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ANNEX III

to the Commission Implementing Decision on the Annual Action Plan in favour of the Republic of Albania for year 2024

Action Document for EU for Food Safety

ANNUAL ACTION PLAN

This document constitutes the annual work programme in the sense of Article 110(2) of the Financial Regulation, and annual and multiannual action plans and measures in the sense of Article 9 of IPA III Regulation and Article 23(3) of NDICI - Global Europe Regulation.

1. SYNOPSIS

1.1. Action Summary Table

Title	EU for Food Safety
	Annual Action Plan in favour of the Republic of Albania for year 2024
OPSYS	OPSYS business reference: ACT-62390
ABAC	ABAC Commitment level 1 number: JAD.1354182
Basic Act	Financed under the Instrument for Pre-accession Assistance (IPA III)
Economic and Investment Plan (EIP)	Yes Priority: Common Regional Market and European Integration
EIP Flagship	No
Team Europe	No
Beneficiar(y)/(ies) of the action	The action shall be carried out in Albania
Programming document	IPA III Programming Framework
	PRIORITY AREAS AND SECTOR INFORMATION
Window and	Window 4: Competitiveness and inclusive growth
thematic priority	Thematic Priority 3: Agriculture and rural development
Sustainable Development Goals (SDGs)	Main SDG: 2 - End hunger, achieve food security and improved nutrition and promote sustainable agriculture
	Other significant SDGs and where appropriate, targets:
	SDG 12: Ensure sustainable consumption and production patterns

DAC code(s)	Main DAC code: 311 – Agriculture							
	Sub-code 1: 31110 - Agricultural		istrative manag	gement				
	Sub-code 2: 31192 - Plant and post-harvest protection and pest control							
	Sub-code 3: 31195 - Livestock/ve	terinary services	-					
	Main DAC code : 430 – Other mu	ltisector						
	Sub-code 1: 43073 - Food safety a	and quality						
Main Delivery Channel	12000 - Recipient Government (12	12000 - Recipient Government (12001- Central Government)						
Targets	□ Climate							
	□ Gender							
	□ Biodiversity							
Markers (from DAC form)	General policy objective	Not targeted	Significant objective	Principal objective				
	Participation development/good governance		\square					
	Aid to environment	\boxtimes						
	Gender equality and women's and girl's empowerment							
	Reproductive, maternal, new- born and child health							
	Disaster Risk Reduction	\boxtimes						
	Inclusion of persons with Disabilities							
	Nutrition		\boxtimes					
	RIO Convention markers	Not targeted	Significant objective	Principal objective				
	Biological diversity	\boxtimes						
	Combat desertification	\boxtimes						
	Climate change mitigation	\boxtimes						
	Climate change adaptation	\boxtimes						
Internal markers and Tags	Policy objectives	Not targeted	Significant objective	Principal objective				
	EIP		\boxtimes					
	EIP Flagship	YES	·	NO				
				\boxtimes				
	Tags:	YES		NO				
	Transport			\boxtimes				

	Energy			\boxtimes		
	Environment and climate resilience			\boxtimes		
	Digital			\boxtimes		
	Economic development (incl. private sector, trade and macroeconomic support)	\boxtimes				
	Human Development (incl. human capital and youth)			\boxtimes		
	Health resilience			\boxtimes		
	Migration and mobility			\boxtimes		
	Agriculture, food security and rural development	\boxtimes				
	Rule of law, governance and Public Administration reform			\boxtimes		
	Other	\boxtimes				
	Digitalisation	\boxtimes				
	Tags	YES		NO		
	digital connectivity			\boxtimes		
	digital governance			\boxtimes		
	digital entrepreneurship			\boxtimes		
	digital skills/literacy			\boxtimes		
	digital services			\boxtimes		
	Connectivity	\boxtimes				
	Tags	YES		NO		
	digital connectivity			\boxtimes		
	energy			\boxtimes		
	transport			\boxtimes		
	health	\boxtimes				
	education and research					
	Migration	\boxtimes				
	Reduction of Inequalities	\boxtimes				
	COVID-19	\boxtimes				
	BUDGET INFORM	MATION				
Amounts concerned	Budget line: 15.020201					
	Total estimated cost: EUR 12 500 (000				
	Total amount of EU budget contrib	ution EUR 12 50	000 000			
MANAGEMENT AND IMPLEMENTATION						

Implementation modalities (management mode and delivery methods)	Indirect management with the entity(ies) to be selected in accordance with the criteria set out in section 4.3.1
Final Date for conclusion of Financing Agreement	At the latest by 31 December 2025
Final date for concluding contribution / delegation agreements, procurement and grant contracts	3 years following the date of conclusion of the financing agreement, with the exception of cases listed under Article 114(2) of the Financial Regulation
Indicative operational implementation period	72 months following the conclusion of the Financing Agreement
Final date for implementing the Financing Agreement	12 years following the conclusion of the financing agreement

1.2. Summary of the Action

Instrument for Pre-Accession Assistance (IPA III) Programming Framework for the period 2021-2027 sets as one of a priority progressive alignment with the European Union (EU) legal framework in the field of the relevant veterinary, food safety and phytosanitary standards (SPS standards). It is underlined that major efforts are still necessary for food safety, animal welfare and the transition towards sustainable food systems, being increasingly important in view of the necessary alignment with the EU food safety *acquis* and the EU Farm to Fork Strategy¹, which is at the heart of the EU Green Deal² aiming to make food systems fair, healthy and environmentally friendly. It should also provide support for institution building' and thus help to ensure the application of good governance standards of a modern public administrations at all level in order to meet the EU accession requirements. This entails continuing the support for the alignment with and the implementation of the EU legal framework of the relevant SPS standards, including overall well-functioning control systems and accredited laboratories.

The aim of the Action is to support Albanian institutions in aligning and implementing EU legislation and best practices in the area of food safety, veterinary and phytosanitary policy which became increasingly important after opening of the accession negotiations in 2022.

This will be achieved through the improvements of physical infrastructure (laboratory and regional offices) and further strengthening of administrative capacities in this sector.

¹ Farm to Fork Strategy - European Commission (europa.eu)

² The European Green Deal - European Commission (europa.eu)

These actions are directly interlinked with SDG 2: End hunger, achieve food security and improved nutrition and promote sustainable agriculture and SDG12: Ensure sustainable consumption and production patterns.

1.3 Beneficiary of the Action

The action shall be carried out in Albania.

2. RATIONALE

2.1. Context

After opening the accession negotiations in June 2022, transposition, implementation and enforcement of the EU *acquis* became the matter of outmost importance for the Albanian food safety, veterinary and phytosanitary administration. The EU is known to have the highest safety and quality requirements and standards in production and processing of agri-food products; It expects therefore that the countries granted access to its common market develop and apply measures equivalent to those of the EU. Development and implementation of such measures in the food safety, veterinary and phytosanitary area requires alignment of national policy and legislation to the requirements of the EU *acquis* and a high level of competence of the administration in charge for implementation of the legislation covering the above areas. More specifically it requires: integrated and reliable control bodies capable of providing assurance to the consumers and the member states' authorities that food products placed on the domestic market, or prepared for export to EU, meet standards as per the *acquis*; a technically and scientifically prepared service, capable of monitoring the situation in the country and able to detect and eradicate diseases or act in the event of any food incident; infrastructure for the administration at central and regional levels, including necessary laboratory infrastructure, to detect and confirm outbreaks, equipment to perform checks and controls and tools for registration and reporting findings and follow up measures undertaken.

The action will also contribute to the European Investment Plan (EIP) priority "Common Regional Market and European Integration", as a stepping-stone to integrate the region more closely with the EU Single Market already before they accede to the Union. One of the key area of the Action Plan for a Common Regional Market (CRM)³ is the development of a regional trade area which includes free movement of goods, services, capital and people, including crosscutting measures, such as the Green Lanes, to align with EU-compliant rules and standards and provide opportunities for companies and citizens. By improving its food safety, veterinary and phytosanitary standards, Western Balkan countries will improve the trade in the region and create conditions to boost their exports to the internal market of EU. This action will contribute to the alignment with the Sanitary Phytosanitary Standards (SPS) and contribute to enabling the export of Albanian agricultural and food products to the EU. In addition, the action contributes also to Europe Horizon Missions, specifically to "Soil Deal for Europe" where the soil is the foundation of the food systems.

In the food safety field, there is a significant improvement in production standards, of control, and traceability along the entire food chain. The safety of food offered to the Albanian consumer has increased significantly. In this framework, the network of food safety laboratories has been more closely aligned with EU standards. The number of tests and accredited laboratories has increased.

However, currently, Albania is not approved to export live animals and food of animal origin to the EU (with the exception of fish products and eggs) and export of other agricultural products is subject to a number of the requirements. This prevents Albania from fully benefiting from the opportunity to export to the EU under the favourable conditions defined by the Stabilisation and Association Agreement. The food safety and veterinary system needs further consolidation.

