COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 11.4.2003 COM(2003) 182 final

2003/0065 (ACC) 2003/0066 (ACC)

Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products

Proposal for a

COUNCIL DECISION

on the conclusion of an Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products - ACAA -

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. EXPLANATORY MEMORANDUM

On the basis of negotiating directives adopted by the Council on 21.9.92 as amended by the decision adopted by the Council on 19.07.2002, and of the specific decision issued by the Council in June 1997 addressing guidelines to the Commission for the negotiation of European Conformity Assessment Agreements with Central and Eastern European Countries, the Commission has negotiated and initialled an Agreement on Conformity assessment and Acceptance of industrial products with Malta (hereinafter referred to as "ACAA").

The text of this Agreement is attached to this Communication. The following provides an assessment of the Agreement in the light of the negotiating directives approved by the Council, and proposes that the Council authorises the signature of the Agreement and decides to approve its conclusion on behalf of the Community. This assessment and these proposals are similar to the relevant documents for the PECAs concluded by the Council with Hungary, the Czech Republic, Latvia and Lithuania.

I.1 ASSESSMENT OF THE AGREEMENT

This sort of agreement is intended to work only during the pre-accession period. However, since, like other candidate countries, there is no Europe Agreement to offer an appropriate legal framework, it was decided, in consultation with the 133 Committee, to adopt this agreement as a stand alone agreement.

The ACAA follows the general principles laid down in the Commission's communication on Community External Trade Policy in the field of standards and conformity assessment¹ under its paragraph 49. The ACAA is a transitional arrangement, and thus will terminate with the candidate country accession.

The ACAA provides for an extension of certain benefits of the Internal Market in sectors already aligned. The ACAA thus facilitates market access by eliminating technical barriers to trade with respect to industrial products. To this end, the ACAA provides for two mechanisms, a) for the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties, and b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent national law.

The first mechanism, i.e. the mutual acceptance of industrial products, provides that products covered by the ACAA that are lawfully placed on the market of one of the Parties has access on the same terms to the other Party's market. This provision adds the predictability that is necessary to manufacturers and exporters, confirming in advance that industrial products under this mechanism may freely move between the Parties. The annexes making this mechanism operational have still to be negotiated.

The second mechanism is a particular type of mutual recognition agreement (MRA) in which the mutual recognition operates on the basis of the *acquis communautaire*. It allows industrial products certified by Notified Bodies in the European Union to be placed on the Maltese market without having to undergo any further approval procedures, and vice-versa. The

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COM(1996) 564 final. 13.11.1996.

following sectors are covered: electrical safety, electromagnetic compatibility, machinery, lifts, personal protective equipment's, equipment and protective systems intended for use in potentially explosive atmospheres, safety of toys, and radio communication and telecommunication terminal equipment.

The draft ACAA with Malta is in line with the PECAs concluded by the Council with Latvia, Lithuania², Hungary and the Czech Republic³. Malta has taken over the Community technical legislation in the sectors covered by the Agreement and participates in the European organisations in the field of standards, metrology, testing laboratories and accreditation.

The ACAA consists of a framework agreement and a series of annexes as referred to above. A unilateral Community declaration inviting the Maltese representatives to experts meetings and committees established under the Community law referred to in the annexes is attached to the Final Act, making it clear that this will not entail any participation in the Community decision-making process. An assessment of the ACAA is made in the next paragraphs.

I.1.1 FRAMEWORK AGREEMENT

An article-by-article assessment follows:

Pre-amble. This sets out the basic objective of the ACAA which is that, as the application for membership of the European Union implies the implementation of the *acquis communautaire* by the applicant country, it provides the opportunity to extend certain benefits of the Single Market in certain sectors already aligned before.

Article 1: Purpose. This article establishes the purpose of the ACAA, namely the elimination of technical barriers to trade in respect to industrial products. The ACAA provides for two mechanisms, a) for the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties, and b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent national law.

Article 2: Definitions. This is self-explanatory. Definitions of industrial products, Community and national law have been included. All pieces of legislation and implementation measures (administrative provisions, guidelines and other means of /implementation of the legislation) are covered by the definitions of Community and national law.

Article 3: Alignment of legislation. This contains a commitment for Malta to take appropriate measures in order to maintain or complete the take-over of Community law, namely in the field of technical legislation and for the purpose of the ACAA. Together with the 4th whereas, it means that the alignment is an ongoing process and the Parties agree to iron out any problems of transposition that could appear later.

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Council Decision 2002/608/EC of 25 June 2002 on the conclusion of a PECA with the Republic of Latvia (OJ L 202, 31.07.2002, p.1) Council Decision 2002/609/EC of 25 June 2002 on the conclusion of a PECA with the Republic of Lithuania (OJ L 202, 31.07.2002, p. 19)

Council Decision 2001/365/EC of 4 April 2001 on the conclusion of a PECA with the Czech Republic (OJ L 135, 17.05.2001, p.1) Council Decision 2001/366/EC of 4 April 2001 on the conclusion of a PECA with Hungary (OJ L 135, 17.05.2001, p.35)

- **Article 4: Mutual acceptance of industrial products**. The principle under Article 1.1) is detailed in this article. It provides that listing industrial products in such annexes will confirm that these products can freely circulate between the Parties. As already stated, no such annex has been negotiated yet.
- Article 5: Mutual recognition of the results of conformity assessment procedures. This provision expands the principle under Article 1.2). This kind of recognition is similar to the one in Mutual Recognition Agreements, with the special feature that all legislation and standards are aligned. The sectoral annexes will contain the references to the relevant Community and national legislation.
- **Article 6: Safeguard clause**. This sets up the right of each Party to deny market access when such Party is able to demonstrate that a product might endanger the legitimate concern which is protected by legislation listed in the annexes (safety and/or public health of users or other persons mainly). The annexes provide for the detailed procedures to be used in such cases.
- **Article 7: Extension of coverage**. The Parties may modify the scope and coverage of this Agreement through an amendment of the annexes or by the addition of new annexes as soon as all alignment conditions are met.
- **Article 8: Origin.** The provisions of this Agreement shall apply to industrial products irrespective of their origin.
- Article 9: Obligations of Parties as regards their authorities and bodies. This article obliges the Parties to ensure that their respective authorities continuously monitor the technical competence and compliance of the notified bodies and have the necessary power and expertise for designating, suspending, and withdrawing their bodies. In addition, it obliges the Parties to ensure that their respective notified bodies continuously comply with the requirements of Community or national law and maintain their technical competence to carry out the tasks for which they have been notified.
- **Article 10: Notified bodies**. This describes the procedure for the notification of bodies to assess conformity in relation to the legal requirements specified in the corresponding annexes. The procedure is simplified and similar to the one applied within the Community. The second paragraph sets out the procedure for the removal of notified bodies.
- Article 11: Verification of notified bodies. This article gives the right to one Party to request a verification of a body notified by the other Party. The verification may be done either by the authorities which have designated the body or together by the authorities of both Parties. If the Parties do not agree on appropriate steps to take, they may notify the Chair of the Association Council of their dissent, and leave to the Association Council to decide on appropriate action. The notified body would then be suspended from the notification of the Association Council until a final decision is taken.
- **Article 12: Exchange of information.** A transparency provision to ensure a correct and uniform application and interpretation of the Agreement. The Parties are advised to encourage their bodies to co-operate in order to establish mutual recognition agreements in the voluntary sphere.
- **Article 13: Confidentiality.** A classical provision to avoid disclosing information acquired under this Agreement.

Article 14: Management of the Agreement. A Joint Committee consisting of representatives of the two Parties is established. This Joint Committee will be responsible for the effective functioning of the Agreement. It shall determine its own Rules of Procedure.

Article 15: Technical co-operation and assistance. This confirms the Community policy on technical co-operation and assistance with a view to properly implementing this Agreement.

