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Contents

[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.

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2016/369

of 15 March 2016

on the provision of emergency support within the Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 122(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Mutual assistance and support in the face of disasters is both a fundamental expression of the universal value of solidarity between people and a moral imperative, as such disasters may lead to a significant number of people being unable to meet their basic needs, with potential severe adverse effects on their health and lives.

(2) The impact of both man-made and natural disasters within the Union is increasingly severe. This is linked to a number of factors, such as climate change, but also to other contributing external factors and circumstances which are unfolding in the Union's neighbourhood. The migration and refugee situation currently affecting the Union is a notable example of a situation where, despite the efforts undertaken by the Union to address the root causes located in third countries, the economic situation of Member States may be directly affected.

(3) This situation led the European Council, on 19 February 2016, to call upon the Commission to put in place the capacity to provide humanitarian assistance internally, in order to support countries facing large numbers of refugees and migrants.

(4) Man-made or natural disasters may be of such a scale and impact that they can give rise to severe economic difficulties in one or several Member States. They can also occur in one or several Member States already facing severe economic difficulties for other reasons, with the result of exacerbating and aggravating even further the overall economic situation of the Member States concerned. In either case, the response capacity of the Member States concerned would be adversely affected, and the assistance and support being provided to people in need would, in turn, be negatively affected.

(5) While the Union is already in a position to grant support of a macro-financial nature to Member States, and to express European solidarity to disaster-stricken regions through the European Union Solidarity Fund (EUSF) established by Council Regulation (EC) No 2012/2002 ([1]), there is currently no appropriate instrument available at Union level to address on a sufficiently predictable and independent basis the humanitarian needs of disaster-stricken people within the Union, such as food assistance, emergency healthcare, shelter, water, sanitation and hygiene, protection and education. Mutual assistance can be offered under the Union Civil Protection Mechanism pursuant to Decision No 1313/2013/EU of the European Parliament and of the Council ([2]), but the operation of

([1]) Council Regulation (EC) No 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund (OJ L 311, 14.11.2002, p. 3).

([2]) Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

that Mechanism is based on voluntary contributions from Member States. There could also be assistance and support provided through existing Union policy and financing instruments, such as those aimed at establishing an area of freedom, security and justice in the Union. Any such assistance and support would, however, be accessory and ancillary to the pursuit of the principal policy objectives of those instruments and, therefore, be limited in its scope and scale.

(6) It therefore seems appropriate for the Union to act in a spirit of solidarity to address the basic needs of disaster-stricken people within the Union, and to contribute to reducing the economic impact of those disasters on the Member States concerned.

(7) Given the similarities in addressing the basic needs of disaster-stricken people within the Union through the provision of emergency support and in providing humanitarian aid to people affected by man-made or natural disasters in third countries, all operations under this Regulation should be conducted in compliance with internationally-agreed humanitarian principles. Those actions constitute measures appropriate to the economic situation of the Member States facing those difficulties and complementing Union action encouraging cooperation between Member States in order to improve the effectiveness of systems for preventing and protecting against natural or man-made disasters.

(8) Given the need to act in a spirit of solidarity, the provision of emergency support under this Regulation should be financed by the general budget of the Union, as well as by contributions which may be made by other public or private donors.

(9) The reimbursement of expenses and award of public procurement contracts and grants under this Regulation should be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ([1]), taking into account the specific nature of emergency support. It is therefore appropriate to provide that grants and public procurement contracts may be awarded directly or indirectly, and that grants may finance up to 100 % of the eligible costs and be awarded with retroactive effect. The Commission should be able to finance emergency support operations of any organisation which, independent of its legal nature, whether private or public, possesses the requisite experience and uses to that effect direct or indirect management, as appropriate.

(10) Furthermore, it is appropriate to rely on organisations with which the Commission has concluded framework partnership agreements pursuant to Council Regulation (EC) No 1257/96 ([2]), in light of the relevance of the experience acquired by those organisations in providing humanitarian aid in close coordination with the Commission. Wherever possible the involvement of local non-governmental organisations should be sought, via partner organisations with framework partnership agreements, in order to maximise synergies and the efficiency of any emergency support provided under this Regulation.

(11) The financial interests of the Union should be protected by means of proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, unduly paid or incorrectly used and, where appropriate, administrative and financial penalties in accordance with Regulation (EU, Euratom) No 966/2012.

(12) This Regulation should lay down the basis for providing financial support in the event of natural or man-made disasters in respect of which, in a spirit of solidarity, the Union would be better placed than Member States, acting alone and in an uncoordinated manner, to mobilise appropriate levels of financing and use them to implement operations of a potentially life-saving nature in an economic, efficient and effective manner, thereby allowing a more effective action by reason of its scale and complementarity.

(13) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

([1]) Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

([2]) Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid (OJ L 163, 2.7.1996, p. 1).

(14) The provision of emergency support under this Regulation should be aptly monitored, relying, where need be, on the most relevant expertise available at Union level. Furthermore, the overall implementation of this Regulation should be evaluated.

(15) Given the urgency of the support needed, this Regulation should enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down the framework within which Union emergency support may be awarded through specific measures appropriate to the economic situation in the event of an ongoing or potential natural or man-made disaster. Such emergency support can only be provided where the exceptional scale and impact of the disaster is such that it gives rises to severe wide-ranging humanitarian consequences in one or more Member States and only in exceptional circumstances where no other instrument available to Member States and to the Union is sufficient.

2. Emergency support provided under this Regulation shall be in support of, and complementary to, the actions of the affected Member State. To this end, close cooperation and consultation with the affected Member State shall be ensured.

Article 2

Activation of the emergency support

1. The decision about the activation of the emergency support under this Regulation in case of an ongoing or potential disaster shall be taken by the Council on the basis of a proposal by the Commission, specifying where appropriate the duration of the activation.

2. The Council shall immediately examine the proposal of the Commission referred to in paragraph 1 and shall decide, in accordance with the urgency of the situation, on the activation of the emergency support.

Article 3

Eligible actions

1. Emergency support under this Regulation shall provide a needs-based emergency response, complementing the response of the affected Member States, aimed at preserving life, preventing and alleviating human suffering, and maintaining human dignity wherever the need arises as a result of a disaster referred to in Article 1.

2. Emergency support, as referred to in paragraph 1, may include any of the humanitarian aid actions which would be eligible for Union financing pursuant to Articles 2, 3 and 4 of Regulation (EC) No 1257/96, and may consequently encompass assistance, relief and, where necessary, protection operations to save and preserve life in disasters or in their immediate aftermath. It may also be used to finance any other expenditure directly related to the implementation of emergency support under this Regulation.

3. Emergency support under this Regulation shall be granted and implemented in compliance with the fundamental humanitarian principles of humanity, neutrality, impartiality and independence.

