in other tissues - e.g. under the skin - etc).
- What is the duration of the viraemia of the different BTV serotypes in cattle and small ruminants and wildlife?

TOR 3.3 *Review and update previous opinions and provide a scientific assessment of the appropriateness of the use of insecticides and repellents against Culicoides as BT competent vectors, including an assessment of their efficacy and recommendations of adequate protocols for their uses, in particular as regards their suitability to protect animals against attacks by vectors performing at least equal to the protection provided by vector-proof establishments - without the need to keep animals in a vector protected facility*

Proposed approach:

- Update the previous opinion with new evidence: literature as collected from VBD mandate, data from ECHA on active substances efficacy, products authorised by national authorities.
- To review past opinion + news about recent products/recent studies lab and field level.
    - Review in *Veterinaria Italiana* to be published on the topic
    - VBD opinion: ECHA approvals
    - At country level: check protocols for protection of animals by biocides (IT, ES, France)
- The criteria of the guidance document to assist Member States or the implementation of the criteria for "Vector Protected Establishments" for bluetongue laid down in Annex II of Commission Regulation (EC) No 1266/2007 were reviewed. For the purposes of the mandate the EC advises to consider the efficacy of protection achieved by establishments fulfilling these criteria, or the efficacy 100% as gold standard can be assumed.
- Check which country (CVO from FR, IT, ES, UK) is using vector proof facilities, system for effectiveness check, and any data available for effectiveness (cross check requirement from the guidance 2012 from EC)

TASK DISTRIBUTION

By next meeting on 15-16 September an update will be provided about the following tasks:

ToR	WHAT	WHO
1.1	Viraemia duration: to cross checked with VBD opinion	EFSA staff

	Demographic data: cattle, sheep, mixed population / lambing seasons (Cross check with the work Schmallenberg)	EFSA staff (AMU, Josè)
	Mortality due to disease: cross check with ADNS data for mortality, stratified per serotypes	EFSA staff
	Table for parameter values to be circulated	EFSA staff
1.2	To check with the model whether not vaccinated animals, with longer viraemia, free ranging, sharing areas with domestic ones, and considering only one farm for demographic mimic.	Simon
	To cross check data from VBD for experimental infection in wild ruminants	EFSA staff
	To cross check with Jim McLachlan and VBD about BTV persistence in tissues different from blood	EFSA staff
ToR 3.2	Text to be drafted: possible mechanisms for virus to overwinter (in host, in vectors, etc.)	Miguel
	To share parameter table with Simon C. to be filled with bionomics data (in particular overwintering parameters)	EFSA staff
	To review past opinion + news about recent products/recent studies lab and field level.	Miguel + help from Simon C. + Lara
3.3	To check protocols for protection of animals by biocides (IT, ES, France)	EFSA staff
	To check which country (CVO from FR, IT, ES, UK) is using vector proof facilities, system for effectiveness check, and any data available for effectiveness (cross check requirement from the guidance 2012 from EC)	EFSA staff

TIMELINE, NEXT MILESTONES AND MEETINGS

- By 6th September: provide model simulations, sections on role of wildlife, on overwintering mechanisms, on biocides and treatments.
- 13-14 September: update to the AHAW Panel: Model to be shown , scenarios at least for UK, scenario for one farm ("wildlife")
- 15 Sept whole day+ 16th September a.m. : WG meeting in Parma

- 20th October (whole day): WG meeting in Parma

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

WG meeting of the Working Group on bluetongue

15-16 September 2016, Parma

Invited participants:

WG members:	CALISTRI Paolo, MIRANDA Miguel Angel, GUBBINS Simon
Hearing experts	CARPENTER Simon, Thomas BALENGHIEN
EFSA:	Alessandro BROGLIA, Francesca BALDINELLI (ALPHA), Josè CORTINHAS, Ana Garcia (AMU)

NOTES

DISCUSSION

An update for each of the sub-questions of the first 3 ToRs was presented and discussed as below.

