European Food Safety Authority

AHAW UNIT

Parma, 16 February 2012

SCIENTIFIC PANEL ON AHAW

Minutes of the 1st meeting of the Working Group on Tb test

Brussels, 15 February 2012

EFSA / Unit /AHAW

Agreed by the WG on 22 February 2012

Participants

WG Experts	A. Stegeman (chair), S. More (rapporteur), J. Alvarez, S. Downs (attended via teleconference)
Observers (EC)	F. Reviriego Gordejo, V. Piazza and A. Malta Reis
EFSA:	A. Afonso (AHAW) D. Verloo (SAS)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Eamonn Gormley.

2. Adoption of agenda

The agenda was adopted. .

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

a) Presentation of the EFSA Mandate

SM informed the WG about the discussions with EC concerning the TOR. The mandate focus on the assessment of gamma interferon and other newer tests for inclusion as official test in CD 64/432/EC for achieving and retaining herd free status and for animal certification for intra community trade between officially free status. The mandate does not contemplate issues related with disease control or confidence in freedom with different design prevalence values. Sensitivity is the main characteristic to be assessed and in order to be included as an alternative test Se must be equal or superior to the one estimated for the official test included in CD 64/432 i.e. tuberculin skin test. If no evidence is available for test evaluation advice must be given on further studies to be developed.

extract information according to a agreed table. The reference list from ANSES and PRIONICS were checked to identify references not yet included in the review.

c) Public call for data

The data was validated and tabled in order to identify different populations where 2 or 3 tests have been used. Some data queries were solved with WG experts.

d) Modelling approach

Preliminary results from latent class modelling were presented. The initial results from data sets of Northern Ireland show a higher sensitivity and a lower specificity for gamma interferon in comparison with skin test.

e) Review of draft opinion

The WG reviewed the draft opinion and addressed comments.

5. Next meeting date

4/9/12 15h WEB Model results check

European Food Safety Authority

AHAW UNIT

Parma, 26 March 2012

SCIENTIFIC PANEL ON AHAW

Minutes of the 2nd meeting of the Working Group on Tb test

Web Conference, 26 March 2012 (10-13h)

EFSA / Unit /AHAW

Agreed by the WG on 30 March 2012

Participants

WG Experts	A. Stegeman (chair), S. More (rapporteur), J. Alvarez, S. Downs , E. Gormley
EFSA:	A. Afonso (AHAW) D. Verloo (SAS)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from the commission observers.

2. Adoption of agenda

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

a) Literature Search VLA

A update of the literature search was conducted. The relevance screening will be conducted by 2 reviewers. Inclusion and exclusion criteria for stage 2 review should be the same than used in the original review (VLA). The data extraction will be done in accordance with the template provided for the call for data.

b) Public call for data

The call for data was published on the EFSA web site 26/3/12

http://www.efsa.europa.eu/en/data/call/120326.htm

c) AHAW Network meeting

A meeting report was prepared and it is a source of information for the draft opinion.

d) Diagnostic accuracy estimation

The methodology for estimation of Diagnostic Se/Sp will depend on the available data. It was agreed that a decision on the use of latent class models and/or Gold standard method will be made at the next meeting.

5. Next meeting date

Utrecht Netherlands 9-10/5

European Food Safety Authority

AHAW UNIT

Parma, 9-10 May 2012

SCIENTIFIC PANEL ON AHAW

Minutes of the 3rd meeting of the Working Group on Tb test

Utrecht, 9-10 MAY 2012

EFSA / Unit /AHAW

Agreed by the WG on 18 May 2012

Participants

WG Experts	A. Stegeman (chair), S. More (rapporteur), J. Alvarez, S. Downs , E. Gormley
EFSA:	A. Afonso (AHAW) D. Verloo (SAS)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from the commission observers.

2. Adoption of agenda

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. The experts S. More and E. Gormley were requested to update their DOI to reflect their participation in the Expert WG of ANSES.

