



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**authorising certain products and substances for use in organic production and
establishing their lists**

(Text with EEA relevance)

EN

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

authorising certain products and substances for use in organic production and establishing their lists

(Text with EEA relevance)

EN

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007¹, and in particular Article 24(9) and point (a) of Article 39(2) thereof,

Whereas:

- (1) Pursuant to Article 9(3) of Regulation (EU) 2018/848, only products and substances authorised under Article 24 of that Regulation may be used in organic production provided that their use in non-organic production has also been authorised in accordance with relevant provisions of Union law. The Commission has already evaluated the use of certain products and substances in organic production on the basis of the objectives and principles laid down in Council Regulation (EC) No 834/2007². The selected products and substances were consequently authorised under specific conditions by Commission Regulation (EC) No 889/2008³ and listed in certain Annexes to that Regulation. The objectives and principles laid down in Regulation (EU) 2018/848 are similar to those in Regulation (EC) No 834/2007. As it is necessary to ensure the continuity of organic production, those products and substances should be included in the restrictive lists to be established on the basis of Regulation (EU) 2018/848.
- (2) In addition, in accordance with Article 24(7) of Regulation (EU) 2018/848, Member States have submitted dossiers on certain products and substances to the Commission and to the other Member States, in view of their authorisation and inclusion in the lists to be established under that Regulation.
- (3) Under certain circumstances and conditions set out, in particular, in point 1.10.2. of Part I of Annex II to Regulation (EU) 2018/848, certain authorised products and substances may be used to protect plants. For that purpose, the Commission should authorise active substances to be used in plant protection products as referred to in

¹ OJ L 150, 14.6.2018, p. 1.

² Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

³ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

- point (a) of Article 24(1) of Regulation (EU) 2018/848 and establish the list of those active substances.
- (4) Under certain circumstances and conditions set out, in particular, in point 1.9.3 of Part I, points 1.9.1.2(b), 1.9.2.2(d), 1.9.3.2(b) and 1.9.5.2(a) of Part II and points 2.2.2(c) and 2.3.2 and the second indent of the fourth paragraph of point 3.1.5.3 of Part III of Annex II to Regulation (EU) 2018/848, certain fertilisers, soil conditioners and nutrients may be used for plant nutrition, litter improvement and enrichment, algae cultivation or husbandry environment of aquaculture animals. For that purpose, the Commission should authorise fertilisers, soil conditioners and nutrients as referred to in point (b) of Article 24(1) of Regulation (EU) 2018/848 and establish their list.
 - (5) Under certain circumstances and conditions set out, in particular, in points 1.4.1(i) and 1.5.2.3 of Part II, point 3.1.3.1(d) of Part III and point 2.3 of Part V of Annex II to Regulation (EU) 2018/848, certain non-organic feed materials of plant, algal, animal or yeast origin, feed materials of microbial or mineral origin, feed additives and processing aids may be used for animal nutrition. For that purpose, the Commission should authorise non-organic feed materials of plant, algal, animal or yeast origin, feed materials of microbial or mineral origin and feed additives and processing aids as referred to in points (c) and (d) of Article 24(1) of Regulation (EU) 2018/848 and establish their lists.
 - (6) In addition, some non-organic feed materials are directly authorised in accordance with Regulation (EU) 2018/848. For the sake of clarity, those feed materials should also be listed together with the feed materials authorised by this Regulation, with a reference to the specific provisions of Regulation (EU) 2018/848.
 - (7) Under certain circumstances and conditions set out, in particular, in points 1.11 of Part I, points 1.5.1.6, 1.5.1.7 and 1.9.4.4(c) of Part II, point 3.1.4.1(f) of Part III, point 2.2.3 of Part IV, point 2.4 of Part V and point 1.4 of Part VII of Annex II and points 4.2 and 7.5 of Annex III to Regulation (EU) 2018/848, only certain products and substances may be used for cleaning and disinfection. For that purpose, the Commission should authorise products for cleaning and disinfection as referred to in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848 and establish their lists.
 - (8) Certain products for cleaning and disinfection of buildings and installations for livestock, aquaculture animals and seaweed production have been evaluated and listed in Annex VII to Regulation (EC) No 889/2008. However, products for cleaning and disinfection of buildings and installations used for plant production and of processing and storage facilities are so far evaluated and authorised only by Member States. Before authorising those products in organic production, an evaluation should be done at Union level by the Commission assisted by the Expert Group for Technical Advice on Organic Production. That evaluation should include a revision of all existing authorised products and substances for cleaning and disinfection.
 - (9) For the sake of ensuring the continuity of organic production, the products listed in Annex VII to Regulation (EC) No 889/2008 and those authorised at Member States' level should continue to be authorised until 31 December 2023 to allow the establishment of the lists of products for cleaning and disinfection in accordance with the provisions laid down in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848. Nevertheless, those products must comply with the relevant requirements of Union law, in particular Regulation (EC) No 648/2004 of the European Parliament and

of the Council⁴ and Regulation (EU) No 528/2012 of the European Parliament and of the Council⁵ and with the organic criteria laid down in Chapter II and points (a) and (b) of Article 24(3) of Regulation (EU) 2018/848.

