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(Continued overleaf)

[1] Text with EEA relevance

EN

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

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

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 835/2012

of 18 September 2012

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium)

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [1], and in particular Article 131 thereof,

Whereas:

(1) Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) [2] modified the scope of the restriction on cadmium and cadmium compounds, introducing provisions applicable to brazing sticks and jewellery in accordance with the risk evaluation and the risk reduction strategies for cadmium and cadmium oxide [3].

(2) Regulation (EU) No 494/2011 furthermore extended the existing restriction on the use of cadmium and cadmium compounds in synthetic organic polymers (plastic material) to all plastic materials, while providing an exception for the use of recovered PVC containing cadmium in the manufacture of certain construction products. This derogation was granted taking into account the discussions in an ad hoc expert meeting on risk management activities under Regulation (EC) No 1907/2006 and the results of the study on Socio-Economic Impact of a Potential Update of the Restrictions on the Marketing and Use of Cadmium in jewelleries, brazing alloys and PVC, published in January 2010 [4]. All elements of the restriction were also subject to consultation with the Member States' competent authorities responsible for the implementation of Regulation (EC) No 1907/2006 and with stakeholders.

(3) Following the adoption of Regulation (EU) No 494/2011, the Commission was informed of uses of cadmium pigments in certain types of plastics materials, restricted for the first time by Regulation (EU) No 494/2011, where suitable alternatives to the use of cadmium compounds appear not to be available and for which, due to the exceptional circumstances of a limited consultation, further assessment is now appropriate.

(4) The Council Resolution of 25 January 1988 calls for an overall strategy to combat environmental pollution by cadmium, including specific measures to restrict the use of cadmium and stimulate the development of further alternatives to the use of cadmium in pigments, stabilisers and plating, asking for limitation of the uses of cadmium to cases where suitable alternatives do not exist.

(5) The Commission will ask the European Chemicals Agency, in accordance with Article 69 of REACH, to prepare a dossier conforming to the requirements of Annex XV relating to the use of cadmium and cadmium compounds in those types of plastic material that were restricted for the first time by Regulation (EU) No 494/2011, taking full account of the Council Resolution of 25 January 1988.

[1] OJ L 396, 30.12.2006, p. 1.
[2] OJ L 134, 21.5.2011, p. 2.
[3] OJ C 149, 14.6.2008, p. 6.
[4] http://ec.europa.eu/enterprise/sectors/chemicals/files/markrestr/study-cadmium_en.pdf

(6) Until the restriction procedure is finalised, the restriction on the use of cadmium and its compounds should be limited to the types of plastic material listed in entry 23 of Annex XVII before the adoption of Regulation (EU) No 494/2011.

(7) For reasons of legal certainty, this Regulation should apply from 10 December 2011.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with 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*.

It shall apply from 10 December 2011.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the table setting out the designation of the substances, groups of substances and mixtures and the conditions of restriction is amended as follows:

(1) in the second column of entry 23, the first and second subparagraphs of paragraph 1 are replaced by the following:

	'1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): — polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] — polyurethane (PUR) [3909 50] — low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.'

(2) in the second column of entry 23, in paragraph 1 the following subparagraph is added:

	'By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted.'

COMMISSION REGULATION (EU) No 836/2012

of 18 September 2012

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [1], and in particular Article 68(1) thereof,

Whereas:

(1) In accordance with Regulation (EC) No 1907/2006, if a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall prepare a dossier after notifying that intention to the European Chemicals Agency (hereinafter 'the Agency').

(2) On 15 April 2010 France submitted to the Agency a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006, in order to initiate a restriction process in accordance with Articles 69 to 73 of that Regulation. In that dossier, it was demonstrated that due to their mouthing behaviour, children, especially those under 36 months, can be repeatedly exposed to lead released from jewellery articles. Such repeated exposure to lead can result in severe and irreversible neurobehavioural and neurodevelopmental effects, to which children are particularly sensitive given that their central nervous system is still under development. The dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, in order to avoid as much as possible the exposure to lead and its compounds in jewellery articles. Accordingly, the dossier proposes a prohibition of placing on the market and the use of lead and its compounds in jewellery articles if the lead migration rate is greater than 0,09 μg/cm^2/h.

(3) In its opinion of 10 March 2011, the Committee for Risk Assessment (hereinafter 'RAC') considered that the most appropriate Union-wide measure to address the identified risks in terms of the effectiveness in reducing the risks is the prohibition of the placing on the market and use of lead and its compounds in metallic and non-metallic parts of jewellery articles, if the lead concentration is equal to or greater than 0,05 % by weight of the individual part, unless it can be demonstrated that the rate of lead released does not exceed the limit of 0,05 μg/cm^2/h (0,05 μg/g/h).

(4) In its opinion of 15 September 2011, the Committee for Socio-Economic Analysis (hereinafter 'SEAC') considered the prohibition of the placing on the market and use of lead and its compounds in jewellery articles, if the lead concentration is equal to or greater than 0,05 % by weight of any individual part thereof. This measure was considered as the most appropriate Union-wide measure to address the identified risks in terms of the proportionality of its socioeconomic benefits to its socioeconomic costs. In view of the current non-availability of a migration testing method mimicking mouthing conditions, SEAC considered that the restriction should be based on the content of lead in any individual part of jewellery articles, and not on the migration rate of lead released from such articles. In addition, SEAC recommended exemptions to be provided for crystal glass, vitreous enamels, internal components of watch timepieces as well as non-synthetic or reconstructed precious and semiprecious stones.

(5) On 23 September 2011 the Agency submitted to the Commission the opinions of the RAC and the SEAC.

(6) Given the lack of information on the release of lead under mouthing conditions and due to the lack of suitable alternatives for all uses in crystal glass and vitreous enamels, the latter are being exempted from the present measure. Moreover SEAC recommended the exemption only for categories 1 and 2 of crystal glass (respectively 'Full Lead Crystal' and 'Lead Crystal') as defined in Annex I to Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass [2]. However categories 3 and 4 of crystal glass ('crystal glass, crystallin') as defined in that Directive should also be exempted from the restriction, in order to ensure consistency with the exemption laid down in the Annex to Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances

[1] OJ L 396, 30.12.2006, p. 1.

[2] OJ L 326, 29.12.1969, p. 36.

in electrical and electronic equipment [1], as amended by Commission Decision 2010/571/EU [2], and as they have a lower content of lead compared to categories 1 and 2.

(7) For the same reasons applicable to crystal glass and vitreous enamels, non-synthetic or reconstructed precious and semiprecious stones in which lead is present as a naturally occurring constituent should be exempted.

(8) Internal components of watch timepieces which are inaccessible to consumers should be exempted from the restriction, as exposure to lead from those components can be excluded.

(9) A restriction on the placing on the market of second-hand and antique jewellery would have a significant socioeconomic impact, as such items would lose their marketable value in the Union, and would pose difficulties for enforcement. Therefore, jewellery articles placed on the market for the first time up to 12 months after the entry into force of the restriction as well as imported antique jewellery articles should be exempted from the restriction.

(10) The Commission should carry out a review of the exemption of crystal, vitreous enamels and precious and semi-precious stones in the light of new available scientific information, including the migration of lead from those exempted uses, the availability of suitable alternatives as well as the development of migration test methods.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

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, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 37, 13.2.2003, p. 19.
[2] OJ L 251, 25.9.2010, p. 28.

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry 63 is added:

'63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.

(*) OJ L 326, 29.12.1969, p. 36.'

COMMISSION IMPLEMENTING REGULATION (EU) No 837/2012

of 18 September 2012

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) as feed additive for poultry, weaned piglets, pigs for fattening and sows (holder of authorisation DSM Nutritional Products)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) as a feed additive for poultry, weaned piglets, pigs for fattening and sows, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 December 2011 [2] that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus utilisation in all target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal 2012*; 10(1):2527.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content / Maximum content (Units of activity/kg of complete feedingstuff with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a18	DSM Nutritional Products	6-phytase (EC 3.1.3.26)	*Additive composition* Preparation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) with a minimum activity of: 50 000 (1) FYT/g in solid form 20 000 FYT/g in liquid form *Characterisation of the active substance* 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594) *Analytical method* (2) Colorimetric method measuring the inorganic phosphate released by the 6-phytase from phytate (ISO 30024:2009)	Poultry Pigs for fattening Piglets (weaned)	—	500 FYT	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kilogram of complete feed for: — poultry, piglets (weaned) and pigs for fattening: 500-4 000 FYT, — sows: 1 000-4 000 FYT. 3. For use in feed containing more than 0,23 % phytin-bound phosphorus. 4. For safety: breathing protection, glasses and gloves shall be used during handling. 5. For use in weaned piglets up to 35 kg.	9 October 2022
				Sows		1 000 FYT			

(1) 1 FYT is the amount of enzyme which liberates 1 µmol of inorganic phosphate from phytate per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and 37 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 838/2012

of 18 September 2012

concerning the authorisation of *Lactobacillus brevis* (DSMZ 21982) as a feed additive for all animal species

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of *Lactobacillus brevis* (DSMZ 21982). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of *Lactobacillus brevis* (DSMZ 21982) as a feed additive for all animal species, to be classified in the additive category 'technological additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 March 2012 [2] that, under the proposed conditions of use, the preparation of *Lactobacillus brevis* (DSMZ 21982) does not have an adverse effect on animal health, human health or the environment, and that the use of the preparation has the potential to improve the production of silage by increasing acetic acid production resulting in an extended aerobic stability of the treated silage. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of *Lactobacillus brevis* (DSMZ 21982) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex belonging to the additive category 'technological additives' and to the functional group 'silage additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal 2012*;10 (3):2617.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives									
1k20715	—	*Lactobacillus brevis* (DSMZ 21982)	*Additive composition* Preparation of *Lactobacillus brevis* (DSMZ 21982) containing a minimum of 8×10^{10} CFU/g additive *Characterisation of the active substance* *Lactobacillus brevis* (DSMZ 21982) *Analytical method* (1) Enumeration in the feed additive: spread plate method (EN 15787). Identification: Pulsed Field Gel Electrophoresis (PFGE).	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when used not in combination with other micro-organisms as silage additive: 1×10^8 CFU/kg of fresh material. 3. For Safety: it is recommended to use breathing protection and gloves during handling.	9 October 2022

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 839/2012

of 18 September 2012

concerning the authorisation of urea as a feed additive for ruminants

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of products authorised pursuant to Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition [2].

(2) Urea was authorised without a time limit by Directive 82/471/EEC. That product was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of urea as a feed additive for ruminants, requesting that additive to be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 March 2012 [3] that, under the proposed conditions of use, urea does not have an adverse effect on animal health, human health or the environment, and that it provides non-protein nitrogen for microbial protein synthesis in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of urea shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

(6) Since modifications to the conditions of authorisation of urea are introduced and as there are no direct immediate effects on safety, a reasonable period should be allowed to elapse before authorisation in order to allow the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, it is appropriate to allow a transitional period for the disposal of existing stocks of urea, as authorised by Directive 82/471/EEC, and of feed containing urea.

(7) It is disproportionately complex for operators to adapt repeatedly and from one day to the other labels of feed containing different additives which have been successively authorised according to the procedure laid down in Article 10(2) of Regulation (EC) No 1831/2003 and for which new labelling rules are to be complied with. It is therefore appropriate to reduce the administrative burden on the operators by providing a period of time allowing a smooth conversion of labelling.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'urea and its derivatives' is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Labelling requirements

Feed containing urea shall be labelled in accordance with this Regulation at the latest by 19 May 2013.

However, feed containing urea which has been labelled in accordance with Directive 82/471/EEC before 19 May 2013 may continue to be placed on the market until stocks are exhausted.

Article 3

Transitional measures

Existing stocks of urea and of feed containing urea at the date of entry into force of this Regulation may continue to be placed on the market and used under the conditions of Directive 82/471/EEC until they are exhausted.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 213, 21.7.1982, p. 8.
[3] EFSA Journal 2012; 10(3):2624.

Article 4

Entry into force

This Regulation shall enter into force on 19 November 2012.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: Urea and its derivatives									
3d1	—	Urea	*Additive composition*: Urea content: minimum 97 % Nitrogen content: 46 % *Characterisation of the active substance*: Diaminomethanone, CAS number 58069-82-2, chemical formula: $(NH_2)_2CO$ *Analytical methods* (1): For the determination of the total nitrogen in the additive: Titrimetry (method 2.3.3 in Annex IV to Regulation (EC) No 2003/2003) For the determination of the biuret contribution to the total nitrogen in the additive: Spectrophotometry (method 2.5 in Annex IV to Regulation (EC) No 2003/2003) For the determination of urea in premixtures, compound feed and feed materials: Spectrophotometry (Annex III.D to Regulation (EC) No 152/2009)	Ruminants with a functional rumen	—		8 800	The directions for use of the feed additive and feed containing urea shall include the following: 'Urea shall only be fed to animals with a functional rumen. Feeding urea to the maximum level dose should be done gradually. The maximum content of urea should be only fed as part of diets rich in easily digestible carbohydrates and low in soluble nitrogen. A maximum 30 % of total nitrogen in the daily ration should come from urea-N.'	19 November 2022

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 840/2012

of 18 September 2012

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens (holder of authorisation Danisco Animal Nutrition)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233). The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens, to be classified in the additive category 'zootechnical additives'.

(4) The use of preparations of 6-phytase EC 3.1.3.26 was authorised for 10 years for chickens for fattening, turkeys for fattening, laying hens, piglets (weaned), ducks for fattening, pigs for fattening and sows by Commission Regulations (EC) No 785/2007 [2] and (EC) No 379/2009 [3].

