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Single Market Programme (SMP Food)

Activities of the EU Reference Laboratories and EU Reference Centres in 2025-2027

SMP-FOOD-2025-EURL-EURC-PJG-IBA 2025-2027

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

SMP-FOOD-2025-EURL-EURC-PJG-IBA 2025-2027

Activities of the EU Reference Laboratory for Foodborne Viruses in 2025-2027

Applicant shall provide information on each question contained in the Form.

The **information** filled in the Form, **shall be clear, concise, consistent and complete.**

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Applicant - COORDINATOR (Name of EURL)	EURL for Foodborne Viruses
Topic	SMP-FOOD-2025-EURL-EURC-PJG-IBA
Implementation period	01/01/2025 – 31/12/2027

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1. LIST OF ABBREVIATIONS AND KEY WORDS

SFA	Swedish Food Agency
NRL	National Reference Laboratory
MB	Member State
PT	Proficiency test
WP	Work Programme
HAV	Hepatitis A virus
HEV	Hepatitis E virus
BMS	Bivalve Molluscan Shellfish
NGS	Next generation sequencing
SOP	Standard operating procedure
RT-qPCR	Reverse transcription quantitative PCR
RT-dPCR	Reverse transcription digital PCR
WG	Working Group

2. INTRODUCTION

The EURL for Foodborne viruses will complete its seventh year and an organisation at the Swedish Food Agency (SFA) has continuously been built up. Moreover, a network of 31 National Reference Laboratories (NRLs) has been designated.

The network of NRLs has been established and in a complex area like foodborne viruses, several countries have designated two and even three laboratories.

Member States (MS) that still have not designated NRLs for Foodborne Viruses are Croatia, Estonia (in the process to designate another MS), Greece (for non-animal matrices) and Malta. The Commission should encourage those countries to finalize their designation processes. Portugal has just finished the designation process, and they joined the annual workshop this year (2024).

During 2020, the EU decided to close the temporary legislation EU 2017/2298, amending EU669/2009, which stated increased level of official control of norovirus and hepatitis A virus (HAV) in frozen raspberries from Serbia. There are currently no microbiological criteria for foodborne viruses in the EU legislation, but a discussion about microbiological criteria for norovirus (and HAV) in bivalve molluscan shellfish, eaten raw, has been initiated by the Commission and will continue in the following period.

Such as previously, annual PT distributions of molluscan shellfish spiked or bioaccumulated with norovirus and HAV are planned. Virus spiked soft fruits PT is also planned for the next coming years. Methods for additional matrices included in ISO 15216 have to be developed at the EURL. Bottled water should be part of future PT schemes and implementation and validation of virus detection in bottled water is included in this WP.

The standardisation process for hepatitis E virus detection and quantification in animal products follow its original plan and will probably be finalised in the next-coming years. The implementation of HEV detection in meat products is planned in this Work Programme (WP).

Inflation has increased almost all costs, especially when it comes to transportation and salaries. To remain continued quality at the EURL for Foodborne Viruses and the NRL network, we foresee an increased budget during the next WP period.

Current director for the EURL for Foodborne Viruses will retire, early summer 2025. We suggest that Dr Katalin Nemes will take Magnus` position. Katalin has a long experience in viruses and has been part of the EURL activities for several years.

[Regulation \(EU\) 2017/625 - Article 94\(2\)](#)

European Union reference laboratories designated in accordance with Article 93(1) shall be **responsible for the tasks** described under section 3 below, 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 16 of Regulation (EU) No 2021/690.

3. WORK PACKAGES

3.1. Work Package 1 - AVAILABILITY AND USE OF HIGH-QUALITY METHODS

Objectives: TO ENSURE AVAILABILITY AND USE OF HIGH-QUALITY METHODS AND TO ENSURE HIGH QUALITY PERFORMANCE BY NRLs

- *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 3.1.1 Development and distribution of Proficiency tests (PT)

Objectives: To ensure harmonised analyses results among NRLs through the distribution of homogenous samples for PT and assess and report the results.