- (10) Under certain circumstances and conditions set out, in particular, in points 2.2.1 and 2.2.2(a) of Part IV of Annex II to Regulation (EU) 2018/848, certain food additives, including food enzymes to be used as food additives, and processing aids may be used in the production of processed organic food. For that purpose, the Commission should authorise food additives and processing aids as referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848 and establish their list.
- (11) Food additives and food processing aids used in the production of processed organic food were listed respectively in sections A, B and C of Annex VIII to Regulation (EC) No 889/2008. However, according to their uses and functions in the final product, certain of those products might be classified as additives and not as processing aids. This classification needs a specific and exhaustive analysis of those products in the production of processed organic food. Such analysis should be conducted on all products listed as processing aids in Regulation (EC) No 889/2008. That process will take time and cannot be completed before the date of application of Regulation (EU) 2018/848. Consequently, the products currently listed as processing aids in Regulation (EC) No 889/2008 will be listed as processing aids in this Regulation until a specific and exhaustive analysis has been carried out.
- (12) Under certain circumstances and conditions set out, in particular, in point 2.2.1 of Part IV of Annex II to Regulation (EU) 2018/848, certain non-organic agricultural ingredients may be used for the production of processed organic food. For that purpose, the Commission should authorise such non-organic agricultural ingredients as referred to in point (b) of Article 24(2) of Regulation (EU) 2018/848 and establish their list. The dossiers on non-organic agricultural ingredients to be used for the production of processed organic food that have been submitted by Member States in accordance with Article 24(7) of Regulation (EU) 2018/848 were evaluated within the Committee on Organic Production. The selected products and substances that comply with the objectives and principles laid down in Regulation (EU) 2018/848 should be included in the restrictive list to be established by this Regulation, where necessary under specific conditions.
- (13) However, in order to give enough time to operators to adapt to the new restrictive list of authorised non-organic agricultural ingredients and, in particular, to find a source of agricultural ingredients that have been produced in accordance with Regulation (EU) 2018/848, it is appropriate that the list of non-organic agricultural ingredients authorised for use in processing of organic food by this Regulation applies from 1 January 2024.
- (14) Given the composition of certain non-organic agricultural ingredients, some of their uses in processed organic food may correspond to uses as food additives, food processing aids or products and substances referred to in point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848. Those uses require a specific authorisation in accordance with point 2.2 of Part IV of Annex II to Regulation (EU) 2018/848 and

⁴ Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1).

⁵ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 26.6.2012, p. 1).

such uses should not be allowed via the authorisation of non-organic agricultural ingredients.

- (15) Under certain circumstances and conditions set out, in particular, in point 1.3(a) of Part VII of Annex II to Regulation (EU) 2018/848, certain processing aids may be used for the production of yeast and yeast products. For that purpose, the Commission should authorise processing aids for the production of yeast and yeast products as referred to in point (c) of Article 24(2) of Regulation (EU) 2018/848 and establish their list.
- (16) In accordance with point 2.2 of Part VI of Annex II to Regulation (EU) 2018/848, only products and substances authorised pursuant to Article 24 of that Regulation for use in organic production may be used for the making of products of the wine sector as referred to point (1) of Article 1(2) of Regulation (EU) No 1308/2013 of the European Parliament and of the Council⁶. For that purpose, the Commission should authorise such products and substances and establish their list.
- (17) Article 45(2) of Regulation (EU) 2018/848 empowers the Commission to grant specific authorisations for the use of products and substances in third countries and in the outermost regions of the Union. How to initiate the procedure to be followed by Member States in respect of the outermost regions of the Union is set out in Article 24(7) of that Regulation. However, the procedure to be followed for such authorisations in respect of third countries is not detailed in Regulation (EU) 2018/848. Therefore, it is appropriate to establish that procedure in this Regulation, in line with the procedure to be followed to authorise products and substances for use in organic production in the Union, as set out in Article 24 of Regulation (EU) 2018/848. As those authorisations may be granted for a renewable period of 2 years, it is appropriate, in order to avoid confusion with products and substances authorised without time limitation, to list the relevant products and substances in a dedicated Annex.
- (18) In the interest of clarity and legal certainty, Regulation (EC) No 889/2008 should be repealed. However, as the list of products for cleaning and disinfection will not be established before 1 January 2024, Annex VII to Regulation (EC) No 889/2008 should continue to apply until 31 December 2023. In that context, it is appropriate to specify that products listed in that Annex which are not authorised pursuant to Regulation (EU) No 528/2012, cannot be used as biocidal products. Furthermore, the list of non-organic agricultural ingredients to be used for the production of processed organic food established by this Regulation will only apply from 1 January 2024. Therefore, it is appropriate to provide that processed organic food that has been produced before 1 January 2024 with non-organic agricultural ingredients listed in that Annex may be placed on the market after that date until the stocks are exhausted.
- (19) The certificate to be issued to operators by the competent authorities, or, where appropriate, the control authorities or control bodies in accordance with Article 35(1) of Regulation (EU) 2018/848 can be issued from 1 January 2022. However, it will not be provided to all operators concerned on that day. For the sake of ensuring the continuity of organic production and by way of derogation from Article 35(2) of Regulation (EU) 2018/848, the documentary evidence issued to operators by the