Article 16: Agreements with other countries. This confirms that, unless otherwise agreed, the ACAA does not entail any obligation, for one Party, to accept conformity assessments carried out in another country, even if there is an agreement on recognition of conformity assessment between the other Party and any other third country.

Article 17: Entry into force. This is a standard provision that provides the arrangement for the entry into force.

I.1.2 THE ANNEXES TO THE AGREEMENT

I.1.2.1 ANNEXES ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

There follows an assessment of the content of the annexes in terms of their coverage, and other implications where relevant. In making this assessment, the Commission has kept in mind the following elements:

- a. the overall consistency with the Community policy objectives in the field of standardisation, certification and conformity assessment for the sectors and industrial products covered;
- b. the overall consistency with Community policy objectives in the field of the removal of technical barriers to trade;

The sectoral assessment is followed in item I.2 by an overall appreciation of the benefits of the Agreement.

Annexes on electrical safety, electromagnetic compatibility, machinery, lifts, personal protective equipment's, equipment and protective systems intended for use in potentially explosive atmospheres, safety of toys, and radio communication and telecommunication terminal equipment

These annexes on mutual recognition of results of conformity assessment cover a range of industrial products subject to third party conformity assessment under the New Approach Directives in the relevant sectors All these annexes present the same structure.

Coverage is determined by the relevant Community or national law, listed under *Section I* of each annex. *Section II*, on notifying authorities, lists the authorities responsible for the designation of bodies in the Member Sates and Malta. *Section III*, on notified bodies, makes reference to the notification of all Conformity Assessment Bodies notified by the Member States and by Malta. *Section IV*, on specific arrangements, fixes the two procedures for the safeguard clause, relating to industrial products and to harmonised standards.

I.1.2.2 ANNEXES ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

No such annexes have been negotiated for the moment. The ACAA provides nevertheless the basis for such acceptance of products, similar to the one which operates in the Community.

I.1.2.3 UNILATERAL DECLARATION

This is attached to the Final Act and is annexed to this Communication.

Unilateral Community Declaration relating to attendance of the Maltese representatives to Committees. Through this declaration, Malta is invited to send observers to the meetings of the Committees established or referred to under the Community legislation included in the annexes. This declaration follows the principles of the Commission Communication on "Participation of candidate countries in Community programmes, agencies and committees" ⁴.

I.1.3 RELATIONS WITH EFTA /EEA MEMBER COUNTRIES

In accordance with the general information and consultation procedures set out in the European Economic Area-Agreement and Agreement 12 of that Agreement, the Commission kept EFTA/EEA Member Countries regularly informed on the progress of the negotiations and informed them on the final result thereof. The EFTA/EEA Member Countries are in the initial stage of negotiating a parallel mutual recognition agreement with Malta.

I.2 OVERALL APPRECIATION

The Commission considers that the proposed ACAA creates an acceptable balance of benefits for all parties in the pre-accession framework. In all sectors the Community has secured effective market access - in terms of access to all mandatory procedures of the other party. The ACAA confirms that Malta has taken over the Community legislation in certain sectors before its accession. Both political and commercial benefits are achieved with the ACAA.

The Agreement will allow Community exporters, if they so choose, to test and certify their industrial products to the same (aligned) requirements prior to export, and then access that market without any further conformity assessment requirements. The certification procedures will only need to be carried out one time for both markets and against the same aligned requirements or standards. The recognition of certification will permit savings and stimulate exports. European industry federations were consulted and supported unequivocally the Agreement.

Industrial groups, while supporting the Agreement, have not always been able to quantify the costs or time taken to obtain conformity assessment of their industrial products in Malta. The precise extent of savings in time, cost and market opportunity of this Agreement is therefore not feasible in every case to determine. This may only be possible once the Agreement has been in operation for some time. However, on the basis of a rough calculation, it is estimated that this Agreement would create cost saving opportunities for the European exporting industry of around \in 5.25 million per year and about \in 2.25 million per year in terms of cost savings to Maltese exporters to the EC. Some of these savings will be passed on to European importers and consumers.

Trade figures between the EC and Malta are attached for information. In 2001 the general trade balance in sectors covered by this Agreement shows a trade surplus for EU of around € 225 million. However, the trade surplus is for Malta in the toys sector . It is expected that trade will increase further when the ACAA is in force.

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⁴ Point 4.2.b. COM(1999) 710 final 20.12.1999.

Working hypothesis that certification and other related costs amount to an average of 1.5 % of trade

In fact, most benefits are clearly not quantifiable, such as reduced time for accessing markets, better predictability, less protectionism, and harmonisation of systems. What can be ascertained is that any agreement provides reciprocal levels of market access, in terms of conformity assessment.

These advantages outweigh greatly the resources that the Commission will have to engage in maintenance activities of the Agreement, evaluated at 0.8 person per year and some travel and other expenses relating to meetings and other activities such as editing guides.

In terms of the benefits to Malta, the ACAA will facilitate access to the Community market and will give political credit for having aligned its legislation. Malta regards the ACAA as a means to develop closer industrial relations with the EU and fully to integrate certain sectors with the Single Market before accession.

II. THE DRAFT COUNCIL DECISIONS

A proposal for two Council decisions is attached. Both are similar to the Commission proposals for the previous Council decisions on the signature on behalf of the Community and conclusion of the PECAs with Hungary and the Czech Republic⁶ and with Latvia and Lithuania⁷, except that the present Agreement stands alone rather than being a Protocol to Europe Agreement, which has not been negotiated with Malta.

The first one is concerned with the signature of the Agreement. Signature is required by Malta for the adoption of this Agreement. It is accordingly proposed that the President of the Council be authorised to designate the person empowered to sign the Agreement on behalf of the Community, subject to conclusion later, on the basis of Articles 133 and 300 of the Treaty.

The proposal for a second decision is concerned with the adoption of the ACAA. In this context, the Council should, in line with the previous Council decisions on the conclusion of PECAs and mutual recognition agreements, establish the appropriate Community procedure for the implementation and management of the Agreement.

In particular, the Council should confer on the Commission, in consultation with the special committee appointed by the Council, the necessary powers for the management and implementation of the Agreement. Moreover, the Council should delegate to the Commission, acting in consultation with the special committee, the necessary powers to determine in certain cases the Community position with regard to this Agreement in the Joint Committee set up under the Agreement. The delegation of powers to the Commission includes delegation of the power to add new Annexes, since, as indicated in the Preamble, membership of the European Union, for which Malta has applied, implies the effective implementation of all the Community *acquis*.

The Commission therefore proposes that the Council adopts the attached decisions on the signature and conclusion of the ACAA.

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For the Czech Republic, Council decision 2001/365/EC of 4 April 2001 (OJ L 135, 17.05.2002, p.1). For Hungary, Council decision 2001/366/EC of 4 April 2001 (OJ L 135, 17.05.2002, p.35).

Council Decision 2002/608/EC of 25 June 2002 on the conclusion of a PECA with the Republic of Latvia (OJ L 202, 31.07.2002, p.1) Council Decision 2002/609/EC of 25 June 2002 on the conclusion of a PECA with the Republic of Lithuania (OJ L 202, 31.07.2002, p. 19).

