

ANNEX II: TERMS OF REFERENCE

"Support to establishing disease surveillance and control programs and alignment with chapter 12 of the acquis"

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1. BACKGROUND INFORMATION

1.1. Partner country

KOSOVO*¹

1.2. Contracting authority

European Union Office in Kosovo

1.3. Country background

Kosovo is land-locked country located in the Western Balkans, with an area of about 10.9K km² and a population of about 1.8 million inhabitants². Agriculture is one of Kosovo's key sectors, a sector that significantly contributes to the overall economic development of the country and has a high potential for development.

Kosovo is a potential candidate to the EU membership. A Stabilisation and Association Agreement (SAA) was concluded in 2015 between the European Union and Kosovo, which entered into force on 1 April 2016 and provides a comprehensive framework for a structured political dialogue and intensification of economic relations.

The Stabilisation and Association Agreement (SAA) envisages progressive reduction of customs duties on imports of agricultural and food products originating from EU member states with the view to completely abolish customs duties or other taxes having an equivalent effect within 5 years from the date when the SAA agreement entered into force. Such a reduction of customs duties defined in the SAA and regional Free Trade Agreements will lead to further increase in imports of agricultural and food products (imports that already account for more than 70% of the food market). At the same time, the SAA agreement provides a massive opportunity for export of agricultural products from Kosovo to the EU market without any quantitative restrictions, custom duties or other measures having an equivalent effect. Considering that the European Union is known to have the highest safety and quality requirements and standards in production and processing of agri-food products, it becomes obvious that Kosovo has to apply safety and quality measures similar or equivalent to those of the EU, in order to be granted access to the EU's common market. This involves comprehensive measures to ensure that food placed on the market is safe and proper rules in the veterinary field, which are essential for safeguarding animal health, animal welfare and safety of food of animal origin in the internal market, are in place and properly met.

1.4. Current situation in the sector

Kosovo needs urgent action to ensure alignment to the EU standards in the food safety, veterinary and phytosanitary areas addressed by the Chapter 12 of the EU acquis.

Development and implementation of quality and safety measures in the area of food safety and animal health require approximation of Kosovo's policies and legislation with the EU acquis, as well as a high level of competence of the administration in charge with implementation of the legislation covering Chapter 12 of the EU acquis.

More specifically, the following are necessary and will be supported under the contract that this ToR is part of:

¹ This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence

² <https://ask.rks.gov.net/media/5128/kosovo-in-figures-2018.pdf>

- Integrated and reliable control bodies able to provide assurance to consumers and the EU Member States' authorities that food products placed on the domestic market or certified for export to EU meet quality and safety standards as per the EU *acquis*.
- A technically and scientifically prepared animal health service, able to monitor the animal health situation in Kosovo and timely detect animal diseases, particularly the transboundary animal diseases which can spread rapidly in the region and wider in Europe; a service fully prepared to implement control and eradication measures for such diseases.

Kosovo had recently several disease outbreaks and endemic disease problems are obvious. This situation is causing public health problems when dealing with zoonotic diseases, economic losses at farm level and costs for disease control and eradication, as well as trade and movement restrictions for live animals and food of animal origin.

The animal health situation in Kosovo is monitored through regular sero-surveillance programmes, annual vaccination schemes and passive surveillance systems whereby veterinarians and farmers report occurring disease to the Animal Health Department of the Food and Veterinary Agency. While much effort has been given for strengthening the capacities of the Animal Health Department in disease identification and control or/and eradication, much remains to be done in order to improve long term planning and implementation of eradication programmes for diseases which are endemic in Kosovo and pose risks to human health, causing at the same time economic losses.

This situation is further hampered by the inability of the Veterinary Laboratory to undertake confirmatory tests for most of the diseases present in Kosovo due to lack of technical capacities and laboratory equipment needed to perform such tests. Most of the confirmatory tests are carried out in accredited laboratories of the region or in Europe; this entails increased costs and time delays in managing the diseases outbreaks and implementing control programs.

Kosovo Food and Veterinary Agency needs support in designing and implementing a comprehensive disease monitoring and control system, in line with EU legislation and animal health requirements established by OIE - World Organization for Animal Health. A strong action is needed in order to improve the long term planning and implementation of eradication programs for diseases which are endemic in Kosovo. Further improvements are necessary with regard to animal health controls starting at the farm level, and continuing with transport of animals and in livestock markets. The quality of implementation of such programs is not satisfactory for now, mostly due to the lack of continuous training and education programs for field veterinarians.

With regards to legislation, the EU *acquis* in Chapter 12 consists of a very large number of Regulations, Directives and Decisions. Apart from transposition, candidate countries and potential candidates are expected to properly implement and enforce rules envisaged by Chapter 12. For implementation of legislation in this area, Kosovo should have appropriate administrative structures to be able to carry out inspection and control of food, including an appropriate laboratory capacity.

Kosovo continuously works on upgrading its legislation to meet EU *acquis* requirements. A comprehensive Action Plan covering all aspects of food safety, veterinary and phytosanitary legislation could serve as a basis for achieving a full alignment with the EU *acquis* in this sector. Specific attention will be required with regard to closing the gaps in the areas which are not yet harmonized.

In terms of institutional set-up, Kosovo Food and Veterinary Agency (KFVA) is the competent authority responsible for public and animal health issues. KFVA is under the direct supervision of the Prime Minister's Office and is headed by a Director who is also the Chief Veterinary Officer (CVO).

The structure, roles, responsibilities and competences of KFVA are laid down in the Food Law, in the Veterinary Law and Regulations No 03/2010 and 01/2011. KFVA is responsible for drafting the legislation and its enforcement, including the official controls undertaken by official veterinarians. The official veterinarians are located either in KFVA' headquarters or in its regional offices.

KFVA has three directorates that share the responsibilities in regards to animal health, namely: (1) Directorate for Animal Health and Welfare, (2) Directorate for Food and Veterinary Laboratory, and (3) Directorate for Inspections.

Private veterinary practitioners are contracted by KFVA in order to secure implementation in the field of the activities related to animal health.

Under the current setup, Kosovo Food and Veterinary Laboratory is the main part of Kosovo Food and Veterinary Agency. Among other, this Laboratory diagnoses animal diseases and analyses microorganisms of food of animal origin and other food sources, for the entire territory of Kosovo. In terms of infrastructure, the Food and Veterinary Laboratory is situated in a new building designed according to the relevant safety requirements. However in order for this laboratory to perform at full capacity and provide reliable results, recognized also by sister organizations in the region and in the EU, the laboratory needs to increase the range of tests carried out, in particular confirmatory tests. The laboratory also needs strengthening of its staff's technical capacities, so that effective implementation of internationally recognized quality management systems such as ISO 17025 becomes possible.

While Kosovo Food and Veterinary Agency has a leading role from a technical point of view, the Ministry of Agriculture and Ministry of Health are responsible for designing policies and legislation. The Prime-minister's Office for the Services of Legal Assistance has the authority to issue legal opinions, check the quality of legislative proposals and provide guidance over the approximation of the national legislation with the EU *acquis*. Nevertheless, the existing capacities related to these functions are pretty weak and the action should also support their development.

In addition, the preparation of the Action Plan for approximation to the EU *acquis* in relation to food safety, veterinary and phytosanitary shall involve other central institutions, such as Prime-minister's Office, to make sure that the Action Plan is consistent with Kosovo's work programme, and the Ministry of Finance, to make sure that costs associated to implementation of the Action Plan are well estimated and sufficient resources are allocated in the budget. Ministry of Administration and Local Government shall also be involved since it has a coordination role in relation to the reforms at policy level and legislative development.

Finally, it should be also noted that monitoring of implementation of the legislation transposed is currently weak and should be strengthened. The contract that this ToR is part of shall contribute to the improvement of overall coordination and strengthening of administrative capacities of the institutions involved in the monitoring process. The Action Plan foreseen should be a proper tool for all stakeholders involved in securing proper monitoring of the progress under Chapter 12 of the EU *acquis*, annual updating of the National Plan for Implementation of the Stabilization and Association Agreement, and planning of the donor support.

