SUMMARY PROJECT FICHE

1. Basic Information
   1.1 Désirée Number: BG 0003.02
   Twinning code: BG/2000/IB/FI/02
   1.2 Title: ESTABLISHING A CONFORMITY ASSESSMENT SYSTEM
   1.3 Sector: Internal market

2. Objectives
   2.1 Wider Objective:
   Meeting the obligations of the Europe Agreement in the field “Free movement of goods” by establishing the respective institutional framework and service infrastructure in the area of conformity assessment.

   2.2 Immediate Objectives:
   • Establishing international recognition of results of measurement and creating the technical conditions to respond to the service demand in certain industry sectors, and in state executive bodies relevant to consumer protection.
   • Developing a network of certification bodies with the capacity of establishing the notified bodies necessary for the implementation of the New Approach (NA) Directives. Strengthening the certification body of the State Agency for Standardisation and Metrology (SASM) to reach the competence to become a multiplier in the field of product and quality system certification; this being facilitated through the establishment of an accredited body for product and quality system certification, which is to become a notified body for toys, for example.
   • Establishing the conditions for international recognition of test and calibration results produced in Bulgaria, as well as of certification of products, quality systems, personnel and inspection by bringing the Bulgarian Accreditation Service to EA (European cooperation for Accreditation) level.
   • Establishing a functioning system and institutional basis for effective market surveillance in the areas covered by the NA Directives.

2.3 Accession Partnership and NPAA priority

   Short term AP priority:

   Free movement of goods: adopt a framework law on technical requirements implementing all New and Global Approach principles, enforce the new law on standardisation and reinforce newly established infrastructure, adopt framework laws on chemicals, foodstuffs and pharmaceuticals;
Medium term AP priority:

Free movement of goods: start implementation of new approach legislation; pursue alignment of traditional technical legislation; implement market surveillance system;

NPAA:

The short-run activities will focus on the transposition of directives related to the national priorities in production and trade. After the adoption of the framework law, efforts will be focused on building the structures necessary for the application of New Approach principles and the stimulation of private initiative for setting up testing, certification and inspection bodies. The priority objective is the implementation of the essential principles under the New Approach and the Global Approach.
- Progressive implementation of the product safety requirements with priority action in the sectors in which Bulgaria has competitive advantages.
- Building up a functioning conformity assessment and market surveillance system.

3. Description

3.1 Background and justification:

Following the passing of new legislation on Standardisation and on Technical Requirements to Products, as framework laws to NA Directives’ transposition into Bulgarian Law, the implementation has shortcomings in:

- Adequate structures meeting the needs of the industry;
- Personnel qualification to operate under the new concept;
- State-of-the-art metrological equipment as reference and working standards for service to industry and society;
- Operational practice in line with EU Member States that would allow for mutual recognition of certificates and test results, and membership in EU expert organisations;
- Exportability and competitiveness of industrial products due to difficulties in responding to international conformity requirements;
- Maintaining the expertise of personnel through continued education;
- Lack of supervision of the market due to changed rules as regards the involvement of the State in conformity matters;
- Deficiencies in protection of fair competition and products safety matters;

This project aims at addressing these shortcomings.

3.2 Linked activities

New legislation on metrology, accreditation, standardisation, technical requirements to products was introduced in 1998 – 1999. A legal basis was created for segregation of legal, industrial and fundamental metrology. Principles of voluntary standardisation with participation of all interested parties were implemented. Training of certification personnel from private and state-owned companies and organisations on operation, auditing and certification of products, quality systems and personnel was carried out, awareness and willingness to develop appropriate
conformity assessment structures were achieved. Under the Phare Programme BG 9602, a project “Upgrading of Laboratories” has been successfully implemented: three laboratories in key work processes – for pressure measurement, electric energy, and time and frequency were equipped, and the respective laboratory personnel underwent the proper training. This new project will be a logical extension of the previous programme. Furthermore, it will emphasise on-the-job training and coaching in organisation and operational practice in conformity assessment activities related to accreditation, certification, and market surveillance.

3.3 Results:
The project foresees to produce the following results in the different areas:

**Accreditation:**

- 10 certification and inspection bodies are accredited to EN 45000 standards;
- 30 testing and calibration laboratories are accredited to EN 45001;
- BAS has demonstrated in a peer-assessment carried out by an audit team of EA member organisations that it is meeting the EA requirements for an accreditation body;
- BAS – is accepted as “affiliated member” of EA.

**Certification:**

- A model certification body is established, fully meets the requirements of EN 45011 and EN 45012 and is accredited by BAS;
- EU recognition of this body is established through accreditation by an EA member;
- At least 4 additional certification bodies are established to fully meet the requirements of EN 45011 and/or EN 45012, and are accredited by BAS;
- 5 newly established certification bodies receive the authorisation of the competent Ministry to serve as “Notified body” in the field of a New Approach Directive.

**Metrology:**

- A long-term strategy for the development of Metrology is elaborated and documented, including the identification of mid-term priority needs;
- 2 laboratories are upgraded, as regards equipment, operating environment and procedures, to correspond to international standard in these aspects;
- 3 metrology laboratories of the NCM are accredited to EN 45001 by BAS;
- 3 calibration laboratories are accredited to EN 45001 by BAS;
- Knowledge management and continued education system for the entire NCM is put in place, documented and operational.

**Market Surveillance (MS):**

This component will be implemented through *twinning*.

- The re-organisation has established a personnel capacity with qualification to assume MS responsibilities in the field of 20 NA Directives;
- The operational procedures for sampling, monitoring, dealing with complaints, enforcement, information, and statistics are in place, documented and applied;
- A computerised management system for data, activities, cases, information exchange developed, documented and operational on a network;
- 3 trainers to work on professional and continuous education as well as public relation matters are formed and held 3 training events (each) under the auspices of EU experts.
3.4 Activities:

Accreditation:

- Accreditation personnel will receive training on the job in EU accreditation bodies;
- Joint assessments will be carried out – i.e. assessments on site in Bulgarian testing laboratories, inspection bodies or certification bodies with participation of EA-recognised experts (lead assessors) on accreditation with sound experience in the relevant sectors and in-depth knowledge of the implementation of accreditation procedures,
- A peer assessment of BAS by a team of experts from different EA member accreditation bodies will be carried out;
- A comprehensive training of assessors meeting EA training requirements will be carried out; this covers the formation of seven trainers on quality matters relevant for accreditation (auditors from third party).