EU-Malta Trade - Annex to the Explanatory Memorandum to the Council. (1000€)

	1999				2000				2001			
	IMPORT	EXPORT	Balance	Total Trade	IMPORT	EXPORT	Balance	Total Trade	IMPORT	EXPORT	Balance	Total Trade
Electrical sector	52.518	92.476	39.958	144.994	63.906	122.185	58.279	186.091	63.360	150.624	87.263	213.984
Machinery	25.247	156.866	131.618	182.113	34.116	195.194	161.078	229.310	45.423	197.669	152.246	243.092
Lifts	0	2.101	2.101	2.101	26	2.852	2.827	2.878	0	2.559	2.559	2.559
Toys	40.166	7.835	-32.331	48.001	51.020	8.100	-42.920	59.120	42.012	8.840	-33.172	50.852
RTTE	205	10.369	10.163	10.574	827	15.323	14.496	16.150	1.208	19.182	17.975	20.390
Total sectors	118.136	269.647	151.509	387.783	149.895	343.654	193.760	493.549	152.003	378.874	226.871	530.877

Source: Comext/Eurostat. . Date extracted on 29/11/02 and elaborated by DG Trade-F2

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on the signature on behalf of the Community of an Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133, in conjunction the first sentence of the first subparagraph of Article 300 (2) thereof,

Having regard to the proposal from the Commission⁸,

Whereas:

- (1) The Agreement on Conformity Assessment and Acceptance of Industrial Products between the European Community and Malta has been negotiated by the Commission on behalf of the Community.
- (2) Subject to its possible conclusion at a later date, the Agreement on Conformity Assessment and Acceptance of Industrial Products initialled in Brussels on 30th April 2002 should be signed.

HAS DECIDED AS FOLLOWS:

Sole Article

Subject to a possible conclusion at a later date, the President of the Council is hereby authorised to designate the person empowered to sign, on behalf of the Community, the Agreement with Malta on Conformity Assessment and Acceptance of Industrial Products.

Done at Brussels, [...]

For the Council The President

⁸ OJ C [...], [...], p. [...].

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on the conclusion of an Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products. - ACAA -

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof, in conjunction with the first sentence of the first subparagraph of Article 300(2), and the first sentence of the first subparagraph of Article 300(3) thereof,

Having regard to the proposal from the Commission⁹,

Whereas:

- (1) The draft Agreement on Conformity Assessment and Acceptance of Industrial Products between the European Community and Malta, has been signed in Brussels on [...2003], on behalf of the Community, and should be approved.
- (2) The appropriate internal procedures should be established to ensure the proper functioning of the Agreement.
- (3) It is necessary to empower the Commission to make certain technical amendments to this Agreement and to take certain decisions for its implementation,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement with Malta on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as "the Agreement"), as well as the declaration annexed to the Final Act thereto, are hereby approved on behalf of the European Community.

The text of the Agreement, and of the declaration annexed to the Final Act thereto, is attached to this Decision.

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⁹ OJ C [...], [...], p. [...].

Article 2

The President of the Council is hereby authorised to designate the person empowered to transmit, on behalf of the Community, the diplomatic note provided for in Article 17 of the Agreement.

Article 3

- 1. The Commission, after consultation with the special committee appointed by the Council, shall:
 - (a) carry into effect the notifications, acknowledgements, suspensions and withdrawals of bodies, and appointments of joint team or teams of experts, in accordance with Articles 10, 11 and 14 (3) (c) of the Agreement;
 - (b) bring about the consultations, exchange of information, the requests for verifications and for participation in verifications, in accordance with Articles 3, 12 and 14 (d) (e), and Sections III and IV of the Annexes to the Agreement concerning Electrical Safety, Electromagnetic Compatibility (EMC), Machinery, Lifts, Personal Protective Equipment (PPE), Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX), Safety of toys and Radio communication and telecommunication terminal equipment
 - (c) if necessary, reply to requests in accordance with Article 11, Sections III and IV of the Annexes to the Agreement concerning Electrical Safety, Electromagnetic Compatibility (EMC), Machinery, Lifts, Personal Protective Equipment (PPE), Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX), Safety of toys and Radio communication and telecommunication terminal equipment
- 2. Following consultation of the special committee referred to in paragraph 1 of this Article, the Commission shall determine the position to be taken by the Community in the Association Council and, where applicable, in the Association Committee, with regard to:
 - (a) amendments to the Annexes in accordance with Article 14, point (a) of the Agreement;
 - (b) addition of new Annexes in accordance with Article 14, point (b) of the Agreement;
 - (c) any decisions regarding disagreements on the results of the verifications and the suspensions, in part or totally, of any notified body in accordance with the second and third subparagraphs of Article 11 of the Agreement;

- (d) any measures taken in the application of the safeguard clauses in Section IV of the Annexes of the Agreement concerning Electrical Safety, Electromagnetic Compatibility (EMC), Machinery, Lifts, Personal Protective Equipment (PPE), Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX), Safety of toys and Radio communication and telecommunication terminal equipment
- (e) any measures concerning the verification, suspension, or withdrawal of industrial products as having mutual acceptance under Article 4 of the Agreement.

Done at Brussels, [...]

For the Council The President

Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products -ACAA-

The European Community and Malta, hereinafter referred to as "the Parties",

Whereas Malta has applied for membership of the European Union and such membership implies the effective implementation of the *acquis* of the European Community,

Recognising that the progressive adoption and implementation of Community law by Malta provides the opportunity to extend certain benefits of the Internal Market and to ensure its effective operation in certain sectors before accession,

Considering that, in the sectors covered by this Agreement, the Maltese national law substantially takes over the Community law,

Considering their shared commitment to the principles of free movement of goods and to promoting product quality, so as to ensure the health and safety of their citizens and the protection of the environment, including through technical assistance and other forms of co-operation between them,

Considering the Agreement of 5 December 1970 creating an Association between the European Economic Community and Malta¹⁰,

Desiring to conclude an Agreement on Conformity Assessment and Acceptance of industrial products (hereafter "the Agreement") providing for the application of the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties and of the mutual recognition of the results of conformity assessment of industrial products which are subject to Community or national law,

Noting the close relationship between the European Community and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel European Conformity Assessment Agreement between Malta and these countries equivalent to this Agreement,

Bearing in mind their status as Contracting Parties to the Agreement establishing the World Trade Organisation, and conscious in particular of their obligations under the World Trade Organisation Agreement on Technical Barriers to Trade,

Have agreed as follows:

Article 1

Purpose

The purpose of this Agreement is to facilitate the elimination by the Parties of technical barriers to trade in respect of industrial products. The means to this end is the progressive adoption and implementation by Malta of national law, which is equivalent to Community law.

This Agreement provides for:

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OJ L61 of 14.03.1971, p.2

- 1) the mutual acceptance of industrial products, listed in the annexes on "mutual acceptance of industrial products", which fulfil the requirements to be lawfully placed on the market in one of the Parties;
- 2) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent Maltese national law, both listed in the annexes on "mutual recognition of results of conformity assessment".

Article 2

Definitions

For the purpose of this Agreement,

"Industrial products" means products listed in Chapters 25 to 97 of the Combined Nomenclature.

"Community law" means any legal act and implementing practice of the European Community applicable to a particular situation, risk or category of industrial products, as interpreted by the Court of Justice of the European Community.

"National law" means any legal act and implementing practice by which Malta takes over the Community law applicable to a particular situation, risk or category of industrial products.

The terms used in this Agreement shall have the meaning given in Community law and the Maltese national law.

Article 3

Alignment of legislation

For the purpose of this Agreement, Malta agrees to take appropriate measures, in consultation with the European Commission, to maintain or complete the take-over of Community law, in particular in the fields of standardisation, metrology, accreditation, conformity assessment, market surveillance, general safety of products, and producer's liability.

Article 4

Mutual Acceptance of industrial products

The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the annexes on "mutual acceptance of industrial products", which fulfil the requirements to be lawfully placed on the market of a Party, may be placed on the market of the other Party, without further restriction.

Article 5

Mutual Recognition of the results of conformity assessment procedures

The Parties agree to recognize the results of conformity assessment procedures carried out in accordance with the Community or national law listed in the annexes on "mutual recognition of the results of conformity assessment". The Parties shall not require procedures to be repeated, nor shall they impose additional requirements, for the purposes of accepting that conformity.

Article 6

Safeguard clause

Where a Party finds that an industrial product placed on its territory by virtue of the present Agreement, and used in accordance with its intended use, may compromise the safety or health of users or other persons, or any other legitimate concern protected by legislation identified in the annexes, it may take appropriate measures to withdraw such a product from the market, to prohibit its placing on the market, putting into service or use, or to restrict its free movement. The annexes shall provide for the procedure to be applied in such cases.