Table 1: KFVA Staff resources and qualifications at central and local level, as well as available resources for the outsourced tasks:

Position	Name	Sumame	Function	Education
Management Staff	Naser	Krasniqi	Deputy CVO	Agriculture University
Procurement Sector	Jeton	Gashi	Head of Procurement	Economy university
	Lavdim	Tahiri	Procurement officer	Economy university
Sector of Human Recourses	Qamil	Ajvazi	Head of Human Recourses	University of Law
	Merita	Shahini	Human Recourses official	Economist
Internal audit office	Vjosa	Zejnullahu	Head of Auditing	Economist
Public Health Directorate	Flamur	Kadriu	Director	Veterinarian
Sector for Animal By-	Saranda	Ahmetaj	Head of Sector	Veterinarian
Sector for Hygiene of Food of non-animal origin	Besa	Gerxhaliu - Osmani	Head of Sector	University of Agriculture
Sector for Hygiene of Food of animal origin	Blerim	Hajdari	Head of Sector	Veterinarian
Sector for residues in food	Festim	Rexhepi	Head of Sector	Public Health
Animal Health and Welfare Directorate	Sadik	Heta	Director	Veterinarian

Animal Health Sector	Bafti	Murati	Head of Sector	Veterinarian
Animal I&R Sector	Berat	Hoxha	Head of Sector	Veterinarian
Animal Welfare Sector	Nol	Kabashi	Head of Sector	Veterinarian
Veterinary Drugs Sector	Bekim	Zhubi	Head of Sector	Veterinarian
Food and Veterinary Laboratory	Kujtim	Uka	Director	Veterinarian
Serology and Molecular Diagnostic Laboratory	Armend	Cana	Head Of Laboratory	Veterinarian
Bacteriology and Parasitology Laboratory	Beqë	Hulaj	Head Of Laboratory	Veterinarian
Pathology Laboratory	Xhavit	Merovci	Head Of Laboratory	Veterinarian
Food Chemistry Laboratory	Drita	Bajraktari	Head Of Laboratory	Chemist
Food Microbiology Laboratory	Besart	Jashari	Head Of Laboratory	Biologist
Milk Quality Laboratory	Hysa	Gërbeshi	Head Of Laboratory	Agriculture University
Inspection Directorate	Ilirjana	Zymberaj	Director	Food Technology
Sanitary Inspection	Ibrahim	Tërshnjaku	Head of Sector	Food Technology
Veterinary in land inspection	Arsim	Arifi	Head of Sector	Veterinarian
Veterinary Border Inspection	Eroll	Shehu	Head of Sector	Veterinarian
Phytosanitary in land Inspection	Ismet	Fejzullahu	Head of Sector	Agriculture University
Phytosanitary Border Inspection	Ibrahim	Hoxha	Head of Sector	Agriculture University

1.5. Related programmes and other donor activities

IPA 2013 project “*Technical Assistance for the Animal Health Department of Kosovo Food and Veterinary Agency (KFVA) KFVA and Kosovo Food and Veterinary Laboratory*”

The overall objective of this project has been to strengthen the safeguarding of measures concerning animal health and reinforce the capacity to implement control and eradication plans for the diseases present in the country. Under the "Animal Health" Component, its key results included (i) a Development plan for the animal health unit, including annual and multiannual work plan, for the period 2017-2021; (ii) Surveillance and vaccination programs for diseases identified by the KFVA and those for which reporting is compulsory, for the period 2017-2021; (iii) cost benefit analyses for control and/or eradication of selected animal diseases, and (iv) updated contingency plans for selected animal diseases have been reviewed and updated. Under the "Laboratory testing" component, the results included training for the laboratory staff, a list of test and analysis to be included in the range of laboratory services to be performed, and updated document management and communications system. The main recommendations included in the final report of this project are:

- 1) To restructure the Department of Animal Health and Welfare of Kosovo Food and Veterinary Agency (KFVA) to create an appropriate structure, particularly an epidemiology department;
- 2) To review the staffing levels of the Department of Animal Health and Welfare of KFVA and ensure that appointed staff have or will gain expertise in the skills required for the post;
- 3) To establish a staff training program based on the needs of the Department of Animal Health and Welfare of KFVA and the Inspectorate with protected allocated time for the training to take place;
- 4) To undertake regular reviews of Contingency Plans and practice their implementation;
- 5) To formally adopt the proposed control policy for brucellosis;
- 6) The safety of laboratory staff requires urgent protection that includes proper installation and ongoing maintenance of biosafety cabinets.

SANTE/2018-G-046 EU regional project “*Regional action on animal disease eradication in the Western Balkans*”

The overall objectives of the project are:

- 1) To control and eradicate important animal diseases in the Western Balkans, in particular those diseases that continue to be a threat to EU Member States.
- 2) To establish a solid cross border cooperation platform with the veterinary services in neighbour countries and EU Member States.
- 3) To improve the access of agriculture products from the Western Balkans to the internal market and to non-EU countries markets.

In summary, the project purpose is to ensure that the technical capacity of the beneficiary competent authorities is upgraded to ensure favourable animal health status for the whole region over long term and enable free access of products of animal origin to the EU markets.

IPA 2014 Project "*Support in the development and implementation of Food Safety and Sanitary and Phytosanitary Controls*"

The aim of the project has been to address implementation of the EU compliant food safety and health control system at all stages, including import, export, production of food, transport, processing, and retail. The project has also been aimed at regulating livestock breeding sector, reviving livestock breeding centre as well as expand milk recording system in Kosovo.

- Specific purpose of the Food Safety component: to strengthen the legislative, institutional and administrative capacity related to food and feed safety, implement traceability of food and feed, and contribute to upgrading of establishments that process food of animal origin in Kosovo.
- Specific Purpose of Animal Breeding component of the project: to establish and/or upgrade Livestock Breeding policies and capacities to improve productivity and protect local breeds.
- Specific Purpose of the Milk Recording component of the project: to support Association of Milk Producers in implementation of milk recording system with included animal health component and becoming financially self-sustainable.

IPA 2014 Project "*Support to Kosovo Food and Veterinary Laboratory*"

The project has been aimed at supporting Kosovo Food and Veterinary Laboratory in increasing the range, quality and reliability of services provided including development and validation of existing services and introduction of new test method, with particular focus on drugs and residue testing program.

IPA 2015 Project "*Support to Kosovo Food and Veterinary Agency (KFVA) in developing its capacity to implement an integrated approach to food safety, including through upgrading and functionalizing of its IT system*"

Technical assistance project which foresees reviewing and upgrading of the existing IT systems, designing of the electronic laboratory information system, designing of the database for registration and control of the agri-food establishments/food business operators, as well as designing, development and testing of the integrated KVFA IT system which will link all relevant systems into a centralized one. The system will allow for internet communication and transfer of files from borders/boundaries to headquarters and back. Provision of comprehensive training to KVFA staff at all levels with regards to the integrated system created, as well as training of the KVFA's IT staff for maintenance of the entire system and training of field operators in usage and reporting under the Veterinary Information System will also be included. Registration campaign in the four Municipalities in the North will also be addressed under the project, including performing information campaign on the legal requirements and benefits of the Animal Identification and Registration system and training and monitoring of the filed operators engaged in the implementation of the Animal Identification and Registration campaign in the North. Preparation of technical specifications and bill of quantities for ear tags and pliers needed for ear tagging of animals is also envisaged under the project.

IPA 2015 Project Title: "*Support to strengthening Kosovo's plant production and protection system and capacities*"

The overall objective of this project has been to strengthen the implementation and operational capacity of the institutions responsible for plant health in Kosovo (Phytosanitary sector) in order to ensure the effective control system of the harmful organisms to plant and plant products in accordance with EU Phytosanitary standards. The project purpose has been to upgrade and strengthen the capacity (administrative and technical) of the Phytosanitary sector for successful implementation of national and EU legislation in phytosanitary area - plant health, plant protection products, food safety, seed and propagating material, plant variety rights and inspections.

