(Annual) Work programme 2016 & 2017:

EU Reference Laboratory for Classical Swine Fever

I. Contractual duties

The contractual duties of the EURL are specified in Council Directive 2001/89/EC (OJ L 316 of 1.12.2001). On this basis the work programme has been set up.

II. Objectives for the period 1st of January 2016 to 31st of December 2017

Activities:	Description:	Objectives:	Expected Outputs:
Activity 1: Production and supply of reference material, provision of information	a) Maintenance and enlargement of the Classical Swine Fever (CSF) virus collection (virus bank); propagation of CSF virus strains for maintenance of existing bank and provision to other laboratories; b) Updating and maintenance of a World Wide Web database for CSF virus collection (including genome sequence data); c) Production of new reference materials, characterization of respective material by comprehensive testing. d) Updating and maintenance of a World Wide Web database for CSF reference sera and tissue samples; e) Storage and supply of cell cultures for use in diagnosis and storage and supply of standardised sera and other reference reagents to the NRLs upon request for test and reagent standardisation, employed in the Member States, e.g. • Reference material (sera, monoclonal antibodies, viruses, clinical specimens, cell cultures); • Serum panels for validation of Antibody ELISA • Panels for validation of PCR tests; • Highly virulent CSF virus for direct use in (vaccination) challenge experiments; • Provision of photographs or slideshows of	Ensure the development and use of high quality methods by supporting NRLs with reference materials and information about these materials for proper validation of test methods and for coordinating and harmonising the applied laboratory techniques in diagnosis of CSF throughout the EU as well as in neighbouring and associated countries.	a) 1-10 new virus stocks collected from possible future CSF outbreaks. b) Collecting data of 1-10 new CSF viruses and include information (e.g. sequence data) in EURL CSF virus database in order to make the information available in a "ready to use format" to the NRLs. c) 5-20 new reference sera . and 20-80 new reference tissue samples from pigs experimentally infected with 4 - 10 different CSF virus isolates at the EURL facilities (depending on current CSF situation and on particular research interest). Reference material will be obtained from animals infected with different recombinant CSFV isolates constructed for testing as possible marker vaccine candidates. d) Collecting data of 5-20 new sera and 20-80 new tissue samples and include data in EURL CSF sera and tissue database. e) 60-80 supplies of reference reagents to NRLs and Third Countries upon request f) Agreement on, set up and comparative testing of a compilation of reference sera for internationally comparable ELISA control (effective comparability of batch control in the different NRLs carried out for registration of tests in the different

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	CSF virus infected pigs for teaching purposes. f) Discussion of the need and implementation of an international standardized and quantifiable reference serum panel for ELISA batch control. Organization of a Meeting at the EURL in Hannover with selected NRL experts for information exchange, determination of the requirements and coordination of the project. g) Establishment of procedures for inactivation of CSFV positive sera to be supplied to the NRLs for serological investigations. h) Updating the Technical part of EU Diagnostic Manual for Diagnosis of Classical Swine Fever (CSF) i) Diagnostic laboratory testing of sample material for confirmation/ exclusion or differential diagnosis when Classical Swine Fever is suspected;		member states; evaluation of new tests etc.). g) Increase biological safety in exchange of sera between laboratories by application of procedures and protocols for effective reduction of infectious virus in porcine serum (rendering the material non-infectious) without affecting test results in diagnostic methods applied for serological testing). h) Availability thorough information about current, state-of-the-art diagnostic techniques with regard to the detection of Classical Swine Fever. i) Confirmation of laboratory diagnosis. Number of tests is depending on the respective outbreak situation in the EU and neighbouring countries.

Activities:	Description:	Objectives:	Expected Outputs:
Activity 2: Inter-laboratory comparison test (ILCT)	Organising comparative tests of diagnostic procedures at Community level **on an annual basis.** • Production of reference material for ILCT panel. • Set up of CSF ILCT panel in cooperation with and according to the advice of the scientific advisory board; • Preparation, validation of CSF ILCT panel; • Notification of participating laboratories, packaging and shipment of CSF ILCT panel. • Collection of results and evaluation of ILCT results. • Communicating results of ILCT to participating laboratories and EU Commission (DG SANCO) by provision of a compiled report and by presenting the data in the frame of the Workshop/ Annual Meeting of Classical Swine Fever Reference Laboratories. • Follow-up of non-conformities of ILCT (by e.g. email communication as well as direct interaction by laboratory visits or training sessions in order to identify and eliminate the source of non-conformity).	To maintain an appropriate level of proficiency testing ensuring efficiency of control analysis methods, by performing control of NRLs in diagnostic techniques for the detection of CSF (European Union laboratories and third countries). Harmonisation of methods applied in NRLs.	Organization of new ILCTs (2016 & 2017) and follow-up of "previous" ILCTs (2015 & 2016) Each ILCT panel will contain about 15-25 samples that can be tested in 8 different diagnostic tests. • Each year 28 panels (to EU NRLs) and about 10 - 20 panels to other laboratories (e.g. EU candidate and pre-accession countries, associated countries as well as strategically important countries). • High level of successful completion of testing by the NRLs after first round of testing, for laboratories with major discrepancies in the first round of diagnostic testing considerable improvement after application of follow-up measures determined by second round of testing.