4. Discussions

a) Tasks from previous meetings

All tasks were completed.

b) Literature Search VLA

<u>Data extraction from SLR:</u>

SD gave a presentation of a) the main results of the AHVLA SLR and b) Results from extraction of data from the SLR for the EFSA meta-analysis

a) SD highlighted the estimates of the tests to be reviewed for the mandate and pointed out the estimates of test performance in the SLR were adjusted (using covariates extracted as part of the review) where possible for GB conditions. Sensitivity data were derived from populations where the reference papers had indicated that cattle were exposed to TB and specificity where the papers had provided good

epidemiological evidence that the herd or area was TB free. SD highlighted the relatively small number of references and records from which data were extracted for each estimate of test performance and that only a small number of covariates had been used to control for differences between populations. Differences in the interpretation criteria used to ensure the performance of blood tests were controlled for by including reported performance counter-parameters (i.e. An estimate of specificity for meta-analysis of sensitivity and vice versa). DV commented that some of the credible intervals for test performance were very narrow – particularly for the estimates of specificity and this might be a problem if they were used as a prior.

b) SD said that reference papers varied in detail provided about study design and there were many different interpretation criteria, scales and cut points used in studies of the performance of blood tests (IFNg and ELISA). In terms of extraction of data for EFSA – the following major issues were highlighted: i) Different categories had been used in the AHVLA SLR to those in the EFSA data call to classify sampling strategy, exposure to TB outbreaks, animal age, evidence that a population was TB free ii) There were many inconsistencies in interpretation criteria, scales and units for measuring performance of blood tests in data extracted by paired reviewers and this coupled with observed differences in these criteria between papers meant that interpretation criteria for blood tests were not included as variables in the final cleaned AHVLA SLR dataset iii) The AHVLA SRL meta-analysis for specificity included studies where the only "reference standard" was evidence that a population was TB free whereas the EFSA analysis required the negative reference standard to include a diagnostic test iv) the AHVLA SLR included data from countries outside Europe whereas the submissions of data to EFSA were from countries inside Europe The WG discussed the value of the information obtained by the SLR as prior for the modelling exercise. It was decided that the results on Se/Sp estimates will be used as prior but there are issues to be solved on the modelling , eg small CI. The estimates to be included are the ones for the tests under evaluation (TUE).

Diagnostic tests to be evaluated (**TUE**)

Test Name	**Abbreviation**	**Long description**
IFN-γ Bovine-Avian	IFN-γ-BA	Gamma - interferon test with bovine PPD and avian PPD diagnostic antigens
IFN-γ Bovine	IFN-γ -B	Gamma - interferon test with bovine diagnostic antigen
IFN-γ CFP10 ESAT6	IFN-γ -CE	Gamma - interferon test with CFP10 and ESAT6 diagnostic antigens
IFN-γ MPB70	IFN-γ -MPB	Gamma - interferon test with MPB70 diagnostic antigen
IFN-γ BACE	IFN-γ -BACE	Gamma - interferon test with bovine PPD and avian PPD diagnostic antigens and CFP10 and ESAT6 diagnostic antigens
IFN-γ OTHER	IFN-γ - OTHER	Gamma - interferon test with OTHER diagnostic antigens – PLEASE SPECIFY
ELISA Bovine-Avian	Elisa-BA	Enzyme-linked immunosorbant assay with bovine PPD and avian PPD diagnostic antigens
ELISA Bovine	Elisa-B	Enzyme-linked immunosorbant assay with bovine diagnostic antigen
ELISA MPB70	Elisa-MPB	Enzyme-linked immunosorbant assay with MPB70 diagnostic antigen
Latex Bead Agglutination	Latex	Latex bead agglutination assay (LBAA)

assay		
Multiplex immunoassay	Multiplex	Multiplex chemiluminescent immunoassay developed by Enfer Scientific
Serological Rapid	Rapid	Rapid immunochromatographic assay (rapid test)