³ <u>Common Regional Market - European Commission (europa.eu)</u>

Also the countries in the region are aligning their national policy to the requirements of the EU *acquis* under Chapter 12 (Food safety, veterinary and phytosanitary policy), which may also have an influence on Albanian export to the regional market. Increased imports and lack of export possibilities will place additional pressure on the competitiveness of the food sector in Albania. Furthermore, delayed integration of food control continues to affect confidence of the Albania consumers in the quality and safety of domestic products.

The action is in line with the National Strategy for Agriculture and Rural Development and Fishery 2021 - 2027 which defines Strengthening institutional and administrative capacities for alignment with the EU *acquis* as one of the priorities, while the National Agri-Food Safety Policy sets four priorities: Strengthen the Legislative and Administrative Framework; Enhancing the Effectiveness of the Agri-Food Control System; Strengthening Compliance throughout the Agri-Food Sector and Empowering the Consumer to make Informed Decisions.

In addition, as per the National Strategy for Development and EU Integration (2022- 2030), it emphasises the following strategic objectives in the field of food safety:

- Preparation of the relevant legal framework, which regulates official controls, in relation to food safety, animal and plant health in line with the submissions of the EU legal framework (EU acquis), in the framework of a consolidated national policy.

- Increasing the Effectiveness of the Agro-Food Control System;

- Empowering the Consumer to make informed decisions;

- Completing the reform for the restructuring of the veterinary service, to make this service fully operational;

- Building effective capacities for the surveillance and control of major infectious diseases, including rabies, and the efficient continuation of the 2020–2022 rabies vaccination program;

For the food safety, veterinary and phytosanitary policy and legislation the Ministry of Agriculture and Rural Development (MARD) is the competent institution, while National Food Authority (NFA), National Authority of Veterinary and Plant Protection (NAVPP), Food Safety and Veterinary Institute (IFSV), and State Entity of Seed and Seedlings (SESS) are sub-ordinated institutions. Those institutions were established at different period of time contributing to a fundamental change in the food control system. However, major needs for investment, both in infrastructure and in building the capacities of staff at headquarters and regional offices to implement the integrated and risk-based system is evident.

As reflected on the recent Commission Report (2023), Albania needs to enhance official controls by adopting the upgraded methodology and train sufficient staff to implement the annual inspection plans. As regards the veterinary policy the reform of the veterinary sector should be completed by establishing the necessary capacities on passive and active surveillance including reliable assessments of the prevalence of diseases, thorough data analysis and appropriate design, planning and implementation of effective systems for disease prevention and/or eradication. With regard to the placing on the market of food, feed and animal by-products, Albania should implement in full the National Residue Monitoring Plan by using validated screening methods to ensure the reliability of results for the relevant species and commodities. The laboratory network of Albania should be improved including management, capacities, accreditation and validation of methods within a consolidated framework. With regard to legislation on feed or genetically modified organisms, there is no progress. The legislation on Genetically Modified Organisms (GMOs) needs to be adopted.

Albania has benefited significant assistance from the EU through IPA programmes with regard to capacity building in the field of food safety, veterinary and phytosanitary. Other donors as Italian Cooperation, Word Bank, German Cooperation are contributing to the development of this sector but still EU remains the main donor. The external assistance is coordinated by the National IPA Coordinator and Ministry of Agriculture and Rural Development.

The current structure of Veterinary Services is organized as follows:

a) Structure Responsible for Veterinary at the Ministry of Agriculture and Rural Development

The Ministry of Agriculture and Rural Development (MARD) plays a central role in policy-making and budget allocation for veterinary services. It is responsible for harmonizing institutional coordination and communicating within Albania and with the EU in sectoral, trade, and governmental agreement areas. The Structure Responsible for Veterinary (SRV) within MARD covers the veterinary service and has several important duties. Main duties include drafting veterinary legislation, designing short-, medium-, and longterm strategies for veterinary activities, preparing prevention, control, and elimination programs for eradicating animal infectious diseases, and designing the technical content of the farm and animal identification-registration system. SRV defines the list of notifiable diseases and has the authority to change the limits of protection and surveillance areas. The SRV informs state institutions, public health institutions, and other interested parties in the country, the World Organization for Animal Health (OIE), the European Union (EU), and other international organizations about the epidemiological situation of animal infectious diseases in Albania. The SRV also programs and plans the budget for animal health and welfare, relying on control programs and in cooperation with institutions responsible for budget planning. SRV designs policies and strategies for identifying and registering animals and livestock farms and monitors NAVPP activity for the implementation and performance of official controls and other veterinary measures. Finally, the SRV prepares annual programs of state veterinary prophylaxis, control, monitoring, and surveillance of diseases that have consequences for animal and veterinary public health, based on the epidemiological situation in the country.

b) National Authority of Veterinary and Plant Protection

National Authority of Veterinary and Plant Protection

The National Authority of Veterinary and Plant Protection (NAVPP) in Albania is a government agency responsible for overseeing animal health and plant protection. NAVPP is responsible for preventing animal diseases, implementing control measures and vaccination programs, and monitoring the overall health of livestock and pets. National Authority of Veterinary and Plant Protection carries out veterinary surveillance by regularly monitoring and reporting animal diseases, which is crucial for early detection and rapid response. In relation to veterinary public health, NAVPP ensures the safety and quality of animal-derived products by performing inspections at various stages of live animal production, including pre- and post-slaughter examinations.

The recent veterinary reform of 2021 introduced an increased by approximately 400 official veterinarians. They are now distributed among the 4 Regional Directorates of Veterinary and Plant Protection (RDVPP), Veterinary Sectors, and Local Offices. This expansion brings official veterinarians closer to farmers, enhancing the implementation of strategies for controlling farm animal health and production. Each official veterinarian is responsible for their respective administrative unit(s) within their coverage area. The reorganization of the Veterinary Service has improved control over the animal slaughter process. Additionally, the movement and trading of live animals in live markets, which are considered epidemiological units and potential sources of infectious disease transmission, have been incorporated into the control measures, though they remain largely unregulated.

c) Food Safety and Veterinary Institute

The Food Safety and Veterinary Institute (FSVI) is an integral part of the Veterinary Services and is mandated as the Reference Laboratory in the Republic of Albania, offering more than 250 accredited tests and analyses. It supports the veterinary services with its diagnostic capabilities and plays a central role in the veterinary surveillance of infectious diseases. FSVI serves as the confirmatory laboratory for suspicious or appealed samples from regional laboratories of the NFA and private labs. Moreover, the FSVI collaborates with international partners, research institutions, and veterinary organizations to continuously improve its testing methods, adopt cutting-edge technology, and maintain the highest standards in laboratory practices. This

commitment to excellence enables the FSVI to play a vital role in safeguarding animal health, promoting veterinary public health, and supporting the growth of the livestock sector in the country.

d) National Food Authority

The mission of the National Food Authority (NFA) is to guarantee the safety and quality of food and animal feed throughout its chain, the safety of animal and plant health as well as plant products at border inspection points and health of plants and plant products placed on the market, through the performance of inspection, technical and scientific activities in this field.

Pursuant to Decision of Council of Ministers no. 708. dated 9.9.2020 "On the Organization and Operation of the National Food Authority", the competent authority for the inspection of consignments of live animals, animal and non-animal origin products in Border Inspection Points (BIP) is the National Food Authority. Border inspection points have been approved by Minister's Order No. 168, dated 24.05.2012 "On the approval

of Border Control Points, where veterinary, phytosanitary and food inspection for humans and animals is carried out in the Republic of Albania."

• 10 permanent border control points which have been approved for the passage of live animals and products of animal origin

• 3 border control points with prior notice which have been approved for the passage of products of animal origin.

For all consignments, the NFA inspectors at the Border Inspection Points perform the following checks:

- Documentation control, (carries out the control over the documents that accompany the products which are controlled at the Border Inspection Points. Veterinary certificates for live animals and products of animal origin for each category of products
- Identity control, (it is verified that the data related to the documents of the companies correspond to the characteristics of the shipment).
- Physical control, (verifies if the product complies with the various changes in the documentation.

An effective inspection system at designated border points should be established in the context of EU accession guided by the relevant Commission Implementing regulation. In addition with the revitalization of the AKU-net system, the performance of online official checks in BIPs is also included thus imposing the need to improve also the BIPs in terms of infrastructure, equipment, trained staff, IT systems etc.

2.2. Problem Analysis

AREA OF SUPPORT #1: Establish the capacity for the transposition the EU *acquis* in Chapter 12 Food safety, veterinary and phytosanitary policy and support in running accession negotiations in Chapter 12.

The EU *acquis* in Chapter 12 consists of a very large number of Regulations, Directives and Decisions. Since the conclusion of the Stabilisation and Association Agreement, Albania continuously works on upgrading its national legislation to meet *acquis* requirements. However, the EU *acquis* is constantly evolving and candidate countries are expected to transpose the EU *acquis* before joining to the EU. In the framework of IPA II the Food Safety Project, three framework laws that transpose provisions of EU Animal Health Law, Plant Health Law and Official Control Regulation were drafted. The approval of the laws is planned for Q 4 2023.

