1. Basic information

1.1 CRIS Number: BG2003/004-937.02.04

1.2 Title: STRENGTHENING FOOD SAFETY POLICY

1.3 Sector: Internal Market and Economic Criteria
   - Twinning Number BG03/IB-FI-04

1.4 Location: Bulgaria

2. Objectives

2.1 Overall Objective(s)
To guarantee the safety of food to both Bulgarian and EU consumers, implementing the EU principles on Food Safety.

2.2 Project purpose
Secure the implementation of the Bulgarian food safety legislation through human resource strengthening and provision of equipment, in order to provide a high level of food safety.

2.3 Accession Partnership and NPAA priority
   The following are quotations from the Accession Partnership:

   **Free Movement of Goods:**
   - ”Pursue alignment of traditional sectoral legislation in the foodstuffs sector. Reinforce market surveillance systems and prepare administration and food operators for EC principles of food safety.”

   **Agriculture:**
   - “Upgrade the capacity of the agriculture administration for the practical implementation and enforcement of the management mechanisms of the common agricultural policy, in particular the integrated administration and control system and the paying agency for the management of common agricultural policy funds, as well as for the implementation and enforcement of veterinary and phytosanitary and food safety legislation.”
   - “Continue the upgrading of food processing establishments so that they are in a position to respect Community food safety standards.”
   - “Continue the reinforcement of the food control administration.”

   **NPAA priority**
   See NPAA 2002 - MoH
   Ref: NPAA 2002 - Chapter 7 Agriculture

Contribution to National Development Plan

**National Development Plan priorities**
Food Safety Strategy (FSS) - See Annex 6
The food safety policy of the Republic of Bulgaria is based on the current legislation in this area. The basic legislation includes the Law on Foodstuffs, Law on Public Health, Veterinary Law, Plant Protection Law and Fodder Law. These laws lay down the requirements to foodstuffs, producers’ and traders’ obligations, as well as the procedures for official control covering the whole food chain. On the basis of these law a number of regulations and ordinances have been adopted and are being adopted, specifying the detailed requirements in the field covered, thus transposing the acquis in the national legislation.

3. Description

3.1 Background and Justification

The quality and safety of food products is an issue of concern to consumers, the food industry and the government. As everywhere, this is of extreme importance for human health protection.

Bulgarian food products were well accepted in many markets worldwide in the years before 1990. The start of land restitution brought the end of the large collective farms, food processing ‘combinats’, and the large dairy and pig herds. Producers and processors experienced sharp declines in production and loss of markets. Consecutive governments began the process of harmonizing national standards with the more stringent EU and international requirements required by membership in the WTO.

The alignment of Bulgarian food legislation with the EU acquis is a major pre-condition for the implementation of market economy mechanisms and an important stage in pre-accession to the EU. It has been the focus on various support and initiatives. The result of these have been analysed and commented by the FVO DG Sanco Mission 8504/2002 from 11/03/2002 to 15/03/2002), which recommendations have been taken into consideration when preparing the activities foreseen under this fiche. The principles for the application of the food legislation already in place in the EU are included in the Acquis Communautaire and the General Principles of Food Law in The European Union (Green Paper Commission). Food safety legislation is being modified to meet EU requirements.

The work on legal harmonisation is well advanced. A thorough gap analysis has been prepared, and negotiations with Brussels on Chapter 1 are closed, and partially closed on Chapter 7. A detailed work plan on this issue is provided in Annexes 4 and 5.

The Food Safety Strategy

The complete Strategy is included in Annex 6. It describes the current situation, and the intended steps in the medium-term. It indicates that there is an intention of (i) streamlining the responsibilities of the Ministry of Health and the Ministry of Agriculture and (ii) reduce the quantity of laboratories 1 or increase their specialisation 2.

Both intentions will be supported via this programme. The Twinning experts will join the working groups defining the streamlining needs, allowing for a clear delineation of responsibilities between the Ministries, the definition of the appropriate amendments to the

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1 In 1990, there were 150 veterinary laboratories under the Ministry of Agriculture. This amount has been reduced since to 70, some of which are very small. The intention is to further reduce the amount to eventually 32 (the three Institutes for animal diseases in Sofia, Veliko Tarnovo and Stara Zagora, and 29 for control of products of animal origin: the Sofia Central Laboratory, and 28 regional laboratories of which 8 major, reference laboratories (milk, meat, etc) and 20 satellite laboratories). Annex six provides all the details on this strategy.

2 The Ministry of Health (MoH) has 28 regional laboratories. The quantity will not change but 6 will become specialised for a broad variety of controls, while the remaining 22 will be small laboratories doing only routine checks such as microbiological and chemical controls.
Laws, and draft proposals for the adaptation of the working procedures at field level. The supplies are foreseen for 6 laboratories from the Ministry of Health and one laboratory from the Ministry of Agriculture. All these laboratories have been identified as long-term laboratories.

The EU policy direction concerning food control, as reflected in the White Paper, is that all parts of the food chain must be subject to official controls. With the harmonisation of its legislation, Bulgaria has introduced the legal framework requiring official controls of all parts of the food chain. This currently falls under the responsibility of the Ministry of Health and also of the Ministry of Agriculture.

Equipment needs

The implementation of the Laws is made difficult because the laboratories of the Ministry of Health are under-equipped. These have not been supported by international projects and are in dear need of modern equipment. In order to allow for appropriate food safety controls as foreseen in the law, the laboratories in Sofia, Plovdiv, Veliko Tarnovo, Pleven, Varna and Bourgas will benefit from equipment to upgrade their existing capacity.

The equipment will allow them to receive certification as required by the Law on Foodstuff, and implement good laboratory practices.

An additional laboratory is foreseen, that depends on the Ministry of Agriculture, for relatively minor yet highly important equipment. As explained in Annex 9, this equipment will replace classic outdated methods that are time and labour consuming. With the supplies foreseen, sampling will be more rapid, more efficient, and less expensive. The savings in time and funds will allow increasing the quality (reliability) and quantity of sampling p.a. and thus increase the control coverage. Also, the delineation of responsibilities between the two Ministries (Health and Agriculture) needs clearer definition to secure optimal coordination and avoid overlapping of responsibilities. This has been identified in the post mission report of the FVO dated 01/08/2002.

The laboratories foreseen to be supported under this fiche are all fully ready to accept the equipment (premises and facilities, staff, funding). These 6 have been selected from a total of 28 MoH laboratories on the basis of existing laboratory quality, geographical distribution, and staff competence.

Bulgaria is convinced that the project activities, as stated in this document, and their implementation will enable food safety in the country to be organised in a more co-ordinated and integrated manner with a view of achieving the highest possible level of consumers’ health protection.

3.2 Linked activities

The project is linked to the following previous and ongoing Phare activities, none of which would be overlapped.

The technical specifications for the equipment to be procured for the laboratories (activities A 1.1 and A 1.2) will be prepared by the Bulgarian experts. In order to secure that the specifications will respect all the rules for fair competition, a short term expert will be mobilised in late 2003, using the PPF, to review the equipment needs and check the specifications (see paragraph 12).

3 Currently, controls of additives, contaminants (pesticides, residues, heavy metals mycotoxins) that are required by the Food Law are not implemented because of the absence of laboratory equipment with the exception of Sofia.
Completed projects in Veterinary Sector:

- BG9806-01- Animal Health and diagnostic/TA to Improvement of veterinary legislation -BG 98/AG/IB/01- The objective of the project was to provide necessary technical assistance to bring the Bulgarian in line with EU standards from the point of view of legislation and inspection practices. The purpose was especially to provide sufficient training to the relevant NVS staff in the selected fields of the official control of foodstuffs and legislation.

- BG9913-01-Animal identification and veterinary Border Control. The objective of the project was to improve the information system in order to establish a well functioning system linking up the NVS Head Quarter with the regional offices, which allowed a faster distribution of information about the identification of animals. The investments for the information system were also focused on modernization of computer nets and unification of net operation systems. The aim of the Veterinary border control sub-project Reconstruction of BVIP Kapitan Andreevo was to complete institutional structures required for ensuring the supervision of veterinary activities to protect consumers against unhealthy food.

Ongoing projects

- BG 0101 .04 Improvement of veterinary control.

Planned projects:


Completed projects in Phytosanitary Sector:

- PHARE project BG 9103-06-06
  Project objectives: to define more accurately the legal and regulatory framework of the NSPPQA in compliance with the requirements of the EU, to improve the organisation and structure of NSPPQA, to train NSPPQA’s staff with regard to the EU phytosanitary legislation.
  Results: evaluation and recommendations for improving the organisation and activities of the NSPPQA, workshop on EU legislation, preparation of draft legislation introducing relevant EU acquis, provision of literature and technical equipment for NSPPQA.

- PHARE project BG 9507-02-03
  Project objectives: work improvement through technical assistance and training of the Central Laboratory for Plant Quarantine (CLPQ) and Central Laboratory for pesticides, nitrates, heavy metals, fertilisers control (CLPNHMFC) as well as of biological testing and registration of pesticides.
  Results: Upgrading of the technical equipment of two laboratories and the sites for biological testing. On-spot training was organised in the Netherlands and the UK, as well as a visit in similar laboratories in the Netherlands.

- PHARE projects BG 9806-01-02 and BG 9913-02. These projects are closely related to twinning project BG98/IB/AG/02 (with France).
  Project objectives: Supply of equipment for the CLPNHMFC, CLPQ, 4 regional phytosanitary laboratories, 2 pilot sites for biological testing and 9 border posts.
  The analyses equipment for the CLPNHMFC (700,000 Euro) has already been delivered and is under testing.
The Twinning project with France includes three sub-projects on:

- Plant health inspections for imported and domestic production which covers border control, production control and laboratory analysis;
- Biological testing and registration of plant protection products;
- Pesticides residue control in plant production and preparing the CLPNHMFC for international accreditation in compliance with the principles of GLP.

All sub-projects include assessment of the existing capacity, harmonisation of legislation, workshops and individual training in Bulgaria and in EU member states. A long-term expert from France has been working constantly in Bulgaria since the beginning of 1999.

3.3 Results

- Capacity of the institutions responsible for food safety control strengthened through equipment delivery and staff training coordinated with the initiatives under TAIEX and according to the recommendations of the last Advisory Visit Mission of the MS experts.
- Existing food control system improved, operating throughout the whole food chain, through better streamlining of responsibilities and coordination between stakeholders implementing food safety policy
- National Rapid Alert System (RAS) fully functional
- Legal framework related to Chapter 1 and Chapter 7 are fully harmonised.

3.4. Activities

Project activities include:

3.4.1. The Twinning Project

Three sub-projects are envisaged under the twinning covenant.

Profile of the PAA

The PAA should have the following profile:
- experience in management of state administration bodies
- substantial experience in implementation of national food safety policy
- excellent inter-personal communication skills
- initiative and co-operative attitude
- fluency in English.

Profile of the Short and medium term experts

The short- and medium-term experts should have the following profile:
- knowledge of the EU food law and food safety policy
- knowledge of developments in systems for food control in the Member States
- fluency in English

Content of the twinning sub-projects:

Sub-project 1. Strengthening the coordination between institutions involved in Food Safety control.

- Institutional review of the Ministries and other partners involved in Food Safety, definition of their roles and responsibilities (in particular related to legislative and executive functions)
- Analysis of the needs of all authorities concerned with regard to their involvement in the implementation of Food Safety Strategy (Annex 5)
- Proposal of a new definition of responsibilities, clearly delineating the roles and functions of the Ministries of Agriculture and Health and their institutions – proposal for amendments to
the Law on Foods and the Law on Veterinary Activities to harmonise them fully between themselves (see activity under Sub-project 3).

- Visit of 4 experts (2 from each Ministry) to Ministry of Health and Ministry of Agriculture of MS to be informed of their coordination mechanisms.
- Identification of the role of the Rapid Alert System (RAS) in the scheme as IT system linking the stakeholders
- Definition of communication protocols between the institutions involved
- Identification of IT needs for RAS and preparation of technical specifications
- Training on RAS and communication protocols

**Means:** corresponds to activities A 2.1 – A 2.2 – A 2.3 and A 3.1 of the logical framework (LFW) in Annex 1.

**Sub-project 2: Strengthening of the food safety control system through training and supply of equipment**

- Elaboration of national programme for training of state inspectors and laboratory staff: training needs analysis and development of a training plan
  - Preparation of training manuals
  - Elaboration of food inspection manual
  - Training of 33 inspectors from the state sanitary control as trainers for one week for each following issues: implementation of RAS and Good Hygiene Practice (GHP) principals in the twinning partner country⁴
  - Training of 8 laboratory specialists from Hygiene Epidemiological Inspectorates (HEI) as trainers for one week on Good Laboratory Practice (GLP) principals in the twinning partner country⁵
  - Training of 5 Veterinary inspectors and 33 HEI state sanitary inspectors for one week on implementation of rapid alert system.

**Means:** corresponds to activities A 1.3 – A 1.4 – A 1.5 and A 1.6 of the logical framework (LFW) in Annex 1.

**Sub-project 3: Adaptation of legislation**

- Based on the gap analysis, the twinning experts will help in reviewing and drafting the Chapter 7 laws in association with a working group of the Ministry of Agriculture. The exact scope of the task will be defined at project start in order to check whether drafting activities might also be needed related to chapter 1.

- Revision of the current harmonised Bulgarian legislation and advice to the responsible authorities on EU food safety legislation developments. This activity will join and continue the activities of the working group (composed of representatives from the Ministry of Health, the Ministry of Agriculture and Forestry, and the Ministry of Economy) currently established to review the Food Law, if this is not yet completed. They would also support the work on

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⁴ This group is composed of one inspector from each of the 28 regions, 3 inspectors from the Ministry of Health, one expert from the National Centre for Hygiene, and one from the National Centre of Radiology. These will subsequently organise cascade training for the 1500 inspectors in the country.

⁵ One from each of the six beneficiary laboratories, and one from each of the two National Centres (Hygiene and Radiology).
the review of the Veterinary Law, by a working group that should be composed of the same Ministries, and which will start upon the completion of the amendments on the Food Law (end 2003).

- Assisting with the transposition and implementation of EU food safety legislation

**Means:** corresponds to activities A 4.1 and A 4.2 of the logical framework (LFW) in Annex 1.

**3.4.2. Supply of equipment:**

- Supply of equipment for the laboratory for veterinary hygienic expertise of foodstuffs from animal origin at the NVDRI under the NVS according the EU food safety requirements;
- Supply of equipment for 6 regional control laboratories for food analysis within the structure of the Ministry of Health;
- Supply of IT equipment (hardware and software) for establishment of a National Rapid Alert System on exchange of information on dangers, arising from food products.

**3.5 Lessons learned:**

Project BG9806-01/ Animal Health and diagnostic/ BG 98/AG/IB/01 The adoption of legislation was the major expected output from of this Twinning Project and we definitely consider it as a weakness of this MS twining partner the unsatisfactory overall situation with completing the transposition of our veterinary legislation.

The Kapitan Andrevevo project demonstrated various complications related particularly to the land issue. Excessive delays were caused by the land expropriation procedure. For this reason, the allocation of land for each of the three BVIPs has been taken as a priority.

**4. Institutional framework**

The responsibility for food control activities related to food safety, quality and standardisation within Bulgaria for domestic, imported and exported consignments is split among the Ministry of Health (MoH) and the Ministry of Agriculture and Forestry (MAF) (see Annex 7 “Structure of the Institutions Responsible for Food Safety Control”). Because of this duality, a National Council on Food Safety (NCFS) has been established within the Council of Ministers, in charge of coordinating the state policy on food safety. An Executive Food Safety Committee within the NCFS has been established and is working since mid 2002, and supervises 5 permanent working groups. The NCFS will be the ultimate responsible institution regarding the proposed streamlining of responsibilities related to Food Safety, as well as the setting-up of the RAS (A 2.1; A 2.2; A 2.3; A 3.1; A 4.1; A 4.2). The RAS will directly benefit both Ministries since it will link them and their agencies.

Ad-hoc working groups will be created for the purpose of the project. Line Ministries and other institutions (e.g. associations of producers) will nominate their representatives in the ad-hoc working groups. The permanent working groups under the NCFS will accompany, comment and support the activities of the ad-hoc working groups. The outputs of the ad-hoc working groups, once reviewed and commented by the permanent working group, will be discussed and endorsed at the NCFS, which will act as a coordination, information exchange forum in the intention of developing consensus on the strategies and solutions proposed by the working groups.

Training will benefit staff from both Ministries according to the indicative breakdown indicated in the activities.

The legal drafting activities will benefit more specifically the Ministry of Agriculture. The equipment will mostly benefit the Ministry of Health. Some minor pieces of equipment will go for the Ministry of Agriculture.
The Ministry of Health:
The Ministry of Health exercises state sanitary food control. The state sanitary control is managed directly by the Deputy-Minister of Health, who is also Chief Sanitary Inspector of the Republic of Bulgaria. At the national level Directorate “Health Prophylactics and State Sanitary Control” (HPSSC) directs, plans, coordinates and controls the activities of the regional inspectorates (HEIs) and exercises their methodological guidance in implementing the food safety legislation.

