Procedure file

Basic information

NLE - Non-legislative enactments Decision	2009/0155(NLE)	Procedure completed

EC/Israel Agreement: Conformity Assessment and Acceptance of Industrial Products (CAA). Protocol to the Euro-Mediterranean Agreement

See also 1995/0276(AVC)
See also 2012/2693(RSP)

Subject
2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance
6.20.03 Bilateral economic and trade agreements and relations
6.40.05.06 Relations with the countries of the Middle East

Geographical area
Israel

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	INTA International Trade		24/05/2011
		S&D MOREIRA Vital	
		Shadow rapporteur	
		PPE ANDRIKIENĖ Laima Liucija	
		ALDE SCHAAKE Marietje	
		Verts/ALE JADOT Yannick	
		ECR ZAHRADIL Jan	
		GUE/NGL SCHOLZ Helmut	
	Committee for opinion	Rapporteur for opinion	Appointed
	AFET Foreign Affairs		08/09/2010
		S&D DE KEYSER Véronique	
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	General Affairs	3200	20/11/2012
	General Affairs	3005	22/03/2010
European Commission	Commission DG	Commissioner	
	Trade	DE GUCHT Karel	

Key events

22/10/2009	Initial legislative proposal published	COM(2009)0559	Summary
02/12/2009	Additional information		Summary
10/02/2010	Initial legislative proposal published	05190/2010	Summary
15/06/2010	Committee referral announced in		

	Parliament, 1st reading/single reading		
19/07/2012	Legislative proposal published	12428/2012	Summary
18/09/2012	Vote in committee, 1st reading/single reading		
26/09/2012	Committee report tabled for plenary, 1st reading/single reading	A7-0289/2012	Summary
23/10/2012	Results of vote in Parliament		
23/10/2012	Debate in Parliament		
23/10/2012	Decision by Parliament, 1st reading/single reading	T7-0385/2012	Summary
20/11/2012	Act adopted by Council after consultation of Parliament		
20/11/2012	End of procedure in Parliament		
04/01/2013	Final act published in Official Journal		

Technical information

Procedure reference	2009/0155(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consent by Parliament
Legislative instrument	Decision
	See also 1995/0276(AVC) See also 2012/2693(RSP)
Legal basis	Treaty on the Functioning of the EU TFEU 207; Treaty on the Functioning of the EU TFEU 218-p6a
Stage reached in procedure	Procedure completed
Committee dossier	INTA/7/02427

Documentation gateway

Initial legislative proposal		COM(2009)0559	22/10/2009	EC	Summary
Initial legislative proposal		05190/2010	10/02/2010	CSL	Summary
Document attached to the procedure		05212/2010	10/02/2010	CSL	Summary
Committee draft report		PE483.808	07/03/2012	EP	
Committee opinion	AFET	PE483.549	13/06/2012	EP	
Legislative proposal		12428/2012	19/07/2012	CSL	Summary
Amendments tabled in committee		PE494.507	19/07/2012	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0289/2012	26/09/2012	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0385/2012	23/10/2012	EP	Summary

Additional information

Final act

Decision 2013/1
OJ L 001 04.01.2013, p. 0001 Summary

2009/0155(NLE) - 22/10/2009 Initial legislative proposal

PURPOSE: to conclude an additional Protocol to the Euro-Mediterranean Association Agreement between the EU-Israel on Conformity Assessment and Acceptance of Industrial Products (ACAA).

PROPOSED ACT: Council Decision.

BACKGROUND: this Agreement is presented as a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, signed on 20 November 1995 rather than as a stand alone Agreement.

The Protocol 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.

LEGAL BASIS: Article 133 in conjunction the first sentence of the first subparagraph of Article 300(2) of the Treaty establishing the European Community.

CONTENT: the Commission proposes that the Council adopts this proposal for a decision to conclude the ACAA with Israel.

General principles of the Agreement: the ACAA facilitates market access by eliminating technical barriers to trade with respect to industrial products.