TOR 1: VACCINATION, ERADICATION AND SURVEILLANCE

TOR 1.1 *Assess the most suitable duration of a BT vaccination campaign intended to achieve disease freedom in a country or region considering any relevant factors that may affect and influence disease spread, and persistence.*

- the livestock model for assessing the nr of vaccinations campaigns to make the epidemics fade out was presented
- The following modifications to this model are proposed:
    - the scenario in UK including animal movements and farm location
    - animal movements will not be considered in other scenarios since data are not available and since this will not be relevant for the purpose of this model.
    - additional lambing season in Autumn (see Schmallenberg data) to be considered
    - for the scenarios where data on farm location are not available, data from EUROSTAT at NUTS 3 level will be used to generate farm location and size

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  - Vaccination coverage+efficacy: to model that it increases as a function of the time-year(as shown it is independent from year to year)
  - P of overwintering of vectors? can be excluded for producing an effect in the model
  - P vertical transmission as distribution, ranges
- A section with a description of modelling approach, inputs and parameters considered to be circulated
- The full methodological details will be shown only to AHAW Panel at October Plenary and kept as confidential; in the opinion in Jan 2017 only a general description will be included, in case full details can be included in June 2017, or reference to the paper when published
- Implementation of model at EU level should include:
  - Spread scenarios will be run for France, Spain, UK
  - Incursions: into France from Belgium and from Spain, south UK, south Spain (Gibraltar), south Italy
  - Consider 5 years vaccination campaigns (this because of practical purposes from the management point of view)

TOR 1.2 *Assess the probability of BT recurrence in BT affected areas that have regained BT freedom, in particular due to BT virus becoming endemic with low level circulation in these areas and reoccurring "spontaneously" (low-noise circulation in livestock or wildlife, maintenance in vectors or other possible mechanism to be considered).*

- A discussion was conducted on the sense of the concept of “low” noise circulation , which is instead something related to the performance of the surveillance scheme. It would be better defined as circulation below the limit of detection, since absence cannot be excluded when the virus presence is under the detection limit. That’s why the point of 1.2 and 1.3 are linked.
- It seems we assist to epidemic waves, BT introduction > for 2-3 years BT outbreaks until all animals are sufficiently immunised, then there is an apparent silent period until BT could start again to be visible.
- Persistence in **wildlife**:

  The approach to the attempt of modelling the BT persistence in the red deer was discussed, and basically it was considered that it is not possible to provide any conclusions by this approach due to the absence of a epidemiological profile of BT in wild and/or due to the lack of a baseline model of BT dynamics in wildlife. It was concluded to present in the opinion a discussion of the role of wildlife for BT persistence based on what has been found in the literature. To consider paper from Talavera et al.(2015) Culicoides Species Communities Associated with Wild Ruminant Ecosystems in Spain: Tracking the Way to Determine Potential Bridge Vectors for Arboviruses. PLoS ONE 10(10): e0141667.
- “low-noise” circulation in **livestock**:

- A proposal was to use the model to check how long it takes for the epidemics to start again after "silent" period in a sufficiently large areas with cattle farms with a certain serological status and a certain turn over of new susceptible animals (constant or seasonal), with constant spike of BTV, and test when the population respond to the epidemics. The model could be let run for 10 years.
- Mechanisms of maintenance in **vectors**:

  This is discussed in the section about overwintering 3.2. Moreover considering the possibility of the role of vectors for BT persistence it is proposed to ask Thomas to argument about vector surveillance in France linked to French case study of last outbreak (from last two years;

TOR 1.3 *Revise and assess the suitability of the provisions on surveillance laid down in Regulation (EC) No 1266/2007 to ensure reliable and robust demonstration of absence of virus transmission in a Member State or epidemiologically relevant area, considering point 1.2 above.*

