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ANNEX1: ACTION FICHE FOR BELARUS 2009

1. IDENTIFICATION

<i>Title/Number</i>	SUPPORT TO QUALITY INFRASTRUCTURE IN BELARUS – FOOD SAFETY (CRIS REFERENCE ENPI 2008 / 20658)		
<i>Total cost</i>	€8.5 million		
<i>Aid method / Method of implementation</i>	Service and supply contract under direct centralised management		
<i>DAC-code</i>	99810	<i>Sector</i>	Other – Not specified

2. RATIONALE

2.1. Sector context

2.1.1. Overview

Within the context of the overall support programme for the development of a Quality Infrastructure¹ environment in Belarus, food safety was selected as a first priority within the areas of mutual interest given the wide spectrum of issues that need to be dealt with. This approach is fully consistent with the overall strategic approach of the partner Government and, in view of securing ownership of the project, it was designed bearing in mind the National Complex Programme on Standardization of Food Products 2007-2010, developed as a plan of action for the State Committee for Standardization (*Gosstandart*). The main objectives of the National Programme are to ensure food safety, improve quality and competitiveness of food products, consumer satisfaction, protection against counterfeit products, etc. The programme foresees the development of technical regulations, standards, and requirements for food products, control of food safety, products traceability and liability.

The selection of food safety as a target for EC support calls for an integrated approach, implying that support must be focused not only on the national Quality Infrastructure, but also on the development of capacity of the food processing sectors. Depending on the propensity of the Belarusian government to take on further reform in this field, the European Commission may decide to pursue its support to the overall quality infrastructure environment in Belarus in its European Neighbourhood Policy (ENP) and specifically through the European Neighbourhood and Partnership Instrument (ENPI) Annual Action Programme (AAP) in 2010 in sector/sectors to be agreed later on with the partner Government.

2.1.2. Issues to be addressed

The programme “Support to Quality Infrastructure to Belarus - Food Safety” envisages addressing the following structural issues:

- The institutional configuration of the Belarusian Quality Infrastructure with focus on the accreditation and market surveillance functions;
- Operational weaknesses and capacity building of the food safety- and quality- related testing services provided by the public laboratories;
- Lack of widespread experience in the Belarusian food sector with internationally accepted and well-proven methods for securing food products safety and quality;

¹ The Quality Infrastructure encompasses standardization, metrology, assurance of conformity (certification and declaration of conformity), and accreditation of laboratories and certification bodies. Certification, in turn, applies to products, services, and personnel.

- Fragmented and relatively weak professional organisations and business associations.
- A rising but yet insufficiently prepared civil society movement for to the protection of consumer rights and the associated lack of a sizeable contingent of well-informed consumers.

2.2. Lessons learnt

In spite of the scarcity of technical assistance activities in respect of food safety, a recent study “*Exploratory mission on enterprise regulation and the progressive harmonisation of norms and standards assessment in Belarus*” was funded by the EC to conduct an in-depth survey of Belarusian Quality Infrastructure. The most relevant aspect to be underlined herein is the favourable political and administrative context for regulatory reform, which derives from *Gosstandart's* positive attitude towards regulatory reform and understanding of the need for fostering a more active involvement of private sector and civil society in the quality infrastructure and food safety domains.

Furthermore, in response to the Paris Declaration on aid effectiveness and subsequent Accra Conference of September 2008, the Commission developed a strategy for the implementation of recommendations made at these events, with a view to, inter alia, increase Partner Government Ownership (Demand driven approach and/or country managed programmes); enhance Capacity Building with a strong result orientation; enhance donor coordination; increase the quality and make better use of available technical expertise; and avoid the creation of parallel PIUs.

These elements are being taken into account whenever applicable in the various stages of the project cycle.

2.3. Complementary actions

FAO developed a project for Belarus entitled “Food safety capacity building”. The project's launch is dependent on signature of an agreement between FAO and Belarus (FAO contribution – USD 350,000). The FAO project activities are mainly concentrated on the organisation of training courses, study tours and workshops. Therefore, as such there is no overlap with the EC-funded programme, while synergy could be achieved by having the training within the FAO project as a preparatory phase of capacity development component within the planned EU action.

2.4. Donor coordination

2.4.1. United Nations Food and Agriculture Organization (FAO)

The coordination with FAO shall ensure synergy and no overlapping with the EC project.