Description: Altogether six PT distributions (two each year) are planned in the coming three-years period. The ongoing discussions about microbiological criteria for noroviruses in oysters implies the importance to include this matrix in the PT scheme every year, so altogether 3 oyster PT distribution.

There have been problems with the establishment of bioaccumulation facilities in Sweden. Because of reorganisation of one of the Swedish Marine Institutes and the building of new facilities in Gothenburg, there seem to be openings for the possibilities to bioaccumulate oysters in Sweden. Meanwhile, we are establishing a cooperation with IFREMER, France to be able to send out bioaccumulated PT samples already in 2024.

We will cover other matrix groups included in ISO 15216 as well. Upon agreement with the NRLs, soft fruit or leaf vegetables should be included in PT distributions at every second year. Soft fruits and leafy greens will be distributed in 2025 and 2027 respectively. In 2026, besides oysters, food surfaces will be included in the PT distribution. ISO 5216 will most probably be revised in the forthcoming years and the method for bottled water will be updated due to filters used during validation of the method is withdrawn from the market. When ISO is updated, the method will be implemented and validated at the EURL. PT distribution of bottled water is therefore not included in this WP period.

Additionally, the EURL will work towards a more quality assured and effective workflow. For that, we plan to digitalize the whole process, from online PT registration to reporting of results.

The cost of shipping and transportation has increased enormously since the Covid-19 pandemic. Additionally, a large part of the costs is made up of cooled (on ice) and frozen (on dry ice) transportation. Some of the matrices such as bivalve molluscan shellfish (BMS), food surface samples should be transported on ice while other matrices such soft fruit are transported on dry ice. Parallel, all the PT distributions include dsDNA quantitative standards as well as external control RNAs for each determinant (norovirus GI, GII and HAV) which is transported on dry ice. The number of logistic companies managing advanced shipments (ca. 25 deliveries within 24 hours and maximum 48 hours; providing ice and dry ice) are very limited. We have included offered costs in the budget with the consequence of an increased budget.

The overall goal of the PT distributions is to ensure the high-quality performance by NRLs. Based on the data of the previous PT distributions (from 2018 up to date), a progress report will be prepared to follow-up the progress of the NRLs in the harmonisation process. The results will help us to improve our workflow (e.g. more specific help to the NRLs) towards high-quality methods and performance within the network.

Quality assurance of the EURL is important to maintain high quality and accreditation. The participation in external PT distribution is therefore of high importance. FAO Reference Centre for Bivalve Mollusc Sanitation (CEFAS, UK) distribute PTs with norovirus and HAV contaminated live Bivalve Molluscs (BMS). BIPEA is a European non-profit organization located in France. Gathering +2600 member laboratories in the world (throughout 130 countries), it offers more than 220 regular proficiency testing programs. The EURL plans to participate in relevant parts of the proficiency testing schemes provided by these organisations. Costs are included in the budget.

Expected Output:

1. PT distribution of virus contaminated soft fruit, 2025
2. PT distribution bioaccumulated oysters, 2025
3. PT distribution of virus-contaminated food surfaces, 2026
4. PT distribution bioaccumulated oysters (with a possibility to report NGS results), 2026
5. PT distribution of virus-contaminated leafy greens, 2027

6. PT distribution bioaccumulated oysters (with a possibility to report NGS results), 2027
7. Assessment and reports for each PT distribution and follow up of NRLs 2025, 2026, 2027
8. Progress report of development of NRLs in the harmonisation process
9. Quality assurance and maintained accreditation for the EURL through PT participation

Duration: 2025-2027

Sub-activity 3.1.2 Implementation and verification of method for detection and quantification of norovirus and HAV in bottled water

Objectives: The ISO 5216 (method for determination of hepatitis A virus and norovirus using real-time RT-PCR in food samples) will most probably be revised in the forthcoming years and bottled water will be updated due to that filters used during validation of the method has been withdrawn from the market. When ISO is updated the EURL will implement and verify the ISO 15216 method for detection and quantification of HAV and noroviruses in bottled water to enable quality assured analyses and PT distributions for this methodology.