The 28 Hygiene and Epidemiological Inspectorates implement food safety control measures at local level. The State Sanitary Control Department and the Laboratory Research Department of the HEI are structures responsible for and directly involved in carrying out the food safety control. The Health Prophylactic and State Sanitary Control Directorate controls at national level the activities of the SSC and laboratory analyses departments of the 28 Hygiene Epidemiological Inspectorates (HEI) for monitoring and controls contaminants in foods, pre-market approval and certification of foods of non-animal origin.

(see Annex 7 Relevant Structure of the MoH)
The Ministry of Agriculture and Forestry, through:

1. The National Veterinary Service (NVS);
2. The National Service for Plant Protection (NSPP);
3. The Chief Directorate of Feeding stuffs Control (CDFC) within the National Grain Service (NGS).

The National Veterinary Service is responsible for official controls in the area of animal health, animal welfare and animal feedingstuffs in respect to meat and bone meal controls and safety issues. The service is also responsible for official control over food establishments producing food of animal origin. This control extends to supervision of retail and catering establishments.

The National Service for Plant Protection is responsible for official controls in the area of plant health (harmful organisms), both in the territory of Bulgaria and for imports of plants, for biological testing of plant protection products, and for controls on the marketing and use of plant products.

The Chief Directorate of Feeding stuffs Control is responsible for official control over animal feeding stuffs in relation to quality issues. Their area of responsibility covers the approval and registration of producers and traders of animal feeding stuffs, controls over additives used in the manufacture of animal feeding stuffs, controls over trade in compound feeding stuffs and feeding stuffs for special purposes. The Directorate also carries out some activities in relation to controls over the use of meat and bone meal in animal feeding stuffs.
5. Detailed Budget

<table>
<thead>
<tr>
<th>Phare Support</th>
<th>Investment Support</th>
<th>Institutional Building</th>
<th>Total Phare (I+IB)</th>
<th>National Co-financing (*)</th>
<th>IFI</th>
<th>TOTAL</th>
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<tr>
<td>Contract (1) Twinning covenant</td>
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<td>0.900</td>
<td>*</td>
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<td>Contract (2) Supply of equipment</td>
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<td>Contract (3) Supply of IT (hardware and software)</td>
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<td>Total</td>
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<td>2.925</td>
<td>0.675</td>
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Note (*) The national co-financing of 25% (€ 0.675 MEURO) for the investment component of the project and up to 10% of the Twinning project will be covered from the national budget through the National Fund Directorate at the Ministry of Finance. Phare and national co-financing will be tendered and contracted jointly. The national co-financing will be covered from the national budget, through the National Fund Directorate at the Ministry of Finance. Detailed lists of equipment are available in Annex 8.

- The Phare contribution for the equipment will be 75% of its cost, with a maximum of Phare contribution of 2.025 MEURO.

All running costs and the maintenance of the equipment purchased under this project will be provided by the Bulgarian authorities.

6. Implementation arrangements

6.1 Implementing Agency

The CFCU will be the Implementing Agency responsible for tendering, contracting and accounting with assisting in good project design and implementation and Phare procurement and payment rules. The CFCU (Ministry of Finance) is in charge of the contracting and financial management of the project. The Deputy Minister of Ministry of Finance will act as PAO of the project. His contact details are:

Deputy Minister of Ministry of Finance and PAO
Address: 102 Rakovski Str.
1040 Sofia
Tel: 359 2 985 927 81
Fax: 359 2 980 68 63

6.2 Beneficiaries

The beneficiaries MoH and MAF will have the responsibility for technical preparation and control (designing, selecting).

The joint beneficiary of the twinning project is MH and MAF.
MoH contact point:
Head of Administration and Project Management Department
Address: Ministry of Health
39, Alexander Stamboliyski Blvd
1000 Sofia, Bulgaria
Tel No: +359 2 9301204 Fax No: +359 2 9872521
E-mail: mmihaylova@mh.government.bg

MAF contact point:
Head of Coordination of European Integration Department
Address: Ministry of Agriculture and Forestry,
55 Hristo Botev Blvd, Sofia, Bulgaria.
Tel No: +359 2 985 11 364 Fax No: +359 2 981 23 18
E-mail: s.chamova@mzgar.government.bg

The Steering Committee, overseeing the project has representatives of the following:
The Contracting authority,
The EC Delegation,
The Beneficiaries
The Contractor

The Phare Implementation Unit will be in charge of the Monitoring and control of the progress of the projects, their implementation. It will also be the platform securing ensuring facilitation and coordination between all the stakeholders (Ministry of Finance (Contracting Authority); the Beneficiaries; and EC Delegation). The contact point is:
Head of Phare Department
Address: Ministry of Agriculture and Forestry,
55 Hristo Botev Blvd, Sofia, Bulgaria.
Tel No: +359 2 981 61 63
Fax No: +359 2 981 75 42
E-mail: demina@phare-agr.orbitel.bg

6.3. Non-standard aspects
The PRAG Procedure will strictly be followed.

6.4 Contracts

Contract (1) – Twinning covenant **0.900 M €** plus national co-financing up to 10%
The procurement of the governmental cofinancing will be done under the National Procurement Act
Contract (2) – Supply of Equipment **2.400 M €**

Contract (3) – Supply of IT (hardware and software) **0.300 M €**
The procurement of the Equipment will be done under PRAG.

7. Implementation Schedule

**Contract 1 - TW**
Start of tendering/call for proposals January 2004
Start of project activity September 2004
End of TW activities August 2005 (12 months)
Project Completion:
- Providing of TS for the supply of RAS IT January 2005
- All activities completed August 2005
Final payment twinning December 2005

**Contract 2 – Supply of Laboratory equipment**

- TS prepared and verified by December 2003
- Start of tendering/call for proposals January 2004
- Start of project activity (sign contract) September 2004
- Project Completion January 2005
- Final payment (excluding retention sums) March 2005

**Contract 3 – Supply of RAS IT equipment**

- Start of tendering/call for proposals January 2005
- Start of project activity (sign contract) September 2005
- Delivery January 2006
- Final payment (excluding retention sums) March 2006

8. **Equal Opportunity**
All participating Bulgarian institutions are equal opportunity employers. No discrimination of whatever nature will be applied.

9. **Environment**

The supplies will be delivered into existing premises. No environmental impact is expected and the supply of equipment falls does not require any sort of environmental assessment. The specifications will take into account the respective standards and norms applicable for IT systems.

10. **Rates of Return**

The equipment will not generate incremental costs related to the current running of the laboratories. Staff and premises exist and are running. It will nevertheless generate additional income thanks to the increased quantity/type of samples per year. Non-tangible benefits will be related to increased human health protection.

11. **Investment criteria**

11.1 **Catalytic effect:**
The Phare contribution will accelerate the implementation of the food safety policy and of the relevant legal framework..

11.2 **Co-financing:**
The recipient will finance 25% of the total project costs.

11.3 **Additionality:**
The Phare contribution shall not displace other financiers, especially from private sectors or IFIs.

11.4 **Project readiness and size:**
Technical specifications and tender documentation will be ready at the time of the signature of the Financing Memorandum.

11.5 **Sustainability:**
Sustainability of project results is assured through the need and commitment by Bulgaria to implement its food safety policy. No new institutions or laboratories will be created, but existing ones refurbished. Staff increase (or decrease) are not expected as a result of the project. All supported investment actions (supplies) are sustainable in the long term.
beyond the date of Accession. They will comply with the EU norm and standards (accredited), and will be coherent with the sector policies of the EU. Future maintenance, IT developing and operation costs will be covered by the Bulgarian national budget.

11.6 Compliance with state aids provisions
All investments will respect the state aid provisions of the European Agreement.

11.7 Contribution to NDP and/or Structural Funds Development Plan/SPD
Not applicable.

12. Conditionality and sequencing
The following assumptions are made or actions are to be undertaken or approved before the Phare supply component can start:

- Projects to be implemented through twinning require the full commitment and participation of the senior management of the beneficiary institutions. In addition to providing the twinning partner with adequate staff and other resources to operate effectively, the senior management will be whole-heartedly involved in the development and implementation of the policies and institutional change required delivering the project results. Commitment in this sense has already been taken.

- The technical specifications for the laboratory equipment will be prepared by Bulgarian experts from the beneficiary institutions/laboratories by September 2003. These will subsequently be reviewed by an external contracted expert (PPF) by the end of 2003. The agenda for this activity is as follows:

  
  February: creation of expert group to prepare first draft of the technical specifications
  June: first draft ready
  February: Terms of Reference for PPF submitted for approval – start of procurement procedure (25,000 EUROs)- see Annex 10
  Contracting by September 2003, finalised technical specifications to be ready by December 2003.

- Before receiving the equipment described in Annexes the Laboratories will be refurbished. Actually, only a few of them need some painting which will be done in the summer of 2003. No other investment is necessary. The final confirmation of the equipment needs and the premises readiness will be made under the twinning project before the start of the tender procedures.

ANNEXES TO PROJECT FICHE
1. Logical framework matrix in standard format
2. Detailed implementation chart
3. Contracting and disbursement schedule by quarter for full duration of programme
4. NPAA 2002 – MoH and MAF
5. List of Relevant Laws and Regulations
6. Food Safety Strategy
7. Structure of the Institutions Responsible for Food Safety Control
8. Lists of Laboratory Equipment
9. Laboratory needs explanation
10. Draft ToR for PPF to review technical specifications
11. STATEMENT on Project Management Capacity of the Ministry of Health
**LOGFRAME PLANNING MATRIX FOR PROJECT: Strengthening Food Safety Policy**

<table>
<thead>
<tr>
<th>Overall objectives(s)</th>
<th>Objective Verifiable Indicators</th>
<th>Sources of verification</th>
<th>Assumptions</th>
</tr>
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<tbody>
<tr>
<td>To guarantee the safety of food to both Bulgarian and EU consumers, implementing the EU principles on Food Safety</td>
<td>By end of 2005 legislation relating to the food safety harmonized</td>
<td>Annual reports from MoH and MAF according to the harmonized legislation</td>
<td>The drafted legislation is adopted by the relevant bodies</td>
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<td>Decreasing by 25% of food contamination cases at national level between 2005 and 2010.</td>
<td>Annual reports from HEIs and Veterinary inspectorates</td>
<td>Support by state budget</td>
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<td>By end of 2005 legislation relating to the food safety (Chapters 1 and 7) harmonized</td>
<td>Official documentation of MoH and MAF</td>
<td>Necessary human resources available.</td>
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<td>Comprehensive policy for ensuring food safety involving all relevant institutions adopted by Government by end 2005</td>
<td>Long term agreement between the relevant institutions according food safety</td>
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<td></td>
<td>Fully functional national RAS by end 2005 as confirmed by FVO</td>
<td>FVO reports</td>
<td></td>
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**Project purpose**

<table>
<thead>
<tr>
<th>Objective Verifiable Indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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<tr>
<td>Secure the implementation of the Bulgarian food safety legislation through human resource strengthening and provision of equipment, in order to provide a high level of food safety.</td>
<td>By EoP: 90 % of samples to be controlled processed in laboratories within 72 hours (R1 equip &amp; train) No contaminated foodstuff is determined as contamination-free (R1 train &amp; equip) Complaints by stakeholders implementing food safety policy (MoH, MoA, regional) about absence of information decrease by 25% (R2) Information about food contamination shared with stakeholders (at state and regional level) within 24 hours. (R3 RAS) DG SANCO recognises the fact that the new Law on Food and Veterinary Law define clearly without overlap the responsibilities of MoA vs MoH Chapters 1 and 7 closed in negotiations with Brussels by 2005 (R4 legal)</td>
<td>Annual progress reports for the European Commission Reports of the Steering Committee on the project Reports of the twinning partners</td>
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**RESULTS**

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<tr>
<th>Objective Verifiable Indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>By EoP: 90 % of samples to be controlled processed in laboratories within 72 hours (R1 equip &amp; train) No contaminated foodstuff is determined as contamination-free (R1 train &amp; equip) Complaints by stakeholders implementing food safety policy (MoH, MoA, regional) about absence of information decrease by 25% (R2) Information about food contamination shared with stakeholders (at state and regional level) within 24 hours. (R3 RAS) DG SANCO recognises the fact that the new Law on Food and Veterinary Law define clearly without overlap the responsibilities of MoA vs MoH Chapters 1 and 7 closed in negotiations with Brussels by 2005 (R4 legal)</td>
<td>Annual progress reports for the European Commission Reports of the Steering Committee on the project Reports of the twinning partners</td>
<td>Support from other relevant institutions Adequate provision from state budget The technical specifications are done on time The equipment is delivered on time Organizations involved recruit and retain adequate staff Proper coordination between the beneficiaries</td>
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<tr>
<td>Activities</td>
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<td>Costs</td>
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<tr>
<td>A 1.1 Supply of equipment for the laboratory for veterinary hygienic expertise of foodstuffs from animal origin at the NVDRI under the NVS according the EU food safety requirements;</td>
<td>• Twinning contract&lt;br&gt;• Two supply contract</td>
<td>• Lump sum costs</td>
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<td>A 1.2 Supply of equipment for 6 regional control laboratories for food analysis within the structure of the Ministry of Health;</td>
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<tr>
<td>A 1.3 Definition/confirmation of training needs by twinning experts and preparation/confirmation of training plan</td>
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<td>A 1.4 Preparation of training material</td>
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<td>A 1.5 Elaboration of food inspection manual</td>
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<tr>
<td>A 1.6 Implementation of training plan involving at least 33 inspectors from state sanitary control (RAS &amp; GHP); 8 HEI laboratory specialists (GLP); and Veterinary Inspectors (RAS) in modules of 1 week training.</td>
<td></td>
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<td>A 2.1 Stakeholder analysis, with respective needs analysis and identification of the current situation – review of the institutional structure, with definition of responsibilities</td>
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<td>A 2.2 Proposal by experts of the twinning partner on modification on streamlining of authorities avoiding duplication of responsibilities between Ministries,</td>
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<td>A 2.3 Proposal of communication protocols between the stakeholders involved - prepare TS for IT</td>
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<tr>
<td>A 2.3 Training on communication protocols</td>
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<tr>
<td>A 3.1 Analysis of the needs of all authorities concerned with regard to their involvement in the future National Rapid Alert System</td>
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<tr>
<td>A 3.2 Supply of IT equipment (hardware and software) for establishment of a National Rapid Alert System on exchange of information on dangers, arising from food products.</td>
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<tr>
<td>A 4.1 Revision of the current harmonized Bulgarian legislation and advice to the responsible authorities on EU food safety legislation developments</td>
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<tr>
<td>A 4.2 Assisting with the transposition and implementation of EU food safety legislation.</td>
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**Pre-conditions:**
- Existing of the main legislation (Law on Foodstuffs, Veterinary Law, Plant Protection Law & Fodder Law)
- Available of comprehensive functional structures and suitable staff to elaborate
### Annex 2

| (i) | preparation technical specifications of laboratory equipment by Bulgarian experts |
| (ii) | submission ToR PPF for approval  C - contract signature - PPF mobilisation  ×  final report with TS submitted |
| (iii) | Preparation covenant for twinning |

#### 2003

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<td>FP: final payment</td>
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ANNEX 3: Cumulative Contracting and Disbursement Schedule  
*Project title:* STRENGTHENING FOOD SAFETY POLICY

**CONTRACTING AND DISBURSEMENT SCHEDULE BY QUARTER FOR FULL DURATION OF PROGRAMME**

Total Budget: 3.600 MEURO

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ANNEX 4

SCHEDULE FOR THE IMPLEMENTATION OF THE ACQUIS ON FOODSTUFFS

Note: All Ordinances applicable at present under the Law on Public Health will be repealed with the entry into force of the relevant Ordinances under the Law on Foodstuffs.

