Minutes of the 9th meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 19-20 June 2019, Parma (Italy)

(Agreed on 28 June 2019)

Participants

- **Working Group Members:**

  Marc Aerts (MA)

  Soizick Le Guyader (SLG)

  Micheal O'Mahony (MO)

- **Hearing Experts[1]:**

  James Lowther (JL)

  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**

  Paolo Caricato (PC)

- **EFSA:**

  AMU: Jose Cortiñas Abrahantes (JCA)

  DATA: Alexandra Papanikolaou (AP)

  BIOCONTAM: Frank Boelaert (FB)

- **Others:**

  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants. MA participated via teleconference in the morning of both meeting days.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declaration of Interest
4.	Update of data collection
5.	Update of data analysis
6.	Draft report
7.	AOB

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[2] and the Decision of the Executive Director on Declarations of Interest[3,] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

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

4. Scientific topic(s) for discussion

<u>Update on data collection</u>: No further updates on the collection of data.

<u>Update on data analysis</u>: All changes in models and plots were completed and incorporated in the draft report by 5 June, as agreed during the previous meeting.

<u>Draft report</u>: The aim of the meeting was to finalise the report. The draft report had been reviewed by two experts of the EFSA BIOHAZ Panel and it had been presented at the Member States representatives during the EC Bivalve mollusc Working Group in Brussels on 14 June. The WG revised the report section by section and modified it where necessary taking into account the comments of the reviewers. The Recommendations section was also modified according to suggestions received by the Member States. The WG finalised and approved the report.

5. Next meeting(s)

No further meetings are planned.

6. Any Other Business

Not Applicable.

Minutes of the 8th meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 20-21 May 2019, Parma (Italy)

(Agreed on 28 May 2019)

Participants

- **Working Group Members:**

  Marc Aerts (MA)

  Soizick Le Guyader (SLG)

  Micheal O'Mahony (MO)

- **Hearing Experts[1]:**

  James Lowther (JL)

  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**

  Not Applicable

- **EFSA:**

  AMU: Jose Cortiñas Abrahantes (JCA)

  DATA: Jane Richardson (JR), Alexandra Papanikolaou (AP)

  BIOCONTAM: Frank Boelaert (FB)

- **Others:**

  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declaration of Interest
4.	Update of data collection
5.	Update of data analysis
6.	Draft report
7.	AOB

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[2] and the Decision of the Executive Director on Declarations of Interest[3,] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

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

4. Scientific topic(s) for discussion

Update on data collection: As agreed in the previous meeting, no further corrections have been accepted for the data on production areas, dispatch centres, and production volumes.

Update on data analysis: The descriptive statistics, the models for the prevalence, and the models for the quantitative outcome have been included in the report. The factors associated with the prevalence and the quantitative outcome were presented and discussed. The current version of all results is considered final. The WG proposed small changes in the presentation of the results that will be implemented in the next few days. The WG discussed whether quantitative models for the dispatch centres should be included considering the very limited number of quantified laboratory results available from dispatch centres. The results of the multiple imputation approach have also been included in the report to justify the use of valid laboratory results only. Plots demonstrating the effect of sensitivity and specificity have also been included and their interpretation has been discussed.

Draft report: The report was checked section by section and corrections were made where necessary. The WG made decisions regarding the terminology to be used in order to be consistent within the report. The interpretation and implications of the results included in the report were discussed. An appendix on statistical methods will be added. Tasks were distributed to the WG members. All contributions by the WG in the report text are due on 5 June.

5. Next meeting(s)

The next physical meeting will take place on 19-20 June 2019 in Parma.

6. Any Other Business

Not Applicable.