2. OBJECTIVE, PURPOSE & EXPECTED RESULTS

2.1. Overall objective

The overall objective of the project of which this contract will be a part is as follows:

- To provide safe food to consumers, improve trade and achieve progress in the alignment to the EU standards in the food safety, veterinary and phytosanitary field

2.2. Purpose

The purposes of this contract are as follows:

- Purpose 1: to strengthen the mechanisms for surveillance, control and eradication of animal diseases in Kosovo towards the EU standards
- Purpose 2: to prepare the "roadmap" for approximation of the national legislation with the EU Acquis' Chapter 12 on food safety, veterinary and phytosanitary, and strengthen further the administrative capacities in these areas

2.3. Results to be achieved by the contractor

In view of achieving its purposes, the project will lead to the following results:

- a) *5-year Development Plan for the Animal Health Section of KFVA's Department of Animal Health and Welfare.*
 - ✓ Deliverable 1: A 5-year³ Development Plan for KFVA's Animal Health and Welfare Directorate⁴.
 - The plan will comprise a training programme for Animal Health and Welfare Directorate, Veterinary Inspectors, Private Veterinary Practitioners, as well as an estimation of the annual budgetary needs of the Animal Health and Welfare Directorate, including for implementation of the animal health measures foreseen in the plan. It will also include a budget for training and simulation exercises for a 5-year period.
- b) *Surveillance and vaccination programmes revised or prepared for the diseases identified by KFVA and those for which reporting is compulsory⁵*
 - ✓ Deliverable 2: Training of Trainers of twelve (12) Food and Veterinary Agency officials on sample collection as well as two (2) officials from the veterinary chambers (training duration: min 2 days).
 - ✓ Deliverable 3: Surveillance Program for ovine and bovine brucellosis revised.
 - ✓ Deliverable 4: Surveillance Program for tuberculosis revised.
 - ✓ Deliverable 5: Surveillance Program for foot and mouth disease revised.

³ The plan is expected to cover, in principle, the period 2022-2026; nevertheless, the exact 5-year interval to be considered will be indicated by KFVA in the inception phase of implementation

⁴ To be prepared in English and translated into Albanian and Serbian

⁵ To be prepared in English and translated into Albanian and Serbian

- ✓ Deliverable 6: Surveillance Program for enzootic bovine leucosis revised.
- ✓ Deliverable 7: Surveillance Program for avian influenza revised.
- ✓ Deliverable 8: Surveillance Program for African and classical swine fever revised.
- ✓ Deliverable 9: Surveillance Program for Q-fever revised.
- ✓ Deliverable 10: Surveillance Program for American and European Foulbrood bee disease revised.
- ✓ Deliverable 11: Surveillance Program for rabies revised.
- ✓ Deliverable 12: Identification and listing of the fish farms, in view of preparation of Deliverable 13.
- ✓ Deliverable 13: Surveillance Program for fish diseases (viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) prepared.
- ✓ Deliverable 14: Surveillance Program on Zoonotic Vector Borne Diseases prepared.
- ✓ Deliverable 15: Surveillance Program on Salmonella in eggs prepared.
- ✓ Deliverable 16: Surveillance Program on BSE⁶/TSE⁷ in bovine prepared.

To be noted that:

The contractor is responsible for preparing the programs, including for determination of the sample size.

Surveillance will be carried out annually (3 times during the implementation of the project). The price indicated for implementation of each surveillance program such as the cost of sample collection by the private veterinarians/veterinary services involved, as well as the cost of testing of the blood samples, including the cost of consumables for the tests performed at KFVA's laboratories will be covered by the FVA.

Contractor should ensure that the surveillance programmes are all in line with the World Organization for Animal Health's (OIE's) recommendations and EU Regulations, which in the long term contribute to gaining the status of free from Animal Diseases according to the World Organization for Animal Health (OIE).

c) Eradication programs prepared, including cost benefit analysis, for Brucellosis (ovine and bovine), bovine tuberculosis and enzootic bovine leucosis

- ✓ Deliverable 17: Eradication program, including cost benefit analysis, prepared for Brucellosis (ovine and bovine).
- ✓ Deliverable 18: Eradication program, including cost benefit analysis, prepared for bovine tuberculosis.
- ✓ Deliverable 19: Eradication program, including cost benefit analysis, prepared for enzootic bovine leucosis.

d) Guidance to decision makers in securing proper surveillance, control and eradication of animal diseases

- ✓ Deliverable 20: Book of rules and procedures regarding decision making process related to surveillance, control and eradication of animal diseases, including relevant documentation and comprehensive recommendations for surveillance and control of animal diseases (note: the process of regularly reviewing, practicing and updating the contingency plans is part of this process and should be therefore considered).

e) Assessment of the Animal Health Laboratory's resources available, in terms of human resources, kits, reagents and equipment

⁶ Bovine spongiform encephalopathy (BSE)

⁷ Transmissible spongiform encephalopathies (TSE)

- ✓ Deliverable 21: Assessment Report on Animal Health Laboratory. Evaluation of the current diagnostic methods and tests, and update of tests methods for parameters which are and will be foreseen in the program of surveillance, control and eradication of animal diseases in Kosovo towards the EU standards.

Evaluation must be based on the bio-risk assessment and quality management system and must include Standard Operating Procedures (SOPs), test methods, validation, reference samples, batch control of diagnostic reagents, proficiency test.

- ✓ Deliverable 22: Assessment of Food and Veterinary Laboratory on Biosafety and Biocontainment and assisting in biosafety requirements.

f) *Training of Kosovo Food and Veterinary Agency's staff*

- ✓ Deliverable 23: On-the-job training in form of internships or study visit in an EU country or specialized courses,⁸ each lasting 2 weeks on veterinary epidemiology and disease control management for 12 staff of KFVA, divided into 3 groups.
- ✓ Deliverable 24: Specialized training courses on animal health, for staff of KFVA's Animal Health and Welfare Directorate, Regional Veterinary Offices as well as Private Veterinary Practices. The focus of training will be on identification and management strategies for endemic diseases in Kosovo. Contractor is expected to organize and implement minimum two workshops with 5 day duration each for minimum 20 participants.
- ✓ Deliverable 25: Training of Food and Veterinary Laboratory staff on Biosafety (1 day, all laboratory staff (40 staff)).
- ✓ Deliverable 26: Biocontainment risk assessment and assisting in biosafety requirements. (2 days, head of laboratory sectors (6 staff)).
- ✓ Deliverable 27: Training on Entomology for surveillance of vector borne diseases. The training should include field work in different locations in Kosovo such as placing light traps and collection of ticks, as well as identification of vectors in the laboratory (10 days, 2 staff members).
- ✓ Deliverable 28: Hands on training for gross pathology and histopathology, including common histopathological and immunohistological staining techniques (10 days, 2 staff members).
- ✓ Deliverable 29: Introduction to cell culture and isolation (viral and bacterial) feasible on Biosafety Laboratory 2+ (10 days, 2 staff).
- ✓ Deliverable 30: Hands on training on serological and molecular techniques for vector-borne diseases which should include testing of animals, ticks and insects such as culicoides (5 days, 3 staff members).
- ✓ Deliverable 31: training on laboratory analysis and tests for bacteria, pests and parasites and viral bee diseases (10 days, two staff members).
- ✓ Deliverable 32: training on laboratory analysis and tests on rabies (10 days, two staff members).
- ✓ Deliverable 33: Ten (10) days training in form of internship or study visit for Entomology for surveillance of vector borne diseases for two laboratory staff.
- ✓ Deliverable 34: Ten (10) days training in form of internship or study visit for two laboratory staff in a laboratory for brucellosis National Reference Laboratory (NRL) or European Union Reference Laboratory (EURL). Training must cover all necessary diagnostic techniques (serological and molecular techniques).
- ✓ Deliverable 35: Ten (10) days training in form of internship or study visit for two laboratory staff in a (National Reference Laboratory (NRL) or European Union Reference Laboratory (EURL) for Avian influenza and Newcastle disease with the emphasis on advanced molecular techniques (Polymerase Chain Reaction (PCR) -virus identification, subtyping and Gene Sequencing).
- ✓ Deliverable 36: Ten (10) days training in form of internship or study visit for one laboratory staff for gross pathology and histopathology, including common histopathological and immunohistological staining techniques.