(5) New data were submitted in support of the application for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) for use as feed additive to all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens. The European Food Safety Authority ('the Authority') concluded in its opinion of 7 March 2012 [4] that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus utilisation in all target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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*.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 175, 5.7.2007, p. 5.
[3] OJ L 116, 9.5.2009, p. 6.
[4] *EFSA Journal 2012*; 10(3):2619.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content / Maximum content (Units of activity/kg of complete feedingstuff with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1640	Danisco Animal Nutrition (legal entity Danisco (UK) Limited)	6-phytase EC 3.1.3.26	*Additive composition* Preparation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) having a minimum activity of: Liquid and solid form: 5 000 FTU [1]/g *Characterisation of the active substance* 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) *Analytical method* [2] Determination of 6-phytase EC 3.1.3.26 in feed additive: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate. Determination of 6-phytase EC 3.1.3.26 in feed premixtures and feedingstuff: EN ISO 30024: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate (after dilution with heat-treated whole grain flour).	All avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening	—	250 FTU		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in compound feed containing more than 0,23 % phytin-bound phosphorus. 3. Maximum recommended dose: 1 000 FTU/kg of complete feedingstuff. 4. For safety: breathing protection glasses and gloves shall be used during handling.	9 October 2022
				All avian species for laying other than laying hens		150 FTU			

[1] 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °C.
[2] Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 841/2012

of 18 September 2012

concerning the authorisation of *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) as feed additives for all animal species

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(1) to (4) thereof sets out specific provisions for the evaluation of products used in the Union as silage additives at the date that Regulation became applicable.

(2) In accordance with Article 10(1)(b) and Article 7 of Regulation (EC) No 1831/2003, the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) were entered in the Community Register of Feed Additives as existing products belonging to the functional group of silage additives, for all animal species.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the authorisation of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) as feed additives for all animal species, requesting those additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The applications concern the authorisation of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) as feed additives for all animal species, to be classified in the additive category 'technological additives'.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 December 2011 [2] that, under the proposed conditions of use, the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) do not have an adverse effect on animal health, human health or the environment, and that these micro-organisms have the potential to improve the production of silage from all forages by increasing the preservation of dry matter and reducing the loss of protein. The Authority also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those micro-organisms should be authorised as specified in the Annexes to this Regulation.

(7) Since modifications to the conditions of authorisation of the micro-organisms *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) are introduced and as there are no direct immediate effects on safety, a reasonable period should be allowed to elapse before authorisation in order to allow the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, it is appropriate to allow a transitional period for the disposal of existing stocks of those micro-organisms and of feed containing them.

(8) It is disproportionately complex for operators to adapt repeatedly and from one day to the other labels of feed containing different additives which have been successively authorised according to the procedure laid down in Article 10(2) of Regulation (EC) No 1831/2003 and for which new labelling rules are to be complied with. It is therefore appropriate to reduce the administrative burden on the operators by providing a period of time allowing a smooth conversion of labelling.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The micro-organism specified in Annex I, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal* 2012; 10(1):2529.

Article 2

The micro-organism specified in Annex II, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 3

Labelling requirements

Feed containing the micro-organisms referred to in Article 1 and in Article 2 shall be labelled in accordance with this Regulation at the latest by 19 May 2013.

However, feed containing the micro-organisms referred to in Article 1 and in Article 2 which has been labelled in accordance with the previous conditions of authorisation before 19 May 2013 may continue to be placed on the market until stocks are exhausted.

Article 4

Transitional measures

Existing stocks of the micro-organisms referred to in Article 1 and in Article 2 and of feed containing them at the date of entry into force of this Regulation may continue to be placed on the market and used under the previous conditions of authorisation until they are exhausted.

Article 5

This Regulation shall enter into force on 19 November 2012.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives									
1k20713	—	*Lactobacillus plantarum* (NCIMB 41028)	*Additive composition* Preparation of *Lactobacillus plantarum* NCIMB 41028 containing a minimum of 7×10^{10} CFU/g additive *Characterisation of the active substance* *Lactobacillus plantarum* NCIMB 41028 *Analytical method* (1) Enumeration in the feed additive: spread plate method (EN 15787) Identification: pulsed field gel electrophoresis (PFGE)	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when used not in combination with other micro-organisms as silage additive: 1×10^9 CFU/kg fresh material. 3. For safety: it is recommended to use breathing protection and gloves during handling.	19 November 2022

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

ANNEX II

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives									
1k20714	—	*Lactobacillus plantarum* (NCIMB 30148)	*Additive composition* Preparation of *Lactobacillus plantarum* NCIMB 30148 containing a minimum of 7×10^{10} CFU/g additive *Characterisation of the active substance* *Lactobacillus plantarum* NCIMB 30148 *Analytical method* (1) Enumeration in the feed additive: spread plate method (EN 15787) Identification: pulsed field gel electrophoresis (PFGE)	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when used not in combination with other micro-organisms as silage additive: 1×10^9 CFU/kg fresh material. 3. For safety: it is recommended to use breathing protection and gloves during handling.	19 November 2022

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 842/2012

of 18 September 2012

concerning the authorisation of a preparation of lanthanum carbonate octahydrate as a feed additive for dogs (holder of authorisation Bayer Animal Health GmbH)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation of lanthanum carbonate octahydrate, CAS number 6487-39-4. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation lanthanum carbonate octahydrate CAS number 6487-39-4 as a feed additive for dogs, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation was authorised for 10 years for cats by Commission Regulation (EC) No 163/2008 ([2]).

(5) New data were submitted in support of the application for authorisation of lanthanum carbonate octahydrate, CAS number 6487-39-4, for dogs. The European Food Safety Authority ('the Authority') concluded in its opinion of 6 March 2012 that, under the proposed conditions of use, lanthanum carbonate octahydrate does not have an adverse effect on the target species ([3]). It further concluded that lanthanum carbonate octahydrate has the potential to reduce the phosphorus bioavailability in adult dogs. It could not, however, comment on the long-term effects. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of lanthanum carbonate octahydrate, CAS number 6487-39-4, shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation. It is appropriate to provide for post-market monitoring as regards long-term adverse effects.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

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, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 50, 23.2.2008, p. 3.
([3]) *EFSA Journal* 2012; 10(3):2618.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (decrease in phosphorus excretion via urine)									
4d1	Bayer Animal Health GmbH	Lanthanum carbonate octahydrate	*Additive composition* Preparation of lanthanum carbonate octahydrate. At least 85 % lanthanum carbonate octahydrate as active substance *Characterisation of the active substance* Lanthanum carbonate octahydrate $La_2 (CO_3)_3 \cdot 8H_2O$ CAS number 6487-39-4 *Analytical method* (1) Quantification of carbonate in the feed additive: Community method (Commission Regulation (EC) No 152/2009) (2) Quantification of lanthanum in the feed additive and feedingstuff: inductively coupled plasma atomic emission spectrometry (ICP-AES).	Dogs	—	1 500	7 500	Post-market monitoring on chronic adverse effects is required. In the directions for use of the additive: '— for adult dogs — recommended dose of inclusion in moist feed with 20-25 % dry matter content: 340 to 2 100 mg per kg — avoid simultaneous use of feeds with high level of phosphorus'	9 October 2022

(1) Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx
(2) OJ L 54, 26.2.2009, p. 1.

COMMISSION IMPLEMENTING REGULATION (EU) No 843/2012

of 18 September 2012

concerning the authorisation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) as a feed additive for turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds (holder of authorisation BASF SE)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of endo-1, 4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) as a feed additive for chickens reared for laying, turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation was authorised for 10 years for chickens for fattening and for ducks by Commission Regulation (EC) No 1096/2009 ([2]) and for turkeys for fattening by Commission Regulation (EC) No 1380/2007 ([3]).

(5) New data were submitted in support of the application for the authorisation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) for chickens reared for laying, turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds. The European Food Safety Authority ('the Authority') concluded in its opinion of 2 February 2012 ([4]) that, under the proposed conditions of use, endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the feed to gain ratio in all target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

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*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 301, 17.11.2009, p. 3.
([3]) OJ L 309, 27.11.2007, p. 21.
([4]) *EFSA Journal* 2012; 10(2):2575.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a62	BASF SE	Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) having a minimum activity of: Solid form: 5 600 TXU (1)/g Liquid form: 5 600 TXU/ml *Characterisation of the active substance* Endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) *Analytical method* (2) Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-xylanase on the xylan-containing substrate (wheat arabinoxylan) at pH 3,5 and 55 °C	Turkeys reared for breeding	—	560 TXU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended maximum dose per kilogram of complete feedingstuff for all species falling within the scope of this Regulation: 840 TXU. 3. For use in feed rich in starch and non-starch polysaccharides (mainly beta-glucans and arabinoxylans).	9 October 2022
				Ornamental birds, minor avian species except ducks and laying birds.		280 TXU			

(1) 1 TXU is the amount of enzyme which liberates 5 micromoles of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 844/2012

of 18 September 2012

setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 19 thereof,

Whereas:

(1) Regulation (EC) No 1107/2009 provides that the approval of an active substance may be renewed upon expiry.

(2) It is appropriate to set out the provisions necessary for the implementation of the renewal procedure.

(3) In particular, periods should be set for the different steps of the renewal procedure to ensure that it functions properly.

(4) Rules should be set out as regards confidentiality and the publication of the application for renewal, the supplementary dossiers and their updates.

(5) Rules should also be set out as regards the submission of the application for renewal and its contents and format. The applicant should be obliged to justify the submission of new information and to list separately studies concerning vertebrate animals that they intend to submit.

(6) Rules should be set out as regards the checking of the application by the rapporteur Member State.

(7) In order to ensure the proper functioning of the renewal procedure, the rapporteur Member State should, at the applicant's request, organise prior to the submission of the supplementary dossier, a meeting to discuss the application.

(8) The supplementary dossiers submitted for renewal should, in particular, include necessary new data and new risk assessments and demonstrate why such data and risk assessments are necessary.

(9) Rules should be set out as regards the establishment of the admissibility of the application by the rapporteur Member State.

(10) Where all applications submitted are inadmissible, the Commission should adopt a Regulation on the non-renewal of the active substance concerned.

(11) Rules should be set out to ensure an independent, objective and transparent assessment of the active substance.

(12) The applicant, the Member States, with the exception of the rapporteur Member State, and the public should be given the opportunity to submit comments on the draft renewal assessment report.

(13) The European Food Safety Authority should provide conclusions and organise consultations of experts, except where the Commission informs it that a conclusion is not necessary.

(14) Rules should be set out as regards the renewal report and the adoption of a regulation on the renewal of the approval of the active substance.

(15) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances [2] should continue to apply with respect to the renewal of the approval of the active substances listed in Annex I thereto.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

ADMISSIBILITY

SECTION 1

Application for renewal

Article 1

Submission of the application

1. An application for the renewal of an approval of an active substance shall be submitted by a producer of the active substance to the rapporteur Member State, as set out in the second column of the Annex to Commission Implementing Regulation (EU) No 686/2012 [3] and to the co-rapporteur Member State, as set out in the third column of that Annex, no later than three years before the expiry of the approval.

When submitting an application, the applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request certain information to be kept confidential. In that event, the applicant shall present such parts of the application physically separated, setting out the reasons for requesting confidentiality.

[1] OJ L 309, 24.11.2009, p. 1.

[2] OJ L 322, 8.12.2010, p. 10.

[3] OJ L 200, 27.7.2012, p. 5.

At the same time, the applicant shall submit any data protection claims pursuant to Article 59 of Regulation (EC) No 1107/2009.

2. The applicant shall send a copy of the application to the Commission, the other Member States and to the European Food Safety Authority ('the Authority'), including the information on those parts of the application in respect of which confidentiality has been requested as referred to in paragraph 1.

3. A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

Article 2

Format and contents of the application

1. The application shall be submitted in the format set out in the Annex.

2. The application shall list the new information the applicant intends to submit. It shall demonstrate that such information is necessary in accordance with the first subparagraph of Article 15(2) of Regulation (EC) No 1107/2009.

The application shall list separately any new studies involving vertebrate animals that the applicant intends to submit.

Article 3

Checking of the application

1. Where the application has been submitted by the date provided for in the first subparagraph of Article 1(1) and contains all the elements provided for in Article 2, the rapporteur Member State shall, within one month of the date of receipt of the application, inform the applicant, the co-rapporteur Member State, the Commission and the Authority of the date of receipt of the application and the fact that it has been submitted by the date provided for in the first subparagraph of Article 1(1) and contains all the elements provided for in Article 2.

The rapporteur Member State shall assess any request for confidentiality. Upon a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

2. Where the application has been submitted by the date provided for in the first subparagraph of Article 1(1) but one or more elements provided for in Article 2 are missing, the rapporteur Member State shall, within one month of the date of receipt of the application, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements to the Rapporteur Member State and to the co-rapporteur Member State.

Where the application contains all the elements provided for in Article 2 at the expiry of that period, the rapporteur Member State shall, without delay, proceed in accordance with paragraph 1.

3. Where the application has not been submitted by the date provided for in the first subparagraph of Article 1(1), or where the application still does not contain all the elements provided for in Article 2 at the expiry of the period set for the submission of the missing elements in accordance with paragraph 2, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application is inadmissible and of the reasons why it is inadmissible.

4. Within 14 days from the date of receipt of the information that the application has been submitted by the date provided for in the first subparagraph of Article 1(1) and that it contains all the elements provided for in Article 2, the applicant shall submit to the Authority a copy of the application, including the information about those parts of the application in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

At the same time, the applicant shall forward a copy of the application to the Authority, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

5. Where, by the date provided for in the first subparagraph of Article 1(1), two or more applications for the same active substance have been submitted separately and each of them contains all the elements provided for in Article 2, the rapporteur Member State shall communicate the contact details of each applicant to the other applicant(s).

6. The Commission shall publish, for each active substance, the names and the addresses of the applicants whose applications have been submitted by the date provided for in the first subparagraph of Article 1(1) and contain all the elements provided for in Article 2.

Article 4

Contacts prior to submission of supplementary dossiers

The applicant may request a meeting with the rapporteur Member State and the co-rapporteur Member State to discuss the application.

