EU/New Zealand Agreement: mutual recognition in relation to conformity assessment (amendment)

2010/0139(NLE) - 13/11/2012 - Final act

PURPOSE: conclusion of the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand.

NON-LEGISLATIVE ACT: Council Decision 2012/828/EU on the conclusion of the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand.

BACKGROUND: the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand entered into force on 1 January 1999.

In accordance with Council Decision 2011/464/EU, the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand was signed by the Commission on 23 February 2012, subject to its conclusion.

The Agreement should be concluded on behalf of the EU.

CONTENT: with this Decision, the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand is hereby approved on behalf of the Union.

Main amendments to the basic Agreement: the amendments are intended to:

- allow greater flexibility in the structure of Sectoral Annexes to the Agreement on Mutual Recognition;
- remove unnecessary restrictions on trade between the Parties;
- reduce the administrative burden related to management of the Agreement;
- facilitate and clarify the operation of the Agreement.

In addition, the Sectoral Annexes on medicinal products GMP (Good Manufacturing Practices) inspection and batch certification and on medical devices have been superseded by changes in technical and administrative practice and by changes in the organisations listed therein, and the opportunity has been taken to revise them.

The main technical amendments made to the Agreement are as follows:

A detailed assessment of the amendments follows:

- **scope**: in order to remove unnecessary restrictions on trade, the restriction in Article 4 of the application of the Agreement to industrial products that originate in the Parties according to non-preferential rules of origin will be deleted. As amended, the Agreement on Mutual Recognition will apply to all products covered by it, irrespective of their origin.
- **comitology**: the references to the Chair of the Joint Committee will be deleted from Articles 8 and 12, in order to reflect the fact that the Joint Committee is co-chaired by the Parties;
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simplification of the operation of the Agreement: in order to simplify operation of the Agreement on Mutual Recognition, a simpler procedure for the recognition, withdrawal of recognition and suspension of conformity assessment bodies will be set up in Article 12. As a result, a decision by a designating authority to designate or withdraw designation of a conformity assessment body will no longer need to be given effect by an amendment to a Sectoral Annex; the need for the Joint Committee to take action will be limited to cases that have been contested by the other Party;

- **adaptations to the Annexes**: in order to make timely adaptations to the Sectoral Annexes to take account of technical progress and other factors such as enlargement of the European Union, Article 12 will also be amended in order to explicitly empower the Joint Committee to amend the Sectoral Annexes in areas other than to give effect to the decision by a designating authority to designate or withdraw designation of a particular conformity assessment body, and also to adopt new Sectoral Annexes;
- **sectoral Annex**: the Sectoral Annex on medicinal products and medical devices have been revised to take account of developments in technical and administrative practice, changes introduced by the Amendment to the main body of the Agreement on Mutual Recognition, updates in the organisations listed, and changes to the Parties' legislation affecting this sector. The principle of operation of this Sectoral Annex remains unchanged.

ENTRY INTO FORCE: the Decision shall enter into force on 13 November 2012. The date of entry into force of the Agreement will be published in the Official Journal of the European Union by the General Secretariat of the Council.