List of tests with performance estimates from the meta-analysis of the AHVLA SLR

IFN-gamma Bovine-Avian	Gamma - interferon test with bovine PPD response minus the avian PPD diagnostic antigen response (This is different to where the interpretation is based on the ratio of the IFNgB/IFNgA response. The latter group were excluded from this category in the AHVLA SLR and included in Bovine Other (not reported because it was a heterogeneous group)
IFN-gamma Bovine	Gamma - interferon test with bovine diagnostic antigen
IFN-gamma CFP10 ESAT6	Gamma - interferon test with CFP10 and ESAT6 diagnostic antigens
IFN-gamma MPB70	Gamma - interferon test with MPB70 diagnostic antigen
ELISA Bovine-Avian	Enzyme-linked immunosorbant assay with bovine PPD and avian PPD diagnostic antigens
ELISA Bovine	Enzyme-linked immunosorbant assay with bovine diagnostic antigen
ELISA MPB70	Enzyme-linked immunosorbant assay with MPB70 diagnostic antigen
Latex Bead Agglutination assay*	Latex bead agglutination assay (LBAA)
Multiplex immunoassay	Multiplex chemiluminescent immunoassay developed by Enfer Scientific
Serological Rapid**	Rapid immunochromatographic assay (rapid test)
SICCT severe interpretation	Single intra-dermal comparative cervical tuberculin test where response to bovine PPD is 3-4mm greater than the response to avian
SICCT standard interpretation	Single intra-dermal comparative cervical tuberculin test where response to bovine PPD is more than 4mm greater than the response to avian
SIT	Single Intradermal skin test (cervical application)

*Sensitivity only **Specificity only

SD will review the section describing the aims and methodology of the SLR making reference to the relevant publications. The tables of results should also be included.

Other priors to be considered are the results of the latent class modelling performed in IE and SP as well as expert opinion.

Update of SLR:

The EFSA staff (AHAW and SAS) has completed the first stage of the relevance screening. The criteria for inclusion were: 1) Does the paper reports primary research, 2) Does the reference include estimates of Se or Sp or does it allow for such estimates to be calculated, 3) The reference includes reports on performance of any of the following tests:gamma interferon,ELISA , Latex bead agglutination assay, Multiplex immunoassay and/or rapid serological assay 4)Was the diagnostic test performance measured on cattle and as a exclusion criteria 1) were the animals experimentally infected.

A total of 150 references were included for the second stage. 4 of the references in the list were already included in the SLR by DEFRA that is being used as a data source. A form for second stage eligibility will be prepared in Destiller using the criteria of the SLR - DEFRA. However in order to gain time the WG reviewed the list of stage 1 references and identified a list of 15 papers that will be requested from the library. The stage 2 eligible papers will be reviewed by the WG experts and the data extraction will follow the data model used for the public call and the variables identified as essential. It was agreed that the new data will be included in a narrative summary but no meta analysis will be performed.

c) Public call for data

The call for data deadline was the 26/4/12. Data was received from:

Data provider	TUE	Test name	Raw	Summary
CRL	Gamma Interferon, ELISA, Multiplex immunoassay	Bovigam , Ideex , Enferplex	Y	Y
Spain	Gamma Interferon	Bovigam	Y	Y
Ireland	Gamma Interferon,	Bovigam	Y	Y
(AHVLA) - UK	Gamma Interferon	Bovigam	Y	Y
Italy	Gamma Interferon	Bovigam	Y	
Prionics	Gamma Interferon,	Bovigam	Y	
Ideex	ELISA	Ideex	Y	Y
Enferplex	Multiplex immunoassay	Enferplex	Y	Y

An additional data set is to be received by the 15/5 from Belgium.

The data sets need yet to be validated but SAS has already combined the data and made some provisional data description

https://sciencenet.efsa.europa.eu/portal/server.pt/gateway/PTARGS_32_0_229_0_-1_47/http:/bea-aps.efsa.eu.int;11930/collab/do/document/overview?projID=730991&folderID=787550

It was noted that there is missing information in some of the variables.

The WG did a eligibility check on the data sets received having in consideration the below pre established criteria:

1. The diagnostic test under evaluation (TUE) is one of the tests included in the table 1 of the call
2. The diagnostic test performance (diagnostic Se and/or Sp) was measured on bovines
3. Each study animal had been individually examined using a official intradermal tuberculin test, either Single intradermal test (SIT) or Single intradermal comparative cervical test (SICCT) as the comparator test (CT) or with a reference standard (RT) for confirmation of infection by culture, microscopic examination or identification of macroscopic lesions. For a study to be included animals must have been tested by at least 2 of the tests considered
4. Any study where animals are experimentally infected with bTB should be excluded.