Certification:

- Key certification personnel will obtain practical training in the EU for the acquisition of operational practice of EU notified bodies;
- 2 joint assessments each of manufacturer quality systems relevant to NA Directives (at least 6 different directives) will be carried out;
- A training of 4 trainers as multipliers to develop further certification bodies will be held;
- Experts will support the creation and putting into operation of a computerised certification management system to manage all data and activities related to certification, in the fields of Low Voltage, Machinery, Equipment for potentially Explosive Atmosphere, Personal Protective Equipment, Toys and Construction Products.

Metrology:

- An analysis of mid-term priority industry needs in calibration will be carried out and a long-term strategy drafted, pointing out mid-term priority needs;
- Metrological equipment, transfer and working standards for 2 laboratories will be procured according to Phare procedures, including their calibration traceable to international standards (for details, see Annex 6);
- For the beneficiary laboratories quality systems needed for accreditation will be developed with support of EU experts;
- 3 metrology laboratories will be jointly assessed by EA member and BAS assessors and accredited;
- Joint assessment by EA member and BAS assessors of several (at least 3) calibration laboratories and accreditation will be carried out;
- A formal knowledge management system, including a continued education system will be developed and implemented.
Market Surveillance:

This component will be implemented through **twinning**.

- Training of the technical personnel in the principles of the New Approach and the technical particularities of the respective directives, especially LVD, EMC, MD, Toys, etc. will be carried out;
- MS personnel will obtain on-the-job training in public administration in charge of market surveillance in corresponding areas of at least 2 EU countries, with compatible to the Bulgarian one legislation;
- A procedural system will be developed, including its documentation, covering the full operation of a market surveillance authority;
- Experienced market surveillance professionals of EU Member State administration will secure the operational practice through jointly operating market surveillance processes with their Bulgarian counterparts;
- A regular review process will be established to ensure an operational practice consistent with Bulgarian laws and EU policies;
- EU experts will support/coach the developing and implementing of computer applications to administer all relevant data, manage actual cases and exchange information with national and international counterparts, on the basis of the newly acquired IT network and communication concept of the SASM that was made operational, including: Training of NEP staff on RAPEX procedures and requirements in RAPEX Headquarters and/or in EU country;
- 3 trainers will be formed through theoretical and practical training events on operational matters and public relations, this includes the development of the training material;
- Establishment of relation with Customs authorities, exchange of information, cooperation;
- Cooperation with other Market Surveillance authorities outside of the scope of NA;
- Cooperation with Consumer organisations.

4. **Institutional Framework**

The following is the institutional framework within which the project will have to operate:

**Accreditation:**

The **Bulgarian Accreditation Service** was created by decree in fall 1998; it is a separate legal entity and became an Executive Agency under the new Ministry of Economy (30.12.1999). The organisation has 4 departments, one for laboratory, one for certification and inspection body accreditation, one for surveillance of accredited bodies and one for administration. It operates with its own staff of 15, partially with previous accreditation experience, and external experts. The Accreditation Council, as an advisory board, is composed of 10 representatives from all relevant ministries, 2 representatives from industry associations, 1 from the Academy of Science, 4 from the university, 3 from the laboratory association BULLAB and 1 from the Bulgarian Insurer’s Association. BAS has accredited about 60 testing or calibration laboratories, 170 further are to be re-accredited. Furthermore, about 200 authorised inspection units are subject to accreditation according to the respective European standards.
Certification:

The potential beneficiaries in the field of Certification are from 15 different organisations that are in the process of establishing certification services in different sectors, see Annex 5. These organisations were already part of a training under the Phare BG9602 programme in 1999. To develop this network of certification bodies, the Directorate for Testing and Certification, currently still within the SASM, will be used as reference organisation and multiplier. The directorate disposes of laboratories for testing of electrical appliances, toys, textile, food & beverages, petroleum products and furniture. Therefore, particular effort will be made to bring the certification body of the Directorate to an operational level that is in line with EU practice. Trainers from the Directorate, to be formed under this project, will train and guide the other institutions in setting up structures and operation of a certification body that meet EA accreditation requirements.

Metrology:

The beneficiary in the field of Metrology is the National Centre of Metrology (NCM), which is a directorate within the SASM. With a staff of about 100 personnel, NCM operates 16 laboratories for different measurement units and for keeping over 35 national measurement standards, plus a laboratory for gambling and fiscal devices. The laboratories are a main contributor to the calibration services rendered in the country. Seven areas are identified as priority areas for renovation of their services to the industry and utility organisations, including the accreditation of respective laboratories in 2001.

Market Surveillance:

The State Agency will assume the function of Market Surveillance by forming the respective structures carrying out the tasks. The organisation disposes of a 120-employee unit, until 1999 in charge of Border Control, a function related to market surveillance. It is to be restructured and shall undergo all necessary organisational and human resource development that is necessary to assume the new function. While the State Agency shall maintain the overall responsibility for the implementation and consistency of market surveillance in the New Approach sectors, some line ministries, such as Health and Telecommunications, may assume the practical functions in their sector.