In addition, creation of full legislative framework requires repeal of the Veterinary Law and Livestock Law, amendments to the Food Law, but also drafting two new law, namely Genetically Modified Organisms Law and Law on Plant Protection Product. New laws should be accompanied with a number of sub-legal acts which will bring Albanian national legislation close to the EU *acquis*.

Experience from the region shows that accession negotiations in Chapter 12 is extremely demanding process implemented through several consequently phases requiring the mobilisation of administrative resources in the preparation for the fulfilment of opening and closing benchmarks, the negotiating positions as well as other activities as required by the accession process. Albanian institutions need substantial support in running the accession negotiations in Chapter 12.

Transposition of the EU *acquis* and accession negotiation in Chapter 12 will constitute main part of the support. Within this component particular attention will be given to the animal health and welfare as well as to animal by-products in Albania.

Albania had several disease outbreaks and endemic disease problems are evident. This situation is causing: public health problems when dealing with zoonotic diseases; economic losses at farm level and costs for disease control and eradication; trade and movement restrictions for live animals and food of animal origin, etc. Animal welfare is an almost completely neglected topic which needs further attention. Therefore, support is needed with regard to designing and implementing a comprehensive disease monitoring and control system, in line with EU legislation and animal health and welfare requirements established by the World Organisation for Animal Health (WOAH).

Throughout the entire territory of Albania, a large number of animals are disposed inadequately. Equally, slaughterhouse by-products are stored without a proper treatment. All this favour the spread of infectious diseases and environmental degradation. The spread of infectious diseases through animal material, animal carcasses, offal or manure, namely inadequate disposal of animal by-products, constitutes a serious threat to society and requires organised problem-solving. Animal by-products and their products not intended for human consumption are not regulated in Albania. Within this component will be provided assistance in establishing an animal waste management system for animal by-products as well as preparation for construction of animal waste facilities for all forms of animal by-products including arrangements for their collection and transportation, which will have a major impact on the reduction of direct risks to human and animal health and the environment.

AREA OF SUPPORT #2: Strengthening administrative capacities of food inspectors, veterinary and plant health services to cope with the requirements of the EU *acquis*.

Apart from transposition, a candidate country is expected to properly implement and enforce rules envisaged by Chapter 12. Track records to demonstrate the efficient EU *acquis* implementation is actually key criteria in assessment of progress in accession negotiation. EU candidate countries must ensure to have adequate human, technical and financial capacities to be able to implement the EU *acquis*. For the implementation of the EU *acquis* in Chapter 12, Albania must have appropriate administrative structures to be able to carry out inspection and control of food of animal and non-animal origin, including an appropriate laboratory capacity. Albania has certain administrative capacities in MARD, NAVPP, NFA, SEES and Food Safety and Veterinary Institute, however it is evident that these institutions still lack sufficient levels of financial, operational and human resources support. The institutions need to be further strengthened in terms of its logistical and operational capacities, to be able to conduct its mission towards ensuring public health and withstand the pressures of the common EU market. Regional branches of the service need adequate office space, IT infrastructure and must be mobile across the country. Further strengthening of capacities requires continuous training and education programmes in a number of areas of Chapter 12.

AREA OF SUPPORT #3: Support on assessing, categorizing, and upgrading the food establishments

Total number of operators which are registered/approved in Albania is 7,176. Nearly 90% are in the category of wholesale, retail and social food. The share of operators producing the food of animal origin is around 10%. At the national level Albania has 63 approved slaughterhouses, 114 meat cutting and meat processing plants, 370 milk processing plants.

Out of the total number of establishments only 43 operators are approved for the export to the EU, the most of those are establishments producing fishery products. Albania has no meat or milk operators approved for the export to the EU market.

List of approved operators from	Albania for the export to the EU market ⁴

Section of Food	No of operators
Treated stomachs, bladders and intestines: casings only	4
Eggs and egg products	6
Frogs' legs and snails	3
Fishery products	31
Total Food	43

Current situation limits or blocks the export of a number of Albanian food products to the EU market and has direct implications on negative balance in trade of agricultural and food products.

Experience from the accession process shows that after the implementation of bilateral screening Albania may expect to receive an opening benchmark in Chapter 12. One of the benchmarks expected to be received in the 2024 is to presents a classification of all food establishments and all establishments handling animal by-products based on the *acquis* which will serve as a basis for a future National Programme for the upgrading of food and animal by-products establishments.

Albania has already taken some activities in the preparation for the categorisation of establishments. In the framework of IPA II Food Safety Project initial steps are taken in the process of categorisation of food of animal origin establishments. Designed model is presented in the document "Procedure for the assessment and upgrading of establishments handling food of animal origin" which envisages categorisation of the establishments in one of the following categories:

- Category 1: in compliance with EU requirements
- Category 2: detected minor non-compliances can be solved within a short period (3-6 months)
- Category 3: detected significant non-compliances or non-compliances that can be solved within a longer period
- Category 4: detected major non-compliances (the establishment presents significant risks for health and should not place the products on the market; should ceased its activities because not in compliance with national legislation; or is unable to reach EU standards).

Also, in the framework of the Food Safety Project (IPA 2016) 13 check lists for the categorisation of food of animal origin are prepared. In addition, in 2022, 28 inspectors received introductory training on the categorisation of establishments and 58 inspectors received training on structural, operational and hygiene requirements.

Further progress in categorization and upgrade of the food establishments will require further technical assistance. The assistance will include trainings and coaching of the inspectors nominated to implement categorisation of the establishment as well as raising awareness among food business establishments. In

⁴ Source: DG SANTE; Establishments List

https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=country.translation/establishment/index#!/search?countryCode=AL&sort=count

addition, a pilot project on upgrade of the establishments will implemented with the aim of reaching the EU standards for the export to the EU market.

AREA OF SUPPORT #4: Strengthen the laboratory infrastructure and human resources to meet accreditation requirements (preparation of detailed designs in line with accreditation needs and safety level, construction works)

With support of the EU, initial support to the laboratories was provided through IPA 2013 project "Restructuring and strengthening of the food safety and veterinary laboratory network in Albania". The project resulted in setting up a cost-efficient laboratory network capable of providing reliable and timely information on the safety of marketed food and animal health, and enhancing the capacity of the laboratory network to carry out monitoring and analysis of food and feed products with specific reference in the fields of pesticide residues monitoring, microbiological diagnostics in food and feed, food quality standards, animal diseases, in accordance with the improved standards.

The current National laboratory network operates under the MARD in following bodies:

- 1. The Food Safety and Veterinary Institute (IFSV)
- 2. The National Food Authority (NFA)
- **3**. State Entity for Seeds and Seedlings (SEES).
- 4. Transfer Centres of Agricultural Technologies (QTTB) (Kruje Field) which offers laboratory services, as a national reference laboratory for the analysis of fertilizer products

IFSV - Food Safety and Veterinary Institute is accredited in accordance to the EN ISO 17025: 2005. Accreditation was granted by General Directorate of Accreditation in 2011. IFSV operates in central and regional level. Central and regional laboratories are responsible for tracking, analysing and diagnosing infectious and parasitic disease in animals and birds. They are also responsible for testing food products of animal and non-animal origin. IFSV collaborates with international entities for confirmation of various epizootic diseases, zoonotic agents and detection of contaminants coming from food.

The National Food Authority laboratories are in ISO 17025 category C, meaning that preparation of capacities and procedures compliant with the management requirement of the standard have not started yet. The laboratories have no parameters accredited and the staff has not been trained in ISO 17025:2005. There are no written procedures and working instructions.

The National Food Authority has 7 Regional laboratories (each of them including 1 to 3 functional departments (food, veterinary and plant health (phytosanitary)). Each food testing Department comprises two sections (physico-chemical and microbiological). The NFA regional laboratory in Vlore has one small branch laboratory in Saranda, with two Sections (physico-chemical and microbiological) performing food tests.

The Chemical-Physical Laboratory performs analyses regarding qualitative indicators of animal and nonanimal food products, labelling indicators, as well as some analytical indicators of food safety; Microbiological Laboratory performs analyses regarding food safety and hygiene process criteria; Animal Health and Welfare Laboratory tests are performed to diagnose various diseases and parasites in animals and the Plant Protection Laboratory performs tests to diagnose pests and parasites in plants and plant products.