<table>
<thead>
<tr>
<th>Foodstuffs acquis</th>
<th>Drafting</th>
<th>Reference of National Legislation</th>
<th>(Foreseen) Date of Adoption</th>
<th>(Foreseen) Date of Entry into force</th>
<th>Compatibility of the transposed legislation</th>
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<tr>
<td>Directive 87/250: Indication of alcoholic strength</td>
<td>Ordinance on labelling and presentation of wines, alcoholic drinks and grape and wine products State Gazette No 31/2000</td>
<td>06.04.2000</td>
<td>14.04.2000</td>
<td>full</td>
<td>Issued by the Minister of economy and the Minister of agriculture and forestry under article 45 of the Law on wine and spirit drinks</td>
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<td>Amendment of the Ordinance on the requirements to labelling and presentation of foodstuffs</td>
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<td>31.12.2002</td>
<td>31.12.2002</td>
<td></td>
<td>The Amendment will introduce the provisions of Directive 87/250: concerning beverages other than wine and spirit drinks like bear</td>
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<td>Foodstuffs acquis</td>
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<td>Reference of National Legislation</td>
<td>(Foreseen) Date of Adoption</td>
<td>(Foreseen) Date of Entry into force</td>
<td>Compatibility of the transposed legislation</td>
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<td>Amendm. 49/2000</td>
<td>Amendment of the Ordinance on the requirements to labelling and presentation of foodstuffs State Gazette No 40/2002</td>
<td>11.04.2002</td>
<td>After publishing in State Gazette</td>
<td>full</td>
<td>Adopted by the Council of Ministers on 11.04.2002 and publishing in State Gazette is pending</td>
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<tr>
<td>Reg. 50/2000: Foodstuffs containing additives and flavourings that have been genetically modified</td>
<td>Ordinance on the requirements to labelling and presentation of foodstuffs, adopted by Council of Ministers Decree No 136/2000 State Gazette No 62/2000</td>
<td>19.07.2000</td>
<td>29.07.2001</td>
<td>full</td>
<td>Adopted by the Council of Ministers under article 10 (3) of the Law on Foodstuffs</td>
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<td>Amendment of the Ordinance on the requirements to labelling and presentation of foodstuffs State Gazette No 40/2002</td>
<td>11.04.2002</td>
<td>After publishing in State Gazette</td>
<td>full</td>
<td>Adopted by the Council of Ministers on 11.04.2002 and publishing in State Gazette is pending</td>
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<td>Reference of National Legislation</td>
<td>(Foreseen) Date of Adoption</td>
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<td>Compatibility of the transposed legislation</td>
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<td>Directive 90/496: Nutrition labelling</td>
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<td>Ordinance No 23 on the conditions and requirements to presentation of nutrition labelling State Gazette No 53/2001</td>
<td>17.05.2001</td>
<td>12.06.2002</td>
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<td>89/107: Food Additives</td>
<td>Amendm. 94/34</td>
<td>Ordinance No 8 on the requirements to food additives State Gazette No 44/2002</td>
<td>16.04.2002</td>
<td>After publishing in State Gazette</td>
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<td>94/35: Sweeteners</td>
<td>Amendm. 96/83</td>
<td>Ordinance No 8 on the requirements to food additives State Gazette No 44/2002</td>
<td>16.04.2002</td>
<td>After publishing in State Gazette</td>
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<td>94/36: Colours</td>
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<td>Ordinance No 8 on the requirements to food additives State Gazette No 44/2002</td>
<td>16.04.2002</td>
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<td>Issued by the Minister of Health under article 6 (2) of the Law on Foodstuffs</td>
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<td>95/2: Food additives other than colours and sweeteners</td>
<td>Amendm. 96/85 Amendm. 98/72 Amendm. 2001/5</td>
<td>Ordinance No 8 on the requirements to food additives State Gazette No 44/2002</td>
<td>16.04.2002</td>
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<td>67/427: Certain preservatives for treatment of citrus fruit</td>
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<td>78/663</td>
<td>Criteria of purity for emulsifiers, thickeners and stabilisers</td>
<td>State Gazette No 104/2002</td>
<td>15.10.2002</td>
<td>After publishing in State Gazette</td>
<td>Issued by the Minister of Health under article 6 (2) of the Law on Foodstuffs</td>
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<td>Methods of analysis for additives</td>
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<td>15.10.2002</td>
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<td>State Gazette No 104/2002</td>
<td>15.10.2002</td>
<td>After publishing in State Gazette</td>
<td>Issued by the Minister of Health under article 6 (2) of the Law on Foodstuffs</td>
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<td>Purity criteria – Additives</td>
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<td>Flavourings</td>
<td>Ordinance No 15 on requirements for use of flavourings in foodstuffs</td>
<td>State Gazette No 70/2002</td>
<td>28.06.2002</td>
<td>21.12.2002</td>
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<td>Directive 88/344: Extraction solvents Amendm. 92/115 Amendm. 94/52 Amendm. 97/60</td>
<td>Ordinance N 9 on extraction solvents used in the production of foodstuffs State Gazette No 44/2002</td>
<td>18.04.2002</td>
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<td>Directive 89/109: Materials and articles to come into contact</td>
<td>Ordinance No 24 on the requirements to materials and articles other than plastic intended to come in contact with foodstuffs State Gazette No 56/2001</td>
<td>17.05.2001</td>
<td>25.06.2001</td>
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<td>Issued by the Minister of Health, Minister of Economy and Minister of Environment under article 8 of the Law on Foodstuffs</td>
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<td>Ordinance No 1 on the requirements to plastic materials and articles intended to come in contact with foodstuffs State Gazette No 13/2002</td>
<td>07.01.2002</td>
<td>06.02.2003</td>
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<td>Issued by the Minister of Health, Minister of Economy and Minister of Environment under article 8 of the Law on Foodstuffs</td>
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<td>Directive 78/142: Materials containing vinyl chloride monomer. Impl.: Dir. 80/766: Methods of analysis of vinyl chloride monomer level in materials</td>
<td>Ordinance No 1 on the requirements to plastic materials and articles intended to come in contact with foodstuffs State Gazette No 13/2002</td>
<td>07.01.2002</td>
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<td>Directive 81/432: Method of analysis of vinyl chloride released by materials</td>
<td>Ordinance No 1/2002 on the requirements to plastic materials and articles intended to come in contact with foodstuffs State Gazette No 13/2002</td>
<td>07.01.2002</td>
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<td>82/711</td>
<td>Testing migration of the constituents of plastic</td>
<td>Ordinance No 1 on the requirements to plastic materials and articles intended to come in contact with foodstuffs</td>
<td>07.01.2002</td>
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<td>90/128</td>
<td>Plastic materials into contact with foodstuffs</td>
<td>Ordinance No 1 on the requirements to plastic materials and articles intended to come in contact with foodstuffs</td>
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<td>84/500</td>
<td>Ceramic articles into contact</td>
<td>Ordinance No 24 on the requirements to materials and articles other than plastic intended to come in contact with foodstuffs</td>
<td>17.05.2001</td>
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<td>93/10</td>
<td>Regenerated cellulose into contact</td>
<td>Ordinance No 24 on the requirements to materials and articles other than plastic intended to come in contact with foodstuffs</td>
<td>17.05.2001</td>
<td>25.06.2001</td>
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<td>93/11</td>
<td>Release of the N-nitrosamines</td>
<td>Ordinance No 24 on the requirements to materials and articles other than plastic intended to come in contact with foodstuffs</td>
<td>17.05.2001</td>
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<td>89/398</td>
<td>Ordinance No 1/2002 on the requirements to plastic materials and articles intended to come in contact with foodstuffs</td>
<td>07.01.2002</td>
<td>06.02.2003</td>
<td>full</td>
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<td>2000/15</td>
<td>Ordinance on foodstuffs intended for particular nutritional uses</td>
<td>06.11.2002</td>
<td>06.11.2003</td>
<td>full</td>
<td>Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>91/321</td>
<td>Ordinance on the requirements to the composition, characteristics and names of infant formulae and follow-on formulae</td>
<td>13.06.2001</td>
<td>29.06.2001</td>
<td>full</td>
<td>Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>96/5</td>
<td>There is a draft on Ordinance on the requirements to content, characteristics and names of baby foods for infants and young children</td>
<td>31.12.2002</td>
<td>31.12.2002</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>Directive</td>
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<td>96/8:</td>
<td>Energy-restricted diets</td>
<td>Ordinance on foods intended for use in energy-restricted diets for weight-reduction</td>
<td>06.11.2002</td>
<td>06.11.2003</td>
<td>full</td>
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<td>99/21:</td>
<td>Dietary Foods</td>
<td>Ordinance on dietary foods for special medical purposes</td>
<td>06.11.2002</td>
<td>06.11.2000</td>
<td>full</td>
<td>Adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>92/52:</td>
<td>Infant formulae, export to third countries</td>
<td>Amendment of the Ordinance on the requirements to the composition, characteristics and names of infant formulae and follow-on formulae</td>
<td>31.12.2003</td>
<td>31.12.2003</td>
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<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>89/397:</td>
<td>Official control</td>
<td>Law on Foodstuffs, Chapter V</td>
<td>30.09.1999</td>
<td>18.10.1999</td>
<td>full</td>
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<td>85/591:</td>
<td>Methods of sampling and analysis</td>
<td>Ordinance No 2 on methods of food sampling</td>
<td>27.01.1997</td>
<td>30.01.1997</td>
<td>partial</td>
<td>Issued by the Minister of Health under paragraph 3 of the Law on Public Health</td>
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<td></td>
<td>Amendment of Law on Foodstuffs</td>
<td></td>
<td>31.12.2003</td>
<td>31.12.2003</td>
<td></td>
<td>As this Directive concerning the introduction of Community methods of sampling and analysis at this stage only the Annex can be transposed. This should be than trough the amendment of Law on Foodstuffs</td>
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<td>Directive</td>
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<td>Directive 93/43: Hygiene.</td>
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<td>Law on Foodstuffs, State Gazette No 90/1999</td>
<td>30.09.1999</td>
<td>18.10.1999</td>
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<td>Issued by the Minister of Health and Minister of Agriculture and Forestry under article 17 (2) of the Law on Foodstuffs</td>
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<td>Ordinance No 7 on hygienic requirements to the establishments for production or trade with foodstuffs and on the conditions for production and trade in qualitative and safety foods State Gazette No 40/2002</td>
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<td>08.04.2002</td>
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<td>Directive 96/3 – Derogation from certain provisions – hygiene</td>
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<td>Ordinance No 7 on hygienic requirements to the establishments for production or trade with foodstuffs and on the conditions for production and trade in qualitative and safety foods State Gazette No 40/2002</td>
<td>08.04.2002</td>
<td>After publishing in State Gazette</td>
<td>full</td>
<td>Issued by the Minister of Health and Minister of Agriculture and Forestry under article 17 (2) of the Law on Foodstuffs</td>
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<td>Directive 98/28: Transport by sea of bulk raw sugar</td>
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<td>Ordinance No 7 on hygienic requirements to the establishments for production or trade with foodstuffs and on the conditions for production and trade in qualitative and safety foods State Gazette No 40/2002</td>
<td>08.04.2002</td>
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<td>Issued by the Minister of Health and Minister of Agriculture and Forestry under article 17 (2) of the Law on Foodstuffs</td>
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<td>Decision 97/830: Import of pistachios Amendm. 98/400 Amendm. 2000/238</td>
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<td>Order of the Minister of Health</td>
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<td>Decision/Directive</td>
<td>Ordinance on quick-frozen foodstuffs, adopted by Council of Ministers Decree No /07.11.2002</td>
<td>Adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>Amendment of Ordinance No 5 on maximum levels for chemical and biological contaminants in foodstuffs</td>
<td>Issued by the Minister of Health under paragraph 2 of the Law on Public Health. The amendment introduces the provisions of the Regulation for maximum levels for nitrates.</td>
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<td>Directive 98/53:</td>
<td>Amendment of Ordinance No 5 on maximum levels for chemical and biological contaminants in foodstuffs</td>
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<td>Ordinance No 11 on maximum levels for mycotoxins in foodstuffs State Gazette No 58/2000</td>
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<td>Ordinance No 5 on maximum levels for chemical and biological contaminants in foodstuffs</td>
<td>Directive 2001/22: Sampling methods, methods of analysis of the levels of lead, cadmium, mercury and 3-MCPD</td>
<td>18.05.1984</td>
<td>18.05.1984</td>
<td>partial</td>
<td>Issued by the Minister of Health under paragraph 2 of the Law on Public Health</td>
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<td>Ordinance No 12 on maximum levels for heavy metals in foodstuffs</td>
<td>Directive 2001/22: Sampling methods, methods of analysis of the levels of lead, cadmium, mercury and 3-MCPD</td>
<td>21.05.2002</td>
<td>01.06.2004</td>
<td>full</td>
<td>Issued by the Minister of Health under article 5 (1) of the Law on Foodstuffs</td>
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<td>There is a Draft on Ordinance on novel foods</td>
<td>Regulation 258/97: Novel Foods</td>
<td>31.12.2002</td>
<td>31.12.2002</td>
<td></td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>Directive 99/2: Foods and food ingredients treated with ionising radiation</td>
<td>Ordinance No 6 on the types of foodstuffs that may be treated with ionising radiation and the conditions and procedure thereof State Gazette No 38/2002</td>
<td>28.03.2002</td>
<td>12.04.2002</td>
<td>full</td>
<td>Issued by the Minister of Health under article 22 of the Law on Foodstuffs</td>
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<td>Directive 99/3: List of foods – ionising radiation</td>
<td>Ordinance No 6 on the types of foodstuffs that may be treated with ionising radiation and the conditions and procedure thereof State Gazette No 38/2002</td>
<td>28.03.2002</td>
<td>12.04.2002</td>
<td>full</td>
<td>Issued by the Minister of Health under article 22 of the Law on Foodstuffs</td>
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<td>Directive 80/777: Natural mineral waters Amendm. 80/1276 Amendm. 85/7 Amendm. 96/70</td>
<td>There is a Draft on Ordinance on natural mineral waters</td>
<td>30.06.2002</td>
<td>30.06.2002</td>
<td></td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>Directive 76/621: Erucic acid</td>
<td>There is a Draft on Ordinance on maximum levels of erucic acid in oils and fats intended for human consumption and in foodstuffs containing added oils or fats</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 80/891: Erucic acid - methods of analysis</td>
<td>There is a Draft on Ordinance on maximum levels of erucic acid in oils and fats intended for human consumption and in foodstuffs containing added oils or fats</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
<td></td>
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<tr>
<td>Directive 2000/36: Cocoa and chocolate products</td>
<td>Ordinance on requirements to cocoa and chocolate products Council of Ministers Decree No 251/06.11.2002 State Gazette No 107/2002</td>
<td>06.11.2002</td>
<td>06.08.2003</td>
<td>full</td>
<td>Adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 74/409 2001/110: honey</td>
<td>Ordinance on requirements to honey, adopted by Council of Ministers Decree No 196/2002 State Gazette No 89/2002</td>
<td>28.08.2002</td>
<td>01.08.2003</td>
<td>full</td>
<td>Adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 79/693 2001/113:</td>
<td>There is a Draft on Ordinance on requirements to fruit jams, jellies and marmalades, submitted for adoption by the Council of Ministers</td>
<td>31.07.2002</td>
<td>31.12.2003</td>
<td></td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 26/118 2001/114: dehydrated preserved milk</td>
<td>There is a Draft on Ordinance on certain partly or wholly dehydrated preserved milk</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td></td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 79/1067: dehydrated preserved milk - methods of analysis</td>
<td>There is a Draft on Ordinance on certain partly or wholly dehydrated preserved milk</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td></td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>Directive 87/524: dehydrated preserved milk - methods of sampling</td>
<td>There is a Draft on Ordinance on certain partly or wholly dehydrated preserved milk</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
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<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 83/417: caseins and caseinates</td>
<td>There is a Draft on Ordinance on requirements to caseins and caseinates intended for human consumption</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 85/503: caseins and caseinates methods of analysis</td>
<td>There is a Draft on Ordinance on requirements to caseins and caseinates intended for human consumption</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<td>Directive 86/424: caseins and caseinates methods of sampling</td>
<td>There is a Draft on Ordinance on requirements to caseins and caseinates intended for human consumption</td>
<td>31.07.2003</td>
<td>31.12.2003</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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<tr>
<td>Directive 99/4: coffee and chicory extracts</td>
<td>There is a Draft on Ordinance on requirements to coffee extracts and chicory extracts, submitted for adoption by the Council of Ministers</td>
<td>31.07.2003</td>
<td>31.12.2004</td>
<td>Will be adopted by the Council of Ministers under article 4 of the Law on Foodstuffs</td>
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</tbody>
</table>
List of relevant laws and regulations

State of Play of Harmonization of Bulgarian Veterinary Legislation with the Veterinary Acquis Communautaire

Published in State Gazette

Animal health


3. Ordinance on prophylaxis and control of some fish diseases. (SG No 30/2001) - Council Directive 93/53 introducing minimum Community measures for the control of certain fish diseases. Table of correspondence has been prepared.


7. Ordinance on prophylaxis and control of rabies (SG 55/04.06.2002) - Council Directive 92/65 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subjected to animal health requirements laid down in specific Community rules referred to in Annex A(1) to Dr 90/425 (in the part concerning rabies) - Partially harmonized.

8. Ordinance on the notification and eradication of contagious animal diseases (SG 55/04.06.2002) - Council Directive 82/894 on the notification of animal diseases within the Community - Table of correspondence has been prepared.


12. Ordinance on the prophylaxis and control of bluetongue (SG 82/27.08.2002) - Council Directive 2000/75 laying down specific provisions for the control and eradication of BT. Table of correspondence has been prepared.


20. Ordinance on the health conditions for the production and placing on the market of fishery products. (SG No 42/23.05.2000) - Council Directive 91/493 laying down the health conditions for the production and placing on the market of fishery products. Table of correspondence has been prepared.

21. Ordinance on the minimum hygiene rules applicable to the fishery products caught on board of certain vessels (SG. No 42/23.05.2000) - Council Directive 92/48 laying down the minimum hygiene rules applicable to the fishery products caught on board certain vessels in accordance with Art. 3(1)(a) (i) of Dr 91/493.


24. Ordinance on the veterinary and sanitary (public health) requirements for construction and operation of establishments for fresh meat and for placing of fresh meat on the market (SG No 34/2002) - Council Directive 64/433 on health problems affecting intra-Community trade in fresh meat. Table of correspondence has been prepared.


26. Ordinance on the veterinary and sanitary requirements to the production and placing on the market of meat products and other products of animal origin (SG 48/17.05.2002) - Council Directive 77/99 on health problems affecting intra-Community trade in meat products. Table of correspondence has been prepared.