- It has been proposed to use the endemic model described above: Extrapolation of affected domestic animal from the model in a close area sufficiently large to let the disease without vaccination for 10 years (to estimate low noise seroprevalence): x% prevalence and then to be compared with surveillance prescriptions of EU
- Use the 95% confidence, test sensitivity: How many animals needed for geo unit? How many animals to be sampled in EU using 2000 kmq?
- Review previous opinion on surveillance about the different prevalence levels under different scenarios

TOR 2: OPTIONS FOR SAFE TRADE APPLICABLE TO MOVEMENTS OF LIVE ANIMALS FROM RESTRICTED ZONES

- An update was given on the work related to ToR 2:
- The procurement has been launched, data model have been provided for the collection of the relevant information.
- EFSA staff in in touch with the contractor.
- The critical appraisal of the studies will be done by the contractor, the further analysis will be performed by EFSA (meta-analysis, presentation of results according to weight of evidence level of studies.

TOR 3: PROTECTION FROM BTV VECTORS AND VECTOR-BASED PROVISIONS APPLICABLE TO MOVEMENTS OF LIVE ANIMALS FROM RESTRICTED ZONES

TOR 3.1 *Review and update previous opinions as regards vectors ecology, in order to have more accurate and applicable criteria for the determination of the seasonally vector-free period*

- A presentation by Thomas was shown, about BT surveillance and reflections on conclusions from previous EFSA opinion on ToR 3

- Opportunity maps by Josè to be used for vector activity:
    - It should be made sure that definition of seasonally vector free period is supported by field data. 2009-2012 vector data from France to be compared with meteorological data from same years in order to check association.
- Italy: 2013-2015 seroconversion data of sentinels animals, 121 seroconversion, location;
- Cross check data of animal movements during VFP.
- Review previous opinion on vector ecology and vector free period

TOR 3.2 *Review and update previous opinions as regards over-wintering mechanisms and the duration of the BT viraemia*

In vectors: Text to be drafted: possible mechanisms for virus to overwinter (review past opinion + news about recent products/recent studies lab and field level)

TOR 3.3 *Review and update previous opinions and provide a scientific assessment of the appropriateness of the use of insecticides and repellents against Culicoides as BT competent vectors, including an assessment of their efficacy and recommendations of adequate protocols for their uses, in particular as regards their suitability to protect animals against attacks by vectors performing at least equal to the protection provided by vector-proof establishments - without the need to keep animals in a vector protected facility.*

- Update of previous opinion, check VBD story maps for efficacy of biocides+repellent
    - Review in *Veterinaria Italiana* to be published on the topic
    - Consider experimental and studies on field efficacy

TIMELINE, NEXT MILESTONES AND MEETINGS

- 18-19th October AHAW Plenary, first draft opinion to be table
- 20th October (whole day): WG meeting in Parma.
- Teleconference on 11th November 9.30-12.30, Italy time.

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

WG meeting of the Working Group on bluetongue

21-23 September 2016, Pirbright

Invited participants:

WG members: GUBBINS Simon

EFSA: José CORTIÑAS ABRAHANTES (AMU)

Agenda: The agenda was adopted without changes.

#	**Items**
1.	**Welcome and administrative issues**
2.	**Model to study long term BTV behaviour**
2.1.	Selection of region to study long term BTV behaviour and model implementation
2.2.	Estimation of potential low BTV infection levels
3.	**Model formulation with cyclic spikes**
4.	**Model to study vaccination scenarios**

NOTES

DISCUSSION

- **Model to study long term BTV behaviour**

The model was implemented to study long term BTV persistence using a region in the south of United Kingdom comprising 5000 farms in total (cattle, sheep and goats), with around 1 million animals. Animal turnover in the cattle population was considered continuous, cattle births were generated considering a continuous time scale. For sheep and goats turnover was considered using information of lambing percentages provided by member states for

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the Schmallenberg scientific report (see page 81 in the report on SBV published in http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2768/epdf). The sheep and goats births were generated using the monthly percentage and a random day within the month was drawn for the farms. The model was run for 25 years for which BTV infection levels were monitored. Preliminary results indicate that for cattle and small ruminants BTV levels remain below 2 and 1% after an initial period of 2-3 years that the disease needs to propagate to all farms in the region.

