

WORK PROGRAMME of EURL for

**FOODBORNE**

**VIRUSES**

PERIOD: 2018

Version 1.0  
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# EURL foodborne viruses

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# EURL foodborne viruses

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## SUMMARY

INTRODUCTION ..... page x

### ACTIVITIES

1. TO ENSURE AVAILABILITY AND USE OF HIGH QUALITY METHODS AND TO ENSURE HIGH QUALITY PERFORMANCE BY NRLs ..... page x
2. TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLS ..... page x
3. TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS ..... page x
4. REAGENTS AND REFERENCE COLLECTIONS..... page x
5. REQUIREMENTS RELATED TO OTHER LEGISLATION..... page x

REMARKS..... page x

# EURL foodborne viruses

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## INTRODUCTION

### Abbreviations

HAV	Hepatitis A virus
HEV	Hepatitis E virus
PT	Proficiency testing
SOP	Standard operating procedure

Increased awareness of the public health impact of foodborne viruses has led to the establishment of an EURL for foodborne viruses. There are currently no microbiological criteria for foodborne viruses in the EU legislation but it is implemented in EU 2017/2298 amending EU669/2009 that there should be increased level of official control on frozen raspberries from Serbia. Because of this will raspberries be the first prioritised matrix for the EURL. Year 2018 is the first year for this EURL and the work programme will contain a description of activities, objectives and expected outputs containing preparatory activities like construction of web pages and development of matrix based proficiency testing (PT) samples.

The work programme for 2018 consists of the following key activities:

1. Development and organisation of proficiency tests
2. Production of Standard Operating Procedures (SOP)
3. Development and validation of alternative analytical methods
4. Development of methods for the detection of hepatitis E virus (HEV) in food of animal origin
5. Training and support to NRLs
6. Provision of expertise to stakeholders (EU Commission and agencies, Member States, candidate and third countries) and preparedness of staff for emergency situations
7. Communication

# EURL foodborne viruses

## Regulation (EU) 625/2017 Art 94(2):

European Union reference laboratories designated in accordance with Article 93(1) shall be responsible for the following tasks insofar as they are included in the reference laboratories' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014:

(taking into account Art 147 of (EU) 625/2017)

1

## TO ENSURE AVAILABILITY AND USE OF HIGH QUALITY METHODS AND TO ENSURE HIGH QUALITY PERFORMANCE BY NRLs.

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- *Art. 94.2.a Providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods.*
- *Art. 94.2.b Providing reference materials to national reference laboratories*
- *Art. 94.2.c Coordinating the application by the national reference laboratories and, if necessary, by other official laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing or proficiency tests and by ensuring appropriate follow-up of such comparative testing or proficiency tests in accordance, where available, with internationally accepted protocols, and informing the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests.*
- *Art. 94.2.l Where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards.*

### Sub-activity 1.1 Provide Standard Operating Procedures (SOP) to NRL:s

Objectives: To ensure that NRL:s have the most recent version of relevant ISO standards accessible in an easy to follow description. Especially for the methods included in distributed PT during 2018.

Description: Provide Standard Operating Procedures (SOP) to NRL:s

# EURL foodborne viruses

Expected Output: Standard operating procedures for detection and quantification of norovirus and hepatitis A in soft fruits and leafy vegetables and bivalve molluscan shellfish are published on the EURL website.

Duration: Duration: 1/2 2018 – 30/4 2018, 22 days

*Sub-activity 1.2 Development of methods for producing norovirus and hepatitis A virus homogenous raspberry samples for PT distributions.*

Objectives: To ensure that homogenous samples for PT are distributed during 2018.

Description: Development of methods for producing norovirus and hepatitis A virus homogenous raspberry samples for PT distributions.

As there are no standard procedures for the production of homogenous virus spiked food matrices, except for bivalve molluscan shellfish (BMS), there is a need for development. The intention is to build up competence in this area, starting in 2018 with spiked samples of raspberries and continue the following years with other matrices of relevance. Meetings with EURL for microbiological monitoring of BMS and other involved laboratories will be organised to access information on methods used during the validation of CEN/ISO 15216. Samples have to be highly homogenous to guarantee that proper evaluation and assessment of NRL:s PT performance. This is achieved by testing different methods for spiking viral samples into different food matrices and statistically evaluation of the results.