The proposed project would provide technical and financial support to facilitate operational compliance with the EU General Food Law (GFL) Regulation (i.e. EC 178/2002), and a set of EU regulations for the risk-based protection from diseases and pests which relate to Animal Health, Plant Health and the EU Official Controls Regulation on monitoring and enforcing inspection controls across the agri-food chain. These and other corresponding regulations constitute the backbone of the EU Chapter 12: Food Safety, Veterinary and Phytosanitary Policy. Significant enhancement of all those elements will substantially contribute to the process of harmonization of the Albania standards and requirements with relevant EU legislation related to animal health, food safety and plant health. They will also be in line with the relevant international organization agreements and standards, namely: World Trade Organization Sanitary and Phytosanitary (WTO-SPS) Agreement, World Health Organization and Food and Agriculture Organization (WHO/FAO) Codex Alimentarius, World Organization for Animal Health, Terrestrial Animals and Aquatic Codes, and

International Plant Protection Convention (IPPC). This would greatly contribute to supporting the "One Health" approach which is particularly relevant for food and water safety, nutrition, control of zoonotic diseases, pollution management and combatting antimicrobial resistance. This will also support Albania with meeting internationally recognized food certification requirements, such as GlobalGAP, EurepGAP, Hazard Analysis and Critical Control Point (HACCP), etc. The MARD and NFA have divided analytical and diagnostics activities between the IFSV and the seven National Food Authority laboratories. In principle, IFSV will play the reference role and will also support The National Food Authority in doing certain routine analyzes and those which require high expertise.

Maintaining all laboratories at the same level of operation does not seem reasonable nor cost effective and may also not be required. Due to diversification of agricultural production, not all laboratories need to carry out the full range of analyses. Therefore, it is planned to concentrate the majority of analyses, especially those requiring more advanced methods and sophisticated equipment, in three main laboratories (in Fier, Korca, and Tirana), whilst the others would handle simpler large-scale routine analyses. The agreed attribution of specific analyses to particular laboratories is presented in the table below.

IFSV area of competence will remain unchanged and will comprise the following:

- (i) Serving as a reference laboratory for all NFA laboratories (in all 3 disciplines, i.e.: food safety, veterinary and plant health);
- (ii) Carrying out more advanced analyses which require specific and sophisticated equipment, methods and competence (such as: marine bio toxins; residues of veterinary medicines and contaminants in food of animal origin; foodborne diseases; etc.);
- (iii) Carrying out rare analyses (e.g. ASF, FMD, TSEs, bluetongue, rabies, etc.);
- (iv) Participating in mass-scale routine analyses (support for the NFA laboratories), especially where it concerns residues of Plant Protection Products in food of non-animal origin.

Specific type of analyses	Durres	Fier	Gjirokastra	Korca	Tirana	Shkodra	Vlora
Residues of Plant Protection Products		X		х			
Pests on plants – viruses, bacteria, fungi		х		х			
Pests on plants – insects and nematodes	Х	x	x	x	Х	Х	х
Brucellosis and Bovine Tuberculosis	X	X		x		Х	
Honeybee health	х			х			
Mass-scale veterinary analyses	X	х	х	х	х	Х	х
Zoonoses	х	х	х	х	х	х	х
Parasites (Trichinella, Echinococcus, Anisakis)	X	х	х	х	Х	Х	х
Mycotoxins and plant toxins	х	х	Х	х	х	х	х
Material intended to come into contact with foodstuffs					Х		
Metals and nitrogenous compounds					х		
Processing contaminants					X		

Division of analytical work within the NFA laboratories network:

SESS is institution subordinated to MARD. SESS follows the performance of field controls, sampling for laboratory analysis for each planting and propagating material, which is required to be certified. SESS performs laboratory analyses, in the seed testing laboratory for all samples received from the zonal test points.

Identification of main stakeholders and corresponding institutional and/or organisational issues (mandates, potential roles, and capacities) to be covered by the action

Under these planned actions, the MARD will be the lead institution for this action document, as well as main beneficiary. According to set of laws MARD is the competent institution for food safety, veterinary and phytosanitary policy through food supply chains from farm to fork. In order to implement sound management practices, the MARD is responsible for defining policies and drafting legislation, implemented by the NAVPP and NFA. NAVPP is adjacent institution responsible for the implementation of the veterinary and phytosanitary policy, while National Food Authority is responsible for the implementation of food safety policy.

In addition, laboratory network operating under the MARD includes IFSV (Food Safety and Veterinary Institute), NFA (The National Food Authority) and SEES (State Entity for Seeds and Seedlings). Their roles are explained under the title "Short problem analysis".

Key stakeholders addressed by this action document are all participants in food supply chains from farm to fork. Inclusion of the key stakeholders will be done through already established dialogue and consultation mechanisms. In the framework of the Partnership Platform of European Integration MARD has an already established communication programme which enables timely provision of information on the new requirements in place, transition periods and availability of advice in implementation of legislation.

2.3. Lessons Learned

In the past years, the Ministry of Agriculture and Rural Development has coordinated the activities of a number of significant projects in the food safety field:

- IPA 2010 project "Rehabilitation of NFA Regional offices and laboratories" project (€5.2 million, including €0.7 million from the Government of Albania GoA. This project was completed in the first quarter of 2014. The aim of this project was to improve the efficiency of the food safety system through improved regional laboratories and offices network of National Food Authority.
- **IPA 2010 project "Construction of Central Veterinary Laboratory in FSVI"** project (€1.4 million) has established the Central Veterinary Laboratory at the Food Safety and Veterinary Institute in accordance with EU veterinary and animal health standards.
- The IPA 2012 project "Improving consumer protection against zoonotic diseases II phase" (4.9 million including € 0.4 million from Albanian Government co-financing) is a follow-up of the IPA 2008 project "PAZA-1" including reform in the veterinary sector, capacity building with regard disease surveillance and laboratory diagnostics on zoonotic diseases, monitoring of rabies vaccination. The overall objective was to increase livestock health and productivity and improved protection of public health in Albania in line with the EU regulations for the control and monitoring of zoonotic agents.
- **IPA 2013** "Strengthening food safety laboratories in Albania (including supplies for FSVI and NFA regional laboratories" (€ 4.4 million, including € 0.4 million from Albanian Government co-financing) aimed to support the improvement of laboratory system toward improved levels of food safety management throughout the whole food chain.
- **IPA 2017 "Supply and Monitoring Rabies Vaccination Phase III"** (1,067,200 Euro). The overall objective of the project was to contribute complete eradication against rabies in Albania and to ensure that implementation of the oral rabies vaccination was carried out in full compliance with international standards.

- **IPA 2020 "Control and eradication of rabies, including monitoring Phase IV"** (1,421,000 Euro) aiming continuation of rabies vaccination to ensure eradication of the disease and establish passive surveillance capacities.
- IPA Regional support "Capacity building of veterinary and plant health services in the Western Balkans ADEWB II and PHWB" aiming capacity building of competent authorities of Western Balkan countries for ensuring favorable animal health status and plant health status for the whole region over long term, thus ensuring proper functioning of the internal market from the moment the Western Balkans are ready to join EU; become familiar and implement the One Health approach in line with the EU acquis and best practices.
- EFSA PRE-ACCESSION PROGRAMME 2023-2026 is a programme supporting competent authorities for food and feed safety in IPA beneficiaries' countries and is continuation of Pre-accession programme 2019-2023.

The areas of intervention foreseen are:

- Strengthening the capacities for risk assessment and communication
- Increasing scientific cooperation and networking activities among IPA
- beneficiaries and with Member States and EFSA
- Increasing harmonisation of IPA risk assessment and data collection methodologies with those from EFSA
- Enhancing preparedness on common food safety issues.

Albania has 48 observers and alternates part of Scientific networks for risk assessment in animal health, plant health, communication, chemical monitoring data for VMPs, network for zoonosis, food contact material, Antimicrobic resistant, GMOs, pesticides, nanotechnology, pest surveillance.

In addition, activities focused on communication, raising awareness for diseases and risks were implemented. From 2020 until now, 4 awareness and education campaigns for African swine fever have been successfully developed, having a concrete impact where Albania is free from this disease.

Other donors support:

• Project "Institutional Strengthening of the Albanian Ministry of Agriculture and Rural Development for the management of food safety" financed by Italian Agency for Development Cooperation – (2,400,000 Euros). The specific objective is strengthening the capacities of Albanian authorities to perform controls and inspections on plant material at the borders and to operate in the veterinary sector".

<u>Result 1:</u> NFA has increased its capacity to perform efficient inspections on incoming foodstuffs at the port of Durres.

- Identification and design and restructuring of an area and premises to be used as offices and laboratory, at the port of Durres for inspections and sampling and for the first analysis of incoming fruit and vegetable products.
- Supply of equipment for sampling and inspection of foodstuffs at the port of Durres (including small laboratory equipment, equipment for the movement of goods, office furniture and equipment).
- Training of NFA inspectors on sampling methods and border controls and Albanian technicians, on the first analyses that can be carried out at customs on fruit and vegetable products entering the Country.

<u>Result 2:</u> The Albanian authorities have increased the capacity to verify the levels of safety (residues from pesticides) in food of plant origin and developed expertise for the diagnosis of potential quarantine agents.