- **Model formulation with cyclic spikes**

The model was not implemented given that the model to study long term BTV persistence using a region in the south of United Kingdom provides evidence that disease does not die out, and low levels of BTV infections can be seen every year for a period of 25 years after the incursion of the disease in the population.

- **Model to study vaccination scenarios**

Vaccination coverage was considered to be increasing with years of vaccination, for which farms that apply vaccination in the first year remain vaccinating for the rest of the 4 years. The proportion of farms vaccinating after the first years increase with time according to the ideas discussing in the working group held on September 15-16. The vaccination effectiveness was also considered to increase with years of vaccination, a simplification was discussed in order not to monitored vaccination status of farms, and uses simply a function were effectiveness increase with the year without considering if the farms vaccinated or not the year before. The impact of such strategy was studied and results indicate that it would be minor and mostly observed the second year after vaccination campaign started, reaching levels below 5% when the effectiveness was considered to be 60% and to 3% if the effectiveness is considered to be 80%.

The model for UK considering information on farm locations with animal movement data as well as ignoring animal movement was set up and it is currently running. Model was also set up for France considering random farm locations using information on NUTS 2 regions and considering introduction from the North, farms neighbouring Belgian borders and farms from the south west regions of France, bordering with Spain. In principle model is already set up for Spain and Italy but information on Imicola seasonality profiles as well as Imicola related parameters should be discuss in order to adjust the model to account for these two countries in which the prevalent culicoides species is Imicola.

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

Minutes of the 5th meeting of the working Group on bluetongue

Held on 20th October 2016 in Parma

(adopted on Monday 24th October)

Invited participants:

WG members:	CALISTRI Paolo, MIRANDA Miguel Angel, GUBBINS Simon; Anette BOTTNER, Stephan ZIENTARA (via teleconference)
Hearing experts[1]	Thomas BALENGHIEN (via teleconference), Simon CARPENTER
EFSA:	Alessandro BROGLIA, Francesca BALDINELLI (ALPHA), Josè CORTINHAS, Ana Garcia (AMU)

NOTES

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Simon Carpenter.

2. Adoption of agenda

The agenda was adopted as distributed.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest2, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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. Agreement of the minutes of the 3rd Working Group meeting

[1] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf .

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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The minutes of the 4th Working Group meeting were agreed by written procedure on 3th October 2016.

DISCUSSION of the draft opinion

***Section 3.1 (*model).**

- Missing scenarios: agreed to reduce Spanish and Italian scenario to Andalucia and Sardinia (Simon G)
- to check parameter for Imicola competence in the model (Miguel M.)
- to add reasoning to comment in 3.1.1 ('Spread between farms via animal movements was not included in the simulations') (Simon G)
- to draft discussion of the model outputs compared to past situation in different countries (Paolo C.)
- to add conclusive remarks for section 3.1 which cover answer to ToR 1.1 and 1.2 (for persistence in domestic) (Paolo C.)

section 3.2 (persistence)

- Wildlife role: to draft conclusions & Recommendation (see Hans comment) about recommendation of repeated surveillance in wild (e.g. France)? (Paolo)
- 3.2.2 transplacental : Consider field and experimental studies (Francesca B.)
- Add section on duration of viraemia (Alessandro B)
- Persistence of BTV in other organs apart from viraemia: To provide example of tissue At lab level where the virus can replicate (provide example), but no other mechanism of transmission to vectors apart from viraemia is known – to cross check with US reality (Ale)
- Section 3.2.4- Persistence of the infection in the vector population through vertical transmission.: Clarify limitation of analysis of parity (nulliparous/parous) and Draft conclusive point (Miguel)