⁸ The contractor should clearly indicate in the methodology what kind of long-term training is foreseen

- ✓ Deliverable 37: Ten (10) days training in form of internship or study visit for one laboratory staff for bee diseases.

Note: Training for the laboratory staff is expected to be carried out at the premises of the Kosovo Food and Veterinary Laboratory and the contractor will use samples taken under the surveillance program as much as they are available. For the other samples, staff of the Kosovo Food and Veterinary Agency is responsible to collect and make samples available for the project experts. Trainings and tests foreseen should be sufficient for developing good capacities of the target beneficiaries. All costs related to delivery of the trainings and tests foreseen (e.g. Reference materials, kits and reagents for training purposes), should be covered/secured by the contractor, hence included in the price(s) proposed. After training, the trainer shall be made available for technical support for a period of one year regarding questions or problems which may arise, related to that training.

g) *Training⁹ of Private Veterinary Practitioners (e.g. private veterinarians and veterinary technicians)*

- ✓ Deliverable 38: Training of 110 private veterinary practitioners on:
 - disease recognition/identification (diseases which are part of the annual and multi annual control and eradication plan);
 - disease reporting and recording;
 - immediate containment measures including biosecurity measures.

Note: 7 trainings of 1 day each in 7 regions, are expected under this deliverable.

h) *Manual on disease identification, control and reporting*

- ✓ Deliverable 39: Manual on disease identification, containment and reporting for notifiable animal diseases according to the World Organization for Animal Health (OIE):
 - One manual will be prepared for all notifiable animal diseases according to the World Organization for Animal Health (OIE) and Kosovo legislation in force. The manual will be prepared in English and translated into Albanian and Serbian. The number of copies of the manual will be 200 in each language.

i) *Support proficiency testing for the diseases identified by Kosovo Food and Veterinary Agency*

- ✓ Deliverable 40: Four (4) Proficiency tests on ovine and bovine Brucellosis.
- ✓ Deliverable 41: One (1) Proficiency test on Bluetongue disease.
- ✓ Deliverable 42: Two (2) Proficiency tests on enzootic bovine leucosis.
- ✓ Deliverable 43: Three (3) Proficiency tests on Avian Influenza.
- ✓ Deliverable 44: Two (2) Proficiency tests on Q-fever.
- ✓ Deliverable 45: One (1) Proficiency test on American and European Foulbrood bee disease.
- ✓ Deliverable 46: One (1) Proficiency test on rabies.

The total number of Proficiency Tests foreseen under the deliverables 40-46 is 14 (fourteen). The Proficiency Tests shall be conducted with National Reference Laboratories (NRL) in EU Member States or European Union Reference Laboratories (CRL).

Note: All costs necessary for carrying out the tests foreseen should be covered/secured by the contractor, hence included in the price(s) proposed.

j) *Simulation exercises for control of outbreak of selective infective diseases effectively carried out*

⁹ Contractor should ensure all consumables

- ✓ Deliverable 47: Simulation exercises on highly pathogenic avian influenza and Newcastle Disease Virus (desk and field drills; minimum 2-day duration). One simulation exercise for each calendar year (3 exercises during the entire implementation of the contract).
 - ✓ Deliverable 48: Simulation exercises on Classical Swine Fever (CSF) and African Swine Fever (ASF), with a particular focus on the areas mostly inhabited by Serbian minority and Albanian community of Catholic religion (desk and field drills; minimum 2-day duration). One simulation exercise for each calendar year (3 exercises during the entire implementation of the contract).
 - ✓ Deliverable 49: Simulation exercises on foot and mouth disease (desk and field drills; minimum 2-day duration). One simulation exercise for each calendar year (3 exercises during the entire implementation of the contract).
- k) *Revision or drafting of Administrative Instructions on animal disease control to provide legal grounds for surveillance and control of the diseases identified as relevant by KFVA*
- ✓ Deliverable 50: Revision of Administrative Instruction on ovine and bovine Brucellosis.
 - ✓ Deliverable 51: Revision of Administrative Instruction on bovine Tuberculosis.
 - ✓ Deliverable 52: Revision of Administrative Instruction on Foot and Mouth Disease.
 - ✓ Deliverable 53: Revision of Administrative Instruction on Enzootic Bovine Leucosis.
 - ✓ Deliverable 54: Revision of Administrative Instruction on Avian Influenza.
 - ✓ Deliverable 55: Revision of Administrative Instruction on African and Classical Swine Fever.
 - ✓ Deliverable 56: Revision of Administrative Instruction on Q-fever.
 - ✓ Deliverable 57: Revision of Administrative Instruction on American and European Foulbrood bee diseases.
 - ✓ Deliverable 58: Revision of Administrative Instruction on Rabies.
 - ✓ Deliverable 59: Revision of Administrative Instruction on Fish diseases (Viral hemorrhagic septicemia (VHS) and Infectious hematopoietic necrosis (IHN)).
 - ✓ Deliverable 60: Drafting of Administrative Instruction on Zoonotic Vector Borne Diseases.
 - ✓ Deliverable 61: Revision Administrative Instruction on Identification and Registration of animals.
 - ✓ Deliverable 62: Revision Administrative Instruction on Technical Conditions to be met by temporary care centers for stray animals.
- l) *Kosovo Food and Veterinary Agency and local authorities effectively supported in preparing and implementing a sustainable action plan for stray dog control as well as owned dogs, having in focus prevention and eradication of rabies*
- ✓ Deliverable 63: Detailed report on stray dog problem in Kosovo, including estimated number of stray dogs per municipality.
 - ✓ Deliverable 64: Stray Dog Control Program prepared, including provisions for shelters, identification of dogs with owners and rabies vaccination programme. This programme should be tailor made to suit the situation and capacities of municipalities to deal with this issue.
 - ✓ Deliverable 65: Drafting of an Action plan for control of stray dogs, including measures to be undertaken, time frame for implementation of measures and cost estimate.
 - ✓ Deliverable 66: Identification and registration of owned dogs with microchips (10,000 owned dogs with microchips). The contractor has to purchase 10,000 microchips, 200 readers for microchips and secure implanting of the microchips procured. Private veterinary practices shall be used in this regard and the costs related to this task shall be covered under this contract.
 - ✓ Deliverable 67: Proposal and cost estimate for annual vaccination of owned dogs. More specifically, the contractor, based on number of dogs with owners identified under Deliverable 64, will include an estimate total cost of vaccination against rabies and treatment against echinococcus disease.
 - ✓ Deliverable 68: Vaccination against Rabies and echinococcosis diseases of an indicative number of 10,000 dogs, to be carried out with private veterinary services (private veterinarians). The contractor will cover the costs of vaccination, while the costs of vaccines will be covered by Kosovo Food and Veterinary Agency. Subject to the actual number of dogs in need for such vaccination at the time of implementation, and subject to available financial

resources under the budget approved for the contract, the number of dogs vaccinated under the contract could be larger than 10,000.

- ✓ Deliverable 69: Development of software program and provision of the IT support necessary for identification and registration of dogs with owners.

m) Increased awareness on the importance of disease control and eradication

- ✓ Deliverable 70: Public education and information campaign¹⁰ with focus on Animal Health and Welfare and Farm Management (target group: farmers). Education campaign shall include:

- Training of minimum 350 farmers in 7 regions of Kosovo through 1-day workshops for each region (minimum 1 workshop/region);
- Dissemination of minimum 3000 brochures and leaflets, which will be available in Albanian and Serbian languages;
- Media campaign, twice a year, lasting minimum 3 weeks each time.