Article 7

Extension of Coverage

As Malta adopts and implements further national law taking over Community law, the Parties may amend the annexes or conclude new ones, in accordance with the procedure laid down in Article 14.

Article 8

Origin

The provisions of this Agreement shall apply to industrial products irrespective of their origin.

Article 9

Obligation of Parties as regards their authorities and bodies

The Parties shall ensure that authorities under their jurisdiction which are responsible for the effective implementation of Community and national law shall continuously apply it. Further, they shall ensure that these authorities are able, where appropriate, to notify, suspend, remove suspension and withdraw notification of bodies, to ensure the conformity of industrial products with Community or national law or to require their withdrawal from the market.

The Parties shall ensure that bodies, notified under their respective jurisdiction to assess conformity in relation to requirements of Community or national law specified in the annexes, continuously comply with the requirements of Community or national law. Further, they shall take all necessary steps to ensure that these bodies maintain the necessary competence to carry out the tasks for which they are notified.

Article 10

Notified bodies

Before the entry into force of this Agreement, Malta and the European Community will agree on the lists of the bodies notified for the purpose of the Agreement.

After the entry into force of the Agreement, the following procedure shall apply for the notification of bodies to assess conformity in relation to the requirements of Community or national law specified in the annexes:

- a) a Party shall forward its notification to the other Party in writing;
- b) on the acknowledgement of the other Party, given in writing, the body will be considered as notified and as competent to assess conformity in relation to the requirements specified in the annexes from that date.

If a Party decides to withdraw a notified body under its jurisdiction, it shall inform the other Party in writing. The body will cease to assess conformity in relation to the requirements specified in the annexes from the date of its withdrawal at the latest. Nevertheless, conformity assessment carried out before that date shall remain valid, unless otherwise decided by the Joint Committee set up by Article 14 of this Agreement (hereafter "the Joint Committee").

Article 11

Verification of notified bodies

Each Party may request the other Party to verify the technical competence and compliance of a notified body under its jurisdiction. Such request will be justified in order to allow the Party responsible for the notification to carry out the requested verification and report speedily to the other Party. The Parties may also jointly examine the body, with the participation of the relevant authorities. To this end, the Parties shall ensure the full co-operation of bodies under their jurisdiction. The Parties shall take all appropriate steps, and use whatever available means may be necessary, with a view to resolving any problems which are detected.

If the problems cannot be resolved to the satisfaction of both Parties, they may notify the chairman of the Joint Committee of their dissent, giving their reasons. The Joint Committee may decide on appropriate action.

Unless and until decided otherwise by the Joint Committee, the notification of the body and the recognition of its competence to assess conformity in relation to the requirements of Community or national law specified in the annexes shall be suspended in part or totally from the date on which the disagreement of the Parties has been notified to the chairman of the Joint Committee.

Article 12

Exchange of information and Co-operation

In order to ensure a correct and uniform application and interpretation of this Agreement, the Parties, their authorities and their notified bodies shall:

- a) exchange all relevant information concerning implementation of law and practice including, in particular, on procedure to ensure compliance of notified bodies;
- b) take part, as appropriate, in the relevant mechanisms of information, co-ordination and other related activities of the Parties.
- c) encourage their bodies to co-operate with a view to establishing mutual recognition arrangements in the voluntary sphere.

Article 13

Confidentiality

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Agreement.

Article 14

Management of the Agreement

- 1. A Joint Committee consisting of representatives of the two Parties shall be established. The Joint Committee will be responsible for the effective functioning of this Agreement.
- 2. The Joint Committee shall take decisions and adopt recommendations by consensus. It shall meet at the request of either Party under the co-chairmanship of both Parties. It shall determine its own Rules of Procedure.
- 3. The Joint Committee may consider any matter related to the operation of this Agreement. In particular, it shall have the power to take decisions regarding:
- a) amending the annexes;
- b) adding new annexes;
- c) appointing a joint team or teams of experts to verify the technical competence of a notified body and its compliance with the requirements;
- d) exchanging information on proposed and actual modifications of the Community and national law referred to in the annexes;
- e) considering new or additional conformity assessment procedures affecting a sector covered by an annex;
- f) resolving any questions relating to the application of this Agreement.

Article 15

Technical co-operation and assistance

The European Community may provide technical co-operation and assistance to Malta where necessary in order to support the effective implementation and application of this Agreement.

Article 16

Agreements with other Countries

Agreements on conformity assessment concluded by either Party with a country which is not a Party to this Agreement shall not entail an obligation upon the other Party to accept the results of conformity assessment procedures carried out in that third country, unless there is an explicit agreement between the Parties in the Joint Committee.

Article 17

Entry into force, modification and duration

- 1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for entry into force of this Agreement.
- 2. This agreement may be amended by the written agreement of the Parties. Amendments or additions of Sectoral Annexes will be made through the Joint Committee.
- 3. Either Party may terminate this Agreement by giving the other Party six months' notice in writing.

4. In case Malta has not become a Member of the European Union by 1 May 2004, both Parties will meet within a six-month period to review this Agreement in view of the new situation.

Article 18

Final provisions

This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Maltese languages, each text being equally authentic.

Done at , [...]

ANNEXES ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS

(For the record)

ANNEXES ON MUTUAL RECOGNITION

OF RESULTS OF CONFORMITY ASSESSMENT

Table of contents

- 1. Electrical Safety
- 2. Electromagnetic Compatibility (EMC)
- 3. Machinery
- 4. Lifts
- 5. Personal Protective Equipment (PPE)
- 6. Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX)
- 7. Safety of toys
- 8. Radio communication and telecommunication terminal equipment

Annex on Mutual Recognition of results of Conformity Assessment

ELECTRICAL SAFETY

Section I

COMMUNITY AND NATIONAL LAW

Community law: Council Directive 73/23/EEC of 19 February 1973 on the

approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 77, 26.03.1973, p. 29), as last amended by Directive

93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p.1).

National law: L.N. 23 of 1999: Low Voltage Electrical Equipment

Section II

NOTIFYING AUTHORITIES

European Community

- Belgium: Ministère des Affaires Economiques/Ministerie van

Economische Zaken.

- Denmark: Økonomi- og Erhvervsministeriet, Elektricitetsrådet

- France: Ministère de l'économie, des finances et de l'industrie. Direction

Générale de l'Industrie, des Technologies de l'Information et des

Postes (DiGITIP) – SQUALPI.

- Germany: Bundesministerium für Arbeit und Sozialordung

- Greece: Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας

(Ministry of Development. General Secretariat of Industry).

- Spain: Ministerio de Ciencia y Tecnología.

- Ireland: Department of Enterprise and Employment

- Italy: Ministero delle Attività Produttive

- Luxembourg: Ministère de l'Economie- Service de l'Energie de l'Etat.

Ministère du Travail (Inspection du Travail et des Mines).

- Netherlands: Minister van Volksgezondheid, Welzijn en Sport (consumer

goods).

Minister van Sociale Zanken en Werkgelegenheid (others).

- Austria: Bundesministerium für Wirtschaft und Arbeit.

- Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade.

- Finland: Kauppa-ja teollisuusministeriö / Handels- och industriministeriet.

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontrol (SWEDAC).

- United Kingdom: Department of Trade and Industry

- Malta Ministry or Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Malta in accordance with Article 10 of this Agreement.

Malta

Bodies which have been authorised by the Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Agreement.

Section IV

SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products:

- 1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out.

- 5. Where the Joint Committee finds that the measure is:
- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

ELECTROMAGNETIC COMPATIBILITY

Section I

COMMUNITY AND NATIONAL LAW

Community law: Council Directive 89/336/EEC of 3 May 1989 on the

approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 139, 23.05.1989, p. 19), as last amended by Council Directive 93/68/EEC of 22 July 1993

(OJ L 220, 30.8.1993, p.1).