4. The actions referred to in paragraph 2 shall be carried out by the Commission or by partner organisations selected by the Commission. The Commission may notably select, as partner organisations, non-governmental organisations, specialised services of the Member States or international agencies and organisations having the requisite expertise. In doing so, the Commission shall maintain a close cooperation with the affected Member State.

Article 4

Types of financial intervention and implementing procedures

1. The Commission shall implement the Union's financial support in accordance with Regulation (EU, Euratom) No 966/2012. In particular, Union financing for support actions under this Regulation shall be implemented by means of direct or indirect management in accordance with points (a) and (c), respectively, of Article 58(1) of that Regulation.

2. Emergency support under this Regulation shall be financed by the general budget of the Union and by contributions which may be made by other public or private donors as external assigned revenue in accordance with Article 21(4) of Regulation (EU, Euratom) No 966/2012.

3. Union financing for support actions under this Regulation to be implemented by means of direct management may be awarded directly by the Commission without a call for proposals, in accordance with Article 128(1) of Regulation (EU, Euratom) No 966/2012. To that effect, the Commission may enter into framework partnership agreements or rely on existing framework partnership agreements concluded pursuant to Regulation (EC) No 1257/96.

4. Where the Commission implements emergency support operations through non-governmental organisations, the criteria concerning financial and operational capacity shall be deemed to be satisfied where there is a framework partnership agreement in force between that organisation and the Commission pursuant to Regulation (EC) No 1257/96.

Article 5

Eligible Costs

1. Union financing may cover any direct costs necessary for the implementation of the eligible actions set out in Article 3, including the purchase, preparation, collection, transport, storage and distribution of goods and services under those actions.

2. The indirect costs of the partner organisations may also be covered in accordance with Regulation (EU, Euratom) No 966/2012.

3. Union financing may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the emergency support to be provided under this Regulation.

4. Union financing for emergency support actions under this Regulation may cover up to 100 % of the eligible costs.

5. Expenditure incurred by a partner organisation before the date of submission of an application for funding may be eligible for Union financing.

Article 6

Complementarity and consistency of Union action

Synergies and complementarity shall be sought with other instruments of the Union, in particular with respect to those instruments under which some form of emergency assistance or support may be offered, such as Regulation (EC) No 2012/2002, Decision No 1313/2013/EU, Regulation (EC) No 1257/96, Regulation (EU) No 223/2014 of the European Parliament and of the Council ([1]), Regulation (EU) No 513/2014 of the European Parliament and of the Council ([2]), Regulation (EU) No 514/2014 of the European Parliament and of the Council ([3]), Regulation (EU) No 515/2014 of the European Parliament and of the Council ([4]) and Regulation (EU) No 516/2014 of the European Parliament and of the Council ([5]).

([1]) Regulation (EU) No 223/2014 of the European Parliament and of the Council of 11 March 2014 on the Fund for European Aid to the Most Deprived (OJ L 72, 12.3.2014, p. 1).

([2]) Regulation (EU) No 513/2014 of the European Parliament and of the Council of 16 April 2014 establishing, as part of the Internal Security Fund, the instrument for financial support for police cooperation, preventing and combating crime, and crisis management and repealing Council Decision 2007/125/JHA (OJ L 150, 20.5.2014, p. 93).

([3]) Regulation (EU) No 514/2014 of the European Parliament and of the Council of 16 April 2014 laying down general provisions on the Asylum, Migration and Integration Fund and on the instrument for financial support for police cooperation, preventing and combating crime, and crisis management (OJ L 150, 20.5.2014, p. 112).

([4]) Regulation (EU) No 515/2014 of the European Parliament and of the Council of 16 April 2014 establishing, as part of the Internal Security Fund, the instrument for financial support for external borders and visa and repealing Decision No 574/2007/EC (OJ L 150, 20.5.2014, p. 143).

([5]) Regulation (EU) No 516/2014 of the European Parliament and of the Council of 16 April 2014 establishing the Asylum, Migration and Integration Fund, amending Council Decision 2008/381/EC and repealing Decisions No 573/2007/EC and No 575/2007/EC of the European Parliament and of the Council and Council Decision 2007/435/EC (OJ L 150, 20.5.2014, p. 168).

Article 7

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors, who have received Union funds under this Regulation.

3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 ([1]) of the European Parliament and of the Council and Council Regulation (Euratom, EC) No 2185/96 ([2]) with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.

4. Without prejudice to paragraphs 1, 2 and 3, contracts and grant agreements as well as agreements with international organisations and Member States' specialised services, resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.

Article 8

Monitoring and evaluation

1. Actions receiving financial support under this Regulation shall be monitored regularly. At the latest 12 months after the activation of the emergency support for a specific situation in accordance with Article 2, the Commission shall present a report to the Council and, where appropriate, proposals to terminate it.

2. By 17 March 2019, the Commission shall submit an evaluation of the operation of this Regulation to the Council, together with suggestions for the future of this Regulation and, where appropriate, proposals to amend or terminate it.

Article 9

Entry into Force and activation

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

2. The Council hereby decides to activate the emergency support under this Regulation as of the day of its entry into force for the current influx of refugees and migrants into the Union, for a period of three years.

([1]) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

([2]) Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

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

Done at Brussels, 15 March 2016.

For the Council
The President
A.G. KOENDERS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/370

of 15 March 2016

approving the active substance pinoxaden, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and allowing the Member States to extend provisional authorisations granted for that active substance

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For pinoxaden the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2005/459/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC, the United Kingdom received on 31 March 2004 an application from Syngenta Crop Protection AG for the inclusion of the active substance pinoxaden in Annex I to Directive 91/414/EEC. Decision 2005/459/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State, the United Kingdom, submitted a draft assessment report on 30 November 2005. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant on 6 June 2011. The evaluation of the additional data by the United Kingdom was submitted in the format of addenda to the draft assessment report on 30 January 2012.

(4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion ([5]) on the peer review of the pesticide risk assessment of the active substance pinoxaden on 14 June 2013. The draft assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 29 January 2016 in the format of the Commission review report for pinoxaden.

(5) It has appeared from the various examinations made that plant protection products containing pinoxaden may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve pinoxaden.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).
([3]) Commission Decision 2005/459/EC of 22 June 2005 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pinoxaden in Annex I to Council Directive 91/414/EEC (OJ L 160, 23.6.2005, p. 32).
([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).
([5]) European Food Safety Authority, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden. EFSA Journal 2013;11(6):3269, 112 pp. doi:10.2903/j.efsa.2013.3269.

(6) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.

(8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing pinoxaden. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.

(9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

(10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [2] should be amended accordingly.

(11) It is also appropriate to allow Member States to extend provisional authorisations granted for plant protection products containing pinoxaden in order to provide them with the time necessary to fulfil the obligations set out in this Regulation as regards those provisional authorisations.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance pinoxaden, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing pinoxaden as an active substance by 31 December 2016.