Minutes of the 7th meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 02-03 April 2019, Parma (Italy)

(Agreed on 12 April 2019)

Participants

- **Working Group Members:**
  Marc Aerts (MA)

  Soizick Le Guyader (SLG)

  Micheal O'Mahony (MO)

- **Hearing Experts[1]:**
  James Lowther (JL)

  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**
  Not Applicable

- **EFSA:**
  AMU: Jose Cortiñas Abrahantes (JCA)

  DATA: Alexandra Papanikolaou (AP)

  BIOCONTAM: Frank Boelaert (FB), Henok Ayalew Tegegne (HAT)

- **Others:**
  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants. MA participated only in the afternoon of both meeting days via teleconference.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Update of data collection
5.	Update of data analysis
6.	Draft report
7.	AOB

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[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

4. Scientific topic(s) for discussion

<u>Update on data collection</u>: The current status of data submissions by Member States was discussed. The data providers have been contacted and they have performed their final corrections. The current datasets for

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production areas, dispatch centres, and production volumes are considered final.

Update on data analysis: The descriptive statistics included in the main text of the draft report were presented and discussed. The binary outcome (Norovirus detected or not detected in samples) has been modelled using Generalised Estimating Equations (GEE) that take into account the correlation structure of the data with the time effect modelled using restricted cubic splines. Risk factors have been incorporated in those models to test the hypotheses formulated by the working group. Quantitative models have also taken into account the time effect using restricted cubic splines. All the modelling results currently available were presented and discussed. The effect of missing values on the model outcome has been assessed using multiple imputations. The working group decided that all descriptive statistics and models will be based on valid results only considering the multiple imputation findings. The risk factors tested and the model weights will be updated according to the decisions of the working group.

Draft report: The progress with the drafting of the report was discussed. Only the descriptive statistics and model results for combined genogroups will be presented in the main text. For the two genogroups separately, descriptive statistics and model results for the binary outcome will be included in the Annex. The working group discussed the best way to present in tables the percentage of laboratory and modelling results that exceed different thresholds of Norovirus copies. Tables with model estimates will be included for the models estimating overall prevalence and time trends in addition to the plots.

5. Next meeting(s)

Physical meetings planned every two months. The next physical meeting will take place on 20-21 May 2019 in Parma.

6. Any Other Business

Not Applicable.

Minutes of the 6th meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 04-05 March 2019, Parma (Italy)

(Agreed on 15 March 2018)

Participants

- **Working Group Members:**
  Soizick Le Guyader (SLG)
  Micheal O'Mahony (MO)

- **Hearing Experts[1]:**
  James Lowther (JL)
  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**
  Not Applicable

- **EFSA:**
  AMU: Jose Cortiñas Abrahantes (JCA)
  DATA: Alexandra Papanikolaou (AP)
  BIOCONTAM: Frank Boelaert (FB), Henok Ayalew Tegegne (HAT)

- **Others:**
  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants and informed the WG members that Hiten Shah has a new job and because of this can not be part of the WG anymore. Apologies were received from Marc Aerts. MO did not participate in the first day of the meeting.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Update of data collection
5.	Update of data analysis
6.	Draft report
7.	AOB

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[2] and the Decision of the Executive Director on Declarations of Interest[3,] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

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

4. Scientific topic(s) for discussion

Update on data collection: The current status of data submissions by Member States was discussed. All countries have submitted values for LOD/LOQ and results for the whole monitoring period (two years, missing values for Production Areas and Dispatch Centres represent less than 10 and 20 % used to define sample size calculations). Majority of countries have reported the available information about the monthly number of batches and the monthly tonnage per dispatch centre. In some cases, information was provided at the year level because it was not available at the month level. The data providers will be contacted for final corrections. The WG agreed to consider as part of the final dataset the data submitted up to March 15 the latest.

Update on data analysis: Descriptive statistics were presented for the combined genogroups for all the variables that the WG decide to include in the main body of the report in the previous meeting. Results of the modelling of the binary outcome (Norovirus detected or not detected in samples) were presented. The models were updated as agreed in the previous meeting: the analysis involved Generalised Estimating Equations (GEE) that take into account the hierarchical structure of the data with the time effect modelled using restricted cubic splines. Preliminary results for the hypotheses to be tested were presented and discussed. Preliminary results for the quantitative models were also presented. It was decided that the risk factors that will be found significant for the binary outcome will be tested with the quantitative models.