28. Ordinance on the health requirements to killed wild game and the veterinary hygiene requirements for the production of wild game meat (SG 55/04.06.2002) - Council Directive 92/45 on public health and animal health relating to the killing of wild game and the placing on the market of wild game meat - Table of correspondence has been prepared.

29. Ordinance on the veterinary and sanitary requirements for production and placing on the market of minced meat and meat preparations (SG 78/13.08.2002) - Council Directive 94/65 laying down the requirements for the production and placing on the market of minced meat and meat preparations - Table of correspondence has been prepared.


36
44. Ordinance on the veterinary and sanitary requirements for the collection and processing of animal waste (SG 75/02.08.2002) - Council Directive 90/667 laying down the veterinary rules for the disposal and processing of animal waste, for in placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Dr 90/425.


Veterinary Medical Products


Ordinances submitted for comments to the Ministry of Agriculture and Forestry (MAF)

Ordinance on the veterinary and sanitary requirements governing the imports of poultry and hatching eggs - Council Directive 90/539 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs, amended by 92/369 – Revised according to the comments of the Council of Ministers and re-submitted.

Ordinance on the health conditions governing trade in fresh meat - Council Directive 72/461 on health problems affecting intra-Community trade in fresh meat. Submitted to Working Group “Agriculture” on 31 July 2002. At the meeting of Working Group “Agriculture” on 12 September 2002 a decision was made not to adopt this Ordinance this year, because it relates to intra-Community trade.

Ordinance on the health condition governing the movement of ovine and caprine animals - Council Directive 91/68 on animal health conditions governing intra-Community trade in ovine and caprine animals. At the meeting of Working Group “Agriculture” on 12 September 2002 a decision was made not to adopt this Ordinance this year, because it relates to intra-Community trade.


Ordinance on the health conditions governing the trade in other animal products - Council Directive laying down animal health and Public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662 and as regards pathogens to Dr 90/425.

Ordinance on health and veterinary inspection problems upon importation of bovine animals, swine and fresh meat - Council Directive 72/462 on health and veterinary inspection problems upon importation of bovine animals, swine and fresh meat from third countries.
Ordinances under preparation

Ordinance on the internal veterinary checks applicable in trade in live animals - Council Directive 90/425 concerning veterinary and zootechnical checks applicable in intra-community trade in certain live animals and products with a view to the completion of internal market.


Ordinance on the health conditions governing trade in other animals - Council Directive 92/65 laying down animal health requirements governing trade in an imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex (I) to Directive 90/425. (Balai 1).

Ordinance on the identification of bovine animals and the registration of animal holdings - Council Regulation 1760/2000 establishing a system for the identification and registration of bovine animals and regarding labeling of beef and beef products and repealing Council regulation 820/97.

Ordinance on the veterinary and sanitary requirements governing imports and trade in embryos from bovine animals – Council Directive 89/556 on animal health conditions governing intra-Community trade in and importation from thirds countries of embryos of domestic animals of the bovine species.


Ordinance laying down veterinary and sanitary requirements governing imports of other animals, semen and ova - Council Directive 92/65 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC.


Ordinance on the animal health conditions governing trade in fresh poultry meat - Council Directive 91/494 on animal health conditions governing intra-Community trade in and imports from third counties of fresh poultry meat. At the meeting of Working Group “Agriculture” on 12 September 2002 a decision was made not to adopt this Ordinance this year, because it relates to intra-Community trade.

Ordinance on the health conditions governing trade in meat products - Council Directive 80/215 on animal health problems affecting intra-Community trade in meat products. At the meeting of Working Group “Agriculture” on 12 September 2002 a decision was made not to adopt this Ordinance this year, because it relates to intra-Community trade.

Ordinance on the internal veterinary checks applicable to trade in animal products - Council Directive 89/662 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market.

Ordinance on the general conditions governing the organization of veterinary checks applicable in import and transit of animal products - Council Directive 97/78 laying down the principles governing the organization of veterinary checks on products entering the Community from 3rd countries.
Food Safety Strategy
of the Republic of Bulgaria

The food safety policy of the Republic of Bulgaria is based on the current legislation in this area. The basic legislation includes the Law on Foodstuffs, Law on Public Health, Veterinary Law, Plant Protection Law and Fodder Law. These laws lay down the requirements to foodstuffs, producers’ and traders’ obligations, as well as the procedures for official control covering the whole food chain. On the basis of these laws a number of regulations and ordinances have been adopted and are being adopted, specifying the detailed requirements in the field covered. These regulations and ordinances transpose in the national legislation the *acquis communautaire* in this field.

1. COMPETENT AUTHORITIES

1.1. Existing administrative structures

As provided by the Law on Foodstuffs National Council on Food Safety (NCFS) has been established within the Council of Ministers. Its main task is to co-ordinate the state policy on food safety. Its members are one Deputy-Minister of Agriculture and Forests, two Deputy-Ministers of Economy, the Vice-President of the State Agency for Standardisation and Metrology, and four representatives of professional associations of food producers. The Chief State Sanitary Inspector chairs the National Council.

The National Council has the following competencies:

- proposes to the Council of Ministers changes in the food safety regulation in accordance with EU and WTO principles;
- proposes to the Council of Ministers structural and administrative changes in the food control system;
- co-ordinates the activities of the competent authorities and public organisations with respect to food control;
- co-ordinates the participation at expert level in the work of international organisations on matters related to food safety.

The National Council operates according to the Rules adopted by the Council of Ministers and the Annual Programme.

The competent authorities implementing the food safety legislation are:

*The Ministry of Health, through:*

1. at national level - the Health Prophylactics and State Sanitary Control Directorate (HPSSCD);
2. at regional level - 28 Hygiene and Epidemiological Inspectorates (HEI), which are the competent authorities for the official control of foodstuffs;
3. the National Centre of Radiobiology and Radiation Protection (NCRRP).

The organisation chart of the services within the Ministry of Health is presented in *Annex 1.*

The Health Prophylactics and State Sanitary Control Directorate has a full time staff of 19 people, five of them are directly involved with food safety issues. The activities of the Directorate are financed by the state budget.

The total number of experts responsible for control of foodstuffs in the 28 HEI is 1909, of which:

- physicians with a master's degree and 4-year postgraduate specialisation in food hygiene and nutrition - 302;
- sanitary inspectors with bachelor's degree – 1080;
- chemists, biologists and physicists with master's degree - 145;
- analytical chemists and medical laboratory assistants with bachelor's degree - 382.

There are nine experts - physicists, chemists and laboratory assistants - at the National Centre on Radiobiology and Radiation Protection, responsible for radiation control on foodstuffs.

The activities of the regional bodies for state sanitary control are financed by the state budget and from revenues of their own. The budget for the year 2001 amounts to 17 051 890 BGL (1 EURO = 1.956 BGL fixed rate).
According to the Strategy for development of health care and the Action plan in the health care sector, adopted by the Government the budget for financing the activities of state sanitary control is planned to increase by 50% by the year 2003 and to double by the year 2006.

The Ministry of Agriculture and Forests, through:

1. The central office of the National Veterinary Service (NVS) and 48 subdivisions in the country, of which 28 are regional services for state control of animals, products of animal origin and fodder.

2. The National Service for Plant Protection, Quarantine and Agro-chemistry (NSPPQA), with a Central laboratory and 15 regional services for phytosanitary control.

3. Feed Control Inspection (FCI) within the National Grain Service (NGS).

The National Veterinary Service has 3190 employees, 1514 of which are doctors in veterinary medicine. The staff of the laboratory control system comprises of 494 qualified laboratory specialists, 108 of whom are researchers, 124 are doctors in veterinary medicine, biologists, chemists and zootechnicians, as well as 180 laboratory assistants.

NSPPQA has 443 employees, 23 of which are in the Central laboratory. These are mainly agronomists, chemists and laboratory specialists with master or bachelor's degrees.

The organisation charts of the services within the Ministry of Agriculture and Forests are presented in Annexes 2, 3 and 4.

1.2. Future development of the administrative structures

At national level

Executive Food Safety Committee (EFSC) will be established within the National Council on Food Safety (NCFS) with representatives of HPSSCD, NVS, NSPPQA and Feed Control Inspection as well as representatives of the Consumer protection Department within the Ministry of Economy. A representative of each institution will chair the Executive Committee in rotation on every six months. Five inter-agency expert working groups will function with the EFSC, with representatives of the branch organisations as well. The working groups will consider issues related to:

- legislation;
- official (state) control on foodstuffs;
- science;
- zoonoses;
- risk communication.

Expert working groups will perform the following activities: periodic review of the relevant legislation and drafting proposals for changes in the legal basis; evaluation of effectiveness, development parameters and co-ordination of the services for food safety control; monitoring and risk assessment; consultations on issues connected with the control on zoonoses and food safety; periodic analysis of the information sent by the systems for rapid information exchange among the services on hazardous foods in the market; proposing comprehensive measures for solving the existing problems; public awareness work.

Based on proposals prepared by the Experts working groups, the EFSC will draw up draft decisions, which will be further submitted for approval to the Council of Ministers. The EFSC will perform executive, implementing and control functions in accordance with the decisions taken.

Annex 5 gives the organisation chart of the proposed structure and co-ordination links in relation to the national policy on food safety and the implementation of food safety legislation.

Subject to a decision of the NCFS, the expert working groups will be established by the end of September 2001, and the EFSC - by December 2001.

Ministry of Health

The establishment of an Executive Agency for official control on foodstuffs, potable waters and goods of general use to the Minister of Health is under consideration. The final decision will be taken by March 2002, after the interservice coordination procedure have been completed. Upon a positive decision the Agency will be operational by the end of 2002. It will have 12 laboratory blocks with chemical and microbiological laboratories specialised on food contaminants, cosmetics, radiology etc. The Executive Agency is designed as a corporate body, financed by the state budget and revenues of own activities. Statute Rules will be adopted by the Council of Ministers to define the Agency’s activities, structure, work organisation and staff.
The Ministry of Agriculture and Forests (MAF)
No changes are envisaged with regard to the structure and organisation of MAF services, implementing food safety legislation.

1.3 LEGISLATIVE ACTIVITIES

1.3.1 Competent authorities
The competent authorities for introducing the EU legislation concerning food safety are as follows:

Food legislation
The Ministry of Health, through the Health Prophylactics and State Sanitary Control Directorate, plays the leading role in this respect.
The National Centre for Hygiene, Medical Ecology and Nutrition assists the Directorate in these activities. The Centre is a research institute with more than fifty scientists working in the field of food safety.

Phytosanitary legislation
Leading institution: Ministry of Agriculture and Forests
Specialized institution to the MAF: National Service for Plant Protection, Quarantine and Agro-chemistry

Veterinary legislation:
Leading institution: Ministry of Agriculture and Forests
Specialized institution to the MAF: National Veterinary Service

The NVS is assisted in its work by the Central Research Institute on Veterinary Medicine and by the Central Laboratory on Veterinary Control and Ecology.

Animal nutrition legislation:
Leading institution: Ministry of Agriculture and Forests
Specialized institution to the MAF: Feed Control Inspection.

1.3.2 Procedures for adoption of food safety legislation

A) Laws (primary legislation)
1. Drafting a legislative proposal by the inter-ministerial working group;
2. Inter-service coordination/consultations procedure – the opinions of all ministries and of the relevant branch organisations are taken into account;
3. EU acquis compliance verification - the draft is passed on a meeting of the respective working group within the Co-ordinating Council on European Integration;
4. The draft is examined and approved by the European Integration and Relations with International Financial Institutions Directorate within the Council of Ministers (opinion of compliance with the EU legislation);
5. Endorsement by the Council of Ministers;
6. Discussion in the relevant parliamentary committees;
7. Two parliamentary readings;
8. Adoption by the National Assembly (Parliament).

New laws and amendments to existing laws follow the same parliamentary procedure.

B) Decrees and Decisions of the Council of Ministers (secondary legislation)
The procedure follows items 1-4 of A). The final decision for adoption is taken by the Council of Ministers.

C) Ordinances, Instructions and Orders (secondary legislation)
The procedure follows items 1-4 of A). The final decision for adoption is taken by the minister of relevant competence, usually supported by a positive vote of the ministry’s collegium.

1.3.3 Co-ordination of the activities on European integration
The overall co-ordination of Bulgaria’s accession preparation is regulated by Decree No. 3 of January 20, 2000 of the Council of Ministers. In accordance with its provisions, 30 inter-ministerial working groups were established and the leading institutions for transposing the EU legislation by sector were identified. The general coordination and management of working groups’ activities is carried out by the Co-ordinating Council for the preparation of the Republic of Bulgaria for EU accession. The detailed measures for the adoption of the acquis communautaire and the time schedule for their implementation are specified in the National Programme for the Adoption of the Acquis (NPAA).
The co-ordination role in the transposition process is performed by the European Integration and Relations with International Financial Institutions Directorate within the Council of Ministers. At working groups’ (expert) level food safety legislative harmonization is in the scope of:
• **Working group 1 ‘Free Movement of Goods’** with the Ministry of Economy as leading institution. Within its functional framework a special subgroup deals with foodstuffs - Subgroup 1.3 “Foodstuffs”; with the Ministry of Health acting as leading institution.

Members of the Working Groups are also representatives of food producers and traders professional associations. They take part in the process of legal harmonisation and drafting of legislative texts. The National Council on Food Safety (NCFS), established with the Council of Ministers, co-ordinates the implementation of the **state policy** on food safety.

The institutions charged with executive functions in relation to the foodstuffs legislation are the structures of the state sanitary control, state veterinary-sanitary control and phytosanitary control. By the end of 2001 the expert working group on food safety legislation to the EFSC will examine the existing legislation in the area of food safety. Proposals for legal amendments will be submitted, with a view to eliminate existing overlapping, inconsistencies and gaps in the current food safety legislation.

### 1.4. CONTROL ACTIVITIES

#### 1.4.1 Control activities related to food legislation

The specialised bodies, determined in the Law on Foodstuffs, exercise the official control on food safety:
- the state control bodies under the Law on Public Health;
- the state control bodies under the Veterinary Law;
- the state control bodies under the Plant Protection Law.

**Under the Law on Public Health, the Ministry of Health** exercises state sanitary food control. The state sanitary control is managed directly by the Deputy-Minister of Health, who is also Chief Sanitary Inspector of the Republic of Bulgaria.

The state sanitary control bodies are:

- a) the Health Prophylactics and State Sanitary Control Directorate of the Ministry of Health;
- b) the State Sanitary Control departments of the Hygiene and Epidemiological Inspectorates (HEI);
- c) the National Centre on Radiology and Radiation Protection, and the State Radiation Control and Protection departments of five HEI in the country.

The Health Prophylactics and State Sanitary Control Directorate of the Ministry of Health:
- drafts legal acts;
- manages, co-ordinates and controls the activities related to state sanitary control of HEI at national level;
- plans, organises and controls the monitoring on food contaminants;
- assesses the health risk, develops and proposes measures for preventing the harmful effects of chemical and biological food contaminants;
- develops implementing rules on the food safety legislation to assist the state inspectors’ activities; works on the setting up and implementation of uniform procedures on food control;
- manages and co-ordinates at national level measures related to the investigation, prohibition, analysis and - if necessary - destruction of foods presenting threat to population’s life and health;
- registers and issues permits for import and local production of foods, products of plants origin and drinks;
- issues health certificates for export of foodstuffs.

28 Hygiene and Epidemiological Inspectorates implement food safety control measures at local level. The State Sanitary Control Department and the Laboratory Research Department of the HEI are the structures responsible for and directly involved in carrying out the food safety control. The HEI performs the following activities at local level:
- state control over foodstuffs and over premises for their production, storage, sale, as well as on their import;
- risk assessment and risk management related to the content of chemical and biological contaminants in foodstuffs;
• registration of food-borne disease outbreaks, organisation and carrying out of related epidemiological studies, undertaking measures for restriction and eradication in case of food-borne disease outbreaks, and reporting to the Ministry of Health;
• laboratory physico-chemical and microbiological tests of food samples and of food production setting. Four specialised mycotoxicological laboratories and five laboratories for radiation control and protection are operating within the Hygiene and Epidemiological Inspectorates;
• consultancy and assistance to food producers and traders in carrying out their activities under the Law on Foodstuffs;
The National Centre of Radiology and Radiation Protection and the Radiation Control and Protection Departments of the HEI monitor foodstuffs for presence of natural and technogenic radio-nuclides. Specification of the competent authorities with the Ministry of Agriculture and Forests, which carry out control activities on food safety, is presented in section 2.2.2.
No changes are envisaged with regard to the structure and organisation of MAF control authorities.
**Co-ordination**: By the end of 2001 the expert working group on food safety state control to the EFSC will examine the existing implementing structures in the area of food safety. Proposals for achieving better co-ordination and precise differentiation and sharing of control activities will be submitted, with a view to set up a fully integrated and consistent national system for food safety control.