To this end, the ACAA provides for two mechanisms:

1. under the first mechanism, mutual recognition of products operates on the basis of the acquis communautaire that has been transposed by the partner country, in the same way as it would apply to products placed on the market of a Member State. It allows industrial products covered by it and attested as compliant according to the procedures of the European Union to be placed on the Israeli market without having to undergo any further approval procedures, and vice versa. At present one sector is included: good manufacturing practice (GMP) for pharmaceutical products. Israel has taken over the Community technical legislation in the sector covered by the Annex to the Protocol and participates in the European organisations in the sector covered by it;
2. the second mechanism, i.e., the mutual acceptance of industrial products not commonly regulated, confirms that Articles 16 and 17 of the Euro-Mediterranean Agreement with Israel apply without other restriction in the product sectors covered by it. That is, Annexes applying this mechanism will provide that where no European technical regulations exist, industrial products listed under such Annexes lawfully traded in the market of either Party (i.e., on the territory of Israel or that of one of the Member States of the EU) may be lawfully traded in the other. No annexes making this mechanism operational are at present included.

Main provisions of the Framework Agreement:

Purpose and means: the ACAA aims to eliminate technical barriers to trade in respect to industrial products. The ACAA provides for two mechanisms, as described above.

Alignment of legislation: Israel has a commitment to take appropriate measures to take over and maintain measures to align with and maintain Community law, as it applies to products covered by the Agreement. For New Approach sectors (which will be explicitly identified as such in the Annexes that relate to them) there is also an obligation on Israel to maintain relevant transposed standards, in the same way as a Member State of the EU.

Infrastructure: Israel is committed to establish and maintain a quality infrastructure equivalent to that of the EU for sectors covered by the Protocol.

Mutual acceptance of industrial products: the principles of the two mechanisms underlying the mutual acceptance of products onto the market of the other Party, as described above, are detailed in this Agreement. There is also a provision that, unless otherwise agreed, the ACAA does not entail any obligation, for one Party, to accept product attested as compliant by bodies other than those of the Parties.

Safeguard clause: each Party has the right to deny market access when that Party is able to demonstrate that a product might endanger legitimate concerns covered by legislation applicable to the products covered by an Annex (mainly to do with safety or public health). The Annexes will provide for the detailed procedures to be used in such cases.

Extension of coverage: Parties may modify the scope and coverage of this Protocol through amendment of the Annexes or by the addition of new ones.

Obligations of Parties as regards their responsible authorities and notified bodies: Parties are obliged to ensure that their responsible authorities monitor the technical competence and compliance of their respective notified bodies and have power and expertise for designating, suspending, and withdrawing such bodies. In addition, they are obliged to ensure that their notified bodies comply with the requirements of Community and aligned national law, and maintain their technical competence to carry out the tasks for which they have been notified.

Notified bodies: a procedure for the notification of bodies to assess conformity in relation to the legal requirements specified in the corresponding annexes is provided. The procedure is similar to the one applied within the Community. It also sets out the procedure for the

withdrawal of notified bodies.

Verification of notified bodies: each Party has the right 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. The notified body would be suspended until a final decision is taken.

Exchange of information: measures are provided as regards the transparency provision. This provision ensures uniform application and interpretation of the Protocol. It also provides for the Parties to encourage their notified bodies to co-operate to establish mutual recognition agreements in the voluntary sphere.

Confidentiality: this standard provision prohibits disclosing information acquired under this Protocol.

Management of the Agreement: responsibility for the effective functioning of this Agreement shall be borne by the Committee (subcommittee "Industry, trade and services" - set up and designated for trade purposes under Article 73 of the Association Agreement). Its main tasks shall be to add and amend Annexes, appoint experts for verifications, consider new arrangements, and resolve questions related to the Protocol.

Technical co-operation and assistance: measures are provided as regards technical co-operation and assistance with a view to properly implementing this Protocol.