National law: L.N. 24 of 1999: Electromagnetic Compatibility

Section II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Ministère des Affaires Economiques/Ministerie van

Economische Zaken.

- Denmark: Telestyrelsen.

- France: Ministère de l'économie, des finances et de l'industrie. Direction

Générale de l'Industrie, des Technologies de l'Information et des

Postes (DiGITIP) - SQUALPI.

- Germany: Bundesministerium für Wirtschaft und Technologie.

- Greece: Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας

(Ministry of Development. General Secretariat of Industry).

- Spain: Ministerio de Ciencia y Tecnología.

- Ireland: Department of Enterprise and Employment

- Italy: Ministero delle Attività Produttive

- Luxembourg: Ministère de l'Economie-Service de l'Energie de l'Etat

- Netherlands: Ministerie van Verkeer en Waterstaat

- Austria: Bundesministerium für Wirtschaft und Arbeit.

- Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade.

ICP – Autoridade Nacional de Comunicações (ANACOM)

- Finland: Kauppa-ja teollisuusministeriö / Handels- och industriministeriet.

For EMC aspects of telecommunications and radio equipment:

Liikenne-javiestintäministeriö / Kommunikatiosministeriet.

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontrol (SWEDAC).

- United Kingdom: Department of Trade and Industry

- *Malta*: Ministry for Economic Services

Section III

NOTIFIED AND COMPETENT BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Malta in accordance with Article 10 of this Agreement.

Malta

Bodies which have been authorised by Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Agreement.

Section IV

SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products:

- 1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out.
- 5. Where the Joint Committee finds that the measure is:

- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

MACHINERY

Section I

COMMUNITY AND NATIONAL LAW

Community law: European Parliament and Council Directive 98/37/EC of 22 June

1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.07.1998, p.1), as amended by European Parliament and Council Directive 98/79/EC of 27

October 1998 (OJ L 331, 07.12.1998, p.1).

National law: L.N. 250 of 2001: Machinery

Section II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Ministère de l'Emploi et du Travail / Ministerie voor Arbeid en

Tewerkstelling

- Denmark: Arbejdsministeriet, Arbejdstilsynet.

- France: Ministère de l'Emploi et de la Solidarité, Direction des relations du

travail, Bureau CT 5.

- Germany: Bundesministerium für Arbeit und Sozialordnung.

- Greece: Ministry of Development. General Secretariat of Industry.

- Spain: Ministerio de Ciencia y Tecnología.

- Ireland: Department of Enterprise and Employment.

- Italy: Ministero delle Attività Produttive

- Luxembourg: Ministère du Travail (Inspection du travail et des Mines).

- Netherlands: Minister van Sociale Zanken en Werkgelegenheid

- Austria: Bundesministerium für Wirtschaft und Arbeit

-Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade.

- Finland: Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet.

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontroll (SWEDAC).

- U.K. Department of Trade and Industry.

Malta: Ministry for Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to the Malta in accordance with Article 10 of this Agreement.

Malta

Bodies which have been designated by the Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Agreement.

Section IV

SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products:

- 1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. n case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out
- 5. Where the Joint Committee finds that the measure is:
- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

- B. Safeguard clause relating to harmonised standards:
- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

Annex on Mutual Recognition of resuls of conformity assessment

LIFTS

Section I

COMMUNITY AND NATIONAL LAW,

Community law: European Parliament and Council Directive 95/16/EC of 29

June 1995 on the approximation of the laws of the Member

States relating to lifts (OJ L 213, 07.09.1995, p.1).

National law: L. N. 249 of 2001: Lifts

Section II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Ministère des Affaires Economiques/Ministerie van

Economische Zaken.

- Denmark: Direktoratet for Arbejdstilsynet

- France: Ministère de l'equipment, des transports et du logement.

Direction Générale de l'urbanisme, de l'habitat et de la

construction

- Germany: Bundesministerium für Arbeit und Sozialordnung

- Greece: Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηγανίας

(Ministry of Development. General Secretariat of Industry).

- Spain: Ministerio de Ciencia y Tecnología.

- Ireland: Department of Enterprise and Employment

- Italy: Ministero delle Attività Produttive

- Luxembourg: Ministère du Travail (Inspection du Travail et des Mines)

- Netherlands: Minister van Sociale Zanken en Werkgelegenheid

- Austria: Bundesministerium für Wirtschaftliche und Arbeit .

- Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade

- Finland: Kauppa-ja teollisuusministeriö/Handels-och industriministeriet

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontrol (SWEDAC).

- United Kingdom: Department of Trade and Industry

Malta: Ministry for Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to Malta in accordance with Article 10 of this Agreement.

Malta

Bodies which have been designated by Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products:

- 1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of its investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out.
- 5. Where the Joint Committee finds that the measure is:
 - (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

(b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

Annex on Mutual Recognition of results of Conformity Assessment

PERSONAL PROTECTIVE EQUIPMENT

Section I

COMMUNITY AND NATIONAL LAW

Community law: Council Directive 89/686/EEC of 21 December 1989 on the

approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18), as last amended by Parliament and Council Directive 96/58/EC of 3 September 1996 (OJ L 236, 18.09.1996, p.44).

National law: L.N. 122 of 1998: Personal Protective Equipment

Section II

NOTIFYING AUTHORITIES

European Community

- Belgium: Ministère de l'Emploi et du Travail/ Ministerie voor Arbeid en

Tewerkstelling

- Denmark: Arbejdsministeriet, Arbejdstilsynet.

- France: Ministère de l'emploi et de la solidarité, Direction des relations

du travail, Bureau CT 5.

Ministère de l'économie, des finances et de l' industrie, Direction générale de l'industrie, des technologies de

l'information et des postes (DiGITIP) - SQUALPI.

- Germany: Bundesministerium für Arbeit und Sozialordnung.

- Greece: Ministry of Development. General Secretariat of Industry.

- Spain: Ministerio de Ciencia y Tecnología.

- Ireland: Department of Enterprise, Trade and Employment.

- Italy: Ministero delle attività produttive.

- Luxembourg: Ministère du Travail (Inspection du Travail et des Mines).

- Netherlands: Ministerie van Volksgezondheid, Welzijn en Sport.

- Austria: Bundesministerium für Wirtschaft und Arbeit.

- Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade.

- Finland: Sosiaali-ja terveyministeriö / Social-och hälsovårdsministeriet.

- Sweden: Under the authority of the Government of Sweden:Styrelsen

för ackreditering och teknisk kontroll (SWEDAC).

- United Kingdom: Department of Trade and Industry.

Malta: Ministry for Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to Malta in accordance with Article 10 of this Agreement.

Malta

Bodies which have been authorised by Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Agreement.

Section IV

SPECIFIC ARRANGEMENTS

Safeguard clauses

A. Safeguard clause relating to industrial products:

- 1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out.
- 5. Where the Joint Committee finds that the measure is:
- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

(b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

Section I

COMMUNITY AND NATIONAL LAW

Community law: European Parliament and Council Directive 94/9/EC of 23

March 1994 on the approximation of the laws of the Member States relating to Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (OJ L 100,

19.4.1994, p.1).

National law: L.N. 107 of 1999: Equipment and Protective Systems in

Potentially Explosive Atmospheres

Section II

NOTIFYING AUTHORITIES

European Community

- Belgium: Ministère des Affaires Economiques/Ministerie van

Economische Zaken.

- Denmark: For electrical aspects:

Økonomi- og Erhvervsministeriet, Elektricitetsrådet

For mechanical aspects:

Arbejdsministeriet, Arbejdstilsynet

- France: Ministère de l'économie, des finances et de l'industrie,

Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI), Sous-direction de la sécurité industrielle

- Germany: Bundesministerium für Arbeit und Sozialordnung

- Greece: Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας

(Ministry of Development. General Secretariat of Industry).

