Policy and Legal Advice Centre (PLAC IV)

Terms of Reference (ToR) for a Short-Term assignment
No. 3

Technical assistance requested:	One (1) Senior Non-Key Expert in the area of drafting legislation on control of residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances One (1) Junior Non-Key Expert in the area of drafting an implementing bylaw on the sampling of food, feed and animals with the aim to discover residues of veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances and investigation procedure.
Project Title:	Policy and Legal Advice Centre (PLAC I4)
Ref:	NEAR/BEG/2023/EA-RP/0175
Service Contract No:	(CRIS) 2024/453-315
Main project beneficiary:	Ministry of European Integration (MEI)
Direct beneficiary of the assignment:	Ministry of Agriculture, Forestry and Water Management (MAFWM)
Content of the assignment:	Technical assistance to ensure the drafting of legislation on the control of residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances and the procedure to follow.
Budget Line/Expert category	Non-Key Short-Term Senior Expert Non-Key Short-Term Junior Expert
Duration of the assignment	Senior NKE 25 working days and Junior NKE 20 working days, to be spent in the period October 2024 - February 2025

1. Background information in relation to PLAC IV project

The overall objective of the PLAC IV is for the Serbian administration to effectively conduct accession negotiations and successfully manage overall EU integration and pre-accession assistance geared towards EU membership.

The project's purpose is "to achieve a high level of effective alignment of national legislation with the Union acquis and its implementation".

PLAC IV should achieve two results:

- R1: Enhanced compatibility of national legislation with EU legislation and its effective implementation.
- R2: Enhanced capacities of relevant national structures for successful carrying out of accession negotiations

Food Safety, Veterinary and Phytosanitary Policy and EU hygiene rules for foodstuff production ensure high food safety. Animal health and welfare, as well as the safety of food of animal origin, are safeguarded together with the quality of seeds, plant protection material, protection against harmful organisms, and animal nutrition.

The EU acquis in the above-mentioned field consists of many regulations, directives, and decisions. The acquis reflects the EU's integrated approach to a high level of food safety, with farm-to-table measures and requirements aimed at reaching a high level of animal and plant health protection and adequate monitoring throughout the internal market.

Each Member State must have appropriate administrative structures, including proper laboratory capacity, to implement food safety legislation and rules in the area of veterinary and phytosanitary policy. These structures must be in place to carry out inspections and control of food products.

As an EU candidate country, the Republic of Serbia must meet the Union's standards to ensure that its agricultural products and foodstuffs are safe for human consumption and compliant with EU legislation. To achieve this, the Republic of Serbia needs to adopt and enforce appropriate regulations and measures aligning with EU standards.

After adopting the Screening Report for Chapter 12, the EU Council informed the Republic of Serbia that it is not ready to open negotiations in this chapter and that three opening benchmarks must be met.

The 1st opening benchmark (OB1) refers to the adoption of a legislative framework aligned with the Union acquis; the 2nd opening benchmark concerns the preparation of a comprehensive national strategy with an action plan specifying deadlines which will serve as a basis for the transposition, implementation and application of the Union acquis, including a contingency plan for classical swine fever (OB2); the 3rd opening benchmark concerns the classification of all food establishments and all establishments handling animal by-products (OB3). Chapter 12 is one of the most demanding parts of the Union acquis because of a wide range of legislation that has to be transposed and implemented.

Besides the demanding rules for animal and plant health and the safety of food, feed and animal products, most provisions require a significant investment in food establishments, agriculture, and biosecurity measures representing trade challenges. The Republic of Serbia is intensively preparing for negotiations with the EU regarding Chapter 12 – Food Safety, Veterinary and Phytosanitary Policy. Some progress has been made in further aligning with the acquis, strategic planning and addressing the recommendations from EC's Annual progress report.

During the EU accession process, a multiannual plan for adopting and transposing the EU acquis is prepared, which the candidate country institutions need to follow. However, legislation needs to be harmonised without delay in certain areas, such as food safety, public health, and trade with the EU.

Veterinary medicines may be used to treat food-producing animals to prevent or cure disease. These medicines contain pharmacologically active substances that may leave residues in the food of treated animals. Food may also contain residues of pesticides and contaminants to which animals have been exposed. In all cases, food residue levels should not harm the consumer.

The obligations of non-EU countries exporting food of animal origin to the EU must also include implementing control plans for residues of pharmacologically active substances, pesticides, and contaminants, guaranteeing an equivalent level of food safety.

Taking into account that legislation in the EU has changed in previous years and that for drafting and implementation of control plans for residues of pharmacologically active substances, competent institutions must have proper legislation, there is an urgent need to prepare the national legislation based on the following EU legislation:

- Commission Delegated Regulation (EU) 2022/1644
- Commission Implementing Regulation (EU) 2022/1646
- Regulation (EU) 2021/808 - Rules for validating analytical methods used in the residue control plan and official sample treatment.

There is no overlapping between this Project and any ongoing and/or planned assistance projects for the activities covered by this ToR.

2. Description of the assignment

a. Specific objectives

The specific objective of this assignment is to provide expert assistance to the beneficiary in drafting legislation covering residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances to ensure alignment with the Union acquis.

