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[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

EN

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION 2012/315/CFSP

of 19 December 2011

on the signing and conclusion of the Agreement between the European Union and New Zealand establishing a framework for the participation of New Zealand in European Union crisis management operations

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, in particular Article 37 thereof, and the Treaty on the Functioning of the European Union, in particular Article 218(5) and (6) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy ('the HR'),

Whereas:

(1) Conditions regarding the participation of third States in European Union crisis management operations should be laid down in an agreement establishing a framework for such possible future participation, rather than defining those conditions on a case-by-case basis for each operation concerned.

(2) Following the adoption of a Decision by the Council on 26 April 2010 authorising the opening of negotiations, the HR negotiated an Agreement between the European Union and New Zealand establishing a framework for the participation of New Zealand in European Union crisis management operations ('the Agreement').

(3) The Agreement should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement between the European Union and New Zealand establishing a framework for the participation of New Zealand in European Union crisis management operations is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement in order to bind the Union.

Article 3

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 16(1) of the Agreement.

Article 4

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 19 December 2011.

For the Council

The President

M. KOROLEC

AGREEMENT

between the European Union and New Zealand establishing a framework for the participation of New Zealand in European Union crisis management operations

THE EUROPEAN UNION (EU),

of the one part, and

NEW ZEALAND

of the other part,

hereinafter referred to as the 'Parties',

WHEREAS:

(1) The European Union may decide to take action in the field of crisis management.

(2) The European Union will decide whether third States will be invited to participate in an EU crisis management operation. New Zealand may accept the invitation by the European Union and offer its contribution. In such case, the European Union will decide on the acceptance of the proposed contribution of New Zealand.

(3) Conditions regarding the participation of New Zealand in EU crisis management operations should be laid down in an Agreement establishing a framework for such possible future participation, rather than defining these conditions on a case-by-case basis for each operation concerned.

(4) Such an Agreement should be without prejudice to the decision-making autonomy of the European Union, and should not prejudge the case-by-case nature of the decisions of New Zealand to participate in an EU crisis management operation.

(5) Such an Agreement should only address EU crisis management operations and should be without prejudice to any existing agreements regulating the participation of New Zealand in an EU crisis management operation that has been already deployed,

HAVE AGREED AS FOLLOWS:

SECTION I

GENERAL PROVISIONS

Article 1

Decisions relating to the participation

1. Following the decision of the European Union to invite New Zealand to participate in an EU crisis management operation, and once New Zealand has decided to participate, New Zealand shall provide information on its proposed contribution to the European Union.

2. The European Union shall provide New Zealand with an early indication of the likely contribution to the common costs of the operation as soon as possible with a view to assisting New Zealand in the formulation of its offer.

3. The assessment by the European Union of New Zealand's proposed contribution shall be conducted in consultation with New Zealand.

4. The European Union shall communicate the outcome of that assessment to New Zealand by letter in a timely fashion with a view to securing the participation of New Zealand in accordance with the provisions of this Agreement.

Article 2

Framework

1. New Zealand shall associate itself with the Council Decision by which the Council of the European Union decides that the EU will conduct the crisis management operation, and with any other decision by which the Council of the European Union decides to extend the EU crisis management operation, in accordance with the provisions of this Agreement and any required implementing arrangements.

2. The participation of New Zealand in an EU crisis management operation shall be without prejudice to the decision-making autonomy of the European Union.

3. Paragraph 1 does not affect the right of New Zealand to withdraw from participation in an EU crisis management operation if it does not agree with a Decision referred to in that paragraph.

Article 3

Status of personnel and forces

1. The status of personnel seconded to an EU civilian crisis management operation and/or of the forces contributed to an EU military crisis management operation by New Zealand shall be governed by the agreement on the status of forces/mission, if available, concluded between the European Union and the State(s) in which the operation is conducted.

2. The status of personnel contributed to headquarters or command elements located outside the State(s) in which the EU crisis management operation takes place, shall be governed by arrangements between the headquarters and command elements concerned and New Zealand.

3. Without prejudice to the agreement on the status of forces/mission referred to in paragraph 1, and subject to any bilateral or multilateral agreements in force, in cases where the forces of New Zealand operate on board a vessel or aircraft of an EU Member State, the latter State shall exercise jurisdiction in accordance with its internal laws and procedures.

4. New Zealand shall be responsible for answering any claims linked to its participation in an EU crisis management operation, from or concerning any of its personnel. New Zealand shall be responsible for bringing any action, in particular legal or disciplinary, against any of its personnel in accordance with its laws and regulations.

5. The Parties agree to waive any and all claims (other than contractual claims) against each other for damage to, loss, or destruction of assets owned/operated by either Party, or injury or death to personnel of either Party, arising out of the performance of their official duties in connection with activities under this Agreement, except in the case of gross negligence or wilful misconduct.

6. New Zealand undertakes to make a declaration as regards the waiver of claims against any State participating in an EU crisis management operation in which New Zealand participates, and to do so when signing this Agreement.

7. The European Union undertakes to ensure that European Union Member States make a declaration as regards the waiver of claims, for any future participation of New Zealand in an EU crisis management operation, and to do so when signing this Agreement.

Article 4

Classified information

1. New Zealand shall take appropriate measures to ensure that EU classified information is protected in accordance with the European Union Council's security regulations, contained in Council Decision 2011/292/EU of 31 March 2011 on the security rules for protecting EU classified information [1], and in accordance with further guidance issued by competent authorities, including the EU Operation Commander concerning an EU military crisis management operation or by the EU Head of Mission concerning an EU civilian crisis management operation.

2. If the EU receives classified information from New Zealand, that information shall be given protection appropriate to its classification and equivalent to the standards established in the regulations for EU classified information.

3. Where the EU and New Zealand have concluded an agreement on security procedures for the exchange of classified information, the provisions of such an agreement shall apply in the context of an EU crisis management operation.

SECTION II

PROVISIONS ON PARTICIPATION IN CIVILIAN CRISIS MANAGEMENT OPERATIONS

Article 5

Personnel seconded to an EU civilian crisis management operation

1. New Zealand shall ensure that its personnel seconded to the EU civilian crisis management operation undertake their mission in accordance with:

(a) the Council Decision and subsequent amendments as referred to in Article 2(1);

(b) the Operation Plan;

(c) implementing measures.

2. New Zealand shall inform in due time the Head of Mission of the EU civilian crisis management operation ('Head of Mission') and the High Representative of the Union for Foreign Affairs and Security Policy ('HR') of any change to its contribution to the EU civilian crisis management operation.