Activities:	Description:	Objectives:	Expected Outputs:
Activity 3: Characterization of virus isolates	Molecular and biological characterisation of CSF virus isolates and novel vaccine candidates by the most up-to-date methods available. a) Animal experiments for studying virulence and pathogenesis of recent CSF virus isolates; and to characterize new candidates for live attenuated marker vaccines. b) Sequence analysis of recent CSF virus isolates from primary outbreaks of CSF in the EU and Third Countries (upon request) and evaluation of data from Member States on molecular epidemiology of CSF c) Sequencing of complete CSF virus genomes in order to fill in gaps of knowledge; d) Optimization of CSF virus sequence analysis in case of outbreaks (e.g. implementation of workflows/expertise for determination of complete CSFV genomes). e) Publication, provision and transfer of new methods to NRLs;	Facilitating the understanding of epizootiology of CSF. Ensure the development and use of high quality analytical methods within the laboratories by improving methods applied in CSF virus phylogeny.	a) Performance of 1-2 animal experiments with CSF field viruses and genetically engineered viruses at the EURL facilities. b) Characterization of 1-10 new viruses collected from future CSF outbreaks in the EU and Third Countries (depending on outbreak situation) and distribution of the generated information by the Classical Swine Fever database and publications. c) Increasing the number of complete CSF viral genome sequences available for phylogenetic analysis.

Activities:	Description:	Objectives:	Expected Outputs:
Activity 4: Gathering of information and expertise	a) Retaining expertise on the virus causing CSF and other relevant viruses (e.g. ruminant pestiviruses and African Swine Fever Virus to enable rapid differential diagnosis); Keeping abreast of new developments regarding CSF surveillance, epizootiology and CSF prevention throughout the world and of developments regarding preparation and use of products of veterinary immunology applied in order to control and eradicate CSF; b) Maintaining and extending networking activities with laboratory experts on CSF diagnosis and scientists working in the field of CSF virus; c) Collecting and collating data and information on the methods of diagnosis and the results of tests carried out; • Collection of the country report data on CSF diagnostic activities via a web based template; • Collection of wild boar data of the countries situation via a web based template and in parallel generation of the wild boar report directly via the "CSF in wild boar" surveillance database; • Editing of data and reporting to NRLs and EC.	Ensure the availability of scientific and technical assistance by the EURL continuous qualification of staff, which is available for emergency situations occurring within the EU in order to assist during outbreaks/ crisis situations. Assistance of the Commission, EFSA, ECDC and EMA in case of specific requests. Contribution to risk assessment and reviews of manuals or codes.	a) 5-12 participations in relevant congresses and meetings **(2016- 2017).** b) On-going reciprocal exchange of information with competent institutions, laboratories and universities in the EU and Third Countries c) Collection of CSF country report and CSF Wild Boar report data and provision of the edited data to NRLs and DG Sanco. d) Timely and adequate answering to all requests for assistance raised by the NRLs or other parties.

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Activity 5: "CSF/ASF Wild Boar surveillance database"	Maintenance of CSF/ASF in wild boar surveillance database (subcontracting with Friedrich-Loeffler-Institute, Greifswald – Insel Riems, Germany) • Telephone and e-mail assistance through a support employee; • Technical maintenance of the CSF/ASF in wild boar surveillance database; • Support of Latvia, Lithuania, Estonia, Austria and Poland through individually customized training sessions and workshops in each country; • Integration of a new "Quick Map Viewer"	Risk assessment: Gathering and processing of data for improving the information available on CSF/ASF in wild boar situation in the EU and neighbouring countries.	• Maintaining CSF/ASF in wild boar surveillance database. • Individually customized training sessions and workshops (5x) held in countries interested in joining the database.
Activity 6: Provision of training in diagnosis of CSF at the EURL	Provision of individual trainings in laboratory diagnosis for CSF (e.g. if there is new personnel at an NRL, if re-training of experts is needed or in case there is need for assistance if new techniques are to be established at an NRL). (Upon request of the European Commission or TAIEX, the training offer may also include the training of experts from non-EU countries).	Ensure the development and use of high quality analytical methods by training sessions carried out for improving the performance level of NRLs (e.g. as a follow-up of poor ILCT results) in diagnostic testing of CSF. Harmonisation of methods applied in different laboratories. Help with establishing new diagnostic techniques in NRLs for improvement of diagnostic standard. Increasing the number of trained personnel available for emergency situations occurring within the Community.	Training in state-of-the-art of analytical methods for the detection of Classical swine fever of 4-6 visitors for a time period of 1-2 weeks training each.