[1] Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

[2] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing pinoxaden as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 June 2016 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing pinoxaden as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2017 at the latest; or

(b) in the case of a product containing pinoxaden as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2017 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 4

Extension of existing provisional authorisations

Member States may extend existing provisional authorisations for plant protection products containing pinoxaden for a period ending on 31 December 2017 at the latest.

Article 5

Entry into force and date of application

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

It shall apply from 1 July 2016 with the exception of Article 4 which shall apply as of the entry into force of this Regulation.

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

Done at Brussels, 15 March 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Pinoxaden CAS No 243973-20-8 CIPAC No 776	8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate	≥ 970 g/kg Toluene max. content 1 g/kg	1 July 2016	30 June 2026	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate. The applicant shall submit confirmatory information as regards: (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; (b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (2) concerning pinoxaden.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'97	Pinoxaden CAS No 243973-20-8 CIPAC No 776	8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate	≥ 970 g/kg Toluene max. content 1 g/kg	1 July 2016	30 June 2026	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate. The applicant shall submit confirmatory information as regards: (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; (b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 concerning pinoxaden.'

(*) Further details on identity and specification of active substance are provided in the review report.

COMMISSION REGULATION (EU) 2016/371

of 15 March 2016

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular the first subparagraph of Article 18(5) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from InQpharm Europe Ltd, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to a standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight (Question No EFSA-Q-2013-00973 ([2])). The claim proposed by the applicant was worded as follows: 'Helps to reduce body weight'.

(6) On 16 July 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Natural Alternative International, Inc. (NAI), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to beta-alanine and increase in physical performance during short-duration, high-intensity exercise (Question No EFSA-Q-2013-00974 ([3])). The claim proposed by the applicant was worded as follows: 'Beta-alanine increases performance during short-duration high intensity exercise'.

(8) On 16 July 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of beta-alanine and increase in physical performance during short-duration, high-intensity exercise. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) EFSA Journal 2014;12(7):3754.
([3]) EFSA Journal 2014;12(7):3755.

(9) Following an application from Federación Nacional de Industrias Lácteas (FeNIL), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to fat-free yogurts and fermented milks complying with the specifications 'fat free', 'low in sugars', 'high protein', 'source of calcium' and 'source of vitamin D' for nutrition claims and reduction of body and visceral fat while maintaining lean body mass in the context of an energy-restricted diet (Question No EFSA-Q-2014-00126 ([1])). The claim proposed by the applicant was worded as follows: 'Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to reduce body and visceral fat in the context of an energy-restricted diet'.

(10) On 7 January 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications 'fat free', 'low in sugars', 'high protein', 'source of calcium' and 'source of vitamin D' for nutrition claims and reduction of body and visceral fat while maintaining lean body mass in the context of an energy-restricted diet. In that opinion, the Authority also noted that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from Federación Nacional de Industrias Lácteas (FeNIL), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications 'fat free', 'low in sugars', 'high protein', 'source of calcium' and 'source of vitamin D' for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet (Question No EFSA-Q-2014-00127 ([2])). The claim proposed by the applicant was worded as follows: 'Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to maintain lean body mass (muscle and bone) in the context of an energy-restricted diet'.

(12) On 7 January 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications 'fat free', 'low in sugars', 'high protein', 'source of calcium' and 'source of vitamin D' for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet. In that opinion, the Authority also noted that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from Avesthagen Limited, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Teestar™, a fenugreek seed extract standardised by its content of galactomannan, and a reduction of post-prandial glycaemic responses (Question No EFSA-Q-2014-00153 ([3])). The claim proposed by the applicant was worded as follows: 'Teestar™ lowers blood glucose levels'.

(14) On 8 January 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of Teestar™, a fenugreek seed extract standardised by its content of galactomannan, and a reduction of post-prandial glycaemic responses. In that opinion, the Authority also noted that in the absence of evidence for an effect of Teestar™ on post-prandial glycaemic responses in humans, animal studies on potential mechanisms do not provide support for the scientific substantiation of the claim. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) The comments from the applicants received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) EFSA Journal 2015;13(1):3948.
([2]) EFSA Journal 2015;13(1):3949.
([3]) EFSA Journal 2015;13(1):3952.

HAS ADOPTED THIS REGULATION:

Article 1

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

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, 15 March 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Rejected health claim

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.)	Helps to reduce body weight	Q-2013-00973
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Beta-alanine	Beta-alanine increases performance during short-duration high intensity exercise	Q-2013-00974
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications 'fat free', 'low in sugars', 'high protein', 'source of calcium' and 'source of vitamin D' for nutrition claims	Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to reduce body and visceral fat in the context of an energy-restricted diet	Q-2014-00126
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications 'fat free', 'low in sugars', 'high protein', 'source of calcium' and 'source of vitamin D' for nutrition claims	Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to maintain lean body mass (muscle and bone) in the context of an energy-restricted diet	Q-2014-00127
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Teestar™, a fenugreek seed extract standardised by its content of galactomannan	Teestar™ lowers blood glucose levels	Q-2014-00153

COMMISSION REGULATION (EU) 2016/372

of 15 March 2016

refusing to authorise a health claim made on foods and referring to the reduction of disease risk

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Lycotec Ltd, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to L-tug lycopene and reduction of blood low-density lipoprotein (LDL)-cholesterol (Question No EFSA-Q-2014-00590 ([2])). The claim proposed by the applicant was worded as follows: 'L-tug lycopene has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease'.

(6) On 26 February 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of L-tug lycopene and reduction of blood LDL-cholesterol concentrations. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) The measure provided for in this Regulation is in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2015;13(2):4025.

Article 2

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, 15 March 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Rejected health claim

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk.	L-tug lycopene	L-tug lycopene has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	Q-2014-00590

COMMISSION IMPLEMENTING REGULATION (EU) 2016/373

of 15 March 2016

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 Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([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, 15 March 2016.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([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	IL	170,8
	MA	104,1
	SN	176,8
	TN	107,9
	TR	111,1
	ZZ	134,1
0707 00 05	MA	84,3
	TR	142,7
	ZZ	113,5
0709 93 10	MA	60,7
	TR	156,0
	ZZ	108,4
0805 10 20	EG	45,7
	IL	75,0
	MA	55,1
	TN	57,2
	TR	65,0
	ZZ	59,6
0805 50 10	MA	124,8
	TR	94,8
	ZZ	109,8
0808 10 80	BR	84,6
	US	170,6
	ZZ	127,6
0808 30 90	AR	89,9
	CL	156,6
	CN	79,6
	TR	153,6
	ZA	103,7
	ZZ	116,7

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COUNCIL DECISION (EU) 2016/374

of 14 March 2016

amending Decision No 529/2013/EU of the European Parliament and of the Council to include reference levels for forest management, minimum values for the definition of forest and base year of emissions for the Republic of Croatia

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Act of Accession of the Republic of Croatia and in particular Article 50 thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Pursuant to Article 50 of the Act of Accession of Croatia, where acts of the institutions adopted prior to accession require adaptation by reason of accession, and the necessary adaptations have not been provided for in the Act of Accession or its Annexes, the Council, acting by qualified majority on a proposal from the Commission, shall, to that end, adopt the necessary acts if the original act was not adopted by the Commission.