Description: We will continue to include additional matrices (included in the ISO 15216) in the PT program. We have sent out a questionnaire to the NRLs and they showed interest in participating in bottled water PT. Therefore, bottled water will be a part of the PT schemes in the future. Prior to that, development, and verification of the method for bottled water will be carried out.

The ISO-method needs to be implemented and there is a need for verification of the method to determine performance characteristics as Limit of detection (LOD) and Limit of quantification (LOQ).

Expected Output: An implemented and verified method for quantification of norovirus and HAV in bottled water to enable PT distributions for this methodology.

Duration: 2027

Sub-activity 3.1.3 Implementation of methods for matrices that are not included in the ISO 15216

Objectives: To implement a method for detection and quantification of norovirus and HAV in dates

Description: The ISO 15216 method describes the detection and quantification of norovirus and HAV in seven food matrices. However, there are other, more complex food matrices that are often considered as a source of virus outbreaks. Imported dates are recurring matrix almost every year suspected in HAV outbreaks. Questions have been raised by the NRLs about the analysis of dates. We will implement a detection method for this matrix then prepare and share a SOP with the NRL network.

Expected Output: Implemented method and an SOP for detection of norovirus and HAV in dates.

Duration: 2025

Sub-activity 3.1.4 Implementation and verification of method for quantification of HEV in animal products

Objectives: To implement and verify a method for quantification of HEV in animal products

Description: HEV cases have drastically increased in Europe during the last 15 years. ISO/TC34/SC9 has formed a working group (with the participation of the EURL) to standardise methods for the detection of HEV in animal products; the outlined work plan is currently followed and will be finalised in the next coming years.

The implementation of HEV detection in meat products is planned in this work programme. The long-term goal is a harmonized process of the detection of HEV in the NRL network. We are planning to include HEV in future PT-distributions. There is an upcoming EURL for foodborne viruses under the remit of ECDC with specific emphasis on HAV and HEV. The EURL for foodborne viruses in food will seek cooperation with this future EURL in the public health area.

Expected Output: An implemented method and an SOP for detection of HEV in animal products.

Duration: 2027

Sub-activity 3.1.5 Test alternative PCR kits used in the ISO 15216 method

Objectives: To test alternative PCR kits for the detection of viruses according to the ISO method

Description: Questions were raised by the NRLs on the alternatives of the different RT-qPCR kits on the market that can be used for the detection of viruses according to the ISO method. These kits differ in price and in performance. To help the NRLs to find good and cost-effective alternatives, we will test PCR kits by different companies and share the performance study with the NRLs. Moreover, this data will help us to ensure the high-quality performance by NRLs and in the harmonisation process.

Expected output: Support the NRLs with a report of cost-effective alternatives for the methods and further harmonisation.

Duration: 2025-2026

Sub-activity 3.1.6 Implementation and development of typing methods for norovirus

Objectives: To develop, harmonize and disseminate Next Generation Sequencing (NGS) typing methods within the NRL network

Description: Typing methods of noroviruses are of high importance both for source tracking in outbreaks and to be able to follow the epidemiological development. Many food samples, such as oysters, tend to harbour multiple types of noroviruses.

With the current NGS technology, amplicon-based sequencing has proven to facilitate the detection of several norovirus type in a single food sample. This will improve our capability for source attribution and tracing in outbreak situations, which, in turn, will help us to better understand the epidemiology, evolution and transmission of foodborne viruses.

Typing, using the capsid region in the norovirus genome, is implemented at the EURL and environmental samples has been analysed by NGS, showing the appearance of several genotypes in a single sample. This method will be further validated and harmonized, within the NRL network.

Many noroviruses are so called recombinant viruses, one virus is a combination of two different types, polymerase type and capsid type. It is important to type such recombinants as they are suggested to break herd immunity and prolong the time a specific pandemic norovirus is circulating and causing disease worldwide. To type recombinant viruses, further development using the latest sequencing technologies will be needed to sequence both the polymerase and capsid region simultaneously. For

example, promising testing has been done with NGS probe-based capture chemistry and will be investigated further.