Draft report: The progress with the drafting of the report was discussed. The *Definitions* section has been added in the Methodology part. It was decided that the *Data description and exploratory analysis* section will focus only on valid samples (not valid and not tested samples will be excluded from the descriptive analysis). Only the descriptive statistics and model results for combined genogroups will be presented in the main text. Descriptive statistics and model results for GI and GII separately will be presented in the Annex of the report.

5. Next meeting(s)

Physical meetings planned every two months. The next physical meeting will take place on 02-03 April 2019 in Parma.

6. Any Other Business

Not Applicable.

Minutes of the 5th meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 05-06 December 2018, Parma (Italy)

(Agreed on 20 December 2018)

Participants

- **Working Group Members:**

  Marc Aerts (MA)

  Soizick Le Guyader (SLG)

  Micheal O'Mahony (MO)

  Hiten Shah (HS)

- **Hearing Experts[1]:**

  James Lowther (JL)

  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**

  Not Applicable

- **EFSA:**

  AMU: Jose Cortiñas Abrahantes (JCA), Kenneth Mulligan (KM)

  DATA: Jane Richardson (JR), Alexandra Papanikolaou (AP)

  BIOCONTAM: Frank Boelaert (FB)

- **Others:**

  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Scientific topic(s) for discussion • Update on the data collection • Structure of the report • Data analysis result discussion o Descriptive statistics o Data analysis of hypothesis discussed in the previous WG meeting
5.	Next meeting and deadlines
6	AOB

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[2] and the Decision of the Executive Director on Declarations of Interest[3,] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

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

4. Scientific topic(s) for discussion

Update on the data collection: The current status of data submissions by Member States was discussed. Almost all countries have submitted values for LOD/LOQ and results for at least the first monitoring year. Few data have been reported on the monthly number of batches and the monthly tonnage per dispatch centre but the data providers have been contacted and they are expected to provide more detailed data before the end of the reporting period (31/01/2019)

Structure of the report: The structure of the report was discussed, its outline was agreed, and the sections were distributed to the WG members to begin the drafting procedure. It was decided that a *Definitions* section will be added at the Methodology part, explaining the terms used in the report such as Apparent prevalence, True prevalence, Weights, and Combined genogroups. No details on the sampling scheme will be presented in this report since they have already been presented in Technical Specification report. Samples taken per country and period will be presented in the *Data description and exploratory analysis* section. Regarding the LOD/LOQ values, two boxplots (one for LOD and one for LOQ) will be presented for each genogroup. Finally, the WG members decided on descriptive statistics and modelling results to be presented in the main body of the report and in the Annex.

Data analysis result discussion: Descriptive statistics were presented for all the variables of interest for each genogroup separately and for combined genogroups. The WG members decided which of the descriptive statistics are the most informative and decided what is to be included in the main body of the report, what to be in the Annex, and what not to be included. The plan of analysis for the binary outcome (Norovirus detected or not detected in samples) as it was agreed in the previous WG meetings started to be implemented and preliminary results were presented and discussed. The analysis of the binary outcome involved Generalised Estimating Equations (GEE). All models include a saturated time effect and take into account the hierarchical structure of the data. The set of hypotheses agreed in the previous WG meeting have been tested with the data submitted so far. The WG members discussed these preliminary results and their inclusion in the main body or the Annex of the report. The plan for the quantitative models was presented and the WG members discussed the context in which it will be presented in the report.

5. Next meeting(s)

Physical meetings planned every two months. The next physical meeting will take place on the 12th-13th of February 2019 in Parma.

6. Any Other Business

Not Applicable.