- ✓ Deliverable 71: Public education and information campaign¹¹ with focus on Animal Welfare, and a particular emphasis on stray dog management, pet keeping, and registration of owned dogs, through:

- training of minimum 50 persons, including dog breeders, pet shop owners, private veterinary practices, municipal officials dealing with stray dog management, civil society for protection of animal rights and welfare, Food and Veterinary Agency's staff;
- dissemination of minimum 1000 brochures and leaflets which will be available in Albanian, Serbian and English;
- Media campaign, twice a year, lasting 3 weeks each time.

n) Detection and reporting of animal/livestock disease in Kosovo well developed

- ✓ Deliverable 72: Early warning system for detection and reporting of animal/livestock disease, which are notifiable according to the World Organization for Animal Health (OIE) and Kosovo Veterinary Law set up.

o) A "roadmap" to serve as basis for transposition, implementation and enforcement of the EU acquis under Chapter 12 – Food Safety, Veterinary, Phytosanitary prepared

- ✓ Deliverable 73: GAP analysis regarding the legislation covering the areas of animal health, animal welfare, and food safety. Previous GAP analysis regarding food safety will be taken into account, as carried out with previous EU financial assistance¹². As far as animal health, the new Animal Health Regulation of the EU, which will enter into force on 21 April 2021 should be taken into account and transposed¹³.

- ✓ Deliverable 74: Strategy and Action Plan for drafting the missing legislation and transposition of the legislation in force drafted.

¹⁰ Contractor should detail in the methodology the elements of the campaign

¹¹ Contractor should detail in the methodology the elements of the campaign

¹² See details in section 1.5

¹³ See deliverable 76 for details

- The Strategy and Action Plan will serve as a basis for transposition, implementation and enforcement of the Chapter 12 of the EU acquis and provide detailed timeline for the gradual alignment, as well as an estimation of the costs for enforcement of the legislation in the following areas: general food safety, veterinary policy, placing on the market of food, feed and animal by-products, specific food safety rules, specific feed safety rules, phytosanitary policy, genetically modified organisms. The Action Plan will serve as basis for monitoring of the progress towards alignment/approximation to Chapter 12.

p) Legislation required under Chapter 12 – Food Safety, Veterinary, Phytosanitary prepared or updated

- ✓ Deliverable 75: Food Law amended and updated in line with EU acquis.
- ✓ Deliverable 76: New Veterinary Law prepared in line with the EU acquis (note: the existing Veterinary Law is very old (since 2003), hence it should be fully revised and approximated with new Regulation (EU) 2016/429 Animal Health Law (this Regulation will enter into force on 21 April 2021).
- ✓ Deliverable 77: Administrative Instruction on health conditions for animal by-products not intended for human consumption in line with EU aquis.
- ✓ Deliverable 78: Administrative instruction on animal welfare at the farm, during transport and slaughtering in line with EU aquis.

Note: achievement of the deliverables 75-78 will include direct expert input and on-the-job training on drafting and transposing the legislation covering the areas of animal health, animal welfare, plant health, and food safety for the relevant administrative staff such as the members of the permanent Working Group on approximation/alignment to Acquis Chapter 12.

q) Implementation of the administrative instruction on health conditions for animal by-products not intended for human consumption effectively supported

- ✓ Deliverable 79: Standard Operating Procedure for implementation of the administrative instruction on health conditions for animal by-products not intended for human consumption.

r) Kosovo Food Safety Laboratory trained on specific topics in the area of food and feed safety

- ✓ Deliverable 80: Training laboratory staff (including kits and reagents) on:
 - Confirmation testing method of antibiotics in food of animal's origins and feed with High Performance Liquid Chromatography (HPLC) and Liquid Chromatography – tandem Mass Spectrometry (LC-MS/MS) (three (3) laboratory staff).
 - Confirmation testing method of additives in food with High Performance Liquid Chromatography (HPLC) (three (3) laboratory staff).
 - Determination pollen in honey with microscope (three (3) laboratory staff).
 - Testing method on Determination sugars in honey with High Performance Liquid Chromatography (HPLC) with Refractive Index Detectors (RID) (three (3) laboratory staff).
 - Testing method of fatty acid with Gas Chromatography – Flame Ionization Detectors (GC-FID) and interpretation of testing results (four (4) laboratory staff).
 - Confirmation testing method of Hormones in meat with Liquid Chromatography – tandem Mass Spectrometry (LC-MS/MS), techniques (four (4) laboratory staff).
 - Confirmation method of mycotoxins in food and feed with Liquid Chromatography – tandem Mass Spectrometry (LC-MS/MS), technique (four (4) laboratory staff).
 - Testing method of Polychlorinated Biphenyls (PCB-s), 3-Monochloro-1,2-propanediol (3-MCPD) with Gas Chromatography – Mass Spectrometry (GC-MS) and interpretation of results (four (4) laboratory staff).
 - Testing method and testing nitrates in food of animal origins and Interpretation of results (four (4) laboratory staff).

- Testing Method on Animal Allergens with Gas Chromatography – Mass Spectrometry (GC-MS) (four (4) laboratory staff).
- Validation of confirmation methods, High Performance Liquid Chromatography (HPLC), Gas Chromatography – Mass Spectrometry (GC-MS), Gas Chromatography – Flame Ionization Detectors (GC-FID), Liquid Chromatography – tandem Mass Spectrometry (LC-MS/MS)(four (4) laboratory staff).
- Method for detection of Staphylococcus including staphylococcal enterotoxins (Staphylococcal Enterotoxin A to Staphylococcal Enterotoxin E, Staphylococcal Enterotoxin G to Staphylococcal Enterotoxin I, Staphylococcal Enterotoxin R to Staphylococcal Enterotoxin T) (four (4) laboratory staff).
- Detection method for Escherichia coli O157:H7 (four (4) laboratory staff).
- Detection method for Shiga – Toxin producing Escherichia coli (non – O157) (STEC) (four (4) laboratory staff).
- Detection method Cronobacter Sakazakii (four (4) laboratory staff).
- Detection method for Staphylococcus Aureus – enterotoxins (four (4) laboratory staff).
- Detection of food microbiology pathogens with Polymerase Chain Reaction (PCR) Techniques (four (4) laboratory staff).

Note: Kosovo Food and Veterinary Agency is responsible to collect and make samples available for the project experts.

s) *Proficiency testing supported for the relevant areas of food and feed safety*

✓ Deliverable 81: Implementation/Delivery of the following Proficiency Tests¹⁴, with direct involvement of the relevant staff of Kosovo Food and Veterinary Agency:

- Proficiency Test on confirmation of antibiotics in food and feed;
- Proficiency Test on determination of additives in food of animal origin;
- Proficiency Test on methods for testing pollen in honey;
- Proficiency Test for determination sugars with High Performance Liquid Chromatography (HPLC) in honey;
- Proficiency Test on testing fatty acids with Gas Chromatography – Flame Ionization Detectors;
- Proficiency Test for hormones in food of animal origin with Liquid Chromatography – tandem Mass Spectrometry (LC-MS/MS);
- Proficiency Test on Contaminants (Aflatoxin M1, Ochratoxin A, Aflatoxin B1, Fusarium toxin- deoxynivalenol (DON), and zearalenone (ZEA), Polychlorinated Biphenyls (PCBs), 3-Monochloro-1,2-propanediol (3-MCPD) with Gas Chromatography – Mass Spectrometry (GC-MS);
- Proficiency Test for nitrates; and
- Proficiency Test for Animal Allergenes with Gas Chromatography – Mass Spectrometry (GC-MS).