- The laboratories are equipped for the analysis of quarantine agents and pesticide residues.
- The laboratory is accredited for the analyses;

<u>Result 3:</u> The Ministry of Agriculture has a strengthened and reorganized veterinary service through livestock assessment and data computerization.

- Climate Resilience and Agriculture Development Project negotiated with the World Bank in March 2023 aims to finance 20,30 million euros fore enhancing compliance with food safety and quality standards. More concretely the following investments will be financed:
 - (*i*) Establishment and upgrading of 6 (six) Border Inspection Posts ("BIPs"). The objective of this activity is to increase the Competent Authority's capacity to perform official controls (documentary, identity and physical checks) for live animals, products of animal and non-animal origin, plants and plant products as well as agricultural inputs. The project will support the rehabilitation and equipping of six BIPs (in Bllata, Kakavija, Kapshtica, Qafe Bota, Qafe Thana, and Vlora) of the 13 currently.
 - (*ii*) Improvement of inspection capacities and diagnostic support in the areas of food safety, veterinary and plant health analyses. The objective of this activity is to enhance the capacity to more effectively and efficiently carry out physical checks, sampling and sample delivery to laboratories, and laboratory testing of food safety, veterinary and plant health laboratories to enable them to implement the necessary monitoring systems and methodologies for testing according to relevant standards in line with EU pre-accession requirements. Specifically, the project will support: (i) technical assistance for the preparation of detailed designs and supervision for the rehabilitation of the laboratories as needed, as well as any necessary site-specific environmental and social instrument; (ii) civil works for the rehabilitation of the facilities; (iii) provision of equipment for inspections, sampling and sample delivery and testing in the laboratories;
 - (*iii*)Development of storage capacity for detained goods which do not comply with food safety, veterinary or plant health standards (such as meat, milk, eggs, food of plant origin, etc.). The project will support the construction of 4 highly energy efficient storage facilities, meeting specified safety and environmental requirements, to be placed in the fenced premises of the NFA Regional Directorates in Korca, Shkodra, Tirana and Vlora. This will allow for detention and storage of questioned commodities, either at frozen stage or in cooling conditions, and would fulfill the NFA needs in the easiest, cheapest, and most effective way forward.

Approximation of legislation is proven to be a cumbersome and complex process. Complexity of legislation and requirements for the implementation of the EU food safety, veterinary and phytosanitary policy are enormous challenges for each candidate country. In some aspects Albania is already rather advanced in the alignment with the EU *acquis*. However, transposition of the EU *acquis* in some areas was not initiated and some areas are not regulated by the national legislation.

A general lesson learned is that despite technical assistance provided for *acquis* alignment, the countries continue to suffer from poor implementation and enforcement record of laws and policies. This is to a large extent due to the fact that support focuses on technical alignment (content) but does not pay sufficient attention to the poor quality of the law- making processes, which largely define whether new laws can be enforced. The common problems are weak (regulatory/fiscal) impact assessments of proposed laws and policies, poor interministerial coordination and external (public) stakeholder consultations as well as lack of estimation of costs of implementation and allocation of the necessary resources.

It has become increasingly evident that whereas EU assistance can contribute to building capacities in one particular sector, it does not always contribute to overall public administration reform. In fact, the past EU assistance has sometimes contributed to creation of sectorial isolated 'islands of excellence', which are rarely sustainable in the overall administrative environment.

Key lessons learned during the previous assistance are that, first and foremost, the beneficiary institutions should have all their structures and infrastructure in place in order to have maximum benefit from the assistance projects. Once established institution and administrative capacities should be retained through the whole process of accession negotiation. Otherwise, risk of losing "institutional memory" is increasing hampering the process of needed reform.

As small countries as Albania suffer from the understaffed institutions facing great challenges in bringing its national policy closer to the EU policy. This is particularly proven in large and demanding chapters such is Chapter 12. The limited number of staff in MARD is under the enormous challenge to properly transpose and

coordinate implementation of rules and standards aligned with those in the EU. In addition, regarding veterinary, the chain of command of the Albanian veterinary competent authority remains fragmented as the CVO, according to the current position within the organisational structure of the veterinary service, does not have executive power and direct contact to the Food Safety and Veterinary Institute (reference laboratory) and the General Directorate of National Veterinary and Plant Protection (responsible body for official controls).

Previous experience has shown that budgetary planning and budget availability is also crucial to enable the appropriate conditions for implementation of an action. For the laboratory, inspections and other services in NAVPP, NFA and IFSV, it is necessary that a budget is available for maintenance of the equipment, procurement of the reagents and other consumables, conducting tests and allocation of budget for proficiency testing.

Compliance with food safety, plant health, veterinary and quality standards is important given the relevant role of the food manufacturing sector and recommended increase in production of high-value agri-food products, as well as the increasing trend in agri-food exports. However, compliance in Albania is limited and most often achievable only by larger, better-equipped and better-informed producers. This leads to low (export) market integration particularly for smallholders. Cost and competitiveness implications of food safety and products quality deficiencies can be significant and can lead to food markets disruptions and impediments to agri-food exports. Future investments and institutional strengthening efforts should address weak compliance and control mechanisms related to food safety, veterinary and sanitary and phytosanitary standards, and reduce the transactions costs related to market access and inclusion.

3. DESCRIPTION OF THE ACTION

3.1. Intervention Logic

The Overall Objective(s)/ (Impact(s)) of this action is:

1. To protect the health and interests of the consumers by approaching EU food safety policies to guarantee the highest level in food safety, animal health and welfare, as well as plant health standards.

The Specific Objective(s) (Outcomes) of this action are:

- 1. Strengthened legislative and administrative framework on food safety, veterinary and phytosanitary area and official controls;
- 2. Strengthened administrative capacities of relevant institutions for coping with food safety inspection, veterinary and plant health services as per EU requirements.
- 3. Strengthened capacities to asses, categorize, and upgrade the food establishments;
- 4. Improved official controls, laboratory capacity, and risk based food safety management.

The Outputs to be delivered by this action contributing to the corresponding Specific Objectives (Outcomes) are

Outputs contributing to Outcome 1 (or Specific Objective 1):

Output 1.1 Framework laws, by-laws and strategies related to Chapter 12 prepared;

Output 1.2 Established capacities for the management and enforcement of Animal by-Products (ABP)

Output 1.3 Improved effectiveness in detecting, fighting and limiting the size of an outbreak of animal disease and plant pests in line with EU standard;

Output contributing to Outcome 2 (or Specific Objective 2)

Output 2.1 Enhanced capacities of the food, veterinary and phytosanitary services as per the requirement of EU acquis;

Output 2.2 Enhanced capacities of the food safety and veterinary services on drafting and implementation of national residue monitoring plan (NRMP);

Output 2.3 Establishment of control plans for contaminants and pesticide residues in line with the EU requirements;

Outputs contributing to Outcome 3 (or Specific Objective 3):

Output 3.1 Enhanced capacities for running the categorisation of the food establishments;

Output 3.2 Enhanced capacities for upgrading the food establishments in compliance with EU requirements;

Outputs contributing to Outcome 4 (or Specific Objective 4):

Output 4.1 Strengthened laboratory capacities to meet accreditation/ validation requirements;

Output 4.2 Upgraded equipment on food safety, veterinary, plant health, and seeds laboratories;

3.2. Indicative Activities

Activities related to Output 1.1

- Support on preparation of the following laws:
 - The law "On Plant Protection Products";
 - The law "On Genetically Modified Organisms (GMOs)"
 - The Law "On Planting Material";
 - The Law "On Animal welfare";
 - Amendment of national Law on Veterinary;
 - The Law on Food;
 - The Law on Animal Feed;
- Support on preparation of legislative acts (by-laws) related to Chapter 12.
- Support on preparation of the multi-year plan for monitoring pesticide residues in food products prepared;
- Support on preparation of Piloting the monitoring of quality of the raw milk at the level of farmers, collection points and processors.

Activities related to Output 1.2

- Supporting for designing the strategy for Animal By Products (ABP) management;
- Support on preparation of Multiannual Action Plan and Contingency Plan for Animal By Products (ABP) management;
- Support on preparation of legislative acts related to ABP;
- Training for official veterinaries on ABP establishments;
- Piloting categorization, handling and disposing ABP (Cat 1+ Cat 2);
- Public awareness activities organized;

Activities related to Output 1.3

- Support on preparation of the Multiannual strategy, action plan on eradication of zoonotic diseases (category A list diseases);
- Support on preparation of the Multiannual control plan for pests;
- Support on implementation and upgrade of of the contingency plans for all the required animal diseases as per the EU Animal Health Law;
- Support on implementation and upgrade of the contingency plans for quarantine pest;
- Establishing 6 protected areas from pests;
- Support on preparation of Surveillance plans for BSE and TDE;

Activities related to Output 2.1:

- Training of respective staff on the implementation and enforcement of new legislation compliant with the EU *acquis;*
- Support on preparation of Professional Qualification Strategy in cooperation with Agriculture University and upgrade of Curricula and/ or agriculture vocation education schools;

Activities related to Output 2.2:

- Support on drafting the Implementation Plan of National Residue Monitoring Plan (NRMP);
- Training of responsible staff for NRMP;

Activities related to output 2.3

• Support the establishment of control plans for contaminants and pesticide residues in line with the EU requirements;

Activities related to Output 3.1:

- Support on concluding the national plan for carrying out the assessment and categorization in all the food establishments across Albania and defining the ones that need to be upgraded;
- Raising awareness for Food Business Operators (FBOs)s on the categorisation of the food establishments an preparation of action plans based on categories.