3. DESCRIPTION

3.1. Objectives

3.1.1. Overall objective

The overall objective of the programme is improve Belarusian food safety and quality through a gradual alignment of the country's Quality Infrastructure system with the relevant EU and international regulatory and administrative practices, with the active involvement of private sector and civil society stakeholders at all stages of the process.

3.1.2. Purpose

The specific objectives of the programme are fourfold:

- (1) **Support the reform of the Belarusian Accreditation system** to enable the demonstration of competence by national, private or public, conformity assessment operators in accordance with internationally recognised procedures

- (2) **Support to the establishment of the Belarusian Market Surveillance system** in line with those of the EU member states and the established capacity to become a part of existing rapid information exchange systems on potentially dangerous products (RAPEX, RASFF)
- (3) **Improvement of the Belarusian Reference Laboratory network** in charge of ensuring the safety of bottled water, fish, meat and milk products for public health reasons;
- (4) **Capacity building of bottled water/fish/meat/milk processing organisations**, for enabling a broad-spectrum industry dissemination of information concerning the adoption of harmonised standards, GHP, GMP and HACCP².

3.2. Expected results and main activities

3.2.1. Expected results

The project shall be structured into four components, within which envisaged results will consist of the following per component:

- (i) **Support the reform of the Belarusian Accreditation system:** Creation of the Belarusian National Accreditation body, as a separate legal entity within Gosstandart, to be subjected to peer assessment³ in order to be admitted as a member by the relevant European and international organisations; namely EA – European Co-operation for Accreditation and ILAC – International Laboratory Accreditation Conference. The objectives of this component are a precondition for potential further interventions that may be pursued under ENPI aimed at continued support to the Quality Infrastructure.
- (ii) **Support to the establishment of the Belarusian Market Surveillance system:** Development and step-wise implementation of a concept for the Belarusian Market Surveillance system that matches the requirements of the EU member states’ systems. For this reason, the model to be developed and implemented must both: (i) satisfy the essential requirement of institutionally separating the services in charge of market surveillance, and the services of the specification and monitoring of mandatory requirements on products and services; and (ii) impose a strict separation between the sampling, product testing and penalty imposition functions.
- (iii) **Improvement of the Laboratory Network:** Strengthened technical competency, services provision capacity and management practices of three laboratories - respectively those operating under Gosstandart (BelGIM’s Laboratory for the Testing of Food and Agricultural products), the Ministry of Agriculture and Food, and the Ministry of Health in order to convert them into National Reference Laboratories (NRLs)⁴. These NRLs will be tasked with the testing of residues and contaminants in food products, and capable of being accredited in accordance with the international standard ISO/IEC 17025:2005 (“General requirements for the competence of testing and calibration laboratories”), as well as satisfying the applicable EU requirements in respect of bottled water, fish, meat and milk exportable products⁵ (including newborn and infant foodstuffs).
- (iv) **Capacity building of the bottled water/fish/meat/milk processing industries:** Improved capacity of water/fish/meat/milk processing industries achieved through increased role of the professional organisations representing the bottled water, fish, meat and milk processing industries and increased awareness within the industries on food safety requirements. To that end, an explanatory Handbook for the bottled water, fish, meat and milk processing industries on the adoption of ISO 22000:2005, GMP and GHP will be prepared and widely disseminated with the assistance of participating professional organisations.

² GHP – Good Hygienic Practices; GMP – Good Manufacturing Practices; HACCP – Hazards Analysis and Critical Control Points.

³ Peer assessment means an evaluation carried out by independent auditors, of acknowledged competence, whose verdict is a necessary and sufficient condition for recognition of the qualification of the assessed entity by the international community.

⁴ The condition of “reference laboratory” implies that the laboratory’s methods and procedures have been assessed by a third party, hence ensuring that test results are exact within an assigned uncertainty interval.

⁵ Accreditation works is not foreseen within the framework of this programme. It is assumed that the accreditation works will be implemented by the Belorussian authorities (see 3.1.1 Assumptions)

3.2.2. *Main activities*

Component 1 – Support the reform of the Accreditation system

The essence of Component 1 is to contribute to the establishment of a fully-fledged Belarusian Quality Infrastructure compatible with international and EU practices in view of its determining role in ensuring the reliability of the whole QI system in Belarus. To this end, the following activities will be undertaken:

- Assessment of the accreditation activities under Gosstandart and development of an action plan to establish the Belarusian National Accreditation body as a separate legal entity under the Gosstandart system, and achieve full compliance with the requirements for EA and ILAC membership
- Implementation of the action plan (institutional restructuring of the Accreditation system, improvement of its legislative and organisational base (laws, by-laws, procedures))
- Institutional capacity building in accordance with the identified needs and requirements
- Peer assessment of the accreditation system as to its compliance with EA and ILAC requirements.