Section 3.3.: (surveillance)

- To compare prevalence data from prev opinions with model outputs for persistence in long time – see Fig 1 in the draft (Alessandro/Simon G./Josè)
- To check if new surveillance system in France is targeting seroprevalence /true prevalence /incidence (Stephan)
- Provide Se and Sp values for the used cELISA (done)
- To check the lowest prevalence level modelled after incursion in France after 10 years and see whether the surveillance in place could detect it or which surveillance would be needed – (Simon G to provide median and percentiles)

Section 3.4 Maternal immunity and vaccines (ToR 2): SLR outputs were discussed.

- Conclusive remarks to be drafted (Alessandro/Anette).
- Graph for Q3 to be fixed (Ana G.)

Section 3.4.1 (ToR 2.4)- It was discussed that the quantitative assessment of this question (to provide a probability range) is not possible., Instead considerations will be done by considering the factors that make this assessment not possible with the current knowledge and the variability of situations that makes the protocol requested by the ToR as not applicable by default.

Section 3.5 - Vector ecology (TOR 3)

to revise these sections and the sequence and check for validity the conclusions from previous EFSA opinion, 2008. (Thomas, Simon Carpenter, Miguel)

- to provide Vectornet maps for imicola and obsoletus (Thomas)

Section 3.5.9 - Vector free period

- to add consideration from Italian data on seroconversion and captures in a radius of 5km and formulate conclusions & recommendations out of that (Paolo)
- Insert graph on R0 and temperatures and nr Culicoides, + explanation and reasoning (Paolo)

Section 3.6 insecticide and repellents

- Agreed to add a section about example of vector proof establishment (VPEs) in Italy, procedure for approval and show the comparison of inside/outside capture. To check if results are published somewhere e.g. proceedings, etc . To add conclusive remarks for efficacy of VPEs. (Paolo)
- Section 3.6.1 until 3.6.5 on update about insecticide repellents, etc.: to be revised (Simon Carpenter /Miguel)
    - To add conclusion about range of efficacy of insecticide/repellents – Miguel/Simon C.
- To add a conclusive section on comparison between vector proof establishment and repellents/insecticide - Miguel/Paolo
- Add withdrawal period of different products , rearrange table for ECHA approved substances (Alessandro)

TIMELINE AND NEXT MEETINGS

- 7th November : deadline for contributions
- 11th November Teleconference 9.30-12.30, Italy time
- 15th November: draft to be distributed to the AHAW Panel.
- 29-30 November: AHAW Plenary meeting, opinion tabled for discussion

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

Minutes of the 6th meeting of the working Group on bluetongue

Held on 11th November 2016 , teleconference

(adopted on 11th November)

Invited participants:

WG members:	CALISTRI Paolo, MIRANDA Miguel Angel, GUBBINS Simon; Anette BOTTNER, Stephan ZIENTARA
Hearing experts[1]	Thomas BALENGHIEN, Simon CARPENTER
EFSA:	Alessandro BROGLIA, Francesca BALDINELLI (ALPHA), Josè CORTINHAS, Ana Garcia (AMU)

NOTES

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Anette BOTTNER and Stephan ZIENTARA.

2. Adoption of agenda

The agenda was adopted as distributed.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest[2], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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. Agreement of the minutes of the 5th Working Group meeting

[1] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf .

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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The minutes of the 5th Working Group meeting were agreed by written procedure on 24th October 2016.

DISCUSSION of the draft opinion

Section 3.1 (model).

- Changes proposed at previous meeting have been made to the document
- conclusive remarks have been added and discussed

Section 3.2 (persistence)

- Changes proposed at previous meeting have been made to the document
- conclusive remarks have been added and discussed
- 3.2.2 transplacental transmission: conclusions have been added and discussed
- section on duration of viraemia and on persistence of BTV has been added
- Section 3.3.: (surveillance): prevalence data from model outputs for persistence in long time have been estimated and presented
    - It has been discussed and decided to compare these data to the target surveillance that was in place in France to demonstrate freedom and with the target of the new surveillance system in France after reoccurrence. Conclusions have to be added.