Drafting Instructions for sampling and conducting investigations is needed as a tool for inspectorates to facilitate the implementation of rules stipulated in the targeted legislation.

b. Requested services

The requested Senior and Junior NKEs are expected to provide the following services:

a) To assist the beneficiaries in drafting a legal act on control of residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances

b) To assist the beneficiaries in drafting the Instructions for sampling food, feed, and animals to discover residues of veterinary medicinal products, feed additives or residues of prohibited or unauthorised pharmacologically active substances and investigating procedures.

c) To develop, organise and implement a workshop to present the target beneficiary (MAFWM employees in charge of implementing the drafted Instruction).

c. Outputs

The outputs delivered by the NKEs shall be as follows:

1. A legal act on control of residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances drafted;
2. The Instructions for sampling food, feed, and animals to discover residues of veterinary medicinal products or as feed additives or residues of prohibited or unauthorised pharmacologically active substances and the investigation procedure have been drafted.

d. Reporting

The NKE shall provide the following reports by using the templates of the Project:

- Brief Mission Report with a description of activities and outputs provided at the end of each month, in which tasks under this assignment have been carried out,
- Final Mission Report, no later than one week after completing tasks under this assignment. This report will include a description of all activities and outputs provided by the NKE in the context of this assignment.

Submission of reports:

- All reports prepared with the relevant quality shall be submitted to the Project Team Leader for review, comments, and final approval. The reports shall be signed by the NKE and the Team Leader responsible for endorsing them.
- The reports and all prepared documents shall be submitted to the project Team Leader in hard copy and electronic form.

e. Specifics

Both NKEs shall collaborate with the Project Technical Assistance Team during the assignment. The senior NKE is responsible for coordinating work and deliverables. The Team Leader may adjust the NKE's activities and outputs mentioned above at any stage in the project's implementation, depending on the evolving needs of the Project and the main beneficiary.

The Senior NKE shall ensure that drafting activities and the workshop implementation are aligned with the Ministry of Agriculture, Forestry and Water Management. The Senior NKE shall closely coordinate the activities with assigned representatives of the institutions and others, as relevant, to ensure that aspects related to implications of EU integration for Serbia are incorporated into all activities carried out by the Project.

3. Expert's input

Total working days	25 Senior and 20 Junior working days (WDs) have been planned for this assignment. An additional number of WDs may be allocated for this ToR should the needs of the main beneficiary require an extension for the activity areas mentioned in this ToR.
Period of the assignment	October 2024 – February 2025
Starting day	The work is expected to be performed from October 2024 onwards. However, the exact starting date will be agreed upon later.
Location/place of assignment	The base of operation will be in Belgrade, Serbia, and the Project will provide office facilities.
Working language	English

4. Expert's profile

Senior NKE	
Qualification and skills (25 points)	• A level of education corresponding to completed university studies of at least 3 years attested by a diploma in veterinary, food safety, law, agriculture, or something other relevant to the assignment • Computer literacy • Be proficient in report drafting • Excellent communication and analytical skills • Proficiency in English language • Be independent and free from conflicts of interest in the responsibilities they take on
General professional experience (25	• At least 8 (eight) years of general postgraduate

points)	professional experience related to the Union acquis, gained in an EU member state, candidate or potential candidate country.
Specific professional experience (50 points)	• At least 5 (five) years of postgraduate professional experience in an EU member state or candidate country related to harmonising legislation on medical, preferably veterinary products, gained in an EU member state, candidate, or potential candidate country. • Postgraduate professional experience in developing a system of official controls of residues of pharmaceutically active substances in line with the Union acquis requirements gained in an EU member state, candidate or potential candidate country; • Professional experience in the transposition and/or implementation of Commission Delegated Regulation (EU) 2022/1644 and Implementing Regulation (EU) 2022/1646 gained in an EU member state or candidate country will be an advantage; • Previous professional experience and/or knowledge of the Serbian legal system will be an advantage.

Junior NKE	
Qualification and skills (25 points)	• A level of education corresponding to completed university studies of at least 3 (three) years attested by a diploma in veterinary, food safety, law, agriculture, or something other relevant to the assignment • Computer literacy • Be proficient in report drafting • Excellent communication and analytical skills • Proficiency in English language • Be independent and free from conflicts of interest in the responsibilities they take on.
General professional experience (25	• At least 5 (five) years of general postgraduate

points)	professional experience related to the Union acquis, gained in an EU member state, candidate or potential candidate country.
Specific professional experience (50 points)	• At least 3 (three) years of postgraduate professional experience in an EU member state or candidate country related to harmonising legislation on medical, preferably veterinary products. • Postgraduate professional experience in the veterinary field of an EU member state or candidate country will be an advantage. • Previous professional experience and/or knowledge of the Serbian legal system will be an advantage.

5. Applications

Applications (EU format CV and application letter, both in English) need to be submitted by e-mail to domi@ibf.be with a copy to bortolameazzi@ibf.be than **17:00 hrs; 20th September 2024**, 2024, titled: "Application for the position – Senior Non-Key Expert in the area of Ch. 9.

References must be available on request. Only short-listed candidates will be contacted.

The Project is an equal-opportunity employer that encourages applications from women and minorities. All applications will be considered strictly confidential.

The advertised post is not available to civil servants or other officials of the public administration in the beneficiary country, Serbia.

For more information, please contact the Project Director at IBF: bortolameazzi@ibf.be .