Expected Output: The possibility to produce highly homogenous samples for PT distributions.

Duration: 1/1 2018 – 30/6 2018, 49 days

*Sub-activity 1.3 Distribution and assessment of PT for qualitative norovirus and HAV detection in raspberry samples.*

Objectives: To assess NRLs' performance to carry out detection of norovirus and HAV in raspberry samples.

Description: Distribution and assessment of PT for qualitative norovirus and HAV detection in raspberry samples. Raspberry samples are chosen as the first year matrix because of the increased level of official control of Serbian frozen raspberries.

Samples will be produced according to what is found out in 1.2 and stored until tested for homogeneity and subsequent distribution. Material for controls and standards used in the method will also be produced and distributed see sub-activity XX. Distribution will be done on dry ice to keep the integrity of the raspberries during the transport. Along with NRLs reporting their results there will be a questionnaire to elucidate variations in implementation of the ISO 15216 between laboratories.

Expected Output: To know NRLs' different needs for support to perform detection of norovirus and HAV in raspberry samples according to ISO 15216.

Duration: 1/4 2018 – 31/12 2018, 85 days

*Sub-activity 1.4 Implementation and or development and in house validation of method for the detection and quantification of hepatitis E virus in products of animal origin.*

Objectives: As support to CEN/TC 275/WG 6 Microbiology of the food chain that will have an upcoming mandate for standardisation of the detection of HEV in animal products.

# EURL foodborne viruses

Description: Implementation and or development and in house validation of method for the detection and quantification of hepatitis E virus in products of animal origin.

ECDC reports during 2017 that there is a marked increase in registered cases of hepatitis E in EU especially in Germany, France and Great Brittan. EFSA also published a scientific opinion on HEV during 2017. The first conclusion in the opinion states “The validation and standardisation of methods for detection and quantification of HEV from meat and meat products should be a high priority. Also, detection methods for other food matrices (e.g. shellfish, fruit and vegetables, food contact surfaces) and bottled water as described in ISO15216 should be validated in order to demonstrate their suitability for the detection of HEV”. It is important for the EURL to be prepared for future standardisation procedures in CEN and method evaluation in this area should be prioritized and start during2018.

A literature scan will be done and promising methods will be tested in relevant matrices.

Expected Output: Improved methodology for the detection and quantification of HEV in animal products.

Duration: 1/1 2018 – 31/12 /2018, 42 days

## Sub-activity 1.5 *Implementation and development of typing methods for norovirus*

Objectives: To improve the typing methods used for norovirus.

Description: Typing of norovirus is to some extent harmonised but there is a need for improved PCR methods to be able to include all variations not captured with present technology. From bioinformatic analyses we will design an RT-PCR that will capture norovirus variation also including so called noroviruses recombinant strains. The method will be tested on collected patient material.

Expected Output: Improved methodology for norovirus typing.

Duration: 1/1 2018 – 31/12/ 2018, 40 days

## Sub-activity 1.6 *Building a next generation sequencing (NGS) platform and build bioinformatics competence*

Objectives: To build a platform for NGS of foodborne viruses and strengthen bioinformatics competence at the EURL.

Description: An NGS platform will be bought. As the platform will be shared with all microbiological NRL:s and species identification we plan to use 10 % of its capacity. Whole genome sequencing (WGS) of human viral samples will be performed and the bioinformatics competence at the EURL will be developed.

Expected Output: Improved capacity to do WGS on viral samples.