Activities related to Output 3.2:

- Pilot support for preparation of upgrade plans for food establishment falling under high risk category;
- Support for assessment of action plans prepared by FBOs, monitoring and supervision the upgrading process;

Activities related to Output 4.1

- Support the accreditation of NFA regional laboratories with ISO standard;
- Support the accreditation of State Entity of Seeds Laboratory.
- Support the accreditation of new laboratory methods on the area of residues of veterinary drugs, analysing of additives and animal health for IFSV.
- Support the different validation methods of laboratory analysis to egg/fish/milk/butter/sausage/food/grain/cereal/animal by products/ products of plant origin/ mollusc
- Training the staff of laboratories;

Activities related to Output 4.2

- Assessment and upgrade of Border Inspection Posts conditions to perform official controls and meet international standards
- Drafting a methodology for risk-based plan of official controls in BIP in alignment with EU regulation.
- Setting up and strengthening forecasting-signalling centres to strengthen the capacities of accurate monitoring of pest disease and pest outbreaks.;
- Purchasing equipment for upgrading laboratories (NFA, IFSV, Seed Entity Laboratory)

3.3. Mainstreaming

Environmental Protection, Climate Change and Biodiversity

The proposed action does not specifically address climate change or biodiversity markers of either mitigation of adaptation but meets these objectives in various ways, such as strengthening of food safety regulations and other food conservation systems in areas affected by higher temperatures; promoting sustainable farming practices aimed at protecting biodiversity in agricultural ecosystems and contributing to sustainable trade in valuable plant or animal species and derived products;

Environmental considerations will be duly reflected in all IPA-financed activities. While climate change has an impact on the occurrence of animal diseases and plant pests, and in particular their spread, this action does not directly contribute to climate change. Improvement of veterinary health and upgrading of laboratory shall include measures of adjustment to higher standards of environmental sustainability (e.g., animal waste). Hazardous waste may cause threats to human health or the environment if managed improperly. Building the system for collection of animal-by products shall lead to the safe and effective handling of hazardous waste thus contributing to the protection of the environment in Albania. However, the Action will have limited direct impact on the environment.

Gender equality and empowerment of women and girls

As per OECD Gender DAC codes identified in section 1.1, this action is labelled as G0. This implies that this Action document means that the project/ programme has been screened against the gender marker but has not been found to target gender equality. However, activities in this Action document will be implemented in accordance with all main principals of gender mainstreaming.

In that sense, the proposed action will provide an opportunity for qualified women to be involved in those activities which are traditionally being implemented by men e.g. inspection services, auditing of the food processing plants etc.

In job openings and all bodies involved, this action will seek to ensure equal gender representation, defined as not less than 30% in any institution, management level, and appointed organ. Their equal rights in Albania are guaranteed by the Law No. 9970, dated 24.07.2008 on "Gender Equality in Society". According to this Law, gender equality means equal participation of women and men in all areas, equal positions between them, equal opportunities and chances to enjoy the rights and to fulfil the obligations in society, benefiting equally from the achievements of its development. Businesses owned by women will be prioritized in getting the benefits from this Action; women being employees in farms and businesses will be treated in priority while being selected to attend trainings provided by this Action. Women will be particularly encouraged to attend training programmes and will also have an advantage under training of trainer's schemes and leadership roles in the functioning of regional offices of the NAVPP and NFA.

Capacity development activities provide the opportunity for monitoring the No. of individuals/ inspectors trained, disaggregated by sex.

Throughout the implementation of this Action, gender analysis shall be carried out to ensure gender mainstreaming across activities, such as plans, the promotion campaign, development of policies, assessments or evaluations. The gender perspective shall facilitate equal access to resources and opportunities and will promote participation of women in planning processes and awareness activities.

Other considerations if relevant

Minority and vulnerable groups' concerns will be reflected in all activities, in particular when it concerns public services, legislative matters and socio-economic development. Equal opportunities and non-discrimination will be respected.

3.4. Risks and Assumptions

Category	Risks	Likelihood (High/ Medium/ Low)	Impact (High/ Medium/ Low)	Mitigating measures
Political	Risk 1: Insufficient support from political commitment to EU integration process	Medium	Low	This risk can be mitigated through continuous implementation of the Stabilisation and Association Agreement.

Corruption/Fraud	Risk 2: Legal and regulatory framework is not effectively enforced	Medium	Low	The risk of corruption and fraud can be mitigated through continuous high- level policy dialogue with the Government on the implementation of Chapters 23 and 24 measures for the prevention and repression of corruption
External environment	Risk 3: Stakeholders coordination and cooperation is reduced during law and policymaking processes, budget preparation, implementation and review of sector strategies involving different stakeholders	Medium	Medium	Ensuring continuous policy dialogue in the framework of Partnership Platform of European Integration
People and organisation	Risk 4: Lack of institutional knowledge management and capacity skills, exacerbated by high turnover of personnel	Medium	High	Develop HR institutional policies with duty-bearers and multi-year capacity building plans, including performance- based budgeting
External environment	Risk 5: Worsening of the socio- economic situation leading to financial/budget ary constraints and limited funds availability, also due the war in Ukraine	High	High	Strengthen donors' and government coordination in the sector

External Assumptions

Outcome 1

- The Albanian Government, in line with the EU accession process, considers the food safety a priority. Economic and political stability is maintained •
- •

Outcome 2

- Sufficient provisions for retaining administrative staff from the national budget
- Individual and institutional willingness to adapt to change for more effective and efficient management of sector policy and programmes

Outcome 3

- Food business operators willing to cooperate
- Financial support provided through IPARD/national budget to upgrade establishments

Outcome 4

• Government allocates the necessary human and financial resources to support an optimal laboratory activity carried out in line with its duties and planned workload.

3.5. Indicative Logical Framework Matrix

Results	Results chain: Main expected results	Indicators [it least one indicator per expected result	Baselines (2023)	Targets (2030)	Sources of data	Assumptions
Impact	To protect the health and interests of the consumers by approaching EU food safety policies to guarantee the highest level in food safety, animal health and welfare, as well as plant health standards.	Number of consumers/citizens affected by diseases of food origin as well as health status of animals and plants;		Reduction by at least 30%	Public health report	Not applicable
Outcome 1	Strengthened legislative and administrative framework on food safety, veterinary and phytosanitary area and official controls;	1.1 Level of acquis alignment in Chapter 12.	1.1 32%	1.1 70%	EC Annual Reports EC Audit Reports EC Per review Reports NPEI monitoring reports	The Albanian Government, in line with the EU accession process, considers the food safety a priority. Economic and political stability is maintained Ensured adequate administrative staff Legislation regarding the right and role of civil society and consumers is in place
Outcome 2	Strengthened administrative capacities of relevant institutions for coping with food safety inspection, veterinary and plant health services as per EU requirements.	2.1 Progress made in the implementation of the rules and standards aligned with the EU rules;	2.1 Modest progress	2.1 Chapter 12 opened for negotiation	European Commission Annual Reports	Sufficient provisions for retaining administrative staff from the national budget

					EC Audit Reports NPEI monitoring reports	Individual and institutional willingness to adapt to change for more effective and efficient management of sector policy and programmes Continuous inflow of know-how transfer
Outcome 3	Strengthened capacities to categorize and upgrade the food establishments;	 3.1 Number of establishments approved for the export to the EU; 3.2 Number of food establishments with inconstancies decreased 	3.1 43 (2022)3.2 Baseline to be established during action	3.1 (85) 3.2 Reduce numbers of inconsistent food establishme nts by 30% in comparison to the baseline.	MARD, NAVPP and NFA reports European Commission Annual Reports EC Audit Reports	
Outcome 4	Improved official controls, laboratory capacity, and risk-based food safety management.	4.1 Level of compliance of laboratories with the EU requirements	4.1 Not defined	4.1 85%	MARD reports	Government allocates the necessary human and financial