(2) Decision No 529/2013/EU of the European Parliament and of the Council [1] sets Member State reference levels for forest management, minimum values for the definition of forest and the base year or period of emissions in Annexes II, V and VI, respectively.

(3) Following the accession of the Republic of Croatia to the European Union on 1 July 2013, the specific reference level, values for the definition of forest and base year for Croatia should also be included in Annexes II, V and VI to Decision No 529/2013/EU, respectively.

(4) Decision No 529/2013/EU should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision No 529/2013/EU is amended as follows:

(1) in Annex II, the following is inserted after the entry for Bulgaria:

'Croatia – 6 289';

(2) in Annex V, the following is inserted for area (ha), tree crown cover (%) and tree height (m), respectively, after the entry for Bulgaria:

'Croatia 0,1 10 2';

[1] Decision No 529/2013/EU of the European Parliament and of the Council of 21 May 2013 on accounting rules on greenhouse gas emissions and removals resulting from activities relating to land use, land-use change and forestry and on information concerning actions relating to those activities (OJ L 165, 18.6.2013, p. 80).

(3) in Annex VI, the following is inserted after the entry for Bulgaria:
'Croatia 1990'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 14 March 2016.

For the Council
The President
M.H.P. VAN DAM

COMMISSION IMPLEMENTING DECISION (EU) 2016/375

of 11 March 2016

authorising the placing on the market of lacto-*N*-neotetraose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2016) 1419)

(Only the Danish text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) On 15 January 2014, the company Glycom A/S made a request to the competent authorities of Ireland to place lacto-*N*-neotetraose on the market as a novel food ingredient.

(2) On 10 June 2014, the competent food assessment body of Ireland issued its initial assessment report. In that report, it came to the conclusion that lacto-*N*-neotetraose meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 7 July 2014, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.

(5) On 13 October 2014, the Commission consulted the European Food Safety Authority (EFSA), asking it to carry out an assessment for lacto-*N*-neotetraose as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 29 June 2015, EFSA in its 'Scientific Opinion on the safety of lacto-*N*-neotetraose as a novel food ingredient pursuant to Regulation (EC) No 258/97' ([2]), concluded that lacto-*N*-neotetraose is safe for the proposed uses and use levels.

(7) On 5 October 2015, the applicant sent a letter to the Commission and provided additional information to support the use and approval of 2′-*O*-fucosyllactose and lacto-*N*-neotetraose in food supplements for general population (excluding infants) under Regulation (EC) No 258/97.

(8) On 14 October 2015, the Commission consulted EFSA asking it to carry out an assessment of the safety of these novel foods in food supplements also for children (excluding infants).

(9) On 28 October 2015, EFSA in its 'Statement on the safety of lacto-*N*-neotetraose and 2′-*O*-fucosyllactose as novel food ingredients in food supplements for children' ([3]), concluded that lacto-*N*-neotetraose is safe for the proposed uses and use levels.

(10) Commission Directive 96/8/EC ([4]) lays down requirements on foods intended for use in energy-restricted diets for weight reduction. Commission Directive 1999/21/EC ([5]) lays down requirements for dietary foods for special

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) EFSA Journal 2015; 13(7):4183.
([3]) EFSA Journal 2015;13(11):4299.
([4]) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).
([5]) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

medical purposes. Directive 2002/46/EC of the European Parliament and of the Council [1] lays down requirements on food supplements. Commission Directive 2006/125/EC [2] lays down requirements for processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC [3] lays down requirements for infant formulae and follow-on formulae. Regulation (EC) No 1925/2006 of the European Parliament and of the Council [4] lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. Commission Regulation (EC) No 41/2009 [5] lays down requirements for the composition and labelling of foodstuffs suitable for people intolerant to gluten. Commission Implementing Regulation (EU) No 828/2014 [6] lays down the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. The use of lacto-*N*-neotetraose should be authorised without prejudice to the requirements of those legislations.

(11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Lacto-*N*-neotetraose as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II without prejudice to the specific provisions of Directives 96/8/EC, 1999/21/EC, 2002/46/EC, 2006/125/EC, 2006/141/EC and Regulations (EC) No 1925/2006, (EC) No 41/2009 and Implementing Regulation (EU) No 828/2014.

Article 2

1. The designation of lacto-*N*-neotetraose authorised by this Decision on the labelling of the foodstuffs containing it shall be 'lacto-*N*-neotetraose'.

2. Information shall be given to the consumer that food supplements containing lacto-*N*-neotetraose should not be used if other foods with added lacto-*N*-neotetraose are consumed the same day.

3. Information shall be given to the consumer that food supplements containing lacto-*N*-neotetraose intended for young children should not be used if breast milk or other foods with added lacto-*N*-neotetraose are consumed the same day.

Article 3

This Decision is addressed to Glycom A/S, Diplomvej 373, 2800 Kgs. Lyngby, Denmark.

Done at Brussels, 11 March 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

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[1] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
[2] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).
[3] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).
[4] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).
[5] Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ L 16, 21.1.2009, p. 3).
[6] Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).

ANNEX I

SPECIFICATION OF LACTO-*N*-NEOTETRAOSE

Definition:

Chemical name	β-d-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-d-glucopyranosyl-(1→3)-β-d-galactopyranosyl-(1→4)-d-glucopyranose
Chemical formula	$C_{26}H_{45}NO_{21}$
Molecular weight	707,63 g/mol
CAS No	13007-32-4

Description: Lacto-*N*-neotetraose is a white to off-white powder.

Purity:

Test	Specification
Assay	Not less than 96 %
D-Lactose	Not more than 1,0 w/w %
Lacto-N-triose II	Not more than 0,3 w/w %
Lacto-N-neotetraose fructose isomer	Not more than 0,6 w/w %
pH (20 °C, 5 % solution)	5,0-7,0
Water (%)	Not more than 9,0 %
Ash, sulphated	Not more than 0,4 %
Acetic acid	Not more than 0,3 %
Residual solvents (methanol, 2-propanol, methyl acetate, acetone)	Not more than 50 mg/kg singly Not more than 200 mg/kg in combination
Residual proteins	Not more than 0,01 %
Palladium	Not more than 0,1 mg/kg
Nickel	Not more than 3,0 mg/kg

Microbiological criteria:

Aerobic mesophilic bacteria total count	Not more than 500 CFU/g
Yeasts	Not more than 10 CFU/g
Moulds	Not more than 10 CFU/g
Residual endotoxins	Not more than 10 EU/mg