Duration: 1/1/2018 – 31/12/2018, 60 days

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## Sub-activity 1.x *(name of Sub-activity)*

Objectives:

Description:

Expected Output:

Duration:

# EURL foodborne viruses

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### TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- **Art. 94.2.d Coordinating practical arrangements necessary to apply new methods of laboratory analysis, testing or diagnosis, and informing national reference laboratories of advances in this field.**
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- **Art. 94.2.e Conducting training courses for staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries.**
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- **Art. 94.2.g Providing information on relevant national, Union and international research activities to national reference laboratories.**

#### Sub-activity 2.1 Annual workshop

**Objectives:** To inform NRLs on methodologies for detection and quantification of norovirus and HAV according to ISO 15216. To inform on foodborne viruses in general and describe the current knowledge about the problem. To be informed about the capacity and relevant activities among NRLs.

**Description:** The two days' workshop will be organised in Uppsala, Sweden Twenty-eight NRLs will be invited and all EFTA countries that reported to host an NRL for foodborne viruses. One expert from EURL for microbiological monitoring of bivalve molluscan shellfish will also be invited. Further, one expert from the laboratory providing raspberry samples during the validation of ISO15216 will be invited to talk about the validation results and methodology used. Before the meeting a questionnaire concerning methodologies used by the NRLs but also general activities and capacity will be sent out. A compilation of the questionnaire will be presented at the workshop.

**Expected Output:** A workshop report shared with NRLs and DG SANTE

**Duration:** 1/3/2018 – 1/10 2018, 66 days

#### Sub-activity 2.2 Two training course occasions

**Objectives:** To give hands on training on the method for detection of norovirus and HAV in raspberries.

**Description:** Training will be offered to eight persons at two different occasions. The training will be held for two and a half day.

**Expected Output:** Better method performance among the laboratories.

**Duration:**55 days

# EURL foodborne viruses

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## Sub-activity 2.3 (*Participation in*)

Objectives:  
Description:  
Expected Output:  
Duration:

## Sub-activity 2.x (*name of Sub-activity*)

Objectives:  
Description:  
Expected Output:  
Duration:

# EURL foodborne viruses

3

## TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- *Art. 94.2.f Providing scientific and technical assistance to the Commission within the scope of their mission.*
- *Art. 94.2.h Collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).*
- *Art. 94.2.i Assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, or of pests of plants, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens.*

Sub-activity 3.1 (name of Sub-activity)

Objectives: Description: Expected Output: Duration:
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Sub-activity 3.2 (name of Sub-activity)

Objectives: Description: Expected Output: Duration:
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Sub-activity 3.3 (name of Sub-activity)

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# EURL foodborne viruses

Objectives:  
Description:  
Expected Output:  
Duration:

## Sub-activity 3.x (*name of Sub-activity*)

Objectives:  
Description:  
Expected Output:  
Duration:

## REAGENTS AND REFERENCE COLLECTIONS

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- **Art. 94.2.j** *Coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of foodborne, zoonotic or animal diseases and pests of plants.*
  
- **Art. 94.2.k** *Where relevant for their area of competence, establishing and maintaining:*
  - i. reference collections of pests of plants and/or reference strains of pathogenic agents;*
  - ii. reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;*
  - iii. up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.*

Sub-activity 4.1 (name of Sub-activity)

Objectives:  
Description:  
Expected Output:  
Duration:

Sub-activity 4.2 (name of Sub-activity)

Objectives:  
Description:  
Expected Output:  
Duration:

Sub-activity 4.3 (name of Sub-activity)

Objectives:

# EURL foodborne viruses

Description:  
Expected Output:  
Duration:

## Sub-activity 4.x (*name of Sub-activity*)

Objectives:  
Description:  
Expected Output:  
Duration:

# EURL foodborne viruses

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5

## REQUIREMENTS RELATED TO OTHER LEGISLATION

Please specify applicable legislation:  
(Number of Sub-activity boxes can be adjusted)

Sub-activity 5.1 (*name of Sub-activity*)

Objectives: Description: Expected Output: Duration:
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Sub-activity 5.2 (*name of Sub-activity*)

Objectives: Description: Expected Output: Duration:
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Sub-activity 5.3 (*name of Sub-activity*)

Objectives: Description: Expected Output: Duration:
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Sub-activity 5.x (*name of Sub-activity*)

Objectives: Description: Expected Output: Duration:
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# EURL foodborne viruses

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**REMARKS**

(if necessary)