Note: One Proficiency Test should be carried out for each method mentioned above. This means that a total of nine (9) Proficiency Tests will be carried out under deliverable 81 during the implementation of the contract that this ToR is part of.

All costs necessary for carrying out these Proficiency Tests should be covered/secured by the contractor, hence included in the price(s) proposed. The costs include both the costs associated to participation of Food and Veterinary Agency's staff in the testing process (e.g. fees for participation in all (9) nine Proficiency Tests) and effective implementation of the proficiency tests themselves (e.g. consumable, referent materials, kits and reagents for testing purposes).

¹⁴ The proficiency tests will be carried out with the Reference Laboratories recognized at EU level for each method/type of proficiency test mentioned

t) *Support development of Kosovo Food and Veterinary Agency's quality management system*¹⁵

- ✓ Deliverable 82: Assessment Report on the existing quality management system and identification of the improvements/revision needed in view of alignment to ISO 17025:2017
 - Based on Assessment report, the contractor shall undertake all necessary activities to prepare Kosovo Food and Veterinary Laboratory for International Accreditation.
- ✓ Deliverable 83: All documents and procedures for implementation of a quality management system in line with ISO 17025:2017
 - The contractor is expected to prepare (either “from scratch” or by revising existing documentation, as necessary) all documents for each step to be followed in aligning Kosovo Food and Veterinary Laboratory to ISO 17025:2017 and establish proper Quality Management System. This work will be based on the Laboratory Information Management System and Document Management System developed with EU assistance under the previous projects.
 - The documentation forming the minimum mandatory requirements as per ISO 17025:2017 will be provided under this deliverable.
- ✓ Deliverable 84: Training of Kosovo Food and Veterinary Laboratory and other relevant staff on Quality Management System
 - The training will comprehensively cover the new Quality Management System (QMS) that secure proper implementation of the ISO 17025 requirements in Kosovo Food and Veterinary Agency. The participants (indicatively 45 staff) will be also trained in drafting/revising all relevant pieces of documentation, in line with the needs for revision.
 - Ten-day (10-day) training in form of internship or study visit for implementation of the Quality Management System based on ISO 17025:2017¹⁶, for two (2) laboratory staff.

3. ASSUMPTIONS & RISKS

3.1. Assumptions underlying the project

- ! Commitment towards EU accession is confirmed throughout the duration of the project.
- ! Kosovo's government allocates adequate funding for sustained control and eradication of priority animal diseases.
- ! KFVA's activities relevant under this contract receive timely and sufficient financing and all staff participating in this contract are timely available for the activities foreseen; this involves sufficient budget allocated to KFVA's Animal Health and Welfare Directorate and Food and Veterinary Laboratory
- ! Qualified veterinarians and/or technicians are available to undergo training and implement plans and measures introduced by the project.

3.2. Risks

- ! Political instability in certain regions of Kosovo could impede full and proper implementation of project activities.
- ! Lack of regional cooperation in control and eradication of transboundary animal diseases.

¹⁵ Note: in case the standard 17025 will be revised during implementation of this project, the last version will be considered in securing the development of KFVA's Quality Management System

¹⁶ Note: in case the standard 17025 will be revised during implementation of this project, the last version will be considered in securing the development of KFVA's Quality Management System

! Present issues due to COVID-19 will continue (e.g. travel restrictions and social distancing requirements) and/or unexpected issues will arise due to COVID-19.

4. SCOPE OF THE WORK

4.1. General

4.1.1. Description of the assignment

This project aims at supporting approximation of Kosovo's national legislation with the EU acquis chapter 12- Food safety, Veterinary and Phytosanitary, as well as at strengthening further Kosovo Food and Veterinary Agency's (KFVA's) capacities to perform its duties, with a particular focus on the animal health.

KVFA is the biggest executive agency in Kosovo, acting under the responsibility of the Prime Minister's Office in three main areas, namely (1) food safety; (2) animal health and animal welfare; and (3) plant health, including plant protection and production.

While much progress has been achieved in terms of organization, staffing and operation of the agency and its laboratories, much remains to be done in upgrading its capacities for planning and implementing control programs, as well as for increasing the range of services provided by its staff and the quality of these services. This is particularly evident when it comes to designing and implementing disease control and eradication programs in the area of animal health. Proper disease surveillance, monitoring and implementation of disease control and eradication programs require not only scientific and organizational capacities within the KVFA, but also good knowledge and proper training for the private veterinarians and private veterinary technicians who implement these programs on behalf of KFVA and are on the front line for animal disease detection and reporting.

The project will provide assistance to the staff of KFVA's Animal Health and Welfare Directorate and private veterinarians in a range of subject areas, as detailed in the specific work section. Furthermore, selected staff of the animal health and welfare directorate (3 staff) will receive long-term training on veterinary epidemiology and disease control and management. The contractor is expected to prepare a detailed surveillance plan for a number of diseases which are notifiable according to OIE - World Organization for Animal Health and Kosovo's legislation in force, as outlined under the specific work.

With regards to Food and Veterinary Laboratory, the main issue remains increase of the range of tests performed and also proficiency and quality control (Quality Management System QMS)). Food and Veterinary Laboratory is well equipped and staffed. Nevertheless, the tests and analyses performed are limited due to the limited technical capacities of the staff. Moreover, the laboratory does not have certified quality control in place although several preconditions for introduction of quality control and management systems are in place. The laboratory was provided with the quality control manuals under a previous EU project, while the Laboratory Information System (LIMS) will be finalized under the EU funded project «*Support to Kosovo Veterinary and Food Agency (KVFA) in upgrading and functionalizing information technology systems and increasing its capacity to implement an integrated approach to food safety*» which establishes the IT infrastructure for KVFA and is expected to end in June 2021. It is therefore expected that project team implementing the contract that this ToR is part of will have the possibility to introduce additions or modifications that might prove necessary in order to have a LIMS fully in line with the ISO (ISO 17025:2017 or the updated version, of an updated version will be issued during implementation of this contract), as well as preparation of the laboratory for international accreditation by an international accreditation body.

A particular problem faced by Kosovo in the veterinary area is created by the massive number of stray dogs which generates significant concerns from both public health and animal welfare perspectives. According to the legislation in force, KVFA provides legal tools and policy advice on how to address the stray dog issue. Nevertheless, the actual management of the stray dogs and cats is with the municipalities. A number of actions and initiatives have been undertaken so far to solve this problem. Nevertheless, their impact is very limited, mainly due to the fact that the actual work has been focused on reducing the number of stray dogs on short-term, rather than establishing proper strategy and action plan on how to address the problem on long term. Establishment of permanent dog shelters in different municipalities, awareness and education of dog owners and general public, identification and regular vaccination of owned dogs are some of the areas that require to be addressed. They will be all considered under this project.

In relation to alignment with the chapter 12 of the acquis, most of the legal acts adopted were crosschecked for compliance with the acquis with the tables of transposition in the last ten years. Nevertheless, the EU legislation on this area was subject to major modifications, updates and introduction of new rules and regulations. Kosovo Food and Veterinary Agency, Ministry of Agriculture and Ministry of Health do not

have the system and knowledge to follow on these changes and revise accordingly the national legislation. Furthermore, despite significant progress made, a number of missing legal acts have to be prepared and adopted. Furthermore, Food Law and Veterinary Law are in force since 2002 and 2003, respectively, without ever undergoing the revisions required for approximating with the relevant EU regulations. The project foresees to solve this problem through preparation of the missing pieces of legislation and revision of the existing ones, with the view to ensure a comprehensive approximation of the national legislation with the Chapter 12 of the EU acquis. Furthermore, the relevant staff of Kosovo Food and Veterinary Agency and the Ministry of Agriculture will be trained on how to plan, monitor, prepare and transpose legal acts after the project ends.

4.1.2. Geographical area to be covered

The entire territory of Kosovo

4.1.3. Target groups

The direct beneficiary is Kosovo Food and Veterinary Agency (KFVA).