If requested, such pre-submission contacts shall take place prior to the submission of supplementary dossiers, as provided for in Article 6.

Article 5

Access to the application

Upon receipt of the application, as provided for in Article 3(4), the Authority shall make it available to the public without delay, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

SECTION 2

Supplementary dossiers

Article 6

Submission of supplementary dossiers

1. Where the rapporteur Member State has informed the applicant in accordance with Article 3(1) that its application has been submitted by the date provided for in the first subparagraph of Article 1(1) and that it contains all the elements provided for in Article 2, the applicant shall submit the supplementary dossiers to the rapporteur Member State, the co-rapporteur Member State, the Commission and the Authority.

2. The contents of the supplementary summary dossier and the supplementary complete dossier shall comply with Article 7.

3. The supplementary dossiers shall be submitted no later than 30 months before the expiry of the approval.

4. Where there is more than one applicant requesting renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly.

Where such dossiers are not submitted jointly by all the applicants concerned, the reasons shall be set out in the dossiers.

5. When submitting the supplementary dossiers, the applicant may pursuant to Article 63 of Regulation (EC) No 1107/2009 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Article 7

Contents of supplementary dossiers

1. The supplementary summary dossier shall include the following:

(a) a copy of the application;

(b) where the applicant is joined or replaced by one or more other applicants, the name and address of that applicant or those other applicants and, if applicable, the name of the association of producers provided for in Article 1(3);

(c) information with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are fulfilled; where the information submitted does not cover all zones or does not concern a widely grown crop, a justification shall be submitted;

(d) data and risk assessments which were not part of the approval dossier or subsequent renewal dossiers and which are necessary:

(i) to reflect changes in legal requirements which have occurred since the approval or last renewal of the approval of the active substance concerned;

(ii) to reflect changes in scientific and technical knowledge since the approval or last renewal of the approval of the active substance concerned;

(iii) to reflect changes to representative uses; or

(iv) because the application is for an amended renewal;

(e) for each point of the data requirements for the active substance, as set out in a Regulation setting out data requirements for active substances under Regulation (EC) No 1107/2009, for which new data are necessary in accordance with point (d), the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried them out and the reason why each test or study is necessary;

(f) for each point of the data requirements for the plant protection product, as set out in a Regulation setting out data requirements for plant protection products under Regulation (EC) No 1107/2009, for which new data are necessary in accordance with point (d), the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies, for one or more plant protection products which are representative of the supported uses, and the reason why each test or study is necessary;

(g) where relevant, documented evidence as referred to in Article 4(7) of Regulation (EC) No 1107/2009;

(h) for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing on vertebrate animals;

(i) where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council [1];

(j) where relevant, a copy of the proposal for classification where it is considered that the substance has to be classified or reclassified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council [2];

(k) an assessment of all information submitted;

(l) a checklist demonstrating that the supplementary dossier provided for in paragraph 3 is complete in view of the uses applied for and indicating which data are new;

(m) the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of Regulation (EC) No 1107/2009.

2. The uses referred to in paragraph 1(c) shall, where appropriate, include the uses evaluated for the approval or subsequent renewals. At least one plant protection product referred to in paragraph 1(c) shall contain no other active substance, where such a product exists for a representative use.

3. The supplementary complete dossier shall contain the full text of each test and study report referred to in paragraph 1(e), (f) and (m).

It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product containing it to humans.

Article 8

Admissibility of the application

1. Where the supplementary dossiers have been submitted by the date provided for in Article 6(3) and contain all the elements provided for in Article 7, the rapporteur Member State shall, within a period of one month, inform the applicant, the co-rapporteur Member State, the Commission and the Authority of the date of receipt of the supplementary dossiers and of the admissibility of the application.

[1] OJ L 70, 16.3.2005, p. 1.
[2] OJ L 353, 31.12.2008, p. 1.

The rapporteur Member State shall assess any requests for confidentiality. In the event of a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

2. Where the supplementary dossiers have been submitted by the date provided for in Article 6(3), but one or more elements provided for in Article 7 are missing, the rapporteur Member State shall, within a period of one month from the date of receipt of the supplementary dossiers, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements to the rapporteur Member State and co-rapporteur Member State.

Where at the expiry of that period the supplementary dossiers contain all the elements provided for in Article 7, the rapporteur Member State shall, without delay, proceed in accordance with paragraph 1.

3. After receiving the information that the application is admissible, the applicant shall immediately forward the supplementary dossiers to the other Member States, the Commission and the Authority, including the information about those parts of the dossier in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

At the same time, the applicant shall forward the supplementary summary dossiers to the Authority, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

4. The Authority shall make the supplementary summary dossier available to the public, without delay, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

5. At the request of the Authority or a Member State, the applicant shall make available the dossiers submitted for the approval and subsequent renewals of the approval, where it has access to them.

6. Where the supplementary dossiers have not been submitted by the date referred to in Article 6(3), or where at the end of the period set for the submission of the missing elements in accordance with paragraph 2 of this Article the supplementary dossiers still do not contain all the elements provided for in Article 7, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application is inadmissible and of the reasons why it is inadmissible.

Article 9

Replacement of the applicant

An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the rapporteur Member State, through a joint declaration by the applicant and the other producer. In that case, the applicant and the other producer shall, at the same time, inform the co-rapporteur Member State, the Commission, the other Member States, the Authority and any other applicants that have submitted an application for the same active substance of the replacement.

Article 10

Adoption of non-renewal Regulation

The Commission shall adopt a Regulation on the non-renewal of the approval of an active substance in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009 where all of the applications submitted for that active substance are inadmissible in accordance with Article 3(3) of this Regulation or Article 8(6) thereof.

CHAPTER 2

ASSESSMENT

Article 11

Assessment by the rapporteur Member State and the co-rapporteur Member State

1. Where the application is admissible in accordance with Article 8(1), the rapporteur Member State shall, after consulting the co-rapporteur Member State, at the latest 12 months after the date referred to in Article 6(3), prepare and submit to the Commission, with a copy to the Authority, a report assessing whether the active substance can be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009 ('the draft renewal assessment report').

2. The draft renewal assessment report shall also include the following:

(a) a recommendation with regard to the renewal of the approval;

(b) a recommendation on whether the substance should be considered a 'low-risk' substance;

(c) a recommendation on whether the substance should be considered a candidate for substitution;

(d) where relevant, a proposal to set maximum residue levels;

(e) where relevant, a suggestion for the classification or reclassification of the active substance in accordance with Regulation (EC) No 1272/2008;

(f) a conclusion on which of the new studies included in the supplementary dossiers are relevant for the assessment;

(g) a recommendation as to the parts of the report on which a consultation of experts is to be organised in accordance with Article 13(1);

(h) the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant.

3. The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge. It shall take into account the supplementary dossiers, and, where appropriate, the dossiers submitted for the approval and subsequent renewals of approval.

4. The rapporteur Member State shall first establish whether the approval criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are satisfied.

Where those criteria are not satisfied, the draft renewal assessment report shall be limited to those parts of the assessment, unless Article 4(7) of Regulation (EC) No 1107/2009 applies.

5. Where the rapporteur Member State requires additional information, it shall set a period for the applicant to supply that information. That period shall not lead to an extension of the period of 12 months provided for in paragraph 1. The applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request such information to be kept confidential.

6. The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States. Such consultations and requests shall not lead to an extension of the period of 12 months provided for in paragraph 1.

7. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first sentence of paragraph 5, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

8. When submitting the draft renewal assessment report to the Commission, the rapporteur Member State shall request the applicant to submit the supplementary summary dossiers, updated to include the additional information requested by the rapporteur Member State in accordance with paragraph 5 or submitted in accordance with Article 56 of Regulation (EC) No 1107/2009, to the co-rapporteur Member State, the Commission, the other Member States and to the Authority.

The applicant may pursuant to Article 63 of Regulation (EC) No 1107/2009 request such information to be kept confidential. Any such requests shall be addressed to the Authority.

Article 12

Comments on the draft renewal assessment report

1. The Authority shall circulate the draft renewal assessment report received from the rapporteur Member State to the applicant and to the other Member States at the latest 30 days after its receipt.

2. The Authority shall make the draft renewal assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63 of Regulation (EC) No 1107/2009, that certain parts of the draft renewal assessment report are kept confidential.

3. The Authority shall allow a period of 60 days from the date the report is made available to the public for the submission of written comments. Such comments shall be communicated to the Authority, which shall collate and forward those comments, including its own comments, to the Commission.

4. The Authority shall make the updated supplementary summary dossiers available to the public, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

Article 13

Conclusion by the Authority

1. Within five months from the expiry of the period referred to in Article 12(3), the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the supplementary dossiers on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority shall, where appropriate, organise a consultation of experts, including experts from the rapporteur Member State and co-rapporteur Member State. The Authority shall communicate its conclusion to the applicant, the Member States and the Commission.

By way of derogation from the first subparagraph, the Commission may inform the Authority without delay after the period referred to in Article 12(3) has expired that a conclusion is not necessary.

2. After giving the applicant two weeks to request, pursuant to Article 63 of Regulation (EC) No 1107/2009, that certain parts of the conclusion be kept confidential, the Authority shall make its conclusion available to the public, excluding any information in respect of which confidentiality has been granted by the Authority, unless there is an overriding public interest in its disclosure.

3. Where the Authority considers that additional information from the applicant is necessary, it shall, in consultation with the rapporteur Member State, set a period not exceeding one month for the applicant to supply such information to the Member States, the Commission and the Authority. The rapporteur Member State shall, within 60 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority.

Where the first subparagraph applies, the period referred to in paragraph 1 shall be extended by the periods referred to in the first subparagraph of this paragraph.

4. The Authority may ask the Commission to consult a European Union reference laboratory designated, pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council [1], for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and complies with the requirements in Article 29(1)(g) of Regulation (EC) No 1107/2009. The applicant shall, if requested by the European Union reference laboratory, provide samples and analytical standards.

5. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

[1] OJ L 165, 30.4.2004, p. 1.

Article 14

Renewal report and renewal Regulation

1. The Commission shall present to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 a renewal report and a draft Regulation within six months from the date of receipt of the conclusion of the Authority or in cases where there is no such conclusion of the Authority, the expiry of the period referred to in Article 12(3) of this Regulation.

The renewal report and the draft Regulation shall take into account the draft renewal assessment report of the rapporteur Member State, the comments referred to in Article 12(3) of this Regulation and the conclusion of the Authority, where such a conclusion has been submitted.

The applicant shall be given the possibility to submit comments on the renewal report within a period of 14 days.

2. On the basis of the renewal report and taking into account comments submitted by the applicant within the period referred to in the third subparagraph of paragraph 1, the Commission shall adopt a Regulation in accordance with Article 20(1) of Regulation (EC) No 1107/2009.

CHAPTER 3

TRANSITIONAL AND FINAL PROVISIONS

Article 15

Transitional provisions

Regulation (EU) No 1141/2010 shall continue to apply with respect to the renewal of the approval of active substances listed in Annex I thereto.

Article 16

Entry into force and 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 January 2013.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Format for applications, as provided for in Article 2(1)

The application shall be in writing, signed by the applicant, and sent to the rapporteur Member State and to the co-rapporteur Member State.

A copy of the application shall be sent to the European Commission, DG Health and Consumers, 1049 Brussels, Belgium, to the European Food Safety Authority, Via Carlo Magno 1/A, 43126 Parma, Italy and to the other Member States.

MODEL

1. Information concerning the applicant

1.1. Name and address of the applicant including the name of the natural person responsible for the application and other obligations resulting from this Regulation:

1.1.1. (a) Telephone No:

(b) E-mail address:

1.1.2. (a) Contact:

(b) Alternative contact:

2. Information to facilitate identification

2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines manufactured by the producer.

2.2. Chemical name (IUPAC and CAS nomenclature).

2.3. CAS, CIPAC and EC numbers (if available).

2.4. Empirical and structural formula, molecular mass.

2.5. Specification of purity of the active substance in g/kg which must be, whenever possible, identical or already accepted as equivalent to the one listed in the Annex to Commission Implementing Regulation (EU) No 540/2011 [1].

2.6. Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council [2] (health and environment effects).

3. New information

3.1. List of new information intended to be submitted together with a justification showing that they are considered necessary, in accordance with Article 15(2) of Regulation (EC) No 1107/2009.

3.2. List of new studies intended to be submitted on vertebrate animals.

3.3. Timetable of any new and ongoing studies.

The applicant confirms that the above information submitted included in the application is correct.

Date and signature (of the person competent to act for the applicant referred to under point 1.1).

[1] OJ L 153, 11.6.2011, p. 1.
[2] OJ L 353, 31.12.2008, p. 1.

COMMISSION REGULATION (EU) No 845/2012

of 18 September 2012

imposing a provisional anti-dumping duty on imports of certain organic coated steel products originating in the People's Republic of China

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community [1] ('the basic Regulation'), and in particular Article 7 thereof,

After consulting the Advisory Committee,

Whereas:

A. PROCEDURE

1. Initiation

(1) On 21 December 2011, the Commission announced, by a notice published in the *Official Journal of the European Union* [2] ('the notice of initiation'), the initiation of an anti-dumping proceeding with regard to imports into the Union of certain organic coated steel products originating in the People's Republic of China ('the country concerned' or 'the PRC').

(2) The proceeding was initiated following a complaint lodged on 7 November 2011 by Eurofer ('the complainant'), representing a major proportion, in this case more than 70 %, of the total Union production of certain organic coated steel products. The complaint contained prima facie evidence of dumping of the said product and of material injury resulting therefrom, which was considered sufficient to justify the opening of a proceeding.

2. Parties concerned by the proceeding

(3) The Commission officially advised the complainants, other known Union producers, the known exporting producers in the PRC, importers, traders, users, suppliers and associations known to be concerned, and the representatives of the PRC of the initiation of the proceeding. The Commission also advised producers in Canada and the Republic of South Africa ('South Africa') which were envisaged in the notice of initiation as possible analogue countries. Interested parties were given the opportunity to make their views known in writing and to request a hearing within the time limit set in the notice of initiation.