Section 3.4 Maternal immunity and vaccines (ToR 2): SLR outputs were discussed.

- Conclusive remarks have been drafted and discussed.
- Graph for Q3 has been agreed

  Section 3.4.1 (ToR 2.4)- this has been drafted, presented and discussed considerations will be done by considering the factors that make this assessment not possible with the current knowledge and the variability of situations that makes the protocol requested by the subToR as not applicable in all situations.

Section 3.5 - Vector ecology (TOR 3)

It has been agreed to revise these sections and the sequence of the sections and check for validity the conclusions from previous EFSA opinion, 2008.

Section 3.5.9 - Vector free period

- considerations from Italian data on seroconversion and captures have been added and discussed as well as conclusions & recommendations
- The graph on R0 and temperatures and nr Culicoides has been presented together with explanation and reasoning

Section 3.6 insecticide and repellents

- Agreed to add a section about example of vector proof establishment in Italy.

- It has been agreed to revise the section 3.6.1 until 3.6.5 about insecticide/repellents. To add conclusion about range of efficacy of insecticide/repellents.

- It has been agreed to add a conclusive section on comparison between vector proof establishment and repellents/insecticide

TIMELINE AND NEXT MEETINGS

- 29-30 November: AHAW Plenary meeting, opinion tabled for discussion
- Next meetings: to be discussed according to the comments provided by the AHAW Panel

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

Minutes of the 7th meeting of the working Group on bluetongue

Held on 6 Dec 2016 in Rome

(adopted on 6 December)

Invited participants:

WG members: CALISTRI Paolo

EFSA: Alessandro BROGLIA

NOTES

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted as agreed.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest1, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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. Agreement of the minutes of the 6th Working Group meeting

The minutes of the 6th Working Group meeting were agreed on 11 November 2016.

DISCUSSION

The main purpose of this meeting was to revise the complete draft according to the comments provided by the Panel at the last Plenary meeting. Body text and conclusions revised according to the version stored in the DMS https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=16483826.

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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It was agreed to consider the map for seasonality to be provided by Vectornet by 5 January 2017 eob.

TIMELINE AND NEXT MEETINGS

- 15-16 January 2017: AHAW Plenary meeting, opinion tabled for adoption

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

Minutes of the 8th meeting of the working Group on bluetongue

Held on 16th December 2016 , teleconference

(adopted on16th December)

Invited participants:

WG members: CALISTRI Paolo, MIRANDA Miguel Angel

Hearing experts[1] Thomas BALENGHIEN, Simon CARPENTER

EFSA: Alessandro BROGLIA (ALPHA)

NOTES

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Simon CARPENTER.

2. Adoption of agenda

The agenda was adopted as distributed.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest[2], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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. Agreement of the minutes of the 5th Working Group meeting

The minutes of the 7th Working Group meeting were agreed by written procedure on 6th December 2016.

5. DISCUSSION

[1] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf .

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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The discussion was focused on the sections of the opinion about vectors, covering ToR 3, in particular

- section 3.5 on vector ecology: the assessment of the validity the conclusions from previous EFSA opinion, 2008 was completed; the conclusions and recommendations were revised.
- the section 3.6.1 until 3.6.5 about insecticide/repellents was revised. the conclusions and recommendations were revised.

6. TIMELINE AND NEXT MEETINGS

- This was the last meeting for this opinion that will be adopted in January 2017.

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

Minutes of the 9TH WG meeting of the Working Group on bluetongue

13-14 March 2017, Parma

Invited participants:

WG members: CALISTRI Paolo, Stephan Zientara

Hearing experts[1] Peter MERTENS, Giovanni SAVINI

EFSA: Alessandro BROGLIA, Francesca, BALDINELLI

NOTES

1. **Welcome and apologies for absence**

The Chair welcomed the participants.