⁶ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

control authorities or control bodies in accordance with Article 68 of Regulation (EC) No 889/2008 before 1 January 2022 should remain valid until the end of the validity period. However, as pursuant to Article 38(3) of Regulation (EU) 2018/848 operators are to be subject to a verification of compliance at least once a year and, in accordance with Article 38(5) of that Regulation, the delivery of the certificate is to be based on the results of that verification, the validity should not go beyond 31 December 2022.

- (20) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848. However, for the reasons set out in recital 18 of this Regulation, the provisions referring to the lists of products for cleaning and disinfection and to the list of non-organic agricultural ingredients to be used for the production of processed organic food should apply from 1 January 2024.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Organic Production,

HAS ADOPTED THIS REGULATION:

Article 1

Active substances in plant protection products

For the purposes of point (a) of Article 24(1) of Regulation (EU) 2018/848, only the active substances listed in Annex I to this Regulation may be contained in plant protection products used in organic production as set out in that Annex, provided that those plant protection products:

- (a) have been authorised pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁷;
- (b) are used in accordance with the conditions for use as specified in the authorisations of the products containing them, granted by the Member States; and
- (c) are used in compliance with the conditions set out in the Annex to Commission Implementing Regulation (EU) No 540/2011⁸.

Article 2

Fertilisers, soil conditioners and nutrients

For the purposes of point (b) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Annex II to this Regulation may be used in organic production as fertilisers, soil conditioners and nutrients for plant nutrition, litter improvement and enrichment or algae cultivation or husbandry environment of aquaculture animals, provided that they are compliant with the relevant provisions of Union law, in particular with Regulation (EC) No 2003/2003 of the European Parliament and of the Council⁹, the relevant applicable Articles of Regulation (EU) 2019/1009 of the European Parliament and of the

⁷ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

⁸ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁹ Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1).

Council¹⁰, Regulation (EC) No 1069/2009 of the European Parliament and of the Council¹¹ and Commission Regulation (EU) No 142/2011¹² and, where applicable, in accordance with national provisions based on Union law.

Article 3

Non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin

For the purposes of point (c) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex III to this Regulation may be used in organic production as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 767/2009 of the European Parliament and of the Council¹³ and, where applicable, in accordance with national provisions based on Union law.

Article 4

Feed additives and processing aids

For the purposes of point (d) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Part B of Annex III to this Regulation may be used in organic production as feed additives and processing aids used in animal nutrition, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council¹⁴ and, where applicable, in accordance with national provisions based on Union law.

Article 5

Products for cleaning and disinfection

1. For the purposes of point (e) of Article 24(1) of Regulation (EU) 2018/848, only the products listed in Part A of Annex IV to this Regulation may be used for the cleaning

¹⁰ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L170 25.6.2019, p. 1).

¹¹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1).

¹² Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

¹³ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

¹⁴ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.

2. For the purposes of point (f) of Article 24(1) of Regulation (EU) 2018/848, only the products listed in Part B of Annex IV to this Regulation may be used for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.
3. For the purposes of point (g) of Article 24(1) of Regulation (EU) 2018/848, only the products listed in Part C of Annex IV to this Regulation may be used for cleaning and disinfection in processing and storage facilities, provided that those products comply with the provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.
4. Pending their inclusion in Part A, B or C of Annex IV to this Regulation, products for cleaning and disinfection referred to in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848 that were authorised for use in organic production under Regulation (EC) No 834/2007 or under national law prior to the date of application of Regulation (EU) 2018/848 may continue to be used if they comply with the relevant provisions of Union law, in particular Regulation (EC) No 648/2004 and Regulation (EU) No 528/2012 and, where applicable, in accordance with national provisions based on Union law.

Article 6

Food additives and processing aids

For the purposes of point (a) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex V to this Regulation may be used as food additives, including food enzymes to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹⁵ and, where applicable, in accordance with national provisions based on Union law.