(4) In view of the apparent high number of exporting producers, Union producers and unrelated importers, sampling was envisaged in the notice of initiation in accordance with Article 17 of the basic Regulation. In order to enable the Commission to decide whether sampling would be necessary and if so, to select samples, all known exporting producers and unrelated importers were asked to make themselves known to the Commission and to provide, as specified in the notice of initiation, basic information on their activities related to the product concerned during the period from 1 October 2010 to 30 September 2011.

(5) As regards the Union producers, the Commission announced in the notice of initiation that it had provisionally selected a sample of Union producers. This sample consisted of six Union producers that were known to the Commission to produce the like product selected on the basis of sales, production volume, size and geographical location in the Union. The sampled Union producers accounted for 46 % of the Union production and 38 % of the Union sales. Interested parties were also invited in the notice of initiation to make their views known on the provisional sample. One of the Union producers stated that it did not wish to be included in the sample and was replaced in the sample by the next largest producer.

(6) 26 exporting producers or groups of exporting producers in the PRC provided the requested information and agreed to be included in the sample. On the basis of the information received from the exporting producers, the Commission initially selected a sample of three exporting producers with the highest export volume to the Union. However, one of the sampled exporting producers did not provide accurate export data and was excluded from the sample. Two other exporting producers that were subsequently included in the sample, withdrew their cooperation. Therefore, the Commission finally decided to limit the sample to the two exporting producers originally selected to form part of the sample and that had the highest export volume to the Union. Their export volume accounts for more than 30 % of total exports of all cooperating Chinese exporting producers.

(7) In order to allow exporting producers in the PRC to submit a claim for market economy treatment ('MET') or individual treatment ('IT'), if they so wished, the Commission sent claim forms to the Chinese exporting producers known to be concerned, the Chinese authorities and to other Chinese exporting producers that made themselves known within the deadlines set out in the notice of initiation. Three Chinese exporting producers, including one that was included in the sample, requested MET pursuant to Article 2(7) of the basic Regulation, or IT should the investigation establish that they did not meet the conditions for MET. One of these exporting producers, which was not included in the

[1] OJ L 373, 22.12.2009, p. 51.
[2] OJ C 373, 21.12.2011, p. 16.

sample, subsequently withdrew its request. The other exporting producer in the sample requested IT only.

(8) Five unrelated importers provided the requested information and agreed to be included in the sample. In view of the limited number of cooperating importers, sampling was deemed to be no longer necessary.

(9) The Commission sent questionnaires to the two sampled exporting producers in the PRC, 14 other exporting producers in the PRC that requested so, four producers in Canada, three producers in South Africa, five producers in the Republic of Korea ('South Korea'), five producers in the Federative Republic of Brazil ('Brazil') – candidate countries of the analogue country choice, the six sampled Union producers, the five cooperating importers in the Union and to the known users.

(10) Replies were received from nine exporting producers and related companies in the PRC, one producer in Canada and one producer in another possible analogue country, South Korea. Furthermore, the six sampled Union producers, two unrelated importers and ten users replied to the questionnaire.

(11) The Commission sought and verified all the information deemed necessary for a provisional determination of dumping, resulting injury and Union interest. Verification visits were carried out at the premises of the following companies:

(a) *Union producers*

— ArcelorMittal Belgium, Belgium and related sales company ArcelorMittal Flat Carbon Europe SA, Luxembourg

— ArcelorMittal Poland, Poland

— ThyssenKrupp Steel Europe AG, Germany

— voestalpine Stahl GmbH and voestalpine Stahl Service Center GmbH, Austria

— Tata Steel Maubeuge SA (formerly known as Myriad SA), France

— Tata Steel UK Ltd, United Kingdom

(b) *Exporting producers in the PRC*

— Zhangjiagang Panhua Steel Strip Co., Ltd and its related companies: Chongqing Wanda Steel Strip Co., Ltd, Zhangjiagang Wanda Steel Strip Co., Ltd, Jiangsu Huasheng New Construction Materials Co. Ltd and Zhangjiagang Free Trade Zone Jiaxinda International Trade Co., Ltd;

— Zhejiang Huadong Light Steel Building Material Co. Ltd and its related company Hangzhou P.R.P.T. Metal Material Company Ltd;

— Union Steel China and its related company Wuxi Changjiang Sheet Metal Co. Ltd.

(c) *Union importers*

— ThyssenKrupp Mannex, Germany

(d) *Union users*

— Steelpartners NV (belonging to Joris IDE group), Belgium

3. **Investigation period**

(12) The investigation of dumping and injury covered the period from 1 October 2010 to 30 September 2011 ('investigation period' or 'IP'). The examination of the trends relevant for the assessment of injury covered the period from 1 January 2008 to the end of the investigation period ('the period considered').

B. **PRODUCT CONCERNED AND LIKE PRODUCT**

1. **Product concerned**

(13) The product concerned is certain organic coated steel products ('OCS'), i.e. flat rolled products of non-alloy and alloy steel (not including stainless steel) which are painted, varnished or coated with plastics on at least one side, excluding so-called 'sandwich panels' of a kind used for building applications and consisting of two outer metal sheets with a stabilising core of insulation material sandwiched between them, and excluding those products with a final coating of zinc-dust (a zinc-rich paint, containing by weight 70 % or more of zinc) currently falling within CN codes ex 7210 70 80, ex 7212 40 80, ex 7225 99 00, ex 7226 99 70, and originating in the People's Republic of China ('the product concerned').

(14) The main application of the OCS is in the construction industry, also for further processing in various products used in construction (like sandwich panels, roofing, cladding, etc.). Other applications include home appliance production (white and brown goods) or equipment for construction (doors, radiators, lights, etc.).

2. **Like product**

(15) The investigation has shown that OCS produced and sold by the Union industry in the Union, OCS produced and sold on the domestic market of the PRC and OCS imported into the Union from the PRC, as well as that produced and sold in Canada, which serves as an analogue country, have the same basic physical and chemical characteristics and the same basic end uses. Therefore these products are provisionally considered to be alike within the meaning of Article 1(4) of the basic Regulation.

(16) Some interested parties argued that the products from the PRC were not comparable with those sold by the Union industry because the former were sold in a different market and price segment and for a different end-use like outdoor construction use, whereas a substantial part of the Union industry products are high quality products used only in the niche home appliances sector.

(17) The investigation showed that while indeed, the Union producers sold a part of their production to such market segments as home appliances, the same products were also sold to construction materials industry, which is allegedly the main market segment of the Chinese exports. Moreover, the price levels between those sectors were found to be largely comparable for the same product types sold to different users.

(18) It should be noted that, as the product concerned is largely standardised, it has similar basic physical and chemical characteristics as the like product irrespective of the end uses. Therefore, the argument is provisionally rejected.

3. **Product exclusion requests**

(19) Several requests for exclusion of certain product types were received from users, Chinese exporters and Union producers. The product types requested to be excluded concern e.g. chromium or tin coated steel, steel plates painted with inorganic zinc silicate primer or painted with other materials than organic ones.

(20) However, no conclusions have been reached so far, as some of those requests are not sufficiently documented to make an informed decision. Therefore, it has been decided to investigate these claims further.

C. **DUMPING**

1. **Market Economy Treatment ('MET')**

(21) Pursuant to Article 2(7)(b) of the basic Regulation, in antidumping investigations concerning imports originating in the PRC, normal value shall be determined in accordance with paragraphs 1 to 6 of the said Article for those producers which were found to meet the criteria laid down in Article 2(7)(c) of the basic Regulation. Briefly and for ease of reference only, these criteria are set out in summarised form below:

— Business decisions are made in response to market signals, without significant State interference, and costs reflect market values;

— Firms have one clear set of basic accounting records, which are independently audited in line with international accounting standards and are applied for all purposes;

— There are no significant distortions carried over from the former non-market economy system;

— Bankruptcy and Property laws guarantee stability and legal certainty; and

— Exchange rate conversions are carried out at market rates.

(22) As set out in recital (8) above, three exporting producers from the PRC requested market economy treatment ('MET') and replied to the MET claim form within the given deadline, of which one exporting producer subsequently withdrew its request.

(23) As regards the remaining two cooperating exporting producers in the PRC having requested MET, following a judgment by the Court of Justice of 2 February 2012 [1] it was decided to examine the claims of both the exporting producer which was included in the sample (Zhangjiagang Panhua Steel Strip Co. Ltd and its related companies) and the exporting producer which was not included in the sample (Union Steel China and its related company). The Commission sought all information deemed necessary and verified information submitted in the MET claim at the premises of the companies in question.

(24) None of the two cooperating groups of exporting producers in the PRC were found to meet the criteria to be granted MET, because the cost of the major raw material, hot-rolled steel coils, is significantly distorted due to State interference in the steel market in the PRC and does not substantially reflect market values, as required by the first indent of Article 2(7)(c) of the basic Regulation.

(25) Interference by the Chinese State in the steel sector is demonstrated by the fact that a large majority of the large Chinese steel producers are State-owned and steel installed capacity and output are influenced by the various five-year Industrial Plans, in particular the current 12th Five-Year Plan (2011-2015) for the iron and steel sector.

(26) The State also exercises significant control over the market of raw materials. Coke (together with iron ore the major raw material to produce steel) is subject to quantitative restrictions on exports and to an export duty of 40 %. It may therefore be concluded that the Chinese steel market is distorted due to significant State interference.

(27) This distortion is reflected in the price paid by the investigated companies for hot-rolled steel coils in the IP. They were found to be significantly lower than international prices. It may therefore be concluded that the production of OCS benefits from abnormally priced hot-rolled steel coils due to government interference which distorts the price of OCS in the PRC. This distortion constitutes a major cost advantage for the Chinese exporting producers as the cost or the major raw material, hot-rolled steel coils, accounts for approximately 80 % of the cost of production. Accordingly, criterion 1 cannot be considered to be met.

[1] Case C-249/10 P. Brossmann Footwear (HK) and Others v Council of the European Union

(28) In addition to the general situation described above, one exporting producer did not meet criterion 2 either due to significant failures of the accounting systems of three of its related group companies.

(29) The Commission officially disclosed the results of the MET findings to the companies concerned in the PRC, the authorities of the PRC and the complainant. They were also given an opportunity to make their views known in writing and to request a hearing if there were particular reasons to be heard.

(30) Written submissions were provided by the complainant, one Chinese exporting producer and the authorities of the PRC. The complainant agreed with the results of the MET findings. The Chinese exporting producer mainly questioned whether prices paid by the investigated companies for hot-rolled steel coils are significantly lower than international prices but provided no information to support its claim. However Eurostat data, confirmed by other available statistical data [1], clearly show that these prices were significantly below international prices when comparing to corresponding prices in Europe, North America, South America and Japan. Therefore the argument is rejected.

(31) The authorities of the PRC argued that the existence of eventual industry wide-level price distortions of the raw material hot-rolled steel coils do not automatically preclude compliance with criterion 1 which calls for a determination at company level. However, as mentioned in recital (27), the distortion of the price of the main raw material is reflected in the price paid by all the investigated companies. First, this fact was not disputed by any party and secondly, the MET examination was done at company-level and the findings are not limited to general horizontal issues. Therefore, this argument is rejected.

(32) It was furthermore submitted by the authorities of the PRC that the five-year plans are non-binding guidelines with no legal force in the PRC. However, as set out in recital (25), irrespective of the exact legal status of these plans, it cannot be denied that by means of these plans, the intervention of the government of the PRC has a significant impact on the steel-installed capacity and output. Therefore, this argument is rejected.

(33) It was also claimed that the handling of the MET claims by the Commission was incompatible with the judgments by the Court of Justice of 2 February 2012 [2] ('Brosmann judgment') and of 19 July 2012 [3] ('Zhejiang Xinan Chemical judgment'). As regards this argument, it should be noted that the proceeding was carried out in accordance with the Brosmann judgment, as also recognised by the authorities of the PRC themselves in their submission. In addition, the issue at stake in the Zhejiang judgment was the interference of the State in company decisions. However, in this proceeding, the main reason to deny MET was that the price of the main raw material does not reflect market values. Therefore, this argument is provisionally rejected.

(34) It was also claimed that since the parallel anti-subsidy proceeding regarding the product concerned also examined the issue of input distortion, the Commission should have taken into account the evidence collected on this issue in the mentioned parallel proceeding. As regards this argument it should be noted that, in the framework of the current anti-dumping proceeding during the MET investigation it was examined whether the costs of the major raw material reflect market values. The conclusion that the production of OCS in the PRC benefits from abnormally priced hot-rolled steel coils, as set out in recital (27), is therefore perfectly valid in this respect and does not by any means prejudice any possible findings of the anti-subsidy proceeding or vice versa. Any possible findings of the anti-subsidy proceedings are quite distinct from the MET determination. Therefore, this argument is provisionally rejected.

(35) The authorities of the PRC also claimed that the Commission did not disclose the MET findings to the Chinese authorities. However, this is not correct as the Commission services provided, by a Note Verbale to the Chinese Mission to the EU of 12 July 2012, with the MET disclosure document.

(36) Finally, it was argued that the Commission is using unverified data from the analogue country producer for imposing provisional duties. However, this is not correct, as the Commission used data which it analysed and found to be reliable, as clearly stated in recital (48). The Commission had to turn to the Canadian analogue producer for co-operation, as the Korean analogue producer withdrew its co-operation just before the planned and agreed verification visit took place as explained in recital (45). The on-spot investigation to the premises of the producer will therefore be made after the provisional stage of the proceeding. It was also argued that the Korean analogue country company withdrew its cooperation because of the MET decision.

[1] SBB/Worldsteelprice.com

[2] Case C-249/10 P. Brossmann Footwear (HK) and Others v Council of the European Union

[3] Case C-337/09 Council of the European Union v. Zhejiang Xinan Chemical Industrial Group Co. Ltd.