ANNEX II

AUTHORISED USES OF LACTO-N-NEOTETRAOSE

Food category	Maximum levels
Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,6 g/l
Unflavoured fermented milk-based products	0,6 g/l for beverages 9,6 g/kg for products other than beverages
Flavoured fermented milk-based products including heat-treated products	0,6 g/l for beverages 9,6 g/kg for products other than beverages
Dairy analogues, including beverage whiteners	0,6 g/l for beverages 6 g/kg for products other than beverages 200 g/kg for whitener
Cereal bars	6 g/kg
Table-top sweeteners	100 g/kg
Infant formulae as defined in Directive 2006/141/EC	0,6 g/l in combination with 1,2 g/l of 2′-*O*-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formulae as defined in Directive 2006/141/EC	0,6 g/l in combination with 1,2 g/l of 2′-*O*-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Processed cereal-based food and baby food for infants and young children as defined in Directive 2006/125/EC	6 g/kg for products other than beverages 0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer
Milk-based drinks and similar products intended for young children	0,6 g/l for milk-based drinks and similar products added alone or in combination with 2′-*O*-fucosyllactose, at concentrations 1,2 g/l, at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Dietary foods for special medical purposes as defined in Directive 1999/21/EC	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Foods intended for use in energy-restricted diets for weight reduction as defined in Directive 96/8/EC (only for products presented as a replacement for the whole of the daily diet)	2,4 g/l for drinks 20 g/kg for bars
Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009 [1]	30 g/kg
Flavoured drinks	0,6 g/l

Food category	Maximum levels
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	4,8 g/l [2]
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	1,5 g/day for general population 0,6 g/day for young children

[1] From 20 July 2016 the category 'Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009' shall be replaced by the following: 'Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014'.

[2] The maximum level refers to the products ready to use.

COMMISSION IMPLEMENTING DECISION (EU) 2016/376

of 11 March 2016

authorising the placing on the market of 2′-*O*-fucosyllactose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2016) 1423)

(Only the Danish text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) On 23 June 2014, the company Glycom A/S made a request to the competent authorities of Ireland to place 2′-*O*-fucosyllactose on the market as a novel food ingredient.

(2) On 3 October 2014, the competent food assessment body of Ireland issued its initial assessment report. In that report, it came to the conclusion that 2′-*O*-fucosyllactose meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 9 October 2014, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.

(5) On 22 December 2014, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an assessment for 2′-*O*-fucosyllactose as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 29 June 2015, EFSA in its 'Scientific Opinion on the safety of 2′-*O*-fucosyllactose as a novel food ingredient pursuant to Regulation (EC) No 258/97' ([2]), concluded that 2′-*O*-fucosyllactose is safe for the proposed uses and use levels.

(7) On 5 October 2015, the applicant sent a letter to the Commission and provided additional information to support the use and approval of 2′-*O*-fucosyllactose and lacto-*N*-neotetraose in food supplements for general population (excluding infants) under Regulation (EC) No 258/97.

(8) On 14 October 2015, the Commission consulted EFSA asking it to carry out an assessment of the safety of these novel foods in food supplements also for children (excluding infants).

(9) On 28 October 2015, EFSA in its 'Statement on the safety of lacto-*N*-neotetraose and 2′-*O*-fucosyllactose as novel food ingredients in food supplements for children' ([3]), concluded that 2′-*O*-fucosyllactose is safe for the proposed uses and use levels.

(10) Commission Directive 96/8/EC ([4]) lays down requirements on foods intended for use in energy-restricted diets for weight reduction. Commission Directive 1999/21/EC ([5]) lays down requirements for dietary foods for special

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) EFSA Journal 2015; 13(7):4184.
([3]) EFSA Journal 2015;13(11):4299.
([4]) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).
([5]) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

medical purposes. Directive 2002/46/EC of the European Parliament and of the Council [1] lays down requirements on food supplements. Commission Directive 2006/125/EC [2] lays down requirements for processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC [3] lays down requirements for infant formulae and follow-on formulae. Regulation (EC) No 1925/2006 of the European Parliament and of the Council [4] lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. Commission Regulation (EC) No 41/2009 [5] lays down requirements for the composition and labelling of foodstuffs suitable for people intolerant to gluten. Commission Implementing Regulation (EU) No 828/2014 [6] lays down the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. The use of 2′-O-fucosyllactose should be authorised without prejudice to the requirements of those legislations

(11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

2′-O-Fucosyllactose as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II without prejudice to the specific provisions of Directives 96/8/EC, 1999/21/EC, 2002/46/EC, 2006/125/EC, 2006/141/EC and Regulations (EC) No 1925/2006, (EC) No 41/2009 and Implementing Regulation (EU) No 828/2014

Article 2

1. The designation of 2′-O-fucosyllactose authorised by this Decision on the labelling of the foodstuffs containing it shall be '2′-O-fucosyllactose'.

2. Information shall be given to the consumer that food supplements containing 2′-O-fucosyllactose should not be used if other foods with added 2′-O-fucosyllactose are consumed the same day.

3. Information shall be given to the consumer that food supplements containing 2′-O-fucosyllactose intended for young children should not be used if breast milk or other foods with added 2′-O-fucosyllactose are consumed the same day.

Article 3

This Decision is addressed to Glycom A/S, Diplomvej 373, 2800 Kgs. Lyngby, Denmark.

Done at Brussels, 11 March 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

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(1) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
(2) Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).
(3) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).
(4) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).
(5) Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ L 16, 21.1.2009, p. 3).
(6) Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).

ANNEX I

SPECIFICATION OF 2′-*O*-FUCOSYLLACTOSE

Definition:

Chemical name	α-l-Fucopyranosyl-(1→2)-β-d-galactopyranosyl-(1→4)-d-glucopyranose
Chemical formula	$C_{18}H_{32}O_{15}$
Molecular weight	488,44 g/mol
CAS No	41263-94-9

Description: 2′-O-fucosyllactose is a white to off-white powder.

Purity:

Test	Specification
Assay	Not less than 95 %
D-Lactose	Not more than 1,0 w/w %
L-Fucose	Not more than 1,0 w/w %
Difucosyl-d-lactose isomers	Not more than 1,0 w/w %
2′-Fucosyl-d-lactulose	Not more than 0,6 w/w %
pH (20 °C, 5 % solution)	3,2-7,0
Water (%)	Not more than 9,0 %
Ash, sulphated	Not more than 0,2 %
Acetic acid	Not more than 0,3 %
Residual solvents (methanol, 2-propanol, methyl acetate, acetone)	Not more than 50 mg/kg singly Not more than 200 mg/kg in combination
Residual proteins	Not more than 0,01 %
Palladium	Not more than 0,1 mg/kg
Nickel	Not more than 3,0 mg/kg

Microbiological criteria:

Aerobic mesophilic bacteria total count	Not more than 500 CFU/g
Yeasts	Not more than 10 CFU/g
Moulds	Not more than 10 CFU/g
Residual endotoxins	Not more than 10 EU/mg

ANNEX II

AUTHORISED USES OF 2′-*O*-FUCOSYLLACTOSE

Food category	Maximum levels
Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l
Unflavoured fermented milk-based products	1,2 g/l beverages 19,2 g/kg products other than beverages
Flavoured fermented milk-based products including heat-treated products	1,2 g/l beverages 19,2 g/kg products other than beverages
Dairy analogues, including beverage whiteners	1,2 g/l beverages 12 g/kg for products other than beverages 400 g/kg for whitener
Cereal bars	12 g/kg
Table-top sweeteners	200 g/kg
Infant formulae as defined in Directive 2006/141/EC	1,2 g/l in combination with 0,6 g/l of lacto-*N*-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formulae as defined in Directive 2006/141/EC	1,2 g/l in combination with 0,6 g/l of lacto-*N*-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Processed cereal-based food and baby food for infants and young children as defined in Directive 2006/125/EC	12 g/kg for products other than beverages 1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer
Milk-based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products added alone or in combination with lacto-*N*-neotetraose, at concentrations 0,6 g/l, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Dietary foods for special medical purposes as defined in Directive 1999/21/EC	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Foods intended for use in energy-restricted diets for weight reduction as defined in Directive 96/8/EC (only for products presented as a replacement for the whole of the daily diet)	4,8 g/l for drinks 40 g/kg for bars
Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009 [1]	60 g/kg
Flavoured drinks	1,2 g/l

Food category	Maximum levels
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9,6 g/l [2]
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	3,0 g/day for general population 1,2 g/day for young children

[1] From 20 July 2016 the category 'Bread and pasta products for people intolerant to gluten as defined in Regulation (EC) No 41/2009' shall be replaced by the following: 'Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014'.

[2] The maximum level refers to the products ready to use.

COMMISSION IMPLEMENTING DECISION (EU) 2016/377

of 15 March 2016

on the equivalence of the regulatory framework of the United States of America for central counterparties that are authorised and supervised by the Commodity Futures Trading Commission to the requirements of Regulation (EU) No 648/2012 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories [1], and in particular Article 25(6) thereof,

Whereas:

(1) The procedure for recognition of central counterparties ('CCPs') established in third countries set out in Article 25 of Regulation (EU) No 648/2012 aims to allow CCPs established and authorised in third countries whose regulatory standards are equivalent to those laid down in that Regulation to provide clearing services to clearing members or trading venues established in the Union. That recognition procedure and the equivalence decision provided for therein thus contribute to the achievement of the overarching aim of Regulation (EU) No 648/2012 to reduce systemic risk by extending the use of safe and sound CCPs to clear over-the-counter ('OTC') derivative contracts, including where those CCPs are established and authorised in a third country.

(2) In order for a third country legal regime to be considered equivalent to the legal regime of the Union in respect of CCPs, the substantive outcome of the applicable legal and supervisory arrangements should be equivalent to Union requirements in respect of the regulatory objectives they achieve. The purpose of this equivalence assessment is therefore to verify that the legal and supervisory arrangements of the United States of America (USA) ensure that CCPs established and authorised therein do not expose clearing members and trading venues established in the Union to a higher level of risk than the latter could be exposed to by CCPs authorised in the Union and, consequently, do not pose unacceptable levels of systemic risk in the Union.

(3) On 1 September 2013, the Commission received the technical advice of the European Securities and Markets Authority (ESMA) on the legal and supervisory arrangements applicable to CCPs established in the USA. That technical advice identified a number of differences between the legally binding requirements applicable, at jurisdictional level, to CCPs in the USA and the legally binding requirements applicable to CCPs under Regulation (EU) No 648/2012. This Decision is not only based, however, on a comparative analysis of the legally binding requirements applicable to CCPs in the USA, but also on an assessment of the outcome of those requirements, and their adequacy to mitigate the risks that clearing members and trading venues established in the Union may be exposed to in a manner considered equivalent to the outcome of the requirements laid down in Regulation (EU) No 648/2012).

(4) In accordance with Article 25(6) of Regulation (EU) No 648/2012, three conditions need to be fulfilled in order to determine that the legal and supervisory arrangements of a third country regarding CCPs authorised therein are equivalent to those laid down in that Regulation.

(5) According to the first condition, CCPs authorised in a third country must comply with legally binding requirements which are equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012.

(6) The legally binding requirements of the USA for CCPs authorised (the term used in the CFTC framework is 'registration') and supervised by the Commodity Futures Trading Commission (CFTC) are contained in the

[1] OJ L 201, 27.7.2012, p. 1.

Commodity Exchange Act ('the CEA'), as amended by Titles VII and VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act ('the Dodd-Frank Act'), and the CFTC's regulations promulgated thereunder. The CFTC is the competent authority for the supervision of all derivative contracts that are not based on a single security (a bond or share), loan or a narrow based group or index of securities, and is responsible for authorising and regulating CCPs which provide clearing services for those derivative contracts ('derivative clearing organizations' or 'DCOs'). The derivative contracts falling under the competence of the CFTC therefore correspond to a subset of the derivative contracts covered by the provisions on CCPs set out in Regulation (EU) No 648/2012. This Decision relates solely to the equivalence of the legal and supervisory arrangements for DCOs and not to the legal and supervisory arrangements for CCPs which provide clearing services for derivative contracts falling under the competence of the Securities and Exchange Commission ('SEC'). Where a CCP is authorised as both a clearing agency under the jurisdiction of the SEC and a DCO, this Decision relates to those CCPs only in so far as they provide clearing services for derivative contracts falling under the CFTC's jurisdiction.

(7) The legally binding requirements applicable to CCPs authorised by the CFTC include high-level standards that are set out by the core principles for DCOs contained in section 5b(c)(2) of the CEA and Subparts A and B of Part 39 of the CFTC Regulations. To be authorised by the CFTC, all CCPs must comply with those core principles. The core principles are complemented by specific enhanced risk management standards applicable to DCOs which have been designated by the Financial Stability Oversight Council of the USA as systemically important and for which the CFTC has been designated as the supervisory agency ('SIDCOs'). The enhanced risk management standards are set out in Subpart C of Part 39 of CFTC regulations (Regulations 39.30 to 39.42). The high-level standards and the specific enhanced risk management standards for SIDCOs (together, the 'primary rules') are applicable to SIDCOs and to DCOs which have not been designated as SIDCOs but have voluntarily opted to be legally bound by those specific risk management standards ('opt-in DCOs'). Those primary rules comprise the first tier of the legally binding requirements applicable to DCOs.

(8) Pursuant to the primary rules, DCOs must adopt internal rules and procedures which must be approved by the CFTC. In respect of certain standards set out under the primary rules, the DCO's internal rules and procedures must provide prescriptive detail on the way in which the DCO will meet those standards. Moreover, those internal rules and procedures contain requirements which complement the ones prescribed by the primary rules. Once approved by the CFTC, the internal rules and procedures become legally binding on the DCO and form an integral part of the legal and supervisory arrangements with which those DCOs must comply. In the case of non-compliance with the primary rules or the DCO's internal rules and procedures, the CFTC has the power to sanction those DCOs, including by imposing penalties and suspension or revocation of the authorisation.

(9) The legally binding requirements in the USA with respect to derivative contracts cleared by DCOs therefore comprise a two-tiered structure. The primary rules for SIDCOs and opt-in DCOs comprise the first tier of the legally binding requirements. The internal rules and procedures of the SIDCOs and opt-in DCOs comprise the second tier of the legally binding requirements. When determining equivalence in accordance with Article 25(6) of Regulation (EU) No 648/2012, the nature and detail of the legal requirements contained within the internal rules and procedures of SIDCOs and opt-in DCOs must, therefore, be considered alongside the primary rules in order to ensure that the legally binding requirements effected through those combined components of the legal and supervisory arrangements can be considered equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012.

(10) The primary rules applicable to SIDCOs and opt-in DCOs complemented by their internal rules and procedures deliver substantive outcomes equivalent to the effects of the rules contained in Title IV of Regulation (EU) No 648/2012. The primary rules include requirements on governance (including organisational requirements, requirements relating to senior management, risk committees, record keeping, qualifying holdings, information transmitted to the competent authority), conflicts of interest, outsourcing, conduct of business, business continuity and segregation, as well as liquidity risk, collateral requirements, investment policy, and settlement risk.

(11) Although the primary rules with respect to liquidity risks do not require SIDCOs and opt-in DCOs to maintain eligible liquidity resources to meet the 'cover 2 principle', that is, liquid resources to cover the default of at least the two clearing members to which it has the largest exposures, those DCOs are nevertheless required to set-up procedures to cover any uncovered liquidity shortfall, ensuring that committed resources are available where losses exceed the default of the clearing member to which it has the largest exposure. Although this is a different

approach than the 'cover 2 principle' contained in Title IV of Regulation (EU) No 648/2012, it delivers substantive outcomes equivalent to the effects of the rules contained in Title IV of Regulation (EU) No 648/2012.

(12) The primary rules with respect to participation, exposure management, margin requirements, default funds, other financial resources, default waterfall and default procedures, follow a similar approach to the rules contained in Title IV of Regulation (EU) No 648/2012 but differ in some aspects. With respect to the initial margin applied to clearing member's proprietary positions the primary rules provide for a minimum liquidation period of one day for non-OTC derivative contracts including futures, options, swaps on agricultural energy commodities and metals and five days for all other derivatives, with margin collected on a net basis. Union rules, however, set out minimum liquidation periods of two days for non-OTC derivative contracts and five days for OTC derivative contracts, typically with margin collected on a net basis. With respect to clearing members' proprietary positions therefore, the higher liquidation period of two days for non-OTC derivative contracts in the Union results in CCPs authorised in the Union collecting more margin in respect of those positions. Conversely, in the case of initial margins collected with respect to the positions of clients of clearing members, the primary rules require margin to be collected on a gross basis for all classes of derivative contracts, whereas Union law has no such requirement. This difference between net and gross margin collection results in equivalent outcomes with respect to the amount of margin that DCOs hold with respect to the positions of clients, which compensates for the difference in the liquidation period. Therefore the primary rules on margin requirements can be considered equivalent to Union law in so far as they relate to the positions of clients of clearing members. Further, Union law requires the application of one of three anti-procyclicality measures to ensure that initial margins do not fall too low in stable economic times and do not increase precipitously in times of stress, whereas the primary rules contain no such specific requirement. In doing so, such measures deliver stable and conservative margins. Additionally, the primary rules require SIDCOs and opt-in DCOs to apply the 'cover 2 principle' where those DCOs have been designated as being systemically important in multiple jurisdictions or where they are involved in activities with a more complex risk profile. Union rules, in contrast, require the 'cover 2 principle' for all CCPs.

(13) The legal and supervisory arrangements of the USA applicable to DCOs should therefore be deemed equivalent provided that, according to the internal rules and procedures of DCOs that are authorised as SIDCOs and opt-in DCOs, they ensure that DCOs comply with the following requirements. Those requirements are: (1) for non-OTC derivative contracts executed on regulated markets, a liquidation period of two days with respect to the initial margin applied to clearing members' proprietary positions; (2) for all derivative contracts, measures to limit procyclicality which deliver stable and conservative margins, and are equivalent to at least one of the options as laid down in Title IV of Regulation (EU) No 648/2012; and (3) a sufficient pre-funded available financial resources enabling the DCO to withstand the default of at least the two clearing members to which it has the largest exposures under extreme but plausible market conditions taking account of additional risks to which those DCOs are exposed arising from the simultaneous failure of entities in the group of defaulting clearing members.

(14) The Commission notes that specific features concerning certain listed agricultural derivative contracts executed on regulated markets in the USA and cleared by DCOs relate to markets that largely serve domestic non-financial counterparties in the USA who manage their commercial risks through those contracts and who have a low degree of systemic interconnectedness with the rest of the financial system. The risk arising from clearing those contracts is negligible with respect to clearing members and trading venues established in the Union. As a result, the assessment of equivalence is not substantially affected by the regulatory features applicable to those agricultural derivative contracts.

(15) It should therefore be concluded that the legal and supervisory arrangements of the CFTC comprising the primary rules and the internal rules and procedures of SIDCOs and the opt-in DCOs which meet the standards set out in this Decision with respect to risk management should be considered legally binding requirements which are equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012. Only SIDCOs and opt-in DCOs complying with those legally binding requirements (i.e. the primary rules as complemented by the internal rules and procedures approved by the CFTC and meeting the standards set out in this act) may be eligible for recognition by ESMA, which should verify, in accordance with Article 25(2)(b) of Regulation (EU) No 648/2012, that those standards are part of the internal rules and procedures of any CCP subject to that regime and applying for recognition in the Union. Likewise ESMA monitors in accordance with Article 25(5) of Regulation (EU) No 648/2012 that the equivalent regime as defined in this Decision, including the conditions contained herein, continues to be met and may withdraw the recognition where this is not the case. In particular, ESMA will check that the CCP applies a two-day liquidation period with respect to clearing members' proprietary positions in non-OTC derivative contracts and that the CCP applies measures designed to limit procyclicality that are equivalent in delivering stable and conservative margins to any of the three measures set out under

Regulation (EU) No 648/2012, and that the CCP maintains sufficient pre-funded available financial resources enabling it to withstand the default of at least the two clearing members to which it has the largest exposures under extreme but plausible market conditions taking account of additional risks to which those CCPs are exposed arising from the simultaneous failure of entities in the group of the defaulting clearing members.

(16) According to the second condition under Article 25(6) of Regulation (EU) No 648/2012, the legal and supervisory arrangements in respect of CCPs established in the USA must further provide for effective supervision and enforcement of CCPs in that jurisdiction on an ongoing basis.

(17) The CFTC conducts ongoing monitoring of DCOs' compliance with risk management requirements through surveillance and risk-based examination procedures including the testing of prudential requirements. The CFTC conducts examinations with examination teams. Upon completion of the examination, the CFTC drafts a report summarising the results of the examination, including any issues of concern. The report outlines any deficiencies perceived, and various measures are available to the CFTC to ensure that DCOs appropriately address any identified issues, including by imposing penalties and suspension or revocation of the authorisation where the deficiencies are not addressed. This report, or information contained in the report, as well as any measure adopted therefrom may be shared with third country regulators under cooperation arrangements.

(18) It should therefore be concluded that the legal and supervisory arrangements in respect of DCOs provide for effective supervision and enforcement on an ongoing basis.

(19) According to the third condition under Article 25(6) of Regulation (EU) No 648/2012, the legal and supervisory arrangements of the USA must include an effective equivalent system for the recognition of CCPs authorised under third country legal regimes ('third country CCPs').

(20) Third country CCPs may apply to the CFTC for DCO authorisation. Pursuant to its statutory authority under 7 U.S.C. § 2(i), the CFTC may provide for substituted compliance in respect of third country CCPs to the extent that it has determined comparability between its requirements for DCOs and the requirements of the third country's regulatory regime. Where substituted compliance is provided, a third country CCP authorised as a DCO may meet the CFTC's requirements by complying with the comparable requirements in its own (third country) jurisdiction. The conclusion of a memorandum of understanding between the CFTC and the competent third-country supervisory authority of the applicant CCP is also required for recognition to be granted.

(21) It should therefore be concluded that the legal and supervisory arrangements of the CFTC provide for an effective equivalent system for the recognition of third country CCPs.

(22) This Decision is based on the legally binding requirements relating to SIDCOs and opt-in DCOs applicable in the USA at the time of the adoption of this Decision. The Commission, in cooperation with ESMA, should continue monitoring on a regular basis the evolution of the legal and supervisory arrangements for SIDCOs and opt-in DCOs and the fulfilment of the conditions on the basis of which this Decision has been taken.

(23) The regular review of the legal and supervisory arrangements applicable to SIDCOs and opt-in DCOs in the USA is without prejudice to the possibility of the Commission to undertake a specific review at any time, where relevant developments and, in particular, the verifications undertaken by ESMA or the information available to it as a result of the supervisory cooperation with CFTC in accordance with the procedures and mechanisms referred to Article 25(7) of Regulation (EU) No 648/2012, make it necessary for the Commission to re-assess the equivalence granted by this Decision. Such re-assessment could lead to the repeal of this Decision.

(24) The measures provided for in this Decision are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS DECISION:

Article 1

1. For the purposes of Article 25(6) of Regulation (EU) No 648/2012, the legal and supervisory arrangements of the United States of America (USA) for derivatives clearing organisations consisting of Section 5b of the Commodity Exchange Act and Subparts A, B and C of Part 39 of the CFTC Regulations, with the exception of Regulation 39.35 and 39.39, shall be considered equivalent to the requirements of Title IV of Regulation (EU) No 648/2012 where the internal rules and procedures of derivatives clearing organisations which have been designated, by the authorities of the USA, as systemically important ('systemically important derivatives clearing organisations'), and of derivatives clearing organisations which have opted to become subject to the rules contained in section Subpart C of Part 39 of the CFTC Regulations and are authorised and supervised by the CFTC ('opt-in derivatives clearing organisations'), contain the elements referred to in paragraph 2 and 3.

2. The specific rules contained in the internal rules and procedures of systemically important derivatives clearing organisations and opt-in derivatives clearing organisations referred to in paragraph 1 shall, with respect to the principle set out in CFTC Regulation 39.13, include specific risk management measures ensuring that initial margins are calculated and collected on the basis of the following parameters:

(a) in the case of clearing members' proprietary positions in derivative contracts executed on regulated markets or designated contract markets pursuant to Section 5 of the Commodity Exchange Act (CEA), 7 USC 7, a liquidation period of two days calculated on a net basis;

(b) in the case of all derivative contracts, measures designed to limit procyclicality equivalent to at least one of the following:

   (i) measures applying a margin buffer at least equal to 25 % of the calculated margins which the central counterparty allows to be temporarily exhausted in periods where calculated margin requirements are rising significantly;

   (ii) measures assigning at least 25 % weight to stressed observations in the look-back period;

   (iii) measures ensuring that margin requirements are not lower than those that would be calculated using volatility estimated over a 10 year historical look-back period.

3. The specific rules contained in the internal rules and procedures of systemically important derivatives clearing organisations and opt-in derivatives clearing organisations referred to in paragraph 1 shall, with respect to the principle set out in CFTC Regulations 39.11 and 39.33, include specific measures in respect of financial resources ensuring that the systemically important derivatives clearing organisation or the opt-in derivatives clearing organisation maintains sufficient pre-funded available financial resources enabling that derivatives clearing organisation to withstand the default of at least the two clearing members to which it has the largest exposures under extreme but plausible market conditions taking account of additional risks to that derivatives clearing organisation arising from the simultaneous failure of entities in the group of defaulting clearing members.

Article 2

1. Derivative contracts referred to in paragraph 2 of Article 1 shall not include agricultural commodity derivative contracts which fulfil all of the following conditions:

(a) they are based on an underlying agricultural product referencing grades, prices, weights, measures or conversion factors for agricultural commodities and their products as published by the United States Department Of Agriculture and traded on a US-designated contract market pursuant to Section 5 of the Commodity Exchange Act (CEA), 7 USC 7, or are based on an underlying agricultural product of sugar, soybean oil, soybean meal, cocoa, coffee, or lumber and traded on a US-designated contract market pursuant to Section 5 of the Commodity Exchange Act (CEA), 7 USC 7;

(b) they are based on an underlying agricultural product that forms the basis of an agricultural commodity derivative contract offered for clearing by a derivatives clearing organization established in the USA;

(c) where they specify one or more places of production of the underlying agricultural product, none of those places of production is inside the Union;

(d) they meet any of the following conditions:

(i) they are physically settled and, except where they are based on an underlying agricultural product of coffee, all the places of delivery are outside the Union;

(ii) they are cash settled and, except where they are based on an underlying agricultural product of coffee or sugar, the settlement amount is not based on prices for an underlying agricultural product for which at least one of the places of delivery is inside the Union.

The condition laid down in point (b) of the first subparagraph shall be deemed not to be fulfilled for a given agricultural commodity derivative contract where the majority of such contracts cleared by the derivatives clearing organization established in the USA are cleared for counterparties established in the Union and those contracts are also offered for clearing by a central counterparty authorised in the Union.

2. Article 1(3) shall not apply to systemically important derivatives clearing organisations or opt-in derivatives clearing organisations which only clear the derivative contracts referred to in paragraph 1 of this Article.

Article 3

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

Done at Brussels, 15 March 2016.

For the Commission
The President
Jean-Claude JUNCKER

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