Minutes of the 4ᵗʰ meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 26-27 September 2018, Parma (Italy)

(Agreed on 23 October 2018)

Participants

- **Working Group Members:**

  Marc Aerts (MA)

  Micheal O'Mahony (MO)

  Hiten Shah (HS)

- **Hearing Experts[1]:**

  James Lowther (JL)

  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**

  Not Applicable

- **EFSA:**

  AMU: Jose Cortiñas Abrahantes (JCA), Alexandra Papanikolaou (AP)

  BIOCONTAM: Frank Boelaert (FB)

- **Others:**

  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Soizick Le Guyader.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Scientific topic(s) for discussion
	• Presentation and Discussion of the Plan of Analysis
	• Presentation and Discussion of the issues with test characteristics and desired hypothesis to be tested
5.	Next meeting and deadlines
6	AOB

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[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

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

4. Scientific topic(s) for discussion

Laboratory-related issues: It has been clarified that all member states follow a very similar procedure to determine LOD/LOQ, despite the high variability in the reported values observed among countries. The LOD/LOQ values reported countries will be discussed in the final report in the context of their implications for number of copies quantification and the interpretation of low values measured in different laboratories. It has also been confirmed during the last NRL meeting in May that all laboratories define positive samples based on the same criteria which are independent of determination of LOD/LOQ. The ISO method does not specify the probes to be used in RT-PCR but all countries use the same probe for genogroup II and in general also for genogroup I. Sensitivity, specificity, and true prevalence will also be discussed in the report. The WG's decision to report only apparent prevalence will be justified in the report.

Plan of Analysis: The plan of analysis agreed during the previous WG was revisited and confirmed. The data from production areas and dispatch centres will be analysed and reported separately. Separate analyses will be performed for the binary (Norovirus detected or not detected in samples) and the continuous (number of copies) outcome. In both cases, the analysis will be performed both for each genogroup separately and for the combination of the two genogroups (overall prevalence of Norovirus in oysters at the European level). Binary data for each genogroup will be analysed using generalized linear models (GLM). The data of the two genogroups will be combined (considering as positive the samples that were found positive for at least one of the two genogroups) and analysed with the same type of model. The hierarchical structure of the sampling will be taken into account in the models (using GEE approaches or GLMM) and potential risk factors will be tested. The continuous outcome for each genogroup will be analysed first separately. The values between LOD and LOQ will be treated as interval censored data, also as a sensitivity analysis values between LOD and LOQ will be considered as accurate contributing to the likelihood function not as censored observations. The modelled continuous outcome will be used to calculate prevalence at different thresholds of copies' number. Finally, a bivariate lognormal model will be used to model the sum of the copies of the two genogroups. All models will include a saturated time effect and take into account the hierarchical structure of the data. The risk factors previously identified by the binary data analysis will be assessed for their effect on the continuous outcome.

Hypotheses: The WG formulated a series of hypotheses that will be the basis for the risk factor analysis. All hypotheses will be tested in

univariate models. It should be decided which interactions would be of interest and should be tested as well. The WG concluded to a list of hypotheses considering the potential factors affecting the presence of Norovirus, the variables that should be mandatorily reported by the MS during data collection, and the limitations of the collected data. Analysis will be conducted after aggregating the data collected during the two years in order to represent an average year.

5. Next meeting(s)

Physical meetings planned every three or four months. A teleconference will take place on the 22nd of October, if considered necessary. The next physical meeting will take place on the 5th-6th of December 2018 in Parma.

6. Any Other Business

Not Applicable.