However, this is not the case, as the withdrawal came on 3 July while the disclosure of MET findings was made on 12 July 2012.

(37) None of the arguments brought forward were such as to alter the findings with regard to the MET determination.

(38) On the basis of the above, neither of the two groups of cooperating exporting producers in the PRC that had requested MET could show that they fulfilled the criteria set out in Article 2(7)(c) of the basic Regulation.

2. **Individual Treatment ('IT')**

(39) Pursuant to Article 2(7)(a) of the basic Regulation a country-wide duty, if any, is established for countries falling under that Article, except in those cases where companies are able to demonstrate that they meet the criteria set out in Article 9(5) of the basic Regulation. Briefly, and for ease of reference only, these criteria are set out below:

— In the case of wholly or partly foreign owned firms or joint ventures, exporters are free to repatriate capital and profits;

— Export prices and quantities, and conditions and terms of sale are freely determined;

— The majority of the shares belong to private persons. State officials appearing on the Boards of Directors or holding key management positions shall either be in minority or it must be demonstrated that the company is nonetheless sufficiently independent from State interference;

— Exchange rate conversions are carried out at the market rate; and

— State interference is not such as to permit circumvention of measures if individual exporters are given different rates of duty.

(40) The exporting producer, which was included in the sample and requested MET, also claimed IT in the event it would not be granted MET. The other exporting producer, which was included in the sample, only claimed IT. On the basis of the information available, it was provisionally established that these two exporting producers in the PRC met the criteria for being granted IT.

3. **Individual Examination ('IE')**

(41) Claims for individual examination were submitted by six cooperating exporting producers pursuant to Article 17(3) of the basic Regulation, of which only one requested MET. It was provisionally decided to carry out IE for the exporting producer which had requested MET, Union Steel China, as it was not unduly burdensome to do so as this exporting producer was already inspected in the framework of the examination of its MET claim.

(42) This exporting producer requested MET, but also IT in the event it would not be granted MET. After examination of this claim, it was provisionally established to grant IT to Union Steel China as it met the criteria for being granted IT.

4. **Normal value**

4.1. *Choice of the analogue country*

(43) According to Article 2(7)(a) of the basic Regulation, normal value for exporting producers not granted MET has to be established on the basis of the domestic prices or constructed normal value in an analogue country.

(44) In the notice of initiation, the Commission indicated its intention to use either Canada or South Africa as an appropriate analogue country for the purpose of establishing normal value and interested parties were invited to comment on this.

(45) The Commission examined whether other countries could be a reasonable choice of analogue country and questionnaires were sent to OCS producers in Canada and South Africa, but also to producers in Brazil and South Korea. Only two OCS producers, one in Canada and one in South Korea, replied to the questionnaires. Both countries appeared to be open markets without any import duties and with significant imports from several third countries. In addition, there were at least four other domestic producers of the product concerned in South Korea, which allows a good level of competition on the domestic market. However, at a very advanced stage of the procedure, on 3 July 2012 and just prior to the verification visit by the Commission services, the South Korean producer inexplicably withdrew its cooperation.

(46) In view of the above, Canada was selected as the analogue country. There are at least four other domestic producers of the product concerned in Canada, which allows a good level of competition on the domestic market. The investigation showed no reason to consider that Canada was not adequate for the purpose of establishing normal value.

(47) Several interested parties argued that the cost structure of a Canadian producer cannot be compared with the cost structure of a Chinese exporting producer. However, no significant differences in cost structure were found and accordingly, this argument was rejected.

(48) The data submitted in the cooperating Canadian producer's reply were analysed and found to be reliable information on which a normal value could be based.

(49) It is therefore provisionally concluded that Canada is an appropriate and reasonable analogue country in accordance with Article 2(7)(a) of the basic Regulation.

4.2. *Determination of normal value*

(50) As the one company selected to be part of the sample and the company whose individual examination claim was accepted could not demonstrate that they fulfil the MET criteria and the other company that was selected to be part of the sample did not request MET, normal value for all Chinese exporting producers was established on the basis of information received from the producer in the analogue country.

(51) In accordance with Article 2(2) of the basic Regulation, the Commission first examined whether the sales of the like product in Canada to independent customers were representative. The sales of the Canadian cooperating producer of the like product were found to be sold in representative quantities on the Canadian domestic market compared to the product concerned exported to the Union by the exporting producers included in the sample and the exporting producer whose individual examination claim was accepted.

(52) The Commission subsequently examined whether these sales could be considered as having been made in the ordinary course of trade pursuant to Article 2(4) of the basic Regulation. This was done by establishing the proportion of profitable sales to independent customers. The sales transactions were considered profitable where the unit price was equal or above the cost of production. The cost of production of the Canadian producer during the IP was therefore determined.

(53) For those product types where more than 80 % by volume of sales on the domestic market of the type in question were above cost and the weighted average sales price of that type was equal to or above the unit cost of production, normal value, by product type, was calculated as the weighted average of the actual domestic prices of all sales of the type in question, irrespective of whether those sales were profitable or not.

(54) Where the volume of profitable sales of a product type represented 80 % or less of the total sales volume of that type, or where the weighted average price of that type was below the unit cost of production, normal value was based on the actual domestic price, which was calculated as a weighted average price of only the profitable domestic sales of that type made during the IP.

(55) As regards the types of product that were not profitable, normal value was constructed using the cost of manufacturing of the Canadian producer plus the SG&A and profit margin for the product types that are profitable.

4.3. *Export prices for the exporting producers granted IT*

(56) As all cooperating exporting producers granted IT made export sales to the Union directly to independent customers in the Union, the export prices were based on the prices actually paid or payable for the product concerned, in accordance with Article 2(8) of the basic Regulation.

4.4. *Comparison*

(57) The normal value and export price were compared on an ex-works basis. For the purpose of ensuring a fair comparison between the normal value and the export price, due allowance in the form of adjustments was made for differences affecting prices and price comparability in accordance with Article 2(10) of the basic Regulation. Adjustments were made, where appropriate, in respect of transport, insurance, handling and ancillary costs, packing, credit, bank charges and commissions in all cases where they were found to be reasonable, accurate and supported by evidence.

5. **Dumping margins**

(58) Pursuant to Articles 2(11) and (12) of the basic Regulation, the dumping margins for the exporting producers granted IT were established on the basis of a comparison of a weighted average normal value established for the analogue country with each company's weighted average export price expressed as a percentage of the CIF Union frontier price, duty unpaid.

(59) A weighted average of the sampled exporting producers' dumping margins was calculated for the cooperating exporting producers not selected in the sample. On this basis the provisional dumping margin for the non-sampled exporting producers, expressed as a percentage of the CIF Union frontier price, duty unpaid is 61,1 %.

(60) In order to calculate the country-wide dumping margin applicable to the non-cooperating or unknown exporting producers in the PRC, the level of cooperation was first established by comparing the volume of exports to the Union reported by the cooperating exporting producers with the equivalent Eurostat statistics.

(61) Given that cooperation from the PRC was approximately 70 %, the country-wide dumping margin applicable to all other exporters in the PRC was established by using the highest dumping margin established for representative product types of exporting producers. On this basis the country-wide level of dumping was provisionally established at 77,9 % of the CIF Union frontier price, duty unpaid.

(62) On this basis, the provisional dumping margins expressed as a percentage of the CIF Union frontier price, duty unpaid, are:

Company	Provisional dumping margin
Zhangjiagang Panhua Steel Strip Co., Ltd, Chongqing Wanda Steel Strip Co., Ltd, Zhangjiagang Wanda Steel Strip Co., Ltd, Jiangsu Huasheng New Construction Materials Co. Ltd) and Zhangjiagang Free Trade Zone Jiaxinda International Trade Co., Ltd	67,4 %
Zhejiang Huadong Light Steel Building Material Co. Ltd and Hangzhou P.R.P.T. Metal Material Company Ltd	54,6 %
Union Steel China and Wuxi Changjiang Sheet Metal Co. Ltd	59,2 %
Weighted average of the sample	61,1 %
Country-wide dumping margin	77,9 %

D. **INJURY**

1. **Union production and Union industry**

(63) All available information concerning Union producers, including information provided in the complaint, data collected from Union producers before and after the initiation of the investigation, and the verified questionnaire responses of the sampled Union producers, was used in order to establish the total Union production for the period considered.

(64) During the IP, OCS was manufactured by 22 producers in the Union. On the basis referred to in the previous recital, the total Union production was estimated to be around 3 645 298 tonnes during the IP. The Union producers accounting for the total Union production constitute the Union industry within the meaning of Articles 4(1) and 5(4) of the basic Regulation and will be hereafter referred to as the 'Union industry'.

2. **Determination of the relevant Union market**

(65) It was found during the investigation that a substantial part of the sampled Union producers' production was destined for captive use, i.e. often simply transferred (without invoice) and/or delivered at transfer prices within the same company or group of companies for further downstream processing.

(66) In order to establish whether or not the Union industry suffered injury and to determine consumption and the various economic indicators related to the situation of the Union industry, it was examined whether and to what extent the subsequent use of the Union industry's production of the like product had to be taken into account in the analysis.

(67) In order to provide as complete a picture as possible of the situation of the Union industry, data have been obtained and analysed for the entire OCS activity and it was subsequently determined whether the production was destined for captive use or for the free market.

(68) For the following economic indicators relating to the Union industry, it was found that a meaningful analysis and evaluation had to focus on the situation prevailing on the free market: sales volume and sales prices on the Union market, market share, growth, export volume and prices and thus the injury indicators were corrected for the known captive use and sales in the Union industry, and captive use and sales were analysed separately.

(69) As regards other economic indicators, however, it was found on the basis of the investigation, that they could reasonably be examined only by referring to the whole activity. Indeed, production (for both the captive and the free market), capacity, capacity utilisation, investments, stocks, employment, productivity, wages, ability to raise capital depend upon the whole activity, whether the production is captive or sold on the free market.

3. **Union consumption**

(70) The like product is sold by the Union industry to unrelated customers as well as sold/transferred to related companies for further downstream processing, e.g. in steel service centres.

(71) In calculating the apparent Union consumption of OCS, the Commission added the volume of total imports of OCS into the Union as reported by Eurostat and the volume of sales and captive use of the like product in the Union produced by the Union industry as reported in the complaint and as verified during the verification visits for the sampled Union producers,

(72) Concerning the Eurostat imports data it should be mentioned that the descriptions of the relevant CN codes (see under recital (13) above) are not limited to the description of the product under investigation and thus the imports reported by Eurostat under those codes may include other products. However, in absence of information as to the eventually affected quantities of

such other imports, or evidence that such quantities might be important, it was provisionally decided to use full data concerning imports under the relevant CN codes as reported by Eurostat.

(73) On this basis, the total Union consumption developed as follows:

	2008	2009	2010	IP
Consumption (in tonnes)	5 691 713	4 327 650	4 917 068	5 177 970
Index (2008 = 100)	*100*	*76*	*86*	*91*

(74) Total consumption on the EU market shrunk by 9 % over the period considered. Between 2008 and 2009 there was a decrease of about 24 % as a result of the global negative effects of the economic crisis, especially on the construction industry. After that the consumption started to recover and increased in total by 20 % from 2009 to the IP but it was still below the initial level of 2008.

4. **Imports from the country concerned and market share**

(75) Imports into the Union from the PRC developed as follows during the period considered:

	2008	2009	2010	IP
Volume of imports from the PRC (tonnes)	472 988	150 497	464 582	702 452
Index (2008 = 100)	*100*	*32*	*98*	*149*
Market share	8,3 %	3,5 %	9,4 %	13,6 %
Index (2008 = 100)	*100*	*42*	*114*	*163*

Source: Eurostat

(76) Notwithstanding the evolution of consumption, the volume of imports from the PRC increased significantly by 49 % over the period considered. Due to the negative effects of the economic crisis, also the volume of imports from the PRC sharply decreased in 2009. However, the imports from the PRC started to recover at an extremely fast pace, so that the increase from 2009 to the IP was an impressive 367 %.

(77) Similarly, the market share held by those imports increased by 63 % over the period considered. Although it dropped from 2008 to 2009 by more than half, it showed an impressive increasing trend from 2009 to the IP and rose by 290 %.

4.1. *Prices of imports and price undercutting*

Imports from the PRC	2008	2009	2010	IP
Average price in EUR/tonne	875	728	768	801
Index (2008 = 100)	*100*	*83*	*88*	*91*

Source: Eurostat

(78) The average import price from the PRC decreased by 9 % during the period considered. Between 2008 and 2009, it decreased significantly by 17 %, then it increased by five percentage points between 2009 and 2010 and by further three percentage points in the IP.

(79) The import prices from the PRC consistently remained below the sales prices of the Union industry during the whole period considered. As highlighted in the table above, while in 2009 during the height of the economic crisis, even the price cut of 17 % could not help the Chinese imports to keep

the market share in a situation of suddenly shrinking consumption and significant market slowdown, continuous undercutting in the subsequent years explains the steady impressive increase in the market share held by the imports from the PRC between 2009 and the IP.

(80) In order to determine price undercutting during the IP, the weighted average sales prices per product type of the sampled Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level, were compared to the corresponding weighted average prices per product type of the imports from the cooperating Chinese producers to the first independent customer on the Union market, established on a CIF basis, with appropriate adjustments for post-importation costs.

(81) The price comparison was made on a type-by-type basis for transactions at the same level of trade, duly adjusted where necessary, and after deduction of rebates and discounts. The result of the comparison, when expressed as a percentage of the sampled Union producers' turnover during the IP, showed weighted average undercutting margins of up to 25,9 % by the cooperating Chinese exporting producers.

5. **Economic situation of the Union industry**

5.1. *Preliminary remarks*

(82) Pursuant to Article 3(5) of the basic Regulation, the Commission examined all relevant economic factors and indices having a bearing on the state of the Union industry.