					EC Audit Reports EC Per review reports	resources to support an optimal laboratory activity carried out in line with its duties and planned workload.
Output 1 related to Outcome 1	1.1 Framework laws, by-laws and strategies related to Chapter 12 prepared;	1.1.1 The law "On Plant Protection Products"Protection Products"prepared;1.1.2 The law "On Genetically Modified Organisms (GMOs)" prepared;1.1.3 The Law "On Planting Planting Material" prepared;1.1.4 The Law "On Animal Prepared;1.1.5 The Law "On Animal Veterinary prepared;1.1.6 The Law on Veterinary prepared;1.1.7 The Law on Prepared;1.1.8 Number of legislative acts (by- laws) prepared.1.1.9 The multi-year plan for monitoring pesticide residues in food products prepared;1.10.10 Piloting the monitoring of quality of the raw milk	1.1.1 -1.1.7 (0) 1.1.8 (0) 1.1.9 (0) 1.1.10 (0)	 1.1.1 -1.1.7 (7) new law prepared; 1.1.8 (100) 1.1.9 (1) 1.10.12 (3) Level of farm, 	European Commission Annual Reports Screening Report EC Per review reports EC Audit Reports NPEI monitoring reports	Political willingness for further alignment to EU standards Individual and institutional willingness to adapt to change for more effective and efficient management of sector policy and programmes Effective coordination of actions by different stakeholders Sufficient provisions to retain administrative staff from the national budget

				collection	
				points and	
				processors.	
		1.2.1Strategy+MultiannualActionPlan+ContingencyPlanforABPmanagement prepared;1.2.2Numberlegislativeactsprepared.	1.2.1 (0) 1.2.2 (0)	1.2.1 (1) 1.2.2 (2)	European Commission Annual Reports Screening Report
Output 2 related to Outcome 1	1.2 Established capacities for the management and enforcement of Animal By-Products (ABP)	1.2.3 Number of official veterinaries trained on ABP establishments 1.2.4 Piloting	1.2.3 (0)	1.2.3 (250)	EC Per review reports
		categorization, handling and disposing ABP (Cat 1+ Cat 2) 1.2.5 Number of public awareness activities organized	1.2.4 (0) 1.2.5 (0)	1.2.4 (3) 1.2.5 (3)	EC Audit Reports NPEI monitoring reports
	1.3 Improved effectiveness in	1.3.1 Multiannual strategy + action plan on eradication of zoonotic diseases prepared; (category A	1.3.1 10% (2022)	1.3.1 75% (2030)	European Commission Annual Reports
Output 3 related to Outcome 1	detecting, fighting and limiting the size of an outbreak of animal disease and plant pests in line with EU standard;	list diseases) 1.3.2 Multiannual control plan for pest prepared; 1.3.3 Number of	1.3.2 (0)	1.3.2 (1)	Screening Report EC Per review reports
		contingency plans for all the required animal diseases as per the EU	1.3.3 5 (2025) ⁵	1.3.3 (10)	EC Audit Reports

⁵ According to Action Document for "Capacity building of veterinary and plant health services in the Western Balkans" / Multi-country multiannual action plan in favour of the Western Balkans and Turkey for 2021-2022/ IPA III/2021/NEAR>SANTE/16 - 3.6. Logical Framework for ACTION MODALITY/ Output 1/ Outcome 2

		Animal Health Law developed/improved; 1.3.4 Number of contingency plans for quarantine pest developed/improved; 1.3.5 Establishment of areas protected from pests 1.3.6 Surveillance plans for BSE and TDE prepared	1.3.4 12 (2025) ⁶ 1.3.5 (0) 1.3.6 (0)	1.3.4 6 (18) 1.3.5 (6 areas) 1.3.6 (2)	NPEI monitoring reports	
Output 1 related to Outcome 2	2.1 Enhanced capacities of the food, veterinary and phytosanitary services as per the requirement of EU <i>acquis;</i>	 2.1.1 No. of staff trained on the implementation and enforcement of new legislation compliant with the EU <i>acquis;</i> 2.1.2 Professional Qualification Strategy prepared; 2.1.3 Number of curricula for the prepared 	2.1.1 0 2.1.2 (0) 2.1.3 (0)	2.1.1 350 2.1.2 (1) 2.1.3 (2)	MARD, NAVPP and NFA reports EC Audit Reports	
Output 2 related to Outcome 2	2.2 Enhanced capacities of the food safety and veterinary services on drafting and implementation of national residue monitoring plan (NRMP).	2.2.1 Implementation Plan of NRMP drafted; 2.2.2 No of staff trained for NRMP;	2.2.1 (0) 2.2.2 (0)	2.2.1 (2 years) 2.2.2 (50)	Annual NRMP Plan submitted to DG SANTE	
Output 3 Outcome 2	2.3 Establishment of control plans for contaminants and pesticide residues in line with the EU requirements;	2.3.1 System of Pharmacovigilance in place	2.3.1 (0)	2.3.1 (1)	Annual Report to DG SANTE	

⁶ According to Action Document for "Capacity building of veterinary and plant health services in the Western Balkans" / Multi-country multiannual action plan in favour of the Western Balkans and Turkey for 2021-2022/ IPA III/2021/NEAR>SANTE/16 - 3.6. Logical Framework for ACTION MODALITY/ Output 1/ Outcome 3

Output 1 related to Outcome 3	3.1 Enhanced capacities for running the categorisation of the food establishments;	 3.1.1 No of inspectors trained; 3.1.2 Number of establishments assessed and categorized and needed to be upgraded 	3.1.1 (28) inspectors were trained on the assessment of establishments; (58) inspectors received introductory training on structural, operatio nal and hygiene requireme nts 3.1.2 (0)	3.1.1 200 inspectors trained 3.1.2 50	MARD, NAVPP and NFA reports European Commission Annual Reports EC Audit	Adequate number of staff is assigned to carry out categorisation of establishments. Food business operators willing to cooperate.
Output 2 related to Outcome 3	3.2 Enhanced capacities for upgrading the food establishments in compliance with EU requirements;	3.2.1 Number of establishments to be upgraded;	3.2.1 (0) This indicator will be defined after the conclusion of assessing and categorization process.	3.2.1 3 (800)	Reports Per review reports	provided through IPARD/national budget to upgrade establishments.
Output 1 related to Outcome 4	4.1 Strengthened laboratory capacities to meet accreditation/ validation requirements;	 4.1.1 Number of regional laboratories of NFA accredited with ISO norm; 4.1.2 State Entity of Seeds Laboratory accredited. 4.1.3 Number new laboratory accredited methods on the area of residues of veterinary drugs, analysing of additives and animal health for IFSV; 	4.1.1 (0) 4.1.2 (0) 4.1.3 (0)	4.1.1 (7) 4.1.2 (1) 4.1.3 (3) Three areas related to residues of veterinary		The strategy on the laboratory network is in place. Roles and responsibilities of laboratories clearly determined

		4.1.4 Number of validated methods different laboratory analysis to egg/fish/milk/butter/sau sage/food/grain/cereal/a nimal by products/ products of plant origin/ mollusc indicated for NRMP 4.1.5 Laboratory staff trained and prepared to carry out assigned set of laboratory analyses	4.1.4 (0) 4.1.5 (0)	drugs, analysing of additives and animal health. 4.1.4 (15) 4.1.5 (75)	
Output 2 Outcome 4	4.2 Upgraded equipment on food safety, veterinary, plant health, and seeds laboratories;	 4.2.1 Number of Border Inspection Posts upgraded to perform official controls and meet international standards; 4.2.2 Setting up and strengthening forecasting-signalling centres 4.2.3 Number of new analysis performed in the laboratories supported by the project 	4.2 7 ⁸ 4.2.2 (0) 4.2.3 (0) 4.2.4 0 ⁹	4.2.1 (13) 4.2.2 (6) 4.2.3 (250)	

4.2.4 Purchased	4.2.4 (2)	
equipment for	upgraded	
upgrading laboratories ⁷	laboratories	

 ⁸ 6 Border Inspection Points will be upgraded by the project Climate Resilience Agriculture Development financed by the World Bank.
 ⁹ IFSV laboratory + 1 Seed Laboratory
 ⁷ The principle of complementarity with other projects will be respected and the overlapping from other project investments will be ensured;

4. IMPLEMENTATION ARRANGEMENTS

4.1. Financing Agreement

In order to implement this action, it is envisaged to conclude a financing agreement with the Republic of Albania.

4.2. Indicative Implementation Period

The indicative operational implementation period of this action, during which the activities described in section 3 will be carried out and the corresponding contracts and agreements implemented, is 72 months from the date of conclusion of the financing agreement.

Extensions of the implementation period may be agreed by the Commission's responsible authorising officer by amending this Financing Decision and the relevant contracts and agreements.

4.3. Methods of Implementation

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures¹⁰.