In addition the WG reviewed the list of variables requested in the call for data and agreed on 15 essential variables. Missing information on these would exclude the data sets.

element	definition
SU_ID	Study identifier that represents all animals or results included in the same study
SU_STRATEGY	sampling strategy used in study
SU_COUNTRY	country where the study was performed
SU_STATUS	TB status of country/region or province/herd
SU_YEAR	year of study
SU_SIZE	number of animals included in the study
TUE_TYPE	Type of test under evaluation
TUE_NAME	Commercial name of evaluation test
TUE_OTHER_ANTIGEN	Name of antigen used in test if not PPD, CFP10, ESAT6,MPB70
TUE_TIMETOCT	When the blood sample was taken in relation to skin test
TUE_CRITERIA	Interpretation criterion used to indicate a positive result
TUE_CRITERIA_OTHER	Specify where criteria is not included in the drop down list
CT_TYPE	Type of comparator test
CT_CRITERIA	Interpretation criteria used for skin test
RS_TYPE	Type of reference standard test

Data sets were excluded, the reasons for exclusion were:

Study	Data provider	Reason for exclusion
CRL 1/2/3		potency data: reactors subjected to repeated skin testing *(Infection risk 1)*
GB study 5/6		No CT/Remove GB data (*EFSAdataGB18-4-12* study identifiers 5 [874 animals] &6 [1243 animals]) and 7 (where no skin test data are available and the assessment of performance is based solely on area status)

The WG evaluated the received data sets to ensure there was no duplication (bias for repeated sampling), the check was done only on the summary data sets by filtering the work sheets by : i) country ii) year of test iii) number of animals in the study. It was observed that same population was used but for different tests.

Issues of dependency (same population, several test/test interpretation)

- 48 animals (3 times), for FS2010_CH
- 13 animals (3 times), for FS2010_UK
- 388 animals (3 times), for FS2010_FR
- 201 animals (4 times), for FS2010_IR (separate by test type and by name and by criteria/cut-offs)
- 208 animals (2 times), EFSAdataGB18-4-12 (different diagnostic antigens)
- 577 animals (2 times), Enferplex Switzerland

- All Enferplex data involves same animals with two test interpretation (high sensitivity, low sensitivity)
- CRL (populations number 1,3-5) include also same populations tested by different TUEs (IFN and IDEXX ELISA for #1,3 and 4 and IFN and Enfer in population #5)

The tests will need to be analysed separately (for example, interferon-γ with different antigens/cut-offs). Conduct analyses solely on test type (test, different antigens, different cut-offs) where sufficient data (number of populations with different prevalence, number of animals) are available.

The WG discussed the potential bias caused by the repeated testing and removal strategy used in Spain. Herds have first been tested by skin test and skin test positive animals have been removed. Next, the remaining animals are tested by skin test and gamma IFN. The removal of true positives and false positives of the skin test might interfere in latent class modelling. DV will think about it and examine it by a simulated dataset.The data from Madrid to be used to estimate the degree of repetition to be applied to data in the rest of Spain. Conduct a sensitivity analysis to determine the impact of measures to adjust for this.

The column on population disease status was not included in the combined data set but the WG was able to classify the study populations into 4 categories or Infection risk status:

Infection risk 1: **potency study**	***Infection risk 2:*** **high infection risk in infected country**	***Infection risk 3:*** **low infection risk in infected country**	***Infection risk 4:*** **OTF, infection free population**
Potency data *(Infection risk 1)* (CRL1/2/3)	Spain High risk situations *(Infection risk 2)*	Spain Low risk situations *(Infection risk 3)*	Switzerland
	France High risk situations *(Infection risk 2)?*		Austria IDEXX OTFC samples
	Great Britain High risk situations *(Infection risk 2)*	Great Britain Low risk situations *(Infection risk 3)* IDEXX OTFH (	
	Ireland High risk situations *(Infection risk 2)* • Bovigam 2 study (201 animals in large breakdown herd) • Redfield study • IDEXX UCD TB Set 1-4	Ireland Low risk situations *(Infection risk 3)* • Greenfield study • IDEXX OTFH (Ireland UCD Negatives)	

A list of queries regarding data received was drafted for clarification:

EFSAdataGB18-4-12

- Ask about year, to ensure not the same population twice?
- Population of 208 animals; a problem of dependence between different interferon-γ
- Need concentration of recombinant protein cocktail

Switzerland

- FS2010_CH. *What was the comparator [skin] test (Standard interpretation)?*

Great Britain (Data not supplied by AHVLA)

- FS2010_UK. *What was the comparator [skin] test (Severe interpretation)?*

For **Enfer test,** retain test criteria based on 'high sensitivity' or 'low sensitivity'
Enfer test & caudal fold test, needs to be checked (GB)

d) Modelling approach

The first task is characterize the data by test/population

	P1	P2	Pn
T1	xxx		xxxx
T2		x	
Tn	xx	xx	x

The WG will need to provide input on which tests may act in similar ways in different populations.