Although the project will deal with two separate organisations, i.e. BAS and SASM, this does not represent a constraint for the implementation of the project. Actually, the participation of both organisations is crucial for the project’s success, as a number of the activities involve the other body and vice-versa. In the course of the project, the certification, standardisation and market surveillance activities will be properly segregated.
5. **Detailed Budget**

<table>
<thead>
<tr>
<th>Sub-project 1: CLASSICAL TA for Accred./Certif., Program Mgmt.</th>
<th>Phare Support</th>
<th>Euro</th>
<th>Euro</th>
<th>National Co-financing*</th>
<th>IFI</th>
<th>TOTAL**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment Support</td>
<td>0</td>
<td>890.000</td>
<td>890.000</td>
<td>170.000</td>
<td>1.060.000</td>
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</tr>
<tr>
<td>Institution Building</td>
<td>0</td>
<td>890.000</td>
<td>890.000</td>
<td>170.000</td>
<td>1.060.000</td>
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<table>
<thead>
<tr>
<th>Sub-project 2: CLASSICAL TA and equipment for Metrology</th>
<th>Phare Support</th>
<th>Euro</th>
<th>Euro</th>
<th>National Co-financing*</th>
<th>IFI</th>
<th>TOTAL**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment Support</td>
<td>675.000</td>
<td>375.000</td>
<td>1.050.000</td>
<td>168.800</td>
<td>1.218.800</td>
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</tr>
<tr>
<td>Institution Building</td>
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<td>890.000</td>
<td>890.000</td>
<td>170.000</td>
<td>1.060.000</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Sub-project 3: TWINNING for Market Surveillance</th>
<th>Phare Support</th>
<th>Euro</th>
<th>Euro</th>
<th>National Co-financing*</th>
<th>IFI</th>
<th>TOTAL**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment Support</td>
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<td>1.060.000</td>
<td>1.060.000</td>
<td>338.800</td>
<td>3.388.800</td>
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</tr>
<tr>
<td>Institution Building</td>
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<td>1.060.000</td>
<td>1.060.000</td>
<td>338.800</td>
<td>3.388.800</td>
<td></td>
</tr>
</tbody>
</table>

* State budget, based on numbers set for current year multiplied by two, subject to approval for further years.

** subject to approval of annual national budget contribution (total est. = 2,5x 2000 - budget)

6. **Implementation Arrangements**

6.1 Implementing Agency

The implementing agency is the CFCU in close co-operation with the beneficiaries which are the Bulgarian Accreditation Service and the State Agency for Standardisation and Metrology. Contact details for all Components:

State Agency for Standardisation and Metrology
Mr. Tsonyo Botev, President
21, 6th September Street
BG-1000 Sofia
Phone: +359-2/989-8488   Fax: +359-2/986-1707

For accreditation:
Executive Agency “Bulgarian Accreditation Service”
M.Sc.Eng. Any Stoilova
21, 6th September Street
BG-1000 Sofia

Twinning
Component 03 “Market Surveillance” will be contracted under a two years Twinning contract.
A brief description of the expected profile of the PAA and the short-term experts is given in Annex 7.
In the event that no suitable twinning proposal is forthcoming, this component of the project will instead be implemented through conventional TA.

Contact details:
State Agency for Standardisation and Metrology
Mr. Tsonyo Botev, President
21, 6th September Street
BG-1000 Sofia
Phone: +359-2/989-8488   Fax: +359-2/986-1707

Non-standard aspects
Procurement of services and goods, strictly follow the procedures of the DIS Manual.

Contracts
The Programme is expected to be contracted under two Technical Assistance, one supply contract for metrology and one Twinning contract. Their estimated € values are as follows:

| Contract 1: TA for Accreditation, Certification, Programme Management | € 890.000 |
| Contract 2: TA for Metrology | € 375.000 |
| Contract 3: Equipment for metrology | € 675.000 |
| Contract 4: Twinning for Market Surveillance | € 1,060.000 |
| **Total of 3 contracts:** | **€ 3,000.000** |

7. **Implementation Schedule**

7.1 Start of tendering
The TORs for all programme components and/or project specifications will be ready end 2000.

7.2 Start of project activity
Expected date of commencement of first contract will be 1 January 2001.

7.3 Project Completion
Expected date of last payment under last contract will be 30 June 2003.

8. **Equal Opportunity**
SASM and BAS management will ensure that men and women are equally represented in all training measures. For and during all training events, lists of participants will be established and kept with the project documentation. The issue of women’s participation will have to be addressed in the progress reports.
9. **Environment** (NA)

10. **Rates of return** (NA)

11. **Investment criteria** (NA)

12. **Conditionality and sequencing**

   1. In accordance with EU Policy, the Government of Bulgaria will ensure that the functions of Certification, Standardisation and Market Surveillance are properly segregated in a way acceptable to the Commission by December 2001. However, before the FM is signed the State Agency for Standardisation and Metrology will present a plan detailing the intermediary steps to arrive at the full segregation together with a precise timetable. The EC Delegation in Sofia will follow up on this conditionality.

   2. Before the signature of the FM the State Agency for Standardisation and Metrology, in consultation, where appropriate, with other relevant Government and non-Government institutions, will submit an Action Plan including the activities envisaged to arrive at the creation of a network of new competing certification/testing bodies laboratories. The Action Plan, which should be acceptable to the Commission, will contain details on how these new bodies will be created (or strengthened), how they will benefit from this project, how knowledge and expertise will be transferred from SASM and will include a timetable for implementation with clear benchmarks. The EC Delegation in Sofia will follow up on this conditionality.

   3. Projects to be implemented through twinning require the full commitment and participation of the senior management of the beneficiary institution. In addition to providing the twinning partner with adequate staff and other resources to operate effectively, the senior management must be whole-heartedly involved in the development and implementation of the policies and institutional change required to deliver the project results.