- Spain: Ministerio de Ciencia y Tecnología.

- Ireland: Department of Enterprise and Employment

- Italy: Ministero delle Attività Produttive

- Luxembourg: Ministère de l'Economie – Service de l'Energie de l'Etat

- Netherlands: Minister van Sociale Zanken en Werkgelegenheid

- Austria: Bundesministerium für Wirtschaft und Arbeit

- Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade

- Finland: Kauppa- ja teollisuusministeriö / Handels-och industriministeriet

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontrol (SWEDAC).

- United Kingdom: Department of Trade and Industry

Malta: Ministry for Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to Malta in accordance with Article 10 of this Agreement.

Malta

Bodies which have been authorised by Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Agreement.

Section IV

SPECIFIC ARRANGEMENTS

1. Transitional arrangements

The certificates issued in the EC Member States in conformity with Directives 76/117/EEC, 79/196/EEC and 82/130/EEC will be recognised as a proof of conformity assessment under the Maltese Act. Based on these certificates, the importer of these products in Malta will issue a declaration of conformity of the relevant product to the applicable requirements referred to in this paragraph.

2. Safeguard Clauses

A. Safeguard clause relating to industrial products.

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out.
- 5. Where the Joint Committee finds that the measure is:
- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards:

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in this Annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION

OF RESULTS OF CONFORMITY ASSESSMENT:

SAFETY OF TOYS

Section I

COMMUNITY AND NATIONAL LAW

Community law: Council Directive of 3 May 1988 on the approximation of

the laws of the Member States concerning the safety of toys (88/378/EEC) (OJ L 187, 16.7.1988, p.1), as amended by Council Directive 93/68/EEC of 22 July 1993

(OJ L 220, 30.08.1993, p.1).

National law: L.N. 16 of 1996: Safety of Toys

Section II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Ministère des Affaires Economiques/Ministerie van

Economische Zaken.

- Denmark: Økonomi- og Erhvervsministeriet, Forbrugerstyrelsen

- France: Ministère de l'Economie et des Finances

- Germany: Bundesministerium für Arbeit und Sozialordnung

- Greece: Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας

(Ministry of Development. General Secretariat of Industry).

- Spain: Ministerio de Ciencia y Tecnología

Instituto Nacional del Consumo

- Ireland: Department of Enterprise and Employment

- Italy: Ministero delle Attività Produttive

- Luxembourg: Ministère du Travail et de l'emploi

- Netherlands: General Inspectorate for Health Protection

- Austria: Bundesministerium für Wirtschaftliche und Arbeit.

- Portugal: Divisao de Estudos de Produtos do Instituto do Consumidor

- Finland: Kauppa-ja teollisuusministeriö/Handels-och industriministeriet

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontrol (SWEDAC).

- United Kingdom: Department of Trade and Industry

- *Malta*: Ministry for Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the Community in accordance with the Community law of Section I and notified to Malta in accordance with Article 10 of this Protocol.

Malta

Bodies which have been authorised by Malta in accordance with the Maltese national law of Section I and notified to the Community in accordance with Article 10 of this Protocol.

Section IV

SPECIFIC ARRANGEMENTS

1. Information concerning the certificate and the technical file

In accordance with Article 10(4) of Directive 88/378/EEC, the Notifying Authorities listed in section II may obtain on request a copy of the certificate and, on reasoned request, a copy of the technical file and the reports on the examinations and tests carried out.

2. Notification of grounds for refusal by approved bodies

In accordance with Article 10(5) of Directive 88/378/EEC, Maltese bodies shall inform the Notifying Authority when refusing to issue an EC type-examination certificate. The Notifying Authority shall likewise notify the Commission of the European Community thereof.

3. Safeguard Clauses

A. Safeguard clause relating to products

- 1. Where a Party has taken a measure to deny free access to its market for products bearing the CE marking, subject to this Annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Joint Committee who may decide to have an expertise carried out.
- 5. Where the Joint Committee finds that the measure is:

- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.
- 3. The Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

RADIO COMMUNICATION AND TELECOMMUNICATION TERMINAL EQUIPMENT

Section I

COMMUNITY AND NATIONAL LAW

Community law: European Parliament and Council Directive 1999/5/EC of 9th

March 1999 on the approximation of the laws of the Member States relating to radio communication and telecommunication terminal equipment and the mutual recognition of their

conformity (OJ L 91, 7.4.1999, p. 10).

Maltese national

law:

national L.N. 329 of 2001: Radio Equipment and Telecommunications

Terminal Equipment and mutual recognition of their conformity

Section II

NOTIFYING AUTHORITIES

European Community:

- Belgium: Ministère des Affaires Economiques

Ministerie van Economische Zaken.

- Denmark: National Telecom Agency (Telestyrelsen)

- France: Ministère de l'Economie, des Finances et de l'Industrie –

Direction Général de l'Industrie, des Technologies de

l'Information et des Postes

- Germany: Bunderministerium für Wirtschaft und Technologie

- Greece: Ministry of Development

- Spain: Ministerio de Ciencia y Technogía

- Ireland: Department of Public Enterprise, Communication Division

- Italy: Ministero delle Comunicazioni

- Luxembourg: Ministère des Transports

- Netherlands: Ministry of Economic Affairs, Radiocommunications Agency

- Austria: Bundesministerium für Verkehr, Innovatioon und Technologie

- Portugal: Under the authority of the Government of Portugal:

Instituto Português da Qualidade

For EMC aspects of telecommunications and radio equipment: Ministerio de Fomento. Subdirección General de Promoción y

Normalización de Servicios de Telecomunicaciones

- Finland: Kauppa-ja teollisuusministeriö/Handels-och industriministeriet

- Sweden: Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontrol (SWEDAC)

- United Kingdom: Department of Trade and Industry

- *Malta*: Ministry for Economic Services

Section III

NOTIFIED BODIES

European Community

Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Malta in accordance with Article 10 of this Protocol.

Malta

Bodies which have been authorized by Malta in accordance with the Maltese national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

Section IV

SPECIFIC ARRANGEMENTS

1. Market Surveillance authorities

In accordance with the general provisions of this Protocol, each Party shall notify to the other Party the authorities established within territory which are to carry out the surveillance tasks related to the operation of the respective legislation listed in Section I.

2. Notification of interface regulations

Each Party shall notify to the other Party the interfaces which they have regulated in their respective territory. When classifying equipment the Community shall take due account of the interfaces regulated in Malta.

3. Application of essential requirements

Where the Commission considers adopting a Decision to apply a requirement contained in article 3.3 of Directive 99/5/EC Malta shall give its opinion on the issue in its capacity of observer in the TCAM before the formal opinion of the Committee is requested.

4. Notification of apparatus causing damage

Where a Party considers that apparatus declared to be compliant with the respective legislation causes serious damage to a network or harmful radio interference or harm to the network or its functioning and has granted the operator the right to refuse its connection, disconnect or to withdraw it from service the Party shall inform such authorisation to the other Party.

5. Safeguard Clauses

A. Safeguard clause relating to industrial products

- 1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.
- 2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.
- 3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.
- 4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.
- 5. Where the Association Council finds that the measure is:
- (a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;
- (b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards

- 1. Where Malta considers that a harmonised standard referred to in the legislation defined in the present annex does not meet the essential requirements of such legislation, it shall inform the Joint Committee giving the reasons therefor.
- 2. The Joint Committee shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.
- 3. The European Community shall keep the Joint Committee and the other Party informed of the proceedings.
- 4. The outcome of the procedure shall be notified to the other Party.
- C. Safeguard clause relating to compliant radio products not intended for the use in a spectrum of one of the Parties

Where a Member State or Malta takes a measure to adopt any appropriate measures with a view to: prohibiting or restricting the placing on its market, and/or requiring the withdrawal from its market,

of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands, the Party shall inform the other Party, giving the reasons therefor.