A section on the reasons for the model choice must be included in the draft opinion

e) Review of draft opinion

The WG reviewed the draft opinion structure to reflect the discussions on data sources and modeling. The section on use of gamma interferon will be reviewed to include reference to other tests under evaluation and it will be part of the background not Materials and Methods. The eligibility check and a description of the data received will be included as annex.

5. Pending actions

SD: Review SLR section and summarise results
Clarify data missing with UK data provider
JA: Check data from Spain (first and second testing by animal)
Review section on current use
EG: Draft opinion section on overview of different tests
Review IDEEX data
ALL : Review draft opinion
AA: Prepare meeting minutes and revision of draft opinion
Request pdf of the selected papers
Prepare summary of data received
AA/SD : Prepare relevance screening stage 2 for in distiller
Distribute pdfs of selected papers to the WG for data extraction
AA: Clarify queries
DV: Validate data received
Prepare data characterization

Deadline for all pending is 22/6/12

6. Next meeting date

Considering the extent of work to be performed in data validation and subsequent modelling the WG has asked for a deadline extension till the 30 Nov. the plan of meetings was reviewed as follow:

29/6/12	**Parma**	**Discuss data and initial modelling done**
4/9/12 15h	**WEB**	**Model results check**
24-25/9/12	Parma	Conclusions
9/10/12		Distribute draft for discussion
17-18/10/12		Discussion plenary
TBC/10/12	**WEB**	**Review comments by panel**
30/10/12		Distribute draft for possible adoption
13-14/11/12		Adoption

European Food Safety Authority

AHAW UNIT

Parma, 2 July 2012

SCIENTIFIC PANEL ON AHAW

Minutes of the 4th meeting of the Working Group on Tb test

Parma, 29 JUNE 2012

EFSA / AHAW

Agreed by the WG on 6 July 2012

Participants

WG Experts	A. Stegeman (chair), S. More (rapporteur), J. Alvarez, S. Downs , E. Gormley
EFSA:	A. Afonso (AHAW) D. Verloo, J. Cortinas, Abrahantes, G. Zancanarlo, J. Richardson (SAS)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from the commission observers.

2. Adoption of agenda

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. The experts S. More and E. Gormley were requested to update their DOI to reflect their participation in the Expert WG of ANSES.

4. Discussions

a) Tasks from previous meetings

All tasks were completed except the preparation of relevance screening stage 2 for in distiller.

b) Literature Search VLA

The presentation of the results from the SLR-VLA was discussed and a new table based on the results of model A will be prepared for inclusion in the report

Update of SLR:

A short list of references to be reviewed in detail was agreed at the previous meeting. The PDFs were made available by EFSA library. Each WG expert will review some papers and

b) Approach to the mandate

A introduction to the mandate shall be drafted explaining relevant issues for test validation following the OIE guidelines and introducing the issue of confidence in freedom and its implications. A section on scope and objectives would provide the context of the mandate.

c) Available Tb tests: Criteria for test inclusion

Tests to be evaluated should comply with 2 criteria:

a. Be suitable for use in large scale surveys of live animals
b. Sufficient evidence for test performance evaluation

d) Criteria for test evaluation

Tests will be evaluated on the basis of performance (diagnostic Se and Sp) assuming ideal test execution conditions. A qualitative evaluation of the factors that may affect performance will be made based on available published data and expert opinion.

e) Data sources:

Systematic literature review,

EU NRL studies

MS experience

Public call for data

f) AHAW Network meeting objectives and agenda

The AHAW network will have a technical meeting on Tuberculosis on the 21/2/12. Next meeting date

Teleconference 26/3/12 10-12h and 14-16h

European Food Safety Authority

AHAW UNIT

Parma, 5 September 2012

SCIENTIFIC PANEL ON AHAW

Minutes of the 5th meeting of the Working Group on Tb test

WEB meeting, 4 September 2012

EFSA / AHAW

Agreed by the WG on 10 September 2012

Participants

WG Experts	A. Stegeman (chair), S. More (rapporteur), E. Authie, J. Alvarez, S. Downs , E. Gormley
EFSA:	A. Afonso (AHAW) D. Verloo, J. Cortinas, Abrahantes, (SAS)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from the commission observers.