Other important beneficiaries are the Ministry of Agriculture and Kosovo's Municipalities. It will be decided during implementation if involvement of other beneficiaries, such as the Ministry of Health and/or the Ministry of Environment is recommendable.

4.2. Specific work

In view of achieving its purposes, the project will target a number of results and deliverables which are presented in detail in section 2.3. They involve the following activities:

- a) *5-year Development Plan for the Animal Health Section of KFVA's Department of Animal Health and Welfare.*
 - The plan will comprise a training programme for Animal Health and Welfare Directorate, Veterinary Inspectors, Private Veterinary Practitioners, as well as an estimation of the annual budgetary needs of the Animal Health and Welfare Directorate, including for implementation of the animal health measures foreseen in the plan. It will also include a budget for training and simulation exercises for a 5-year period.
- b) *Surveillance and vaccination programme revised or prepared for the diseases identified by KFVA and those for which reporting is compulsory (see section 2.3 for details)*
 - Collection of samples regarding surveillance as well as the vaccination programme shall be done by the Food and Veterinary Agency, covering all costs. The contractor is responsible for preparing the program, including determination of sample size etc.
- c) *Surveillance programme(s) for the animal diseases selected by KFVA effectively supported by the contractor of this project to be carried out by Kosovo Food and Veterinary Agency as planned under the Deliverable 1.*
 - Surveillance will be carried out annually (3 times during the implementation of the project).
 - Collection of samples regarding surveillance as well as the vaccination programme shall be done by the Food and Veterinary Agency, covering all costs. The contractor is responsible for preparing the program, including determination of sample size etc.
- d) *Eradication programs prepared, including cost benefit analysis, for Brucellosis (ovine and bovine), bovine tuberculosis and enzootic bovine leucosis*

- e) *Guidance to decision makers in securing proper surveillance, control and eradication of animal diseases*
- f) *Assessment of the Animal Health Laboratory's resources available, in terms of human resources, kits, reagents and equipment*
- g) *Training of Kosovo Food and Veterinary Agency's staff*
- h) *Training¹⁷ of Private Veterinary Practitioners (e.g. private veterinarians and veterinary technicians)*
- i) *Manual on disease identification, control and reporting*
 - One manual will be prepared for all notifiable animal diseases according to The World Organization for animal Health (OIE) and Kosovo legislation in force. The manual will be prepared in English and translated into Albanian and Serbian. An indicative number of 2 (two) such manuals are expected to be printed in English, while the number of copies translated into Albanian and Serbian will be 200 in each language.
- j) *Support proficiency testing for the diseases identified by KFVA*
- k) *Simulation exercises for control of outbreak of selective infective diseases effectively carried out*
- l) *Revision or drafting of Administrative Instructions on animal disease control to provide legal grounds for surveillance and control of the diseases identified as relevant by KFVA*
- m) *Kosovo Food and Veterinary Agency and local authorities effectively supported in preparing and implementing a sustainable action plan for stray dog control as well as owned dogs, having in focus prevention and eradication of rabies*
- n) *Increased awareness on the importance of disease control and eradication*
- o) *Detection and reporting of animal/livestock disease in Kosovo well developed*
- p) *A "roadmap" to serve as basis for transposition, implementation and enforcement of the EU acquis under Chapter 12 – Food Safety, Veterinary, Phytosanitary prepared*
 - The Strategy and Action Plan will serve as a basis for transposition, implementation and enforcement of the Chapter 12 of the EU acquis and provide detailed timeline for the gradual alignment, as well as an estimation of the costs for enforcement of the legislation in the following areas: general food safety, veterinary policy, placing on the market of food, feed and animal by-products, specific food safety rules, specific feed safety rules, phytosanitary policy, genetically modified organisms. The Action Plan will serve as basis for monitoring of the progress towards alignment/approximation to Chapter 12.
- q) *Legislation required under Chapter 12 – Food Safety, Veterinary, Phytosanitary prepared or updated*

¹⁷ Contractor should ensure all consumables

- Note: achievement of this deliverable will include direct expert input and on-the-job training on drafting and transposition of the national legislation covering the areas of animal health, animal welfare, plant health, and food safety for the relevant administrative staff (e.g. members of the permanent Working Group on approximation/alignment to Acquis Chapter 12).
- r) *Implementation of the administrative instruction on health conditions for animal by-products not intended for human consumption effectively supported*
- s) *Kosovo Food Safety Laboratory trained on specific topics in the area of food and feed safety*
- Note: Kosovo Food and Veterinary Agency is responsible to collect and make samples available for the project experts.
- t) *Proficiency testing supported for the relevant areas of food and feed safety*
- All costs necessary for carrying out these proficiency tests should be covered/secured by the contractor, hence included in the price(s) proposed. The costs include both the costs associated to participation of Food and Veterinary Agency's staff in the testing process (e.g. fees for participation in all (9) nine proficiency tests) and effective implementation of the proficiency tests themselves (e.g. consumable, referent materials, kits and reagents for testing purposes).
- u) *Support development of Kosovo Food and Veterinary Agency's quality management system*

4.3. Project management

4.3.1. Responsible body

The contracting authority is the European Union Office in Kosovo, which is responsible for managing this contract.

4.3.2. Management structure

The Contracting Authority will establish the Project Steering Committee (PSC). The function of the PSC will be to guide the contractor in achieving its tasks, monitor progress of the project activities, and ensure timely achievement of results as set out in these ToRs.

The contractor will ensure the provision of secretarial and administrative support. The Project Steering Committee will meet first at the end of the Inception phase (within 45 days after the contract commencement date) and continue to meet on a quarterly basis, as well The Team Leader shall submit all progress reports, on behalf of the contractor. The reports include the inception report, quarterly progress reports and the final report. All relevant progress reports have to be sent to the members of the Project Steering Committee at least two weeks prior to each Steering Committee meeting , together with the meeting agenda.

4.3.3. Facilities to be provided by the contracting authority and/or other parties

The contracting authority and Kosovo Food and Veterinary Agency will assist the contractor in obtaining the staff permits, authorizations and licenses/permits required for performance of the services expected under this contract.

The beneficiary institution(s) will provide free of charge all existing available information, data and reports and assist the contractor in obtaining other relevant pieces of information and materials that

prove necessary in performing the contract and belong to other institutions and/or authorities. Nevertheless, it is the contractor's responsibility to check availability, quality, and suitability of the necessary information/documentation. The contractor will have access to the available information/documentation for unlimited use during the entire period of implementation. The contractor shall arrange for the translation of any document necessary in view of performing the contract, as applicable.

The contractor shall make its own arrangements related to office equipment, including computers, necessary software, printers, photocopiers, e-mail connection, translation, interpretation etc.

5. LOGISTICS AND TIMING

5.1. Location

The project will be based in Prishtina, but local travelling within the country will be required for the purpose of conducting project activities.

5.2. Start date & period of implementation of tasks

The intended start date is May 2021 and the period of implementation of the contract will be 36 months from this date. Please see Articles 19.1 and 19.2 of the special conditions for the actual start date and period of implementation.

6. REQUIREMENTS

6.1. Staff

Note that civil servants and other staff of the public administration of the partner country, or of international/regional organisations based in the country, shall only be approved to work as experts if well justified. The justification should be submitted with the tender and shall include information on the added value the expert will bring as well as proof that the expert is seconded or on personal leave.

6.1.1. Key experts

Key experts are defined and they must submit CVs and signed statements of exclusivity and availability.

All experts who have a crucial role in implementing the contract are referred to as key experts. The profiles of the key experts for this contract are as follows:

Key expert 1: Animal Health expert

Qualifications and skills

- A Master Degree (where a University degree has been awarded on completion of studies in a University or equivalent institution) in medicine, animal husbandry, biology, veterinary science, zoology, or agricultural science, preferably in veterinary medicine or veterinary science, or additional 7 years of relevant experience in addition to the minimum required as "general experience". A PhD is an advantage.