Minutes of the 3rd meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 21-22 June 2018, Parma (Italy)

(Agreed on 31 July 2018)

Participants

- **Working Group Members:**
  Marc Aerts (MA)

- **Hearing Experts[1]:**
  Anne Thebault (AT)

- **European Commission and/or Member States representatives:**
  Not Applicable

- **EFSA:**
  AMU: Jose Cortiñas Abrahantes (JCA), Alexandra Papanikolaou (AP)
  BIOCONTAM: Frank Boelaert (FB)

- **Others:**
  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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[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. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Scientific topic(s) for discussion • Presentation of the data submitted to EFSA • Discussion on the Plan of Analysis • Discussion on the Structure of the Scientific Report
5.	AOB
6	Next meeting and deadlines

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[2] and the Decision of the Executive Director on Declarations of Interest[3,] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

4. Scientific topic(s) for discussion

<u>Plan of Analysis</u>: The plan of analysis has been updated taking into account the objectives of the survey and the data already submitted to EFSA. As previously agreed, data from production areas and dispatch centres will be analysed and reported separately. Separate analyses will be performed for the binary (Norovirus detected or not detected in samples) and the continuous (number of copies) outcome. In both cases, the analysis will be performed both for each genogroup separately and for the combination of the two genogroups (overall prevalence of Norovirus in

oysters at the European level). Binary data for each genogroup will be analysed using logistic regression. Presence/absence of the virus will be defined using different thresholds of copies number. The same model will be used for analysing the combined data of the two genogroups, considering as positive the samples that were found positive for at least one of the two genogroups. The hierarchical structure of the sampling will be taken into account in the models and potential risk factors will be tested. The continuous outcome for each genogroup will be analysed first separately. Two approaches will be compared for the values between LOD and LOQ; in the first approach they will be treated as interval censored data, while in the second one as accurate values. Finally, a bivariate lognormal model will be used to model the sum of the copies of the two genogroups. All models will be saturated for time and take into account the hierarchical structure of the data. The risk factors previously identified by the binary data analysis will be assessed for their effect on the continuous outcome.

LOD/LOQ: It has been clarified that almost all member states follow the same procedure to determine LOD/LOQ, despite the high variability in the reported values observed among countries. The high LOD/LOQ values reported by some countries will be discussed in the final report in the context of their implications for number of copies quantification and the interpretation of low values measured in different laboratories. It has also been confirmed that all laboratories define positive samples based on the same criteria. Information will be sought regarding the uncertainty of values below LOQ. Sensitivity, specificity, and true prevalence will also be discussed in the report.

5. Any Other Business

Not Applicable.

6. Next meeting(s)

Physical meetings planned every three or four months. The next physical meeting will take place in September in Parma.

Minutes of the 2nd meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 17-18 April 2018, Brussels (Belgium)

(Agreed on 16 May 2018)

Participants

- **Working Group Members:**

  Marc Aerts

  Soizick Le Guyader

  Micheal O'Mahony

  Hiten Shah

- **Hearing Experts[1]:**

  Anne Thebault

- **European Commission and/or Member States representatives:**

  Paolo Caricato

- **EFSA:**

  AMU: Jose Cortiñas Abrahantes, Alexandra Papanikolaou

  BIOCONTAM: Frank Boelaert

- **Others:**

  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from James Lowther.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Scientific topic(s) for discussion • Presentation of the data submitted to EFSA • Discussion on the Plan of Analysis • Discussion on the Structure of the Scientific Report
5.	AOB
6	Next meeting and deadlines

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[2] and the Decision of the Executive Director on Declarations of Interest[3,] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Specific Declaration of Interest with the working group members were discussed at the beginning of the meeting.