(83) As mentioned in recital (5) above, sampling was used for the examination of the possible injury suffered by the Union industry.

(84) The data provided and verified at the six sampled EU producers was used in order to establish microeconomic indicators, such as unit price, unit cost, profitability, cash flow, investments, return on investments, ability to raise capital and stocks.

(85) The data provided by the complainant for all producers of OCS in the Union, as cross-checked with other available sources and verified data of sampled Union producers, was used to establish macro-economic indicators, such as Union industry production, production capacity, capacity utilization, sales volume, market share, employment and productivity

5.2. *Data relating to the Union industry as a whole*

5.2.1. Production, production capacity and capacity utilization

(86) All available information concerning the Union industry, including information provided in the complaint, data collected from Union producers before and after the initiation of the investigation, and the verified questionnaire responses of the sampled Union producers, was used in order to establish the total Union production for the period considered.

	2008	2009	2010	IP
Production volume (tonnes)	4 218 924	3 242 741	3 709 441	3 645 298
Index (2008 = 100)	*100*	*77*	*88*	*86*
Production capacity (tonnes)	5 649 268	5 754 711	5 450 138	5 431 288
Index (2008 = 100)	*100*	*102*	*96*	*96*
Capacity utilisation	75 %	56 %	68 %	67 %
Index (2008 = 100)	*100*	*75*	*91*	*90*

Source: Complaint, questionnaire replies

(87) The table above shows that production decreased by 14 % over the period considered. In line with a decrease in demand, production decreased sharply in 2009, after which it partially recovered in 2010 before dropping back slightly in the IP despite an increase in consumption.

(88) Production capacity declined by 4 % over the period considered. Capacity utilisation followed the trend of production and declined by 10 % during the period considered.

5.2.2. Sales volume, market share and growth

	2008	2009	2010	IP
Sales volume (tonnes)	3 355 766	2 707 611	3 003 917	2 936 255
Index (2008 = 100)	*100*	*81*	*90*	*87*
Market share (tonnes)	59,0 %	62,6 %	61,1 %	56,7 %
Index (2008 = 100)	*100*	*106*	*104*	*96*

Source: Complaint, questionnaire replies

(89) In 2009 the Union industry sales volume to unrelated customers decreased sharply by 19 %. In 2010, sales volume increased by nine percentage points, but then dropped by three percentage points in the IP.

(90) The Union industry's market share decreased by 4 % over the period considered. After an initial increase in market share in 2009, the Union industry saw its share decrease in 2010 and the IP with the result that its share of the market was 6 % less in the IP than in 2009; this occurred against the background of an increase of more than 20 % in consumption in the same period. It was thus unable to benefit from the growing consumption and to regain the sales volumes and some of the market share previously lost.

(91) While Union consumption declined by 9 % during the period considered and the Union industry sales volume to unrelated parties decreased by 13 %, the market share of the Union industry decreased by 2,3 percentage points from 59 % in 2008 to 56,7 in the IP.

5.2.3. Employment and productivity

	2008	2009	2010	IP
Employment (in FTE)	6 790	5 953	5 723	5 428
Index (2008 = 100)	*100*	*88*	*84*	*80*
Productivity (tonnes/FTE)	621	545	648	672
Index (2008 = 100)	*100*	*88*	*104*	*108*

Source: Complaint, questionnaire replies, Eurofer

(92) Employment in the Union industry followed a progressively declining trend. Thus, the total number of employees measured in full time equivalents (FTE) in the industry decreased by 20 % over the period considered and reached its lowest level in the IP. However, the productivity increased by 8 % over the period considered, which shows that the industry was also trying to rationalise the production costs.

5.3. *Data relating to the sampled Union producers*

5.3.1. Average unit sales prices in the Union and cost of production

(93) The average sales prices of the sampled Union producers to unrelated customers in the EU decreased by 3 % over the period considered. In the period from 2009 to the IP, in line with an increasing consumption and sales volumes, prices recovered by 23 % but did not reach the level of 2008.

(94) In parallel, the average costs to produce and sell the like product increased by 6 % over the period considered due to increasing cost of manufacturing per unit, as the SG&A costs per unit dropped by 34 %.

(95) After the drop in unit price to unrelated customers by 21 % in 2009 and accompanying loss, the unit price started to recover. In 2010 and during the IP, the Union industry experienced an increase in costs and could only moderately increase the prices to cover them, enough just to keep the profitability on the same level for 2010 and the IP. However, this resulted in a further loss in market share since the Chinese imports prices were constantly lower than the Union industry prices.

	2008	2009	2010	IP
Unit price in EU to unrelated customers (EUR/tonne)	1 023	805	911	994
Index (2008 = 100)	*100*	*79*	*89*	*97*
Unit cost of production (EUR/tonne)	925	884	893	978
Index (2008 = 100)	*100*	*95*	*97*	*106*

Source: Verified questionnaire replies of the sampled producers

5.3.2. Profitability, cash flow, investments, return on investments and ability to raise capital

	2008	2009	2010	IP
Profitability of sales in the EU to unrelated customers (% of sales turnover)	6,7 %	– 9,3 %	2,8 %	2,6 %
Index (2008 = 100)	*100*	*– 138*	*41*	*39*
Cash flow (EUR)	328 190 880	211 298 356	152 030 083	204 650 414
Index (2008 = 100)	*100*	*64*	*46*	*62*
Investments (EUR)	55 717 957	4 537 128	12 530 132	15 302 264
Index (2008 = 100)	*100*	*8*	*22*	*27*
Return on investments	13,8 %	– 13,9 %	5,9 %	6 %
Index (2008 = 100)	*100*	*– 101*	*43*	*44*

Source: Verified questionnaire replies of the sampled producers

(96) The profitability of the Union industry was established by expressing the pre-tax net profit of the sales of the like product to unrelated customers as a percentage of the turnover of these sales. In the year of economic crisis, 2009 the profitability of the Union industry decreased dramatically and resulted in loss of 13,9 %. From 2010, it started to recover, but the increasing costs of production prevented them achieving the level considered healthy and sustainable for the industry (6,7 % - see recital (156)). Over the whole period considered, profitability dropped by 61 %.

(97) The trend in cash flow followed to a large extent the negative trend in profitability. The lowest level was achieved 2010. Similarly, the return on investment decreased by 56 % from 13,8 % in 2008 to 6 % in the IP.

(98) The evolution of profitability, cash flow and return on investment during the period considered limited the ability of the Union industry to invest in its activities and undermined its development. The Union industry managed to make substantial investment in the beginning of the period considered, however, thereafter the investments dropped sharply in 2009 and overall decreased by 73 % over the period considered.

(99) As stated above, the financial performances of the Union industry deteriorated, but it did not reveal that its ability to raise capital was seriously affected during the period considered.

5.3.3. Stocks

	2008	2009	2010	IP
Closing stocks (tonnes)	116 852	97 533	124 848	130 593
Index (2008 = 100)	*100*	*83*	*107*	*112*

Source: Verified questionnaire replies of the sampled producers

(100) For the six sampled Union producers, stocks represented around 8 % of the production volume in the IP. The closing stock level increased by 12 % during the period considered. Although, it should be noted that stocks are not an important indicator for the industry as the production mainly takes place on order, the main increase in stocks took place from 2009 to the IP and coincided with the surge in the dumped imports from the PRC.

5.3.4. Labour costs

Average labour costs per employee (EUR, sampled EU producers)	60 959	57 892	58 637	62 347
Index (2008 = 100)	*100*	*95*	*96*	*102*

(101) The average labour costs of the sampled Union producers rose by only 2 % over the period considered which is lower than the inflation rate. The investigation showed that the sampled producers made significant cuts, especially in general and administrative costs, and has held a tight grip on the efficiency.

5.3.5. Captive use and captive sales

(102) As indicated in recital (65), there is a significant market for OCS in the EU that is formed by the downstream use of OCS by the Union industry. To analyse this market, all volumes of captive use and sales to related parties (captive sales) by the sampled Union producers and other Union producers were considered.

(103) It was found that the captive use and captive sales were destined for further transformation by the companies themselves or their related companies within the groups of the sampled Union producers dealing with mainly construction material business, i.e. being end-users of OCS.

(104) On the basis identified above, it was established that the captive use and captive sales of the Union producers constituted 27 % of the total production volume in the IP. Over the period considered, the captive use and related sales volumes decreased by 19 % and the market share dropped by 11 %.

	2008	2009	2010	IP
Captive use and captive sales (tonnes)	1 225 686	935 374	994 933	993 701
Index (2008 = 100)	*100*	*76*	*81*	*81*

	2008	2009	2010	IP
Market share	22 %	22 %	20 %	19 %
Index (2008 = 100)	*100*	*100*	*94*	*89*

Source: Complaint and verified questionnaire replies of the sampled producers

(105) The value of captive use and captive sales was analysed on the basis of questionnaire replies provided by and verified during verification visits at the sampled producers. The investigation found that there was no material difference between captive use and captive sales in terms of end use of the product. Captive use was reported by companies where the downstream production was taking place in the same legal entity, however, captive sales were the sales to other related legal entities with an invoice. Furthermore, the pricing method both in captive use and sales to related parties was similar, i.e. a fair value ("cost plus" method) of the product was charged to both the related companies as well as internal downstream production units of the sampled companies.

(106) Thus, the average value per ton increased by 1 % during the period considered and as such was 2 % lower than the sales price to unrelated customers in the IP of the sampled Union producers.

	2008	2009	2010	IP
Captive use and captive sales (EUR/tonne)	967	787	910	975
Index (2008 = 100)	*100*	*81*	*94*	*101*

Source: Verified questionnaire replies of the sampled producers

(107) Considering that most of the captive sales and captive use were destined to the downstream construction material business of the Union producers, those sales and captive use were also indirectly exposed to competition from other market players including the dumped imports from the PRC. The internal demand of the downstream production would depend on the chance to sell the downstream products on the free market which is not affected by dumped imports. Thus, it can be concluded that the shrinking volumes and market share during the period considered were due to competition from dumped imports from the PRC.

5.3.6. Effects of past dumping or subsidisation

(108) Since this is the first anti-dumping proceeding regarding the product concerned, no data are available to assess effects of possible past dumping or subsidisation.

6. **Magnitude of the actual dumping margin**

(109) All margins established and specified above in the dumping section are significantly above the *de minimis* level. Furthermore, given the volume and the prices of dumped imports from the PRC the impact on the EU market of the actual margin of dumping cannot be considered negligible.

7. **Conclusion on injury**

(110) The investigation showed that all injury indicators pertaining to the economic situation of the Union industry deteriorated or did not develop in line with consumption during the period considered.

(111) Over the period considered, in the context of a decreasing consumption, the volume of imports from the PRC increased steadily and significantly. At the same time, the Union industry sales volume decreased overall by 13 % and its market share dropped from 59 % in 2008 to 56,7 % in the IP. Although consumption recovered by 20 %, from 2009 to the IP, after the year of economic crisis affecting demand, the Union industry market share was decreasing. The Union industry was unable to regain the lost market share in view of the significant expansion of the dumped imports from the

PRC in the EU market. The low-priced dumped imports increased over the period considered, constantly undercutting the prices of the Union industry.

(112) Furthermore, the injury indicators related to the financial performance of the Union industry, such as cash flow and profitability were seriously affected. This means that the ability of the Union industry to raise capital and to invest was undermined.

(113) In the light of the foregoing, it was concluded that the Union industry suffered material injury within the meaning of Article 3(5) of the basic Regulation.

E. **CAUSATION**

1. **Introduction**

(114) In accordance with Article 3(6) and 3(7) of the basic Regulation, it was examined whether the dumped imports originating in the PRC have caused material injury to the Union industry to a degree that enables it to be classified as material. Known factors other than the dumped imports, which could at the same time have injured the Union industry, were examined to ensure that any injury caused by those other factors was not attributed to the dumped imports.

2. **Effect of the dumped imports**

(115) The investigation showed that the Union consumption decreased by 9 % over the period considered, while the volume of dumped imports from the PRC increased dramatically by about 49 %, their market share also increased by 63 % from 8,3 % in 2008 to 13,6 % in the IP. At the same time, the sales volume of the Union industry to unrelated parties decreased by 13 % and market share of those sales dropped by 4 % from 59 % in 2008 to 56,7 % in the IP.

(116) Furthermore, while the imports from the PRC were also affected by the economic crisis and dropped by 68 % from 2008 to 2009, they recovered from 2009 to the IP at a very fast pace increasing by 367 % at the end of the IP, even though Union consumption only increased by 20 % during this period. By lowering the unit price by 9 % compared to 2008 and undercutting the Union industry by 25,9 % during the IP, Chinese imports increased their market share from 2008 to the IP by 63 % up to 13,6 %.

(117) At the same time, from 2008 to the IP the Union producers' sales volumes to unrelated parties overall dropped by 13 %. At the time of market recovery, from 2009 to the IP, the Union industry could raise their sales volumes to unrelated parties by only 8 % but lost a market share of 9 % thus benefitting to a limited extent from the increased consumption. It were indeed the Chinese imports that benefitted most from the recovering consumption leaving other market players far behind.

(118) The average import prices from the PRC dropped by 9 % over the period considered. Although on a rising trend after the sharp drop in 2009, from 2009 to the IP, they remained constantly below the levels charged by the Union industry. The unit price to unrelated customers in the EU decreased by only 3 %, showing some resistance to price pressure exerted by the Chinese imports. However, these prices were obviously sustained at a cost of lower sales volumes and decreased profitability on those sales as these dropped by 61 % from 6,7 % in 2008 to 2,6 % in the IP, as the costs of manufacturing were increasing.

(119) Based on the above, it is concluded that the surge of dumped imports from the PRC at prices constantly undercutting those of the Union industry have had a determining role in the material injury suffered by the Union industry, which has prevented the Union industry to fully benefit from the recovering Union consumption.