General professional experience

- At least 7, preferably 10 years of experience, in the veterinary sector, accumulated in the last 20 calendar years, preferably within national¹⁸ or EU veterinary authorities.

¹⁸ The term "national" in definition of the expertise required for the key experts involved in this contract, refers to the authorities of the EU Member States or EU candidate countries or EU potential candidates

Specific professional experience

- At least 5, preferably 7 years, of professional experience in the field of design or implementation of animal health policy in line with the EU acquis, accumulated in the last 20 calendar years, preferably within national or EU veterinary authorities.
- At least 1, preferably 3 years of experience in designing or implementing animal health policy in the European Union or EU candidate countries or EU potential candidates, accumulated in the last 10 years.
- Experience in EU projects financed in the EU pre-accession context in the veterinary area is preferred.
- Experience in the Western Balkans represents an advantage.

Key expert 2: Legal expert

Qualifications and skills

- A Master Degree (where a University degree has been awarded on completion of studies in a University or equivalent institution) in law, veterinary medicine, veterinary science, animal husbandry, biology, zoology, agricultural science, food science, food technology, agronomy, horticulture, or botany, preferably in law, or additional 7 years of relevant experience in addition to the minimum required as “general experience”. A PhD represents an advantage.

General professional experience

- At least 7, preferably 10 years of experience, in drafting legislation in the European Union or an EU candidate country or potential EU candidate, accumulated in the last 20 calendar years

Specific professional experience

- At least 1, preferably 3 years of experience, in drafting legislation in line with the EU acquis in the areas addressed by Chapter 12: food safety, veterinary, phytosanitary, accumulated in the last 10 years.
- Experience in more sub-sectors of Chapter 12¹⁹ is preferred²⁰.
- Experience in EU projects financed in the EU pre-accession context in the areas addressed by the Chapter 12 of the EU acquis is preferred.
- Experience in the Western Balkans is an advantage.

One of the two key experts will act as Team Leader, having responsibilities regarding planning and coordination of the project activities carried out under the contract, quality assurance for deliverables foreseen under the contract, communication with the beneficiary institution Kosovo Food and Veterinary Agency (KFVA) and Contracting Authority (EU Office in Kosovo), and reporting. Appointment of the Team Leader is subject to the contractor’s decision.

All experts must be independent and free from conflicts of interest in the responsibilities that they take on.

6.1.2. Other experts, support staff & backstopping

CVs for experts other than the key experts should not be submitted in the tender but the tenderer will have to demonstrate in their offer that they have access to experts with the required profiles. The contractor shall select and hire other experts as required according to the needs. The selection

¹⁹ The sub-sectors of the EU acquis are: food safety, veterinary, and phytosanitary.

²⁰ Maximum score awarded for experience accumulated in all 3 sub-sectors, minimum score awarded for experience accumulated in only one sub-sector, average score awarded for 2 sub-sectors

procedures used by the contractor to select these other experts shall be transparent, and shall be based on pre-defined criteria, including professional qualifications, language skills and work experience.

The costs for backstopping and support staff, as needed, are considered to be included in the tenderer's financial offer.

The profiles of the other experts necessary to successfully implement the project shall be clearly identified in the Organization & Methodology proposed by the contractor. Indicatively, they may include:

- Animal Health experts;
- Veterinary epidemiologists;
- Food, Veterinary and Phytosanitary Inspection experts;
- Laboratory experts with experience in animal disease testing methods and food testing and analysis;
- Laboratory experts with experience in adoption of ISO 17025 quality standard;
- Legislation Experts with experience in the areas for which new/revised pieces of legislation are foreseen;
- Animal welfare experts;
- Economic expert (e.g. for cost-benefit-analysis);
- Communication/public awareness expert (e.g. for public awareness campaigns).

The quality of the expert team proposed will be subject to the scoring of the Organization & Methodology proposed by the contractor.

To be noted that the all experts involved in the project (beside the key experts) must be subject to approval by the contracting authority before the start of their implementation of tasks. In addition, these other experts should have at least a Bachelor and a master degree in the required field of expertise as well as an adequate experience proportionate to the task to be carried out and in any case a minimum of three years of professional experience.

6.2. Office accommodation

Office accommodation for each expert working on the contract is to be provided by the contractor.

6.3. Facilities to be provided by the contractor

The contractor shall ensure that experts are adequately supported and equipped. In particular it must ensure that there is sufficient administrative, secretarial and interpreting provision to enable experts to concentrate on their primary responsibilities. It must also transfer funds as necessary to support their work under the contract and to ensure that its employees are paid regularly and in a timely fashion.

6.4. Equipment

No equipment is to be purchased on behalf of the contracting authority / partner country as part of this service contract or transferred to the contracting authority / partner country at the end of this contract. Any equipment related to this contract which is to be acquired by the partner country must be purchased by means of a separate supply tender procedure.

7. REPORTS

7.1. Reporting requirements

The contractor will submit the following progress reports in English, both in electronic version and printed version. The printed version shall be submitted in one original and three copies:

- **Inception Report** of maximum 20 pages to be produced after 45 days from the start of implementation. In the report the contractor shall describe the work planned under the contract, as well as the initial findings, progress in collecting necessary data and any difficulties encountered or expected. The inception report will be subject of discussion during the first meeting of the Steering Committee and its provisions considered acceptable once the Steering Committee endorses and contracting authority approves it.
- **Annual Interim Reports** will provide a description of the progress in implementation and deliverables achieved, serving as grounds for approval of the interim payments. The narrative section will indicate clearly the deliverables achieved during the reporting period, while the financial report will indicate the corresponding amounts to be paid for each deliverable, in line with the budget approved and subject to prior approval of each deliverable by Kosovo Food and Veterinary Agency. Interim Annual Reports shall be submitted no later than 1 month after the end of period of reporting.
- **Draft final report** of maximum 25 pages (main text, excluding annexes). The draft final report shall be submitted no later than one month before the end of the period of implementation.
- **Final report** will be based on the draft final report and incorporate the comments received from and accepted by the Steering Committee and contracting authority. The deadline for sending the final report is 15 days after receipt of the comments on the draft final report sent and agreed by the members of the Steering Committee and contracting authority. The final report will make a clear presentation of the results achieved during implementation, as well as of the extent to which the objectives foreseen under this ToR have been reached. The report will include a section detailing the lessons learnt from implementation and recommendations relevant for the future functioning of the beneficiary institution(s) in the areas addressed by this ToR.

7.2. Submission and approval of reports

The progress reports shall be submitted to the project manager identified in the contract. The project manager is responsible for approving the progress reports, on behalf of the contracting authority and subject to their endorsement by the Steering Committee established for the contract that this ToR is part of.

The members of the Steering Committee will have a maximum of 10 working days (2 weeks) for expressing an opinion on the draft progress reports received from the contractor. The formal representative in the Steering Committee of Kosovo Food and Veterinary Agency will be in charge with consolidation of the comments and recommendations received from the various members of the Steering Committee and submission of these consolidated comments in written form to the contractor, in copy to the EU Office project manager, within 15 working days from the receipt of the draft progress report concerned from the contractor and 5 working days from the meeting of the Steering Committee during which the progress report concerned was subject of discussion and endorsement.

Reports are to be submitted in electronic version to each member of the Steering Committee at least 10 working days before the date when the Steering Committee meeting is planned to take place. The reports are to be prepared in English and translated into Albanian and Serbian language(s).

The contractor shall provide the contracting authority and beneficiary with electronic and printed copies of the documentation/materials prepared under this project in line with the requirements of these two key stakeholders²¹.

²¹ To be clarified during implementation, subject to the actual circumstances at the time of implementation

8. MONITORING AND EVALUATION

8.1. Definition of indicators

Project monitoring and evaluation will be based on the assessment of the achievement of the deliverables foreseen, with due consideration of the planning proposed in the Organization & Methodology, as well as of the quality of the deliverables produced under the contract.

8.2. Special requirements

N/A