2. Adoption of agenda

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

a) Tasks from previous meetings

All tasks were completed. The review of the draft opinion is ongoing.

b) Presentation of the "Population overview" reasons for inclusion/exclusion

A summary excel file with all data received was prepared by EFSA. The main variables as agreed in the previous meeting and reasons for inclusion /exclusion of data sets in the latent class modelling were included.

c) Presentation of modelling results

The results for the different data sets and scenarios show higher sensitivity and lower specificity for IFN in comparison with skin test. These results are consistent with the results

of the systematic literature review. In order to better understand the observed differences between results several issues need to be raised in the discussion

d) Literature Review update

The literature review update is almost finished. Data was extracted regarding estimates of Se and Sp.

5. Next meeting date

24-25/9/12 Parma

European Food Safety Authority

AHAW UNIT

Parma, 27September 2012

SCIENTIFIC PANEL ON AHAW
Minutes of the 6th meeting of the Working Group on Tb test
WEB meeting, 24 - 25September 2012

EFSA / AHAW

Agreed by the WG on 1 October 2012

Participants

WG Experts	A. Stegeman (chair), E. Authie, J. Alvarez, S. Downs , E. Gormley
EFSA:	A. Afonso (AHAW), J. Cortinas, Abrahantes (SAS)
EC Observers:	F. Reviriego Gordejo, Marina Marini (joined the meeting by Web conference on the 25/9 from 11.00 -12.30)

1. Welcome and apologies

The Chair welcomed the participants. Due to his new responsibilities as AHAW panel chair Simon More has resigned from the Tb test WG.

2. Adoption of agenda

3. Declarations of interest

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4. Discussions

a) Tasks from previous meetings

All tasks were completed. The review of the draft opinion is ongoing.

b) Systematic Literature Review

The results and main conclusions from the SLR were discussed. It was agreed to include results from post mortem tests and a discussion on the results.

c) Literature Review update

The data extraction from the literature review update was reviewed. The results and main conclusions from the LR were discussed. It was agreed to include a discussion on the results. SD and AA are reviewing the results of the stage 2 eligibility to decide if other papers need to be reviewed.

d) Presentation of modelling results

The WG discussed the results and possible reasons for Low IFN Sp.

e) Conclusions and recommendations

EA suggested that it will improve clarity of the document if material and methods and results are presented in blocks: SLR, Update, Modelling. The discussion should be common integrating all sources of information The WG discussed conclusions and recommendations for the different TORs.

The discussion with the EC focused in 3 different points:

1. Equivalence (suitability) as a stand-alone test means:

to have sufficient diagnostic sensitivity (Se). Sufficient is defined in this opinion that the Se should be equivalent or superior to the current standard test used in the EU; and

to have sufficient diagnostic specificity (Sp). The test should be able to perform as a stand-alone test, so Sp should not be significantly lower than that of the current standard test with lowest Sp used in the EU which is SIT.

2. Suitability is a risk management decision and although the focus is on the predictive value of the negative results the assessment must provide also information regarding Sp in a clear manner.
3. In order to include additional tests on the annex to the directive it is important to provide a description of the type of IFN test(s) (PPD) assessed with a view to standardization

5. Next meeting dates

22/10/12	**WEB**	**Review comments by panel**

European Food Safety Authority

AHAW UNIT

Parma, 23 October 2012

SCIENTIFIC PANEL ON AHAW
Minutes of the 7th meeting of the Working Group on Tb test
WEB meeting, 22 October 2012

EFSA / AHAW

Agreed by the WG on 26 October 2012

Participants

WG Experts	A. Stegeman (chair), E. Authie, J. Alvarez, S. Downs , E. Gormley
EFSA:	A. Afonso (AHAW), J. Cortinas, Abrahantes (SAS)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from the EC observers

2. Adoption of agenda

3. Declarations of interest

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4. Discussions

The draft opinion was discussed with AHAW panel on the plenary meeting of the 17-18/10/2012. Writen comments were received from the panel and discussed with the WG. The WG has distributed tasks in order to solve some of the comments and made proposals for recommendations. The draft opinion will be submitted for possible adoption by the plenary on the 13-14/11/12.