3. Personnel seconded to the EU civilian crisis management operation shall undergo a medical examination, vaccination as may be deemed necessary by the competent New Zealand authorities, and be certified medically fit for duty by a competent authority from New Zealand. Personnel seconded to the EU civilian crisis management operation shall produce a copy of that certification.

Article 6

Chain of command

1. Personnel seconded by New Zealand shall carry out their duties and conduct themselves solely with the interests of the EU civilian crisis management operation in mind.

2. All personnel shall remain under the full command of their national authorities.

3. National authorities shall transfer operational control to the European Union.

4. The Head of Mission shall assume responsibility and exercise command and control of the EU civilian crisis management operation at theatre level.

5. The Head of Mission shall lead the EU civilian crisis management operation and assume its day-to-day management.

[1] OJ L 141, 27.5.2011, p. 17.

6. New Zealand shall have the same rights and obligations in terms of day-to-day management of the operation as European Union Member States taking part in the operation, in accordance with the legal instruments referred to in Article 2(1).

7. The EU civilian crisis management operation Head of Mission shall be responsible for disciplinary control over EU civilian crisis management operation personnel. Where required, disciplinary action shall be taken by the national authority concerned.

8. A National Contingent Point of Contact (NPC) shall be appointed by New Zealand to represent its national contingent in the operation. The NPC shall report to the EU civilian crisis management operation Head of Mission on national matters and shall be responsible for day-to-day discipline of the contingent.

9. The decision to end the operation shall be taken by the European Union, following consultation with New Zealand if it is still contributing to the EU civilian crisis management operation at the date of termination of the operation.

Article 7

Financial aspects

1. New Zealand shall assume all the costs associated with its participation in the operation apart from the running costs, as set out in the operational budget of the operation. This shall be without prejudice to Article 8.

2. In case of death, injury, loss or damage to natural or legal persons from the State(s) in which the operation is conducted, issues of possible liability and compensation by New Zealand shall be governed by the conditions foreseen in the applicable status of mission agreement referred to in Article 3(1) or any applicable alternative arrangements.

Article 8

Contribution to operational budget

1. New Zealand shall contribute to the financing of the budget of the EU civilian crisis management operation.

2. The financial contribution of New Zealand to the operational budget shall be calculated on the basis of either of the following formulae, whichever produces the lower amount:

(a) the share of the reference amount which is in proportion to the ratio of New Zealand's GNI to the total GNIs of all States contributing to the operational budget of the operation; or

(b) the share of the reference amount for the operational budget which is in proportion to the ratio of the number of personnel from New Zealand participating in the operation to the total number of personnel of all States participating in the operation.

3. Notwithstanding paragraphs 1 and 2, New Zealand shall not make any contribution towards the financing of per diem allowances paid to personnel of the European Union Member States.

4. Notwithstanding paragraph 1, the European Union shall, in principle, exempt New Zealand from financial contributions to a particular EU civilian crisis management operation when:

(a) the European Union decides that New Zealand's participation in the operation provides a significant contribution which is essential for this operation; or

(b) New Zealand has a GNI per capita which does not exceed that of any Member State of the European Union.

5. An arrangement on the payment of the contributions of New Zealand to the operational budget of the EU civilian crisis management operation shall be signed between the EU civilian crisis management operation Head of Mission and the relevant administrative services of New Zealand. That arrangement shall, inter alia, include the following provisions:

(a) the amount concerned;

(b) the arrangements for payment of the financial contribution; and

(c) the auditing procedure.

SECTION III

PROVISIONS ON PARTICIPATION IN MILITARY CRISIS MANAGEMENT OPERATIONS

Article 9

Participation in the EU military crisis management operation

1. New Zealand shall ensure that its forces and personnel participating in the EU military crisis management operation undertake their mission in accordance with:

(a) the Council Decision and subsequent amendments as referred to in Article 2(1);

(b) the Operation Plan; and

(c) implementing measures.

2. New Zealand shall inform the EU Operation Commander in due time of any change to its participation in the operation.

Article 10

Chain of command

1. All forces and personnel participating in the EU military crisis management operation shall remain under the full command of their national authorities.

2. Personnel seconded by New Zealand shall carry out their duties and conduct themselves solely with the interest of the EU military crisis management operation in mind.

3. National authorities shall transfer the Operational and Tactical command and/or control of their forces and personnel to the EU Operation Commander, who is entitled to delegate his authority.

4. New Zealand shall have the same rights and obligations in terms of the day-to-day management of the operation as participating European Union Member States.

5. The EU Operation Commander may, following consultations with New Zealand, at any time request the withdrawal of New Zealand's contribution.

6. A Senior Military Representative (SMR) shall be appointed by New Zealand to represent its national contingent in the EU military crisis management operation. The SMR shall consult with the EU Force Commander on all matters affecting the operation and shall be responsible for the day-to-day discipline of contingent of New Zealand.

Article 11

Financial aspects

1. Without prejudice to Article 12 of this agreement, New Zealand shall assume all the costs associated with its participation in the operation unless the costs are subject to common funding as provided for in the legal instruments referred to in Article 2(1) of this Agreement, as well as in Council Decision 2008/975/CFSP [1] establishing a mechanism to administer the financing of the common costs of EU operations having military or defence implications.

2. In case of death, injury, loss or damage to natural or legal persons from the State(s) in which the operation is conducted, issues of possible liability and compensation by New Zealand shall be governed by the conditions foreseen in the applicable status of forces agreement referred to in Article 3(1) or any applicable alternative arrangements.

Article 12

Contribution to the common costs

1. New Zealand shall contribute to the financing of the common costs of the EU military crisis management operation.

2. The financial contribution of New Zealand to the common costs shall be calculated on the basis of either of the following two formulae, whichever produces the lower amount:

(a) the share of the common costs which is in proportion to the ratio of New Zealand's GNI to the total GNIs of all States contributing to the common costs of the operation; or

(b) the share of the common costs which is in proportion to the ratio of the number of personnel from New Zealand participating in the operation to the total number of personnel of all States participating in the operation.

Where the formula under point (b) of the first subparagraph is used and New Zealand contributes personnel only to the Operation or Force Headquarters, the ratio used shall be that of its personnel to that of the total number of the respective headquarters personnel. In other cases, the ratio shall be that of all personnel contributed by New Zealand to that of the total personnel of the operation.