2. **Adoption of agenda**

The agenda was adopted as distributed.

- Introduction to the ToR 4 and 5 of the mandate
- Review of previous opinion on different BT serotypes: which information/literature to refer to
- Criteria for grouping serotypes
- Feasibility of grouping

3. **Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest[2] , EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in

[1] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. DISCUSSION

For the ToR 4.1 it was discussed that a descriptive section on the currently described BTV serotypes could be drafted. This could comprise a description of:

1. serotypes currently present or present in the past in EU, here 3 major groups of serotypes can be identified, the field virus (1-24 serotypes), vaccine strains (BTV 6, 11, 14, 16), the "new" serotypes where goat is considered the reservoir (BTV25, 27).
2. serotypes present in the Mediterranean basin or EU neighbouring countries;
3. serotypes present others countries.
    a. African serotypes
    b. India/Asia serotypes

For the ToR 4.2 about the criteria for grouping serotypes, it was discussed that the serotype distinction of bluetongue virus is useful since it influences the choice of a suitable vaccine, but it is only one characteristic of the virus outbreak-strain (determined by only one of the ten viral genes) and is therefore incomplete for a full description on animal health impact. It was underlined the importance of connecting the full genomic information with biological information as observed in the field. Some laboratory tools can support the differentiation of biological characteristics, but still the animal health impact is linked to what the field evidence suggests in the different situations. Full genome analysis provides a complete identification on of any outbreak strains. This can in itself identify vaccine derived strains, or the novel goat strains, but cannot yet give a definitive identification of virulent and avirulent strains. However, together with the field data concerning virulence sequence analyses can provide a firmer basis for the categorisation of different strains within the three groups. Moreover, when BTV serotypes are categorised according to the level of impact on animal health, in some cases the same serotypes would fit into different groups since they showed different pathological and epidemiological characteristics in different situations in time and space, confirming the extremely diverse and dynamic behaviour of BTV, with potential for further mutational changes in the field.

For this reason it was proposed to compile a matrix table where the different BTV strains, according to serotype and to phylogenetic heterogeneity, observed in the outbreaks since 1998 up to date, are retrospectively shown, with a classification of their level of pathogenicity, epidemiological behaviour, geographical and temporal occurrence from the one initially observed until the last one. The criteria include classes of i) morbidity and ii) mortality in the different host species (cattle, sheep, goat), epidemiological characteristics such as iii) way of transmission (vector-borne, direct, transplacental), iv) capability to spread into different episystems (northern Europe, south-eastern and south-western Europe; v) the geographical occurrence and the start and end date of the epidemics with that particular strain. The classes values of morbidity and mortality are derived from the levels observed in the field in worst and best cases observed in the past.

This table can be structured for the 3 major groups considered field strains, vaccine strains, and 'goat' strains, i.e. those strains which use goats as reservoir and considered to be directly

transmitted without the need of insect vectors. If the vaccine strains have to be considered inside the scope of the mandate can be clarified with EC.

For ToR 4.3 which asks to group the serotypes and indicate which one could be excluded from BT policy, it was discussed that the tables as described above would provide all the elements to assess the impact of the different strains observed in the past, and according to those certain groups with common features could be highlighted. Still the grouping and the following indication for excluding those "low impact BTV strain groups" from BT policy would not be possible on the basis of serotype alone, would be extremely risky and not appropriate, due to the dynamic nature of BTV, as expressed above. It would be difficult to extrapolate the evidence from the past for a specific strain or group and consider it valid for a future occurrence, unless there are clear linkages in time and space (e.g. BTV 3 is circulating in Tunisia and northern Africa, if occurred in Sicily or Sardinia it may be plausible to consider as the same strain, and thus expect the same virulence). Therefore laboratory integrated surveillance at national and EU level would be useful, so to early characterise any emerging strain.