To improve the norovirus typing methods and to ensure the high-quality performance by NRLs we will prepare a reference library of norovirus genotypes by designing synthetic DNA and/or RNA fragments. The fragments will cover the pol-cap region. We will investigate two possibilities; to order long synthetic-DNA and produce RNA or to order synthetic RNA molecules directly. This reference library can be used to verify the method used by the NRLs. This work is very expensive and labour intensive, so it is planned to be done in collaboration with the NRLs involved in the NRL WG on NGS.

There is a need for general extended knowledge in both bioinformatics and platform competence to support NRLs in the start-up and use of NGS typing. We will continue the work to increase the EURL skills by collaboration with the “NRL WG for NGS” and the inter “EURL WG for NGS” (see Sub-activity 3.3.1 Participation in the EURL Working Group for NGS and in the WG for NRLs on NGS).

Expected Output:

An NGS method for norovirus typing based on the cap region has been implemented at the EURL and the validation of the method is its final stage. An SOP will be published at the EURL website in 2025.

A sensitive pol-cap sequencing method using either probe-based capture chemistry or long read NGS to enable the identification of recombinant noroviruses will be communicated with the NRLs.

A library of synthetic reference strains will be published on the EURL website.

Duration: 2025-2027

List of Indicators WP1:

- Number of laboratory methods for which details and guidance as regards their techniques, validation and interpretation are available in the EURL website
- Number of new laboratory methods developed in the reporting period
- Number of laboratory methods improved in the reporting period
- Number of Proficiency Tests (PTs) organised by the EURL for national reference laboratories/NRLs (indicate for each year – 2025, 2026 & 2027)
- Cost of PTs
- Cost of CTs
- Success rate of Member States NRLs/OLs in PTs/CTs
- Number of corrective actions undertaken (aggregated data on corrective actions for all NRLs)

3.2. Work Package 2 - SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

Objectives: TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

- *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.*

- *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.*
- *Art. 94.2.g Providing information on relevant national, Union and international research activities to national reference laboratories.*

Sub-activity 3.2.1 Annual workshops

Objectives: To inform the NRLs about PT results, development of standardisation processes and scientific progress concerning foodborne viruses and the detection and quantification of those in food matrices. Furthermore, to discuss the actual needs among NRLs and future work that can be done in the network.

Description: Physical workshops has been held since 2022 since they are more valuable and effective compared to the digital meetings. The aim is to hold physical meetings in 2025, 2026 and 2027. As requested by the NRLs, DG SANTE, EFSA and ECDC will be invited to the workshops (similar to the previous years). The budget will include three physical meetings, one each year. In 2025 and 2027, the workshop will be held in Uppsala, Sweden. In 2026, the workshop will be hosted by the NRL France in Nantes.

In general, the workshops will contain information on PT results, standardisation processes, updates on relevant legislation, and progress in method development. Discussions will be held about how NRL network collaboration promotes scientific progress and how the network cooperation may facilitate harmonisation of analytical results amongst the Member States. We will continue the discussion on microbiological criteria for norovirus in oysters and on the possibilities for the network to support the Commission towards a relevant decision on the matter. A section for NRL presentations will be included at each workshop on method development and surveillance; as well as a specific section for NGS techniques.

Expected Output:

1. Information to the NRL network about harmonisation and standardisation progresses
2. An NRL network that shares information on method development for improved analysis of foodborne viruses in complex matrices
3. An NRL network functioning as a facilitator of progresses in the scientific field of foodborne viruses

Duration: 2025-2027

Sub-activity 3.2.2 Technical training courses

Objectives: To give theoretical background and hands-on training in analytical methods and techniques to less experienced NRLs.

Description: A basic course in the use of NGS for capsid-typing of norovirus from food samples will be held in late 2024 and due to high interest in the topic, this course will be included in this upcoming WP as well.

Since the future PT distributions give the possibility for the NRLs to provide results from both RT-qPCR and RT-dPCR, a practical course on RT-dPCR will be held.

DNA standards are a crucial part of the quantitative detection of viruses by RT-qPCR, and as a request by the NRLs, a course for standard preparation for qPCR will be organized.