- 1. Where, after such information, the other Party considers that the measure may be unjustified, and when the problems can not be resolved to the satisfaction of both Parties, they may consult the Joint Committee on the measure, giving their reasons.
- 2. Where, after such consultation, the Joint Committee finds that the measure is:
- (a) justified, it shall immediately so inform the Party who took the initiative and the other Party.
- (b) unjustified, it shall immediately so inform the Party who took the measure and request it to withdraw it.

DECLARATION BY THE COMMUNITY ON THE ATTENDANCE OF MALTESE REPRESENTATIVES AT COMMITTEE MEETINGS

In order to ensure a better understanding of the practical aspects of the application of the acquis communautaire, the Community declares that Malta is invited, under the following conditions, to the meetings of the committees established or referred to under the Community law on electromagnetic compatibility, electrical safety, machinery and gas appliances.

This participation shall be limited to meetings or parts thereof during which the application of the acquis is discussed; it shall not entail attendance at meetings intended to prepare and issue opinions on implementation or management powers delegated to the Commission by the Council.

This invitation may be extended, on a case-by-case basis, to groups of experts convened by the Commission.

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): External trade relations, including access to the markets of non-Community countries

Activit(y/ies): Conformity Assessment Procedures and Acceptance of Industrial Products

TITLE OF ACTION:

Agreement establishing an Association between the European Community and their Member States, of the one part, and Malta, of the other part, on Conformity Assessment and Acceptance of Industrial Products (ACAA)

1. BUDGET LINE(S) + HEADING(S):

B7-8500

A-7010

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): €72380

2.2. Period of application:

The general action undertaken will be of a definite duration. The ACAA has a lifetime limited to the pre-accession period of Malta. The initial period of confidence building will require a more intensive effort but the expenditure should be substantially less after 1 year. However, during the life of the ACAA a continued effort will be needed to ensure management and maintenance of confidence.

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) (see point 6.1.1) \in

	Year					Total
	2003	2004	2005	2006	2007	
Commitments	14550	12270	8520	8520	8520	52380
Payments	14550	12770	8520	8520	8520	52380

(b) Technical and administrative assistance and support expenditure (see point 6.1.2)

Commitments	10000	5000	5000			20000
Payments	10000	5000	5000			20000
Subtotal a+b	2003	2004	2005	2006	2007	Total
Commitments	24550	17270	13520	8520	8520	72380
Payments	25550	17270	13520	8520	8520	72380

(c) Overall financial impact of human resources and other administrative expenditure (see points 7.2 and 7.3)

	2003	2004	2005	2006	2007	Total
Commitments	96310	94300	94300	94300	94300	473510
Payments	96310	94300	94300	94300	94300	473510
TOTAL a+b+c	2003	2004	2005	2006	2007	Total
Commitments	120860	111570	107820	102820	102820	545890
Payments	120860	111570	107820	102820	102820	545890

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:

Proposal does not involve any type of revenue.

3. BUDGET CHARACTERISTICS

Type expend		New	EFTA contribution	Contributions form applicant countries	Heading in financial perspective
Non-comp	Diff	NO	NO	NO	No 4

4. LEGAL BASIS

Article 133 of the Treaty establishing the European Community.

Council Decision 98/552/EC of 24 September 1998 on the implementation by the Commission of activities relating to the Community market access strategy (OJ L 265, 30.9.1998, p. 31).

Proposal for a Council decision N°.... on the conclusion by the European Community of an additional Agreement establishing an Association between the European Community and their Member States, of the one part, and Malta, of the other part, on Conformity Assessment and Acceptance of Industrial Products (ACAA).

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention

5.1.1. Objectives pursued

Community trade objectives in the field of standards and conformity assessment can be summarised. First, to reduce technical barriers to trade in external markets and to prevent the emergence of new ones; and second, to encourage our trading partners to adopt standards and regulatory approaches based on, or compatible with international or European practice.

These Community's trade objectives have so far been pursued through a four-fold strategy. One of them is the negotiation of Mutual Recognition Agreements (MRAs). ACAAs are mutual recognition agreements in which the mutual recognition operates on the basis of the *acquis communautaire*. They are trade agreements with the applicant countries, and are an important element of the pre-accession strategy.

The main objective of the ACAA is to facilitate trade by means of the elimination of technical barriers in respect of industrial products in certain sectors in which the candidate country has aligned its legislation on the *acquis communautaire*.

The purpose of this ACAA is to establish the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market and the mutual recognition of the results of conformity assessment of industrial products subject to the Community technical regulations and to the equivalent Maltese national legislation.

5.1.2. Measures taken in connection with ex ante evaluation

The Agreements on Conformity Assessment and Acceptance of Industrial products (ACAAs) are to be considered in the context of Enlargement policy of the European Union.

The Europe Agreements recognise that a major precondition for the Associated Countries' economic integration into the Community is the integration into the internal market via the approximation of their legislation to the Community.

The Article 76 of the Europe Agreement establishing an Association between the European Community and their Member States, of one part, and Malta, of the other part, promotes the conclusion of agreements on mutual recognition in the field of industrial standards and conformity assessment.

5.1.3. Measures taken following ex post evaluation

The major actions, which will be pursued by the Commission under this budget line, will be the following:

- -Confidence-building activities to facilitate the proper implementation of the ACAA.
- -Management of the ACAA and maintenance of the necessary degree of confidence.
- -Extension of the ACAA to new sectors.

The Commission will be assisted by experts, particularly in regard to sectoral activities. It will however remain the final arbiter in the management of this ACAA.

5.2. Action envisaged and budget intervention arrangements

-the target population

The target population are the exporting companies, business associations, chambers of commerce and public institutions of the European Union and the general consumer which will benefit, or have an interest in, the mutual acceptance of industrial products and recognition of results of conformity assessment certification.

The specific objectives of ACAAs (Agreements on Conformity Assessment and Acceptance of Industrial Products) are:

- -to avoid duplication of certification by economic operators
- -to promote exports, employment, competitivity and investment
- -to reduce costs, in particular for small and medium-sized enterprises and ultimately for the consumer.
- -to extend certain benefits of the Internal Market to Malta
- -to ensure the effective operation of the Internal Market in certain sectors before accession of Malta
- -the concrete measures to be taken to implement the action are:

A. Attendance at the Association Council, the Association Committee or any special subcommittee or group to which has been delegated the management of the ACAA.

This will be attended by Commission officials and some experts from the Member States. Travel and per diem expenses should be foreseen within the normal range of such expenses. The travel expenditure for officials will be covered by the "Mission budget" (A-7010). The reimbursement of travel and related expenses for experts will be made on line B7-8500.

B. Workshops and Seminars

These will be held to familiarise economic and other operators with the requirements of the ACAA. The cost of these seminars will vary according to the subject matter and location, and will include travel and organisational costs (when in the EC) and substantial travel costs when in Malta. Organisational costs will cost c. 3000 Euro each. The number of seminars will vary depending on the individual industrial sectors covered by the ACAA.

C. <u>Verification actions</u>

The competence of the notified bodies will in some cases have to be checked, more so in the initial period of the ACAA, but as a matter of course throughout the life of the ACAA to maintain confidence in the system.

This will involve on-site assessment by teams of experts of notified bodies in the partner country in the initial stages, and subsequently investigation of complaints. This expenditure will cover all sectors of the ACAA and may involve several notified bodies in each sector.

D. Production and dissemination of information

Certain costs may need to be incurred for the dissemination of information. Guides to regulations and assessment procedures may be needed typically at a cost of 10,000 Euro.

5.3. Methods of implementation

Under Article 133 of the Treaty, the Community has exclusive competence for commercial policy and this agreement have been negotiated in accordance with a mandate of the Council of Ministers and in consultation with the 133 Committee. The Commission will be responsible for implementation and management of this Agreement.

The choice of management method (Association Council) has been set out in the ACAA and constitute a minimum necessary for the proper functioning of the ACAA. The use of seminars in the initial phases will allow ensuring familiarity with other systems.