3. Notwithstanding paragraph 1 above, the European Union shall, in principle, exempt New Zealand from financial contributions to the common costs of a particular EU military crisis management operation when:

(a) the European Union decides that New Zealand's participation in the operation provides a significant contribution to assets and/or capabilities which are essential for the operation; or

(b) New Zealand has a GNI per capita which does not exceed that of any Member State of the European Union.

4. An arrangement shall be concluded between the Administrator provided for in Decision 2008/975/CFSP establishing a mechanism to administer the financing of the common costs of EU operations having military or defence implications, and the competent administrative authorities of New Zealand. That arrangement shall include inter alia provisions on:

(a) the amount concerned;

(b) the arrangements for payment of the financial contribution; and

(c) the auditing procedure.

SECTION IV

FINAL PROVISIONS

Article 13

Arrangements to implement the Agreement

Without prejudice to the provisions of Articles 12(4) and 8(5), any necessary technical and administrative arrangements in pursuance of the implementation of this Agreement shall be concluded between the High Representative of the Union for Foreign Affairs and Security Policy, and the appropriate authorities of New Zealand.

Article 14

Non-compliance

Should one of the Parties fail to comply with its obligations under this Agreement, the other Party shall have the right to terminate this Agreement by serving notice of one month.

Article 15

Dispute settlement

Disputes concerning the interpretation or application of this Agreement shall be settled by diplomatic means between the Parties.

Article 16

Entry into force

1. This Agreement shall enter into force on the first day of the first month after the Parties have notified each other of the completion of the internal procedures necessary for this purpose.

2. This Agreement shall be reviewed upon the request of either Party.

3. This Agreement may be amended on the basis of a mutual written agreement between the Parties.

[1] OJ L 345, 23.12.2008, p. 96.

4. This Agreement maybe denounced by either Party by written notice of denunciation given to the other Party. Such denunciation shall take effect six months after receipt of notification by the other Party.

Done at Brussels, this eighteenth day of April in the year two thousand and twelve.

For the European Union

For New Zealand

DECLARATION BY THE EU MEMBER STATES

The EU Member States applying an EU Council Decision of an EU crisis management operation in which New Zealand participates will endeavour, insofar as their internal legal systems so permit, to waive as far as possible claims against New Zealand for injury, death of their personnel, or damage to, or loss of, any assets owned by themselves and used by the EU crisis management operation if such injury, death, damage or loss:

— was caused by personnel from New Zealand in the execution of their duties in connection with the EU crisis management operation, except in case of gross negligence or wilful misconduct, or

— arose from the use of any assets owned by New Zealand, provided that the assets were used in connection with the operation and except in case of gross negligence or wilful misconduct of EU crisis management operation personnel from New Zealand using those assets.

DECLARATION BY NEW ZEALAND

New Zealand, when applying an EU Council Decision of an EU crisis management operation, will endeavour, insofar as its internal legal system so permits, to waive as far as possible claims against any EU Member State participating in the EU crisis management operation for injury, death of its personnel, or damage to, or loss of, any assets owned by itself and used by the EU crisis management operation if such injury, death, damage or loss:

(a) was caused by personnel in the execution of their duties in connection with the EU crisis management operation, except in case of gross negligence or wilful misconduct; or

(b) arose from the use of any assets owned by States participating in the EU crisis management operation, provided that the assets were used in connection with the operation and except in case of gross negligence or wilful misconduct of EU crisis management operation personnel using those assets.

REGULATIONS

COMMISSION REGULATION (EU) No 523/2012

of 20 June 2012

amending Regulation (EC) No 661/2009 of the European Parliament and of the Council as regards the inclusion of certain Regulations of the United Nations Economic Commission for Europe on the type-approval of motor vehicles, their trailers and systems, components and separate technical units intended therefor

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor [1], and in particular Article 14(1) thereof,

Whereas:

(1) By Council Decision 97/836/EC [2], the Union has acceded to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement').

(2) By Decision 97/836/EC, the Union has also acceded to UNECE Regulation No 30 on pneumatic tyres for motor vehicles and their trailers, Regulation No 54 on pneumatic tyres for commercial vehicles and their trailers, and Regulation No 64 on temporary-use spare unit, run-flat tyres, run-flat system and tyre pressure monitoring system.

(3) By a separate Council Decision [3], the Union has acceded to UNECE Regulation No 117 on tyre rolling sound emissions and adhesion on wet surfaces.

(4) In accordance with Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) [4], vehicles manufacturers seeking approval for their systems, components, or separate technical units have the choice of meeting the requirements of either the relevant Directives or the corresponding UNECE Regulations. Most of the requirements under Directives on vehicle parts are taken over from the corresponding UNECE Regulations. As technology progresses, UNECE Regulations are constantly amended and the relevant Directives have to be regularly updated to keep them in line with the content of the respective UNECE Regulations. In order to avoid this duplication, the CARS 21 High Level Group recommended the replacement of several Directives by the corresponding UNECE Regulations.

(5) The possibility to apply UNECE Regulations for the purpose of EC vehicle type-approval on a compulsory basis and to replace Union legislation by those UNECE Regulations is provided for in Directive 2007/46/EC. According to Regulation (EC) No 661/2009 type-approval in accordance with UNECE Regulations which apply on a compulsory basis is to be considered as EC type-approval in accordance with that Regulation and its implementing measures.

(6) Replacing Union legislation by UNECE Regulations helps to avoid duplication not only of technical requirements but also of certification and administrative procedures. In addition, type-approval that is directly based on internationally agreed standards should improve market access in third countries, in particular in those which are contracting parties to the Revised 1958 Agreement, thus enhancing the competitiveness of the Union industry.

[1] OJ L 200, 31.7.2009, p. 1.
[2] OJ L 346, 17.12.1997, p. 78.
[3] COM(2003) 635 final — Adoption by unpublished document.
[4] OJ L 263, 9.10.2007, p. 1.

(7) Therefore, Regulation (EC) No 661/2009 provides for the repeal of several Directives concerning the type-approval of motor vehicles, their trailers and systems, components and separate technical units intended therefor, which, for the purposes of EC type-approval in accordance with that Regulation, should be replaced by corresponding UNECE Regulations in order to ensure that type-approval provisions are maintained and to facilitate scientific and technological developments.

(8) For that reason, it is appropriate to include UNECE Regulations Nos 30, 54, 64 and 117 into Annex IV to Regulation (EC) No 661/2009, which lists the UNECE Regulations that apply on a compulsory basis.