Most important milestones of the project in terms of impact in the areas of:

**Accreditation:**

- BAS meeting the EA requirements
- First certification body accredited

**Certification:**

- Accreditation certificate issued by EA accreditation body and BAS
- 4 trainers held quality course independently
- Computerised certification management system is operational

**Metrology:**

- Analysis of mid-term priority industry needs completed and long-terms strategy drafted
- 3 Metrology laboratories technically upgraded and accredited
• Education policy endorsed and published by SASM management

**Market Surveillance:**

• Procedure manual drafted and endorsed by SASM management
• Multi-user computerised administration system operational
• 3 trainers held first course fully independently in public

**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 (including disbursement period)
4. List of relevant Laws and Regulations
5. List of candidate organisations preparing for certification services
6. Specification of the necessary metrological equipment
7. Brief description of the expected profile of the PAA and the short-term expert
<table>
<thead>
<tr>
<th><strong>LOGFRAME PLANNING MATRIX FOR ESTABLISHING OF CONFORMITY ASSESSMENT SYSTEM</strong></th>
<th><strong>Programme name and number</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project number</strong></td>
<td><strong>Contracting period expires : Dec 2002</strong></td>
</tr>
<tr>
<td><strong>Disbursement period expires : Dec 2003</strong></td>
<td><strong>Total Budget : 4,306 MEURO</strong></td>
</tr>
<tr>
<td><strong>Phare contribution : 3 MEURO</strong></td>
<td><strong>Wider Objectives</strong></td>
</tr>
<tr>
<td>Meeting the obligations of the Europe Agreement in the field “Free movement of goods” by establishing the respective institutional framework and service infrastructure in the area of conformity assessment.</td>
<td><strong>Indicators of Achievement</strong></td>
</tr>
<tr>
<td>Successful screening results</td>
<td><strong>Source of information</strong></td>
</tr>
<tr>
<td>European Commission</td>
<td><strong>Assumptions and Risks</strong></td>
</tr>
<tr>
<td>Economic Conditions continue to improve</td>
<td></td>
</tr>
<tr>
<td>Political stability and commitment to accession prevails</td>
<td></td>
</tr>
<tr>
<td>Conditions for employment in public sector improve to reduce fluctuation</td>
<td></td>
</tr>
<tr>
<td>Immediate Objectives</td>
<td>Indicators of Achievement</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Establishing international recognition of results of measurement and creating the technical conditions to respond to the service demand in certain industry sectors, and in state executive bodies relevant to consumer protection                                                                 | Acceptance of certificates by international organisations  
Number of high-level calibrations                                                                                                                                                                                                         | EA, OIML, BIPM, EUROMET NCM                                                                                                                                                                                                                   | None  
Industry continues to recover and modernises production                                                                                                                                                                               |
| Developing a network of certification bodies with the capacity of establishing the notified bodies necessary for the implementation of the New Approach (NA) Directives. Strengthening the certification body of the State Agency for Standardisation and Metrology (SASM) to reach the competence to become a multiplier in the field of product and quality system certification; this being facilitated through the establishment of an accredited body for product and quality system certification, which is to become a notified body for toys, for example. | Number of accredited and authorised bodies  
SASM certification body accredited  
4 ext. certification bodies accredited                                                                                                                                                                                      | BAS BAS BAS                                                                                                                                                                                                                                      | Existing testing laboratories follow through in their willingness to invest in certification body development, in spite of difficult economic situation.  
SASM is able to keep qualified staff, in light of unattractive employment conditions                                                                                                                                                          |
| Establishing the conditions for international recognition of test and calibration results produced in Bulgaria, as well as of certification of products, quality systems, and personnel by bringing the Bulgarian Accreditation Service to EA (European cooperation for Accreditation) level.                                                                 | Successful peer assessment in relevant areas of laboratory and certification body accreditation                                                                                                                                              | EA                                                                                                                                                                                                                                             | BAS is able to attract additional experienced personnel to become lead auditors of or for the organisation.                                                                                                                                 |
| Establishing a functioning system and institutional basis for effective market surveillance in the areas covered by the NA Directives.                                                                                                                                                                                                                      | Internal review and management report                                                                                                                                                                                                        | SASM                                                                                                                                                                                                                                           | Restructuring and formation of staff successful to deal with the various technical issues  
Competence and functions are resolved issues between concerned ministries                                                                                                                                                                      |
<table>
<thead>
<tr>
<th>Results</th>
<th>Indicators of Achievement</th>
<th>Source of Information</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accreditation:</strong></td>
<td>• Accreditation certificates</td>
<td>• BAS</td>
<td>• Interest in building CBs prevails in light of difficult economical situation</td>
</tr>
<tr>
<td>10 accredited certification bodies (CB)</td>
<td>• Accreditation certificates</td>
<td>• BAS</td>
<td>• Interest in accreditation prevails with view to the related cost, in light of the difficult economical situation</td>
</tr>
<tr>
<td>30 accredited testing and calibration laboratories</td>
<td>• Successful peer assessment</td>
<td>• EA</td>
<td>• BAS is able to maintain and strengthen its personnel</td>
</tr>
<tr>
<td>BAS meeting the EA requirements</td>
<td>• Membership agreement</td>
<td>• EA</td>
<td>• dto.</td>
</tr>
<tr>
<td>BAS – affiliated member of EA</td>
<td>• Accreditation certificate</td>
<td>• BAS</td>
<td>• Organisational issues are resolved</td>
</tr>
<tr>
<td><strong>Certification:</strong></td>
<td>• Successful peer assessment</td>
<td>• EA</td>
<td>• dto.</td>
</tr>
<tr>
<td>Established (model) certification body; accredited</td>
<td>• Membership agreement</td>
<td>• EA</td>
<td>• Interest in accreditation prevails</td>
</tr>
<tr>
<td>EU recognition of this body through accreditation by EA member</td>
<td>• Accreditation certificate</td>
<td>• BAS</td>
<td>• None</td>
</tr>
<tr>
<td>Establishing of 4 additional certification bodies</td>
<td>• Successful peer assessment</td>
<td>• BAS</td>
<td>• Political stability and current reforms allow for predictability of industry development</td>
</tr>
<tr>
<td>Notification of established (5) certification bodies</td>
<td>• Membership agreement</td>
<td>• BAS</td>
<td></td>
</tr>
<tr>
<td><strong>Metrology:</strong></td>
<td>• Accreditation certificate</td>
<td>• EA member organisation</td>
<td></td>
</tr>
<tr>
<td>A long-term strategy for the development of Metrology, mid-term priority needs identified</td>
<td>• Accreditation certificates</td>
<td>• BAS / EA member organisation (if appl.)</td>
<td></td>
</tr>
<tr>
<td>2 laboratories are upgraded to correspond to international standard</td>
<td>• Accreditation certificates</td>
<td>• SASM National Enquiry Point</td>
<td></td>
</tr>
<tr>
<td>3 metrology laboratories of the NCM are accredited</td>
<td>• Authorisation documents by Bulgarian authorities</td>
<td>• NCM</td>
<td></td>
</tr>
<tr>
<td>3 calibration laboratories are accredited</td>
<td>• Strategy paper and priority plan</td>
<td>• NCM</td>
<td></td>
</tr>
<tr>
<td>Knowledge management and continued education system in place for the entire NCM</td>
<td>• Accreditation certificates</td>
<td>• BAS</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Indicators of Achievement</td>
<td>Source of Information</td>
<td>Assumptions and Risks</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Market Surveillance (MS):</strong> Personel capacity established and qualified to cover MS in 20 NA Directives</td>
<td>• Laboratories operational, service contracts; accreditation (3 laboratories)</td>
<td>• NCM</td>
<td>• SASM contributes to establish the respective environmental conditions</td>
</tr>
<tr>
<td>Operational procedures for sampling, monitoring, dealing with complaints, enforcement, information, and methods for statistics in place and applied</td>
<td>• Accreditation certificates</td>
<td>• BAS</td>
<td>• Laboratories invest in setting up quality systems</td>
</tr>
<tr>
<td>Computerised management system for data, activities, cases, information exchange developed and operational</td>
<td>• Accreditation certificates</td>
<td>• BAS</td>
<td>• Laboratories invest in setting up quality systems</td>
</tr>
<tr>
<td>3 trainers to work on professional and continuous education as well as public relation matters</td>
<td>• Policy endorsed; dedicated staff for knowledge management, procedures, education plans and reports</td>
<td>• NCM</td>
<td>• Education policy published by SASM management and enforced</td>
</tr>
<tr>
<td></td>
<td>• Sections to cover 20 NA Directives established and properly staffed</td>
<td>• SASM</td>
<td>• Restructuring, staffing and qualification of personnel successful</td>
</tr>
<tr>
<td></td>
<td>• Procedure manual, Internal reports</td>
<td>• SASM</td>
<td>• None</td>
</tr>
<tr>
<td></td>
<td>• Functioning network application</td>
<td></td>
<td>• SASM finalises its computerisation concept</td>
</tr>
<tr>
<td></td>
<td>• Job descriptions, training manuals, training plans and reports</td>
<td>• SASM</td>
<td>• SASM is able to identify or hire suitable trainers</td>
</tr>
<tr>
<td>Results</td>
<td>Indicators of Achievement</td>
<td>Source of Information</td>
<td>Assumptions and Risks</td>
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<tr>
<td>Activities</td>
<td>Accreditation:</td>
<td></td>
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<td></td>
<td>An accreditation body that is an EA member will train 5 experts of BAS and give them the opportunity to work for one month as interns in order for them to study the operational practice and to participate in all relevant activities of the organisation. Experts from EA member accreditation body(ies) will coach and monitor up to 10 BAS personnel in carrying out at least 3 assessments and accreditation activities, each of laboratories and certification bodies, up to the decision on accreditation. A team of lead assessors from at least two EA member organisations review the procedures and monitor the operational practice of BAS, in laboratory and certification body accreditation. EA qualified trainers will carry out at least 2 assessor training courses, select suitable trainers among the participants, involve, coach and examine them in carrying out training and the preparation of training material that shall be available in Bulgarian language.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Personnel qualification achieved; letters of recommendation.</td>
<td>• Training report, endorsed by training organisation</td>
<td>• None</td>
</tr>
<tr>
<td></td>
<td>• Assessment reports; accreditation certificates; Satisfactory qualification report.</td>
<td>• Project report</td>
<td>• Sufficient organisations are prepared for accreditation</td>
</tr>
<tr>
<td></td>
<td>• successful peer assessment report</td>
<td>• EA</td>
<td>• BAS has sufficient qualified internal or external assessors available</td>
</tr>
<tr>
<td></td>
<td>• Assessors, qualified through courses; training manuals; At least 25 assessors are successfully trained independently by BAS personnel under supervision of EU expert; Satisfactory course evaluation sheet</td>
<td>• Project report</td>
<td>• BAS has staff available to act as trainers</td>
</tr>
<tr>
<td></td>
<td>• 10 Personnel qualification achieved; letters of recommendation.</td>
<td>• Training report, endorsed by training organisation</td>
<td>• none</td>
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</table>
### Results

**Certification:** Notified bodies of relevant sectors in the EU will train about 10 experts of the SASM Directorate for Testing and Certification and of selected other certification bodies and give them the opportunity to work for one month as interns in order for them to study the operational practice and to participate in all relevant certification activities of the organisation. Certified EU auditors will coach and monitor 12 experts of the SASM Directorate for Testing and Certification and selected other certification bodies in carrying out at least 2 assessments and certification activities in conjunction with conformity assessment processes according to the relevant modules of the Global Approach. Certified EU auditors will carry out at least 2 training courses on the requirements of EN 45011 through 45013, select 4 suitable trainers, involve, coach and examine them in carrying out training and the preparation of training material that shall be available in Bulgarian language. EU experts from related certification bodies and local IT experts will develop a standardised application under a database system to manage and administer all relevant data and processes in certification bodies, and customise it for the particular situations of the various types of notified body. The applications will be suitable to run on networks in a multi-user environment, and will be installed at the organisations involved in the project measures. The developers will train the users, and local staff will provide technical support for the remainder of the project.

### Indicators of Achievement

- Audit reports; certificates
- Minimum of 30 persons qualified through courses by local trainers; examination certificates; satisfactory course evaluation sheets; training manuals
- Functional multi-user application; at least 2 persons per CB trained in application; all past certification activities and current certificate data are traceable through the system.
- Strategy paper and priority plan
- Tender documents, contracts, acceptance protocols for 2 laboratories
- 5 Quality and procedure manuals, endorsed by EU experts
- 3 Accreditation certificates

### Source of Information

- Project report
- Project report; SASM
- SASM, other organisation
- NCM
- NCM; EU Delegation
- NCM
- BAS, EA member organisation

### Assumptions and Risks

- Sufficient organisations are prepared for certification
- SASM has staff available to act as trainers
- Adequate computer equipment is available and operational in network
- Political stability and current reforms allow for predictability of industry development
- SASM contributes to establish the respective environmental conditions
- Laboratory personnel is sufficiently qualified to develop quality system by internal or external measures
- Laboratory is sufficiently prepared for accreditation
<table>
<thead>
<tr>
<th>Results</th>
<th>Indicators of Achievement</th>
<th>Source of Information</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| **Metrology:** EU metrology and economy experts will analyse the demand in metrology services to be expected mid-term (5 to 10 years) considering current demand and trends in the development of the Bulgarian economy. The metrology experts will project the equipment demand on the basis of the current metrology laboratory technology and measurement capacity. EU and NCM experts will jointly draft a long-term strategy. EU metrology experts will assist the NCM in writing the technical specification for transfer and working standards to be procured for 2 laboratories, work with the SASM in the preparation of tender documents and the evaluation of the offers, as well as in drafting of the contracts. EU experts will coach the personnel of 5 laboratories in developing an operation according to the respective EN 45000 standards and in preparing the documentation of the quality system. An EA member accreditation body will carry out an assessment of 3 laboratories of the NCM, jointly with the Bulgarian Accreditation Service BAS, for accreditation by both organisations. An EA member accreditation body will carry out an assessment of 3 calibration laboratories, which are not a unit of SASM, jointly with the Bulgarian Accreditation Service BAS for accreditation by both organisations. Two staff members of the NCM will obtain the opportunity to study the continued education practice of at least 2 EU metrology institutes and undergo specialised courses in knowledge management by a EU organisation specialised in personnel management and education. EU experts will coach NCM in setting up knowledge management and a continuous education system to benefit all technical and admin. staff. | • 3 Accreditation certificates  
• Policy endorsed; dedicated staff for knowledge management, procedures, education plans and reports; at least 100 persons have benefited from continuous education measures by the end of the project  
• Minimum of 30 successful participants in training; possibly certificate of examination  
• Minimum of 10 successful participants in training; possibly certificate of examination  
• Completed procedure manual; Internal reports  
• Internal reports, showing at least 50 concluded market surveillance activities  
• Internal audit report and management report; Successfully implemented improvement plan | • BAS, EA member org  
• NCM  
• SASM  
• Project report  
• SASM  
• SASM  
• SASM  
• BAS, EA member org  
• NCM  
• SASM  
• Project report  
• SASM  
• SASM | • Laboratory is sufficiently prepared for accreditation  
• Education policy published by SASM management and enforced  
• Restructuring, staffing and qualification of personnel successful  
• Restructuring, staffing and qualification of personnel successful  
• none  
• none  
• Procedural system in place allowing for internal review processes |
**Market Surveillance:**
EU experts will train all enforcement personnel in the principles of the New Approach and the Global Approach. Additional training will be provided for the sector specialists in all conformity issues of the relevant New Approach directives and the particular conformity assessment procedures.
For each relevant NA Directives, two staff members will be trained in an EU market surveillance institution in the operational practice of market surveillance, including all the processes of information handling with other authorities of the country, and with Member countries and the EC, through the National Enquiry Point, as far as applicable. 3 suitable SASM staff members, having participated in the training in EU market surveillance institutions, will obtain a specialised formation as market surveillance trainers for new staff, to carry out continuous education and to train enforcement personnel from other institutions involved in market surveillance aspects, such as customs officers, labour safety inspectors, etc. The trainers will prepare training material under the guidance of EU market surveillance experts, which is suitable for training own staff, personnel from other institutions involved in market surveillance aspects, and also economic operators in special training events. The trainers will carry out such training, assisted by the EU experts.
EU market surveillance experts will assist SASM in developing a procedural system for carrying out effective market surveillance, and consult the staff in establishing a documentation of those procedures that are in line with EU policies on market surveillance. EU market surveillance experts will coach SASM staff in ensuring an operational practice in developing a

<table>
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<tr>
<th>Results</th>
<th>Indicators of Achievement</th>
<th>Source of Information</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| • Functioning network application and history of use; all past MS activities are traceable in the system
• Job descriptions, training manuals, training plans and reports; at least 1 training conducted independently for each of 4 different target groups of at least 15 participants each (internal, customs, other ministries, economic operators). | • SASM | • SASM finalises its computerisation concept and equips relevant work places with client stations and software
• SASM is able to identify or hire suitable trainers |
focus on problem areas and in dealing with actual cases.

A team of EU market surveillance and quality assurance experts will assist SASM to set up a regular and systematic review process to ensure the functioning of the system and consistency with Bulgarian legislation and EU policies, and to support a continuous improvement process. Actually carried out review processes will be documented in management reports.

EU experts and local IT experts will develop an application under a database system to manage and administer all relevant data and processes in market surveillance. The application will be suitable to run on the SASM network in a multi-user environment. The developers will train the users and provide technical support for the remainder of the project.
ANNEX 2

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<th>Sub-project 3:</th>
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<th>2000</th>
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<th>2002</th>
<th>2003</th>
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- **Black** represents Tendering, contracting, twinning covenant finalisation
- **Gray** represents Implementation and disbursement
- **Yellow** represents Disbursement and completion

Tendering, contracting, twinning covenant finalisation
Implementation and disbursement
Disbursement and completion
ANNEX 3: Contracting and Disbursement Schedule

Institution Building and Investment Projects for the State Agency for Standardisation and Metrology of Bulgaria

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ANNEX 4

**List of relevant Laws and Regulations**


- Law on National Standardisation, adopted 4 June 1998

- Law on Technical Requirements to Products, adopted 1 October 1999

- Decree of the Council of Minister for establishing of State Agency for Standardisation and Metrology

- Decree of the Council of Minister for establishing of Executive Agency “Bulgarian Accreditation Service”
ANNEX 5

LIST OF COMPANIES HAVING EXPRESSED THEIR INTENTION TO ESTABLISH A CERTIFICATION BODY IN THE RELATED FIELDS – POTENTIAL BENEFICIARY OF PHARE PROGRAMME 2000

<table>
<thead>
<tr>
<th>No.</th>
<th>COMPANY</th>
<th>FIELD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Balkancar Holding, Sofia</td>
<td>Fork-lifts</td>
</tr>
<tr>
<td>2</td>
<td>CITZGT (Center for tractors and forestry machines testing), Plovdiv</td>
<td>Tractors, agriculture and forest machinery</td>
</tr>
<tr>
<td>3</td>
<td>DICTCGT (State testing center for tractors, agriculture and forestry machines), Russe</td>
<td>Tractors, agriculture and forest machinery</td>
</tr>
<tr>
<td>4</td>
<td>IKKS-BAN (Bulgarian Academy of Sciences), Sofia</td>
<td>Electronic Equipment</td>
</tr>
<tr>
<td>5</td>
<td>ELMA AD, Troyan</td>
<td>Electromotors, House appliances</td>
</tr>
<tr>
<td>6</td>
<td>ICM (Testing Center for machines), HRANINVEST, Haskovo</td>
<td>Machinery</td>
</tr>
<tr>
<td>7</td>
<td>ELAN OOD, Sofia</td>
<td>Machinery</td>
</tr>
<tr>
<td>8</td>
<td>ITEM – Engineering AD, Sofia</td>
<td>Heating, Gas Boiler, Pressure Vessels</td>
</tr>
<tr>
<td>9</td>
<td>CL – Ministry of Regional Development, Sofia</td>
<td>Construction materials</td>
</tr>
<tr>
<td>10</td>
<td>LGI (Laboratory geological testing), Ltd., Sofia</td>
<td>Construction products</td>
</tr>
<tr>
<td>11</td>
<td>ELPROM JSC, Sofia</td>
<td>Machinery</td>
</tr>
<tr>
<td>12</td>
<td>NISI (Scientific and Testing Construction Institute), Sofia</td>
<td>Construction materials – composites, steel, ceramic tiles</td>
</tr>
<tr>
<td>13</td>
<td>Chimatex – AD, Sofia</td>
<td>Agriculture products – vegetables, fruits</td>
</tr>
<tr>
<td>14</td>
<td>NPIPAB (Scientific and applied Institute for fire and urgent safety)</td>
<td>Construction elements on fire constancy, safety, inflammables</td>
</tr>
<tr>
<td>15</td>
<td>General Directorate “Testing and Certification”</td>
<td>Machinery, toys, textile, QS</td>
</tr>
</tbody>
</table>
METROLOGICAL EQUIPMENT
The two metrological laboratories that are going to be supported under this project Phare 2000 are “Thermophysics Laboratory” and “Chemical Laboratory”.

Thermophysics Laboratory: The main objective of this project is the improvement of the necessary equipment of the national standard laboratories the temperature unit Kelvin [K], the unit for quantity of heat Jaul [J] and flame temperature in Kelvin [K], measurements related mainly to energy and energy efficiency of different fields of the economy. The functions that have to be provided are in pursuance of the enforcement of the Law on Measurements, particularly the metrological control of the measuring instruments used:
in the field of health care, the control of medical devices;
in environment;
in payments for thermal energy and caloricity of energy-carriers;
in control and provision of the fire-safety and labour protection;

This equipment will be also used for establishing of modern accredited laboratories for testing and calibration.

Technical specification of the necessary equipment

Fixed point cells, realizing National Temperature Scale of the Country according to ITS-90
1.1. Triple point of Argon (Ar) \( T = 83.8058 \text{K}, \quad u = \pm 1 \text{mK} \)
1.2. Boiling Point of Liquid Nitrogen (N) \( T = -195.798^\circ \text{C}, \quad u = \pm 2 \text{mK} \)
1.3. Triple point of Mercury (Hg) \( T = 234.3156 \text{K}, \quad u = \pm 0.5 \text{mK} \)
1.4. Triple Point of Water (H_2O) \( T = 273.16 \text{K}, \quad u = \pm 0.1 \text{mK} \)
1.5. Melting Point of Gallium (Ga) \( T = 29.7646^\circ \text{C}, \quad u = \pm 0.2 \text{mK} \)
1.6. Freeze Point of Indium (In) \( T = 156.5985^\circ \text{C}, \quad u = \pm 0.5 \text{mK} \)
1.7. Freeze Point of Tin (Sn) \( T = 231.928^\circ \text{C}, \quad u = \pm 0.5 \text{mK} \)
1.8. Freeze Point of Zinc (Zn) \( T = 419.527^\circ \text{C}, \quad u = \pm 1 \text{mK} \)
1.9. Freeze Point of Aluminum (Al) \( T = 660.323^\circ \text{C}, \quad u = \pm 2 \text{mK} \)
1.10. Freeze Point of Silver (Ag) \( T = 961.78^\circ \text{C}, \quad u = \pm 2 \text{mK} \)
1.11. Freeze Point of Gold (Au) \( T = 1064.18^\circ \text{C}, \quad u = \pm 3 \text{mK} \)
1.12. Freeze Point of Copper (Cu) \( T = 1084.62^\circ \text{C}, \quad u = \pm 5 \text{mK} \)
1.13. Annealing Furnace, ambient to 1000^\circ \text{C} with single ramp to set point.
1.14. Software according to ITS-90
1.15. Automatic computer based control and process information acquisition.