1.4.2. Control activities related to phytosanitary, veterinary and animal nutrition legislation
(See section 2.2.2.)

2. PREPARATION FOR ACCESSION

2.1. Legislation
The Law on Foodstuffs was adopted in October 1999. It introduces the provisions and requirements of Directive 89/397 on the official control of foodstuffs, Directive 93/43 on the hygiene of foodstuffs and Directive 79/112 on food labelling, and creates the legal framework for gradual introduction of all EU Directives in the field of food safety.
**Annex 6** presents the schedule for introduction and implementation of the EU food legislation.
The Plant Protection Law, passed in October 1997, is the basis for introduction of the EU phytosanitary legislation.
The schedule for introduction and implementation of the EU phytosanitary legislation is presented in **Annex 7**.
Implementing Rules of the Veterinary Law were adopted in August 7, 2000.
**Annex 8** presents the timetable for introduction and implementation of the EU veterinary legislation.

2.2. Preparation of administration and operators

2.2.1. CHAPTER 1 - Control/Hygiene

**2.2.1.1. Training of the state inspectors on carrying out inspection missions in the food production premises and on the implementation of the Hazard Analysis and Critical Control Points System (HACCP)**
The administration involved in the process of legal harmonization and implementation includes:
• state experts of the Health Prophylactics and State Sanitary Control Directorate - physicians with a master's degree in medicine and 4-year postgraduate specialisation in food hygiene and nutrition, or general hygiene. Improvement of experts’ qualification is achieved through training courses and seminars organised by the TAIEX Office of the European Commission, ILSI, FAO or within the framework of bilateral co-operation activities with EU Member States in specific areas of food safety acquis.
• state sanitary inspectors with the Hygiene and Epidemiological Inspectorates - physicians with a master's degree in medicine and 4-year postgraduate specialisation on food hygiene and nutrition;
- state sanitary inspectors, medical laboratory staff and laboratory specialists - analysts with the Hygiene and Epidemiological Inspectorates with a bachelor's degree, graduates of the Medical Colleges with the Medical Universities in the country (the study course covers all aspects of food hygiene, food expertise and state control on foodstuffs). The National Centre on Hygiene, Medical Ecology and Nutrition (NCHMEN) is responsible for the training of the inspectors (usually in the form of annual training courses or in-service training).

So far several experts from the Ministry of Health and from NCHMEN have been trained in a training of trainers course organised by FAO on the HACCP system and good manufacturing practices implementation. As a follow up the trained specialists organized two courses on the implementation of GMP principles and HACCP system for the state sanitary inspectors from the hygiene and epidemiological inspectorates. Trained experts from the Ministry of Health participate as lecturers in seminars on these issues, organised by professional associations for the food manufacturers.

(2.2.1.2. HACCP implementation by food operators: state of advancement and future plans

According to the Law on Foodstuffs, in meeting the requirements for production and trade of safe foods, the food operators and traders may elaborate Recommendations for good hygiene practices by sub-sector, as well as implement the HACCP system.

The professional organisations of food operators started to develop methodologies for implementing the HACCP system and methodological instructions for applying the good manufacturing and hygiene practices.

The Meat Producers Association has already drafted Guidelines on the application of the good manufacturing practices in the slaughterhouses and meat-processing enterprises.

So far, HACCP-plans have been introduced in the establishments of Coca-Cola, Pepsi and Kraft Jacobs Suchard. Partial HACCP-plans have been developed and introduced in four meat-processing companies.

The professional organisations of food operators are very active in training their members on food safety problems by organising seminars with participation of foreign consultants and Bulgarian experts. Branch standards by type of food are being developed with a view to harmonising the criteria for their production.

It is envisaged:

- to develop and apply good hygiene practice Codes in all branches;
- to develop and implement complete HACCP systems in all food establishments approved for export and for production of foodstuffs allowed for unlimited distribution throughout the country, as well as in the food catering chains;
- to develop and apply elements of HACCP in the small food establishments, public catering units and food trade.

2.2.1.3. Laboratories for hygiene control and food analysis: current state and activities planned with a view to achieving compliance with the EU system

State laboratory hygiene control and foods analysis are carried out at specialized laboratories to the food control services of the Ministry of Health and the Ministry of Agriculture and Forests (Annex 9). The laboratories in the Laboratory Research Department of the hygiene and epidemiological inspectorates of the Ministry of Health carry out microbiological testing/analysis of samples taken from
the working environment and from the personnel involved in food manufacturing and trade, as well as chemical and microbiological analysis of potable water used in the processing facilities. Laboratory analyses are made of both domestic and imported foods, including sensory, chemical and microbiological tests, as well as tests for presence and content of additives, contaminants (pesticide residues, heavy metals, mycotoxins) and migration of monomers from materials intended to come into contact with foodstuffs.

The laboratories are supplied with standard laboratory equipment: pH-meters, spectrophotometers, photometers, analytical scales, thermostats, sterilising equipment, etc. Few laboratories are equipped with advanced laboratory machinery, such as atomic-absorption spectrophotometer, UV-spectrophotometer and gas chromatographic equipment.

If needed, state sanitary control bodies are entitled to assign expert investigations to research institutions and laboratories, irrespective of their affiliation or subordination. The samples, as well as the laboratory analyses and tests for the needs of the state sanitary food control, are made available free of charge.

So far, five laboratories carrying out analyses for the needs of the state sanitary control have been accredited, the rest are in a process of accreditation. The Executive Agency “Bulgarian Accreditation Service” acts as national accreditation body, charged with the official accreditation procedure. Sampling for tests and analyses is carried out by official state control inspectors, or by specially trained laboratory analysts or samplers, in accordance with Ordinance No. 2 of the Ministry of Health on the conditions and procedures for food sampling for analysis, partially harmonised with Directive 85/591/EEC.

The analyses and the tests are performed according to harmonised uniform methods specified in the Bulgarian state standards, according to methods endorsed by the Minister of Health, and methods defined in Ordinances introducing the relevant EU provisions concerning contaminants, materials and objects intended to come into contact with foodstuffs, etc.

The National Centre of Radiology and Radiation Protection, as well as the six Radiation Control and Protection departments of the Hygiene and Epidemiological Inspectorates in the country monitor the presence of natural or technogenic radionuclides in the food stuffs manufactured and imported in the country.

(Information on the laboratories for hygiene foods control and analysis to the food control services of the Ministry of Agriculture and Forests is presented in Chapter 7.)

Food testing is also carried out in the laboratories of the State Agency of Standardisation and Metrology. The Department for Testing Food Products, Grain and Animal Feed with the General Directorate on Testing and Certification is equipped with five testing laboratories, which are specialised in testing of food and agricultural products according to physico-chemical, microbiological, mycotoxicological and sensory parameters. The testing is done for the purposes of certification of compliance with regard to the requirements of the Bulgarian standards and for the purposes of conformity assessment. The laboratories were first accredited by the national accreditation body in the 1993-1995 period. Later on their scope was expanded and they were re-accredited.

Planned activities

The Ministry of Health envisages changes in the food control organisation (as specified in Section 1: COMPETENT AUTHORITIES - FUTURE DEVELOPMENT). The plans are to reduce the number of laboratories and upgrade their analytical equipment, as well as to increase their specialisation in doing different types/groups of tests.

Under the Law on Foodstuffs, the Minister of Health and the Minister of Agriculture and Forests appoint the laboratories authorized to perform analyses and testing on foodstuffs for the purposes of the state sanitary control, after their conformity assessment with regard to Bulgarian standard BSS EN 45 001. By the end of 2001 an Ordinance on the conditions and procedures for authorising these laboratories will be issued.

The accreditation of the laboratories (12 in number) within the Ministry of Health (in compliance with the EU acquis) is dependent on their supplying with additional equipment, on the introduction of EU methodologies and the adequate staff training. This can be achieved by the end of 2004 if backed by EU pre-accession financial assistance. By the end of 2002 four laboratories within the system of the Ministry of Health will achieve compliance with the EU requirements.

2.2.1.4. Registration and licensing procedures, systems for registration (enlisting) of food establishments

The Law on Foodstuffs introduces a registration procedure for the food manufacturing establishments in the Republic of Bulgaria. Under Chapter Four of this law the Ministry of Economy is appointed as the competent authority in charge of the registration procedure. The registration shall be completed by the end of 2001.
Under the Law on Foodstuffs, food establishments supplying or trading in foodstuffs shall operate only after a special permit is issued by the state sanitary control and/or state veterinary-sanitary control authorities.

### 2.2.1.5. Current and planned resources

(With regard to the current resources of the foodstuffs control service within the Ministry of Health see Section 1: COMPETENT AUTHORITIES.)

The following measures are envisaged:

**Staff:**
- increase of the staff of the Health Prophylactics and State Sanitary Control Directorate in the Ministry of Health by five people;
- increasing the total number of food control specialists to 1,500 and their appointment as civil servants under the Laws on State Administration and Civil Servants.

**Financing:**
- increase of the budget for wages.

**Financial resources are needed (including on consultancy) for:**
- translation into Bulgarian of the *acquis communautaire* in the field of food safety, as well as translation into English of Bulgarian legislation transposing the *acquis communautaire* and the tables of correspondence;
- assistance in drafting ordinances introducing the EU food safety directives, as well as practical guidelines for their implementation;
- education and training of inspectors and laboratory staff in applying EU methods of sampling and laboratory analyses of foodstuffs - approximately 500,000 EURO;
- drafting food inspections practical Guidelines to assist the official inspectors;
- purchasing transport vehicles for sampling and inspection - 1,500,000 EURO;
- equipment of the laboratories in the system of the Ministry of Health and implementation of the good laboratory practices - approximately 12,000,000 EURO.

(The existing and planned resources of the food control services within the Ministry of Agriculture and Forests are presented in Chapter 7.)

### 2.2.1.6. Current and planned frequency of control checks, planning of inspection activities

According to the Law on Foodstuffs, state food control is carried out on a regular basis and in cases of suspicion, without prior notification.

The food control authorities within the Ministry of Health monitor and control foodstuffs and the conditions for their production, distribution and sale with a view to reducing risk factors to human health, connected with consumption of unsafe or poor quality food. Planning of control frequency is based on the risk, which certain food production processes or foodstuffs present to consumers' health.

Establishments where perishable foods are produced, so-called risk establishments, are inspected at least four times per year, the others - at least once per year.

(The current and planned control frequency of the food control bodies within the Ministry of Agriculture and Forests are presented in Chapter 7.)

### 2.2.1.7. Current and planned procedures and measures for elaborating Guidelines of the good hygiene practices and for their assessment

State authorities assist the development and implementation of the good manufacturing practices and good hygiene practices through:
- drafting legal acts specifying the hygiene requirements to the production of safe foodstuffs of high-quality;
- providing expert information and consulting food operators in the drafting of codes and guidelines for applying the good manufacturing practices and good hygiene practices;
- participation of state experts in the work of the Expert Councils of food producers’ professional organisations.

Professional organisations of food producers and traders, in cooperation with consumers associations may develop guidelines for good manufacturing practices and good hygiene practices by sub-sector. Prior to their application the guidelines should be assessed and co-ordinated with the National Council on Food Safety. Implementation of the HACCP system is also co-ordinated with the state food control authorities.

### 2.2.1.8. Assessment of the control services

Within the framework of the Ministry of Health

Each year the Health Prophylactics and State Sanitary Control Directorate delivers written instructions to the hygiene inspectorates:
• on the annual planning of food control activities, with a specification of the minimum requirements to their frequency, subject and scope,

• for carrying out monitoring and analysis of local and imported foodstuffs with regard to their quality (content of salt, fats and sugar) and safety (presence of microbiological and chemical contaminants).

Yearly experts from the Directorate carry out comprehensive inspections of the HEI departments’ food control activities, providing also methodological advise and assistance on matters related to work organisation and inspection capacity and effectiveness. A written facts finding report is afterwards prepared, containing recommendations for corrective measures with regard to the deficiencies and weaknesses identified during the inspection. A follow-up inspection mission controls the implementation of these recommendations and evaluates the improvements achieved.

Within the framework of the Ministry of Agriculture and Forests (See Chapter 7 presentation)

2.2.1.9. Control on imported food (existing and planned system)

Imported foodstuffs (except those of animal origin) are allowed in the country after their registration and upon issuing of a sanitary permit by the Ministry of Health under the terms of Ordinance No. 27 of the Ministry of Health on the import of goods having effect on human health (State Gazette, No. 75/1995).

Registration and issuing of a sanitary permit is carried out after the importer fills in an application to the Ministry of Health, containing data on the manufacturing company, on the importing company and the list of products intended for import. The application should be accompanied by original documents (with translation into Bulgarian), issued by the producer or importer, guaranteeing for their safety with regard to consumers health. The sanitary permit for import of foods is issued for an indefinite period of time.

Each consignment of imported foodstuffs is marketed only after receiving sanitary conclusion that it is fit for human consumption. These conclusions are issued by the respective regional Hygiene and Epidemiological Inspectorates.

As a mandatory requirement, imported foodstuffs must have labels and instructions for use in Bulgarian language, on both the consumer and the transport packages. Import of foods with expired ‘best before’ date is not allowed. Imports of foods in the form of humanitarian aid or donations are allowed only after the respective regional Hygiene and Epidemiological Inspectorate has carried out laboratory analyses and has issued a conclusion that the food is fit for human consumption.

Planned system

Upon Bulgaria’s accession to the EU, the Bulgarian borders will become external borders of the European Union, and that calls for improvements in the organisation and implementation of the border control on imported food (including that of non-animal origin).

It is planned:

• to stop issuing import sanitary permits;

• to exercise border control on imported food of non-animal origin at eight border crossing points, where documentary, identity and physical checks will be carried out;

• to enhance the work co-ordination between the officials carrying out border control on imported food of non-animal origin and the other control bodies (customs authorities, veterinary bodies, border police, etc.);

• the due laboratory tests, carried out by the state control authorities, to be effected at the place of acceptance.

The organisation and implementation of the control on imported food of animal origin is presented under Chapter 7 issues.

In accordance with the Law on Foodstuffs, by the end of 2001 the Council of Ministers shall issue a decree, adopting an Ordinance on the requirements, detailed procedures and conditions for imports of foods in the country and on the organisation and coordination of control activities of all control institutions involved.

2.2.1.10. System for rapid response (notification) in the event of foods presenting risk for consumer health identified on the market

The Ministry of Health is designated as national contact point with regard to the TRAPEX system for rapid exchange of information in the event of dangerous products (foods) identified on the market. The objective of the system is to ensure prompt information exchange (notification) among all member-countries of the system, in the event of dangerous goods (foods) found on the market on the territory of any member-country, and thus providing for timely and adequate control and prevention measures.

TRAPEX system has been working since May 15, 1999.
The forms for notification of the TRAPEX Secretariat for foodstuffs in Budapest are identical to those used by the RAPEX system in the EU. Currently the structures of the Ministry of Health (28 Hygiene and Epidemiological Inspectorates - HEI) exchange by fax information on dangerous foodstuffs identified on the territory of the country.

Future development

A national information system for rapid exchange of information on dangerous foodstuffs will be set up. The system will follow the principles of the RAPEX system of the EU. Each of the 28 HEI will provide electronic information on dangerous foodstuffs identified in the country to a central coordinating unit that will notify the remaining 27 HEI and consumers.

2.2.1.11. Genetically modified food

In view of the increasing production and global spread of transgenic plant varieties, in 1996 Rules on the Spreading of Genetically Modified Higher Plants Created by Recombinant DNA Technology were adopted (State Gazette, 70/1996). Accordingly, Council for Safe Use of Genetically Modified Higher Plants within the Ministry of Agriculture and Forests was established. Representatives of the Ministry of Agriculture and Forests, Ministry of Health and Ministry of the Environment and Waters participate as members of the Council. An expert commission for studying the food qualities and safety of products obtained from genetically modified higher plants operates within the Council.

The Council is authorised to:

- issue permits for distribution of genetically modified higher plants for research and commercial purposes;
- keep registers on the distribution of genetically modified higher plants for research and commercial purposes;
- exercise control on the proper use of issued permits for distribution of GMO and control of compliance with the requirements and conditions specified in the permits;
- issue mandatory prescriptions to the persons allowed to distribute genetically modified higher plants;
- represent the Republic of Bulgaria in international organisations on the distribution of genetically modified higher plants;
- develop annual reports and provide data on the distribution of genetically modified higher plants to the Minister of Agriculture and Forests.

Bulgaria is currently in preparation of a consistent legislative framework laying down procedures for safety assessment of the genetically modified foodstuffs to be placed on the market. It will be based on the precautionary principle. Currently analyses of GMO in agricultural production and processed farm produce are carried out in the laboratory of the Agrobio-Institute in Kostinbrod.

2.2.2. Chapter 7 (Phytosanitary issues, Veterinary issues, Animal nutrition)

2.2.2.1. Official surveillance/monitoring/control

National Service for Plant Protection, Quarantine and Agro-chemistry (NSPPQA)

Under the Plant Protection Law NSPPQA has the following competence with regard to food safety:

- Protection of plants and products of plant origin from diseases, harmful organisms and pests;
- Phytosanitary control on imports, exports, production and trade with plants and products of plant origin;
- Control on imports, production and trade with plant protection products and fertilisers;
- Control on the levels of chemical contaminants (pesticide residues, heavy metals, mycotoxins, nitrates etc.) in plants and products of plant origin at the time of their production and storage;
- Biological testing of plant protection products for efficiency and residues.