(9) It is also appropriate to clarify Annex IV to Regulation (EC) No 661/2009, as amended by Commission Regulation (EU) No 407/2011 ([1]), as regards the application of UNECE Regulation No 13 on braking of vehicles and trailers, Regulation No 13-H on braking of passenger cars, Regulation No 34 on the prevention of fire risks (liquid fuel tanks) and Regulation No 55 on mechanical coupling components of combinations of vehicles.

(10) Regulation (EC) No 661/2009 should therefore be amended accordingly.

(11) The UNECE Regulations listed in the Annex to this Regulation should apply following the implementation dates set out in Article 13 of Regulation (EC) No 661/2009.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Technical Committee — Motor Vehicles,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EC) No 661/2009 is amended in accordance with the Annex to this Regulation.

Article 2

1. With effect from 1 November 2012, UNECE Regulation No 30, supplement 16 to the 02 series of amendments ([2]), and UNECE Regulation No 117, 02 series of amendments ([3]), including the stage 2 rolling sound requirements set out in paragraph 6.1.1, the requirements for wet grip performance set out in paragraph 6.2, and the stage 1 rolling resistance requirements set out in paragraph 6.3.1 of that UNECE Regulation, shall apply for the purpose of type-approval of new types of tyres of Class C1.

2. With effect from 1 November 2014, UNECE Regulation No 30, supplement 16 to the 02 series of amendments, and UNECE Regulation No 117, 02 series of amendments, including the wet grip performance requirements set out in paragraph 6.2 of that UNECE Regulation, shall apply for the purpose of the sale and entry into service of new tyres of Class C1.

3. With effect from 1 November 2012, UNECE Regulation No 54, supplement 17 to the original version of the Regulation ([4]), and UNECE Regulation No 117, 02 series of amendments, including the stage 2 rolling sound requirements set out in paragraphs 6.1.2 to 6.1.3 and the stage 1 rolling resistance requirements set out in paragraph 6.3.1 of that UNECE Regulation, shall apply for the purpose of type-approval of new types of tyres of Classes C2 and C3.

4. With effect from 1 November 2014, UNECE Regulation No 54 supplement 17 to the original version of the Regulation, shall apply on a compulsory basis for the purpose of the sale and entry into service of new tyres of Classes C2 and C3.

5. With effect from 1 November 2016, UNECE Regulation No 117, 02 series of amendments, including the stage 2 rolling sound requirements set out in paragraphs 6.1.1 to 6.1.3 of that UNECE Regulation, shall apply for the purpose of the sale and entry into service of new tyres of Classes C1, C2 and C3.

6. With effect from 1 November 2014, UNECE Regulation No 117, 02 series of amendments, including the stage 1 rolling resistance requirements set out in paragraph 6.3.1 of that UNECE Regulation, shall apply for the purpose of the sale and entry into service of new tyres of Classes C1 and C2.

7. With effect from 1 November 2016, UNECE Regulation No 117, 02 series of amendments, including the stage 1 rolling resistance requirements set out in paragraph 6.3.1 of that UNECE Regulation, shall apply for the purpose of the sale and entry into service of new tyres of Class C3.

8. With effect from 1 November 2016, UNECE Regulation No 117, 02 series of amendments, including the stage 2 rolling resistance requirements set out in paragraph 6.3.2 of that UNECE Regulation, shall apply for the purpose of type-approval of new types of tyres of Classes C1, C2 and C3.

9. With effect from 1 November 2018, UNECE Regulation No 117, 02 series of amendments, including the stage 2 rolling resistance requirements set out in paragraph 6.3.2 of that UNECE Regulation, shall apply on a compulsory basis for the purpose of the sale and entry into service of new tyres of Classes C1 and C2.

10. With effect from 1 November 2020, UNECE Regulation No 117, 02 series of amendments, including the stage 2 rolling resistance requirements set out in paragraph 6.3.2 of that UNECE Regulation, shall apply for the purpose of the sale and entry into service of new tyres of Class C3.

([1]) OJ L 108, 28.4.2011, p. 13.
([2]) OJ L 201, 30.7.2008, p. 70.
([3]) OJ L 231, 29.8.2008, p. 19.
([4]) OJ L 183, 11.7.2008, p. 41.

11. New tyres of Classes C1, C2 and C3 that were manufactured prior to the dates set out in paragraph 2 concerning general requirements and wet grip performance, paragraph 4 concerning general requirements, paragraph 5 concerning stage 2 rolling sound requirements, paragraphs 6 and 7 concerning stage 1 rolling resistance requirements as well as paragraphs 9 and 10 concerning stage 2 rolling resistance requirements, and which do not comply with these requirements, may be sold and entering into service for an additional period not exceeding 30 months from those dates.

Article 3

1. With effect from 1 November 2012, national authorities shall refuse to grant EC type-approval of new types of vehicles of category M_1 which are not fitted with a tyre pressure monitoring system (TPMS) complying with the relevant requirements laid down in UNECE Regulation No 64, 02 series of amendments, corrigendum 1 ([1]).

2. With effect from 1 November 2014, national authorities shall prohibit the registration, sale and entry into service of vehicles of category M_1 which are not fitted with a TPMS complying with the relevant requirements laid down in UNECE Regulation No 64, 02 series of amendments, corrigendum 1.

Article 4

1. With effect from 1 November 2012, UNECE Regulation No 64, 02 series of amendments, corrigendum 1, shall apply for the purpose of EC type-approval of new types of vehicles of categories M_1 and N_1 where such vehicles are fitted with equipment covered by that Regulation.

2. With effect from 1 November 2014, UNECE Regulation No 64, 02 series of amendments, corrigendum 1, shall apply on a compulsory basis for the purpose of the registration, sale and entry into service of new vehicles of categories M_1 and N_1, where such vehicles are fitted with equipment covered by that Regulation.

Article 5

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2012.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 310, 26.11.2010, p. 18.