3. **Effect of other factors**

3.1. *Imports from third countries*

Country		2008	2009	2010	IP
South Korea	Volume (tonnes)	228 123	226 568	173 935	237 164
	Index (2008 = 100)	*100*	*99*	*76*	*104*

Country		2008	2009	2010	IP
	Market share (%)	4 %	5,2 %	3,5 %	4,6 %
	Index (2008 = 100)	*100*	*131*	*88*	*114*
	Av. price	901	727	846	903
	Index (2008 = 100)	*100*	*81*	*94*	*100*
India	Volume (tonnes)	159 999	149 138	155 384	141 391
	Index (2008 = 100)	*100*	*93*	*97*	*88*
	Market share (%)	2,8 %	3,4 %	3,2 %	2,7 %
	Index (2008 = 100)	*100*	*123*	*112*	*97*
	Av. price	932	667	773	824
	Index (2008 = 100)	*100*	*72*	*83*	*88*
Other countries	Volume (tonnes)	249 151	158 461	124 319	167 007
	Index (2008 = 100)	*100*	*64*	*50*	*67*
	Market share (%)	4,4 %	3,7 %	2,5 %	3,2 %
	Index (2008 = 100)	*100*	*84*	*58*	*74*
	Av. price	951	809	924	955
	Index (2008 = 100)	*100*	*85*	*97*	*100*
Total of all third countries except the PRC	Volume (tonnes)	637 274	534 167	453 637	545 562
	Index (2008 = 100)	*100*	*84*	*71*	*86*
	Market share (%)	11,2 %	12,3 %	9,2 %	10,5 %
	Index (2008 = 100)	*100*	*110*	*82*	*94*
	Av. price	929	735	842	898
	Index (2008 = 100)	*100*	*79*	*91*	*97*

Source: Eurostat

(120) While imports from the PRC constituted 56 % of all imports in the EU during the IP, other important sources of imports were from the Republic of India ('India') (11 %) and South Korea (19 %). Unlike imports from the PRC, imports from India, although their average price dropped sharply by 12 %, overall decreased by 12 % over the period considered and lost market share by 3 %. Imports from South Korea increased by only 4 % with the average price remaining on the same level as in 2008. The market share of imports from India was 2,7 % in the IP, while imports from South Korea held a share of 4,6 %.

(121) Other imports representing 14 % of the total imports, decreased by 33 % and their average price stayed at the same level as in 2008.

(122) Although the average price of all other imports was below the price level of the Union industry, the effect of these imports, if any, can possibly be only marginal. Firstly, there is no evidence that the imports from other sources were unfairly traded. Secondly, in contrast to the Chinese imports, the overall price level from main sources of other imports remained rather stable over the whole period considered, and thus shows that the Union industry can successfully compete in the market segments with those imports. Thirdly, the imports from other countries have declined over the period

considered and still remain at a low level, both overall and for main exporting countries individually. Moreover, the dropping market share of other imports confirms that those imports could not have caused injury to the Union industry.

3.2. *Export performance of the Union industry*

	2008	2009	2010	IP
Exports, Eurostat (tonnes)	669 790	612 204	580 477	605 760
Index (2008 = 100)	*100*	*91*	*87*	*90*
Average price (EUR/tonne)	1 068	937	995	1 092
Index (2008 = 100)	*100*	*88*	*93*	*102*
Exports by sampled Union producers	53 542	46 516	48 102	46 228
Index (2008 = 100)	*100*	*87*	*90*	*86*
Average selling price (EUR/tonne)	1 086	826	984	1 132
Index (2008 = 100)	*100*	*76*	*91*	*104*

Source: Eurostat and verified questionnaire replies

(123) The total exports of OCS by the Union industry to third countries according to Eurostat decreased by 10 % over the period considered. However, the average price has been relatively high and increased by 2 % over the period considered. Exports represented 17 % of the total EU production and as such helped the Union industry to achieve economies of scales and reduce overall costs of production. Hence, it can be concluded that the export activity of the Union industry could not be a potential cause of the material injury.

(124) This general picture is mirrored by the situation in exports to unrelated customers in third countries by the sampled Union producers. They decreased by 14 % over the period considered, however, also here the export price per unit has been constantly higher (on average by 2 to 12 % depending on year) than the price in the EU. As the export volume was only 3 % of the total production, they cannot have contributed to the injury suffered on the EU market.

3.3. *Union industry's own imports from the PRC*

(125) During the investigation, it was claimed that the complainants (through their related companies) were engaged in importing the product concerned from the PRC themselves and that those imports constituted 20 to 40 % of the total imports from the PRC. However, no evidence was provided to support this allegation. Having investigated these allegations, it was found that only about 10 000 tonnes were imported during the IP by the Union producers, which was largely in line with the data provided at initiation by the complainant. About a similar volume, not disclosed in accordance with Article 19 of the basic Regulation, was found to be imported by related companies of the Union producers. These imports together accounted for only about 2-3 % of total imports from the PRC. Consequently, it cannot be concluded that the Union industry was importing from the PRC in such quantities and in such a pattern as (1) to put in question their own status as Union producers according to Article 4 (1)(a) of the basic Regulation, or (2) to cause the injury to themselves. Therefore, the argument is provisionally rejected.

3.4. *Captive use and captive sales*

(126) It has been alleged by some interested parties that the injury to the Union industry was caused from its engagement in the downstream business of producing construction materials (e.g. sandwich panels, trapezoidal sheets etc.) either directly or through related companies within the groups. Specifically, it was claimed that the Union industry made OCS available to its own downstream business at lower prices than to unrelated companies, thus "subsidising" them within the group and enabling them to undercut their competitors in the downstream segment.

(127) As shown in recitals (102) to (107) above, the average value of captive use and captive sales per tonne was only 2 % lower than the sales price to unrelated customers in the IP. Moreover, the investigation showed that the captive use and captive sales were most likely themselves indirectly affected by the unfair competition from dumped imports. Indeed, should there have been any advantage for the downstream business of the Union producers as alleged, it should have shown in the development of this injury indicator. Therefore, this argument is provisionally rejected.

3.5. *Economic crisis*

(128) The economic crisis and its effect on the construction business at least partially explains the contraction of demand and price pressure during the period considered. As mentioned above, in 2009 the consumption shrunk by 24 %. However, as of 2010, the market started recovering and, by the end of the IP, consumption increased by 20 %.

(129) However, the injury and causality analysis has separated the market breakdown of 2009 and the subsequent recovery from 2009 to the IP. It has been clearly demonstrated in the injury and causality analysis that the imports from the PRC took full advantage of the recovering consumption and in addition constantly undercut the Union industry's prices, and thus turning the possibility of equal chance to all players to recover from the drop, into a continuous battle for survival.

3.6. *Structural overcapacity*

(130) It has been claimed by some interested parties that the cause of injury to the Union industry, which mostly are vertically integrated steel producers, has not been the imports from the PRC but that it was due to structural problems of the EU steel industry such as overcapacity. It was also argued that the consolidation of the steel industry that took place before the period considered had led to overcapacity and that any injury suffered was a consequence of too many production facilities.

(131) Indeed, the production of the OCS is capital intensive and the industry has relatively high fixed costs. However, it cannot be concluded that the consolidation of the steel industry that took place before the period considered had led to overcapacity. The findings show that after a small increase in installed capacity in 2009, the industry decreased its capacity in 2010 and again in the IP. The level of capacity in the IP was at a lower level than the actual consumption in 2008, the year before the full effects of the economic crisis were felt. Consumption in the EU has not yet returned to the 2008 level.

(132) Moreover, the findings of the investigation are that the negative effect of the overcapacity can only be attributed to a minimal extent to the EU producers of OCS. First, the investigation showed that the Union industry has obviously been taking steps to sustain efficiency – SG&A was reduced significantly by 34 %, and productivity increased by 8 % for the whole industry and by 6 % for the sampled companies. Second, continued investment in the production lines and flexibility in their use for producing other products helped achieving economy of scales and reducing the ultimate fixed costs. Thus, with capacity utilisation of the sampled companies going down by 18 % over the period considered, the average costs of manufacturing increased by only 9 %, and that including the raw material costs. Thus, it cannot be concluded that the overcapacity would break the causal link. This argument is therefore provisionally rejected.

4. **Conclusion on causation**

(133) It has been demonstrated that there was a substantial increase in the volume and market share of the dumped imports originating in the PRC in the period considered, especially from 2009 to the IP. It was also found that these imports were constantly undercutting the prices charged by the Union industry on the Union market and in particular during the IP.

(134) This increase in volume and market share of the low priced dumped imports from the PRC coincided with the negative development in the economic situation of the Union industry. This situation worsened in the IP, when, despite recovering consumption, the Union industry was unable to regain its lost market share and profitability and other financial indicators such as cash flow and return on investments stagnated at the level of 2010, and employment reached its lowest level.

(135) The examination of the other known factors which could have caused injury to the Union industry revealed that these factors are not such as to break the causal link established between the dumped imports from the PRC and the injury suffered by the Union industry.

(136) Based on the above analysis, which has properly distinguished and separated the effects of all known factors on the situation of the Union industry from the injurious effects of the dumped exports, it was provisionally concluded that the dumped imports from the PRC have caused material injury to the Union industry within the meaning of Article 3(6) of the basic Regulation.

F. UNION INTEREST

1. Preliminary remarks

(137) In accordance with Article 21 of the basic Regulation, the Commission examined whether, despite the provisional conclusion on injurious dumping, compelling reasons existed for concluding that it is not in the Union interest to adopt provisional measures in this particular case. The analysis of the Union interest was based on an appreciation of all the various interests involved, including those of the Union industry, importers, and users of the product concerned.

2. Interest of the Union industry

(138) The Union industry as a whole is composed of 22 known producers representing all of the Union OCS production according to Eurofer. The producers are located in different Member States of the Union, employing directly over 5,400 people in relation to the product concerned.

(139) None of the producers opposed the initiation of the investigation. As shown above in the macroeconomic indicators, the whole EU industry experienced a deterioration of their situation and was negatively affected by the dumped imports.

(140) The Union industry has suffered material injury caused by the dumped imports from the PRC. It is recalled that all injury indicators showed a negative trend during the period considered. In particular, injury indicators related to the financial performance of the cooperating Union producers, such as profitability and return on investments, were seriously affected. In the absence of measures, a further deterioration in the Union industry's economic situation appears very likely.

(141) It is expected that the imposition of provisional anti-dumping duties will restore fair trade conditions on the Union market, allowing the Union industry to align the prices of OCS to reflect the costs of the various components and the market conditions. It can also be expected that the imposition of provisional measures would enable the Union industry to regain at least part of the market share lost during the period considered, with a positive impact on its profitability and overall financial situation.

(142) Should measures not be imposed, further losses in market share could be expected and the Union industry's profitability would deteriorate. This would be unsustainable in the medium to long-term. It is also likely that some individual producers would have to close down their production facilities, as they have been heavily lossmaking over the period considered. In view of the losses incurred and the high level of investment in production made at the beginning of the period considered, it can be expected that most Union producers would be unable to recover their investments, should measures not be imposed.

(143) It is therefore provisionally concluded that the imposition of anti-dumping duties would be in the interest of the Union industry.

3. Interest of users and importers

(144) As mentioned above in recital (10) five importers came forward but only two replied to the questionnaire. Out of about 100 users listed in the complaint, 19 came forward expressing interest in the proceeding. Subsequently, ten companies provided questionnaire replies.

(145) The most active users and importers have made joint written submissions and several hearings were held in the course of the investigation. Their main arguments regarding imposition of measures are analysed below.

3.1. *Competition on the EU market*

(146) It was submitted that the EU market of OCS was not sufficiently competitive and that imports from the PRC were necessary to give more bargaining power to companies importing and using OCS. Furthermore, it was suggested that the Union industry was engaged in oligopolistic arrangements to control the market. The investigation at the provisional stage did not confirm these allegations Moreover, it was found that the Union producers were competing on the same markets and often selling to the same customers, or to the construction companies of each other. Considering that no evidence beyond anecdotal complaints about difficulties in price negotiations was provided and that besides the five groups of complaining Union producers, another 11 producers of OCS operate in the EU, among which some are very large, and the variety of other import sources, this claim seems not substantiated and is provisionally rejected.

3.2. *Shortage of supply*

(147) It has also been alleged that imposition of measures on Chinese imports would create a shortage of OCS on the EU market. However, considering the wide variety of supply sources described above, as well as the free production capacity of the Union industry, it is not considered likely that such shortage could take place. Therefore, the argument is provisionally rejected.

3.3. *Conclusion on the interests of users and importers*

(148) The ten cooperating users represented 7 % of total imports from China during the IP. The investigation showed that all users maintain various sources of supply. On average, purchases from China constituted around 15 % of their total purchases of the OCS products; moreover, the largest volumes were found to be sourced from the EU producers (73 %) and 12 % were imported from other third countries. Indeed, as the product concerned is highly standardised, the importance

of customer binding is rather relative, and both users and importers can quite easily change the sources of supply as far as the product quality is concerned.

(149) The investigation showed that all cooperating users except one, were profitable in the sector which uses the product concerned and their profitability during the IP ranged from 1 % to 13 %, depending on the company. Moreover, the profitability of those companies did not significantly depend on imports of the product concerned form the PRC.

(150) On the basis of questionnaire replies from the users, the likely effect of the proposed measures was estimated. Thus, even assuming the unlikely worst-case scenario for cooperating users, i.e. that no price increase could be passed on and they would be bound to import from China in previous volumes, the impact of the duty level on their cost of production would be an increase between 1 to 5 % and on profitability could mean a decrease by 1 to 2.8 percentage points for most of the imports and by about 4 percentage points for importing under residual duty. However, the more likely scenario is an impact significantly less than this, as the imports from China represent a rather small part of the users' business, it can be expected that the cost increase from the anti-dumping measures will be relatively easily passed on. Furthermore, given that in addition to the many EU producers alternative significant import sources, not subject to measures, are available e.g. India and South Korea, it is expected that prices in the market, following the imposition of measures will take into account these factors as well.