For ToR 5, the feasible option could be to draft three factsheets according to the 3 major groups, as above.

5. Task distribution

Below the table with the assigned tasks for the WG members

task	WHO	deadline
Section on criteria definition circulated to the AHAW Panel	Paolo, Alessandro	End of March
Matrix table field virus to be filled	Paolo, Peter	17th April
Matrix table vaccine strains to be filled	Paolo, Peter	17th April
Matrix table goat strains to be populated	Stephan, Giovanni	17th April
To draft factsheet field virus	Giovanni, Peter (provide slide)	17th April
To draft factsheet vaccine template	Alessandro	17th April
To draft factsheet on goat strain, extract from draft factsheet	Alessandro	17th April

6. TIMELINE AND NEXT MEETINGS

- The next WG meeting is foreseen on 19th April (full day)
- The circulation of the draft factsheet to the AHAW panel is foreseen by 28th April
- The following WG meeting is foreseen on 17-18 may (lunch to lunch
- The adoption is foreseen at the AHW plenary on 30 June

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

10TH WG meeting of the Working Group on bluetongue

19 April 2017, Parma

Invited participants:

WG members: CALISTRI Paolo, Stephan Zientara

Hearing experts[1] Peter MERTENS, Giovanni SAVINI

EFSA: Alessandro BROGLIA

NOTES

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest[2] , EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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. DISCUSSION

- Some introductory sections were discussed, about:
    - Which serotypes will be considered in the opinion

[1] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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- Why the vaccine strains are not taken into account in the opinion and what kind of possible risks may be linked to them
- Definition of the term "BTV strains as will be used in the opinion, which is characterised by different patterns both geographical, epidemiological, temporal ,etc.
- The analysis will be based on evidence from past epidemics, but would not imply the same behaviour of the same strain in the future

- The overview table about past epidemics was compiled regarding the type of isolate, the country and years of occurrence and related episystem.
- The draft fact-sheet was revised and the criteria that were applicable to all serotypes were highlighted.

5. Task distribution

Below the table with the assigned tasks for the WG members

task	WHO	deadline
To revise the sections of the fact-sheets that are valid for all serotypes, indicate missing references, add relevant information, shorten the text to make it more focus to what requested by each criterion and parameter	Peter, Stephan, Giovanni	26 April
To complete table with range values (median, C.I.) of nr outbreak per week/month, intra herd morbidity , mortality and case fatality for the 3 species for all serotypes using the ADNS data; Circulate the table to the WG	Paolo, Alessandro	23 April

6. TIMELINE AND NEXT MEETINGS

- The circulation of the draft factsheet to the AHAW panel is foreseen by 30 April
- The next WG meeting is foreseen on 17-18 May (lunch to lunch)
- The adoption is foreseen at the AHW plenary on 30 June

European Food Safety Authority

ALPHA UNIT

Scientific Panel on Animal Health and Welfare

Notes of the 11TH WG meeting of the Working Group on bluetongue

17-18 May 2017, Parma

Invited participants:

WG members: CALISTRI Paolo, Stephan Zientara

Hearing experts[1] Peter MERTENS, Giovanni SAVINI

EFSA: Alessandro BROGLIA

NOTES

1. Welcome and apologies for absence

The WG Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest[2] , EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest 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. DISCUSSION

The draft opinion was revised, the comments provided by the EC and by the AHAW Panel were discussed and endorsed in the document. It was proposed to include some recommendation points.

5. Task distribution

Below the table with the assigned tasks for the WG members

[1] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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task	WHO	deadline
Revise section on methodology	Paolo, Alessandro	End of May
Revise the text and check that all comments are properly addressed	Alessandro, Paolo	5th June
Provide missing references, advise on comments and queries	WG members	End of May

6. TIMELINE AND NEXT MEETINGS

- The circulation of the draft opinion to the AHAW panel is foreseen by 8 June
- The adoption is foreseen at the AHW plenary on 30th June