Expected Output:

1. Courses to NGS for norovirus typing and digital PCR has been held for a subset of NRLs.

Duration: 2025-2027

Sub-activity 3.2.3 Preparedness of staff and assistance to NRLs

Objectives: To follow the national and international scientific development in the area of foodborne viruses and to inform about the EURL and its activities. Support NRLs with scientific and methodological knowledge in a timely manner. The EURL website should be continuously updated and improved as a means of communication with NRLs and other stakeholders.

Current director for the EURL for Foodborne Viruses will retire in early summer 2025. We suggest that Dr Katalin Nemes will take Magnus position. Katalin has a long experience in viruses and has been part of the EURL activities for several years. There should be a decision from the Commission about a new director of the EURL for Foodborne Viruses. The EURL will provide any documentation needed for such a decision.

Description: This activity seeks to keep the staff knowledgeable in the area of foodborne viruses to be able to support NRLs in the best way with such knowledge. Workshops and training courses organised by the EURL will be continuously evaluated to improve those activities over the years. Preparation of WP and budget are included as well as the internal organisation of the EURL.

It is important to follow scientific publications as well as to participate in conferences. Three staff members will participate in the biennial Food and Environmental Virology Conference in Glasgow during 2026. Relevant abstracts will be presented about progress in method development achieved at the EURL. A Calicivirus conference will be held in 2026. We plan to send one representative to present relevant progresses in norovirus method developments at the EURL.

We will continue the assistance to NRLs providing technical and scientific support. We usually receive questions about method implementation, method verification, questions regarding outbreaks, recommendations on instruments, PCR kits, analysing results/data etc. The support varies between answering in e-mail or to have online meetings.

Expected Output:

1. Improved competence among and organisation of staff members to enable improved support to the NRLs.
2. Opportunities to inform the scientific community about the EURL activities.

Duration: 2025-2027

List of Indicators WP2:

- Number of technical and scientific enquires requested from national support networks and bodies and competent authorities
- Number and quality of replies provided to technical and scientific enquiries of national support networks and bodies and competent authorities
- Number of training and collaboration activities with national support networks and bodies and competent authorities
- Number of workshops & meetings organised
- Cost for workshops & meetings and average cost for participant
- Number of technical requests provided by the EURL to NRLs enquiries

3.3. Work Package 3 - SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS

Objectives: TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS

- *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 3.3.1 Participation in the EURL Working Group for NGS and in the WG for NRLs on NGS

<p>Objectives: Further promotion of the usage of next generation sequencing (NGS), across the EURLs' network and method development</p> <p>Description:</p> <p>The EURL will participate in two meetings in the Inter EURL WG on NGS each year and give continuous input to the EURL working group.</p> <p>Beside the EURL working group for NGS, the EURL for Foodborne Viruses have formed a WG for NRLs for Foodborne Viruses on NGS. The goal for the WG is to increase the possibility for a faster development and harmonization of NGS techniques used in the area of foodborne viruses and to promote collaboration and knowledge transfer between laboratories. The group have digital meetings and physical meetings in connection to the yearly workshop. The WG is a core group of experienced NRLs to enable faster progress in the area. The NRLs agreed to this on the 2022 workshop and the decision was included in the resolutions. General discussions on NGS will be included in the yearly workshop. Production of a workflow document for NGS for typing of norovirus will be part of the assignments of the Core Group. This will also be used as an input to the inter EURL WG on NGS.</p>
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The group will organize a course in Uppsala, covering the basic use of NGS for typing of norovirus, during late 2024. The courses in 2024 cannot harbour all the applicants. So new courses are planned in the 2025-27 period with the help of the Core Group (see 3.2.2 Technical training courses).

Expected Output: Support to the commission, EFSA and ECDC in their work to ensure the development of NGS as a typing method in EU MS.