Agreements with other countries: the agreement can be extended to other countries by explicit agreement, and encourages - but does not force - Israel to make agreements similar to the Protocol, and covering the same products, that the EU might make with another country.

Annexes

- annex on Mutual Acceptance of Industrial Products: there is one Annex, covering good manufacturing practice (GMP) for pharmaceutical products. It operates by the mechanism described above whereby mutual recognition of products operates on the basis of the acquis communautaire that has been transposed by Israel. Advanced therapy products, special medicinal products based on tissues and cells of human origin, and medicinal products that include blood products shall not be concerned. The inclusion of these fields may be agreed between the Parties if the Israeli legislation governing them is brought into alignment;
- annexes on Mutual Acceptance of Industrial Products no commonly regulated: no such annexes have been negotiated for the moment. The ACAA provides nevertheless the basis for such acceptance of products.

BUDGETARY IMPLICATION: the proposal has no implication for the European Union budget.

2009/0155(NLE) - 02/12/2009 Additional information

The Lisbon Treaty, which entered into force on 1 December 2009, amended the EU's two core treaties, the Treaty on European Union (TEU) and the Treaty establishing the European Community (EC Treaty). The latter was renamed the Treaty on the Functioning of the European Union (TFEU).

These changes had various consequences for many proposals presented by the Commission, on the basis of the "old" treaties, before that date. For more information, see COM (2009)0665. In some cases, a new legal framework was conferred on certain proposals that had not previously been subject to the interinstitutional decision-making process. The European Parliament would now be involved in any decision on those proposals.

The proposal in this procedure file is one such case. It was previously based on Articles 133 and 300 of the EC Treaty, (covering the common commercial policy and the conclusion of agreements between the European Community and one or more States or international organisations). It now falls under Articles 207 and 218(6)(a) of the TFEU, under which the European Parliament's consent must be obtained, under the new interinstitutional non-legislative procedure, before the Council adopts any decision concluding an international agreement relating to the common commercial policy.

2009/0155(NLE) - 10/02/2010 Document attached to the procedure

This document presents the definitive text of the Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA).

The purpose of this Protocol is to facilitate the elimination by the Parties of technical barriers to trade in respect of certain industrial products, listed in the Annexes to this Protocol, which form an integral part of this Protocol.

The Protocol provides for the mutual acceptance of industrial products that operates on the basis of the acquis communautaire that has been transposed by the partner country, in the same way as it would apply to products placed on the market of a Member State. It allows industrial products covered by it and attested as compliant according to the procedures of the European Union to be placed on the Israeli market without having to undergo any further approval procedures, and vice versa. At present one sector is included: good manufacturing practice (GMP) for pharmaceutical products.

The application of the mutual acceptance of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties also implies the mutual recognition of the results of obligatory conformity assessment of industrial products.

In order to achieve full conformity in the sectors covered by this Agreement, Israel's national law should be substantially aligned with relevant EU law.

For the purpose of this Protocol, Israel agrees to take appropriate measures, in consultation with the European Commission, to align with and maintain relevant EU law as it applies to the placing on the market of products covered by this Protocol.

The purpose shall be met through:

- the adoption and implementation by Israel of national technical regulations, standards and conformity assessment procedures which are equivalent to those of relevant EU law;
- the implementation by Israel of a regulatory and technical infrastructure which is equivalent to that in place in the Member States of the EU;
- the mutual acceptance on their markets by both Parties of industrial products which fulfil the requirements for being lawfully placed on the market in one of the Parties, including where appropriate the mutual recognition of the results of obligatory conformity assessment of industrial products subject to relevant EU law and to the equivalent Israeli national law;
- the acceptance on their markets by both Parties of industrial products which fulfil the requirements for being lawfully placed on the market in Israel and any one of the Member States of the EU, on conditions analogous to those applying to trade in goods between the Member States of the EU.

Safeguard clause: the Protocol comprises a safeguard clause which stipulates that where a Party finds that an industrial product placed on the market on its territory by virtue of this Protocol, 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.