ANNEX

Annex IV to Regulation (EC) No 661/2009 is amended as follows:

(1) the list of UNECE Regulations which apply on a compulsory basis is amended as follows:

(a) the entry for Regulation No 13 is replaced by the following:

'13	Braking of vehicles and trailers	Supplement 5 to the 10 series of amendments Corrigenda 1 and 2 to Revision 6 Supplement 3 to the 11 series of amendments	OJ L 257, 30.9.2010, p. 1 OJ L 297, 13.11.2010, p. 183	M, N, O [b]'

(b) the following Regulation No 30 is inserted between Regulation No 28 and Regulation No 31:

'30	Pneumatic tyres for motor vehicles and their trailers (Class C1)	Supplement 16 to the 02 series of amendments	OJ L 201, 30.7.2008, p. 70 OJ L 307, 23.11.2011, p. 1	M, N, O'

(c) the entry for Regulation No 34 is replaced by the following:

'34	Prevention of fire risks (liquid fuel tanks)	Supplement 2 to the 02 series of amendments	OJ L 194, 23.7.2008, p. 14	M, N, O [d]'

(d) the following Regulation No 54 is inserted between Regulation No 48 and Regulation No 55:

'54	Pneumatic tyres for commercial vehicles and their trailers (Classes C2 and C3)	Supplement 17 to the original version of the Regulation	OJ L 183, 11.7.2008, p. 41 OJ L 307, 23.11.2011, p. 2	M, N, O'

(e) the entry for Regulation No 55 is replaced by the following:

'55	Mechanical coupling components of combinations of vehicles	Supplement 1 to the 01 series of amendments	OJ L 227, 28.8.2010, p. 1	M, N, O [e]'

(f) the following Regulation No 64 is inserted between Regulation No 61 and Regulation No 66:

'64	Temporary-use spare unit, run-flat tyres/system and tyre pressure monitoring system	02 series of amendments, corrigendum 1	OJ L 310, 26.11.2010, p. 18	M_1, N_1'

(g) the following Regulation No 117 is inserted between Regulation No 116 and Regulation No 118:

'117	Tyres with regard to rolling sound emissions, adhesion on wet surfaces and rolling resistance (Classes C1, C2 and C3)	02 series of amendments	OJ L 307, 23.11.2011, p. 3	M, N, O'

(2) the notes to the table are amended as follows:

(a) notes (b) and (c) are replaced by the following:

'(b) The fitting of an electronic stability control system is required in accordance with Article 12 of this Regulation. Therefore, the application of Annex 21 to UNECE Regulation No 13 is mandatory for the purposes of EC type-approval of new types of vehicles as well as for registration, sale and entry into service of new vehicles. However, the implementation dates concerning electronic stability control systems mentioned in this Regulation shall apply instead of the dates mentioned in that UNECE Regulation.

(c) The fitting of an electronic stability control system is required in accordance with Article 12 of this Regulation. Therefore, the application of Part A of Annex 9 to UNECE Regulation No 13-H is mandatory for the purposes of EC type-approval of new types of vehicles as well as for registration, sale and entry into service of new vehicles. However, the implementation dates concerning electronic stability control systems mentioned in this Regulation shall apply instead of the dates mentioned in that UNECE Regulation.';

(b) the following notes (d) and (e) are added:

'(d) Compliance with Part II of UNECE Regulation No 34 is not compulsory.

(e) Whenever it is declared by the vehicle manufacturer that a vehicle is suitable for towing loads (point 2.11.5 of Annex I to Directive 2007/46/EC), no mechanical coupling device fitted to it shall obscure any lighting component (e.g. rear fog lamp) or the space for mounting and the fixing of the rear registration plate, unless the mechanical coupling device can be removed or repositioned without the use of any tools, including release keys.'.

COMMISSION IMPLEMENTING REGULATION (EU) No 524/2012

of 20 June 2012

amending Annex I to Council Regulation (EC) No 73/2009 establishing common rules for direct support schemes for farmers under the common agricultural policy

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003 ([1]), and in particular Article 142(i) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 73/2009 establishes the list of support schemes giving right to a direct payment under that Regulation.

(2) Article 129(1) of Regulation (EC) No 73/2009 gives new Member States applying the single area payment scheme the possibility to grant a separate soft fruit payment from 2012. Bulgaria, Hungary and Poland have decided to use that possibility.

(3) The separate soft fruit payment is not listed in Annex I to Regulation (EC) No 73/2009. However, by its very nature, that payment should be considered a direct payment as defined in Article 2(d) of that Regulation since it replaces, from the 2012 calendar year, the transitional soft fruit payment granted pursuant to Article 98 of that Regulation, which is listed in Annex I to that Regulation as a direct payment. Moreover, according to Article 129(2) of Regulation (EC) No 73/2009 the separate soft fruit payment is to be granted within the limits of the amounts referred to in Annex XII to that Regulation corresponding to the soft fruit payment.

(4) For that reason, the non-inclusion of the separate soft fruit payment in Annex I to Regulation (EC) No 73/2009 constitutes an omission that needs to be remedied.

(5) Annex I to Regulation (EC) No 73/2009 should therefore be amended accordingly.

(6) Since the separate soft fruit payment may be granted from 2012, this Regulation should apply from 1 January 2012.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Direct Payments,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex I to Regulation (EC) No 73/2009, the following entry is inserted after the entry 'Fruit and vegetables':

'Fruit and vegetables	Article 129(1) of this Regulation	Separate soft fruit payment'

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2012.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 30, 31.1.2009, p. 16.

COMMISSION IMPLEMENTING REGULATION (EU) No 525/2012

of 20 June 2012

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors [2], and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	TR	41,0
	ZZ	41,0
0707 00 05	MK	18,0
	TR	110,4
	ZZ	64,2
0709 93 10	TR	96,7
	ZZ	96,7
0805 50 10	AR	85,2
	TR	91,2
	UY	109,5
	ZA	90,9
	ZZ	94,2
0808 10 80	AR	111,3
	BR	87,7
	CH	68,9
	CL	102,2
	NZ	126,8
	US	161,4
	UY	61,2
	ZA	108,6
	ZZ	103,5
0809 10 00	IL	705,0
	TR	216,5
	ZZ	460,8
0809 29 00	TR	341,2
	ZZ	341,2
0809 40 05	ZA	249,8
	ZZ	249,8

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION IMPLEMENTING REGULATION (EU) No 526/2012

of 20 June 2012

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Implementing Regulation (EU) No 971/2011 for the 2011/12 marketing year

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector [2], and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2011/12 marketing year are fixed by Commission Implementing Regulation (EU) No 971/2011 [3]. Those prices and duties were last amended by Commission Implementing Regulation (EU) No 496/2012 [4].

(2) The data currently available to the Commission indicate that those amounts should be amended in accordance with Article 36 of Regulation (EC) No 951/2006.