The competent authority authorized to exercise phytosanitary control is NSPPQA and its regional services (RSPPQA), and border inspection posts.

NSPPQA is responsible for the official control on plants and products of plant origin, soils and irrigation waters with regard to pesticide residues, mycotoxins, heavy metals and nitrates. The control is carried out regularly, during the vegetation period, harvesting and storage of production. Monitoring of pesticide residues is carried out as part of the general National Monitoring System. Plant production cultivated on soils polluted with heavy metals and pesticides is subject to control before it is placed on the market. Soils polluted with heavy metals and pesticides are placed under special restrictive regime with respect to their usage for agricultural purposes. Subject to control is also the use of plant protection products – compliance with quarantine periods and applied quantities, keeping of log books with full record of sprayings of plant protection chemicals.
NSPPQA controls compliance of plant protection products and fertilisers with declared chemical and physicochemical properties at the time of their production, import, export and distribution.

National Veterinary Service (NVS)

NVS controls the entire chain of food products of animal origin – “from farm to table”, and issues safety certificates for these products.

Veterinary inspections cover: animal health; animal welfare; zootechnics; veterinary medicinal and biological products; additives in animal feedingstuffs; raw materials of animal origin; foods of animal origin; establishments for processing of animal products.

The administrative bodies responsible for the veterinary control are structured in three levels:

- Headquarters of NVS,
- Regional Veterinary Services (RVS),
- Regional Veterinary inspections (RVI).

Headquarters of the National Veterinary Service:

- Prepare draft legislation;
- Provide administrative and methodical guidance to the Regional Veterinary Services and exercise control on their work;
- Prepare programs for epizootic surveillance of dangerous contagious animal diseases and zoonoses, programs for feedingstuffs monitoring and control of the use of veterinary medicinal products, monitoring programs for contaminants in foodstuffs of animal origin;
- Decide on implementing measures, based on risk analysis covering production and processing of raw materials and foodstuffs of animal origin;
- Organise, co-ordinate and control the activity of the veterinary border inspection posts;
- Prepare annual programs for prophylactic of contagious and parasite diseases and provide for the implementation of all measures specified in the programs;
- Develop schemes for disinfection, desinfection, deratisation and devastation in the event of disease incidence;
- Propose measures related to the work of the rendering plants;
- Carry out prevention and regular control on animals, raw materials and products of animal origin, feedingstuff additives and feedingstuffs;
- Authorise and control the use of biological products and chemical substances in animal breeding and of additives and raw materials of animal origin in the production of animal products.

The headquarters of the National Veterinary Service keep registers of:

- veterinary units;
- issued licenses to all private veterinarians involved in the implementation of state prophylactic programs;
- animal holdings;
- diagnostic laboratories for control of animal contagious diseases, and for control of raw materials and food products of animal origin;
- establishments for production of raw materials and food products of animal origin.

Regional veterinary services (RVS) are responsible for:

- Immuno-prophylactic, medicinal-prophylactic and laboratory-diagnostic activities;
- Carrying out laboratory tests and providing expertise on animals, raw materials and products of animal origin, additives, feedingstuffs and feedingstuffs additives;
- Implementation of veterinary and sanitary measures aimed at eliminating negative effects caused by disease incidence, or food intoxication with regard to people and animals;
- Issuing authorisation certificates for production and processing of raw materials and products of animal origin;
- Control on the activities of border veterinary control officials and their co-ordination with the other competent authorities at border inspection points;
- Organising animal identification and registration of animal holdings;
- Undertaking (in coordination with the bodies of the State Sanitary Control (SSC)) eradication measures for diseases common for people and animals, as well as sanitary measures in cases of food intoxication;
- Border control on import, export and transit of animals and animal products.
Regional inspections of the State Veterinary-Sanitary Control Directorate carry out:
- Checks of identification, place of origin, health condition;
- Documentary and identity checks;
- Checks of origin, quality and safety of raw materials and products of animal origin, as well as of additives, feedingstuffs and feedingstuffs additives;
- Compliance checks with regard to veterinary requirements for production, processing, storage, transportation and trade;
- Control on the use of veterinary medical products, bioproducts and feedingstuffs additives;
- Laboratory tests of microbiological and toxicological parameters, including with regard to the production environment;
- Testing of water and ice, used in animal breeding, production, processing, storage and transportation of raw materials and products of animal origin;
- Checks of supporting and packaging materials;
- Checks of premises and equipment, used in animal breeding, production, processing, storage and transportation of animal products;
- Checks of production and internal control systems ensuring product safety.

NVS decides on the frequency of veterinary inspections and laboratory tests taking into account the individual characteristics of each enterprise, type of raw materials and products, volume of production, risk assessment etc.

Slaughterhouses and red meat, chicken and fish processing enterprises are subject to regular veterinary control. Large-scale enterprises and refrigerators of industrial capacity are subject to daily inspections. Small and medium sized enterprises and enterprises producing bee products and preserved foods of animal origin are inspected 1-4 times per month.

The control activity of veterinary inspectors responsible for enterprises approved for export is checked at least once a year by the Head of the Regional Inspection, while in the enterprises approved for export to the EU member states – checks are carried out at least twice a year by experts from the headquarters of the NVS.

National Veterinary Service (NVS) and Feed Control Inspection (FCI) under the National Grain Service (NGS)

The Feed Control Inspection and the National Veterinary Service are in charge of the control on animal nutrition.

The Feed Control Inspection controls:
- The approved and registered producers and traders of feedingstuffs;
- Feedingstuffs additives as anti-oxidants, emulsifiers, stabilizers, colorants, etc;
- Trade in compound feedingstuffs;
- Feedingstuffs for special purposes;

The National Veterinary Service controls:
- Additives as antibiotics, anti-parasite chemicals, preservatives, vitamins, pro-vitamins, enzymes, etc.;
- Maximum permitted levels of undesirable substances and products in feedingstuffs;
- Compound feedingstuffs safety.

Control activities cover:
- Documentary checks;
- Identity checks;
- Physical checks through sampling and laboratory analyses;
- Elaboration and implementation of annual Inspection Programs.

Sampling and testing is carried out in compliance with validated methods of analysis by laboratories approved by the National Grain Service and National Veterinary Service. Based on the analyses results the competent control body issues a certificate.

When the feedingstuffs consignment does not meet safety requirements the competent control bodies decide on the following measures:
- Bringing the feedingstuffs in compliance with the safety requirements;
- Decontamination where possible;
- Using the feedingstuffs for other purposes or;
- Destruction.

In the event of non-compliance with the prescribed measures, sanctions are imposed in accordance with the provisions of the Veterinary Law and the Animal Feed Act.
Setting up of an Inter-ministerial Expert Advisory Council on animal nutrition to the Ministry of Agriculture and Forests is imminent. Preparation of annual lists of approved products and substances for animal feeding will be the main function of the Council.

The action plan of the National Veterinary Service for the next 5 years is presented in Annex 10.

2.2.2.2. System of approval/authorisation of establishments

The National Veterinary Service carries out preliminary, regular or permanent veterinary-sanitary control on raw materials and products of animal origin in the production, processing and trading establishments. The Veterinary Public Health Control (VPHC) bodies approve and authorise establishments in accordance with the Veterinary Law and the Rules of its implementation. RVS register and keep a dossier of all establishments authorised on its territory. Each registered enterprise is given a veterinary registration number.

If the VPHC structures find out deficiencies resulting in violation of the veterinary-sanitary requirements, they suspend the authorisation by an order of the General Director of NVS. This order is entered into the register.

The headquarters of the NVS approve/authorize enterprises for export following the procedure stipulated in the Rules of Implementation of the Veterinary Law.

If the VPHC structures find out deficiencies resulting in violation of the veterinary-sanitary requirements, the Head of NVS suspends the export certificate until the deficiencies are corrected.

2.2.2.3. Official Certification

National service for plant protection, quarantine and agro-chemistry

NSPPQA, respectively its regional divisions RSPPQA register producers, traders/ importers of plants and products of plant origin. To certify the health status of each consignment, Phytosanitary passport is issued to producers and Phytosanitary certificate - to exporters.

NSPPQA issues permits for import of plant protection products, which are entered into a register. The import, sale, production and packaging of plant protection products with commercial purposes or for providing plant protection services are subject to licensing.

For raw materials and products of plant origin designed for export into countries with specific requirements on the levels of chemical contaminants (pesticides residues, heavy metals, mycotoxins, etc.) the Central Laboratory for Pesticides, Nitrates, Heavy Metals and Fertilizers Control /CLPNHMFC/ to the NSPPQA issues special test protocols.

The rules and procedures of issuing permits and licenses are introduced by Ordinances of the Minister of Agriculture and Forests under the Plant Protection Law.

National Veterinary Service

According to the Veterinary Law the NVS bodies issue veterinary certificates for the transportation of live animals, raw materials and products of animal origin between their various points of destination (place of origin, quarantine premises, warehouse, slaughterhouse, processing enterprise, wholesale storehouse, market-place, retail store). These certificates have veterinary registration numbers.

Each imported consignment of live animals, raw materials and products of animal origin have to be accompanied by a veterinary certificate, which is checked at the border inspection posts.

The NVS bodies issue veterinary certificates for each exported consignment. The certificate's form is in compliance with the specific national requirements of the importing country.

Imports and exports of live animals, raw materials and products of animal origin are subject to authorisation by the NVS.

2.2.2.4. Laboratory network, system of accreditation

Laboratory network operates within the framework of the national services of the Ministry of Agriculture and Forests (Annex 11) – NVS, NSPPQA and NGS. A staff of 517 laboratory experts (325 with master's - and 192 with bachelor's degree) carries out the laboratory control.

Central laboratory for pesticides, nitrates, heavy metals and fertilisers control (CLPNHMFC)

CLPNHMFC is a Directorate to the specialised administration of the NSPPQA with a staff of 23 employees. The Central laboratory has the following competencies:

• Sampling and analysis of products of plant origin and soils for presence/levels of pesticides residues, mycotoxins, heavy metals, nitrates, etc.;

• Sampling and analysis of plant protection products and fertilisers;

• Study, development and validation of new methods for sampling and analysis of plants, soils, plant protection products and fertilisers;

• Carrying out inspections (together with the RSPPQA).

CLPNHMFC is supplied with advanced analytical equipment and is staffed with adequately qualified specialists.

CLPNHMFC is accredited by the Executive Agency “Bulgarian Accreditation Service” - Attestation No. 524 – I/16.11.1998 and is under preparation for GLP certification.
By 2002 the Plant Protection Law will be amended and complemented with detailed secondary legislation. That will outline the activity of the CLPNHMFC as concentrated basically in the field of plant protection products and pesticide residues:

- Participation in the determination of maximum permitted levels of pesticide residues, terms of quarantine, application dose rates etc., pursuant to Directive 91/414 EEC;
- Reconsideration of some previous decisions especially with regard to the quarantine terms, justified by field tests for pesticides residues;
- Official surveillance of compliance with the Good agriculture practices (quarantine terms in particular), as specified in the decisions for registration;
- Establishment of a National system for monitoring of pesticide residues in products of plant origin.

II. National Veterinary Service

The National Veterinary Service carries out laboratory and diagnostic control in accordance with the Veterinary Law and the Rules for its implementation. There are 494 qualified laboratory experts involved in the system of laboratory control (108 research assistants, 124 doctors in veterinary medicine, biologists, chemists, and zoo-technicians, and 180 laboratory assistants).

The official diagnostics and analyses cover:
1. Animal health;
2. Animal welfare;
3. Research and control on the technological parameters in animal breeding;
4. Veterinary medicinal and biological products;
5. Feedingstuffs and feedingstuffs additives;
6. Environment protection aspects;
7. Raw materials and products of animal origin.

Laboratory diagnostic control under items 1, 2, 3 and 5 is related to:

- Elaboration of annual State Prophylactic Programme;
- Listing of animal contagious and parasite diseases subject to compulsory veterinary prophylactic;
- Planning of laboratory research activities of the laboratory scientific and diagnostic units at regional level under the RVS;
- Laboratory analyses and control on animal toxicological diseases and of levels of contamination of feedingstuffs, soil, and drinking water sources with pesticides, heavy metals (lead, cadmium, copper, zinc, arsenic, etc.), fertilisers (nitrates and nitrates), feedingstuffs additives (sodium chloride, carbamide, etc.), nutritive antibiotics and coccidiostatics, pathogenic bacteria, mycotoxins and fungi;
- Control of imports, exports, production and trade with compound feedingstuffs, including medicated feedingstuffs, premixes, raw materials and feed components.

Laboratory and diagnostic analyses are carried out in specialised laboratories within the system of NVS:
- on a regular basis,
- in case of suspicion for disease,
- in case of mass disease incidences.

Structure of laboratory diagnostic control over contagious and parasite diseases and non-contagious pathology, intoxication and feedingstuffs

The analyses are carried out in specialised laboratories under the NVS – Central Veterinary Medical Research Institute (CVMRI) - Sofia, Regional Veterinary-Medicine Institute (RVI)-Veliko Tarnovo and Stara Zagora, RVS-Blagoevgrad, Burgas, Varna, Pleven, Haskovo and diagnostic laboratories under the RVS-Pazardjik, Plovdiv, Russe, Sliven, Smolyan and Targovishte. The General Director of the NVS approves the type- and disease specialization of analyses by area location and by scientific-diagnostic and diagnostic units in the regions, depending on the level of competence and equipment of each unit (see Annex 11).

Laboratory diagnostic control under items 4, 6 and 7 (p.21) within the system of the Veterinary Public Health Control (VPHC) is carried out by one central and 30 regional laboratories for veterinary analyses (RLVA) of raw materials and products of animal origin. Regional laboratories are
administered by the RVS, and the Central Laboratory for Veterinary Control and Ecology (CLVCE) provides methodical guidance. The laboratories in the VPHC system carry out standard analysis on live animals, feedingstuffs, raw materials, and products of animal origin. Analyses verify their safety and intended use suitability. Laboratory control covers all products – imported, domestically produced, including those intended for export. The CLVCE is accredited by the Executive Agency “Bulgarian Accreditation Service” (EA’BAS) and is designated by the Minister of Agriculture and Forestry as reference laboratory within the Ministry of Agriculture and Forests for control of residues of technogenic contaminants and veterinary medicinal products in raw materials, products of animal origin, and feedingstuffs – Order No. 1-114/25.01.1995. By the time being 16 RLVA have been accredited by EA’BAS to carry out analysis for microbiological product safety, organoleptic assessment, as well as for certifying physical and chemical composition. Two laboratories are under accreditation procedure and their authorization is imminent. The other 12 laboratories are divided into three groups according to their preparedness for accreditation with regard to premises, equipment, staff and documentation. The evaluation follows the provisions of the BDS EN 45001. The NVS has designated 8 of the accredited laboratories to carry out specialised analyses and control of certain types of products of animal origin. New laboratory analytical equipment has been supplied in the framework of PHARE Project BG 9806/01/01 to create the necessary capacity for carrying out the specialised control. The structure of the laboratory control within the system of NVS is given in Annex 11.

2.2.2.5 Control of Import and Export

Within the system of NSPPQA
Phytosanitary control on imports of plants, plant raw materials and products of plant origin is carried out at the border inspection points, in the distribution, processing and storage establishments or at the time of growing and production in the exporting country. Products of plant origin subject to phytosanitary control are exported only at border inspection points designated by the Council of Ministers. RSPPC and CLPTNPC carry out control of chemical contaminants in raw materials and products of plant origin during their production if the importing country requires so.

The control of imported plant protection products and fertilisers is made at the border inspection point, in the storehouses and on the market when there is a suspicion for non-compliance with the declared chemical and physical parameters. Within the system of the NVS
Veterinary control is carried out on imports and exports of live animals, raw materials and products of animal origin, and feedingstuffs to prevent the import of products dangerous for public or animal health, and which may cause the spread of contagious diseases.

The headquarters of NVS through its Border Inspections for Veterinary Control and Quarantine (BIVCQ) exercise control on imports, exports and transit covering:
1. Live animals, raw materials and products of animal origin, feedingstuffs, feedingstuffs additives and veterinary medicinal products;
2. Vehicles used for transportation of products specified in Item 1;
Control is performed at border inspection points designated by the Council of Ministers. Veterinary control is carried out by border veterinary inspectors at BIVCQ, situated at the border inspection points, railway stations, seaports, roads and airports in the country. Veterinary checks of live animals and analyses of raw materials and products of animal origin, feedingstuffs, premixes etc. designed for import or export are carried out only by state veterinarians (doctors in veterinary medicine) and VPHC laboratories, which is in full compliance with the provisions of Directive 97/78/EEC. Customs, transport and other authorities cannot clear, or transport in or out of the country live animals, raw materials and products of animal origin, feedingstuffs, bio- products, premixes, semen, embryos, cell cultures etc., without a written permission issued by the respective BIVCQ. The procedure is in full compliance with the provisions of Directives 91/496 EEC and 97/78 EEC. A written permission issued by the National Veterinary Service is required for the import, export and transit of products under veterinary control. Consignments of these products have to be accompanied by official veterinary certificates, protocols of analyses etc., issued by the competent veterinary authority of the country of origin. The procedure is in full compliance with the provisions of Directive 97/78/EEC. The BIVCQ have the following competencies:
• To check and certify the documents accompanying consignments of live animals, raw materials and products of animal origin, feedingstuffs etc.;
• To take, if needed, certain number of samples from imported and exported raw materials and products of animal origin and feedingstuffs for laboratory analysis of quality and safety.

