Basic information

2010/0139(NLE) NLE - Non-legislative enactments Decision	Procedure completed
EU/New Zealand Agreement: mutual recognition in relation to conformity assessment (amendment) **Subject** 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 6.20.03 Bilateral economic and trade agreements and relations **Geographical area** New Zealand	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
INTA International Trade	MOREIRA Vital (S&D)	23/06/2010
	Shadow rapporteur FJELLNER Christofer (PPE) KAZAK Metin (ALDE)	

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	3198	2012-11-13

European Commission

Commission DG	Commissioner
Trade and Economic Security	DE GUCHT Karel

Key events

Date	Event	Reference	Summary
28/05/2010	Preparatory document	COM(2010)0258	Summary
13/07/2011	Legislative proposal published	12126/2010	Summary
13/03/2012	Committee referral announced in Parliament		
21/06/2012	Vote in committee		

25/06/2012	Committee report tabled for plenary, 1st reading/single reading	A7-0210/2012	Summary
12/09/2012	Decision by Parliament	T7-0331/2012	Summary
12/09/2012	Results of vote in Parliament		
13/11/2012	Act adopted by Council after consultation of Parliament		
13/11/2012	End of procedure in Parliament		
22/12/2012	Final act published in Official Journal		

Technical information

Procedure reference	2010/0139(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consent by Parliament
Legislative instrument	Decision
Legal basis	Treaty on the Functioning of the European Union TFEU 207-p4 Treaty on the Functioning of the European Union TFEU 218-p6a
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	INTA/7/03040

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE450.688	08/10/2010	
Committee report tabled for plenary, 1st reading/single reading		A7-0210/2012	25/06/2012	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0331/2012	12/09/2012	Summary

Council of the EU

Document type	Reference	Date	Summary
Legislative proposal	12126/2010	13/07/2011	Summary
Document attached to the procedure	12151/2010	13/07/2011	

European Commission

Document type	Reference	Date	Summary
Preparatory document	COM(2010)0258	28/05/2010	Summary

Additional information		
Source	**Document**	**Date**
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act	
Decision 2012/0828 OJ L 356 22.12.2012, p. 0001	Summary

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

2010/0139(NLE)

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.

PROPOSED ACT: Council Decision.

BACKGROUND: the Agreement between the European Community and New Zealand on mutual recognition in relation to conformity assessment entered into force on 1 January 1999. With a view to further improving and simplifying the functioning of the Agreement on Mutual Recognition, the Parties have decided to amend some of its provisions.

On the basis of the negotiating directives from the Council, the Commission initialled negotiated and initialled an Amendment to the Agreement on Mutual Recognition.

IMPACT ASSESSMENT: no impact assessment was carried out.

LEGAL BASIS: Article 207(4), first subparagraph, in conjunction with Article 218(6)(a) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the amendment is 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.

A detailed assessment of the amendment 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;
- **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.

The Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Union and Australia is identical in form to the Agreement, and is therefore being amended in parallel in order to retain coherence between the Agreements.

BUDGETARY IMPLICATION: this proposal has no implications for the European Union's budget.

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;
- **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.

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

2010/0139(NLE) - 13/07/2011 - Legislative proposal

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.

PROPOSED ACT: Council Decision.

BACKGROUND: the Agreement between the European Community and New Zealand on mutual recognition in relation to conformity assessment entered into force on 1 January 1999. With a view to further improving and simplifying the functioning of the Agreement on Mutual Recognition, the Parties have decided to amend some of its provisions.

On the basis of the negotiating directives from the Council, the Commission initialled negotiated and initialled an Amendment to the Agreement on Mutual Recognition.

IMPACT ASSESSMENT: no impact assessment was carried out.

LEGAL BASIS: Article 207(4), first subparagraph, in conjunction with Article 218(6)(a)(v) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the amendment is 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.

A detailed assessment of the amendment 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;
- **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.

The Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Union and Australia is identical in form to the Agreement, and is therefore being amended in parallel in order to retain coherence between the Agreements.

BUDGETARY IMPLICATION: this proposal has no implications for the European Union's budget.

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

2010/0139(NLE) - 28/05/2010 - Preparatory document

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.

PROPOSED ACT: Council Decision.

BACKGROUND: the Agreement between the European Community and New Zealand on mutual recognition in relation to conformity assessment entered into force on 1 January 1999. With a view to further improving and simplifying the functioning of the Agreement on Mutual Recognition, the Parties have decided to amend some of its provisions.

On the basis of the negotiating directives from the Council, the Commission initialled negotiated and initialled an Amendment to the Agreement on Mutual Recognition.

IMPACT ASSESSMENT: no impact assessment was carried out.

LEGAL BASIS: Article 207(4), first subparagraph, in conjunction with Article 218(6)(a) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the amendment is 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.

A detailed assessment of the amendment 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;
- **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.

The Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Union and Australia is identical in form to the Agreement, and is therefore being amended in parallel in order to retain coherence between the Agreements.

BUDGETARY IMPLICATION: this proposal has no implications for the European Union's budget.

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

2010/0139(NLE) - 25/06/2012 - Committee report tabled for plenary, 1st reading/single reading

The Committee International Trade unanimously adopted the report drafted by Vital MOREIRA (ADLE, PT) in which it recommends the European Parliament to give its consent to 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.

Members welcome the improvements made to this Agreement which aim in particular to:

- allow greater flexibility in the structure of sectoral annexes,
- remove unnecessary restrictions on trade between the parties,
- reduce the administrative burden related to management of the MRA,
- facilitate and clarify the operation of the MRA.

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

2010/0139(NLE) - 12/09/2012 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 669 votes to 6, with 6 abstentions, a legislative resolution concerning the conclusion of an 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.

Parliament gives its consent to the conclusion of the agreement.