Duration: 2025-2027

Sub-activity 3.3.2 Reference material (standard DNA) for quantification of noroviruses and HAV according to ISO 15216

Objectives: Availability of verified standard material used in ISO15216

Description: The quantification standards (plasmid or synthetic DNA) are crucial part of the ISO15216:1, however there is no reference standard material available. The EURL supports the NRLs with provision of quantification standards (distributed with PT samples) and with help during preparations of standards but still there is a potential issue of variability between standards prepared in different laboratories. Moreover, there is a potential variability between standards prepared by the EURL and other international organizations and laboratories. So, the availability of verified standard material would be desirable and introduction of commercially available standards would reduce one possible source of the variability of results between laboratories. The EURL will initiate a discussion between JRC (European Commission's Joint Research Centre) and CEFAS (FAO Reference Centre for Bivalve Mollusc Sanitation) regarding the possibilities on having a reference centre (stocks material) for quantification standards used in ISO15216 and on further harmonization of the preparation of quantification standards in different laboratories.

Expected Output: Commercially available quantification standards

Duration: 2025-2027

Sub-activity 3.3.3 Standardisation and periodic revision of ISO methods (ISO 15216-2:2019)

Objectives: Revision of ISO15216

Description: The ISO method 15216-2:2019 will be reviewed in July 2025 and the national standardization bodies will be asked if the method should be confirmed as it is or if a revision should be undertaken. We have had an ongoing discussion and agreement with the NRLs about problems regarding specifications in the ISO method. This periodic review process will be a good opportunity to start a revision process (e.g. as an amendment to the ISO) and solve some of these problems. The NRLs are interested to proceed in this direction and the EURL will support this revision process by offer to convene a group in ISO and through intensive communication with the NRLs.

The EURL will continue its engagement in the standardisation process of HEV in animal products and validation of methods towards a reference method for viruses and parasites.

Expected Output:

1. A revised ISO 15216 method that fits better for its purpose.
2. A new ISO standard for detection of HEV in animal products

3. A new ISO standard for the validation of a method against a reference method for viruses and parasites.

Duration: 2025-2027

List of Indicators WP3:

- Number of technical and scientific feedback provided by the EURL based on European Commission enquiries
- Number of collaboration activities with other organisations

3.4. Work Package 4 - REAGENTS AND REFERENCE COLLECTIONS

- *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 3.4.1 Production of standard DNA, control RNA and process control virus

Objectives: To ensure that NRLs have access to standards and controls to increase uniformity of method performance between laboratories. To provide means for quality assurance and method evaluations to laboratories.

Description: The EURL will continue the evaluation of synthetic DNA as an alternative standard for the quantification of noroviruses and HAV. Synthetic DNA fragments designed for affordable and easy gene construction or modification, suited for qPCR and

NGS controls. We have started to test three commercially available synthetic DNAs and we continue the evaluation in this WP period. Our aim is to have DNA standards that could be easily and uniformly used of all laboratories involved in quantification of noroviruses and HAV according to ISO 15216. Moreover, we will evaluate and test commercially available synthetic RNA to produce EC RNA used as a control according to ISO 15216.

Expected Output:

1. Produced standards and controls to increase uniformity of method performance.
2. Standard and controls are shared with the NRLs for improved quality assurance of the analyses performed at the NRLs for detection of foodborne viruses.

Duration: 2025-2027

Sub-activity 3.4.2 Organise and collect reference materials such as faecal samples and cultivated viruses

Objectives: To have an up-to-date collection of reference substances and reagents and to store these in an accessible manner.

Description: Continuous collection of reference material as norovirus positive faecal samples has been successful during 2024 and norovirus positive faecal material will be continuously characterized and quantified. Reference material is essential for PT distributions as well as for method implementations and verifications as faecal samples used as a spiking material.

In cooperation with hospitals and other partners we will continuously collect norovirus faecal samples and other relevant enteric viruses to be registered and stored. Typing of such virus stocks will be done.

Mengovirus will be cultivated in cooperation with the Swedish National Veterinary Institute. Costs for this is included in the budget. Mengovirus is used as a process control virus in our methods and we provide it in our PT distributions as well.

Expected Output: A collection of stored and available substances and reagents is maintained and continuously updated.

Duration: 2025-2027