Activities:	Description:	Objectives:	Expected Outputs:
Activity 7: Organization of an "Workshop on CSF/ ASF diagnosis and control" for National Reference Laboratories (in cooperation with DG Sanco and the EURL for ASF)	• Preparation and organization of Workshop • Compilation of programme and working documents for CSF part; • Scientific contribution: presentation of ILCT results, EURL activities and latest research activities; • Collection and editing of material for a report on Workshop; • Preparation of Workshop report; • Providing Workshop´s presentations for download on the website of the EURL in an access-restricted area.	Dissemination of information on newly developed analytical methods/ news on reference methods in laboratory diagnosis of CSF to the NRL experts for ensuring the use of high quality analytical methods among the NRLs, with a view to harmonize the applied diagnostic techniques. Exchange of information on current CSF situation in Member States and in neighbouring countries of the EU. Platform for presenting news with regard to epidemiology and control of CSF and updates on relevant research topics.	• Organization of a joint Workshop on CSF and ASF diagnosis and control for 2016 taking place in Hannover (EURL for CSF is host of the meeting) and for 2017 in Valdeolmos (hosted by the EURL for ASF). • Harmonization and thus application of state-of-the-art analytical methods within EU and associated countries. • Exchange of relevant practical experience and findings regarding laboratory diagnosis and control of CSF for identifying future requirements for the applied diagnostic techniques and determining the possibilities for further optimization. • Participation of representatives from 29 EU NRLs and in addition of representatives from strategically important non-EU laboratories in the Workshop.
Activity 8: Missions and permanent training of staff	a) Provision of trained personnel for missions to National Swine Fever Laboratories/ Member States asking for assistance. Provision of trained personnel for missions on demand of DG SANCO; b) Permanent training of staff to keep abreast of new developments, including the attendance of	Ensure the availability of scientific and technical assistance to the NRLs and other parties by supporting the professional development of personnel, and sending trained personnel whenever necessary (e.g. in case of emergency situations occurring within the	a) 1-4 visits to NRLs for training sessions and/ or inspection visits for determination of laboratory capacities regarding CSF diagnosis (number of visits is depending on CSF situation in the EU and e.g. on performance of NRLs in ILCT testing). b) Participation in international meetings and conferences, attending of seminars on virology.

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	international meetings and conferences;	Community).	
Activity 9: Projects and activities related to improved CSF virus diagnosis and control	• Identification and characterization of new pestiviruses Testing of experimentally derived sera obtained after application of novel genetically engineered CSFV marker vaccines in combination with a recently developed Erns double-antigen ELISA as the serological DIVA assay. • Preparation and publication of articles and reports associated with above work, attendance of international meetings and conferences.	Performing research activities and whenever possible coordinate research activities directed towards an improved control of CSF.	• Enhancing knowledge on heterogeneity of pestiviruses in order to improve differentiation between CSFV and other porcine as well as ruminant pestiviruses; • To gather information about performance of a novel Erns ELISA for application as a putative DIVA assay in combination with several prototypes of marker vaccines differing to the CP7-E2alf marker vaccine • Mutual exchange of information with competent laboratories /authorities in the EU and in Third Countries. • Contribution to scientific conferences, e.g. presentations of research results (speaker, posters). • Publications in peer-reviewed journals.

It is understood that the above mentioned objectives are not exclusive to other work of more immediate priority which may arise during the given period.

ANNEX

Projects and related research activities funded by other sources

- Project “Mechanisms and biological significance of genetic variability of RNA viruses“ (BE 2333/2-2) funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Council**)**;
- Project „Identification and characterization of novel viruses originating from farm animals“. Part of the activities of the DZIF (“Deutsches Zentrum für Infektionsforschung“). Funded by the Bundesministerium für Bildung und Forschung.
- Member of the *Flaviviridae* Study group of the International Committee on Taxonomy of Viruses, ICTV (Prof. Paul Becher);
- Participation in international research projects and networks, e.g. European Research Group (former “EPIZONE”);