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

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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.