These seminars and verifications are also designed to build mutual confidence; verifications will also be required to ensure this confidence is maintained throughout the life of the ACAA. Confidence and its maintenance are keys to the successful operation of the ACAA.

The importance of this budget is justified when put in perspective with the trade involved in this ACAA and the yearly savings for EU exporters which are expected (estimated on a yearly basis at € 26 million for EU exporters to Malta).

There is no main factors of uncertainty which could affect the specific results of the operation.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. Financial intervention

Commitments (in €)

Breakdown	Year					Total	
	2003	2004	2005	2006	2007		
Committees	5360	5360	5360	5360	5360	26800	
Seminars	6030	3750				9780	
Verifications	3160	3160	3160	3160	3160	15800	
TOTAL	14550	12270	8520	8520	8520	52380	

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)

	Year					Total	
	2003	2004	2005	2006	2007		
1) Technical and administrative assistance							
a) Technical assistance offices							
b) Other technical and administrative assistance: - intra muros:							
- extra muros:							
of which for construction and maintenance of computerised management systems							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications	10000	5000	5000			20000	
Subtotal 2	10000	5000	5000			20000	
TOTAL	10000	5000	5000			20000	

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)11

(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.)

Commitments (in €)

Breakdown	Meetings/year	Number of outputs (total for years 1n)	Average unit cost	Total cost (total for years 1n)
Action 1: Committees (B7-8500)				
-Meetings in Bxl	1	5	2200	11000
- Meetings in Malta	1	5	3160	15800
Action 2 : Seminars (B7-8500)				
- In Bxl		1	3750	3750
- In Malta		1	6030	6030
Action 3: Verifications (B7-8500)		,		
-In Malta	1	5	3160	15800
TOTAL COST				52380

If necessary explain the method of calculation (See table annexed)

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		_	be assigned to nt of the action using and/or additional	Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
	A	0,6	None	0,6	If necessary, a fuller
Officials or temporary staff	В				description of the tasks may be annexed.
1 3	C	0,2		0,2	
Other human resources		None			
Total		0,8		0,8	

These resources are expected to be met from efficiency savings in the services involved

For further information, see separate explanatory note.

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials	86.400	0,8 staff (108.000 € per staff
Temporary staff		member per year
Other human resources		
(specify budget line)		
Total	86.400	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line		2003	2004	2005	2006	2007	Total 200	03-2007
A0701- Missions (Committee)		5800	5800	5800	5800	5800	29000	
A0701- Semin	A0701- Seminars in Malta		0				1750	
A0701-Verifications in Malta		1450	1450	1450	1450	1450	7250	
TOTAL		9000	7250	7250	7250	7250	38000	

Budget line (number and heading)	Amount €	Method of calculation
Overall allocation (Title A7) A0701 – Missions (Committee) . A0701 – Seminars in Malta . A0701- Verifications in Malta	29000 1750 7250	2 days meeting in Malta:Travel €1150, per diem € 150, 4 Commission officials; 1 meeting a year, 5 years 4 days seminar in Malta; Travel €1150; per diem €150; 1 Commission official; 1 meeting year 2003 2 days meeting in Malta; Travel €1150; per diem €150; 1 Commission official; 1 meeting a year; 5 years
Total	38000	

The amounts are total expenditure for the period 2003-2007

Specify the type of committee and the group to which it belongs.

I.	Annual total $(7.2 + 7.3)$	ϵ
	2003	95400
_	2004-2007	374600
II.	Total cost of action (2003-2007)	€ 470000

(In the estimate of human and administrative resources required for the action, DGs/Services must take into account the decisions taken by the Commission in its orientation/APS debate and when adopting the preliminary draft budget (PDB). This means that DGs must show that human resources can be covered by the indicative pre-allocation made when the PDB was adopted.

Exceptional cases (i.e. those where the action concerned could not be foreseen when the PDB was being prepared) will have to be referred to the Commission for a decision on whether and how (by means of an amendment of the indicative preallocation, an ad hoc redeployment exercise, a supplementary/amending budget or a letter of amendment to the draft budget) implementation of the proposed action can be accommodated.)

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The success of this ACAA can be quantified by trade facilitation through avoidance of duplication of testing and certification and costs. It is estimated on a yearly basis at € 26 million for EU exporters to Malta.

Success can also be measured by increased EU and Maltese exports and this factor will be taken into consideration although export performance is subject to such a wide range of variables (e.g. changes in exchange rates, general economic trends) that this can never been the sole factor for evaluation. In addition, official trade data are not always available for all types of specific products covered by the sectoral annexes to the ACAA.

Success can also be measured increased certificates delivered to companies in accordance with the ACAA. This could be put into relation to the number of certificates delivered under the domestic systems before the ACAA entered into force.

8.2. Arrangements and schedule for the planned evaluation

Progress in the attainment of the ACAA objectives will be monitored by Commission officials, the Association Council and by the economic operators concerned.

The evaluation of the effectiveness and usefulness of the ACAA will be regularly monitored by the Commission, by the Association Council at its annual meeting, by the Association Committee at its annual meeting, or by any special subcommittee or group to which the Association Council has delegated the management of the ACAA. At least, the first major evaluation will be two years after the entry into force.

9. ANTI-FRAUD MEASURES

Methods of control (submission of reports, etc.) will be included in all contracts or grant agreements between the Commission and beneficiaries.

A close co-operation with the delegations of the Commission and the participation of a representative of the Commission at events in third countries will check on the spot the work to ensure that it corresponds with the terms of reference, contract provisions and required professionalism.

The checks take place before the final payment. The same rule applies to the financial incentives paid to participating companies. Where appropriate, agreements also require organisations to submit financial accounts certified by their auditors.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS with special reference to small and medium-sized enterprises

Title of proposal

Proposal for Council Decisions on the signature and conclusion of an additional Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products (ACAA).

Reference number

The proposal

These decisions are necessary to conclude the Agreement between the European Community and Malta on Conformity Assessment and Acceptance of Industrial Products. The Commission negotiated the draft Agreement in accordance with the negotiating guidelines for the negotiation of European Conformity Assessment Agreement with the Central Eastern European Countries, adopted by the Council in June 1997.

The impact on business

The business sectors affected are electrical safety, electromagnetic compatibility, machinery and gas appliances.

The ACAA provides to extend certain benefits of the Internal Market in industrial sectors already aligned. The ACAA permits certification of conformity with technical regulations on product safety, etc, to be conducted in the European Union for exports destined Malta. This avoids the need for further certification by Maltese conformity assessment bodies before putting them on Maltese market. The certification procedure and the technical regulations are the same as the Community one.

The ACAA also envisages acceptance of industrial products that fulfil the requirements to be legally placed on the EU market by Malta without subject further requirement. Annexes under this mechanism have still to be negotiated.

The ACAA therefore presents important advantages from the point of view of transparency, market access, avoidance of duplication especially of cost, effective operation in certain sectors before accession and general facilitation of trade. This is of particular importance for small and medium-sized enterprises. The ACAA covers a wide range of sectors and therefore affects an extensive range of firms both large and small. The advantages are not limited to specific geographical areas in the Community.

Businesses will have to apply Maltese regulations and procedures. However, these are aligned on the EC ones in sectors covered by the ACAA. Furthermore, certification, as stated above, will be conducted by conformity assessment bodies located and already designated by the Member States in the Community, and not in Malta. The ACAA will substantially reduce certification costs and improve prospects for exports, employment, investment and competitiveness by Community firms.

The ACAA does not contain measures to take account of the specific situation of small and medium-sized firms, but by its nature and by reducing certification costs which are the same for all firms, the agreement will benefit small and medium sized enterprises to a greater extent proportionately than larger firms.

Consultation

The main industry organisations (e.g. EFPIA, Eurobit, Unice and Orgalime) have been consulted and have declared their support for this Agreement.