4.3.1 Indirect Management with a pillar-assessed entity

This action may be implemented in indirect management with a pillar assessed entity, which will be selected using the following criteria:

- Proven capacity of the entity on implementation of similar projects in terms of complexity, technical and managerial capacities in the field of food safety, with particular reference to policy drafting and procurement of technical equipment to comply with the EU acquis.
- The entrusted entity should ideally cooperate for this action with an EU member state public authority or organization dealing with food safety.
- Experience on implementation of projects in the context of EU accession negotiations is considered as an asset.
- Experience in the region, especially in Albania, is considered an added value
- Financial capacity and willingness to provide co-financing (added value)

4.3.2 Changes from indirect to direct management (and vice versa) mode due to exceptional circumstances

If the implementation modality under indirect management as defined in section '4.3.1' cannot be implemented due to circumstances beyond the control of the Commission, the modality of implementation by grants under direct management would be used according to the following:

(a) Purpose of the grant(s)

¹⁰ <u>EU Sanctions Map</u>. Please note that the sanctions map is an IT tool for identifying the sanctions regimes. The source of the sanctions stems from legal acts published in the Official Journal (OJ). In case of discrepancy between the published legal acts and the updates on the website it is the OJ version that prevails.

The grant will contribute to achievement of all specific objectives of this action.

(b) Type of applicants targeted

The entity may be a specific type of organization such as: government department, public body, or relevant mandated body of a Government department or public body authority of a European Union Member State in the fields related to this action.

4.4 Scope of geographical eligibility for procurement and grants

The geographical eligibility in terms of place of establishment for participating in procurement and grant award procedures and in terms of origin of supplies purchased as established in the basic act and set out in the relevant contractual documents shall apply, subject to the following provisions.

The Commission's authorising officer responsible may extend the geographical eligibility on the basis of urgency or of unavailability of services in the markets of the countries or territories concerned, or in other duly substantiated cases where application of the eligibility rules would make the realisation of this action impossible or exceedingly difficult (Article 28(10) NDICI-Global Europe Regulation).

4.5 Indicative Budget

Indicative Budget components	EU contribution (amount in EUR)	Indicative third party contribution (EUR)
Methods of implementation – cf. section 4.3.1		N.A.
Outcome 1, 2, 3, 4 composed of	12 500 000	N.A.
Indirect management with a pillar-assessed entity – cf. section 4.3.1	12 500 000	N.A.
Evaluation – cf. section 5.2 Audit – cf. section 5.3	may be covered by another Decision	N.A.
Strategic Communication and Public Diplomacy – cf. section 6	will be covered by another Decision	N.A.
Total	12 500 000	

4.6 Organisational Set-up and Responsibilities

The Lead Beneficiaries for the Action shall be the Ministry of Agriculture and Rural Development. The National Food Authority, the Institute for Food Safety and Veterinary, National Agency for Veterinary and Plant Protection, Agency for Technology Transfer Centre and any other institutions as requested by MARD will be supporting the project implementation implementing.

A Project Steering Committee (PSC) will be established that will steer the project implementation. The PSC shall involve representatives from the main stakeholders, as well as from the National IPA Coordinator (NIPAC) and EUD. The PSC shall closely monitor the fulfilment of the project objective and the project results. The NIPAC shall have the role of monitoring the fulfilment of the objectives at the level of the Action and shall coordinate its monitoring in the context of the Sectoral Monitoring Committee on Agriculture and Rural Development.

As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the European Commission may participate in the above governance structures set up for governing the implementation of the action.

5. PERFORMANCE MEASUREMENT

5.1 Monitoring and Reporting

The day-to-day technical and financial monitoring of the implementation of this action will be a continuous process, and part of the implementing partner's responsibilities. To this aim, the implementing partner shall establish a permanent internal, technical and financial monitoring system for the action and elaborate regular progress reports (not less than annual) and final reports. Every report shall provide an accurate account of implementation of the action, difficulties encountered, changes introduced, as well as the degree of achievement of its Outputs and contribution to the achievement of its Outcomes, and if possible at the time of reporting, contribution to the achievement of its Impacts, as measured by corresponding indicators, using as reference the log frame matrix (for project modality).

The Commission may undertake additional project monitoring visits both through its own staff and through independent consultants recruited directly by the Commission for independent monitoring reviews (or recruited by the responsible agent contracted by the Commission for implementing such reviews).

Arrangements for monitoring and reporting, including roles and responsibilities for data collection, analysis and monitoring:

MARD, as lead beneficiaries will follow the achievement of indicators and outputs and outcomes defined within the action. They shall have the responsibility to collect the data concerning the indicators and timely to report to NIPAC, regularly inform NIPAC and the relevant stakeholders on the implementation of the indicators, and follow the implementation of the respective activities and alert on any delays and the reasons that caused such delays. As described in section 4.6 above, the overall monitoring of the implementation of the action will be performed at the level of the Sector Monitoring Committee for Agriculture and Rural Development and at the level of the Project Steering Committee. The respective institutions shall use the Results-Oriented Monitoring tool in reporting on performance and results, referring to criteria of relevance, efficiency, effectiveness, sustainability, and provide basic information that can be exploited to orient future monitoring/evaluation/audit and management decision at the action level.

The NIPAC shall be responsible at national level to monitor, review and evaluate the progress on the implementation of the indicators established within the action's Log-frame Matrix and to communicate the information with the European Commission services.

The statistical and monitoring systems as well as the quality of official data in the policy filed covered have been assessed.

5.2 Evaluation

Having regard to the importance of the action, a final evaluation(s) will be carried out for this action or its components via independent consultants contracted by the Commission.

The Commission shall form a Reference Group (RG) composed by representatives from the main stakeholders at both EU and national (representatives from the government, from civil society organisations (private sector, NGOs, etc.), etc.) levels. If deemed necessary, other donors will be invited to join. The Commission shall inform the implementing partner at least three months in advance of the dates envisaged for the evaluation exercise and missions. The implementing partner shall collaborate efficiently and effectively with the

evaluation experts, and inter alia provide them with all necessary information and documentation, as well as access to the project premises and activities.

The evaluation reports shall be shared with the partner country and other key stakeholders following the best practice of evaluation dissemination. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, in agreement with the partner country, jointly decide on the follow-up actions to be taken and any adjustments necessary, including, if indicated, the reorientation of the project.

Evaluation services may be contracted under a framework contract.

5.3 Audit and Verifications

Without prejudice to the obligations applicable to contracts concluded for the implementation of this action, the Commission may, on the basis of a risk assessment, contract independent audit or verification assignments for one or several contracts or agreements.

6. STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

All entities implementing EU-funded external actions have the contractual obligation to inform the relevant audiences of the Union's support for their work by displaying the EU emblem and a short funding statement as appropriate on all communication materials related to the actions concerned. To that end they must comply with the instructions given in the 2022 guidance document <u>Communicating and raising EU visibility:</u> <u>Guidance for external actions</u> (or any successor document).

This obligation will apply equally, regardless of whether the actions concerned are implemented by the Commission, the partner country, service providers, grant beneficiaries or entrusted or delegated entities such as UN agencies, international financial institutions and agencies of EU Member States. In each case, a reference to the relevant contractual obligations must be included in the respective financing agreement, procurement and grant contracts, and contribution agreements.

For the purpose of enhancing the visibility of the EU and its contribution to this action, the Commission may sign or enter into joint declarations or statements, as part of its prerogative of budget implementation and to safeguard the financial interests of the Union. Visibility and communication measures should also promote transparency and accountability on the use of funds. Effectiveness of communication activities on awareness about the action and its objectives as well as on EU funding of the action should be measured.

Implementing partners shall keep the Commission and the EU Delegation/EU Office fully informed of the planning and implementation of specific visibility and communication activities before the implementation. Implementing partners will ensure adequate visibility of EU financing and will report on visibility and communication actions as well as the results of the overall action to the relevant monitoring committees.

7. SUSTAINABILITY

The sustainability of project activities beyond the implementation period is expected to be high. Project activities are supporting Albania to build the capacity of MARD and relevant institutions to become EU compliant with EU pre-accession requirements. Increasing the institutions capacity as well as establishing the required systems will help Albania access future EU funding for agricultural and rural development under the Instrument for Pre-Accession Assistance.

Activities take into consideration and complement other ongoing activities supporting Albania in increasing its institutional capacity to implement food safety, veterinary and phytosanitary requirements. Fulfilling these

requirements will continue to be critical in the long term both to increase competitiveness of agriculture production and to fulfill the EU accession negotiation benchmarks.

Enhanced capacities to transpose, implement and enforce rules and standards compliant with the EU *acquis* will have a direct impact on advancing and accelerating accession negotiations with the EU, which is the ultimate goal of the Government of Albania and will improve economic performances of the food sector in Albania. Therefore, the Action will contribute to the progress and sustainability of achieved results within the reforms of the process of accession to the EU, supported by IPA III.

The Actions will have an impact on the national food safety, veterinary and phytosanitary system. It will help to ensure the same level of control and protection to food products sold within the territory of Albania. The expected direct impact of the action will be the reduction of the food incidence and diseases. The proposed Action is also expected to have a major impact on the health of consumers in Albania.

It will increase competitiveness of the Albanian products in the internal market of the EU and markets in the region.

The trainings which are an integral part of this Action will improve knowledge and skills of administration staff, inspection and laboratory staff, field veterinarians and other stakeholders, in a number of areas in Chapter 12. This capacity building component will contribute to sustainability of the achieved results.