

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of XXX

amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91¹, and in particular Articles 12(3), 14(2), 16(1) and (3)(a) thereof,

Whereas:

- (1) Chapter 2 of Title III of Regulation (EC) No 834/2007 lays down basic requirements with regard to farm production. The detailed rules for the implementation of those basic requirements have been established by Commission Regulation (EC) No 889/2008².
- (2) Article 12 of Regulation (EC) No 834/2007 allows the use of farm-inputs such as fertilisers, soil conditioners and plant protection products under certain conditions, provided that they have been authorised for use in organic production. In accordance with the procedure provided for in Article 16(3) of that Regulation, Member States have submitted dossiers to the other Member States and the Commission, in view of including certain products in Annexes I and II to Regulation (EC) No 889/2008. Those dossiers have been examined by the Expert group for technical advice for organic production (hereinafter 'EGTOP').
- (3) Based on the recommendations of the EGTOP³, which concluded as regards fertilisers and soil conditioners that the substances biogas digestate, hydrolysed proteins from animal by-product origin, leonardite, chitin and sapropel comply with the organic objectives and principles, those substances should be included in Annex I to Regulation (EC) No 889/2008 for use under certain specific conditions.

¹ OJ L 189, 20.7.2007, p. 1.

² Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.(OJ L 250, 18.9.2008, p. 1.).

³ Final report:
http://ec.europa.eu/agriculture/organic/files/eu-policy/expert-recommendations/expert_group/final_report_on_fertilizers_to_be_published_en.pdf

- (4) Based on the recommendations of the EGTOP, the limit of “0” for chromium (VI) relating to certain substances listed in Annex I to Regulation (EC) No 889/2008 should be replaced with "not detectable".
- (5) For plant protection products, the EGTOP concluded in its recommendations⁴ that the substances sheep fat, laminarin and aluminium silicate (Kaolin) comply with the organic objectives and principles. Therefore, those substances should be included in Annex II to Regulation (EC) No 889/2008 for use under certain specific conditions.
- (6) As regards the horizontal legislation for plant protection products, Commission Implementing Regulation (EU) No 540/2011⁵ established a Union list of active substances previously included in Annex I to Council Directive 91/414/EEC⁶ and of active substances approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁷. It is appropriate to adapt the relevant parts of Annex II to Regulation (EC) No 889/2008 to that list. In particular, gelatine, rotenone extracted from *Derris spp.* and *Lonchocarpus spp.* and *Terphrosia spp.*, diammonium phosphate, copper octanoate, potassium aluminium (aluminium sulphate, kalinite), mineral oils and potassium permanganate should be deleted from that Annex.
- (7) As regards the active substances lecithin, quassia extracted from *Quassia amara* and calcium hydroxide for which applications for approval have been already submitted to the Commission under Regulation (EC) No 1107/2009, it is appropriate at this stage to keep them exceptionally on the list in Annex II to Regulation (EC) No 889/2008 until their assessment is finalised. In view of the conclusions of the assessment the Commission will take appropriate action regarding the presence of the three substances concerned on the list in Annex II to Regulation (EC) No 889/2008.
- (8) In the light of that horizontal legislation, it is also appropriate to adapt the name, description, compositional requirement and conditions of use for certain substances and micro-organisms listed in Annex II to Regulation (EC) No 889/2008, in particular for, plant oils, micro-organisms used for biological pest and disease control, pheromones, copper, ethylene, paraffin oil and potassium bicarbonate.
- (9) Article 24(2) of Regulation (EC) No 889/2008 was amended by Commission Implementing Regulation (EU) No 505/2012⁸ in order to update the references to

⁴ Final report:

http://ec.europa.eu/agriculture/organic/files/eu-policy/expert-recommendations/expert_group/final_report_on_plant_protection_products.pdf

⁵ 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).

⁶ 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).

⁷ 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 (OJ L 309, 24.11.2009, p. 1).

⁸ Commission Implementing Regulation (EU) No 505/2012 of 14 June 2012 amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 154, 15.6.2012, p. 12).

Annexes V and VI to Regulation (EC) No 889/2008, which had been replaced by Implementing Regulation (EU) No 505/2012. In the amended wording of Article 24(2) of Regulation (EC) No 889/2008, "homeopathic products" had erroneously been omitted. Since those products appeared in that provision before the amendment by Implementing Regulation (EU) No 505/2012, they need to be reinserted.

- (10) In Annex V to Regulation (EC) No 889/2008 as amended by Implementing Regulation (EU) No 505/2012, the former entries defluorinated monocalciumphosphate and defluorinated dicalciumphosphate have been erroneously replaced by a generic description, namely defluorinated phosphate. However, defluorinated phosphate is not equivalent to the products defluorinated monocalciumphosphate and defluorinated dicalciumphosphate. Therefore, those two products should be reinserted into Annex V to Regulation (EC) No 889/2008 and defluorinated phosphate deleted.
- (11) Commission Implementing Regulation (EU) No 651/2013⁹ has deleted the former authorisation for clinoptilolite from Commission Regulation (EC) No 1810/2005¹⁰, has expanded its use as an additive in animal nutrition to all animal species and has changed its code to 1g568. Therefore, in order to allow a continuous use of clinoptilolite in organic production, Annex VI to Regulation (EC) No 889/2008 needs to be adapted in accordance with Implementing Regulation (EU) No 651/2013.
- (12) Regulation (EC) No 889/2008 should therefore be amended and corrected accordingly.
- (13) For the sake of legal certainty, the correction of Article 24(2) and Annex V of Regulation (EC) No 889/2008 should apply from the date of entry into force of Implementing Regulation (EU) No 505/2012.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the regulatory Committee on organic production,

HAS ADOPTED THIS REGULATION:

Article 1
Amendment of Regulation (EC) No 889/2008

Annexes I, II, and VI to Regulation (EC) No 889/2008 are amended in accordance with points 1, 2 and 4 of the Annex to this Regulation.

Article 2

⁹ Commission Implementing Regulation (EU) No 651/2013 of 9 July 2013 concerning the authorisation of clinoptilolite of sedimentary origin as a feed additive for all animal species and amending Regulation (EC) No 1810/2005 (OJ L 189, 10.7.2013, p. 1).

¹⁰ Commission Regulation (EC) No 1810/2005 of 4 November 2005 concerning a new authorisation for 10 years of an additive in feedingstuffs, the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs (OJ L 291, 5.11.2005, p. 5).

Article 2
Correction of Regulation (EC) No 889/2008

Regulation (EC) No 889/2008 is corrected as follows:

(1) In Article 24, paragraph 2 is replaced by the following:

"2. Phytotherapeutic and homeopathic products, trace elements and products listed in Section 1 of Annex V and in Section 3 of Annex VI shall be used in preference to chemically-synthesised allopathic veterinary treatment or antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended."

(2) Annex V is amended in accordance with point 3 of the Annex to this Regulation.

Article 3
Entry into force and application

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

However, Article 2 shall apply from 16 June 2012.

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

Done at Brussels, [...]

For the Commission
The President
José Manuel Barroso

ANNEX

Annexes I, II, V and VI to Regulation (EC) No 889/2008 are amended as follows:

(1) Annex I is amended as follows:

(a) the row relating to "*composted or fermented household waste*" is replaced by the following:

"

B	Composted or fermented mixture of household waste	<p>Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production</p> <p>Only vegetable and animal household waste</p> <p>Only when produced in a closed and monitored collection system, accepted by the Member State</p> <p>.</p> <p>Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable</p>
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(b) after the row relating to "*composted or fermented mixture of vegetable matter*", the following row is inserted:

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B	Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	<p>Animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories 2 and 3 as defined in Regulation (EC) No 1069/2009 of the European Parliament and of the Council)* must not be from factory farming origin</p> <p>Not to be applied to edible parts of the crop</p>
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* Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

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(c) the row relating to "*products or by-products of animal origin*" is replaced by the following:

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B	Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or degelatinised bone meal Fish meal Meat meal Feather, hair and «chiquette» meal Wool Fur ¹ Hair Dairy products Hydrolysed proteins ²	¹ Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable ² Not to be applied to edible parts of the crop
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(d) the following rows are added:

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B	Leonardite (Raw organic sediment rich in humic acids)	Only if obtained as a by-product of mining activities
B	Chitin (Polysaccharide obtained from the shell of crustaceans)	Only if obtained from sustainable fisheries, as defined in Article 3(e) of Council Regulation (EC) No 2371/2002* or organic aquaculture
B	Organic rich sediment from fresh water bodies formed under exclusion of oxygen (e.g: sapropel)	Only organic sediments that are by-products of fresh water body management or extracted from former freshwater areas When applicable, extraction should be done in a way to cause minimal impact on the aquatic system Only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable

* Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (OJ L 358, 31.12.2012 p. 59)."

(2) Annex II is amended as follows:

(a) Sections 1 and 2 are replaced by the following:

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1. Substances of crop or animal origin

Authorisation	Name	Description, compositional requirement, conditions for use
A	Azadirachtin extracted from <i>Azadirachta indica</i> (Neem tree)	Insecticide
A	Beeswax	Pruning agent
B	Hydrolysed proteins excluding gelatine	Attractant, only in authorised applications in combination with other appropriate products of this list
A	Lecithin	Fungicide
B	Plant oils	Insecticide, acaricide, fungicide, and sprout inhibitor. Products as specified in the Annex to Commission Implementing Regulation (EU) No 540/2011*
A	Pyrethrins extracted from <i>Chrysanthemum cinerariaefolium</i>	Insecticide
A	Quassia extracted from <i>Quassia amara</i>	Insecticide, repellent

2. Micro-organisms used for biological pest and disease control

Authorisation	Name	Description, compositional requirement, conditions for use
A	Micro-organisms	Products as specified in the Annex to Implementing Regulation (EU) No 540/2011 and not from GMO origin

* 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).

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(b) Section 4 is replaced by the following:

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4. Substances to be used in traps and/or dispensers

Authorisation	Name	Description, compositional requirement, conditions for use
A	Pheromones	Attractant, sexual behaviour disrupter; only in traps and dispensers. Products as specified in the Annex to Implementing Regulation (EU) No 540/2011 (numbers 255, 258 and 259)
A	Pyrethroids (only deltamethrin or lambda-cyhalothrin)	Insecticide; only in traps with specific attractants; only against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i> Wied.

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(c) Sections 6 and 7 are replaced by the following:

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6. Other substances from traditional use in organic farming

Authorisation	Name	Description, compositional requirement, conditions for use
B	Copper compounds in the form of: copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture, and tribasic copper sulphate	Only uses as bactericide and fungicide up to 6 kg copper per ha per year. For perennial crops, Member States may, by derogation from the first paragraph, provide that the 6 kg copper limit can be exceeded in a given year provided that the average quantity actually used over a 5-year period consisting of that year and of the four preceding years does not exceed 6 kg. Risk mitigation measures shall be taken to protect water and non-target organisms such as buffer zones. Products as specified in the Annex to Implementing Regulation (EU) No 540/2011 (number 277)
A	Ethylene	Degreening bananas, kiwis and kakis; degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus; flower induction of pineapple; sprouting inhibition in potatoes and onions. Only indoor uses as plant growth regulator may be authorised. Authorisations shall be limited to professional users.
A	Fatty acid potassium salt (soft soap)	Insecticide
A	Lime sulphur (calcium polysulphide)	Fungicide

Authorisation	Name	Description, compositional requirement, conditions for use
A	Paraffin oil	Insecticide, acaricide Products as specified in the Annex to Implementing Regulation (EU) No 540/2011 (numbers 294 and 295)
A	Quartz sand	Repellent
A	Sulphur	Fungicide, acaricide
B	Repellents by smell of animal or plant origin/sheep fat	Repellent Only on non-edible parts of the crop and where crop material is not ingested by sheep or goats Products as specified in the Annex to Implementing Regulation (EU) No 540/2011 (number 249)

7. Other substances

Authorisation	Name	Description, compositional requirement, conditions for use
B	Aluminium silicate (Kaolin)	Repellent
A	Calcium hydroxide	Fungicide only in fruit trees, including nurseries, to control <i>Nectria galligena</i>
B	Laminarin	Elicitor of crop's self defence mechanisms Kelp shall be either grown organically in accordance with Article 6d or harvested in a sustainable way in accordance with Article 6c
B	Potassium hydrogen carbonate (aka potassium bicarbonate)	Fungicide "

(3) In Annex V, Section 1 is replaced by the following

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1. Feed materials of mineral origin:

A	Calcareous marine shells	
A	Maerl	
A	Lithotamn	
A	Calcium gluconate	
A	Calcium carbonate	

A	Defluorinated monocalciumphosphate	
A	Defluorinated dicalciumphosphate	
A	Magnesium oxide (anhydrous magnesia)	
A	Magnesium sulphate	
A	Magnesium chloride	
A	Magnesium carbonate	
A	Calcium magnesium phosphate	
A	Magnesium phosphate	
A	Monosodium phosphate	
A	Calcium sodium phosphate	
A	Sodium chloride	
A	Sodium bicarbonate	
A	Sodium carbonate	
A	Sodium sulphate	
A	Potassium chloride	

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(4) In Annex VI, Section (d) "Binders, anti-caking agents and coagulants", the entry on clinoptilolite is replaced by the following:

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Authori- sation	ID number		Substance	Description, conditions for use
B	1	1g568	Clinoptilolite of sedimentary origin, [All species]	

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