Component 2 – Support to the establishment of the Belarusian Market Surveillance system

The establishment of a national Market Surveillance system implies the concurrence of five basic factors. These are: (1) an appropriate regulatory basis, both legal and procedural; (2) an operational structure well suited to national conditions and specificities; (3) an efficient co-ordination mechanism between concerned authorities; (4) an adequately sized body of well trained inspectors and experts; and (5) a commensurate level of financing. In light of the above conditions, the following activities will be undertaken:

- Assistance in the drafting of laws transposing the fundamental EU legislation, specifically the Regulation 178/2001 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (where in the Articles 50, 51 and 52 scope and procedures of the RASFF are defined) and 1831/2003 laying down requirements for feed hygiene, the 2001/95/EC Directive on General Product Safety and the 85/374/EEC Directive on Product Liability and support to the translation of the required set of harmonised standards;
- Assistance in the development of the concept of a Belarusian Market Surveillance system based upon the EC, Parliament and Council Regulation 765/2008 on Accreditation and Market Surveillance and European market surveillance best practices;
- Assistance to the establishment and implementation of the action plan to introduce a concept developed in the previous activity.
- Assistance to the operation of the inter-ministerial working group in charge of the adoption of the appropriate policy guidelines for ensuring that: (a) the system to be implemented satisfies the requirements of all sectors (not just the food sector); (b) a regional structure is planned to be installed in parallel with the central one, in order to guarantee country-wide coverage by the system; and (c) the society at large and specific stakeholders are consulted with when and where appropriate.

Component 3 – Improvement of the Laboratory network

This component envisages supporting the adoption of current (and technically dependable) testing methods with respect to the target products mentioned above, and the procurement of crucial testing equipment to convert these laboratories into National Reference Laboratories. Activities to be undertaken under this component are:

- Preparation of the tender for the supply of equipment, software and purchase of reference materials to the selected laboratories dealing with testing of residues and contaminants in food products;

- Identification of training needs of the three laboratories with regard to the usage of the equipment to be supplied, preparation of the corresponding training programme and subsequent implementation;
- Assistance in the attainment of the status of National Reference Laboratory by the three concerned laboratories, on the basis of appropriate legislation and by-laws;
- Capacity building of the three laboratories in order to enable them to perform their role as reference laboratories with respect to the relevant national laboratory network
- Assistance to the definition and implementation of administrative and procedural practices ensuring the independence of market surveillance associated testing activity in respect of the current testing services provision.

Component 4 – Capacity building of the bottled water/fish/meat/milk processing industries

This component aims at testing, the openness, motivation and capabilities of a small number of Belarusian enterprises for adopting procedures compatible with an EU food safety approach. These will be selected on the basis of agreed criteria, with the assistance of sectorial professional organisations. Moreover, the engagement of the professional organisations is aimed at fostering the necessary product safety and quality accountability of the Belarusian food industry. The activities to be undertaken are, therefore, the following:

- Mapping of existing organisations representing the Belarusian bottled water-, fish-, meat- and the milk- processing industries and, in case of non-existence of appropriate professional organisations, fostering their set-up;
- Identification of needs and provision of means for supporting the selected organisations to fulfil their statutory objectives;
- Establishment of the criteria for the selection of twenty enterprises, and the indicative selection of five enterprises per sector for participating in pilot experiments for the adoption of ISO 22000:2005, GMP, GHP;
- Support to standardization work in Belarus (translation and adoption of EN⁶ standards, development of new standards) as required by the food sector processing industries;
- Preparation of an explanatory Handbook for the concerned processing industries on the adoption of ISO 22000:2005, GMP, GHP based on reports on lessons learnt by each participating enterprise;
- Industry-wide dissemination of the Handbook performed by the professional organisations.

3.3. Assumptions and risks

3.3.1. Assumptions

The programme provisions are based upon the following assumptions:

- Continuous commitment and determination of the Belarusian government to align with EU/international standards and quality assurance procedures;
- Smooth development and approval of the legislation and implementation of reforming measures;
- Co-ordination and co-operation of the main stakeholders in implementing the project activities;
- Commitment of the concerned Ministries and Gosstandart to proceed with the necessary steps to achieve the accreditation of the three laboratories in accordance with ISO/IEC 17025:2005, “General requirements for the competence of testing and calibration laboratories”.