(3) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Implementing Regulation (EU) No 971/2011 for the 2011/12 marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 178, 1.7.2006, p. 24.
[3] OJ L 254, 30.9.2011, p. 12.
[4] OJ L 151, 12.6.2012, p. 29.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 21 June 2012

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 12 10 (1)	39,66	0,00
1701 12 90 (1)	39,66	2,71
1701 13 10 (1)	39,66	0,00
1701 13 90 (1)	39,66	3,01
1701 14 10 (1)	39,66	0,00
1701 14 90 (1)	39,66	3,01
1701 91 00 (2)	48,62	2,88
1701 99 10 (2)	48,62	0,00
1701 99 90 (2)	48,62	0,00
1702 90 95 (3)	0,49	0,22

(1) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.
(2) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.
(3) Per 1 % sucrose content.

COMMISSION IMPLEMENTING REGULATION (EU) No 527/2012

of 20 June 2012

withdrawing the suspension of submission of applications for import licences for sugar products under certain tariff quotas

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products ('Single CMO' Regulation) [1],

Having regard to Commission Regulation (EC) No 891/2009 of 25 September 2009 opening and providing for the administration of certain Community tariff quotas in the sugar sector [2], and in particular Article 5(2) thereof,

Whereas:

(1) Submission of applications for import licences concerning order number 09.4321 were suspended as from 19 January 2012 by Commission Implementing Regulation (EU) No 41/2012 of 18 January 2012 suspending submission of applications for import licences for sugar products under certain tariff quotas [3], in accordance with Regulation (EC) No 891/2009.

(2) Following notifications on unused and/or partly used licences, quantities became available again for that order number. The suspension of applications should therefore be withdrawn,

HAS ADOPTED THIS REGULATION:

Article 1

The suspension laid down by Implementing Regulation (EU) No 41/2012 of submission of applications for import licences for order number 09.4321 as from 19 January 2012 is withdrawn.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 254, 26.9.2009, p. 82.
[3] OJ L 16, 19.1.2012, p. 40.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 18 June 2012

approving restrictions of authorisations of biocidal products containing difethialone notified by Denmark in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council

(notified under document C(2012) 4025)

(Only the Danish text is authentic)

(2012/316/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1], and in particular Article 4(4) thereof,

Whereas:

(1) Annex I to Directive 98/8/EC contains the list of active substances approved at Union level for inclusion in biocidal products. The active substance difethialone was approved for inclusion in products belonging to product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC, by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto. [2]

(2) Difethialone is an anticoagulant rodenticide known to pose risks of accidental incidents with children, as well as risks for animals and the environment. It has been identified as potentially persistent, liable to bioaccumulate and toxic ('PBT'), or very persistent and very liable to bioaccumulate ('vPvB').

(3) For reasons of public health and hygiene, it was nevertheless found to be justified to include difethialone and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise difethialone-based products. However, Directive 2007/69/EC obliges Member States to ensure, when granting authorisation of products containing difethialone, that primary as well as secondary exposure of humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures.

(4) The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that the most significant reductions in exposure to and risks posed by difethialone are achieved by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait and removing unused bait and dead and moribund rodents during a baiting campaign in order to minimise the opportunity of primary or secondary exposure of non-target animals. The evaluation also concluded that only professional users are expected to follow such instructions. The risk mitigation measures mentioned in Directive 2007/69/EC therefore include restriction to professional use only.

(5) The company LiphaTech S.A.S. ('the applicant') has, in accordance with Article 8 of Directive 98/8/EC, submitted an application to the United Kingdom for authorisation of nine rodenticides containing difethialone ('the products'). The products' names and reference numbers in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this decision.

(6) The United Kingdom granted the authorisations on 20 April 2011 (Generation Pat'), on 26 April 2011 (Generation Block) and on 27 April 2011 (Generation Grain'Tech and Rodilon Trio) ('the first authorisations'). The products were authorised with restrictions to ensure that the conditions of Article 5 of Directive 98/8/EC were met in the United Kingdom. Those restrictions did not include a restriction to trained professional users with a license.

(7) The applicant submitted a complete application to Denmark for mutual recognition of the first authorisations in respect of seven of the products (Rodilon Paste, Kvit Muse-Pasta, Rodilon Block, Generation Korn'Tech, Rodilon Trio and Kvit Røde Musekorn, and the product now referred to as Generation Blok) on 9 June 2011, and in respect of two of the products (Generation Museblok and Generation Musekorn) on 14 October 2011.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 312, 30.11.2007, p. 23.

(8) On 2 November 2011, Denmark notified the Commission, the other Member States and the applicant of its proposal to restrict the first authorisations in accordance with Article 4(4) of Directive 98/8/EC. Denmark proposed to impose a restriction on the products to use by trained professionals with a license.

(9) The Commission invited the other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC.

(10) Only the applicant submitted comments within that deadline. The notification was also discussed between Commission representatives, representatives of Member States' Competent Authorities for biocidal products and the applicant in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 6-7 December 2011 and in the meeting of the Competent Authorities for Biocidal Products of 29 February to 2 March 2012.

(11) The applicant has argued that the restriction to use by trained professionals with a license is unjustified and should not be accepted, since its products are also suitable for rodent control by non-trained professionals and non-professionals. Furthermore, the applicant has put forward the arguments that the products are ready-to-use products; that the active ingredient content in the products is low; that an antidote exists; that the products can easily be kept out of the reach of children and non-target animals; that non-professional users are likely to remove dead rodents and that non-professional users can be trained.

(12) The Commission notes that, in accordance with Directive 2007/69/EC, authorisations of biocidal products containing difethialone are to be subject to all appropriate and available risk mitigation measures, including the restriction to professional use only. The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that only professional users could be expected to follow the instructions leading to the most significant reductions in exposure and risk. A restriction to professional users should therefore in principle be considered to be an appropriate risk mitigation measure. The arguments put forward by the applicant do not undermine that conclusion.

(13) In the absence of any indication to the contrary, the Commission therefore considers that a restriction to professional users is an appropriate and available risk mitigation measure for the authorisation of products containing difethialone in Denmark. The fact that the United Kingdom did not consider such a restriction to be appropriate and available for an authorisation in its territory is immaterial for that conclusion. The decision of the United Kingdom to authorise non-professional use was based in particular on the risk of a delay in treatment of household infestations due to the costs involved in hiring trained professionals, and the associated risks to public hygiene. Denmark, however, has explained that that risk is less prevalent in Denmark, thanks to a system of mandatory rat infestation reporting and tax financed controlling by trained professionals, together with the general public's access to alternative methods for control of minor mice infestations.

(14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Denmark may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC for the products mentioned in the Annex to this Decision to use by trained professionals with a license.