It should be noted that more specific details as regards the mutual recognition mechanism of products established by this Protocol are set out in the former initial proposal of 22/10/2009.

2009/0155(NLE) - 10/02/2010 Initial legislative proposal

PURPOSE: to conclude a Protocol to the Euro Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA).

PROPOSED ACT: Council Decision.

LEGAL BASE: Articles 207 and 218(6)(a)v) of the Treaty on the Functioning of the European Union.

IMPACT ASSESSMENT: no impact assessment was carried out.

BACKGROUND: the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel of the other part entered into force on 20 November 1995.

Article 47 of the Association Agreement provides, where appropriate, for the conclusion of a European conformity assessment agreement, and Article 55 of the same Agreement provides for the use of best endeavours to approximate the laws of the Parties.

CONTENT: the proposed decision aims to conclude, on behalf of the European Union, the Protocol to the Euro Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel of the other part, on Conformity Assessment and Acceptance of Industrial Products.

For further details on the content of this Protocol, please refer to the summary of the former initial proposal of 22/10/2009.

An EU-Israel consultation procedure is provided for in the proposal in order to strengthen relations between the parties. This procedure aims to:

- carry into effect the information, co-operation, notification, amendment, verification and management functions provided for the Protocol;
- carry into effect the information, co-operation, notification, amendment, verification and management functions provided for in the Annexes to the Protocol;
- if necessary, reply to requests in accordance with the Annexes to the Protocol.

BUDGETARY IMPLICATION: the proposal has no implications for the Union?s budget.

2009/0155(NLE) - 19/07/2012 Legislative proposal

PURPOSE: to conclude a Protocol to the Euro-Mediterranean Association Agreement between the EU-Israel on Conformity Assessment and Acceptance of Industrial Products (ACAA).

PROPOSED ACT: Council Decision.

BACKGROUND: the Euro-Mediterranean Association Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part came into force on 20 November 1995.

Article 47 of the Association Agreement provides, where appropriate, for the conclusion of a European conformity assessment agreement, and Article 55 of the same Agreement provides for the use of best endeavours to approximate the laws of the Parties.

In this context, a Protocol to the Association on Conformity Assessment and Acceptance of Industrial Products was signed on behalf of the European Union on 6 May 2010.

This Protocol should be approved on behalf of the European Union.

IMPACT ASSESSMENT: no impact assessment was undertaken.

LEGAL BASIS: Article 207 of the Treaty on the Functioning of the European Union (TFEU), in conjunction with Article 218(6)(a)(v) and Article 218(7) thereof.

CONTENT: by means of this Decision, it is proposed to conclude a Protocol to the Euro-Mediterranean Association Agreement between the EU and Israel on Conformity Assessment and Acceptance of Industrial Products (ACAA) on behalf of the European Union.

The draft protocol is identical to the proposal that dates from 22/10/2009. For further information on the detailed content of the protocol, please refer to the summary of the initial proposal of October 2009.

Overall, the Protocole seeks to facilitate the market access of each of the partners by eliminating technical barriers to trade in industrial products.

To this end, provision is made in the Protocol for two mechanisms of mutual recognition and mutual acceptance of the products of the partners. The recognition mechanism is set in place involving:

- safeguard clauses for sensitive products;
- a dispute settlement procedure for resolving any problem between the two parties regarding recognition; and
- an information exchange mechnism to facilitate the recognition of the industrial products covered by the Protocol.

Management of the agreement and notification procedure: the Commission shall be responsible for the external representation of the Union for what concerns the Protocol, including the tasks of information and notification, as well as for providing responses to requests in accordance with the Annexes to the Protocol.

The Protocol shall be implemented on the basis of the EU legislation applicable to accreditation, market surveillance and commercialisation of products.

The Commission shall be empowered to make technical amendments to the Protocol.

BUDGETARY IMPLICATION: the proposal has no implication for the European Union budget.