Article 7

Non-organic agricultural ingredients to be used for the production of processed organic food

For the purposes of point (b) of Article 24(2) of Regulation (EU) 2018/848, only the non-organic agricultural ingredients listed in Part B of Annex V to this Regulation may be used for the production of processed organic food, provided that their use is in accordance with the

¹⁵ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.

The first paragraph is without prejudice to the detailed requirements for organic production of processed food provided in Section 2 of Part IV of Annex II to Regulation (EU) 2018/848. In particular, the first paragraph shall not apply to non-organic agricultural ingredients that are used as food additives, processing aids or products and substances referred to in point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848.

Article 8

Processing aids for the production of yeast and yeast products

For the purposes of point (c) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part C of Annex V to this Regulation may be used as processing aids for the production of yeast and yeast products for food and feed, provided that their use is in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.

Article 9

Products and substances for use in organic production of wine

For the purposes of point 2.2 of Part VI of Annex II to Regulation (EU) 2018/848, only the products and substances listed in Part D of Annex V to this Regulation may be used for the production and conservation of organic grapevine products as referred to in Part II of Annex VII to Regulation (EU) No 1308/2013, provided that their use is in accordance with the relevant provisions of Union law, in particular within the limits and conditions set out in Regulation (EU) No 1308/2013 and Commission Delegated Regulation (EU) 2019/934¹⁶ and, where applicable, in accordance with national provisions based on Union law.

Article 10

Procedure to grant specific authorisations for the use of products and substances in certain areas of third countries

1. Where a control authority or control body recognised under Article 46(1) of Regulation (EU) 2018/848 considers that a product or substance should be granted a specific authorisation for use in a certain area outside the Union due to the specific conditions set out in Article 45(2) of that Regulation, it may request the Commission to carry out an assessment. For that purpose, it shall notify the Commission of a dossier describing the product or substance concerned, giving the reasons for such specific authorisation and explaining why the products and substances authorised under this Regulation are not adequate to be used due to the specific conditions in the relevant area. It shall ensure that the dossier is fit to be made publicly available subject to Union and national legislation of the Member States on data protection.

¹⁶ Commission Delegated Regulation (EU) 2019/934 of 12 March 2019 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards wine-growing areas where the alcoholic strength may be increased, authorised oenological practices and restrictions applicable to the production and conservation of grapevine products, the minimum percentage of alcohol for by-products and their disposal, and publication of OIV files (OJ L 149, 7.6.2019, p. 1).

2. The Commission shall forward the request referred to in paragraph 1 to the Member States and shall publish any such requests.
3. The Commission shall analyse the dossier referred to in paragraph 1. The Commission shall authorise the product or substance in the light of the specific conditions referred to in the dossier only if its analysis concludes, as a whole that:
 - (a) such specific authorisation is justified in the area concerned;
 - (b) the product or substance described in the dossier complies with the principles laid down in Chapter II, the criteria set out in Article 24(3) and the condition set out in Article 24(5) of Regulation (EU) 2018/848; and
 - (c) the use of the product or substance is in accordance with the relevant provisions of Union law, in particular for active substances contained in plant protection products with Regulation (EC) No 396/2005 of the European Parliament and of the Council¹⁷.

The authorised product or substance shall be included in Annex VI to this Regulation.

4. When the 2-year period referred to in Article 45(2) of Regulation (EU) 2018/848 expires, the authorisation shall be automatically renewed for another period of 2 years, provided that no new elements are available and no Member State or control authority or control body recognised under Article 46(1) of Regulation (EU) 2018/848 has objected, justifying that the conclusion by the Commission referred to in paragraph 3 need to be reassessed.

Article 11

Repeal

Regulation (EC) No 889/2008 is repealed.

However, Annexes VII and IX shall continue to apply until 31 December 2023.

Article 12

Transitional provisions

1. For the purposes of Article 5(4) of this Regulation, the products for cleaning and disinfection listed in Annex VII to Regulation (EC) No 889/2008 may continue to be used until 31 December 2023 for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production, subject to Part D of Annex IV to this Regulation.
2. For the purposes of point (b) of Article 24(2) of Regulation (EU) 2018/848, the non-organic agricultural ingredients listed in Annex IX to Regulation (EC) No 889/2008 may continue to be used for the production of processed organic food until 31 December 2023. Processed organic food that has been produced before 1 January

¹⁷ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

2024 with those non-organic agricultural ingredients may be placed on the market after that date until the stocks are exhausted.

3. Documentary evidence issued in accordance with Article 68 of Regulation (EC) No 889/2008 prior to 1 January 2022 shall remain valid until the end of its validity period but not beyond 31 December 2022.

Article 13

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 2022.

However, Article 5(1), (2) and (3) and Article 7 shall apply from 1 January 2024.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN