Standard Summary Project Fiche for the Transition Facility

1. **Basic Information**

1.1 CRIS Number: 2004/16762.01.01

1.2 Title: Further institutional building, consolidation and strengthening of MSA

1.3 Sector: Internal Market

1.4 Location: Malta

2. **Objectives**

2.1 **Overall Objective(s):**

To effectively manage and implement the Acquis in the fields of accreditation, metrology and conformity assessment.

2.2 **Project purpose:**

The purpose of the project is to ensure the mutual recognition of the services provided by the Malta Standards Authority in the fields of accreditation, metrology, technical regulatory and conformity assessment.

2.3 **Justification:**

The previous project MT-01-04 entitled Capacity building of MSA helped to build the necessary, basic, quality and measurement infrastructure.

However certain technical areas need to be further developed and new areas were identified during the execution of the project. By virtue of the assistance received through the Capacity Building Fiche and the activities identified in this new proposal, would see Malta meeting the requirements of Chapter 1 of the Acquis – Free Movement of Goods.

In the conclusion of Chapter 1 Free Movement of Goods of the last Commission Comprehensive Monitoring Report (Page 17) on Malta’s preparation for membership (Nov. 2003), emphasis is made on the adoption of pending legislation in the field of mutual recognition:

“The **horizontal and procedural measures** necessary for the administration of the Community product Acquis in the new approach sector are in place. Legislation has been transposed and is in line with the Acquis. The implementation structures for standardisation, metrology, accreditation, conformity assessment and market surveillance are all in place. Training programmes being carried out by these bodies should ensure their operational efficiency by the date of accession. Malta’s standardisation body is a full member of CEN, CENELEC and ETSI.”

This transition project will facilitate Malta meeting this part of the acquis.

The main beneficiaries of this project are the following Directorates of the Malta Standards Authority:
3. Description

3.1 Background and justification:

The Malta Standards Authority (MSA) was set up in 1996 by an Act of Parliament (Cap. 187) so as to co-ordinate standardisation and other related activities in Malta. Since the MSA’s mandate - besides being the national standards body entrusted to adopt, publish and disseminate voluntary standards - was very much broader and included related standardisation activities such as technical advise, notification of standards and regulations (the 98/34/EC notification point) and co-ordinating testing, certification, accreditation, market surveillance and metrology activities in Malta, the founding Cap 187 was repealed by the new Malta Standards Authority Act (Act XIX of 2000) approved by Parlament on 18 July 2000. As indicated in the Operations Review conducted within the Ministry for Economic Services (MES), through a system of Directorates, Accreditation, Metrology, Standardisation, Consumer and Industrial Goods and Foodstuffs, Chemicals and Cosmetics. Co-ordination of core services is assured through the link of each arm with central administration.

The project fiche “Capacity building of MSA” will terminate in March 2004. During the execution of the project a number of shortcomings were identified which if not addressed would mean that Malta is not yet in a position to fulfil its full obligations with respect to Chapter 1 - Free Movement of Goods. Some of the transition facility projects being submitted are of utmost importance in this regard.

The pre-accession project was instrumental to set up the necessary quality and measurement infrastructure, training of staff, establishing useful networks, as well as refurbishing and procurement of equipment to equip the National Metrology laboratory. MSA still lacks recognition of the services being provided to local organizations, mainly laboratories and industry from other EU Member States. Malta has not yet signed any MLA (Multi-lateral agreement - mutual recognition by EU Member States of certificates issued by Maltese laboratory - NPAA target), MRA’s (Mutual recognition agreements) and acceptance of product (i.e. agricultural products etc.) certificates, management and environmental management system certificates and other certificates required in the EU. For EU Member States to have confidence in the services provided by MSA, it is imperative that after a period of operational time, the responsible directorates should undergo a peer evaluation (metrology and accreditation) and accreditation (various certification areas). This is what MSA is requesting from the transition projects.

MSA has also been identified as the competent body for EU Regulations -EMAS (Eco-Management and Audit Scheme) and EU Eco-labelling Scheme. These processes were not included in the pre-accession projects and therefore MSA has included them in the transition projects.
## Gap Analysis

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<tr>
<th>Activity Description (Activities 1 to 4)</th>
<th>Present Situation</th>
<th>As of 1st May 2004</th>
<th>At end of project</th>
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| NAB-MSA has been set up by a Legal Notice and is the sole recognized accreditation body in Malta.
- Administrative capacity within the accreditation body (NAB-MSA) has reached a satisfactory level. However the IT system covering the accreditation system needs to be developed further to offer a more secure, stable and reliable system.
- The quality system of NAB-MSA has been implemented according to the requirements of ISO/IEC/FDIS17011.
- The accreditation scheme for testing and calibration laboratories against ISO17025 has been developed. NAB-MSA personnel have received the necessary training to cover this scheme.
- The scheme covering the accreditation of inspection bodies is in preparation. At present further training and technical advice is required to cover this scheme.
- The scheme covering the accreditation of certification bodies is in preparation. Further training for NAB-MSA is required. This scheme will be delivered gradually to cover | NAB-MSA is a full member of EA.
- NAB-MSA will have carried out the first accreditation assessments of Maltese laboratories.
- NAB-MSA staff knows the basic principles involved in the accreditation of inspection bodies. | Further development of the accreditation system by getting technical assistance in various schemes as per details in this project fiche. This will enable the NAB-MSA to extend its scope of activities and will thus be in a better position to cover the requirements of the Maltese economy.
- The NAB-MSA needs technical assistance in the following areas:
  - EA Multi-Lateral Agreement (MLA) peer evaluation
  - EMAS
  - E-signatures
  - Monitoring of GLP facilities
  - Strengthening of IT infrastructure |

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  - EMAS
  - E-signatures
  - Monitoring of GLP facilities
  - Strengthening of IT infrastructure

- The supply of IT equipment for the Accreditation Directorate within the Malta Standards Authority has also been identified as a specific need within the accreditation system.
- NAB-MSA will also need further technical assistance to develop the accreditation schemes for inspection bodies and certification bodies, especially as regards training of personnel, including witnessing how established European accreditation members carry out such assessments.
| 5. Notified Bodies in Malta | • NAB-MSA is operational as regards the accreditation of testing and calibration laboratories. Other information about NAB-MSA as per above.  
  • NAB-MSA needs further training to be able to accredit Inspection and Certification Bodies.  
  • Further technical assistance to the NAB-MSA and CGID in certain specific areas as per details of this project fiche.  
  • The procedure for the designation of conformity assessment bodies defined in Legal notice 136.  
  • Legal infrastructure regarding the New Approach Directives is in place. | There will be no Maltese Notified Bodies applying on the date of accession.  
  • The scheme for e-signatures will need to be developed further, involving the Malta Communications Authority, as appropriate. | The Consumer and Industrial Goods Directorate and the NAB-MSA will have the necessary technical and administrative infrastructure to fully perform their obligations under L.N. 136 of 2003 and as per NPAA for the notification of Maltese CABs, that will eventually be notified to the Commission and to the other member states.  
  • The Consumer and Industrial Goods Directorate and the NAB-MSA have the technical competence to be able to assess Conformity Assessment Bodies in specific areas.  
  • The Consumer and Industrial Goods Directorate and NAB-MSA staff will be able to assist potential notified bodies through the stages leading to their notification under and surveillance. |
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<td>6.</td>
<td>NMS has the capacity to conduct measurement in the areas of Mass, Dimension and Temperature with state of the art equipment provided through pre-accession funds. The staff is all trained at leading European MMI’s. To attain a higher degree of competence the Directorate is embarking on a whole serious of inter-comparisons on a bilateral and multilateral level.</td>
<td>NMS would have initiated calibration services at the local level and would have a better working knowledge of both equipment and environment. A confirmation of the competency level reached would however still be lacking.</td>
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<td>7.</td>
<td>The Malta Standards Authority Act (Act XIX of 2000) provides the legal framework for MSA to ensure that certification services are present in Malta. MSA is a full member of CEN, CENELEC, ETSI and ISO and is meeting all the obligations as regards adoption of European and international standards as Maltese standards. Full benefit to standards users can be achieved when certification against these standards can be provided. This provides an essential element in the Maltese quality infrastructure. It also safeguards European citizens from inferior goods and services and secures the free movement of goods principle (such as certain products manufacture in Malta requiring CE marking). Certification was launched in November 2003. A number of interested organisations have approached MSA for possible certification.</td>
<td>Provision of certification services will be provided by May 2004. Recruitment of personnel to provide certification services has been done and training in certification against MSA EN ISO 9000 quality management system will also have been provided in a European national standards body.</td>
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<td>EUEB and knowledge build-up of the scheme.</td>
<td>scheme.</td>
<td>Participate in new schemes and hopefully a number of organization certified with the scheme requirements.</td>
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<td>Designation of origin and certification of specific character: Steering committee in place to provide advice to MSA. General Certification scheme approved.</td>
<td>Designation of origin and certification of specific character: Application from interested parties for the recognition of specific products under EC regulations 2081/92 and 2082/92 will be accepted and processed.</td>
<td>Designation of origin and certification of specific character: A number of successful applications processed and accepted at European level. Promotion of scheme – seminar, leaflets, etc. At the end of the project to identify niche products which could benefit from these regulations and establishing of targeting products to encourage producers to apply for recognition.</td>
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<td>Organic Farming – Undergoing basic training. Formal decision has yet to be confirmed to designate MSA as the Certification Body.</td>
<td>Organic Farming: Training to be provided for staff to achieve a minimum knowledge of the regulations.</td>
<td>Organic Farming: Promotion of scheme in conjunction with the Ministry for Environment and Rural Affairs. Continuous support by foreign experts. Accreditation of certification body, Drawing up of a list of approved technical experts.</td>
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| 9. Currently, Directive 98/34/CE as amended by 98/48/CE has been transposed into local legislation by means of the Notification Procedure Regulations, 2003. These regulations transpose in to the Notification Procedure as envisaged by the said Directive. Moreover, currently, meetings are being held with all the officials who will be involved ex officio, in the notification procedure. These meetings are being organised by Dr. Lorna Cachia, the EU Notification Contact Point who is tailoring the meetings to fit the remit of the attendees to the meetings. The aim of the meetings is to follow up a seminar which has been held in July, 2003 for all government officials operating also in the procedure, in such way as to make it easier for these officials to fully understand the implications of the procedure and their duties and rights under the said procedure. | The Notification Procedure Regulations, 2003, will become fully operational on May 1st, 2004. This means that Malta would be fully participating in the full procedure, that is, it would be making and receiving notifications, comments and detailed opinions. Moreover, the one-to-one meetings which were started in November 2003 would be ready and therefore, all officials would have a rough idea how the procedure works in theory. They would also have had some hands-on training given that the authorities concerned would be involved in the simplified notification procedure as per Agreement reached by Malta and the EU. Moreover, preparations for another seminar in July 2004, the second in a series of two | At the end of the project, the Malta Standards Authority would have dealt with more notifications, comments and detailed opinions. The whole system would be automated. Therefore, all notification/comments/detailed opinions received would be forwarded to enter the database and from there on, an electronic filing system would be kept. Moreover, a website which lists all notifications Malta would have done and received would be accessible online and thus enabling all interested parties to have easy access to all the documents concerned (as long as they have not been indicated as confidential). This would enable quick access to and easy retrieval of information. Moreover, the officials would have had another seminar regarding their duties and |
Moreover, currently, Malta is participating as observer member in the 98/34/EC meetings being held periodically in Brussels, the last one being held on the 10th and 11th December, 2003 (the notification of Technical Regulations and the notification of standards respectively.)

Finally, by means of the project fiche entitled “Capacity building at the Malta Standards Authority”, the EU Notification Contact Point in Malta, Dr. Lorna Cachia, has attended two attachments, in London with the Standards and Technical Regulations Directorate (STRD) within the Department of Trade and Industry (DTI) and in Rome with the Spettorato Tecnico within the Ministero delle Attivita’ Produttive. She is also preparing for a third with the STRD which deals with the day-to-day running of the procedure.

The final preparations of the Simplified Notification Procedure Agreement are also being applied and it is projected that the Agreement would be in operations by year end. This would mean that Malta would be fully participating in the simplified notification procedure by effecting and receiving notifications and receiving and effecting comments.

Malta is also receiving and effecting notifications and comments from other member States. However, there is no electronic form of cataloguing which is being used. Therefore, for this reason, there isn’t the creation of a database in which to keep all catalogued information.

started in July 2003, would be underway. The aim of this seminar will be to discuss what would have happened that far in the procedure and to discuss any problems which the officials in question could have encountered.

Moreover, the EU Notification Point, Dr. Lorna Cachia, will be preparing herself for an exchange of information visit which would take place at a European Central Notification Unit with the aim of exchanging information, and above all, discussing any problems which Malta would be facing in the procedure and any possible solutions which might arise, taking in on other Member States’ experience.

At this stage, Malta is not only receiving comments and notifications form other Member States but also detailed opinions. For this reason, the need to have an electronic cataloguing system coupled with a database and a searchable website (as long as the material concerned would not be confidential) is even more stringent.

Moreover, problems which they might enquire in the ordinary course of their duties as officials operating within 98/34/EC. For this reason, Malta would be more efficient in the full implementation of the procedure, and the risk of Malta falling foul of the obligations imposed by Directive 98/34/EC as amended by Directive 98/48/EC would be notably decreased.

Moreover, the fact that the EU Notification Focal Point would have discussed the problems which might have arisen in the course of the day-to-day running of the procedure with fellow Notification Central Units would definitely make her – and consequently – Malta, even more prepared to be able to face all the difficulties which the implementation of this Directive could bring with it. Moreover, the meeting other Central Units enables, the Notification Central Unit to be able to acquire more experience in the subject and would be in a position to offer more support to all the government officials who would be involved in the procedure and therefore, again, the overall result would be that the Directive would be fully complied with without any risks that any technical regulation be enacted without adherence to the 98/34/EC procedure.
Accreditation

THE DEVELOPMENT OF THE EMAS SCHEME IN MALTA

According to the NPAA Chapter 22 (Environment), MSA is responsible for the administration of the EMAS scheme, MSA has been identified as the EMAS Competent Body, Malta’s representative on EMAS Article 14 Committee as well as the Accreditation Body for EMAS verifiers.

The EMAS scheme will be recognised as a conformity mark for the purposes of the Malta Standards Authority Act (Cap. 419). The MSA EN 45000 series of standards and the MSA EN ISO14001 standard have been adopted as Maltese National Standards by MSA.

There is currently one site in Malta which is quasi EMAS registered. MSA has the duty to register this site and supervise the work of the EMAS Verifier validating this site as from the 1st of May 2004 i.e. on Malta becoming full member of the EU.

The EMAS scheme needs to be developed and implemented so that applications for registrations of sites as well as accreditation as EMAS verifiers can begin to be processed.

THE PEER EVALUATION OF THE NATIONAL ACCREDITATION BODY OF MALTA FOR MSA TO SIGN THE MULTI-LATERAL AGREEMENT

To make accreditation effective across borders it is essential that all EA members demonstrate adequate competence and apply a consistent approach to the assessment of laboratories, certification and inspection bodies, etc. To ensure that this is happening EA members apply for peer group evaluation of their activities by the other members. Following a successful outcome they are invited to sign the appropriate multilateral agreement. Signatories guarantee equivalence of their accreditation activities by continuous and rigorous mutual evaluation, surveillance and re-evaluation.

Evaluation, using internationally agreed and published procedures, is based on peer assessments of Multi-Lateral Agreement (MLA) signatories and applicants. The evaluation team assesses thoroughly the accreditors’ compliance with accepted criteria, mainly the standards EN 45003 (ISO Guide 58 – “Calibration and testing laboratory accreditation requirements – General requirements for operation and recognition”), EN 45010 (ISO Guide 61 – “General requirements for assessment and accreditation of certification bodies”) and ISO/IEC TR17010 (for inspection bodies). These three standards will soon be replaced by ISO/IEC17011 which is currently at FDIS stage.

Success in satisfying these regular evaluations is necessary for becoming and continue being a signatory to the EA Multilateral Agreement. Through the MLA, a uniform level of competence of the comparable accredited bodies is assured and the need for multiple assessments is diminished or eliminated. This means that a supplier should only need one certificate or report to satisfy the entire European and international market and the demands of all European governments.
EA promotes the recognition and acceptance in all the MLA countries of certificates and reports issued by organisations accredited by national accreditation bodies who have signed the MLA.

In order to make the accreditation bodies perform their assessments in a harmonised way, application documents to the various standards for assessment of conformity assessment bodies’ competence must be drawn up. EA and its predecessors have drawn up a number of such documents, which to a very large extent have been accepted on a worldwide basis. Nowadays, the drafting of application documents is mainly done within the framework of the two international co-operation organisations for accreditation bodies, the International Laboratory Accreditation Co-operation (ILAC) and the International Accreditation Forum (IAF).

At present EA’s MLA agreements include the areas of calibration, testing, certification of quality management systems, certification of products, certification of personnel, and certification of environmental management systems. In addition there are bilateral agreements between the EA MLA and a number of nationally recognised accreditation bodies from non-European countries.

An EA MLA will ensure that certificates and reports issued by Maltese Conformity Assessment Bodies are accepted by all the EA MLA signatories.

The Accreditation Directorate is operating under the name NAB-MSA (National Accreditation Body – Malta Standards Authority) and according to Maltese legislation it is the sole nationally recognized accreditation body for the Maltese islands. NAB-MSA is currently in a position to accredit testing and calibration laboratories and will progressively extend its activities to include accreditation of inspection bodies and eventually to certification bodies.

MSA is currently a full member of the European Co-operation for Accreditation (EA) but still needs to sign the EA MLA (Multi-Lateral Agreements) for certificates issued in Malta to be freely accepted throughout EU and EFTA countries.

According to the NPAA Chapter 1 (Free Movement of Goods), the Malta Standards Authority is responsible for the administration of the national accreditation scheme.

A current communication has recently been issued by the European Commission giving more importance to accreditation as regarding the evaluation of conformity assessment bodies, which will be designated as notified bodies.

The signing of EA MLA’s is an NPAA requirement.

The transition facility project will result in NAB-MSA being fully conversant with the EA MLA requirements and in MSA signing the EA MLA in calibration, testing and inspection.

THE DEVELOPMENT OF THE E-SIGNATURES ACCREDITATION SCHEME IN MALTA

The E-Signatures accreditation scheme reflects the provisions of the E-Signatures Directive 1999/93/EC. The Directive provides for EU Member States
to introduce national accreditation schemes reflecting the Directive and the national transposing legislation.

The E-Signatures Directive has been transposed under the Electronic Commerce Act Chapter 426, Act III of 2001.

It is being proposed to relate the national accreditation scheme as closely as possible to the provisions of the EU directive and to utilise as far as possible other existing “building blocks” to support the scheme. These include the BS7799 standard for Information Security Management Systems, the CEN Workshop Agreements and the ETSI standards. The Maltese Law transposing the E-Signatures Directive and related and supporting legislation will be respected and reflected in the scheme.

As a result of this transition facility project, the e-signatures scheme will be developed and implemented.

THE DEVELOPMENT OF THE GOOD LABORATORY PRACTICE SCHEME IN MALTA

The Malta Standards Authority has been designated as the competent authority for verifying compliance with the principles of good laboratory practice of any testing laboratory in Malta claiming to use GLP in the conduct of test chemicals.

This is defined in Legal Notice 234 of 2003, issued under the Product Safety Act (Act No. V of 2001), with the title “The Good Laboratory Practice Regulations, 2003”. This Legal Notice transposes Directive 88/320/EEC.

NAB-MSA will require to include the GLP requirements within its quality system and will also need to train its staff.

STRENGTHENING THE ADMINISTRATIVE INFRASTRUCTURE OF MSA IN THE FIELD OF ASSESSMENT OF MALTESE CONFORMITY ASSESSMENT BODIES.

The Method for Designating Conformity Assessment Bodies (L.N 136 of 2003) - to be referred to as ‘the Regulations’ - sets the legal framework for the recognition, requirements, duties and responsibilities of Conformity Assessment Bodies. As the name implies, these regulations, besides fully implementing Council Decision 93/465/EEC (concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives), are setting out the conditions for the recognition of the competence and the subsequent approval of bodies to carry out work on the certification and/or inspection of industrial products pursuant to regulations issued under the Product Safety Act, either to bring Maltese legislation in line with the European Union's, New Approach, CE marking Directives, or as national regulations governing the manufacture and control of industrial products. These regulations, which came into force as from 1st July 2003, marked the final step to fully harmonize our administrative/legal system with that of the EU "New Approach" policy, thus making it technically and legally possible to have Maltese Notified Bodies operating anywhere within the EU territory under the same EU rules as from 1st May 2004.
Metrology

AVAILABILITY OF TECHNICAL EXPERTS TO CONDUCT PEER ASSESSMENT OF THE MALTA STANDARDS AUTHORITY–NATIONAL METROLOGY SERVICES LABS.

The Malta Standards Authority has the remit to make available and maintain national reference standards, which are of primary importance in the dissemination of traceable measure, in those areas related to the Acquis. The Metrology Labs constitute the de jure National Metrology Institute for Malta, and are recognized as such by the BIPM (Bureau International de Poids est Measures) that is the highest international entity in the traceability chain for international measurement. The Metrology Labs within the Metrology Directorate have the role of sustaining part of the requirements of the Acquis, but also serve as an important support structure for the proper functioning of the NAB-MSA the role of which is that of accrediting test and calibration laboratories locally, by making available, reference standards and calibration capabilities at par with other European counterparts.

Whereas the NAB-MSA conducts the technical competence of local testing and calibration laboratories, using technical assessors from within the Metrology Directorate, the technical assessment of competence for the NMI is to be achieved through Peer Assessments by recognised European experts from other EUROMET affiliated NMI’s. This model of competence assessment is accepted as a norm by BIPM for all NMI’s.

The declared goal of MSA in the accreditation field is that of functioning in the areas of test and calibration laboratories, an essential parameter in ensuring that the highest quality of competence is exercised in the work related to all forms of testing and calibration services, which would be needed locally. The synergy that must exist between the NAB-MSA and the technical assessors coming from the Metrology labs must be based on a clear evaluation of the competencies of the MSA-NMS technical staff.

The Metrology labs will be operating in three of the fundamental fields of mass, dimension and temperature, the latter will be eventually segmented into contact thermometry and humidity. The peer assessment exercise will necessarily involve three experts from the different fields who would be nominated by the EUROMET TC chairperson for the particular fields. The expert will carry out a detailed three day evaluation of the procedures employed and conduct intensive interviews with staff members to ascertain that the level of technical competence suffices for the function that must be executed by the NMI in the particular field, in relation to the dissemination of traceable measure at the highest level of local competencies, and that these competencies are at par with those that are to be expected of staff of other European NMI’s.

Conformity Assessment

ACCREDITATION OF CERTIFICATION SERVICES IN MALTA

Quality management system certification is a requirement of three modules specified in New Approach Directives for companies producing goods which require the CE-Marking.
The MSA Act stipulates that certification activities fall under its remit. Originally, certification was not in the plans of MSA as foreign certification bodies were providing Quality Management System certification. With Malta’s EU membership, a lot of pressure was exerted by SME’s to have a local certification body, as the fees asked by foreign certification bodies comprised also travelling and accommodation which left them at a disadvantage with similar SME’s abroad. These organisations realised that the opening of the vast European market can only be penetrated if they possess ISO 9001 certification.

Because of the conflicts between accreditation and certification, a study was commissioned by the renowned European expert Dr. Jos Leferink (head of the Dutch Accreditation body) entitled, ‘Advice to the Chairman of the Malta Standards Authority Concerning Issues of Accreditation and Conformity Assessment within MSA’. His final advice was that MSA can, for a limited time, until the signing of the EA MLA have the two activities running parallel with the necessary firewalls and suggested that then, one of the following options would be followed:

a) Bring certification under a division (different to the Economic Policy Division) of the Ministry of Finance
b) Create an Authority for the Accreditation activities
c) Create an Authority for the accreditation and regulatory activities

The necessary actions as suggested by Mr. Leferink will be duly followed.

The MSA Act (2000) provides the necessary legal infrastructure to provide certification services in Malta. MSA is in a position to accept applications for quality management systems as from 1st November 2003. To ensure acceptance of quality management system certification (MSA EN ISO 9001) issued by MSA in EU member states, it is compulsory that the certification body obtains accreditation.

SETTING UP OF CERTIFICATION SCHEMES IN MALTA

The Acquis communitarie includes a number of provisions were certification is included as an integral part of the legislation, three such schemes are the EU Eco-label scheme, designation of origin and certificates of specific character and organic farming.

The EU eco-label scheme was launched in 1992 to encourage the production and consumption of green products at a European scale. The same Flower logo is used across different product groups and Member States, making it easier to recognise products with a superior environmental performance. This helps to avoid distortions of competition and ensures the protection of the interests of producers and consumers.

The aim is to award a Community Eco-label to products and services with reduced environmental impacts. The scheme is VOLUNTARY. Criteria are established for individual product groups, such as hotel accommodation, paper products, textiles, detergents, paints and appliances such as refrigerators or dishwashers.

Designation of origin and certificates of specific character – 4 study visits to certification bodies operating in the community focusing on the following
product categories – meat and dairy products, honey, fruit and vegetables, bakery and confectionery products.

Organic Farming – one study visit to an EU-based certification body preferably one operating in climatic and farming conditions similar to those prevalent in Malta.

98/34/EC NOTIFICATION PROCEDURE

Subsequent to the project entitled Capacity Building at the Malta Standards Authority, the notification system is fully implemented and operational. However, currently, there is no electronic cataloguing of all the documentation which is received and there is the need of more formation programmes for the officials who will be involved in the project.

Through the project entitled Capacity Building at the Malta Standards Authority, there has been an ongoing programme of formation for the Notification Focal Point in Malta. This programme involved mainly the training of the MSA official involved in the notification procedure. After the training of the said official, what now needs to be undertaken is the development of the system which would start operating after May 1st, 2004, when the notification procedure becomes fully operational in Malta.

3.2 Linked activities:

Through previous pre-accession funding (2001-2003), the MSA developed its quality and measurement infrastructure to meet the requirements laid out in Chapter 1, as were identified during the pre-accession negotiations.

Various experts were consulted to help develop the present infrastructure. Furthermore MSA staff underwent rigorous training with various European institutions. The presently submitted project is aimed at further consolidating the technical expertise required by the Authority, particularly in areas not covered in the previous project fiche.

Regulation (EC) 761/2001 of the European Parliament and of the Council allowing voluntary participation by organizations in EMAS mandates that MS must have the infrastructure in place and Article 12 also mandates MS obligation for information. This project will ensure that Malta meets these obligations. Similar obligations are found in Regulation (EC) 1980/2000 of the European Parliament and of the Council on revised Community Eco-label award scheme.

3.3 Results:

Through technical assistance provided:

- The MSA will register EMAS sites and NAB-MSA will extend its role to the accreditation of EMAS Verifiers.
- The MSA will sign the EA MLAs for testing, calibration and inspection.
- The role of the NAB-MSA will extend to the accreditation of Certification System Providers. The accreditation scheme will support “qualified signatures” issued by Certification Service Providers using Annex I and Annex II of the e-signatures directive to define the certification requirements.
The peer assessment of the MSA-NMS will help in place the technical competencies of the MSA-NMS staff maintaining the Maltese Measurement System in a firm placing within the European framework.

The NAB-MSA will be in a position to monitor laboratories with respect to the Good Laboratory practices.

Quality management system certified organisations would have their certificates recognised throughout the EEA.

Maltese organisations would be in a position to apply for eco-labelling, certificates of specific character (EC regulation 2082/92), organic farming (EC Regulation 2092/91) and protected designations and geographical indications (EC Regulation 2081/92);

The CONSUMER AND INDUSTRIAL GOODS DIRECTORATE/NAB-MSA was never intended to act as a Notified Body. However, through this project it will be able to assist ‘potential’ notified bodies as required by New Approach Directives leading to their notification.

3.4 Activities:

The length of expertise required and cost per activity are detailed below.

Although the basic infrastructure within MSA has been established additional technical support in the areas of conformity assessment and 98/34 notification is needed to ensure that areas of responsibility within the relevant Directorates are fully developed.

It is envisaged that through the technical assistance requested in this project, MSA officers will be fully capable, and obtain the necessary experience, to meet the requirements of the Acquis falling under the MSA.

The sectors to be covered throughout this project are Accreditation, Metrology and Conformity assessment.

This project will be implemented through a 24-month technical assistance service contract that will deliver the activities below.

The Project Leader will have the following required qualifications:

- At least five years of experience in an advisory capacity in the field of legal approximation and alignment of quality infrastructure, preferably gained in the EU accession countries
- Full familiarity with EU technical regulations (old approach, new approach)
- Full familiarity and working links with relevant European Organisations (CEN, CENELEC, ETSI, EA, EUROMET, EOTC, CEOC, EOTA, EUROLAB, EOQ, EFQM, etc.)
- Ability to draft Terms of Reference and manage short-term technical assistance missions.
Accreditation:

Activity 1: THE DEVELOPMENT OF THE EMAS SCHEME IN MALTA

Technical advice will be required to help the MSA to fully develop and implement the EMAS scheme. This will involve the need for two or three experts, based on a development plan prepared at the start of the project. The activity should cover:

- briefings on the EMAS Regulation and the supporting guidance, FAB (Forum of Accreditation Bodies) requirements, Article 14 Committees role, etc;
- preparation of a development plan for the EMAS scheme which will include the development of a process flowchart of the implementation procedures for EMAS registrations and EMAS Verifiers.
- the supervision of verifiers accredited in Malta and the supervision of verifiers accredited in other countries while working in Malta;
- to prepare and deliver a training course for accreditation assessors based on the Maltese EMAS system and covering EMAS requirements, legal compliance, responsibilities and requirements for verifiers, the EMAS statement;
- to verify the possibility of accrediting individual verifiers;
- to brief EMAS Competent Body and Environmental Regulators on their roles and to ensure that there are no conflicts in their approaches with that of the EMAS accreditation body;
- for the audit of the scheme and all supporting documentation as developed in Malta against the FAB requirements and for the eventual peer evaluation by the FAB;
- Attendance to Competent Bodies and Article 14 meetings
- for the training of the NAB-MSA staff in the EMAS accreditation scheme, including the observation of EMAS verifications in other Member states;
- for the training of the Accreditation Advisory Board members on EMAS accreditation and supervision;
- for NAB-MSA during its first EMAS assessment and in the preparation of the report for the Accreditation Advisory Board;

The assignment should also cover the costs of the peer evaluation of the FAB. It is envisaged that this peer evaluation will be carried out by two people.

<table>
<thead>
<tr>
<th>Activity 1: Development of EMAS Scheme in Malta</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMAS Competent Body - 15 man-days expert @ €650</td>
<td>9750</td>
</tr>
<tr>
<td>Travel expenses for experts - 5 flights @ €600</td>
<td>3000</td>
</tr>
<tr>
<td>Per diem for experts 15 @ €196</td>
<td>2940</td>
</tr>
<tr>
<td>EMAS Verifier - 18 man-days expert @ €650</td>
<td>11700</td>
</tr>
<tr>
<td>Travel expenses for experts - 5 flights @ €600</td>
<td>3000</td>
</tr>
<tr>
<td>Per diem for experts 18 @ €196</td>
<td>3528</td>
</tr>
<tr>
<td>Per diem for MSA staff 40 man-days @ €199 (for budgetary purposes only)</td>
<td>7960</td>
</tr>
</tbody>
</table>

Peer evaluation

| 9 man-days @ €650 | 5850 |
| Travel expenses for 3 experts @ €600 | 1800 |
Activity 2: THE PEER EVALUATION OF THE NATIONAL ACCREDITATION BODY OF MALTA

Technical advice will be required to help the NAB-MSA to fully meet the EA MLA requirements, including advice in the preparation of the KPI (Key performance indicators) self-assessment report. This will involve the need for one expert, based on a development plan prepared at the start of the project. Additional expert/s in different areas of expertise may be required depending on the issues raised during the course of the project.

- support for the finalisation of the quality system prior to submission to the EA MAC committee;
- training of NAB-MSA staff in preparing for the EA MLA, including knowledge how to complete the EA key performance indicators [KPI];
- the preliminary peer evaluation visit by EA;
- assistance required to clear corrective actions required following the preliminary visit;
- the peer evaluation visit by the EA assessment team;
- assistance required to settle corrective actions required following the EA visit;
- any additional visits by EA assessment team members required following the corrective actions taken by NAB-MSA;
- participation in the various EA Committees.

<table>
<thead>
<tr>
<th>Activity 2: Peer Evaluation of NAB-MSA</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert support prior to peer evaluation - 30 man-days @ €650</td>
<td>19500</td>
</tr>
<tr>
<td>Travel expenses for experts - 6 flights @ €600</td>
<td>3600</td>
</tr>
<tr>
<td>Per diem for experts 30 @ €196</td>
<td>5880</td>
</tr>
<tr>
<td>Peer evaluation - preliminary visit</td>
<td></td>
</tr>
<tr>
<td>9 man-days @ €650</td>
<td>5850</td>
</tr>
<tr>
<td>Travel expenses for experts - 3 flights @ €600</td>
<td>1800</td>
</tr>
<tr>
<td>Per diem for experts 9 @ €196</td>
<td>1764</td>
</tr>
<tr>
<td>Peer evaluation</td>
<td></td>
</tr>
<tr>
<td>16 man-days @ €650</td>
<td>10400</td>
</tr>
<tr>
<td>Travel expenses for experts - 4 flights @ €600</td>
<td>2400</td>
</tr>
<tr>
<td>Per diem for experts 16 @ €196</td>
<td>3136</td>
</tr>
<tr>
<td>Follow-up to Peer evaluation</td>
<td></td>
</tr>
<tr>
<td>8 man-days @ €650</td>
<td>5200</td>
</tr>
<tr>
<td>Travel expenses for experts - 3 flights @ €600</td>
<td>1800</td>
</tr>
<tr>
<td>Per diem for experts 8 @ €196</td>
<td>1568</td>
</tr>
<tr>
<td>Per diem for MSA staff - 24 man-days @ 199 € (for budgetary purposes only)</td>
<td>4776</td>
</tr>
</tbody>
</table>
Activity 3: THE DEVELOPMENT OF THE E-SIGNATURES ACCREDITATION SCHEME IN MALTA

Technical advice will be required to help the NAB-MSA to develop and implement the e-signatures accreditation scheme in Malta. This will involve the need for one expert, based on a development plan prepared at the start of the project. Additional expert/s in different areas of expertise will be required on short-term missions. This will depend on the issues raised during the course of the project, especially when one consider the technical aspect of this assignment.

• Hold a course for BS7799-2 familiarisation and auditing;
• preparation of a development plan for the e-signatures accreditation scheme which will include the development of a process flowchart of the accreditation procedures for this scheme, the development of the accreditation assessment procedures for BS7799-2 and e-signatures consistent with the existing NAB-MSA quality system, and in particular the accreditation of certification bodies providing certification against BS7799-2;
• carry out a general introduction to the EU directives, CWAs (CEN Working Agreements), ETSI standards and accreditation models for E-signatures operating in other member states;
• prepare a concept model for the Maltese accreditation scheme, taking into account associated Maltese law and accreditation practice and to identify any legal implications resulting from the model;
• prepare the accreditation assessment criteria and a general description of the scheme;
• identify possible technical assessors to be used,
• train potential local technical assessors;
• train the Accreditation Advisory Board on this scheme.

<table>
<thead>
<tr>
<th>Activity 3: Development of E-Signatures Accreditation Scheme</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 man-days expert @ €650</td>
<td>19500</td>
</tr>
<tr>
<td>Travel expenses for experts - 6 flights @ €600</td>
<td>3600</td>
</tr>
<tr>
<td>Per diem for experts 30 @ €196</td>
<td>5880</td>
</tr>
<tr>
<td>Per diem for MSA staff - 10 man-days @ €199 (for budgetary purposes only)</td>
<td>1990</td>
</tr>
<tr>
<td>Course in Malta (for MSA staff) on BS 7799-2</td>
<td>15500</td>
</tr>
<tr>
<td>4 day course in Malta (3 experts with different backgrounds)</td>
<td></td>
</tr>
<tr>
<td>4 by 3 = 12 man-days @ €650</td>
<td>7800</td>
</tr>
<tr>
<td>Travel expenses for experts - 3 flights @ €600</td>
<td>1800</td>
</tr>
<tr>
<td>Per diem for experts 12 man-days @ €196</td>
<td>2352</td>
</tr>
<tr>
<td>Publications</td>
<td>1500</td>
</tr>
<tr>
<td>Total</td>
<td>60000</td>
</tr>
</tbody>
</table>
Activity 4: THE DEVELOPMENT OF THE GOOD LABORATORY PRACTICE SCHEME IN MALTA

The assignment should cover the following activities:

- on the GLP scheme;
- for the development of the system procedures consistent with the existing NAB-MSA quality system;
- for the supervision of GLP-certified labs;
- for the training of MSA technical staff in the inspection of GLP-certified laboratories and other related GLP activities;
- to participate in the meetings of the GLP Working Group;
- for the training of the Accreditation Advisory Board members on GLP requirements;

<table>
<thead>
<tr>
<th>Activity 4: Development of Good Laboratory Practice Scheme</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting up GLP Scheme - 25 man-days expert @ €650</td>
<td>16250</td>
</tr>
<tr>
<td>Travel expenses for experts - 6 flights @ €600</td>
<td>3600</td>
</tr>
<tr>
<td>Per diem for experts 25 @ €196</td>
<td>4900</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Per diem for MSA staff - 12 man-days @ €199 (for budgetary purposes only)</td>
<td>2388</td>
</tr>
<tr>
<td>Publications</td>
<td>1400</td>
</tr>
<tr>
<td>Seminar and awareness program</td>
<td>1500</td>
</tr>
<tr>
<td>Total</td>
<td>30000</td>
</tr>
</tbody>
</table>

Activity 5: STRENGTHENING THE ADMINISTRATIVE INFRASTRUCTURE WITHIN MSA IN THE FIELD OF ASSESSMENT OF MALTESE CONFORMITY ASSESSMENT BODIES

Technical advice will be required to help MSA through the CGID and the NAB-MSA to develop the necessary competence to be able to administer the system for Notified Bodies in Malta.

The project can be conveniently combined by bringing experts having hands-on experience on doing risk assessments and, consequently, compiling complete technical files: it is envisaged that an overall 15 man-days multiplied by the number of experts (say 3) will be required. Initially the training is to be performed in-house, taking as many examples of New Approach Directives (product families) as possible, over, say, 9 full working days. Following general (academic-type) training on how to perform risk assessment, it would be useful to take specific cases like a Construction Product (brick or plank), Machinery (Hand Saw, Hoist), Electrical/EMC (Computer), R&TTE (Satellite Dish), Recreational Craft, Pressure Equipment, etc. and go through the whole process till the Technical File is completed. For the last day, MSA would propose to hold a Workshop, open to the general public, run by anyone of the experts and taking the form of plenary sessions (covering general aspects) and working groups run by CIGD/NAB staff under the supervision of the experts.

Experts responsible for national notifications of (in order of preference) construction products, lifts, machinery, medical devices, recreational craft, pressure equipment, low voltage, EMC:
- Technical advice from experts who have hands-on experience on performing risk assessments and on compiling technical files.
- Holding of workshops for the general public. Established experts will run these.
- Technical advice from experts responsible for national notification under the construction products, lifts, machinery, medical devices, recreational craft, pressure equipments, low voltage, EMC (in that order of preference) Directives. This advice, which will take the form of training to MSA technical staff, is to include:
  - The provision of knowledge from practical experiences;
  - Training on the procedures involved in the notification of potential Maltese CABs;
  - Carry out a case study, based on a real-life situation, on the assessment of a notified body.
  - Witnessing of assessment of Notified Bodies by MSA technical staff.
  - Supervision and assistance to MSA staff during the first assessments of conformity assessment bodies;
  - Technical assistance during the preparation of the application packs for notified bodies, including technical guides where necessary;
  - Publication of technical guides and information packs for applicants.
  - Visit the MSA to exchange their views and their practical experience with CIGD/NAB-MSA staff in their respective fields;
  - Lecture MSA staff on the procedures involved in notification of potential Maltese notified bodies;
  - Bring over examples of audits they undertook or (preferably) that they are currently undertaking and supervise a “desk-audit” performed by CIGD/NAB-MSA staff in Malta;
  - Reciprocate their visit in Malta by inviting CIGD/NAB-MSA staff to accompany them in actual audits on-site;
  - Supervise CIGD/NAB-MSA staff to perform the first audits.

<table>
<thead>
<tr>
<th>Activity 5: Strengthening the administrative infrastructure within MSA in the field of assessment of Maltese conformity assessment bodies</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert advice: 36 man-days expert @ €650</td>
<td>23400</td>
</tr>
<tr>
<td>Travel expenses for experts - 10 flights @ €600</td>
<td>6000</td>
</tr>
<tr>
<td>Per diem for experts 36 @ €196</td>
<td>7056</td>
</tr>
<tr>
<td>Per diem for MSA staff - 20 man-days @ €199 (for budgetary purposes only)</td>
<td>3980</td>
</tr>
<tr>
<td>Publications and Technical Guides</td>
<td>3600</td>
</tr>
<tr>
<td>Workshops/seminar and awareness programs in Malta</td>
<td></td>
</tr>
<tr>
<td>5 workshops - 4 experts for 2 days - 8 man-days expert @ €650</td>
<td>5200</td>
</tr>
<tr>
<td>Travel expenses for experts - 4 flights @ €600</td>
<td>2400</td>
</tr>
<tr>
<td>Per diem for experts 8 @ €196</td>
<td>1568</td>
</tr>
<tr>
<td>Total</td>
<td>53200</td>
</tr>
</tbody>
</table>

**Metrology:**
Activity 6: AVAILABILITY OF TECHNICAL EXPERTS TO CONDUCT PEER ASSESSMENT OF THE MALTA STANDARDS AUTHORITY METROLOGY LABS.

The Metrology labs will be operating in three of the fundamental fields of mass, dimension and temperature, the latter will be eventually segmented into contact thermometry and humidity. The peer assessment exercise will necessarily involve three experts from the different fields who would be nominated by the EUROMET TC chairperson for the particular fields. The expert will carry out a detailed three day evaluation of the procedures employed and conduct intensive interviews with staff members to ascertain that the level of technical competence suffices for the function that must be executed by the NMI in the particular field, in relation to the dissemination of traceable measure at the highest level of local competencies, and that these competencies are at par with those that are to be expected of staff of other European NMI’s.

A fourth expert is being suggested to conduct an updating review of the Metrology Labs quality system in preparation of a second Quality system review that will be executed by EUROMET Quality System Forum.

Comprehensive analysis of all procedures employed within the labs, the manner in which all data is retained and analysed. An examination of the software tools employed, a direct one on one assessment of all staff members.

- Coordination with Euromet TC for identification of most appropriate assessors
- Assessment of all lab procedures
- Verification of data evaluation methods
- Validation of software tools generated in house
- Assessment of the performance of MSA-NMS staff during the execution of their tasks
- Assessment of data analysis conducted in previous intercomparison exercises

<table>
<thead>
<tr>
<th>Activity 6: Peer Assessment of MSA-NMS</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer assessment: 12 man-days expert @ €650</td>
<td>7800</td>
</tr>
<tr>
<td>Travel expenses for experts - 4 flights @ €600</td>
<td>2400</td>
</tr>
<tr>
<td>Per diem for experts 12 @ €196</td>
<td>2352</td>
</tr>
<tr>
<td>Total</td>
<td>12552</td>
</tr>
</tbody>
</table>

Execution of assessments should be conducted over a three to four month period, to allow for proper feedback on required action points in the different labs.

Conformity Assessment:

Activity 7: ACCREDITATION OF CERTIFICATION SERVICES IN MALTA

The certification unit within MSA will need to draft, adopt and implement standard operating procedures (SOPs) and checklists for ISO 9000 certification activities. In view of the fact that certification in these areas is still a new area for Malta, MSA would greatly benefit from the advice of experts in quality management system certification. This could best be done through study visits and short-term attachments with organizations in Europe carrying out similar
functions. The certification unit staff would also acquire first hand experience of certification procedures in these areas.

The following assistance and/or expert technical advice will be required to:

- Draft the documentation required to meet the requirements of ISO/IEC Guide 62 "General requirements for bodies operating assessment and certification / registration of quality systems ” or equivalent standard.
- Assist in building the necessary infrastructure
- Train personnel as lead assessors
- MSA personnel placed for a short period of time within a European accredited certification body to gain field experience
- Support in the evolution of the quality management scheme
- Accreditation of the MSA certification.

<table>
<thead>
<tr>
<th>Activity 7: Accreditation of certification services in Malta</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert advice: 15 man-days expert @ €650</td>
<td>9750</td>
</tr>
<tr>
<td>Travel expenses for experts - 3 flights @ €600</td>
<td>1800</td>
</tr>
<tr>
<td>Per diem for experts 15 @ €196</td>
<td>2940 €</td>
</tr>
<tr>
<td>Per diem for MSA staff - 10 man-days @ €199 (for budgetary purposes only)</td>
<td>1990</td>
</tr>
<tr>
<td>Accreditation of certification service</td>
<td>20000</td>
</tr>
<tr>
<td>Post accreditation support: 4 man-days @ €650</td>
<td>2600</td>
</tr>
<tr>
<td>Travel expenses for experts - 1 flights @ €600</td>
<td>600</td>
</tr>
<tr>
<td>Per diem for experts 4 @ €196</td>
<td>784</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>40464</td>
</tr>
</tbody>
</table>

**Activity 8: SETTING UP CERTIFICATION SCHEMES IN MALTA**

The following visits are envisaged as being sufficient for the initial phase of implementation of the following regulations:

Eco-labelling – Visits by EU competent authorities focusing on different product categories to be determined according to prevalent interest from local companies;

Designation of origin and certificates of specific character – 4 visits by a certification body operating in the community focusing on the following product categories – meat and dairy products, honey, fruit and vegetables, bakery and confectionery products.

Organic Farming – Visit by an EU-based certification body preferably one operating in climatic and farming conditions similar to those prevalent in Malta.

The successful implementation of these 4 EC regulations in Malta would also depend on increasing awareness of these regulations among operators. Provision should therefore be made for four awareness seminars, one on each EC regulations as well as for the preparation of information material in both official languages, promoting EU schemes.

<table>
<thead>
<tr>
<th>Activity 8: Setting up certification schemes in Malta</th>
<th>€</th>
</tr>
</thead>
</table>
### Activity 9: 98/34/EC NOTIFICATION PROCEDURE

- The publication of information booklets and CD ROMS
- Information seminars for all the parties involved in the Notification Procedure
- Attending to Commission and other MS Central Units for information exchange and meetings.

<table>
<thead>
<tr>
<th>Activity 9: 98/34 Notification Procedure</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per diem for MSA staff - 24 man-days @ €199 (for budgetary purposes only)</td>
<td>4776</td>
</tr>
<tr>
<td>Seminars/workshops</td>
<td>1000</td>
</tr>
<tr>
<td>Publication of information material</td>
<td>1300</td>
</tr>
<tr>
<td>Total</td>
<td>7000</td>
</tr>
</tbody>
</table>
3.5 Lessons learned:

A number of lessons were learnt throughout the implementation of the pre-accession project:

a) Whenever an expert was identified to provide advice or training, we ensured that a clear terms of reference have to be prepared, giving leeway for adjustment/s that might have to be included during the execution of the contract. In the first stages of the product, some experts left gaps in their advice to extend their contract.

b) Experience in the area of advice or training was always requested from experts, as well as references. In one occasion, we even interviewed the candidate in Brussels before being accepted.

c) In the latter days of the project we have acquired enough know-how of who’s who in Europe that we started identifying experts ourselves.

4. Institutional Framework

The Authority is made up of Council representing the stakeholders in standardization. The Council is responsible to set the policy of the Authority. The day-to-day administration is the responsibility of the CEO. Within the Authority, there are five functionally independent directorates established by secondary legislation under the MSA Act. The staff compliment is the following:

**Central Administration:**

- CEO
- Legal and PR Officer also responsible for WTO and 98/34 Notification
- Financial Officer
- Secretary
- Clerical staff.

**Accreditation:**

- Director
- Accreditation Officer

**Consumer and Industrial Goods**

- Director
- 2 Engineers

**Foodstuff, Chemical and Cosmetics**

- Director
- 2 Scientists

**Metrology**

- Director
- Scientist
- Technician
**Standardization**

Director  
2 Engineers  
Scientist  
Certification Officer  
Librarian

Refer to Organisation Chart (Annex V).

5. **Detailed Budget (EUROS)**

<table>
<thead>
<tr>
<th>Transition Facility Support</th>
<th>Investment Support</th>
<th>Institution Building</th>
<th>Total TF (I+IB)</th>
<th>National Co-financing*</th>
<th>IFI*</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component 1</td>
<td>-</td>
<td>368,000</td>
<td>368,000</td>
<td>-</td>
<td>-</td>
<td>368,000</td>
</tr>
<tr>
<td>Total</td>
<td>-</td>
<td>368,000</td>
<td>368,000</td>
<td>-</td>
<td>-</td>
<td>368,000</td>
</tr>
</tbody>
</table>

The cost of air tickets of Maltese officials participating in study visits will be paid for out of the Travel vote of the beneficiary.

The co-financing expenses will be monitored by the beneficiary and the NAO. For the earmarked co-finance, a clear and verifiable set of costs will be provided. The beneficiary will define which budget lines are the source for co-finance.

The beneficiary together with the NAO commits to sound financial management and control.

6. **Implementation Arrangements**

6.1 **Implementing Agency**

Malta Standards Authority  
Level 2,  
Evans Building  
Merchants Street  
Valletta  
VLT 03

**Contact Person:**

Mr. Joseph Spiteri, Chief Executive Officer  
Tel: +356 21 242420  
Fax: +356 21 242406  
Email: info@msa.org.mt

Project leader:

Mr. Joseph Spiteri, Chief Executive Officer  
Tel: +356 21 242420  
Fax: +356 21 242406  
Email: info@msa.org.mt
Contracting Authority

Department of Contracts
Notre Dame Ravelin
Floriana CMR 02
Malta

Contact person:

Mr Dennis Attard, Assistant Director
Tel: +356 21247682
Fax: +356 21247681
Email: dennis.attard@gov.mt

6.2 Twinning:

N/A

6.3 Non-standard aspect:

The contract will be directly awarded to CEN.

6.4 Contracts

One technical assistance service contract is envisaged for a total of €368,000.

7. Implementation Schedule

7.1 Start of tendering/call for proposals

September 2004

7.2 Start of project activity

December 2004

7.3 Project Completion

June 2007

8. Sustainability

MSA has the administrative infrastructure in place and has over the last three years taken on board the technical and administrative staff to handle aspects of the project fiche and the absorption of the technical assistance to be gained from this project. As a result of this project MSA will consolidate its competence level in all areas of its remit.

9. Conditionality and sequencing

The component on training on organic farming is conditional upon formal confirmation of MSA as the certification body.
ANNEXES TO PROJECT FICHE

1. Logical Framework matrix
2. Implementation Schedule
3. Contracting and Disbursement Schedule
4. Organigram
### Annex 1: TF log frame template

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX:</th>
<th>Programme name and number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project</td>
<td></td>
</tr>
<tr>
<td><strong>Further Institutional Building, Consolidation and Strengthening of the Malta Standards Authority</strong></td>
<td>Contracting period expires: 15/12/2006</td>
</tr>
<tr>
<td></td>
<td>Disbursement period 15/12/2007</td>
</tr>
<tr>
<td></td>
<td>Total budget: €368,000</td>
</tr>
<tr>
<td></td>
<td>TF budget: €368,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>To consolidate and strengthen the Malta Standards Authority.</td>
<td>• As below, for the various activities.</td>
<td>• As below, for the various activities.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
| To ensure the mutual recognition of the services provided by the Malta Standards Authority in the fields of accreditation, metrology and certification. | Project completion envisaged as follows:  
Accreditation - Q4/2005  
Metrology - Q1/2006  
Certification - Q2/2005  
EMAS Scheme peer evaluated by FAB  
EA-Multi Lateral Agreement (MLA) pre-Evaluation and Evaluation Reports  
The accreditation scheme will support “qualified signatures” issued by | FAB Peer Evaluation Report  
EA MAC and EA GA minutes of meeting; EA Website  
NAB-MSA Quality Manual and related procedures and guides.  
NAB-MSA Quality Manual and related procedures  
Databases  
IT system  
Government Gazette; | Malta drafts standards and technical regulations which would be subject to the 98/34/CE Procedure.  
Malta feels the need to issue comments or detailed opinions.  
Full commitment of managerial staff of ministries’ departments and of other authorities |
<p>| List of Notified Bodies; Guidance documents; Participation in Commission work; Effective pre-market surveillance Mission report by the experts, together with individual report on the assessments of the technical staff Delivery of NMS quality system to EUROMET QS forum Standard Operating Procedures MSA catalogue of ISO certified bodies Successful processing of a number of applications. Draft standards are regularly notified to CEN and CENELEC | Minutes of QS Forum Meeting MSA official Website Accreditation Body Products are certified or recognised as appropriate. CEN and CENELEC Databases DG Enterprise Statistics by the European Commission The TRIS and CIRCA websites |</p>
<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
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<tbody>
<tr>
<td>The MSA will register EMAS sites and NAB-MSA will extend its role to the accreditation of EMAS verifiers.</td>
<td>• EMAS Competent Body in operation • FAB peer evaluation • NAB-MSA Quality Manual. • NAB-MSA publications and technical guides</td>
<td>• Attendance at Competent Body and Article 14 meetings • FAB peer evaluation report • Supervision report • Published information material. • FAB minutes of meeting</td>
<td>• Sites applies for EMAS registration • EMAS Site verified by an EMAS verified accredited by the NAB-MSA</td>
</tr>
<tr>
<td>The MSA will sign the EA MLA for testing, calibration and inspection.</td>
<td>• EA-MLA Pre-Evaluation and Evaluation Reports • EA Committee meeting minutes</td>
<td>• EA MAC and EA GA minutes of meeting; • EA Website • EA Committees attendance lists.</td>
<td></td>
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<tr>
<td>E-Signatures accreditation scheme developed.</td>
<td>• Accreditation Certificate of CSP.</td>
<td>• Accreditation Certificate of CSP.</td>
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<tr>
<td>The NAB-MSA will be in a position to monitor laboratories with respect to the Good Laboratory practices.</td>
<td>• NAB-MSA Quality Manual and related procedures.</td>
<td>• NAB-MSA Quality Manual and related procedures.</td>
<td>• An organisation is prepared to be accredited as a CSP</td>
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<td>Quality management system certified organisations would their certificates recognised throughout the EEA.</td>
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</table>
Maltese organisations in a position to apply for eco-labelling certificates of specific character, organic farming and protected designations and geographical indications.

The CONSUMER AND INDUSTRIAL GOODS DIRECTORATE/NAB-MSA staff able to assist “potential” notified bodies through all stages leading to their notification under L.N, 136 of 2003; i.e. from the initial application, assessment, accreditation, reporting and periodic monitoring procedures.

- List of Notified Bodies;
- Guidance documents;
- Participation in Commission work;
- Effective pre-market surveillance;
- Expert action plans available for follow up corrective actions;
- Website;
- Database of ISO 9000 registered companies;
- Meeting customer requirements;
- The availability of PR publications;
- The holding of seminars and the subsequent reports and write-ups also in the media since media coverage is given by the principal news agencies in Malta of these seminars.

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<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>1. THE DEVELOPMENT OF THE EMAS SCHEME IN MALTA</td>
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<tr>
<td>1.1 Competent Body in a position to register sites.</td>
<td>Technical Assistance contract</td>
<td>Resources available to the MSA.</td>
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<tr>
<td>1.2 Briefings on the EMAS Regulation and the supporting guidance, FAB (Forum of</td>
<td></td>
<td>Applications for registration received</td>
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Accreditation Bodies) requirements, Article 14 Committees role, etc;
1.3 Preparation of a development plan for the EMAS accreditation scheme, including the development of a process flowchart of the accreditation procedures for EMAS Verifiers, the development of the EMAS accreditation procedures consistent with the existing NAB-MSA quality system, and in particular the accreditation of ISO 14001 certification bodies;
1.4 Supervision of verifiers accredited in Malta and the supervision of verifiers accredited in other countries while working in Malta;
1.5 Preparation and delivery of a training course for accreditation assessors based on the Maltese EMAS system and covering EMAS requirements, legal compliance, responsibilities and requirements for verifiers, the EMAS statement;
1.6 Investigation of the possibility of accrediting individual verifiers;
1.7 Briefing of the other participants in EMAS (Competent Body, Environmental Regulators, etc) on their roles and to ensure that there are no conflicts in their approaches with that of the EMAS accreditation body;
1.8 Audit of the scheme and all supporting documentation as developed in Malta against the FAB requirements in from interesting sites.

- Application received from a local verifier.
preparation for the eventual peer evaluation by the FAB;

1.9 NAB-MSA to familiarise itself with the operation of the FAB including assistance to participate in FAB meetings;

1.10 Training of MSA staff in the EMAS scheme.

1.11 Training of the Accreditation Advisory Board members on EMAS accreditation and supervision;

1.12 Assistance for MSA during its first EMAS assessment.

1.13 Preparation and publication of information material.

2. THE PEER EVALUATION OF THE NATIONAL ACCREDITATION BODY OF MALTA (NAB-MSA).

2.1 Support for the finalisation of the quality system prior to submission to the EA MAC committee;

2.2 Training of NAB-MSA staff in preparing for the EA MLA, including knowledge how to complete the EA KPIs (key performance indicators);

2.3 The preliminary peer evaluation visit by EA;

2.4 Assistance required to clear corrective actions required following the preliminary visit;

2.5 The peer evaluation visit by the EA
2.6 Assistance required to settle corrective actions required following the EA visit;
2.7 Any additional visits by EA assessment team members required following the corrective actions taken by NAB-MSA;
2.8 Participation in the various EA Committees.

3. THE DEVELOPMENT OF THE E-SIGNATURES ACCREDITATION SCHEME IN MALTA

3.1 familiarisation and auditing;
3.2 Preparation of a development plan for the e-signatures accreditation scheme which will include the development of a process flowchart of the accreditation procedures for this scheme, the development of the accreditation assessment procedures for BS7799 and e-signatures consistent with the existing NAB-MSA quality system, and in particular the accreditation of certification bodies providing certification against BS7799-2;
3.3 General introduction to the EU directives, CWAs (CEN Working Agreements), ETSI standards and accreditation models for E-signatures operating in other member states;
3.4 Preparation of a concept model for the Maltese accreditation scheme, taking into
account associated Maltese law and accreditation practice and to identify any legal implications resulting from the model;

3.5 Preparation of the accreditation assessment criteria and a general description of the scheme;

3.6 Identification of possible technical assessors to be used,

3.7 Training of NAB-MSA personnel;

3.8 Training of potential local technical assessors;

3.9 Training of the Accreditation Advisory Board on this scheme

4. THE DEVELOPMENT OF THE GOOD LABORATORY PRACTICE SCHEME IN MALTA

4.1 Preparation of a development plan for the GLP scheme including the development of the system procedures consistent with the existing NAB-MSA quality system;

4.2 Supervision of Maltese GLP-certified laboratories;

4.3 Training of NAB-MSA technical personnel in the inspection of GLP-certified laboratories and other related GLP activities;

4.4 Participation in the meetings of the GLP Working Group;

4.5 Training of the Accreditation Advisory
Board members on GLP requirements.

5. ASSESSMENT AND NOTIFICATION OF MALTESE CONFORMITY ASSESSMENT BODIES (CABS)

- Technical advice from experts who have hands-on experience on performing risk assessments and on compiling technical files.
- Holding of workshops for the general public. Established experts will run these.
- Technical advice from experts responsible for national notification under the construction products, lifts, machinery, medical devices, recreational craft, pressure equipments, low voltage, EMC (in that order of preference) Directives. This advice, which will take the form of training to MSA technical staff, is to include:
  - The provision of knowledge from practical experiences;
  - Training on the procedures involved in the notification of potential Maltese CABs;
  - Carry out a case study, based on a real-life situation, on the assessment of a notified body.
- Witnessing of assessment of Notified Bodies by MSA technical staff.
- Supervision and assistance to MSA staff during the first assessments of conformity assessment bodies;

- CONSUMER AND INDUSTRIAL GOODS DIRECTORATE and NAB-MSA recruit and retain adequate staff.
• Technical assistance during the preparation of the application packs for notified bodies, including technical guides where necessary;
• Publication of technical guides and information packs for applicants.

6. AVAILABILITY OF TECHNICAL EXPERTS TO CONDUCT PEER ASSESSMENT OF THE MALTA STANDARDS AUTHORITY METROLOGY LABS.

• Comprehensive analysis of all procedures employed within the labs, the manner in which all data is retained and analysed. An examination of the software tools employed, a direct one on one assessment of all staff members.

7. ACCREDITATION OF CERTIFICATION SERVICES IN MALTA

Draft, adopt and implement standard operating procedures (SOPs) and checklists for ISO 9000 certification activities.

• Determine the best model to be set up in Malta
• Assist in building the necessary infrastructure
• Train personnel as lead assessors
• Attach MSA personnel for a short period of
time within a European accredited certification body to gain field experience
• Support in the evolution of the ISO 9000 quality management scheme
• Accredit the certification body of MSA.

8. SETTING UP OF CERTIFICATION SCHEMES IN MALTA FOR THE IMPLEMENTATION OF EC REGULATIONS

• Eco-labelling – 4 study visit to EU competent authorities focusing on different product categories to be determined according to prevalent interest from local companies.
• Designation of origin and certificates of specific character – 4 study visits to certification bodies operating in the Community focusing on the following product categories: meat and dairy products, honey, fruit and vegetables, bakery and confectionery products.
• Organic Farming – 1 study visit to an EU-base certification body preferably one operating in climatic and farming conditions similar to those prevalent in Malta.
• 4 Awareness seminars – one on each EC regulation
• Preparation of information material in Maltese and English promoting the EU schemes.
9. 98/34/EC NOTIFICATION PROCEDURE

- The development of the software for the management of the notification procedure and relative database and website.
- The publication of information booklets and CD ROMS
- Information seminars.
- Visits to other MS Central Units for information exchange.

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## SUMMARY DETAILED TIME IMPLEMENTATION CHART FOR THE PROJECT

**Title:** Further institutional building, consolidation and strengthening of MSA

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**Legend:**
- **D** = Design
- **C** = Contracting
- **I** = Implementation
- **X** = Closure
Annex 3

CUMULATIVE CONTRACTING AND DISBURSEMENT SCHEDULE OF EU FUNDING

Title: Further institutional building, consolidation and strengthening of MSA

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<th></th>
<th>01/12/2004</th>
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<td>DISBURSED</td>
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All figures in Euros