The above functions are in compliance with Directives 89/662/EEC and 97/78/EEC. Import is permitted on the basis of an investigation of the epizootic situation, hygienic conditions for production/storage/distribution, and veterinary-sanitary control in the country of origin. The procedure complies with the provisions of Directive 97/78/EEC, Article 5, regarding the obligation of veterinary authorities to issue certificates. Import of consignments not accompanied with proper veterinary documents is not allowed. In cases of non-compliance a protocol in two copies is drawn up – one for the National Veterinary Service and one for the importer.

If the import is not allowed the consignment is kept at the border inspection point and could be sent back to the country of origin. If this is not possible, the products are subject to confiscation and destruction following the veterinary and sanitary requirements pursuant to the Veterinary Law. The importer assumes all the costs thereof.

Border veterinary control operates at a 24-hour regime and covers:
• Documentary checks;
• Identity checks;
• Physical checks.

The BIVCQ work in close co-operation with the other control bodies (customs authorities, border Police, etc.). Laboratory tests are carried out by the VPHC bodies at the place of receipt. Certification of goods is performed in compliance with the Veterinary Law. The Director General of the NVS endorses the veterinary requirements for import of live animals, raw materials and products of animal origin.

Feedingstuffs import and export control

Each consignment of imported or exported products is subject to control regarding its type, origin, and final destination. A veterinary certificate, a quality certificate, and a compliance declaration accompany all imported products.

NVS issues permissions for import and export of feedingstuffs. Importers and exporters should also notify the FCI.

Planned system

Upon accession Bulgaria’s borders will become external borders of the European Union. Bulgaria has favourable geographical position for trade with the Middle East and the countries of North Africa. This creates a serious risk for spread of contagious animal diseases typical for Asia and Africa. Disease control and eradication measures in cases of disease incidence result in substantial financial expenditure and need significant human resources. Therefore, prevention control is essential for Bulgaria. Programmes for prevention control introduce regimes for veterinary checks of live animals and products of animal origin, approved by the EU.

EU experts have determined 8 border inspection points for trade with live animals and products of animal origin, which will stay operational on the future external borders of the EU upon Bulgaria’s accession. EU financing of projects for setting up border veterinary post has been initiated under the PHARE program. The main objective of such projects is the implementation of EU requirements for efficient veterinary border control, which includes:
• Improvement (upgrading) of border veterinary control inspection points;
• bringing the procedures of issuing veterinary permissions and of veterinary control in full compliance with the EU requirements for import of live animals and products of animal origin.

The first Border Inspection Veterinary Control (“Kapitan Andreevo”) in full compliance with the acquis requirements will be constructed under PHARE project BG9913-01. It will serve as pilot project for the construction of the remaining BIVC.

Although current veterinary border checks are reliable they do not meet completely the general requirements for veterinary control on the EU borders. The lack of laboratories and adequate infrastructure at the border points is the main obstacle for introducing the new regime of testing of live animals and products of animal origin.

2.2.2.6. Follow-up actions and sanctions

In case of non-compliance with/ violation of veterinary rules, the VPHC bodies undertake proportionate measures as follows:
• Give prescriptions for correcting measures in the establishments;
• Discontinue production and marketing of raw materials and products until these prescriptions are fulfilled;
• Order confiscation and destruction, or reprocessing of products dangerous for public and animal health;
• Stop operation or suspend authorisation of establishments;
• Suspend for a certain period or permanently the export permission. Damages, losses and missed benefits from imposed prohibitions are at the expense of the exporter.

The above measures are imposed by written prescriptions, acts for prohibition, orders, acts of identification of infringements. These acts may be contested with an appeal to the Minister of Agriculture and Forests, but the procedure does not automatically suspend the measures.

The VPHC bodies ban raw materials and products of animal origin, if:
• They do not correspond by type, quality and quantity to the data indicated in the documents;
• They are of unidentified origin;
• There is suspicion, that they are fake, unfit for consumption or dangerous for public and animal health;
• Prints of the seals, stamps and labels are unclear and illegible;
• The accompanying veterinary documents do not contain a certificate for trichinoscopy test (for products subject to obligatory testing for trichinosis);
• Imported without veterinary permission;
• Official information is received that they are dangerous for public and animal health.

NVS bodies confiscate live animals, raw materials and products of animal origin, notwithstanding due fines or sanction imposed, if:
• Raw materials and products of animal origin are found fake, unfit for consumption and dangerous for public health or do not correspond by type and quality to the data indicated in the documents;
• Live animals are transported/moved without being accompanied by veterinary documents;
• Products and raw materials are of unidentified origin;

The NVS bodies dispose of the confiscated raw materials and products of animal origin. By the time the penalty decree becomes effective the confiscated raw materials and products of animal origin are kept:
• In the owner’s or importer’s premises;
• In Municipality’s premises.

The veterinary inspector who draws up the penalty decree chooses and designates appropriate premises. Confiscated raw materials and products of animal origin fit for human consumption are delivered for distribution to the Ministry of Labour and Social Policy, the Ministry of Interior and the Ministry of Defence. The procedure is launched by the Director of the relevant RVS, after the penalty decree becomes effective. If the raw materials and products cannot be distributed before the expiry date the NVS bodies order their destruction or processing in rendering plants. In case of destruction an appointed commission (in the presence of a representative of the Municipality) draws up a protocol. In case of reprocessing the rendering plant issues a certificate. In case of confiscation of perishable products, fit for human consumption, the Director of the RVS immediately orders their release for marketing.

In case of serious infringements, which cause danger or present risk for public and animal health, the NVS bodies close the establishment for a period of one to six months and notify the Prosecutor’s Office.

2.2.2.7. Training

National Service for Plant Protection, Quarantine and Agro-chemistry (NSPPQA)
Under PHARE project BG 9103-06-06 with a budget of 199,798 ECU.
Project objectives: to define more accurately the legal and regulatory framework of the NSPPQA in compliance with the requirements of the EU, to improve the organisation and structure of NSPPQA, to train NSPPQA’s staff with regard to the EU phytosanitary legislation.
Results: evaluation and recommendations for improving the organisation and activities of the NSPPQA, workshop on EU legislation, preparation of draft legislation introducing relevant EU acquis, provision of literature and technical equipment for NSPPQA.

Under PHARE project BG 9507-02-03 with a budget of 350,000 ECU.
Project objectives: work improvement through technical assistance and training of the Central Laboratory for Plant Quarantine (CLPQ) and Central Laboratory for pesticides, nitrates, heavy metals, fertilisers control (CLPNHMFC) as well as of biological testing and registration of pesticides.
Results: Upgrading of the technical equipment of two laboratories and the sites for biological testing. On-spot training was organised in the Netherlands and the UK, as well as a visit in similar laboratories in the Netherlands.

Under PHARE projects BG 9806-01-02 with a budget of 1,100,000 Euro and BG 9913-02 with a budget of 1,290,000 Euro. These projects are closely related to twinning project BG98/IB/AG/02 (with France).

Project objectives: Supply of equipment for the CLPNHMFC, CLPQ, 4 regional phytosanitary laboratories, 2 pilot sites for biological testing and 9 border posts.

The analyses equipment for the CLPNHMFC (700,000 Euro) has already been delivered and is under testing.

The Twinning project with France includes three sub-projects on:

- Plant health inspections for imported and domestic production which covers border control, production control and laboratory analysis;
- Biological testing and registration of plant protection products;
- Pesticides residue control in plant production and preparing the CLPNHMFC for international accreditation in compliance with the principles of GLP.

All sub-projects include assessment of the existing capacity, harmonisation of legislation, workshops and individual training in Bulgaria and in EU member states. A long-term expert from France has been working constantly in Bulgaria since the beginning of 1999.

National Veterinary Service (NVS)

TAIEX has been supporting staff training in the veterinary field for 4 years already. Annually three workshops are organised and financed by the EU for the experts from the 7 sub-groups established within the working group of the Chief Veterinary Officers of the applicant countries. More than 30 experts from the NVS attend these training courses annually. More than 30 experts from the NVS use the TAIEX information system - VETLEX.

Experts from laboratories and institutes in charge of contagious and parasite diseases diagnostics and research were trained under the multinational veterinary diagnostics and control program. In the last 4 years many training courses were organised and a lot of supporting materials (manuals, contingency plans, video materials etc.) were prepared.

At present the NVS is part of a PHARE twinning project with the Ministry of Health of Italy (Improvement of Veterinary Control). The purpose of the project is to strengthen the administrative capacity and improve the qualification of NVS experts. The budget of the project is 1 million Euros for two years period. 75 veterinary experts from Italy consult NVS on a short-term basis. 132 Bulgarian veterinary specialists will be trained in Italy in veterinary control of production, processing, storage and distribution of foods of animal origin. Six workshops will be organised in Bulgaria where other 240 experts and members of producers’ organisations will be trained. Workshops on Zoonosis, Animal welfare, Fish diseases, Introduction of good manufacturing practices and the HACCP in meat-processing industry have been organised so far.

Training for trainers courses on good manufacturing practices and HACCP and on measures for implementation of the WTO requirements regarding veterinary and phytosanitary measures were organised with the support of FAO.

The veterinary staff at the border inspection points was trained on border veterinary control procedures under 1999-2001 PHARE project. Another training course on diagnostics of transmittable diseases, registration and control of veterinary medicinal products etc. will be organised.

The NVS is committed to ensure the necessary training programs with a view to meeting the EU acquis standards and requirements.

Representatives of the NVS are members of the Experts Councils of producers’ organisation and assist them in developing guidelines for good manufacturing practices and model HACCP–plans for different sub-sectors of the food industry.
LEGEND

NVS - National Veterinary Service

NSPPQA - National service for Plant Protection, Quarantine and Agro-chemistry

CLPNHMFC – Central laboratory of pesticides, nitrates, heavy metals and fertilisers control

RHEI – Regional hygiene epidemiological inspectorates

NCHMEN – National centre for hygiene, medical ecology and nutrition

CLVCE – Central laboratory for veterinary control and ecology
CVMRI – CENTRAL VETERINARY MEDICAL RESEARCH INSTITUTE

TL – TESTING LABORATORY

* - accredited by Executive Agency “Bulgarian Service for Accreditation”

FOOD SAFETY LABORATORY CONTROL

MINISTRY OF AGRICULTURE
AND FORESTRY

NATIONAL GRAIN

FEED CONTROL INSPECTION

NVS

CLVCE *

NVDRI

NSPPQA

CLPNHMFC *
Annex 8 – List with price estimates of laboratory equipment requested
MINISTRY OF AGRICULTURE AND FORESTRY

LIST OF LABORATORY EQUIPMENT FOR VETERINARY HYGENIC EXPERTISE OF ANIMAL ORIGINE FOODSTUFFS AT THE NATIONAL VETERINARY DIAGNOSTIC AND RESEARCH INSTITUTE - SOFIA

<table>
<thead>
<tr>
<th>No</th>
<th>Specification</th>
<th>Unit</th>
<th>Price Estimate</th>
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<tbody>
<tr>
<td>1</td>
<td>Penetrometre</td>
<td>1</td>
<td>3500</td>
</tr>
<tr>
<td>2</td>
<td>Automated Identification System with ATB Expression (ATB Identification)</td>
<td>1</td>
<td>32000</td>
</tr>
<tr>
<td>3</td>
<td>Anaerobic Plus System</td>
<td>1</td>
<td>3700</td>
</tr>
<tr>
<td>4</td>
<td>GC Equipment for Fatty Acids Analyses with Head-Space System</td>
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<td>35000</td>
</tr>
<tr>
<td>5</td>
<td>Moisture Determination Balance</td>
<td>1</td>
<td>2500</td>
</tr>
<tr>
<td>6</td>
<td>Laminar Flow, class 2</td>
<td>2</td>
<td>4500</td>
</tr>
<tr>
<td>7</td>
<td>HPLC for Food Preserves, Dyes&amp;Additives</td>
<td>1</td>
<td>30000</td>
</tr>
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<td>8</td>
<td>Water Analyses Spectrophotometer System</td>
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</tr>
<tr>
<td>9</td>
<td>Luminiscence Microscope</td>
<td>1</td>
<td>7400</td>
</tr>
<tr>
<td>10</td>
<td>Direct Heat CO$_2$ Incubator</td>
<td>1</td>
<td>1650</td>
</tr>
<tr>
<td>11</td>
<td>Anaerocult A</td>
<td>1</td>
<td>900</td>
</tr>
<tr>
<td>12</td>
<td>Anaerocult C</td>
<td>1</td>
<td>1000</td>
</tr>
<tr>
<td>13</td>
<td>Anaerocult IS</td>
<td>1</td>
<td>1200</td>
</tr>
<tr>
<td>14</td>
<td>Explosion-Proof Balance</td>
<td>1</td>
<td>3500</td>
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<tr>
<td>15</td>
<td>Muffle Furnace</td>
<td>1</td>
<td>3000</td>
</tr>
<tr>
<td>16</td>
<td>HP Utility Bath</td>
<td>1</td>
<td>800</td>
</tr>
<tr>
<td>17</td>
<td>PH Meter</td>
<td>1</td>
<td>1000</td>
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<tr>
<td></td>
<td><strong>Total</strong></td>
<td></td>
<td><strong>154150</strong></td>
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<tr>
<td></td>
<td>Contingency 10%</td>
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<td><strong>15000</strong></td>
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<tr>
<td></td>
<td><strong>Rounded up grand total</strong></td>
<td></td>
<td><strong>170.000</strong></td>
</tr>
</tbody>
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MINISTRY OF HEALTH

Project title: STRENGTHENING FOOD SAFETY POLICY
Equipment for the departments for laboratory research in 6 of the Hygiene Epidemiological Inspectorates: in Sofia, Plovdiv, Varna, Bourgas, Veliko Tarnovo and Pleven

<table>
<thead>
<tr>
<th>?</th>
<th>Name of the apparatuses</th>
<th>Minimum quantity</th>
<th>Unit price</th>
<th>Total Price in EURO</th>
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<tbody>
<tr>
<td>1</td>
<td>Nuclear absorbing spectrophotometer</td>
<td>6</td>
<td>83600</td>
<td>501600</td>
</tr>
<tr>
<td>2</td>
<td>Nuclear absorbing spectrophotometer ACP</td>
<td>1</td>
<td>97000</td>
<td>97000</td>
</tr>
<tr>
<td>3</td>
<td>Gas chromatograph</td>
<td>6</td>
<td>77000</td>
<td>462000</td>
</tr>
<tr>
<td>4</td>
<td>Liquid chromatograph</td>
<td>6</td>
<td>77000</td>
<td>462000</td>
</tr>
<tr>
<td>5</td>
<td>UV – VIS spectrophotometer - with a set of cells</td>
<td>6</td>
<td>4620</td>
<td>27720</td>
</tr>
<tr>
<td>6</td>
<td>Stationary turbidity meter – with a set of standard 40 NT and 6 cells</td>
<td>6</td>
<td>2640</td>
<td>15840</td>
</tr>
<tr>
<td>7</td>
<td>Analytical electronic balances with automatic calibration</td>
<td>6</td>
<td>4400</td>
<td>26400</td>
</tr>
<tr>
<td>8</td>
<td>Technical balances with automatic calibration /0-200//0-1 500//0-120/</td>
<td>6</td>
<td>1100</td>
<td>6600</td>
</tr>
<tr>
<td>9</td>
<td>ABBE’s refract meter - T-O-75o C</td>
<td>6</td>
<td>3850</td>
<td>23100</td>
</tr>
<tr>
<td>10</td>
<td>Ultra thermostat for ABBE’s refract meter</td>
<td>6</td>
<td>880</td>
<td>5280</td>
</tr>
<tr>
<td>11</td>
<td>Portable conductor meter with a set of batteries and standards</td>
<td>6</td>
<td>1100</td>
<td>6600</td>
</tr>
<tr>
<td>12</td>
<td>Stationary ph-meter with a set of electrodes</td>
<td>6</td>
<td>550</td>
<td>3300</td>
</tr>
<tr>
<td>13</td>
<td>Microscope with “Walton Becket”</td>
<td>6</td>
<td>2500</td>
<td>15000</td>
</tr>
<tr>
<td>14</td>
<td>Sound-level meter along with a track device – integrating, measuring equivalent level and dose, with built-in octaves and terzaoctave filters, with a possibility for measuring infrasound and ultrasound, accuracy class – at least 1</td>
<td>6</td>
<td>5500</td>
<td>33000</td>
</tr>
<tr>
<td>15</td>
<td>Vibration meter with built-in filter – a set with vibration mass, vibration pick-up, spare cables, with a possibility to measure root-mean-square value – class 1</td>
<td>6</td>
<td>10000</td>
<td>60000</td>
</tr>
<tr>
<td>16</td>
<td>Luximeter – electronic, with a possibility for switching while measuring the different types of illuminating bodies, the cylindrical illumination, the brightness, the pulsation coefficient and KEO – accuracy class 0,1</td>
<td>6</td>
<td>300</td>
<td>1800</td>
</tr>
<tr>
<td>17</td>
<td>Apparatuses for microclimate – temperature, relative humidity, speed of air movement, infrared radiation – electronic type – fast, with the appropriate set of probes and a possibility to measure VBGT – index, accuracy class 0,1 :</td>
<td>6</td>
<td>1500</td>
<td>9000</td>
</tr>
<tr>
<td>18</td>
<td>Equipment for measurement of electromagnetic fields, including the whole frequency range from 0 Hz up to G Hz; set of 3 or 4 apparatuses, which should cover the whole frequency range;</td>
<td>6</td>
<td>30000</td>
<td>180000</td>
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</tbody>
</table>

Sub total 1936240
15% contingencies 290436
Grand total 2226676
Annex 9

Justification

of the need for laboratory equipment for the laboratory for microbiological and physico-chemical analyses – section “Veterinary expertise of foodstuffs of animal origin and technical animal raw materials” and the laboratory of Ministry of Health

Section “Veterinary expertise of foodstuffs of animal origin and technical animal raw materials” is one of the oldest units of the National Veterinary Diagnostic and Research Institute (NVDRI). It is successor of the Veterinary and Hygiene and Control Institute which, together with the Institute of Veterinary Virology, the Institute for Contagious and Parasitic Diseases, the Institute of Biology and Pathology of reproduction and the Institute for Non-contagious Diseases and Zoonohygiene, formed the NVDRI of today. Since the date of its establishment (in 1901) the Institute has been a state body. In 2001 it became part of the structure of the National Veterinary Service (NVS) under the Ministry of Agriculture and Forestry (MAF).