3.3.2. Risks

The main risks to be faced in the carrying out of the project are the following:

⁶ EN standard" (or European *norm*) is the agreed terminology applied to all voluntary standards developed under the European standardization organisations: CEN, CENELEC (electrical field) and ETSI (telecommunications).

Component 1: *Gosstandart*'s inability to fully implement the institutional and procedural reforms.

Component 2: a partial implementation of the Market Surveillance concept that could potentially lead to structural weaknesses of the installed product safety assurance system, and the inability of consumers protection associations to take advantage of the opportunity for building capacity and reaching even broader segments of the Belarusian society.

Component 3: Laboratory(ies) failure to be designated as reference laboratories within the programme framework despite the provision of equipment and training.

Component 4: Inability or unwillingness of Belarusian bottled water, fish, meat and/or milk professional organisations to undertake the role assigned to them under the programme.

3.4. Crosscutting issues

3.4.1. Environmental sustainability

The project as such does not contribute to harming the environment. Nevertheless, laboratories produce four types of waste: chemical, biological (infectious wastes), other wastes (oils and filters), and animal by-products. The project will ensure that the upgrade of the laboratory is matched with a corresponding upgrade of the waste management facilities.

3.4.2. Gender equality

The project is strictly neutral in respect of equal opportunities.

3.4.3. Good governance

All four project components include provisions for good management practices.

3.4.4. Human rights

Although not specifically related to human rights, food safety being a consumers' right, this programme contributes to securing that right for the population as a whole.

3.5. Stakeholders

The direct Beneficiaries of the programme are *Gosstandart* and the Ministries of Agriculture and Food, and of Health. *Gosstandart* with respect to the accreditation activities and through BelGIM's Laboratory for the Testing of Food and Agricultural products; the other Ministries will be beneficiaries through the respective food products and raw materials testing laboratories. The following entities are also stakeholders:

- Professional and business associations;
- Consumer rights protection organisations;
- Manufacturing and services companies.

4. IMPLEMENTATION ISSUES

4.1. Method of implementation

Direct centralised management.

4.2. Procurement and grant award procedures

4.2.1. Contracts

It is expected that this action will be implemented as services and supply contracts covering the service and supply components of this action.

All contracts implementing the action must be awarded and implemented in accordance with the procedures and standard documents laid down and published by the European Commission for the implementation of external operations, in force at the time of the launch of the procedure in question.

4.3. Budget and calendar

4.3.1. Budget

The overall cost of the project is €8.5 million.

The indicative breakdown of the budget is as follows: Component One: Support to the Reform of the Accreditation system, €1.5 million; Component Two: Support to the establishment of the Belarusian Market Surveillance system, €1.5 million; Component Three: Improvement of Laboratory Network, €3.25 million (2,5M€ Supply and €0.75 million capacity building); Component Four: €2 million; and a provision for visibility, evaluation and audit of €0.25 million.

4.3.2. Calendar

The foreseen operational duration is thirty six (36) months from the signature of the service contract. The procedure for the procurement of supplies will indicatively be launched within 6 months of the signature of the service contract. All contracting will be concluded within three years of the signature of the Financing Agreement.

4.4. Performance monitoring

4.4.1. Overview

On account of the non-specific project DAC code, no EuropeAid Standard Indicator is seen as immediately relevant for the required performance monitoring. In the course of the programme implementation, the beneficiaries shall propose objectively verifiable indicators. These may be of the following types:

- Efficiency - quantitative, i.e. a measure of quantities, such as time required by an assessing entity for delivering the assessment result, or
- Performance - qualitative, i.e. subjective evaluations, such as the level of satisfaction of participants in an awareness campaign.

The detailed list of specific indications is given in Annex 1.

4.5. Communication and visibility

4.5.1. Communication

The project has three built-in communication channels of differentiated nature and range:

(1) With respect to Component 1, the required consultations within the National Accreditation body's constituency for achieving a desirable consensus as to intervention scope and procedures (to be consolidated later by the appointment of the Accreditation body's steering committee and the operation of its technical committee(s)),

(2) Within Component 2, on account of the need for the adoption of political decisions supported by a public that understands the importance and implications of the market surveillance alternative to pre-market control will require a well structured public information campaign;

(3) Within Component 3, communication will be engaged through the pilot project results dissemination stage that will mainly be done by professional and business associations' organisations

4.5.2. Visibility

The programme objective of involving consumers' organisations in the setting up of a "watchdog" function for marketed bottled water, fish, meat and milk products safety will also ensure the visibility of the programme. To that end, resources have been made available for public information campaigns that will necessarily publicly identify the project as its funding source. A role for consumer organisations is also foreseen as the organisers of wide public information campaigns promoting public awareness on food safety issues.