2009/0155(NLE) - 26/09/2012 Committee report tabled for plenary, 1st reading/single reading

The Committee on International Trade adopted the recommendation by Vital MOREIRA (S&D, PT) on the draft Council decision on the conclusion of a Protocol to the Euro Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA).

Members recall that an Oral Question O-000129/2012 was tabled by the Committee on International Trade and the Committee on Foreign Affairs whereby the Commissioner was asked to define the scope of the territorial competence of the Israeli Responsible Authority in connection to the Protocol. In view of the replies given by Commissioner De Gucht in Plenary Session on 3 July 2012, in which the Commission clarified all the concerns of the Committee on International Trade and the Committee on Foreign Affairs, the committee recommends that the European Parliament consent to conclusion of the Protocol.

Members also call on the Commission to regularly report to the Parliament on any progress in the implementation of the Protocol.

2009/0155(NLE) - 23/10/2012 Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a legislative resolution on the draft Council Decision on the conclusion of a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA).

Parliament gave its consent to the conclusion of the Protocol by 379 votes to 230, with 41 abstentions and in spite of its fundamental reservations on Israeli policy with respect to the Palestinians.

To recap, the EU-Israel Agreement on the mutual recognition of pharmaceutical certificates will remove technical barriers to trade, cut manufacturers costs and enable them to get their products to market faster. This Agreement will apply to all pharmaceuticals except for advanced therapy products based on tissues and cells of human origin and medicinal products that include blood products.

However, Parliament had feared that its consent to this Agreement would send the wrong political message to Israel at a time when Members condemn its policy in regard to Palestinians. It recalls that Members tables an Oral Question O-000129/2012 to Commissioner De GUCHT asking for the scope of the territorial competence of the Israeli Responsible Authority to be defined in respect of the Protocol. At the plenary session of 3 July 2012, the Commission clarified all the concerns of the parliamentary committees.

As a result, Parliament gives its consent to the Protocol but calls on the Commission to provide it with regular reports on the progress of the Protocols implementation.

2009/0155(NLE) - 20/11/2012 Final act

PURPOSE: to conclude an additional Protocol to the Euro-Mediterranean Association Agreement between the EU-Israel on Conformity Assessment and Acceptance of Industrial Products (ACAA).

NON-LEGISLATIVE ACT: Council Decision 2013/1/EU on the conclusion of a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA).

BACKGROUND: the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, entered into force on 20 November 1995.

Article 47 of the Association Agreement provides for the conclusion, where appropriate, of agreements on mutual recognition in the field of conformity assessment, and Article 55 of the Agreement provides for the use of best endeavours to approximate the laws of the Parties in order to facilitate the implementation of the Agreement.

It is within this context that the Protocol to the Association Agreement on Conformity Assessment and Acceptance of Industrial Products (CAA) which was signed on behalf of the Union on 6 May 2010 should now be approved.

The Protocol 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.

The Protocol should be approved on behalf of the European Union.

CONTENT: with this Decision, the Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA) is hereby approved on behalf of the Union.

General principles of the Agreement: the ACAA facilitates market access by eliminating technical barriers to trade with respect to industrial products.

To this end, the ACAA provides for two mechanisms:

1. under the first mechanism, mutual recognition of products operates on the basis of the acquis communautaire that has been transposed by the partner country, in the same way as it would apply to products placed on the market of a Member State. It allows industrial products covered by it and attested as compliant according to the procedures of the European Union to be placed on the Israeli market without having to undergo any further approval procedures, and vice versa. At present one sector is included: good manufacturing practice (GMP) for pharmaceutical products. Israel has taken over the Community technical legislation in the sector covered by the Annex to the Protocol and participates in the European organisations in the sector covered by it;
2. the second mechanism, i.e., the mutual acceptance of industrial products not commonly regulated, confirms that Articles 16 and 17 of the Euro-Mediterranean Agreement with Israel apply without other restriction in the product sectors covered by it. That is, Annexes applying this mechanism will provide that where no European technical regulations exist, industrial products listed under such Annexes lawfully traded in the market of either Party (i.e., on the territory of Israel or that of one of the Member States of the EU) may be lawfully traded in the other. No annexes making this mechanism operational are at present included.