Article 2

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 18 June 2012.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

Products for which Denmark may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC to use by trained professionals with a license

Product name in the United Kingdom	United Kingdom application reference number in R4BP	Product name in Denmark	Danish application reference number in R4BP
Generation Block	2009/4329/3928/UK/AA/4786	Generation Blok	2011/4329/3928/DK/MA/18746
Generation Block	2009/4329/3928/UK/AA/4786	Rodilon Block	2009/4329/3928/DK/MA/5109
Generation Block	2009/4329/3928/UK/AA/4786	Generation Museblok	2009/4329/3928/DK/MA/5089
Generation Pat'	2009/4329/3926/UK/AA/4788	Rodilon Paste	2009/4329/3926/DK/MA/5111
Generation Pat'	2009/4329/3926/UK/AA/4788	Kvit Muse Pasta	2010/4329/3926/DK/MA/16305
Generation Grain'Tech	2009/4329/3929/UK/AA/4785	Generation Korn'Tech	2011/4329/3929/DK/MA/18745
Generation Grain'Tech	2009/4329/3929/UK/AA/4785	Generation Musekorn	2009/4329/3929/DK/MA/5125
Rodilon Trio	2009/4329/3930/UK/AA/4792	Rodilon Trio	2010/4329/3930/DK/MA/5108
Rodilon Trio	2009/4329/3930/UK/AA/4792	Kvit Røde Musekorn	2010/4329/3930/DK/MA/16306

COMMISSION IMPLEMENTING DECISION

of 18 June 2012

approving restrictions of authorisations of biocidal products containing difethialone notified by Germany in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council

(notified under document C(2012) 4026)

(Only the German text is authentic)

(2012/317/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1], and in particular Article 4(4) thereof,

Whereas:

(1) Annex I to Directive 98/8/EC contains the list of active substances approved at Union level for inclusion in biocidal products. The active substance difethialone was approved for inclusion in products belonging to product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC, by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto [2].

(2) Difethialone is an anticoagulant rodenticide known to pose risks of accidental incidents with children, as well as risks for animals and the environment. It has been identified as potentially persistent, liable to bioaccumulate and toxic ('PBT'), or very persistent and very liable to bioaccumulate ('vPvB').

(3) For reasons of public health and hygiene, it was nevertheless found to be justified to include difethialone and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise difethialone-based products. However, Directive 2007/69/EC obliges Member States to ensure, when granting authorisation of products containing difethialone, that primary as well as secondary exposure of humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures.

(4) The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that the most significant reductions in exposure to and risks posed by difethialone are achieved by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait and removing unused bait and dead and moribund rodents during a baiting campaign in order to minimise the opportunity of primary or secondary exposure of non-target animals. The evaluation also concluded that only professional users are expected to follow such instructions. The risk mitigation measures mentioned in Directive 2007/69/EC therefore include restriction to professional use only.

(5) The company LiphaTech S.A.S. ('the applicant') has, in accordance with Article 8 of Directive 98/8/EC, submitted an application to the United Kingdom for authorisation of six rodenticides containing difethialone ('the products'). The products' names and reference numbers in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this Decision.

(6) The United Kingdom granted the authorisations on 20 April 2011 (Generation Pat'), on 26 April 2011 (Generation Block, Generation B'Block and Generation S'Block) and on 27 April 2011 (Generation Grain'Tech and Rodilon Trio) ('the first authorisations'). The products were authorised with restrictions to ensure the conditions of Article 5 of Directive 98/8/EC were met in the United Kingdom. Those restrictions did not include restriction to trained or licensed professional users.

(7) On 6 November 2009, the applicant submitted a complete application to Germany for mutual recognition of the first authorisations in respect of the products.

(8) On 22 November 2011, Germany notified the Commission, the other Member States and the applicant of its proposal to restrict the first authorisations in accordance with Article 4(4) of Directive 98/8/EC. Germany proposed to impose a restriction on the products to use by trained or licensed professionals.

(9) The Commission invited the other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. Only the applicant submitted comments within that deadline. The notification was also discussed between Commission representatives, representatives of Member States' Competent Authorities for biocidal products and the applicant in the meeting of the Product Authorisation and Mutual

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 312, 30.11.2007, p. 23.

Recognition Facilitation Group of 6-7 December 2011, in which the applicant participated, and in the meeting of the Competent Authorities for Biocidal Products of 29 February to 2 March 2012.

(10) The applicant has argued that the restriction to use by trained or licensed professionals is unjustified and should not be accepted, since its products are also suitable for rodent control by non-trained professionals and non-professionals. Furthermore, the applicant has put forward the arguments that the products are ready-to-use products; that the active ingredient content in the products is low; that an antidote exists; that the products can easily be kept out of the reach of children and non-target animals; that non-professional users are likely to remove dead rodents; and that non-professional users can be trained.

(11) The Commission notes that, in accordance with Directive 2007/69/EC, authorisations of biocidal products containing difethialone are to be subject to all appropriate and available risk mitigation measures, including the restriction to professional use only. The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that only professional users could be expected to follow the instructions leading to the most significant reductions in exposure and risk. A restriction to professional users should therefore in principle be considered to be an appropriate risk mitigation measure. The arguments put forward by the applicant do not undermine that conclusion.

(12) In the absence of any indication to the contrary, the Commission therefore considers that restriction to professional users is an appropriate and available risk mitigation measure for the authorisation of products containing difethialone in Germany. The fact that the United Kingdom did not consider such a restriction to be appropriate and available for an authorisation in its territory is immaterial for that conclusion. The decision of the United Kingdom to authorise non-professional use was based in particular on the risk of a delay in treatment of household infestations due to the costs involved in hiring trained professionals, and the associated risks to public hygiene. Germany, however, has explained that that risk is less prevalent in Germany thanks to Germany's well functioning infrastructure of trained pest control operators and licensed professionals, such as farmers, gardeners and foresters, together with the availability of alternative methods for pest control within buildings, especially for control of mice.