(151) The two cooperating importers represented around 6 % of total imports from China during the IP, the exact amount not disclosed in accordance with Article 19 of the basic Regulation. Similarly as for the users, the importers also maintained different sources of supply besides the PRC. Furthermore, it was established that the profitability of the importers would be possibly more affected by the measures than that of the users, if they were to maintain the importing pattern practiced during the IP. However, in practice importers as traders tend to be even more flexible than users, and they would most likely be first to turn to the alternative sources of supply.

(152) It should be also considered in this context that part of the benefit from Chinese imports on the user and importer side is effectively drawn from and made possible by the unfair price discrimination practiced by the Chinese exporters, and not from a natural competitive advantage. Thus, reinstating the level playing field on the EU market by correcting the trade distortion coming from dumped imports, will actually enable the OCS market to return to healthy, market-economy-driven dynamics and price development, by not putting at disadvantage other players (users, producers, end-consumers) who are not immediately able to benefit from dumped imports.

4. **Conclusion on Union interest**

(153) In view of the above, it is provisionally concluded that based on the information available concerning the Union interest, there are no compelling reasons against the imposition of provisional measures on imports of the product concerned originating in the PRC.

G. **PROVISIONAL ANTI-DUMPING MEASURES**

1. **Injury elimination level**

(154) In view of the conclusions reached with regard to dumping, injury, causation and Union interest, provisional anti-dumping measures should be imposed in order to prevent further injury being caused to the Union industry by the dumped imports.

(155) For the purpose of determining the level of these measures, account was taken of the dumping margins found and the amount of duty necessary to eliminate the injury sustained by the Union industry.

(156) When calculating the amount of duty necessary to remove the effects of the injurious dumping, it was considered that any measures should allow the Union industry to cover its costs of production and to obtain a profit before tax that could be reasonably achieved by an industry of this type in the sector under normal conditions of competition, i.e. in the absence of dumped imports, on sales of the like product in the Union. It is considered that the profit that could be achieved in the absence of dumped imports should be based on the year 2008 when Chinese imports were less present on the Union market. It is thus considered that a profit margin of 6,7 % of turnover could be regarded as an appropriate minimum which the Union industry could have expected to obtain in the absence of injurious dumping.

(157) On this basis, a non-injurious price was calculated for the Union industry for the like product. The non-injurious price was obtained by adding the above-mentioned profit margin of 6,7 % to the cost of production.

(158) The necessary price increase was then determined on the basis of a comparison of the weighted average import price of the cooperating exporting producers in the PRC, duly adjusted for importation costs and customs duties with the non-injurious price of the Union industry on the Union market during the IP. Any difference resulting from this comparison was then expressed as a percentage of the average CIF import value of the compared types.

2. **Provisional measures**

(159) In the light of the foregoing, it is considered that, in accordance with Article 7(2) of the basic Regulation, provisional anti-dumping measures should be imposed in respect of imports originating in the PRC at the level of the lower of the dumping and the injury margins, in accordance with the lesser duty rule.

(160) The individual company anti-dumping duty rates specified in this Regulation were established on the basis of the findings of the present investigation. Therefore, they reflect the situation found during that investigation with respect to these companies. These duty rates (as opposed to the country-wide duty applicable to 'all other companies') are thus exclusively applicable to imports of products originating in the PRC and produced by the companies and thus by the specific legal entities mentioned. Imported products produced by any other company not specifically mentioned in the operative part of this Regulation including entities related to those specifically mentioned, cannot benefit from these rates and shall be subject to the duty rate applicable to 'all other companies'.

(161) Any claim requesting the application of these individual company anti-dumping duty rates (e.g. following a change in the name of the entity or following the setting up of new production or sales entities) should be addressed to the Commission [1] forthwith with all relevant information, in particular any modification in the company's activities linked to production, domestic and export sales associated with, for example, that name change or that change in the production and sales entities. If appropriate, the Regulation will accordingly be amended by updating the list of companies benefiting from individual duty rates.

(162) In order to ensure a proper enforcement of the anti-dumping duty, the residual duty level should not only apply to the non-cooperating exporting producers but also to those producers which did not have any exports to the Union during the IP.

(163) On the basis of the above, the dumping and injury margins established and the provisional duty rates are as follows:

Company	Dumping margin	Injury margin	Provisional duty
Zhejiang Huadong Light Steel Building Material Co. Ltd and Hangzhou P.R.P.T. Metal Material Company Ltd	54,6 %	29,2 %	29,2 %
Zhangjiagang Panhua Steel Strip Co., Ltd and Chongqing Wanda Steel Strip Co., Ltd, Zhangjiagang Wanda Steel Strip Co., Ltd, Jiangsu Huasheng New Construction Materials Co. Ltd) and Zhangjiagang Free Trade Zone Jiaxinda International Trade Co., Ltd	67,4 %	55,3 %	55,3 %
Union Steel China and Wuxi Changjiang Sheet Metal Co. Ltd	59,2 %	13,2 %	13,2 %
Other co-operating companies	61,1 %	42,5 %	42,5 %
All other companies	77,9 %	57,8 %	57,8 %

H. **FINAL PROVISION**

(164) In the interest of sound administration, a period should be fixed within which the interested parties which made themselves known within the time limit specified in the notice of initiation may make their views known in writing and request a hearing. Furthermore, it should be stated that the findings concerning the imposition of duties made for the purposes of this Regulation are provisional and may have to be reconsidered for the purpose of any definitive measures.

HAS ADOPTED THIS REGULATION:

Article 1

1. A provisional anti-dumping duty is hereby imposed on imports of certain organic coated steel products, i.e. flat rolled products of non-alloy and alloy steel (not including stainless steel) which are painted, varnished or coated with plastics on at least one side, excluding so-called 'sandwich panels' of a kind used for building applications and consisting of two outer metal sheets with a stabilising core of insulation material sandwiched between them, and excluding those products with a final coating of zinc-dust (a zinc-rich paint, containing by weight 70 % or more of zinc) currently falling within CN codes ex 7210 70 80, ex 7212 40 80, ex 7225 99 00, ex 7226 99 70 (TARIC codes 7210 70 80 11, 7210 70 80 91, 7212 40 80 01, 7212 40 80 21, 7212 40 80 91, 7225 99 00 11, 7225 99 00 91, 7226 99 70 11 and 7226 99 70 91) and originating in the People's Republic of China.

[1] European Commission, Directorate-General for Trade, Directorate H, 1049 Brussels, Belgium.

2. The rate of the provisional anti-dumping duty applicable to the net, free-at-Union-frontier price, before duty, of the product described in paragraph 1 and manufactured by the companies listed below, shall be as follows:

Company	Duty	TARIC additional code
Union Steel China; Wuxi Changjiang Sheet Metal Co. Ltd	13,2 %	B311
Zhangjiagang Panhua Steel Strip Co., Ltd; Chongqing Wanda Steel Strip Co., Ltd; Zhangjiagang Wanda Steel Strip Co., Ltd; Jiangsu Huasheng New Construction Materials Co. Ltd; Zhangjiagang Free Trade Zone Jiaxinda International Trade Co., Ltd	55,3 %	B312
Zhejiang Huadong Light Steel Building Material Co. Ltd; Hangzhou P.R.P.T. Metal Material Company Ltd	29,2 %	B313
Angang Steel Company Limited	42,5 %	B314
Anyang Iron Steel Co. Ltd	42,5 %	B315
Baoshan Iron & Steel Co. Ltd	42,5 %	B316
Baoutou City Jialong Metal Works Co. Ltd.	42,5 %	B317
Changshu Everbright Material Technology Co.Ltd.	42,5 %	B318
Changzhou Changsong Metal Composite Material Co.Ltd.	42,5 %	B319
Cibao Modern Steel Sheet Jiangsu Co Ltd.	42,5 %	B320
Inner Mongolia Baotou Steel Union Co.Ltd.	42,5 %	B321
Jiangyin Ninesky Technology Co.Ltd.	42,5 %	B322
Jiangyin Zhongjiang Prepainted Steel Mfg Co.Ltd.	42,5 %	B323
Jigang Group Co., Ltd.	42,5 %	B324
Maanshan Iron&Steel Company Limited	42,5 %	B325
Qingdao Hangang Color Coated Sheet Co. Ltd.	42,5 %	B326
Shandong Guanzhou Co. Ltd.	42,5 %	B327
Shenzen Sino Master Steel Sheet Co.Ltd.	42,5 %	B328
Tangshan Iron And Steel Group Co.Ltd.	42,5 %	B329
Tianjin Xinyu Color Plate Co.Ltd.	42,5 %	B330
Wuhan Iron And Steel Company Limited	42,5 %	B331
Wuxi Zhongcai New Materials Co.Ltd.	42,5 %	B332
Xinyu Iron And Steel Co.Ltd.	42,5 %	B333
Zhejiang Tiannu Color Steel Co. Ltd.	42,5 %	B334
All other companies	57,8 %	B999

3. The application of the provisional anti-dumping duty rates specified for the companies mentioned in paragraph 2 shall be conditional upon presentation to the customs authorities of the Member States of a valid commercial invoice, which shall be conform to the requirements set out in the Annex. If no such invoice is presented, the duty applicable to all other companies shall apply.

4. The release for free circulation in the Union of the product referred to in paragraph 1 shall be subject to the provision of a security, equivalent to the amount of the provisional duty.

5. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

1. Without prejudice to Article 20 of Council Regulation (EC) No 1225/2009, interested parties may request disclosure of the essential facts and considerations on the basis of which this Regulation was adopted, make their views known in writing and apply to be heard orally by the Commission within one month of the date of entry into force of this Regulation.

2. Pursuant to Article 21(4) of Council Regulation (EC) No 1225/2009, the parties concerned may comment on the application of this Regulation within one month of the date of its entry into force.

Article 3

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

Article 1 of this Regulation shall apply for a period of six months.

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

Done at Brussels, 18 September 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

A declaration signed by an official of the entity issuing the commercial invoice, in the following format, must appear on the valid commercial invoice referred to in Article 1(3):

(1) The name and function of the official of the entity issuing the commercial invoice.

(2) The following declaration: "I, the undersigned, certify that the (volume) of [product concerned] sold for export to the European Union covered by this invoice was manufactured by (company name and address) (TARIC additional code) in (country concerned). I declare that the information provided in this invoice is complete and correct."

(3) Date and signature.

COMMISSION IMPLEMENTING REGULATION (EU) No 846/2012

of 18 September 2012

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

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 18 September 2012.

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

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

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MK	50,7
	XS	59,9
	ZZ	55,3
0707 00 05	MK	31,3
	TR	106,4
	ZZ	68,9
0709 93 10	TR	116,5
	ZZ	116,5
0805 50 10	AR	93,8
	BO	100,6
	CL	89,9
	TR	97,0
	UY	76,0
	ZA	95,7
	ZZ	92,2
0806 10 10	MK	41,5
	TN	197,3
	TR	122,2
	ZZ	120,3
0808 10 80	AR	201,7
	BR	89,7
	CL	158,8
	NZ	122,8
	US	119,9
	ZA	111,4
	ZZ	134,1
0808 30 90	CN	65,0
	TR	112,6
	ZA	145,4
	ZZ	107,7
0809 30	TR	153,9
	ZZ	153,9
0809 40 05	BA	60,9
	IL	63,3
	TR	107,6
	XS	74,4
	ZZ	76,6

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

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 17 September 2012

on the recognition of Egypt pursuant to Directive 2008/106/EC of the European Parliament and of the Council as regards the systems for the training and certification of seafarers

(notified under document C(2012) 6297)

(2012/505/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2008/106/EC of the European Parliament and of the Council of 19 November 2008 on the minimum level of training of seafarers [1], and in particular the first subparagraph of Article 19(3) thereof,

Having regard to the requests from Cyprus on 13 May 2005, from the United Kingdom on 25 September 2006 and from the Hellenic Republic on 26 October 2006

Whereas:

(1) According to Directive 2008/106/EC Member States may decide to endorse seafarers' appropriate certificates issued by third countries, provided that the third country concerned is recognised by the Commission. Those third countries have to meet all the requirements of the International Maritime Organisation (IMO) Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978 (STCW Convention) [2], as revised in 1995.

(2) The requests for the recognition of Egypt were submitted by letters of 13 May 2005 from Cyprus, of 25 September 2006 from the United Kingdom and of 26 October 2006 from the Hellenic Republic. Following these requests, the Commission assessed the training and certification system in Egypt in order to verify whether Egypt meets all the requirements of the STCW Convention and whether the appropriate measures have been taken to prevent fraud involving certificates. That assessment was based on the results of an inspection carried out by experts of the European Maritime Safety Agency in December 2006. During that inspection certain deficiencies in the training and certification systems were identified.

(3) The Commission provided the Member States with a report on the results of the assessment.

(4) By letters of 16 February 2009, 21 September 2010 and 20 December 2011, the Commission requested Egypt to provide evidence demonstrating that the deficiencies identified had been corrected.

(5) By letters of 12 November 2009, 25 November 2010 and 28 February 2012, Egypt provided the requested information and evidence concerning the implementation of appropriate and sufficient corrective action to address the deficiencies identified during the assessment of compliance.

(6) The outcome of the assessment of compliance and the evaluation of the information provided by Egypt demonstrates that Egypt complies with the requirements of the STCW Convention, while this country has taken appropriate measures to prevent fraud involving certificates.

(7) The measures provided for in this Decision are in accordance with the opinion of the Committee on Safe Seas and the Prevention of Pollution from Ships,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of Article 19 of Directive 2008/106/EC, Egypt is recognised as regards the systems for the training and certification of seafarers.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 17 September 2012.

For the Commission

Siim KALLAS

Vice-President

[1] OJ L 323, 3.12.2008, p. 33.

[2] Adopted by the International Maritime Organisation.

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