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

4. Scientific topic(s) for discussion

Plan of Analysis: The plan of analysis was updated taking into account the objectives of the survey and the data already submitted to EFSA. As previously agreed, data from two different segments of the food chain (production areas, dispatch centres) will be analysed and reported separately. A preliminary model focusing on the data submitted for the production areas during the first monitoring year was presented and its results were discussed. This model illustrates the prevalence across sampling period and it will be the basis for analysing the binary data (Norovirus detected or not detected in samples). The analysis will be performed both for the combination of the two genogroups (overall prevalence of Norovirus in oysters at the European level) and for each genogroup separately. The inclusion of potential risk factors as covariates in the model was discussed and the list of potential risk factors to be studied was agreed. Regarding the quantification of Norovirus copies, limitations arising from the variability in the submitted values of LOD and LOQ among countries were discussed. Two solutions for dealing with the left-censored data were presented and compared. It was agreed to apply a log-normal model in order to obtain the continuous distribution (quantification outcome) for each genogroup which will serve as the basis to estimate the distribution of the sum. This model will be used to assess potential effects of previously identified risk factors on the distribution. The estimated distribution for the sum will be used to estimate the expected prevalence based on specific thresholds for the number of norovirus copies.

Structure of the Scientific Report: The basic structure of the report was agreed. The aim is a short and concise report with additional analyses of interest provided in appendices. The main body of the report will focus on the analysis of the combined data for genogroups I and II, while separate analyses for each genogroup will be presented in the Appendix.

5. Any Other Business

Not Applicable.

6. Next meeting(s)

Physical meetings planned every three or four months. Next physical meeting to take place in Parma.

Minutes of the 1st meeting of the Working Group on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters

Held on 07-08 December 2017, Parma (Italy)

(Agreed on 15 January 2018)

Participants

- **Working Group Members:**

  Micheal O'Mahony

  Hiten Shah

  Marc Aerts

- **Hearing Experts[1]:**

  Anne Thebault

  James Lowther

- **European Commission and/or Member States representatives:**

  Not Applicable

- **EFSA:**

  AMU: Jose Cortiñas Abrahantes, Alexandra Papanikolaou

  DATA: Jane Richardson

- **Others:**

  Not Applicable

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[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.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Soizick Le Guyader, Doreen Dolores Russel, and Friedemann Ringwald.

2. Adoption of agenda

#	Items
1.	Welcome and apologies for absence
2.	Adoption of agenda
3.	Declarations of Interest
4.	Scientific topic(s) for discussion • Presentation of the protocol and objectives of the survey • Presentation of the data submitted to EFSA • Discussion on the Plan of Analysis • Discussion on the Structure of the Scientific Report
5.	AOB
6	Next meeting(s)

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[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

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

4. Scientific topic(s) for discussion

Plan of Analysis: the plan of analysis was discussed taking into account the objectives of the survey and the data already submitted to EFSA. It was agreed to potentially conduct two types of analysis: (i) analysis of binary data (Norovirus detected or not detected in samples), (ii) analysis of count data (number of Norovirus copies in samples where Norovirus was detected).

Structure of the Scientific Report: it was agreed to aim at a short and concise report with potential additional analyses of interest provided in appendices (template to be circulated). Deadline July 2018.

The working group agreed to model the prevalence of Norovirus in oysters at the European level. Solutions to combine the number of copies from two different genogroups were discussed. Data from two different segments of the food chain (production areas, dispatch centres) will be analysed and reported separately. Limitations arising from the limited number of samples with Norovirus copy numbers were also discussed. Discussion on variables to be included in the models as risk factors and variables to be used for explorative graphical representation in the final report were conducted.

5. Any Other Business

Not Applicable.

6. Next meeting(s)

Physical meetings planned in Parma every three or four months. Next physical meeting to take place in March 2018.

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the ADoI or in the SDoI filled for the present meeting, Mr Hiten Shah, declared the following interest: he has involvement in risk assessment activities at national level; Dr. Soizick Le Guyader declared the following interest: she has involvement in risk assessment activities at national level; Mr. Micheal O'Mahony declared the following interest: he has involvement in risk assessment and management activities at national level. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director on Declarations of Interest[5], and taking into account the specific matters discussed at the meeting in question, a waiver was granted.
Therefore the concerned experts shall be allowed to take part in the discussions and in the drafting phase of the EFSA Scientific report on Request for scientific and technical assistance on the baseline survey of Norovirus in oysters December 2017 – July 2019.

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[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014