Set of Standard Platinum Resistance Thermometers according to ITS-90
Uncertainties:
\( U = \pm 2 \text{mK} \) for the range 0.65K to 303K
\( U = \pm 2 \text{mK} \) for the range 84K to 600^\circ \text{C}
\( U = \pm 2 \text{mK} \) to \( \pm 5 \text{mK} \) for the range 0^\circ \text{C} to 1070^\circ \text{C}
Drift rate: \( \pm 1.0 \) to \( \pm 2.5 \text{mK} \).
Resistance ratio:
\( W(29.7646^\circ \text{C}) = 1.11807 \)
\( W(-38.8344^\circ \text{C}) = 0.844235 \)
\( W(961.78^\circ \text{C}) = 4.2844 \)
Resistance value: 2.5 O, 10 O, 25 O, 100 O at 0^\circ \text{C}
Wiring: 4 wire
For all SPRT NAMAS Calibration Certificates.
Quantity:
2.5 O - 2pcs
10 O - 2pcs
25 O - 4pcs
100 O - 2pcs
Black Body Sources according to ITS-90

**Low Temperature Radiation Pyrometer Primary Source**
Range: -10ºC to +80ºC  
Cavity size: 50 mm diameter  
Uncertainty: \( u = \pm 0.1 \text{ to } \pm 0.2 K \)
Set of orifice plates to restrict cavity aperture diameter to 40, 30, 20, 10mm.
Standard Probe  
Carry Case  
NAMAS Calibration Certificates

**Medium Temperature Radiation Pyrometer Primary Source**
Range: 50ºC to 700ºC  
Cavity size: 65mm diameter  
Uncertainty: \( u = \pm 0.2 \text{ to } \pm 1 K \)
Set of orifice plates to restrict cavity aperture diameter to 50, 40, 30, 20, 10mm.
Standard Probe  
Fixed Point Cells of Gallium, Indium, Tin and Zinc.  
Carry Case  
NAMAS Calibration Certificates.

**High Temperature Radiation Pyrometer Primary Source**
Range: 100ºC to 1300ºC  
Cavity size: 50mm diameter  
Uncertainty: \( u = \text{ up to } \pm 4 K \)
Set of orifice plates to restrict cavity aperture diameter to 50, 40, 30, 20, 10mm.
Standard Probe  
Fixed Point Cells of Gallium, Indium, Tin, Zinc, Aluminum, Silver and Cooper.  
Carry Case  
NAMAS Calibration Certificates.

4. **Standard automatic adiabatic bomb calorimeter for solid state materials and fluids, with computer based control and measurements information acquisition:**  
   - measuring range for the heat energy of combustion: 0 ÷ 30 000 J/g;  
   heat energy of combustion uncertainty: \( u = 3 \text{ J/g} \);  
   benzoic acid calorimetric standard with a purity of 0,999996 mol/mol;  
   calibration certificate.

5. **Standard automatic adiabatic bomb calorimeter for gaseous materials, with computer based control and measurements information acquisition:**  
   - measuring range for the energy of combustion: 0 ÷ 30 000 J/g;  
   heat energy of combustion uncertainty: \( u = 3 \text{ J/g} \);  
   benzoic acid calorimetric standard with a purity of 0,999996 mol/mol;  
   calibration certificate.

6. **Standard heat meters energy calibration stand based on electrical energy measurements.**
Parameters of the energy standard:  
   - units applied at calibration MJ, kWh;  
   - uncertainty: better than 0,4 \%;  
   - temperature range: 30 °C ÷ 90°C;  
   - working pressure: 1,6 bar.  
   automatic computer based control and process information acquisition;  
   calibration certificate.
7. Type approval testing stand for heat cost allocators as described in the technical standards EN 834 and EN 835:
automatic computer based control and process information acquisition;
calibration certificate.

Chemical Laboratory: The purpose of this project is the supply of chemical-analytical apparatuses with the relevant subsidiary equipment for the full setting of a standard chemical laboratory in accordance with the international requirements of OIML, EUROLAB and EUROCHEM. The equipment is intended for:

Control on the quality of the reference materials, manufactured or imported in Bulgaria (levels national and working standards), for chemical composition of inorganic and organic materials. Participation in international proficiency testings using reference materials (RM) and following the procedure of ray analyses. Comparison of analogous and/or similar types RM aiming at finding out their interchangeability and compatibility according to metrological characteristics. Developing and/or testing of methodological documents for standardizing and evaluating of the metrological characteristics (standardizable, additional) of RM, as well as the requirements to RM in their use in measurements. Calibration of analogous MI on the basis of developed methods for calibration etc.

This equipment will be used for the needs of the science metrology, industrial metrology and legal metrology (including the metrology referred to the health and safety).

Technical specification of the necessary equipment

Measuring instruments for chemical composition of substances and materials

Nomenclature of Certified Reference Materials for Chemical Composition of Substances and Materials
Inductively Coupled Plasma Atomic Emission Spectrometer (ICP-AES)
Atomic Absorption Spectrometer (AAS) with Graphite Furnace and Zeeman background correction
Atomic Absorption Spectrometer (AAS) with Flame and Hydride System
Complex of precision analytical balances with internal calibration and PTB Certificate of Calibration (Germany)
Microwave Sample Preparation System
Laser Diffraction Micro-analyzer for Automatic Granulometric Express Analysis
Laboratory Equipment
ANNEX 7

Brief description of the expected profile of the PAA and short-term experts for Market Surveillance contract

Pre-Accession Advisor:
- to work in a Market Surveillance authority from a country with a similar administrative structure (preferably from a recently accessed Member State);
- to have knowledge and experience in the scope of the NA directives;
- to be aware of the operational practice of market surveillance in the different Member States as well as to be acquainted with their working procedures in details;
- to demonstrate good organizational and leadership skills, success oriented
- to be a good communicator, listener and facilitator;
- to have operational experience in Central and Eastern European countries.

Short-term Experts:
- short-term specialist in information exchange system for Market Surveillance;
- to have detailed knowledge and experience in enforcement of legislation on LVD, MD, EMC, Toys, etc.;