(13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Germany may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC for the products mentioned in the Annex to this Decision to use by trained or licensed professionals.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 18 June 2012.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

Products for which Germany may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC to use by licensed or trained professionals

Product name in the United Kingdom	United Kingdom application reference number in R4BP	Product name in Germany	German application reference number in R4BP
Rodilon Trio	2009/4329/3930/UK/AA/4792	Brumolin Forte	2009/4329/3930/DE/MA/5214
Generation B'Block	2009/4329/3927/UK/AA/4789	Generation B'Block	2009/4329/3927/DE/MA/5169
Generation Block	2009/4329/3928/UK/AA/4786	Generation Block	2009/4329/3928/DE/MA/5170
Generation Pat'	2009/4329/3926/UK/AA/4788	Generation Pat'	2009/4329/3926/DE/MA/5171
Generation Grain'Tech	2009/4329/3929/UK/AA/4785	Generation Grain'Tech	2009/4329/3929/DE/MA/5172
Generation S'Block	2009/4329/3927/UK/AA/4790	Generation S'Block	2009/4329/3927/DE/MA/5173

COMMISSION IMPLEMENTING DECISION

of 18 June 2012

approving restrictions of authorisations of biocidal products containing difethialone notified by Sweden in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council

(notified under document C(2012) 4027)

(Only the Swedish text is authentic)

(2012/318/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1], and in particular Article 4(4) thereof,

Whereas:

(1) Annex I to Directive 98/8/EC contains the list of active substances approved at Union level for inclusion in biocidal products. The active substance difethialone was approved for inclusion in products belonging to product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC, by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto [2].

(2) Difethialone is an anticoagulant rodenticide known to pose risks of accidental incidents with children, as well as risks for animals and the environment. It has been identified as potentially persistent, liable to bioaccumulate and toxic ('PBT'), or very persistent and very liable to bioaccumulate ('vPvB').

(3) For reasons of public health and hygiene, it was nevertheless found to be justified to include difethialone and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise difethialone-based products. However, Directive 2007/69/EC obliges Member States to ensure, when granting authorisation of products containing difethialone, that primary as well as secondary exposure of humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures.

(4) The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that the most significant reductions in exposure to and risks posed by difethialone are achieved by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait and removing unused bait and dead and moribund rodents during a baiting campaign in order to minimise the opportunity of primary or secondary exposure of non-target animals. The evaluation also concluded that only professional users are expected to follow such instructions. The risk mitigation measures mentioned in Directive 2007/69/EC therefore include restriction to professional use only.

(5) The company LiphaTech S.A.S. ('the applicant') has, in accordance with Article 8 of Directive 98/8/EC, submitted an application to the United Kingdom for authorisation of eight rodenticides containing difethialone ('the products'). The products' names and reference numbers in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this Decision.

(6) The United Kingdom granted the authorisations on 20 April 2011 (Generation Pat'), on 26 April 2011 (Generation Block) and on 27 April 2011 (Generation Grain'Tech and Rodilon Trio) ('the first authorisations'). The products were authorised with restrictions to ensure that the conditions of Article 5 of Directive 98/8/EC were met in the United Kingdom. Those restrictions did not include a restriction to trained professional users with a license.

(7) On 9 June 2011, the applicant submitted a complete application to Sweden for mutual recognition of the first authorisations of the products. For the products with the Swedish product names Rodilon Block, Rodilon Trio and Rodilon Paste, the applications were restricted to authorisation for professional use only.

(8) On 11 October 2011, Sweden notified the Commission, the other Member States and the applicant of its proposal to restrict the first authorisations in accordance with Article 4(4) of Directive 98/8/EC. Sweden proposed to impose a restriction on the products to use by trained professionals with a license.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 312, 30.11.2007, p. 23.

(9) The Commission invited the other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. Only the applicant submitted comments within that deadline. The notification was also discussed between Commission representatives, representatives of Member States' Competent Authorities for biocidal products, and the applicant in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 6-7 December 2011 and in the meeting of the Competent Authorities for Biocidal Products of 29 February to 2 March 2012.

(10) The applicant has argued that the restriction to use by trained professionals with a license is unjustified and should not be accepted, since its products are also suitable for rodent control by non-trained professionals and non-professionals. Furthermore, the applicant has put forward the arguments that the products are ready-to-use products; that the active ingredient content in the products is low; that an antidote exists; that the products can easily be kept out of the reach of children and non-target animals; that non-professional users are likely to remove dead rodents; that non-professional users can be trained and that the proposed restriction to use by trained professionals is likely to increases the cost of householder's insurances in Sweden in the long term.

(11) The Commission notes that, in accordance with Directive 2007/69/EC, authorisations of biocidal products containing difethialone are to be subject to all appropriate and available risk mitigation measures, including the restriction to professional use only. The scientific evaluation leading to the adoption of Directive 2007/69/EC concluded that only professional users could be expected to follow the instructions leading to the most significant reductions in exposure and risk. A restriction to professional users should therefore in principle be considered as an appropriate risk mitigation measure. The arguments put forward by the applicant do not undermine that conclusion.

(12) In the absence of any indication to the contrary, the Commission therefore considers that restriction to professional users is an appropriate and available risk mitigation measure for the authorisation of products containing difethialone in Sweden. The fact that the United Kingdom did not consider such a restriction to be appropriate and available for authorisation in its territory is immaterial for that conclusion. The decision of the United Kingdom to authorise non-professional use was based in particular on the risk of a delay in treatment of household infestations due to the costs involved in hiring trained professionals, and the associated risks to public hygiene. Sweden, however, has explained that that risk is less prevalent in Sweden thanks to the Swedish insurance system, in which householder insurances typically cover the cost of professional pest control in case of an infestation.

(13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Sweden may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC for the products mentioned in the Annex to this Decision to use by trained professionals with a license.

Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 18 June 2012.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX

Products for which Sweden may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC to use by trained professionals with a license

Product name in the United Kingdom	United Kingdom application reference number in R4BP	Product name in Sweden	Swedish application reference number in R4BP
Rodilon Trio	2009/4329/3930/UK/AA/4792	Radar mus och råtta korn	2009/4329/3930/SE/MA/5034
Generation Pat'	2009/4329/3926/UK/AA/4788	Rodilon Paste	2009/4329/3926/SE/MA/5036
Generation Pat'	2009/4329/3926/UK/AA/4788	Radar mus och råtta pasta	2009/4329/3926/SE/MA/5037
Generation Grain'Tech	2009/4329/3929/UK/AA/4785	Generation Grain'Tech	2009/4329/3929/SE/MA/5038
Generation Pat'	2009/4329/3926/UK/AA/4788	Generation Pat'	2009/4329/3926/SE/MA/5039
Rodilon Trio	2009/4329/3930/UK/AA/4792	Rodilon Trio	2009/4329/3930/SE/MA/5040
Generation Block	2009/4329/3928/UK/AA/4786	Rodilon Block	2009/4329/3928/SE/MA/5041
Generation Block	2009/4329/3928/UK/AA/4786	Generation Block	2009/4329/3928/SE/MA/5042

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