Other technical provisions:

- Alignment of legislation: Israel has a commitment to take appropriate measures to take over and maintain measures to align with and maintain Community law, as it applies to products covered by the Agreement. For New Approach sectors (which will be explicitly identified as such in the Annexes that relate to them) there is also an obligation on Israel to maintain relevant transposed standards, in the same way as a Member State of the EU.

- Infrastructure: Israel is committed to establish and maintain a quality infrastructure equivalent to that of the EU for sectors covered by the Protocol.

Mutual acceptance of industrial products: the principles of the two mechanisms underlying the mutual acceptance of products onto the market of the other Party, as described above, are detailed in this Agreement. There is also a provision that, unless otherwise agreed, the ACAA does not entail any obligation, for one Party, to accept product attested as compliant by bodies other than those of the Parties.

- Safeguard clause: each Party has the right to deny market access when that Party is able to demonstrate that a product might endanger legitimate concerns covered by legislation applicable to the products covered by an Annex (mainly to do with safety or public health). The Annexes will provide for the detailed procedures to be used in such cases.

Extension of coverage: Parties may modify the scope and coverage of this Protocol through amendment of the Annexes or by the addition of new ones.

Obligations of Parties as regards their responsible authorities and notified bodies: Parties are obliged to ensure that their responsible authorities monitor the technical competence and compliance of their respective notified bodies and have power and expertise for designating, suspending, and withdrawing such bodies. In addition, they are obliged to ensure that their notified bodies comply with the requirements of Community and aligned national law, and maintain their technical competence to carry out the tasks for which they have been notified.

Notified bodies: a procedure for the notification of bodies to assess conformity in relation to the legal requirements specified in the corresponding annexes is provided. The procedure is similar to the one applied within the Community. It also sets out the procedure for the withdrawal of notified bodies.

Verification of notified bodies: each Party has the right 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. The notified body would be suspended until a final decision is taken.

Exchange of information: measures are provided as regards the transparency provision. This provision ensures uniform application and interpretation of the Protocol. It also provides for the Parties to encourage their notified bodies to co-operate to establish mutual recognition agreements in the voluntary sphere.

Confidentiality: this standard provision prohibits disclosing information acquired under this Protocol.

Management of the Agreement: responsibility for the effective functioning of this Agreement shall be borne by the Committee (subcommittee "Industry, trade and services" - set up and designated for trade purposes under Article 73 of the Association Agreement). Its main tasks shall be to add and amend Annexes, appoint experts for verifications, consider new arrangements, and resolve questions related to the Protocol.

Technical co-operation and assistance: measures are provided as regards technical co-operation and assistance with a view to properly implementing this Protocol.

Agreements with other countries: the agreement can be extended to other countries by explicit agreement, and encourages - but does not force - Israel to make agreements similar to the Protocol, and covering the same products, that the EU might make with another country.

Annexes

- annex on Mutual Acceptance of Industrial Products: there is one Annex, covering good manufacturing practice (GMP) for pharmaceutical products. It operates by the mechanism described above whereby mutual recognition of products operates on the basis of the acquis communautaire that has been transposed by Israel. Advanced therapy products, special medicinal products based on tissues and cells of human origin, and medicinal products that include blood products shall not be concerned. The inclusion of these fields may be agreed between the Parties if the Israeli legislation governing them is brought into alignment;
- annexes on Mutual Acceptance of Industrial Products no commonly regulated: no such annexes have been negotiated for the moment. The ACAA provides nevertheless the basis for such acceptance of products.

ENTRY INTO FORCE: the Decision shall enter into force on 4 January 2013. The Protocol shall enter into force when the necessary procedures have been completed. It shall be concluded for an unlimited period of time.