Appendix 1.

Component 1 specific indicators

Indicator	Definition
Performance	Entering in operation of National Accreditation body and adequacy of permanent personnel to work to be performed (Law on establishment of National Accreditation body approved by the Cabinet of Ministers and progress reports of the National Accreditation body)
Efficiency	Number of appeals upon accreditation granted, refused, suspended, or terminated

Component 2 specific indicators

Indicator	Definition
Performance	Adoption of the basic Belarusian Market Surveillance system legislation (e.g. transposition of 2001/95/EC Directive on General Product Safety and the 85/374/EEC Directive on Product Liability)
Efficiency	Quantity of product quality related mandatory standards cancelled

Component 3 specific indicators

Indicator	Definition
Performance	Existence of regional laboratories network whose proficiency is routinely checked by means of round-robin tests and ring tests by the national reference laboratories
Efficiency	Average time from sample reception in the reference laboratory to report delivery to customer

Component 4 specific indicators

Indicator	Definition
Performance	Coverage of the all sectors (bottled water, fish, meat, milk) by the correspondent professional organisations actively participating at application of industries' food safety standards
Efficiency	Percentage of conforming/non-conforming samples, collected at a participating enterprises, identified by a reference laboratory; number of food safety standards developed within the programme framework and practically introduced throughout the food industry; membership and territorial coverage of professional organisations engaged in the programme

Appendix 2.

This proposal concerns the development of laboratorial facilities for controlling the quality and safety indicators in bottled water, fish, milk and meat products in accordance with the requirements of the Council Directive 90/23/EC dated April 29, 1990: "Quality and safety control of milk, meat, and milk and meat products for determining the presence of contaminants residues" by the laboratories of the three departments of the Republic of Belarus (Ministry of Agriculture and Food, Ministry of Health, *Gosstandart*).

Testing laboratory of the Ministry of Agriculture and Food (Belgosvetcentre):

GROUP A:

- A1) Stilbenes and their derivatives, salts and esters (diethylstilbestrol);
- A2) Antithyroid agents (methylthourasile);
- A3) Steroids (19-nortestosteron, trenbolon);
- A4) Lactones of resorcylic acids (zeranol) not in all matrixes;
- A5) Beta-agonists (clenbuterol);
- A6) Nitrofurans metabolites (AOZ, AMOZ, SEM, AHD), metronidazole.

GROUP B:

- B2) Veterinary drugs:

B 2a) Anthelmintics (albendazol, fenbendazol, ivermectine);

B 2b) Coccidiostatics including nitroimidazols (monenzine, salinomycin);

B 2e) Non-steroidal anti-inflammatory preparations (metamizol).

Necessary equipment:

1. Chromatograph-mass spectrometer
2. Liquid chromatographs
3. Gas chromatographs

Testing laboratory of the Ministry of Health of the Republic of Belarus:

GROUP B:

- B1) Antibacterial substances (antibacterial means, sulfanilamides, enrofloxacin, gentamicin);

Necessary equipment:

1. Liquid mass spectrometer;
2. Complex: preparation of samples for pesticides.

Testing laboratory of Gosstandart of the Republic of Belarus:

GROUP A:

- A 6) Chloroamphenicol;

GROUP B:

- B 1) Tetracycline, oxytetracycline, benzylpenicillin;
- B 2c) Urethanes and pyrethroids (cypermethrin).
- B 3) Other substances and environmental contaminating substances:

B 3a) Chlorine-organic compounds including polychlorinated biphenyls;

B 3b) Phosphorus-organic compounds;

B 3c) Chemical elements;

B 3d) Micotoxines; (B1, M1, oxpatoxine A)

B 3e) Dyes;

B 3f) Radionuclides (strontium-90, cesium-134/137).

Necessary equipment:

1. Gas chromatograph with electronic entrapment detector and thermo-ion detector with the programmed evaporator;
2. Gas chromatograph with flame-ionization detector;
3. Liquid chromatograph with diode-matrix and fluorometric detector;
4. Equipment for immune-enzyme analysis
5. Automatic Protein (Nitrogen) Determination System,
6. Equipment and materials for preparation of samples.