The NVDRI is an important diagnostic center performing special diagnostic tests and expertise in the framework of the National Prophylactic Program. The main priorities of the Institute for the next years are:

- To proceed with the refurbishment and to complete the equipment of the national reference diagnostic laboratories for certain epizootic animal diseases;
- To strengthen the human resource capacity by appointing young specialists to replace the retired staff and to provide for their further qualification;
- To continue the preparation for national accreditation of laboratories;
- To continue the exchange of information and co-operation with TAIEX Office experts;
- To support the process of upgrading laboratory methods and development of new methods of laboratory diagnostics in line with the EC requirements.

An important task of the Institute is to assure the quality and safety of foodstuffs, to perform prophylaxis and control of food toxic infections, toxicoses, etc. Section “Veterinary expertise of foodstuffs of animal origin and technical animal raw materials” is the unit that deals with these problems. The main responsibilities of the section are:

- To control foodstuffs of animal origin in view of assuring their safety in respect of pathogenic and hygienically indicative microorganisms and dangerous parasites;
- To ensure and control the hygiene status in establishments producing foods of animal origin through introduction of the principles of good manufacture and hygiene practices;
- To ensure high-quality and safe dietary foods of balanced chemical composition, high nutritive value;
- To perform control on the toxicological safety of foods of animal origin as regards residues of biogenic amines, food additives, synthetic colorants, preservatives, biotoxines and other harmful substances.

In the forthcoming three years the section will focus its efforts on:

- Establishment of reference laboratories for microbiological and physico-chemical analyses of foods of animal origin and preparation for accreditation of these laboratories as control bodies under Bulgarian State Standard (BSS) ?N 45004;
- Implementation of national legislation in the field of laboratory control and analyses of foods of animal origin harmonized with the relevant EC legislation and introduction of GLP principles;
- Organization of training courses on food safety for experts working in the system of veterinary public health and representatives of food producing companies under the auspices
The experts working in the section are highly qualified. Presently 23 people work in the section - 1 professor, 8 associate professors, 3 res. assoc., 4 specialists with higher education and 8 laboratory assistants.

The existing equipment is old and morally out-dated: 5 thermostats (made 40 year ago), 1 anaerostat (15 years ago), 2 dry ovens (20 years ago), 2 binocular microscopes (30 years ago), 1 trichinaeloscope (25 years ago), 2 analytical balances "Sartorius" (respectively 45 and 10 years ago), 1 analytical balance "Metler" (17 years ago), 2 pH-meters (12 years ago), 1 gas chromatographer "Pye Unicam" 104 with 1 spectrometer “Lambda 3” and 1 atomic-absorption spectrophotometer “Perkin Elmer” 3030.

Annually over 4500 samples are received for testing at the section. These include meat samples from different animals species, samples from meat products, canned meat, eggs and egg products, animal fats, etc. The samples are sent by both state-owned and private companies, dealing with production, processing, storage and export of foodstuffs of animal origin.

According to Ordinance No. 31 of 24 July 2001 of the MAF on meat and meat preparations and Ordinance No. 40 of 4 October 2002 of MAF on the placing on the market of egg products, these products must undergo checks according to microbiological parameters, including mesophilic aerobic bacteria; E.coli, S. aureus, and other hygienically indicative and pathogenic microorganisms. The identification of the type of isolated micro-organisms is a necessary condition for the correct assessment of foods’ microbiological safety. Presently this type of assessment is carried out using analyses which take from 24 to 72 hours according to the adopted classical media consuming methods.

These labor-consuming, expensive and slow methods for microbiological analyses must be replaced by contemporary methods. The optimal solution to this problem can be reached with the help of the equipment for determining the type of gramme-positive and gramme-negative microorganisms - Automated Identification System with ATB Expression and the Anaerobic Plus System (items 2 and 3).

According to the above Ordinances these analyses must be carried out in class 2 laminar flows (item 6) using the equipment listed under items 9 – 13 (Luminescence Microscope, CO₂ incubator, Anaerocults). Presently microbiological checks are performed on laboratory tables and in morally out-dated cabinets, which is incompatible with the EU norms and regulations.

Similar is the situation with the complex microbiological and physico-chemical analyses of water from water resources situated on the territory of food establishments (establishments producing meat, canned meat, storage plants, cold stores, etc.). According to Ordinance No. 12/18.06.2002 (of the Ministry of Environment and Water, the Ministry of Health and the Ministry of regional Development and Public Works) laying down requirements for surface water, intended for household and industrial use, in addition to the microbiological parameters (faecal coliforms and streptococci, etc.), the water is tested for a number of physico-chemical parameters – pH, anions, micro- and macro-elements etc. Annually over 300 water samples are tested for over 50 parameters, as required by the EC Directives. The methods used for determination of water quality are old and labor-consuming and require a lot of energy, media and chemical reagents. By means of the apparatuses listed under items 8, 14 – 17 (Water Analyses Spectrophotometer, Explosion-Proof Balance, Muffle Furnace, HP Utility Bath, pH Meter) and the above-mentioned equipment for microbiological analyses, the laboratory will be able to carry out the necessary analyses with modern equipment using contemporary methods, recognized in the EC member states and introduced in our country as BSS EN.

According to Ordinance No. 8/16.04.2002 of MH on the requirements for the use of additives in food production, the analyses of different preservatives (salts of benzoic, sorbic, ascorbic, boric acids), food additives, colorants, etc. are carried out only in this section by old methods on the basis of titrmetric, colorimetric and chromatographic analysis for lack of necessary equipment. A contemporary solution of this problem would be the purchase of equipment for physico-chemical analysis listed under items 4 and 7 (GC Equipment with Head space system and HPLC). This equipment will also resolve the problem of determination of fatty acid composition of animal fats and falsifications. The identity of animal fats can only be determined by means of this equipment. The Penetrometer – item 1 serves for precise and objective determination of meat and meat product density, which is an important
parameter, part of all standards for meat and meat products. Presently the assessment is made on the basis of organoleptic qualities and is therefore subjective. The laboratories of the Ministry of Health carry out microbiological testing/analysis of samples taken from the working environment and from the personnel involved in food manufacturing and trade, as well as chemical and microbiological analysis of both domestic and imported foods and potable water used in the processing facilities. The implementation of the basic legislation is made difficult because of the laboratories are under equipped. The existing equipment is old and amortized and there is no possibility to make tests for presence and content of additives, contaminants (pesticide residues, heavy metals, mycotoxins) and migration of monomers from materials intended to come into contact with foodstuffs. The laboratories from the Ministry Of Health have not been supported by international projects and are in dear need of modern equipment.

The laboratories foreseen to be supported under this fiche are all fully ready to accept the equipment (premises and facilities, staff, funding). These 6 have been selected from a total of 28 MoH laboratories on the basis of existing laboratory quality, geographical distribution, and staff competence.
Annex 10

Terms of Reference
Technical assistance – Review of the technical specifications for the procurement of food safety laboratory equipment

1. BACKGROUND INFORMATION

Beneficiary country: Bulgaria

Contracting Authority: CFCU (Ministry of Finance) on behalf of the Ministry of Health and the Ministry of Agriculture and Forestry

Background

The quality and safety of food products is an issue of concern to consumers, the food industry and the government. As everywhere, this is of extreme importance for human health protection.

The alignment of Bulgarian food legislation with the EU acquis is a major pre-condition for the implementation of market economy mechanisms and an important stage in pre-accession to the EU. The legal harmonisation is nearly completed, and additional support is planned under Phare 2003 funding to equip food safety laboratories with additional equipment.

Six laboratories from the Ministry of Health and one laboratory from the Ministry of Agriculture (in Sofia) have been selected as the beneficiary of the supply of training and equipment. They have prepared the list of equipment needed with the draft technical specifications.

This equipment will be procured in 2004, starting as early as possible.

2. DESCRIPTION OF THE ASSIGNMENT

Requested services

The objective of the assignment is to assist in the revision of the needs analysis and definition of technical specifications that are compliant with open competition.

a-Initial screening of needs

The expert will review the existing equipment used in the laboratories, both the ones to receive support and the other laboratories. Looking at the volume of tests required, he will confirm that the equipment is needed, will not lead to large over-capacity of the capacity of the laboratories (meaning under-utilisation of the equipment procured or existing), and that the supplies will lead to substantial improvement in food safety (either via increased efficiency or via the capacity to undertake new tests). If necessary, the expert might propose to replace some of the equipment listed by others, with all necessary arguments for the services concerned to take a decision.

b- Review of laboratory readiness

During his visits to the laboratories concerned by the potential deliveries, the expert will check that the premises are ready to accept the equipment. He will check that rooms are available, services available (water, electricity, heating, ...), and that there is sufficient staff.

Should some premises not be ready, the expert will explain why and detail the type of intervention needed, differentiating between heavy and light (e.g. painting) investments to assess whether the premises can be made ready by the time of delivery.
c- Review/Preparation of the technical specifications

Bulgarian experts have prepared technical specifications for the equipment needed. Under this assignment, the specifications will be reviewed. In particular care will be taken on:

(i) avoiding the use of brand names
(ii) ensuring that the specifications do not match exclusively one item or producer
(iii) ensuring nevertheless that they are sufficiently specific to secure that the necessary equipment of the necessary quality and specifications are targeted

The expert will ensure that he consults and informs his Bulgarian colleagues in this process.

Should the list of equipment have changed, either as a result of recommendations of the expert under this assignment or in another manner, the expert will contribute to the preparation of new specifications.

In reviewing the specifications, the expert will also assess whether the budget is realistic. Any major discrepancy between the available budget and the estimations will be immediately discussed with the beneficiaries.

d- Participation to the evaluation

The expert will participate – either as observer or as independent voting member – in the proceedings of the Evaluation Committee for the tender of laboratory supplies. In particular, the expert will:

• participate in the briefing meeting of the evaluation committee in Sofia
• contribute to the administrative and technical evaluation of the offers received
• provide the contracting authority with a technical statement on any potential claims formulated by the bidders which may arise in the context of the tender

The expert will act as independent expert, either voting or non-voting member of the evaluation committee. The expert declares explicitly that he or his company have no bindings, future or past, with any prospective bidder. Additionally, they will commit themselves not to disclose any information related to the tender (budgets, precise scope, proceedings of evaluation committee, etc).

e- Report

The expert will provide a report mid-term report upon his first mission describing the findings related to

(i) the readiness of the premises and proposals of potential remediation measures
(ii) an argumented confirmation of the needs assessment
(iii) an estimation of the budget

The final report will include:

(iv) the final terms of reference
(v) the final estimated budget

3. EXPERT’S PROFILE

An expert is required will be required. The expert must:

• possess a degree in a relevant field (medical – chemistry – food – veterinary science with a specialisation relevant to the work of laboratories);
• have minimum of 10 (ten) years relevant working experience (Cat II);
• have knowledge of the European Commission procedures;
• have substantial experience in equipment for food safety laboratories;
• be able to read and communicate fluently in English.

4. LOCATION AND DURATION

4.1 Mission dates
The assignment will be implemented in three missions, the last one being for the participation to the evaluation committee. The first mission will start from 06/10/2003 until 24/10/2003 when the mid-term report will be submitted.

The second mission will be from the 01/12/2003 to the 12/12/2003. The final report will be provided by the 26/12/2003.

The third mission, lasting for five days, will indicatively be in June 2004. The final dates for the last mission will be confirmed as soon as they are made available and will depend on the tendering procedure.

4.2 Location of assignment

Bulgaria – in particular the laboratories in Sofia (2 laboratories), Burgas, Varna, Pleven, Plovdiv, Veliko Tarnovo

4.3 Duration

36 days for the expert

Annex 11

STATEMENT on Project Management Capacity of the Ministry of Health

Ministry of Health has accumulated a significant experience and has built capacity for international project management, including project definition according to set health priorities, management of big investment projects, coordination of activities between donor institutions under multi-institutional funding of planned activities, organization and carrying out of international and local tenders. The management and coordination of projects with international funding is performed by the Department of "Project Administration and Management", which is part of the Directorate of International Cooperation and European Integration in the Ministry of Health.

The Department has 10 full-time experts. Part of the Department is structured in Health Policy Analyses Unit. This unit is created under World Bank Project "Restructuring of Health sector in Bulgaria", and the staff of the unit has passed adequate training and qualification on health policy, health economics and health care administration. The unit is contributing to the elaboration of health policy documents and analyses, activities related to strategic planning, as well as to the definition of projects according Bulgarian health priorities.

Until 20001, another part of the department functioned as separate structure - Project Management Unit (PMU), dealing with the management and coordination of activities under mentioned above World Bank Project.

The overall experts of the Department have acquired the necessary training and qualification on project management. 5 experts passed internationally training on World Bank procedures for investment projects management, including procedures for tendering and contracting of implementing agencies, as well as financial management. 4 experts were trained on project fiche and terms of reference elaboration and PHARE bidding and contracting procedures (PRAG). The experts are subject to continuous training and qualification through participation in health management, public health and healthcare administration courses and programs in Bulgaria, as well as in universities and schools of public health abroad - in USA, UK, Greece, Spain, Holland, Hungary etc.

Every expert knows written and spoken English, as well as other western languages.

The experience of the department is directed to the management and coordination of projects in three main areas of implementation:

1. Management of investment projects:
   • Project for Restructuring of the Health Sector, funded by the following organizations: World Bank (26 MUSD), Council of Europe Development Bank (11 MUSD), PHARE Program (2.3 MUSD) and 7.7 MUSD from the Republican Budget, has been started in 1996. The project has been entirely managed by the PMU, that is part of the department. The activities have supported the reform in the primary health care (PHC), emergency medical care and the blood transfusion network by provision of refurbishment works, supply of equipment for the PHC, for the Emergency Medical Care Centers and for the Centers for blood
transfusion. The personnel of these health institutions have been trained. Information system for the blood transfusion network was build. The project has completed its activities by the end of 2001 and evaluated by World Bank “highly satisfactory” for the overall achievement of the results.

- Project “Ensuring Minority Access to Health Care” with the amount of 1.1 MEURO funded by PHARE 2001 Program. A study of the health status for the Roma population is foreseen to be made. Refurbishment activities for GP practices in 15 towns are also to be performed in the framework of the project. Medical equipment and furniture for 15 GP practices, providing health services for predominantly Roma population, will be supplied. And finally, medical staff and Roma mediators will be trained aiming to health promotion amidst Roma population.

2. Management and coordination of the projects directed toward improvement of the administrative capacity of the health system:

- In total, 17 PHARE projects (estimated 25 MEURO) have been realized during the period 1992-2000. In the framework the projects supported the health care system with medical equipment, ambulances, computers and office furniture, as well as training of the staff.
- Twinning project “Radiation Protection and Safety at the Medical Use of the Ionizing Radiation” in the amount of 2.7 MEURO funded by the PHARE 2001 Program. The project supports harmonization of the Bulgarian legislation with the acquis in accordance with the ionizing radiation in relation of medical exposure.
- Twinning project “Assistance to the implementation of the EC directives on drinking water, bathing water, surface water intended for the abstraction of drinking water and methods of measurement and frequencies of sampling and analysis of water” estimated 2.2 MEURO funded by the PHARE 2001 Program. The project foresees supply of laboratory equipment for monitoring of drinking water and is managed jointly with Ministry of Environment.

3. Projects directed to implementation of National Health Strategy according to health priorities:

- Project BUL/98/005 Elaboration and implementation of National Strategy on HIV/AIDS prevention, funded by UNDP;
- Support to the National Health Strategy for Reproductive Health, funded by UN Population Fund.

The Department performs also the overall monitoring of internationally funded projects within the network of the Ministry of Health, as well as in collaboration with non-governmental organizations.